Exhibit F

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EXHIBIT 46

Letter from SFP to Stephen Ostroff (Feb 4, 2016)

CONFIDENTIAL

February 4, 2016

Stephen Ostroff, M.D., Acting Commissioner of Food and Drugs
Robert M. Califf, M.D., Deputy Commissioner for Medical Products and Tobacco
Janet Woodcock, M.D., Director of the Center for Drug Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Drs. Ostroff, Califf, and Woodcock,

The following 30 organizations write to ask the U.S. Food and Drug Administration (FDA) to lift the Risk Evaluation and Mitigation Strategy (REMS) imposed in 2000 when it approved the use of Mifeprex© (mifepristone) for pregnancy termination, and to extend the indicated use through a gestational age of 70 days. In the 15 years since mifepristone's approval, multiple clinical trials, dozens of studies, and extensive experience across the globe have confirmed the FDA's finding that mifepristone is a safe and reliable method of abortion. Studies have shown that mifepristone in combination with misoprostol is up to 99% effective for first trimester abortion[1,2] and that serious complications are rare.[3] The steady increase in use of medication abortion – now 23% of U.S. abortions – shows that many women prefer this option, and that it has the ability to improve access to abortion, even in states with restrictive laws. Provider interest in offering mifepristone has also increased substantially: in 2011, 59% of abortion providers offered early medication abortions, up from 33% in 2008.[4] This growing use of medication abortion has made a major difference in people's lives. We thank the FDA for ensuring mifepristone is available on the market for patients' reproductive health care needs.

However, many who could benefit from mifepristone still do not have access to it due to multiple types of restrictions, including those required by the FDA. In November 2015, a group of organizational and individual researchers submitted a letter to the FDA (hereinafter "Technical Letter") asking the agency to lift the REMS on mifepristone and extend the indicated use to 70 days gestational age, presenting data showing that the current restrictions and limited gestational age indication are unnecessary for the safe and effective use of the drug for pregnancy termination.

As policy, advocacy, social science, research, and academic organizations, we ask the FDA to consider the substantial evidence presented in the Technical Letter, alongside the burdens that the REMS and the label's 49-day gestational age indication place on patient access, which we describe here. The FDA held a public meeting in October 2015 to discuss improving patient access to drugs under REMS,[5] evidencing the agency's own awareness of patient burden caused specifically by restrictions imposed under REMS. We applaud these efforts and urge the FDA to use its regulatory authority to remove the medically unnecessary barriers to mifepristone.

Mifepristone underwent a lengthy approval process in the late 1990s, during which it became subject to a rarely-used approval mechanism: Subpart H of the FDA's Title 21, Chapter 314 regulations. Subpart H is used primarily for drugs with very serious and well-documented safety concerns.[6] In 2007, Subpart H restrictions on all drugs were converted automatically into a Risk Evaluation and Management Strategy (REMS),[7] a mechanism created by Congress whereby FDA can impose Elements to Assure Safe Use (ETASU). Under this law, as the Agency stated in preparation for its October 2015 meeting on REMS,[8] Congress mandated that the FDA engage in a balancing analysis to ensure that the risks mitigated by a REMS program do not unduly burden patients' access to health care:

> [E]lements to assure safe use [ETASU] ... shall–
>
> (A) be commensurate with the specific serious risk listed in the labeling of the drug;
>
> ...
>
> (C) considering such risk, not be unduly burdensome on patient access to the drug, considering in particular–
>
> (i) patients with serious or life-threatening diseases or conditions; and
>
> (ii) patients who have difficulty accessing health care (such as patients in rural or medically underserved areas)….[9]

Although the FDA may have decided 15 years ago that the balance of risk and burden came out in favor of restricting mifepristone's indicated use and distribution, today both science and the current conditions surrounding patient access to abortion care call strongly for a reevaluation of the mifepristone label and REMS restrictions, especially its Elements to Assure Safe Use (ETASU).

We support the following changes to the mifepristone label:

- The drug should be indicated for use in medication abortions beyond 49 days gestation.
- The recommended dose regimen should be mifepristone 200 mg followed 24-48 hours later by misoprostol 800 mcg.
- The location where the patient should take these drugs should not be restricted.
- An in-person visit should be indicated as not always necessary for follow-up assessment.
- Any licensed health care provider should be able to prescribe the drug.

We expand below upon further specific changes that should be made based on scientific evidence of mifepristone's safety and efficacy, as well as the numerous burdens on patients' access to abortion care that would be greatly alleviated if the REMS were eliminated and the gestational age indication in the label were increased to 70 days.

1. **Eliminate the REMS and ETASU for mifepristone.**
   a. **Expand dispensing venues.** The ETASU state that mifepristone may only be dispensed to patients in a clinic, medical office, or hospital, and not through pharmacies.[10] The Technical Letter discusses why this requirement is not medically warranted. The requirement should be removed entirely, so that mifepristone can also be distributed via retail pharmacies like other prescription medications, in addition to being directly distributed to providers.

      This requirement significantly curtails mifepristone's potential to expand patient access to abortion care. The up-front costs (including substantial costs for pre-ordering the drug) and logistical requirements (e.g., increased staffing at provider offices) are a burden to providers and, therefore, deter some health care providers from offering medication abortion. When fewer providers are willing to stock mifepristone in their offices because of the REMS and ETASU, fewer patients can access medication abortion. In some cases this requirement may also force the patient to make an unnecessary visit to a clinic, medical office, or hospital to pick up the medication, rather than being able to pick up an order called into a pharmacy. This requirement is especially significant in underserved and rural areas where access to a health care provider is already difficult, and for those with low incomes for whom taking off work or getting to a provider multiple times in short order is impossible due to cost or family needs.[11] The Turnaway Study, a prospective longitudinal study conducted by Advancing New Standards in Reproductive Health (ANSIRH) at the University of California-San Francisco examining the effects of unintended pregnancy on individuals' lives, demonstrates that the majority of people who seek abortion care are already in difficult financial situations, and are

disproportionately people of color.[12] Costly and unnecessary visits to the doctor significantly increase financial and logistical burdens for these individuals and communities.

Any venue expansion, however, should not preclude the direct distribution of mifepristone to providers who want to dispense from their clinical settings. In many places, pharmacy refusal laws allow pharmacists to decline to fill prescriptions for reproductive health drugs such as emergency contraception and birth control, and federal policy allows providers to refuse to provide abortions.[13] So, although pharmacists' ability to dispense mifepristone would expand patient access to medication abortion in places where providers cannot easily store mifepristone in their offices, providers should retain the option to have mifepristone directly distributed to their offices to ensure continued access to medication abortion for those living in places where pharmacists can refuse to fill mifepristone prescriptions.

b. **Eliminate the Prescriber Agreement certification requirement.** Under the REMS and ETASU, providers must have a physician supervisor submit a Prescriber Agreement form to the drug's distributor attesting: 1) that mifepristone will only be provided by or under the supervision of a physician; and 2) that the physician can assess pregnancy duration, 3) diagnose ectopic pregnancies, and 4) make a plan for a patient to have surgical intervention if necessary.[10] This requirement should be eliminated for several reasons:

i. *The Prescriber's Agreement is unnecessary for the safe dispensation of mifepristone.* As the Technical Letter explains, health care professionals are already subject to many laws, policies, and ordinary standards of practice that ensure they can accurately and safely understand and prescribe medications. Provider certification is not required for health care professionals to dispense other drugs, including drugs that carry black box, or boxed, warnings about their medical risks. Accutane, for example, has a boxed warning that describes the potential risks of the drug,[14] but Accutane prescribers are not required to submit a certification form in order to prescribe it. Mifeprex also has a boxed warning[15] and there is no medical reason for a Prescriber's Agreement to be required in addition.

ii. *The Prescriber's Agreement forces providers to identify themselves as abortion providers to a centralized entity (Danco Laboratories) inspected and regulated by the FDA, which could discourage some from offering medication abortion care to their patients*. In 2014, more than half of U.S. health care facilities that provide abortions (52%) experienced threats and other types of targeted intimidation, and one in five experienced severe violence, such as blockades, invasions, bombings, arsons, chemical attacks, physical violence, stalking, gunfire, bomb threats, arson threats, or death threats.[16] Robert Dear's November 27, 2015, standoff at a Planned Parenthood health center in Colorado, which resulted in three deaths, provides one recent and chilling example of anti-abortion violence.[17] Given such escalating harassment and violence against known abortion providers,[18] clinicians may be understandably reluctant to add their names to a centralized database of mifepristone providers.

iii. *The Prescriber's Agreement would be incompatible and unnecessary if there were an expanded distribution system*. If dispensing venues are expanded as proposed in section 1a, ordinary standards of practice and state regulations would govern pharmacists' and providers' distribution of mifepristone, and a specific certification process would be unnecessary. Furthermore, a distribution system that incorporates the Prescriber's Agreement would be extremely difficult to maintain as a practical matter. Pharmacists would need to check the certification status of each prescriber before filling a prescription, which they do not normally have to do when filling other prescriptions.

Alternatively, pharmacists would need to become certified providers themselves, thus facing the deterrence problem of adding their names to a centralized database of mifepristone providers.

iv. *The Prescriber's Agreement as currently written prevents independent non-physician prescribers from being able to prescribe mifepristone without supervision by a physician*. The Prescriber's Agreement currently states that mifepristone "must be provided by or under the supervision of a physician."[19] However, nowhere in the outline piece of the REMS document written by the FDA is the word "physician" used. The REMS references only "providers" and "prescribers." [10] The Prescriber's Agreement's narrow interpretation of the REMS is medically unnecessary and severely limits patients' access to medication abortion care, because non-physician providers must work under physician supervision to prescribe mifepristone. All states give certain advanced practice clinicians prescribing authority, including for controlled substances, and 27 states allow them to dispense medications directly.[20] Advanced practice clinicians provide an increasing proportion of basic health care in the U.S., and several states authorize these clinicians to provide abortion care. If the Agreement is not eliminated, then at least enlarging the pool of health care providers that can submit the Prescriber's Agreement would help improve access and be consistent with individual state law regarding scope of practice. If the FDA does not eliminate the Agreement altogether, it should make clear that any licensed health care provider with prescribing authority is also eligible for certification to prescribe mifepristone.

c. **Remove the confusing and unnecessary Patient Agreement.** The REMS requires that each patient sign a Patient Agreement form before receiving mifepristone. This requirement is medically unnecessary and interferes with the clinician-patient relationship. It should be eliminated entirely.

In addition to being outdated and inconsistent with requirements for drugs with similar safety profiles, the Patient Agreement creates confusion for patients. Except in the few states that require that patients follow the regimen that appears on the mifepristone label, the majority of clinicians use an evidence-based regimen that is different from the regimen described in the label. Requiring a patient to sign an agreement to a treatment plan that differs from the one prescribed by her provider is confusing and could undermine trust in the clinician.

Patients have been using mifepristone safely and effectively according to evidence-based regimens recommended by their clinicians for many years, diverging from the regimen described in the Patient Agreement.[3] A wealth of data and experience since mifepristone's approval have demonstrated that this drug is extremely safe, that clinicians with routine professional training can provide it appropriately, and that patients are able to use it as directed by their health care provider.[21,22] Requiring a patient to sign an agreement to a treatment plan that differs from the one prescribed by her provider may create unnecessary confusion.

d. **Allow evidence-based follow-up assessment.** Under the Federal Food, Drug, and Cosmetic Act, the FDA should ensure that a REMS does not unduly burden patients, especially those in rural or medically underserved areas.[9] However, the documents appended to the REMS (the Medication Guide, Prescriber's Agreement, and Patient Agreement) all indicate the patient should to return to the clinic for follow-up 14 days after the patient takes mifepristone.[10] Such an in-person appointment is not always medically necessary and, when required, creates significant additional costs for patients, who must find time for another appointment at the provider's office and potentially incur substantial costs for travel, childcare, and/or lost wages.

These burdens are often increased for patients living in rural and other medically underserved areas. In 2008, 33% of all abortion patients traveled more than 25 miles to obtain care, and 74% of all patients living in rural areas traveled at least 50 miles to obtain the procedure.[23] Medical technology and telemedicine have advanced considerably since 2000,[24] and a growing body of evidence shows that alternatives to in-person follow-up, such as serum chorionic gonadotropin (hCG), multi-level pregnancy tests, and telephone counseling are safe, effective, and improve access and satisfaction for patients.[25,26,27]

2. **Increase the gestational age for indicated use on the label.**
The current label indicates use of mifepristone through 49 days after the start of the patient's last menstrual period (LMP). The Technical Letter discusses the substantial evidence demonstrating that the evidence-based medication abortion regimen is highly effective later than 49 days LMP, through at least the 10th week (64-70 days) of gestation.[28,29,30] The National Abortion Federation's (NAF) annual *Clinical Policy Guidelines*, which NAF develops by consensus based on a rigorous review of current medical literature and known patient outcomes, recommend that an evidence-based medication abortion regimen be used through 70 days LMP.[31] The time between 49 and 70 days LMP is critical for patient access, as approximately 30% of women who seek an abortion present for care during this time, according to the Centers for Disease Control.[32]

Consider the current legal and social climate

The overall legal and social climate around abortion care intensifies all of the burdens that the mifepristone REMS places on patients and makes it even more critical that the FDA lift medically unnecessary restrictions on the drug. Since mifepristone's approval, a multitude of laws and regulations at the federal and state level have dramatically restricted access to abortion care. In the first five years of this decade alone, states enacted 288 abortion restrictions – more than the entire previous decade.[33] These restrictions are typically unsupported by medical evidence and serve only to reduce access to abortion care.[34] In 2000, the Guttmacher Institute, a nonpartisan research and policy organization that seeks to advance sexual and reproductive health and rights and ensure the highest standard of sexual and reproductive health care, considered 13 states to be hostile to abortion, meaning that those states had 4-5 types of restrictions on abortion. In 2014, the number of states considered hostile had more than doubled, now including more than half of all states. [34]

Providers have increasingly been forced to close their doors as a result of mounting restrictions. There were about 1,800 abortion providers in the U.S. in 2000. Stand-alone abortion clinics constituted 447 (25%) of all providers in 2000, and those clinics provided 71% of all abortions.[35] By 2008, only 378 abortion clinics were still providing 70% of abortions.[36] Abortion clinic closures have accelerated since 2008, as lawmakers began passing restrictions at an unprecedented rate.[37] The Associated Press estimated in June 2015 that 70 abortion clinics had closed in a dozen states since 2010.[38] This wave of state restrictions and clinic closures has continued unabated in the last five years.

Some of these measures specifically block access to medication abortion by invoking the FDA-approved label. North Dakota, Ohio, and Texas currently require mifepristone to be administered solely according to the regimen that appears on the FDA label.[39] The Arkansas legislature just passed a similar law in 2015, though a federal judge issued a temporary restraining order blocking enforcement of the law until a hearing on March 14, 2016.[40] In these states, mifepristone cannot be prescribed in accordance with evidence-based practices developed in the last 15 years,[*] which improve patient access in multiple ways:

- enabling patients to take a lower dose of mifepristone, resulting in fewer side effects and lower cost;

[*]The one deviation that Texas allows from the label is one other dosage amount of Mifeprex and misoprostol.[39]

- allowing patients to take mifepristone, misoprostol, or both at home, and/or confirm termination of pregnancy at home, resulting in fewer visits to the provider;
- and offering medication abortion to patients later than 49 days LMP. [3]

Studies have also shown that these "label laws" have had a negative impact on patient access to abortion. For example, a recent study showed that after passage of laws that restricted use of mifepristone to the FDA label in Texas and Ohio, medication abortion declined dramatically while it rose in New York and California, states without restrictive laws.[41] Furthermore, these laws run counter to the FDA's own guidance, which states that a "package insert is informational only."[42,43,44] As long as the FDA-approved label diverges from evidence-based regimens, states can hide behind it as they restrict access to abortion. If the FDA does not update mifepristone's label to reflect the most current, evidence-based practice, the number of women adversely affected will only increase as additional states pass laws to exploit this discrepancy.

Other state restrictions are not specific to medication abortion, but affect all kinds of abortion care, including access to mifepristone. These medically unnecessary restrictions include the following: requirements that facilities where abortion is provided meet standards for ambulatory surgical centers; physician admitting privileges at local hospitals; and requirements that the patient and prescribing clinician must be in the same physical location, prohibiting the use of telemedicine technology. On top of these legal restrictions, anti-abortion stigma, harassment, and violence deter many health care professionals from providing abortion care. Authorizing distribution of mifepristone in pharmacies could diminish the impact of these barriers and allow providers to offer abortion care without fear of retaliation.

These restrictions, and the concomitant politicization and stigmatization of abortion care, have also seeped into other aspects of health care and prevented progress on the use of mifepristone for other indications. Removing the REMS program would make mifepristone more readily available for non-abortion therapies as well.[45,46]

In summary, the burdens on patient access to medication abortion, exacerbated by the REMS requirements placed on mifepristone, strongly outweigh any medical risk to the patient associated with the drug. In this climate of legal restrictions, clinic closures, and mounting stigma, it is increasingly important that any regulation of mifepristone be based solely on medical evidence, rather than the discretion of politicians who are determined to restrict access to abortion at any price. We recognize that the FDA is not responsible for most restrictions on abortion access. However, whenever the FDA evaluates indications and restrictions on an approved product, it does so in the context of the real-world circumstances in which the product is sold and the condition is treated. We believe this is vital in the case of mifepristone in particular, where the broad landscape of laws regulating abortion has measurable negative impact on the clinical provision of abortion care.

Mifepristone continues to hold immense promise for patient access to a safe and effective early abortion option, but medically unnecessary regulations are impeding its full potential. Extensive scientific and clinical evidence of mifepristone's safety and efficacy, and the ever-increasing burden on patient access to abortion care, clearly demonstrate that mifepristone's REMS program is not needed to protect patients. In light of the FDA's statutory mandate from Congress to consider the burden caused to patients by REMS, and the agency's own stated commitment to ensuring that drug restrictions do not unduly burden patient access, we ask that the FDA lift mifepristone's REMS and amend the label to extend the indicated use to 70 days.

Sincerely,

Advancing New Standards in Reproductive Health (ANSIRH), Department of Obstetrics, Gynecology & Reproductive Sciences, University of California, San Francisco
American Civil Liberties Union
Association of Reproductive Health Professionals
Bixby Center for Global Reproductive Health, Department of Obstetrics, Gynecology & Reproductive Sciences, University of California, San Francisco
Cambridge Reproductive Health Consultants
Carafem
Center for Reproductive Rights
Center on Reproductive Rights and Justice at the University of California, Berkeley, School of Law
Feminist Majority Foundation
Guttmacher Institute
Gynuity Health Projects
Ibis Reproductive Health
Jacobs Institute of Women's Health
Legal Voice
Medical Students for Choice
NARAL Pro-Choice America
National Abortion Federation
National Advocates for Pregnant Women
National Institute for Reproductive Health
National Latina Institute for Reproductive Health
National Network of Abortion Funds
National Partnership for Women and Families
National Women's Health Network
National Women's Law Center
Planned Parenthood Federation of America
Physicians for Reproductive Health
Provide
Reproaction
Reproductive Health Technologies Project
Society of Family Planning

cc:
Valerie Jarrett, Chair, White House Council on Women and Girls
Tina Tchen, Executive Director, White House Council on Women and Girls
Jordan Brooks, Deputy Executive Director, White House Council on Women and Girls
Nancy C. Lee, M.D., Deputy Assistant Secretary of Health, Women's Health, Director of the Office on Women's Health, Department of Health and Human Services
Bobby Clark, Counselor for Public Health and Science, U.S. Department of Health and Human Services, Office of the Secretary

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[42] U.S. Food and Drug Administration, Drug Bulletin 12:1, 4-5 (1982) ("The FD&C Act does not… limit the manner in which a physician may use an approved drug …. With respect to its role in medical practice, the package insert is informational only").
[43] Agency Request for Comments: Citizen Petition Regarding the Food and Drug Administration's Policy on Promotion of Unapproved Uses of Approved Drugs and Devices, 59 Fed. Reg. 59820-01 (Nov. 18, 1994) ("FDA has long recognized that physicians and other health care professionals may prescribe approved therapies for unapproved uses").
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[45] Dzuba IG, Grossman D, Schreiber CA. Off-label indications for mifepristone in gynecology and obstetrics. *Contraception*, 2015;92:203-05, doi: 10.1016/j.contraception.2015.06.021 (showing that data from around the world suggests mifepristone could be used to treat patients with a wide variety of cancers, tumors, and other hormone-sensitive conditions who have exhausted other standard treatments).
[46] Mifepristone Compassionate Use Program. Feminist Majority Foundation website (discussing a program that has been able to help treat a small cadre of eligible patients, but must contend with FDA-mandated paperwork that is onerous to most physicians and creates needless delays in quickly and effectively accessing a potentially life-saving treatment option). http://www.feminist.org/rrights/compassionateuse.asp. Accessed December 21, 2015.

EXHIBIT 47

The FDA and RU-486: Lowering the Standard for Women's Health: Hearing Before the Subcomm. on Crim. Just., Drug Pol'y, & Hum. Res. of the H. Comm. on Gov't Reform, 109th Cong. 4 (2006)

UNITED STATES HOUSE OF REPRESENTATIVES
GOVERNMENT REFORM COMMITTEE

OCTOBER 2006

THE FDA AND RU-486: LOWERING THE STANDARD FOR WOMEN'S HEALTH

STAFF REPORT

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I. EXECUTIVE SUMMARY

This report explores the Food and Drug Administration's activities as they relate to RU-486 – the abortion pill – including the highly unusual process by which the drug was approved, the failures to ensure that the drug is dispensed as the Food and Drug Administration (FDA) requires, the subsequent illnesses, hospitalizations and deaths known to be associated with the drug and the failure to provide any meaningful restrictions despite evidence of its association with a 100% fatal septic infection.

On May 17, 2006, Congressman Mark Souder, Chairman of the Subcommittee on Criminal Justice, Drug Policy and Human Resources ("Subcommittee"), House Committee on Government Reform, convened a hearing to inquire into the safety of the FDA-approved drug Mifeprex (the trade name for mifepristone) commonly known as RU-486. The hearing was entitled, "RU-486 - Demonstrating a Low Standard for Women's Health?" The Subcommittee's hearing followed several months of investigative inquiries with the FDA after the Agency's July 2005 disclosure that four women had died of a septic infection after taking RU-486 to induce an abortion.[1]

This Subcommittee Staff Report ("Report") provides background information about RU-486, including the reasons the drug was brought to market. It also explores the allegation that FDA disregarded various statutes and rules in the RU-486 approval process, and it examines RU-486's safety record in the United States. The accumulation of safety data from "real world" use of the drug in America has allowed Subcommittee investigators to more completely grasp FDA's understanding of the risks posed by RU-486 when it approved the drug on September 28, 2000.

Based on the significant demonstrated danger this drug poses to women, the Report examines options for withdrawing this drug from the market.

II. BACKGROUND

RU-486 is the common name for mifepristone, which in the United States is marketed under the trade name Mifeprex. Shanghai HuaLian Pharmaceutical Co., Ltd.[2] of China produces the drug, which is imported and distributed by Danco Laboratories,[3] a corporate entity located in the Caribbean nation of the Cayman Islands. RU-486, Danco's sole product,[4] is approved for the

[1] FDA Public Health Advisory: Sepsis and Medical Abortion, July 19, 2005. Available at http://www.fda.gov/cder/drug/advisory/mifeprex.htm (last visited October 14, 2006).

[2] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Senator Jim DeMint (August 11, 2006) (on file with Subcommittee).

[3] *See, Foes criticize Chinese manufacture of abortion pill for U.S.*, CNN.com, (Oct. 13, 2000) at http://archives.cnn.com/2000/HEALTH/women/10/13/abortionpill.plant.ap/index.html (last visited October 10, 2006).

[4] Unlike other drug companies with multiple products that are approved by or in application before the FDA--and which therefore cooperate with the FDA to withdraw drug products when recognizable problems arise--Danco has

termination of an established pregnancy through 49 days development (LMP),[5] when used in conjunction with the prostaglandin, misoprostol.[6]

RU-486 terminates pregnancy by blocking progesterone receptors in the uterus, a hormone necessary for the maintenance of pregnancy.[7] This leads to degeneration of the uterine lining, blocking nutrition to the prenate, thus resulting in its death.[8] Mifeprex is used in combination with a prostaglandin called misoprostol, which causes contractions that expel the contents of the uterus.[9] This is an off-label use for misoprostol, which contains an FDA-mandated black-box warning against using the drug during pregnancy.[10]

Under the protocol approved by the FDA – one considerably less stringent than the agency's proposed protocol leaked to the public a few months prior to approval – if the patient is

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no other products for which it must be answerable to the FDA. *See also,* Rogoff, Natasha L, *Haven or Havoc?,* PBS Frontline, February 19, 2004 at http://www.pbs.org/wgbh/pages/frontline/shows/tax/schemes/cayman.html.

[5] FDA Approval Memo (September 28, 2000); "LMP" refers to the first day of the last menstrual period, and is the customary measure of gestational age, from approximately 14 days pre-fertilization of the conceptus.

[6] The FDA examined misoprostol to see if the deadly *Clostridium Sordellii* bacteria that killed four California women after taking RU-486 was associated with misoprostol, rather than the Mifeprex: "An FDA Public Health Advisory in mifepristone dated July 22, 2005 reported 4 cases of septic death in California following the use of mifepristone and intravaginal misoprostol for medical abortion. For this reason, DRUP [Division of Reproductive and Urologic Products] and DDRE [Division of Drug Risk Evaluation] met on July 19, 2005, to discuss searches of the AWRS database to further investigate this cluster of repo0rts. At this meeting, DDRE agreed to provide 3 consults to examine this issue… The proposed consults were as follows:

- Consult #1: Review of all reports of serious infections with misoprostol in women of childbearing age
- Consult #2: Review of all reports for suspected intravaginal products with a fatal outcome
- Consult #3: Review of all serious, unusual infections with intravaginal products."

"This review did not identify any new safety signal associated with intravaginal product administration, especially in regards to infection or pregnancy status." FDA Office of Drug Safety Postmarketing Safety Review, December 8, 2005 (on file with the Subcommittee).

The FDA also tested the manufacturing lots from which the misoprostol was distributed and eliminated that drug product as a source of contamination that would have caused the fatal *C. Sordellii* infections. *See* Marc Fischer, M.D., M.P.H., CDC, *Clostridium sordelli Toxic Shock Syndrome Following Medical Abortion*, Public Workshop on Emerging Clostridial Disease," (CDC Conference Center: Atlanta, Georgia, May 11, 2006). Available at http://www.fda.gov/cder/meeting/clostridial/fisher.pdf (last visited October 20, 2006).

[7] See., e.g., University of Chicago Department of Obstetrics and Gynecology, Information on Hormonal Imbalance, available at http://babies.bsd.uchicago.edu/endo/hormoneImbalance.htm (last visited October 10, 2006).

[8] Etienne-Emile Baulieu, "RU-486 as an Antiprogesterone Steroid: From Receptor to Contragestion and Beyond," *Journal of the American Medical Assn*. 262:13; 1808-1814 (October 6, 1989).

[9] Pfizer (along with their generic subsidiary) and Teva Pharmaceuticals, the makers of misoprostol, have never filed a New Drug Application to seek approval from the FDA for its use in abortion. It was approved for use with ulcers, and is contraindicated for pregnancy. Pfizer's German affiliate recently pulled the drug from the market.

[10] Cytotec (misoprostol) Full Revised Label, April 17, 2002, available at www.fda.gov/cder/foi/label/2002/19268slr037.pdf (last visited October 10, 2006).

found to be a candidate for a chemical abortion (according to criteria such as gestational age of 49 days or less, absence of ectopic pregnancy and a host of health contraindications), she is given 600 mg of Mifeprex to consume at once and instructed to return two days later to consume orally 400 mcg of misoprostol. Patients are further instructed to return in 14 days for a follow-up, which could include a surgical abortion in the three percent to 7.9% of cases in which the chemical abortion fails.[11]

Many providers, however, deviate from the FDA protocol, extending the RU-486 abortion cut-off to 56 and even 63 days' gestation,[12] cutting the dose of Mifeprex by two-thirds, and handing the patient misoprostol pills to insert vaginally at home two days later.[13] Failure rates at these gestational ages are approximately 17% and 23% respectively.

In the decade preceding FDA approval of RU-486 for use in the United States, advocates of RU-486 promoted the drug as a private, easy, safe and effective method of pregnancy termination,[14] offering women the choice of ending pregnancy at an earlier stage and in a less "invasive," instrumented manner, when compared to surgical and suction abortion methods.[15] In sum, the public was told that access to RU-486 had everything to do with women's privacy and choices.

Cited as justification for RU-486 approval and use were the following goals: "defusing the abortion conflict,"[16] putting abortion "into the medical mainstream and out of this ghettoized place it's been in,"[17] making "abortion … more socially acceptable,"[18] "expanding the number

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[11] See Mifeprex Label ("Medical abortion failures should be managed with surgical termination." Also, "Each patient must understand…that medical abortion treatment failures are managed by surgical termination.") at http://www.fda.gov/cder/foi/label/2005/020687s013lbl.pdf (last visited October 10, 2006).

[12] Some abortion providers (e.g., Planned Parenthood of New York City at www.ppnyc.org/services/factsheets/mifep.htm, Capital Care Women's Center at www.capitalcarewomenscenter.com/services.php, and Camelback Family Planning at www.camelbackfamilyplanning.com/abortionpill.html.), even advertise the availability of RU-486 through 63 days LMP, by which time the rate of incomplete abortion, infection, and other complications rises sharply. In U.S. clinical trials, the failure rate for RU-486 abortions jumps to 17% at 50-56 days LMP, and to 23% at 57-63 days LMP, from 8% at 49 days or less. Irving Spitz *et al*., "Early pregnancy termination with mifepristone and misoprostol in the United States," *New England Journal of Medicine* 1998, 338:1241-47.

[13] Evidence of this method deviation can be found in many Adverse Event Reports, including those reporting on the deaths of four California women from toxic shock related to *C. Sordellii.*

[14] Lawrence Lader. RU486: The Pill that Could End the Abortion Wars and Why American Women Don't Have It. Reading, Mass.: Addison-Wesley Publ. Co., 1991, 17-26.

[15] Planned Parenthood of New York City Press Release, December 4, 2000: "Women will now have access to this option of a very safe, early abortion without undergoing an invasive procedure. … By allowing women to take part in their own care, mifepristone offers women more privacy in their decisions and control over their bodies."

[16] Margaret Talbot, "The Little White Pill," *New York Times Magazine*, July 11, 1999, quoting Seattle abortion provider Suzanne Poppema, M.D.

[17] *Ibid*, quoting Carole Joffe, professor of sociology, University of California-Davis.

[18] *Ibid*.

of abortion providers"[19] and even advancing the U.S. aim of "population control"[20] in the developing world. One vocal advocate explained: "Abortion in the U.S. is this degraded, shameful, violence-surrounded thing. …It's not like that in Europe. So that makes our context for medical [e.g., RU-486] abortion unique."[21] Safety and efficacy questions were brushed aside with assurances that several hundred thousand women in France and China had already used RU-486 to induce abortion.[22]

One might reasonably wonder why, when the surgical option is readily available and exponentially safer,[23] the FDA would approve, or the abortion industry would support, a chemical procedure that subjects women to increased pain and risk. To answer this question, it is helpful to understand abortion industry fears concerning the dwindling number of providers, and to assess the industry's leverage and access within the FDA.

The National Abortion Federation reported in May 2004 that the "number of abortion providers has declined by 37% since 1982."[24] In 1997, 36% of ob/gyns reported ever performing elective abortions.[25] Among them, 57% were fifty years of age or older and another 30% were 40 or older.[26] In other words, the abortion industry perceived that—unless drastic measures were taken—it was in danger of losing nearly 57% of its doctors by 2012 and 87% of its doctors by 2022, significantly reducing the availability of abortion in the United States.[27]

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[19] Margaret Talbot, "The Little White Pill," *New York Times Magazine*, July 11, 1999, quoting Seattle abortion provider Suzanne Poppema, M.D.

[20] Nathanson, Bernard, "Drugs for the Production of Abortion: A Review," Obstet & Gyn Survey 25:8; 727-731 (1970); Renate Klein *et al*., RU 486: Misconceptions, Myths and Morals. Melbourne, Aus.: Spinifex Press, 1991 The book is out of print, but the full text is available at http://www.spinifexpress.com.au/non-fict/ru486.htm (last visited October 20, 2006) at 59: "It is a further misconception to believe that this [RU-486] research took place in order to expand or improve women's 'choices' to control their reproduction. Quite unmistakenly, the concept evolved as a means of population control. More than 20 years ago, the Center of Population Research of the U.S. National Institutes of Health became interested in the corpus luteum and called for research to determine whether to find 'means to inhibit corpus luteum function is a desirable goal'. The specific intention of such research was to restrict population growth in countries that were judged to be 'under-developed.' If successful, the method(s) could be extended to groups in the United States, Black, Hispanic and Native American Women (Department of Health, Education and Welfare, NIH, USA, 1969)."

[21] Margaret Talbot, "The Little White Pill," *New York Times Magazine*, July 11, 1999, quoting Carole Joffe, professor of sociology, University of California-Davis.

[22] Lawrence Lader. A Private Matter: RU-486 and the Abortion Crisis. Amherst, N.Y.: Prometheus Books, 1995, 115-117.

[23] The Alan Guttmacher Institute, an affiliate of Planned Parenthood, reports that the mortality rate for women who procure a surgical abortion is 0.1 in 100,000 during the first eight weeks of pregnancy, the period for which RU-486 is available for women. Dr. Michael Green, based on usage rates of 460,000 and 4 deaths, suggested that the risk of death from chemical abortion is ten times greater. *See,* Michael F. Green, M.D., *Fatal Infections Associated with Mifepristone-Induced Abortion*, Dec. 1, 2005, N. ENGL. J. MED 353;22 *at* 2318.

[24] Abortion Access Project, Fact Sheet: The Shortage of Abortion Providers, May 6, 2004, available at www.abortionaccess.org/AAP/publica_resources/fact_sheets/shortage_provider.htm (last visited October 10, 2006).

[25] Kaiser Family Foundation, *Abortion*, Issue update, Menlo Park, CA: Kaiser Family Foundation, May 1999.

[26] *Ibid.*

[27] Lawrence B. Finer and Stanley K. Henshaw, "Abortion Incidence and Services In the United States in 2000," Perspectives on Sexual and Reproductive Health, 2003, 35(1):6-15.

The industry, then, out of concern for its own preservation, pinned its hopes on chemical abortion. A Kaiser Family Foundation survey, for example, noted: "Many reproductive health groups in the U.S. have looked to widespread availability and marketing of mifepristone … to expand access to abortion in this country."[28] Pediatrician Eric Schaff, who oversaw at least one RU-486 trial, put the matter somewhat more crudely. Objecting to an FDA proposal (never formally adopted) that any doctor dispensing RU-486 would have to be trained in surgical abortion, Dr. Schaff explained, "The whole idea of [RU-486] was to increase access. … [The FDA proposal] kills the drug if it can't be used by primary care providers."[29]

Despite the problems associated with RU-486 (discussed in depth in Section III, below), it looked like a panacea for the abortion industry. Advocates predicted that the number of providers would increase. The Kaiser Family Foundation stated that one-third of all ob/gyns who did not perform abortions said they would be "very" or "somewhat" likely to prescribe mifepristone for abortions if approved by the FDA.[30] Furthermore, rather than limiting abortion procedures to medical doctors alone, advocates saw an opportunity for nurse practitioners, nurses, and others to administer abortions to women.[31]

In June 1989, one year after its introduction into the French market, the FDA issued an import alert on RU-486. The concern was that women would obtain the drug themselves and use it without support from a physician. The wisdom of this policy is supported by the fact that, as the RU-486 label states, nearly *all* users of RU-486 will experience adverse events.[32] But it wasn't long before Democrats, led by then-Representative Ron Wyden of Oregon, seized this opportunity to politicize the approval process.

Under the auspices of the Committee on Small Business's Subcommittee on Regulation, Business Opportunities and Energy, as early as September 18, 1990, Representative Wyden was investigating the FDA's import alert on RU-486, alleging that the FDA's overriding concerns for the alert were political, rather than medical, and that the actions of the FDA were preventing cures for several diseases, including breast and brain cancer, Cushing's disease, glaucoma and

[28] Kaiser Family Foundation, News Release, June 8, 2000, available at www.kff.org/womenshealth/20000613a-PressRelease2.cfm (last visited October 10, 2006).

[29] Sheryl Gay Stolberg, "F.D.A. Adds Hurdles in Approval of Abortion Pill," *New York Times*, June 8, 2000.

[30] Kaiser Family Foundation, News Release, June 8, 2000, available at www.kff.org/womenshealth/20000613a-PressRelease2.cfm (last visited October 10, 2006).

[31] Press release, Ibis Reproductive Health, the National Abortion Federation, and the Abortion Access Project, May 9, 2006, available at www.prochoice.org/news/releases/20060509.html (last visited October 10, 2006).

[32] Mifeprex Label, available at http://www.fda.gov/cder/foi/label/2005/020687s013lbl.pdf (last visited September 28, 2006): "Nearly all of the women who receive Mifeprex and misoprostol will report adverse reactions, and many can be expected to report more than one such reaction."

diabetes. Two hearings in his committee followed, one in November of 1990[33] and another in December, 1991.[34]

Following these hearings, Representative Wyden introduced legislation to prohibit the FDA from taking any action to bar the import of RU-486 unless the FDA finds that it is being imported for an illegal use.[35]

It is interesting to contrast the interests of Representative Wyden and the abortion industry with the concerns of the American Medical Association (AMA), which offered this view about the health and safety of women who might obtain and use RU-486 without a physician's supervision:

> "[I]t is the AMA's understanding that RU-486 poses a severe risk to patients unless the drug is administered as part of a complete treatment plan under the supervision of a physician…Rumors exist that the FDA, due to political pressure, is standing in the way of research on RU-486. We do not believe this to be true. On the contrary, it is the FDA's responsibility to ban a drug that has not met legal and regulatory requirements for importation into the United States. Because RU-486 has not met these requirements, the FDA complied with its charge and acted well within its authority in issuing its June 9, 1989, automatic detention import alert concerning the drug."[36]

In the meantime, women's groups orchestrated an offensive consisting of media stunts to exert political pressure on the FDA. Lawrence Lader, founding chairman of the then-National Abortion Rights Action League (NARAL), and Ms. Leona Benton, who volunteered to serve as a "test case," traveled to Europe to acquire RU-486 with the specific purpose of being apprehended by Customs agents when they returned on July 1, 1992.[37] Agents seized the pills, and 45 members of the press showed up to publicize her "plight."

Ms. Benton immediately filed suit against the FDA in federal district court (Brooklyn), and Judge Charles Sifton ruled in her favor on July 14. Before she could physically recover the confiscated pills, however, government attorneys filed an appeal with the U.S. Court of Appeals for the Second Circuit, where a three-judge panel reversed Judge Sifton's order. The U.S. Supreme Court accepted an expedited appeal and, on July 17, ruled 7-2 against releasing the

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[33] *RU-486: The Import Ban and its Effect on Medical Research: Hearing before the House Subcommittee on Regulation, Business Opportunities and Energy, Committee on Small Business*, 101st Cong. (Nov. 19, 1990).

[34] *Safety and Effectiveness of the Abortifacient RU-486 in Foreign Markets: Opportunities and Obstacles to U.S. Commercialization: Hearing before the House Subcommittee on Regulation, Business Opportunities and Energy, Committee on Small Business*, 101st Cong. (Dec. 5, 1991).

[35] H.R. 875 "RU-486 Regulatory Fairness Act of 1991," introduced February 6, 1991.

[36] *RU-486: The Import Ban and its Effect on Medical Research: Hearing before the House Subcommittee on Regulation, Business Opportunities and Energy, Committee on Small Business*, 101st Cong. (Nov. 19, 1990) (statement of Dr. John P. Seward, Board Member, American Medical Association).

[37] Lawrence Lader, A Private Matter: RU 486 and the Abortion Crisis. Amherst, N.Y.: Prometheus Books, 1995, 135-136.

pills.[38] In the interim, she and Lawrence Lader gained widespread publicity concerning RU-486 in the media. She had a surgical abortion.[39]

In that same month, Public Media Video released a documentary financed by the Chicago abortion advocacy group, Women's Issues Network, entitled, "Science Held Hostage: RU-486 and the Politics of Abortion," hosted by Cybil Shepard. They held a screening on Capitol Hill.

In the six years since approval, mounting evidence points unavoidably to one conclusion: the political motivations for bringing RU-486 to the U.S. market overwhelmed considerations of women's health and safety.

In a September 28, 2000 interview following the announcement of the FDA's approval of RU-486, then-FDA Commissioner Dr. Jane E. Henney stated: "Politics had no role in this decision."[40] That assurance has been called into question by documents made public this year which reveal the Clinton Administration's vigorous role from 1993 forward[41] in facilitating the abortion drug's entry and approval. The actors behind these documents approached approval as a matter of logistics rather than as involving an open-minded scientific inquiry. One memorandum goes so far as to advise the Administration on how to contextualize the anticipated FDA approval of the drug in terms of "promoting women's health and maintaining the close relationship of the Administration to these [pro-choice women's] groups."[42]

However, had the FDA undertaken a thorough review of the scientific literature evaluating RU-486/prostaglandin abortions before approving RU-486, the agency would have been alerted to paramount safety concerns. Certainly, the FDA Medical Officer's Review, discussed in detail below, falls short of endorsing the safety of RU-486. Even so, only two additional studies are referenced in the Medical Officer's Review[43] apart from discussion of the U.S. clinical trials and the two so-called "pivotal French trials" conducted by the manufacturer. In light of this omission, and more significantly, in light of the FDA's approval of RU-486, one wonders why numerous studies demonstrating the inherent risks to women who undergo RU-486 abortions did not appear to influence the FDA's decision to approve RU-486.

And, in fact, such a thorough review of medical and scientific literature on RU-486 had already been published in 1991 by three women who describe themselves as pro-choice

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[38] *Benten v. Kessler*, 505 U.S. 1084 (1992).

[39] *Ibid*., at 139.

[40] Gina Kolata, "U.S. Approves Abortion Pill; Drug Offers More Privacy, and Could Reshape Debate," *The New York Times*, September 29, 2000.

[41] See, various documents compiled by Judicial Watch, Inc.. and appended to "A Judicial Watch Special Report: The Clinton RU-486 Files," April 26, 2006, available at http://JudicialWatch.org/archive/2006/jw-ru486-report.pdf.

[42] HHS Chief of Staff Kevin Thurm, Memorandum to White House Director of Public Policy Carol Rasco, Subject: RU-486, dated May 11, 1994.

[43] Beverly Winikoff *et al*., "The Acceptability of Medical Abortion In China, Cuba and India," *Int Fam Plan Perspect*. (1997) 23:73-78 & 89; and J.T. Jensen *et al*., "Outcomes of Suction Curettage and Mifepristone Abortion in the United States," *Contraception* (1999): 153-159.

feminists. A brief synopsis of some of the studies they review will help set the context for the discussion of the FDA's approval process, which follows in Part II (below).

Renate Klein,[44] Janice G. Raymond[45] and Dr. Lynette J. Dumble[46] co-authored a "comprehensive literature review and analysis of hundreds of medical and scientific articles on RU 486/PG [prostaglandin], a large percentage of which have a connection with Roussel Uclaf,"[47] the pharmaceutical company that developed RU-486 in the 1980s.

The first clinical trial of RU-486 in humans took place in October 1981 in Geneva, Switzerland after only 17 months of animal research with rats, rabbits and monkeys,[48] although the results of animal trials were not such a resounding success that they justified the rush to human trials. "RU 486 caused the death in two out of three monkeys in toxicity tests,"[49] for example. None of the eleven women in Geneva who were given 200 mg of RU-486 per day for three consecutive days died, but only nine pregnancies were terminated (eight after five days and the ninth at nine days). Furthermore, one woman claimed initially as a "success" later required uterine evacuation, and another woman needed emergency surgery and a blood transfusion due to heavy bleeding.[50] Klein *et al.* describe how the Parisian newspaper *Liberation* reported on the Geneva trial: "Liberation commented that, given these associated complications and risks, RU 486 was no 'abortion miracle.' *Liberation* also reported that RU 486 is not only an anti-progesterone but an anti-glucocorticosteroid which can take the place of cortisone in the adrenal glands, and that contraindications emanating from this double action of the drug could be a problem,"[51] as it turned out to be for two out of three monkeys.

Roussel Uclaf staff proceeded next to clinical trials on small groups of women in France, Sweden, Australia, Holland, the United States of America, England, Finland and China. The manufacturer supplied RU-486 for these trials, and its staff and consultants co-authored articles reporting on the results.[52] The success rates (defined as "a complete termination of pregnancy

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[44] Ms. Klein is a biologist, professor of sociology and women's studies and author/editor of numerous books on reproductive technologies.

[45] Then Professor, University of Massachusetts and associate director of MIT's Institute on Women and Technology.

[46] Then visiting professor of surgery at the University of Texas and senior research fellow in the University of Melbourne's Department of Surgery, Royal Melbourne Hospital.

[47] Renate Klein *et al*., RU 486: Misconceptions, Myths and Morals. Melbourne, Aus.: Spinifex Press, 1991 The book is out of print, but the full text is available at http://www.spinifexpress.com.au/non-fict/ru486.htm (last visited October 20, 2006) at 4.,.

[48] *Ibid*., at 9-10.

[49] Lawrence Lader. RU486: The Pill that Could End the Abortion Wars and Why American Women Don't Have It. Reading, Mass.: Addison-Wesley Publ. Co., 1991, 17-26, at 48.

[50] Renate Klein *et al*., RU 486: Misconceptions, Myths and Morals. Melbourne, Aus.: Spinifex Press, 1991 The book is out of print, but the full text is available at http://www.spinifexpress.com.au/non-fict/ru486.htm (last visited October 20, 2006) at 10, citing Etienne-Emile Baulieu, "RU-486 as an Antiprogesterone Steroid: From Receptor to Contragestion and Beyond," *Journal of the American Medical Assn*. 262:13; 1808-1814 (October 6, 1989)..

[51] *Ibid*., at 10.

[52] *Ibid*.

without the need for further medical intervention") using RU-486 alone ranged from 54%[53] and 61%[54] to a high of 85%[55] and 90%[56] -- at best substantially below the 99% success rate for surgical abortion.

The Kovacs *et al*. trial, finding a 61% average efficacy, illustrates some of the risks encountered in RU-486 use. A total of 37 women "with amenorrhea of 42 days or less" were given RU-486 twice daily for four days at several different levels of dosage. All patients attended three follow-up visits at one, two and five-to-six weeks after the "therapy" began. In three patients (8%) pregnancy was unaffected by the drug. Two patients required blood transfusion and curettage due to heavy bleeding, and another was found at the second follow-up visit to have an extra-uterine pregnancy. Kovacs *et al*. concluded that "treatment with RU 486 may provide a novel therapy for 'menstrual regulation' but the efficacy of the treatment needs to be improved to compete with alternatives such as vacuum aspiration."[57]

In 1984, researchers in Sweden began using a prostaglandin in conjunction with RU-486 to improve efficacy rates (achieving complete abortions in 32 of 34 women subjects, or 94%), without, however, having first undertaken basic research into the potential adverse effects arising from interactions between these drugs.[58]

In late 1988, the French Minister of Health issued approval for the marketing of RU-486 in France.[59] A distinguished committee of scientific and medical experts, which included the president of France's National Academy of Medicine, the head of Nephrology Department, Necker Hospital (Paris), research directors at the (French) National Institute for Health and Medical Research and National Center for Scientific Research, began reviewing data on 30,000 women who by then had used RU-486. In April 1990, this committee issued its scathing "Report of the International Inquiry Commission on RU 486", which faults the approval of RU-486 on several grounds and which warns of the inherent and well-documented risks of RU-

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[53] Herrmann, W.L., Wyss, Rolf, Riondel, A., Philibert, Daniel, Teutsch, Georges, Sakiz, Eduoard and Baulieu, Etienne-Emile. (1982). Effet d'un stéroide antiprogesterone chez la femme: interruption du cycle menstruel et de la grossesse au début. *C R Acad Sci Paris* 294.933-938.[The effect of an anti-progesterone steroid on women: interruption of the menstrual cycle and early pregnancy. Reports of Proceedings of the Academy of Sciences, Paris].

[54] Kovacs, L., Sas, M., Resch, B.A, Ugocsai, G. Swahn, Marja-Lisa, Bygdeman, Marc and Rowe, PJ. (1984). Termination of early pregnancy by RU 486 - an antiprogestational compound. *Contracep* 29.399-410.

[55] Couzinet, Béatrice, Le Strat, Nelly, Ulmann, André, Baulieu, Etienne-Emile and Schaison, Gilbert. (1986). Termination of early pregnancy by the progesterone antagonist RU 486 (Mifepristone). *New England Journal of Medicine* 315.1565-1570.

[56] Grimes, David A., Mishell, Daniel R., Shoupe, Donna and Lacarra, Maria. (1988). Early abortion with a single dose of the antiprogestin RU-486. *American Journal of Obstetrics and Gynecology* 158: 1307-1312.

[57] Kovacs, L., Sas, M., Resch, B.A, Ugocsai, G. Swahn, Marja-Lisa, Bygdeman, Marc and Rowe, PJ. (1984). Termination of early pregnancy by RU 486 - an antiprogestational compound. *Contracep* 29.399-410.

[58] Bygdeman, Marc and Swahn, Marja-Liisa. (1985). Progesterone receptor blockage: Effect on uterine contractility and early pregnancy. *Contraception* 32; 45-51, cited in Klein *et al*., RU 486: Misconceptions, Myths and Morals. Melbourne, Aus.: Spinifex Press, 1991 The book is out of print, but the full text is available at http://www.spinifexpress.com.au/non-fict/ru486.htm (last visited October 20, 2006) at 11.

[59] Report of the International Inquiry Commission on RU 486, April 1990, available at http://www.trdd.org/RU486/RUCIEE.HTM (last visited Oct. 18, 2006).

486/prostaglandin abortions. They note cardiovascular and respiratory risks – a full year before the first such fatality, but already evident from the report of one woman who lapsed into a 36-hour-long coma during an RU-486 abortion.[60]

Among the many serious issues raised by the International Inquiry Commission on RU 486 are these:

- the "very strong anti-glucocorticoid" effect of RU-486 (with which the FDA is now familiar, following the deaths from septic shock of four California women)
- the continued uncertainty surrounding RU-486's mode of action
- the necessity of using a prostaglandin to achieve marginally acceptable effectiveness, in light of the known serious side effects of prostaglandin
- metrorrhagia in over 90% of cases, lasting from 1 to 35 days (in "many cases an emergency 'Revision Uterine' [uterine evacuation] was necessary to contain the hemorrhaging. In certain cases, the only recourse was an emergency blood transfusion, with all the risks this involves.")
- "Beyond far heavier risks [compared to] the surgical method … there is – with the medicinal method – an uncertainty about the result during 5 to 12 days," as well as
  - "failure for 5% of the women who will therefore undergo surgery,
  - "around 5 to 10% persistent hemorrhages will need medicinal or surgical treatment,
  - "absolute necessity, some days after abortion, to [perform] an ultrasound examination and a HCG dosage, to be completely sure there [are] no traces of the fetus."
- the risks to women who do not return for follow-up treatment
- recently published studies demonstrating "a strong stimulating effect by RU 486 on the growth of a breast cancerous cellular line"[61] and immune system inhibition.[62]

On immune system inhibition, one wonders how the FDA could have failed to take note of the World Health Organization's 1991 study,[63] in which "9 of the 341 women (2.6%) with complete abortion and … 5 of the 17 subjects (29.4%) with incomplete abortion" had to be given "antibiotic therapy to prevent or cure suspected genitourinary infection" during the six-week follow-up period.[64] Nearly *thirty percent* of incomplete abortions involved infection.

A last example of facts the FDA should have taken into account in the agency's review of RU-486 is the personal story of Tamara Keta Hodgson, a nurse who took part in the RU-486

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[60] *Ibid*.

[61] The referenced report cites RT Bowden, JR Hissom, MR Moore. (1989) "Growth stimulation of T47D human breast cancer cells by the anti-progestin RU-486," *Endocrinology* 124; 2642-2644.

[62] BJ Van Voorhis, DJ Anderson, and JA Hill (1989), "The effects of RU 486 on immune function and steroid-induced immunosuppression in vitro," *J Clin Endocrinol Metab* 69:1195-1199.

[63] World Health Organization. (1991) "Pregnancy termination with mifepristone and gemeprost: a multicenter comparison between repeated doses and a single dose of mifepristone. *Fertil Steril* 56: 32-40.

[64] *Id*., at 37.

trials conducted by Dr. David Grimes in Los Angeles. In a letter published in the *Los Angeles Times* under the heading "Pros and Cons of 'Dr. Grimes' bitter pill,' " Ms. Hodgson writes:

> I took RU-486 in December, 1986, when I was three weeks pregnant. Twenty-four hours later I began to have severe cramping and started vomiting. When this had gone on for 10 to 12 hours, a friend took me to the County-USC Emergency Room. After an excruciating pelvic exam, I was given a shot of Demerol, which did nothing, and a prescription for a prostaglandin inhibitor to slow down the process, which did relieve the pain. I had mild bleeding for a few days and then six days after taking the drug, I began to hemorrhage. I continued to bleed or spot until mid-March, 1987.
>
> I'm not sure why I had such an extreme response. I chose to take the drug rather than have a surgical abortion because it had been presented to me as a relatively benign experience. I also thought it might help advance the causes of both science and women.
>
> Do I think RU-486 should be licensed in the United States? I'm not sure. I had access to many resources not available to the general population of women who might take this drug. I am a registered nurse who works at one of the most sophisticated hospitals in the world. I was cared for by the research team investigating the drug. I had no children who needed to be cared for.
>
> The same cannot be said for women of the Third World. It also cannot be said for women in the United States who do not have access to adequate health care.[65]

Despite all this, what many abortion advocates promoted as a "miracle pill"[66] has turned out to be anything but. Even before its approval, the medical community knew what American women would soon learn by experience:

- mifepristone interferes with the body's immune response[67]

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[65] *Los Angeles Times*, May 6, 1990, at E-20.

[66] David Van Biema, "But Will It End the Abortion Debate?" *Time*, June 14, 1993; available at http://www.time.com/time/magazine/article/0,9171,978680,00.html (last visited October 20, 2006).

[67] *See,* Jeanette I. Webster and Esther M. Sternberg, *Role of the Hypothalamic-Pituitary-Adrenal Axis, Glucocorticoids and Glucocorticoid Receptors in Toxic Sequelae of Exposure to Bacterial and Viral Products*, Journal of Endocrinology 2004, 181:207-221 ("Natural and synthetic glucocorticoids protect against the lethal effects of many bacterial and viral components...agents that block the hypothalamic-pituitary-adrenal axis, as in…mifepristone…enhance lipopolysaccharide (LPS) and endotoxin lethality and LPS-induced fever. Even the normally endotoxin-nonresponsive C3H/HeJ mice could be made endotoxin sensitive by RU-486."). *See also,* Ralph P. Miech, *Pathophysiology of Mifepristone-Induced Septic Shock Due to Clostridium Sordellii*, The Annals of Pharmacotherapy, September 2005, 39:

> "Mifepristone is a potent progesterone antagonist that, in addition to its ability to block glucocorticoid receptors, blocks progesterone receptors...Blockade of progesterone receptors…results in rejection of the developing placenta and death of the embryo. Prolonged ischemia of the decidua and the embryonic placenta causes necrosis [death] of these tissues. Mifepristone also [causes] cervical dilation and liquefaction of the cervical mucus plug. The combined loss of a closed cervix and the protective cervical mucus plug permits contamination of

- it is more inconvenient than surgical abortion[68]
- it is more painful[69]
- it is less effective[70]
- it is associated with more adverse events[71]
- it causes more frequent and more severe hemorrhage than its surgical counterpart[72]

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the decidua and the intrauterine necrotic cells with aerobic and anaerobic bacteria from the normal vaginal flora."

See also, Sharon Worchester, *Mifepristone Deaths Raise Unanswered Questions*, Ob. Gyn. News, (October 1, 2005) at 13. (Quoting Dr. James A. McGregor)("Mifepristone has multiple pharmacologic properties that may interfere with innate immune responses to infection, toxin exposures, and inflammatory stimuli.").

[68] *See* FDA Medical Officer's Review of Amendments 024 and 033, Final Reports for the U.S. Clinical Trials Inducing Abortion up to 63 Days Gestational Age and Complete Responses Regarding Distribution System and Phase 4 Commitments, Finalized November 22, 1999 (dated January 27, 2000), available at http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_medr_P1.pdf (last visited September 28, 2006):

> This method of pregnancy termination is of limited value because of the relatively short window of opportunity, [sic] in which it can be employed. Its safety and effectiveness is based on its use during the seven weeks following the first day of the last menstrual period. This means that most women would not suspect that they are pregnant and have a confirmatory pregnancy test until at least four weeks after the beginning of their last menses. This, then, leaves only a three week period for the women to secure this method of abortion.
>
> Another disadvantage of this method of pregnancy termination is the need for at least three visits to the medical facility [sic] including at least a four hours [sic] stay after the administration of the misoprostol.
>
> In addition, medical follow-up is required to ensure that surgical termination is performed in case the medical termination attempt fails since misoprostol has been reported to be teratogenic in humans (limb defects and skull defects)...
>
> [In a comparison of medical termination of pregnancy with surgical termination,] [t]he medical regimen had more adverse events, particularly bleeding, than did surgical abortion. Failure rates for medical abortion exceeded those for surgical abortion…[and] increased with gestational age. Specific symptoms and adverse events, including cramping, nausea, and vomiting, were far more frequent among the medical than the surgical abortion patients… On the whole, medical abortion patients reported significantly more blood loss than did surgical abortion patients…

[69] *See, e.g.,* B. Elul, et.al, *Side Effects of Mifepristone-Misoprostol Abortion Versus Surgical Abortion, Data From a Trial in China, Cuba, and India*, Contraception 59:107-114, 111 (1999): China—60.3% chemical, 36.0% surgical patients experienced pain / cramps; Cuba—89.2 % chemical, 65.4% surgical; India—61.9% chemical, 36.8% surgical.

[70] *See, e.g.,* Beverly Winikoff, et. al., *Safety, efficacy and acceptability of medical abortion in China, Cuba, and India: A comparative trial of Mifepristone-misoprostol versus surgical abortion*, Am. J. Obstet. Gynecol. 431, 434 (Feb. 1997). Failure Rates: China—chemical 8.6%, surgical .4%; Cuba—chemical 16.0%, surgical 4.0%; India—chemical 5.2%, surgical 0%.

[71] *See, e.g.,* E. Cabezas, *Medical versus surgical abortion,* 63 Internat. J Gynecol. & Obstet. Supp. 1, S141, S144 (1999). Cramping: chemical 60.0%, surgical 48.3%; Nausea: chemical 30.6%, surgical 8.9%; Vomiting: chemical 15.1%, surgical 2.0%.

[72] *See Ibid.*, chemical abortion patients experienced 2.3 days of heavy bleeding, 4.8 days of normal bleeding, and 4.9 days of light bleeding compared to 0.3, 1.8, and 3.3 days for surgical, respectively. Furthermore, 50.8% of chemical abortion patients bled more than expected, compared to 7.3% for surgical patients; and 64.1% of chemical abortion patients bled longer than expected, compared to 18.7% of surgical abortion patients. *See also,* Y.F. Chan, et.al.,

The safety issues associated with RU-486 are discussed in depth in Section III, below.

III. RU-486 APPROVAL IRREGULARITIES

Since FDA approved RU-486 in September 2000, a number of criticisms have been lodged against FDA alleging procedural irregularities in the approval process.[73] The Subcommittee investigators were aware of these criticisms and requested information from FDA regarding the issues raised by opponents of the approval. This section assesses the claims made and FDA's responses to the following allegations: 1) that FDA's approval was based solely on data from uncontrolled trials; 2) that FDA used Subpart H unlawfully when it approved the drug and, furthermore, that the clinical data used in support of the application was insufficient to satisfy Subpart H requirements; and, 3) that FDA unlawfully mandated the unapproved use of a drug, misoprostol, as part of the RU-486 abortion regimen.

A. The Approval was Unlawfully Based Solely on Data from Uncontrolled Trials

FDA's reputation as the world's foremost regulator of drug products is based largely on the rigor which it demands for data submitted in support of drug applications. The law requires, in Section 505(d)(5) of the Food, Drug and Cosmetic Act, that FDA shall not approve a drug when "there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling."[74] "Substantial evidence" means "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved . . . ."[75]

Over the years, FDA's high standard in supervising the production of clinical trial data has been referred to as its "gold standard." Typically, FDA requires data from two clinical trials that are randomized, blinded and controlled against a "comparator" – often a placebo but more typically an alternative therapy.[76] FDA's Section 314.126(e) indicates that "[u]ncontrolled

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Blood Loss in Termination of Early Pregnancy by Vacuum Aspiration and by Combination of Mifepristone and Gemeprost, Contraception 47:85-95, 90 (1993): Groups receiving 200mg, 400mg, and 600mg of mifepristone experienced an average loss of 84.1ml, 99.9ml, and 101.4ml of blood respectively (ranges were 16.8 - 371.3ml, 16.7 - 524.3ml, and 20.8 - 472.4ml, respectively) compared to an average blood loss of 53.2ml for patients undergoing a vacuum aspiration abortion (range of 29.3ml - 226.0ml).

[73] For example several groups have filed a "citizen petition" with FDA regarding RU-486's approval. *See* Citizen Petition of the American Association of Pro Life Obstetricians and Gynecologists, the Christian Medical Association, and Concerned Women for America, Request for Stay and Repeal of the Approval of Mifeprex (mifepristone) for the Medical Termination of Intrauterine Pregnancy through 49 Days' Gestation, Docket No. 02P-0377 (filed Aug. 20, 2002) ("Mifeprex Citizen Petition"). On October 10, 2003, these groups filed a response to the Danco Laboratories and the Population Council's Opposition to the Citizen Petition which was filed in March 2003. These documents are available in FDA Docket No. 02P-0377.

[74] 21 U.S.C. § 355(d)(5).

[75] 21 U.S.C. § 355(d).

[76] FDA issued a guidance document in 1998 ("Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products," May 1998)("FDA Clinical Evidence Guidance") that outlines the

studies or partially controlled studies are not acceptable as the sole basis for the approval of claims of effectiveness."[77] The question of whether the RU-486 trial data was produced solely by uncontrolled clinical trials was examined by the Subcommittee investigators.

The French and American trial data were generated by trials in which the participants were given mifepristone and misoprostol to chemically end pregnancies. The RU-486 regimen was judged to have been effective, "defined as the termination of pregnancy with complete expulsion of the conceptus without the need for a surgical procedure."[78] The studies measured the rate at which RU-486/misoprostol abortions succeeded or failed at different gestational ages.

However, neither the French nor American RU-486 trials randomized trial participants concurrently against either a placebo or the most similar RU-486 alternative, first-trimester surgical abortion.[79] Neither the French trials,[80] nor the American trial was concurrently controlled.[81] Furthermore, no discussion of controls can be found in FDA analyses of the French trials[82] or in the Spitz Study[83] that reported the results of the U.S. trial. Thus, the question arose as to whether the RU-486 trials were in fact uncontrolled.

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requirements of its drug trial policies with respect to proving effectiveness. Additionally, FDA has signed on to the principles enunciated in documents produced by the International Conference on Harmonization on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ("ICH").

[77] 21 C.F.R. § 314.126(e).

[78] Spitz, Bardin, Benton, and Robbins, "Early Pregnancy Termination with Mifepristone and Misoprostol in the United States," 338 *New England Journal of Medicine* (1998), 1241-47.

[79] Blinding would have been very difficult to achieve with respect to the medical personnel performing the surgical abortion or dispensing the drugs to the patient, but blinding of abortion evaluators might have been achievable. In any event, scientifically rigorous randomized and concurrently controlled trials could have been performed with limited or no blinding.

[80] Center for Drug Evaluation and Research, Food and Drug Administration, Statistical Review and Evaluation for NDA 2-687 (Mifepristone), at 2-4 (May 21, 1996). The French trial is referred to as FFR/91/486/14. Available at http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_statr.pdf.

[81] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (August 17, 2006) (on file with Subcommittee).

[82] Center for Drug Evaluation and Research, Food and Drug Administration, Statistical Review and Evaluation for NDA 2-687 (Mifepristone) (May 21, 1996). The French trial is referred to as FFR/91/486/14. Available at http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_statr.pdf.

[83] Spitz, Bardin, Benton, and Robbins, "Early Pregnancy Termination with Mifepristone and Misoprostol in the United States," 338 *New England Journal of Medicine* (1998), 1241-47.

At the Subcommittee's May 17, 2006 hearing, *RU-486: Demonstrating a Low Standard for Women's Health?,* Dr. Woodcock, Deputy Commissioner for Operations for the Food and Drug Administration, asserted in her written testimony for the Subcommittee that "[FDA's] finding of drug effectiveness was based on a comparison to a historical control of the expected rate of continued pregnancy."[84]

In response to a post-hearing Subcommittee question, FDA noted that the historical control, used in the RU-486 clinical trials, comprised of "the well-established data and pool of medical knowledge concerning both the natural course of pregnancy itself, including the well-documented rate of spontaneous abortion or miscarriage (less than 20%), and surgical abortion."[85] We take this to mean that the spontaneous abortion rate and the rate of induced abortion were together subtracted from the expected rate of ongoing pregnancy. It is important, then, to examine the FDA's claim that the French and U.S. trials were historically controlled.

First, FDA's assertion that the French and U.S. trials were historically controlled appears to be a *post hoc* assertion. There is no mention of any control group in the Spitz Study;[86] the word "control" does not appear in the article. Moreover, an FDA statistician reviewing the French trial data asserted that "[i]n the *absence of a concurrent control group* in each of these studies, it is a matter of clinical judgment whether or not the sponsor's proposed therapeutic regimen is a viable alternative to uterine aspiration for the termination of pregnancy"[87] (emphasis added). The reviewer made no mention of a historical control to which mifepristone would be compared, and it is well known that controls have to be specified *before* trials are performed. The lack of a prior delineation of the controls demonstrates that FDA's claims are not supported by the record.

Second, the U.S. RU-486 trials were conducted with specific groups of persons excluded. The Spitz Study[88] lists those disqualified from participation as follows:

> "Women with liver, respiratory, renal, adrenal, or cardiovascular disease, thromboembolism, hypertension, anemia, insulin-dependent diabetes mellitus, coagulopathy, or known allergy to prostaglandins were excluded, as were women less than 18 years of age or those more than 35 years of age who smoked more

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[84] See *RU-486: Demonstrating a Low Standard for Women's Health? Hearing before the House Subcommittee on Criminal Justice, Drug Policy and Human Res., Committee on Government Reform*, 109th Cong. (May 17, 2006) (statement of Janet Woodcock, M.D., Deputy Commissioner for Operations, FDA) Available at http://reform.house.gov/UploadedFiles/Woodcock%20Testimony.pdf.

[85] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (August 17, 2006) (on file with Subcommittee).

[86] Spitz, Bardin, Benton, and Robbins, "Early Pregnancy Termination with Mifepristone and Misoprostol in the United States," 338 *New England Journal of Medicine* (1998), 1241-47.

[87] Center for Drug Evaluation and Research, Food and Drug Administration, Statistical Review and Evaluation for NDA 2-687 (Mifepristone) at 7-8 (May 21, 1996). The French trial is referred to as FFR/91/486/14. Available at http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_statr.pdf.

[88] Spitz, Bardin, Benton, and Robbins, "Early Pregnancy Termination with Mifepristone and Misoprostol in the United States," 338 *New England Journal of Medicine* (1998), 1241-47.

> than 10 cigarettes per day and had another cardiovascular risk factor. Women were also excluded if they had in situ intrauterine devices, were breast-feeding, were receiving anticoagulation or long-term glucocorticoid therapy, had adnexal masses, had ectopic pregnancies, or had signs or symptoms suggesting they might abort spontaneously.[89]

Yet when FDA was asked what populations were excluded from its control group, the Subcommittee was told that "[a] historical control group does not include specific individuals, but rather is based on experience historically derived from the adequately documented natural history of the condition."[90] FDA made this additional point: "Thus, historical control populations usually cannot be assessed with respect to certain variables, such as the inclusion or exclusion of specific sub-populations."[91] This answer is methodologically insufficient, and it underscores the conclusion that, regardless of FDA's statement to the contrary, these trials were uncontrolled. The trial and control groups must be matched to each other in almost all possible ways if there is to be a meaningful control. If it was not possible to match the populations with the historical data set, then a concurrent control should have been used.

Finally, FDA allowed the use of uncontrolled trials for medical abortion because it defined the clinical endpoint too restrictively.[92] Neither spontaneous nor medical abortions produce only simple zero or one outcomes – that is, one-dimensional instances of success or failure. Not all abortions, whether spontaneous or medical, pass by themselves. Many require surgical intervention to be completed, or serious complications may ensue. FDA's cramped definition of RU-486 "effectiveness" ignores this.[93] A control should have been used in the RU-486 trial that compared different methods of producing the experimental outcome – first-trimester pregnancy termination – while assessing each method's ability to manage highly predictable, regular complications of medical abortion (*i.e.*, hemorrhage, incomplete abortion). As the International Conference on Harmonization[94] has noted, "non-defined" external controls

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[89] *Ibid*, at 1241-2.

[90] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (August 17, 2006) (on file with Subcommittee).

[91] *Ibid*.

[92] *Ibid*.

[93] *Ibid*. ("In the case of medical abortion, determining the effectivness of the drug is straightforward, because it is relatively easy to determine whether the pregnancy has been terminated. Therefore, it is unnecessary to utilize a randomized clinical trial design.").

[94] FDA, "International Conference on Harmonisation; Guidance on General Considerations for Clinical Trials," *Notice*, 62 Fed. Reg. 66113 (Dec. 17, 1997) (*FDA Guidance (ICH: E8): General Considerations*). The International Conference on Harmonization "is a unique project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration. The purpose is to make recommendations on ways to achieve greater harmonisation in the interpretation and application of technical guidelines and requirements for product registration in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines. The objective of such harmonisation is a more economical use of human, animal and material resources, and the elimination of unnecessary delay in the global development and availability of new medicines whilst maintaining safeguards on quality, safety and efficacy, and regulatory obligations to protect public health." *See* www.ich.org (last visited October 10, 2006).

– those in which "a comparator group [is] based on general medical knowledge of outcome" – are "particularly dangerous" and "such trials are generally considered uncontrolled."[95] Such a characterization pertains in instances like this in which the study's dependent variable (i.e., the termination of pregnancy) has been defined so narrowly as to give the false impression of complete knowledge of a simple medical outcome.

B. FDA's Abuse of Subpart H

RU-486 was approved through an important part of FDA's drug approval rules called "Subpart H."[96] In the Subcommittee's May 17 hearing, Dr. Woodcock told the Subcommittee, "FDA approved the Mifeprex NDA [new drug application] under Subpart H at the sponsor's request because the Agency determined that post-marketing distribution restrictions on the product were necessary to ensure its safe use."[97]

These rules were promulgated by FDA in 1992 as part of an attempt to correct perceived deficiencies in FDA's approval process made apparent by the need to quickly develop drugs for HIV/AIDS patients. However, in order to benefit from the provisions contained in Subpart H (*e.g.*, its restricted distribution provisions in the case of RU-486) certain conditions must be satisfied, and in the RU-486 instance, Subpart H was unlawfully used for its approval.

Inducing Medical Abortion Does Not Qualify for Subpart H

Supbart H can only be applied to drug products "that have been studied for their safety and effectiveness in treating *serious or life-threatening illnesses*…."[98] (emphasis added). FDA was aware of this requirement, and FDA asserted in its approval memo to the Population Council "that the termination of an unwanted pregnancy is a *serious condition* within the scope of Subpart H…."[99] (emphasis added).

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[95] *FDA Guidance (ICH E10): Choice of Control Group* at 5 (§ 1.3.5). Section 2.5.4 adds the following point to this discussion: "An externally controlled trial should generally be considered only when prior belief in the superiority of the test therapy to all available alternatives is so strong that alternative designs appear unacceptable and the disease or condition to be treated has a well-documented, highly predictable course. It is often possible, even in these cases, to use alternative, randomized, concurrently controlled designs."

[96] Medical Officer's Review of Amendments 024 and 033, Final Reports for the U.S. Clinical Trials Inducing Abortion up to 63 Days Gestational Age and Complete Responses Regarding Distribution System and Phase 4 Commitments, Finalized November 22, 1999 (dated January 27, 2000), available at http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_medr_P1.pdf (last visited September 28, 2006).. The Subpart H rules are found at 21 C.F.R. § 314.500ff.

[97] See *RU-486: Demonstrating a Low Standard for Women's Health? Hearing before the House Subcommittee on Criminal Justice, Drug Policy and Human Res., Committee on Government Reform*, 109th Cong. (May 17, 2006) (statement of Janet Woodcock, M.D., Deputy Commissioner for Operations, FDA) Available at http://reform.house.gov/UploadedFiles/Woodcock%20Testimony.pdf. We note that the Mifeprex Citizen Petition references a letter from Sandra Arnold of the Population Council to FDA, dated Sept. 6, 2000, in which she vociferously protests Mifeprex's approval under Subpart H. Mifeprex Citizen Petition at 20 (". . . it is clear that the imposition of Subpart H is unlawful, unnecessary, and undesirable. We ask FDA to reconsider.").

[98] 21 C.F.R. § 314.500.

[99] Medical Officer's Review of Amendments 024 and 033, Final Reports for the U.S. Clinical Trials Inducing Abortion up to 63 Days Gestational Age and Complete Responses Regarding Distribution System and Phase 4

Linguistic gymnastics notwithstanding, pregnancy or the termination of pregnancy is not a "serious or life-threatening illness," and therefore does not fall within the defined reach of Subpart H; the term "serious condition" is not found in the Subpart H rule. Subpart H is intended for the treatment of "serious or life-threatening illnesses," not conditions. There are situations in which pregnancies become serious or life-threatening, but the underlying condition is not "serious or life-threatening." Moreover, pregnancy itself is not an illness. There are situations in which serious or life-threatening complications may arise, but these are atypical events.

It is difficult to find a credible counter-argument from FDA or any private party defending the use of Subpart H to approve RU-486. This is not a mere technicality. If the condition being treated did not qualify for Subpart H approval, then the various restrictions that could be imposed pursuant to Subpart H to ensure the safe distribution of the drug would not have been available to the agency.

The FDA imposed several such restrictions on the distribution of Mifeprex.[100] (These restrictions, however, are less rigorous than what was initially proposed prior to approval.[101])

Mifepristone must be provided by or under the supervision of a physician who meets the following qualifications:

- Ability to assess the duration of pregnancy accurately
- Ability to diagnose ectopic pregnancies
- Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through other qualified physicians, and are able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary
- Has read and understood the prescribing information of Mifeprex
- Must provide each patient with a Medication Guide and must fully explain the procedure to each patient, provide her with a copy of the Medication Guide and Patient Agreement, given her an opportunity to read and discuss both the Medication Guide and the Patient Agreement, obtain her signature on the Patient Agreement and must sign it as well
- Must notify the sponsor or its designate in writing as discussed in the Package Insert under the heading DOSEAGE AND ADMINISTRATION in the event of an on-going

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Commitments, Finalized November 22, 1999 (dated January 27, 2000), available at http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_medr_P1.pdf (last visited September 28, 2006).

[100] Memorandum from FDA Center for Drug Evaluation and Research to Population Council 6, (Sept. 28, 2000). Available at http://www.fda.gov/cder/drug/infopage/mifepristone/memo.pdf (last visited October 15, 2006).

[101] FDA "Division Director Memo to File" on Mifepristone NDA, September 17, 1996 (on file with the Subcommittee): "The applicant has appropriately proposed that drug distribution be limited to licensed physicians (with prior training in assessing the length of pregnancy, in diagnosing ectopic pregnancy, and in the performanceof surgical abortion) who will attend educational seminars on the safe use of this regimen." The final restrictions allow for distribution under the supervision of a physician, rather than limiting it to licensed physicians, and do not require educational training on the safe use of the regimen.

pregnancy, which is not terminated subsequent to the conclusion of the treatment procedure
- Must report any hospitalization, transfusion or other serious events to the sponsor or its designate
- Must record the Mifeprex package serial number in each patient's record

With respect to the aspects of distribution other than physician qualifications described above, distribution of Mifeprex will be in accordance with the system described in the Population Council's submission of March 30, 2000, which includes the following:

- Secure manufacturing, receiving, and holding areas for the drug
- Secure shipping procedures, including tamper-proof seals
- Controlled returns procedures
- Tracking system ability to trace individual packages to the patient level, while maintaining patient confidentiality
- Use of authorized distributors and agents with necessary expertise to handle distribution requirements for the drug
- Provision of drug through a direct, confidential physician distribution system that ensures only qualified physicians will receive the drug for patient dispensing

In addition, the Population Council agreed to two post-marketing studies on the effects of RU-486 on women[102] (though earlier reviews considered six post-marketing studies, four of them were dropped when the drug was approved[103]). In the six years since the approval of RU-486, these studies have not been completed.[104]

The RU-486 Trials Did Not Establish a "Substantial Benefit" for Subpart H

In addition to being intended for drug products studied for their safety and effectiveness in treating serious or life-threatening illnesses, Subpart H is intended only for those products that "provide meaningful therapeutic benefit to patients over existing treatments (e.g., ability to treat patients unresponsive to, or intolerant of, available therapy, or improved patient response over available therapy.)"[105] FDA's Approval Memo stated that, for RU-486, "….[t]he meaningful therapeutic benefit over existing surgical abortion is the avoidance of a surgical procedure."[106] The French and American clinical trial data did not satisfy the requirements established in the

[102] Memorandum from FDA Center for Drug Evaluation and Research to Population Council 6, (Sept. 28, 2000). Available at http://www.fda.gov/cder/drug/infopage/mifepristone/memo.pdf (last visited October 15, 2006).

[103] Center for Drug Evaluation and Research, Food and Drug Administration, Office Memo to Population Council (documenting the approval action for RU-486) September 28, 2000. Available at http://www.fda.gov/cder/drug/infopage/mifepristone/memo.pdf (last visited October 15, 2006).

[104] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (July 31, 2006) (on file with Subcommittee).

[105] 21 C.F.R. § 314.500.

[106] Memorandum from FDA Center for Drug Evaluation and Research to Population Council 6, (Sept. 28, 2000). Available at http://www.fda.gov/cder/drug/infopage/mifepristone/memo.pdf (last visited October 15, 2006).

Subpart H rules for establishing a meaningful therapeutic benefit to patients over existing treatments.

First, RU-486 was not approved for a medical indication intended for only the treatment of patients who were intolerant of surgical abortion. It was approved to treat the general population of women seeking first-trimester abortions. FDA baldly asserted that there was a clinical benefit for chemical abortion, and made no effort to produce statistical evidence of an actual benefit.

Second, surgery is an integral part of the RU-486 abortion process, because a substantial proportion of women require D&C's after beginning the mifepristone regimen. Therefore, women who have RU-486 abortions must be able to tolerate the surgical procedure. This fact alone makes it all the more difficult to accept FDA's bald assertion of a meaningful therapeutic benefit above that presented by surgical abortion. While such a benefit may exist, the law requires FDA to make its judgments based on scientific evidence. Subpart H requires that both safety and effectiveness be established for the Subpart H drug above the existing standard of care. At the very least, FDA should have required the drug sponsor to conduct non-inferiority trials to generate data for the drug application.

Third, even though some women may prefer RU-486 abortions over surgical abortions, that fact does not establish the existence of a therapeutic benefit in and of itself. One can imagine numerous ways of delivering therapies that are more desirable for the patient – for example, pills rather than injection – but FDA must establish this fact statistically.

Fourth, it appears that no concurrently-controlled trials comparing medical and surgical abortion were required by FDA, because the Agency already knew that medical abortion—i.e., abortion by RU-486—is unambiguously inferior to surgical abortion with respect to safety and effectiveness. Prior to the approval of the RU-486 NDA, the FDA medical officer made the following observations about studies that had compared medical and surgical abortion:

> [In a study comparing medical and surgical abortion in India, Cuba, and China (n = 1373)], [t]he medical regimen had more adverse events, particularly bleeding, than did surgical abortion. Failure rates for medical abortion exceeded those for surgical abortion (8.6% versus 0.4% in China, 16.0% versus 4.0% in Cuba, and 5.2% versus 0% in India)…. Three patients (all medical abortions) received blood transfusions. This is a serious potential disadvantage of the medical method. On the whole, medical abortion patients reported significantly more blood loss than did surgical abortion patients….[107]
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> [In another non-concurrent study of 377 patients comparing mifepristone to surgical abortion in the U.S patients], [f]our mifepristone patients required curettage for acute bleeding while no surgical patients did. Nine mifepristone

[107] Medical Officer's Review of Amendments 024 and 033, Final Reports for the U.S. Clinical Trials Inducing Abortion up to 63 Days Gestational Age and Complete Responses Regarding Distribution System and Phase 4 Commitments, Finalized November 22, 1999 (dated January 27, 2000), available at http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_medr_P1.pdf (last visited September 28, 2006).

> patients required curettage to manage ongoing pregnancy while no surgical patients did. Five mifepristone patients required suction curettage because of incomplete abortion while no surgical patients did. Fourteen mifepristone and eight surgical patients required suction curettage for persistent bleeding. The median time delay for therapeutic curettage was significantly longer in the mifepristone group than in the surgical group (35 days versus 8 days). Mifepristone patients experienced significantly longer postprocedure bleeding than did surgical patients. The mean difference in bleeding days between cohorts was 9.6 days (95% CI, 6.8, 12.4)…. Overall, mifepristone abortion patients reported significantly higher levels of pain, nausea, vomiting, and diarrhea during the actual abortion than did surgical patients… Mifepristone patients reported more problems during the follow-up interval than did surgical patients. Post-abortion pain occurred in 77.1% of mifepristone patients compared with only 10.5% of surgical patients…. Nausea or vomiting in the follow-up interval was common in the mifepristone group (68.6%), but rare among surgical patients."[108]

Given these comments, it is impossible to conclude that RU-486 medical abortions provide a meaningful therapeutic benefit over surgical abortion. Consequently, FDA's approval of the RU-486 NDA using Subpart H was unjustified and unlawful.

C. The Highly Unusual Placement of Misoprostol on the Mifeprex Label

When FDA approved the Population Council's RU-486 application it also mandated the use of another drug, misoprostol, as part of a two-drug abortion regimen. The use of misoprostol was not only an unapproved or off-label use – it was actually contraindicated at that time.[109] This aspect of the approval highlights another irregular component of FDA's approach to reviewing the RU-486 NDA. Shortly after FDA's approval of mifepristone, Peter Barton Hutt, a former FDA general counsel and noted commenter on food and drug law, told the Wall Street Journal that FDA appeared to have created "an extraordinary precedent", because FDA was "seemingly encouraging a drug's unapproved use."[110] He added that the agency is in an "embarrassing and uncomfortable position."[111]

The Subcommittee's questions to FDA on this matter have produced some information but no clear sense as to what FDA's policy is with respect to placing off-label or contraindicated drug uses on another drug's label.[112]

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[108] *Ibid*.

[109] On April 17, 2002, the misoprostol label was amended to remove "the contraindication and precaution that Cytotec should not be used in women who are pregnant."

[110] Rachel Zimmerman, "Clash Between Pharmacia and FDA May Hinder the Use of RU-486," *Wall Street Journal* (Oct. 18, 2000): at B1.

[111] *Ibid*.

[112] In addition to questioning the FDA on this matter, the Subcommittee has looked for, and failed, to find any FDA Guidance documents on this topic.

Attention is drawn to two problems. First, it is well known that the NDA-holder for misoprostol (Searle) did not want to have its product used or labeled to reflect off-label uses as an abortifacient. [113] Thus, FDA mandated misoprostol's use in this abortion regimen and placed information about Searle's product on the Mifeprex label. Second, the entire edifice of FDA's regulation of drugs rests on the principle that only indications whose effectiveness has been demonstrated with "substantial evidence" may be placed on the label. FDA has procedures by which new indications can be approved using the supplementary new drug applications. No supplementary drug application was ever filed for misoprostol's use as an abortifacient.

In her prepared testimony before the Subcommittee, Dr. Woodcock noted that the FDA was "aware that questions ha[d] been raised about the use of misoprostol, a drug indicated for the prevention of NSAID-induced gastric ulcers, in the medical abortion regimen with mifepristone, without a separate approval and labeling of misoprostol for this use."[114] She then observed that numerous cases existed "where the labeling of one drug recommends its use with a second drug without the approval of the sponsor of the second drug."[115]

This statement is troubling and warrants further investigation. First, Woodcock's use of "recommends" is grossly inaccurate. In the Mifeprex regimen, the use of misoprostol is mandated. A physician might use an off-label variant of the regimen and, therefore, use another prostaglandin, but the Mifeprex label gives very specific directives to use misoprostol.[116] The non-optional nature of the regimen is carried forward into the language of the Patient Agreement Form which states: "I understand that I will take misoprostol in my provider's office two days after I take Mifeprex (Day 3)."[117] Second, Subcommittee investigators finds it problematic that FDA can dictate that a drug – under the proprietary control of a firm whose NDA has been approved – can be approved for a use to which it objects.

In a letter to Chairman Souder, FDA provided two examples in which non-approved uses appear on FDA-approved labels.[118] The examples relate to coronary heart disease and metastatic

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[113] See letter from Searle warning against the use of misoprostol in abortion: http://www.fda.gov/medwatch/safety/2000/cytote.htm (last visited October 20, 2006).

[114] See *RU-486: Demonstrating a Low Standard for Women's Health? Hearing before the House Subcommittee on Criminal Justice, Drug Policy and Human Res., Committee on Government Reform*, 109th Cong. (May 17, 2006) (statement of Janet Woodcock, M.D., Deputy Commissioner for Operations, FDA) Available at http://reform.house.gov/UploadedFiles/Woodcock%20Testimony.pdf.

[115] *Ibid*.

[116] Mifeprex Label, available at http://www.fda.gov/cder/foi/label/2005/020687s013lbl.pdf (last visited September 28, 2006).

[117] Mifeprex Patient Agreement, Item # 6, available at http://www.fda.gov/cder/drug/infopage/mifepristone/patientAgreement20050719.pdf (last visited October 20, 2006).

[118] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (May 2, 2006) (on file with Subcommittee). *See also*, See *RU-486: Demonstrating a Low Standard for Women's Health? Hearing before the House Subcommittee on Criminal Justice, Drug Policy and Human Res., Committee on Government Reform*, 109th Cong. (May 17, 2006) (statement of Janet Woodcock, M.D., Deputy Commissioner for Operations, FDA) Available at http://reform.house.gov/UploadedFiles/Woodcock%20Testimony.pdf.

breast cancer, and the relevant labels should be read to understand the comments that follow.[119] Some comments are in order. First, there is no *mandated* use of the second/off-label drug in either example. Second, in the coronary disease case, the drugs were designed and approved to work on aspects of cardiovascular system-blood pressure regulation. There is nothing unusual in this use of drugs intended to manage cardiac failure.

These facts provide a qualitative difference with the Mifeprex regimen in which misoprostol was *not* designed to work to produce abortions – or uterine contractions for that matter. Rather, misoprostol was a medication intended to protect the gastro-intestinal tract from adverse events related to the use of non-steroidal anti-inflammatory medication – an indication far removed from misoprostol's novel application as an abortifacient.

Finally, FDA's Herceptin/Taxol example is somewhat disingenuous. After reading each drug's label, one recognizes that Taxol is approved for metastatic breast cancer treatment as a single agent, and so is Herceptin, but neither is specifically indicated for metastatic breast cancer treatment where no prior chemotherapy has been given. The combination use is approved (but not MANDATED) for patients with metastatic breast cancer overexpressing HER2 protein who have not received any prior chemotherapy.

Both drugs are approved for use in metastatic breast cancer. Herceptin's indication is more specifically tied to use when there is overexpression of HER2 protein. If there has been no other chemotherapy given then both may be used together. FDA seems to be splitting hairs when it claims that the use of Taxol in such cases is off-label. That characterization depends upon a fine distinction having to do with a specific tumor marker and whether or not other chemotherapy had been used.

The tenuousness of FDA's examples leads the Subcommittee to conclude that FDA is having difficulty finding examples that parallel the mandated, dissimilar off-label use of misoprostol in the Mifeprex regimen.

IV. SAFETY

Since the introduction of RU-486 to the U.S. market, the FDA has acknowledged, as of May 2, 2006, the deaths of six women associated with the drug, nine life-threatening incidents, 232 hospitalizations, 116 blood transfusions, and 88 cases of infection.[120] These and other cases have added up to a total of 1070 adverse event reports (AERs) as of April 2006.[121]

[119] The relevant information can be found using the website: <www.rxlist.com>.

[120] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (May 2, 2006) (on file with Subcommittee).

[121] Numbers do not convey the full story. More telling are the first-hand accounts of women who have lived these events. Below are some examples from the Individual Safety Reports (ISRs) which describe in detail the type of experience RU-486 chemical abortion has turned out to be (mistakes are as they appear in the originals):

Event of January 1, 2000, reported September 27, 2000, one day before the approval of Mifeprex: "I was issued RU-486 in effort of obtaining an abortion. I followed directions exactly, and after taking the ru-486, I was in

excrutiating physical pain, for at least 12 hours straight and I was bleeding extremely excessively. I was bleeding through my pants but was in so much pain I couldn't even clean myself. It was the worst physical pain I've ever experienced in my life. This extreme pain was constant the whole 12 hours, it did not let up at all the whole time. I vomited continuously but couldn't even hold my head up. I had unbelievable abdominal pains, I can't even put in words. I couldn't speak, eat, drink, sit up, and had difficulty breathing. The only thing I could do was lie on the floor and pull my hair to deal with the pain. I couldn't clean myself or go to the bathroom, I thought I was going to die. After about 7 hours of this, I really wanted to die because I couldn't take the pain anymore. I wanted to call the hospital but I was hours from any hospital because I went to our cabin in a remote area to have privacy during this time. The administering clinic was closed since it was the weekend…. I was not informed of the extent of these side effects, I was told it would be just like a menstrual period. I never would have taken this had I been properly informed, even of the possibility of those effects…I was not told that this drug was experimental and not approved by the FDA…I believe they outright lied to me…when I returned to the clinic after the abortion was complete, they were not very attentive or interested in me, I explained to them my pains even though they didn't ask me any questions. I filled out a questionairre that they gave me before I took the drug and they said I have to do the questionnaire ever couple hours during the abortion, but when I offered it to them upon return, they didn't even want the questionaire, they didn't take it."

Event of July 26, 2002, reported September 28, 2002: "28 year old Gr5. Para 2 Ab 2 at 6 weeks 5 days gestation received 200 mg Mifeprex on [redacted] and inserted 800 mcg misoprostol vaginally on [redacted] at 11:00 a.m. The bleeding was 'normal' until 3:30 p.m. when it became heavier. That evening she stated 'it was like water coming out of me' and she felt dizzy. That evening she reported that she briefly 'passed out' twice. She went to an emergency room and received [missing] litres of IV fluid and had a D&C. Her hemoglobin on arrival was 8.7 gm/dl and was [missing] gm/dl after the D&C. She was started on iron supplementation. On [redacted] her hematocrit was 28% at the clinic and she reported that she was resting, on limited to light activity and doing well."

Event of August 15, 2004, reported July 25, 2005: "I took RU-486 last year and it caused me serious problems. After 15 days after taking it I hemorrhaged while at work requiring subsequent D&C, then had an infection that would not go away despite multiple antibiotics. I ended up being hospitalized and having multiple tests due to the infection and pain. I was hospitalized for four days in september of last year. Even after being hospitalized I was very ill for quite some time. I believe it took me until December to fully recover, during this time I lost quiet a bit of weight and had to enter counseling as a result of all the problems after using RU486."

Event of October 31, 2002, reported August 13, 2005: "Previous to 2002 I had two pregnancies and two live births…In 2002, 2003, and 2004, I had a three abortions at a very early stage, using the 'French' pill—RU-486—with each being almost exactly a year apart. I had the same experience each time. I developed a very bad case of bacterial vaginosis…I also was told to insert the final pill vaginally in all three cases. I had no idea it could even be taken orally."

Event of September 8, 2004, reported August 17, 2005: "I was given 2-step Abortion Pill. In the middle of the night I was awoken by severe abdominal pains. Having had endometriosis has built my pain tolerance quite high, but this pain was excruciating. Between the pain and diarrhea, I wanted to pass-out. I laid on the cold tile of the bathroom floor for 4 hours to keep me from fainting and because I couldn't get up. I thought it would eventually taper off, but after 4 hours I was exhausted and couldn't tolerate the pain. I yelled until my sister woke up to help me and asked her to call 911. She knew that I never go to the hospital, much less ask for 911, she immediately called. At the hospital, blood tests –b-hcg- kept coming back positive and I was still in alot of pain. They sent me for ultrasounds, blood tests again, and pelvic exams. I asked for more morphine, but they told my sister that they gave me the maximum dose and were surprised that I was still moaning of pain. The doctor said that my body was going through labor over and over, but wasn't ridding of anything. After the 3rd pelvic exam and blood test, the HCG count started coming down."

Event of December 14, 2005, reported December 27, 2005: "Approximately 2 1/2 weeks after taking Mifeprex and Cytotec to end a pregnancy, I began having very heavy bleeding. This was after I had not bled for a week, and after a 2 week follow up at a clinic—in which was told I was fine—I began hemorraging on the evening of the 14th, passing clots approximately 3 inches in size. I went through approximately 7 pads in 2 hours. The clinic wanted me to wait until the morning to get care from their facility, but when we called the local ER, they told me I needed to come in right away to get examined. I was cold, weak, and fatigued during the 2 hours my bleeding was excessively heavy. Unfortunately I was not able to make it into the ER because I am a single mother of 4, and had noone to care

A. Adverse Events for RU-486

These reports are based on the FDA's Adverse Event Reporting System (AERS), a voluntary system, with inherent underreporting. Common estimates of the proportion of adverse events actually captured by FDA in AERS are from one to ten percent. FDA acknowledges that it does not capture all adverse events associated with a drug: "When evaluating reports from the AERS system, it is important to recognize several caveats. First, *accumulated case reports cannot be used to calculate actual incidences of adverse events or estimates of risk for a product, as the reporting of adverse events is a voluntary process with inherent underreporting*"[122] (emphasis added).

The Government Accountability Office (GAO) has also commented on the underreporting of Adverse Events: "FDA cannot establish the true frequency of adverse events in the population with AERS data. The inability to calculate the true frequency makes it hard to establish the magnitude of a safety problem, and it makes comparisons of risks across similar drugs difficult."[123]

FDA nonetheless claims that it is capturing most adverse events associated with RU-486: "Because healthcare professionals who prescribe Mifeprex have agreed in writing" (with the manufacturer, Danco, *not* the FDA) "to report 'any hospitalizations, transfusions or other serious events' to the manufacturer, FDA believes that there are unlikely to be significant numbers of serious adverse events, including deaths, associated with Mifeprex that have not been reported to the Agency."[124]

During the Subcommittee staff's review of the 1070 Adverse Event Reports that had been reported through April 2006, ISRs were found that had been submitted through MedWatch, the voluntary reporting mechanism for AERS, rather than through Danco. FDA acknowledged that these reports were not matched by reports submitted through Danco,[125] undermining the Agency's claim that it is capturing most adverse events.

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for my children. Luckily for me, the bleeding lessened. I was told it was 'normal' to bleed for up to 4 weeks, but I am NOW at day 32 and still bleeding."

[122] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (May 2, 2006) (on file with Subcommittee).

[123] Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process GAO-06-402 March 31, 2006.

[124] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (July 31, 2006) (on file with Subcommittee).

[125] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (June 30, 2006) (on file with Subcommittee).

In light of FDA's repeated claim that it captures most RU-486-related adverse events—despite the Agency's own acknowledgement of underreporting and experience to the contrary—it is important to note that there is no true enforcement mechanism, either by Danco or the FDA, for ensuring that doctors report all adverse events, and there is little incentive on the part of the prescribing physician to do so.[126]

Even Danco has noted that the FDA's "obligatory" reporting system is of little value. In 2003, Dr. Richard Hausknecht, Medical Director for Danco, wrote that "[t]he obligatory reporting of adverse events is limited to transfusions, hospitalizations, ongoing pregnancies or 'other serious adverse events,' which allows considerable subjective judgment on the part of the providers. In addition, the reporting of other common adverse events may not be reported at all."[127]

Moreover, emergency room personnel and medical professionals who do not prescribe RU-486, but who may likely treat the infected or hemorrhaging patient, or provide surgical intervention, *have no obligation whatsoever to report adverse events for RU-486*, even assuming that the healthcare worker is aware the patient took the RU-486 drug regimen.[128] In such scenarios, prescribing physicians may remain unaware of adverse events that take place after they administer RU-486, alleviating them of reporting requirements. This underscores the fact that there is not an accurate picture of the total adverse events that are being experienced with this drug.

In addition to the fact that there is no accurate number of adverse events to serve as a realistic "numerator" for evaluating the rate of adverse events actually being experienced in the population, the FDA does not use an accurate figure for the true number of patients who have taken RU-486 as a "denominator." Rather, FDA accepts and reports "estimates" proposed by Danco. The most recent estimate is that 612,000 women in the U.S. have used RU-486 as of July 24, 2006.[129]

This estimate is likely inflated, since Danco arrives at its estimate by basing it on the number of packages sold (in three-pill packages of 200 mg pills) and multiplying that number by three to account for the number of doses that are given at the off-label 200 mg dose (rather than

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[126] Although RU-486 is approved for use through 49 days of pregnancy, it is commonly prescribed in the United States up to 63 days of pregnancy. Physicians also commonly prescribe a dosing regimen that is different from that approved by the FDA. Therefore, it has been suggested that in fact there is a *dis*incentive on the part of prescribing physicians to report adverse events that may be attributed to a physician's negligence or willingness to prescribe a regimen that is outside the FDA-approved regimen for RU-486.

[127] Hausknecht, R., "Mifepristone and Misoprostol for Early Medical Abortion: 18 Months Experience in the United States," *Contraception* 67 (2003) 463-465.

[128] Treating personnel might never know that a woman has taken RU-486; Women who seek medical treatment for adverse reactions after RU-486 may be too sick to disclose, may fail to disclose, or may simply refuse to disclose (because she does not want it in her medical record) that she has taken the RU-486 drug regimen.

[129] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (August 17. 2006) (on file with Subcommittee).

the FDA approved 600 mg dose).[130] That Danco is allowed to provide a loosely-figured *estimate* flouts the restricted approval provision for RU-486, which requires Danco to distribute the drug with a tracking system allowing the company to track packages "to the patient level while maintaining patient confidentiality."[131]

For FDA to rely upon guesses as a basis for understanding safety problems with RU-486 is highly problematic. Danco's estimate is used as the denominator for determining the rate of adverse events associated with the drug. The larger the denominator, the lower the percentage of adverse events. This inaccuracy of using Danco's estimate is inexcusable in light of the way the estimate is relied upon to determine and discuss the rate of adverse events associated with RU-486.

B. RU-486 Safety Issues Known Prior to Approval

Prior to FDA's approval of RU-486, the Agency's own medical experts recognized that any benefits that could be gained from the use of this drug for a "medical abortion" were limited at best and that significant dangers were inherent in its use. These dangers are especially acute when compared to surgical abortion. According to the FDA's medical reviewer, writing before the drug's approval:

> This method of pregnancy termination is of limited value because of the relatively short window of opportunity, [sic] in which it can be employed. Its safety and effectiveness is based on its use during the seven weeks following the first day of the last menstrual period. This means that most women would not suspect that they are pregnant and have a confirmatory pregnancy test until at least four weeks after the beginning of their last menses. This, then, leaves only a three week period for the women to secure this method of abortion.
>
> Another disadvantage of this method of pregnancy termination is the need for at least three visits to the medical facility [sic] including at least a four hours [sic] stay after the administration of the misoprostol.
>
> In addition, medical follow-up is required to ensure that surgical termination is performed in case the medical termination attempt fails since misoprostol has been reported to be teratogenic in humans (limb defects and skull defects)...
>
> [In a comparison of medical termination of pregnancy with surgical termination,] [t]he medical regimen had more adverse events, particularly bleeding, than did surgical abortion. Failure rates for medical abortion exceeded those for surgical

[130] Richard Hausknecht, Medical Director for Danco, described how Danco estimates the usage figures for RU-486: "Denominators… were estimated from sales figures. Although the FDA-approved regimen specified a single oral dose of mifepristone 600 mg, many physicians are using a lower dose (200 mg), …[an] estimated range was based upon Planned Parenthood practices and National Abortion Federation (NAF) polling of their membership practices…[and by] [a]djusting for utilization patterns of providers." *Contraception* 67 (2003): 463-65.

[131] CDER Office Memo to Population Council, September 28, 2006. At http://www.fda.gov/cder/drug/infopage/mifepristone/memo.pdf (last visited September 28, 2006).

> abortion…[and] increased with gestational age. Specific symptoms and adverse events, including cramping, nausea, and vomiting, were far more frequent among the medical than the surgical abortion patients… On the whole, medical abortion patients reported significantly more blood loss than did surgical abortion patients….[132]

The negative physical experience of RU-486 was explained this way by Dr. Tom Tvedten, an abortion provider in Little Rock, Arkansas: "With medical termination, the discomfort is significant because they have to go through mini-labor…There's a lot of hard cramps and usually significant bleeding. It's cheaper, safer and less painful to have a surgical termination."[133]

In fact, as explained in the RU-486 label, "nearly all of the women who receive Mifeprex and misoprostol will report adverse reactions, and many can be expected to report more than one such reaction,"[134] including: abdominal pain; uterine cramping; nausea; headache; vomiting; diarrhea; dizziness; fatigue; back pain; uterine hemorrhage; fever; viral infections; vaginitis; rigors (chills/shaking); dyspepsia; insomnia; asthenia; leg pain; anxiety; anemia; leucorrhea; sinusitis; syncope; endrometritis / salpingitis / pelvic inflammatory disease; decrease in hemoglobin greater than 2 g/dL; pelvic pain; and fainting.[135]

The FDA's Medical Officer's review notes that, "[m]ore than one adverse event was reported for most patients…Approximately 23% of the adverse events in each gestational age group were judged to be severe."[136]

In addition to these known, startling adverse effects, of which the FDA was aware during the RU-486 NDA review process, the incredibly high failure rate of the drug was also known, averaging 14.6% in the U.S. trial testing the drug through 63 days gestation.

The FDA's Medical Officer's review noted that in the U.S. trial of 2015 women, "[a] total of 295 patients were classified as having failed medical abortion."[137] This represents a

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[132] Medical Officer's Review of Amendments 024 and 033, Final Reports for the U.S. Clinical Trials Inducing Abortion up to 63 Days Gestational Age and Complete Responses Regarding Distribution System and Phase 4 Commitments, Finalized November 22, 1999 (dated January 27, 2000), available at http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_medr_P1.pdf (last visited September 28, 2006).

[133] John Leland, *Under Din of Abortion Debate, an Experience Shared Quietly*, N.Y. TIMES, Sept. 18, 2005, *at* http://www.nytimes.com/glogin?URI=http://www.nytimes.com/2005/09/18/national/18abortion.html&OQ=_rQ3D1&OP=41647c1fQ2FQ2AQ7EklQ2AbBG)ABB7FQ2AFqqjQ2AqQ2FQ2A42Q2A-_7VB-_YQ2A42_lBA7VB-vC7KY. (Quoting Dr. Tom Tvedten of Little Rock, Arkansas).

[134] Mifeprex Label, available at http://www.fda.gov/cder/foi/label/2005/020687s013lbl.pdf (last visited September 28, 2006).

[135] *Ibid.*

[136] Medical Officer's Review of Amendments 024 and 033, Final Reports for the U.S. Clinical Trials Inducing Abortion up to 63 Days Gestational Age and Complete Responses Regarding Distribution System and Phase 4 Commitments, Finalized November 22, 1999 (dated January 27, 2000), available at http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_medr_P1.pdf (last visited September 28, 2006).

[137] *Ibid*.

failure in 14.6% of total patients. "Of these patients, 79 (27%) had ongoing pregnancies, 126 (43%) had incomplete abortions, 30 (10%) requested and had surgical terminations, and the remaining 60 (20%) patients had surgical terminations performed because of medical indications directly related to the medical procedure."[138]

The "best" outcome was in the patient group consisting of women whose pregnancies were less than or equal to 49 days. In this group, 7.9% of patients required surgical intervention after taking RU-486. As the gestational age increases, the failure rate of RU-486 increases rapidly, to 17% in the 50-56 days gestation group, and 23% in the 57-63 days gestation group.

By any objective standard, a failure rate approaching eight percent and requiring subsequent surgical intervention as the "best" outcome is a dismal result. Nonetheless, the Medical Officer stated that "[t]he 92% success rate in the ≤ 49 days group is an acceptable one."[139] This failure rate, along with the anticipated adverse events that patients would experience, is explicit in the FDA Medical Officer's review, and also part of the RU-486 label.[140]

Despite these known problems with adverse events and high failure rates, the FDA recommended and gave approval for distributing this drug to women.

B. Post-Approval Hemorrhage, Infections and Deaths

As stated above, the FDA has acknowledged the deaths of six U.S. women associated with RU-486, nine life-threatening incidents, 232 hospitalizations, 116 blood transfusions and 88 cases of infection. [141] A quarter all the patients were hospitalized.[142] These and other cases add up to a total of 1070 adverse event reports (AERs) as of April 2006.

A review[143] of only a portion of all the reported AERs demonstrates in real world experience how women have suffered after taking dangerous drug. Out of only 607 unique adverse events submitted to the FDA, the high number of serious and life-threatening events is startling:

> The most frequent [adverse event reports] were hemorrhage (n=237) and infection (66). Hemorrhages included 1 fatal, 42 life threatening, and 168 serious case; 68 required transfusions. Infections included 7 cases of septic shock (3 fatal, 4 life-threatening) and

[138] *Ibid*.

[139] *Ibid*.

[140] Mifeprex Label, available at http://www.fda.gov/cder/foi/label/2005/020687s013lbl.pdf (last visited September 28, 2006).

[141] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (May 2, 2006) (on file with Subcommittee).

[142] *Ibid*.

[143] M. M. Gary, D. J. Harrison, *Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient*, The Annals of Pharmacotherapy, February 2006, 40.

> 43 cases requiring parenteral antibiotics. Surgical interventions were required in 513 cases (235 emergent, 278 nonemergent). Emergent cases included 17 ectopic pregnancies (11 ruptured). Second trimester viability was documented in 22 cases (9 lost to follow-up, 13 documented fetal outcome). Of the 13 documented cases, 9 were terminated without comment on fetal morphology, 1 was enrolled in fetal registry, and 3 fetuses were diagnosed with serious malformations, suggesting a malformation rate of 23%.[144]

Since this review by Gary and Harrison, there have been hundreds more adverse event reports and two additional reported septic infection deaths. Nearly all among the afflicted and dead who experienced these serious adverse events following RU-486 were healthy women of child-bearing age. (This is in sharp contrast to other drugs with inherent risks—Viagra, for example—which result in adverse events often after repeated use over long intervals of time, in patients with other risk factors associated with age or disease.) Without access to emergency room services, women who suffered severe hemorrhage would have died.

In total, there are eight known deaths following RU-486: four Californians and one Canadian from *C. Sordellii* septic infection; a Tennessee woman with ruptured ectopic pregnancy; a Swedish teen, from massive hemorrhage; and a British female, from "unknown etiology," (but her clinical presentation of shock and an autopsy revealing one liter of blood in her stomach makes sepsis a plausible etiology).[145]

Five of the eight known deaths following the use of RU-486 have been the result of a toxic shock-like syndrome initiated by the bacteria *C. Sordellii.* This bacteria is thought to exist in low numbers in the reproductive tracts of many women and is normally contained by the immune system.[146] Experts in immunology,[147] pharmacology[148] and maternal-fetal medicine[149]

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[144] *Ibid*.

[145] *Ibid*.

[146] Letter to the Editor, James A. McGregor and Ozlem Equiles, *Risks of Mifepristone Abortion in Context*, Contraception 2005, 71: 161.

[147] *See,* Jeanette I. Webster and Esther M. Sternberg, *Role of the Hypothalamic-Pituitary-Adrenal Axis, Glucocorticoids and Glucocorticoid Receptors in Toxic Sequelae of Exposure to Bacterial and Viral Products*, Journal of Endocrinology 2004, 181:207-221 ("Natural and synthetic glucocorticoids protect against the lethal effects of many bacterial and viral components...agents that block the hypothalamic-pituitary-adrenal axis, as in…mifepristone…enhance lipopolysaccharide (LPS) and endotoxin lethality and LPS-induced fever. Even the normally endotoxin-nonresponsive C3H/HeJ mice could be made endotoxin sensitive by RU-486.")

[148] *See,* Ralph P. Miech, *Pathophysiology of Mifepristone-Induced Septic Shock Due to Clostridium Sordellii*, The Annals of Pharmacotherapy, September 2005, 39:

> "Mifepristone is a potent progesterone antagonist that, in addition to its ability to block glucocorticoid receptors, blocks progesterone receptors...Blockade of progesterone receptors…results in rejection of the developing placenta and death of the embryo. Prolonged ischemia of the decidua and the embryonic placenta causes necrosis [death] of these tissues. Mifepristone also [causes] cervical dilation and liquefaction of the cervical mucus plug. The combined loss of a closed cervix and the protective cervical mucus plug permits contamination of the decidua and the intrauterine necrotic cells with aerobic and anaerobic bacteria from the normal vaginal flora."

have suggested that because RU-486 interferes with the immune response, the bacteria, if present, are then able to flourish, causing a widespread, multi-organ infection in the woman.

The infections are *not* accompanied by a fever, and symptoms match those that are expected after taking the RU-486 regimen (cramping, pain, bleeding, nausea, vomiting), making detection of the fast-spreading infection difficult. Each of the women infected with *C. Sordellii* after RU-486 were dead within five to seven days.

The FDA describes the clinical presentation of *C. Sordellii* infection the following way:

- Rapid onset of influenza like symptoms (nausea, vomiting, and weakness)
- Hypothermia or *absence* of fever
- *Absence* of purulent discharge
- Localized pelvic tenderness may be *absent*
- Elevated hematocrit and marked leukemoid reaction
- Progressive refractory hypotension
- Marked edema with peritoneal and pleural effusions
- Rapidly fatal despite aggressive treatment[150] (emphasis added).

To investigate the nature of the *C. Sordellii* bacteria, the FDA and CDC held the "Emerging Clostridial Disease" workshop on May 11, 2006.[151] Workshop presenters – experts in the fields of pharmacology, immunology, and maternal-fetal medicine – noted that the rapid growth of the *C. Sordellii* bacteria likely forecloses effective treatment;[152] that there is no currently identifiable "window of opportunity" for treatment once a woman is infected, even with major interventions such as hysterectomy;[153] and that antibiotic prophylaxis was unlikely to provide any protection in the RU-486 / *C. Sordellii* context.[154] The fatality rate has been 100% for the women who contracted *C. Sordellii* infection after RU-486.

In an effort to dismiss any association between RU-486 and the *C. Sordellii* deaths, some have promoted the idea that *C. Sordellii* is linked to pregnancy and childbirth, not the abortion pill. However, in five years, five women have died from this infection after taking RU-486. In contrast, the FDA has noted that there were "only five additional cases not associated with

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[149] *See*, Sharon Worchester, *Mifepristone Deaths Raise Unanswered Questions*, Ob. Gyn. News, (October 1, 2005) at 13. (Quoting Dr. James A. McGregor)("Mifepristone has multiple pharmacologic properties that may interfere with innate immune responses to infection, toxin exposures, and inflammatory stimuli.").

[150] Food and Drug Administration "Center Director Briefing" June 27, 2005 (on file with the Subcommittee).

[151] A full transcript for the meeting is available at: http://www.fda.gov/cder/meeting/clostridial/transcript.pdf (last visited October 13, 2006).

[152] Letter to the Editor, James A. McGregor and Ozlem Equiles, *Risks of Mifepristone Abortion in Context*, Contraception 2005, 71: 161.

[153] Public Workshop on Emerging Clostridial Disease," (CDC Conference Center: Atlanta, Georgia, May 11, 2006). Transcript available at http://www.fda.gov/cder/meeting/clostridial/transcript.pdf (last visited October 13, 2006).

[154] *Ibid*.

mifepristone/misoprostol retrieved with a text search of the entire AERS database"[155] of 3.5 million records.[156]

Distinguishing the 100% fatality rate with this infection following RU-486 among women who were otherwise healthy, the FDA noted, "[t]he patients in these 5 [non-RU-486 related] cases had weakened or altered immune function due to chemotherapy and age (neonatal & elderly patients), and use of multiple antibiotics. None of these five cases involved intravaginal product administration and 3 cases had a fatal outcome. *In contrast to these 5 additional cases in [3.5 million] AERS, the 4 U.S. confirmed cases of Clostridium Sordellii infection with medical abortion involved healthy patients and all cases had fatal outcome*"[157] (emphasis added).

A more extensive database search for any reported *C. Sordellii* infections since 1925 found a total of eleven fatal cases related to post-partum/ob-gyn infection or to spontaneous abortion.[158] In contrast with this small number of cases (11 since 1925) five women in five years are known to have died from *C. Sordellii* following RU-486.

Experts studying the immune suppression properties of RU-486 have found that it has the ability to block innate immune response.[159] Lazar had published information as early as 1992

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[155] Memorandum, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, April 12, 2006, From [redacted], Division of Drug Risk Evaluation, Through: [redacted] Division of Drug Risk Evaluation, TO: [redacted] Division of Reproductive and Urologic Products. Subject: Supplementary investigations related to reports of fatal infections associated with mifepristone and misoprostol use for medical abortion. [handwritten note: DFS 4/17/06 Consult #3]

[156] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (May 2, 2006) (on file with Subcommittee).

[157] Memorandum, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, April 12, 2006, From [redacted], Division of Drug Risk Evaluation, Through: [redacted] Division of Drug Risk Evaluation, TO: [redacted] Division of Reproductive and Urologic Products. Subject: Supplementary investigations related to reports of fatal infections associated with mifepristone and misoprostol use for medical abortion. [handwritten note: DFS 4/17/06 Consult #3]

[158] Dennis L. Stevens, M.D., PhD., *Clostridium sordellii: Clinical Settings, Diagnostic Clues and Pathogenic Mechanisms*, Public Workshop on Emerging Clostridial Disease," (CDC Conference Center: Atlanta, Georgia, May 11, 2006). Available at http://www.fda.gov/cder/meeting/clostridial/stevens.pdf (last visited October 13, 2006).

[159] *See,* Jeanette I. Webster and Esther M. Sternberg, *Role of the Hypothalamic-Pituitary-Adrenal Axis, Glucocorticoids and Glucocorticoid Receptors in Toxic Sequelae of Exposure to Bacterial and Viral Products*, Journal of Endocrinology 2004, 181:207-221 ("Natural and synthetic glucocorticoids protect against the lethal effects of many bacterial and viral components...agents that block the hypothalamic-pituitary-adrenal axis, as in…mifepristone…enhance lipopolysaccharide (LPS) and endotoxin lethality and LPS-induced fever. Even the normally endotoxin-nonresponsive C3H/HeJ mice could be made endotoxin sensitive by RU-486."). *See also,* Ralph P. Miech, *Pathophysiology of Mifepristone-Induced Septic Shock Due to Clostridium Sordellii*, The Annals of Pharmacotherapy, September 2005, 39:

> "Mifepristone is a potent progesterone antagonist that, in addition to its ability to block glucocorticoid receptors, blocks progesterone receptors...Blockade of progesterone receptors…results in rejection of the developing placenta and death of the embryo. Prolonged ischemia of the decidua and the embryonic placenta causes necrosis [death] of these tissues. Mifepristone also [causes] cervical dilation and liquefaction of the cervical mucus plug. The

about the increase in fatal septic infection in mice after receiving RU-486, which caused the survival rate to drop dramatically from the control level of 71% to only 15%.[160] Nonetheless, the theory that RU-486 suppresses the immune system was only noted by the FDA as late as 2003,[161] and it wasn't until 2004 that the Agency conducted the minimal inquiry of a literature review to examine the immune suppression properties of RU-486:.

> "The Division of Anti-Infective Drug Products (DAIDP) reviewed the medical literature to examine the potential impact that either or both mifepristone and misoprostol might have on human immune function. They concluded, 'Systemic levels of mifepristone and misoprostol may both influence the host response to infection via their anti-inflammatory effects, respectively. In theory, *these effects may predispose an individual to infection or may predispose an infected individual to a worse outcome*. Such roles are apparently dependent on dose, timing, and rates of uptake and intracellular degradation in different target tissues'"[162] (emphasis added).

Beyond this, there is little more in the thousands of pages of documents provided to the Subcommittee to indicate an extensive FDA examination of the immune suppression properties of RU-486.

In the meantime, women who take RU-486 are exposing themselves to an exponentially greater risk of infection or death as compared to the alternative of surgical abortion. The risk of death from infection is at least ten times greater than surgical abortion during the first eight weeks of pregnancy.[163] In addition to *C. Sordellii* infection, women taking RU-486 have developed other infections following the abortion pill regimen. The FDA has acknowledged 88 reported cases of infection following RU-486.

The most frequent serious adverse event is hemorrhage, where women who lost enough blood as to require transfusions. These cases of massive hemorrhage comprise 12% of the RU-

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> combined loss of a closed cervix and the protective cervical mucus plug permits contamination of the decidua and the intrauterine necrotic cells with aerobic and anaerobic bacteria from the normal vaginal flora."

See also, Sharon Worchester, *Mifepristone Deaths Raise Unanswered Questions*, Ob. Gyn. News, (October 1, 2005) at 13. (Quoting Dr. James A. McGregor)("Mifepristone has multiple pharmacologic properties that may interfere with innate immune responses to infection, toxin exposures, and inflammatory stimuli.").

[160] G. Lazar, *et al.*, *Modification of septic shock in mice by the antiglucocorticoid RU 38486*, 36 Circulatory Shock 180 (1992).

[161] FDA Division of Anti-Infective Drug Products, Report of Medical Officer Consultation (Intravaginal Misoprostol), November 19, 2003, at 4 (on file with the Subcommittee)..

[162] FDA Mifeprex plus Misoprostol Postmarketing Safety Review, November 15, 2004, at 24 (on file with the Subcommittee).

[163] *See,* Michael F. Green, M.D., *Fatal Infections Associated with Mifepristone-Induced Abortion*, Dec. 1, 2005, N. ENGL. J. MED 353;22 *at* 2318. The mortality rate for women who procure a surgical abortion is 0.1 in 100,000 during the first eight weeks of pregnancy, the period for which RU-486 is available for women. Dr. Michael Green, based on usage rates of 460,000 and 4 deaths, suggested that the risk of death from chemical abortion is ten times greater. The rate could be higher, if an accurate numerator is used for the true number of patients who have taken RU-486.

486 AERS.[164] A review of the AERS through September 2005 finds that fifteen women suffered hemorrhages so serious that they lost over half of their entire blood volume and would have died without rapid access to emergency room services.[165]

According to Dr. Donna Harrison, who testified before the Subcommittee at the May 17 hearing *RU-486: Demonstrating a Low Standard for Women's Health?*, "In my experience as an ob-gyn, the volume of blood loss seen in the life-threatening cases is comparable to that observed in major surgical trauma cases like motor-vehicle accidents. This volume of blood loss is rarely seen in early surgical abortion without perforation of the uterus, and it is rarely seen in spontaneous abortion."[166]

As with other adverse events associated with RU-486, no risk factors for hemorrhage have been identified. Rather, they are unpredictable and sporadic.[167]

The proven health risks and demonstrated association with fatal septic infections necessarily prompt urgent consideration of this drug's immediate withdrawal from the market.

V. RECOMMENDATIONS

The high incidence of adverse events has prompted Danco, in cooperation with the FDA, to take steps to alert women and the medical community to the dangers of the drug:[168]

- "Dear Health Care Provider" Letter, April 19, 2002 (warning of danger of ruptured ectopic pregnancies).[169]
- "Dear Emergency Room Director" Letter, November 12, 2004 (warning of infection, heavy bleeding and ruptured ectopic pregnancy).[170]
- "Dear Health Care Professional" Letter, November 12, 2004 (warning of infection, heavy bleeding and ruptured ectopic pregnancy).[171]
- Updated label, December 22, 2004 (reflecting danger of infection, heavy bleeding and ruptured ectopic pregnancy).[172]

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[164] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (May 2, 2006) (on file with Subcommittee).

[165] See *RU-486: Demonstrating a Low Standard for Women's Health? Hearing before the House Subcommittee on Criminal Justice, Drug Policy and Human Res., Committee on Government Reform*, 109th Cong. (May 17, 2006) (statement of Donna Harrison, M.D.) Available at http://reform.house.gov/UploadedFiles/Harrison%20Testimony%20-%20scan%20test.%20w%20attchmts.pdf.

[166] *Ibid*.

[167] *Ibid*.

[168] See Danco's website, http://www.earlyoptionpill.com/.

[169] Available at http://www.fda.gov/medwatch/SAFETY/2002/mifeprex_deardoc.pdf (last visited October 14, 2006).

[170] Available at http://www.fda.gov/cder/drug/infopage/mifepristone/DearER.pdf (last visited October 14, 2006).

[171] Available at http://www.fda.gov/cder/drug/infopage/mifepristone/DearHCP.pdf (last visited October 14, 2006).

- "Dear Health Care Provider" Letter, July 19, 2005 (warning of the cases of fatal septic shock).[173]
- Updated label, July 19, 2005 (warning of danger of fatal *C. Sordellii* infections).[174]

In light of the significant health risks posed by this drug, the current restrictions, and the letters and label changes subsequent to approval are demonstrably insufficient to protect women from the dangers of RU-486. Rather, the FDA possesses the authority to suspend or withdraw approval of the drug under various provisions. The most important, and perhaps necessary and justified for removing RU-486 from the market, is the Imminent Hazard authority possessed by the Secretary of Health and Human Services.

"Imminent Hazard" is defined and the criteria to be considered are set forth in 21 CFR 2.5:

> (a) Within the meaning of the Federal Food, Drug and Cosmetic Act an imminent hazard to the public health is considered to exist when the evidence is sufficient to show that a product or practice, posing a significant threat of danger to health, creates a public health situation (1) that should be corrected immediately to prevent injury and (2) that should not be permitted to continue while a hearing or other formal proceeding is being held. The imminent hazard may be declared at any point in the chain of events which may ultimately result in harm to the public health. The occurrence of the final anticipated injury is not essential to establish that an imminent hazard of such occurrence exists.
>
> (b) In exercising his judgment on whether an imminent hazard exists, the Commissioner will consider the number of injuries anticipated and the nature, severity, and duration of the anticipated injury.

Under this provision, the Secretary's decision is subject to judicial review, but the courts are deferential to the Secretary's conclusions.[175] Within the context of RU-486, the unpredictability and frequency of serious adverse event and death (discussed in Section III above) warrants withdrawal of this dangerous drug from the market.

The FDA also possesses the authority to unilaterally withdraw approval of a drug under 21 CFR 314.530. RU-486 falls into the withdrawal categories of this provision:

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[172] Available at http://www.fda.gov/cder/foi/label/2004/020687lbl_Revised.pdf (last visited October 14, 2006).

[173] Available at http://www.fda.gov/medwatch/safety/2005/mifeprex_deardoc_071905.pdf (last visited October 14, 2006).

[174] Available at http://www.fda.gov/cder/drug/infopage/mifepristone/DearHCP.pdf (last visited October 14, 2006).

[175] See *Forsham v. Califano*, 442 F. Supp. 203 (D. D.C. 1977)(this case appears to be the only instance in which the "imminent hazard" authority of the HHS Secretary has invoked). See also *RU-486: Demonstrating a Low Standard for Women's Health? Hearing before the House Subcommittee on Criminal Justice, Drug Policy and Human Res., Committee on Government Reform*, 109th Cong. (May 17, 2006) (statement of O. Carter Snead, Assoc. Professor, University of Notre Dame Law School). Available at http://reform.house.gov/UploadedFiles/Snead%20Testimony.pdf.

(a)(1) A post-marketing clinical study fails to verify clinical benefit

Since its approval, RU-486 has been associated with six known U.S. deaths of healthy women.[176] The safety problems associated with RU-486 are discussed above. Additionally, because women who visit the emergency room arrive with symptoms virtually identical to those associated with miscarriage,[177] deaths within the U.S. following the use of RU-486 may be higher, but unreported.

Moreover, as discussed above, the mortality rate for surgical abortion for the first eight weeks of pregnancy is 0.1 per 100,000.[178] The makers of RU-486 report that 575,000 women have used the drug (based on units shipped, not units prescribed, and based on the assumption that one tablet—rather than the FDA-approved three—is administered to the patient;[179] the actual number of women who have taken the drug may be much lower). Using the figure of 575,000 women having taken RU-486, this works out to a known death rate of approximately 1.39 per 100,000, nearly *14 times* greater than surgical abortion. As noted above, Subpart H drug approval is conditioned on "meaningful therapeutic benefit." The statistics demonstrate that medical abortion is far more dangerous than the existing treatment of surgical abortion, which is proof of a lack of clinical benefit.

(a)(3) Use after marketing demonstrates that post-marketing restrictions are inadequate to assure safe use of the drug product

Experience shows that post-marketing restrictions on RU-486 are inadequate to assure the safe use of the product, because the medical community has ignored them on a widespread basis. As noted earlier in this report, abortion providers routinely use RU-486 beyond the time periods approved by the FDA[180] and with dosing regimens that stray from the FDA's approved

[176] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources, (May 2, 2006) (on file with Subcommittee).

[177] "Dear Emergency Room Director" Letter from Danco Laboratories to emergency room directors, (Nov. 12, 2004), *at* http://www.fda.gov/cder/drug/infopage/mifepristone/DearER.pdf.

[178] Michael F. Green, M.D., *Fatal Infections Associated with Mifepristone-Induced Abortion*, Dec. 1, 2005, N. ENGL. J. MED 353:22 *at* 2318.

[179] *Ibid.*

[180] Some abortion providers (e.g., Planned Parenthood of New York City at www.ppnyc.org/services/factsheets/mifep.htm, Capital Care Women's Center at www.capitalcarewomenscenter.com/services.php, and Camelback Family Planning at www.camelbackfamilyplanning.com/abortionpill.html.), even advertise the availability of RU-486 through 63 days LMP, by which time the rate of incomplete abortion, infection, and other complications rises sharply. In U.S. clinical trials, the failure rate for RU-486 abortions jumps to 17% at 50-56 days LMP, and to 23% at 57-63 days LMP, from 8% at 49 days or less. Irving Spitz *et al*., "Early pregnancy termination with mifepristone and misoprostol in the United States," *New England Journal of Medicine* 1998, 338:1241-47.

regimen.[181] While off-label use of drugs is common, it runs contrary to the entire purpose of the regulatory regime approved for RU-486 under Subpart H.

The FDA is aware of the medical community's refusal to heed the regulations it instated on RU-486. In its own words, the FDA "is aware that…some [physicians] may have chosen to use a modified version of the Patient Agreement form. However, these decisions are made by physicians exercising their own judgment about what is best for their patients**.**"[182]

This is contrary to the detailed Risk Management Program, explained in the FDA memo detailing the drug's approval, which states: "the signed agreement form will be given to the patient for her reference and another kept in the medical records," and "[the prescribing physician] must provide each patient…with a copy of the Medication Guide and Patient Agreement, give her an opportunity to read and discuss both the Medication Guide and the Patient Agreement, obtain her signature on the Patient Agreement and must sign it as well."[183] The FDA determined that these restrictions were critical to the safe use of the drug, and in spite of this, physicians have refused to heed them.

(a)(4) The applicant fails to adhere to the post-marketing restrictions agreed upon

Although the FDA stipulated that the manufacturer have systems in place to track the distribution of RU-486 "to the patient level," and that require physicians to "record the Mifeprex package serial number in each patient's record,"[184] Danco has not provided reliable patient numbers, but rather estimates.[185]

In addition to the FDA requiring patients to sign a Patient Agreement form, the Population Council agreed, as part of the approval process, to "auditing prescribers to ascertain whether they have obtained signed copies of the Patient Agreement forms." It is unclear whether the Population Council, Danco, or any other entity associated with the production of RU-486 has adhered to this requirement.

(a)(5) The promotional materials are false or misleading

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[181] R. Hausknecht, "Mifepristone and Misoprostol for Early Medical Abortion: 18 Months Experience in the United States," *Contraception* 67 (2003): 463-65: "Although the FDA-approved regimen specified a single oral dose of mifepristone 600 mg, many physicians are using a lower dose (200 mg)."

[182] Letter from Patrick Ronan, Associate Commissioner for Legislation Department of Health and Human Services FDA to Hon. Mark E. Souder, (March 16, 2006) (on file with Govt. Reform Subcommittee on Criminal Justice, Drug Policy, and Human Resources).

[183] Memorandum from FDA Center for Drug Evaluation and Research to Population Council 6, (Sept. 28, 2000) (available at http://www.fda.gov/cder/drug/infopage/mifepristone/memo.pdf).

[184] *Ibid.*

[185] Richard Hausknecht, Medical Director for Danco, described how Danco estimates the usage figures for RU-486: "Denominators… were estimated from sales figures. Although the FDA-approved regimen specified a single oral dose of mifepristone 600 mg, many physicians are using a lower dose (200 mg), …[an] estimated range was based upon Planned Parenthood practices and National Abortion Federation (NAF) polling of their membership practices…[and by] [a]djusting for utilization patterns of providers." *Contraception* 67 (2003): 463-65.

The FDA conditioned approval of RU-486 on tracking its use "to the patient level." In spite of this, the manufacturer estimates the usage of its drug for its promotional materials.[186] This affects the perceived safety of the drug, as the manufacturer may be overstating its actual usage in comparison with the adverse events reported.

Both the "Imminent Hazard" provision and the regulatory provision for approval withdrawal under Subpart H provide sufficient authority for the Administration to remove this dangerous drug from the market.

VI. CONCLUSION

The integrity of the FDA in the approval and monitoring of RU-486 has been substandard and necessitates the withdrawal of this dangerous and fatal product before more women suffer the known and anticipated consequences or fatalities. RU-486 is a hazardous drug for women, its unusual approval demonstrates a lower standard of care for women, and its withdrawal from the market is justified and necessary to protect the public's health.

[186] *Ibid*. *See also*, Letter from David W. Boyer, Assistant Commissioner for Legislation, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources, (May 2, 2006) (on file with Subcommittee); *FDA Announces Mifeprex Not Cause of One of Two Recent Abortion-Related Deaths*, KAISER NETWORK DAILY REPORTS, (April 11, 2006) *at* http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=36534. ("We stand behind the safety profile of the drug, which has been used by approximately 575,000 women in this country since FDA approval in 2000," quoting Cynthia Summers, director of marketing and public affairs at Danco Laboratories, originally in Wall Street Journal, April 11, 2006.)

EXHIBIT 48

Memorandum on RU-486 from HHS Chief of Staff Kevin Thurm to White House Director of Domestic Policy Carol Rasco (May 11, 1994)

Tab 4 Political Issue Discussion

A Judicial Watch Special Report:

The Clinton RU-486 Files

♦

The Clinton Administration's Radical Drive to Force an Abortion Drug on America

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Introduction

This Judicial Watch Special Report analyzes newly uncovered documents from the National Archives at the Clinton Presidential Library in Little Rock, Arkansas, describing the Clinton administration's radical drive to introduce the abortion drug RU-486 (mifepristone) into the American marketplace.

The records include the Clinton administration's legal, political and press strategies for rushing RU-486 through the Food and Drug Administration (FDA) processes, despite the manufacturer's historical refusal to permit marketing the drug here. The legal, political and press memos articulate the Clinton administration's views regarding various players in the drug approval and marketing process -- women's groups, members of Congress, public interest groups and the media.

Judicial Watch has engaged in a five-year legal battle with the FDA for release of records under the provisions of the Freedom of Information Act (FOIA), 5 U.S.C. §552, concerning RU-486. We uncovered over 9,300 pages of documents and 840 Adverse Event Reports pertaining to the abortion drug. To date, the deaths of at least six women have been attributed to RU-486. The FDA scheduled a scientific conference for May 11, 2006 in order to study the controversial abortion drug and the circumstances leading to the deaths.

Judicial Watch promotes transparency, integrity and accountability in government, politics and the law. We make aggressive use of open records and open meetings laws as a means to obtain documents with which to educate the American public on the operations of their government and to hold public officials accountable. Judicial Watch also provides technical, research and litigation assistance to public interest groups interested in obtaining information about government activity which may not have the necessary resources or experience to pursue information on their own as part of the Judicial Watch Open Records Project.

Thomas Fitton
President
Judicial Watch, Inc.

April 26, 2006

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The Clinton RU-486 Files:
The Clinton Administration's Radical Drive to Force an Abortion Drug on America

Executive Summary

During a February 2006 research trip to the National Archives at the Clinton Presidential Library, Judicial Watch uncovered new records detailing the Clinton administration's rush to market the abortion drug RU-486 (mifepristone) to American women. The documents include political, legal and press strategy memoranda from Health and Human Services (HHS) Secretary Donna Shalala, FDA Commissioner, Dr. David Kessler, and HHS Chief of Staff Kevin Thurm. Some of the memoranda are addressed to the White House -- in particular, Carol Rasco, the Clinton administration Director of Domestic Policy.

Analysis of the records shows:

- President Clinton ordered HHS and FDA to coordinate and promote the marketing of RU-486 as his first official act in office.
- Within one month, the FDA Commissioner had met with the RU-486 manufacturer and their parent company.
- Official U.S. Government political, economic and diplomatic pressure was brought to bear to strong-arm the companies into changing their policies in order to make the drug available in the United States.
- The FDA was compromised in its role as objective reviewers of the safety and efficacy of the drug.
- The five standard requirements for certifying a drug "safe and effective" were circumvented to rush RU-486 to market.
- Radical, pro-abortion extremists dominated the Clinton administration's "women's health care" agenda and their reckless drive to bring RU-486 to America ultimately cost at least six women their lives and the lives of over 560,000 unborn children.

The Clinton RU-486 Files:
The Clinton Administration's Radical Drive to Force an Abortion Drug on America

* * *

"Hoechst has historically refused to permit Roussel Uclaf to seek marketing approval for RU-486 as an abortifacient in the United States. Both Dr. Kessler [FDA Commissioner] *and I have taken steps to persuade Roussel Uclaf and Hoechst to change their position."*

Donna Shalala
Health & Human Services Secretary
Clinton Administration
November 15, 1993
Confidential Memo to White House

* * *

In February 2006, Judicial Watch uncovered previously confidential files and working papers from the holdings of the National Archives at the Clinton Presidential Library in Little Rock, Arkansas that provide remarkable insight into the Clinton administration's relentless drive to market RU-486 (mifepristone), a drug used to cause abortion, to American women. The documents offer a window into the political strategy, legal theories and media "spin" on the Clinton administration's abortion program.

RU-486 was first developed in France in 1981. It is a manmade steroid designed to work against the hormone progesterone, which is required to promote a baby's proper growth and development. RU-486 works to chemically destroy the unborn child's environment, cutting off nourishment and starving the baby to death in the mother's womb. A second chemical, misoprostol, is then used to create cramping and contractions to expel the dead baby from the mother's womb. The "procedure" must begin within 49 days of conception. The Clinton administration considered this method of abortion part of "women's health care." President Clinton thanked the maker of RU-486 in writing, "On behalf of the government of the United States and for the women of America. . ."[i]

On January 22, 1993, in his first official act, President Clinton issued a memorandum directing HHS Secretary Donna Shalala to promote the testing and licensing of RU-486 in the United States. (See Tab A)

Abortion was a key domestic policy item for President Clinton. RU-486 was just one part of the overall strategy for his administration's agenda. For example, in a

National Archives document entitled, "President William J. Clinton -- Eight Years of Peace, Prosperity and Progress," the first "accomplishment" listed reads:

> **Abolished Restrictions on Medical Research and the Right to Choose** As his first executive actions, President Clinton revoked the Gag Rule, which prohibited abortion counseling in clinics that receive federal funding to serve low-income patients. He also revoked restrictions on a woman's legal right to privately funded abortion services in military hospitals, restrictions on the import of RU-486, and restrictions on the award of international family planning grants (the "Mexico City Policy"). The President also lifted the moratorium on federal funding for research involving fetal tissue, allowing progress on research into treatments for Parkinson's disease, Alzheimer's, diabetes and leukemia. (Executive Memoranda, 1/22/93)[ii]

The tone was set for the Clinton administration's drive towards promoting abortion as "health care." Shalala and FDA Commissioner, Dr. David Kessler, engaged in a political, legal and economic campaign to force the French pharmaceutical firm, Roussel Uclaf, and their German parent corporation, Hoechst, A.G., to file a "new drug application" (NDA) with the FDA, and begin marketing RU-486 to American women.[iii]

In April 1993, the FDA brokered a meeting between Roussel Uclaf and the Clinton administration's anointed abortion proponent, the Population Council, a non-profit organization that conducts research on so-called "reproductive health issues." Roussel Uclaf and the Population Council already had an existing contractual relationship concerning provision of abortifacients (substances that induce abortion) for various clinical trials.[iv] It is difficult to understand the FDA's role in bringing the parties together, other than to continue to bring official U.S. government pressure on Roussel Uclaf and to designate the Population Council as the Clinton administration's abortion drug development and marketing proxy.

The Population Council claims to be " . . . an international, nonprofit, nongovernmental organization, seeks to improve the well-being and reproductive health of current and future generations around the world and to help achieve a humane, equitable, and sustainable balance between people and resources."[v] The organization was founded by John D. Rockefeller III in 1952. In 2005, they projected spending over $71 million in 70 countries around the world. Their work is funded by governments, foundations, individuals and "multilateral organizations."[vi]

According to the Clinton RU-486 files, Roussel Uclaf made the decision to use the Population Council as the administration's surrogate for forcing RU-486 on America.

There is no mention in the memoranda of Planned Parenthood or the National Abortion and Reproductive Rights Action League (NARAL). There is no mention of public disclosure, discussion, competition or bidding. One might imagine a selection process or staff discussion of the relative pros and cons for selection of another abortion group, but there is no evidence of any such discussion or consideration. In a memo by HHS Chief of Staff Kevin Thurm (discussed in detail below), the Clinton administration seems to have been predisposed to using the Population Council to carry out their abortion plans based on an existing relationship of the abortion non-profit with the maker of RU-486.

Roussel Uclaf repeatedly sought total U.S. government-sponsored indemnification from any damages it might incur by bringing RU-486 to the U.S. marketplace. Roussel Uclaf President, Dr. Edouard Sakiz, specifically expressed concerns over liability actions against his firm "if a woman had an incomplete abortion and delivered a deformed fetus." Dr. Sakiz was also particularly concerned about "consequential damages," such as the economic costs from boycotts. The Clinton administration's fervent commitment to making RU-486 part of the American abortion industry is demonstrated through Dr. Sakiz's reservations concerning legal and economic exposure. The Clinton administration's near-obsession with introducing a "safe and effective" abortion drug is revealed in Shalala's confidential memo to the White House of November 15, 1993:

> "Dr. Sakiz's view was that if the United States Government wanted RU-486 to be marketed in the United States, it should compensate Roussel Uclaf for any damages that the company might suffer from complying with the United States Government's request."

(See Tab B)

Dr. Sakiz was saying, in other words, "If <u>you</u> want it so badly, <u>you</u> pay the consequences." The Clinton administration was attempting to trump a business decision of the pharmaceutical company while exposing the corporation to risk for abiding by a U.S. government request.

Even Clinton FDA Commissioner Kessler understood and memorialized the controversy over the administration's aggressive efforts to introduce RU-486 when he wrote in a September 30, 1993 memorandum to Shalala:

> " . . . other Congressional members have written to Hoechst expressing their strong opposition to the marketing of RU-486 in this country. This, and the well-publicized activities of anti-abortion groups, have provided Hoechst and Roussel Ucalf with evidence that the U.S. population

> lacks cohesiveness on this issue and that the abortion debate continues."

(See Tab C)

The Clinton administration realized that attempting to enact blanket indemnification by the U.S government of a foreign corporation for an abortion drug was politically and practically impossible. According to the Clinton RU-486 files, Dr. Sakiz still went ahead and committed to negotiating with the Clinton administration surrogates – the Population Council – agreeing:

- To license RU-486 to the Population Council which would conduct a clinical trial involving 2000 women pursuant to an investigational new drug application;

- The Population Council would ultimately submit an NDA to the FDA based on the results of the clinical trial and on other studies conducted by Roussel Uclaf; and

- The Population Council, with the concurrence of Roussel Uclaf, would chose a new manufacturer for the drug, and that Roussel Uclaf would transfer its technology for making the drug to that manufacturer because Roussel Uclaf did not want to manufacture the drug for sale in this country. [Emphasis added.]

(See Tab B)

According to the Clinton RU-486 files, over the next few months Roussel Uclaf reiterated its desire for protective federal legislation providing blanket indemnification from the use of RU-486. Roussel Uclaf did not anticipate any profit from selling RU-486 in the United States; and was only entering the American market at the insistence of the Clinton administration. FDA representatives told Roussel Uclaf that such protection was extremely unlikely.

In a September 30, 1993 memorandum to Shalala, FDA Commissioner Kessler recounts a conversation he had with Jim Boynton, legal counsel for the Population Council, concerning the Roussel Uclaf indemnification legislation. Kessler pointed out the recent passage of the Hyde Amendment (restricting federal funds for abortion), and that with one exception (swine flu event), the United States had never agreed to indemnify any drug manufacturer. Apparently sensing that it might be perceived as inappropriate for the FDA commissioner to be discussing indemnification with a drug company representative for a supposedly safe drug, Kessler tried to cover his tracks. Kessler wrote that he, ". . . further explained that it would go far beyond FDA'S

appropriate role to seek such protection for a drug company." [Emphasis added.] Nonetheless, the FDA offered to advance the idea within HHS.

Not satisfied with the denials of indemnification from the FDA and HHS, in September 1993 Roussel Uclaf hired legal counsel (reportedly, Lester Hyman and John Hoff of the firm Swidler & Berlin) to lobby the federal government for indemnification "at levels higher than the FDA" – presumably from President Clinton and other pro-abortion advocates in the Congress, such as Rep. Ron Wyden and Rep. Henry Waxman. Concerned with these moves, HHS Chief of Staff Kevin Thurm and HHS General Counsel Harriet Rabb initiated a meeting with attorneys from Swidler & Berlin. During that meeting Roussel Uclaf's lawyer suggested that the United States could exercise its statutory powers of eminent domain and seize the patent for RU-486 for the abortifacient uses of the drug.[vii]

Meanwhile, the Population Council and Roussel Uclaf pressed forward with licensing details, and simultaneously made plans to sway the leadership of Hoechst to allow their subsidiary to enter into an agreement with the Population Council. Shalala's confidential memo to the White House warns, ". . . we do not think the negotiations will be successfully concluded without pressure on Roussel Uclaf/Hoechst."[viii]

Shalala suggested the Clinton administration bring the force of the United States Government to bear on the Hoechst and Roussel Uclaf corporations. She also went on to suggest that the United States exercise its international diplomatic and economic pressure on the German and French governments, as a means of further "influence" against the corporations. In a November 15 confidential memo to the White House, Shalala wrote: "The French and German governments might be displeased to learn that their companies are not accommodating a request made by the United States Government."

While the Clinton administration pondered exercising the full economic and diplomatic weight of the United States Government to advance its abortion agenda, it is important to note that Roussel Uclaf was willing to give a royalty-free license to any major U.S. pharmaceutical company – but no U.S. company would take the license.

The Clinton RU-486 files show specualtion among administration officials concerning delays in the negotiations between Roussel Uclaf and the Population Council. The pending retirement of the chief executive officer of Hoechst, Professor Wolfgang Hilger, was discussed in Kessler's September memo, noting that Prof. Hilger was "very staunchly Catholic." There was also a discussion of the likelihood of an international foundation being created by the drug's inventor, Dr. Etiene Balieu, for broader marketing opportunities. Apparently the Clinton administration was concerned about competition from an abortion drug "insider."[ix]

Just as the name of the Population Council "appeared" in the Clinton administration's confidential memos without a trace of how it became the administration's surrogate, so too does the recommendation for Felix Rohatyn to serve as an "expert advisor."[x]

After a review of the economic, political and diplomatic issues involved in strong-arming Hoechst and Roussel Uclaf, Dr. Kessler advanced Mr. Rohatyn's name by concluding with a political point: "We think that someone familiar to these circles would advance the Administration's goal to bring a safe and effective abortifacient to the U.S. market." Again, there is no discussion, alternatives or explanation offered for this appointment. The question of appointment of an "expert advisor" for the U.S. government is raised and answered in the space of one paragraph.

In a remarkable admission that the FDA had been thoroughly politicized in the Clinton administration's radical drive for RU-486, the agency's commissioner, Dr. Kessler, wrote in his September memo, " . . . the FDA cannot take this issue too far without compromising its role as objective reviewers of the safety and efficacy of the drug."

The Clinton RU-486 file offering the most comprehensive treatment of the administration's strategic campaign to introduce RU-486 to the American market is a memorandum dated May 11, 1994 from HHS Chief of Staff Kevin Thurm to the White House – in particular, Carol Rasco, Director of the Clinton administration Domestic Policy Council. (See Tab D)

Thurm's memo details three issues submitted for decision by the President:

- Whether the President is willing to write a letter to the maker of RU-486, asking that the U.S. patents for the drug be assigned to a non-profit entity in this country [Population Council].

- If the negotiations between Roussel Uclaf and the Population Council fail, and the "only" available option is the "gift offer," is the U.S. Government willing to accept the RU-486 patent rights, and under what conditions?

- If the government is not willing to accept the patent rights, what will be the basis for that decision, and how will it be communicated to the American public?

Thurm develops and discusses each of the factors bearing on the subject in a series of tabs and exhibits to his memo. He provides a history and background tab recounting the Clinton administration's position on RU-486; a tab discussing legal issues;

a brief marketing study addressing timing, administration, and abortion proxies; political considerations; and finally, a discussion of press strategies and concerns.

Thurm explains that on April 26, 1994, the Board of Roussel Uclaf passed a resolution authorizing the assignment of RU-486 patent rights to either the U.S. Government or to a non-profit organization. If the rights were to go to a non-profit organization [Population Council], then Roussel Uclaf demanded a letter from the President of the United States requesting RU-486 on behalf of the women of the United States. President Clinton signed exactly such a letter on May 16, 1994. (See Tab E)

President Clinton's extraordinary letter is direct documentary evidence of his personal intervention as a politician, and clear evidence that the RU-486 patent rights would never have been assigned to the Population Council without his compliance with Roussel Uclaf's demands.

President Clinton's RU-486 request letter to Dr. Edouard Sakiz of Roussel Uclaf claims that it is important for the women of the United States to have "safe and effective medical treatments." Under that rubric, President Clinton writes that he "understands" Roussel Uclaf has been in negotiations with the Population Council. Of course, the Population Council had been serving as a Clinton administration abortion "front" for several months. President Clinton closes his RU-486 request letter by stating: "On behalf of the government of the United States and for the women of America, I thank you for your work."

Thurm's memo specifically addresses the requirements for RU-486 clinical trials and the Population Council's requirements for marketing application for the FDA. The significance of speedy approval and abbreviation of various timelines is a theme throughout his analysis. Not surprisingly, the Clinton administration's radical drive to bring RU-486 to the American market manifested itself in other ways, once the patent rights were obtained by the Population Council. For example, the five standard requirements for certifying a drug "safe and effective" were circumvented to rush RU-486 to market.[xi] Probably the most reckless act by the FDA was the waiver of the normal requirement for random, double-blind, control tests for new drugs. The FDA's expedition in this process was justified with language reserved for drugs developed to cure life-threatening conditions. Certainly, pregnancy is not a disease, nor is it likely to be life threatening – so how could they have twisted the rules so dramatically? What political pressure was brought to bear?

The "political issue discussion" tab to Thurm's memo offers a glimpse into the Clinton administration's abortion politics techniques. The Clinton administration steadfastly continues the manipulation of language that seeks to forever separate the words "kill," "baby" and "abortion." Thurm states: "It is, therefore, extremely important that the decision concerning RU-486 be placed in the context of promoting women's

health and maintaining the close relationship of the administration to these ["pro-choice" and women's groups] groups."

The Clinton administration wanted a quick victory on RU-486 and was deeply concerned that RU-486 might remain a "front burner" issue through the 1996 presidential election. They were particularly sensitive to the prospect of prolonged, intense, public attention and debate on RU-486. Thurm advised political caution concerning unintended consequences, allowing " . . . Republicans and others opposed to the administration to focus attention on this decision and its aftermath."

The Clinton press strategy documents discuss the ramifications of accepting or rejecting the gift of the RU-486 patents. Acceptance of the patent gifts was relegated to Secretary Shalala "on behalf of American women," but specifically as a means of "insulating the White House." While seeking insulation, the press memo stresses the need to credit President Clinton for keeping his campaign promises and giving a major "reproductive rights victory" to American women. The memo also contains a disturbing directive:

> " . . . there should also be a concerted effort on the part of HHS Public affairs team to place stories that outline the hurdles that must be overcome to shield the Administration against fallout from our allies in the event efforts to get RU-486 to the market become stalled in bureaucratic process, in Congress or for other reasons."[xii]

If the Clinton administration's RU-486 strategy failed all together, it appears the press response included a calculated scenario for resorting to lying to the American public. Working through the various scenarios, the author of the memo offers an "alternative":

> " . . . another potential argument we could embrace is the position that we wanted more than the rights they were willing to grant because our interest in this drug goes beyond the issue of abortion, the need for which we are committed to making as rare as possible."[xiii]

Still worried about potential fallout and damage with abortion proponents and allied political groups, the press memo ends stating:

> "Without a doubt, a 'no' will subject the Administration to a firestorm of protest by pro-choice and women's groups; and there will be few natural political allies vocally defending this decision, particularly in light of the relative difficulty of explanation."[xiv]

Beyond the Clinton Files -- RU-486 in 2006

As Judicial Watch reviewed the Clinton RU-486 files, documenting the extraordinary lengths the administration went to rush the abortion drug to U.S. markets, the earliest correspondence on file at the Archives caught our attention and, in hindsight, provided some perspective for examining RU-486 matters in 2006. (See Tab F)

The file contained a handwritten letterhead note from Betsey Wright, President Clinton's former Chief of Staff, and the White House staff member charged with covering-up "bimbo eruptions." The note reads: "To Carol Rasco. This just got forwarded to me. Please handle. BW 3/9/93." There is an additional notation that reads: "cc for Shalala on Tues. MK," with the name Shalala circled and a line drawn to the words "To handle."[xv]

Betsey Wright's note was attached to a letter dated January 6, 1992, from Ron Weddington, an attorney that served as co-counsel in the infamous *Roe v. Wade* lawsuit. Weddington attached an "open letter" to President-elect Clinton. Weddington's letter recommends that the new president should, " . . . start immediately to eliminate the barely educated, unhealthy and poor segment of the country . . ." and that the " . . . government is going to have to provide vasectomies, tubal ligations and abortions . . . RU-486 and conventional abortions."[xvi]

Weddington states: "Condoms won't do it. Depo-Provera, Norplant and the new birth control injection being developed in India are not a complete answer, although the savings that could be effected by widespread government distribution and encouragement of birth control would amount to billions of dollars."

The full text of Weddington's letter is a breathtakingly arrogant exegesis on the abortion lobby's culture of death. As disturbing as the Weddington letter is to read, what is more disturbing is the fact that Betsey Wright, one of President Clinton's closest confidantes, tasked Donna Shalala to "handle" it along with the Director of the White House Domestic Policy Council, Carol Rasco. Weddington's ravings were not relegated to a file for unsolicited constituent correspondence. On the contrary, the Weddington letter is, chronologically and philosophically, the foundation document for the Clinton RU-486 files.

Today we are faced with the horrible results of the political and "health care" campaign to put RU-486 on the market. Since RU-486 was approved for use in the United States in September 2000, at least six women have died after taking the abortion drug. Only after the death of 18 year old Holly Patterson, on September 17, 2003, did the media and the FDA begin to pay attention to the dangers of RU-486.

In November 2004, following the third woman's death, the FDA elected to "strengthen the warning notice," a step that may have provided some sort of "informational" or disclaimer insulation for the FDA, but a tactic that certainly did not make RU-486 any safer for women.

Planned Parenthood, which had ignored the FDA's warnings concerning how to administer the drug regimen, played a role in the deaths of four women as the "procedure" provider. The FDA has determined that the four California women who died after taking RU-486 all suffered from a highly lethal bacterial infection -- Clostridium sordellii. The bacterium flourishes in the uterus and then enters the bloodstream, eventually leading to toxic shock.

It is quite likely that more women have died from RU-486 and their deaths have gone unreported because doctors, medical examiners and coroners are not obligated to forward reports dealing with RU-486 side effects to the FDA. This is particularly true in cases where local health officials may not associate a death with an RU-486 abortion, especially if the woman's death occurs several days or even weeks later.

Even abortion providers now have low regard for the safety of RU-486. Dr. Warren Hern, an abortionist in Denver, Colorado has stated: "I think surgery should be the procedure of choice." Pills, he said, "are a lousy way to perform an abortion." He is not alone. Dr. Damon Stutes, an abortionist from Reno, Nevada reluctantly agrees with Pro-Life critics of RU-486, stating, "the truth is the truth," and that, "The complications from RU-486 far exceed the complications of surgical abortion." [xvii]

It seems that the federal government has finally come to grips with the growing number of deaths attributed to the use of RU-486 and is prepared to take some action, however late. The government will convene a scientific conference at the Center for Disease Control in Atlanta, Georgia on May 11, 2006. More than two dozen scientists and doctors will make presentations concerning the deadly bacterial infections that killed the California women mentioned above.

Conclusion

Judicial Watch hopes that this special report on the Clinton RU-486 files has provided the reader with sufficient documentary evidence from primary sources to illuminate the Clinton administration's rush to achieve part of its abortion agenda through bringing RU-486 to America. Armed with the long-delayed facts from Clinton insider memoranda, the reader is now equipped to evaluate policy and hold public officials accountable.

On September 28, 2000, the day RU-486 was approved for U.S. markets, the FDA Commissioner, Dr. Jane E. Henney, said in an interview, "Politics had no role in this

decision."[xviii] The public now has copies of the the Clinton RU-486 files that unequivocally say otherwise.

Endnotes

[i] See Tab E: Letter from President William J. Clinton to Dr. Edouard Sakiz, Chaiman of Roussel Uclaf, dated May 16, 1994.

[ii] See: http://clinton5.nara.gov/media/pdf/eightyears.pdf

[iii] Hoechst had a historical reason for wanting to keep a low profile concerning RU-486. Hoechst was part of a cartel connected to the infamous I.G. Farben Chemical Company, the makers of Zyklon-B -- the cyanide gas used in Nazi death camps. In 1999, Hoechst merged with another European pharmaceutical company to form Aventis.

[iv] Copies of the Roussel Uclaf – Population Council contract were not available from the Archives.

[v] See: http://www.popcouncil.org/about/index.html

[vi] See: http://www.popcouncil.org/mediacenter/PC_Key_Facts.html

[vii] See Tab C: FDA Commissioner Kessler's Memorandum to HHS Secretary Shalala, dated September 30, 1993.

[viii] See Tab B: HHS Secretary Shalala's Confidential Memorandum to White House Director of Domestic Policy Carol Rasco, dated November 15, 1993.

[ix] See Tab C, pages 4-5.

[x] Felix Rohatyn is a Wall Street investment banker and served as President Clinton's Ambassador to France from 1997 to 2000.

[xi] Donna J. Harrison, M.D., "Dangerous Medicine," *The New York Times*, November 19, 2004.

[xii] See Tab D: HHS Chief of Staff Kevin Thurm's Memorandum to White House Director of Domestic Policy Carol Rasco, Subject: RU-486, dated May 11, 1994; Tab 5: Press Strategies and Concerns.

[xiii] *Ibid.*

[xiv] *Ibid.*

[xv] See Tab F: Clinton Transition Team Director of Public Outreach Betsey Wright's correspondence file Re: RU-486 from Mr. Ron Weddington, dated 3/9/93.

[xvi] *Ibid.*

[xvii] Gardiner Harris, "Some Doctors Voice Worry Over Abortion Pill's Safety," *The New York Times*, April 1, 2006.

[xviii] Gina Kolata, "U.S. Approves Abortion Pill; Drug Offers More Privacy, and Could Reshape Debate, *The New York Times*, September 29, 2000.

Tab A

THE WHITE HOUSE

WASHINGTON

January 22, 1993

MEMORANDUM FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

SUBJECT: Importation of RU-486

In Import Alert 66-47, the Food and Drug Administration ("FDA") excluded the drug Mifepristine -- commonly known as RU-486 -- from the list of drugs that individuals can import into the United States for their "personal use," although the drugs have not yet been approved for distribution by the FDA. (See FDA Regulatory Procedures Manual, Chapter 9-71.) Import Alert 66-47 effectively bans the importation into this Nation of a drug that is used in other nations as a nonsurgical means of abortion.

I am informed that in excluding RU-486 from the personal use importation exemption, the FDA appears to have based its decision on factors other than an assessment of the possible health and safety risks of the drug. Accordingly, I hereby direct that you promptly instruct the FDA to determine whether there is sufficient evidence to warrant exclusion of RU-486 from the list of drugs that qualify for the personal use importation exemption. Furthermore, if the FDA concludes that RU-486 meets the criteria for the personal use importation exemption, I direct that you immediately take steps to rescind Import Alert 66-47.

In addition, I direct that you promptly assess initiatives by which the Department of Health and Human Services can promote the testing, licensing, and manufacturing in the United States of RU-486 or other antiprogestins.

You are hereby authorized and directed to publish this memorandum in the Federal Register.

William J. Clinton

Tab B

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

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DATE: 4/14/04

MEMORANDUM FOR CAROL RASCO

The purposes of this memorandum are: (1) to inform you of the Department's progress in implementing the President's directive of January 22, 1993, to "assess initiatives by which the Department of Health and Human Services can promote the testing, licensing, and manufacturing in the United States of RU-486 or other antiprogestins;" and (2) to outline the necessary next steps to accomplish the President's directive.

Background: You may recall that RU-486 is manufactured by the French firm Roussel Uclaf and is approved to induce abortions in France, the United Kingdom, and Sweden. Roussel Uclaf has stated that it can act in the United States only with the approval of its parent company, Hoechst AG, a German firm. Hoechst has historically refused to permit Roussel Uclaf to seek marketing approval for RU-486 as an abortifacient in the United States.

Both Dr. Kessler and I have taken steps to persuade Roussel Uclaf and Hoechst to change their position. In February Dr. Kessler met with Dr. Edouard Sakiz, the President of Roussel Uclaf, to discuss the availability of RU-486 in the United States for research and marketing. In March I wrote to Professor Wolfgang Hilger, President of the Board of Hoechst, to ask him to permit Roussel Uclaf to begin any necessary testing of RU-486 in the United States in preparation for filing a new drug application with the FDA. Later in March there were press reports that Roussel Uclaf would respond to the requests of the Clinton Administration to make RU-486 available in this country and that testing of the drug would begin approximately two months later (i.e., in May).

In April 1993, FDA arranged a meeting between Roussel Uclaf and the Population Council, a non-profit corporation that conducts research on reproductive health issues. The meeting's purpose was to facilitate an agreement between those parties to work together to test RU-486 and file a new drug application for the drug. The Population Council was identified as the most likely group to work with Roussel Uclaf because of an existing contract between these two parties that required Roussel Uclaf to give the Population Council sufficient amounts of the drug for the Population Council to conduct clinical trials. The contract also appeared to require Roussel Uclaf to license the drug to the Population Council if Roussel Uclaf were unwilling to sell the drug in the United States.

At the April meeting, Dr. Edouard Sakiz, President of Roussel Uclaf, raised the issue of federal legislation to indemnify

Roussel Uclaf from any damages it might incur by permitting RU-486 to be marketed in the United States. Dr. Sakiz was worried about product liability actions against Roussel Uclaf if a woman had an incomplete abortion and delivered a deformed fetus. Dr. Sakiz was also concerned about consequential damages, such as the economic costs from boycotts of other Roussel Uclaf or Hoechst products, or bombings of Roussel Uclaf/Hoechst facilities by right-to-life groups. Dr. Sakiz's view was that if the United States Government wanted RU-486 to be marketed in the United States, it should compensate Roussel Uclaf for any damages that the company might suffer from complying with the United States Government's request.

Dr. Sakiz was clearly informed at the April meeting that such legislation would never be enacted and that the FDA would not support Roussel Uclaf in seeking it.

Despite being told that there was no possibility of obtaining federal legislation to protect Roussel Uclaf from consequential damages or product liability suits, Dr. Sakiz committed Roussel Uclaf to negotiate with the Population Council to bring RU-486 onto the United States market. Specifically, at the April meeting Roussel Uclaf and the Population Council agreed:

- That Roussel Uclaf would license RU-486 to the Population Council, which would conduct a clinical trial involving 2000 women pursuant to an investigational new drug (IND) application;

- That the Population Council would ultimately submit a new drug application (NDA) to FDA, based on the results of the clinical trial and on other studies that have been conducted by Roussel Uclaf; and

- That the Population Council, with the concurrence of Roussel Uclaf, would choose a new manufacturer for the drug, and that Roussel Uclaf would transfer its technology for making the drug to that manufacturer because Roussel Uclaf does not want to manufacture the drug for sale in this country.

It was then left for the Population Council and Roussel Uclaf to revise the terms of their contract, while Roussel Uclaf began sending scientific information to FDA and the Population Council. A tentative goal of September 15 was established for concluding the contract negotiations. As of late July 1993, the Population Council thought that the negotiations were proceeding smoothly, though slowly.

CURRENT STATUS

On August 2, 1993, the Population Council's lawyer notified FDA that **Roussel Uclaf had recently reasserted its demand for protective federal legislation.** Roussel Uclaf insisted that the Population Council obtain a commitment from the United States Government that: 1) legislation would be enacted making it a crime for any person to hurt or harass any doctor administering RU-486, their patients, or the drug's manufacturers, distributors, and salespersons; 2) the Department of Justice publicly commit to enforce this law, if enacted; 3) legislation would be enacted indemnifying Roussel Uclaf for any product liability exposure resulting from the use of RU-486 in this country, or, as an alternative, a prohibition of any product liability actions against Roussel Uclaf for RU-486; 4) as part of any legislation, indemnification for consequential damages.

In exchange Roussel Uclaf would give the Population Council a royalty-free license because it has decided to forego any profit from entering the United States market. **In short, Roussel Uclaf's position is that it should not incur any liability exposure as a result of making RU-486 available in this country** as an abortifacient because it does not anticipate any profit from selling RU-486 for that use in the United States and is entering the American market only at the request of the United States Government. Roussel Uclaf remains willing to exploit its patent for non-abortifacient uses of RU-486, should any other use be found to be safe and effective.

FDA advised the Population Council's lawyer that it could not make a commitment to seek such legislation and that its enactment was extremely unlikely, both for political reasons and because the United States had never agreed to indemnify any drug manufacturer, with the exception of the swine flu precedent. The FDA also communicated that seeking such protection for a drug company far exceeded FDA's appropriate role, but that the agency would discuss the situation with the Department.

In mid-September Roussel Uclaf hired legal counsel, Swidler and Berlin, to lobby the federal government at levels above FDA to obtain the legislation described above. On October 5, Kevin Thurm, the Department's Chief of Staff, and Harriet Rabb, the Department's General Counsel, met with lawyers from Swidler and Berlin to discuss the situation. The Department initiated the meeting to assess how the United States Government might facilitate successful completion of the negotiations between Roussel Uclaf and the Population Council. At that meeting, the company reiterated its concerns about obtaining indemnification for potential losses and was again told emphatically that the Department would not support its efforts to obtain federal legislation. Roussel Uclaf's lawyer then suggested that the

United States could exercise its statutory powers of eminent domain and take over the patent for RU-486 insofar as it covers abortifacient uses of the drug.

The Population Council appears to be attempting to meet those demands of Roussel Uclaf that do not require the enactment of federal legislation. We have been advised by the Population Council that they sent a proposed licensing agreement to Roussel Uclaf on October 11, although we do not know whether Roussel Uclaf and Hoechst will find this proposal acceptable. In addition, the Population Council's President recently met with the President of Roussel Uclaf, and is planning to send a delegation to Germany during the first few weeks of November in the hope that if Hoechst understands that the Population Council is a serious, credible organization, Hoechst will withdraw its objections and permit Roussel Uclaf to enter into an agreement with the Population Council. Despite these moderately positive developments, we do not think that the negotiations will be successfully concluded without pressure on Roussel Uclaf/Hoechst.

Moreover, we have learned that Hoechst is interested in using an American venture capitalist group as a partner for the Population Council; this group is thought to be able to secure funds sufficient to indemnify Hoechst at the level it desires. However, it is our understanding that the Population Council appears unwilling to work with this group. This issue has further complicated the negotiations.

AVAILABLE OPTIONS TO MOVE FORWARD NEGOTIATIONS

The negotiations between Roussel Uclaf and the Population Council have not been successfully concluded because of the insistence of Roussel Uclaf and Hoechst that they be protected from all economic harm if they permit RU-486 to be marketed in this country. There are two options for moving forward the stalled negotiations:

One option is to enlist the aid of Felix Rohatyn, or someone of comparable stature, to negotiate with Roussel Uclaf and Hoechst on behalf of the United States Government. The negotiations require a person with extensive experience in the international business community, especially France and Germany. In addition the person must understand the pharmaceutical industry and have the standing to participate in high-level discussions that might involve appropriate ambassadors, as well as the Health Ministers in France and Germany.

A second option is for the United States to exercise its statutory powers of eminent domain and take over the patent for RU-486, insofar as it covers the abortifacient use of the drug. The Government could then contract with a company to manufacture

and distribute the drug. As noted above, this option was suggested by Roussel Uclaf's lawyers in their October 5 meeting with the Department's Chief of Staff and is clearly the company's preferred approach. While the United States government has the legal authority to take over the patent, such an approach is rare and in this case is politically complex. Although legal, there are particular concerns about the political viability of this approach and the willingness of Congress to permit such an action to stand. We note that Roussel Uclaf did not demand that the governments of France, England, or Sweden take such steps.

NEXT STEPS

Unless you object, the Department plans to engage the services of Felix Rohatyn or someone comparable as a negotiator. This negotiator would require the State Department's support in making appropriate diplomatic contacts, both with the United States Ambassadors to France and Germany, the French and German Ambassadors to this country, and other high-level officials in France and Germany, such as the respective Health Ministers. The purpose of such contacts would be to assess the situation and determine what measures the United States could take to persuade Roussel Uclaf and Hoechst to make RU-486 available in the United States. The French and German governments might be displeased to learn that their companies are not accommodating a request made by the United States Government. In addition, a negotiator of Felix Rohatyn's caliber might identify means other than federal legislation to satisfy Roussel Uclaf's and Hoechst's concerns.

In order for the negotiator to succeed, the Department and the Administration must be unequivocal in the position that taking over the patent for RU-486 is not an option. To avoid any ambiguity on this point, the negotiator should have a letter signed by the Secretary of Health and Human Services making clear on behalf of herself and the Administration that the United States government will not take over the patent. In addition the letter should request on behalf of the Administration that Hoechst and Roussel Uclaf conclude negotiations for the entry of RU-486 onto the U.S. market expeditiously. Roussel Uclaf will have every incentive to delay the negotiations if it thinks that the United States will ultimately take over the patent. It is the Department's position that this option should be unambiguously rejected, not only because it is controversial, but because its continued existence will make it impossible for the negotiator to obtain any other agreement.

Donna E. Shalala

Tab C

Food and Drug Administration
Rockville MD 20857

September 30, 1993

NOTE TO: The Secretary

FROM: The Commissioner of Food and Drugs

SUBJECT: RU-486

On January 22, 1993, President Clinton issued a memorandum directing you to assess initiatives to promote the testing, licensing, and manufacturing in the United States of RU-486 (mifepristone).[1] The Agency has had ongoing dialogue with Roussel Uclaf to get a marketing application submitted to FDA for the drug. Both you and the FDA are on record as stating that if RU-486 is a safe and effective alternative to surgical abortion, then women in the U.S. should have access to that drug. The President also directed you to reassess whether RU-486 qualifies for importation under FDA's personal use importation policy.[2]

I. Current Marketing of the Drug

RU-486 is manufactured by the French firm Roussel Uclaf and it is approved to induce abortions in France, the United Kingdom, and Sweden. Roussel Uclaf has stated that it can act in the United States only with the approval of its parent company, Hoechst AG. Hoechst has historically refused to permit Roussel Uclaf to seek marketing approval for RU-486 as an abortifacient in the United States. Both you and I have asked Hoechst to permit Roussel Uclaf to file a new drug application (NDA) for the drug. Hoechst remains adamant in its refusal. While some members of Congress have written to Hoechst urging the company to

[1] Although there are several investigational new drug applications (INDs) on file with FDA for RU-486 for other uses, including Cushing's syndrome, diabetes, meningioma, and breast cancer, Roussel Uclaf will not pursue marketing applications for these indications until the abortion issue is resolved. FDA representatives have met with representatives from the National Institutes of Health (NIH) to discuss initiatives to promote the testing in the United States of RU-486 and other antiprogestins. NIH is limited in what it can do by the restrictions placed on its appropriation by the Hyde Amendment.

[2] In accordance with the President's January 22 memorandum, FDA has reassessed whether RU-486 might qualify for importation under FDA's personal use importation policy and whether the import alert should be rescinded. There are significant public health implications associated with rescinding the import alert, especially related to whether the drug could be safely used under these circumstances; the availability of counterfeit RU-486 on the world market for which the Agency cannot attest to purity, quality, or safety; and the fact that Roussel Uclaf's RU-486 is so tightly controlled as to be unavailable for personal importation even if the import alert were to be rescinded. The Agency submitted its recommendation on this issue to PHS on July 14, 1993. Because the import alert has been challenged by a woman who attempted to bring a small quantity of RU-486 into the country, the Agency is working with the Department on an appropriate response to this ongoing litigation.

submit a marketing application for RU-486, other Congressional members have written to Hoechst expressing their strong opposition to the marketing of RU-486 in this country. This, and the well-publicized activities of anti-abortion groups, have provided Hoechst and Roussel Uclaf with evidence that the U.S. population lacks cohesiveness on this issue and that the abortion debate continues.

II. Summary of Discussions with Roussel Uclaf Regarding Testing of the Drug

In April 1993, FDA arranged a meeting between Roussel Uclaf and the Population Council to attempt to get those parties to agree to work together to test RU-486 and file a new drug application for the drug. The Population Council was identified as the most likely group to work with Roussel Uclaf because the Population Council had a contract with Roussel Uclaf which required Roussel Uclaf to give the Population Council sufficient amounts of the drug so that the Population Council could conduct clinical trials. The contract also appeared to require Roussel Uclaf to license the drug to the Population Council if Roussel Uclaf was unwilling to sell the drug in the United States. A copy of that contract, which must remain confidential, is attached.

At the April meeting, Dr. Edouard Sakiz, president of Roussel Uclaf, raised the issue of federal legislation to indemnify Roussel Uclaf from any damages it might suffer from permitting RU-486 to go onto the United States market. Dr. Sakiz was worried about product liability actions against Roussel Uclaf if a woman had an incomplete abortion and a deformed fetus. Dr. Sakiz was also concerned about consequential damages, such as the economic costs from boycotts of Roussel Uclaf (or Hoechst) products, bombings of Roussel Uclaf/Hoechst facilities, etc. by right-to-life groups. Dr. Sakiz's view was that if the United States Government wanted RU-486 on the U.S. market, then the United States Government should make Roussel Uclaf whole for any damages Roussel Uclaf might suffer because it had agreed to the United States Government's request.

Dr. Sakiz was told quite clearly at the April meeting that such legislation would never be enacted and the FDA would not support Roussel Uclaf in its advancement of that idea.

Despite being told that there was no possibility of obtaining favorable legislation, Dr. Sakiz committed Roussel Uclaf to go forward with the Population Council to bring RU-486 onto the United States market. Specifically, at the April meeting Roussel Uclaf and the Population Council agreed:

- That Roussel Uclaf would license RU-486 to the Population Council, which would conduct a clinical trial involving 2000 women pursuant to an investigational new drug (IND) application;

- That the Population Council would ultimately submit an NDA to FDA, based on the results of the clinical trial and on other studies that have been conducted by Roussel Uclaf; and

- That the Population council, with the concurrence of Roussel Uclaf, would choose a new manufacturer for the drug, and that Roussel Uclaf would transfer its technology for making the drug to that manufacturer, because Roussel Uclaf does not want to manufacture the drug for sale in this country.

It was then left for the Population Council and Roussel Uclaf to revise the terms of their contract, while Roussel Uclaf began sending scientific information to FDA and the Population Council. The contract negotiations continued from sometime after the April meeting until recently. As of late July 1993, the Population Council thought the contract negotiations were proceeding smoothly, though slowly. In those negotiations the Population Council was represented by Jim Boynton of Christy and Viener and Roussel Uclaf was represented by Joe Orsini, its corporate council in Paris.

On August 2, 1993, Jim Boynton, the Population Council's lawyer, notified FDA that Roussel Uclaf had recently demanded that the Population Council obtain a commitment from the U.S. Government that the U.S. would enact legislation that would protect all persons who had anything to do with RU-486. This was described as similar to "right-to-access" legislation that would make it a crime for any person to hurt or harass any doctor administering RU-486, their patients, and the manufacturers, distributors, and salespersons for the drug. Roussel Uclaf also demanded that the Department of Justice promise to expend its resources to enforce this law, if enacted. Roussel Uclaf also asked for legislation that would indemnify Roussel Uclaf against any product liability exposure as a result of the use of RU-486 in this country or, as an alternative, that would ban any product liability actions against Roussel Uclaf for RU-486. Finally, Roussel Uclaf asked for legislation that would indemnify Roussel Uclaf against consequential damages. Roussel Uclaf's principal assertion is that it is willing to give the Population Council a royalty-free license, because it has decided (given a push by Hoechst), that it will forego any monetary gain from entering the U.S. market. In short, because Roussel Uclaf does not expect to make any money off of RU-486 in the U.S. market, and sees itself as permitting RU-486 to enter the U.S. market only because asked to do so by the United States Government, then it should not incur any liability exposure on account of the drug.

FDA advised Mr. Boynton that the FDA could not make a commitment to seek such legislation, pointing out that Congress had recently reenacted the Hyde Amendment and that other than the swine flu situation, the United States had never agreed to indemnify any drug manufacturer. The FDA further explained that it would go far beyond FDA's appropriate role to seek such protection for a drug company. The FDA offered to advance the idea within the Department, but was advised by Mr. Boynton that the answer given was sufficient.

In mid-September, Roussel Uclaf hired legal counsel (allegedly, Lester Hyman and John Hoff of Swindler and Berlin) to lobby the federal government at levels above FDA to obtain legislation protecting the company from potential losses, as described above.

III. Analysis

The FDA's principle objection to Roussel Uclaf's request for indemnification and related relief has been pragmatic--we did not (and do not) think Congress would ever pass such legislation. Having said that, we also think that there are other policy reasons for refusing to seek indemnification of a drug manufacturer, for example:

- It would create an unacceptable precedent for any manufacturer of a significant vaccine or drug to seek indemnification as a condition for bringing the product to market. There is little basis to distinguish RU-486 from a breakthrough AIDS drug or unique vaccine. The swine flu indemnification plan proved very problematic for the United States Government.

- If public health problems were to occur post-approval, the interest of the United States as an indemnifying party would be to disprove that problems had occurred, while FDA's obligation would be to objectively investigate and take appropriate actions to protect the public health. This would be an untenable conflict for the United States Government.

Roussel Uclaf's liability and boycott concerns should not be underestimated. Because Roussel Uclaf is willing to give the Population Council a royalty-free license, it wants to eliminate any potential for expenses due to the drug's introduction into the United States market. Roussel Uclaf has also expressed its willingness to give a royalty-free license to any other major U.S. pharmaceutical company, but has found no company willing to take the license. Roussel Uclaf could, possibly, sell the drug to the Population Council (or to others) but it appears unwilling to do so, perhaps because the drug may have important other therapeutic benefits in the future, and it may want to maintain the right to sell to those markets. However, Hoechst may be willing to simply abandon the patent or give it to the United States.

There are some that suggest that Roussel Uclaf is simply playing a delaying game--waiting until the very staunchly Catholic Hoechst CEO (Prof. Wolfgang Hilger) retires in April 1994--so that then Roussel Uclaf would be free to exploit the drug in the United States and elsewhere for all uses. Others suggest that Roussel Uclaf does not want to reach agreement with the Population Council, but is merely stalling until an international foundation is created by Dr. Etienne Balieu, the inventor of the drug and a former Roussel Uclaf employee, to which Roussel Uclaf could then sell the rights to the drug.

The speculation is fueled by the essentially unanswered question--as to why Roussel Uclaf is willing to manufacture and sell RU-486 to some markets (England, France, and Sweden) but not to others (e.g., the United States). The common thinking is that Hoechst is only willing to permit Roussel Uclaf to sell RU-486 in a country when Hoechst is forced to do so politically, and, therefore, the only way to get RU-486 onto the U.S. market is to exercise political pressure on Roussel Uclaf and on Hoechst.

This thinking appears borne out by the circumstances here--Roussel Uclaf was willing to come to the table (at FDA) when it had received pressure from President Clinton (the January 23, 1993, Executive Order), you (your March 12, 1993, letter to Prof. Hilger at Hoechst), and FDA, but that since that pressure has waned the incentive to come to an agreement has also waned.

Another possibility is that the Population Council is simply attempting to reach an agreement that leaves Roussel Uclaf with too little, and that if the Population Council were willing to settle for less (e.g., the ability to study, but not to market the drug or to indemnify Roussel Uclaf) then a deal could be reached.

IV. Recommendation for Expert Advisor

This situation calls for someone of Felix Rohatyan's caliber for several reasons. At the outset, we must make it clear that the FDA cannot take this issue too far without compromising its role as objective reviewers of the safety and efficacy of the drug. But equally as important is the fact that this is an issue where business and politics intersect quite dramatically. Because of the abortion debate, Roussel Uclaf is left alone to promote its drug. Other major U.S. drug manufacturers have, to date, refused to join forces with Roussel Uclaf--either by agreeing to go forward with their own abortifacient drug products, or by agreeing to be the manufacturer or distributor of RU-486. Therefore, Roussel Uclaf feels isolated (and vulnerable) by the U.S. demands. It will take an experienced person, familiar with the drug industry, to sort out these issues.

Second, there are pragmatic, economic concerns to be faced. Roussel Uclaf's concerns about indemnification are realistic concerns that need to be satisfied. Someone with extensive experience in the business community (in France and Germany as well as in the United States) will have a better understanding of the various ways this concern can be overcome.

Finally, there are diplomatic issues that may need to be addressed. It may be that France and Germany would be unhappy to learn that their companies were not accommodating a request made by the United States Government. The U.S. Ambassadors to France and Germany will

need to be consulted on these issues, and your counterparts in France and Germany may also need to be involved. We think that someone familiar to these circles would advance the Administration's goal to bring a safe and effective abortifacient to the U.S. market.

Mary Pendergast
for David A. Kessler, M.D.

Attachment: Contract

cc: Dr. Philip Lee
Mr. Kevin Thurm

THE WHITE HOUSE

WASHINGTON

January 22, 1993

MEMORANDUM FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

SUBJECT: Importation of RU-486

In Import Alert 66-47, the Food and Drug Administration ("FDA") excluded the drug Mifepristine -- commonly known as RU-486 -- from the list of drugs that individuals can import into the United States for their "personal use," although the drugs have not yet been approved for distribution by the FDA. (See FDA Regulatory Procedures Manual, Chapter 9-71.) Import Alert 66-47 effectively bans the importation into this Nation of a drug that is used in other nations as a nonsurgical means of abortion.

I am informed that in excluding RU-486 from the personal use importation exemption, the FDA appears to have based its decision on factors other than an assessment of the possible health and safety risks of the drug. Accordingly, I hereby direct that you promptly instruct the FDA to determine whether there is sufficient evidence to warrant exclusion of RU-486 from the list of drugs that qualify for the personal use importation exemption. Furthermore, if the FDA concludes that RU-486 meets the criteria for the personal use importation exemption, I direct that you immediately take steps to rescind Import Alert 66-47.

In addition, I direct that you promptly assess initiatives by which the Department of Health and Human Services can promote the testing, licensing, and manufacturing in the United States of RU-486 or other antiprogestins.

You are hereby authorized and directed to publish this memorandum in the Federal Register.

William J. Clinton

Tab D

MAY 11 1994

TO: Carol Rasco

FROM: Kevin Thurm

SUBJECT: RU 486

Background

Roussel Uclaf, a French subsidiary of the German company, Hoechst, holds two United States patents for its product, RU 486, which has abortifacient and potentially scores of other medical uses. The French company has engaged the Population Council, a not-for-profit organization, in over 14 months of negotiations designed to transfer Roussel Uclaf's United States patent rights to the Population Council which would then take steps to bring RU 486 to market in this country. Those negotiations are on-going.

On May 9, 1994, Roussel Uclaf wrote a letter to Secretary Shalala stating the company's wish, instead, to offer the RU 486 United States patent rights to the American government insofar as the abortifacient and other gynecological uses are concerned. The company proposes voluntarily to assign its patent rights, as so limited, to the government free of charge, asking nothing in return.

Were the government willing to accept the "gift" offer, negotiations with the Population Council would be discontinued, and the patents, as so delimited, would be made available for assignment to the United States.

Alternatively, Roussel Uclaf has advised that should its bilateral negotiations with the not-for-profit be resolved, the deal cannot be finally closed unless and until the President of the United States writes a letter to the French company asking, on behalf of the women in America, that the patents be assigned to a non-profit entity in this country.

Roussel Uclaf strongly favors the gift to the government arrangement. Your advisors strongly favor the bilateral arrangement and have taken steps consistently and firmly to so insist.

Issues for Decision

One: Whether the President is willing to write a letter to the manufacturer of RU 486 asking that the United States patents for that product be assigned to a not-for-profit entity in this country. A suitable letter might read as follows:

> It is important for the health of women in the United States that they have access to the widest possible range of safe and effective medical treatments. In support of

> that goal, in January 1993, I asked the Secretary of Health and Human Services to promote the testing and licensing of mifepristone [RU 486] and other antiprogestins in the United States.
>
> To permit the appropriate testing, development and distribution of RU 486 in the United States, I ask that your company give its mifepristone patent rights in the United States to a non-profit organization that would take all necessary steps to file a new drug application with the Food and Drug Administration [FDA], so that the FDA can determine whether the drug is safe and effective for use in the United States.

Two: If the bilateral negotiations between Roussel Uclaf and the not-for-profit entity fail, and the only option then currently on the table is the gift offer, is the government of the United States willing, and if so, under what conditions, to accept the offer of the patent rights for RU 486?

Three: If the government is not willing to accept the offer of the patent rights, on what is that decision to decline based, and how will it be communicated to the American people?

* * * * * * * * * * * * * * *

The following tabs set forth discussion of the various factors that may be brought to bear on the decision-making:

Tab 1:	History and background of RU 486 in this Administration
Tab 2:	Legal issues
Tab 3:	Bringing RU 486 to market [timing, available entities, administrative hurdles]
Tab 4:	Political considerations
Tab 5:	Press strategies and concerns

The following documents are attached for your reference;

Exhibit 1:	The President's Memorandum of January 22, 1993
Exhibit 2:	Roussel Uclaf's May 9, 1994 letter to Secretary Shalala attaching a draft offer of the gift
Exhibit 3:	Roussel Uclaf's draft letter to the President
Exhibit 4:	Minutes in French and translation of the April 26, 1994 Roussel Uclaf board meeting setting out the need for a letter from the President

BACKGROUND

Roussel Uclaf, a French subsidiary of the German company, Hoechst, holds two United States patents for its product RU 486, which has abortifacient and various other medical uses. The patents will expire in the years 2000 and 2001. Hoechst, the parent company, is co-owned by the Celanese Corporation, whose direct or indirect product lines include Nike sneakers and seat belts; the company does about $8 billion worth of business per year in the United States.

On January 22, 1993, the President directed the Secretary to "assess initiatives by which the Department of Health and Human Services can promote the testing, licensing, and manufacturing in the United States of RU 486 or other antiprogestine" (Exhibit 1). Within the month, the FDA, through Commissioner David Kessler, requested both Roussel Uclaf and Hoechst to expedite the process and met with representatives of Roussel to discuss issues. In March 1993, Secretary Shalala wrote to the president of Hoechst urging him to eliminate all corporate barriers to introduction of RU 486 in the United States.

Roussel Uclaf identified the Population Council, a non-profit organization based in New York, as the most likely vehicle through which to produce, distribute and test RU 486; the two parties have a 1982 contract which gives the Population Council some limited rights to license Roussel Uclaf product in this country.

Over the past fourteen months, the two parties have conducted on-again/off-again negotiations over a distribution scheme, liability insurance (product and damage to property), and insurance for lost profits due to economic boycotts of non-related products. During these talks, Roussel, in addition to the three main issues, occasionally raised subsidiary matters; these bumps in the road served to delay the negotiations (some believe that Roussel was in a holding pattern in anticipation of corporate leadership changes in January and April of this year). In several newspaper stories on this issue during this period, representatives of the two parties have been quoted saying they expected a deal shortly. Obviously this has yet to materialize.

Last fall, lawyers representing Roussel Uclaf met with HHS officials to discuss ways the federal government might help the negotiations. Over a series of meetings, the corporation's lawyers presented a variety of requests, including whether the Administration would seek legislation indemnifying Roussel for all potential damages or would seize the patents. HHS officials repeatedly told Roussel's lawyers that neither was a possibility, and that the deal should be done through the private parties.

On April 14, 1994, the Secretary, along with other HHS officials, met with representatives of the two parties, including Professor

Ernst Afting (current CEO of Roussel), Dr. Edouard Sakiz (past CEO and current Board Chair of Roussel), and Margaret Carlson (head of the Population Council). The Secretary stated that the U.S. government would neither seek legislation indemnifying Roussel nor seize the patents. She made clear to the parties the importance she attached to the introduction of the product in the U.S. through an agreement between them. She ended the meeting by imposing a May 15, 1994 deadline for successful completion of their negotiations.

In light of this deadline and hearings scheduled by Congressman Ron Wyden for 10:00 a.m. on May 16 to obtain a status report, the parties have continued their negotiations. Although many issues have been resolved, some remain: the extent of insurance coverage for product liability and damage to property, and a "pull the plug" option which would give Roussel the authority to require the Population Council to withdraw the product from the market if the potential liability from all lawsuits exceeded a specified amount.

On April 26, 1994, the Board of Roussel Uclaf passed a resolution authorizing under certain circumstances the assignment of patent rights to either the United States government or to a non-profit organization (Exhibit 4). If the rights are to be given to a non-profit, the President of the United States must so request by letter on behalf of the women of the country (see draft letter in cover memo).

By letter of May 9, 1994, Roussel notified the Secretary that it was prepared to assign the patent rights (for abortifacient and other gynecological uses) to the government and attached a draft letter to the President from Professor Afting, the president and CEO of Roussel (Exhibits 2 and 3). This draft letter closely mirrored an earlier informal draft discussed with Kevin Thurm, Harriet Rabb and David Kessler during the prior week.

Discussions between the parties are scheduled to continue through the end of the week. If the private arrangement is not concluded, we must be prepared to have an answer to Roussel's letter which we believe the company would send (or at least publicize). There is some "buzz" among pro-choice and women's groups about this issue so there is a chance developments will leak before the deal is finished or the letter is formally sent.

LEGAL ISSUES DISCUSSION

I. **Gift Acceptance.** The first question is whether the government should insist that any gift be for all known medical uses, not just abortifacient and gynecological [including, perhaps, "morning after"] uses. On the one hand, the broader rights may make the patent more attractive to potential licensees. On the other hand, some potential licensees may be appropriate repositories of the government's patent rights for the designated uses, but not the full range of known medical uses. Finally, the burden of testing and bringing forward the product for abortifacient and gynecological uses may be more than enough obligation. The responsibility of pursuing research and testing on all the known medical uses to bring the promising ones to fruition may be more than the government and any licensee want to assume.

The Secretary has statutory authority to accept a gift, such as a patent, on behalf of HHS's Public Health Service. Alternatively, the directors of the national research institutes at HHS's National Institutes of Health (NIH) have statutory authority to accept gifts to support the activities of their institutes. Each option has pluses and minuses.

A. Secretarial gift acceptance. Because patents are intangible property, by statutory directive, the evidence of the gift (in this case, the original patent assignments), must be lodged with the Department of the Treasury. Treasury has the discretion to hold the property or liquidate it at HHS's request. There is unlikely to be a problem raised by Treasury, but, to date, that Department has had no part in the RU 486 issue and must be consulted should this route be chosen.

B. NIH gift acceptance. No involvement of Treasury is required. Gifts to NIH institutes must be made to support the activities of the receiving institute - so a showing of such purpose would have to be made. This is not likely to pose a problem, but no work has been done to identify a likely institute recipient or to prepare the gift justification.

Finally, with regard to gift acceptance, since Roussel Uclaf is an entity doing business with HHS, including specifically the Public Health Service and its components, the government will have to be sure that accepting the gift does not give rise to a public perception concern. There is no ethical impediment to accepting gifts from entities so positioned, but care must be taken to weigh the benefits and consequences so that the public can be assured that no favor has been curried or promised. In fact, it has not.

II. **Transfer of the Gift.** Roussel Uclaf has offered to assign its rights to the abortifacient and gynecological patent uses to the government. Were the United States to accept the assignment

from Roussel Uclaf, the government would in turn find a licensee or licensees willing and able to take responsibility for obtaining FDA approval and bringing the product to market. Although it is conceivable that the government could perform these tasks itself, only the Department of Defense now manufactures drugs on a large scale.

Since, by law, federal agencies are authorized to grant licenses in federally owned patents, were the government to have the patents by assignment, subsequent licensing arrangements are possible. Additionally, patent law provides the patent owner (or, in this case, the patent assignee) with the right to sue for patent infringement. Such capacity to bring suit could be consequential if counterfeit product began to appear in the United States.

III. **Licensing the United States Patent Rights.** Government agencies are authorized by law to grant non-exclusive, exclusive or partially exclusive licenses under federally-owned patents. Licenses to PHS-owned inventions are negotiated by the NIH Office of Technology Transfer in accordance with government-wide regulations.

Under the regulations, non-exclusive licenses can be given by the government relatively easily and directly to any applicants, generally speaking, whose capacity to act responsibly regarding the license has been demonstrated.

Exclusive or partially exclusive licenses are subject to a different, but not much more difficult process. Notice of the patent's availability must be published in the Federal Register, and a sixty day period for filing written objections must be allowed. No less than three months after the date of publication, and after consideration of any objections received, an exclusive or partially exclusive license may be granted. In that event, the agency must make determinations regarding the necessity for an exclusive license, rather than a nonexclusive one, the effect of the license on competition, and whether small business firms have been given first preference in accordance with the statute and regulations.

If and once the United States accepts the gift, it will be critically important that some bidder(s) come forward seeking a license to bring the product to market. Roussel Uclaf's efforts to shop this product around to United States pharmaceutical companies to get one or more to take up the responsibility of bringing RU 486 to market have been unsuccessful. Roussel Uclaf reports that the reluctance reflects other companies' unwillingness to bear (i) the product liability risks associated with the abortifacient or (ii) the political pressure from anti-abortion forces.

IV. **Possible United States Tort Liability.** The likelihood of United States tort liability depends, in large measure, on the

government's role in bringing RU 486 to market. Through sovereign immunity, the United States government is not subject to liability except to the extent that it consents to be sued. The Federal Tort Claims Act (FTCA) is a statutory limited waiver of sovereign immunity and, thus, acts as consent to being sued. Under the FTCA, the government is liable for personal injury caused by the negligent or wrongful act or omission of a Federal employee under circumstances where the government, if a private party, would be liable to the plaintiff. It would be unlikely for a court to allow a suit to go forward against the government under the FTCA if the government merely performed the "discretionary functions" of accepting a gift, licensing the patents, and acting on an application for FDA to approve a drug.

However, were the government to become enmeshed in facilitating or playing a direct role in the transfer of the technical background information that makes it possible actually to make RU 486, for example, the government risks being drawn into liability. An approach which limits the government's role in bringing RU 486 to market, while solving the lion's share of the potential government liability risk, creates other problems. Without the backup technical "know how," it would be years before any government licensee could create the product. Since it is unlikely that a licensee would bid for these patent rights without the actual prospect of bringing the product into existence, the United States could be left holding the patents with no licensee willing to step up and take them.

Alternatively, if a European or other off-shore manufacturer made the product in a fashion that meets FDA standards, the product is potentially importable by a government licensee. One wrinkle on this process results from the technology transfer regulations referenced above which note that normally, licensees of United States patents have to agree that the product will be produced substantially in the United States.

In short, to the extent the government refuses to become involved in actually transferring the technology, tort liability is kept at bay. But licensees may be kept at bay as well, leaving the government holding the patents with no prospect of bringing RU 486 to the women in America.

BRINGING RU 486 TO MARKET

A. Direct Patent Transfer to Population Council

If Roussel Uclaf agrees to license its patent rights in RU 486 to the Population Council, the Population Council would then have to take the following steps:

o Locate a drug manufacturer that would be willing to manufacture RU 486 for the United States market (we are advised that such a manufacturer has been identified by the Population Council).

o Obtain information from Roussel Uclaf on how Roussel Uclaf manufactures RU 486 and on its testing of the drug, so that the new manufacturer could follow parallel processes and the Population Council could refer to Roussel Uclaf's animal and human testing of RU 486 in any submission to the Food and Drug Administration. If Roussel Uclaf provides this information and technology transfer, it will significantly shorten the amount of time it will take to bring the drug to the United States market (assuming the drug is found to be safe and effective by FDA). With Roussel Uclaf's information, it might take six to twelve months for the Population Council's manufacturer to begin production of the drug, and for the Population Council to file its marketing application with the FDA. If Roussel Uclaf refuses to provide such information, it will take the Population Council eighteen months to two years to begin production, and up to five years to repeat the animal and human tests that show whether the drug is safe and effective.

Roussel Uclaf has stated that they will transfer the technology to the Population Council, but we do not consider this a strong assurance.

o Begin some clinical testing of the drug in the United States. Clinical trials, though not absolutely necessary for FDA approval, would permit women in the United States to have access to the drug, and for United States physicians to become familiar with the drug, while the Population Council prepared its marketing application for the FDA.

If Roussel Uclaf were to provide French-made RU 486 to the Population Council for the clinical trials, such trials could begin in the United States in approximately six months (five months for the Population Council to design its trials and find physicians willing to do the trials, and one month for FDA approval). If Roussel Uclaf were not willing to provide the drug for clinical trials, such trials would have to wait until (1) the Population Council's manufacturer could begin production of the drug, and (2) either Roussel Uclaf gave the Population Council its animal studies or the Population Council did its own animal studies.

Roussel Uclaf has stated that it would provide the French-made RU 486 to the Population Council for the clinical trials, but again we do not consider this a strong assurance.

o File a marketing application with the FDA. As indicated above, if Roussel Uclaf provides information and transfers its technology to the Population Council, a marketing application could be filed with the FDA within six to twelve months. FDA review would take no longer than six months. Many of the scientific decisions on the proper use and distribution of the drug have already been considered by the FDA, based on information already provided to FDA by Roussel Uclaf and the Population Council. Roussel Uclaf would not need to finish its United States clinical trials before filing a marketing application with FDA; such trials could be used to refine the use of the drug at a later time.

B. Patent Transfer to the United States

If Roussel Uclaf gives its patents to the United States, the United States would have to take the following steps:

o The United States would have to determine the scope of the rights given to the United States -- are the rights only in the abortifacient and other gynecological uses of the drug, or in all uses of the drug (e.g., gynecological uses, Cushing's disease, breast cancer).

o The United States would then need to transfer its rights in the patents to a third party. This process is discussed at Tab 2, and would take at least six months.

o The license holder would then need to take all of the steps outlined above, i.e., find a manufacturer, conduct the necessary tests, and file a marketing application with the FDA. The length of time these steps will take depends on whether Roussel Uclaf is willing to transfer its information, technology, and the drugs necessary for clinical trials to the license holder. Roussel Uclaf has advised the government that it would provide the information and French-made RU 486 for clinical trials to the United States' licensee, but it could change its mind.

It is difficult to determine whether the United States's license holder would take appreciably longer to bring RU 486 to market than the Population Council would need if the Population Council received a direct transfer of rights from Roussel Uclaf. Obviously, if the United States licensee is the Population Council, little time will be lost above that associated with the transfer of the patent rights from the United States to the Population Council. If another group becomes the United States's

licensee, that group might be able to bring the drug to the United States market slightly faster than the Population Council (if the group chosen was very familiar with the drug, had a good manufacturing facility, the cooperation of Roussel Uclaf, experience in FDA marketing applications, and excellent contacts with United States physicians) or much slower (if the group falls short on any factor).

We anticipate that if Roussel Uclaf gives its patent to the United States, it will add at least six months, and quite possibly twelve to eighteen months, onto the time needed to bring the drug to the United States market. This estimate excludes any additional time generated by litigation (see Tab 2).

POLITICAL ISSUE DISCUSSION

In viewing the various options, it is important to place them in a broader political context, particularly as they relate to health care reform, given the likelihood that Congress will narrow the current Health Security Act provisions that provide for abortions under pregnancy-related services.

Because of this situation with the Health Security Act, the introduction of RU 486 will be of greater significance to the pro-choice and women's groups. If the Administration is viewed as closing the door or rejecting an apparently reasonable offer on RU 486, then the path toward reaching a non-confrontational agreement with the advocates on the Health Security Act could become much more difficult. It is, therefore, extremely important that the decision concerning RU 486 be placed in the context of promoting women's health and maintaining the close relationship of the Administration to these groups.

With regard to other political considerations, the acceptance of RU 486 by the federal government, as opposed to by a private non-profit organization, would most certainly lead to a floor amendment on the Labor, HHS appropriations bill, or other legislative vehicle to prohibit federal funds from being used in conjunction with RU 486. It is difficult to predict the exact nature of the amendment. However, in the last Congress, Representatives Dornan, Dannemeyer, Lent, Bartlett, Bunning and Hunter co-sponsored a bill to prohibit federal funds from being used for clinical studies of RU 486 as an abortifacient. Given the likelihood of another Hyde-type amendment on the House and Senate floors this year, as well as the expected abortion-related amendments on health care reform, the members of the House and Senate will be frustrated at having to face another abortion-related vote (on RU 486 appropriation limits). The outcome of such a vote is difficult to predict.

To date, we have worked very cooperatively with Congressman Ron Wyden, the chief Congressional advocate in providing access to RU 486 to women in this country. We expect to be able to continue this close working relationship through the upcoming hearing on May 16. Because Congressman Wyden has postponed past hearings, and is very frustrated by the fourteen months of negotiations, it is unlikely that he would be willing to postpone the May 16 hearing. He is convinced that Roussel Uclaf and Hoechst have been stalling for time, and that it is important to remain firm on the hearing date in order to force agreement or to make it clear to the American public that the companies have no intention of providing RU 486 to the American market.

Finally, regardless of the precise wording of the President's January 22, 1993 memorandum, the expectation it created among the pro-choice and women's groups is that the federal government will do everything possible to get RU 486 introduced in this country. Leaders of these groups will be concerned with Administration action on health care reform and other issues, including the choice to replace Justice Blackmun. Saying "no" to a facially reasonable offer by Roussel Uclaf weakens our political base and may subject the President to criticism that he is not sticking to his original position.

Given the expression of Presidential support for RU 486 in January 1993, a "yes" adds marginal political cost (separate from issues like health care reform). For 1996 purposes, we probably lose few friends and anger few voters not already positioned on this or related issues.

A "yes", however, also means the Administration will have this issue on its front burner for a significant period of time. Anticipated floor amendments in Congress, rallying at HHS or other government buildings by pro-life groups, and the necessarily public process to secure licensees will provide ample opportunity for Republicans and others opposed to the Administration to focus attention on this decision and on its aftermath.

LIST OF MEMBERS INTERESTED IN THE RU-486 ISSUE

HOUSE

Ron Wyden
Henry Waxman
Michael McNulty (D-NY)
Jim Bunning (R-KY)
Robert Dornan (R-CA)
Duncan Hunter (R-CA)

SENATE

Carol Moseley Braun (D-IL)
Paul Simon (D-IL) (wrote on behalf of constituent)
John Breaux (D-LA) (wrote on behalf of constituent)

BACKGROUND

For five years Wyden has been by far the most active and vocal Member on RU-486. He has held numerous hearings and cosponsored a bill with Waxman in the last Congress to overturn the FDA import ban. Also in the last Congress, 6 Republicans (Dornan, Dannemeyer, Lent, Bartlett, Bunning, and Hunter) cosponsored a bill to prohibit federal funds from being used for clinical studies of RU-486 as an abortifacient. No one in the Senate is consistently active on this issue.

Obviously, the womens' caucus will be interested in any actions taken on Ru-486 as will the pro-life caucus (especially Hyde, Helms, and C. Smith). However, in the last four years the Department has not received RU-486 letters from either group.

Very little mail has been received by the Clinton Administration on RU-486. A typical letter is the attached C. Moseley-Braun letter inquiring as to the status of the President's Directives.

In the Bush Administration a typical letter is the attached California delegation letter on RU-486 as an important option for American women. Also, letters often stressed the importance of allowing research on RU-486 to go forward in areas of breast cancer, glaucoma, Cushing's disease, etc.

Please let me know if I can get additional information for you.

PRESS ISSUES DISCUSSION

If negotiations with the Population Council collapse, the Clinton Administration will be left with two possible courses of action. The following is an examination of the public relations ramifications of both choices:

If the Administration decides to accept the gift of the patent from Roussel Uclaf, for purposes of insulating the White House, it should be accepted by Secretary Donna Shalala at the direction of the President of the United States and on behalf of the women in America. This could be done in a press conference on Friday, May 13, 1994, with up to four principals: Secretary Shalala, Roussel Uclaf President, Population Council (if they would agree to run the clinical trials) and possibly Congressman Ron Wyden (who has been pushing this issue on Capitol Hill).

It would be made very clear that this step is the result of the process that was set in motion by President Clinton's memorandum of January 22, 1993, and that it is being taken because it was impossible for Roussel Uclaf to come to closure with a private sector entity. Because a non-surgical (and sometimes safer) abortion alternative would thus be available to women in the United States (as it is to many women in Europe), accepting the patent gift should be touted as a reproductive rights victory for American women and another example of the Clinton Administration's commitment to deliver on its promises. However, Secretary Shalala's remarks would be tempered by caution about the long and difficult road ahead and the potential roadblocks to bringing RU 486 to the marketplace.

While it should not be a part of the formal press conference, there should be a concerted effort on the part of the HHS Public Affairs team to place stories that outline the hurdles that must be overcome to shield the Administration against the fallout from our allies in the event efforts to get RU 486 to market become stalled in bureaucratic process, in Congress or for other reasons.

Because the Clinton Administration would actually be in possession of the RU 468 patent for a period of time while the licensing process moves foreward, during that time, the Administration may well be the focus of protest by conservative organizations that have become increasingly vocal and militant. These groups have suffered recent setbacks in court (e.g. a ruling that has imposed massive fines and barred them from physically blocking access to abortion facilities). They would welcome an extremely high visibility focal point for their activities. Protest marches in front of the White House and HHS are imaginable, and the conservative talkshow circuit would help to sustain the furor. This could go on while other abortion-related issues are before Congress, including debate on the Health Security Act and the FY 1995 enactment of the Hyde

Amendment. In the worst case, it could put the abortion issue centerstage, with the Clinton Administration as a high-profile player right up through the kick-off of the 1996 re-election campaign.

It would also be necessary to recruit a cadre of lawmakers, pro-choice and women's advocates willing and able to speak up for the Administration over the course of this heated debate. That is critically important for holding our own on the conservative talkshow circuit.

If the Administration decides to reject the gift of the patent from Roussel Uclaf, news of that decision should be disclosed in a press conference on Friday, May 13, 1994, by Secretary Shalala and FDA Commissioner David Kessler. It will be necessary to construct a rationale for why that course of action is better than the alternative one for American women. The argument will have to be that giving the patent to the United States government does not speed the drug to the American marketplace. In fact, it does just the opposite. Administrative regulatory process and the potential for legislative stonewalling could be very time consuming and could ultimately prevent the women in America from gaining access to
RU 486.

We should also highlight in the Secretary's statement the unprecedented nature of what Roussel Uclaf was attempting to position the United States to do. Never before has a patent been accepted by the government. The novelty of the situation makes the issue potentially more likely to be tied up in litigation or legislative maneuvering. One of the speakers would provide details of the formidable obstacles that may delay or even prevent the United States from moving the drug onto the market.

If Roussel Uclaf is willing to grant the United States patent rights for using RU 486 only for abortifacient and other gynecological purposes, another potential argument we could embrace is the position that we wanted more than the rights they were willing to grant because our interest in this drug goes beyond the issue of abortion, the need for which we are committed to making as rare as possible.

We would stress that a private sector deal is the only viable option for getting RU 486 quickly through clinical trials and into the market place. We should outline in detail all that the Population Council did to try and close the deal during the 14-month negotiations with Roussel Uclaf. The message, either implicitly or explicitly, is that Roussel Uclaf does not really want to close a deal with an entity that clearly has the potential to bring RU 486 to the marketplace because the company fears pressure from American conservatives.

Our position should be publicly to challenge Roussel Uclaf to go back to the bargaining table with the Population Council or to open negotiations with another entity; to stop playing games; and to get serious about responding to the request that President Clinton made of them almost a year and a half ago.

Without a doubt, a "no" will subject the Administration to a firestorm of protest by pro-choice and women's groups; and there will be few natural political allies vocally defending this decision, particularly in light of the relative difficulty of explanation.

* * * * * * *

It should be noted that Roussel Uclaf has already begun, informally, to circulate word of its potential offer to the United States. Many representatives of the pro-choice community already know about the potential gift offer. We may be forced to confront a news account of the issue prior to the Congressional hearings on May 16, 1994. Such a story will, undoubtedly, be presented from the Roussel Uclaf perspective as opposed to the Administration's point of view.

THE WHITE HOUSE

WASHINGTON

January 22, 1993

MEMORANDUM FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

SUBJECT: Importation of RU-486

In Import Alert 66-47, the Food and Drug Administration ("FDA") excluded the drug Mifepristine -- commonly known as RU-486 -- from the list of drugs that individuals can import into the United States for their "personal use," although the drugs have not yet been approved for distribution by the FDA. (See FDA Regulatory Procedures Manual, Chapter 9-71.) Import Alert 66-47 effectively bans the importation into this Nation of a drug that is used in other nations as a nonsurgical means of abortion.

I am informed that in excluding RU-486 from the personal use importation exemption, the FDA appears to have based its decision on factors other than an assessment of the possible health and safety risks of the drug. Accordingly, I hereby direct that you promptly instruct the FDA to determine whether there is sufficient evidence to warrant exclusion of RU-486 from the list of drugs that qualify for the personal use importation exemption. Furthermore, if the FDA concludes that RU-486 meets the criteria for the personal use importation exemption, I direct that you immediately take steps to rescind Import Alert 66-47.

In addition, I direct that you promptly assess initiatives by which the Department of Health and Human Services can promote the testing, licensing, and manufacturing in the United States of RU-486 or other antiprogestins.

You are hereby authorized and directed to publish this memorandum in the Federal Register.

William J. Clinton

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ROUSSEL UCLAF

Professeur Daniel-Ghislain Afting
Président du Directoire

Paris, May 9, 1994

Honorable Donna SHALALA
Secretary of Health and Human Services
Room 615 F
Hubert Humphrey Building
200 Independence Avenue SW
WASHINGTON, D.C. 20201
USA

Attention : Mr. Kevin THURM

Dear Secretary Shalala,

Following various meetings with your Staff and with FDA officers, the latest on May 6, 1994 with Dr. Kessler, we would like to confirm that we are ready to assign our US patent rights on RU 486 in accordance with the attached draft letter from us to the President of the United States of America.

This document is substantially similar to the draft that was given to Mr. Kevin Thurm, on April 29, 1994, by our counsel Lester Hyman, to allow a review of the situation by your Administration.

Of course we will continue to work with you and all relevant people in a constructive spirit and we look forward to meet you personally by the end of this week, as planned.

Sincerely,

Pr. D-G. AFTING
President & CEO

cc. Dr. KESSLER

35, Boulevard des Invalides 75325 Paris Cedex 07
Tél. 01 40 62 40 00 Fax 01 40 62 46 01 Télex 200 772 F

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ROUSSEL UCLAF

DRAFT

Paris, May ..., 1994

Honorable William J. CLINTON
President of the United States
The White House
1600 Pennsylvania Avenue NW
WASHINGTON, D.C. 20500
USA

Attention : Ms. Nancy HERNREICH

Dear Mr. President,

You have requested that ROUSSEL UCLAF allow the RU 486 compound to be used in your country.

We have been working to react to that request in a responsible manner.

I now am pleased to inform you that we have decided to contribute mifepristone (RU 486) for abortifacient purposes (and other gynecological uses) to the people of the United States of America, completely free of charge, by voluntarily assigning our relevant patent rights to the US Government.

This an unconditional gift, we ask for nothing in return.

Sincerely,

Pr. E-G. AFTING
President & CEO

35, Boulevard des Invalides 75323 Paris Cedex 07

PROJET 09.05.94

ROUSSEL UCLAF
Société anonyme à Directoire et Conseil de Surveillance
au capital de 544.749.360 F.
Siège social : 35, Boulevard des Invalides 75007 PARIS
R.C.S. Paris B 542 008 021

Extrait du Projet de Procès-Verbal
de la séance du Conseil de Surveillance du 4 Mai 1994
à 17 h 30

Etaient

Membres du Conseil de Surveillance :

Dr. E. SAKIZ, Président,
Dr. M. FRUEHAUF, Vice-Président,
MM. P. BOISSON, C. de CROISSET, le Pr. J. DAUSSET, B. ESAMBERT,
le Pr. G. MILHAUD, H. MONOD, E. de ROYERE, le Dr. K.G. SEIFERT.

Sans voix délibérative :

Pr. R.G. APTING, Président du Directoire,
M. G. JACQUINSON, Directeur Général, Membre du Directoire,
M. D. CAMUS, Membre du Directoire,
M. B. WINCKI, Membre du Directoire.

M. J.F. CHAVANCE et Mme D. PIERRON, Délégués du Comité Central d'Entreprise.

M. F. DESCOURS, Secrétaire du Conseil.

Absents excusés

M. le Dr. G. METZ, Membre du Conseil de Surveillance,
M. J. MISCHE, Membre du Conseil de Surveillance.
MM. F. BRECHARD et D. GAILLET, Délégués du Comité Central d'Entreprise.

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PROJET 09.05.94

MIFEPRISTONE - ÉTATS-UNIS

Le Docteur E. SAKIZ informe le Conseil de Surveillance que son assentiment est demandé sur les décisions que le Directoire va être amené à prendre à propos de la mifépristone aux États-Unis d'Amérique, compte tenu des exigences pressantes formulées au plus haut niveau par les autorités gouvernementales fédérales de ce pays.

Étant donné les caractères très particuliers du système médical des États-Unis par comparaison à celui des pays d'Europe où la mifépristone est actuellement utilisée, et considérant également le climat hautement conflictuel créé autour de ce produit aux États-Unis, le Directoire estime que ROUSSEL UCLAF ne saurait en aucune façon s'impliquer elle-même dans la production ou la diffusion de la mifépristone aux États-Unis.

Toutefois, prenant acte de la volonté du gouvernement américain de procurer aux citoyennes des États-Unis cette alternative médicale à l'interruption chirurgicale de la grossesse, le Directoire s'est résolu à offrir au gouvernement des États-Unis de lui céder, sans rémunération, les deux brevets référencés "U.S. Patents Nos. 4,386,085 and 4,447,424".

Au cas où ce gouvernement déclinerait cette offre pour lui-même tout en la jugeant recevable par une institution qu'il désignerait à cet effet, ROUSSEL UCLAF accepterait de poursuivre dans cette voie et de passer les accords nécessaires, à condition d'en être formellement requise par une lettre officielle, portant la signature du Président des États-Unis, et d'obtenir un certain nombre de garanties contractuelles.

Le Conseil de Surveillance prend acte de cette position qui n'appelle de sa part aucune objection, et manifeste ainsi au Directoire l'assentiment de principe sollicité.

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[Translation of Fax from Dr. Sakiz to Mary Pendergast of draft minutes of the Supervisory Board Meeting of May 4, 1994]

MIFEPRISTONE - UNITED STATES

Dr. E. SAKIZ informed the Supervisory Board ("Conseil de Surveillance") that its assent is requested concerning decisions that the Director ["le Directoire"] is being led to take a propos mifepristone in the United States of America, taking account of pressing exigencies formulated at the highest level by authorities of the federal government of that nation.

Given the very particular characteristics of the U.S. medical system, in comparison to that of the European countries where mifepristone is currently used, and considering equally the highly conflicted climate created around this product in the U.S., the Director deems that ROUSSEL UCLAF would be in no way implicated itself in the production or distribution of mifepristone in the United States.

Nevertheless, considering the wish of the American government to procure for U.S. citizens this medical alternative to the surgical termination of pregnancy, the Director has resolved to offer to cede to the government of the United States, without remuneration, the two patents referred to as "U.S. Patents Nos. 4,386,085 and 4,447,424."

In the event that the government should decline this offer for itself and at the same time judging it receivable by an institution that it would designate to this end, ROUSSEL UCLAF would accept this path and would adopt the necessary agreements, on the condition of being formally required by an official letter, bearing the signature of the President of the United States, and of obtaining a certain number of contractual guarantees.

The Supervisory Council acknowledged this position, which generated no objections, and manifested to the Director its assent to the principle being offered.

[translated by L. Bachorik, 5/10/94]

Tab E

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THE WHITE HOUSE

WASHINGTON

May 16, 1994

Dr. Edouard Sakiz
Chairman, Supervisory Board
Roussel Uclaf
35, boulevard des Invalides
75323 Paris Cedex 07
FRANCE

file

Dear Dr. Sakiz:

It is important for the health of women in the United States that they have access to the widest possible range of safe and effective medical treatments. In support of that goal, in January 1993, I asked the Secretary of Health and Human Services to promote the testing and licensing of mifepristone (RU 486) and other antiprogestins in the United States.

I understand that since at least that time, your company has been in negotiations with The Population Council, Inc., a nonprofit organization with whom you have had dealings on mifepristone since early in the last decade. Those discussions, I understand, have been directed toward the purpose on which I charged the Secretary. I am grateful for the effort those negotiations represent.

In order to permit the appropriate testing, development, and distribution of your product, I urge, at the conclusion of your negotiations, that you bring your plans to fruition. I understand that your company will assign without remuneration your United States patent rights on mifepristone to The Population Council, Inc. which has been studying this product since 1982 and which would take all necessary steps to file a new drug application with the Food and Drug Administration, so that the agency can determine whether the drug is safe and effective for use in the United States.

On behalf of the government of the United States and for the women in America, I thank you for your work.

Sincerely,

Bill Clinton

Tab F

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Jeffrey M. Friedman
James R. (Ron) Weddington

Shari L. Nichols
Kirk W. Tate

F&W

Friedman & Weddington, Attorneys, L.L.P.

502 W. 13th Street
Austin, Texas 78701
(512) 477-9641
Fax: (512) 320-8312

January 6, 1992

file

Betsey Wright
Director for Public Outreach
Transition Team
P. O. Box 615
Little Rock, AR 72203

Dear Betsey,

Enclosed is a "letter" to your boss, which I am going to try to get published. If I am unsuccessful, I may try to raise the money to print it as an ad in The N. Y. Times and other places.

Sarah and I have been discussing the notion of our setting up a non-profit corporation to license and distribute R U 486. Being non-profit would eliminate the need for products liability insurance, which is a major hang-up for a company thinking about marketing a new drug.

It's possible that such an endeavor could be the vehicle for a number of birth control efforts. Something's got to be done very quickly. 26 million food stamp recipients is more than the economy can stand.

Congratulations on your work for Clinton. It's good to see a UTYD doing good. I hope the new President can find the time to deal with the issues I raise in my letter. Please give it to him if you get a chance.

Sincerely,

Ron

Ron Weddington

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Jeffrey M. Friedman
James R. (Ron) Weddington

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Dear President-To-Be Clinton,

Some years ago another Southern Governor, when asked about the possibilities for prison reform, supposedly said something to the effect of, "Well, I don't think we're going to get very far until we get a better class of prisoner."

Well, I don't think you are going to get very far in reforming the country until we have a better educated, healthier, wealthier population.

Face it, you know that anything that even resembles the programs of Democratic Presidents in the past is going to make you a one term President. Reagan spent all our money on bombs and even if there were money for programs such as pre-natal health care, job training and day care centers it would be years before we would see any dramatic results. And, as anyone who follows education can see, more money doesn't necessarily translate into better educated kids.

But you can start immediately to eliminate the barely educated, unhealthy and poor segment of our country. No, I'm not advocating some sort of mass extinction of these unfortunate people. Crime, drugs and disease are already doing that. The problem is that their numbers are not only replaced but increased by the birth of millions of babies to people who can't afford to have babies.

There, I've said it. It's what we all know is true, but we only whisper it, because as liberals who believe in individual rights, we view any program which might treat the disadvantaged differently as discriminatory, mean-spirited and...well...so Republican.

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In 1989, 27 percent of all births were to unmarried mothers, a huge percentage of whom were teenagers. If current trends continue, soon a majority of the babies born will be born into poverty and one half of the country cannot support the other half, no matter how good our intentions.

I am not proposing that you send federal agents armed with Depo-Provera dart guns to the ghetto. You should use persuasion rather than coercion. You and Hillary are a perfect example. Could either of you have gone to law school and achieved anything close to what you have if you had three or four or more children before you were 20? No! You waited until you were established and in your 30's to have one child. That is what sensible people do. For every Jesse Jackson who has fought his way out of the poverty of a large family there are millions mired in poverty, drugs and crime.

If Ronald Reagan could use the media to convince the American public that a trillion dollars of borrowed money needed to be spent to combat the "Evil Empire," then you ought to be able to persuade people to only have children when they are able to afford them. Point out that only people like George Bush who inherit money can pay for more than one or two kids in today's economy. (And even then, some of the kids grow up to do embarassing things like loot savings and loans.)

You made a good start when you appointed Dr. Elders, but she will need a lot of help. You will have to enlist the aid of sports and entertainment stars to counteract the propaganda spread by church officials seeking parishioners, generals seeking cannon fodder and businessmen seeking cheap labor that, throughout the ages, has convinced the poor that children are necessary to fulfillment as a person.

It wouldn't hurt to point out that while only 11.1 percent of three person families are below the poverty level, 20.2 percent of six person families and 28.6 percent of families of seven or more are poor. (1992 Statistical Abstract of the United States, p. 459)

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And, having convinced the poor that they can't get out of poverty when they have all those extra mouths to feed, you will have to provide the means to prevent the extra mouths, because abstinence doesn't work. The religious right has had 12 years to preach their message. It's time to officially recognize that people are going to have sex and what we need to do as a nation is prevent as much disease and as many poor babies as possible.

Condoms alone won't do it. Depo-Provera, Norplant and the new birth control injection being developed in India are not a complete answer, although the savings that could be effected by widespread government distribution and encouragement of birth control would amount to billions of dollars.

No, government is also going to have to provide vasectomies, tubal ligations and abortions...RU 486 and conventional abortions. Even if we make birth control as ubiquitous as sneakers and junk food, there will still be unplanned pregnancies. There have been about 30 million abortions in this country since Roe v. Wade. Think of all the poverty, crime and misery ...and then add 30 million unwanted babies to the scenario. We lost a lot of ground during the Reagan-Bush religious orgy. We don't have a lot of time left.

You could do it, Mr. President-To-Be. You are articulate and you've already alienated the religious right with your positions on abortion and homosexuals. The middle-class taxpayer will go along with this plan because it will mean fewer dollars for welfare. The retirees will also go along because because poor people contribute very little to Social Security.

And the poor? Well, maybe if we didn't have to spend so much on problems like low birth weight babies and trying to educate children who come to school hungry, we might have some money to help lift the ones already born, out of their plight.

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The biblical exhortation to "Be fruitful and multiply," was directed toward a small tribe, surrounded by enemies. We are long past that. Our survival depends upon our developing a population where everyone contributes. We don't need more cannon fodder. We don't need more parishioners. We don't need more cheap labor. We don't need more poor babies

Very truly yours,

Ron Weddington

P.S. I was co-counsel in Roe V. Wade, have sired zero children and one fetus, the abortion of which was recently recounted by my ex-wife in her book, A Question Of Choice. (Grosset/Putnam, 1992) I had a vasectomy in 1969 and have never had one moment of regret.

EXHIBIT 49

Maarit Niinimaki et al., *Immediate complications after medical compared with surgical termination of pregnancy*, 114 Obstetrics & Gynecology 795 (2009)

Immediate Complications After Medical Compared With Surgical Termination of Pregnancy

Maarit Niinimäki, MD, Anneli Pouta, MD, PhD, Aini Bloigu, Mika Gissler, BSc, PhD, Elina Hemminki, MD, PhD, Satu Suhonen, MD, PhD, and Oskari Heikinheimo, MD, PhD

OBJECTIVE: To estimate the immediate adverse events and safety of medical compared with surgical abortion using high-quality registry data.

METHODS: All women in Finland undergoing induced abortion from 2000–2006 with a gestational duration of 63 days or less (n=42,619) were followed up until 42 days postabortion using national health registries. The incidence and risk factors of adverse events after medical (n=22,368) and surgical (n=20,251) abortion were compared. Univariable and multivariable association models were used to analyze the risk of the three main complications (hemorrhage, infection, and incomplete abortion) and surgical (re)evacuation.

RESULTS: The overall incidence of adverse events was fourfold higher in the medical compared with surgical abortion cohort (20.0% compared with 5.6%, *P*<.001). Hemorrhage (15.6% compared with 2.1%, *P*<.001) and incomplete abortion (6.7% compared with 1.6%, *P*<.001) were more common after medical abortion. The rate of surgical (re)evacuation was 5.9% after medical abortion and 1.8% after surgical abortion (*P*<.001). Although rare, injuries requiring operative treatment or operative complications occurred more often with surgical termination of pregnancy (0.6% compared with 0.03%, *P*<.001). No differences were noted in the incidence of infections (1.7% compared with 1.7%, *P*=.85), thromboembolic disease, psychiatric morbidity, or death.

CONCLUSION: Both methods of abortion are generally safe, but medical termination is associated with a higher incidence of adverse events. These observations are relevant when counseling women seeking early abortion.
(Obstet Gynecol 2009;114:795–804)

LEVEL OF EVIDENCE: II

Termination of pregnancy is one of the most common gynecologic procedures. For instance, in the United States, nearly half of pregnancies are unintended,[1] and 22% of all pregnancies (excluding miscarriages) end in termination.[2] Abortion practices have changed dramatically in recent years since the medical method with antiprogestin mifepristone and prostaglandins was introduced. For example, in 2007 in Finland 64%,[3] in Sweden 61%,[4] and in the United Kingdom 35%[5] of all abortions were performed using the medical method. Thus, the safety of induced abortion in general, especially that of the medical method, is of great public health interest.

Most previous studies focused on the short-term complications of induced abortion have been small or have not involved comparison of the two dominant methods of abortion (medical and surgical). In a large, register-based study, 5% of the patients had a complication (bleeding, infection, or (re)evacuation) after surgical abortion during a short-term follow-up period of 2 weeks.[6] In a previous meta-analysis in which medical and surgical termination of pregnancy in the

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Funded by Helsinki University Central Hospital (Drs. Suhonen and Heikinheimo), University Hospital of Oulu (Dr. Niinimäki), and The Finnish Cultural Foundation (Dr. Niinimäki).

The authors thank Matti Kesti for his help with computation.

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Financial Disclosure

Dr. Suhonen has lectured at meetings organized by Schering Plough (Helsinki, Finland). Dr. Heikinheimo has been a paid consultant and lecturer for Bayer Schering Pharma AG (Berlin, Germany) and for Schering-Plough (Helsinki, Finland). He also belongs to both the international and Finnish advisory boards for Bayer Schering Pharma. The other authors did not disclose any potential conflicts of interest.

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first trimester were compared, no differences in pelvic infection or ongoing pregnancies were noted between the methods. Evidence of different rates of other potential side effects or complications between the two abortion techniques could not be confirmed because the trials included were small.[7]

Only a few randomized controlled trials have been performed to compare success rates and complications between medical and surgical abortion.[8–10] In a previous, partly randomized study, no difference in the number of complications was noted. Although the rate of complete abortion was significantly higher in the surgical group (98% compared with 94%), the surgically treated women had a higher incidence of antibiotic treatment than did those undergoing medical abortion.[8] In another randomized controlled trial, complete abortion without a second procedure occurred in 98% of cases after surgical abortion and in 95% after medical abortion. Moreover, no differences in the rates of major complications were observed.[11]

The purpose of the present study was to compare medical and surgical abortion in regard to the incidence and risk factors of immediate (ie, within 42 days after termination of pregnancy) adverse events and complications in a large nationwide cohort. A nationwide cohort with high-quality data derived from national health registries offers the possibility to estimate extensively the risk of adverse events associated with the two methods of early termination of pregnancy. Using this same cohort, we recently reported that the risk of repeat abortion after medical compared with surgical termination of pregnancy depends on various sociodemographic factors but not on the method of abortion.[12]

MATERIALS AND METHODS

This was a cohort study including all women undergoing termination of pregnancy in Finland between January 1, 2000, and December 31, 2006. According to the current law on induced abortions, women need permission with legal indication for termination of pregnancy, but the legislation is interpreted liberally. The Finnish legislation on induced abortion[13] was summarized in our recent study.[12]

The present study was conducted after receiving approval from the ethics committee of the Northern Ostrobothnia Hospital District. The Ministry of Social Affairs and Health and Statistics Finland gave their permission to use the confidential personal-level data from the registries. The Data Protection Ombudsman was notified regarding the data linkage before the analyses as required by the national data-protection legislation.

All women who underwent induced abortion by either medical or surgical methods at a gestational age of 63 days or less were included. The duration of gestation was limited to 63 days because, during the study period of 2000–2006, medical abortions, for the most part, were performed only up to that time.[14] The time of follow-up after abortion was 42 days (6 weeks). Medical abortion was defined as the use of mifepristone alone or in combination with misoprostol or other prostaglandins. Surgical abortion included induced abortions with dilation and curettage or vacuum aspiration. The participants were divided into two arms of the study according to the primary abortion method. For women having more than one abortion, only the first termination of pregnancy during the study period was included.

The study was based on three national registries: the Abortion Registry,[3] the Care Registry for Health Institutions (later renamed the Hospital Registry)[15] complied by the National Institute for Health and Welfare, and the Cause-of-Death Registry of Statistics Finland.[16] The study participants were selected from the Abortion Registry as described in our previous study,[12] after which the other registries were linked with the cohort.

We linked information on the study participants in the Hospital Registry concerning all hospital-inpatient episodes (all hospitals) and outpatient visits (public hospitals) within 42 days after termination of pregnancy to analyze complications related to induced abortion. All of the diagnoses (based on the International Classification of Diseases [ICD]-10, International Statistical Classification of Diseases and Related Health Problems[17]) and codes for surgical procedures (based on the Nordic Classification of Surgical Procedures[18]) found in the cohort were evaluated to select those considered to be of clinical importance.

Complications were divided into seven categories: 1) hemorrhage (all reported hemorrhages), 2) postabortal infections (pelvic inflammatory disease, endometritis, cervicitis, wound infections, pyrexia of unknown origin, urinary tract infections, and septicemia), 3) incomplete abortion (surgical [re]evacuation, any reported incomplete abortion), 4) injuries or other reasons for surgical operation (all injuries, cervical laceration, uterine perforation, all surgical interventions during the time of follow-up), 5) thromboembolic disease (pulmonary embolism, deep vein thrombosis), 6) psychiatric morbidity (depression, intoxication, psychoses) and 7) death (death from any cause, pregnancy-related death according to the World Health Organization definition). The classification was based on that reported in the Joint Study of

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the Royal College of General Practitioners and the Royal College of Obstetricians and Gynaecologists[19] and modified for the present study.

The Cause-of-Death Register kept by Statistics Finland contains data from death certificates and includes all deaths of Finnish citizens and permanent residents in Finland classified according to ICD-10 codes.[20] All of the early deaths (within 42 days of termination of pregnancy) were classified as direct, indirect, or unrelated. This classification was based on that in an earlier study by Deneux-Tharaux et al.[21]

Differences between the groups were assessed using Student's *t*-test for continuous variables and the χ^2 test for categorical variables. Logistic regression analyses were performed to adjust for the differences in background characteristics in the comparisons of medical and surgical abortions. Furthermore, logistic regression was used to identify risk factors for complications. Variables that showed statistically significant associations with complications in univariable analysis were further entered in multivariable analysis. The estimated risks are presented as odds ratios with 95% confidence intervals. The statistical analyses were performed by using SPSS 16.0 for Windows (SPSS Inc., Chicago, IL).

RESULTS

The total number of women in the cohort was 42,619. Of these, 22,368 had primary medical and 20,251 primary surgical termination of pregnancy. The characteristics of the women in the cohort are presented in Table 1. The women in the medical-abortion cohort were somewhat younger and more often primigravid, nulliparous, and single. The most notable difference between the groups was the shorter duration of gestation in the cohort undergoing medical abortion; surgical abortions in Finland usually are performed after the 6th week of gestation.

The incidence of various adverse events and complications is shown in Table 2. The most common adverse events were hemorrhage and incomplete abortion, both of which were more common in the medical group. The incidence of infection did not differ between the groups. Injuries requiring operation were rare but were more common in the surgical group. No differences between the two groups were noted in the incidence of thromboembolic disease, psychiatric morbidity, or death, partly because the overall incidence of these events was low. All of the deaths were unrelated to pregnancy: suicide (n=3), homicide (n=1), subarachnoid hemorrhage (n=1), and traffic accident (n=1).

When comparing the numbers of women with adverse events or complications, the difference between the two groups was notable: 20% of women in the medical-abortion group and 5.6% of women in the surgical-abortion group had at least one type of adverse event. When looking at the number of complications per patient, there were fewer multiple complications after surgical abortion (Table 2).

We also analyzed the three most common complications in relation to the duration of gestation (Fig. 1). In the medical-abortion cohort, the proportion of women with hemorrhage decreased with advancing duration of gestation; with surgical abortion it increased, albeit not significantly. In both groups, the incidence of infection and incomplete abortion increased with advancing duration of gestation.

Univariable and multivariable analyses were performed concerning the risk factors for three major classes of complications (hemorrhage, infection, and incomplete abortion) and for surgical (re)evacuation, separately for the medical and surgical abortion cohorts (Table 3), and for the whole cohort combined (Fig. 2). In multivariable analysis, the risk of hemorrhage after medical abortion was increased in the age group of 20–24 years, among parous women, among those of lower socioeconomic status, and among those living in densely populated or rural areas. The risk decreased with advancing duration of gestation. After surgical termination of pregnancy, an increased risk of hemorrhage was seen in the age groups of 20–24, 25–29, 30–34, and 35–39 years when compared with women younger than 20 years. A rural type of residence was associated with a decreased risk of hemorrhage.

Multivariable analysis revealed an increased risk of infection after medical abortion in the age group of 20–24 years and with advanced duration of gestation of 50–56 and 57–63 days. After surgical abortion, an increased risk of infection was found in the age group of 20–24 years, with increasing duration of gestation, and among women of lower socioeconomic class. A decreased risk of infection was associated with parity and with women living in densely populated or rural areas.

The risk factors associated with incomplete medical abortion were age of 20–24 years, parity, previous abortion, being single, living in a densely populated or rural area, and advanced duration of gestation. The risk of experiencing incomplete surgical abortion was associated with previous abortion, cohabiting or being single, and with a duration of gestation of 57–63 days.

In multivariable analysis, the risk of bleeding was almost eightfold higher, the risk of incomplete abor-

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Table 1. Characteristics of the Participants Included in the Study

	Medical Abortion (n=22,368)	Surgical Abortion (n=20,251)	*P*
Age (y)			
Median (mean)	25.0 (26.3)	26.0 (27.3)	<.001
95% confidence interval	26.2–26.4	27.2–27.4	
Age category (y)			
Younger than 20	5,058 (22.6)	4,352 (21.5)	<.001
20–24	5,665 (25.3)	4,337 (21.4)	
25–29	4,098 (18.3)	3,442 (17.0)	
30–34	3,406 (15.2)	3,393 (16.8)	
35–39	2,934 (13.1)	3,130 (15.5)	
40 or older	1,207 (5.4)	1,596 (7.9)	
Parity			
0	12,819 (57.3)	10,171 (50.2)	<.001
1	3,444 (15.4)	3,384 (16.7)	
2	3,897 (17.4)	4,125 (20.4)	
3 or more	2,207 (9.9)	2,570 (12.7)	
Previous abortions			
0	18,626 (83.3)	15,461 (76.4)	<.001
1	2,856 (12.8)	3,471 (17.1)	
2	664 (3.0)	927 (4.6)	
3 or more	221 (1.0)	390 (1.9)	
Marital status			
Married	4,350 (19.5)	4,718 (23.3)	<.001
Cohabiting	3,592 (16.1)	3,113 (15.4)	
Single	14,394 (64.4)	12,412 (61.3)	
Social status			
Upper white-collar worker	1,595 (7.1)	1,497 (7.4)	<.001
Lower white-collar worker	4,799 (21.5)	4,794 (23.7)	
Blue-collar worker	2,691 (12.0)	3,060 (15.1)	
Student	7,598 (34.0)	5,990 (29.6)	
Other	1,072 (4.8)	1,386 (6.8)	
Unknown	4,613 (20.6)	3,524 (17.4)	
Type of residence			
Urban	16,668 (74.5)	15,118 (74.7)	<.001
Densely populated area	2,788 (12.5)	2,286 (11.3)	
Rural	2,912 (13.0)	2,847 (14.1)	
Indication for abortion			
Social reasons	19,691 (88.0)	17,175 (84.8)	<.001
Age 17 y or younger	1,507 (6.7)	1,459 (7.2)	
Age 40 y or older	754 (3.4)	1,076 (5.3)	
Four children or more	366 (1.6)	457 (2.3)	
Other	50 (0.2)	84 (0.4)	
Duration of gestation (d)			<.001
42 or fewer	6,012 (26.9)	1,895 (9.4)	
43–49	7,355 (32.9)	4,724 (23.3)	
50–56	6,014 (26.9)	7,033 (34.7)	
57–63	2,987 (13.4)	6,599 (32.6)	

Data are n (%) unless otherwise specified.

tion was fivefold higher, and the risk of (re)evacuation was twofold higher after medical abortion compared with surgical abortion. The risk of infection, as derived from univariable analysis, was not associated with the method of abortion.

DISCUSSION

In the present study, we found that the two methods of pregnancy termination (medical and surgical) are generally safe. However, the incidence of the two most common adverse events (hemorrhage and incomplete abortion) were notably higher among women undergoing medical abortion, whereas complications requiring surgical treatment, although rare, were more common after surgical abortion. The rates of postabortal infection and serious morbidity (such as thromboembolic events) did not differ between the two groups. There were no pregnancy-related deaths

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Table 2. Incidence of Adverse Events in the Cohort

	Medical Abortion (n=22,368)	Surgical Abortion (n=20,251)	*P**	Adjusted OR† (95% CI)
Hemorrhage	3,487 (15.6)	433 (2.1)	<.001	7.93 (7.15–8.81)
Hemorrhage with surgical (re)evacuation	645 (2.9)	173 (0.9)	<.001	
Infection	383 (1.7)	342 (1.7)	.85	1.15 (0.98–1.34)
Infection with surgical (re)evacuation	172 (0.8)	122 (0.6)	.02	
Incomplete abortion	1,495 (6.7)	323 (1.6)	<.001	5.37 (4.49–6.28)
Incomplete abortion with surgical (re)evacuation	1,320 (5.9)	77 (0.4)	<.001	
Injury	6 (0.03)	122 (0.60)	<.001	NA‡
Thromboembolic disease	18 (0.08)	17 (0.08)	.90	NA
Psychiatric morbidity	2 (0.009)	1 (0.005)	.62	NA
Death	2 (0.009)	4 (0.020)	.35	NA
Women with adverse events	4,479 (20.0)	1,127 (5.6)	<.001	4.23 (3.94–4.54)
Surgical (re)evacuation	1,320 (5.9)	363 (1.8)	<.001	3.58 (3.18–4.03)
Number of adverse events per woman				
0	17,889 (80.0)	19,124 (94.4)	<.001	
1	3,624 (16.2)	1,021 (5.0)		
2	796 (3.6)	97 (0.5)		
3	59 (0.26)	9 (0.04)		

OR, odds ratio; CI, confidence interval; NA, not applicable.
Data are n (%) unless otherwise specified.
* Chi-square test for comparison between medical and surgical cohort.
† Surgical cohort as a reference adjusted for age, parity, previous abortion, social status, marital status, type of residence, and duration of gestation.
† Not applicable owing to small number of patients in one or both groups.

in our data. Because medical abortion is being used increasingly in several countries, it is likely to result in an elevated incidence of overall morbidity related to termination of pregnancy.

The present study covers almost all of the induced abortions performed in Finland during the years 2000–2006 and thus is a unique data source regarding even uncommon adverse events. However, the validity of the data is a potential problem in register-based studies such as the present one. In the Registry of Induced Abortions, 95% of the information has been proven to be identical to that in medical records.[22] However, the reliability of diagnoses and interventions can vary, and underreporting or overreporting by physicians cannot be ruled out. In addition, the Hospital Registry, which was used as a data source, contains data concerning hospital care only. Thus, adverse events dealt with outside the public hospital system, especially those treated in primary health care, will have been missed. Moreover, a single patient may have various diagnoses and complications, such as incomplete abortion and bleeding, and thus may have been registered more than once. The participants, however, each had a unique personal identification number, and we were able to eliminate double counting in our study.

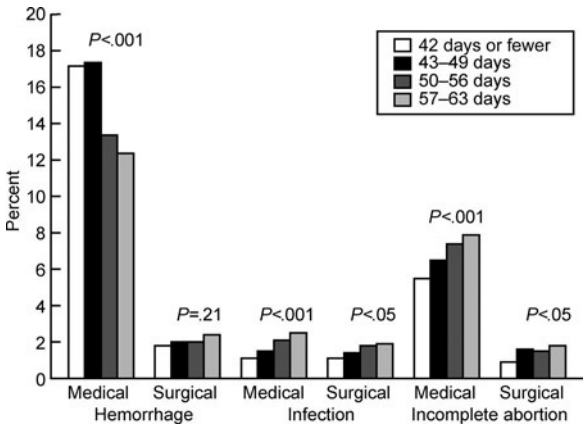


Fig. 1. Complications according to the duration of gestation in the medical and surgical cohorts (%).

Niinimäki. Complications After Medical and Surgical Abortion. Obstet Gynecol 2009.

It is important to note that the severity of the diagnoses found in the Hospital Registry may vary substantially. Thus, another problem in this kind of study is the definition of criteria for complications and adverse events. We evaluated all the ICD-10 diagnoses and codes for surgical procedures included in the Hospital Registry and classified them into seven categories.[19] In addition, women choosing surgical and medical abortion differed subtly in several respects and thus may be prone to different types of adverse events.

The rate of consultation related to a diagnosis of hemorrhage was high and eight times more common after medical termination of pregnancy. Because

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Table 3. Results of the Multivariable Analysis in Three Major Complications and Surgical (Re)Evacuation

	Hemorrhage		Infection	
	Medical	Surgical	Medical	Surgical
Age (y)	1.00 (0.96–1.04)			
Age category (y)				
Younger than 20	1	1	1	1
20–24	1.26 (1.00–1.58)	1.72 (1.25–2.37)	1.37 (1.03–1.83)	1.72 (1.13–2.62)
25–29	1.29 (0.88–1.91)	1.82 (1.30–2.54)	1.31 (0.95–1.80)	1.31 (0.77–2.23)
30–34	1.47 (0.83–2.58)	2.01 (1.45–2.79)	0.82 (0.56–1.19)	1.77 (1.02–3.08)
35–39	1.17 (0.56–2.46)	1.79 (1.28–2.52)	1.10 (0.77–1.58)	1.05 (0.54–2.01)
40 or older	1.01 (0.40–2.56)	0.50 (0.26–0.95)	0.95 (0.56–1.61)	1.54 (0.74–3.20)
Parity				
None	1			1
Yes	1.25 (1.08–1.45)			0.80 (0.56–1.14)
Previous abortion				
None	1			
Yes	1.07 (0.93–1.22)			
Social status				
Upper white-collar worker	1			1
Lower white-collar worker	1.14 (0.92–1.40)			3.21 (1.38–7.46)
Blue-collar worker	1.54 (1.23–1.93)			4.40 (1.87–10.36)
Student	1.50 (1.19–1.88)			3.47 (1.44–8.36)
Other	1.58 (1.20–2.08)			4.50 (1.80–11.27)
Marital status				
Married	1			
Cohabiting	1.12 (0.94–1.34)			
Single	1.05 (0.90–1.22)			
Residence				
Urban	1	1		1
Densely populated	1.43 (1.23–1.66)	0.98 (0.72–1.33)		0.85 (0.55–1.32)
Rural	1.25 (1.07–1.45)	0.71 (0.51–0.98)		0.54 (0.33–0.87)
Duration of gestation (d)				
42 or fewer	1		1	1
43–49	0.93 (0.82–1.05)		1.33 (0.98–1.80)	1.03 (.0.59–1.80)
50–56	0.74 (0.64–0.85)		1.91 (1.42–2.56)	1.15 (0.68–1.94)
57–63	0.63 (0.51–0.76)		2.26 (1.62–3.15)	1.15 (0.68–1.96)

Data are odds ratio (95% confidence interval).
Only those variables that showed a statistically significant association with a complication in univariable analysis (data not shown) were entered in multivariable analysis.

medical abortion is associated with uterine bleeding lasting approximately 2 weeks,[23] the high rate of consultation is not surprising. Uterine bleeding requiring surgical evacuation probably better reflects the severity of bleeding after termination of pregnancy. The incidence of such bleeding was relatively low, but it was more common in the medical-abortion group. In earlier studies, an average of 10% of women who underwent medical abortion complained of excessive bleeding.[24]

In line with uterine bleeding, the rate of incomplete abortion was higher in the cohort undergoing medical abortion. Surgical evacuation performed because of incomplete abortion occurred in approximately 6% of women having medical termination of pregnancy. The highest rates of complete medical abortion, reported from centers with extensive experience of the technique, are up to 98%.[11,25] However, it is reassuring to note that a high rate of complete abortion, approaching those reported from centers with extensive experience, was reached in the present national cohort.

One of our key findings was that the rates of infectious morbidity were similar after medical and surgical abortion. In a previous survey, the need for postabortal antibiotics for suspected endometritis was higher after surgical abortion.[26] Moreover, the use of medical abortion previously has been associated with rare cases of severe infectious morbidity and mortality.[27] Reassuringly, only two cases with serious infections (septicemia caused by *Staphylococcus aureus* and *Streptococcus*) occurred in the present cohort, one in

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Incomplete Abortion		Surgical (Re)Evacuation	
Medical	Surgical	Medical	Surgical
1.04 (0.99–1.10)		1.05 (0.99–1.11)	
1		1	
1.14 (0.80–1.62)		1.15 (0.79–1.67)	
1.05 (0.60–1.86)		1.03 (0.56–1.88)	
0.89 (0.40–2.00)		0.89 (0.38–2.09)	
0.66 (0.23–1.88)		0.66 (0.22–2.00)	
0.41 (0.11–1.52)		0.39 (0.10–1.57)	
1		1	
1.65 (1.33–2.03)		1.59 (1.27–1.98)	
1	1	1	
1.34 (1.11–1.60)	1.38 (1.08–1.76)	1.30 (1.08–1.58)	
1		1	
0.97 (0.75–1.24)		0.97 (0.74–1.28)	
0.83 (0.62–1.11)		0.88 (0.65–1.20)	
1.04 (0.77–1.40)		1.02 (0.74–1.40)	
0.74 (0.50–1.08)		0.84 (0.57–1.25)	
1	1	1	
1.07 (0.84–1.35)	1.46 (1.00–2.13)	1.10 (0.86–1.41)	
0.94 (0.76–1.15)	1.46 (1.09–1.97)	0.92 (0.74–1.14)	
1		1	1
1.40 (1.13–1.74)		1.43 (1.14–1.79)	0.75 (0.52–1.08)
1.38 (1.12–1.70)		1.48 (1.19–1.84)	0.68 (0.48–0.96)
1	1	1	1
0.96 (0.78–1.16)	1.64 (0.97–2.75)	1.01 (0.81–1.24)	1.63 (0.97–2.73)
1.34 (1.12–1.66)	1.59 (0.96–2.62)	1.41 (1.14–1.75)	1.92 (1.17–3.15)
1.55 (1.22–1.98)	1.91 (1.16–3.14)	1.77 (1.38–2.28)	2.23 (1.36–3.65)

the medical and one in the surgical group. However, as previously reported, cases of *Clostridium sordellii* septicemia occurred at a rate of 1 per 100,000[27]; even the present cohort is too small to assess the incidence of such a rare infection.

Injuries and surgical interventions for other reasons were relatively rare in both groups. Not surprisingly, the incidence of postabortal surgical intervention was lower among women undergoing medical abortion. Some other serious and rare complications were identified as well. These included thromboembolic and psychiatric complications as well as some deaths. The incidence of thromboembolic complications is in line with earlier reports of an increased risk during pregnancy.[28,29] In a previous register-based study, it was concluded that deaths from external causes of injury and poisoning (including unintentional and intentional injuries, suicides, and homicides) are significantly more common in women after induced abortion compared with nonpregnant women or women after birth.[30] In the present cohort also, five out of six cases of death were the result of external causes. In addition, psychiatric diagnoses, such as depression and psychoses, were identified, but the rates of these complications did not differ between the two cohorts. Similarly, in an earlier, partly randomized study, no differences between women with medically or surgically performed abortions emerged in regard to postabortal anxiety, depression, or self-esteem.[31] Naturally, the present kind of study setting (register-based study) gives only a crude idea of short-term psychiatric morbidity associated with termination of pregnancy.

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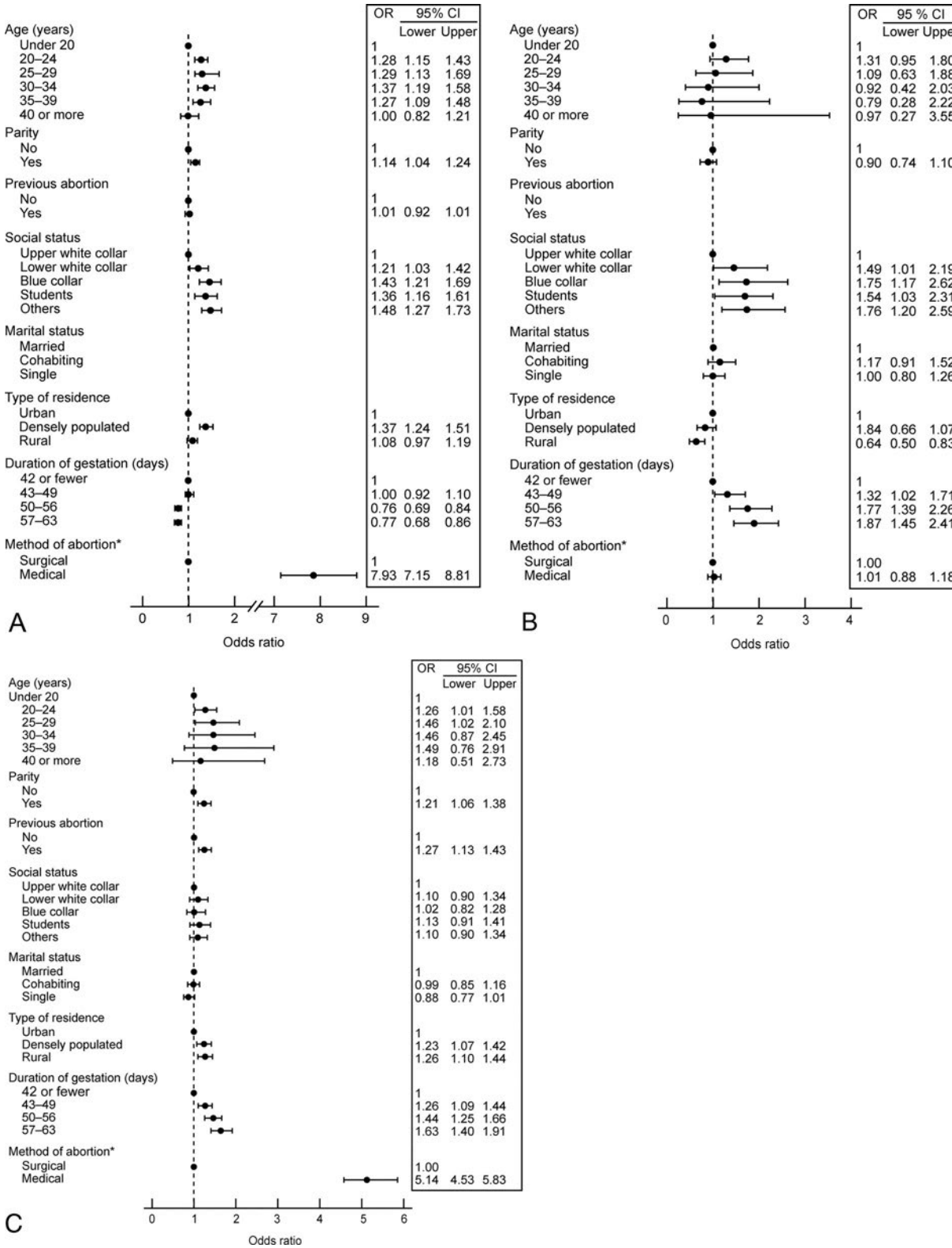


Fig. 2. Risk factors regarding three major complications (bleeding [**A**], infection [**B**], and incomplete abortion [**C**]) among the entire cohort (medical and surgical cohorts combined). OR, odds ratio; CI, confidence interval. *OR for infections is derived from univariable analysis.

Niinimäki. Complications After Medical and Surgical Abortion. Obstet Gynecol 2009.

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The most important risk factor with regard to the two most common adverse events (hemorrhage and incomplete abortion) was the method of abortion. Other risk factors were, for the most part, in line with those reported previously–advanced gestational age, parity, and previous induced abortions.[11,32–34] For unknown reasons, the risk of hemorrhage after medical abortion diminished with advancing duration of gestation. Tolerance of bleeding–a natural part of medical abortion–varies from one woman and physician to another and also depends on preabortion counseling. Other explanations, such as possible bias in reporting the events in the registry, are possible but cannot be verified in the present study. We included all cases requiring consultation in specialized health care because they are registered uniformly in Finland. In addition, every such visit adds to the costs of the health care system. More detailed analysis of all health care costs related to termination of pregnancy and its complications, according to the method, is needed.

In conclusion, termination of pregnancy by means of either medical or surgical methods is associated with a low level of serious complications. On the basis of the present data, however, it appears that medical abortion results in an increased incidence of adverse events.

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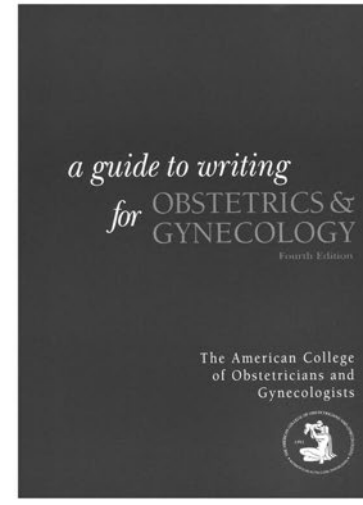
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EXHIBIT 50

Pet. and App. for Temporary and Permanent Injunctive Relief, *Texas v. Carpenter*, No. 471-08943-2024 (Tex. Collin Cnty. Dec. 12, 2024)

Filed: 12/12/2024 9:18 AM
Michael Gould
District Clerk
Collin County, Texas
By Sara Jones Deputy
Envelope ID: 95232968

CAUSE NO. 471-08943-2024

STATE OF TEXAS, ***Plaintiff*,**	§	**IN THE DISTRICT COURT OF**
v.	§	**COLLIN COUNTY, TEXAS**
MARGARET DALEY CARPENTER, M.D. a/k/a MAGGIE CARPENTER, M.D., ***Defendant.***	§	**___ JUDICIAL DISTRICT**

PETITION AND APPLICATION FOR TEMPORARY AND PERMANENT INJUNCTIVE RELIEF

Dr. Margaret Daley Carpenter (Carpenter) of New York violates Texas law by providing abortion-inducing drugs to Texans through telehealth. Carpenter is not a licensed Texas physician, nor is she authorized to practice telemedicine in the State of Texas. The Court should enjoin Carpenter from continuing to operate outside the bounds of the law and impose civil penalties for her violation of Texas law.

DISCOVERY CONTROL PLAN

1. Discovery is intended to be conducted under Level 2 of Texas Rules of Civil Procedure 190.3.

2. The State of Texas seeks injunctive relief. Therefore, this suit is not governed by the expedited actions process in Texas Rules of Civil Procedure 169.

JURISDICTION AND VENUE

3. Plaintiff seeks monetary relief of $250,000 or less and non-monetary relief. The relief sought is within the jurisdiction of this court. Tex. Const. art. V, § 8; Tex. Gov't Code §§ 24.007, 24.008; and Tex. Civ. Prac. & Rem. Code § 65.021(a). As the nonresident defendant contracted by mail or otherwise with a resident of Collin County, Texas, with performance in whole or in part in Texas, this court has personal jurisdiction over the nonresident defendant. Tex. Civ. Prac. & Rem. Code § 17.042.

4. Venue is proper in Collin County, Texas under Texas Civil Practice & Remedies Code § 15.002(a)(1) because a substantial part of the events or omissions giving rise to this claim occurred in Collin County, Texas.

PARTIES

5. Plaintiff is the State of Texas.

6. Defendant Margaret Daley Carpenter, M.D. a/k/a Maggie Carpenter, M.D. a/k/a M. Carpenter, M.D. ("Carpenter") is a physician licensed by the State of New York (license no. 236802). She is not licensed as a physician in the State of Texas. As Carpenter is a nonresident, the Texas Secretary of State is her agent for service of process. Tex. Civ. Prac. & Rem. Code § 17.044(b). Service of process or citation may be mailed by registered or certified mail in accordance with Tex. Civ. Prac. & Rem. Code § 17.045(a),(d) and Tex. R. Civ. P. 106, 108 to the Defendant at her residence 1156 Old Ford Rd., New Paltz, New York 12561-2654 or her business address 2578 Broadway, #580, New York, New York 10025-5642.

LEGAL BACKGROUND

7. The Texas Occupations Code defines "practicing medicine" as "the diagnosis, treatment, or offer to treat a mental or physical disease or disorder or a physical deformity or injury by any system or method, or the attempt to effect cures of those conditions, by a person who publicly professes to be a physician or directly or indirectly charges money or other compensation for those services." Tex. Occ. Code § 151.002(a)(13)(A). A person who is physically located in another jurisdiction but who, through the use of any medium, including an electronic medium, performs an act that is part of a patient care service initiated in this state, including the taking of an x-ray examination or the preparation of pathological material for examination, and that would affect the diagnosis or treatment of the patient, is considered to be engaged in the practice of medicine in this state. Tex. Occ. Code § 151.056(a).

8. Texas law prohibits a person from practicing medicine in this state unless the person holds a license and complies with registration requirements. Tex. Occ. Code §155.001; Tex. Occ. Code § 165.159. *See also* Tex. Admin. Code §§ 174.8, 174.12(d).

9. An "abortion" is defined as "the act of using or prescribing an instrument, drug, a medicine, or any other substance, device, or means with the intent to cause the death of an unborn child of a woman known to be pregnant." Tex. Health & Safety Code § 245.002(1).

10. An abortion in the State of Texas may only be performed by a physician licensed to practice medicine in the State of Texas. Tex. Health & Safety Code § 171.003. A physician performing or inducing an abortion, on the date the abortion is performed or induced must have active admitting privileges at a hospital that is located not further than 30 miles from the location at which the abortion is performed or induced. Tex. Health & Safety Code § 171.0031(a).

11. No physician shall treat or prescribe residents of the State of Texas with telehealth services, via communications technology, unless the individual possesses a full Texas medical license. 22 Tex. Admin. Code § 174.8. In addition, the validity of a prescription issued as a result of telemedicine medical service is determined by the same standards that would apply to the issuance of a prescription in an in-person setting. 22 Tex. Admin. Code § 174.5(a),(c). *See also* Tex. Occ. Code § 111.001(3),(4).

12. A physician or supplier may not provide to a patient any abortion-inducing drug by courier, delivery, or mail service. Tex. Health & Safety Code § 171.063(b-1).

13. Before a physician provides an abortion-inducing drug, the physician must examine the pregnant woman in person and such physician must ensure that the physician does not provide an abortion inducing drug for a pregnant woman whose pregnancy is more than 49 days of gestational age. Tex. Health & Safety Code § 171.063(c)(1),(6). A physician providing an abortion-inducing drug is required to schedule a follow-up visit to confirm that a woman's pregnancy is completely terminated and to assess any continued blood loss. Tex. Health & Safety Code § 171.063(e).

14. The Texas Health and Safety Code generally prohibits a person from knowingly performing, inducing, or attempting an abortion. Tex. Health & Safety Code § 170A.002(a).

15. The attorney general is authorized to collect a civil penalty of not less than $100,000 for each violation of Tex. Health & Safety Code § 170A.002 and may also recover costs and attorney's fees. Tex. Health & Safety Code § 170A.005. In addition, the attorney general may seek other civil remedies. Tex. Health & Safety Code § 170A.006.

FACTUAL BACKGROUND

16. Carpenter holds a medical license in the State of New York.

17. Carpenter is not licensed to practice medicine in Texas. *See* https://profile.tmb.state.tx.us/SearchResults.aspx?8c92ec07-d491-40c0-840f-d289c57fcd58. Carpenter has no hospital admitting privileges in the State of Texas.

18. Carpenter knowingly treats patients in Texas even though she is not a licensed Texas physician.

19. Carpenter is the Co-Medical Director and Founder of the Abortion Coalition for Telemedicine ("ACT"), a nationwide advocacy organization proactively working to advance telemedicine abortion. ACT references the "two-step process of mifepristone and misprostol" as a method for terminating pregnancies up to 12 weeks.

20. Carpenter's ACT biography states "[s]he has provided medical and surgical abortions since 1999. She started working with Aid Access in 2020 and helped launch Hey Jane in December 2020 and continues to work with both organizations." *See* https://www.theactgroup.org/our-team. Aid Access works to provide abortion pills to people in all 50 states. *See* https://aidaccess.org/en/page/561/who-are-we. Hey Jane advertises "no clinic visit needed" and that Hey Jane is a safe space for reproductive and sexual care like abortion pills, "from the comfort and convenience of your phone." *See* https://www.heyjane.com/. The Privacy Policy of heyjane.com states the site collects and uses personal information by or on behalf of Possible Health Medical, P.C., and Jane Medical, PLLC. *See* https://www.heyjane.com/legal/privacy-policy.

21. Carpenter is the CEO of Possible Health Medical, P.C., a New York professional service corporation with her address as 1156 Old Ford Rd., New Paltz, New York 12561 and her principal executive office address as 2578 Broadway, #580, New

York, New York 10025. Carpenter is also an officer / manager of Jane Medical, PLLC, incorporated in the State of Illinois and lists her office address as 2578 Broadway, #580, New York, New York 10025.

22. About mid-May 2024, a 20-year-old female resident of Collin County, Texas became pregnant. The mother of the unborn child did not communicate her pregnancy to the biological father of the unborn child. The mother did not have any life-threatening physical condition aggravated by, caused by, or arising from the pregnancy that placed her at risk of death or any serious risk of substantial impairment. The mother proceeded to utilize telemedicine or telehealth services and received, through Carpenter, two abortion-inducing drugs or prescriptions. The first was a box for the drug mifepristone, 200 mg, followed by the "#1" and the directions to take 1 tablet by mouth and to "take this medication first." The second was a pill bottle of misoprostol 200 mcg with directions to take 4 tablets (i.e., 800 mcg.) after the mifepristone.

23. "Mifepristone is a drug that blocks a hormone called progesterone that is needed for a pregnancy to continue. Mifepristone, when used together with another medicine called misoprostol, is used to end a pregnancy through ten weeks gestation (70 days or less since the first day of the last menstrual period). The approved mifepristone dosing regimen is: on day one, 200 mg of mifepristone taken by mouth; then 24 to 48 hours after taking mifepristone, 800 mcg of misoprostol taken buccally (in the cheek pouch), at a location appropriate for the patient; and about seven to fourteen days after taking mifepristone: follow-up with the health care provider."[1]

24. On July 16, 2024, the mother asked the biological father of her unborn child to be taken to the hospital because of hemorrhage or severe bleeding. After the mother was seen by health care professionals at a hospital in Collin County, Texas, the biological father

[1] *Questions and answers on Mifepristone for medical termination of pregnancy through ten weeks gestation,* US Food & Drug Admin., https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation#:~:text=Mifepristone%20is%20a%20drug%20that,of%20the%20last%20menstrual%20period) (last visited October 30, 2024).

of the unborn child was told that the mother of the unborn child was experiencing a hemorrhage or severe bleeding as she "had been" nine weeks pregnant before losing the child. The biological father of the unborn child, upon learning this information, concluded that the biological mother of the unborn child had intentionally withheld information from him regarding her pregnancy, and he further suspected that the biological mother had in fact done something to contribute to the miscarriage or abortion of the unborn child. The biological father, upon returning to the residence in Collin County, discovered the two above-referenced medications from Carpenter.

25. Carpenter provided abortion-inducing drugs to the pregnant Collin County woman, which caused an adverse event or abortion complication and resulted in a medical abortion. *See* Tex. Health & Safety Code § 171.061 (providing statutory definitions).

26. Carpenter's conduct violates the Texas Health and Safety Code's prohibition on prescribing abortion-inducing drugs via telemedicine.

27. Carpenter's knowing and continuing violations of Texas law places women and unborn children in Texas at risk.

28. Carpenter sees Texas patients via telehealth and prescribes them abortion-inducing medication.

REQUESTS FOR RELIEF

A. Request for Temporary and Permanent Injunctive Relief

29. Pursuant to Texas Health & Safety Code Section 170A.006, Texas Civil Practice and Remedies Code Section 65.011 and Texas Rule of Civil Procedure 680 *et seq.*, to preserve the status quo pending a full trial on the merits, *see, Butnaru v. Ford Motor Co*., 84 S.W.3d 198, 204 (Tex. 2002), the State of Texas requests a temporary injunction against Carpenter that enjoins her from illegally prescribing abortion-inducing drugs to Texas residents and illegally practicing medicine in the State of Texas.

30. To obtain a temporary injunction, the applicant must plead and prove three specific elements: (1) a cause of action against the defendant; (2) a probable right to the relief sought; and (3) a probable, imminent, and irreparable injury in the interim. *Butnaru*,

84 S.W.3d at 204.

31. The State of Texas has a valid cause of action and probable right to relief because, for the reasons stated herein, Carpenter is violating our Texas statutes. *See, e.g.,* Tex. Health & Safety Code § 170A.002(a).

32. It is well-established that the State suffers an irreparable injury when it is precluded from enforcing its own laws. *See, e.g., Abbott v. Perez*, 585 U.S. 579, 602 n. 17, 138 S.Ct. 2305, 2324 n. 17, 201 L.Ed2d 714, 734 n. 17 (2018) (*citing Maryland v. King*, 567 U.S. 1301, 133 S.Ct. 1, 3, 183 L.Ed.2d 667, 670 (2012) (Roberts, C.J., in chambers)) ("[T]he inability to enforce its duly enacted plans clearly inflicts irreparable harm on the State.").

33. Unless Carpenter is restrained by this Court, with relief that is enforceable by a contempt order, Carpenter will continue to defiantly violate Texas Law. Carpenter's continued violation of our Texas statutes as stated herein is probable and imminent. The State is not required to establish that it will prevail at trial to obtain a temporary injunction as it only needs to plead a cause of action and show a probable right to the relief sought. *Butnaru*, 84 S.W.3d at 211.

34. Furthermore, there is no adequate remedy at law. For a legal remedy to be adequate, it must give the plaintiff complete, final, and equal relief. *Huynh v. Blanchard*, 694 S.W.3d 648, 685 (Tex. 2024) (quoting *Henderson v. KRTS, Inc.*, 822 S.W.2d 769, 773 (Tex. App.—Houston [1st Dist.] 1992, no writ)). If an otherwise complete and adequate remedy at law will lead to a multiplicity of suits, that very fact prevents it from being complete and adequate. *Id.* While the Legislature has provided civil penalties in Tex. Health & Safety Code § 170A.005, Carpenter's knowing, and continued violations of Texas law demonstrate that the civil penalties do not provide complete and adequate final relief. Thus, the multiplicity of suits necessary to address each instance of Carpenter's greater scheme to flout Texas law means that the State does not have an adequate remedy at law and is thus entitled to injunctive relief.

35. The State of Texas is not required to post a bond prior to issuance of injunctive relief. Tex. Civ. Prac. & Rem. Code § 6.001(a),(b)(1).

36. In addition to the temporary relief requested, the State of Texas also requests that this Court set the matter for trial and, upon final hearing, that this Court enter a permanent injunction against Carpenter on the grounds asserted herein.

B. Request for Civil Penalties

37. Carpenter is not licensed to practice medicine in Texas. By seeing patients via telehealth appointments, she is practicing medicine in Texas in violation of state law. 22 Tex. Admin. Code § 174.8.

38. Under Texas Health & Safety Code § 170A.002 it is illegal to prescribe abortion-inducing drugs without meeting specific conditions outlined in the code. "A person who violates Section 170A.002 is subject to a civil penalty of not less than $100,000 for each violation."

C. Request for Attorney's Fees and Other Costs

39. Pursuant to Texas Health and Safety Code § 170A.005, the State of Texas, by and through the Attorney General, may recover attorney's fees and costs incurred in bringing this action.

40. Additionally, in cases where the state is entitled to recover a penalty or damages, the attorney general is entitled, in addition to any other remedy available by law and on behalf of the state, to reasonable attorney's fees, court costs and filing fees. Tex. Gov't Code § 402.006(c),(e)

41. The State of Texas requests that, upon final trial, the Court order Carpenter to reimburse the State of Texas, by and through the Attorney General for all costs of investigation and litigation including attorney's fees, reasonable investigative expenses, court costs, witness fees, deposition expenses, and civil administrative costs.

PRAYER

The State of Texas respectfully requests the following relief:

a. A temporary and permanent injunction enjoining Margaret Daley Carpenter, M.D. a/k/a Maggie Carpenter, M.D. a/k/a M. Carpenter, from

further violating Texas Health & Safety Code § 170A.002 and Texas Occupations Code § 165.159.

b. Civil penalties payable by Margaret Daley Carpenter, M.D. in the amount of not less than $100,000 for any and every violation under Section 170A.005 of the Texas Health and Safety Code.

c. Award the State of Texas all litigation and investigative costs, including, court costs, witness fees, deposition expenses, civil administrative costs, and reasonable attorney's fees in prosecuting this case through trial and, if necessary, through appeal, and that upon final trial, enter judgment against Carpenter.

d. All other relief as the Court deems equitable and just.

Date: November 19, 2024

Respectfully submitted,

KEN PAXTON
Attorney General of Texas

BRENT WEBSTER
First Assistant Attorney General

RALPH MOLINA
Deputy First Assistant Attorney General

JAMES LLOYD
Deputy Attorney General for Civil Litigation

ERNEST C. GARCIA
Chief, Administrative Law Division

/s/ *Ernest C. Garcia*
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Attorneys for Plaintiff

Declaration

My name is Alexandre Louis Dubeau, and I am an employee / investigator of the following governmental agency: Office of the Texas Attorney General, Administrative Law Division, located at 300 W. 15th Street, Austin, Texas 78701. I am executing this declaration as part of my assigned duties and responsibilities. I declare under penalty of perjury that the foregoing factual statements in the *Petition and Application for Temporary and Permanent Injunctive Relief*, are true and correct.

Executed in Travis County, Texas, on the 15th day of October, 2024.

Alexandre Louis Dubeau

Automated Certificate of eService

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Catherine Hughes on behalf of Ernest Garcia
Bar No. 7632400
catherine.hughes@oag.texas.gov
Envelope ID: 95232968
Filing Code Description: Plaintiff's Original Petition (OCA)
Filing Description: Petition and Application for Temporary and Permanent Injunctive Relief
Status as of 12/12/2024 10:33 AM CST

Case Contacts

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EXHIBIT 51

Final Judgment and Order Granting Permanent Injunction, *Texas v. Carpenter*, No. 471-08943-2024 (Tex. Collin Cnty. Feb. 13, 2025)

CAUSE NO. 471-08943-2024

STATE OF TEXAS, *Plaintiff*	§	**IN THE DISTRICT COURT OF**
v.	§	**COLLIN COUNTY, TEXAS**
MARGARET DALEY CARPENTER, M.D. a/k/a MAGGIE CARPENTER, M.D., *Defendant.*	§	**471st JUDICIAL DISTRICT**

FINAL JUDGMENT AND ORDER GRANTING PERMANENT INJUNCTION

On the 12th day of February 2025, the court considered the State of Texas' ("State"), verified Second Amended Petition and Application for Permanent Injunctive Relief, Motion for Default Judgment, factual allegations, evidence, and arguments of counsel. The court finds that although the defendant was properly served; the defendant has not filed any answer or responsive pleading; has therefore defaulted and the factual allegations in the Plaintiff's Second Amended Petition are deemed admitted. The court also finds that the State continued to notify defendant by correspondence of the settings in this case and defendant still failed to appear. The court finds that the record reflects that Margaret Daley Carpenter, M.D.: (a) is not a resident of the State of Texas, but is a resident of the State of New York that has done business in Texas; (b) has not and does not maintain a regular place of business in the State of Texas; (c) has not maintained or designated an agent for service of process in the State of Texas; and (d) has been properly served with process, citation and petition, by certified mail, return receipt requested. The court finds that it has subject matter and in personam jurisdiction. The court also finds that the defendant has violated the Texas Medical Practice Act, Tex. Occ. Code, Title 3 Health Professions, Subtitle B Physicians and 22 Tex. Admin. Code § 174.8 by practicing medicine without a license and registration in the State of Texas and that the defendant has also violated Tex. Health & Safety Code § 170A.002 and that an unborn child died as a result of these violations and concludes that the State of Texas should have a judgment and a permanent injunction.

It is therefore, ordered that the State's request for civil penalties, fees, costs, attorney fees and a permanent injunction are hereby and in all things granted.

It is further ordered that plaintiff have and recover a $100,000 civil penalty in accordance with Tex. Health & Safety Code § 170A.005, an award of $12,400 in reasonable attorney fees, and $819.59 in filing fees and costs from and against defendant Margaret Daley Carpenter, M.D. a/k/a Maggie Carpenter, M.D.

It is further ordered that the total amount of the judgment here rendered will bear post judgment interest at the rate of 7.50 percent from today's date until paid, in accordance with Tex. Fin. Code Ann. § 304.003(b),(c).

It is further ordered, that, Margaret Daley Carpenter, M.D. a/k/a Maggie Carpenter, M.D., Defendant, is hereby permanently enjoined from prescribing abortion-inducing drugs to Texas residents and shall not practice medicine in the State of Texas without a license and registration in the State of Texas.

It is further ordered that, Margaret Daley Carpenter, M.D. a/k/a Maggie Carpenter, M.D. is hereby expressly also permanently enjoined from any further violation of Texas Health & Safety Code §§ 170A.002 171.003, 171.0031, 171.063, Texas Occ. Code, Title 3 Health Professions, Subtitle B Physicians, §§ 155.001, 156.001 and 22 Tex. Admin. Code § 174.8.

It is further ordered that the Clerk of the Court shall file this Order and enter it of record and issue a permanent injunction in conformity with the law and terms of this order.

SIGNED on this 13th day of February, 2025.

BRYAN GANTT
JUDGE PRESIDING

EXHIBIT 52

Bill of Indictment, *Louisiana v. Carpenter et al.*, No. 250187 (La. 18th Jud. Dist. Jan. 31, 2025)

Clerk of Court Demographic Information Report for

Judicial District:	18th
DA Name:	Tony Clayton
Judge:	
Parish:	West Baton Rouge
Defendant Name:	Dr. Margaret D Carpenter, and Nightingale Medical, PC
DOB:	12/17/1969
Race:	
Sex:	
Date of Arrest:	
Arr. Agency:	Attorney Generals Office
SID:	
US Citizen:	
Drivers License #:	
Drivers License State:	
City:	New Paltz
State:	NY
Deputy Clerk:	Sharon Saul
Minute Clerk:	Kelli Arnold
Charge:	14:87.9.B(1)
Plea:	
Date Filed:	JAN 31 2025
Date Arraigned:	

THE EIGHTEENTH JUDICIAL DISTRICT COURT
FOR THE PARISH OF WEST BATON ROUGE

STATE OF LOUISIANA

STATE OF LOUISIANA

VERSUS

DR. MARGARET D. CARPENTER AND
NIGHTINGALE MEDICAL, PC
1156 Old Ford Rd
New Paltz, NY 12561
DOB: 12/13/1969

FILED: January 31, 2025
Sharon Paul
Deputy Clerk of Court

NO. 250187

A TRUE BILL
Foreman
Date: 1-31-2025

BILL OF INDICTMENT

The GRAND JURY OF THE STATE OF LOUISIANA, *duly impaneled sworn and charge in and for the body of the Parish of West Baton Rouge, in the name and by authority of said State, upon their oath, PRESENT: that one DR. MARGARET D. CARPENTER AND NIGHTINGALE MEDICAL, PC, late of the State of New York, County of Ulster, with force and arms, in the Parish of West Baton Rouge, State of Louisiana, aforesaid, and within the jurisdiction of the Eighteenth Judicial District Court in and for the Parish of West Baton Rouge charges that* :

LA R.S. 14:87.9 (A) AND (B)(1) CRIMINAL ABORTION BY MEANS OF ABORTION-INDUCING DRUGS, Dr. Margaret D Carpenter, and Nightingale Medical, PC, on or about April 5, 2024, did knowingly cause an abortion to occur by means of delivering, dispensing, distributing, or providing a pregnant women with an abortion-inducing drug.

Contrary to the law of the State of Louisiana and against the peace and dignity of the same.

TONY CLAYTON
DISTRICT ATTORNEY

BY: Tony Clayton #21191
Assistant District Attorney
Eighteenth Judicial District
State of Louisiana

EXHIBIT 53

Letter from Governor Jeff Landry to the Governor Kathy Hochul (Feb. 11, 2025)

State of Louisiana

EXECUTIVE DEPARTMENT

JEFF LANDRY, GOVERNOR OF THE STATE OF LOUISIANA,
TO: HIS EXCELLENCY THE GOVERNOR OF THE STATE OF NEW YORK

WHEREAS, it appears by the annexed application for requisition and copies of **APPLICATION FOR REQUISITION, PROSECUTOR'S AFFIDAVIT WITH PROBABLE CAUSE ORDER, CROSS CERTIFICATION, INDICTMENT, ARREST WARRANT AND AFFIDAVIT, IDENTIFICATION MATERIALS, AND RELEVANT STATUTE,** which I certify are authentic and duly authenticated in accordance with the laws of the State of Louisiana, that under the laws of this State, **MARGARET D. CARPENTER** stands **CHARGED** with the crime(s) of **CRIMINAL ABORTION BY MEANS OF ABORTION-INDUCING DRUGS,** and it has been represented, and is satisfactorily shown to me, that the accused was present in this State at the time of the commission of said crime, and fled from the justice of this State, and has taken refuge, and can presently be found at [redacted] and

NOW, THEREFORE, pursuant to the provisions of the Constitution and the laws of the United States and the laws of the State of Louisiana and the laws of the State of New York, I do hereby respectfully demand that the above-named fugitive from justice be arrested and secured and delivered to, **WEST BATON ROUGE SHERIFF JEFF BERGERON, AND ONE/OR THEIR DULY AUTHORIZED FEMALE AGENT(S) OF THE PARISH OF WEST BATON ROUGE, STATE OF LOUISIANA,** as the proper person(s) appointed as agent(s) of the State of Louisiana, who is hereby authorized to receive, convey, and transport said fugitive to this State, here to be dealt with according to law.

IN WITNESS WHEREOF, I have set my hand officially and caused to be affixed the Great Seal of Louisiana in the City of Baton Rouge on this 11th day of February 2025.

Jeff Landry, Governor

By the Governor:

Nancy Landry, Secretary of State

State of Louisiana

EXECUTIVE DEPARTMENT

AGENT'S COMMISSION

TO ALL TO WHOM THESE PRESENTS SHALL COME:

I, **JEFF LANDRY, GOVERNOR**, hereby appoint **WEST BATON ROUGE SHERIFF JEFF BERGERON, AND ONE/OR THEIR DULY AUTHORIZED FEMALE AGENT(S) OF THE PARISH OF WEST BATON ROUGE, STATE OF LOUISIANA**, as the agent(s) of the State of Louisiana to receive **MARGARET D. CARPENTER,** fugitive from justice, from the appropriate authorities of the State of **NEW YORK** and convey said fugitive to **WEST BATON ROUGE SHERIFF JEFF BERGERON, AND ONE/OR THEIR DULY AUTHORIZED FEMALE AGENT(S) OF THE PARISH OF WEST BATON ROUGE, STATE OF LOUISIANA**, there to be dealt with according to law. The fugitive stands **CHARGED** with the crime(s) of **CRIMINAL ABORTION BY MEANS OF ABORTION-INDUCING DRUGS.**

IN WITNESS WHEREOF, I have hereunto signed my name and caused to be affixed the Great Seal of State, at Baton Rouge, Louisiana, this 11th of February 2025.

Jeff Landry, Governor

By the Governor:

Nancy Landry, Secretary of State

EXHIBIT 54

Order, *Comprehensive Health of Planned Parenthood Great Plains et al. v. Missouri*, No. 2416-CV31931 (Mo. Cir. Ct. Jackson Cnty. July 3, 2025)

FILED
DIVISION 3
03-Jul-2025 16:23
CIRCUIT COURT OF JACKSON COUNTY, MO
BY

IN THE CIRCUIT COURT OF JACKSON COUNTY, MISSOURI
AT KANSAS CITY

COMPREHENSIVE HEALTH OF PLANNED PARENTHOOD GREAT PLAINS, et al.,	)	
Plaintiffs,	)	
v.	)	**Case No. 2416-CV31931**
	)	**Division 3**
STATE OF MISSOURI, et al.,	)	
Defendants.	)	

ORDER

NOW on this day, the Court takes up the injunctive relief requested in Plaintiffs' Motion for Preliminary Injunction, or, in the Alternative, Temporary Restraining Order, filed on November 6, 2024 and Plaintiffs' Motion for Reconsideration, filed on December 30, 2024. The Court held hearings on these motions and previously entered two Orders granting preliminary injunctive relief. On May 27, 2025, the Missouri Supreme Court issued a peremptory writ directing this Court to vacate its Orders granting preliminary injunctive relief with respect to the enjoinment of the state statutes and regulations identified therein and to reevaluate Plaintiffs' requests for preliminary injunctive relief. The Court, after reviewing the Court's file, in particular, Plaintiffs' Motions for Injunctive Relief and accompanying Suggestions in Support as well as Defendants' Opposition thereto, affidavits,[1] stipulated facts, and oral argument of counsel, and being apprised on the relevant law and having the full record before it, now finds as follows:

[1] Plaintiffs and State Defendants agreed to the submission of affidavits for the purposes of the pre-trial hearings only.

AMENDMENT 3

On November 5, 2024, Missouri voters approved Amendment 3 by majority vote. Election results were certified on December 5, 2024. Amendment 3 is now Article I, Section 36 of the Missouri Constitution. It states as follows:

> Section 36.1. This Section shall be known as "The Right to Reproductive Freedom Initiative."
>
> 2. The Government shall not deny or infringe upon a person's fundamental right to reproductive freedom, which is the right to make and carry out decisions about all matters relating to reproductive health care, including but not limited to prenatal care, childbirth, postpartum care, birth control, abortion care, miscarriage care, and respectful birthing conditions.
>
> 3. The right to reproductive freedom shall not be **denied, interfered with, delayed, or otherwise restricted** unless the Government demonstrates that such action is justified by a **compelling governmental interest** achieved by the **least restrictive means**. **Any denial, interference, delay, or restriction of the right to reproductive freedom shall be presumed invalid.** For purposes of this Section, a **governmental interest is compelling only if it is for the limited purpose and has the limited effect of improving or maintaining the health of a person seeking care, is consistent with widely accepted clinical standards of practice and evidence-based medicine, and does not infringe on that person's autonomous decision-making**.
>
> 4. Notwithstanding subsection 3 of this Section, the general assembly may enact laws that regulate the provision of abortion after Fetal Viability provided that under no circumstance shall the Government deny, interfere with, delay, or otherwise restrict an abortion that in the good faith judgment of a treating health care professional is needed to protect the life or physical or mental health of the pregnant person.
>
> 5. No person shall be penalized, prosecuted, or otherwise subjected to adverse action based on their actual, potential, perceived, or alleged pregnancy outcomes, including but not limited to miscarriage, stillbirth, or abortion. Nor shall any person assisting a person in exercising their right to reproductive freedom with that person's consent be penalized, prosecuted, or otherwise subjected to adverse action for doing so.

> 6. The Government shall not discriminate against persons providing or obtaining reproductive health care or assisting another person in doing so.
>
> 7. If any provision of this Section or the application thereof to anyone or to any circumstance is held invalid, the remainder of those provisions and the application of such provisions to others or other circumstances shall not be affected thereby.
>
> 8. For purposes of this Section, the following terms mean:
>
> (1) "Fetal Viability", the point in pregnancy when, in the good faith judgment of a treating health care professional and based on the particular facts of the case, there is a significant likelihood of the fetus's sustained survival outside the uterus without the application of extraordinary medical measures.
>
> (2)"Government",
>
> a. the state of Missouri; or
>
> b. any municipality, city, town, village, township, district, authority, public subdivision or public corporation having the power to tax or regulate, or any portion of two or more such entities within the state of Missouri.

(emphasis added).

STANDARD FOR PRELIMINARY INJUNCTION

Missouri Supreme Court Rule 92.02 and Chapter 526 of the Missouri Revised Statutes govern injunctive relief where "immediate and irreparable injury, loss, or damage will result in the absence of relief." Mo. Sup. Ct. R. 92.02(1). In *Dataphase*, the United States Court of Appeals for the Eighth Circuit set out to "clarify the standard to be applied . . . in considering requests for preliminary injunctive relief" and held that "whether a preliminary injunction should issue involves consideration of (1) the threat of irreparable harm to the movant; (2) the state of the balance between this harm and the injury that granting the injunction will inflict on other parties litigant; (3) the probability that movant will succeed on the merits; and (4) the public interest." *Dataphase Sys. v. C L Sys.,* 640 F.2d 109, 112-14 (8th Cir. 1981).

The Eighth Circuit provided additional clarity regarding the third prong of this test in *Rounds,* holding "a party seeking a preliminary injunction of the implementation of a state statute must demonstrate more than just a 'fair chance' that it will succeed on the merits," characterizing "this more rigorous standard . . . as requiring a showing that the movant 'is likely to prevail on the merits.'" *Planned Parenthood Minn., N.D., S.D. v. Rounds*, 530 F.3d 724, 731-32 (8th Cir. 2008). The Court further states, "[i]f the party with the burden of proof makes a threshold showing that it is likely to prevail on the merits, the [court] should then proceed to weigh the other *Dataphase* factors." *Id*. at 732.

Thus, this Court will address Plaintiffs' claims for injunctive relief by evaluating (1) the threat of irreparable harm to the moving party; (2) balancing this harm with any injury an injunction would inflict on other interested parties; (3) the moving party is likely to prevail on the merits; and (4) the effect on the public interest.

I. The Threat of Irreparable Harm

"The United States Supreme Court has held being subject to an unconstitutional statute, 'for even minimal periods of time, unquestionably constitutes irreparable injury.'" *Rebman v. Parson*, 576 S.W.3d 605, 612 (Mo. banc 2019) (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976)). An injunction may issue "to prevent the doing of any legal wrong whatever, whenever in the opinion of the court an adequate remedy cannot be afforded by an action for damages." § 526.030 RSMo.[2] Injunctive relief is unavailable unless irreparable harm is otherwise likely to result, *see City of Grandview v. Moore*, 481 S.W.2d 555, 558 (Mo. App. 1972), and plaintiff has no adequate remedy at law. *See State ex rel. Taylor v. Anderson*, 242 S.W.2d 66, 72 (Mo. 1951). Irreparable harm can also be established if monetary remedies cannot provide adequate compensation for

[2] Unless otherwise indicated, statutory citations refer to the 2016 edition of the Revised Statutes of Missouri, updated through the 2023 Cumulative Supplement.

improper conduct. *Peabody Holding Co., Inc. v. Costain Grp. PLC*, 813 F. Supp. 1402, 1421 (E.D. Mo. 1993). Movant need not show that damages have accrued, only that there is a threat of irreparable harm absent injunctive relief. *Id*.

The threat of irreparable harm is especially apparent in the context of abortion care, because it is a decision and procedure that "simply cannot be postponed, or it will be made by default with far-reaching consequences." *Bellotti v. Baird,* 443 U.S. 622, 643 (1979). Where the statutes at issue unquestionably conflict with the newly established rights afforded by Amendment 3, because they "den[y], interfer[e] with, dela[y], or otherwise restric[t]" the right to reproductive freedom, or because they discriminate against persons providing or obtaining reproductive health care or assisting another person in doing so, irreparable injury has been established. Mo. Cont. Art. I, §36.3; §36.6

II. Balance of Harm Versus Injury to Other Interested Parties

In order to obtain injunctive relief, movants need only show that the balance of equities tips in their favor. *Peabody Holding Co., Inc. v. Costain Grp. PLC*, 813 F. Supp. 1402, 1422 (E.D. Mo. 1993) (citing *Dataphase Systems Inc.,* 640 F.2d 109, 113-14 (8th Cir. 1981)). The balance-of-harms and public-interest factors "merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). State Defendants argue that preliminarily enjoining the laws at issue would also impose irreparable harm on the State, whose legislature has democratically enacted these laws. "[A]ny time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury." *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers) (quoting *New Motor Vehicle Bd. of Cal. v. Orrin W. Fox Co.*, 434 U.S. 1345, 1351 (1977) (Rehnquist, J., in chambers)). It is this alleged harm the Court needs to balance against the alleged irreparable harm incurred by Plaintiffs. As Plaintiffs

argue, they and their patients are suffering serious harm, whereas Defendants only stand to lose the ability temporarily to enforce some laws that are likely to be held unconstitutional and which further no valid compelling state interest. *See Kirkeby v. Furness*, 52 F.3d 772, 775 (8th Cir. 1995) (public interest favored injunction against unconstitutional ordinance).

III. Likely to Prevail on the Merits

As discussed above, "a party seeking a preliminary injunction of the implementation of a state statute must demonstrate more than just a 'fair chance' that it will succeed on the merits." *Rounds*, 530 F.3d 724, 731-32 (8th Cir. 2008). The Court characterized "this more rigorous standard . . . as requiring a showing that the movant 'is likely to prevail on the merits.'" *Id.*

"A statute's validity is presumed, and a statute will not be declared unconstitutional unless it clearly contravenes some constitutional provision." *Planned Parenthood of Kan. & Mid-Mo., Inc. v. Nixon*, 220 S.W.3d 732, 737 (Mo. banc 2007) (citing *Doe v. Phillips*, 194 S.W.3d 833, 841 (Mo. banc 2006)). However, if a statute conflicts with a constitutional provision, the statute must be declared invalid. *Jackson County v. State*, 207 S.W.3d 608 (Mo. banc 2006). A statute cannot supersede, nor can judicial interpretation thereof, abrogate a constitutional right. *Doe v. Phillips*, 194 S.W.3d 833, 841 (Mo. banc 2006); *United C.O.D. v. State*, 150 S.W.3d 311, 313 (Mo. banc 2004) ("Courts will enforce a statute unless it plainly and palpably affronts fundamental law embodied in the constitution.") "Words used in constitutional provisions are interpreted to give effect to their plain, ordinary, and natural meaning." *Faatz v. Ashcroft*, 685 S.W.3d 388, 400 (Mo. banc 2024) (internal citation omitted).

In light of this guidance, the Court will assess whether Plaintiffs are likely to prevail on the merits by reviewing the language of the challenged statutes through the heightened scrutiny framework provided in the language of Amendment 3, namely, whether the government's

purported compelling interest (one that is "for the limited purpose and has the limited effect of improving or maintaining the health of a person seeking care, is consistent with widely accepted clinical standards of practice and evidence-based medicine, and does not infringe on that person's autonomous decision-making") is achieved by the least restrictive means.

IV. The Public Interest

Amendment 3 was passed by a majority vote on November 5, 2024, the results of which were certified on December 5, 2024. *See* Plaintiffs' Supplement Notice of Authority filed on December 5, 2024. By the language of Amendment 3, the public interest is clear that voters, i.e. the public, intended to create a new fundamental right of reproductive freedom for all Missourians, "which is the right to make and carry out decisions about all matters relating to reproductive health care, including but not limited to prenatal care, childbirth, postpartum care, birth control, abortion care, miscarriage care, and respectful birthing conditions." Mo. Const. Art. I, 36.2. It is this public interest that the Court must consider when weighing the factors for preliminary injunction, as provided above.

LEGAL ANALYSIS

For the sake of clarity, the Court will address each category of statutes at issue as they are discussed in the Motion for Preliminary Injunction, as provided below:

1. Missouri's Abortion Bans: The Total Ban, § 188.017 RSMo; Gestational Age Bans, §§ 188.056, 188.057, 188.058, 188.375, RSMo; and Reasons Ban §§ 188.038, 188.052 RSMo.,19 C.S.R. § 10-15.010(1).[3]

a. Total Ban. Section 188.017 provides, in pertinent part, that

> …no abortion shall be performed or induced upon a woman, except in cases of medical emergency…[and a]ny person who knowingly performs or induces an abortion of an unborn child in violation of this subsection shall be guilty of a class B felony, as well

[3] The State Defendants concede the Total Ban and Gestational Age Bans are no longer enforceable and argue that a preliminary injunction on this issue is not needed because there is no controversy. However, Johnson remains as a Defendant and has not conceded the same.

> as subject to suspension or revocation of his or her professional license by his or her professional licensing board…. § 188.017.2 RSMo.

The Court finds the plain language of this statute is directly at odds with Amendment 3, specifically, Art. I, § 36.2 of the Missouri Constitution. Pursuant to Art. I § 36.3, the statute is therefore presumptively invalid and, because the State Defendants have not demonstrated that the statute is justified by a compelling governmental interest achieved by the least restrictive means, this Court finds Plaintiffs are likely to prevail on the merits. Further, because "being subject to an unconstitutional statute, 'for even minimal periods of time, unquestionably constitutes irreparable injury,'" the threat of irreparable harm exists here. The parties do not articulate, and this Court does not find, that issuance of this injunction would inflict harm and injury on other interested parties. The Court also finds that the public interest, as illustrated by the majority who voted to pass Amendment 3, is on the side of granting this injunction. Therefore, the Court finds that Section 188.017 must be enjoined.

b. Gestational Age Bans. Section 188.056 provides, in pertinent part,

> …no abortion shall be performed or induced upon a woman at **eight weeks gestational age** or later, except in cases of medical emergency… [and a]ny person who knowingly performs or induces an abortion of an unborn child in violation of this subsection shall be guilty of a class B felony, as well as subject to suspension or revocation of his or her professional license by his or her professional licensing board…. § 188.056.1. RSMo. (emphasis added).

Likewise, Section 188.057 provides, in part,

> …no abortion shall be performed or induced upon a woman at **fourteen weeks gestational age** or later, except in cases of medical emergency… [and a]ny person who knowingly performs or induces an abortion of an unborn child in violation of this subsection shall be guilty of a class B felony, as well as subject to suspension or revocation of his or her professional license by his or her professional licensing board…. § 188.057.1. RSMo. (emphasis added).

Section 188.058 provides, in part,

> …no abortion shall be performed or induced upon a woman at **eighteen weeks gestational age** or later, except in cases of medical emergency… [and a]ny person who knowingly performs or induces an abortion of an unborn child in violation of this subsection shall be guilty of a class B felony, as well as subject to suspension or revocation of his or her professional license by his or her professional licensing board…. § 188.058.1 RSMo. (emphasis added).

Finally, Section 188.375 provides, in part,

> …no abortion shall be performed or induced upon a woman carrying a late-term pain-capable unborn child [defined in § 188.375.2 as "unborn child at **twenty weeks gestational age** or later"], except in cases of medical emergency… [and a]ny person who knowingly performs or induces an abortion of a late-term pain-capable unborn child in violation of this subsection shall be guilty of a class B felony, as well as subject to suspension or revocation of his or her professional license by his or her professional licensing board. § 188.375.3 RSMo. (emphasis added).

As with the Total Ban, these statutes are clearly contrary to the language of Amendment 3 in that they infringe on a person's "autonomous decision making" and violate the provision prohibiting the penalization and prosecution of a person based on pregnancy outcomes. Mo. Const. Art. I, §§ 36.3, 36.5. Consistent with this Court's analysis above, the laws are presumptively invalid under Article I, Section 36.3. Because Defendants have not demonstrated a compelling governmental interest achieved by the least restrictive means justifying these statutory provisions, the Court finds that Plaintiffs are likely to prevail on the merits. As set out above, the threat of irreparable harm is apparent here as well. Parties do not articulate, and this Court does not find, that issuance of this injunction would inflict harm and injury on other interested parties. The Court also finds that the public interest, as illustrated by the majority who voted to pass Amendment 3, is on the side of granting this injunction. Therefore, the Court finds that Sections 188.056, 188.057, 188.058, and 188.375 shall be enjoined.

c. Reasons Ban. Section 188.038.2 states,

> [n]o person shall perform or induce an abortion on a woman if the person knows that the woman is seeking the abortion solely because of a prenatal diagnosis, test, or

screening indicating Down Syndrome or the potential of Down Syndrome in an unborn child. 188.038.2 RSMo.

Section 188.038.3 states, "[n]o person shall perform or induce an abortion on a woman if the person knows that the woman is seeking the abortion solely because of the sex or race of the unborn child." 188.038.3 RSMo. Any physician or other person "who performs or induces or attempts to perform or induce an abortion prohibited by [Section 188.038] shall be subject to all applicable civil penalties under this chapter including, but not limited to, sections 188.065 [license revocation] and 188.085 [civil liability for medical malpractice]." § 188.038.4 RSMo. Section 188.052 contains a related provision which requires the physician who performed or induced the abortion to complete an individual abortion report that certifies that physician does not have knowledge that the person seeking an abortion is doing so solely because one of the reasons stated in § 188.038. § 188.052.1 RSMo.; 19 CSR 10-15.010(1).

Consistent with this Court's analysis above, the laws are presumptively invalid under Article I, Section 36.3. Because Defendants have demonstrated no compelling governmental interest achieved by the least restrictive means justifying these statutory provisions, the Court finds that Plaintiffs are likely to prevail on the merits. As above, the threat of irreparable harm is apparent here as well. Parties do not articulate and this Court does not find that issuance of this injunction would inflict harm and injury on other interested parties. The Court also finds that the public interest, as illustrated by the majority who voted to pass Amendment 3, is on the side of granting this injunction. Therefore, the Court finds that § 188.038 and reporting requirements provided in § 188.052 and 19 CSR § 10-15.010(1) shall be enjoined.

2. Missouri's Abortion Facility Licensing Requirements: §§ 197.200-.235, 334.100.2(27) RSMo. and all of its implementing regulations; 19 C.S.R. §§ 30-30.050 –.070, 20 C.S.R. § 2150-7.140(2)(V).

Sections 197.200 to 197.235 and 334.100.2(27), 19 CSR 30-30.050-.070, and 20 CSR § 2150-7.140(2)(V) contain a number of requirements specifically directed at abortion facilities and ambulatory surgical centers, as those terms are defined by § 197.200. The Missouri Constitution Article I, Section 36.6 states, "[t]he Government shall not discriminate against persons providing or obtaining reproductive health care or assisting another person in doing so." Mo. Cont. Art. I, § 36.6. This set of statutes and regulations apply only to abortion facilities and not to any other similarly situated health care facility. The regulations require physicians to perform certain exams and tests that are unnecessary when the physicians themselves are authorized and enabled to make the determination on what is and is not necessary for their individual patients. Additionally, miscarriage management can be provided on an outpatient basis without a special facility license. The stipulated affidavits show that miscarriage management and abortion medication/procedures often mirror each other. Based on the foregoing, the Court finds the facility licensing requirement is facially discriminatory because it does not treat services provided in abortion facilities the same as other types of similarly situated health care, including miscarriage care.

The Court finds Plaintiffs are likely to prevail on the merits and have met the other requirements for entry of a preliminary injunction provided in *Dataphase*. *Rounds*, 530 F.3d 724; *Dataphase,* 640 F.2d 109. Therefore, §§ 197.200 to 197.235 and 334.100.2(27), 19 CSR 30-30.050-.070, and 20 CSR § 2150-7.140(2)(V) shall be enjoined.

3. Missouri's Hospital Relationship Restrictions: §§ 188.080, 188.027.1(1)(e), 197.215.1(2) RSMo.; 19 C.S.R. § 30-30.060(1)(C)(4).

This category of laws requires physicians providing abortions to have admitting privileges at hospitals that offer obstetric or gynecological care within thirty miles or fifteen-minutes travel

time to the health center where they provide any abortion. A written transfer agreement with a nearby hospital is one option for complying with some, but not all, of these requirements. Section 188.080[4] makes it a class A misdemeanor for any physician performing or inducing an abortion to not have clinical privileges as set forth in these laws. This admitting privileges requirement and geographical limitations clearly "…den[y], interfer[e] with, dela[y], or otherwise restric[t]" reproductive freedom and since there was no evidence demonstrating that these laws are "for the limited purpose and ha[ve] the limited effect of improving or maintaining the health of a person seeking care, consistent with widely accepted clinical standards of practice and evidence-based medicine, and [do] not infringe on that person's autonomous decision-making," no compelling governmental interest exists. Mo. Const. Art. I, § 36.3. Nor was it shown that these statutes are the "least restrictive means." *Id.*

The Court finds Plaintiffs are likely to prevail on the merits, as the threat of irreparable harm has already been established as provided above, and balancing potential harm to other interested parties with the public interest also weigh in Plaintiffs' favor as this Amendment was passed by a majority vote. For all of the foregoing, §§ 188.080 (limited as provided in footnote 7), 188.027.1(1)(e), 197.215.1(2), as well as 19 C.S.R. § 30-30.060(1)(C)(4) shall be enjoined.

4. Missouri's Medication Abortion Complication Plan Requirement: § 188.021.2 RSMo.; 19 C.S.R. § 30-30.061.

Pursuant to § 188.021.2, before providing medication abortion, providers must have a DHSS-approved complication plan. This plan requires medication abortion providers to have a written contract with a board-certified or board-eligible Ob-Gyn (or Ob-Gyn group) who has agreed to be "on-call and available twenty-four hours a day, seven days a week" to "[p]ersonally

[4] The analysis in this section only pertains to the language of § 188.080 requiring a physician's clinical privileges within 30 miles from the location of the abortion facility. The analysis of the statutory requirement permitting only physicians to perform abortions is discussed in the section labeled Missouri's Advanced Practice Clinician Ban.

treat all complications" from medication abortion "except in any case where doing so would not be in accordance with the standard of care, or in any case where it would be in the patient's best interest for a different physician to treat her." 19 C.S.R. § 30-30.061. Plaintiffs argue it is difficult to find physicians willing to agree to the required responsibilities and some facilities are not able to comply.

The Court finds the language of § 188.021.2 does not necessarily deny, interfere with, delay or otherwise restrict reproductive freedom; rather it is the language in the regulations that contain this specific requirement that do deny, interfere with, delay or otherwise restrict reproductive freedom without the necessary showing that such restriction has the limited purpose and effect of improving or maintaining the health of the person seeking care. For example, a person who travels three hours to get a medication abortion and then returns home, would not benefit from this requirement. If complications arise after taking the medication, the individual would need to seek emergency care at the nearest hospital emergency room, as with any other medical emergency. Plaintiffs have demonstrated they are likely to prevail as to the regulations only, and considering all of the other factors for granting a preliminary injunction, 19 C.S.R. § 30-30.061, as it pertains to the complication plan, is enjoined.

5. Missouri's Pathology Requirements: § 188.047 RSMo.; 19 C.S.R. §§ 10-15.030, 19 C.S.R. 30-30.060(5)(B).

Missouri law requires that "[a]ll tissue . . . removed at the time of abortion shall be submitted within five days to a board-eligible or certified pathologist for gross and histopathological examination." § 188.047 RSMo. The pathologist is then required to file a "tissue report" with DHSS and provide a copy of the report to the health center that provided the abortion. *Id.*; *see also* 19 C.S.R. § 10-15.030, 19 C.S.R. § 30-30.060(5)(B). Plaintiffs stipulated, for purposes of the preliminary injunctive relief requested, that they have not attempted to contact any

pathologists in Missouri about the Pathology Requirements since at least 2022, and state that they are currently "unaware of any pathologists in Missouri who are willing to contract with them to provide such an examination and report." Plaintiffs' Suggestions in Support of Their Motion for Preliminary Injunction or, in the Alternative, Temporary Restraining Order at 37 (citing Wales Aff. ¶ 30; Muniz Aff. ¶ 31).

State Defendants argue that these laws further patient health because it helps detect incomplete abortions, however, pathology of pregnancy tissue after an abortion cannot determine whether the abortion is complete or incomplete. Plaintiffs' Reply Suggestions in Support of Their Motion for Preliminary Injunction or, In the Alternative, Temporary Restraining Order, and Suggestions in Opposition to State Defendants' Motion to Dismiss at 42 (citing Grossman Aff. ¶ 112). These pathology requirements "den[y], interfer[e] with, dela[y], or otherwise restric[t]" reproductive freedom and there was no evidence provided that these laws are "for the limited purpose and ha[ve] the limited effect of improving or maintaining the health of a person seeking care, [are] consistent with widely accepted clinical standards of practice and evidence-based medicine, and [do] not infringe on that person's autonomous decision-making" to support the government's purported compelling interest. Mo. Const. Art. I, § 36.3. Nor was it shown that this statute and regulations are the "least restrictive means." *Id.*

The Court finds Plaintiffs are likely to prevail on the merits, the threat of irreparable harm has already been established as provided in the above, and balancing potential harm to other interested parties and the public interest also weigh in Plaintiffs' favor as this Amendment was passed by a majority vote. Therefore, § 188.047 and 19 C.S.R §§ 10-15.030 and 30-30.060(5)(B) shall be enjoined.

6. Missouri's Abortion-Specific Informed Consent Laws: §§ 188.027, 188.033, 188.039, RSMo.[5]

Plaintiffs challenge §§ 188.027, 188.033, and 188.039, which the Court will refer to as Missouri's Abortion-Specific Informed Consent Laws. Pursuant to these statutes, before a patient obtains an abortion, they must receive certain state-mandated information and materials that Plaintiffs argue are biased and meant to stigmatize patients' decision to obtain an abortion. As an example, § 188.027.1(2) requires individuals be presented with "…printed materials provided by [DHHS], which describe the probable anatomical and physiological characteristics of the unborn child at two-week gestational increments from conception to full term, including color photographs or images of the developing unborn child at two-week gestational increments." 188.027.1(2) RSMo. That section further requires,

> [s]uch descriptions shall include information about brain and heart functions, the presence of external members and internal organs during the applicable stages of development and information on when the unborn child is viable. The printed material shall prominently display the following statement: "The life of each human being begins at conception. Abortion will terminate the life of a separate, unique, living human being." § 188.027.1(2) RSMo.

Section 188.027 is a long statute and encompasses many of the other legal requirements Plaintiffs seek to enjoin, such as the 72-hour waiting period that is discussed in the next section. Section 188.033 requires the same information be provided to individuals who are considering obtaining an abortion outside of the state. Plaintiffs have shown they are likely to prevail on the merits because there was no evidence that any compelling governmental interest was achieved by utilizing the "least restrictive means" as required by Mo. Const. Art. I, § 36.3. The threat of irreparable harm has already been established as provided above, and balancing potential harm to

[5] Plaintiffs collectively refer to these as the "Biased Information Law."

other interested parties with the public interest also weigh in Plaintiffs' favor as this Amendment was passed by a majority vote. Therefore, §§ 188.027 and 188.033 shall be enjoined.

Section 188.039 primarily addresses the 72-hour waiting period that the Court will address in the section below. However, the language in § 188.039.4 pertains to informed consent, specifically, that a person must sign and give their "informed consent freely and without coercion" after discussing "…the indicators and contraindicators, and risk factors, including any physical, physiological or situational factors." § 188.039.4. RSMo.

The Court finds for purposes of Plaintiffs' requests for injunctive relief, the general laws of informed consent for any medical treatment and procedures sufficiently cover any separate purposes that may be served by § 188.039.4 and that Plaintiffs are likely to prevail on the merits. There was no evidence demonstrating that any compelling governmental interest would be achieved by the "least restrictive means" as required by Mo. Const. Art. I, § 36.3. The threat of irreparable harm has already been established as provided above, and balancing potential harm to other interested parties with the public interest also weigh in Plaintiffs' favor as this Amendment was passed by a majority vote. Therefore, § 188.039.4, solely as it pertains to this special informed consent requirement, shall be enjoined.

7. Missouri's Waiting Period, In-Person, and Same Physician Requirements: §§ 188.027, 188.039, RSMo.

Sections 188.027 and 188.039 require abortion patients to make two in-person visits to see the same physician, at least 72 hours apart. If the 72-hour waiting period is enjoined, the law specifies that a 24-hour waiting period is to take its place. §§ 188.027.12, 188.039.7 RSMo. At the patient's first appointment, the physician is required to provide the patient with the information described in the preceding section. State Defendants do not contest that these requirements delay patients' access to abortion care by at least 72 hours (or, in the alternative, 24 hours). A mandatory

waiting period clearly "den[ies], interfere[s] with, delay[s], or otherwise restrict[s]" reproductive freedom and since there was no evidence presented that these laws are "for the limited purpose and ha[ve] the limited effect of improving or maintaining the health of a person seeking care, consistent with widely accepted clinical standards of practice and evidence-based medicine, and [do] not infringe on that person's autonomous decision-making," there is no compelling governmental interest. Mo. Const. Art. I, § 36.3. Nor was there any evidence to explain why a waiting period of 72 hours, or in the alternative 24 hours, is the "least restrictive means" in carrying out any purported government interest. *Id.*

The Court finds Plaintiffs are likely to prevail on the merits, the threat of irreparable harm has already been established, and balancing potential harm to other interested parties with the public interest also weigh in Plaintiffs' favor, as this Amendment was passed by a majority vote. Therefore, the provisions in Sections 188.027 and 188.039 pertaining to the waiting period shall be enjoined.

As for the In-Person requirement, State Defendants argue that an in-person appointment is necessary because only an in-person appointment can confirm gestational age for purposes of appropriate use of the abortion pill (which the FDA has approved for the first ten weeks of a pregnancy) and to rule out an ectopic pregnancy. The Court finds Plaintiffs have not demonstrated they are likely to prevail on the merits as to the In-Person requirement. The Court further finds there may be a compelling governmental interest and therefore, denies the request to enjoin this requirement.

Similarly, State Defendants argue the Same Physician requirement is necessary to establish continuity of care. Plaintiffs argue that this creates scheduling issues. The Court notes these alleged scheduling issues occur in conjunction with the 72-hour waiting period. Therefore, absent the 72-

hour waiting period, the Court finds Plaintiffs have not demonstrated they are likely to prevail on the merits as it pertains to this requirement, and denies the request to enjoin the Same Physician requirement.

8. Missouri's Telemedicine Ban: § 188.021 RSMo.

Plaintiffs challenge § 188.021,[6] which states, in part,

> [w]hen RU-486 (mifepristone) or any drug or chemical is used for the purpose of inducing an abortion, the initial dose of the drug or chemical shall be administered in the same room and in the physical presence of the physician who prescribed, dispensed, or otherwise provided the drug or chemical to the patient. § 188.021.1 RSMo.

Plaintiffs refer to this as the "Telemedicine Ban." This language prohibits telehealth appointments and requires a physician to be physically present in the room while a patient is taking the medication. This seemingly would not allow a physician to prescribe the medication after an in-person appointment and having the patient subsequently take the medication at home or even in a medical facility in the presence of a nurse or other medical professional.

The language of this portion of the statute "…den[ies], interfere[s] with, delay[s], or otherwise restrict[s]" reproductive freedom and there was no evidence that this law is "for the limited purpose and has the limited effect of improving or maintaining the health of a person seeking care, is consistent with widely accepted clinical standards of practice and evidence-based medicine, and does not infringe on that person's autonomous decision-making" to establish a compelling governmental interest. Mo. Const. Art. I, § 36.3. Nor was it shown that this statute is the "least restrictive means." *Id.*

The Court finds Plaintiffs are likely to prevail on the merits, the threat of irreparable harm has already been established as provided above, and balancing potential harm to other interested

[6] Plaintiffs cite to §188.021 in its entirety in this portion of the argument, but only 188.021.1 has language that could be interpreted as a ban on "telehealth" appointments.

parties with the public interest also weigh in Plaintiffs' favor as this Amendment was passed by a majority vote. Therefore, § 188.021.1 shall be enjoined.

9. Missouri's Advance Practice Clinician Ban: §§ 188.020, 188.080, 334.245, 334.735.3 RSMo.

Missouri law requires abortions to be performed by physicians only, rather than physician's assistants ("PAs") and Advanced Practice Registered Nurses ("APRNs"), collectively known as Advanced Practice Clinicians ("APCs"). *See* §§ 188.020, 188.080, 334.245, 334.735.3 RSMo. Plaintiffs argue that if APCs were allowed to perform abortions, it would increase their ability to provide care. Plaintiffs also argue that APCs are just as qualified as physicians to provide many forms of abortion care. There are many forms of abortion care, making this facial challenge by Plaintiffs a difficult one at this stage of litigation because there may be a compelling governmental interest to allow only physicians to perform some kinds of abortion care. Therefore, Plaintiffs have not made their threshold showing that they are likely to prevail on the merits on this point and the request for injunctive relief is denied.

10. Criminal Penalties for Abortion Providers: §§ 188.017.2, 188.030.3, 188.056.1, 188.057.01, 188.058.1, 188.075, 188.080, 188.375.3, 197.235, 334.245, 574.200.2 RSMo.

Article I, § 36.5 states:

> No person shall be **penalized, prosecuted, or otherwise subjected to adverse action** based on their actual, potential, perceived, or alleged pregnancy outcomes, including but not limited to miscarriage, stillbirth, or abortion. **Nor shall any person assisting a person in exercising their right to reproductive freedom** with that person's consent **be penalized, prosecuted, or otherwise subjected to adverse action** for doing so.

(emphasis added.)

Several of these statutes have already been discussed in the preceding sections. Specifically, the Court has already found §§ 188.017, 188.056, 188.057, 188.058, 188.375, shall be enjoined, and as such, it is appropriate that their respective criminal penalties be enjoined at this time pursuant to Mo. Const. Art. I, § 36.5.

Sections 197.235 and 334.245 were also previously discussed and were not enjoined, and their respective criminal penalties shall not be enjoined at this time.

Section 188.080 was previously discussed and enjoined only as it pertains to physicians' admitting privileges at a hospital within 30 miles of the abortion facility. The requirement to have only physicians perform abortions was not enjoined. As such, the criminal penalties will apply only to the portion of that statute that is not enjoined pursuant to Mo. Const. Art. I, § 36.5.

Plaintiffs include §§ 188.030.3 and 574.200.2 in this category of laws, but do not provide any argument regarding these specific provisions. Therefore, the Court finds the Plaintiffs have not met their burden for a preliminary injunction as to these two statutes.

BOND

Missouri Supreme Court Rule 92.02(d) requires Plaintiffs to execute a bond. Plaintiffs requests a bond of $100.00. No objection was made by Defendants. The Court finds bond set at $100.00 is appropriate.

CONCLUSION

For all of the foregoing, it is, therefore

ORDERED, ADJUDGED, AND DECREED that the requests for injunctive relief contained in Plaintiffs' Motion for Preliminary Injunction, or, in the Alternative, Temporary Restraining Order, filed on November 6, 2024 and Plaintiffs' Motion for Reconsideration, filed on December 30, 2024, are **GRANTED IN PART AND DENIED IN PART**.

IT IS FURTHER ORDERED, ADJUDGED, AND DECREED that Plaintiffs shall file a bond in the amount of $100.00.

IT IS FURTHER ORDERED, ADJUDGED, AND DECREED that any and all other relief not specifically granted herein is hereby DENIED.

IT IS SO ORDERED.

July 3, 2025
Date

HON. JERRI J. ZHANG
Judge, Division 3

CC: All counsel via e-Notification

Not an Official Court Document

EXHIBIT 55

Substitute Op., *Idahoans United for Women and Families v. Labrador et al.*, No. 52636-20255 (Idaho June 24, 2025)

IN THE SUPREME COURT OF THE STATE OF IDAHO

Docket No. 52636-2025

Re: Verified Petition for Writs of Certiorari and Mandamus.	
----------	**Boise, April 2025 Term**
IDAHOANS UNITED FOR WOMEN AND FAMILIES,	**Opinion filed: June 24, 2025**
Petitioner,	**Melanie Gagnepain, Clerk**
v.	**SUBSTITUTE OPINION, THE OPINION DATED JUNE 16, 2025, IS WITHDRAWN**
RAUL LABRADOR, in his official capacity as the Idaho Attorney General; PHIL MCGRANE, in his official capacity as the Idaho Secretary of State; LORI WOLFF, in her official capacity as the Administrator of the Idaho Division of Financial Management; and the IDAHO DIVISION OF FINANCIAL MANAGEMENT,	
Respondents.	

Original proceeding in the Idaho Supreme Court seeking writs of certiorari and mandamus.

Petitioner's Verified Petition against the Idaho Secretary of State is dismissed; its Verified Petition for a Writ of Mandamus against the Idaho Attorney General and the Idaho Division of Financial Management is partially granted; and its Verified Petition for a Writ of Certiorari against the Idaho Attorney General and the Idaho Division of Financial Management is denied.

Holland & Hart LLP, Boise, for Petitioner. Anne Henderson Haws argued.

Raúl R. Labrador, Idaho Attorney General, Boise, for Respondents. Alan M. Hurst argued.

ZAHN, Justice.

This original action concerns the fiscal impact statement and ballot titles for a citizen initiative entitled the "Reproductive Freedom and Privacy Act" ("Initiative"). Petitioner, Idahoans

United for Women and Families ("Idahoans United"), filed this original action seeking a writ of certiorari and writ of mandamus ordering the Idaho Division of Financial Management ("DFM") to revise its Fiscal Impact Statement ("FIS") and ordering the Idaho Attorney General to revise his long and short ballot titles. Idahoans United also seeks a writ against the Idaho Secretary of State but does not specify which writ is requested or what it seeks to compel.

After considering the arguments of counsel, we agree with some, but not all, of Idahoans United's arguments. For the reasons explained below, we dismiss the Petition against the Secretary of State because Idahoans United has failed to properly invoke our original jurisdiction. We partially grant the request for a writ of mandamus against DFM because the FIS fails to substantially comply with Idaho Code section 34-1812. We partially grant the request for a writ of mandamus against the Idaho Attorney General because the short ballot title fails to substantially comply with Idaho Code section 34-1809. However, we deny the request for a writ of mandamus as it pertains to the long ballot title because it substantially complies with Idaho Code section 34-1809.

I. BRIEF SUMMARY

Article III, section 1 of the Idaho Constitution reserves to the people the power to legislate directly through the initiative process, under such conditions and in such manner as provided by laws enacted by the Idaho Legislature. Idaho law requires citizens to first submit a copy of the initiative petition to the Idaho Secretary of State. Idaho law then triggers a series of events that must occur within specified timeframes. One is DFM's preparation of an FIS. Another is the Attorney General's preparation of short and long ballot titles. Idaho law identifies mandatory requirements for both the FIS and the ballot titles.

Idahoans United filed a Petition with this Court, seeking a writ of mandamus or writ of certiorari against DFM, the Attorney General, and the Secretary of State. Idahoans United argues that neither the FIS nor the ballot titles for the Initiative meet the requirements of Idaho law. It asks this Court to either certify the FIS and ballot titles it has prepared or order DFM and the Attorney General to prepare a new FIS and new ballot titles that substantially comply with Idaho law.

For reasons we discuss in more detail below, we partially grant the requested writ of mandamus against DFM. We conclude that the FIS fails to substantially comply with the requirements of Idaho Code section 34-1812 because DFM has failed to establish a factual basis

for its estimated fiscal impact. We also conclude that the FIS fails to substantially comply with the clear and concise requirement of the statute because it contains conflicting statements concerning whether there will be a fiscal impact on the budget of the Idaho Department of Correction, and its reference to the state Medicaid budget creates confusion concerning the total fiscal impact. Finally, we conclude that the FIS fails to substantially comply with the statutory requirement to avoid legal and technical terms whenever possible because it includes unnecessary references to state statutes and a vague mention of "Medicaid references." However, we deny the requested writ concerning the references to the Medicaid and prisoner populations. We conclude those references substantially comply with the statutory requirement to provide an explanation of the assumptions underlying any estimated fiscal impact.

As to the Attorney General, we partially grant and partially deny Idahoans United's Petition seeking a writ of mandamus. We conclude that the Attorney General's short ballot title fails to substantially comply with the distinctive and comprehensive requirement of Idaho Code section 34-1809 because it fails to alert a prospective signer of the Initiative to the Initiative's four distinctive characteristics. However, we deny the requested writ concerning the use of "fetus viability" in the short ballot title. We conclude that the short title substantially complies with the statutory requirement to use language by which the Initiative is commonly referred. The phrase to which Idahoans United objects, "fetus viability," has been used in Idaho before. While Idahoans United's preferred term, "fetal viability," has been used more frequently, the meaning of the two phrases does not substantially differ and they simply use different parts of speech for the same word. We therefore conclude that the short title substantially complies with section 34-1809. We deny the requested writ concerning the long ballot title and conclude that it substantially complies with the statutory requirements.

For the reasons explained below, we decline to certify Idahoans United's proffered ballot titles and FIS. This Court has previously declined to dictate the form of ballot titles because it is not our job to determine the best way to draft a ballot title. Rather, our job is to determine whether the ballot titles substantially comply with the requirements of Idaho law. The same holds true for the FIS. Therefore, we remand the short ballot title to the Attorney General and the FIS to DFM. We order them to provide us with a revised short ballot title and a revised FIS by 4 p.m. MDT on June 23, 2025. To avoid further litigation and to finalize the FIS as quickly as possible, we also

order DFM to submit a sworn declaration by the preparer of the FIS describing the process utilized, including the evidence gathered and the assumptions utilized to create the FIS.

II. FACTUAL AND PROCEDURAL BACKGROUND

Idahoans United is attempting to qualify a voter initiative entitled the "Reproductive Freedom and Privacy Act" to appear on the 2026 general election ballot. On November 20, 2024, Idahoans United submitted the Initiative to the Secretary of State. When an initiative petition is submitted to the Secretary of State, "Idaho law trigger[s] a series of events, which must occur within specific timeframes." *Idahoans for Open Primaries v. Labrador* (*In re Verified Pet. for Writs of Cert. & Mandamus*) ("*Open Primaries*"), 172 Idaho 466, 473, 533 P.3d 1262, 1269 (2023).

Upon receiving an initiative petition, the Secretary of State must immediately transmit a copy of the initiative to DFM for the issuance of an FIS under Idaho Code section 34-1812. I.C. § 34-1804(2). DFM has twenty days from its receipt of the initiative petition to write and file an FIS with the Secretary of State's office. I.C. § 34-1812(1). The Secretary of State then must immediately transmit the FIS to the party who filed the initiative. *Id.*

When soliciting signatures for an initiative, signature gatherers must offer a copy of the FIS summary to electors. I.C. § 34-1812(3). The FIS summary must also be published in the state voters' pamphlet and on the official ballot. *Id.* The FIS summary and the detailed FIS must be available to the public on the Secretary of State's website "no later than August 1." *Id.*

Upon receiving the initiative petition, the Secretary of State must also transmit a copy of the initiative to the Attorney General for the issuance of a certificate of review under Idaho Code section 34-1809. I.C. § 34-1804(1). Upon receipt of the initiative petition, the Attorney General has twenty days to review the initiative, to "recommend to the petitioner such revision or alteration of the measure as may be deemed necessary and appropriate," and to issue a certificate of review to the Secretary of State. I.C. § 34-1809(1)(a), (c).

If the party who filed the initiative chooses to proceed, the proponent has fifteen days to file the initiative with the Secretary of State for the issuance of ballot titles. I.C. § 34-1809(2). The Secretary of State must immediately submit the initiative to the Attorney General to assign ballot

titles. *Id.* The Attorney General must then prepare a short and a long ballot title[1] and submit them to the Secretary of State within ten days. I.C. § 34-1809(2)(a), (d). The Secretary of State must then provide the ballot titles to the party who filed the initiative. I.C. § 34-1809(2)(b). "The ballot titles shall be used and printed on the covers of the petition when in circulation[.]" I.C. § 34-1809(2)(c).

In this action, the Secretary of State transmitted the Initiative to DFM, which prepared an FIS that projected additional costs to the State if voters approved the Initiative:

> The laws affected by the initiative would not impact income, sales, or product taxes. There is no revenue impact to the General Fund found.
>
> The initiative could change state expenditures in minor ways. Costs associated with the Medicaid and prisoner populations may occur; see Idaho Codes 20-237B and 56-255 and the Medicaid references from Health and Welfare.
>
> Passage of this initiative is likely to cost less than $20,000 per year. The Medicaid budget for providing services was about $850 million in FY2024. If passed, nominal costs in the context of the affected total budget are insignificant to the state.
>
> Assumptions
>
> Changes in costs associated with the ballot initiative could impact state funding expenditures for Corrections [sic] and Medicaid budgets. The amount of those costs would be dependent on the frequency of need for reproductive services within the agencies. The manner of the budget impacts would be different for Corrections [sic] due to the health care provisions used by the agency; there is no expected changes to the Corrections [sic] health care budget. Billing history prior to the Dobbs decision suggests that $20,000 per year is a conservative over-estimate of the costs. Neither of these agencies reverted funding when the Dobbs decision was made in 2022 (and already established legislation in Idaho code took effect). It is assumed that any additional costs due to the passage of this ballot initiative could be absorbed in the Corrections [sic] and Health and Welfare budgets should the ballot initiative pass.

Idahoans United filed the Initiative with the Secretary of State for the assignment of ballot titles. The Attorney General sent the ballot titles to the Secretary of State, and the Secretary of State provided them to Idahoans United that same day. The short ballot title states:

> Measure establishing a right to abortion up to fetus viability and to make reproductive decisions regarding one's own body.

[1] Idaho Code section 34-1809 refers to the ballot titles as the "short title" and "general title." The parties and prior decisions of this Court often colloquially refer to the general title as the "long title." This opinion will similarly use the term "long title" to refer to the general title.

The long ballot title states:

> The measure seeks to change Idaho's laws by introducing a right to reproductive freedom and privacy including a right to abortion up to the point of the fetus's ability to survive outside the womb. After fetal viability, there would be no general right to abortion except in cases of "medical emergency." The "medical emergency" exception would expand Idaho's current life exception and allow abortions when pregnant women face complicating physical conditions that threaten their life or health, "including serious impairment to a bodily function" or "serious dysfunction of any bodily organ or part."
>
> The proposed measure codifies a right to make reproductive decisions, including contraception, fertility treatment, and prenatal and postpartum care. This includes a "right of privacy" in making these decisions. The measure seeks to prevent the state from enforcing certain abortion laws protecting the life of the unborn child. It would also impose a requirement that any restrictions on reproductive decisions, including abortion prior to fetus viability, must be "narrowly tailored to improve or maintain the health of the person seeking reproductive health care." The measure would also prevent the state from penalizing patients, healthcare providers, or anyone who assists in exercising the proposed right.

After receiving the ballot titles, Idahoans United filed a Verified Petition for Writs of Certiorari and Mandamus with this Court, arguing that the FIS and the short and long ballot titles violate Idaho law. Idahoans United asks this Court to issue a writ of certiorari or mandamus directing DFM to issue the proposed FIS prepared by Idahoans United or to issue an FIS that complies with Idaho law. It also asks this Court to issue a writ of certiorari or mandamus certifying the ballot titles prepared by Idahoans United or directing the Attorney General to provide ballot titles that comply with Idaho law.

III. ISSUES ON APPEAL

1. Whether Idahoans United has properly invoked this Court's original jurisdiction.
2. Whether the FIS substantially complies with Idaho Code section 34-1812.
3. Whether the short ballot title substantially complies with Idaho Code section 34-1809.
4. Whether the long ballot title substantially complies with Idaho Code section 34-1809.
5. Whether Idahoans United is entitled to attorney fees on appeal.

IV. ANALYSIS

A. Idahoans United has properly invoked this Court's original jurisdiction to issue a writ of mandamus.

Idahoans United seeks writs of mandamus and of certiorari from this Court. Our jurisdiction to issue the writs stems from Article V, section 9 of the Idaho Constitution, which

states that "[t]he Supreme Court shall . . . have original jurisdiction to issue writs of mandamus, certiorari, prohibition, and habeas corpus, and all writs necessary or proper to the complete exercise of its appellate jurisdiction." Before this Court will exercise its original jurisdiction to issue a writ, the petitioning party must demonstrate that the elements of the writ are met. *Labrador v. Idahoans for Open Primaries*, ___ Idaho ___, ___, 554 P.3d 85, 90 (2024).

A writ of mandamus "may be issued by the [S]upreme [C]ourt . . . to compel the performance of an act which the law especially enjoins as a duty resulting from an office, trust or station[.]" I.C. § 7-302. The writ of certiorari may be granted when an inferior tribunal, board or officer exercising judicial functions has exceeded its jurisdiction. I.C. §§ 7-201, 7-202. "It is only appropriate for a court to issue an extraordinary writ 'where there is not a plain, speedy and adequate remedy in the ordinary course of law.' " *Idaho State Athletic Comm'n ex rel. Stoddard v. Off. of the Admin. Rules Coordinator*, 173 Idaho 384, 393, 542 P.3d 718, 727 (2024) (quoting *Westover v. Cundick*, 161 Idaho 933, 936, 393 P.3d 593, 596 (2017)); I.C. §§ 7-303, 7-402. We conclude that Idahoans United has failed to demonstrate these elements are met with regard to the Secretary of State. However, it has demonstrated that the elements are met with regard to DFM and the Attorney General.

1. *We dismiss the Petition against the Secretary of State.*

Idahoans United asks this Court to issue a writ against the Secretary of State but does not specify which writ it seeks. It has not alleged that the Secretary of State has failed to comply with a clear legal duty or that the Secretary of State acted in a quasi-judicial function in excess of his jurisdiction. Instead, Idahoans United alleges that DFM and the Attorney General failed to perform the duties imposed by Idaho Code sections 34-1809 and 34-1812. They have made no such allegation concerning the Secretary of State. At oral argument, Idahoans United admitted that the Secretary of State has performed the ministerial duties required of him up to this point and that it named the Secretary of State as a party in this action out of "an abundance of caution." Idahoans United has failed to establish the elements required for a writ of mandamus or a writ of certiorari and we therefore dismiss the Petition against the Secretary of State.

2. *Idahoans United has properly invoked this Court's original jurisdiction to issue a writ of mandamus against DFM.*

Idahoans United also seeks a writ of mandamus against DFM. "[M]andamus is not a writ of right and the allowance or refusal to issue a writ of mandate is discretionary." *Coeur d'Alene Tribe v. Denney*, 161 Idaho 508, 512, 387 P.3d 761, 765 (2015). A writ of mandamus may be

issued by the Supreme Court "to compel the performance of an act which the law especially enjoins as a duty resulting from an office, trust or station[.]" I.C. § 7-302. "A writ of mandamus will lie if the officer against whom the writ is brought has a '*clear legal duty*' to perform the desired act, and if the act sought to be compelled is *ministerial or executive in nature*." *Idaho State Athletic Comm'n*, 173 Idaho at 393, 542 P.3d at 727 (emphasis added) (citation omitted). Additionally, this Court will only issue an extraordinary writ "where there is not a plain, speedy and adequate remedy in the ordinary course of law." I.C. §§ 7-303, 7-402.

Idahoans United argues that a writ is proper here because DFM has a duty to prepare an FIS that complies with Idaho Code section 34-1809, that the FIS prepared by DFM is inaccurate and does not comply with the statute, and that Idahoans United cannot begin collecting signatures for the Initiative until it has a valid FIS. Idahoans United has submitted a declaration asserting that any delay in collecting signatures will hinder its chances of collecting enough signatures to qualify for the 2026 election. DFM argues that, while it has a clear duty to prepare an FIS, it has discretion in deciding the content of the FIS, so mandamus relief is not appropriate.

We conclude that Idahoans United has properly invoked this Court's original jurisdiction. The plain language of Idaho Code section 34-1812 imposes a clear legal duty on DFM to prepare an FIS that meets the mandatory requirements of the statute. Specifically, this statute enumerates those requirements as follows:

- It "*shall* prepare an unbiased, good faith statement of the fiscal impact of the law proposed by the initiative." I.C. § 34-1812(1) (emphasis added).
- It "*shall* describe any projected increase or decrease in revenues, costs, expenditures, or indebtedness that the state or local governments will experience if the ballot measure is approved by the voters." I.C. § 34-1812(2) (emphasis added).
- It "*shall* include both immediate expected fiscal impacts and an estimate of any state or local government long-term financial implications." *Id.* (emphasis added).
- It "*must* be written in clear and concise language and *shall* avoid legal and technical terms whenever possible." *Id.* (emphasis added).
- It "*must* include both a summary of the fiscal impact statement, not to exceed one hundred (100) words, and a more detailed statement of fiscal impact that includes the assumptions that were made to develop the fiscal impact." I.C. § 34-1812(3) (emphasis added).

DFM's statutory duty to prepare an FIS that meets these requirements is clear and non-discretionary as evidenced by the statute's repeated use of the words "shall" and "must." The preparation of the FIS is an act that is ministerial or executive in nature.

The fact that DFM exercises discretion in estimating the amount of any fiscal impact does not alter our conclusion that DFM has a clear legal duty to prepare an FIS that complies with section 34-1812. DFM is correct that, generally, a writ of mandamus is improper to review acts of discretion. *See Brady v. City of Homedale*, 130 Idaho 569, 571, 944 P.2d 704, 706 (1997). However, our caselaw is clear that in instances where there is a clear legal duty for an officer to act but the details of those actions are left to an officer's discretion, mandamus may still be proper. *See Beem v. Davis*, 31 Idaho 730, 736, 175 P. 959, 961 (1918) ("The fact that certain details are left to the discretion of the authorities does not prevent relief by mandamus."); *Moerder v. City of Moscow*, 74 Idaho 410, 415, 263 P.2d 993, 996 (1953) ("Public officials may, under some circumstances, be compelled by writ of mandate to perform their official duties, although the details of such performance are left to their discretion."); *Musser v. Higginson*, 125 Idaho 392, 394–96, 871 P.2d 809, 811–13 (1994) ("For more than three-quarters of a century, the Court has adhered to the following principle: The fact that certain details are left to the discretion of the authorities does not prevent relief by *mandamus*." (internal quotation marks and citation omitted)). That principle applies with equal force to the facts of this action. While DFM has discretion in preparing the contents of the FIS, it has no discretion concerning whether to prepare an FIS that meets the requirements of section 34-1812.

We also conclude that Idahoans United has demonstrated that "there is not a plain, speedy and adequate remedy in the ordinary course of law." I.C. §§ 7-303, 7-402. In *Open Primaries*, we held that a petitioner's inability to begin collecting signatures for its initiative until the Secretary of State certifies the ballot titles was sufficient to invoke this Court's original jurisdiction. *Idahoans for Open Primaries v. Labrador* (*In re Verified Pet. for Writs of Cert. & Mandamus*) ("*Open Primaries*"), 172 Idaho 466, 475–76, 533 P.3d 1262, 1271–72 (2023). This action presents a similar situation because Idahoans United is prevented from collecting signatures until the Secretary of State certifies an FIS. I.C. § 34-1802(1); *see also Buchin v. Lance* (*In re Writ of Prohibition Entitled "Ballot Title Challenge Oral Arg. Req."*), 128 Idaho 266, 273, 912 P.2d 634, 641 (1995) (holding that "any signature collected by the circulation of a petition with . . . invalid titles cannot be valid"). Idahoans United also submitted a declaration from its executive director,

Melanie Folwell, which asserts that any delay in collecting signatures will adversely impact its efforts to qualify the Initiative for the 2026 general election. Having demonstrated both the elements of a writ of mandamus and the lack of an adequate remedy, we hold that Idahoans United has properly invoked this Court's original jurisdiction.

We decline DFM's invitation to adopt the reasoning of a recent Washington Supreme Court decision that dismissed a petition for a writ of mandamus seeking to prevent the publication of a public investment impact disclosure for several ballot initiatives. *See Walsh v. Hobbs*, 557 P.3d 701, 703, 706 (Wash. 2024) (en banc). While the Washington Supreme Court may have reached a different result under its precedent, we apply this Court's precedent and conclude that Idahoans United has properly invoked our original jurisdiction.

Idahoans United also seeks writs of certiorari against DFM and the Attorney General. We decline to separately analyze the elements of those writs because mandamus relief fully resolves Idahoans United's claim. In this action, the resolution of both writs turns on whether the FIS substantially complies with section 34-1812. The relief that Idahoans United seeks for each writ is the same: a writ requiring DFM to prepare an FIS that substantially complies with the requirements of section 34-1812. We have already held that Idahoans United properly invoked our original jurisdiction to issue a writ of mandamus. Thus, if the FIS substantially complies, then Idahoans United is not entitled to a writ of mandamus. The result would be no different for the requested writ of certiorari. If the FIS does not substantially comply, then Idahoans United is entitled to a writ of mandamus. A writ of certiorari would not award any greater relief than the requested writ of mandamus. Given that the outcomes would be the same for either writ, and given our conclusion that Idahoans United properly invoked this Court's original jurisdiction on the writ of mandamus, we do not need to address its claim for a writ of certiorari. We therefore deny Idahoans United's request for a writ of certiorari as duplicative of the relief sought in its request for a writ of mandamus.

3. *Idahoans United has properly invoked this Court's original jurisdiction to issue a writ of mandamus against the Attorney General.*

Finally, Idahoans United seeks a writ of mandamus against the Attorney General. The Attorney General does not challenge this Court's jurisdiction to issue a writ of mandamus concerning the ballot titles. We conclude that Idahoans United has properly invoked our original jurisdiction to issue a writ of mandamus against the Attorney General.

Section 34-1809 mandates that "the attorney general *shall* provide ballot titles," I.C. § 34-1809(2)(a) (emphasis added), that "*shall* contain: . . . [a] [d]istinctive short title not exceeding twenty (20) words by which the measure is commonly referred to or spoken of" and "[a] general title expressing in not more than two hundred (200) words the purpose of the measure," I.C. § 34-1809(2)(d)(i), (ii) (emphasis added). Section 34-1809 also mandates that, "[i]n making the ballot title, the attorney general *shall*, to the best of his ability, give a true and impartial statement of the purpose of the measure and in such language that the ballot title *shall* not be intentionally an argument or likely to create prejudice either for or against the measure." I.C. § 34-1809(2)(e) (emphasis added).

Idahoans United has properly pleaded that section 34-1809 imposes a clear legal duty on the Attorney General to prepare ballot titles that meet the mandatory requirements of the statute. The preparation of the ballot titles is an act that is ministerial or executive in nature. And for the reasons discussed above regarding Idahoans United's petition against DFM, we conclude that Idahoans United has properly demonstrated that "there is not a plain, speedy and adequate remedy in the ordinary course of law" with regard to the ballot titles. Further, for the reasons discussed above, we deny its request for a writ of certiorari as duplicative of its request for a writ of mandamus.

B. The FIS does not substantially comply with Idaho Code section 34-1812.

Idahoans United argues that the FIS prepared by DFM fails to comply with Idaho Code section 34-1812. The statute requires DFM to prepare "an unbiased, good faith statement of the fiscal impact of the law proposed by the initiative." I.C. § 34-1812(1). It must include both a 100-word summary of the statement and a more detailed statement of fiscal impact that includes the assumptions that were made to develop the fiscal impact. I.C. § 34-1812(3). The FIS "must be written in clear and concise language and shall avoid legal and technical terms whenever possible. Where appropriate, [an FIS] may include both estimated dollar amounts and a description placing the estimated dollar amounts into context." I.C. § 34-1812(2). Idahoans United argues that the FIS prepared for the Initiative violates these requirements because it was not made in good faith, is unclear, and impermissibly includes legal and technical terms.

Before we address the specific challenges raised by Idahoans United, we first must determine the appropriate legal standard to apply. In *Open Primaries*, we determined that we would employ a "substantial compliance" standard when reviewing ballot titles prepared by the

Attorney General. 172 Idaho at 479, 533 P.3d at 1275. We concluded this standard was appropriate because we had applied it in other situations where the critical inquiry was whether a party had met statutory requirements. *Id.* Idahoans United's arguments here require us to engage in a similar critical inquiry: whether DFM has fulfilled its mandatory duties set forth in section 34-1812. As a result, we conclude that our reasoning expressed in *Open Primaries* applies with equal force here. Therefore, we will review the FIS to determine whether it substantially complies with the requirements of Idaho Code section 34-1812.

We now turn to the specifics of Idahoans United's challenge. It claims that the FIS fails to meet nearly every statutory requirement:

- It is not drafted in good faith because it estimates a fiscal impact on taxpayers despite language in the Initiative that it "does not create a financial obligation on the state, its agencies, or their programs." It also lacks a factual basis for its conclusions that there may be a fiscal impact on the Idaho Department of Correction ("IDOC") and Medicaid budgets.
- It is not clear and concise because it creates confusion regarding whether there will be a fiscal impact.
- It fails to avoid legal and technical terms whenever possible because it cites statutes and regulatory references.
- It is prejudicial because it unnecessarily references Medicaid and prisoner populations and the Idaho Department of Health and Welfare's ("IDHW") total Medicaid budget.

We address each argument in turn.

1. *The FIS does not substantially comply with the good faith requirement.*

Idahoans United argues that the FIS fails to substantially comply with the requirements of section 34-1812 because there is no factual basis supporting the estimated fiscal impact and the Initiative specifically states that it will not impose a financial obligation on the State. DFM responds that it acted in good faith by consulting with a Medicaid expert from IDHW.

We hold that the FIS does not substantially comply with the good faith requirement of section 34-1812 because DFM has not established a reasonable basis for its estimated fiscal impacts. Idaho Code section 34-1812 requires DFM to "prepare an *unbiased, good faith* statement of the fiscal impact of the law proposed by the initiative." I.C. § 34-1812(1) (emphasis added). Good faith includes "honesty in belief or purpose" and "faithfulness to one's duty or obligation." *Good Faith*, Black's law Dictionary (12th ed. 2024). Section 34-1812 requires DFM to project and

estimate the potential fiscal impact. As such, the statute does not require certainty or exactness. However, the statute's requirement that the FIS be a "good faith statement" requires that it be more than a guess or speculation. In other words, while section 34-1812 does not require DFM to perfectly project the future, the requirement that the FIS be "a good faith statement" requires that DFM have a reasonable basis for its estimated fiscal impact.

In this case, the FIS posits that, if the Initiative passed, there may be a potential increase in state expenditures for the Medicaid and prisoner populations. However, the evidence in the record before us does not support these conclusions. As a result, the FIS fails to substantially comply with the good faith requirement of section 34-1812.

Both parties submitted evidence to this Court related to DFM's investigation of the fiscal impact of the Initiative. The evidence submitted includes DFM emails with Juliet Charron, the deputy director for Medicaid and Behavioral Health at IDHW. Those emails show that IDHW provided DFM data concerning abortion-related Medicaid claims for the years 2018 through 2022. The emails also indicate that a DFM economist had a phone call and a meeting with Charron. However, none of the materials indicate that DFM spoke with anyone at the IDOC or that it conducted any investigation of whether IDOC paid for any abortion-related care for the prisoner population. While DFM submitted several declarations to this Court, it did not provide a declaration from the economist who prepared the FIS or from anyone else at DFM to explain the evidence gathered, process employed, or reasoning underlying its FIS. DFM did submit two declarations from IDHW employees concerning abortion data and Medicaid claims data. We will evaluate the evidence before us to determine whether the FIS is a good faith statement, or put differently, whether DFM had a reasonable basis for the estimated fiscal impacts contained in the FIS.

Initially, we note that there is no evidence supporting the FIS's statement that there may be a fiscal impact to the IDOC budget due to increased costs for medical care for the prisoner population. There is no evidence that DFM communicated with IDOC or conducted any research relating to the IDOC budget and spending for abortion-related care provided to the prisoner population. As a result, it appears that the FIS's statement that the Initiative could increase the budget for prisoner medical care lacked a reasonable basis and, therefore, was entirely speculative. We hold that the FIS fails to substantially comply with the statutory requirement for a good faith statement as it relates to the estimated impact on the IDOC budget.

Next, we conclude that the FIS lacks a reasonable basis for the estimated impact on the Medicaid budget. While there is evidence that DFM investigated certain Medicaid costs, the evidence is insufficient to support the FIS's estimate that passage of the Initiative may result in additional state expenditures.

The emails between DFM and Charron include data concerning abortion-related Medicaid claims for the years 2018 through 2022:

2018: 2 claims billed, totaling $2,576; $0 paid

2019: 5 claims billed, totaling $9,795; $500 paid

2020: 4 claims billed, totaling $24,323; $9,591 paid

2021: 2 claims billed, totaling $13,806; $0 paid

2022: No claims billed

The emails do not describe what the claims were for or the reasons why the claim amounts were not fully covered by Medicaid.

DFM submitted to this Court a declaration from Miren M. Unsworth, IDHW's deputy director of the Health and Human Services Division. Unsworth's declaration provided data on the "Total Reported Idaho Abortions and Chemical Abortions by Year" between 2015 and 2023. That data indicated that beginning in 2022, the year the United States Supreme Court issued its decision in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), the number of Idaho resident abortions and chemical abortions decreased dramatically.

DFM also submitted to this Court a declaration from Charron. Charron testified that between July 2020 and June 2021, the average monthly enrollment for Idaho Medicaid of women between the ages of 14 and 45 was 97,055. She also testified that Idaho Medicaid provides coverage for treatment and follow-up care at hospitals following abortion complications, including complications from chemically-induced abortions. She stated that it is often difficult to quantify Idaho's costs for providing this coverage due to a variety of factors. She testified that Idaho Medicaid expended $3,025.94 in state funds to cover treatment and follow-up care for abortion-related medical complications in calendar year 2019, and $3,797.42 in state funds in calendar year 2022.

Idahoans United claims that the Initiative would not increase the State dollars expended by Idaho Medicaid on abortion-related claims for two reasons. First, the Initiative specifically states that it "does not create a financial obligation on the state, its agencies, or their programs to pay for,

fund, or subsidize the reproductive health care protected by this act." Second, federal and Idaho law significantly restrict the use of public funds for abortion and the Initiative does not change those laws.

The federal Hyde Amendment prohibits the Secretaries of Labor, Health and Human Services, and Education from utilizing federal funds for any abortion or health benefits coverage that covers abortions except in the case of rape or incest, or where the pregnancy places the mother in danger of death. *See* Further Consolidated Appropriations Act of 2024, Pub. L. No. 118-47, § 506(a), 138 Stat. 460, 703 (2024). The Hyde Amendment is significant in this context because the bulk of Idaho's Medicaid spending is accomplished with federal funds. The Charron Declaration establishes that between July 2020 and July 2021, Idaho Medicaid expended $3.24 billion on all services for Medicaid participants. Of that total, $2.27 billion was federal funds. With regard to state funds, Idaho's "No Public Funds for Abortion Act" provides that no public funds made available by the State can be used to provide for abortions. I.C. § 18-8705(1), (2). Likewise, Idaho Code section 56-209c provides that "[n]o funds available to the department of health and welfare . . . shall be used to pay for abortions" except when necessary to save the life of the mother or in the case of rape or incest. I.C. § 56-209c. The Initiative does not purport to change these laws.

Idahoans United argues that there is no evidence that DFM analyzed whether Idaho Medicaid would be required to cover any additional abortion-related claims if the Initiative passed, given state and federal law restricting the use of public funds and the Initiative's language. DFM notes that Medicaid costs related to abortion complications "are nearly certain to materialize."

We conclude that, while DFM has some evidence indicating that the number of abortions would likely increase if the Initiative passed, it has not established a reasonable basis to support its estimated fiscal impact to the Idaho Medicaid program. DFM argues that there will be a fiscal impact because Medicaid expenses will increase due to complications related to an increased number of chemically induced abortions. However, DFM did not submit a declaration from the DFM economist that prepared the FIS explaining the basis for the estimated fiscal impact. As a result, we are left to review the evidence in the record to determine whether it provides a reasonable basis for the estimated fiscal impact to the Medicaid program. We conclude that it does not.

The only evidence in the record that it appears DFM had when it prepared the FIS are the emails between DFM and IDHW. Neither the Unsworth nor the Charron declarations indicate that the data contained in those declarations was provided to DFM prior to its preparation of the FIS.

The emails only contain data on abortion-related claims made to Idaho Medicaid and the amounts paid on those claims. As noted above, both federal and Idaho law permit Medicaid funds to be used for abortions necessary to save the life of the mother. Charron has also testified that Idaho Medicaid covers claims to treat abortion-related complications resulting from chemically induced abortions. But the emailed claims data does not indicate whether the Medicaid claims paid between 2018 and 2022 were for abortions to save the life of the mother, to treat abortion-related complications resulting from chemically induced abortions, or both. Without knowing how many of the previously paid claims were for abortion-related complications, it is unclear whether the claims data provides a reasonable basis for DFM's estimated fiscal impact on the Medicaid budget.

DFM also points to the Unsworth Declaration as support for its contention that the number of chemically induced abortions will increase. While the Unsworth Declaration indicates that Idaho residents had significantly more abortions before the *Dobbs* decision than after, those numbers fail to differentiate how many of the abortions involved Medicaid recipients. The numbers also fail to differentiate between abortions that Medicaid funds would cover and those that it would not. Finally, the numbers give no indication concerning how many of the women who received chemically induced abortions could be expected to experience abortion-related complications.

The evidence contained in the record does not provide a reasonable basis supporting the estimated fiscal impact to the Medicaid program if the Initiative passed. As previously discussed, Idaho Code section 34-1812 does not require certainty or exactness, but it requires more than speculation or a guess. While DFM consulted IDHW concerning Idaho Medicaid claims, the data received from IDHW is unclear whether there could be an increase in Idaho Medicaid claims for abortion-related complications if the Initiative passes. Given the lack of a reasonable basis in the record to support the estimated fiscal impact in the FIS, we hold that the estimated impact on the Medicaid program failed to substantially comply with the good faith statement requirement of section 34-1812.

Finally, we are not persuaded by Idahoans United's argument that the only good faith estimate is zero fiscal impact because the Initiative stated that it would not impose a financial obligation on the State. Idaho Code section 34-1812 does not require DFM to adopt the Initiative's stated fiscal impact. *See* I.C. § 34-1812. Rather, it authorizes DFM to prepare a good faith statement of the fiscal impact proposed by the law and in doing so, authorizes DFM to work "in

consultation with any other appropriate state or local agency." I.C. § 34-1812(1). DFM would fail to act in good faith if it simply adopted an initiative's assertion that it would have no financial impact. Rather, DFM must conduct its own investigation to prepare the FIS.

2. The FIS does not substantially comply with the clear and concise requirement.

Idahoans United also asserts that the FIS fails to substantially comply with the requirement that it "must be written in clear and concise language." I.C. § 34-1812(2). Idahoans United contends that the FIS contains conflicting statements concerning whether passage of the Initiative will result in increased expenditures. On one hand, the FIS states that:

- "Costs associated with the Medicaid and prisoner populations may occur,"
- "Passage of this initiative is likely to cost less than $20,000 per year," and
- "Changes in costs associated with the ballot initiative could impact state funding expenditures for Corrections [sic] and Medicaid budgets."

However, on the other hand, the FIS states:

- "[T]here is no expected changes to the Corrections [sic] health care budget," and
- "[A]ny additional costs due to the passage of this ballot initiative could be absorbed in the Corrections [sic] and Health and Welfare budgets should the ballot initiative pass."

Idahoans United argues that these conflicting statements are neither concise nor clear, and they create confusion concerning whether the Initiative will have a fiscal impact.

We agree with Idahoans United that these conflicting statements in the FIS fail to substantially comply with the clear and concise requirement contained in section 34-1812(2). As quoted above, the FIS both asserts that passage of the Initiative may have a fiscal impact on the IDOC and Medicaid budgets and that there is no expected change to budgets, or changes could be absorbed in existing budgets. The inclusion of the conflicting statements not only causes confusion but also makes it longer than it would be without the conflicting statements. As a result, the FIS is neither clear nor concise.

Additionally, Idahoans United argues that the FIS is unclear due to its reference to the $850 million Medicaid budget:

> Passage of the initiative is likely to cost less than $20,000 per year. The Medicaid budget for providing services was about $850 million in FY2024. If passed, nominal costs in the context of the affected total budget are insignificant to the state.

Idahoans United argues that inclusion of the Medicaid budget also creates prejudice against the Initiative. DFM argues that it included the Medicaid budget to put the Initiative's expected fiscal impact into context.

We conclude that the reference to the Medicaid budget also fails to substantially comply with the clear and concise requirement. While it is true that Idaho Code section 34-1812(2) allows the FIS to "include a description placing the estimated dollar amounts in context[,]" in the context of this FIS, the reference creates confusion. If we read the FIS to conclude that there are potential increases in IDOC expenditures, the FIS estimates a fiscal impact of $20,000 per year but it does not specify how much of the $20,000 is due to potential increases in IDOC expenditures versus potential increases in Medicaid expenditures. As a result, the total Medicaid budget cannot provide context for the $20,000 estimated impact because we do not know how much of that impact is due to Medicaid expenditures.

If we read the FIS to attribute the entire $20,000 impact to a potential increase in Medicaid expenditures, the total Medicaid budget does little to put that amount into context and undermines the clarity of other statements in the FIS. The FIS already indicates that the changes would be "minor" and "nominal." Listing the total Medicaid budget adds no clarity to this statement and tends to play to the passions of voters who may take issue with the size of the State's Medicaid budget. Instead, it requires citizens to recognize that the total impact is not $850 million and then do the math in their heads to determine how much the total impact is. If they did that math, the estimated increased expenditures are 0.000023% of the Medicaid budget. If the desire is to represent the scope of the impact through a percentage, then DFM should either stick with "nominal," or simply include the percentage and save voters from having to do a math problem in their heads while standing in a voting booth.

3. *The FIS does not substantially comply with the requirement to avoid legal and technical terms whenever possible.*

Idahoans United argues that DFM included unnecessary legal and technical terms by citing statutes:

> The initiative could change state expenditures in minor ways. Costs associated with the Medicaid and prisoner populations may occur; see Idaho Codes 20-237B and 56-255 and the Medicaid references from Health and Welfare.

It contends that the legal citations are unnecessary because the FIS does not explain why they apply to the Initiative. Their inclusion thus creates confusion. DFM responds that it is within its

discretion to decide whether legal terms are unavoidable. Here, it claims that providing the legal citations was necessary to convey what laws would contribute to costs in conjunction with the Initiative.

We hold that DFM's inclusion of legal citations in the FIS fails to substantially comply with the statutory requirement to "avoid legal and technical terms whenever possible." I.C. § 34-1812(2). The references do not assist the FIS in "describ[ing] any projected increase or decrease in revenues, costs, expenditures, or indebtedness" as required by the statute. I.C. § 34-1812(2). The cited statutes do not mention abortions. Rather, they provide that the State will pay for certain medical services. *See* I.C. §§ 20-237B, 56-255. The mention of "Medicaid references" is vague and unclear. The legal terms referencing statutes and vague Medicaid references do nothing to help explain the potential fiscal impact of the Initiative. Indeed, a citation to "see" a specified statute is of little use to a voter standing in a voting booth deciding how to vote.

For the forgoing reasons, we conclude that it was entirely possible for DFM to explain the estimated fiscal impact without including the legal citations.

4. *DFM's references to "Medicaid and prisoner populations" substantially comply with the statutory requirements.*

Finally, Idahoans United argues that DFM's references in the FIS to the "Medicaid and prisoner populations" will prejudice the Initiative because the public generally has a negative impression of those populations, and the references will therefore cause prejudice against the Initiative. DFM responds that "Medicaid and prisoner populations" are not legal or technical terms, and the references are included to provide an explanation of the source for the increased expenditures.

We hold that DFM's use of the terms "Medicaid and prisoner populations" substantially complies with the requirements of Idaho Code section 34-1812. DFM's estimated fiscal impact for the Initiative was based on assumptions related to Idaho's prisoner population and Medicaid recipients. DFM's inclusion of this information substantially complies with the statute because it explains the basis for the estimated fiscal impact.

To summarize, we agree with some, but not all, of Idahoans United's arguments concerning the FIS. We hold that the FIS does not substantially comply with the requirements of Idaho Code section 34-1812 because its estimate lacks a good faith basis, it is not clear, and it unnecessarily includes legal terms. However, we conclude that references to the Medicaid and prisoner

populations do not prejudice the Initiative and therefore substantially comply with the statutory requirements applicable to the FIS.

C. The short ballot title does not substantially comply with Idaho Code section 34-1809.

Idahoans United next argues that the short ballot title drafted by the Attorney General fails to comply with Idaho Code section 34-1809 because it uses uncommon terms and it is not distinctive or comprehensive. We agree with Idahoans United on the latter argument and hold that the short title does not substantially comply with Idaho Code section 34-1809 because it fails to capture all of the distinctive features of the Initiative.

As noted, Idaho Code section 34-1809 requires the Attorney General to draft ballot titles for voter initiatives. I.C. § 34-1809(2)(a). The ballot title must contain "a short title of no more than twenty (20) words . . . . The short title must provide a distinctive statement by which the measure would be commonly referred. *Buchin v. Lance* (*In re Writ of Prohibition Entitled "Ballot Title Challenge Oral Arg. Req."*), 128 Idaho 266, 269, 912 P.2d 634, 637 (1995) (citing I.C. § 34-1809). When reviewing ballot titles, this Court considers whether the Attorney General substantially complied with the requirements of section 34-1809. *Open Primaries*, 172 Idaho at 479, 533 P.3d at 1275. This Court has "long recognized that 'it is not the Court's role to find another way or the best way to draft a [ballot] title, but rather to examine the Attorney General's language and ask whether it expresses the purpose of the measure without being argumentative or prejudicial.' " *Id.* (quoting *Buchin*, 128 Idaho at 270, 912 P.2d at 638).

1. *The short title substantially complies with the statutory requirement to use language by which the Initiative is commonly referred.*

The Attorney General prepared the following short title for the Initiative:

> Measure establishing a right to abortion up to fetus viability and to make reproductive decisions regarding one's own body.

Idahoans United argues that the short title fails to substantially comply with Idaho Code section 34-1809 because the phrase "fetus viability" is not language by which the measure is commonly referred or spoken of and it will therefore prejudice the Initiative. The Attorney General counters that the phrase "fetus viability" is a common phrase that substantially complies with the statute and is not argumentative or prejudicial.

We conclude that the phrase "fetus viability" has been used before in Idaho and is a variation of Idahoans United's suggested phrase "fetal viability." The two phrases employ different parts of speech for the same word and as such, the meaning of the two phrases does not

substantially differ. As a result, we hold that the short title substantially complies with the requirement that it use language by which the measure is commonly referred.

"The plain and unambiguous language of section 34-1809(2)(d)(i) requires the Attorney General to ascertain how an initiative is commonly referred to or spoken of and incorporate that language into the short title." *Open Primaries*, 172 Idaho at 481, 533 P.3d at 1277. "This task necessarily requires the Attorney General to determine how Idahoans commonly refer to and speak of the measure." *Id.* "When ascertaining the language used to commonly refer to the measure, the Attorney General must remain mindful that the statute requires him to use language that is not 'intentionally an argument or likely to create prejudice either for or against the measure.' " *Id.* (citing I.C. § 34-1809(2)(e)). The Attorney General can achieve this by, "to the best of his ability, giv[ing] a true and impartial statement of the purpose of the measure." I.C. § 34-1809(2)(e).

Idahoans United argues that the situation here is nearly identical to the one we addressed in our decision in *Open Primaries*. We disagree. In *Open Primaries*, this Court determined that the phrase "nonparty blanket primary" had not been used by any court in the United States, including the United States Supreme Court and that "it appear[ed] that the term [was] one of the Attorney General's own creation." *Id.* at 481, 533 P.3d at 1277. We also determined that the term would likely prejudice the initiative because it was confusingly similar to a different term used by the United States Supreme Court:

> The Supreme Court held that a "partisan blanket primary" is unconstitutional, but a "nonpartisan blanket primary" is constitutional. It has never discussed a "nonparty blanket primary." Using an undefined term that is very similar to, but slightly different from those discussed by the Supreme Court could cause a voter to conclude that the system proposed in the [i]nitiative has been or would be held unconstitutional, when in fact it has not.

Id. at 484, 533 P.3d at 1280.

The situation in *Open Primaries* is distinguishable from that in this action. First, the phrase "fetus viability" is not a new, undefined term of the Attorney General's own creation. In *Buchin*, the Attorney General advanced a ballot title that referred to a "viable fetus." *Buchin*, 128 Idaho at 269, 912 P.2d at 637. The parties did not challenge the use of that phrase, and this Court determined the ballot title was insufficient on other grounds. *Id.* at 272–73, 912 P.2d at 640–41. However, this Court wrote a ballot title that it "would deem acceptable[,]" which included the phrase "fetus viability." *Id*. at 273, 912 P.2d at 641. Thus, the phrase has been used in Idaho. Further, the Idaho Code discusses when a "fetus becomes viable" and a "viable fetus." I.C. § 18-604(13) to (15). As

a result, this action is distinguishable from *Open Primaries* because the challenged phrase is not one of the Attorney General's own creation and is one that has been used in Idaho.

This action is also distinguishable from *Open Primaries* because the phrase "fetus viability" is not likely to create confusion. In *Open Primaries*, we concluded that the Attorney General's terminology was likely to prejudice the initiative because it could confuse voters concerning the constitutionality of the initiative given its similarity to the name of two other voting systems discussed by the United States Supreme Court. *Id.* The short ballot title in this action is different. The words "fetus" and "fetal" are different parts of speech used for the same concept; one is a noun and the other is an adjective. *Fetus*, Merrium-Webster's Online Dictionary (assigning "fetus" as a noun); *Fetal*, Merrium-Webster's Online Dictionary (assigning "fetal" as an adjective, defined as "of, relating to, or being a *fetus*"). Regardless of which form of speech is used, the meaning is substantially the same and therefore not confusing. Applying the relevant legal standard, we hold that in this instance, the use of the term "fetus viability" substantially complies with the statutory requirement that the short title not create prejudice against the Initiative.

Next, Idahoans United argues that the phrase "*fetal* viability" is significantly more common in Idaho than the phrase "*fetus* viability." Idahoans United's argument may be persuasive if we employed a de novo standard to review the short ballot title. The applicable legal standard, however, is one of substantial compliance. *Open Primaries*, 172 Idaho at 479, 533 P.3d at 1275. Applying this standard does not involve reviewing the short title to determine if the Attorney General used the most common term, but instead whether the Attorney General accomplished the general purpose of the statute. We reiterate that "it is not the Court's role to find another way or the best way to draft a [ballot] title, but rather to examine the Attorney General's language and ask whether it expresses the purpose of the measure without being argumentative or prejudicial." *Id.* (quoting *Buchin*, 128 Idaho at 270, 912 P.2d at 638). Given that the phrase "fetus viability" has substantially the same meaning as Idahoans United's suggested phrase "fetal viability," and given that Idaho has some history of using the term "fetus viability," we hold that the short title substantially complies with the statute's common language requirement.

Idahoans United also argues that using the phrase "fetus viability" rather than "fetal viability" would prejudice the Initiative. It presented a declaration from Dr. Hillary Shulman, Ph.D., an associate professor at Ohio State University, who studies how word choice influences information processing and public engagement in politics. She opines that the individual term

"fetus" will lead people to have a more emotional response to the Initiative and thereby cause prejudice against it, while use of the term "fetal" would lead the public to have a more cognitive response.

The Attorney General first argues this Court may not consider Dr. Shulman's testimony because the expedited briefing schedule requested by Idahoans United causes difficulty in obtaining discovery concerning Idahoans United's expert and in obtaining a rebuttal expert. The Attorney General argues that the evidentiary record in this case should be limited to information the Attorney General could have considered when writing the ballot titles.

The Attorney General's arguments are unpersuasive. To the extent the Attorney General argues he is prejudiced by our consideration of the expert's testimony, he did not oppose Idahoans United's motion to expedite, move for expedited discovery concerning Dr. Shulman's report, or move for additional time to submit an opposing expert declaration. We observe that the Attorney General had more time to obtain an expert declaration than Idahoans United. Idahoans United only had twenty days to file its petition after receiving the ballot titles. I.C. § 34-1809(3)(a). After this Court granted the motion to expedite and set a briefing schedule, the Attorney General received an extension for the due date to file a response brief. The Attorney General thus had over a month to obtain a declaration from an opposing expert, which exceeded the twenty days Idahoans United had to prepare its expert's declaration. We find no prejudice to the Attorney General in this circumstance.

Nor has the Attorney General cited any rule of evidence precluding admission of the declaration or constraining our ability to consider it. In fact, when exercising our original jurisdiction, this Court often reviews evidence submitted in declarations so long as the testimony complies with the Idaho Rules of Evidence. *See, e.g.*, *Planned Parenthood Great Nw. v. State*, 171 Idaho 374, 398–99, 522 P.3d 1132, 1156–57 (2022); *Reclaim Idaho v. Denney*, 169 Idaho 406, 416–17, 497 P.3d 160, 170–71 (2021); *Ybarra v. Legislature by Bedke*, 166 Idaho 902, 907–08, 466 P.3d 421, 426–27 (2020). We therefore will consider the declaration of Idahoans United's expert.

However, nothing in the testimony of Idahoans United's expert alters our conclusion that the short title's use of "fetus viability" substantially complies with section 34-1809. Idahoans United's expert opines that the term "fetal" would be less likely to prejudice the Initiative. As previously discussed, the terms "fetus" and "fetal" are different parts of speech concerning the

same concept, so the meanings of the two phrases are substantially the same. As a result, we cannot conclude that fetus viability does not substantially comply, but fetal viability would. It bears repeating that we are not employing a de novo standard of review, and that it is not our role to determine whether the Attorney General used the best language for the short title. *See Open Primaries*, 172 Idaho at 486, 533 P.3d at 1262 ("While we understand that Petitioners would prefer different language, 'it is not the Court's role to find another way or the best way to draft a long title[.]' " (quoting *Buchin*, 128 Idaho at 270, 912 P.2d at 638)).

2. *The short title fails to substantially comply with the distinctive and comprehensive requirement.*

Idahoans United also argues that the short title is not distinctive and comprehensive because it omits two important characteristics of the Initiative: the right to abortion in medical emergencies and the right to privacy. The Attorney General contends that the short title is distinctive because it highlights the "[I]nitiative's most distinctive change to Idaho law." He claims that the Initiative includes too many distinctive features to fit in a twenty-word short title, but that the short title properly sets forth the general topic of the Initiative and informs potential signers of what they would be sponsoring.

"In drafting the short title, the Attorney General must, by force of circumstances, analyze and appraise the initiative in order to determine what the initiative means and its *distinctive* characteristics. *The short title is to be comprehensive in nature*." *Buchin*, 128 Idaho at 270, 912 P.2d at 638 (emphasis added) (citing *In re The Pet. of Idaho State Fed'n of Labor (AFL)*, 75 Idaho 367, 373, 272 P.2d 707, 710 (1954)). "The Court has defined 'distinctive' as a statement that would refer to that which would distinguish one thing as it related to other things." *Id.* at 272, 912 P.2d at 640 (citing *AFL*, 75 Idaho at 373, 272 P.2d at 710). "[I]n order to be distinctive, a short title must communicate the chief characteristics of the initiative—including, when necessary how the initiative proposes to alter current law." *Open Primaries*, 172 Idaho at 482, 533 P.3d at 1278 (first citing *Buchin*, 128 Idaho at 272, 912 P.2d at 640; and then citing *Am. Civ. Liberties Union, Idaho Chapter v. Echohawk*, 124 Idaho 147, 151, 857 P.2d 626, 630 (1993)). "When assessing the sufficiency of a short title, the fundamental inquiry is whether the short title sets forth the characteristics which distinguish this proposed measure and expeditiously and accurately acquaint the prospective signer with what he or she is sponsoring." *Open Primaries*, 172 Idaho at 482, 533 P.3d at 1278 (cleaned up) (quoting *Echohawk*, 124 Idaho at 151, 857 P.2d at 630).

The Attorney General claims that there are at least ten key characteristics in the Initiative and they cannot all be included in the short title. In contrast, Idahoans United argues that there are three key characteristics in the Initiative and that the short title fails to acknowledge two of them. We conclude that the Initiative contains four distinctive characteristics because it proposes four changes to existing Idaho law:

- It establishes a statutory right to abortion before the viability of the fetus.

  Idaho law currently criminalizes the termination or attempted termination of a clinically diagnosable pregnancy except when "necessary to prevent the death of the pregnant woman" or during the first trimester in certain cases of rape or incest. I.C. § 18-622(2)(a)(i). The Initiative would create an unfettered right to abortion prior to fetal viability, which the Initiative defines as the point when "the fetus has a significant likelihood of sustained survival outside of the uterus without extraordinary medical measures."

- It establishes a statutory right to abortion after fetal viability to protect the health of the mother.

  As discussed above, existing Idaho law only permits the termination of a clinically diagnosable pregnancy in limited circumstances. I.C. § 18-622(2)(a)(i). The Initiative proposes to change Idaho law by allowing abortions after fetal viability if continued pregnancy may "place the health of the pregnant patient in serious jeopardy," "cause serious impairment to a bodily function," or "cause serious dysfunction of any bodily organ."

- It establishes statutory protections for healthcare providers.

  Idaho law currently states it is a crime to perform or attempt to perform an abortion. I.C. § 18-622(1). Further, healthcare professionals who perform, attempt to perform or assist in performing an abortion may have their professional licenses suspended. *Id.* The Initiative would limit the criminal and licensure liability of healthcare providers: "[i]n no case may reproductive health care provided consistent with this act by a health care provider be a basis for professional discipline, civil liability, or criminal liability."

- It establishes a statutory right to freedom in making reproductive healthcare decisions.

> The Initiative creates a "right to reproductive freedom and privacy," which includes "the right of privacy in making personal decisions about reproductive health care in consultation with a health care provider."

We conclude that the Attorney General's short title fails to capture two key characteristics of the Initiative: the expanded right to an abortion post-viability and the limitations on healthcare provider liability. In doing so, the short title indicates that the Initiative only concerns two changes to Idaho law: a right to abortion up to fetal viability and a right to make reproductive healthcare decisions. As a result, the short title is misleading and fails to "accurately acquaint the prospective signer with what he or she is sponsoring." *See Open Primaries*, 172 Idaho at 482, 533 P.3d at 1278 (cleaned up) (quoting *Echohawk*, 124 Idaho at 151, 857 P.2d at 630).

However, we do not agree with Idahoans United that the short title fails to accurately capture the right to privacy aspect of the Initiative. The short title provides that the Initiative establishes "a right . . . to make reproductive decisions regarding one's own body." In comparison, the Initiative defines the right to reproductive freedom and privacy as "the right to make personal decisions about reproductive health care that directly impact the person's own body." The short title language is very similar to the Initiative's definition of the right to privacy. We conclude that the short title therefore accurately captures the right to privacy aspect of the Initiative.

We are not persuaded by the Attorney General's argument that the short title is substantially compliant with the distinctiveness requirement because it includes the "general topic" of the Initiative. Citing our decision in *Echohawk*, the Attorney General claims that the short title does not need to be "all-encompassing" to be distinctive. Our decision in *Echohawk* is distinguishable.

In *Echohawk*, the petitioners filed an initiative that proposed several changes to then-existing Idaho law. 124 Idaho at 151, 857 P.2d at 630. The Court identified four distinctive elements of the initiative:

> the prohibition of granting homosexuals "minority status," the prohibition of "same-sex marriages" and "domestic partnerships," restrictions against discussing homosexuality in the public schools, and restrictions against the expenditure of public funds for certain purposes relating to homosexuals.

Id. The Attorney General's short title stated: "An act establishing state policies regarding homosexuality." *Id.* at 149, 857 P.2d at 628. The Court found that the short title included the

distinctive characteristic of the initiative that "it would establish various state policies towards homosexuality." *Id.* at 151, 857 P.2d at 630.

In *Echohawk*, the Court specifically noted that the short title captured the *distinctive* characteristic of the initiative, which was to establish state policies relating to homosexuality. *Id.* This action presents a different situation. Here, because the short title only identifies two distinctive characteristics, it suggests that those are the only two changes to Idaho law proposed by the Initiative. While the Attorney General's short title in this case may identify what he believes to be the Initiative's most distinctive changes, the Initiative proposes to change Idaho law in other significant ways. Different people may find different aspects of the Initiative to be the most distinctive. For instance, the most important characteristic of the Initiative to healthcare providers may be that it limits their liability in certain circumstances. Another group may find the most distinctive feature to be the expanded right to an abortion after fetal viability to protect the health of the mother. However, the short title fails to alert a prospective signer to either of these proposed changes to Idaho law.

We acknowledge that fitting the distinctive characteristics of an initiative into twenty words is a challenging task. Idaho law, however, has long required that the short title be distinctive and comprehensive. *AFL*, 75 Idaho at 373, 271 P.2d at 710 ("[T]his short title . . . must also be distinctive."); *Echohawk*, 124 Idaho at 151, 857 P.2d at 631 ("[T[he fundamental inquiry is whether the short title is 'distinctive.' "); *Buchin*, 128 Idaho at 270, 912 P.2d at 638 ("The short title is to be comprehensive in nature."). While *Echohawk* provides one example of how this may be done for a short title with multiple distinctive elements, the Attorney General is not constrained to the method used in *Echohawk.* It may be possible to include all four characteristics into a twenty-word short ballot title. The Attorney General is free to exercise his discretion in writing the short ballot title so long as he substantially complies with the statutory requirements in a manner consistent with this opinion.

D. The long title substantially complies with Idaho Code section 34-1809.

The Attorney General's long ballot title states:

> The measure seeks to change Idaho's laws by introducing a right to reproductive freedom and privacy including a right to abortion up to the point of the fetus's ability to survive outside the womb. After fetal viability, there would be no general right to abortion except in cases of "medical emergency." The "medical emergency" exception would expand Idaho's current life exception and allow abortions when pregnant women face complicating physical conditions that

> threaten their life or health, "including serious impairment to a bodily function" or "serious dysfunction of any bodily organ or part."
>
> The proposed measure codifies a right to make reproductive decisions, including contraception, fertility treatment, and prenatal and postpartum care. This includes a "right of privacy" in making these decisions. The measure seeks to prevent the state from enforcing certain abortion laws protecting the life of the unborn child. It would also impose a requirement that any restrictions on reproductive decisions, including abortion prior to fetus viability, must be "narrowly tailored to improve or maintain the health of the person seeking reproductive health care." The measure would also prevent the state from penalizing patients, healthcare providers, or anyone who assists in exercising the proposed right.

Idahoans United argues that the long title is prejudicial because "fetus viability" is "uncommon and potentially politically charged terminology." It further argues that the long title is confusing because it uses the phrases "fetus viability" and "fetal viability" interchangeably.

Idaho Code section 34-1809 tasks the Attorney General with writing a long title "expressing in not more than two hundred (200) words the purpose of the measure." I.C. § 34-1809(2)(d)(ii). "[U]nlike the short title, the long title is not required to be distinctive or to use language by which the measure is commonly referred to or spoken of." *Open Primaries*, 172 Idaho at 487, 533 P.3d at 1283. It bears repeating that "[i]t is not the Court's role to find another way or the best way to draft a long title, but rather to examine the Attorney General's language and ask whether it expresses the 'purpose of the measure' without being argumentative or prejudicial." *Id.*

For the reasons previously discussed, we hold that the phrase "fetus viability" substantially complies with the statutory requirement that the language of the long title not prejudice the Initiative. We further hold that the use of both "fetal viability" and "fetus viability" in the long title does not create confusion. As previously noted, the terms "fetus" and "fetal" are different parts of speech describing the same concept and as a result the use of both phrases is not confusing. We hold that the long title substantially complies with Idaho Code section 34-1809.

E. We retain jurisdiction of this matter and issue writs of mandamus ordering DFM to provide a new FIS and ordering the Attorney General to provide a new short ballot title to this Court for review.

Having determined that the FIS and the short ballot title fail to substantially comply with Idaho law, we now turn to the appropriate remedy. Idahoans United asks this Court to certify the FIS and short ballot title drafted by Idahoans United. In the alternative, it asks us to issue writs of mandamus to DFM and the Attorney General directing them to issue an FIS and a short ballot title

in accordance with Idaho law. We decline to certify the FIS or the ballot titles provided by Idahoans United and instead issue writs of mandamus to DFM and the Attorney General.

As in *Open Primaries*, the most appropriate remedy in this action is to retain jurisdiction of this matter and order DFM to provide a statutorily compliant FIS and order the Attorney General to provide a statutorily compliant short ballot title. *See Open Primaries*, 172 Idaho at 490, 533 P.3d at 1286. It is not appropriate at this stage for the Court to dictate the details of either document or draft a short ballot title itself. However, given that the people's constitutional right to direct legislation reserved in Article III, section 1 of the Idaho Constitution is at issue, and the time concerns expressed by Idahoans United, we will retain jurisdiction to ensure a timely resolution of this action. *Id.*

We understand that DFM may require some time to gather the necessary information and input to calculate the fiscal impact of the Initiative's proposed changes to Idaho law. Accordingly, we will give DFM seven calendar days to prepare a new FIS. We order DFM to provide a new FIS that complies with Idaho Code section 34-1812 to this Court by 4 p.m. MDT on June 23, 2025. To avoid further litigation concerning the reasonable basis for any estimated impact that may be described in the FIS, we also order DFM to submit a sworn declaration by the preparer of the FIS describing the process utilized, including the evidence gathered and the assumptions utilized to create the FIS. We will review the FIS and supporting declaration to determine whether it substantially complies with section 34-1812. No further briefing or oral argument will be granted concerning the new FIS.

We order the Attorney General to provide a new short title to this Court. In the interest of consistency, we will also grant the Attorney General seven calendar days to prepare a new short ballot title. We order the Attorney General to provide a new short ballot title that complies with Idaho Code section 34-1809 to this Court by 4 p.m. MDT on June 23, 2025. We will review the short ballot title to determine whether it substantially complies with the statute. No further briefing or oral argument will be granted concerning the short ballot title.

F. We decline to grant attorney fees to Idahoans United.

Idahoans United seeks attorney fees under Idaho Code section 12-117(1). Idaho Code section 12-117(1) allows the prevailing party in a proceeding between a person and a governmental entity to be awarded attorney fees if the "nonprevailing party acted without a reasonable basis in fact or law." I.C. § 12-117(1); *Open Primaries*, 172 Idaho at 491, 533 P.3d at 1287. This Court

"examines the prevailing party question from an overall view, not a claim-by-claim analysis." *Open Primaries*, 172 Idaho at 491, 533 P.3d at 1287 (quoting *Dep't of Transp. v. Grathol*, 158 Idaho 38, 53, 343 P.3d 480, 495 (2015)).

Considering the mixed results in this action, and taking an overall view of the proceedings, we decline to grant attorney fees to Idahoans United against DFM. The claims against DFM presented an issue of first impression and DFM's arguments were reasonable. We also decline to grant attorney fees to Idahoans United against the Attorney General. Both parties prevailed in part and therefore we hold there is no prevailing party for purposes of attorney fees.

V. CONCLUSION

For the reasons discussed herein, we dismiss the Petition against the Secretary of State, partially grant the Petition for writs of mandamus against DFM and the Attorney General, and deny the Petition for writs of certiorari.

We retain jurisdiction of this matter and order DFM to provide a new FIS that complies with Idaho Code section 34-1812 to this Court by 4 p.m. MDT on June 23, 2025. At that time, DFM shall also file with this Court a sworn declaration by the preparer of the submitted FIS that explains the process utilized, evidence gathered, and assumptions used to create the new FIS. We order the Attorney General to submit a new short ballot title that complies with Idaho Code section 34-1809 to this Court by 4 p.m. MDT on June 23, 2025. No party is awarded costs or attorney fees.

Chief Justice BEVAN, and Justices BRODY, MOELLER, and MEYER CONCUR.

ON THE SUBMISSION OF A NEW FISCAL IMPACT STATEMENT AND A NEW SHORT BALLOT TITLE

ZAHN, Justice.

DFM timely submitted a new FIS along with a sworn declaration by the preparer of the submitted FIS in accordance with this Court's June 16, 2025, opinion and order. The new FIS states:

> ***Summary of Fiscal Impact Statement***
> The State estimates the initiative would increase state expenditures between $3,100 and $7,800 annually, less than 0.001% of the state share of Idaho's Medicaid budget. This impact is derived from the costs of treating chemical abortion complications for women enrolled in Idaho's Medicaid program. Medicaid covers medically necessary services to treat complications from all abortions. It is

anticipated that as legal abortions increase, the complications will also increase. This will likely result in an increase in Medicaid covered services and expenditures to treat complications from chemical abortions, which the State has reliable and readily available data to support.

Detailed Statement of Fiscal Impact Including Assumptions

Based on the amount of reliable data gathered by the Division [sic] Financial Management (DFM) and the outcome of the initiative (if passed), DFM limited its assumptions about any increase in costs to the state to those costs arising from the treatment of Medicaid recipients for chemical abortion complications. DFM does not have reliable and readily accessible data to reasonably calculate the fiscal impact attributable to the complications for surgical abortions.

Based on data provided by Department of Health and Welfare (DHW), DFM considered the number of childbearing women on Medicaid in 2021 which was 97,055. This represents about 25% of the total Idaho population for women in this same age group. DFM assumed that, as a result of this initiative, the number of chemical abortions conducted annually would increase to the levels prior to 2022, the year of the U.S. Supreme Court's decision returning the regulation of abortion to the States. Based on the number of chemical abortions performed in Idaho using the 2021 data from the vital records report (approximately 1,180), DFM assumed 25% (approximately 300) of those individuals were Medicaid recipients.

Taking the number of Medicaid recipients who would receive a chemical abortion, DFM assumed that 2% - 5% of those chemical abortions would result in complications. DFM assumed this based on information provided in (1) the United State's [sic] Food and Drug Administration's warning label for the Mifeprex and (2) studies related to abortion complications that were published on the National Library of Medicine website, which DHW provided to DFM.

Based on the claims for complications from chemical abortions provided by DHW for 2019 and 2022 claims data, DFM applied an average per person claim cost and added a 4% medical inflation year over year to account for current medical costs in FY2026. Based on that calculation, DFM assumes that about 300 individuals on Medicaid in Idaho could receive a chemical abortion and of those, 6 to 15 individuals could have complications from that chemical abortion with an average claim cost of about $531 (state portion of the cost). Based on the process utilized, evidence readily available and gathered, and assumptions used to create the fiscal impact statement, total expenditures for the state would range from $3,100 to $7,800 per year.

While the specific fiscal impact to the state's expenditures is difficult to quantify, DFM cannot in good faith conclude that the proposed initiative will have no fiscal impact on state expenditures.

Having reviewed the new FIS and accompanying declaration, we conclude that the new FIS is consistent with the views expressed in our prior opinion dated June 16, 2025. We also conclude that the FIS substantially complies with the requirements of Idaho Code section 34-1812.

The Attorney General timely submitted a new short ballot title in accordance with this Court's June 16, 2025, opinion and order. The revised short ballot title states:

> Measure creating right to abortion before fetus viability, and post-viability to protect health; right to privacy; healthcare provider liability protections.

Having reviewed the new short ballot title, we conclude that it is consistent with the views expressed in our prior opinion dated June 16, 2025, and that it also substantially complies with the requirements of Idaho Code section 34-1809. Therefore, we certify the new short ballot title to the Idaho Secretary of State as required by Idaho Code section 34-1809(3)(c).

Chief Justice BEVAN, and Justices BRODY, MOELLER, and MEYER CONCUR.

EXHIBIT 56

HHS, Identification of Drug and Biological Products Deemed to Have Risk Evaluation and Mitigation Strategies for Purposes of the Food and Drug Administration Amendments Act of 2007, 73 Fed. Reg. 16,313, 16,314 (Mar. 27, 2008)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0174]

Identification of Drug and Biological Products Deemed to Have Risk Evaluation and Mitigation Strategies for Purposes of the Food and Drug Administration Amendments Act of 2007

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing this notice to notify holders of certain prescription new drug and biological license applications that they will be deemed to have in effect an approved risk evaluation and mitigation strategy (REMS) under the Food and Drug Administration Amendments Act of 2007 (FDAAA). Holders of applications deemed to have in effect an approved REMS are required to submit a proposed REMS to FDA.

DATES: Submit proposed REMSs to FDA by September 21, 2008.

ADDRESSES: Written communications regarding the applicability of this notice to a specific product should be identified with Docket Number FDA–2008–N–0174 and submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic communications to *http://www.regulations.gov*. Information about FDA implementation of FDAAA is available on the Internet at *http://www.fda.gov/oc/initiatives/advance/fdaaa.html*.

FOR FURTHER INFORMATION CONTACT: Mary Dempsey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4326, Silver Spring, MD 20993–0002, 301–796–0147.

SUPPLEMENTARY INFORMATION:

I. Introduction

On September 27, 2007, the President signed into law FDAAA (Public Law 110–85). Title IX, subtitle A, section 901 of FDAAA created new section 505–1 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355–1). Section 505–1(a) of the act authorizes FDA to require persons submitting certain applications[1] to submit and implement a REMS if FDA determines that a REMS is necessary to ensure that the benefits of a drug outweigh the risks of the drug and informs the holder of the application for the drug of the determination. Section 909 of FDAAA provides that Title IX, subtitle A takes effect 180 days after its enactment, which is March 25, 2008.

FDAAA also contains REMS requirements for drug and biological products approved before the effective date of Title IX, subtitle A. Section 909(b)(1) of FDAAA specifies that a ''drug that was approved before the effective date of this Act is * * * deemed to have in effect an approved risk evaluation and mitigation strategy under section 505–1 of the Federal Food, Drug, and Cosmetic Act * * * if there are in effect on the effective date of this Act elements to assure safe use—(A) required under section 314.520 or section 601.42 of title 21, Code of Federal Regulations; or (B) otherwise agreed to by the applicant and the Secretary [of Health and Human Services] for such drug.''

Section 909(b)(3) of FDAAA states: ''Not later than 180 days after the effective date of this Act, the holder of an approved application for which a risk evaluation and mitigation strategy is deemed to be in effect * * * shall submit to the Secretary a proposed risk evaluation and mitigation strategy. Such proposed strategy is subject to section 505–1 of the Act as if included in such application at the time of submission of the application to the Secretary.''[2]

Section 909(b)(2) of FDAAA states that a REMS for a drug deemed to have a REMS consists of the timetable required under section 505–1(d) of the act and any additional elements under section 505–1(e) and (f) of the act in effect for the drug on the effective date of FDAAA.

The purpose of this notice is to identify those drugs that FDA has determined will be deemed to have in effect an approved REMS and to notify holders of applications for such drugs that they are required to submit a proposed REMS by September 21, 2008. FDA is developing guidance on the preferred content and format of a proposed REMS required to be submitted under section 909(b) of FDAAA and will issue it as soon as possible.

II. List of Drug and Biological Products Deemed to Have a REMS

Drug and biological products deemed to have in effect an approved REMS are those that on March 25, 2008 (the effective date of Title IX, subtitle A of FDAAA), had in effect ''elements to assure safe use.'' ''Elements to assure safe use'' include the following: (1) Health care providers who prescribe the drug have particular training or experience, or are specially certified; (2) pharmacies, practitioners, or health care settings that dispense the drug are specially certified; (3) the drug is dispensed to patients only in certain health care settings, such as hospitals; (4) the drug is dispensed to patients with evidence or other documentation of safe use conditions, such as laboratory test results; (5) each patient using the drug is subject to certain monitoring; or (6) each patient using the drug is enrolled in a registry (see section 505–1(f)(3) of the act).

Some applications approved before the effective date of FDAAA Title IX, subtitle A contain these elements to assure safe use.[3] Some of these applications were approved under § 314.520 (21 CFR 314.520) or § 601.42 (21 CFR 601.42). Others were not approved under part 314, subpart H or part 601, subpart E, but still contain elements to assure safe use that were agreed to by the applicant and the Secretary for such drug. Since 2005, these elements typically appeared in approved risk minimization action plans (RiskMAPs) (see the guidance for industry entitled ''Development and Use of Risk Minimization Action Plans'' (70 FR 15866, March 29, 2005)).

FDA has reviewed its records to identify applications that were approved before the effective date of Title IX of FDAAA with elements to assure safe use and has identified the drug and biological products listed in table 1 of this document as those that will be deemed to have in effect an approved REMS.

[1] Section 505(p)(1) of the act (21 U.S.C. 355(p)(1)) states that section 505–1 of the act applies to applications for prescription drugs approved under section 505(b) or (j) of the act and applications approved under section 351 of the Public Health Service Act (42 U.S.C. 262).

[2] Title IX, subtitle A of FDAAA, which includes section 909, takes effect March 25, 2008; 180 days after that date is September 21, 2008.

[3] These plans sometimes contain other elements to minimize risk such as a Medication Guide (21 CFR part 208) or a communication/educational plan for health care providers or patients. A drug will not be deemed to have a REMS if it has only a Medication Guide, patient package insert, and/or communication plan (see section 505–1(e)(2) and (e)(3) of the act).

TABLE 1.—PRODUCTS DEEMED TO HAVE IN EFFECT AN APPROVED REMS

Generic or Proper Name	Brand Name	Application Number[1]	Date of Approval[2]
Abarelix	Plenaxis[3]	NDA 21–320	11/25/2003
Alosetron	Lotronex	NDA 21–107	02/09/2000
Ambrisentan	Letairis	NDA 22–081	06/15/2007
Bosentan	Tracleer	NDA 21–290	11/20/2001
Clozapine	Clozaril	NDA 19–758 ANDA 74–949 ANDA 75–417 ANDA 75–713 ANDA 75–162 ANDA 76–809	09/26/1989 11/26/97 5/27/99 11/15/02 4/26/05 12/16/05
	Fazaclo ODT	NDA 21–590	02/09/2004
Dofetilide	Tikosyn	NDA 20–931	10/01/1999
Eculizumab	Soliris	BLA 125166	03/16/2007
Fentanyl PCA	Ionsys[3]	NDA 21–338	05/22/2006
Fentanyl citrate	Actiq	NDA 20–747	11/04/1998
Isotretinoin	Accutane Amnesteem Claravis	NDA 18–662 ANDA 75–945 ANDA 76–135 ANDA 76–356	05/07/1982 11/2002 04/2003 04/2003
	Sotret	ANDA 76–041 ANDA 76–503	12/2002 06/2003
Lenalidomide	Revlimid	NDA 21–880	12/27/2005
Mifepristone	Mifeprex	NDA 20–687	09/28/2000
Natalizumab	Tysabri	BLA 125104	11/23/2004
Small pox (Vaccinia) Vaccine, Live	ACAM2000	BLA 125158	08/31/2007
Sodium oxybate	Xyrem	NDA 21–196	07/17/2002
Thalidomide	Thalomid	NDA 20–785 NDA 21–430	07/16/1998

[1] New drug application (NDA), abbreviated new drug application (ANDA), biologics license application (BLA).
[2] The original date of approval of the drug. FDA may have required elements to assure safe use at a later date.
[3] Product is not currently marketed in the United States.

FDA is further asking members of the public to please notify the agency if they are aware of applications that have not been identified in this document and that they believe should be deemed to have in effect an approved REMS. Please provide the information to Mary Dempsey, Risk Management Coordinator (see the **FOR FURTHER INFORMATION CONTACT** section of this document).

Any application holder that believes its product identified in this notice should not be on the list of drug or biological products that will be deemed to have in effect an approved REMS should submit a letter identified with Docket Number FDA–2008–N–0174 to the Division of Dockets Management (see **ADDRESSES**) stating why the application holder believes its product was improperly identified in this notice. FDA will notify the application holder within 30 days of receipt of the letter of its determination.

Dated: March 19, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–6201 Filed 3–26–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committees: Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

EXHIBIT 57

FDA, Questions and Answers on FDA's Adverse Event Reporting System (FAERS)

U.S. Department of Health and Human Services
Food and Drug Administration

FDA Adverse Events Reporting System (FAERS) Public Dashboard

The FAERS public dashboard is a new, user-friendly and interactive web-based tool that was created to give the public the ability to query the FDA FAERS database and improve transparency. The data presented in the FAERS public dashboard has several key limitations. The existence of adverse event reports for a drug or biologic in FAERS does not mean that the drug or biologic caused the adverse event. Importantly, the FAERS data is not an indicator of the safety profile of the drug or biologic. For more information, please refer to the question What points should I consider while viewing the dashboard content?

Frequently Asked Questions (FAQs)

Expand all | Collapse all

General Questions

[+] What is FAERS?

[+] How does FDA use the information in FAERS?

[+] Who sends reports to FAERS?

[+] How can I report an adverse event or medication error to FDA?

[+] Can mandatory reporters submit adverse events electronically?

[–] Does FAERS data have limitations?

Yes, FAERS data does have limitations. First, there is no certainty that the reported event (adverse event or medication error) was due to the product. FDA does not require that a causal relationship between a product and event be proven, and reports do not always contain enough detail to properly evaluate an event. Furthermore, FDA does not receive reports for every adverse event or medication error that occurs with a product. Many factors can influence whether an event will be reported, such as the time a product has been marketed and publicity about an event. There are also duplicate reports where the same report was submitted by a consumer and by the sponsor. Therefore, FAERS data cannot be used to calculate the incidence of an adverse event or medication error in the U.S. population. For more information, please refer to the question What points should I consider while viewing the dashboard content?

[+] Is FAERS data available to the public?

[+] How do I find or confirm my report is in FAERS?

[+] What are the benefits of the FAERS public dashboard?

[+] Will there be a tutorial so I can learn how to use this database?

[+] Is the FAERS public dashboard accessible on an Android™ or iPhone®?

[+] Can I download my search results from the dashboard?

[+] Where else can I find safety information?

[+] How are versions of a case in FAERS handled?

[+] How frequently is the data in the FAERS public dashboard updated?

[+] What points should I consider while viewing the dashboard content?

Data Questions

[+] How do I know if a side effect I saw on the dashboard is related to the drug I was taking?

[+] If an adverse event wasn't caused by a drug, what could have caused it?

[+] Is every adverse event reported with a drug on the dashboard caused by the drug?

[+] Are drugs with fewer side effects reported to the dashboard safer than those that have a higher number of side effects reported?

[+] How should reports of death be interpreted?

[+] Does the FAERS Dashboard have all the side effects that have occurred with a drug?

[+] What is the difference between an adverse event, a side effect, and an adverse drug reaction?

[+] Should I discontinue a prescription drug I'm taking if I think that it's causing an adverse event?

[+] I looked up a drug that I am taking on the FAERS dashboard and the list of adverse events includes deaths. What should I do?

[+] Where can I find the safety profile of the drug?

[+] After the data refresh for Q4 2021, why do I now see reduced counts in the Home page for previous time periods (Q3 2021 and older)?

Technical Questions

[+] Which internet browsers can I use to access the dashboard?

- What is the recommended screen resolution for viewing the dashboard?
- How do I navigate through different sheets of the dashboard?
- How can I view report statistics for quarters and months of a specific year?
- How do I search for cases for a product or products?
- Can I search for generic products as well as specific trade names?
- How can I change my product search?
- Does FAERS include over-the-counter (OTC) or just prescription drugs?
- How can I search for cases for specific side effects/reactions?
- How can I change my reaction search?
- What can I search for using the search box in the navigation bar?
- How many products or reactions can I search for at a time?
- Does the “Search” sheet allow selecting products and reactions for the same search?
- How can I view the distribution of report or case counts for different parameters?
- Can I view charts and tables in full screen mode? How do I exit from full screen mode?
- Can I filter data in charts and tables?
- How do I reset selected search criteria and remove all filters?
- Can I extract or download dashboard data?
- When using filter panes (or drop-downs) for filtering, I have noticed that different colors are used to highlight different values. What do these colors indicate?
- Can I use the dashboard without accepting the disclaimer?
- Why does the sum of case counts for individual reactions not add up to the overall case count for the product?
- Why does the sum of individual outcome counts not add up to the overall count for the product?
- How do I scroll in the “Listing of Cases” table?
- Can I rearrange columns in the “Listing of Cases” table?
- Some of the cells seem to be showing only partial data. How can I see the entire content of such cells?
- How do I filter and sort data in the “Listing of Cases” table?
- How do I download data from the “Listing of Cases” table?

EXHIBIT 58

Supplemental Approval Letter from FDA to Danco Laboratories, LLC (Apr. 11, 2019)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020687/S-022

SUPPLEMENT APPROVAL

Danco Laboratories, LLC
(b) (4), (b) (6)
P.O. Box 4816
New York, NY 10185

Dear (b) (4), (b) (6):

Please refer to your Supplemental New Drug Application (sNDA) dated November 4, 2015, received November 5, 2015, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Mifeprex (mifepristone) Tablets.

This Prior Approval supplemental new drug application proposes modifications to the approved risk evaluation and mitigation strategy (REMS) for Mifeprex to establish a single, shared system (SSS) REMS for mifepristone products for the medical termination of intrauterine pregnancy and updates to the approved Prescribing Information, Medication Guide, and REMS materials including the Prescriber Agreement and Patient Agreement Forms to incorporate language reflecting the proposed SSS REMS.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at:

http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Mifeprex (mifepristone) Tablets was originally approved on June 8, 2011. The most recent modification was approved on March 29, 2016. The REMS consists of elements to assure safe use, an implementation system, and a timetable for submission of assessments of the REMS. Your proposed modifications to the REMS establish a SSS REMS for the elements to assure safe use and the implementation system required for the reference listed drug (RLD) Mifeprex and ANDAs referencing Mifeprex, called the Mifepristone REMS Program.

Your proposed modified REMS, submitted on January 25, 2018, and appended to this letter, is approved.

The timetable for submission of assessments of the REMS must be revised to one year from the date of the initial approval of the SSS REMS (04/11/19) and every three years thereafter.

The revised REMS assessment plan must include, but is not limited to, the following:

Both cumulative data from the date of the initial approval of the SSS REMS (04/11/19) and data from the reporting period (i.e., from the preceding Mifeprex REMS assessment cut-off date to the cut-off date for the Mifepristone REMS Program.)

REMS Assessment Plan

Provide each metric for the current reporting period and cumulative for the RLD and ANDA(s):

1. Number of prescribers enrolled
2. Number of prescribers ordering mifepristone
3. Number of healthcare providers who attempted to order mifepristone who were not enrolled; describe actions taken
4. Number of women exposed to mifepristone
5. Summary and analysis of any program deviations and corrective action taken
6. Based on the information reported, an assessment and analysis of whether the REMS is meeting its goals and whether modifications to the REMS are needed

The requirements for assessments of an approved REMS under section 505-1(g)(3) include with respect to each goal included in the strategy, an assessment of the extent to which the approved strategy, including each element of the strategy, is meeting the goal or whether 1 or more such goals or such elements should be modified.

We remind you that in addition to the REMS assessments submitted according to the timetable in the approved REMS, you must include an adequate rationale to support any proposed REMS modification for the addition, modification, or removal of any of goal or element of the REMS, as described in section 505-1(g)(4) of the FDCA.

We also remind you that you must submit a REMS assessment when you submit any future supplemental application for a new indication for use as described in section 505-1(g)(2)(A) of the FDCA. This assessment should include:

a) An evaluation of how the benefit-risk profile will or will not change with the new indication;
b) A determination of the implications of a change in the benefit-risk profile for the current REMS;
c) If the new indication for use introduces unexpected risks: A description of those risks and an evaluation of whether those risks can be appropriately managed with the currently approved REMS.
d) *If a REMS assessment was submitted in the 18 months prior to submission of the supplemental application for a new indication for use*: A statement about whether the REMS was meeting its goals at the time of that the last assessment and if any modifications of the REMS have been proposed since that assessment.
e) If a REMS assessment has not been submitted in the 18 months prior to submission of the supplemental application for a new indication for use: Provision of as many of the currently listed assessment plan items as is feasible.
f) *If you propose a REMS modification based on a change in the benefit-risk profile or because of the new indication of use, submit an adequate rationale to support the modification, including*: Provision of the reason(s) why the proposed REMS modification is necessary, the potential effect on the serious risk(s) for which the REMS was required, on patient access to the drug, and/or on the burden on the health care delivery system; and other appropriate evidence or data to support the proposed change. Additionally, include any changes to the assessment plan necessary to assess the proposed modified REMS. *If you are not proposing REMS modifications*, provide a rationale for why the REMS does not need to be modified.

If the assessment instruments and methodology for your REMS assessments are not included in the REMS supporting document, or if you propose changes to the submitted assessment instruments or methodology, you should update the REMS supporting document to include specific assessment instrument and methodology information at least 90 days before the assessments will be conducted. Updates to the REMS supporting document may be included in a new document that references previous REMS supporting document submission(s) for unchanged portions. Alternatively, updates may be made by modifying the complete previous

REMS supporting document, with all changes marked and highlighted. Prominently identify the submission containing the assessment instruments and methodology with the following wording in bold capital letters at the top of the first page of the submission:

NDA 020687 REMS CORRESPONDENCE
(insert concise description of content in bold capital letters, e.g.,
UPDATE TO REMS SUPPORTING DOCUMENT - ASSESSMENT METHODOLOGY

An authorized generic drug under this NDA must have an approved REMS prior to marketing. Should you decide to market, sell, or distribute an authorized generic drug under this NDA, contact us to discuss what will be required in the authorized generic drug REMS submission.

We remind you that section 505-1(f)(8) of FDCA prohibits holders of an approved covered application with elements to assure safe use from using any element to block or delay approval of an application under section 505(b)(2) or (j). A violation of this provision in 505-1(f) could result in enforcement action.

Prominently identify any submission containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission as appropriate:

NDA 020687 REMS ASSESSMENT

NEW SUPPLEMENT FOR NDA 020687/S-000/ SECONDARY TRACKING NUMBER
CHANGES BEING EFFECTED IN 30 DAYS
PROPOSED MINOR REMS MODIFICATION

Or

NEW SUPPLEMENT FOR NDA 020687/S-000/ SECONDARY TRACKING NUMBER
PRIOR APPROVAL SUPPLEMENT
PROPOSED REMS MODIFICATIONS DUE TO SAFETY LABEL CHANGES SUBMITTED IN SUPPLEMENT XXX

Or

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 020687/S-000
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

Should you choose to submit a REMS revision, prominently identify the submission containing the REMS revisions with the following wording in bold capital letters at the top of the first page

Reference ID: 4418041

of the submission:

REMS REVISIONS FOR NDA 020687

To facilitate review of your submission, we request that you submit your proposed modified REMS and other REMS-related materials in Microsoft Word format. If certain documents, such as enrollment forms, are only in PDF format, they may be submitted as such, but the preference is to include as many as possible in Word format.

SUBMISSION OF REMS DOCUMENT IN SPL FORMAT

FDA can accept the REMS document in Structured Product Labeling (SPL) format. If you intend to submit the REMS document in SPL format, as soon as possible, but no later than 14 days from the date of this letter, submit the REMS document in SPL format using the FDA automated drug registration and listing system (eLIST).

For more information on submitting REMS in SPL format, please email REMS_Website@fda.hhs.gov.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call (b) (6)

Sincerely,

{See appended electronic signature page}

(b) (6)

Center for Drug Evaluation and Research

ENCLOSURES:

Content of Labeling
Prescribing Information
Medication Guide
REMS

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

(b) (6)

04/11/2019 02:13:59 PM

EXHIBIT 59

FDA Supplemental Approval Letter to Danco Laboratories, LLC (May 14, 2021)

NDA 020687/S-024

SUPPLEMENT APPROVAL

Danco Laboratories LLC
(b) (4), (b) (6)

P.O. Box 4816
New York, NY 10185

Dear (b) (4), (b) (6):

Please refer to your supplemental new drug application (sNDA) dated and received March 15, 2021, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Mifeprex (mifepristone) Tablets.

This Changes Being Effected sNDA provides for changes to the single, shared system risk evaluation and mitigation strategy (REMS) for mifepristone products for the medical termination of intrauterine pregnancy, known as the Mifepristone REMS Program, to include gender neutral language in the Patient Agreement Form. This sNDA also provides for minor changes to the REMS document to be consistent with the changes made to the Patient Agreement Form.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

The REMS for Mifeprex was originally approved on August 7, 2012, and the most recent REMS modification, establishing the Mifepristone REMS Program, was approved on April 11, 2019. The Mifepristone REMS Program consists of elements to assure safe use, an implementation system, and a timetable for submission of assessments of the REMS. Your proposed modification to the Mifepristone REMS Program consists of a

revised Patient Agreement Form to include gender neutral language and minor revisions to the REMS document to be consistent with the revisions to the Patient Agreement Form.

The timetable for submission of assessments of the REMS remains the same as that approved on April 11, 2019.

There are no changes to the REMS assessment plan described in our April 11, 2019 letter.

We remind you that in addition to the REMS assessments submitted according to the timetable in the approved Mifepristone REMS Program, you must include an adequate rationale to support a proposed REMS modification for the addition, modification, or removal of any goal or element of the Mifepristone REMS Program, as described in section 505-1(g)(4) of the FDCA.

We also remind you that you must submit a REMS assessment when you submit a supplemental application for a new indication for use, as described in section 505-1(g)(2)(A) of the FDCA. This assessment should include:

a) An evaluation of how the benefit-risk profile will or will not change with the new indication;

b) A determination of the implications of a change in the benefit-risk profile for the current REMS;

c) *If the new indication for use introduces unexpected risks*: A description of those risks and an evaluation of whether those risks can be appropriately managed with the currently approved REMS.

d) *If a REMS assessment was submitted in the 18 months prior to submission of the supplemental application for a new indication for use*: A statement about whether the REMS was meeting its goals at the time of that last assessment and if any modifications of the REMS have been proposed since that assessment.

e) *If a REMS assessment has not been submitted in the 18 months prior to submission of the supplemental application for a new indication for use:* Provision of as many of the currently listed assessment plan items as is feasible.

f) *If you propose a REMS modification based on a change in the benefit-risk profile or because of the new indication of use, submit an adequate rationale to support the modification, including*: Provision of the reason(s) why the proposed REMS modification is necessary, the potential effect on the serious risk(s) for which the REMS was required, on patient access to the drug, and/or on the burden on the

health care delivery system; and other appropriate evidence or data to support the proposed change. Additionally, include any changes to the assessment plan necessary to assess the proposed modified REMS. *If you are not proposing REMS modifications*, provide a rationale for why the REMS does not need to be modified.

If the assessment instruments and methodology for your REMS assessments are not included in the REMS supporting document, or if you propose changes to the submitted assessment instruments or methodology, you should update the REMS supporting document to include specific assessment instrument and methodology information at least 90 days before the assessments will be conducted. Updates to the REMS supporting document may be included in a new document that references previous REMS supporting document submission(s) for unchanged portions. Alternatively, updates may be made by modifying the complete previous REMS supporting document, with all changes marked and highlighted. Prominently identify the submission containing the assessment instruments and methodology with the following wording in bold capital letters at the top of the first page of the submission:

NDA 020687 REMS ASSESSMENT METHODOLOGY
(insert concise description of content in bold capital letters, e.g., ASSESSMENT METHODOLOGY, PROTOCOL, SURVEY METHODOLOGIES, AUDIT PLAN, DRUG USE STUDY)

An authorized generic drug under this NDA must have an approved REMS prior to marketing. Should you decide to market, sell, or distribute an authorized generic drug under this NDA, contact us to discuss what will be required in the authorized generic drug REMS submission.

We remind you that section 505-1(f)(8) of FDCA prohibits holders of an approved covered application with elements to assure safe use from using any element to block or delay approval of an application under section 505(b)(2) or (j). A violation of this provision in 505-1(f) could result in enforcement action.

Prominently identify any submission containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission as appropriate:

NDA 020687 REMS ASSESSMENT

or

NEW SUPPLEMENT FOR NDA 020687/S-000
CHANGES BEING EFFECTED IN 30 DAYS
PROPOSED MINOR REMS MODIFICATION

or

NEW SUPPLEMENT FOR NDA 020687/S-000
PRIOR APPROVAL SUPPLEMENT
PROPOSED MAJOR REMS MODIFICATION

or

NEW SUPPLEMENT FOR NDA 020687/S-000
PRIOR APPROVAL SUPPLEMENT
PROPOSED REMS MODIFICATIONS DUE TO SAFETY LABELING CHANGES SUBMITTED IN SUPPLEMENT XXX

or

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 020687/S-000/
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

Should you choose to submit a REMS revision, prominently identify the submission containing the REMS revisions with the following wording in bold capital letters at the top of the first page of the submission:

REMS REVISIONS FOR NDA 020687

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U.S. Food and Drug Administration
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www.fda.gov

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Sincerely,

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Center for Drug Evaluation and Research

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EXHIBIT 60

Rachel Roubein, *'Shield' Laws Make it Easier to Send Abortion Pills to Banned States*, Washington Post (July 20, 2023)

This article was published more than **1 year ago**

Democracy Dies in Darkness

Health Brief

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'Shield' laws make it easier to send abortion pills to banned states



Analysis by Rachel Roubein
with research by McKenzie Beard

July 20, 2023 at 7:14 a.m. EDT

Happy Thursday! A big shout out to **Caroline Kitchener** for her excellent reporting in the top of today's newsletter.

And one note: I'll be heading out on summer vacay for a few days, and you'll have a great rotating cast of Post reporters bringing you this newsletter. See you next week! In the meantime, send all your news and tips to mckenzie.beard@washpost.com.

Today's edition: A hearing continues today on a lawsuit seeking clarity over exceptions to Texas's strict abortion ban. Sen. **Bernie Sanders** (I-Vt.) introduces a competing bill to fund community health centers as a critical deadline nears. **But first ...**

Aid Access launches new way to send abortion pills into states with bans

There's a new, more efficient pipeline sending abortion pills into states with bans.

Europe-based **Aid Access,** one of the largest abortion pill suppliers, revamped its protocols in mid-June. **The result?** Doctors in certain Democratic-led states with "shield" laws can now mail and prescribe pills directly to patients in antiabortion states.

The new process could ignite a complex interstate battle over abortion, where U.S. doctors in blue states are empowered to legally circumvent abortion laws in red states. The move could also undermine abortion bans at a time when antiabortion groups and doctors are seeking to revoke the approval of key medication used in over half of all abortions in the country.

Our colleague **Caroline Kitchener** dove deep into the new effort — and here's what she found.

The details

Previously, Aid Access only allowed Europe-based doctors to prescribe abortion pills to women in states where abortion is restricted. Those pills were shipped from India, and often took weeks to get to patients, which could push abortions well into the second trimester. (The **Food and Drug Administration** has approved mifepristone through 10 weeks gestation, though some studies have shown it can be used safely and effectively later in pregnancy.)

But new laws enacted over the past year are helping to streamline the process. Democratic-led states have moved to protect medical professionals and others who practice in states where abortion is legal from potential punishment in states with bans. **New York, Massachusetts, Washington, Vermont** and **Colorado** explicitly protect abortion providers who mail pills to restricted states from inside their borders, Caroline writes.

The new landscape: In less than a month, seven U.S.-based providers affiliated with Aid Access have mailed **3,500 doses** of abortion pills to people residing in states with bans. All together, the small group could help facilitate at least **42,000 abortions** in antiabortion states in a year. (Those numbers could grow, of course, if more providers join in.)

- As one expert told Caroline, the shield laws are "a huge breakthrough for people who need abortions in banned states," said **David Cohen,** a **Drexel University** law professor who focuses on abortion legislation. "Providers are protected in many ways as long as they remain in the state with the shield law."

Could doctors face legal risks?

That's a key question. And it could ultimately be resolved by the courts.

Some lawyers say the doctors — who are preparing and packaging the pills sent to restricted states themselves — could face repercussions, even if they don't travel to states that prosecute abortion providers. Some wonder whether states with abortion bans would try to extradite medical providers from states with shield laws, though that could prove difficult.

Jonathan Mitchell, the former solicitor general of Texas and architect of the state's roughly six-week ban, said it seems too early to predict what will happen, but that "there absolutely is a world in which they could get in trouble for it." (In many states with bans, those found guilty of distributing abortion pills could be sentenced up to at least several years in prison.)

But some involved in the effort say they're not worried.

"Everything I'm doing is completely legal," a doctor in New York's Hudson Valley, who spoke on the condition of anonymity to protect her safety, told Caroline. "Texas might say I'm breaking their laws, but I don't live in Texas."

Read the full story here.

Reproductive wars

Testimony begins in hearing seeking clarity on Texas's abortion exceptions

Three women gave accounts yesterday of being denied abortions or given delayed medical care due to confusion over the exceptions in Texas's strict abortion laws.

The testimony in a Texas courtroom was often emotional. At one point, one woman was reading a letter from her doctor describing how her baby had been diagnosed with a condition incompatible with life. She became sick on the stand, and the judge quickly recessed.

The case, which was filed by the Center for Reproductive Rights, is believed to be the first lawsuit from women denied abortions since the nation's highest court overturned *Roe v. Wade* last summer. The hearing began yesterday, as three women and a doctor took the witness stand for the plaintiffs, and will continue today.

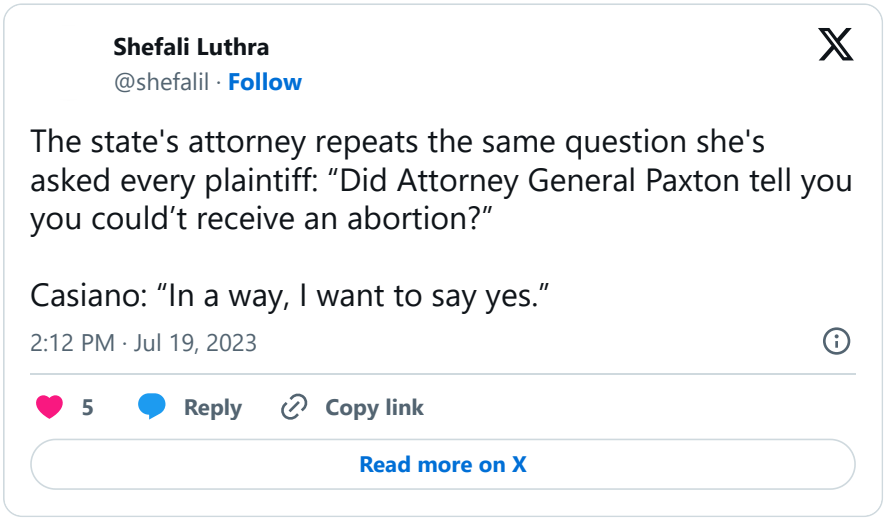
The legal challenge isn't seeking to overturn the state's abortion ban, but rather to clarify when an abortion is allowed in the case of a medical emergency. The plaintiffs are also seeking a temporary injunction blocking the state's ban in instances where a patient experiences a pregnancy complication.

During the hearing, **Molly Duane** — an attorney with the **Center for Reproductive Rights** — argued that the exceptions in the state's abortion ban are either "conflicting or lack definitions," and that doctors fear the high penalties they'd face if they're found to violate the law.

On the other side, **Amy Pletscher,** who represented the Republican attorney general's office, called the legal challenge an "ideological crusade."

"Plaintiffs simply do not like Texas's restrictions on abortion," she said.

Shefali Luthra, reporter at the 19th:



On the Hill

Sanders introduces bill to fund community health centers

Senate HELP Committee Chair Bernie Sanders (I-Vt.) unveiled a bill yesterday that aims to overhaul the country's primary health-care system — a move that indicates there isn't a bipartisan compromise in the Senate over funding for health centers that provide care to the country's most vulnerable.

The details: The legislation would invest **$20 billion** per year over a five-year period to expand community health centers and expand the health workforce. **The panel is slated to mark up the legislation next Wednesday.**

Sanders's proposal comes days after the panel's top Republican, Sen. **Bill Cassidy** (La.), introduced a bill to reauthorize the fund comprising roughly **70 percent** of federal dollars for health centers, which is set to expire Sept. 30. That legislation mirrors the funding plan the **House Energy and Commerce Committee** advanced with unanimous support in late May.

The view from Cassidy: "This is partisan legislation that cannot pass the Senate," he said in a statement. "There is already reauthorization legislation that unanimously passed out of the House E&C committee, has been introduced in the Senate and is endorsed by community health centers. **That is the bill we should mark up next week**."

EXHIBIT 61

Rachel Roubein, *How Blue States are Responding to the Post*-Roe *World*, Washington Post (June 21, 2023)

This article was published more than **1 year ago**

Democracy Dies in Darkness

Health Brief

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How blue states are responding to the post-Roe world



Analysis by Rachel Roubein
with research by McKenzie Beard

June 21, 2023 at 8:11 a.m. EDT

Happy official first day of summer (the absolute best season) Send news and tips for the longest day of the year to rachel.roubein@washpost.com. Not a subscriber? Sign up here.

Today's edition: Half of OBGYNS in states with bans say they've had patients who were unable to obtain an abortion despite seeking one, a new survey finds. A federal judge strikes down Arkansas's first-in-the-nation ban on gender transition care for minors. **But first ...**

Democratic-led states are passing shield laws, solidifying abortion rights post-Roe

Democratic-led states rushed to shore up abortion protections in the first legislative season of the post-*Roe* era.

Lawmakers in blue states passed an array of bills, from solidifying abortion rights to expanding access to medication abortion to shielding providers who practice in states where abortion is legal.

The goal? Democrats are seeking to ensure abortion remains legal in their states, while continuing to serve as a destination for women who live in conservative areas with strict abortion bans. Their efforts this year built on legislation passed in 2022 in anticipation of the Supreme Court overturning *Roe v. Wade* — and some abortion rights advocates say it's just the beginning.

- "This is truly the next iteration of innovation and creativity at the state level, as well as at the local level," said **Andrea Miller,** the president of the **National Institute for Reproductive Health.**

We've written a lot about how abortion bans fared during state legislative sessions this year. This morning, we're turning to trends in states seeking to counteract such restrictions.

Trend #1: Some states sought to shore up abortion rights.

There were several prominent examples of this effort popular among liberal states and abortion rights groups.

In Minnesota: In a surprising upset during November's midterm elections, Democrats took full control of the state government for the first time since 2014. They rushed to enact a law codifying the right to an abortion into state law. (The procedure was already protected under a 1995 state Supreme Court decision, but supporters said they wanted to take the decision out of the hands of "individual judges.")

In Michigan: Democrats also won control of both the state House and Senate for the first time in nearly four decades. In April, Gov. **Gretchen Whitmer** (D) signed legislation to repeal a 1931 near-total abortion ban, which came after voters in the state approved a constitutional amendment to enshrine the right to an abortion into the state constitution.

In Maryland: The General Assembly gave the greenlight to let voters decide whether to enshrine abortion rights into the state constitution next year.

In New York: For the second time, state lawmakers passed an amendment to enshrine abortion rights into the state constitution. That means the measure will also now head to voters next year.

More from Whitmer:

> Today, we are repealing Michigan's extreme 1931 law that bans abortion and criminalized nurses and doctors for doing their jobs.
>
> This is long overdue. pic.twitter.com/PCOqJhTtb4
> — Governor Gretchen Whitmer (@GovWhitmer) April 5, 2023

Trend #2: Democrats look to shield providers.

While the specifics in states may differ, this policy is generally aimed at protecting medical professionals and others who practice in states where abortion is legal from punishment in states with bans.

Advocates for such laws acknowledge there don't appear to be cases of charges filed against providers in such instances. But they say the new measures send a message and act as a guard against lawsuits.

In New York: The legislature gave approval yesterday to legislation granting legal protection for doctors in the state to prescribe and send abortion pills to patients in states with bans. Gov. **Kathy Hochul** (D) has indicated her support for the idea of a new shield law, per **the New York Times.**

The state certainly isn't the only one to enact new shield laws. In Vermont, Republican Gov. **Phil Scott** signed a shield law that explicitly protects access to mifepristone, even if the federal government withdraws approval of the commonly used abortion pill.

Other states passing various forms of shield laws include **Hawaii, Illinois, Minnesota, Colorado** and **several more.**

David S. Cohen, a professor at Drexel University's law school:

> BIG NEWS out of New York. It becomes the fifth state to pass this type of shield law, but the first with providers who are openly talkingTh about how they are going to mail pills to ban states. 1/2 https://t.co/g75rKXqbJS
> — David S. Cohen (@dsc250) June 20, 2023

Trend #3: States are testing out a smattering of new bills.

States tend to follow each other's lead, so it's worth watching closely what could emerge as a trend during the next legislative cycle.

Some bills that caught our eye:

- In **New York,** Hochul signed a bill aimed at ensuring all public colleges and universities offer medication abortion.
- In **Washington state,** a new law will ensure the Department of Corrections can sell, deliver, distribute and dispense abortion pills.
- And **Rhode Island** has become the latest state with a measure letting state funds cover abortion in the Medicaid program and for those on state employee insurance plans.

Meanwhile ... State and local governments are putting more money toward expanding access to abortion. Since the Supreme Court's decision, at least 15 municipal governments and six states have put **nearly $208 million** toward funding abortion, reproductive health services, patient navigation programs and other services, according to the **National Institute for Reproductive Health.**

Rhode Island Gov. Dan McKee (D):

> Here in Rhode Island, we will always protect a woman's right to choose and ensure equal access to these crucial health care services.
>
> I'm proud to sign the Equality in Abortion Coverage Act into law and include related funding in my budget proposal. pic.twitter.com/wJvHG6p5Q0
> — Governor Dan McKee (@GovDanMcKee) May 18, 2023

Chart check

New this a.m.: How OBGYNs say new abortion restrictions are affecting maternal care

In the year since the Supreme Court overturned *Roe v. Wade*, half of OBGYNs working in states with abortion bans say they have had patients who were unable to terminate their pregnancies despite seeking to do so, according to a new survey out this morning from **KFF**.

By the numbers: Across the country, **68 percent** of OBGYNs said the effects of the *Dobbs* ruling have made managing pregnancy-related medical emergencies worse, while **64 percent** said they believe the ruling has exacerbated pregnancy-related mortality, according to the poll.

Zooming out: The findings represent the first nationally representative survey of OBGYNs since the ruling and provide one of the clearest views yet of how the decision has affected reproductive and sexual health care in the United States, The Post's **Kim Bellware** writes.

Transition care

Federal judge in Ark. blocks first ban on gender transition care

A federal judge struck down a 2021 Arkansas law prohibiting gender-affirming care for youth as unconstitutional yesterday, finding that the first-in-the-nation ban violated the rights of doctors and discriminated against transgender people, our colleague **Anne Branigin** reports.

U.S. District Judge **James Moody** of the Eastern District of Arkansas issued a permanent injunction forbidding the enforcement of the ban, which he had previously temporarily blocked from taking effect. The state plans to appeal the decision, Arkansas Attorney General **Tim Griffin** (R) said in a statement yesterday.

The bigger picture: Moody's closely watched ruling marks the first time a federal court has decided the legality of such restrictions, which have been adopted by at least 20 additional states in recent years, according to data compiled by the **ACLU**.

Arkansas Gov. Sarah Huckabee Sanders (R):

This is not "care" — it's activists pushing a political agenda at the expense of our kids and subjecting them to permanent and harmful procedures.

Only in the far-Left's woke vision of America is it not appropriate to protect children.

We will fight this and the Attorney… https://t.co/7wCeR4I1Vo
— Sarah Huckabee Sanders (@SarahHuckabee) June 20, 2023

The ACLU of Arkansas:

VICTORY! A federal district court judge has ruled against the Arkansas law banning gender-affirming care for trans youth, marking a groundbreaking victory to #ProtectTransYouth. We stand with all brave Arkansans fighting for their right to thrive & be healthy.🏳️‍⚧️#arpx #arleg pic.twitter.com/TQrDoq3DED
— ACLU of Arkansas (@ArkansasACLU) June 20, 2023

Meanwhile …

The U.K.'s publicly funded **National Health Service for England** announced this month that it would limit the use of most puberty blockers for youth to clinical trials, saying more evidence is needed about their potential benefits and harms, the Wall Street Journal's **Jathon Sapsford** and **Stephanie Armour** reported over the weekend.

It's an argument that has cropped up among Republicans in Congress, with GOP lawmakers seizing on European doubts last week to support their push for increased caution and restrictions.

On the other side, Democrats contend Republicans are attempting to score political points. The U.S. medical community largely hasn't wavered in its support for clinical interventions. Last week, delegates from the **American Medical Association** endorsed a resolution reiterating support for access to gender-affirming care, saying that GOP claims "do not reflect the research landscape."

State scan

Inside how Gov. DeSantis used secretive panel to flip Florida Supreme Court

Our colleagues **Beth Reinhard** and **Josh Dawsey** published a deep dive yesterday on how Florida Gov. **Ron DeSantis** (R) seized on the unusual retirement of three liberal justices on the state Supreme Court at once to quickly reshape the panel into a conservative stronghold.

The details: After DeSantis narrowly won election in 2018, he enlisted the help of a secretive panel led by **Leonard Leo** — the key architect of the U.S. Supreme Court's conservative majority — to quietly vet judicial nominees to fill the vacancies.

The group grilled finalists on whether their principals matched those of the Federalist Society, an organization for conservative and libertarian attorneys that's led by Leo, people familiar with the process told The Post. DeSantis would go on to appoint three new justices in his first two weeks in office, flipping the court from what he described as a **4-3** liberal majority to a **6-1** conservative advantage.

Why it matters: The governor's efforts have yielded one of the most conservative state Supreme Courts in the country, and it is set to weigh the constitutionality of Florida's 15-week abortion ban in the coming months. A six-week ban that DeSantis approved this year also hangs in the balance, Beth and Josh write.

Our colleague Caroline Kitchener, who covers abortion for The Post:

> Soon, the FL supreme court is expected to issue a decision that will end most abortions in the third most populous state.
>
> DeSantis reshaped the court for this exact moment.
>
> Crucial reporting on how he did it, from @bethreinhard + @jdawsey1 https://t.co/C29lx3oDvd
> — Caroline Kitchener (@CAKitchener) June 20, 2023

In other news from the states ...

In Kansas: State officials have agreed to not yet enforce a new law requiring clinics to inform patients of the disputed notion that a medication abortion can be interrupted using an unproven drug regimen until a judge weighs in on a formal request to block it, the **Topeka Capital-Journal**'s **Andrew Bahl** reports.

In Missouri: A judge rejected Republican Attorney General **Andrew Bailey**'s bid to stop a constitutional amendment to restore abortion rights, ordering him to approve Republican Auditor **Scott Fitzpatrick**'s cost estimate of the proposal within 24 hours of the ruling, **Kurt Erickson** reports for the **St. Louis Post-Dispatch**.

In other health news

- **The Senate voted 51-43 yesterday to confirm Julie Rikelman** to the U.S. Court of Appeals for the 1st Circuit, overcoming opposition from some Republicans and antiabortion advocates over her work as an abortion rights attorney.
- **The Supreme Court threw out a lower-court ruling yesterday** stopping South Carolina from cutting off public funding to Planned Parenthood, remanding the case to the U.S. Court of Appeals for the 4th Circuit for further consideration.
- **On the move: Anne Esposito**, **PhRMA**'s senior vice president for federal advocacy, will leave the lobbying group later this summer after over three years at the organization, **Stat**'s **Rachel Cohrs** reports.
- **The U.S. Preventive Services Task Force finalized its recommendation yesterday** urging primary care providers for the first time to screen all adults younger than 65 for anxiety disorders, The Post's **Lindsey Bever** reports.

Health reads

EXHIBIT 62

Rebecca Grant, *Group Using 'Shield Laws' to Provide Abortion Care in States That Ban It*, The Guardian (July 23, 2023)

Abortion

This article is more than **1 year old**

Group using 'shield laws' to provide abortion care in states that ban it

Aid Access ships medication abortion to all 50 states under the protection provided to clinicians serving patients in banned states



Boxes of mifepristone. Each of the Aid Access providers is sending approximately 50 packages a day. Photograph: Evelyn Hockstein/Reuters

Rebecca Grant

Sun 23 Jul 2023 07.00 EDT

Dr Linda Prine is providing abortion access to people in all 50 states, even those that have banned it. That might seem like an admission to be discreet about in post-Roe America, but Prine and her colleagues at Aid Access, a telemedicine abortion service, are doing it openly and in a way they believe is on firm legal ground.

On 14 July, Aid Access announced that over the past month, a team of seven doctors, midwives and nurse practitioners have mailed medication abortion to 3,500 people under the protection of "shield laws", which protect clinicians who serve patients in states where providing abortion is illegal. As soon as she learned about shield laws, Prine knew it represented an opportunity to go on the offensive, for those bold enough to try it.

"It made me think, OK, we need to fight back," Prine said. "We can't just take this lying down. We've got to do something. And this was what we can do."

From its origins, Aid Access has always been willing to test legal boundaries. It was started in 2018 by the Dutch physician Dr Rebecca Gomperts. At the time, FDA regulations prevented licensed US providers from mailing mifepristone, one of the two drugs in the medication abortion regimen, so Aid Access was structured like Gomperts' other telemedicine service, Women on Web. That process involved abortion seekers filling out an online consultation, and if eligible, Gomperts wrote a prescription from Europe and the pills were dispatched by a pharmaceutical partner in India.

Then, in 2020, Covid hit. And a federal judge suspended the FDA's in-person dispensing requirement for mifepristone. For the first time, legally prescribed medication abortion could be put in the mail. Aid Access used this opportunity to implement a hybrid model: in states where telemedicine abortion was legal, US clinicians handled the prescriptions, while in states where it wasn't, the pills continued to be mailed from India.

One drawback of shipping from India was the packages could take weeks to arrive. In addition to the stress and uncertainty involved in waiting, the time lag could push people past the 12-week limit recommended by the World Health Organization (although there is some emerging research that abortion pills can safely be taken later.) Covid also created concerns about shipping delays, and there was always the chance that customs could seize the packages.

> *then needing to wait three or four weeks to get it to happen ... that's just so hard*
> **Dr Linda Prine**

"The whole experience of wanting an abortion and then needing to wait three or four weeks to get it to happen, and not even be sure if those pills are ever going to come, that's just so hard," said Prine, who started working with Aid Access in 2021. "Who wants to do that? Nobody."

In March 2022, Prine read an op-ed by three legal scholars - David S Cohen of Drexel University, Rachel Rebouché of Temple University, and Greer Donley of the University of Pittsburgh - that introduced her to the idea of shield laws. The trio had published a paper titled The New Abortion Battleground in the Columbia Law Review, which outlined the ways that shield laws could protect abortion providers who treated patients in banned states if Roe fell.

"Certainly, it's not a surprise that post-Dobbs, there are going to be medical care providers who want to push the limits and care for as many people as they can, including people in other states," Cohen said in an interview. "People are going to do this, so we were thinking about what can the states where they live do to help them the most?"

Inspired by their work, a wave of states started passing shield laws. The first, in Connecticut, passed in May 2022. Massachusetts, the fifth state to pass a shield law in July 2022, was the first to include a telemedicine provision, meaning the state pledged to protect a provider licensed there who prescribed and mailed medication abortion pills, via telemedicine, to a patient in a state where abortion was banned - like Texas or Alabama. Currently, 15 states have shield laws in place, and five - Massachusetts, Washington, Vermont, Colorado and New York - have specific telemedicine protections.

> *Post-Dobbs, there are going to be medical providers who want to push the limits and care for as many people as they can*
> **David S Cohen**

Before Aid Access, no US providers had publicly tested them. Then, on 18 June, the organization started serving patients nationwide with providers licensed in those five states. Up to 13 weeks, they offer prescriptions for $150 with a sliding scale that asks people to pay whatever they can afford, with a shipping time of two-five days. (In a physical clinic, the median cost of medication abortion is over $500.)

"Now Aid Access is completely US provider-led," Lauren Jacobson, a nurse practitioner licensed in Massachusetts who joined Aid Access in February 2023, told the Guardian this month. "I think this is important because it sends the broader message that this is an American issue, a US problem, and taking advantage of the shield laws means we are returning this to an at-home solution."

In addition to enabling faster shipping times, Jacobson said some people also feel more secure knowing that the pills are coming from licensed clinicians through an FDA-approved pipeline. This is part of what distinguishes Aid Access from abortion pill suppliers that operate through unofficial channels, such as unregulated online pharmacies and clandestine community networks. While the non-profit Plan C has found those medications to be as advertised, and reliably safe and effective (and also, in the case of community networks, free), they don't offer interaction with a licensed clinician, and some people want that support as part of the process.

Right now, each of the Aid Access providers is sending approximately 50 packages a day. Prine said all the packing and postage and shipping tasks are a "big pain in the rear", but it's manageable. They are prepared to scale, both in terms of infrastructure and in terms of the legal challenges their actions could invite.

Cohen suggests there will be a "coming battle" as shield laws get tested, and emphasized that providers have the greatest amount of protection while they are in shield law states. Jacobson and Prine are not overly concerned about legal repercussions, but that doesn't mean they're not taking precautions.

If it happens, it happens, and we are prepared," Prine said. "But I'm definitely not taking any vacations in Texas."

Because shield laws are designed to protect providers, patient risk is a separate factor - one that's particularly acute for people from communities that face heightened surveillance from law enforcement. A state doesn't need to have an explicit law criminalizing people who have abortions to prosecute them, often under unrelated statutes, like the illegal concealment of human remains. Even before Dobbs, people were arrested for self-managing abortions. The risk is real, but in a moment where people have too few options and time is of the essence, Prine said, every option counts.

"I do consults all the time, and people are not saying, 'What about the legality of this?'" Prine said. "That is not their concern. Their question is, 'How soon will the pills arrive?' That is the number one question."

More on this story

US appeals court upholds restrictions on abortion pill access

16 Aug 2023



Girl, 13, gives birth after she was raped and denied abortion in Mississippi

14 Aug 2023



Texas questions rights of fetus in prison guard lawsuit despite arguing opposite on abortion

12 Aug 2023



Most viewed

EXHIBIT 63

Abigail Brooks and Dasha Burns, *How A Network of Abortion Pill Providers Works Together in the Wake of New Threats*, NBC News (April 7, 2024)

ABORTION RIGHTS

How a network of abortion pill providers works together in the wake of new threats

Groups such as Aid Access, Hey Jane and Just the Pill stay in close contact to help women seeking abortions in states with bans.



A shield law provider packs abortion pills into envelopes to be sent from New York to states with bans.

Callan Griffiths / NBC News

April 7, 2024, 6:00 AM CDT

By Abigail Brooks and Dasha Burns

When the U.S. Supreme Court heard oral arguments in March about restricting access to the abortion drug mifepristone, Elisa Wells, co-founder and co-director of Plan C, was ready.

Plan C, an information resource that connects women to abortion pill providers, almost immediately saw a spike in searches for the medication.

W

more search activity and more creative thinking from providers.

“When these egregious decisions happen, first, they cause harm,” she says. “And the second thing that happens is people get organized and mad and take action.”

Since the Supreme Court overturned Roe v. Wade in its 2022 Dobbs decision, upending abortion access in the U.S., a network of abortion providers has sprung into action, weaving an abortion safety net across the country even as the procedure has been effectively banned in 15 states.

Providers such as Aid Access, Hey Jane and Just the Pill operate both within and outside the established health care system – including mailing abortion medications to women in states with bans, setting up mobile clinics and offering financial assistance – often staying in close contact with one another.



— Bottles of Misoprostol Tablets. NBC News

Many of those efforts center on access to abortion medication by mail, which the Food and Drug Administration made fully legal in 2021, creating a sort of “sisterhood of the traveling pill” that keeps groups connected as new restrictions on abortion arise.

Wells says Plan C called different providers for a meeting on how best to pivot in the changing abortion landscape.

“

would be competing with one another to come together and discuss, you know, how can we make a difference? How can we collectively address this issue?”

One such group is Aid Access, an online-only service based in the Netherlands. Originally a resource for women in the U.S. to get abortion pills from overseas, providers for the organization now ship pills from within the U.S. under telemedicine shield laws. The shield laws have been enacted in six states: California, Colorado, Massachusetts, New York, Vermont and Washington. The laws protect providers who prescribe and ship abortion pills to patients who live in states where abortion is banned or severely restricted.

“Before we had the shield law, we were mailing pills to the blue states, and only [pills from] overseas could be sent to the restricted states,” said Dr. Linda Prine, a New York City-based shield law provider.

After New York’s shield law passed, Prine said, “the first month we sent about 4,000 pills into restricted states, and now we’re up to around 10,000 pills a month.”

In a basement in upstate New York, another Aid Access provider who asked to not be identified for safety reasons underscored the importance of sending these pills from the U.S., rather than overseas.

“Sometimes they got stuck in customs,” the provider explained as more than 100 prescriptions were being packaged around them, preparing to be shipped into states with bans.

“When you’re doing a medication abortion, the faster you can get these medications, the better,” the provider said in an interview. “It’s easier, there’s less bleeding, there’s less cramping, and not to mention the anxiety that these women go through when they’re waiting for those medications to get to them in the mail.”



— Boxes of pills will be packed into envelopes to ship around the country. Callan Griffiths / NBC News

Aid Access providers say they're sending pills to some who are in the most desperate situations – people who are willing to risk going outside the established health care system to access abortion services. The organization is exploring contingency plans in the event that access to the abortion pill through the mail is disrupted.

"We have so many patients who write to us who've been raped, who can't travel," the provider explained. "So we have to come up with other ways. I would say the last resort would be that these medications come again from overseas."

And while shield laws have yet to be challenged in courts, anti-abortion groups have taken notice.

"The fact remains that just because you are sitting in California does not mean that you are not violating the laws of Florida, Texas and 30 other states," Katie Daniel, state policy director for the anti-abortion group Susan B. Anthony Pro-Life America, told NBC News. "So I think they have a false sense of security about this."

In the six months after Dobbs, researchers saw an increase in women getting abortion medication outside the traditional health care system, with more than 27,000 additional instances, according to a recent study in the journal JAMA.

"These are groups like Las Libres, WeSaveUs, Arkansas Together," said Wells, who was a co-author of the study. "They're serving a significant number of people for an all volunteer-led effort."

Even within the traditional health care system, abortions via medication are increasing, too. Medication abortions accounted for 63% of all abortions in 2023, up 10% from the year before, according to research from reproductive rights think tank the Guttmacher Institute, making it the most common method for terminating a pregnancy.



— Envelopes filled with abortion pills. Callan Griffiths / NBC News

New York-based Hey Jane has seen that demand firsthand. Founder Kiki Freedman, an early Uber employee, launched the telemedicine-only abortion provider in 2018 after seeing other startups deliver medications and savings to customers via online-only prescription services. After the FDA eased restrictions on mifepristone prescriptions during pandemic, allowing women to get the abortion pill through the mail, Hey Jane took off. The company has shipped abortion pills to at least 50,000 patients, according to a statement.

“We have the added benefit of this sort of geographic fluidity where a doctor in New York can serve a patient in Illinois, or New Mexico if the doctor in New Mexico or the provider in New Mexico is busy,” said Freedman. “The other piece is financial accessibility and being able to access scalable ways of doing that, so via insurance, in particular.”

Hey Jane only prescribes and ships abortion medication to states where it’s legal, marking a difference from shield law providers and organizations like Aid Access.

Access to medication abortion helps patients avoid traveling and wait times at in-person clinics, and allows them to take the pills in private at home. While providers who ship to states with bans have struggled with traditional payment platforms, Hey Jane’s focus is on keeping access covered by insurance.

"Still, 75% of abortions are taking place in these 20 states we're in. It's still where the vast majority of care occurs," said Freedman. "It's not like access in those states has been seamless to date, right? It's always been difficult even there, and particularly post-Dobbs, wait times and things like that have really surged within those states."



Empty pill bottles in the basement of a shield law provider in New York will be filled with abortion medication.
Abigail Brooks / NBC News

Just the Pill provides abortion access to women in states with bans using discreet mobile clinics set up just across state lines.

The group has bulletproof vans in Colorado, Minnesota and Montana, and a brick-and-mortar location in Wyoming. Appointments are conducted via telemedicine, always within a state where abortion is legal, making shield laws unnecessary, a backstop a Just the Pill provider said is intentional, so care won't be interrupted if the shield laws are challenged.

"I totally support what these other organizations are doing," she said in an interview, asking not to be identified for safety reasons. "I'm cheering them on from afar, but want to make sure our service isn't challenged."

Just the Pill works with abortion funds, which provide financial assistance to patients who are seeking the procedure, to help patients travel across state lines for their appointments. After a telemedicine visit, pills are then prescribed and patients can pick them up and take them, all within the borders of a state where the procedure is

legal. Because Just the Pill's clinics are mobile, they can travel along the borders of banned states and ensure they get as close as possible to women traveling from rural areas or long distances for care.

Meanwhile, Plan C is already working with more international pill providers to help with telehealth prescription access in the U.S. if telehealth visits for mifepristone are affected here, Wells said.

"We know we live in a time when anything can happen," Wells said. "We want to have as many alternate routes and access as possible. Many eggs and many baskets."

Abigail Brooks
Abigail Brooks is a producer for NBC News.



Dasha Burns
Dasha Burns is a correspondent for NBC News.

EXHIBIT 64

Elissa Nadworny, I*nside a Medical Practice Sending Abortion Pills to States Where They're Banned*, NPR (Aug. 7, 2024)

Case 2:22-cv-00223-Z Document 254-7 Filed 08/22/25 Page 254 of 266 PageID 16549

NATIONAL

Inside a medical practice sending abortion pills to states where they're banned

AUGUST 7, 2024 · 9:00 AM ET



Elissa Nadworny



“Welcome to modern abortion care,” says Angel Foster, who leads operations at what’s known as the MAP, a Massachusetts telehealth provider sending pills to people who live in states that ban or restrict abortion.

Elissa Nadworny/NPR

The packages, no bigger than a hardcover book, line the walls of the nondescript office near Boston. It's not an Etsy retailer or a Poshmark seller or, as the nearby post office workers believe, a thriving jewelry business.

These boxes contain abortion pills.

"Welcome to modern abortion care," says Angel Foster, as she holds up a box for mailing. Foster, who has an M.D. degree, leads operations at what's known as the MAP, a Massachusetts telehealth provider sending pills to people who live in states that ban or restrict abortion.

The MAP is one of just four organizations in the U.S. operating under recently enacted state shield laws, which circumvent traditional telemedicine laws requiring out-of-state health providers to be licensed in the states where patients are located. Eight states have enacted these shield laws.

Sponsor Message

Pregnant patients can fill out an online form, connect with a doctor via email or text and, if approved, receive the pills within a week, no matter which state they live in.



SHOTS - HEALTH NEWS

Abortion is becoming more common in primary care clinics as doctors challenge stigma

Shield law practices account for about 10% of abortions nationwide. There were 9,200 abortions a month provided under shield laws from January to March of this year, according to fresh data from the Society of Family Planning's WeCount project. And some researchers estimate that this number has risen since then and could be as high as 12,000 per month.

The rise of telehealth is part of why the number of abortions in the U.S. has continued to go up since the Supreme Court overturned *Roe v. Wade* in 2022 — even though 14 states have near-total abortion bans. In those states, shield law providers represent the only legal way people can access abortions within the established health care system.



"If you want to have your abortion care in your state and you live in Texas or Mississippi or Missouri, right now shield law provision is by far the most dominant way that you'd be able to get that care," says Foster.

Elissa Nadworny/NPR

Back in Massachusetts, Foster glances down at the list of today's patients. The practice's four OB-GYNs have signed off on prescriptions for nearly two dozen women — in Texas, Florida, Tennessee, Georgia, Alabama, Oklahoma and South Carolina. Most of today's patients are around six weeks along in their pregnancy. Many already have children.

"I really need an abortion pill. My state has banned it. My funds are really low," one patient wrote on the online form she filled out for the doctor.

"I'm a single mom with a kid under two," another wrote. "I can't afford a baby. I can't even afford this abortion."

Foster and her team serve patients who are up to 10 weeks pregnant and who are 16 or older. It costs $250 to get the two-drug regimen — mifepristone and misoprostol — in the mail, but there's a sliding scale and patients can pay as little as $5. The MAP is funded through abortion funds, individual donations and philanthropic gifts, and Foster has plans to apply for grants and state funding to help make the organization more sustainable. The MAP currently sends out about 500 prescriptions a month.

Yet to be tested in court, shield laws have some legal vulnerability

In the eight states with shield laws, abortion providers can treat out-of-state patients just as if they were in-state patients. The laws give abortion providers some protection from criminal prosecution, civil claims and extradition, among other threats. The laws have yet to be tested in court, but they certainly haven't gone unnoticed by lawmakers and groups looking to limit abortion.

"These websites are breaking the law … aiding and abetting crimes in Texas," says John Seago, the president of Texas Right to Life. "We want to use all the instruments that we have, all the tools available, to really fight against this new trend of abortion pills by mail."

Seago says providers should still be held responsible for committing a crime that is executed across state lines. "Mailing the abortion pill is a state jail felony according to our pro-life laws," he says, "but enforcement of those policies has been a real, real challenge."



Mifepristone, a drug used in abortion care, at the MAP's office in Massachusetts.
Elissa Nadworny/NPR

His organization has been looking for the right individual or circumstance to challenge shield laws directly in court. Three Republican-led states recently tried to sue the Food and Drug Administration over regulations allowing doctors to send pills through the mail, but the Supreme Court threw out the case in June over issues of standing. Those plaintiffs say they'll fight on. And a Republican attorney general in Arkansas sent a cease-and-desist letter to a shield law provider.

SHOTS - HEALTH NEWS



Seago thinks many conservative prosecutors have been hesitant to take legal action, especially in an election year. But he says it's important to act quickly, before abortion by mail becomes pervasive.

The people who are sending these pills know that there's risk in what they're doing. Some providers say they won't travel to or through states with bans so that they can't be subpoenaed, be served legal papers or even be arrested if there's a warrant. That may mean avoiding layovers at Dallas Love Field airport or a detour around those places on a cross-country road trip. For Foster, it means she can't visit her mom and stepdad, who retired to South Carolina.

"The thing about shield laws is that they're new, so we don't have a precedent to go off of," says Lauren Jacobson, a nurse practitioner who prescribes abortion medication through Aid Access, the largest of the four shield law providers. She says she avoids large swaths of the United States. "We don't really know what will or won't happen. But I'm not going to Texas. I've been before though, so that's OK for me."



SHOTS - HEALTH NEWS

Abortion bans still leave a 'gray area' for doctors after Idaho Supreme Court case

Shield laws don't offer blanket protection. The doctors and nurse practitioners who prescribe the pills have malpractice insurance in their states, but it's unclear whether those policies would cover suits from states with abortion restrictions. Patients use third-party payment services like Cash App or PayPal, which are also

untested in how they would work under a shield law. Would they give up information on a provider or patient if requested to do so by law enforcement?

How the experience looks

Lauren, who is 33 and lives in Utah, got pregnant while on birth control and decided that she couldn't afford another child. (NPR is not using her last name because she's worried about professional repercussions.)

Abortion is legal in Utah until 18 weeks, but there are only a handful of clinics in the state. The closest one to Lauren was several hours away by car. Several years prior, she had an abortion at a clinic in Salt Lake City, and it hadn't been a pleasant experience — she had to walk through protesters. The guilt from her conservative Christian upbringing was overwhelming.



Shield law practices account for about 10% of abortions nationwide. There were 9,200 abortions a month provided under shield laws from January to March of this year, according to fresh data from the Society of Family Planning's WeCount project. Some researchers estimate that this number has risen since then and could be as high as 12,000 per month.

Elissa Nadworny/NPR

"I got in my car and I cried," she recalls. "I just never wanted to go through it again."

This time, Lauren got pills from Aid Access, a shield law provider similar to the MAP. "I was a little bit sketched out, I won't lie," she says. "Because like, well, where is this coming from? Who is this under? How are they prescribing this?"

She and her partner did research to try to figure out whether what they were doing was legal. She says ultimately she couldn't find anything that clearly stated that what she wanted to do — have pills sent from an out-of-state doctor — was illegal.

She filled out a form online with questions about how far along she was and her medical history and then connected with a doctor via email and text messages. She googled the doctor, who she found was legit and practicing out of New York.

A few days later, she received abortion medication in the mail and had her abortion at home.

"To do it in the privacy of your own home, where I felt more support as opposed to going through protesters," Lauren says. "Especially with a provider within the state of Utah. I feel like there's always a judgmental indication or undertone."

The online doctor also followed up to make sure everything had gone OK, which Lauren appreciated. "I felt it was a little bit more thorough," she says. "They're checking in on you, like, 'How did you respond? What symptoms? What's going on?'"



A staff member of the MAP brings the boxes containing abortion medication to the local post office.
Elissa Nadworny/NPR

In Massachusetts, the folks who run the MAP hear much the same from their patients. Many emails and messages are logistical, like this email: "I took the first pill on Friday and all the other pills on Saturday. For how long should I be bleeding as I'm still bleeding this morning?"

Many others offer disbelief, relief and gratitude. "I just wanted to say thank you so much," wrote one woman. "I was terrified of this process. It goes against everything I believe in. I'm just not in a place where I can have a child. Thank you for making the pills easily accessible to me."

When Foster, who runs operations for the MAP, does a final tally of the patients who are ready to have their pills sent out, she notices a new note from a woman who just paid, bringing the day's total number of patients from 20 to 21.

"I am a single mother on a fixed income, and I can not afford a kid right now."

It's from a woman in Alabama who is six weeks pregnant and filled out her form around lunchtime. Within an hour, a MAP doctor had reviewed her case and prescribed her the medication. She paid the fee as soon as she was approved. All in all, the whole process took about three hours. Foster is able to pack up those pills and add them to the batch headed to the post office.

By 3 p.m., the Alabama woman's package is scanned by the Postal Service worker.

It's expected to arrive by the week's end.

abortion drugs mifepristone abortion provider misoprostol dobbs v jackson women's health organization roe v. wade

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EXHIBIT 65

Caroline Kitchener, *Blue-State Doctors Launch Abortion Pill Pipeline Into States With Bans*, Washington Post (July 19, 2023)

Abortion providers in Democrat-led states work with Aid Access to funnel pills into antiabortion states

washingtonpost.com/politics/2023/07/19/doctors-northeast-launch-abortion-pill-pipeline-into-states-with-bans

July 20, 2023

clockThis article was published more than **1 year ago**



Blue-state doctors launch abortion pill pipeline into states with bans

At least 3,500 doses have been shipped to antiabortion states since mid-June, a process enabled by new shield laws

A doctor reviews mailing labels as she prepares to ship abortion pills from her home in New York's Hudson Valley. (Nadia Sablin for The Washington Post)

11 min



By Caroline Kitchener
July 19, 2023 at 8:19 p.m. EDT

The doctor starts each day with a list of addresses and a label maker.

Sitting in her basement in New York's Hudson Valley, next to her grown children's old bunk beds, she reviews the list of towns and cities she'll be mailing to that day: Baton Rouge, Tucson, Houston.

A month ago, a phone call was the only thing the doctor could offer to women in states with abortion bans who faced unexpected pregnancies. Hamstrung by the laws, she could only coach them through the process of taking abortion pills they received from overseas suppliers.

Then, all of a sudden, the whole system changed. Now she can legally mail them pills herself.

A new procedure adopted in mid-June by one of the largest abortion pill suppliers, Europe-based Aid Access, allows U.S. medical professionals in certain Democratic-led states that have passed abortion "shield" laws to prescribe and mail pills directly to patients in antiabortion states.

Previously, Aid Access allowed only Europe-based doctors to prescribe abortion pills to women in states where abortion is restricted and then shipped those pills internationally, leaving patients to wait weeks. The telemedicine shield laws, enacted over the past year in New York, Massachusetts, Washington, Vermont and Colorado, explicitly protect abortion providers who mail pills to restricted states from inside their borders.

The result is a new pipeline of legally prescribed abortion pills flowing into states with abortion bans. In less than a month, seven U.S.-based providers affiliated with Aid Access — including the Hudson Valley doctor, who spoke on the condition of anonymity because she was concerned for her safety — have mailed 3,500 doses of abortion pills to people in antiabortion states, according to Aid Access, putting just this small group aloneon track to help facilitate at least 42,000 abortions in restricted states over the next year. If more doctors and nurses sign up, as current providers hope they will, the numbers could climb far higher.

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"Everything I'm doing is completely legal," the Hudson Valley doctor said, her family's ping-pong table covered with abortion pills bound for the South and Midwest, where abortion has been largely illegal since the Supreme Court overturned *Roe v. Wade* in June 2022.

"Texas might say I'm breaking their laws, but I don't live in Texas."

The development tees up a complicated interstate battle where doctors on U.S. soil are empowered to legally circumvent abortion laws — allowing blue states to potentially undermine the red state bans that many Republicans hoped would end abortion within their borders. Meanwhile, some conservative groups are angling to outlaw the abortion pill nationwide, attempting to outlaw the medication in the courts as well as calling for a national abortion ban.

The increasing flow of prescribed pills adds to an already expanding underground network for pills being imported from overseas and illegally distributed by abortion rights advocates largely without medical oversight, underscoring the prominent role pills are playing in post-*Roe* America.

The shield laws are “a huge breakthrough for people who need abortions in banned states,” said David Cohen, a Drexel University law professor who focuses on abortion legislation. “Providers are protected in many ways as long as they remain in the state with the shield law.”

Some lawyers say these doctors could face repercussions, even if they steer clear of traveling to states in which abortion bans call for prosecuting abortion providers. At a minimum, some experts said, the question of legal peril could wind up in a gray area ultimately resolved by the courts,such as whether shield law states have the power to block other states from extraditing people charged with crimes.

Major groups that support abortion rights, including Planned Parenthood and the American College of Obstetricians and Gynecologists (ACOG), have been largely silent on the subject of mailing pills from shield law states. Several Aid Access providers say the groups have expressed concern about backing the approach, worried that providers could put themselves at risk.

Molly Meegan, the ACOG’s general counsel and chief legal officer, said the group is “not positioned to provide legal advice to individual members,” adding that “it is wrong for a state to be able to prosecute clinicians and patients in other states where abortion remains legal and unrestricted.” Planned Parenthood issued a statement saying that its advocacy arm was “doing everything possible, and looking into every opportunity, to ensure that patients can access care no matter where they live.”

Jonathan Mitchell, the former solicitor general of Texas and architect of the state’s six-week abortion ban, said it was too early to predict how these shield laws would play out, but said the providers may face consequences.

“There absolutely is a world in which they could get in trouble for it,” he said. “Someone in Texas could do a sting operation and charge them with attempted murder.”

In many states, including Texas, someone found guilty of distributing abortion pills could be sentenced to at least several years in prison. Current abortion bans explicitly exempt those seeking abortions from prosecution, though prosecutors have a history of charging people who have abortions with other crimes.

The Hudson Valley doctor said she’s not worried about her own legal risk. When she arrives at the post office with dozens of new packages every afternoon, she said, no one ever asks any questions.

“Nobody has any idea. I could be doing so many different mailer businesses from home,” she said. “It could be beaded necklaces. It could be soaps. It could be candy.”

Massachusetts passed the first telemedicine abortion shield law of its kind just days after *Roe v. Wade* was overturned. The most recent law passed in New York in mid-June.

The New York law specifies that no state or local government employee “shall cooperate with or provide information to any individual or out-of-state agency or department regarding any legally protected health activity in this state.”

With shield laws, abortion rights advocates have seized an opportunity to “define the landscape,” said Julie F. Kay, a human rights lawyer and the legal director of the Abortion Coalition for Telemedicine Access. One key question that could emerge in the coming months is whether prosecutors in any antiabortion states would attempt to extradite medical providers from shield law states, thereby challenging the power of the new laws.

Kay said that traditional extradition laws would be difficult to apply in these circumstances.

“One state can extradite if a person commits the crime in the state, then flees,” Kay said. “But no one is fleeing here. You are just sitting in your office in New York.”

Aid Access started sending abortion pills to women in the United States long before the June 2022 Supreme Court ruling. The service, which costs $150 or less, is far cheaper than having a surgical abortion or obtaining medication at a clinic — usually between $500 and $800 — making it an appealing option even to people in states where abortion is readily accessible.

Once *Roe* fell, the organization operated in a legal gray area, shipping pills to antiabortion states from India. Aid Access providers mail pills sealed in clearly marked boxes, setting the organization apart from many other overseas pills suppliers, which send pills without a prescription, sometimes unmarked and unsealed.

Demand for pills from Aid Access has soared since the June 2022 Supreme Court ruling, with the organization receiving almost 60 percent more requests for pills this spring than in the months immediately following the decision, according to Abigail Aiken, lead investigator of the Self-managed Abortion Needs Assessment Project at the University of Texas at Austin. People seeking an abortion often find the group online, then make their request through its website. The request gets forwarded to one of the providers.

U.S.-based Aid Access providers were used to the process of receiving and processing requests for abortion pills, accustomed to working with patients in states where abortion is legal — but the process of ordering the medication and mailing it out was far less familiar.

The providers order mifepristone and misoprostol — the pills in a two-step medication abortion regimen — from licensed pill distributors, and ship out the pills to patients fairly quickly along with detailed instructions.

Before the recent change in procedure, the Aid Access providers would send all of their prescriptions to an online pharmacy in California to handle shipping, one of two online pharmacies nationwide that dispenses abortion pills. But neither of those pharmacies is located in a state with a shield law. Until California passes one, a development that is expected this fall, the doctors have to prepare and package the pills bound for restricted states themselves, creating their own labels to stick on the pill boxes they receive, providers said. (Doctors are legally permitted to order and distribute pills on their own, the providers said — it’s just not typical.)

“We’re medical providers suddenly thrown into this world of shipping,” said Lauren Jacobson, a nurse practitioner who operates out of Massachusetts. “Do we write labels by hand? What if we mess up an address? How on earth do we ship 50 packages a day?”

Jacobson concedes that this system is far from perfect. While medication abortion is overwhelmingly safe and effective, she said, on rare occasions her patients in restricted states require in-person care — and they fear the legal risk that could come with a trip to the hospital. In those cases, she said, she will try to help them navigate their state’s health-care system safely, searching online for a trustworthy provider and advising them on what to say. Sometimes, she said, she’ll go on LinkedIn and scope out the local OB/GYNs, searching for someone who has posted something that supports abortion rights.

“This isn’t normal health care,” she said. “We don’t want to have to do this.”

Providers also recognize that many patients prefer or require a surgical procedure to end their pregnancy instead of pills.

One major impetus for Aid Access changing its protocol was the shipping time, said Linda Prine, an Aid Access provider and doctor based in New York. Patients would have to wait weeks for pills shipped from India, she said, often pushing their abortions well into the second trimester — a far more difficult and complicated process. (The U.S. Food and Drug Administration endorses the use of abortion pills up to 10 weeks, though some studies show it's safe and effective to use them significantly later in pregnancy.)

"They were having a really scary miserable experience," Prine said, with some far enough along that they wouldpass a recognizable fetus.

Prine founded the Miscarriage and Abortion Hotline, where people often call with questions about medication abortion. Since Aid Access's protocol change, she said, she has noticed a significant decrease in calls from women who are taking pills in their second trimester.

Eventually, the Aid Access providers fully expect Republicans to take a swing at their efforts.

"We're all like, 'Okay which one of us is going to be the case?'" said the doctor in the Hudson Valley. "It's not if there will be lawsuits, it's when."

Jacobson said she trusts the Massachusetts courts to protect her.

"We have seven American providers who are stepping in and saying, 'You know what, we're not going to be intimidated,'" Jacobson said.

The providers are eagerly waiting for the shield law to pass in California.

Once that passes, the Hudson Valley doctor may no longer have to run a complex shipping operation from her basement. She'll likely be able to send her prescriptions to the pharmacy, just like she used to, she said.

For now, she said, she doesn't mind staying up until 1 a.m. to finish the packing.

"It feels like I'm giving a big middle finger to that part of the country that has done this," she said.

U.S. abortion access, reproductive rights

Tracking abortion access in the United States: Since the Supreme Court struck down *Roe v. Wade*, the legality of abortion has been left to individual states. The Washington Post is tracking states where abortion is legal, banned or under threat.

Abortion and the election: Voters in about a dozen states could decide the fate of abortion rights with constitutional amendments on the ballot in a pivotal election year. Here's where Vice President Kamala Harris and former president Donald Trump stand on abortion.

Abortion pills: The Supreme Court refused to limit access to the abortion pill mifepristone. Here's how mifepristone is used and where you can legally access the abortion pill.

Reproductive rights: The Senate voted to block a bill to create a federal right to contraception access. Since *Roe v. Wade* was overturned, far-right conservatives have been trying to curtail birth-control accessby sowing misinformation about how various methods work to prevent pregnancy. See how every senator voted on the Right to Contraception Act.

Exhibit G

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EXHIBIT 66

Caroline Kitchener, *Alone in a Bathroom: The Fear and Uncertainty of a Post-Roe Medication Abortion,* Washington Post (April 11, 2024)

Alone in a bathroom:

The fear and uncertainty of a post-Roe medication abortion

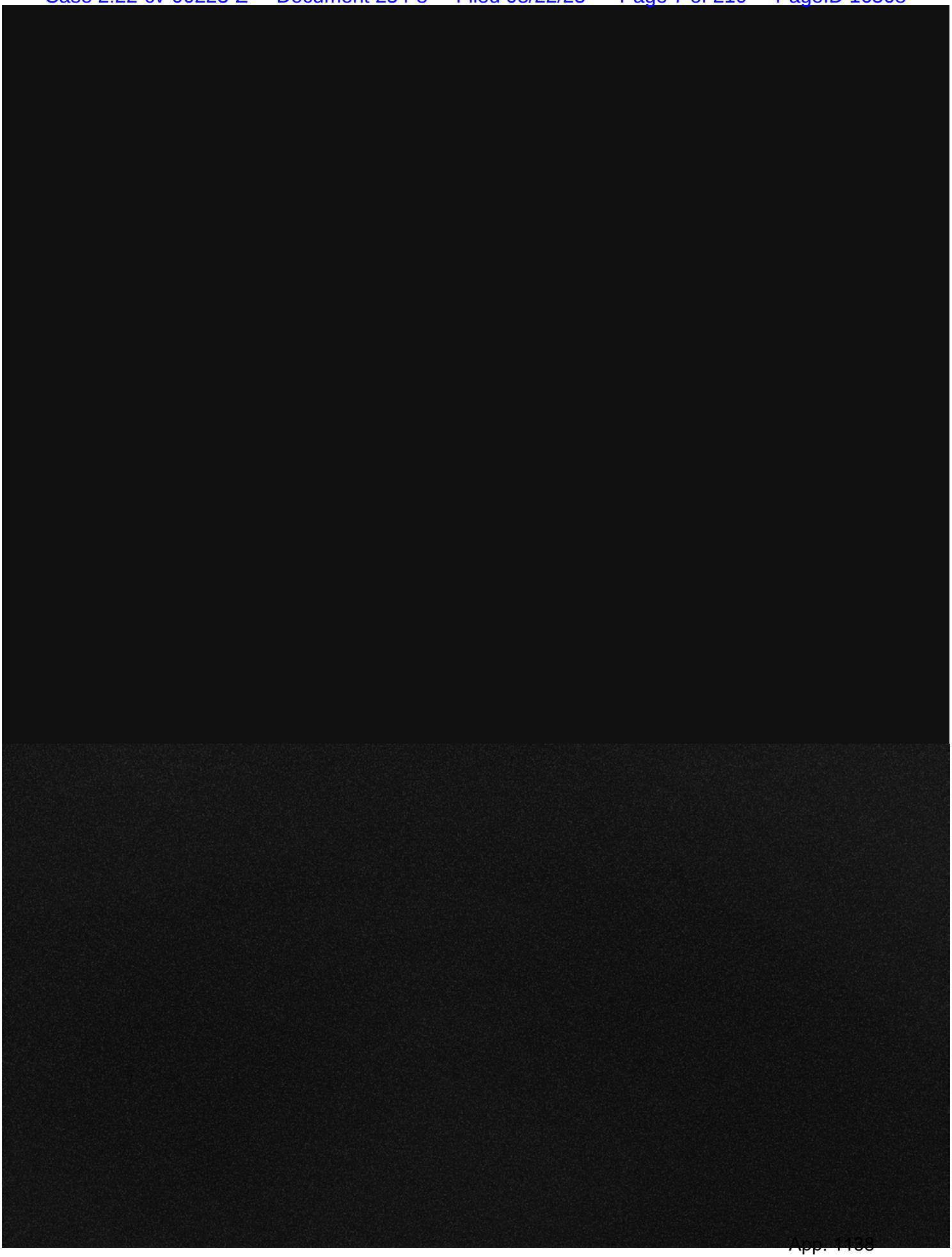
By Caroline Kitchener

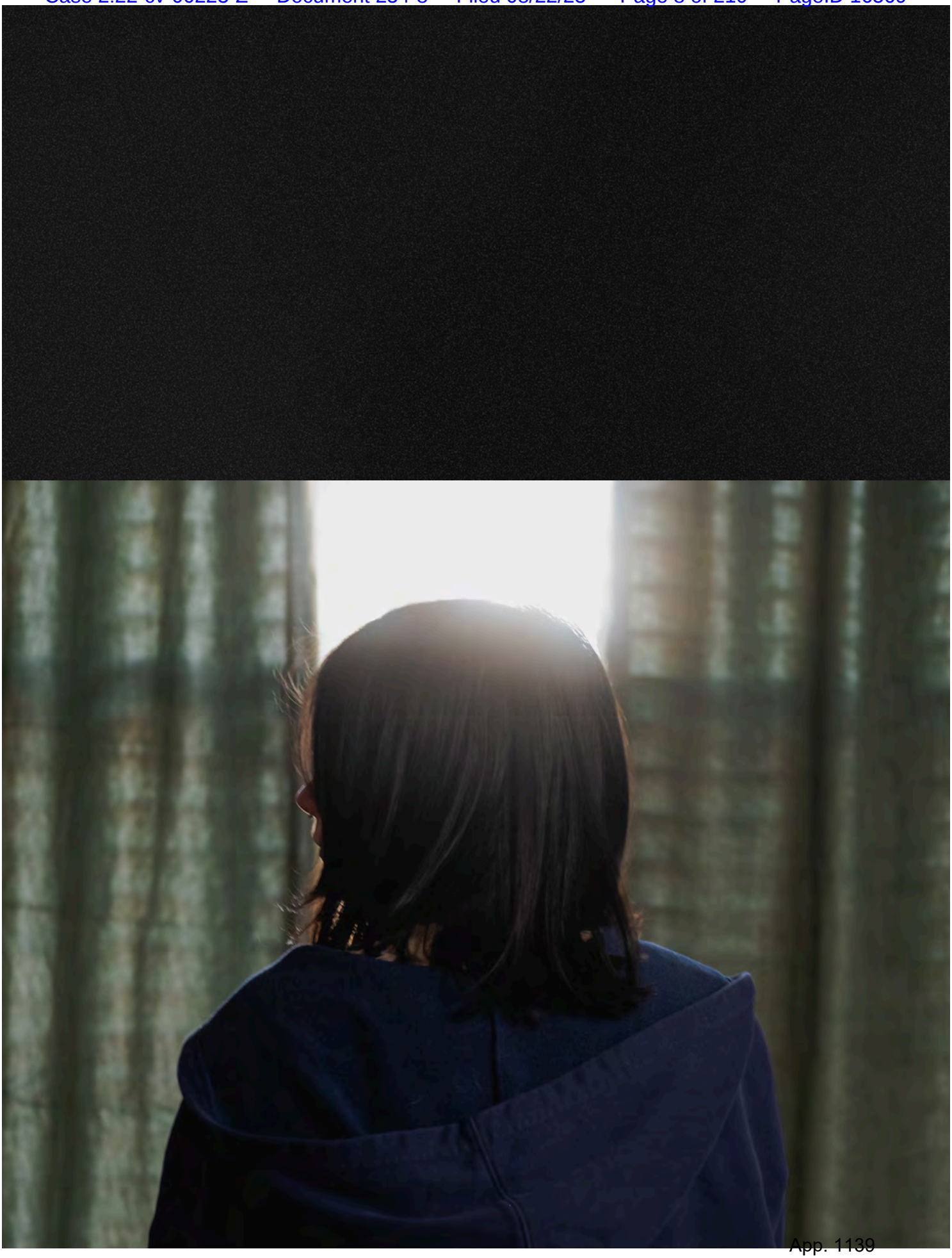
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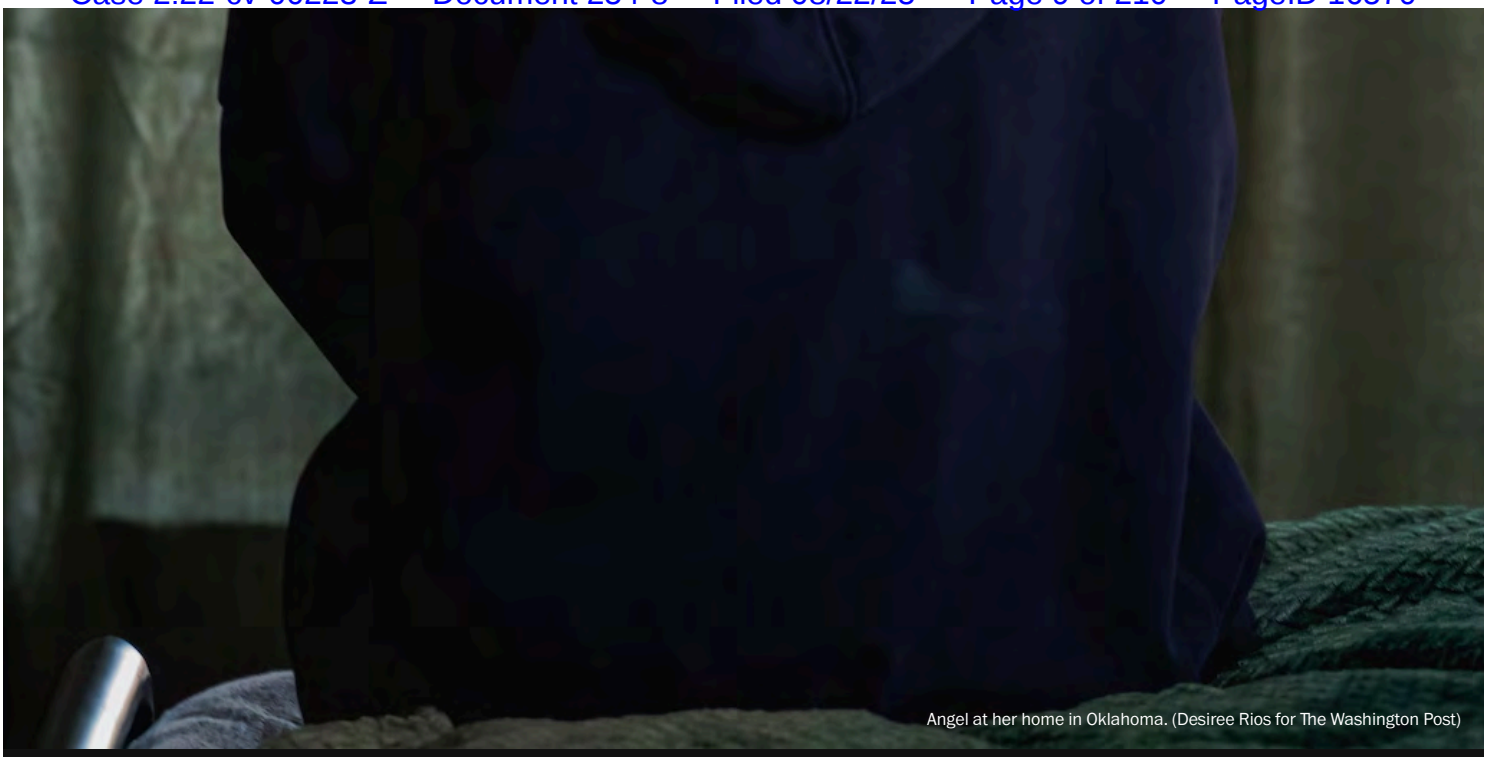
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SCROLL TO CONTINUE

Angel tucked two white pills into each side of her mouth, bracing herself as they began to dissolve.







Angel at her home in Oklahoma. (Desiree Rios for The Washington Post)

Angel had wanted to talk to a doctor before she took the pills to end her pregnancy, worried about how they might interact with medication she took for her heart condition.

But in her home state of Oklahoma, where almost all abortions are banned, that wasn't an option.

The pain kicked in after about an hour, around midnight on a Sunday in January, eventually becoming sharp enough that the 23-year-old said she struggled to stand. While Angel would be fine by the next morning, she worried that something might be very wrong as she lay on the cold bathroom tile, her body racked by some of the worst pain she could remember.

When Angel's fiance came in to check on her, she was having diarrhea while vomiting into their popcorn bowl.

"F---," she remembered yelling, over and over. "I feel like I need to push."

Overwhelming evidence shows that abortion pills are safe and effective, and that many patients who take them go through the process without much difficulty, experiencing little more than the sharp cramping and bleeding of an unusually heavy period. That is true even when the pills, approved by the U.S. Food and Drug Administration with a prescription for use through 10 weeks of pregnancy, are taken somewhat independently — administered by a doctor over text, email, or a call and mailed to the patient at home.

But the experience can feel very different in states where abortion is illegal. As more women in states with abortion bans choose to end their pregnancies on their own, without directly interacting with a medical professional, they are thrust into a largely ad hoc, unregulated system of online and grass-roots abortion pill distributors — an experience that, while deemed generally safe by medical experts, can be confusing, scary and, at times, deeply traumatic.

"I feel like I need to push."

"Self-managed" abortions increased dramatically after *Roe v. Wade* was overturned — with women in antiabortion states obtaining pills through several distinct channels. At least 6,000 women every month in states with bans are now receiving pills from Aid Access, a Europe-based online clinic that prescribes the medication without requiring a patient to interact with a doctor in real time, according to founder Rebecca Gomperts. Thousands of others are turning to at least 25 nonmedical websites that sell the pills, or one of several volunteer-led networks that distribute them for free.

With abortion clinics shuttered across the South and Midwest, many women said they have nowhere to go to confirm that their abortion pill supplier is "legit" or that their symptoms after taking the medication are normal. They worry that a call to a doctor or a trip to the emergency room could land them in jail. And while abortion rights advocates have tried to build new infrastructure to support women in these situations — with volunteer doctors answering phone calls or former abortion providers staffing the occasional bricks-and-mortar office in an antiabortion state — organizers say that such resources are no replacement for the array of choices women had before *Roe* fell.

The demand for self-managed abortions in states with bans, already enormous, is sure to increase dramatically in the coming weeks, as strict new abortion laws

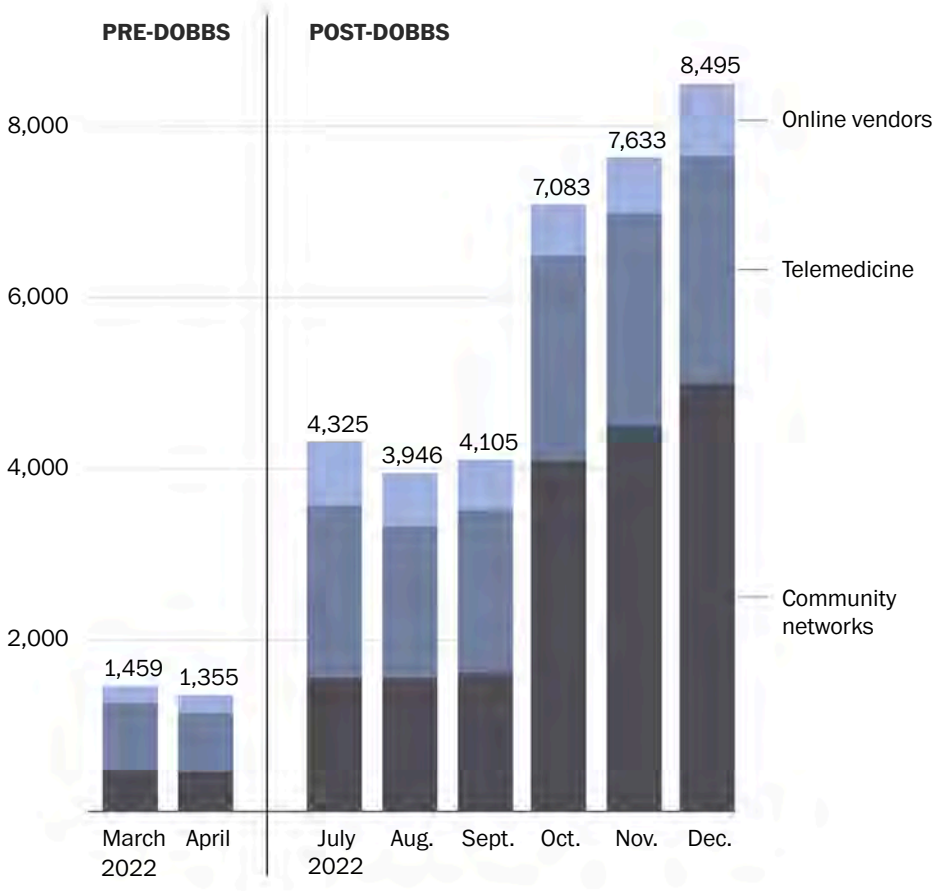
take effect in Florida and Arizona — the result of two recent court rulings.

"This is not the way health care should be," said Linda Prine, a New York-based doctor who prescribes pills through Aid Access and co-founded a hotline for people taking them. "All the options have been taken away from people by these bans and this is all that's left," she added, referring to the networks providing pills for women self-managing their abortions.

"It really is all we can do."

Supply of abortion pills for self-managed abortions

The supply of abortion pills outside of the formal health-care setting increased sharply in the six months after *Dobbs v. Jackson Women's Health Organization*, a landmark ruling that eliminated the constitutional right to abortion. A major factor in the increase was the rise of community-based, volunteer-led networks that organized to help women in states with abortion bans.



Source: JAMA (2024)

Adding to the difficulty is a polarized political debate with dueling narratives about what it's actually like to take abortion pills. Antiabortion activists say the pills are highly dangerous, or even deadly, for pregnant women — false assertions based largely on studies that have now been retracted by the journal that published them. Meanwhile, many abortion rights advocates describe the experience as straightforward and easy to handle on your own, a

characterization that some women say glosses over what can be a more complicated reality of ending a pregnancy alone in your bathroom.

The Washington Post spoke with more than three dozen doctors, advocates, leading researchers, and women who took the pills in states where abortion has been banned since *Dobbs v. Jackson Women's Health Organization,* the Supreme Court case that overturned *Roe* in June 2022. Over the phone and in person, many women described experiencing deep anxiety and uncertainty about doing something they assumed was illegal. These feelings often intensified after they took the medication, with some not expecting the level of pain or amount of bleeding they would experience, or how much of the fetus they would see. A few used the pills later in pregnancy than the FDA recommends.

"I wish I would have known that it wasn't just blood clots. … I was really confused and shocked," said Briana, a 34-year-old in Alabama who took pills she ordered online when she was at least five weeks beyond the FDA's 10-week limit. Like other women interviewed for this article, Briana spoke on the condition that her last name not be used so she could discuss sensitive medical information in a state that outlaws abortion — describing her experience in graphic detail because she said she wanted other women to know what to expect.

The complex legal landscape can be hard to understand. Abortion bans do not allow people seeking abortions to be prosecuted, targeting only doctors and others involved in facilitating the abortion. But people have been charged under other laws for self-managing their abortions, especially later in pregnancy.

A legal challenge to the abortion drug mifepristone brought by conservative advocates — which drew skeptical questions from the Supreme Court during oral arguments last month — seeks to further restrict the post-*Roe* landscape by requiring in-person medical visits for all legally administered medication abortions. Such a change could prevent U.S.-based medical providers from mailing pills into antiabortion states under "shield laws," recently enacted in a handful of blue states, that protect doctors from prosecution under red state bans.



Angel pours out her heart medication at her home. (Desiree Rios for The Washington Post)



Angel was worried about how abortion pills might interact with medication she takes for her heart condition.

In Oklahoma, Angel ordered her pills from Aid Access, according to emails reviewed by The Post, and took them five to six weeks into her pregnancy. She'd told doctors at the online clinic about her heart medication when she filled out its online form, she said, but no one ever reached out about it — a silence easily explained, Prine said, because Angel's medication is not one that would raise concerns.

Angel had no way of knowing that.

Sitting on the toilet, she could hear her heart pounding in her ears. She placed two fingers on the side of her neck to take her pulse and started a timer, she recalled — counting about 190 beats per minute.

With her heart condition, she said, she was supposed to seek medical attention if her heart rate got that high.

Angel had no idea who to call. She vaguely remembered a hotline number in the Aid Access instructions, but figured the line would be closed that time of night.

The hospital didn't feel like an option, either. She worried about the questions she might get from suspicious doctors if she showed up at the emergency room.

She closed her eyes and tried to steady her breath, determined to keep her heart rate down. Then she spoke to herself as she imagined a doctor might.

"You will be okay," said Angel, who would wake up the next morning no longer pregnant, the worst moments of her abortion behind her.

"This pain can't last forever."

"Your body will be just fine."

"Your uterus knows what to do."

A doctor answers panicked calls

"It's normal to be scared."

"Just wait it out."

"Call back any time."

Linda Prine was answering a few emails, coffee mug in hand, when her cellphone rang.

"Hi, this is the hotline doctor," the 72-year-old said from her New York City home one Sunday morning in January. "Can I help you?"

The voice Prine heard was quiet and scared — belonging to a 15-year-old with an area code in a state with an abortion ban who had taken pills and passed a fetus larger than she'd expected.

Unable to flush the fetus down the toilet, the girl asked about throwing it away.

She was young enough to be Prine's granddaughter.

Prine cradled the phone in both hands and leaned in, trying to channel every ounce of reassurance and understanding she could muster through the phone line.

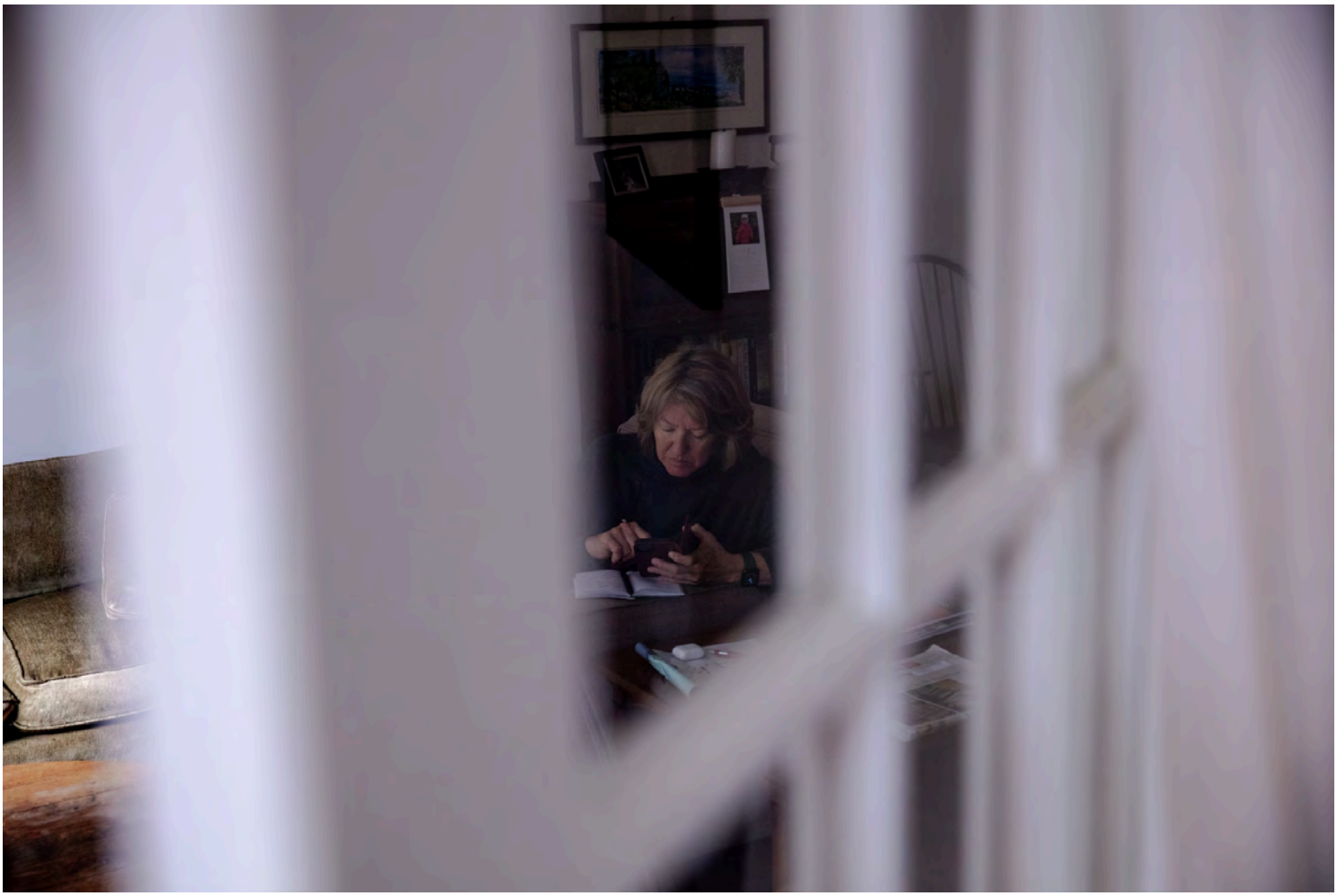
"There's nothing in there that's traceable back to you," she said. "As long as you don't tell anybody."

The girl asked if the abortion made her a bad person.

"No it doesn't," Prine said. "Not a bit."

"You are doing what's right for you and your future family," she added, her voice firm.

"This way you can be a good mom when you're ready to be a good mom."



Linda Prine answers calls and texts for the Miscarriage and Abortion Hotline. (Natalie Keyssar for The Washington Post)

A semiretired family medicine physician, Prine co-founded the Miscarriage and Abortion Hotline in 2019 as a resource for people self-managing miscarriages or abortions at home. She got the idea from Gomperts, of Aid Access, who had already been mailing pills to Americans who struggled to access abortion. The American patients had a lot of questions and concerns about ordering pills outside a formal health-care setting, Gomperts told Prine — and her inbox was constantly flooded with emails.

They needed a U.S.-based doctor to call.

> "You are doing what's right for you and your future family."

Calls to the hotline surged after Texas enacted an early law banning most abortions in the fall of 2021, Prine said, and again after new abortion bans took effect across the South and Midwest when *Roe* fell. Now the line is staffed by over 50 U.S.-based medical providers who volunteer their time, a mix of doctors, midwives, nurse practitioners and physician assistants with experience in abortion care. The doctors who run the hotline recruit volunteers through word-of-mouth recommendations, then administer a few hours of virtual training before they start.

In interviews, Prine stressed that hotline doctors are not practicing medicine under their licenses or establishing a doctor-patient relationship — a posture Prine said legally protects the physicians. By design, the hotline volunteers don't ask for the names, locations or full medical histories of the people who call. On the hotline's website, a disclaimer notes that they are not offering "legal or medical advice," and that the information they provide "does not substitute for the … advice of a doctor."

The hotline typically receives roughly 30 calls and 50 texts from people every day. Many say they are in states that ban abortion.

"They'll say, 'I'm in a state where this is illegal, so I can't go get medical care. I want to check in and make sure everything is going okay,'" Prine said.

She and her colleagues hear the same questions again and again: Am I bleeding too much? Am I not bleeding enough? Is it normal to have this much pain? People call to see if they can drink alcohol or smoke marijuana after taking the pills. One woman asked whether it was safe to walk up the stairs.

[What to know after taking abortion pills]

Anxiety and uncertainty are common even among patients who receive the medication at an abortion clinic in a state where abortion is legal, said Prine — because they're at home by the time they start feeling the full effects.

"People from anywhere can be freaking out because everyone is taking these pills at home alone," Prine said.

Still, some feel better taking the pills after having a direct conversation with a medical professional. Since *Dobbs*, many women in antiabortion states who

have the resources to travel have continued to leave the state to obtain pills at a clinic instead of ordering online, preferring the experience of being face to face with a doctor, even if it means a long drive or a flight.



The Miscarriage and Abortion Hotline is staffed by over 50 U.S.-based medical providers, a mix of doctors, midwives, nurse practitioners and physician assistants with experience in abortion care. (Natalie Keyssar for The Washington Post)



A cross stitch at the home of Linda Prine.

For those who choose to self-manage their abortions, Prine said, she is there to offer reassurance that their experiences are nothing out of the ordinary, and that they almost certainly don't need to go to the emergency room. A medication abortion is just like a miscarriage, she'll tell them, with hundreds of women going through the same process every day.

Of the approximately 5.9 million patients in the United States who took mifepristone — the first drug in a two-step medication abortion regimen — between its 2000 approval and December 2022, just 32 died, according to the FDA. Those cases, the agency says, "cannot with certainty be causally attributed to mifepristone." Major adverse events — in which a blood transfusion, major surgery or overnight hospital stay is required — occur in fewer than 0.5 percent of cases, a figure that remains the same whether a patient has met with a doctor in person.

A significantly larger share of patients who take abortion pills seek emergency care, ranging from 1.3 to 8 percent in leading studies.

Adverse effects are extremely rare among those who take abortion pills

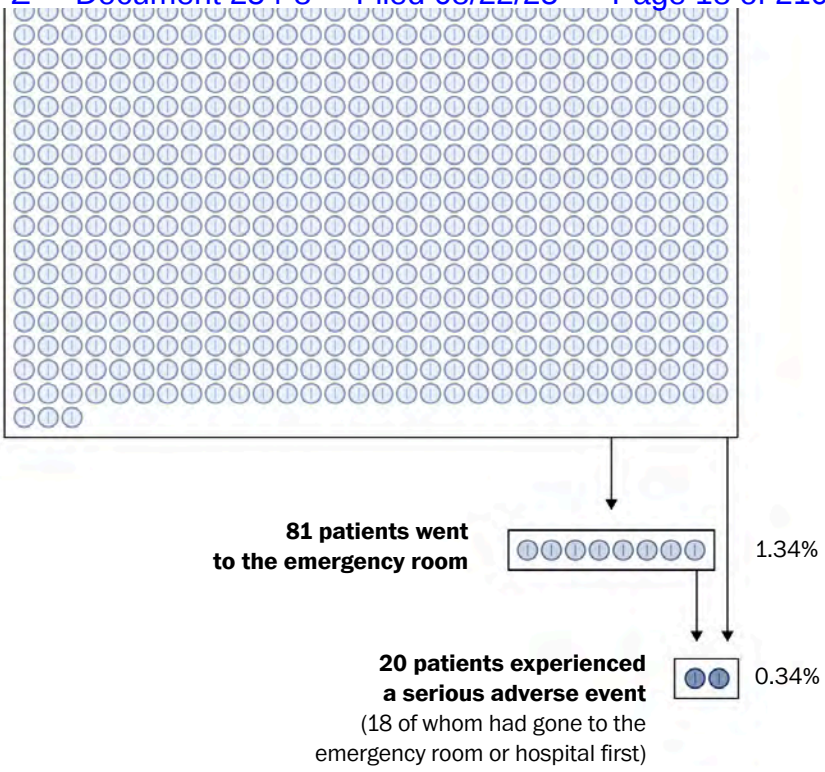
A tiny fraction of patients who take abortion pills have a serious adverse event such as a blood transfusion, major surgery or overnight hospital stay.

ⓘ = 10 estimated patients who took abortion pills

6,034 patients took abortion pills



100%



Note: Estimated patient numbers are based on percentages included in a 2024 study and are rounded to whole people.

Source: Ushma Upadhyay/Nature Medicine

Antiabortion activists portray those emergency room visits as an indication of a safety issue, but leading medical experts say they instead highlight the confusion and fear that many women experience after taking the pills. Patients often go for a gut check, doctors and medical researchers said, wanting to confirm that they're not bleeding too much, or that the pills worked and they are no longer pregnant. Studies show that 35 to 50 percent of people who go to an ER after taking abortion pills receive no treatment.

"With medication abortion, there's no one saying, 'You're doing great. This is normal,'" said Ushma Upadhyay, a professor at the University of California at San Francisco and a leading researcher on the safety of abortion pills, drawing a distinction between the pill and a surgical procedure. "Often people are going through it alone, so they want to know everything is okay."

On the hotline, Prine said she's felt the need to send someone to the emergency room only once in nearly five years.

"Your uterus knows what to do," Prine told a woman who called that January morning with reports of unexpectedly heavy bleeding. "It's going to take care of itself."

Others in the medical community are quicker to suggest that someone be seen in

person.

On the infrequent occasions when a patient calls with concerns about their medication abortion, Clayton Alfonso, an OB/GYN at Duke University, said he'll try to evaluate how much she is bleeding and how her body is tolerating the blood loss. But he said it can sometimes be difficult to make those assessments over the phone.

"When you take a patient call, it's always hard because their definition of heavy bleeding could be different from my definition of heavy bleeding," said Alfonso, adding that he usually tries to bring patients into his clinic if he has space on the schedule. "I would much rather see someone than leave someone in limbo at home not knowing what to do."

In states with abortion bans, the emergency room is often the only option for women who want in-person care during their medication abortions. Even if they say they had a miscarriage — a condition that presents with symptoms indistinguishable from a medication abortion — many women in these situations have bad experiences at the hospital, Prine said, encountering physicians who provide inaccurate information or ask suspicious questions about why they're bleeding.

"Your uterus knows what to do."

Prine said she recognizes that the landscape for self-managed abortions is tenuous. The antiabortion movement is ready to seize on any experience with pills that is difficult or complicated, she said, especially the relatively rare cases in which women take pills later in pregnancy.

At the Conservative Political Action Conference last year, prominent antiabortion activist Abby Johnson said women are delivering "fully formed babies" in their bathrooms — a false description of what women see during a medication abortion, even in the second trimester.

"They're passing these babies into the toilet," said Johnson, founder of the antiabortion group And Then There Were None. "Then these women have to make a decision: What do I do with this fully formed baby?... Do I flush my child down the toilet?"

These kinds of incendiary attacks make it hard for abortion rights advocates to discuss the details of a medication abortion later in pregnancy, said Prine and Gomperts — because the specifics could be weaponized by the antiabortion movement.

As a result, Prine said, women who take pills later in pregnancy are sometimes surprised by what they see.

"How much bleeding is normal?"

"Do I push it out?"

A woman struggles to pass her pregnancy

"Should I go to the hospital?"

"I'm totally alone."

At her home in Alabama, Briana waited to take the pills until she'd put all of her children to sleep.

The cramps in her lower back came first, followed by full-body chills and, eventually, contractions more painful than those she remembered from childbirth.

After lying in bed for two hours, Briana felt something "pop" under the comforter, followed by a gush of warm liquid seeping down her legs. She ran to the bathroom, she recalled in interviews and a journal entry, where she felt a mass larger than her palm drop into the toilet.

"This can't be happening," she thought to herself.

Then she looked down to see a bloody umbilical cord dangling between her legs.



When the pills first arrived in the mail a few days earlier, in April 2023, Briana had expected her experience would be more difficult than most. The doctors who administered the medication through Aid Access cautioned Briana that they "do

not like to recommend medical abortions "as far into pregnancy as she would be when the pills reached her, according to emails reviewed by The Post.

Briana felt she had no choice. By the time she found out she was pregnant, she was already 11 or 12 weeks along. The abortion clinic she'd called in a different state, more than a six-hour drive from her home in Alabama, where abortion is banned, was booked for surgical procedures for over a month, busy treating patients from other antiabortion states across the South. She spent nearly two weeks researching her other options, then the pills she ordered took two weeks to arrive.

The 34-year-old was struggling to support the kids she already had.

"I didn't want to take any more away from them ... time, attention, money," said Briana, who estimates that she was 15 or 16 weeks along when she took the pills.

"This can't be happening."

Experts and advocates say it is relatively rare for women to self-manage their abortions well beyond the FDA's 10-week limit, particularly since passage of the shield laws, allowing U.S.-based doctors to mail pills directly into antiabortion states instead of relying on international pharmacies. That change has reduced the shipment time from several weeks to between three and five days.

At the time Briana ordered her medication, over a year ago, Aid Access generally did not send pills to anyone who said they were further than 11 weeks into their pregnancy, Gomperts said. It now allows people to place orders through 12 weeks of pregnancy, because pills reach patients more quickly.

"If we think people might be longer than that, they get an email to make sure they can navigate the situation," said Gomperts, who personally prescribed Briana's medication, according to documentation reviewed by The Post. "Women have agency. They are perfectly capable of making these choices about their own health, and we are there to support them the best we can."

According to data compiled by Aid Access, and shared with The Post, 1 in 20 patients who responded to the organization's survey in January took the pills beyond 11 weeks of pregnancy. One in 100 took the pills beyond 13 weeks. (About 20 percent of people who took the pills responded to the survey.)

Still, Prine said, she has fielded far more of these calls from women later in pregnancy than she would like — averaging one a day on the hotline in the months after the Supreme Court decision. Some of the callers had no idea how

far along they were until they passed the pregnancy, she said. Others knew, but chose to go ahead anyway.

Beyond 12 or 13 weeks, women will see a much more developed fetus, with identifiable features.

“We hear the trauma when we talk to people,” Prine said. “It’s an image you can’t get out of your head.”

How we reported this story

Caroline Kitchener reported this story from four states. She witnessed Ashley’s ultrasound in Texas, watched Linda Prine answer hotline calls in New York, and interviewed Angel and Briana in Oklahoma and Alabama. She also spoke on the phone to women who self-managed their abortions at home.

Alone in her bathroom, Briana had no idea what to do. The Aid Access doctors had told her to expect nausea, vomiting, chills, blood clots and a fetus at least the size of an orange, emails show.

They said nothing about an umbilical cord.

“Do I pull the cord out?” Briana wondered, frantically trying to remember what the doctors had done when she gave birth. “Do I just wait to try to push it out?”

Her boyfriend was sleeping in the next room. Even if she woke him up, she wondered, what could he do? If she went to the emergency room, she said, she felt sure she’d be prosecuted.

Finally, Briana decided to call the number for the Miscarriage and Abortion Hotline she’d seen in an email from Aid Access.

“That’s the placenta you need to push out,” Briana recalled the woman on the hotline saying. “When you feel the next contraction, I want you to push like you’re giving birth.”

Briana said she sat there with her umbilical cord hanging loose for at least 15 minutes before the placenta finally dropped into the toilet.

While there are no major U.S.-based studies on the experience of self-managing an abortion with pills later in pregnancy, international research suggests that women in these situations more frequently seek in-person care. One study conducted with patients in Argentina, Nigeria and Southeast Asia between nine and 16 weeks of pregnancy found that about 24 percent went to a medical facility during or after the experience of taking the pills on their own. Approximately 10 percent required medical intervention to complete the abortion or treat a complication.

One major concern later in pregnancy is that the body won't be able to expel all of the pregnancy tissue, several doctors said.

When the Miscarriage and Abortion Hotline received its first call from a woman who was unable to pass her placenta — at least five weeks further into her pregnancy than the FDA's 10-week limit — a group of hotline doctors started messaging one another, trying to decide what to say to her, Prine said.

One doctor in the group insisted that the woman had to go straight to the ER, but Prine and others disagreed. Worried the woman could face prosecution or mistreatment if she went to the hospital, Prine said, they walked her through her abortion at home, instructing her to take more abortion pills and gently massage her stomach until the placenta came free — the same advice Briana said she received.

"We didn't feel like it was a medical emergency. She wasn't bleeding heavily and she wasn't lightheaded," said Prine, adding that they would have recommended the woman go the ER if a hospital visit was medically necessary.

A woman in that situation could have hemorrhaged or become septic, according to five OB/GYNs interviewed for this article.

"Whenever there is something inside the uterus that is trying to come out and won't come out, the risk of bleeding and infection gets higher with every passing moment," said Keri Garel, an OB/GYN at Boston Medical Center, adding that she would advise someone in Briana's situation to go to the hospital immediately. "At that point, your life is the most important thing."

"Do I pull the cord out?"

As difficult as the situation was, Briana says she is extremely grateful that Aid Access was willing to send her the pills — and that someone on the hotline was

available to talk her through taking them.

"Without the hotline I would have been completely lost and literally completely alone," she said.

"The lady ... stayed talking to me for hours," Briana added. "I wish I knew her name."

Briana stayed in the bathroom that night for more than an hour. She knew she shouldn't look at the fetus, she said, but she couldn't help it. In the toilet bowl, she could make out a head. She remembered thinking that the legs looked long.

"I felt like a monster," she said, reflecting back on that moment.

A year later, Briana said, she is certain she made the right decision for herself and her family. But she wishes someone had told her more about what to expect. If she had known the full extent of what could happen during a medication abortion at 15 or 16 weeks, she said, she probably would have searched harder for an out-of-state clinic with available appointments — and figured out a way to drive six hours or more to Florida, Illinois or North Carolina.

Before *Roe v. Wade* was overturned, Briana could have gone to a clinic less than 30 minutes from her house.

"We can see you tomorrow."

"Here's what you should expect."

A former abortion provider offers some relief

"That website is real."

"You are going to get through this."

"Your uterus looks beautiful."

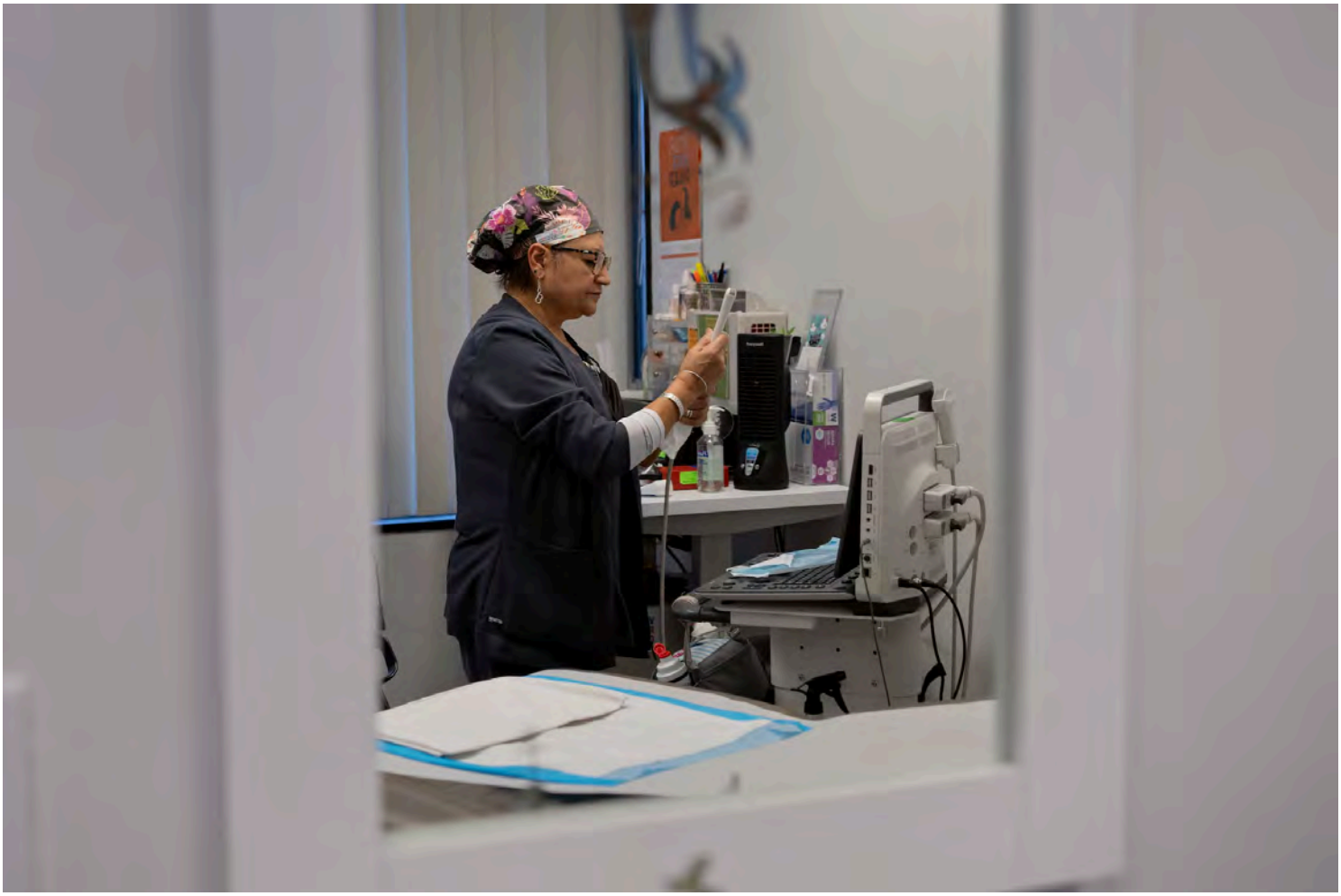
In Houston, a woman lay back on an exam table in a clinic that once offered abortions, hoping to hear that her medication abortion was finally complete.

Ashley, a 25-year-old mother with a baby, opened her legs and stared up at a mermaid mobile hanging from the ceiling, her sweatpants and Converse

sneakers in a heap on the floor.

“Are you ready?” Glenda Lima, the sonographer, asked on a Tuesday morning in mid-February. “There will be a little cold and just a little pressure, okay?”

It was Ashley’s fourth visit in two months to Houston Women’s Reproductive Services, one of a handful of former abortion clinics that have remained open in states with near-total abortion bans. While the staff originally imagined a new version of the clinic that offered ultrasounds and referrals to patients planning to travel out of state for medication and procedures, a large share of the women they serve are now self-managing their abortions with pills they got online.



Glenda Lima cleans ultrasound equipment at Houston Women's Reproductive Services in Texas. (Danielle Villasana for The Washington Post)

As soon as she found out she was pregnant in mid-December, Ashley had ordered pills from Aid Access, which she’d heard about on TikTok. But the whole process seemed a little sketchy, she said. What kind of medical organization collected money through Venmo, she wondered? They were asking for a picture of her driver’s license. What if it was all a scam?

She decided that she needed to talk to someone. Not a disembodied voice on the phone or an anonymous commenter in an online forum — but a real, live person

she could actually meet.

“If I’m putting this in my body,” Ashley recalled thinking to herself, “I need to know I’m going to be okay.”

Ashley struggled to come up with the right terms to Google, she said, wondering if it was even possible to get advice on abortions in a state where abortion is banned. She came across contact information for Houston Women’s Reproductive Services only after first messaging a crisis pregnancy center — an email thread she abandoned when she realized it was actually an antiabortion organization designed to dissuade women from ending their pregnancies.

Kathy Kleinfeld, the administrator of Houston Women’s, responded to Ashley’s panicked message on a Sunday, offering her an appointment for a pre-abortion ultrasound and consultation the next day the clinic was open.

“I was like, ‘Oh my God, I feel like I have been searching for this,’” Ashley said. For the first time since finding out she was pregnant, she said, “I just felt safe.”



Glenda Lima performs an ultrasound for a patient at Houston Women's Reproductive Services. (Danielle Villasana for The Washington Post)



A patient holds her hands while getting an ultrasound at Houston Women's Reproductive Services.

As other Texas clinics moved to New Mexico and Illinois after *Roe* was overturned, Kleinfeld and Lima decided to downsize and stay put, anticipating that some women would continue to seek out ultrasounds, emotional support and general guidance in their home state, services that remain legal under Texas law. If all the abortion clinics shuttered, they said, they knew crisis pregnancy centers would be the only places left to go.

Now, the women see their clinic as a helpful counterpart to the online pill networks: a soothing space with a “relaxation” scented diffuser and three portraits of the late Supreme Court justice Ruth Bader Ginsburg, where Texans

can get the help they need to feel comfortable self-managing their abortions at home.

There are major challenges to providing this kind of care in a state where abortion is illegal. Perhaps the biggest, Lima said, is that women assume there are no abortion resources left in Texas. Those that find them often do so by chance.

Lima said she regularly gets frantic calls and texts from Spanish-speaking patients she's never met before on her cellphone, a number she gives out only to patients she sees in the clinic.

"I ask them, 'How did you get my number?'" she said. "They say, 'A friend of a friend of a friend.'"

"I need to know I'm going to be okay."

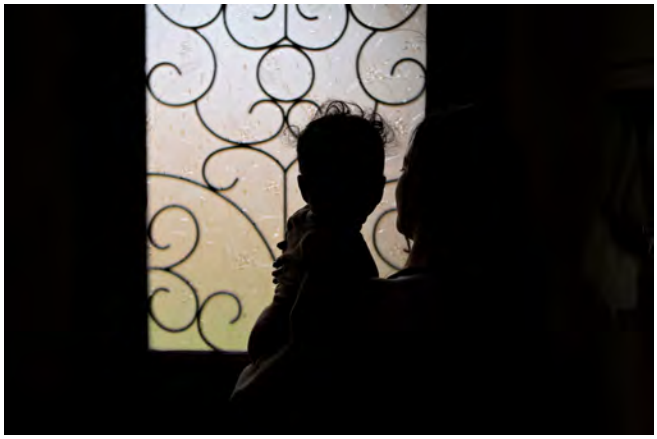
Kleinfeld acknowledges that the very existence of a clinic like theirs — which, unlike some other former abortion clinics that have remained open in states with bans, has no doctors on site and offers no health services other than ultrasounds — is somewhat controversial in the abortion rights community. With abortion rights advocates arguing vehemently that in-person consultations and ultrasounds are entirely unnecessary for a medication abortion, Kleinfeld said, some likely see her clinic as an impediment to women accessing the care they need.

Kleinfeld would never want to see an in-person visit mandated for all patients — most women have no problem handling everything at home, she said. But she has learned that some need the additional hand-holding, especially when they are obtaining pills from unfamiliar sources.

"Not everybody needs an ultrasound, not everyone needs a phone number to call," Kleinfeld said. "But some really do."

Blair Cushing, a family medicine doctor who provided abortions in McAllen, Tex., before the clinic there was forced to close, recently opened a small medical practice near the Mexico border to offer ultrasounds and other support to women who self-manage their abortions. When she meets with patients, she said, they'll often stay to talk for an hour or more — experiencing "information overwhelm" from everything they've read online and desperate for reassurance.

"They're worried because something didn't go the way they were expecting," Cushing said. "They need to decompress about this experience they had and make sure they're okay."



Ashley holds her baby at her home. (Danielle Villasana for The Washington Post)



As soon as she found out she was pregnant in mid-December, Ashley ordered pills from Aid Access.

Ashley first went to Houston Women's Reproductive Services for an ultrasound before she took the pills on Dec. 19 — then returned a week later, wondering why she was still bleeding and experiencing a dull pain in her lower back.

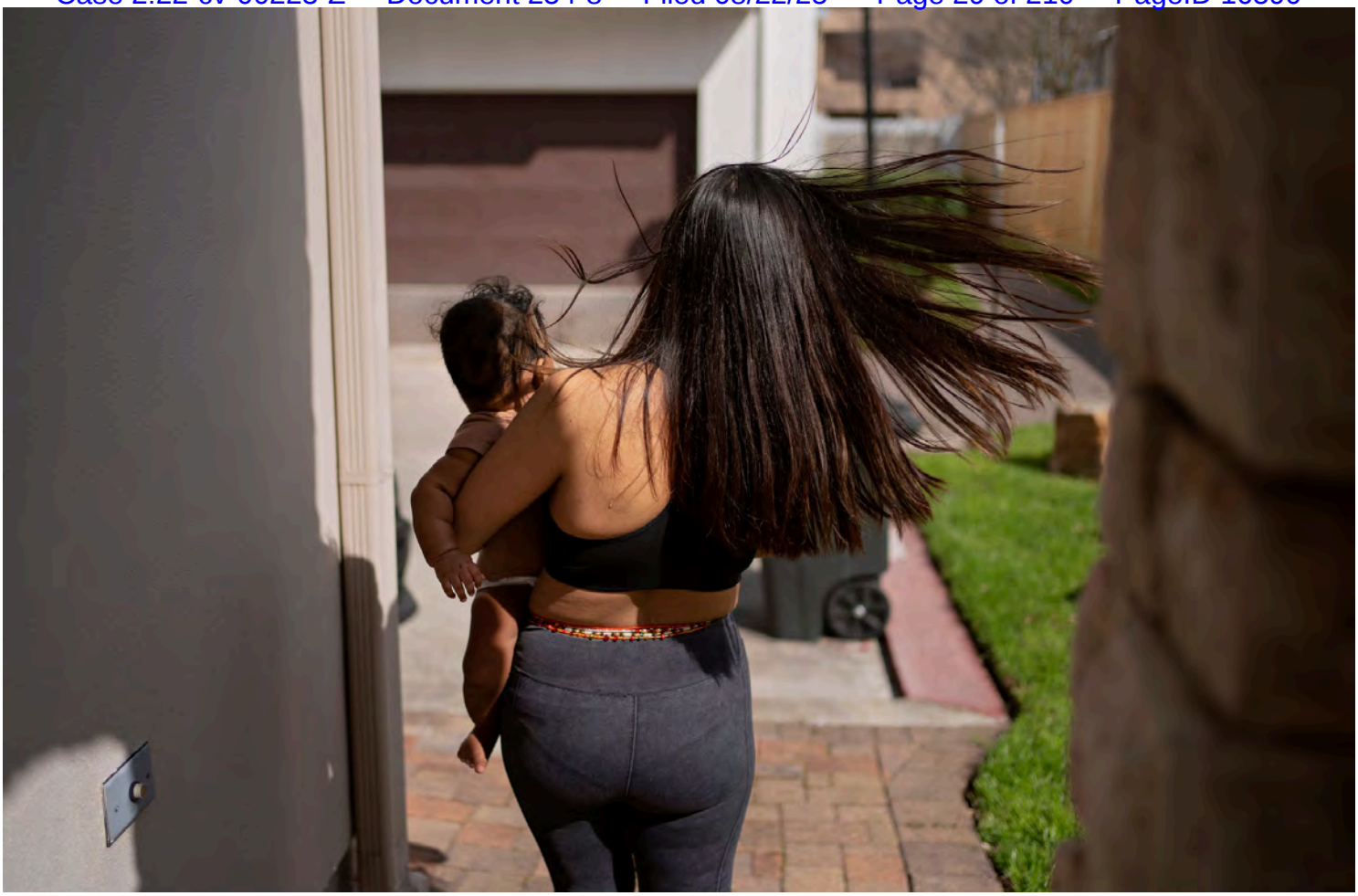
Lima, the sonographer, told Ashley that she still had some blood clots left in her uterus. And while Lima assured her that this was nothing to worry about — the body can typically expel remaining clots without any medical intervention — Ashley wanted to be sure.

She returned to Houston Women's for three more appointments, until Lima was able to confirm that all the clots were gone.

"Your uterus looks beautiful … nice and clean," Lima said at Ashley's final appointment in mid-February. "You're good to go, okay?"

Ashley smiled, closing her eyes as she felt all the muscles in her shoulders finally relax.

"Thank you," she said. "That's all I needed to hear."



Ashley carries her baby outside her home. (Danielle Villasana for The Washington Post)

About this story

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Caroline Kitchener

Caroline Kitchener is a reporter covering abortion at The Washington Post. She won the 2023 Pulitzer Prize for National Reporting. @CAKitchener

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EXHIBIT 67

C.S.H.B. 3446, House Committee Report, 84th Legis. (Mar. 12, 2015)

EXHIBIT 67

C.S.H.B. 3446, House Committee Report, 84th Legis. (Mar. 12, 2015)

BILL ANALYSIS

C.S.H.B. 3446
By: Laubenberg
State Affairs
Committee Report (Substituted)

BACKGROUND AND PURPOSE

Human trafficking, child pornography, and international sex tourism reportedly generate billions of dollars a year worldwide and there are indications that a significant number of U.S. citizens and foreign nationals are trafficked within the borders of the United States. Texas law already requires certain places of business to post signs that are visible to employees and patrons that provide a toll-free phone number for a national human trafficking helpline. It has been noted, however, that there is no law requiring these postings at an abortion facility despite the fact that many of the women who undergo abortions may be victims of human trafficking, especially sex trafficking. Due to the potentially high number of trafficking victims who undergo abortion procedures, abortion facility employees are uniquely situated to identify and assist victims of sex trafficking. C.S.H.B. 3446 seeks to require signs relating to human trafficking to be displayed at certain abortion facilities.

CRIMINAL JUSTICE IMPACT

It is the committee's opinion that this bill does not expressly create a criminal offense, increase the punishment for an existing criminal offense or category of offenses, or change the eligibility of a person for community supervision, parole, or mandatory supervision.

RULEMAKING AUTHORITY

It is the committee's opinion that rulemaking authority is expressly granted to the executive commissioner of the Health and Human Services Commission in SECTION 1 of this bill.

ANALYSIS

C.S.H.B. 3446 amends the Health and Safety Code to require a licensed ambulatory surgical center that performs more than 50 abortions in any 12-month period or a licensed abortion facility to conspicuously display in each patient admission area, waiting room, restroom, and patient consulting room signs that contain a phone number for the Department of Public Safety and a toll-free phone number of a nationally recognized information and referral hotline for victims of human trafficking, as well as the following information: a woman cannot be forced to have an abortion against her will, regardless of her age; if a woman is being forced to have an abortion or being abused, the state is able to help the woman; and human trafficking, including sex trafficking, is a violation of state law. The bill prohibits the signs from containing any information other than that information and prescribes the required sign measurements. The bill requires an applicable center or facility to post a sign in English and a sign in Spanish, as well as any other language in which the political subdivision within which the facility is located is required under the Election Code to provide election materials, if applicable. The bill requires the executive commissioner of the Health and Human Services Commission, not later than December 1, 2015, to adopt rules as necessary to implement and enforce the bill's provisions and establishes that an ambulatory surgical center or abortion facility is not required to comply with the bill's provisions before January 1, 2016.

EFFECTIVE DATE

September 1, 2015.

COMPARISON OF ORIGINAL AND SUBSTITUTE

While C.S.H.B. 3446 may differ from the original in minor or nonsubstantive ways, the following comparison is organized and formatted in a manner that indicates the substantial differences between the introduced and committee substitute versions of the bill.

INTRODUCED	HOUSE COMMITTEE SUBSTITUTE
SECTION 1. Subchapter B, Chapter 171, Health and Safety Code, is amended by adding Sections 171.0125 and 171.0126 to read as follows:	SECTION 1. Subchapter B, Chapter 171, Health and Safety Code, is amended by adding Section 171.0125 to read as follows:
Sec. 171.0125. REQUIRED SIGNS AT CERTAIN FACILITIES: AVAILABLE RESOURCES. (a) An ambulatory surgical center licensed under Chapter 243 that performs more than 50 abortions in any 12-month period or an abortion facility licensed under Chapter 245 shall conspicuously display a sign that satisfies the requirements of this section in each patient admission area, waiting room, and patient consulting room.	Sec. 171.0125. REQUIRED SIGNS AT CERTAIN FACILITIES: AVAILABLE RESOURCES. (a) An ambulatory surgical center licensed under Chapter 243 that performs more than 50 abortions in any 12-month period or an abortion facility licensed under Chapter 245 shall conspicuously display signs that satisfy the requirements of this section in each patient admission area, waiting room, restroom, and patient consulting room.
(b) The sign required by this section must be in English and Spanish and display the following text:	(b) The signs required by this section must contain the following information:
You can't be forced. No one can make you have an abortion against your will, even if you are a minor. In fact, forcing a minor to have an abortion is considered child abuse. If you are a minor being forced into making a particular decision, you can report it by calling the Texas Abuse Hotline at 1-800-252-5400. The call is free and the hotline operates 24 hours per day, 365 days per year.	(1) a woman cannot be forced to have an abortion against her will, regardless of her age;
You and the father. The father of your child must provide support for the child, even if he has offered to pay for an abortion. The Child Support Division of the Office of the Attorney General can help you locate your child's father and determine that he is the father. The Child Support Division can also help establish and enforce child support orders and collect money owed, as well as distribute child support payments. To learn more about child support services, call the Child Support Division at (512) 460-6000.	(2) if a woman is being forced to have an abortion or being abused, the state is able to help the woman; and
You and adoption. The law allows adoptive parents to pay costs of prenatal care, childbirth, and newborn care. To learn more about adoption services and the organizations available to assist you, call Woman's Right to Know at (512) 776-6917.	(3) human trafficking, including sex trafficking, is a violation of state law.
You are not alone. Many agencies are willing to help you carry your child to term and to assist you after your child's birth. This includes providing access to health care services for mother and baby, supplies, healthy food items, nutrition education, and in-home support.	(c) The signs required by this section must also contain a phone number for the Department of Public Safety and a toll-free phone number of a nationally recognized information and referral hotline for victims of human trafficking.
	(d) The signs required by this section may not contain any information other than the information described by Subsections (b) and (c).

INTRODUCED
(See subsection (b) above.)
(c) The executive commissioner of the Health and Human Services Commission shall adopt rules as necessary to implement and enforce this section.
Sec. 171.0126. REQUIRED SIGNS AT CERTAIN FACILITIES: HUMAN TRAFFICKING. (a) An ambulatory surgical center licensed under Chapter 243 that performs more than 50 abortions in any 12-month period or an abortion facility licensed under Chapter 245 shall conspicuously display a sign that satisfies the requirements of this section in each patient admission area, waiting room, and patient consulting room. (b) The sign required by this section must be in English and Spanish and display the following text: WARNING: Being forced to engage in sexual activity or forced to obtain an abortion is illegal under Texas law. Call the national human trafficking hotline: 1-888-373-7888. (c) The executive commissioner of the Health and Human Services Commission shall adopt rules as necessary to implement and enforce this section.
SECTION 2. Not later than December 1, 2015, the executive commissioner of the Health and Human Services Commission shall adopt the rules necessary to implement Sections 171.0125 and 171.0126, Health and Safety Code, as added by this Act.
SECTION 3. An ambulatory surgical center or abortion facility is not required to comply with Sections 171.0125 and 171.0126, Health and Safety Code, as added by this Act, before January 1, 2016.
SECTION 4. This Act takes effect September 1, 2015.

(e) The signs required by this section must each be at least 11 inches in width and 17 inches in length. (f) A facility described by Subsection (a) shall post a sign required by this section in English and a sign in Spanish. If the facility is located in a political subdivision that is required to provide election materials in a language other than English or Spanish under Section 272.011, Election Code, the facility shall also post a sign in that language. (g) The executive commissioner shall adopt rules as necessary to implement and enforce this section.
SECTION 2. Not later than December 1, 2015, the executive commissioner of the Health and Human Services Commission shall adopt the rules necessary to implement Section 171.0125, Health and Safety Code, as added by this Act.
SECTION 3. An ambulatory surgical center or abortion facility is not required to comply with Section 171.0125, Health and Safety Code, as added by this Act, before January 1, 2016.
SECTION 4. Same as introduced version.

EXHIBIT 68

Pam Belluck, *Abortion Shield Laws: A New War Between the States*, New York Times (Feb. 22, 2024)

Abortion Shield Laws: A New War Between the States

Doctors in six states where abortion is legal are using new laws to send abortion pills to tens of thousands of women in states where it is illegal.



By Pam Belluck
Pam Belluck spent time with abortion providers sending pills to states that outlaw abortion and talked with patients receiving those pills.

Published Feb. 22, 2024 Updated Feb. 23, 2024

Behind an unmarked door in a boxy brick building outside Boston, a quiet rebellion is taking place. Here, in a 7-by-12-foot room, abortion is being made available to thousands of women in states where it is illegal.

The patients do not have to travel here to terminate their pregnancies, and they do not have to wait weeks to receive abortion medication from overseas.

Instead, they are obtaining abortion pills prescribed by licensed Massachusetts providers, packaged in the little room and mailed from a nearby post office, arriving days later in Texas, Missouri and other states where abortion is largely outlawed.

This service and others like it are operating under novel laws enacted in a half-dozen states — Massachusetts, Washington, Colorado, Vermont, New York and California — that have sought to preserve abortion access since the Supreme Court overturned the nationwide right to abortion in June 2022. The laws have been in use only since the summer and have not been tested in the courts, but they are already providing abortion access to tens of thousands of women in states with bans, especially low-income patients and others who cannot travel.

Called telemedicine abortion shield laws, they promise to protect doctors, nurse practitioners and midwives licensed in those six states who prescribe and send abortion pills to patients in the nearly two dozen states that ban or sharply restrict abortion.

The laws stipulate that officials and agencies of their states will not cooperate with another state's efforts to investigate or penalize such providers — a stark departure from typical interstate practices of extraditing, honoring subpoenas and sharing information, legal experts on both sides of the abortion issue say. Many expect them to ultimately be challenged in federal court.

Abortion opponents see the laws as brazen infringement on state sovereignty.

“You have states not just picking their own strategy but really trying to completely sabotage the governing efforts of their neighboring states,” John Seago, the president of Texas Right to Life, said.

“It can’t stand, and we can’t be content with this new development,” he added.



“Some people who might not have gotten an abortion if they had to take off work and go to a clinic, or wait three weeks and all of that, are doing it now,” said Dr. Linda Prine, a New York shield-law provider. Ilvy Njiokiktjien for The New York Times

The threat of shield laws is one reason that three states — Idaho, Kansas and Missouri — petitioned to join a case the Supreme Court will hear next month that seeks to bar the mailing of abortion pills and to require in-person doctor visits instead of telemedicine. The petition was denied.

"When you have states actively seeking to circumvent each other's laws, that raises a very real legal problem that will stretch far beyond just the abortion sphere," said Will Scharf, a Republican candidate for attorney general in Missouri, who helped draft anti-abortion legislation when serving as policy director for the state's governor six years ago.

Pills have become the most common abortion method nationally, and abortion rights advocates consider shield laws a crucial way to counter the wave of bans enacted since the Supreme Court's decision in Dobbs v. Jackson Women's Health Organization.

"This might be the most important event since Dobbs on so many levels," said Rachel Rebouché, the dean of Temple University Law School, who has worked with shield law advocates and legislators. "Thousands and thousands of pills are being shipped everywhere across the United States from a handful of providers. That alone speaks to the nature of what mailed medication abortion can do."

Before shield laws were enacted, Aid Access, one of the organizations in the forefront of telemedicine abortion, served patients in states with bans by issuing prescriptions from Europe and shipping pills from a pharmacy in India. Pills could take weeks to arrive, potentially putting patients beyond 12 weeks' gestation, the recommended threshold for taking the medication.

With shield laws, "some people who might not have gotten an abortion if they had to take off work and go to a clinic, or wait three weeks and all of that, are doing it now," said Dr. Linda Prine, a New York shield law provider.

Aid Access providers are now using shield laws to serve about 7,000 patients a month, nearly 90 percent of them in states with bans or severe restrictions, according to Dr. Abigail Aiken, an associate professor at the University of Texas at Austin, who studies Aid Access data.

The shield laws upend the usual telemedicine model, under which out-of-state health providers must be licensed in the states where patients are located.

Beyond providing abortion access to individual patients, the shield-law movement carries broader implications for abortion politics, and supporters are working to enact similar laws in as many states as possible so the approach becomes commonplace, according to Francine Coeytaux, a co-founder of Plan C, a clearinghouse for medication abortion information.

"The shield laws are about a state's legislative and justice system having skin in the game," she said.

Inside the room



Telemedicine abortion shield laws are intended to protect doctors, nurse practitioners and midwives who prescribe and send abortion pills to patients in the nearly two dozen states that ban or sharply restrict abortion. Sophie Park for The New York Times

Carol, who asked to be identified by her middle name to help keep her role private, met me behind the brick building outside Boston and escorted me through a back door, down a warren of hallways. Others who rent offices in the building haven't asked what she does there, she said, adding: "I'm kind of hoping that most people aren't really that curious about what's going on."

At a plain white table, Carol, who has a master's degree in public health, began her routine: checking a spreadsheet of prescriptions; printing out labels with medication information and patients' names; printing address labels with tracking numbers and adding them to the

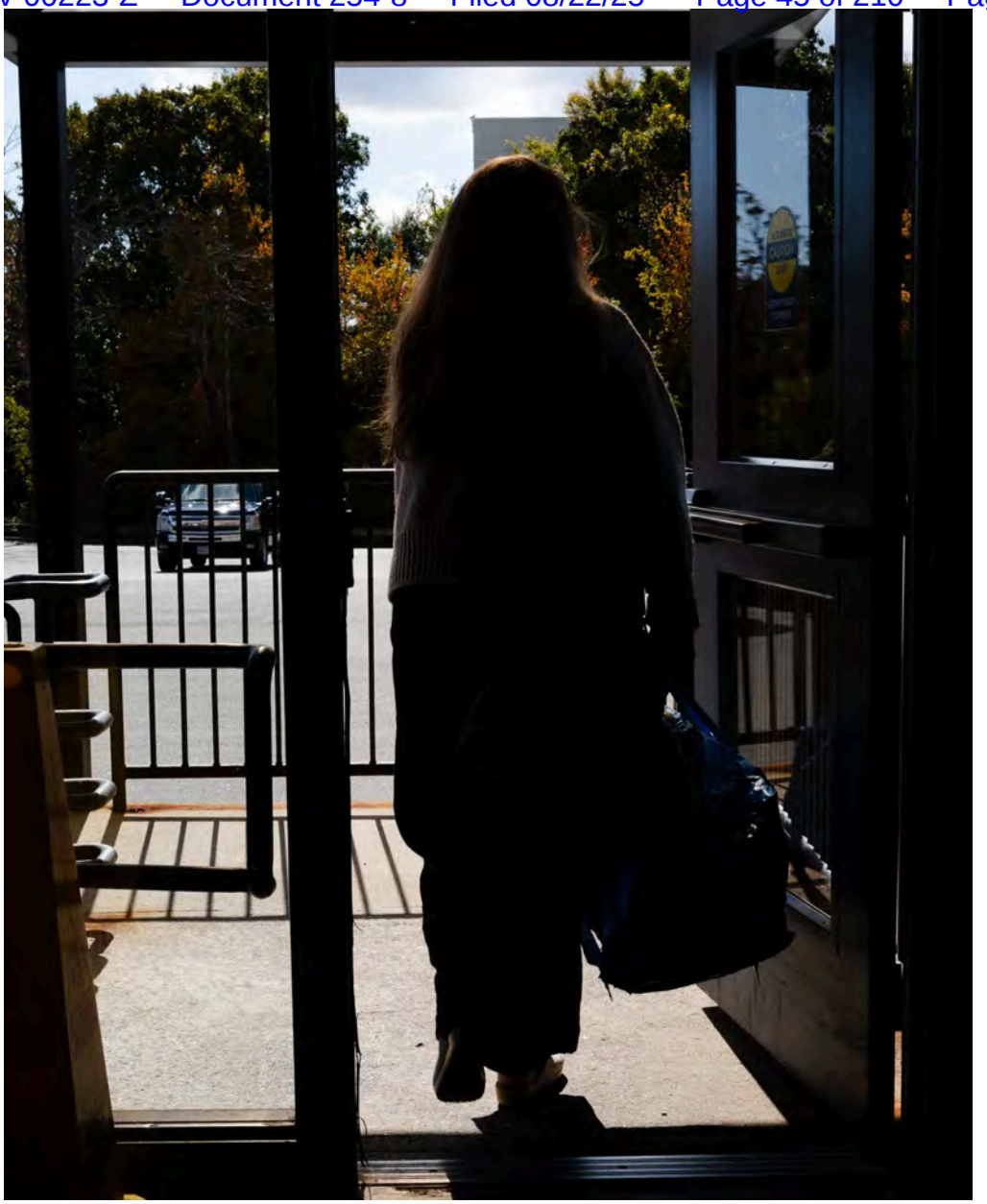
spreadsheet.

Patients contact this service and others online and fill out forms providing information about their pregnancy and medical history. Carol's colleague, Lauren Jacobson, a nurse practitioner, writes prescriptions, evaluating whether patients are medically eligible. They can be up to 12 weeks pregnant and must have no disqualifying medical issues like an ectopic pregnancy or a blood-clotting disorder. Patients and providers can communicate by email or phone if needed.

"We're a free country," said Ms. Jacobson, who sometimes writes 50 prescriptions a day. "So let's put that to the test. Here we are and we're not going to be intimidated, and we have our states backing us."

Carol pulled the two abortion medications from storage boxes: mifepristone, which stops a pregnancy from developing, and misoprostol, taken 24 to 48 hours later to spur contractions to expel pregnancy tissue.

"I don't really consider myself a rule breaker," she said. "So it's funny that here I am sitting in this tiny little closet surrounded by pill bottles."



Carol and others who use shield laws to send abortion pills to patients are taking precautions to protect themselves, including not traveling to states with abortion bans, where they could be more vulnerable to arrest. Sophie Park for The New York Times

The operation resembles a small-scale assembly line, preparing medication for six packages at a time: one mifepristone pill in a manufacturer's prepackaged box and 12 misoprostol tablets counted out by hand from bottles of 100 supplied by a wholesaler. Carol slid the medications into plain envelopes lined with bubble wrapping, along with a 10-page pamphlet from the mifepristone manufacturer and illustrated instructions from Aid Access about taking the medication and expected side effects, like cramping and bleeding.

She drove several miles to a post office to mail the envelopes.

"Getting ready for Christmas?" another customer in the post office asked one day, she recalled.

“Surprise, I’m actually Santa Claus,” she replied cheerfully.

One of Carol’s envelopes arrived at the home of Ashley Dickey in Texas.

Ms. Dickey has two young children and said she had experienced serious postpartum depression after those pregnancies. She said she dissolved in tears when she became pregnant again and concluded that she could not manage another pregnancy and raise another child. “It’s just not good for anybody,” she said.

When she learned she could receive pills by mail, “I was so grateful,” she said, adding, “If I would have had to travel somewhere, it would have been catastrophic, financially and then just emotionally.”



“If I would have had to travel somewhere, it would have been catastrophic, financially and then just emotionally,” said Ashley Dickey, a Texas patient who received abortion

pills from Massachusetts shield law providers. Monumique Monroe for The New York Times

Reaching low-income patients

Supporters say shield laws are already making substantial progress toward an important goal: helping patients who cannot afford — financially or logistically — to travel to another state for an abortion.

“It’s reaching the ones that were impacted the most: low-income, poor people, communities of color, Indigenous,” said Michelle Colón, the executive director of SHERo Mississippi, an organization supporting reproductive rights for people of color.

Nationally, there are three main providers: Aid Access; the Massachusetts Medication Abortion Access Project (called The MAP); and a service called Abuzz, which does not yet serve all states with abortion bans. They charge $150 or $250, though all three services provide pills for reduced prices or even at no cost, based solely on what patients say they can pay.

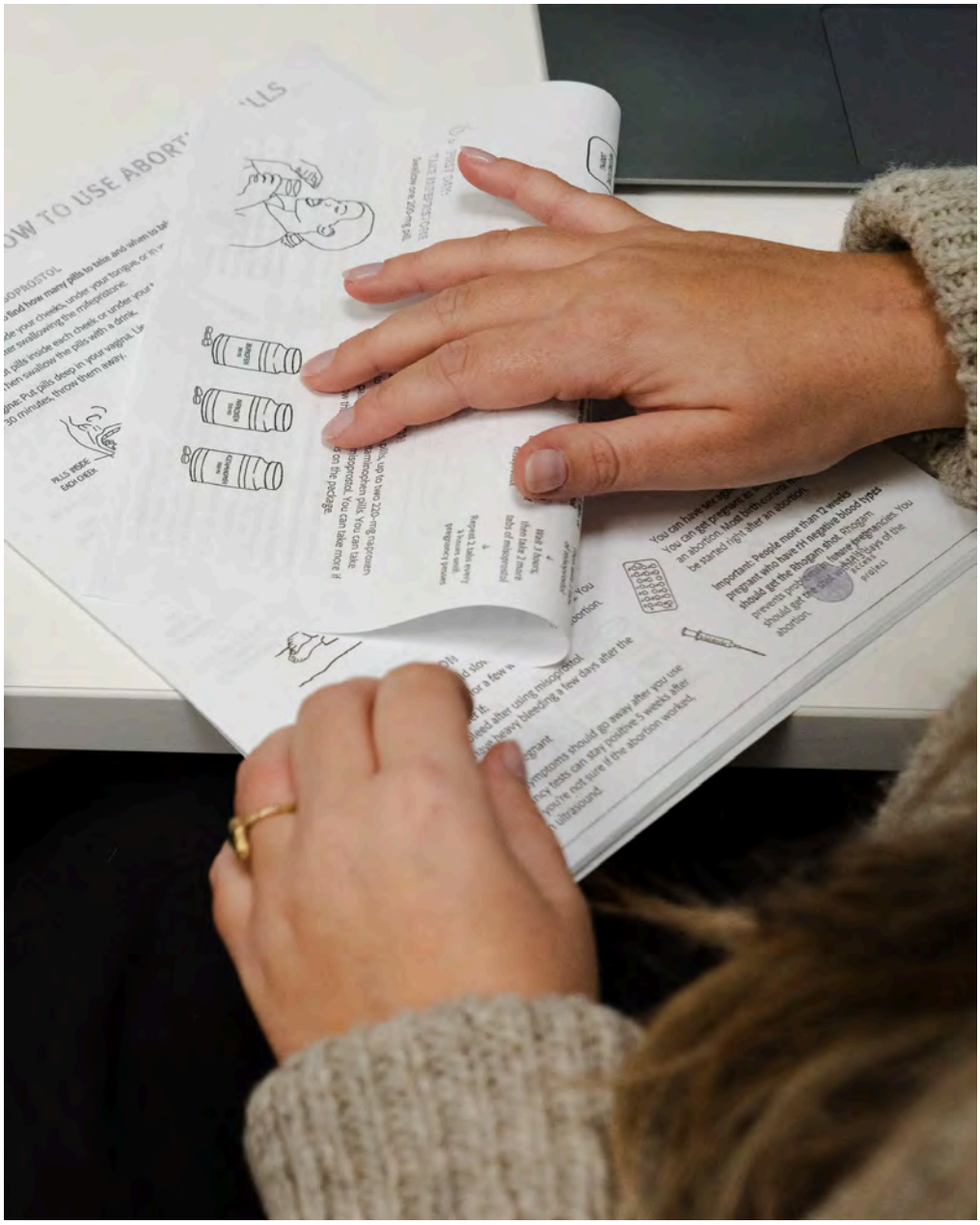
Dr. Rebecca Gomperts, a Dutch physician who founded Aid Access, said over half of its shield-law patients cannot pay full price. About a third of The MAP’s patients can afford only the service’s $5 minimum, said Dr. Angel M. Foster, director of The MAP.

But shield-law providers say it is uncertain whether they can sustain their pay-what-you-can approach. Most providers are absorbing the cost for thousands of patients who can’t pay full price. So far, most abortion funds — organizations that provide financing to help patients obtain abortions — have not given money for sending pills to anti-abortion states, partly because they do not know if shield laws would protect the funds.

“I’ve had several funds say, ‘Our lawyers say we cannot do this,’” said Susan Yanow, a longtime reproductive health activist working with The MAP, who has nonetheless gotten some funds to contribute.

A few funds openly support shield-law activity. “We are here to boldly make a statement,” said Karen Middleton, president of Cobalt Abortion Fund in Colorado, which gives $2,500 a month to that state’s provider. And some advocates are starting funds, including Jodi Jacobson, an activist based in California, who said she wanted to support “providers who are losing money” performing what she called “medical civil disobedience.”

Legal strategizing



Authorities in states with abortion bans have not yet tried to prosecute, sue or otherwise target shield law providers, but some advocates on both sides say it is only a matter of time before that happens. Sophie Park for The New York Times

Several Republican attorneys general from states with strict abortion prohibitions declined requests to discuss shield laws. But Mr. Scharf, who is challenging Missouri's incumbent attorney general in the Republican primary, predicted that the shield laws would almost certainly be challenged in court.

"Constitutional litigation is obviously an option here," he said. "Ultimately, whenever you get attempts like this to circumvent our constitutional system of federalism, that's going to be something that's litigated."

Dr. Seago of Texas Right to Life said taking action against shield-law providers would be "a difficult challenge" that would require "the right case," including a patient "on the receiving side of those illegal activities" who would cooperate with a civil suit or prosecution.

"We can definitely promise that in a pro-life state like Texas with committed elected officials and an attorney general and district attorneys who want to uphold our prolife laws, this is not something that's going to be ignored for long," he said.

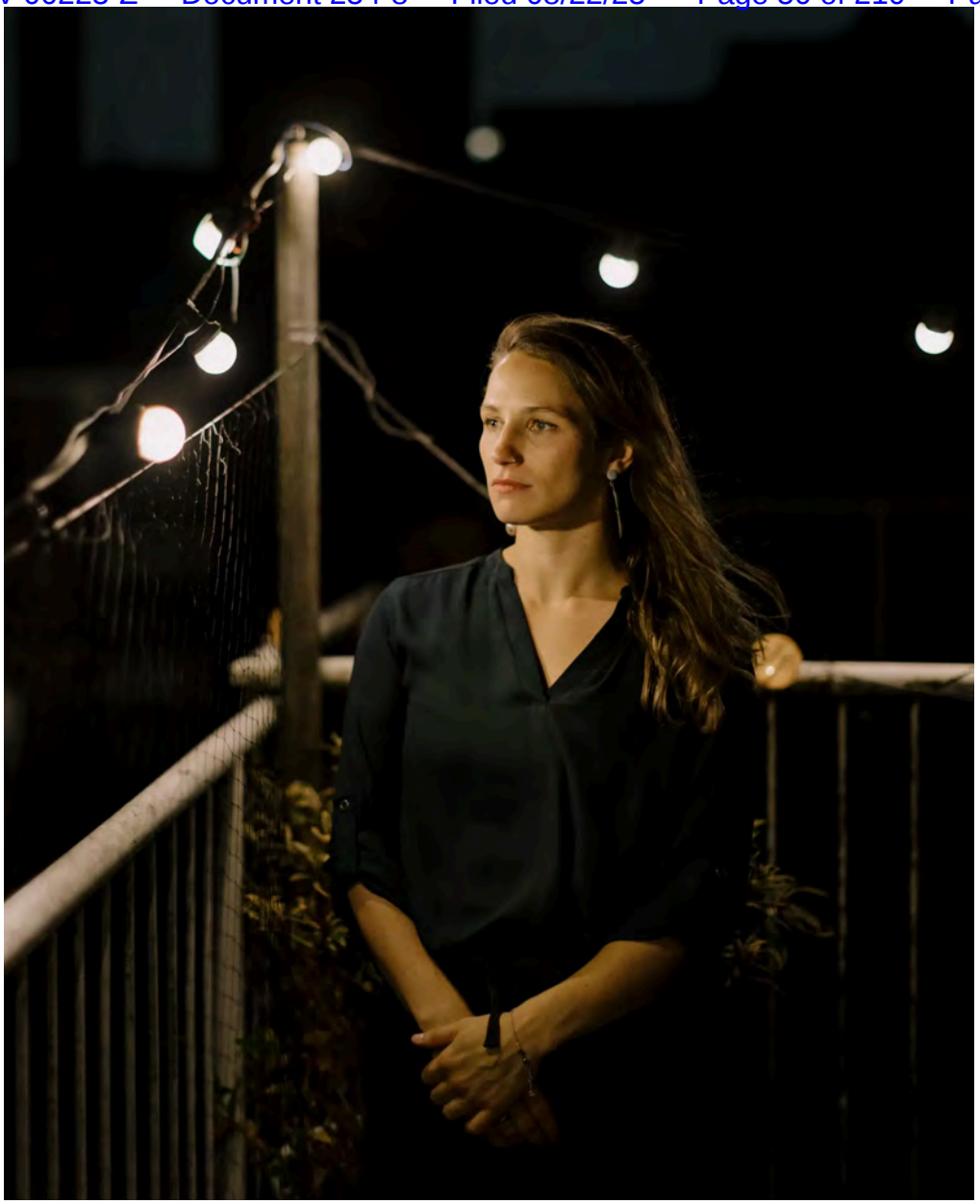
Many shield-law providers are taking precautions, including not traveling to states with abortion bans, where they could be more vulnerable to arrest. Some are not sending pills to states where they have family. Some are creating trusts to protect their assets from civil suits.

"At any moment, I might get a cease-and-desist order, or I might get a lawsuit, or I might get some district attorney coming after me, I have no idea," said Dr. David Wiebe, who operates under Colorado's shield law. "I'm absolutely flying out at full risk here."

The MAP has taken several protective steps. All of its prescribers are within Massachusetts. Pills are stocked and packaged at a separate location by workers hired by Cambridge Reproductive Health Consultants, a nonprofit Dr. Foster leads. "Our model is about distributing risk," she said.

One national mail-order pharmacy, Honeybee Health, based in California, is evaluating whether it can send pills to states with abortion bans under California's shield law, a step that would allow providers in any shield-law state to send their prescriptions to Honeybee and avoid stocking and shipping pills themselves.

Honeybee's co-founder and president, Jessica Nouhavandi, said she hoped to do so, but worried about jeopardizing her business, which dispenses other medications too. If an anti-abortion state like South Carolina pulled her license, "what happens to my thousands of South Carolina patients who get their blood thinners from me?" she said.



"We're a free country," said Lauren Jacobson, a nurse practitioner who sometimes writes 50 prescriptions a day. "So let's put that to test. Here we are and we're not going to be intimidated, and we have our states backing us." Ilvy Njiokiktjien for The New York Times

Another unknown is the outcome of the lawsuit by abortion opponents seeking to curtail mifepristone. An appeals court ruling effectively barred the mailing of mifepristone and required in-person doctor visits. The case is now before the Supreme Court.

"If we prevail on that, all these shield laws will be rendered moot at that point because then there'll be a federal policy prohibiting such a transaction," said Erik Baptist, senior counsel for the Alliance Defending Freedom, which represents abortion opponents in that case. Some shield law providers say they will look for legal ways to continue.

Texas, which has strict bans, is home to about a third of shield-law patients, including Elizabet, who asked to be identified by her middle name to protect her privacy. She considered traveling to California, where a friend lives, but medication abortion at a clinic there would cost $750, plus transportation expenses.

She was relieved to find Aid Access and to receive pills mailed from Massachusetts. Although abortion bans target providers and not patients, she said she was still nervous about people in Texas finding out.

“That’s been very scary,” she said, “but I was like, you know what, I have to trust it.”

Weeks later, Elizabet said she planned to visit a doctor for birth control, but worried about being asked if she’d taken abortion pills.

Ms. Jacobson, who prescribed her the medication under Massachusetts’ shield law, reassured her, noting that there was no medical reason to disclose having taken abortion pills.

“The symptoms that the abortion pills cause are exactly the same as those that a miscarriage causes, so there is no possible way for a provider, a doctor, to look at you, do any test and know that you took the pills,” she said, adding, “We’ve helped a lot of people navigate situations in places like Texas.”

Pam Belluck is a health and science reporter, covering a range of subjects, including reproductive health, long Covid, brain science, neurological disorders, mental health and genetics. More about Pam Belluck

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A version of this article appears in print on , Section A, Page 1 of the New York edition with the headline: New Shield Laws Allowing Women Abortion Access

EXHIBIT 69

MAP - Frequently asked questions

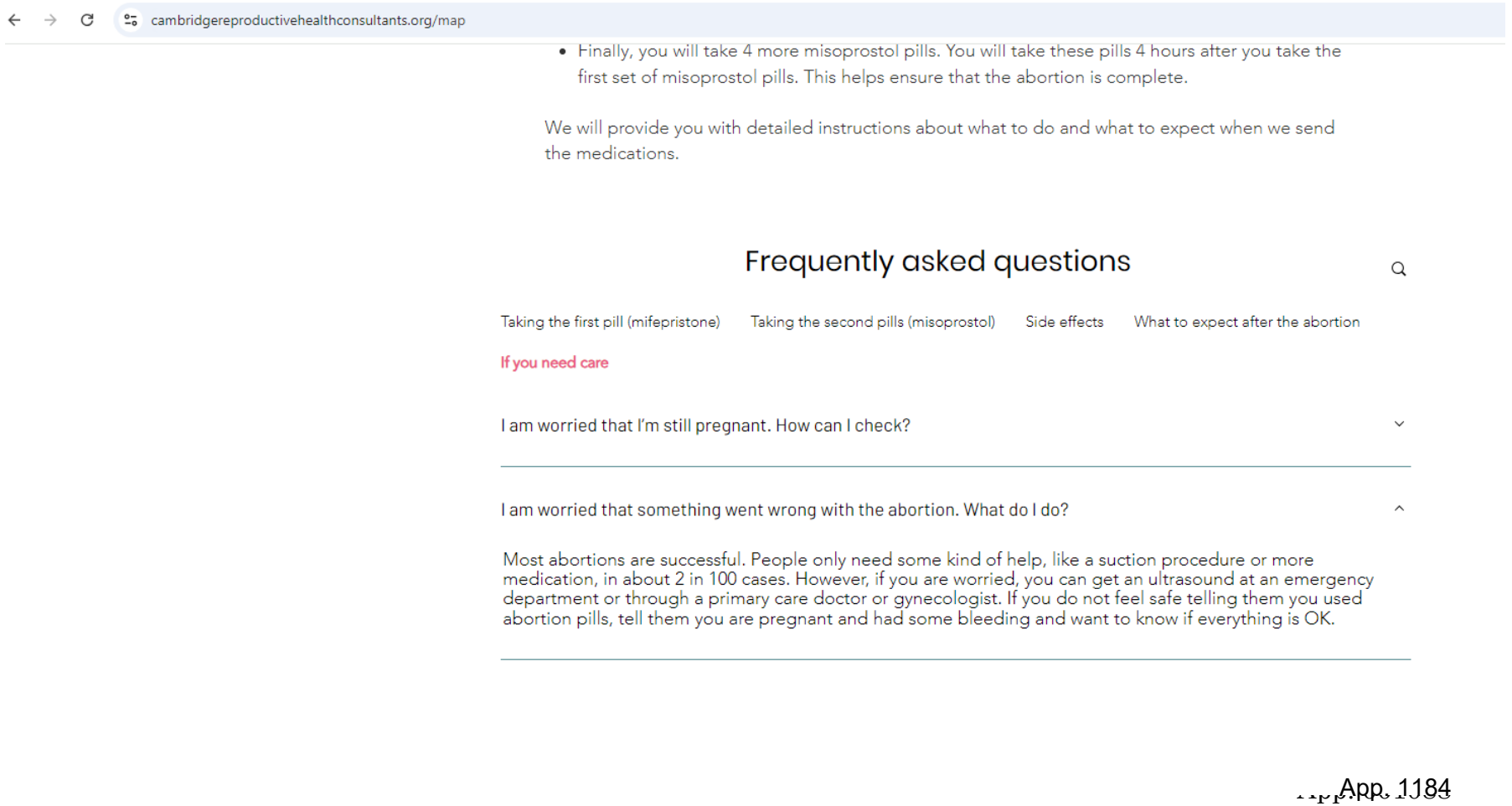

cambridgereproductivehealthconsultants.org/map
Finally, you will take 4 more misoprostol pills. You will take these pills 4 hours after you take the first set of misoprostol pills. This helps ensure that the abortion is complete.
We will provide you with detailed instructions about what to do and what to expect when we send the medications.
Frequently asked questions
Taking the first pill (mifepristone)
Taking the second pills (misoprostol)
Side effects
What to expect after the abortion
If you need care
I am worried that I'm still pregnant. How can I check?
I am worried that something went wrong with the abortion. What do I do?
Most abortions are successful. People only need some kind of help, like a suction procedure or more medication, in about 2 in 100 cases. However, if you are worried, you can get an ultrasound at an emergency department or through a primary care doctor or gynecologist. If you do not feel safe telling them you used abortion pills, tell them you are pregnant and had some bleeding and want to know if everything is OK.

EXHIBIT 70

Abuzz

abuzz

Need abortion care at home?

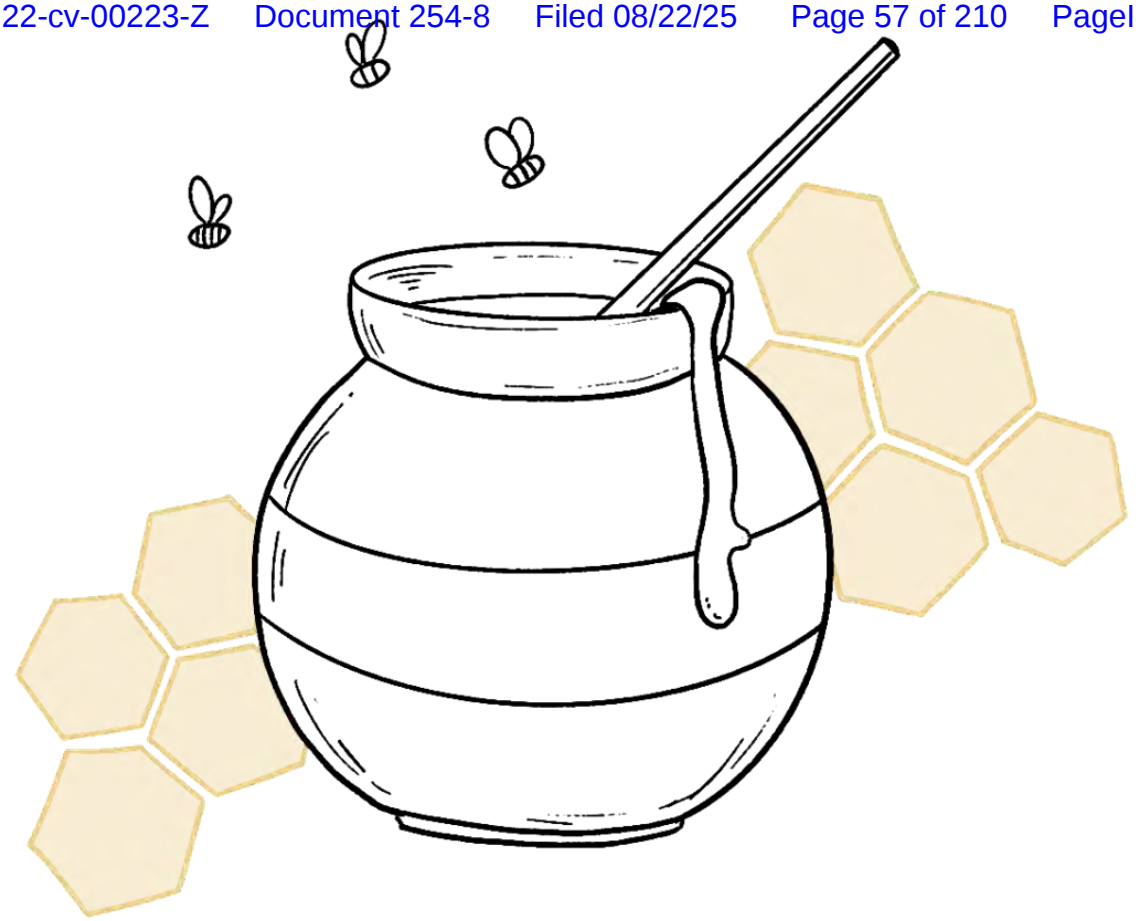
Get access today





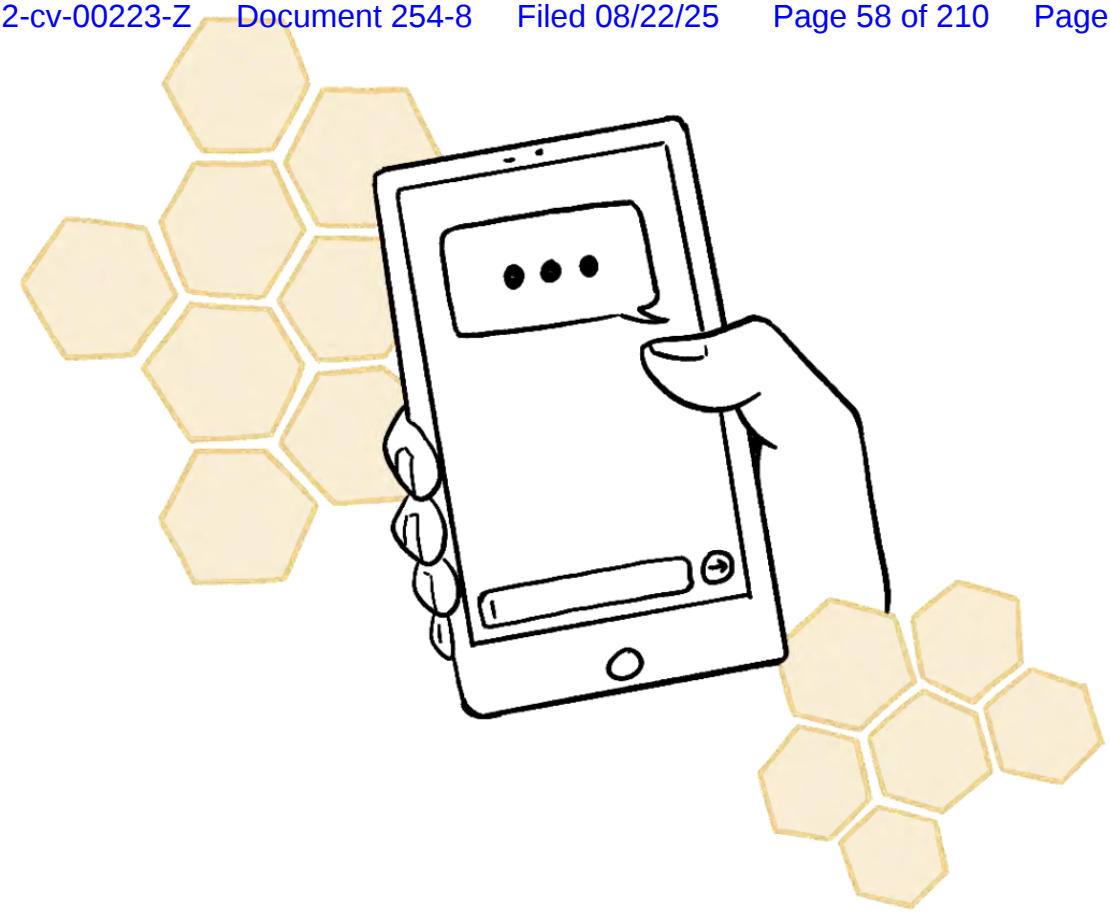
Fast, discreet shipping.

Packages arrive in 2-5 days. Medications are shipped in a plain mailing envelope.



Affordable care for everyone.

Accessing safe and affordable healthcare is a fundamental right. Services are available for $0-150 sliding scale.



The support you need, when you need it.

An experienced medical team is here to answer your questions, provide support, and guide you through the process.

Abuzz may be able to help you if...



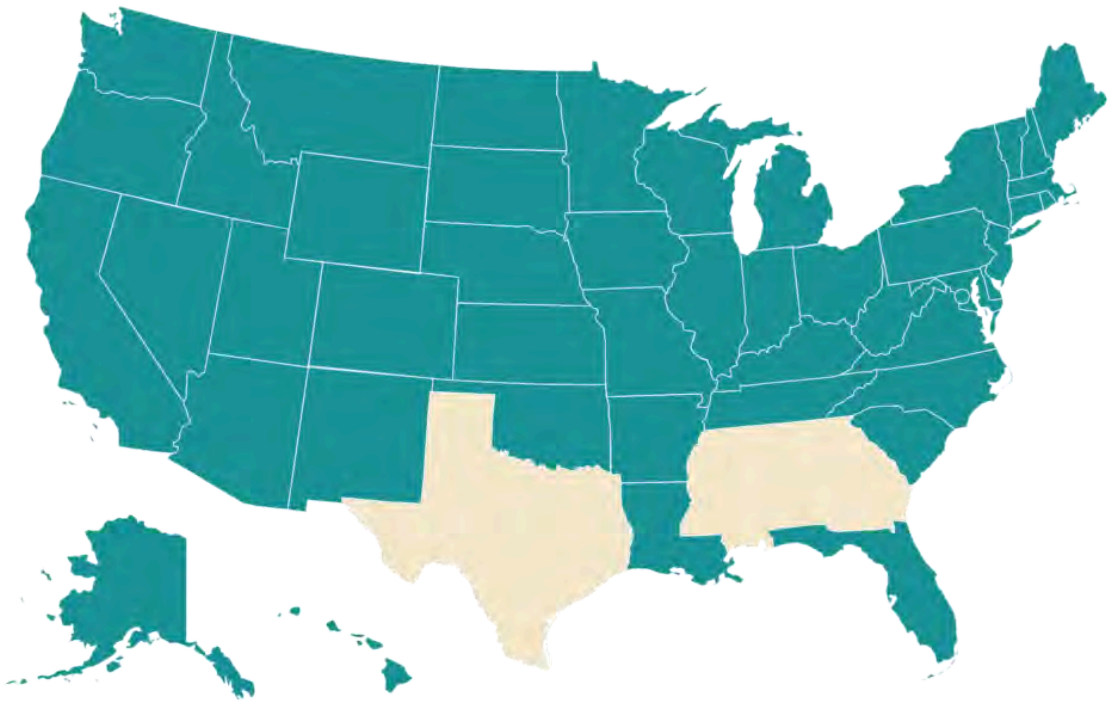
You're less than 13 weeks pregnant.

You must be less than 13 weeks pregnant to access abortion through Abuzz. Remember that pregnancy is measured from the first day of your last menstrual period, which is around two weeks before conception.

→ How do I estimate the length of my pregnancy?

You're comfortable with virtual abortion care.

In most cases, providers do not require a phone call or video visit. After you fill in the form, a clinician will arrange payment with you and review your information. If you're approved to receive abortion pills by mail, your pills will be shipped out in 1-2 business days.



You have a mailing address in one of our states.

Options for at-home abortion pill access will vary based on your location. Click below to find options in your state or territory.

Still have questions? Check out our FAQ

Abuzz: Abortion Pill Access At Home

About Us

How it Works

FAQ

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Provider Payments

Donations allow us to help all pregnant people, regardless of their ability to pay. Please consider supporting our work.

DONATE

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EXHIBIT 71

Abuzz FAQ

abuzz

Frequently Asked Questions*

Services | About Abortion Pills | Before Taking Abortion Pills | How to Use Abortion Pills | During An Abortion With Pills | After An Abortion With Pills

Services

I can't afford $150. Can I still get help? –

Yes, you can still get help! Just let your provider know what you can afford when you fill out the form.

Can I get abortion pills even if I'm not pregnant? –

Yes, clinicians offer abortion pills "just in case" you do get pregnant. These are sometimes called "advance provision" or "pills for future use."

Do I have to have a video visit or phone call? –

In most cases, a phone or video call is not required. Everything is done through the intake form. You will receive a phone number so that you can contact the medical team for any follow up questions. We are here to support you if you choose.

What happens after I ll out the form? –

We will connect you with a provider that is best suited to support your care. The provider will arrange payment with you and review your file. They might ask you some follow up questions. If you are eligible to receive services, they will mail you abortion pills.

How do I get started? –

Fill in the form here.

About abortion with pills

What comes in the abortion pill kit? –

The abortion pill kit has two medicines: mifepristone and misoprostol. The combination of mifepristone and misoprostol is very effective and has the fewest side effects.

How do the abortion pills work? –

Mifepristone stops the pregnancy from growing. Misoprostol makes the uterus contract and push out the pregnancy just like a natural miscarriage.

How effective are abortion pills? –

The combination of mifepristone and misoprostol has been shown to be 98% effective at ending a pregnancy.

Is there a difference between the generic (mifepristone) and brand (Mifeprex) versions of mifepristone? –

There is no difference between them.

Are abortion pills safe? –

They are very safe – safer than Tylenol and safer than driving in a car! The risk of severe, life-threatening complications requiring hospitalization is less than 1%.

If abortion pills are so safe, why are they so restricted? –

Restrictions on abortion pills have nothing to do with medical safety or effectiveness. The restrictions are made by politicians who are against abortion.

Will the abortion pills affect my ability to get pregnant in the future? –

No, abortion pills do not affect your future fertility. You can still get pregnant again.

I have an Rh negative blood type. Will I need Rhogam if I am less than 12 weeks when I take the abortion pills? –

No, Rhogam is only needed for people with Rh negative blood *after* 12 weeks.

Do abortion pills increase the risk of infection? –

Infections from abortions are very rare. They occur in less than 2% of all abortions and usually are easily treated with antibiotics when they do occur.

How far in pregnancy can I use abortion pills? –

The clinicians we refer to will send the pills to people up to 12 weeks and 6 days pregnant. If you are 13 weeks pregnant or more, you can find services here.

What is an ectopic pregnancy and how would I know if I had one? –

Ectopic (tubal) pregnancies are located outside of the uterus. The risk of having an ectopic pregnancy is very low (less than 2%), but if it bursts it is a medical emergency. The only way to know for sure if you have an ectopic pregnancy is by ultrasound. If you are pregnant and have any of the following signs of a ruptured ectopic pregnancy, you should go to the hospital right away: severe abdominal pain on one side, dizziness, lightheadedness, feeling very weak. There is a higher risk of ectopic pregnancy if you have an IUD or history of ectopic pregnancies.

Will the pills work if I have an ectopic pregnancy? –

The abortion pills will NOT work for an ectopic pregnancy. If you take abortion pills and do not have any bleeding within 24 hours after taking misoprostol, you should speak to your abortion pill provider right away. They may recommend an ultrasound to check the location of the pregnancy.

Can I use abortion pills if I have an IUD in place? –

It is very rare to become pregnant with an IUD in place. If you are pregnant with an IUD, there is a higher risk of it being an ectopic pregnancy. Ectopic pregnancies are dangerous because they can burst suddenly and cause severe internal bleeding. While an ultrasound is not required, it would show the location of the pregnancy and the IUD. You don't need to have the IUD taken out before taking abortion pills. They will still work (unless it is an ectopic pregnancy) and a risk is that the IUD may come out with the pregnancy. Since you have become pregnant, it also means you will need to have the IUD replaced after the abortion since it is no longer working correctly.

I got an abortion pill kit for future use. How long is it good for? –

You can store the pills for at least two years (and probably longer) in a cool, dry, dark place. It's not recommended to store them in the bathroom because the heat and humidity can make the pills less

effective.

Can I receive just misoprostol? –

Using mifepristone and misoprostol together is considered the “gold standard” protocol for abortion with pills. Typically, clinicians prefer to prescribe the two medications together as they have fewer side effects and the process is easier. If you cannot take or do not want to take mifepristone, you can fill in the online form and ask your clinician about a misoprostol-only abortion.

Can I ll an abortion pill prescription at my local pharmacy? –

Local pharmacies in the U.S. are allowed to dispense mifepristone after getting certified. You can locate a pharmacy here. Some clinicians may be able to send a prescription for you to fill at a local pharmacy. At this time, Abuzz does not offer this service.

Before taking abortion pills

What should I do before taking abortion pills? –

Before taking pills, it is helpful to do a pregnancy test to confirm you’re pregnant. This avoids taking pills unnecessarily and prevents confusion. If you don’t want to take a pregnancy test, you don’t have to. You should also estimate how far along the pregnancy is. Pregnancies are measured starting from the first day of your last period (and not from conception or when you had sex). You can figure out how far along the pregnancy is using your last period in a **pregnancy calculator like this one** or by getting an ultrasound.

What kind of pregnancy test should I use before taking the pills? –

Almost any pregnancy test will work. Dollar store tests work great. We do not recommend using any digital (positive/negative or +/-) pregnancy tests because we have noticed many people having false positives (a positive test result when they are not actually pregnant).

Do I need to get an ultrasound before taking abortion pills? –

No, getting an ultrasound is not required for most people. You do not need to get an ultrasound as long as your provider can figure out how far along your pregnancy is and you do not have signs of an ectopic pregnancy.

How should I get ready to take my abortion pills? –

1. Read our information on how to take the pills, what you might see and feel, and how to identify signs of complications.
2. Have a plan for where and when you will take the pills. You will want to be in a comfortable place and have access to a bathroom for up to 12 hours after taking misoprostol (the second medicine).
3. Have a plan for how to get emergency medical care in the unlikely event that you need it. It can be good to have a support person (in-person or virtually) in case you need help – especially the day you take misoprostol because this is when you'll have the most cramping/pain and bleeding.
4. Have on hand whatever you usually use to help with your periods (ex: large overnight pads, painkillers, anti-nausea medicine, heating pads, comfortable clothes, snacks, netflix/movies, etc).

How to use abortion pills

How should I take the abortion pills? –

Check out the instructions. How you take the abortion pills depends on how far along the pregnancy is. You can figure out how far along the pregnancy is based on your last period or by getting an ultrasound. There are many different ways to take the pills and most work well. The World Health Organization recommends:

Less than 9 weeks	• Swallow 1 mifepristone 200mg pill orally • Wait 1-2 days • Take 4 misoprostol 200mcg pills under the tongue, in the cheek, or in the vagina. If you don't start bleeding after 24 hours, take another 4 pills.
9-11 weeks	• Swallow 1 mifepristone 200mg pill orally • Wait 1-2 days • Take 4 misoprostol 200mcg pills under the tongue, in the cheek, or in the vagina. 4 hours later, take another 4 misoprostol 200mcg pills.
12+ weeks	• Swallow 1 mifepristone 200mg pill orally • Wait 1-2 days • Take 2 misoprostol 200mcg pills under the tongue, in the cheek, or in the vagina every 3 hours until the pregnancy tissue is out.

How long do I have to wait to take misoprostol (the second medicine)? –

We recommend taking misoprostol 1-2 days (24-48 hours) after mifepristone because this will be the most effective.

How do I take misoprostol (the second medicine)? –

Misoprostol can be taken in 3 different ways – vaginally, buccally, or sublingually. Vaginally means inserting the medicine with your fingers into the vagina. Buccally means holding the medicine in your cheeks like how a chipmunk holds food. Sublingually means holding the medicine under your tongue. If you take the misoprostol sublingually or buccally, after 30 minutes you can swallow whatever remains of the pills.

What is the difference between putting the misoprostol (the second medicine) under your tongue, in your cheek, or in the vagina? –

In areas where abortion is restricted, it can be safer to put the misoprostol in your cheek or under your tongue. After 30 minutes you can swallow or spit out anything that is left. Using the medicines in your cheeks or under your tongue can give you more side effects (nausea, vomiting, diarrhea). Using the medicines in the vagina gives you less side effects, but the pills could be seen during a vaginal exam. If this is a concern for you, we recommend that you use the pills in your cheek or under your tongue.

What can I take for nausea? –

You can take over the counter anti-nausea medicine like Unisom or Dramamine. Other things that can help with nausea include ginger tea, chewing gum, and sucking on hard candies. A prescription for anti-nausea medication can be sent if needed.

What can I take for pain? –

1. It's most effective to wait until you feel some pain before taking painkillers (but do not wait until the pain is unbearable). You can take over-the-counter painkillers like ibuprofen (Motrin/Advil) and acetaminophen (Tylenol). You can take 600-800mg ibuprofen every 6-8 hours with food. You can take 1000mg of acetaminophen every 6 hours. You can also take ibuprofen and acetaminophen together. If you do not want to use ibuprofen, you can try taking naproxen (Aleve) 550mg every 12 hours. To be more comfortable during the process, you can also try using a hot water bottle or heating pad on the belly, listening to music, having a support person, being someplace private, etc.

Why do I start with fewer misoprostol pills when I'm 12+ weeks pregnant? –

The farther along you are, the fewer misoprostol pills you need for each dose. After 12 weeks, people should take 1 mifepristone followed by 2 misoprostol pills repeated every 3 hours until the pregnancy passes.

Why do I have extra pills and what should I do with them? –

Extra misoprostol pills are sent in case:

1. You vomit after taking the pills
2. You don't bleed enough after taking the pills
3. You have too much bleeding after taking the pills

Please keep any extra misoprostol for at least 2 months. This way you will have it on hand in case you experience a complication and are advised to take it.

What do I do with my extra pills? –

Please keep any extra misoprostol for at least 2 months. This way you will have it on hand in case you experience a complication and are advised to take it.

What if I throw up after taking the abortion pills? –

As long as you can keep the mifepristone (first medicine) down for at least 30 minutes, it will most likely be effective. If you vomit less than 30 minutes after taking mifepristone, it might not be as effective, so contact us for further information.

As long as you keep the misoprostol (second medicine) in your mouth for at least 20 minutes, that should be enough time for the medication to absorb and be effective. If you vomit less than 20 minutes after taking the misoprostol by mouth, it's recommended to take anti-nausea medication, wait a few hours, and try again.

During an abortion with pills

What happens after taking the abortion pills? –

Most people don't have any symptoms after taking mifepristone (the first medicine). Some people might have light bleeding or nausea. The main symptoms of bleeding and cramping usually begin after taking the misoprostol (the second medicine).

How much bleeding and cramping will I have? –

Every person is different, and there is a range of normal bleeding and cramping. . Most people have bleeding and cramping that is heavier than a period and can include blood clots the size of lemons. Some people only have light bleeding. It usually starts 4-6 hours after taking the misoprostol (the second medicine) and starts to slow down within 1 day. Some people have mild pain, and other people have very intense cramps.

What if I start bleeding/having a miscarriage before I use the abortion pills? –

Signs of a miscarriage don't always mean you had a complete miscarriage so it is recommended that you still use the abortion pills to make sure the pregnancy passes fully.

What are the side effects of misoprostol (the second medicine)? –

The side effects of misoprostol include nausea, vomiting, headache, diarrhea, fever, and chills. These are usually temporary and go away on their own. If the fever (more than 101 degrees) continues for more than 24 hours after taking misoprostol, please contact your abortion pill provider because this can be a sign of infection.

How much bleeding is too much? −

It is normal to have heavy bleeding and blood clots. If you are soaking 2 large overnight pads per hour for 2 hours in a row (4 pads in 2 hours) that is too much bleeding. You should seek medical attention right away if this happens. Sometimes providers recommend taking 2 more misoprostol pills to slow the bleeding down while waiting for medical attention.

What are signs of a complication? −

If you have very heavy bleeding (soaking 2 large overnight pads per hour for 2 hours in a row), fever for over 24 hours since taking misoprostol, or severe pain that is not relieved by painkillers, these are signs of severe medical complications, and you should seek medical attention right away.

Will anyone be able to tell that I took abortion pills? −

No, there are no tests to detect that you took abortion pills by mouth. The only way for the providers to know is if you tell them or if you took the pills vaginally and they see them on an internal exam. You do not need to say that you took abortion pills.

If I have to go to the hospital, what should I say? −

The treatment for a miscarriage and abortion are the same, so you can just say something like “I’m bleeding but it doesn’t feel like my usual period. I’m afraid something is wrong” or “I’m pregnant and bleeding. I’m scared there’s something wrong” and you should get the care you need.

After an abortion with pills

How do I know if the abortion pills worked? −

Most people can tell if the pills worked by what they experience and how they feel. Some signs that the abortion pills worked can include: bleeding (light or heavy), cramping after taking the pills, passing clots and/or tissue, and no longer feeling pregnant. Pregnancy tests can stay positive for up to 5 weeks after a successful abortion, so they are not reliable before that time. If you still feel pregnant, you should contact your abortion pill provider.

What if I have little or no bleeding after taking the abortion pills? −

This could be a sign that the pills didn't work, so you need to talk to your abortion pill provider for further guidance.

How long will I bleed after taking abortion pills? −

Bleeding should start to slow down after the pregnancy passes. However, light bleeding and/or spotting can continue off and on for up to 6 weeks. If you have been bleeding more than 6 weeks, contact your abortion pill provider.

What if I have vaginal odor after using the pills? −

Your vagina needs time to adjust to the changing hormones after ending the pregnancy, so any odor changes can be normal. Burning or pain from the discharge are reasons to seek medical attention.

When can I get pregnant again after an abortion? −

You can get pregnant as soon as 1 week after your abortion. If you want to prevent pregnancy, it is important to start birth control soon after your abortion.

When can I start birth control after my abortion? −

You can start most methods right away. If you start within 1 week, you are protected from pregnancy right away. Here is a guide to starting birth control after an abortion.

When can I start exercising or return to work/school after an abortion with pills? −

Everybody is different. Most people are able to return to normal activities the day after you finish taking misoprostol (the second medicine).

When can I have sex again after an abortion? −

This is up to you and what feels right for your body. You can have sex again whenever you feel ready.

* Nothing on this website is to be construed as medical advice. Please consult with a trusted healthcare professional before making any medical or healthcare decisions.

Abuzz: Abortion Pill Access At Home

About Us

How it Works

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Terms of Use

Privacy Policy

Provider Payments

Donations allow us to help all pregnant people, regardless of their ability to pay. Please consider supporting our work.

DONATE

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EXHIBIT 71a

Abuzz - How It Works

abuzz

X Quick Exit

How It Works

The process is simple, con dential, and designed to meet your needs.

1. Fill in the form.

The form asks a few basic questions to help the clinician know if you are eligible to get abortion pills by mail.

You will also be asked to upload a copy of your photo ID (if you do not have one, please let us know) and sign a consent form.

Fill in the form →

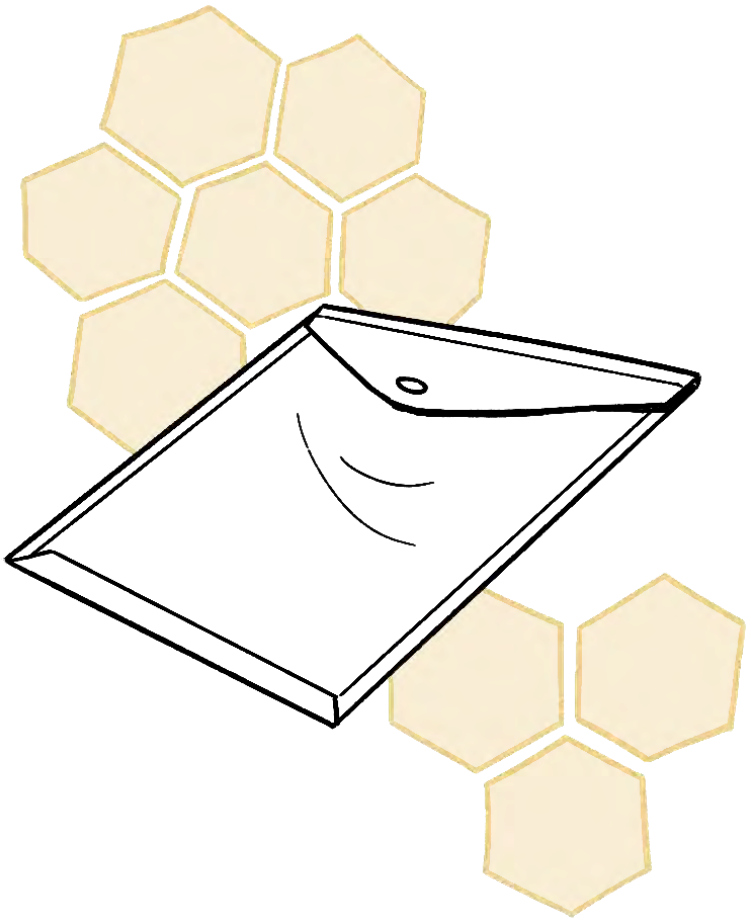
2. Check your email.

You'll get instructions for making a payment and signing into the secure portal. Follow those instructions to complete your request.

3. Review

A US-licensed clinician will review your eligibility for an at-home abortion with pills within 1-2 business days. In most cases, Abuzz providers do not require a phone/video call. If your provider has more questions, they will contact you via the portal.





4. Receive and use abortion pills at home

Your FDA-approved medications (mifepristone and misoprostol) will be sent by mail. Shipping takes 1-5 business days. Detailed instructions and support are provided. Clinicians are available to answer your questions 7 days a week.

Still have questions? Check out our FAQ

→Go to the FAQ

abuzz

Abuzz: Abortion Pill Access At Home

About Us

How it Works

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Terms of Use

Privacy Policy

Provider Payments

Donations allow us to help all pregnant people, regardless of their ability to pay. Please consider supporting our work.

DONATE



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EXHIBIT 72

Declaration of Ann Dalton

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

STATE OF MISSOURI, *et al.*,

Intervenor-Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants,

DANCO LABORATORIES, LLC,

Intervenor-Defendant, and

GENBIOPRO, INC.,

Intervenor-Defendant.

Case No. 2:22-cv-00223-Z

DECLARATION OF ANN DALTON

I, Ann Dalton, hereby declare and swear as follows:

1. I am over 18 years of age, have personal knowledge of the matters set forth here, and am competent to make this declaration.

2. I currently work in Florida's Agency for Healthcare Administration (AHCA) as the Assistant Deputy Secretary for Medicaid Policy and Quality.

3. In my role with AHCA, I am familiar with the administration of the Florida Medicaid program.

4. The statements in this declaration are based on my professional knowledge and experience.

5. When a provider seeks coverage for medical services, it submits a claim to Florida Medicaid.

6. Claims typically include information regarding services rendered, diagnosis codes, and payment amounts.

7. In my role with AHCA, I am familiar with Florda Medicaid claim records, and in preparing this declaration, Agency staff reviewed a subset of paid claim amounts for Calendar Years 2020 and 2022.

8. As a matter of State policy, Florida Medicaid does not provide coverage for elective abortions. However, Florida Medicaid does provide coverage for treatment and follow-up care at hospitals following abortion *complications*, including complications from abortifacients like mifepristone.

9. Often, the cost to Florida for providing such coverage is not quantified, or is difficult to identify, in the medical records due to a range of factors, including coding variances.

10. Nonetheless, through a review of a subset of Florida's Medicaid records, Agency staff has identified the below coverage costs to the State of Florida provided for treatment and follow-up care at hospitals following chemical abortion complications.

11. The review was initiated in April 2025. First, AHCA identified Medicaid diagnosis codes associated with mifepristone complications. AHCA then sent letters to approximately 500 healthcare providers requesting medical records for approximately 1,000 recipients with Florida Medicaid claims filed under those diagnosis

codes. AHCA requested that the records be delivered within 14 days after receipt of the notification. Many healthcare providers did not meet this deadline, and some have not responded. Many records received by AHCA required decryption. Once records were received and decrypted, AHCA narrowed its search by uploading the records into a document review software and filtering by keyword searches. The remaining records were manually reviewed by certified nurses to determine whether treatment was related to complications from a chemical abortion. The records described below were identified in July 2025. The review is ongoing.

12. In Calendar Year 2020, Florida Medicaid expended $543.73 in total funds to reimburse UF Health Shands Hospital for services provided to a Medicaid recipient in January 2020. Based on a review of the records documenting the services provided, AHCA staff concluded that the services were provided for the patient's treatment and follow-up care for medical complications caused by a chemical abortion.

13. In Calendar Year 2022, Florida Medicaid expended $433.39 in total funds to reimburse the Jackson Health System for services provided to a Medicaid recipient in March 2022. Based on a review of the records documenting the services provided, AHCA staff concluded that the services were provided for the patient's treatment and follow-up care for medical complications caused by a chemical abortion.

* * *

I declare that the foregoing is true and correct to the best of my knowledge, information, and belief.

Executed August 21, 2025.

/s/
Ann Dalton

EXHIBIT 73

Declaration of Julie Webster

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

STATE OF MISSOURI, *et al.*,

Intervenor-Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants,

DANCO LABORATORIES, LLC,

Intervenor-Defendant, and

GENBIOPRO, INC.,

Intervenor-Defendant.

Case No. 2:22-cv-00223-Z

DECLARATION OF JULIE WEBSTER

I, Julie Webster, hereby declare and swear as follows:

1. I am over 18 years of age, have personal knowledge of the matters set forth here, and am competent to make this declaration.

2. I currently work in Florida's Agency for Healthcare Administration (AHCA) as an Operations & Management Consultant Manager in the Division of Health Quality Assurance.

3. I am a registered nurse licensed in the State of Florida.

4. The statements in this declaration are based on my professional knowledge and experience.

5. In July 2025, I was asked to review medical records that had been collected from hospitals by AHCA's Division of Medicaid. These records were requested based on a review of paid Medicaid claims in which I was not involved. Upon reviewing the records, I concluded that two of the records reflected instances in which hospitals in Florida provided services for patients' treatment and follow-up care for medical complications caused by chemical abortions.

6. In the first instance, I reviewed records related to services provided to a patient by UF Health Shands Hospital in January 2020. The patient presented at UF Health Shands Hospital with fever, abdominal pain, nausea, and vomiting for the previous two days. The patient was seen at Bread & Roses, an abortion clinic, six days before reporting to the hospital, when she was pregnant at approximately six weeks' gestation. The abortion clinic performed an elective chemical abortion. The patient was given one tablet of mifepristone in the clinic and four tablets of misoprostol to take at home, which she completed. She passed large clots and fetal tissue followed by light bleeding for a few days. The day before reporting to the hospital, the patient developed nausea, vomiting, and abdominal pain with a fever of 103 degrees at home. She took Tylenol but continued to feel worse and could not tolerate food or drink by mouth. The patient denied upper respiratory infection symptoms, diarrhea, or recent sick contacts. The hospital administered laboratory testing, an ultrasound, IV fluids, and antibiotics for suspected endometritis. By the third day of treatment, the patient was tolerating intake, had improved pain, and was stable and ready for discharge.

7. In the second instance, I reviewed records related to services provided to a patient by the Jackson Health System in March 2022. The patient presented to the emergency department at the Jackson Health System with left flank pain for the previous 13 days. The patient was seen at Total Women's Clinic, an abortion clinic, 16 days before reporting to the hospital, when she was pregnant at seven weeks' gestation. The abortion clinic performed an elective chemical abortion. The patient was given one tablet of mifepristone in the clinic and two tablets of misoprostol to take at home, which she completed. She experienced heavier bleeding over the next two days and believed she saw the passage of tissue. Her flank pain started laterally, travelling down to her right lower quadrant. The hospital administered laboratory tests, an ultrasound, pain medications, and a pelvic exam. Tissue from the patient's cervical os and vaginal vault was removed and sent to pathology for evaluation. Pathology determined it was degenerated chorionic villi in a background of purulent exudate consistent with inflamed/infected products of conception.

* * *

I declare that the foregoing is true and correct to the best of my knowledge, information, and belief.

Executed August 21, 2025.

/s/ Julie Webster
Julie Webster

EXHIBIT 74

We Take Care of Us
FAQ

Frequently asked questions

About medication abortion

Before medication abortion

During medication abortion

After medication abortion

About our care

Resources

How to take abortion pills

ABOUT medication abortion

- Who is eligible for medication abortion?
- Is medication abortion safe?
- Is medication abortion effective?
- If medication abortion is safe, why am I hearing about abortion restrictions in the news?
- Is abortion legal? Can I get in trouble for having or taking abortion pills?
- I'm in a restrictive state, how can I access abortion pills safely?

BEFORE medication abortion

- How do I confirm that I'm pregnancy?
- How do I know how many weeks pregnant I am?
- How do I find out about my options?
- How does medication abortion work?
- When during pregnancy is medication abortion an option?
- Will abortion pills affect my ability to get pregnant in the future?
- My blood type is Rh negative. Do I need to take Rhogam if I have a medication abortion?
- What is ectopic pregnancy? How do I know if I have one?
- I have an IUD. Is medication abortion an option for me?
- Do I need an ultrasound?
- How should I prepare for a medication abortion?

EXIT

DURING medication abortion

- How do I take abortion pills?
- What is the best way to take misoprostol?
- What should I expect after taking mifepristone?
- What should I expect after taking misoprostol?
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- Can I eat and drink as usual during my medication abortion?
- How can I manage my symptoms after taking abortion pills?
- How do I know if my bleeding is normal?

What should I do if I think I'm having a complication?

AFTER medication abortion

How do I know if the abortion pills worked?

How long will my bleeding last?

Is it normal to continue to have cramps?

When can I return to my usual work, school and/or exercise routine?

When can I have sex again after taking abortion pills?

When can I get pregnant again after taking abortion pills?

When can I start taking birth control?

How do I know if I have an infection?

What should I do if I have misoprostol pills left over?

EXIT

ABOUT our care

Who are the providers?

What is telehealth? Is it safe and private?

How much does care cost?

Do you take insurance?

I can't pay $150 for an abortion. Is financial assistance available?

Do I have to schedule a video visit?

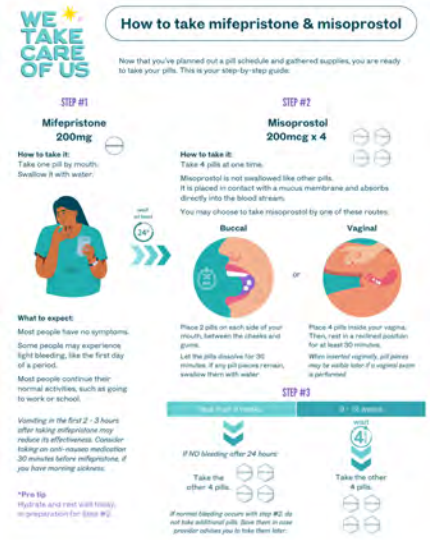
No. A video visit is not required. Most of the care we provide is asynchronous. The first step is completing an online intake form. When completing the form, you tell us what contact method you would like to use for ongoing coordination of your care. Options include a secure

messaging app, text and email. If you would like to have a video visit to ask questions, that option is also available.

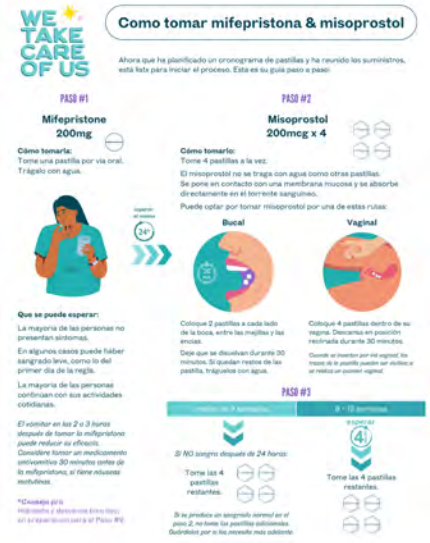
For some care services, such as perimenopause and menopause care, we may recommend a video visit as the best way to work with you to understand your priorities and goals, and develop your plan of care.

Is support available if I have questions?

How to take abortion pills



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EXIT

Resources

- Medical Support
- Emotional Support
- Legal Support
- Security



EXIT

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EXIT

Frequently asked questions

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ABOUT medication abortion

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BEFORE medication abortion

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DURING medication abortion

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When can I get pregnant again after taking abortion pills?

When can I start taking birth control?

How do I know if I have an infection?

What should I do if I have misoprostol pills left over?

EXIT

ABOUT our care

Who are the providers?

We Take Care of Us is a cooperative run by Certified Nurse Midwives (CNMs). We are primary healthcare providers for individuals who have a uterus; from menarche, during the reproductive years and throughout menopause. CNMs focus on health promotion, wellness care, gynecologic and family planning services, as well as childbearing. Our midwives specialize in providing whole-person, trauma-informed and gender-expansive care. We are here to accompany you on your journey toward health and well being.

What is telehealth? Is it safe and private?

How much does care cost?

Do you take insurance?

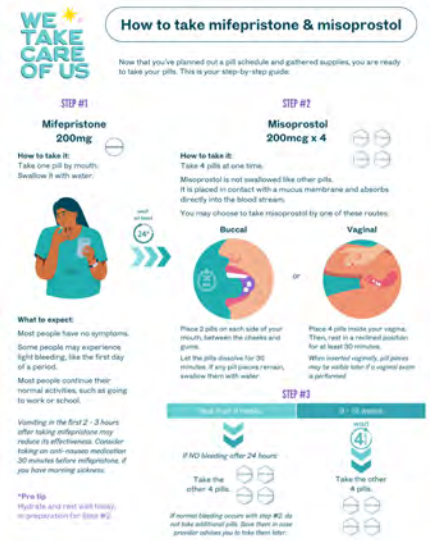
I can't pay $150 for an abortion. Is financial assistance available?

Do I have to schedule a video visit?

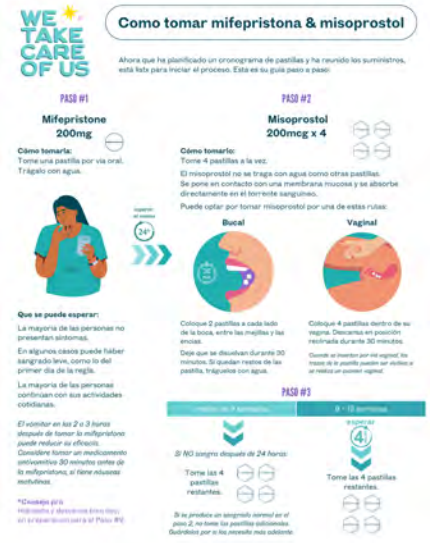
Is support available if I have questions?

EXIT

How to take abortion pills



Click to download



Haga clic para descargar

EXIT

Resources

- Medical Support
- Emotional Support
- Legal Support
- Security



EXIT

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EXHIBIT 74a

We Take Care of Us

Community Supported Abortion



Our Community Supported Abortion program provides medication abortion during the first 12 weeks of pregnancy, throughout the United States. Sliding scale pricing ranges from $150 - $600. You choose a payment amount that fits your economic and social situation. Additional assistance is available to those who need it.

GET STARTED EMPIEZA AHORA

How it works:

- Complete a 10-15 minute online intake request

  This form asks a series of screening questions to ensure that medication abortion is a safe option for you. We review your intake within 24 hours.

- Make your selected sliding scale payment
- Abortion pills are delivered to your door
- Receive ongoing support and accompaniment

The legal context of abortion care is different in every state and policies are in flux. Find up-to-date information about your state's abortion laws, and the potential risks of receiving abortion pills by mail in your state here.

Abortion pills in advance

Get abortion pills when you're not pregnant to have on hand just in case. If you decide to use them in the future, our midwives will be available to accompany you. Complete a quick intake request to get started.

PILLS IN ADVANCE PASTILLAS POR ADELANTADO



Period pills

Is your period late, but you haven't taken a pregnancy test? Period pills may help reestablish your period, even if you prefer not to confirm pregnancy. Complete a quick intake request to get started.

PERIOD PILLS PASTILLAS PARA EL PERIODO

EXIT

perimenopause

Perimenopause and menopause have long been overlooked by the medical community. Unfortunately, this leaves many providers unprepared to respond to your symptoms and concerns during this time of life.

We Take Care of Us is different. We are up-to-date on the evidence and the available treatment options. We work with you to develop an individualized plan of care. Then we follow up and make adjustments as needed, to maximize your quality of life.

Get started with our online intake request. We follow up in 24-48 hours.
Sliding scale: $80-$200 consult fee.

Other care offerings:

EXIT

Emergency Contraception

Emergency Contraception (EC) can be used to prevent pregnancy within the first 5 days after unprotected penis-in-vagina sex. We can order EC if you've had unprotected sex in the last 72 hours, or just want to have EC available for future use.

Sliding scale: $10-$60 consult fee, plus the cost of your medication.

Fill out this brief intake form and we'll follow up within 24 hours.

GET STARTED NOW EMPIEZA AHORA

Emergency Contraception

Contraception Counseling and Prescriptions

Vaginal & Urinary Tract Infections

Sexual Health, Wellness & Education



Home

Care

Cooperative

FAQs

EXIT

Follow Us

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EXHIBIT 75

Plan C – Where people get abortion pills online in Florida

Stay safe: Read our digital privacy tips ›
Quick Exit (esc)



Where People Get Abortion Pills Online in Florida

Abortion access in Florida is restricted after 6 weeks of pregnancy. But, abortion pills are still available by mail from providers outside of Florida, before and after the 6-week mark. Options below.

Show my options ↓

Have legal questions? →

Pregnancy Calculator →

If you live in this state and are seeking an abortion, you may qualify to participate in a paid research study about abortion access. **Click here to learn more.**



Did you know you can order abortion pills ahead of time, just in case?

View Options

Options for getting pills

We group providers based on the type of service they offer.

How do I choose from these provider types?

Online clinics that mail pills

For people who want abortion pills by mail and follow-up support from a clinician.

💵 $0–150+ 🚚 1–5 days

🧑🏾 Clinician support

💊 FDA-approved medications

Medically safe, possible legal risk

Stay safe: Read our digital privacy tips › Quick Exit (esc)

Websites that sell pills

For people who want abortion pills by mail without consulting a clinician.

💵 $58 and up 🚚 3-6+ days

💊 Generic medications

ⓘ Medically safe, possible legal risk

See 10 results ↓

Community networks that mail pills

For people who can't afford other services and want free pills mailed by volunteers.

💵 Free 🚚 5-14 days

💊 Generic medications

ⓘ Medically safe, possible legal risk

See 2 results ↓

Stay safe: Read our digital privacy tips ›
Quick Exit (esc)

For people who have access to transportation and would prefer to pick up abortion pills in person from an abortion clinic.

💵 Pricing varies 🧑🏾 Clinician support

💊 FDA-approved medications

See results ↓

Filter Results

- ☐ Accepts insurance
- ☐ Accepts Medicaid
- ☐ Sliding scale pricing
- ☐ Get pills in advance
- ☐ Se habla español

Stay safe: Read our digital privacy tips ›
Quick Exit (esc)

Online Clinics That Mail Pills

US-Based Online Clinics

Online clinics are US-licensed clinicians who ship pills to you after a brief online form or phone/video visit. Follow up support is available.

Showing 6 of 6 results Sort by: **Price**

Abuzz

Price	Delivery	Ages
$0–150	**1–5 days**	**16+**

Pills by mail with clinician support
For pregnancies up to 13 weeks

- Get pills in advance
- Financial assistance available
- Medically safe, possible legal risk

MORE INFORMATION REQUEST PILLS

The MAP: Cambridge Reproductive Health Consultants

Price	Delivery	Ages

Get pills in advance

Financial assistance available

Medically safe, possible legal risk

MORE INFORMATION REQUEST PILLS

Aid Access

Price	Delivery	Ages
$150 or less	2–5 days	All

Pills by mail with clinician support
For pregnancies up to 14 weeks

Get pills in advance

Financial assistance available

Medically safe, possible legal risk

MORE INFORMATION REQUEST PILLS

Community Supported Abortion, by We Take Care of Us

Price	Delivery	Ages
$5–$300+	2–5 days	All

Get pills in advance

Financial assistance available

Medically safe, possible legal risk

MORE INFORMATION REQUEST PILLS

Choices Rising

Price	Delivery	Ages
$150	2–5 days	15+

Pills by mail with clinician support (Hablamos Español)

For pregnancies up to 12 weeks

Get pills in advance

Medically safe, possible legal risk

MORE INFORMATION REQUEST PILLS

A Safe Choice

Price	Delivery	Ages
$150	1–5 days	All

Pills by mail with clinician support

MORE INFORMATION REQUEST PILLS

International Online Clinics

These services are provided by clinicians licensed in the US or abroad who mail pills after the patient completes a brief online or video visit. Pills provided are generic versions.

Showing 2 of 2 results

Abortion Pills in Private

Price	Delivery	Ages
$95	**3–6 business days**	**16+**

Pills by mail with clinician support (Hablamos Español)
For pregnancies up to 11 weeks

No financial assistance available

Medically safe, possible legal risk

MORE INFORMATION REQUEST PILLS

Women on Web

For pregnancies up to 12 weeks

- Get pills in advance
- Financial assistance available
- Medically safe, possible legal risk

MORE INFORMATION REQUEST PILLS

Why are online clinics listed if my state does not allow telehealth for abortion?

How do I choose a provider?

What if I have medical questions?

Back to top

Websites That Sell Pills

(some provide up to 14 misoprostol tablets). It may not be necessary to use all of these tablets, but doctors recommend having extra pills on hand in case you need them.

Important: These websites may not follow strict digital security protocols. Read our digital privacy tips to learn how to protect yourself when ordering or searching for abortion pills online.

Read the FAQs below for more information on how these sites work.

Showing 4 of 10 results

Sort by: **Price**

Private Emma

Price	Delivery	Ages
$59	**3–6 business days**	**All**

1 mifepristone plus 14 misoprostol
For pregnancies up to 12 weeks

- Get pills in advance
- Financial assistance available
- Medically safe, possible legal risk

MORE INFORMATION REQUEST PILLS

Privacy Pill Rx

Price	Delivery	Ages
$59–79	**10–12 business days**	**All**

Stay safe: Read our digital privacy tips › Quick Exit (esc)

MORE INFORMATION REQUEST PILLS

Life Easy On Pills

Price	Delivery	Ages
$60-80	**3-6 business days**	**All**

1 mifepristone plus 14 misoprostol

Get pills in advance

Medically safe, possible legal risk

MORE INFORMATION REQUEST PILLS

Abortion Privacy

Price	Delivery	Ages
$60-80	**3-6 business days**	**All**

1 mifepristone plus 14 misoprostol

Get pills in advance

Medically safe, possible legal risk

See all 10 websites that sell pills

What are websites that sell pills?

Are these websites legit?

How many pills do I need?

What if I have medical questions?

Back to top

Community Networks That Mail Pills

These are community-based (mostly volunteer) networks in the US that ship generic abortion pills for free. The pills often come repackaged in plastic baggies. Request pills by email.

These services are for confirmed pregnancies only. To learn about services that offer pills in advance, visit plancpills.org/in-advance).

Stay safe: Read our digital privacy tips › Quick Exit (esc)

Price	Delivery	Ages
$0	**5–12 days**	**All**

Community network that mails pills - FOR CONFIRMED PREGNANCIES ONLY

Medically safe, possible legal risk

MORE INFORMATION REQUEST PILLS

DASH

Price	Delivery	Ages
$0	**5–14 days**	**All**

Community network that mails pills - FOR CONFIRMED PREGNANCIES ONLY

Medically safe, possible legal risk

MORE INFORMATION REQUEST PILLS

Stay safe: Read our digital privacy tips ›
Quick Exit (esc)

Back to top

In-Person Clinics

Clinics offer abortion pill pickup and other in-person abortion care options. To find the nearest clinic to Florida, use any of these search tools:

I Need an Abortion

A comprehensive, regularly updated, and personalized resource for abortion seekers in the US.

VISIT WEBSITE

Learn about potential legal risk

Learn about potential legal risks of accessing pills from alternative suppliers by reading the FAQ below, "Can someone get in trouble for using abortion pills?"

You can also contact the free, confidential Repro Legal Helpline (online or at 844-868-2812) to discuss your specific situation.

Can someone get in trouble for using abortion pills?



Have feedback about Plan C or a provider?

Let us know

Stay safe: Read our digital privacy tips › Quick Exit (esc)



Live Phone & Text Support

For Medical Questions

The M+A Hotline

Free, confidential support from expert clinicians. They don't sell pills.

CALL OR TEXT VISIT WEBSITE

For Logistical & Emotional Support

Reprocare Healthline

Free, confidential peer-based support for getting and using abortion pills.

CALL OR TEXT VISIT WEBSITE

For Legal Questions

ReproLegal Helpline

Free, confidential legal information from expert lawyers.

Stay safe: Read our digital privacy tips ›
Quick Exit (esc)



Automated Support

NEW

Charley the Chatbot

A free, secure chatbot that helps identify nearby local clinics, online providers and support services.

VISIT WEBSITE

Frequently Asked Questions

Answers to common questions about how abortion pills work and how people access them.

READ FAQ

ALL SUPPORT & RESOURCES →



Sign up for our newsletter to get the latest updates and opportunities to take action, delivered straight to your inbox.

Your Email

Sign Up

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EXHIBIT 76

Plan C – Where people get abortion pills online in Texas

Stay Safe: Read our digital privacy tips ›

Quick Exit (esc)

PLAN C

Find Pills FAQ Support & Resources Get Involved About Plan C Donate Español

Plan C Guide > Texas



Where people get abortion pills online in Texas

Abortion access in Texas is restricted, but abortion pills are still available by mail from providers outside of Texas. Options below.

- Show my options ↓
- Learn about potential legal risk →
- Pregnancy Calculator →

⚠ **Please note:** Plan C does not sell pills. Use this guide to find an abortion pill provider.

Stay Safe: Read our digital privacy tips ›

Quick Exit (esc)



Online clinics that mail pills

For people who want abortion pills by mail and follow-up support from a clinician.

- $150 or less
- 1-5 days
- Clinician support
- FDA-approved medications
- Potential legal risk

See 8 results ↓



Websites that sell pills

For people who want abortion pills by mail without consulting a clinician.

- $30 and up
- 3-9 days
- Generic medications (from India)
- Potential legal risk

See 13 results ↓



Community networks that mail pills

For people who can't afford other services and want free pills mailed by volunteers.

- Free
- 5-10 days
- Generic medications (from India)
- Potential legal risk

See 1 result ↓



In-person clinics

For people who have access to transportation and would prefer to pick up abortion pills in person from an abortion clinic.

- $500 or more
- Clinician support

Stay Safe: Read our digital privacy tips ›
Quick Exit (esc)

⚠ **Learn about potential legal risks of accessing pills from alternative suppliers by reading the FAQ below, "Can I get in trouble for using abortion pills?"**

You can also contact the free, confidential Repro Legal Helpline (online or at 844-868-2812) to discuss your specific situation.

Can I get in trouble for using abortion pills?

The short answer is: it depends, and it's complicated.

Legal risk can depend on:

- where you live,
- your identity: race, ethnicity, income level, etc.
- and how far along you are in pregnancy.

In the end, it's up to each person to make their own decision about risk. Click the headings below for more information about these risks.

Where someone lives makes a difference.

What if a state totally bans abortion?

Stay Safe: Read our digital privacy tips ›
Quick Exit (esc)

Have Legal Questions?

The **Repro Legal Helpline** provides free and confidential legal advice that can help people better understand the laws and legal risk they may face. Contact them **online** or call **844-868-2812**.

For more analysis of potential legal risk, **read this article**.

How do I choose from these provider types?

Here are a few factors to consider when choosing a provider type:

What kind of support do you want?

How much will it cost?

How long will it take to get pills?

Other important factors

Stay Safe: Read our digital privacy tips ›
Quick Exit (esc)

Online clinics that mail pills



US-based online clinics

Online clinics are US-licensed clinicians who ship pills to you after a brief online form or phone/video visit. Follow up support is available.

Why are online clinics listed if my state does not allow telehealth for abortion?

This is possible because some states have "shield laws" in place that protect clinicians when they provide telehealth care to someone in another state. **Read our FAQ** about potential legal risks of getting abortion pills by mail and taking them in a state that restricts access. If you want to speak to someone about legal risk, contact the **Repro Legal Helpline**.

For more information about shield laws, **read this article**.

How do I choose a provider?

People usually choose an online clinic based on what kind of telehealth care they are comfortable with. Some providers require a phone or video visit while other providers communicate with you through text or email.

Stay Safe: Read our digital privacy tips ›
Quick Exit (esc)

What if I have medical questions?

Online clinics usually offer medical support during and after your abortion. The format of this care depends on the provider. Some providers use phone or video visits (we call this a "Virtual visit with provider") while others communicate through text or email (we call this "Online consultation by form").

You can also get free medical support from **The Miscarriage and Abortion Hotline**, which provides confidential medical information and support by phone and text to anyone in any state.

Important: If you live in an abortion restrictive state and are traveling to another state to receive telehealth care, the provider will not be able to provide care to you if you tell them you have returned to the restrictive state.

Filter by:

- ☐ Accepts insurance
- ☐ Accepts Medicaid
- ☐ Sliding scale pricing
- ☐ Get pills in advance
- ☐ Se habla español

Showing 5 of 5 results

Sort by: **Price**

AID ACCESS		
Price	Delivery	Ages
$150 or less	**2-5 days**	**All**

ARMADILLO CLINIC		
Price	Delivery	Ages
$200 or less	**2-5 days**	**18+**

CAMBRIDGE REPRODUCTIVE HEALTH CONSULTANTS		
Price	Delivery	Ages

Stay Safe: Read our digital privacy tips ›
Quick Exit (esc)

Financial assistance available

Learn about the potential legal risk of using this service

MORE INFORMATION | REQUEST PILLS

Learn about the potential legal risk of using this service

MORE INFORMATION | REQUEST PILLS

Get pills in advance

Financial assistance available

Learn about the potential legal risk of using this service

MORE INFORMATION | REQUEST PILLS

WE TAKE CARE OF US

Price	Delivery	Ages
$150–$600	**1–5 days**	**All**

Pills by mail with clinician support (hablamos español)

For pregnancies up to 12 weeks

Get pills in advance

Financial assistance available

Learn about the potential legal risk of using this service

MORE INFORMATION | REQUEST PILLS

A SAFE CHOICE

Price	Delivery	Ages
$150	**1–5 days**	**All**

Pills by mail with clinician support

For pregnancies up to 13 weeks

Get pills in advance

Learn about the potential legal risk of using this service

MORE INFORMATION | REQUEST PILLS

International online clinics

ivacy tips ›
Quick Exit (esc)

Showing 3 of 3 results

ABORTION PILLS IN PRIVATE

Price	Delivery	Ages
$90	8–14 days	16+

Pills by mail with clinician support

For pregnancies up to 11 weeks

No financial assistance available

Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

WOMEN ON WEB

Price	Delivery	Ages
$120 or less	3–5 business days	All

Pills by mail with clinician support (Hablamos Español/falamos Português)

For pregnancies up to 12 weeks

Get pills in advance

Financial assistance available

Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

TELEFEM MEXICO

Price	Delivery	Ages
$200	3 days	All

Pills by mail with clinician support, Hablamos Español--SHIPS TO MEXICO ADDRESSES ONLY, BUT CAN BE PICKED UP ALONG U.S. BORDER AT COURIER LOCATIONS

For pregnancies up to 10 weeks

No financial assistance available

MORE INFORMATION REQUEST PILLS

Back to top

Websites that sell pills

privacy tips ›
Quick Exit (esc)

our digital privacy tips to learn how to protect yourself when ordering or searching for abortion pills online.

Read the FAQs below for more information on how these sites work.



What are websites that sell pills?

Websites that sell pills are e-commerce websites that sell and ship pills to addresses in all U.S. states. They do not require a prescription for the medications, do not require you to upload your ID, and do not provide a medical consultation or any kind of support.

Are these websites legit?

Yes, these websites are legit. They sell generic abortion pills that are not regulated or inspected by the US government. Plan C regularly tests these websites by buying pills from them. The services we list in our guide all shipped pills to a home address. The pills were real (based on laboratory testing). But, we do not operate these sites, and cannot guarantee they will be reliable in the future.

Important: These websites may not follow strict digital security protocols. Read our **digital privacy tips** to learn how to protect yourself when ordering or searching for abortion pills online.

How do I choose one of these websites?

Stay Safe: Read our digital privacy tips ›
Quick Exit (esc)

We suggest you check their website and pick the one that you feel most comfortable ordering from. If you are not sure what pills to order, read the FAQ below, "What kind of kit do I order?".

What kind of kit do I order?

Most of these websites sell abortion pills in a blister pack called an MTP Kit. These kits usually contain 5 pills: 1 dose of mifepristone (1 pill) and 1 dose of misoprostol (4 pills). Sometimes these packs will be listed under different names, or will be sold in bulk quantities, which may seem confusing. What is important is that you get the correct dosage for your pregnancy. Read the next section "How many pills do I need?" for dosage information.

Important note about payment: It is very common for these websites to email or call soon after they get your order to request a different form of payment. They often say the credit card did not go through. They often ask the buyer to use a PayPal account in a person's name or in the name of another business. These payment requests do seem unusual, but they worked every time we tested them.

The pills usually arrive by the US Postal Service. They usually do not require a signature.

How many pills do I need?

If you are *under* 9 weeks pregnant you usually need 1 mifepristone pill and 4 misoprostol pills. **People who are more than 9 weeks pregnant may need additional misoprostol pills (4 or 8 pills) to complete the abortion.** Many of these websites sell misoprostol pills separately (sometimes called Cytotec or Cytolog), which can be added to your order.

Stay Safe: Read our digital privacy tips ›
Quick Exit (esc)

What if I have medical questions?

Websites that sell pills do not offer medical support. If you have medical questions during your abortion, you can get support and have your questions answered by contacting **The Miscarriage and Abortion Hotline**. This hotline provides free, confidential medical information and support by phone and text. Often they can help you address a problem without needing to go to a clinic or hospital.

If you are experiencing complications and feel the need to seek care from a health care provider at a clinic or hospital, you should do so. Your clinician does not need to know that you have used abortion pills to provide appropriate follow up care. Clinicians also can't tell you've taken abortion pills unless you tell them, or if you inserted the misoprostol vaginally and the pills did not fully dissolve. Many people use misoprostol orally to prevent this possible detection.

Some people who have told their clinician that they used abortion pills have faced legal prosecution. This is why many people just say they are having a miscarriage. The symptoms after taking abortion pills are the same as a miscarriage, and **blood tests do not reveal any differences between a miscarriage and a medication abortion**.

You can also get free, nonjudgmental emotional support before, during, and after your abortion from the folks at **All-Options Talkline**, **Exhale**, **Faith Aloud**, or **Reprocare**.

Showing 4 of 13 results

Sort by: **Price**

LIFE EASY ON PILLS

HOME ABORTIONRX

PRIVATE EMMA

Stay Safe: Read our digital privacy tips ›

Quick Exit (esc)

PLAN C

Find Pills FAQ Support & Resources Get Involved About Plan C Donate Español

Get pills in advance

Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

Get pills in advance

Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

Get pills in advance

Financial assistance available

Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

MEDSIDE 24

Price	Delivery	Ages
$44	**3-6 business days**	**All**

Pills by mail

Get pills in advance

Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

See all 13 websites that sell pills

Stay Safe: Read our digital privacy tips ›
Quick Exit (esc)

Community networks that mail pills



These are networks of volunteers in the US that ship generic abortion pills for free. The pills often come repackaged in plastic baggies. You will need to request pills by email.

What are community support networks?

These are networks of community-based volunteers who ship generic abortion pills to people in the U.S. with confirmed pregnancies. They believe in a model of community care and ship pills for free. The pills often come repackaged in plastic or mylar baggies.

What if I have medical questions?

Community support networks sometimes offer emotional or medical support through secure texting apps. You can also get support and have your medical questions answered by contacting **The Miscarriage and Abortion Hotline**. This hotline provides free, confidential medical information and support by phone and text. Often they can help you address a problem without needing to go to a clinic or hospital.

Stay Safe: Read our digital privacy tips ›
Quick Exit (esc)

and the pills did not fully dissolve. Many people use misoprostol orally to prevent this possible detection.

Some people who have told their clinician that they used abortion pills have faced legal prosecution. This is why many people just say they are having a miscarriage. The symptoms after taking abortion pills are the same as a miscarriage, and **blood tests do not reveal any differences between a miscarriage and a medication abortion**.

You can also get free, nonjudgmental emotional support before, during, and after your abortion from the folks at **All-Options Talkline**, **Exhale**, **Faith Aloud**, or **Reprocare**.

Showing 1 of 1 results

LAS LIBRES

Price	Delivery	Ages
$0	**5–12 days**	**All**

Community network that mails pills

⚠ Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

Stay Safe: Read our digital privacy tips ›

Quick Exit (esc)

PLAN C

Find Pills FAQ Support & Resources Get Involved About Plan C Donate Español

In-person clinics



Clinics offer abortion pill pickup and other in-person abortion care options. To find the nearest clinic to Texas, use any of these search tools:

I Need an Abortion

A comprehensive, regularly updated, and personalized resource for abortion seekers in the US.

VISIT WEBSITE

Texas: Abortion Clinic Guide

Information about Texas abortion clinics, nearby clinic options, and financial assistance from local support resources.

VISIT WEBSITE

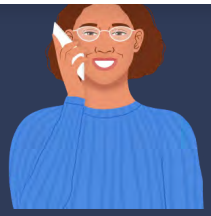
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Stay Safe: Read our digital privacy tips ›

Quick Exit (esc)

PLAN C

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Live phone & text support

For Medical Questions

The M+A Hotline

Free and confidential support from a clinician at the Miscarriage + Abortion Hotline. (M+A does not sell pills)

CALL OR TEXT ↗ VISIT WEBSITE

For Logistical & Emotional Support

Reprocare Healthline

Free and confidential help understanding how to get pills and how to use them.

CALL OR TEXT ↗ VISIT WEBSITE

For Legal Questions

ReproLegal Helpline

Connect with a lawyer for free and confidential legal information.

CALL OR TEXT ↗ VISIT WEBSITE



Automated support

NEW

Charley the Chatbot

Provides users with personalized abortion options, including information about different

Frequently Asked Questions

Get answers to common questions about how abortion pills work and how to access them.

Stay Safe: Read our digital privacy tips ›

Quick Exit (esc)

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Get the Plan C Newsletter

For breaking developments in abortion pill access and opportunities to take action.

Your Email

Sign Up

Plan C is a project under the fiscal sponsorship of the National Women's Health Network, a 501c3 organization. Our generous donors make this critical work possible.

Find Pills →

FAQ

- Finding Abortion Pills
- About Abortion Pills
- Using Abortion Pills
- Can I get in Trouble for Using Abortion Pills?

Support and Resources

- Quick Resource List
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- Legal Support
- Financial Support
- Abortion Pill Instructions
- Abortion Care Apps
- Other Options for Getting an Abortion

Get Involved

- Plan C Community
- Take Action
- Stickers & Flyers
- Plan C Merch
- Social Media Toolkit
- Partner with Us
- For Medical Professionals
- Work with Plan C
- Donate

About Plan C

- Mission
- Team
- Press
- Research & Learning
- PLAN C: The Documentary
- 2023 Annual Report
- Media inquiries
- Contact Us

Stay Safe: Read our digital privacy tips ›

Quick Exit (esc)

Find Pills FAQ Support & Resources Get Involved About Plan C Donate Español

Site by Eyes Open

Disclaimer: This is not legal or medical advice and does not substitute for the representation of an attorney or the advice of a doctor. No attorney client relationship has been formed by reviewing this material.

Abortion Care Network

EXHIBIT 77

Plan C – About Us



About Us

Plan C is a public health creative campaign on abortion pill access, started in 2015 by a small team of veteran public health advocates, researchers, social justice activists. Read about our values here.

Plan C works to transform access to abortion in the US by normalizing the self-directed option of abortion pills by mail.

Our Vision: A near future in which the ability to end an early pregnancy is directly in the hands of anyone who seeks it.

Read more about our work in the 2024 Annual Report.

We Work in 4 Ways:

- **Conducting research** and publicly sharing information about how people are accessing abortion pills in the US, including domestic and global evidence about safety and efficacy of medication abortion;
- **Building collaborative relationships** with providers, reproductive health and justice organizations, and technology innovators who share our vision of demedicalizing pills by mail;
- **Calling for universal access to abortion pills**, de-stigmatizing and normalizing the modern option of self-managing an abortion at home, and
- **Centering the transformative nature of abortion pills** and building on decades of their safe self-use, to move agency over abortion back to the individuals who seek them.



Press & Media

Plan C in the Press

Media inquiries

Who We Are

Plan C is a public health creative campaign, started in 2015 by a small team of veteran public health advocates, researchers, social justice activists and digital strategists.

Our team holds an array of identities. Some have children, others are childless by choice. Some have had abortions and others have not. This diversity of experiences informs what and how we do our work.

Our Values

Work With Us

Stay safe: Read our digital privacy tips ›
Quick Exit (esc)

History of the Plan C Campaign

Founded in 2015 to do research and share information on abortion pills by mail in the U.S., Plan C is a fiscally sponsored project of Possibility Labs, a 501c3 nonprofit organization.



2 min video

The Story of Plan C

Watch our animated history of the abortion pill.

Timeline

1990's

In the mid 1990s, Elisa Wells and Francine Coeytaux were on the team to bring Plan B, the "morning after pill," over the counter – a long but successful journey catalyzing business, FDA and public goals. (Read *From Secret to Shelf, 1999*).

2013

In 2013, Coeytaux, then at Public Health Institute, coordinated a meeting with National Women's Health Network and Ipas to bring together reproductive justice organizations to discuss how to move the issue of self-managed care forward. A key revelation was that misoprostol was available online in the United States, which Wells and others outlined in an unpublished paper called *Surfing for Abortion*.

2015

In 2015, Wells and Coeytaux prepared an analysis for the Reproductive Health Technologies Project about how the lessons learned from emergency contraception could be used to spread awareness of abortion pills as a self-managed method in the United States. During these years, Coeytaux and Wells were also working internationally and witnessing the expansion of access to abortion pills through pharmacies in many countries, and the positive impact that access was having on reducing maternal mortality.

In late 2016, we noticed online vendors selling "abortion kits." We researched and tested these vendors and published this research in the journal *Contraception*, as well as on our website as the Plan C Report Card, documenting what we knew to be reliable online sources of pills.

Over the next three years, our website grew and the Plan C data and team were featured in major publications worldwide.

2018

In 2018 we collaborated with UCSF on a study to demonstrate the feasibility and acceptability of online access to abortion pills throughout California. But the FDA refused to approve the study, for the same reason the restrictions remain in place—politics. Instead, we took our idea to the state of Washington, where a respected clinic ran with it instead.

By now, dozens of online vendors were selling abortion pills, most from within the United States. This was unprecedented. But still there were so many people reaching out to reproductive health organizations, asking for help in self-managing their abortion--and no US organization was able to step up. So AidAccess.org came online to serve the US from the Netherlands, initially helping around 1,000 people/month with medically-supported at-home abortion care. By operating from outside the US, they were able to sidestep the politics of abortion for the time being.

2019

By 2019 the Plan C website was receiving upwards of 50,000 hits/month, from all over the US, with over half of those visitors seeking out the Report Card. The work of the Plan C team was featured in major press and led to speaking engagements at events like Essence Festival and the Cycles+Sex Conference (now allbodies.com). The Plan C team meanwhile spent time incubating and advising new telehealth providers as they considered coming

2020

In April 2020, as the global pandemic hit, Plan C sent a call-out to medical providers across the nation, asking them to step up and consider providing telemedicine and pills shipped directly to patients during the pandemic's state of emergency. Hundreds responded to the call, and a handful found ways to launch their new services from permissive states. In collaboration with the University of Washington, Plan C developed a Toolkit to assist them as they began to revolutionize access to early abortion across the U.S. by mailing pills.

In July 2020, a judge's ruling allowed mifepristone to be mailed. Clinics and telehealth startups fast-tracked the adoption of new protocols that reduced the need for blood tests and physical exams, opening the door to rapid expansion of online abortion care.

2021

In January 2021, on one of the deadliest days of the pandemic, SCOTUS ruled to reinstate restrictions on mifepristone by mail, creating chaos for telehealth abortion providers and those seeking this new form of care. Aid Access continued to mail pills to patients across the U.S. and providers considered how much they were willing to risk to provide patient-centered care in a public health crisis. Plan C continued to share information about alternate routes of access to pills, including online pill vendors and Aid Access.

In April of 2021, the court once again removed restrictions against mailing, but left other barriers in place: blocking mife from pharmacies and keeping burdensome provider registration processes in place. Telehealth abortion care came online with full force.

In summer of 2021, Texas announced passing the first "aid and abet" abortion ban, deputizing citizens to target helpers of abortion access with civil suits. In response, Plan C contacted local Texas partners

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in Plan C's online reach, with Plan C accounts reposted far and wide: AOC's tweet about Plan C garnered more than 8M views.

2022

In May 2022 the U.S. media "leaked" the *Dobbs* decision, alerting the public and organizations of what was to come. Unfortunately, the repro movement and governmental administrations were unable to coordinate or mobilize a response or defense.

Six weeks later, the *Dobbs* decision effectively overturned the protections of *Roe v. Wade*. Plan C responded on social media, in the press and in community with partner organizations sharing information on alternate routes of access and resources for self-managed abortion (including advance provision and mail forwarding. Abortion access was now a human rights imperative and our harm reduction response garnered a groundswell of support, with people amplifying our information about self-managed abortion far and wide.

Nevertheless, tens of millions of people in the U.S. were impacted by not only clinics closing and providers withdrawing from care, but also consistent misinformation and censorship of health info online.

In late 2022, Plan C was recognized in MIT's 2022 Technology Review and won the Anthem/Webby awards Gold Award for non-profit websites.

2023

In Winter 2022/2023 we began a research and messaging development process to support new communications campaign called "Know Your Plan C / Conoce a Tu Plan C:" learning from grassroots organizations and audiences in six restricted states (Florida, Georgia, Kentucky, Mississippi, Oklahoma, and Texas) and rolling out content to those states designed to be educational, approachable, action-oriented, and empowering.

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with additional creators and expand the campaign's reach to other states.

2023's breakthroughs came in the form of "Shield Laws:" passed in six states to protect providers in mailing pills over state lines, into states with bans. These shield laws also provide protections for people traveling into permissive states for abortion services. Existing and new telehealth services immediately operationalized these laws, serving thousands of people with pills by mail every month, even in states that ban abortion. Plan C's Guide to Pills is a critical mechanism to help people know about the availability of these services and we have been actively fundraising for these providers, who offer a sliding scale model that ensures that no one is denied access to care due to inability to pay.

The Plan C co-founders were named as part of Fast Company's Most Creative People in Business 2023. This recognition aligned with Plan C's long standing goal for abortion pills to be in mainstream culture.

With a looming SCOTUS ruling on mifepristone, continued state bans and a digital landscape rife with misinformation and censorship, Plan C's work is far from done. But in just seven years, Plan C has helped to accelerate the demedicalization of medication abortion, changing the narrative and normalizing the method across the U.S. as well as catalyzing partners and services that represent a new era of access and self-care.

Have a question not answered here?

Contact us

"I love this project, thank you for giving me hope."

"I've used Plan C and it saved my life. Now I go around teaching about safe sex to high schoolers in the summer."

"I'm a dude but I stand with y'all. I have 3 sisters and an amazing wife and I learned so much from them...my way of helping y'all is putting these [stickers] everywhere ♥."

Plan C at Sundance for the documentary screening, Jan 2023.



Want to stay updated on abortion pill news?

Sign up for our newsletter to get the latest updates and opportunities to take action, delivered straight to your inbox.

Your Email

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Site by Eyes Open

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EXHIBIT 78

Plan C – 2023 Annual Report

2023 Annual Report

Activities, Financials & Impact



From the Co-founders



What a journey this year (and decade) has been.

From the initial question we posed nearly 10 years ago - why aren't people in the US talking about abortion pills? - to a campaign to spread this information widely, we've watched as Plan C has grown into a national resource, a recognized creative force, a documentary, and a movement of self-directed access in the face of harmful bans to care.

It has been a journey that has required tenacity and grit, sensitivity and humility. The past year we harnessed the talents of our deeply skilled and imaginative team to spread the word that - in the devastating aftermath of Roe - abortion pills are still available by mail in every state.

We can't imagine any other way to participate in this historic and challenging moment, and we remain so grateful to be able to share good news: abortion pills are real, available, and inevitable.

Thank you for being on the journey with us.

Onward,

Amy Merrill Elisa Wells

Amy Merrill & Elisa Wells
Co-Founders & Co-Directors

Who we are and what we do

Plan C is a public health information campaign and a catalyst for direct access to abortion pills by mail in the US.

Since 2015, Plan C has led the way in normalizing self-directed abortion care in the US, actively increasing awareness of safe and effective abortion pills (mifepristone and misoprostol). We share evidence-based information on how the method works, where it's found online and by mail, and how people are accessing pills and free confidential support services, from any state.

At Plan C our #1 tool is plancpills.org, where we maintain a comprehensive Guide to Pills, which includes tested and vetted sources of pills available through both mainstream and alternate routes, FAQs and referrals to free and confidential support hotlines - information that centers the end user in their decision, allowing them to make the decision that is best for them, especially in states with harmful bans.

As a creative campaign, Plan C works with artists, brands and media to make the method more known and available and tell new stories about abortion access and autonomy over reproductive outcomes.

Plan C operates under a vision of pills in hands: disentangling the method from politics and moving agency over abortion back to the individual.

Learn more at plancpills.org.



2023 & looking ahead

In spite of bans and restrictions, more people are getting abortions across the country, avenues to access abortion pills are increasing, and providers, community support networks, and websites are providing pills by mail options that are more affordable, more convenient and faster than ever.

Public support for abortion is as high as ever.

The public is on our side: recent data show 9 in 10 people in the US support abortion access.

Over the last two years, abortion has been a winning issue on state ballots, including California, Kansas, Kentucky, Michigan, Montana, New York, Ohio, and Virginia.

Messaging from the abortion pill access movement is becoming even bolder.

Alongside a handful of movement partners, we're getting the word out about abortion pill access in restricted states in even more direct ways.

And with the 2024 elections on the horizon, we'll be working to elevate abortion pills in the political conversation and inspire our community to vote.

Shield laws are expanding access to abortion pills by mail.

Six states - California, Colorado, Massachusetts, New York, Vermont, and Washington - have passed "Shield Laws" to protect providers as they offer telemedicine abortion and ship pills to all 50 states. This is a historic development in policy efforts to protect abortion access.

Supporting shield law providers.

Shield laws are not a total or permanent solution, but right now they're a game-changer for abortion pill access. We will continue to secure funding for shield provider care, to ensure equitable access no matter what the abortion seeker's financial situation. We're also helping to spread the word about shield law provision: still a relatively unknown development.

More providers are coming on board to supply abortion pills.

Shield laws have been operationalized by Aid Access and US-based telehealth abortion startups Abuzz and Cambridge Reproductive Health Consultants, shipping pills over state lines into restricted states to thousands per month, with sliding scale costs and 2-5 day ship times.

Catalyzing, supporting, and incubating the abortion pill ecosystem.

We know how important the ecosystem of services, hotlines and funds is together, and we'll continue to bolster mechanisms for access to abortion pills and sources of self-managed pills, information and support.

There are more avenues to access abortion pills.

Creating diverse routes of accessing abortion pills is vital to protecting this form of care, especially in light of ongoing bans and potential SCOTUS decisions.

Online vendors are selling pills for as low as $25. Providers are now supplying abortion pills in advance of need, and new "period pill" services send people the same medications for a late period, no pregnancy test required.

Keeping abortion pills visible.

To keep the momentum going on these exciting developments and capture the public's enthusiasm for abortion, we're expanding our media engagement work: leveraging the PLAN C documentary, building our presence online and at in-person events, activating our community, and exploring creative partnerships.

We also update our Guide to Pills as things change.

Plan C by the numbers

1.8M

Total Visitors to the Plan C website in 2023. Traffic to the Plan C website doubled in the year after Roe fell.

300K

Total click-offs from the Plan C website to other sites: this represents people finding the resources they seek.

40M

Total impressions on social media platforms, both paid and organic.

20B

Total impressions from press and media articles and interviews
(yes, that B is for billion!).

123K

Total social media followers on Plan C's active platforms.

1.4M

Stickers and flyers distributed this year.

147

Number of events featuring Plan C representatives, materials or talks.

We also forged 18 on-campus partnerships this year.

$382,810

Total money given by Plan C to partner organizations: to catalyze access, awareness, and support for on-the-ground efforts around pills by mail.

Key Campaigns & Updates

The Plan C Documentary Premieres at Sundance

Shot over the past four years by award-winning filmmaker Tracy Droz Tragos, PLAN C is a documentary capturing the work of the Plan C campaign and the work of activists and providers who began to mail abortion pills, during the pandemic and in the face of crumbling reproductive rights & access across the US.

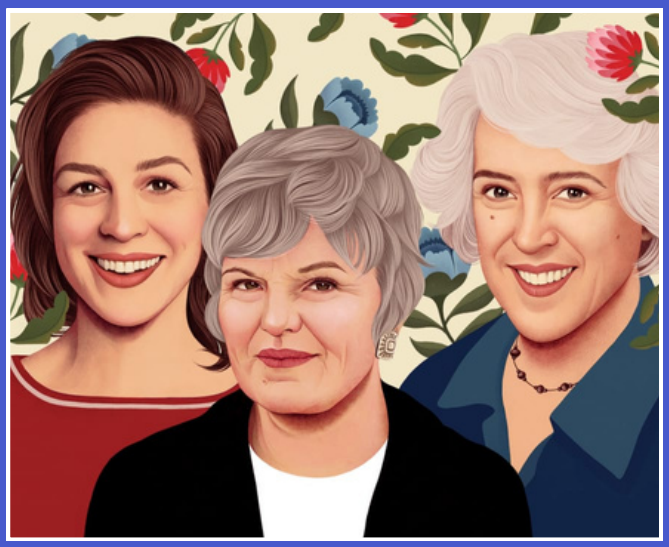
See more at plancmovie.com.



Plan C Co-Founders named in Fast Company's Most Creative People in Business 2023

The Plan C co-founders were named as part of Fast Company's Most Creative People in Business list for 2023. This recognition aligned with Plan C's longstanding goal for abortion pills to be in mainstream culture. It credits our team's ongoing work at the intersection of creativity, innovation and public health.

Read the announcement here.

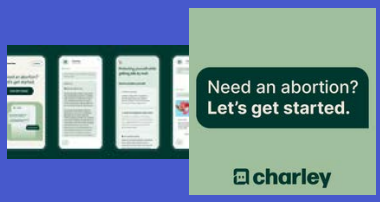


Key Campaigns & Updates, continued

"Know Your Plan C" Campaign Rollout

This year, Plan C launched a new multi-state information campaign to ensure that people know about abortion pills by mail developed with comprehensive research from nonprofit communications agency Public Good Projects and ongoing substantive input from state and local partners. So far the campaign has drawn more than 30M impressions across six states that restrict or ban abortion through radio, digital audio, social media, and Hulu ads.

Visit KnowYourPlanC.com to view the campaign.



The Abortion Chatbot Will See You Now

This fall, alongside ineedana.com, the Miscarriage and Abortion Hotline, and other reproductive health and advocacy experts, Plan C advised on the development of new online chatbot, Charley: designed to provide abortion seekers with personalized, direct and comprehensive information about their options, including care methods, nearby clinics, accessing abortion pills, and referrals to support services.

Visit www.chatwithcharley.org to give it a try.



Fighting Digital Suppression, in Coalition

After years of fighting censorship and information suppression online, Plan C joined forces with larger efforts to create solidarity amongst international sexual and reproductive health and research organizations that experience similar challenges.

In 2023, Plan C was an active participant in this coalition to fight Big Tech's suppression of online abortion information, alongside Amnesty International, Women on Web, Reproaction, Center for Intimacy Justice, and Women First Digital at RightsCon, Netroots, the UN General Assembly and online.

Plan C SMA 101 Workshops + ABCs of SMA

The Plan C Community facilitated monthly online information sessions that drew participation from school groups, activist groups, medical students, and community organizations. The sessions shared information about abortion pills, resources to support abortion seekers, and how to get more involved in advocating for access to pills by mail, with guest speakers from If/When/How, Amnesty International, National Abortion Federation, and Women on Web.

The sessions were an essential entry point for volunteers, supporters and partners.
Learn more at plancpills.org/community.

What they're saying

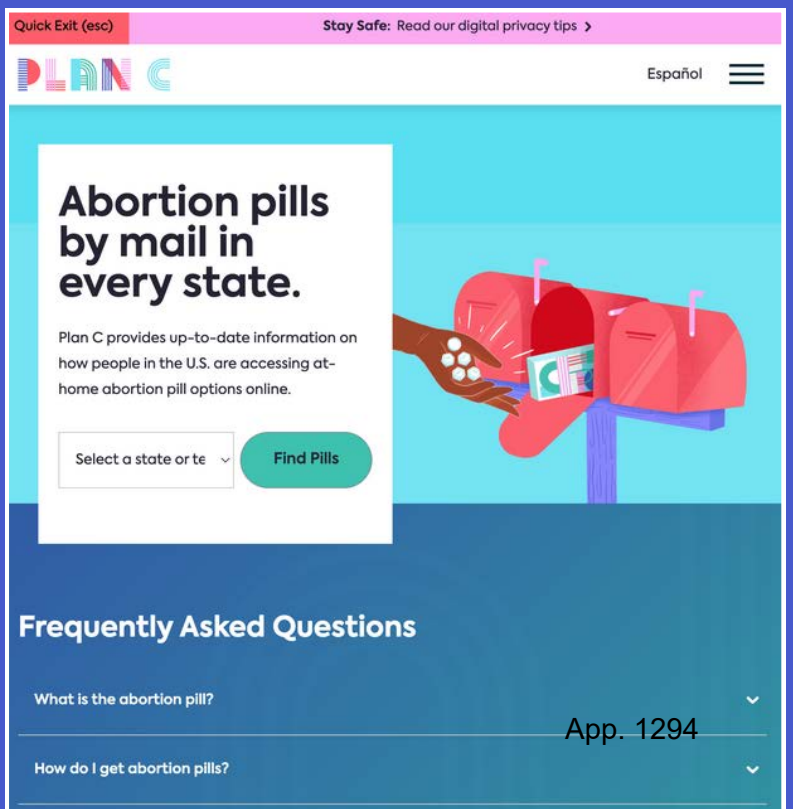
Everything about this process was amazing.

I could do everything at home, in private. Everything was fast, efficient - the people I spoke to were so caring and non judgemental."

I believe that this not only is, but should be, the future of abortion access in our country.

It allows for patient-centered care, and removes a piece of the process that revolves around stigma.

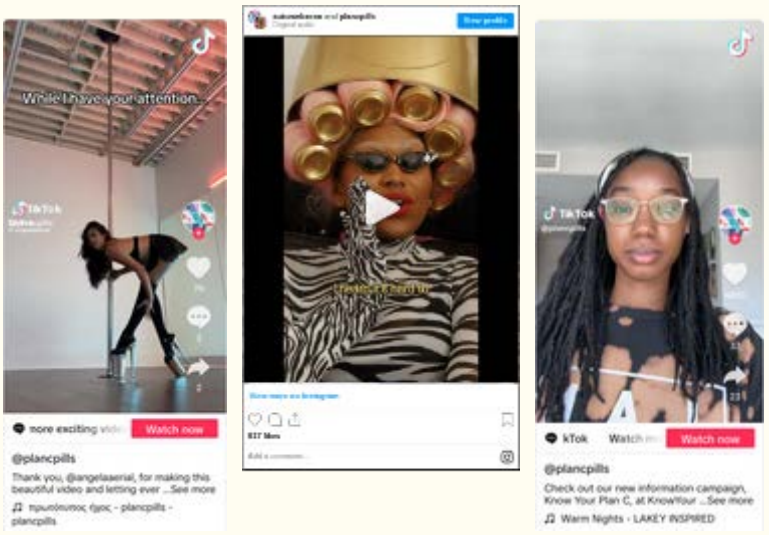
It allows that patient to directly access the services they need without having to confront stigma in the face."



Creative Partnerships

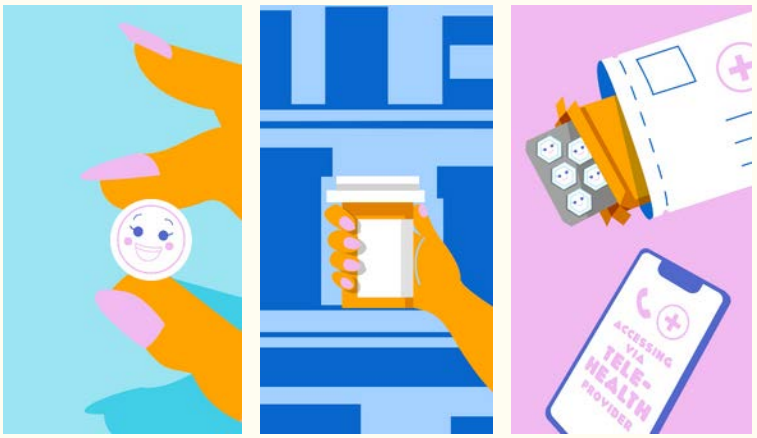
Check us out on TikTok

Our TikTok following has grown by 11k followers this year thanks to great content by our Partnerships Manager and collaborations with creators like @angelaaerial.



Mife + Miso: Animated Series

We worked with Runaway Train Productions and Reel Black Studios to create a series of 4 educational animations with mife + miso pills as the "heroes" of the story. Topics included miso-only protocols, the M+A Hotline, and the availability of pills in advance. Find the videos on our website here.



Day of A at SXSW

The Plan C team took SXSW with a post-Roe panel alongside Planned Parenthood and Center for Reproductive Health and Day of A, an event in coordination with the PLAN C documentary and Future Front TX in support of local partners, which drew hundreds of guests.



Creative Partnerships, continued

Our first artist-in residency, Autumn Breon

Plan C partnered with artist Autumn Breon on video content and the launch of her Care Machine: a free vending machine stocked with reproductive and beauty resources. Works appeared at the Crenshaw Dairy Mart and Miami Art Basel, and will continue in 2024 at Frieze and other art & culture festivals.



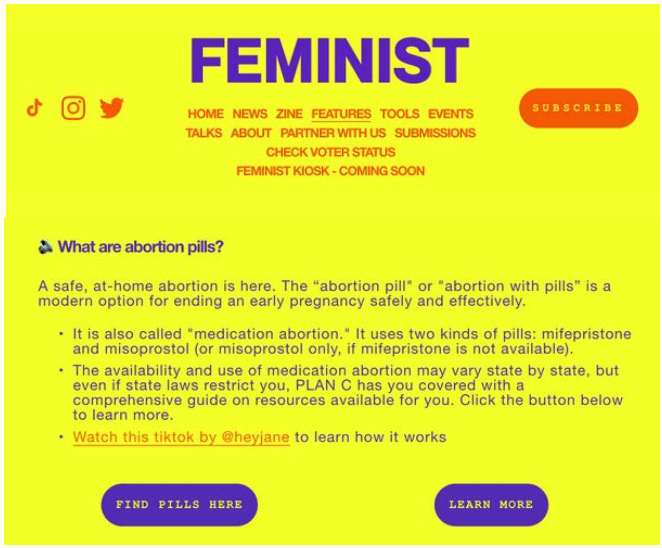


The Power of Music

Plan C was beneficiary of Demi Lovato's new pro-abortion song launch: 'SWINE' which garnered major press. The team also aligned with artist/musician Amanda Palmer and Runway Productions on a short film about abortion pills by mail set to Amanda's song, "Voicemail for Jill."



Creative Partnerships, continued



Featured in Feminist

With a social media following of 6M+, Feminist knows how to engage the public around issues that matter: and their info page is a model example of how brands and groups can feature abortion pill info alongside other resources, for audiences who want
to know.

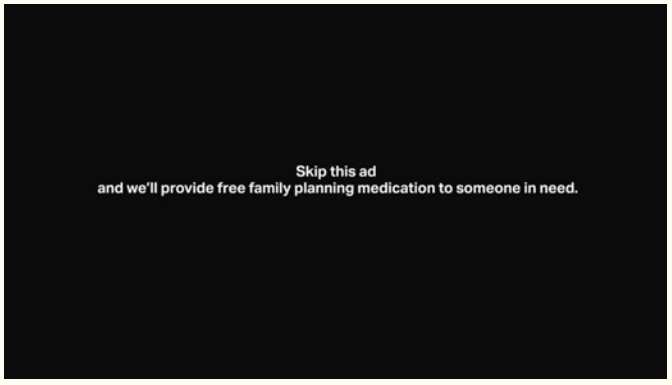
Visit the page on feminists.co here.

Partnering with brands

Plan C partnered with brands August and Stix on campaign SyncPeriodsNotData to call out digital surveillance via a clever pregnancy test package containing additional reproductive health and abortion information.

Plan C also partnered with agency 72andsunny on Made By Choice: a YouTube campaign where viewers could watch the abortion ad, or skip it and trigger a donation to fund pills, with the message: you have a choice.





A Tech-First Approach to Abortion Access



Plan C leverages technology, digital tools, and creative content to share information and change the narrative.

Technology Challenges:

Digital Suppression.

Our content on social media is routinely suppressed or blocked by social media companies. Plan C has been shadowbanned, we've reported fake Plan C accounts and copycat websites, and our content has been routinely blocked from followers' feeds. In February 2023, we led a digital campaign calling out Instagram and Meta for suppressing our account and shadow banning our content.

Ad Blocks.

Since July 2022 our account has been blocked on Google Ads. Meanwhile Google allows crisis pregnancy centers aka "fake clinics" to advertise on search, under abortion keywords (even when they don't provide abortions) and Google reportedly made $10M in ad revenues from these CPCs in the past year. in the past year. Plan C ads on Meta often get rejected as well, which leads to exhaustive appeals with their policy team, delaying or blocking the flow of critical public health information at this urgent moment in history.

"Anti" bots.

Recently we discovered and tracked artificially-enhanced results for keyword "abortion pill," likely designed by anti-abortionists to inflate their own CPC listings. On days when the bot was active, Plan C's listing was pushed far down the search results page.

Tech, continued...

Shadow-ban (verb):

To block (a user) from a social media site or online forum without their knowledge, typically by making their posts and comments no longer visible or with limited visibility to other users.

Censorship (noun):

The suppression of speech, public communication, or other information.

Digital suppression (verb):

The restraint of an idea, information, or activity online by institutions with power.

Tech, continued...

How We're Overcoming These Challenges:

Search Engine Optimization (SEO):

Our world-class SEO lead helps ensure that our website and Guide to Pills rises to the top of organic search results, above deceptive resources and meeting the individual in their moment of need as they search for abortion information.

In 2023 we also embarked upon a UX and development process to improve the Plan C Guide to Pills, incorporating user feedback to make information more understandable and digestible, improve the backend databases of providers and services, and ensure high levels of digital security and privacy along the way.

In one year:

- Organic traffic landing on the Guide's state pages increased by 26%.
- Google visibility of the Guide's state pages increased by 448%.
- Plan C ranked #1 in search for 122 keywords (previously 20 keywords).

Breaking Through Censorship & Suppression:

This past year we partnered with Amnesty International, Women on Web, Reproaction, Center for Intimacy Justice, and Women First Digital in a coalition to fight against digital suppression of sexual and reproductive health information and collectively troubleshoot issues faced. We also gave a grant to OARS, who runs the Reddit /abortion page, answering thousands of questions each month from anonymous abortion seekers in need of for support.

We're also bringing issues to coalitions like Techies for RJ and the Charley Chatbot team. In 2024 we will continue to build power in coalition, to solve problems and share resources across the many organizations experiencing similar challenges in the face of ensuring ongoing access to abortion.

Strategic Paid Ads Approach:

We continue to prioritize digital paid advertising to reach target audiences and restricted states, especially with the launch of our "Know Your Plan C" campaign. This has been one of Plan C's most successful strategies in reaching harder-to-reach members of target audiences.

We've been steadfast and creative in getting ads on platforms like Facebook, Instagram, TikTok, and Hulu and have been proud to partner with companies like iHeart Media who value and support our public health message.

> **"You can't stop people from going on the internet. How are you going to stop them?"**
>
> *Francine Coeytaux, Plan C cofounder, in opening scene of new documentary PLAN C*

Press Highlights

Rolling Stone

Here's What Happens If Trump Judge Ends Access To Critical Abortion Drug Nationwide

Elisa Wells, co-founder and co-director of Plan C, an organization that helps individuals obtain abortion pills, says regardless of Kacsmaryk's decision, women will still have options.

The New York Times

Inside the Online Market for Overseas Abortion Pills

This New York Times piece brought huge visibility to the option of obtaining abortion pills through ecommerce websites, informed heavily by Plan C's research over the past 10 years.

The Washington Post

The abortion bot will see you now

This overview of our collaboration on Charley describes the bold new abortion bot that helps abortion-seekers find access to vetted health care resources, from any state.

abc NEWS

Plan C on ABC News

This episode of ABC News addressed the proliferance of online pill vendor sites, as a real and available option for people in states with bans.

teen VOGUE

Abortion Pills Are in My Medicine Cabinet. They Should Be in Yours Too

Cofounder & Digital Director Amy Merrill wrote a widely-viewed op-ed for Teen Vogue to spread the word about Plan C's "No Roe. Get Pills in Advance" advance provision information campaign.

The Dallas Morning News

Texans still getting abortion pills by mail with out-of-state help

This Dallas Morning News interview reached millions of people in Texas. It was picked up by MSN for enormous amplification, translated for the Spanish language community in Texas, and led to further coverage of Plan C's work on the local news stations in-state.



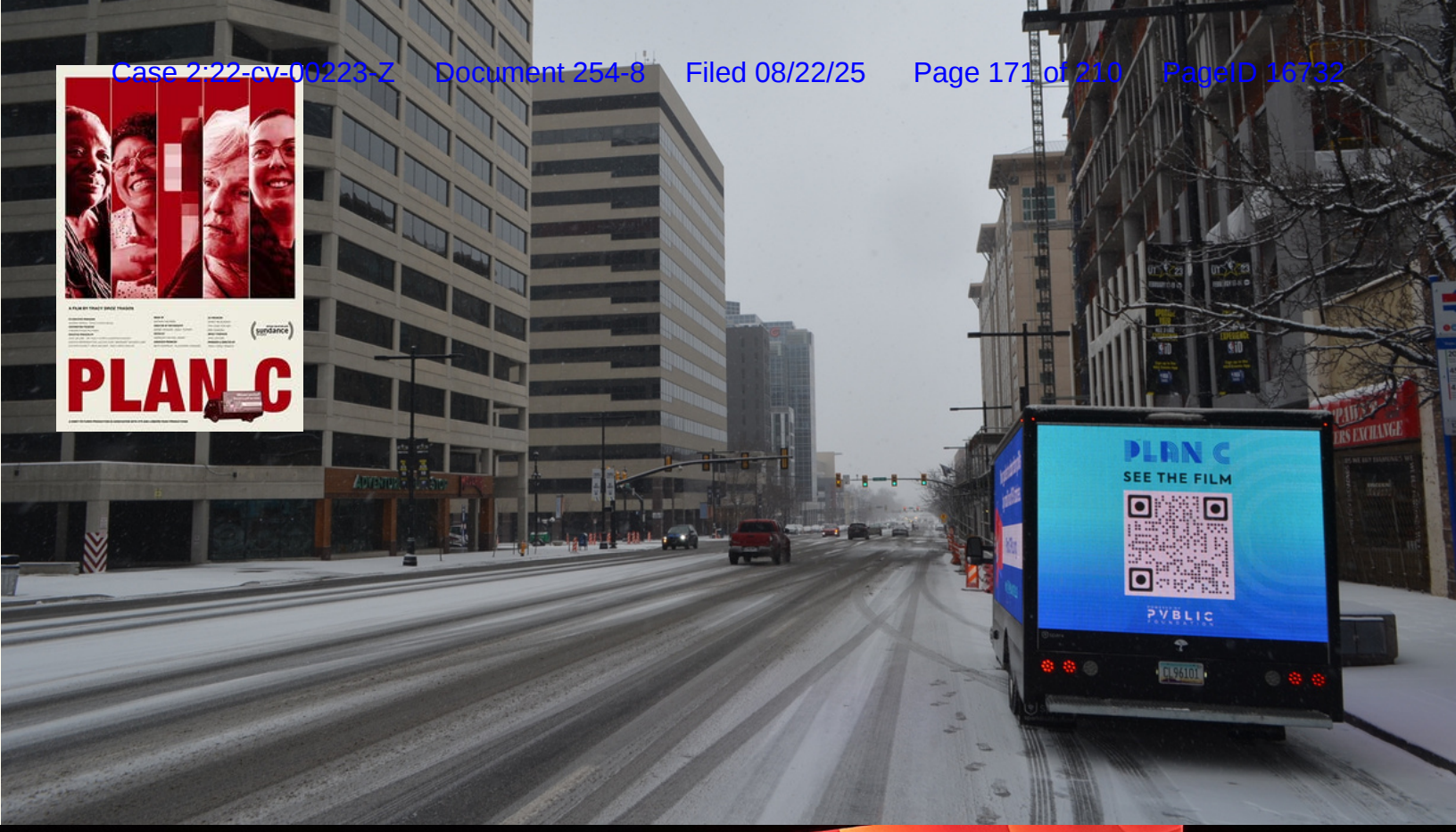
Savage Love podast with Elisa Wells

Co-Director Elisa Wells appeared on Dan Savage's Savage Love Cast, a personal highlight for members of Plan C who are fans of the show.

COSMOPOLITAN

This Documentary About the Fight for Abortion Information and Access Is One of the Must-Sees of 2023

Cosmopolitan was one of the scores of publications that wrote about the PLAN C documentary premiere and release. This was one of the major ways Plan C showed up in entertainment and culture news in 2023.

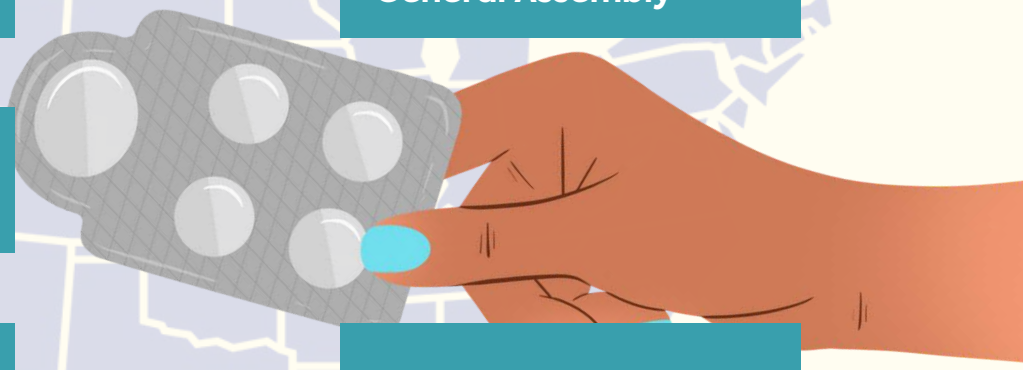




Plan C at Sundance Film Festival, January 2023

Conferences

- **Nexus Summit**
- **SXSW**
- **RightsCon**
- **United Nations** General Assembly
- **NOW** National Conference
- **Abortion Camp** by SYA
- **Creating Change**
- **CES Vegas**
- **NetRoots**



Changing the Narrative

One of our big realizations in 2023 was that so many people still don't know about abortion pills by mail, or how to access them from all states.

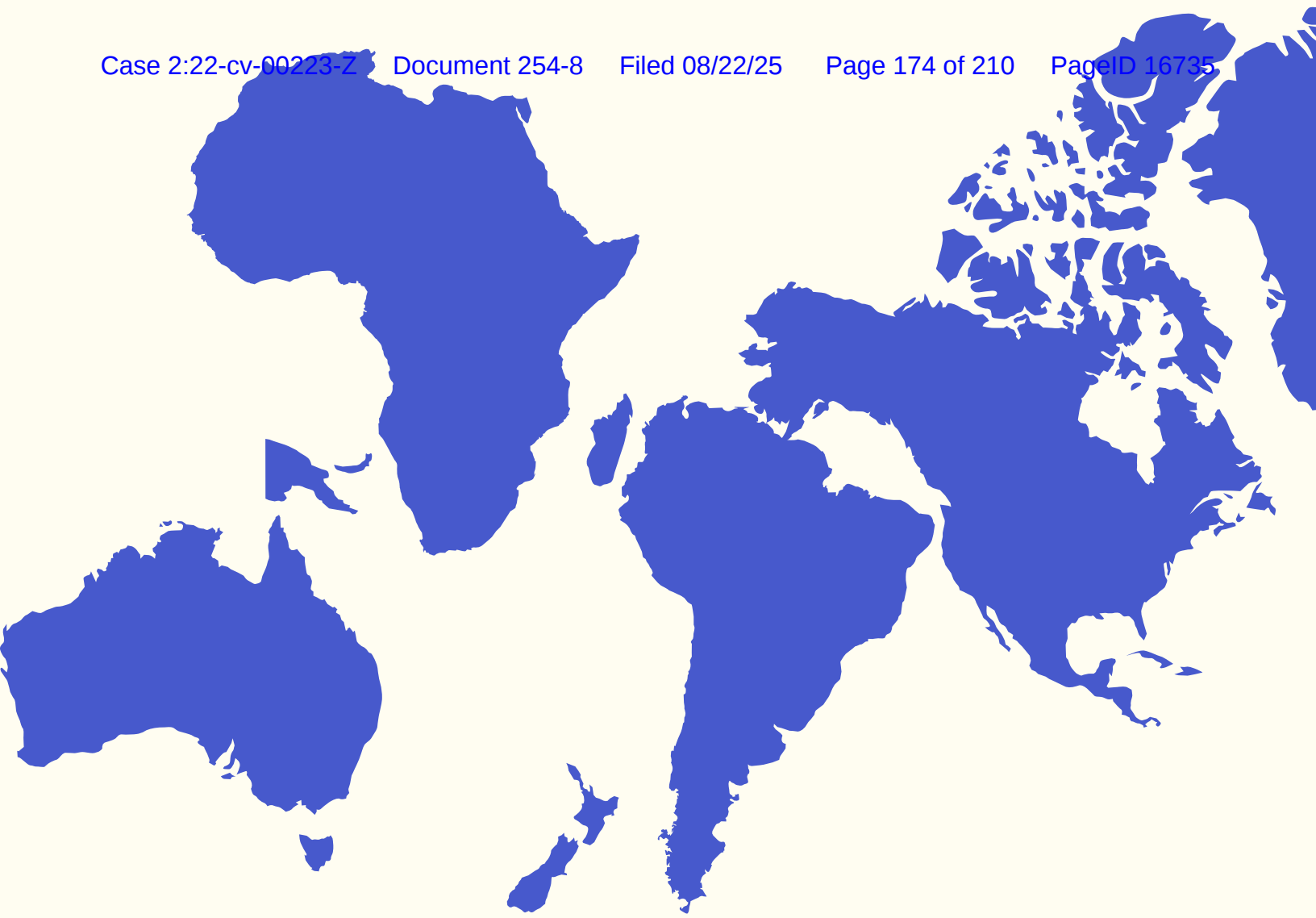
Plan C is committed to continuing to show up in spaces related to reproductive rights & access and also mainstream pop culture. We do this to share information, and also to expand the general public's current notion of what is an abortion: from self-managed, to miscarriage management, to "period pills," to getting pills in advance, we are describing a paradigm shift, one that contains a spectrum of experiences and needs, and introduces the transformative potential of abortion pills to meet those needs for people living in a post-Roe US.



Day of A

A Day of Action in Austin, TX - March 2023

In partnership with Future Front Texas we produced an activation during SXSW that brought hundreds of people through... highlighted local orgs and destigmatized abortion and shared information on how Texans could still access abortion pills by mail, despite bans to local access and care.



This is a global movement.

- Abortion pills are endorsed by the World Health Organization as an essential medication.
- They are used by millions worldwide every year, and are available over the counter in many countries.
- In India, abortion pills used outside of health facilities account for over 70% of all abortions.
- In the US, we have seen great progress in catching up - but we still have a long way to go.
- There is much to learn from the international movement and from countries who have lived under abortion bans for a long time. Plan C is committed to showing up in global coalition, and exchanging learnings and practices with groups, activists and researchers from other countries.

2023 Impact & Financial Highlights

Starting with Texas' SB8 in the fall of 2021, the Plan C campaign has experienced generous upticks in donations and commitments. People and organizations wanting to fund abortion access recognize the potential of sharing information about abortion pills by mail, and channel their outrage and passion toward our work.

We are always happy to talk to donors about the measurable results of their donations: in materials created and distributed, resources shared, ad views, cost-per-clicks and website visitors, administrative and team support.

We also know that we are dealing in not just numbers but in paradigm shifts, introducing concepts of self-directed care and empowering others with information so they can then spread it further. Because of this will never truly see the extent of our impact.

One of our core strategies is to support other activists and organizations with not just information and collaboration, but with funding to do the work. This past year we gave over $350,000 to other organizations making a difference in abortion pill access for restricted states and across the US.

We also talked to our donors and partners about how they can fund this landscape as well.

We believe in supporting the multi-faceted ecosystem working to ensure holistic support for self-directed abortion, and that a rising tide lifts all ships.

We are endlessly grateful for the support of our donors and foundation partners, to enable us to do this critical work as such a poignant moment in history.

Together we are making change and showing up for people in need of abortion care.

2023 BUDGET

Administrative: Travel, Team & Consulting Fees	$1,233,789
Grants to Partners	$361,451
Paid Ad Placements	$353,435
Creative Partners	$104,325
Stickers & Outreach Materials	$131,020
Telecom, Software & Website	$130,466
Fiscal Sponsorship Fees (10%)	$278,459
Total Expenses	$2,592,945

Our Vision & Values



Since 2015 our vision has stayed the same: abortion pills in the hands of the person who seeks them, full stop. We are laying the groundwork for over-the-counter access: disentangling this safe and effective option from politics, and moving agency over abortion back to the individual.

The efforts described in this report fall under two major goals, namely that:
1. People Know (about the pills), and
2. People Have Access (to pills).

These two concepts are what drive us.

Our team of public health researchers, social justice activists and digital strategists is dedicated to centering the abortion seeker in the work, and leading and collaborating from values of self-determination, equity and justice.

Read more at plancpills.org/about.

Where we're headed

In this report we've described our recent work in context of the current domestic and global landscape. At Plan C we are structured like a campaign, designed to be nimble and responsive to the moment. When we achieve our mission, we will go "out of business."

Unfortunately in the US, our work is far from complete.

We are energized and equipped to show up clear and focused in 2024: building on previous successes, in deep service to abortion seekers, in support of activists and partners, and under the same shared vision of pills in hands.

We will continue to provide research-based information about where to obtain medication abortion, both mifepristone and misoprostol, as the landscape continues to change. We will lead creative campaigns and outreach, with a focus on restricted states, push back against censorship and bullying, and cultivate partnerships to build power in coalition.

At Plan C we believe abortion is basic health care and a human right. We believe everyone deserves full, legal access to this safe and effective medication through clinics, telehealth, and self-managed sources in every zip code in the US.

We aren't slowing down yet.

> **"We hear all the time from our patients that Plan C was an incredible resource and helped them connect to trustworthy care.**
>
> *Telehealth company HeyJane*

Thank you.

The support of our donors, our partners and our community and makes this work possible.

Have a question, idea or offering?
Reach out at info@plancpills.org.

Visit us online at plancpills.org
@plancpills on Instagram, TikTok, Facebook and Twitter.

"Nobody can stop us from getting abortions when we are informed about how and where to get them."

– comment on Plan C Instagram, Summer 2023

EXHIBIT 79

Free Medication Abortion

FREE MEDICATION ABORTION

In a restricted state? Looking for information on safe abortion access? We're here for you.

Scroll down for a list of providers!

Abortion pills by mail are a reality even in states with restrictions.

Please use a privacy app like Duck Duck Go
when looking at abortion resource sites like ours.

En Español

This site is an information sourc ***s not give medical or legal advice or sell abortion pills.***

For references to free, trusted, community support providers for people with ***confirmed*** *pregnancies, find your state and corresponding contact email below.*

**See below notes for how states and providers are identified.*

For your ***safety*** *and the providers' safety, we encourage you to set up a secure, free email account on* ***protonmail*** *to use when contacting them.*

iCloud email *is not compatible with our system.*

Please note, *these services may take up to* ***14 days*** *to arrive after request. If it is not possible to wait 14 days (may come sooner, USPS service is out of their control)* ***please visit PlanCPills.org for alternative providers.***

INCLUDE IN YOUR EMAIL :

-The name of the person receiving the medication

-Your full mailing address

-Estimated number of weeks gestation

-The first day of your last menstrual period

-The date of your positive pregnancy test

PLEASE CONFIRM YOUR INFORMATION HAS THE CORRECT ADDRESS *- only one kit is shipped per request and the most frequent reason for non-delivery is an incorrect address or missing address information. Make sure to include ALL information - name, street, city, state, zip code and apartment number if available.*

Current Coverage by State

^Alabama - sjog2010@proton.me

^American Samoa - AccessInformation13@proton.me

Arizona - IdahoAccess@proton.me

***Arkansas - ARTogether@proton.me**

^Florida - FLCompanionRequest@proton.me

^Geo[illegible]essInformation13@proton.me

^Guam - AccessInformation13@proton.me

Idaho - IdahoAccess@proton.me

^Indiana - AccessMidAmerica@proton.me

^Iowa - AccessMidAmerica@proton.me

^Kansas - AccessMidAmerica@proton.me

^Kentucky - AccessMidAmerica@proton.me

^Louisiana - AccessInformation13@proton.me

^Mississippi - AccessInformation13@proton.me

^Missouri - AccessMidAmerica@proton.me

Nebraska - IdahoAccess@proton.me

^Nevada - AccessInformation13@proton.me

^New Hampshire - AccessMidAmerica@proton.me

^North Carolina - AccessMidAmerica@proton.me

North Dakota - IdahoAccess@proton.me

^Northern Mariana Islands - AccessInformation13@proton.me

^Ohio - AccessMidAmerica@proton.me

Oklahoma - IdahoAccess@proton.me

^Pennsylvania - AccessMidAmerica@proton.me

^South Carolina - AccessInformation13@proton.me

South Dakota - IdahoAccess@proton.me

^Tennessee - AccessMidAmerica@proton.me

^*Texas - TexasAccess@proton.me

^US Virgin Islands - AccessInformation13@proton.me

^Utah - AccessInformation13@proton.me

^Virginia - AccessMidAmerica@proton.me

^West Virginia - AccessMidAmerica@proton.me

^Wisconsin - AccessMidAmerica@proton.me

^Wyoming - AccessInformation13@proton.me

ⓘ above contact information is provided for community support groups that follow verified protocols (listed below) to ensure consistency and security for all clients regardle

States prefaced wi :risk (*) follow different mailing protocols.

States prefaced with (^) follow different dosing protocols.

See coverage tab for full list of community networks.

1) Client response provided within 24 hours, seven days a week
2) Medicines shipped by USPS priority mail in discreet packaging with no tracking. (unless prefaced with an asterisk (*))
3) Kits in states prefaced by (^) all contain one (1) 200 mg Mifepristone and 16 - 200 mcg Misoprostol for pregnancies 20 weeks and under (as recommended by MAHotline). Those without (^) contain (1) 200 mg Mifepristone and 12 - 200 mcg Misoprostol.
4) Choice for clients of loose, unidentifiable pills or foil, blister packs depending on their security concerns and community provider stock. Loose is sent default if no choice is made or other inventory is not available.
5) Access to a personal, trained companion available for all clients and automatically assigned for clients over 14 weeks
6) Service for all gestations
7) No personal data retained or collected
8) Clinicians available on request

Residents of other states may find abortion funding assistance through the National Network of Abortion Funds.
PlanCPills lists all vendors, including for-profit, for all states and territories.

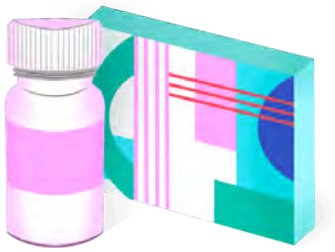


EXHIBIT 80

Plan C - Websites that Sell Pills

Stay Safe: Read our digital privacy tips ›
Quick Exit (esc)

Websites That Sell Pills



These websites sell abortion pills but do not include any additional support. You can still get free medical support for your abortion from the M+A Hotline.

Important: These websites may not follow strict digital security protocols. Read our digital privacy tips to learn how to protect yourself when ordering or searching for abortion pills online.

Read the FAQs below for more information on how these sites work.

What are websites that sell pills?

Websites that sell pills are e-commerce websites that sell and ship pills to addresses in all U.S. states. They do not require a prescription for the medications, do not require you to upload your ID, and do not provide a medical consultation or any kind of support.

Are these websites legit?

Yes, these websites are legit. They sell generic abortion pills that are not regulated or inspected by the US government. Plan C regularly tests these websites by buying pills from them. The services we list in our guide all shipped pills to a home address. The pills were real (based on laboratory testing). But, we do not operate these sites, and cannot guarantee they will be reliable in the future.

Important: These websites may not follow strict digital security protocols. Read our **digital privacy tips** to learn how to protect yourself when ordering or searching for abortion pills online.

How do I choose one of these websites?

We suggest you check their website and pick the one that you feel most comfortable ordering from. If you are not sure what pills to order, read the FAQ below, "What kind of kit do I order?".

What kind of kit do I order?

Most of these websites sell abortion pills in a blister pack called an MTP Kit. These kits usually contain 5 pills: 1 dose of mifepristone (1 pill) and 1 dose of misoprostol (4 pills). Sometimes these packs will be listed under different names, or will be sold in bulk quantities, which may seem confusing. What is important is that you get the correct dosage for your pregnancy. Read the next section "How many pills do I need?" for dosage information.

Important note about payment: It is very common for these websites to email or call soon after they get your order to request a different form of payment. They often say the credit card did not go through. They often ask the buyer to use a PayPal account in a person's name or in the name of another business. These payment requests do seem unusual, but they worked every time we tested them.

The pills usually arrive by the US Postal Service. They usually do not require a signature.

How many pills do I need?

If you are *under* 9 weeks pregnant you usually need 1 mifepristone pill and 4 misoprostol pills. **People who are more than 9 weeks pregnant may need additional misoprostol pills (4 or 8 pills) to complete the abortion.** Many of these websites sell misoprostol pills separately (sometimes called Cytotec or Cytolog), which can be added to your order.

Read this guide for instructions on how to take abortion pills and for recommended dosages. If you don't know how many weeks pregnant you are you can use our **pregnancy calculator**.

What if I have medical questions?

Websites that sell pills do not offer medical support. If you have medical questions during your abortion, you can get support and have your questions answered by contacting **The Miscarriage and Abortion Hotline**. This hotline provides free, confidential medical information and support by phone and text. Often they can help you address a problem without needing to go to a clinic or hospital.

If you are experiencing complications and feel the need to seek care from a health care provider at a clinic or hospital, you should do so. Your clinician does not need to know that you have used abortion pills to provide appropriate follow up care. Clinicians also can't tell you've taken abortion pills unless you tell them, or if you inserted the misoprostol vaginally and the pills did not fully dissolve. Many people use misoprostol orally to prevent this possible detection.

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You can also get free, nonjudgmental emotional support before, during, and after your abortion from the folks at **All-Options Talkline**, **Exhale**, **Faith Aloud**, or **Reprocare**.

Can I get in trouble for using abortion pills?

The short answer is: it depends, and it's complicated.

Legal risk can depend on:

- where you live,
- your identity: race, ethnicity, income level, etc.
- and how far along you are in pregnancy.

In the end, it's up to each person to make their own decision about risk. Click the headings below for more information about these risks.

Where someone lives makes a difference.

Many states allow legal access to abortion pills through clinics or telehealth services. People who get pills in states where these services are legal should face no legal risk.

Pills are available by mail in all states, even in states that ban clinic-based abortion care. This is possible because some states have "shield laws" that protect clinicians when they provide telehealth care to someone in another state. People in all states can also get abortion pills from alternate suppliers like international online clinics, community networks, and websites that sell pills. We mark alternate suppliers with an alert icon ⚠ in our **Guide** to let you know that they may have legal risk.

To understand the potential legal risks of using alternate suppliers, you can contact the ReproLegal Helpline, a free legal resource that can help answer your questions: visit **reprolegalhelpline.org** or call or text 844-868-2812.

What if a state totally bans abortion?

Some states have laws against abortion. These laws mean that with limited exceptions medical providers and clinics in those states can't do an abortion procedure or provide abortion pills.

A ban that blocks providers from offering care does not necessarily block a person from using pills on their own. However, a person who self-manages their abortion can face legal risk: people in the US are criminalized for all kinds of reasons, with outsized impact on certain identities or socioeconomic backgrounds.

People in states that ban abortion can still get abortion pills by mail from telehealth providers in "shield law" states (see above) or alternate suppliers, like international online clinics, websites that sell pills, and community networks that mail them for free.

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instance if they are not free to leave their home or do not want to risk going through an immigration checkpoint (which can be within 100 miles of any US border).

The **Repro Legal Helpline** provides free and confidential legal advice that can help people better understand the laws and legal risk they may face. Contact them **online** or call **844-868-2812**.

How big is the legal risk?

This is a really hard question to answer.

We have some information about what has happened in the past. From 2000 to 2020, at least 61 people who have self-managed an abortion or have helped someone else **were arrested or prosecuted.** During that same time, many people self-managed abortions (tens of thousands or more).

It is unclear how new abortion laws will affect future criminalization of people for self-managing an abortion.

Those who are already at greater risk of criminalization because of their race, gender identity, economic status, or other factors may have a higher risk of prosecution.

The **Repro Legal Helpline** provides free and confidential legal advice that can help people better understand the laws and legal risk they may face. Contact them **online** or call **844-868-2812**.

Why have some people gotten in legal trouble?

Have Legal Questions?

The **Repro Legal Helpline** provides free and confidential legal advice that can help people better understand the laws and legal risk they may face. Contact them **online** or call **844-868-2812**.

For more analysis of potential legal risk, **read this article**.

Showing 14 of 14 results

Sort by: **Price**

PILL PULSE

Price	Delivery	Ages
$29	**3-6 business days**	**All**

Pills by mail

LIFE EASY ON PILLS

Price	Delivery	Ages
$30-50	**3-6 business days**	**All**

Pills by mail

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MORE INFORMATION REQUEST PILLS

MORE INFORMATION REQUEST PILLS

HOME ABORTIONRX

Price	Delivery	Ages
$33	12-19 business days	All

Pills by mail

- Get pills in advance
- Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

PRIVATE EMMA

Price	Delivery	Ages
$35	3-6 business days	All

Pills by mail
For pregnancies up to 12 weeks

- Get pills in advance
- Financial assistance available
- Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

MEDSIDE 24

Price	Delivery	Ages
$44	3-6 business days	All

Pills by mail

- Get pills in advance
- Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

HOME ABORTION PILLSRX

Price	Delivery	Ages
$45	3-6 business days	All

Pills by mail

- Get pills in advance
- Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

YBYCMEDS

Price	Delivery	Ages
$46	3-6 business days	All

Pills by mail

- Get pills in advance

PRIVACY PILL RX

Price	Delivery	Ages
$120	3-6 business days	All

Pills by mail

- Get pills in advance

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SAFE PHARMACY

Price	Delivery	Ages
$198	3-6 business days	All

Pills by mail

Get pills in advance

Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

ABORTION PILLS RX

Price	Delivery	Ages
$230	4-6 business days	All

Pills by mail

Get pills in advance

Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

GENERIC ABORTION PILLS

Price	Delivery	Ages
$291	3-6 business days	All

Pills by mail

Get pills in advance

Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

ABORTION RX

Price	Delivery	Ages
$299	3-6 business days	All

Pills by mail

Get pills in advance

Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

ONLINE ABORTION PILL RX

Price	Delivery	Ages
$470	3-6 business days	All

Pills by mail

Get pills in advance

Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

ABORTION PRIVACY

Price	Delivery	Ages
$470	3-6 business days	All

Pills by mail

Get pills in advance

Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

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Live phone & text support

For Medical Questions

The M+A Hotline
Free and confidential support from a clinician at the Miscarriage + Abortion Hotline. (M+A does not sell pills)

CALL OR TEXT VISIT WEBSITE

For Logistical & Emotional Support

Reprocare Healthline
Free and confidential help understanding how to get pills and how to use them.

CALL OR TEXT VISIT WEBSITE

For Legal Questions

ReproLegal Helpline
Connect with a lawyer for free and confidential legal information.

CALL OR TEXT VISIT WEBSITE



Automated support

NEW

Charley the Chatbot

Provides users with personalized abortion options, including information about different abortion care methods, nearby clinics,

Frequently Asked Questions

Get answers to common questions about how abortion pills work and how to access them.

Stay Safe: Read our digital privacy tips ›
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Get the Plan C Newsletter

For breaking developments in abortion pill access and opportunities to take action.

Your Email

Sign Up

Plan C is a project under the fiscal sponsorship of the National Women's Health Network, a 501c3 organization. Our generous donors make this critical work possible.

Find Pills →

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Site by Eyes Open

Privacy & Terms

Disclaimer: This is not legal or medical advice and does not substitute for the representation of an attorney or the advice of a doctor. No attorney client relationship has been formed by reviewing this material.

Abortion Care Network

EXHIBIT 81

Ryan T. Anderson & Jamie Bryan Hall, T*he Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event*, Ethics & Public Policy Center (Apr. 28, 2025)

LIFE AND FAMILY INITIATIVE

ETHICS AND PUBLIC POLICY CENTER
Shaping Policy, Renewing Culture.

The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event

Jamie Bryan Hall, Director of Data Analysis, Ethics and Public Policy Center
Ryan T. Anderson, President, Ethics and Public Policy Center

April 28, 2025

Summary

- This largest-known study of the abortion pill is based on analysis of data from an all-payer insurance claims database that includes 865,727 prescribed mifepristone abortions from 2017 to 2023.
- 10.93 percent of women experience sepsis, infection, hemorrhaging, or another serious adverse event within 45 days following a mifepristone abortion.
- The real-world rate of serious adverse events following mifepristone abortions is at least 22 times as high as the summary figure of "less than 0.5 percent" in clinical trials reported on the drug label.
- The FDA should immediately reinstate its earlier, stronger patient safety protocols to ensure physician responsibility for women who take mifepristone under their care, as well as mandate full reporting of its side effects.
- The FDA should further investigate the harm mifepristone causes to women and, based on objective safety criteria, reconsider its approval altogether.

Danco Laboratories markets Mifeprex as "the safe and effective abortion pill," but our research shows that mifepristone abortion, as currently practiced in the U.S., is not safe and effective.[1] The manufacturer and the FDA rely on the results of 10 clinical trials with a total of 30,966 participants, less than 0.5 percent of whom reportedly experienced serious adverse reactions. In contrast, we analyzed real-world insurance claims data for 865,727 prescribed mifepristone abortions, broadly representative of women who obtain mifepristone abortions in the U.S. today, and we find a serious adverse event rate of 10.93 percent—at least 22 times as high as the summary figure reported on the drug label. In light of this research, we urge the FDA to reinstate earlier, stronger patient safety protocols and reconsider its approval of mifepristone altogether. Women deserve better than the abortion pill.

Our Key Findings

10.93 percent of women experience sepsis, infection, hemorrhaging, or another serious or life-threatening adverse event within 45 days following a mifepristone abortion, far greater than the summary figure of "less than 0.5 percent" in clinical trials reported on the drug label. *Figure 1, next page.*

[1] Danco Laboratories, "The Safe and Effective Abortion Pill | Mifeprix (mifepristone)," https://www.earlyoptionpill.com (accessed April 14, 2025)

Figure 1

Serious Adverse Events by Category

	Number with adverse events	Serious adverse event rate
Sepsis	824	0.10%
Infection	11,707	1.34%
Transfusion	1,257	0.15%
Hemorrhage	28,658	3.31%
Hospitalization (related to the abortion)	5,699	0.66%
ER visit (related to the abortion)	40,960	4.73%
Ectopic pregnancy	3,062	0.35%
Other life-threatening adverse events (cardiac, pulmonary, thrombosis, anaphylaxis, surgery)	1,956	0.22%
Repeated (surgical) abortion	24,563	2.84%
Other abortion-specific complications	49,169	5.68%
Overall	94,605	10.93%

Note: The overall serious adverse event rate of 10.93% is adjusted for the fact that some women suffer from adverse events in multiple categories.

Simply stated, mifepristone, as used in real-world conditions, is not "safe and effective."

Our real-world post-market observational study of mifepristone is, to our knowledge, the most comprehensive study of chemical abortion safety ever conducted in the U.S.:

- We identify and include 865,727 prescribed mifepristone abortions, 28 times as many as were included in all FDA-cited clinical trials combined.
- Our dataset is more recent, no earlier than 2017, while the FDA approval of mifepristone relies entirely on data from more than a decade ago.
- The women in our dataset are broadly representative of the women who obtain mifepristone abortions in the U.S.; they are not a prescreened group of generally healthy women recruited into various clinical trials conducted at different times around the world.
- The women in our dataset receive (or fail to receive) pre- and post-abortion healthcare of the real-world quality that prevails in the U.S. today, not the carefully controlled regimen of care that ordinarily prevails in a clinical trial.

Policy Implications

The FDA should reinstate the original patient safety protocols that were required when mifepristone was first approved. Doing so will likely reduce the harms to women and permit better monitoring to determine whether this drug should remain on the market:

- Prescribing mifepristone and misoprostol for the termination of pregnancy should require at least three in-person office visits by the patient—as originally required by the FDA.
- Mifepristone should be prescribed only by physicians—as originally required by the FDA—who have read and understood the prescribing information.
- Mifepristone should be administered only in a clinic, medical office, or hospital, by or under the supervision of a physician, able to assess the gestational age of an embryo and to diagnose ectopic pregnancies—all of which was originally required by the FDA.
- Physicians must be able to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through others, and be able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
- Healthcare providers should be required once again to report to the FDA (and manufacturers of mifepristone) all serious adverse events resulting from the use of mifepristone.
- Mifepristone should only be prescribed to a woman who is confirmed by a physician to be in the first seven weeks of pregnancy—as originally required by the FDA.

Background on FDA Approval and Regulation of Mifepristone

Mifepristone was developed by the French pharmaceutical company Roussel Uclaf S.A. and brought to the United States at the urging of President Clinton and after Congressional pressure. The FDA approved it under a little-used approval process for "certain new drug products that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments."[2] Thus, to grant approval in this manner, the FDA had to consider an unwanted pregnancy a "serious or life-threatening illness" and find that mifepristone was more effective than surgical abortion in treating it. The FDA's decision cites minimal data: clinical trials with only 859 participants in the U.S. and 1,800 in France.[3]

The original FDA-approved drug label for Mifeprex (the brand name of mifepristone) from September 2000 indicated use of the drug for "the medical termination of intrauterine pregnancy through 49 days' pregnancy."[4] It required several modest safeguards for women's health:

> Treatment with Mifeprex and misoprostol for the termination of pregnancy requires three office visits by the patient. Mifeprex should be prescribed only by physicians who have read and understood the prescribing information. Mifeprex may be administered only in a clinic, medical office, or hospital, by or under the supervision of a physician, able to assess the gestational age of an embryo and to diagnose ectopic pregnancies. Physicians must also be able to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through others, and be able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.[5]

During the Obama and Biden administrations, the FDA chipped away at these initial safeguards, risking women's health in order to increase access to abortion. Under the current Risk Evaluation and Mitigation Strategy (REMS) in effect since 2023:

1. a mifepristone abortion now requires as a little as one telehealth visit with any approved healthcare provider (not necessarily a physician),
2. a woman may self-administer drugs obtained from a mail-order pharmacy, and
3. the prescriber need not report any adverse events unless he or she knows that a patient has died. *Figure 2.*

Figure 2

Weakening FDA Safeguards for Mifepristone

	2000 Clinton Initial Approval	2016 Obama REMS Changes	2023 Biden REMS Changes
Required number of in-person visits	3	1	0
Maximum gestational age (LMP)	7 weeks	10 weeks	10 weeks
Drugs prescribed only by physician	✓	✗	✗
Drugs dispensed only in office	✓	✓	✗
Drugs taken only in office	✓	✗	✗
Required in-office follow-up	✓	✗	✗
Required reporting of adverse events	✓	✗	✗

2 Alliance for Hippocratic Medicine v. FDA, Complaint, https://adflegal.org/wp-content/uploads/2022/11/Alliance-for-Hippocratic-Medicine-v-FDA-2022-11-18-Complaint.pdf
3 Mifeprex (mifepristone) drug label, September 2000, page 3, https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.pdf
4 Mifeprex (mifepristone) drug label, September 2000, page 6, https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.pdf
5 Mifeprex (mifepristone) drug label, September 2000, page 14, https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.pdf

The current FDA-approved drug label refers to the results of 10 clinical trials with a total of 30,966 participants, less than 0.5 percent of whom reportedly experienced serious adverse reactions.[6] But these figures are based entirely on data from trials taking place more than a decade ago.

The Increasing Market Share of Chemical Abortion

Increased access to chemical abortion has coincided with a rapid increase in its prevalence. Chemical abortions—the vast majority of which are performed using a combination of mifepristone and misoprostol—now account for roughly two-thirds of all abortions in the United States. *Figure 3.*

In fact, Danco Laboratories boasts that more than 5 million U.S. women have used its abortion pill since it was approved in 2000.[7] Thus, it has become increasingly important to understand the risks and harms to women from chemical abortion in general and from mifepristone in particular.

How We Identified Mifepristone Abortions

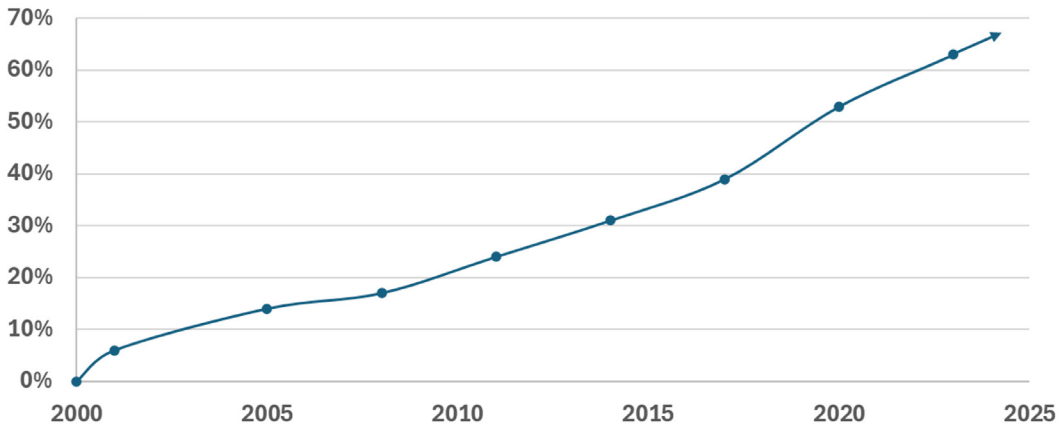
In our data, a mifepristone abortion was identified in one of three ways:

1. procedure code S0199: medically induced abortion by oral ingestion of medication including all associated services and supplies,
2. a prescription for mifepristone (with or without misoprostol within the next 3 days), or
3. a diagnosis code for elective termination or unwanted pregnancy, along with other billing coding consistent with manufacturer instructions for reimbursement for a mifepristone abortion for a given state and insurer combination.[8]

Following this method, we identified a total of 865,727 mifepristone abortions prescribed for a total of 692,873 women from 2017 to 2023. This includes 566,446 women, each of whom had one such abortion, and 126,427 women with multiple such abortions.

Figure 3

Chemical abortion has increased rapidly since approval in 2000 and now accounts for approximately two-thirds of all abortions.



Source: Guttmacher Abortion Provider Census and Monthly Abortion Provision Study,via https://www.guttmacher.org/2024/03/medication-abortion-accounted-63-all-us-abortions-2023-increase-53-2020

6 Page 7 of the drug label states, "Serious adverse reactions were reported in <0.5% of women. Information from the U.S. and non-U.S. studies is presented in Table 2." Table 2 on page 8 indicates that some categories of serious adverse reactions were observed at higher rates in some trials, but this is never discussed in the text, leaving only the previous statement with which to interpret the table. See Mifeprex (mifepristone) drug label, January 2023, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s026lbl.pdf

7 Danco Laboratories, "The Safe and Effective Abortion Pill | Mifeprex (mifepristone)," https://www.earlyoptionpill.com (accessed April 14, 2025)

8 Danco Laboratories, "Mifeprex State Payer Policies," https://www.earlyoptionpill.com/how-do-i-get-mifeprex/state-payer-policies (accessed April 14, 2025)

How We Identified Serious Adverse Events

We followed the official FDA definition of "serious adverse event."[9] To do so, we identified relevant ICD-10 diagnosis codes and CPT/HCPCS procedure codes for adverse events from multiple sources:

- CDC Severe Maternal Morbidity (SMM) indicators,[10]
- CMS Diagnosis-Related Group (DRG) 770 and 769 codes,[11]
- FDA Adverse Events Reporting System (FAERS) reports (interpreted and translated into diagnosis and procedure codes by the doctors on our team),[12] and
- a small number of (mostly gynecological) codes suggested by our doctors.

These codes were then graded by a team of physicians using the the NIH Common Terminology Criteria for Adverse Events (CTCAE version 5), which categorizes adverse events by severity on a 5-point scale.[13] We included CTCAE Grade 3 (severe) and Grade 4 (life-threatening). We did not include Grade 1 (mild) or Grade 2 (moderate). (Grade 5 is death, which would count as a serious adverse event under the FDA definition but could not necessarily be observed in the insurance claims data. We hope to show the rate of death in a subsequent report.)

For reporting, we have grouped the relevant diagnosis and procedure codes as follows:

1. The mifepristone label divides serious adverse events into six categories identified in the clinical trials: sepsis, infection, transfusion, hemorrhage, hospitalization, and emergency room visit. Only those hospitalizations and emergency room visits with abortion-related diagnosis and procedure codes are included in our analysis.
2. FAERS received reports of various events that our doctors judge to be life-threatening and have grouped into broad categories: ectopic pregnancy, surgery, cardiac, pulmonary, thrombosis, and anaphylaxis.
3. Repeated (surgical) abortion procedures are considered serious adverse events.
4. Other abortion complications include codes specifically related to an abortion or miscarriage, as well as life-threatening mental health diagnoses, etc.

We consider only serious adverse events that occurred within 45 days following the abortion. This is conservative, as some adverse events may present later (and studies relied on by the FDA used a timeframe as long as 72 days). Additionally, the likelihood of a subsequent pregnancy within this timeframe is negligible, which ensures that adverse events are related to the abortion rather than to a subsequent pregnancy.

Our Data

Our team has purchased access to a commercially available all-payer health insurance claims database including de-identified data for all U.S. patients during the years 2017 to 2023. It includes information on hospital and office visits, diagnoses, procedures, and prescriptions processed through private health insurance, Medicaid, Medicare, TRICARE, and the Department of Veterans Affairs (VA). The data excludes transactions for which the insurer is also the provider (as is the case with some HMOs and much VA care), as well as cash pay transactions (which are disproportionately common for abortion). This dataset provides longitudinal tracking of medical diagnoses, procedures, and prescriptions for each patient and is widely used in academic and regulatory research.

9 FDA, "What is a Serious Adverse Event?," https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event
10 CDC, "Identifying Severe Maternal Morbidity (SMM)," https://www.cdc.gov/maternal-infant-health/php/severe-maternal-morbidity/icd.html
11 CMS, "ICD-10-CM/PCS MS-DRG v37.0 Definitions Manual," https://www.cms.gov/icd10m/version37-fullcode-cms/fullcode_cms/P0287.html
12 FDA, "FDA Adverse Events Reporting System (FAERS) Public Dashboard," https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f-7f1c25ee/sheet/33a0f68e-845c-48e2-bc81-8141c6aaf772/state/analysis
13 NIH, "Common Terminology Criteria for Adverse Events (CTCAE)," https://ctep.cancer.gov/protocolDevelopment/electronic_applications/ctc.htm

Our Research Project Team

Our research project was conducted and validated by a team of data scientists, analysts, and engineers, with assistance from our clinical team of board-certified obstetricians and gynecologists. Members have a history of academic research and peer-reviewed publication.

Conclusion

Our research shows unequivocally that mifepristone abortion, as currently practiced in the U.S., is considerably more dangerous to women than is represented on the FDA-approved drug label. The FDA should immediately reinstate its earlier, stronger patient safety protocols to ensure physician responsibility for women who take mifepristone under their care, as well as mandate full reporting of its side effects. The FDA should further investigate the harm this drug causes to women and, based on objective safety criteria, reconsider its approval altogether. Women deserve better than the abortion pill.

This paper is the first in a series investigating women's health and abortion using real-world data.

ETHICS AND PUBLIC POLICY CENTER

Shaping Policy, Renewing Culture

EXHIBIT 82

Declaration of Dr. Ingrid Skop

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; **JANET WOODCOCK, M.D.**, in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration **PATRIZIA CAVAZZONI, M.D.**, in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**; and **XAVIER BECERRA,** in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

Case No. _____

DECLARATION OF DR. INGRID SKOP

I, Ingrid Skop, a citizen of the United States and a resident of San Antonio, Texas, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.
2. I am a board-certified obstetrician and gynecologist working for OB Hospitalist Group with privileges in the Baptist Hospital System.
3. I also serve as a Senior Fellow and Director of Medical Affairs at the Charlotte Lozier Institute.
4. I am a member of Plaintiff American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG), where I served as a member of the board from 2018-2020. I am also a member of the Christian Medical & Dental Associations.
5. I received my medical degree from Washington University School of Medicine in 1992 and completed my residency in obstetrics and gynecology at the University of Texas Health Sciences Center at San Antonio in 1996.
6. My current practice involves delivering babies and performing surgeries in a hospital setting as an obstetric hospitalist. In my prior 25-year career in a large single-specialty OB/GYN practice, I also provided clinic-based obstetric and gynecologic care to women and girls.

7. I have provided written and oral expert testimony about chemical abortion to several state legislatures and to the United States Congress.

8. I have also published the peer-reviewed articles "Chemical Abortion: Risks Posed by Changes in Supervision" and "Medical Abortion: What Physicians Need to Know" in the Journal of American Physicians and Surgeons.

9. The articles I published reflect the research I have performed on the risks associated with unsupervised chemical abortion—a practice that is becoming more common.

10. A chemical abortion includes providing patients with a combination of two drugs. One drug—mifepristone—blocks hormonal support, killing the unborn child, while the other—misoprostol—induces uterine contractions to expel the unborn child and the pregnancy tissue.

11. The drugs mifepristone and misoprostol may cause serious complications for the women and girls who take them.

12. In my practice, I often treat patients who are admitted through the hospital's emergency department with complications from chemical abortions.

13. In my practice, I have cared for several dozen women in the emergency department who were totally unprepared for the pain and bleeding they experienced due to chemical abortion.

14. In my experience caring for women who have gone through chemical abortion, the doctors who prescribed or administered chemical abortion drugs

to these women often did not adequately prepare them for the drugs' effects, so these women could not have truly achieved informed consent.

15. At least a dozen patients have expressed significant emotional distress to me when they viewed the body of their unborn child in the toilet after the chemical abortion.

16. I have treated patients who have experienced trauma and emotional distress because of complications from chemical abortion. Those women were not anticipating that complications were possible and likely did not have sufficient informed consent to proceed with chemical abortion.

17. In my practice, I have cared for at least a dozen women who have required surgery to remove retained pregnancy tissue after a chemical abortion. Sometimes this includes the embryo or fetus, and sometimes it is placental tissue that has not been completely expelled.

18. I have cared for approximately five women who, after a chemical abortion, have required admission for a blood transfusion or intravenous antibiotics or both.

19. Complications from chemical abortion are not uncommon. In fact, chemical abortions involve more complications than surgical abortions.

20. The FDA's actions in 2016 and 2021 have increased the frequency of complications from chemical abortion.

21. Given my experience, I expect to see and treat more patients presenting with complications from chemical abortion.

22. For example, in one month while covering the emergency room, my group practice admitted three women to the hospital. Of the three women admitted in one month due to chemical abortion complications, one required admission to the intensive care unit for sepsis and intravenous antibiotics, one required a blood transfusion for hemorrhage, and one required surgical completion for the retained products of conception (*i.e.*, the doctors had to surgically finish the abortion with a suction aspiration procedure).

23. In my office, I treated one young woman who had been bleeding for six weeks after she took the chemical abortions drugs given to her by a doctor at a Planned Parenthood clinic. After two follow-ups at Planned Parenthood, during which she was given additional misoprostol but not offered surgical completion, she presented to me for help. I performed a sonogram, identified a significant amount of pregnancy tissue remaining in her uterus, and performed a suction aspiration procedure to resolve her complication.

24. I have also cared for minor women below the age of 18 who have obtained chemical abortion drugs. Although mifepristone has not been studied specifically in minor women, the FDA has negligently allowed their provision to this special age group, assuming their response will be the same as adult women.

25. The FDA's actions deregulating mifepristone and expanding access to unsupervised chemical abortion harm women and their doctors, including me. Concerns about "unsafe, back-alley abortions" were used to overturn all

state abortion restrictions in 1973 and they are being recycled today to allow the abortion industry to continue perpetuating dangerous abortion methods. Yet, a clear-eyed look at the FDA's actions allowing unsupervised "mail-order abortions" shows that they are now promoting illegal, unsafe "chemical coat hangers" to the women they falsely say they want to protect.

26. The FDA's actions harm women, including my patients, because without proper oversight, chemical abortions can become even more dangerous than when they are supervised.

27. The FDA's actions harm women, including my patients, because clinics and physicians prescribing or dispensing chemical abortion drugs, or websites that provide these drugs through mail order delivery without any physician involvement, often underprepare women for the severity and risks of chemical abortion, and they often provide insufficient or no follow-up care to those women. Many women are inadequately prepared for the effects of the drugs, the severity of the pain and bleeding they will experience, the human tissue they will expel, and some are unaware that they have complicating factors such as ectopic implantation, more advanced gestation than estimated, and Rh-negative blood type. These patients are being abandoned because in many cases there is no doctor-patient relationship, so they often present to overwhelmed emergency rooms in their distress, where they are usually cared for by physicians other than the abortion prescriber.

28. Unsupervised chemical abortion—authorized by the FDA—harms women because they may have underestimated the gestational age of their unborn child. Women who should not be a candidate for chemical abortion because they are past the FDA-approved cutoff of ten weeks gestation may consume chemical abortion drugs, which will increase their chances of complications due to the increased amount of tissue, leading to hemorrhage, infection and/or the need for surgeries or other emergency care.

29. For example, approximately 2% of pregnancies are ectopic pregnancies, implanted outside of the uterine cavity. Chemical abortion drugs will not effectually end an ectopic pregnancy because they exert their effects on the uterus, which leaves women at risk of severe harm from hemorrhage due to tubal rupture, in need of emergent surgery or potentially at risk of death. Failure to perform an ultrasound prior to prescribing abortion drugs will cause some women to remain undiagnosed and at high risk for these adverse outcomes.

30. The FDA's removal of the reporting requirement for adverse events of mifepristone harms women by creating an inaccurate safety profile, and it harms my practice because it makes it more difficult to practice evidence-based medicine. The incidence of abortion-related complications remains unknown if there is no accurate system for data collection.

31. The FDA's actions also harm women because the lack of oversight will likely exacerbate human trafficking, which happens frequently in San Antonio. In

my practice, part of my care of my patients is ensuring that they are making medical decisions free of coercion. Many trafficked women experience unintended pregnancies and alert doctors serve as an important resource to intervene on behalf of women. Removing the in-person medical interaction removes an opportunity to identify and rescue these women. It also leaves them at risk of being coerced into an abortion they may not desire.

32. Deregulated chemical abortion harms my practice because it increases the number of women who come to the emergency department with complications. When I must perform surgery to deal with complications from chemical abortions, this takes attention away from my other patients. As a hospitalist, I am often supervising multiple laboring patients on labor and delivery. When I am called to the operating room to address an emergency resulting from chemical abortion, this necessarily means I may not be immediately available if an emergency should occur with one of my laboring patients.

33. Unsupervised chemical abortion is heartbreaking to me because it causes women to suffer unnecessarily, and my patients deserve quality medical care.

34. The FDA's expansion of chemical abortion also harms my conscience rights because it could force me to have to surgically finish an incomplete elective chemical abortion. I object to abortion because it ends a human life. My moral and ethical obligation to my patients is to promote human life and health.

But the FDA's actions may force me to end the life of a human being in the womb for no medical reason.

Executed this November 11, 2022.

By: Ingrid Skop MD
Ingrid Skop, MD

Exhibit H

Appendix of Exhibits to Proposed Complaint in Intervention

Vol. VII of VII

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EXHIBIT 83

Declaration of Dr. Shaun Jester

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; **JANET WOODCOCK, M.D.**, in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration **PATRIZIA CAVAZZONI, M.D.**, in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**; and **XAVIER BECERRA,** in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

Case No. _____

DECLARATION OF DR. SHAUN JESTER

I, Shaun Jester, a citizen of the United States and a resident of Dumas, Texas, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.
2. I am a board-certified obstetrician and gynecologist and am the Medical Director of Moore County Ob/Gyn in Dumas, Texas. I have been board-certified since 2007.
3. I received my medical degree in 1999 from the Texas College of Osteopathic Medicine at the University of North Texas Health Science Center at Fort Worth.
4. I have a busy medical practice. I am one of three doctors on call. My practice includes cesarean section deliveries, hysterectomies, and other women's health treatments. My practice includes about thirty deliveries each month.
5. A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.
6. I understand that the FDA approved chemical abortion drugs for use in the United States in 2000.

7. I am also familiar with the FDA's regulatory changes regarding chemical abortion drugs, especially the REMS issued in 2016 and associated with the use of mifepristone and misoprostol for chemical abortions.
8. I understand that the FDA approved the use of mifepristone up to 70 days (or 10 weeks) of gestation in 2016, which is longer than the previous standard of 49 days (or 7 weeks).
9. I am familiar with the FDA's suspension and elimination of the in-person dispensing requirements for administering these dangerous drugs in 2021.
10. I am familiar with the removal of the requirement for an in-person, post-abortion office visit, which is when a physician determines whether any fetal parts or other products of conception remain. These visits are essential to ensure that women experience no complications after chemical abortion.
11. I am also familiar with the relaxed reporting requirements for adverse events related to chemical abortions.
12. I believe these FDA actions will harm my patients, women, and women's medicine.
13. I believe that the FDA's approval for using mifepristone at a later gestational age, and the elimination of the in-person dispensing requirement and follow-up visit requirement, are especially dangerous for women.
14. Based on my experience, mothers are often mistaken about how far along they are in pregnancy. According to the Listening to Mothers III survey, 26% of women's due dates are changed.

15. Without an in-person visit to obtain an ultrasound, there is no way to be certain about the gestational age of an unborn child. Women may be further along in pregnancy than is currently acceptable for chemical abortion. Similarly, without an in-person examination, it is impossible to rule out an ectopic pregnancy, which would not be terminated by a chemical abortion and could put women at an increased risk of rupture or even death.

16. Based on my experience treating patients, I believe unsupervised chemical abortions are dangerous and potentially life-threatening especially due to increased risk of hemorrhage and/or infection the further along they are after 6 weeks' gestation.

17. For instance, I treated a woman who traveled from Texas to obtain chemical abortion drugs from Planned Parenthood New Mexico to complete an abortion at 10 weeks' gestation. The woman returned to Texas, suffered from two weeks of moderate to heavy bleeding, and then developed a uterine infection. At the hospital, I provided her with intravenous antibiotics and performed a dilation and curettage procedure. If she had waited a few more days before receiving care, she could have been septic and died. I reported this adverse event to the FDA.

18. The FDA's actions harm my practice by causing unnecessary harm to my patients that could have been avoided by retention and enforcement of the REMS.

19. Doctors like me serve patients as professional health care providers. I provide care to all women and unborn children, and I give them the best professional services possible. Just like other employed obstetrical providers, my hospital will bill for the cost of obstetrical and medical services rendered. When my patients have chemical abortions, I lose the opportunity to provide these obstetrical and medical services to care for the woman and child through pregnancy and bring about a successful delivery of a new life.

20. Additionally, the wider availability of chemical abortion drugs will result in more patients experiencing complications and the number of patients in emergency situations will rise. These situations are naturally higher risk for both the patient and for the physician providing care. In the chemical abortion case that I reported as an adverse event to the FDA, I had no existing patient relationship or prior knowledge of the patient's medical history. Such cases can be a high-pressure, high-risk situation for practitioners like me.

21. The FDA's deregulation of these dangerous drugs increases our exposure to liability.

22. There are many contraindications to prescribing mifepristone, including adrenal failure, steroid use, severe anemia, bleeding disorders, the use of intrauterine devices, undiagnosed ectopic pregnancy, and others. I do not believe telemedicine can rule out all contraindications to prescribing

mifepristone because some of these conditions can only be ascertained with an in-person examination or lab work.

23. Telemedicine does not allow for a critical ultrasound assessment to rule out ectopic pregnancies and verify that the patients are within the 70 days allowed for chemical abortions. In this way, the FDA's loosening of regulations for abortifacient drugs harms women and practitioners by exposing them to increased risk of complications.

24. I believe the relaxed reporting requirements for adverse events related to chemical abortion drugs harm women and physicians because they create an inaccurate and false safety profile for the use of mifepristone and misoprostol. Many women and girls do not fully understand the nature of chemical abortion and the risks that these drugs present to them.

25. The elimination of mandatory follow-up visits after chemical abortion drugs have been administered is also dangerous and harms women and practitioners. Without follow-up visits, physicians cannot identify potential complications like sepsis and hemorrhage, lingering products of conception, and others until the patient is at a critical time or it is too late to help the patient.

26. I care for my patients and give them the best medical care and guidance that I can. I believe that chemical abortions harm women, including my patients, and harm the medical practice. The elimination of REMS critical to ensuring safe use of the chemical abortion drugs prevents doctors from fulfilling their

oath to "do no harm" by permitting the administration of abortifacient drugs to patients without full knowledge or appreciation for the impact those drugs would have on them.

27. As with my patient who suffered an adverse event, it disturbed me that she was not informed that it was not normal to bleed for multiple weeks and that if she had a routine follow-up visit, as required by past REMS, this situation could have been avoided before requiring overnight hospitalization and her being at risk for developing sepsis.

Executed this November 14, 2022.

By: _____, D.O.
Shaun Jester, D.O.

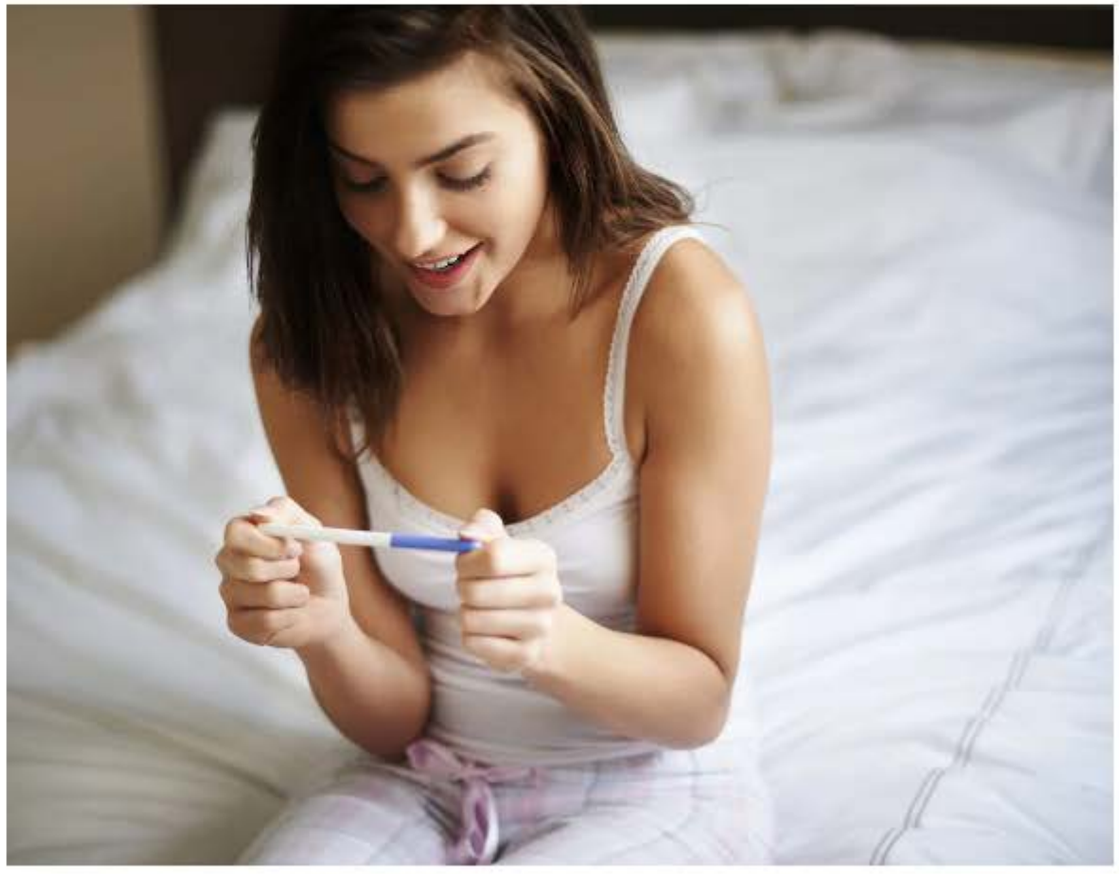
EXHIBIT 84

Her Safe Harbor

Where Can I Get The Abortion Pill?

You can get medication abortion (AKA abortion pills) delivered from from Her Safe Harbor for just $150. Our caring doctors and nurses are experts at providing safe abortion and non-judgmental support throughout the process. You can also get abortion pills from some private doctors or gynecologists, family planning clinics, and abortion.

When you're looking for a place to get an abortion, beware of "crisis pregnancy centers." These are places that seem like normal medical centers, but they don't provide abortion or a full range of health care — they're actually run by people who want to scare or shame people out of getting an abortion. They often give you false or misleading information about pregnancy, abortion, and birth control, and they usually don't have to follow privacy laws.



Getting the abortion pill in the mail

Medication is mailed in plain packaging to protect your privacy and avoid unwanted suspicion.

EXHIBIT 85

Her Safe Harbor - Abortion Pills for Future Use

Buy Abortion Pills For Future Use

You can order abortion pills before you are pregnant, as a precaution for future needs. This service is known as Advance Provision. By providing access to abortion pills before they are needed, individuals can access abortions earlier in their pregnancy.

Ordering abortion pills for future use is similar to the process for ordering pills when you are pregnant. However, it may take longer (usually a few days) to receive a response, as we prioritize those who are currently pregnant.

Begin Consultation



EXHIBIT 86

Declaration of Dr. Regina Frost-Clark

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; **JANET WOODCOCK, M.D.**, in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration **PATRIZIA CAVAZZONI, M.D.**, in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**; and **XAVIER BECERRA,** in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

Case No. _____

DECLARATION OF DR. REGINA FROST-CLARK

I, Regina R. Frost-Clark, a citizen of the United States and a resident of Michigan, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.
2. I am board-certified in obstetrics and gynecology. I practice with St. John OB/Gyn Associates, part of Ascension Medical Group.
3. I received my M.D. from Wayne State University and did my residency at St. John Hospital and Medical Center in Detroit, Michigan.
4. I am in a hospital owned practice and am often called to the emergency department for consultations.
5. I am familiar with the approval and regulatory changes by the United States Food and Drug Administration (FDA) regarding chemical abortion. Specifically, I am familiar with the relaxing of supervision requirements for administering these very serious drugs, and I am familiar with the relaxed reporting requirements for adverse events related to chemical abortions.
6. I believe these FDA actions will harm women, including my patients, and my practice.
7. As an OB/Gyn, I have treated several women who have suffered complications from chemical abortions.

8. The wider availability of chemical abortion drugs will result in an increase in the frequency of complications related to the drugs' use.

9. In at least a dozen cases, I have treated women who were suffering significant bleeding after taking chemical abortion drugs. Occasionally, women have to be admitted to the hospital for observation due to bleeding complications.

10. In my experience, women who have been given chemical abortion drugs often do not know what they were given or how much of a particular drug they took.

11. In most instances where I treat women who have complications from chemical abortion drugs, they have received it from an abortion facility. Recently a woman told me she obtained these drugs by herself—likely online—and took them without any medical supervision.

12. The FDA's suspension of the in-person dispensing requirement of mifepristone and misoprostol harms women and doctors because it has resulted in an increase in complications.

13. Without an in-person dispensing requirement for chemical abortion drugs, there is a greater chance that women with a molar or ectopic pregnancy will be given drugs that will be ineffectual, leaving them exposed to potentially deadly complications like a rupture or hemorrhage.

14. Similarly, without an in-person dispensing requirement, patients may be given chemical abortion drugs without a confirmed pregnancy or for an inappropriate gestational age.

15. In these instances, patients may avoid seeking appropriate medical care because they are unaware of the risks they potentially face, which puts them in greater danger of complications.

16. Women presenting with complications from chemical abortion pose a challenging situation because I may not have access to their medical history—either because I am unable to access any medical records from prescribers of the chemical abortion drugs or because they obtained the chemical abortion drugs without any medical oversight to begin with. Additionally, the patients themselves usually do not understand what they have been given, how much they have taken, or their follow-up instructions.

17. The lack of patient history and knowledge harms my ability to treat patients. For example, with patients experiencing bleeding, the course of treatment will vary if I believe the bleeding is regular or abnormal cyclical bleeding as opposed to bleeding resulting from attempted abortion.

18. I expect to see more and more women with chemical abortion complications as the use of the drugs increases. Because of the increased complications and the limited information available to me due to the FDA's actions, I fear that I will have greater exposure to liability in my practice.

19. The FDA's actions have led to more confusion for patients and providers. The FDA has forced my colleagues and me to make decisions about patient care based on limited information. It also requires me to spend a lot of time trying to reconstruct patient medical histories to best serve my patients.

20. The FDA's actions make it difficult for patients to have informed consent. Doctors cannot confirm the pregnancy, the location of the pregnancy, or the gestational age without an examination. In abortion clinic settings, it is unclear whether patients are seeing the same physician each time. And often there are no patient follow-up visits with the dispensing facility.

21. Under the current practice by those who prescribe chemical abortion drugs like mifepristone and misoprostol, there is no follow-up or additional care provided to patients and therefore no rapport between patients and their physicians. This makes it difficult to assess who is responsible for these patients when they experience complications.

22. The FDA's removal of the adverse event reporting requirement for all adverse events except death harms my ability to perform evidence-based medicine. I am unable to assess the risks present to women because the FDA's removal of reporting requirements undermines the legitimacy of risk data. For example, Ranitidine, commonly known as Zantac, was pulled from the market due to cancer associations after years of use. Without adverse event reporting, I cannot properly assess the risks that my patients face from abortifacient drugs.

23. I have not reported adverse events that I have witnessed as a result of chemical abortions because the process is so cumbersome. In addition to the burdensome paperwork, it is difficult to file an accurate report given that in many cases I am not certain what the patient was given by the chemical abortion prescriber.

Executed this November 13, 2022.

By: _____

Regina Frost-Clark, M.D.

EXHIBIT 87

Declaration of Mario R. Dickerson

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; **JANET WOODCOCK, M.D.**, in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration **PATRIZIA CAVAZZONI, M.D.**, in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**; and **XAVIER BECERRA,** in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

Case No. _____

DECLARATION OF MARIO R. DICKERSON

I, Mario R. Dickerson, a citizen of the United States and a resident of Willow Grove, Pennsylvania, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.
2. I serve as the Executive Director of the Catholic Medical Association ("CMA"). Given my involvement in CMA, I am familiar with the organization's history, the issues confronting it, and the views of the organization and its members concerning various emerging issues, including the deregulated use of mifepristone, or RU-486, to accomplish chemical abortions. I am also familiar with CMA members and their practices.
3. CMA is the largest association of Catholic individuals in healthcare. CMA is a national, physician-led community that includes about 2700 physicians and healthcare professionals nationwide.
4. CMA is a nonprofit organization incorporated in Virginia, and its registered agent is in Virginia.
5. CMA's mission is to inform, organize, and inspire its members, in steadfast fidelity to the teachings of the Catholic Church, to uphold the principles of the Catholic faith in the science and practice of medicine.
6. CMA seeks to pursue its mission in conformity to Christ the Divine Physician. Its members are challenged to be a voice of truth spoken in charity, to show

how Catholic teachings on the human person, human rights and the common good intersect with and improve the science and practice of medicine, and to defend the sacredness and dignity of human life at all stages.

7. CMA is a member of the Alliance for Hippocratic Medicine (AHM).

8. CMA is committed to taking a Catholic and Hippocratic approach to medicine.

9. Consistent with Catholic teaching, CMA and its members are morally and ethically opposed to all forms of abortion—chemical or surgical.

10. I have spoken with CMA members who have treated women harmed by chemical abortion drugs.

11. The FDA's unauthorized approval of mifepristone (also known as "Mifeprex" and "RU-486") and subsequent elimination of certain safeguards for the use of the dangerous chemical abortion drug regimen, including those found in the Risk Evaluation and Mitigation Strategy (REMS) for mifepristone, has led to an increasing risk that women and girls may suffer adverse events from chemical abortion.

12. The FDA has continued to eliminate safeguards such that the chemical abortion drugs can now be administered and dispensed with no in-person examination or oversight by a physician. This leaves physicians, including CMA members, to treat the complications that women and girls suffer due to the actions of the FDA and abortionists.

13. CMA's member physicians include OB/GYNs and emergency department physicians who have treated women suffering complications from chemical abortion.

14. The FDA's actions harm CMA and its member physicians who are called away from other patients to render emergency treatment to women and/or girls who present to emergency departments with symptoms, such as heavy bleeding and severe pain, and more serious complications, including hemorrhage and sepsis caused by chemical abortion drugs. This causes CMA's member physicians much stress and grief, while impeding their ability to perform their practice of medicine in the manner that they desire.

15. Often, emergency department doctors do not have a prior relationship with these patients and lack access to the patient's medical history. Sometimes these patients were underinformed about the effects of the chemical abortion drug regimen, they may not even know what drugs they consumed, or they are told to say they are suffering a miscarriage if there is a need for them to seek emergency help following a chemical abortion. This leaves doctors at increased risk of liability and could impact their ability to render the best care possible to the patient—all because of the FDA's elimination of necessary safeguards.

16. Moreover, the FDA's removal of necessary safeguards could force CMA members to treat women and girls who present to emergency departments following an elective chemical abortion requiring those doctors to complete an

unfinished elective abortion—terminating the life of an unborn child—in violation of their conscience rights.

17. Since 2005, CMA has called upon the FDA to respond to citizens petitions calling for removal of RU-486 from the market in an urgent action. CMA renewed this resolution in 2015.

18. In 2016, CMA enacted a resolution that called for the FDA to require a central registry for all those having a chemical abortion, with mandatory reporting from every state and territory of complications and mortalities from chemical abortions; that the drug be administered only by a physician with surgical privileges at a hospital within 30 minutes of the facility where the drug is dispensed; that the dispensing physician be responsible for follow-up and handling of complications; and that the patient be informed that the process could be stopped without harm to her or the baby.

19. These resolutions are vital to ensure the safety of women and girls, and to protect doctors, including CMA members.

20. CMA has spent considerable time, effort and resources challenging the FDA's actions—at the expense of other CMA priorities. For example, to implement these resolutions, committees have had to review them, it has taken time during General Assembly meetings to discuss them, which takes our members away from their other business, and it has taken time for our Executive Director and Board to review, taking them away from other priorities such as fundraising and membership recruitment and retention.

21. Due to inadequate adverse event reporting, the true rates of risks associated with chemical abortion drugs remain unknown and undercounted. This prevents CMA from providing the public, their members, and their members' patients with accurate statistics and complete information regarding the risks associated with the use of chemical abortion drugs.

22. CMA is a leading national voice on applying the principles of the Catholic faith to medicine. CMA creates and organizes educational resources and events; advocates for members, the Church, and the medical profession in public forums; and provides guidance for bishops and other national leaders on healthcare ethics and policy. The inability to share accurate information on the risks of chemical abortion frustrates and complicates CMA's purpose to educate doctors, their patients, and the public about these dangers.

Executed this November 12, 2022.

By: Mario R. Dickerson
Mario R. Dickerson

EXHIBIT 88

Declaration of Dr. Tyler Johnson

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; **JANET WOODCOCK, M.D.**, in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration **PATRIZIA CAVAZZONI, M.D.**, in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**; and **XAVIER BECERRA,** in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

Case No. _____

DECLARATION OF DR. TYLER JOHNSON

I, Tyler Johnson, D.O., a citizen of the United States and a resident of Leo, Indiana, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.
2. I received my Bachelor of Science in Biology from the University of Saint Francis in Fort Wayne. I attended medical school at the Lake Erie College of Osteopathic Medicine. My residency was at Michigan State University's Kalamazoo Center for Medical Studies.
3. I am an emergency department physician certified by the American Board of Emergency Medicine. I practice in the emergency departments of hospitals in northern Indiana. My practice includes treating patients throughout rural northern Indiana into the inner-city of Fort Wayne. I am also the director of emergency medicine at Parkview Dekalb Hospital.
4. I am a member of the American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG).
5. I am familiar with the U.S. Food and Drug Administration's (FDA) Risk Evaluation and Mitigation Strategy (REMS) drug safety program. I am also familiar with the REMS issued by the FDA for the chemical abortion drugs mifepristone and misoprostol in 2016.

6. The FDA's 2016 REMS for mifepristone and misoprostol expanded the acceptable gestational age for chemical abortion, eliminated the in-person administration requirement for these dangerous drugs, eliminated mandatory post-abortion follow-up visits, and eliminated the requirement for prescribers to report all non-fatal adverse events.

7. The FDA's actions harm both women and practitioners.

8. Mifepristone and misoprostol are dangerous drugs that have serious effects on a woman's body. Without the medical supervision, women taking these drugs are at risk of serious and life-threatening complications and even death.

9. I have seen at least a dozen cases of life-threatening complications from the use of abortifacient drugs over the years. These emergency situations are becoming more common as more women are turning to chemical abortion as the FDA has relaxed its regulations.

10. In one case, for example, I treated a woman in the emergency department who had been given an abortion pill from a clinic in Chicago. She took the pill and began to experience heavy bleeding on the drive back to Fort Wayne. By the time she arrived at the hospital, she was unconscious. I performed emergent treatment and gave her a necessary blood transfusion. The patient required further evaluation and observation in the hospital. I have seen multiple cases similar to this one.

11. About a month ago, I treated an 18-year-old woman in the emergency department who was experiencing severe pain. Although the situation was not life-threatening to her, she was terrified, and it was clear to me that she did not understand what she had been given. It is not uncommon for women who take mifepristone and misoprostol to come to the emergency department because the pain is so terrible.

12. Many of the patients I have treated for complications with chemical abortion experience trauma. They usually have no follow-up with the doctors who prescribed or dispensed the abortifacient drugs, and they are not adequately prepared to understand what the drugs will do to them. In these situations, it is clear to me that these women and girls could not have given informed consent to chemical abortion.

13. In many cases, women are hesitant to tell us that they have taken chemical abortion drugs. On multiple occasions I have treated women in the emergency department who are experiencing extremely heavy bleeding even after they have already passed the unborn child. The women will sometimes eventually explain that they took abortifacient drugs, which helps us understand what is happening to them. I understand that many women are told by staff at the dispensing clinics to tell emergency department doctors that they are experiencing a "miscarriage."

14. Because of the FDA's relaxed regulation of these dangerous drugs, it is extremely easy for women to obtain mifepristone and misoprostol with little

or no supervision. This leaves emergency physicians like me to deal with preventable emergent and life-threatening situations after these women have taken these drugs. The unsupervised administration of chemical abortion drugs simply harms women and physicians.

15. The FDA's actions have created a culture of chaos for emergency room physicians. In my experience, patients who are given abortifacient drugs at clinics do not understand what they have taken and are often reluctant to tell emergency doctors what they have taken. This puts me and my colleagues in a position where we have to treat women in emergency situations without crucial information. This culture puts us in increasingly higher risk situations, which increases our exposure to claims of malpractice and liability.

16. The increase in women presenting in the emergency department for complications with chemical abortions harms other patients too. Because more women are unnecessarily presenting in the emergency department, more of my time and attention is taken away from other patients who need it.

17. I also believe the FDA's elimination of reporting requirements for non-fatal adverse events harms women and practitioners. I believe we are not tracking these medications closely enough to know the extent of the negative side-effects commonly experienced. This also harms physicians' ability to practice evidence-based medicine. Moreover, women and girls cannot give informed

consent to chemical abortion when they do not receive accurate information about the risks associated with mifepristone and misoprostol.

18. Given my experience, I expect to see and treat more patients presenting themselves with complications from chemical abortion.

Executed this November 11, 2022.

By: _____
Tyler Johnson, D.O.

EXHIBIT 89

Declaration of Dr. Steven A. Foley

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; **JANET WOODCOCK, M.D.**, in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration **PATRIZIA CAVAZZONI, M.D.**, in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**; and **XAVIER BECERRA,** in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

Case No. _____

DECLARATION OF DR. STEVEN A. FOLEY

I, Steven A. Foley, a citizen of the United States and a resident of Carmel, Indiana, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.
2. I am board-certified in obstetrics and gynecology. I practice in Angola, Indiana, and Evansville, Indiana.
3. As a hospitalist, I am associated with several hospitals and cover the emergency department for hospitals. As an OB/Gyn in a hospital setting, I have treated numerous women who have suffered complications from abortions.
4. I have practiced obstetrics and gynecology in Indiana and other states for many years.
5. I am a member of Plaintiff Christian Medical and Dental Associations.
6. During my time in Colorado, I was one of the only OB/Gyn doctors available to many patients. For example, during my time working in the plains of Colorado, it was 120 miles to the next OB/Gyn doctor.
7. I believe regulatory actions of the United States Food and Drug Administration (FDA) on chemical abortion will harm my practice and my patients.

8. Women suffer more complications from chemical abortions than surgical abortions.

9. The removal of the supervision requirements before administering chemical abortion drugs harms patients because it does not allow a doctor to establish gestational age, determine whether the woman has an ectopic pregnancy, or to check the Rhesus (Rh) levels of the patients. Giving women abortifacient drugs without these simple screening steps is simply against the standard of care and will cause more complications.

10. The FDA's actions will especially harm my practice in Indiana since the state's ban on abortions after 15 weeks took effect on September 15, 2022. This means more women will turn to chemical abortion drugs that they are able to obtain online and through the mail because they will seek to use these drugs to obtain surreptitious abortions after the gestational age limit. The increase in number of women taking chemical abortion drugs, especially later in gestational age, will lead to an increased demand in the emergency department.

11. Under the current practice by those who prescribe and dispense chemical abortion drugs like mifepristone and misoprostol, there is no follow-up or additional care provided to patients. Instead, with no established relationship with a physician, patients are simply left to report to the emergency room when they experience adverse effects.

12. Many women are underinformed on the severity of the effects associated with chemical abortions, including the duration and severity of bleeding, the pain associated with the process, and the emotional trauma that they experience.

13. When chemical abortion drugs work as intended, a woman will effectively deliver her unborn child and the placental and any other pregnancy tissues.

14. Many women who report to the emergency department do not disclose that they have taken abortifacient drugs. In some instances, women will tell medical providers that they are suffering a miscarriage. The lack of information or misinformation received by doctors by their patients impacts the course of treatment and the care that doctors can provide.

15. Because abortionists do not adequately inform a woman or a girl about what happens during a chemical abortion and give these drugs to her to take outside of the abortion facility, I have needed to treat and care for many women who have presented to the emergency department with intense bleeding and other effects of the chemical abortion drugs—although not considered complications from the regimen.

16. I have also treated several women for abortion-pill reversal, where women seek to stop a chemical abortion from occurring after they have taken mifepristone. I prescribe the drug progesterone for these patients in an attempt to save their pregnancy. These women experience mental anguish

over the experience of having chosen chemical abortion, and some of them do not feel like they were properly advised as to what they were choosing.

17. The FDA's removal of the adverse event reporting requirement for all adverse events except death harms my ability to perform evidence-based medicine. I am unable to assess the risks present to women because the FDA's removal of reporting requirements undermines the legitimacy of risk data.

Executed this November 13, 2022.

By: _____
Steven A. Foley, M.D.

EXHIBIT 90

Declaration of Dr. Nancy Wozniak

IN IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; **JANET WOODCOCK, M.D.**, in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration **PATRIZIA CAVAZZONI, M.D.**, in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**; and **XAVIER BECERRA,** in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

Case No. _____

DECLARATION OF DR. NANCY WOZNIAK

I, Nancy Wozniak, M.D., a citizen of the United States and a resident of Fishers, Indiana, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.
2. I am a board-certified obstetrician and gynecologist practicing in the greater Indianapolis area. My practice includes obstetrics at two Indianapolis-area hospitals.
3. I am a member of the Board of Directors of Plaintiff American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG) and serve as AAPLOG's Secretary. I am familiar with AAPLOG, its policy positions, its members, the members' interests and concerns. AAPLOG and its members oppose elective abortions, both surgical and chemical.
4. I am familiar the approval of mifepristone and misoprostol as chemical abortion drugs by the U.S. Food and Drug Administration (FDA) and with the FDA's Risk Evaluation and Mitigation Strategy (REMS) for the use of mifepristone and misoprostol for chemical abortions.
5. A REMS is a drug safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.

6. Under the REMS established by the FDA in 2016 for mifepristone and misoprostol, the agency eliminated (a) the in-person administration requirement, (b) mandatory post-abortion follow-ups, and (c) the requirement that prescribers report all adverse events except death.
7. In 2016, the FDA also expanded the gestational age for approved mifepristone use to 70 days (or 10 weeks) from 49 days (or 7 weeks).
8. The FDA's actions harm patients and practitioners like me.
9. Mifepristone and misoprostol are dangerous drugs that can harm women. Without the appropriate supervision, women taking these drugs are at risk of serious complications and even death in the worst cases.
10. I believe the FDA's expansion of the approved timeframe for mifepristone and misoprostol use to 10 weeks of gestation harms women. An abortionist should never prescribe these drugs to any woman for an abortion after 8 weeks' gestation because I have seen so many women get into trouble with bleeding past that gestational age.
11. Few people die from chemical abortions because of the excellent care they receive from OBGYN doctors, but the infrequency of deaths conceals the danger that these drugs pose to women and girls—especially when administered without proper supervision.
12. In my experience, most of the complications related to the use of mifepristone and misoprostol for chemical abortions result in "near misses" due to the timely intervention of healthcare providers.

13. Recently many states like Indiana have enacted laws to regulate abortions more carefully. To circumvent those laws, abortion providers are relying on increased access to chemical abortion drugs through mail-order schemes or telemedicine.

14. The increasing number of chemical abortions through mail-order or telemedicine methods means that more women will suffer complications from unsupervised use of mifepristone and misoprostol.

15. The risk of complications from chemical abortions is four to seven times greater than from surgical abortions.

16. Currently, many women are now being prescribed mifepristone and misoprostol without a sonogram to verify the gestational age of the unborn child or to rule out ectopic pregnancies or other potential complications.

17. Women have the potential to present to the emergency department with torrential bleeding due to taking mifepristone and misoprostol for a chemical abortion without accurate dating and appropriate supervision. This places enormous stress and pressure on physicians and OB/Gyns who work in hospitals.

18. In my observation, incidents of women presenting to emergency departments with complaints of bleeding are becoming increasingly more common.

19. Due to the FDA's elimination of the adverse event reporting requirements, however, it is impossible to know how frequently women and doctors are facing these complications.

20. The FDA's elimination of the adverse event reporting requirements for non-fatal complications harms doctors' ability to practice evidence-based medicine and to provide their patients about the risks of chemical abortion and obtain their informed consent. Doctors are only as good as the information that they receive.

21. These physicians must treat women in emergency situations without an existing relationship with the patient, without a known gestational age, and without any known medications that the patient may have been prescribed. This dynamic also increases doctors' exposure to allegations of malpractice and potential liability.

22. The FDA's loosening of regulations related to chemical abortions harms hospitalists by putting them in higher-risk situations with less critical information about patients, which increases their exposure to allegations of malpractice and potential liability.

23. In the last six months, I had an experience treating a woman that illustrates how dangerous and damaging the FDA's actions are to women and practitioners.

24. One of my patients, who was about nine weeks pregnant, had previously been treated by hospital staff for a pulmonary embolism with anti-coagulants. She was advised that she could not seek a chemical abortion because it was contraindicated due to the medications; yet the woman left the hospital and sought an abortion at Planned Parenthood of Indiana. The woman was given

mifepristone by the doctor at Planned Parenthood and took the drug. The woman called an Uber for a ride home from Planned Parenthood. The woman began to experience bleeding and other adverse side effects from the mifepristone. The woman's Uber driver did not take her home because she was so ill and instead brought her to the hospital's emergency department. At the hospital, the woman came under my care. The woman had not yet taken the second abortion drug, misoprostol. I treated the patient for the adverse effects she suffered and told her not to take the misoprostol given to her by Planned Parenthood because of the grave risk that she could bleed out and die. The woman had a subsequent ultrasound, which showed that her unborn child was still alive. I advised the internists treating this patient to avoid administering certain medications that could harm the patient and her unborn child.

25. This experience that I had illustrates one of many "near misses" where women and girls face potentially deadly situations, but they are saved by intervention at a hospital's emergency department.

26. Under the FDA's current reporting requirements, this experience need not be reported as an adverse event. I attempted to report this event to the Indiana Department of Public Health, but my report was rejected because the State said it was not a "true" adverse event because the patient ultimately recovered.

27. In my experience with the patient I just described, I spent a significant amount of time that day working to save her life from unnecessary complications due to the irresponsible administration and use of mifepristone and misoprostol. As a result of the significant time that I devoted to that patient, my time and attention was taken away from my other patients, who also need my care.

28. I also know that many women who are suffering complications from chemical abortions tell their doctors that they are experiencing miscarriages. This phenomenon—regardless of why it occurs—means that doctors cannot be certain of what their patients have taken or are experiencing. The lack of information makes it extremely difficult to provide proper treatment to these patients. This inaccurate information also means that the true number of incidences of complications from chemical abortions are significantly underreported or not fully known.

29. Given my experience, I expect to see and treat more patients presenting themselves with complications from chemical abortion.

Executed this November 11, 2022.

By: _____
Nancy Goodwine-Wozniak, M.D.

EXHIBIT 91

Declaration of Dr. Jeffrey Barrows

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; **JANET WOODCOCK, M.D.**, in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration **PATRIZIA CAVAZZONI, M.D.**, in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**; and **XAVIER BECERRA,** in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

Case No. _____

DECLARATION OF DR. JEFFREY BARROWS

I, Jeffrey Barrows, D.O. M.A. (Ethics), a citizen of the United States and a resident of Blountville, Tennessee, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.
2. I am a board-certified obstetrician and gynecologist and am the Senior Vice President of Bioethics and Public Policy for Plaintiff Christian Medical & Dental Associations (CMDA).
3. I practiced obstetrics and gynecology for approximately 18 years. I practiced gynecology in an office setting for an additional ten years.
4. I am familiar with CMDA, its members, their fields of practice, and CMDA's policies and positions.
5. CMDA is a national nonprofit organization headquartered in Tennessee. Its members are more than 13,000 Christian physicians, dentists, and allied healthcare professionals. CMDA has more than 1,200 members in Texas, including more than 600 physicians and approximately 35 OBGYNs.
6. CMDA is opposed to elective abortions as contrary to sacred scripture, respect for the sanctity of human life, and traditional, historical Judeo-Christian medical ethics.
7. CMDA's mission includes advocating on behalf of its members, including in litigation.

8. CMDA brings this suit on behalf of itself and its members.

9. CMDA has members in Texas and around the country who care for pregnant women in hospitals and clinics. CMDA's members care for women who suffer complications from chemical abortions.

10. A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.

11. I am familiar with the FDA's approval of chemical abortion drugs in 2000.

12. I am familiar with the FDA's regulatory changes regarding chemical abortion drugs, especially the REMS issued in 2016 and associated with the use of mifepristone and misoprostol for chemical abortions.

13. I understand that the FDA's 2016 changes expanded the gestational age for approved mifepristone use to 70 days (or 10 weeks) from 49 days (or 7 weeks), that it eliminated the in-person administration requirements for chemical abortion drugs, that it eliminated the requirement for a follow-up appointment after those drugs have been taken, and that it eliminated the prescriber reporting requirement for all adverse events except for death.

14. I also understand that the FDA subsequently eliminated the in-person dispensing requirements in 2021.

15. The FDA's actions harm women, practitioners, CMDA members, CMDA as an organization, and the medical profession generally.

16. Mifepristone and misoprostol are dangerous drugs that can potentially harm women. Relaxing the required medical supervision and oversight for patients taking these drugs puts women's health at risk.

17. By eliminating the in-person dispensing requirement and the requirement for a post-abortion follow-up, the FDA has exposed women to a higher likelihood of undetected serious complications. Specifically, the expanded use of telemedicine for chemical abortions means that some women who are beyond 70 days' gestation because they are mistaken or wrong about the gestational age of their unborn child will take these drugs outside of the appropriate window.

18. Similarly, without in-person visits and sonograms, women with ectopic pregnancies may escape diagnosis, which puts them at a greater risk of serious and life-threatening complications such as rupture of the Fallopian tube and secondary hemorrhage. Undetected ectopic pregnancies are especially dangerous for women because in some cases they can result in extreme bleeding for women.

19. By eliminating the adverse event reporting requirement for all events except death, the FDA has also undermined physicians' ability to practice evidence-based medicine. By failing to collect accurate information about the complications associated with chemical abortion, the FDA leaves doctors without accurate information about the drugs' safety for women.

20. As an organization, CMDA is harmed by the FDA's failure to require reporting of all adverse events, which prevents CMDA from providing the public, our members, and our members' patients with accurate statistics and complete information regarding potential risks associated with the use of chemical abortion drugs.

21. The inability to share accurate information with member physicians, their patients, and the public on the risks of chemical abortion frustrates and complicates CMDA's purpose to provide professional healthcare and to educate doctors, their patients, and the public about the dangers of chemical abortion.

22. By removing the requirements for in-person visits, the FDA has increased the risk of malpractice claims against physicians. The best way to prevent malpractice is for physicians to establish relationships with patients who they can treat over time. By doing away with the necessary medical supervision, the FDA will cause more women to present in life-threatening circumstances into the care of hospitalists and emergency department physicians who have no prior history with these patients.

23. By putting more doctors into riskier, emergent medical situations, the FDA's regulatory actions expose physicians to increased claims of liability.

24. The increased risks of exposure to liability and malpractice claims also impacts physicians because it drives up their insurance costs, especially those who practice in the hospital.

25. The FDA's loosening of chemical abortion regulations impacts the standard of care and the demands and expectations that hospitals will put on their physicians. The FDA has radically altered the standard of care for mifepristone and misoprostol. The agency did this without the requisite evidence to support its actions.

26. I am also concerned that the FDA's actions will force CMDA members to complete an unfinished elective abortion in an emergency situation, causing immediate emotional and moral distress for our members who are opposed to elective abortion and do not want to feel complicit in an immoral, unnecessary procedure.

27. CMDA has been involved with challenging the FDA's approval of chemical abortion drugs for 20 years. In 2002, we submitted a Citizen Petition with other pro-life groups challenging the FDA's actions, diverting valuable time and effort from CMDA's routine functions in order to assist in filing the petition.

Executed this November 12, 2022.

By: BARROWS DO MA
Jeffrey Barrows, D.O. M.A.

EXHIBIT 92

Rachel K. Jones & Amy Friedrich-Karnik, *Medication Abortion Accounted for 63% of All US Abortions in 2023—An Increase from 53% in 2020*, Guttmacher Institute (March 2024)

Medication Abortion Accounted for 63% of All US Abortions in 2023—An Increase from 53% in 2020



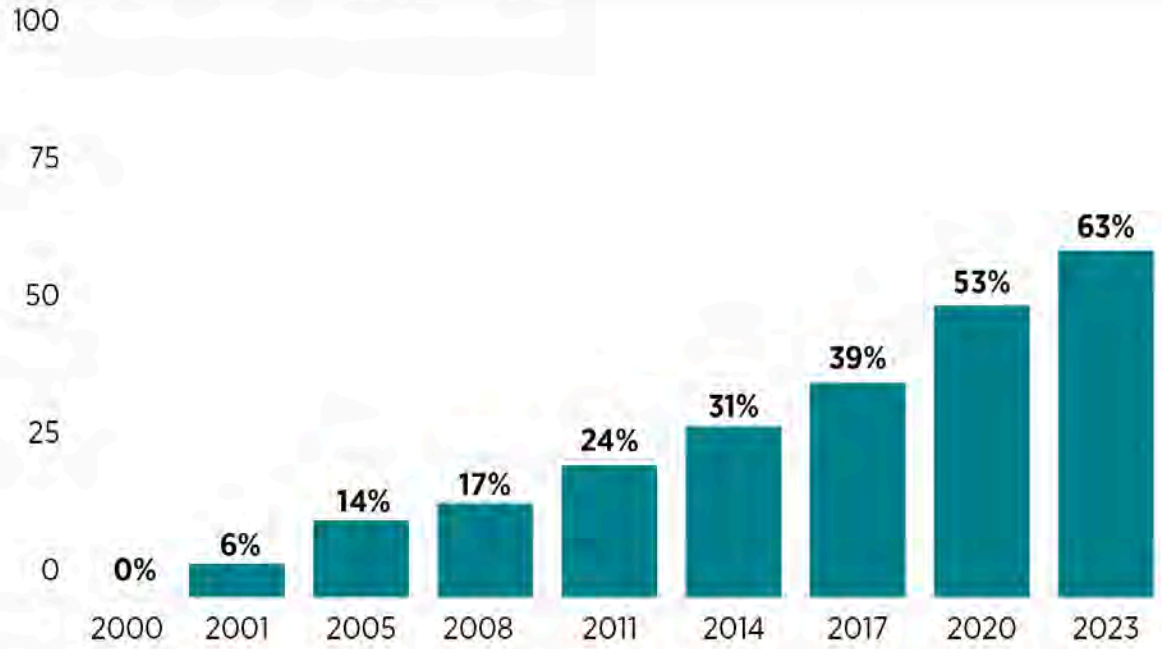
AUTHORS

Rachel K. Jones, Guttmacher Institute

Amy Friedrich-Karnik, Guttmacher Institute

Reproductive rights are under attack. Will you help us fight back with facts? Donate

New Guttmacher Institute research from the **Monthly Abortion Provision Study** shows that there were approximately 642,700 medication abortions in the United States in 2023, accounting for 63% of all abortions in the formal health care system. This is an increase from 2020, when medication abortions accounted for 53% of all abortions.



Sources: Guttmacher Abortion Provider Census and Monthly Abortion Provision Study.
guttmacher.org

Medication abortion using mifepristone was first approved for use in the United States by the U.S. Food and Drug Administration (FDA) in 2000, and reliance on medication abortion has increased steadily as it has become more accessible over time. The two-drug combination of mifepristone and misoprostol is the most common medication abortion regimen offered by US providers, and decades of research have established that medication abortion using mifepristone is **highly safe and effective**. Increased access to and use of medication abortion is likely one reason why the overall number of abortions in the formal health care system **increased 10% nationally** between 2020 and 2023.

The medication abortion counts for 2023 do not include **self-managed medication abortions** that take place outside of the formal health care system or abortion medication mailed to people in states with total abortion bans. While there are no comprehensive data on the number of self-managed medication abortions in the United States, evidence suggests they **have been increasing** in the past several years. Therefore, the total count of medication abortions nationally is higher than our count of those offered within the formal health care system.

Unfortunately, gains in access to and use of medication abortion are at risk. The US Supreme Court will hear a case on March 26—*Alliance for Hippocratic Medicine v. FDA*—

and reinstate the requirement for the drug to be provided in person. If outdated and medically unnecessary restrictions are placed on the provision of mifepristone—in contrast with the FDA's evidence-based protocol—access to abortion across the country would be greatly impacted.

Medication Abortion Has Become More Widely Available

For many people, medication abortion is more accessible than a procedural abortion. In 2021 (the most recent year with available data), 40% of facilities known to provide abortion care **offered only medication abortion**. And, starting in 2021, the FDA lifted medically unnecessary restrictions that had required in-person provision of mifepristone. That **regulation change**, which the FDA finalized in January 2023, meant that health care providers and online pharmacies could mail abortion medication to patients, including those who live far from a provider or are otherwise unable to make an in-person visit. In addition, brick-and-mortar pharmacies can now become certified to **dispense and fill mifepristone prescriptions**, so access is expected to continue growing.

The number of US providers offering a telemedicine consultation—by video, phone call, text or online platform—and **mailing abortion pills increased** from 7% of all providers known to offer medication abortion in 2020 to 31% in 2022. Online-only clinics, after first appearing as a new type of abortion provider in 2021, accounted for **8% of all abortions** provided within the formal health care system in the first six months of 2023.

Medication abortion provided via telemedicine is as **safe and effective** as provision in a health care facility. Offering options besides in-person care can reduce, or even remove, some of the secondary costs related to seeking an abortion, such as transportation, child care and missed wages from taking time off work. Like with other types of health care, having the option to access abortion care via telemedicine allows for more flexibility and can expand **person-centered care** by meeting patients where they want to be served.

Not All People Prefer Medication Abortion Over Procedural Abortion

While broader access to medication abortion has likely contributed to its increased use, it does not necessarily indicate that all people are getting their preferred method.

Since the Supreme Court's *Dobbs v. Jackson Women's Health Organization* decision in ne 2022 ended a right to abortion nationally, there has been an increase in patients at linics in states where abortion continues to be available. Sixteen percent of abortion

banned. At the same time, abortion has also increased among residents in almost all of these bordering states. In some places, these developments have led to **wait times** of two weeks or longer for abortion care.

Some individuals may opt to access care through telehealth options to avoid long wait times for appointments, even if they would have preferred in-clinic care. Even at brick-and-mortar clinics, wait times may be shorter for medication abortion than procedural abortion since the pills can be offered by methods such as "**quick pick-up**." Finally, for some patients, the closest abortion provider may only offer medication abortion, limiting their access to a procedural abortion unless they can travel to a clinic where it is offered.

When procedural abortion is harder to access relative to medication abortion, the impact of those restricted options falls hardest on groups of people historically marginalized within the health care system. For example, research suggests that Black individuals, people who have had a prior abortion and those with incomes below the federal poverty level are less likely than other groups **to prefer**, and **to have**, a medication abortion (vs. a procedural abortion).

State Restrictions on Use of Medication Abortion

Anti-abortion policymakers have been working to restrict access to abortion care on many fronts. Besides the 14 states that are **enforcing a total ban on abortion**, five states where abortion remains legal until at least six weeks' gestation have laws that restrict access to medication abortion via telemedicine. Arizona, Nebraska, North Carolina, South Carolina and Wisconsin require that a patient being prescribed medication abortion have an in-person visit with a physician, and Arizona and North Carolina also ban mailing medication abortion pills to a patient. Furthermore, 15 states require medication abortion to be provided by a physician, despite evidence that advanced practice clinicians can provide it safely, as they do in other states.

It Is Critical to Ensure Full Access to Medication Abortion

Medication abortion has proven to be a game changer in expanding abortion care in the United States. Unfortunately, legal attacks and restrictive policies continue to challenge access. When the Supreme Court rules on the case challenging access to mifepristone this spring, it will have to decide whether to ignore the FDA and reimpose unnecessary

Any return to restrictions on medication abortion provision via telemedicine would be detrimental for people who either prefer or only have access to abortion using telemedicine. While the current court case only affects use of mifepristone—and a misoprostol-only regimen is also a **safe and effective method** of medication abortion—everyone seeking an abortion should have access to the full range of safe, effective options.

Methodology

Data on medication abortion for 2023 are from Guttmacher's **Monthly Abortion Provision Study**, which produces national and state estimates of the number of abortions provided within the formal health care system in the United States based on data collected from samples of abortion providers. Questions about medication abortion were included in versions of the survey distributed to providers in August and September 2023 and in February 2024 (with the latter asking providers for annual medication abortion figures for 2023). Estimates include abortions provided at brick-and-mortar facilities (including those that use telehealth) and online-only providers. These estimates do not include abortions obtained outside of the formal health care sector or any abortions—whether self-managed or provided by out-of-state clinicians—involving medication mailed to states with total abortion bans.

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EXHIBIT 93

Society of Family Planning, #*WeCount Report April 2022 to March 2024* (August 7, 2024)

#WeCount report, April 2022 to December 2024
Released: June 23, 2025

#WeCount is a time-limited reporting effort that aims to capture national shifts in abortion volume, by state and month, following the *Dobbs v Jackson Women's Health Organization* Supreme Court decision to overturn *Roe v Wade*. This report includes data from April 2022 to December 2024.

For media inquiries, please contact SFP@ConwayStrategic.com.

For questions about #WeCount and information on how to enroll your practice, please contact WeCount@SocietyFP.org.

Please use the citation below to cite this #WeCount report.

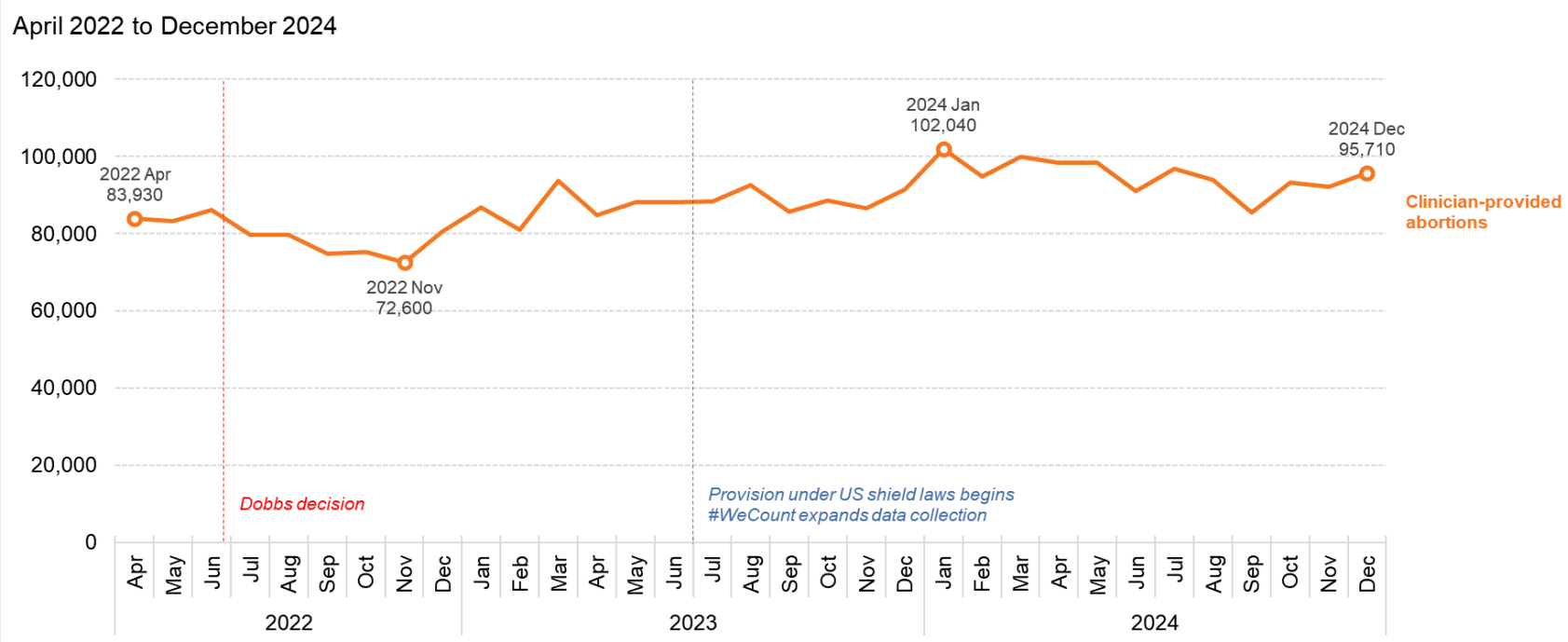
> *Society of Family Planning. #WeCount Report April 2022 through December 2024. 23 Jun. 2025, https://societyfp.org/wecount-report-9-december-2024-data/, https://doi.org/10.46621/725961gzsnai.*

Key findings

- The total number of abortions was **higher in 2024** than it was in 2023 or 2022.
- The majority of abortions occurred **in-person**.
- The number of abortions delivered via **telehealth has continued to increase** since April 2022, when #WeCount became the first national study to track telehealth.
- By the end of 2024, 1 in 4 abortions was provided via telehealth.
- **Shield laws** continue to facilitate the receipt of medication abortion, with an average of 12,330 abortions per month provided under shield laws by the end of 2024.
- Drivers of these trends are unclear, especially in the context of multiple changes in the service delivery environment; new evidence that helps contextualize these findings continues to emerge.

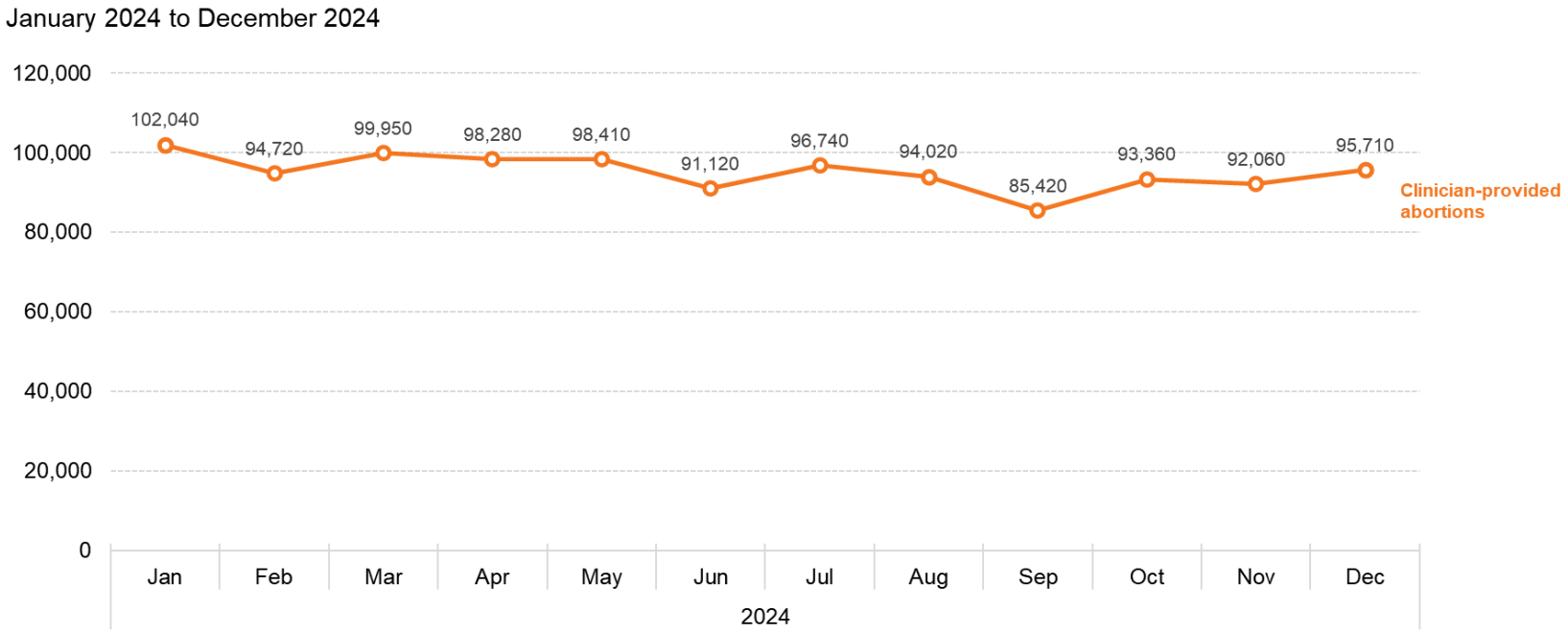
National findings

Total abortions in the US have increased since Dobbs



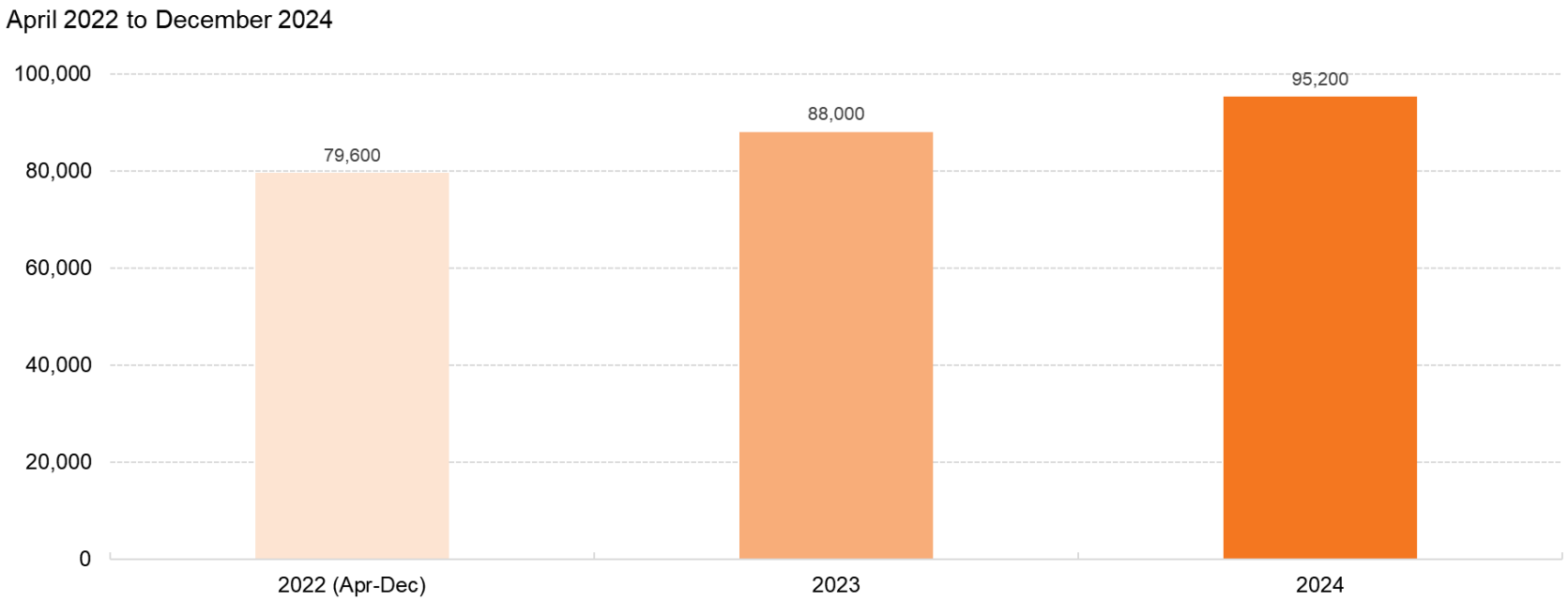
The monthly number of abortions increased gradually over time in the US since 2022.

US abortions totaled 1.14 million in 2024



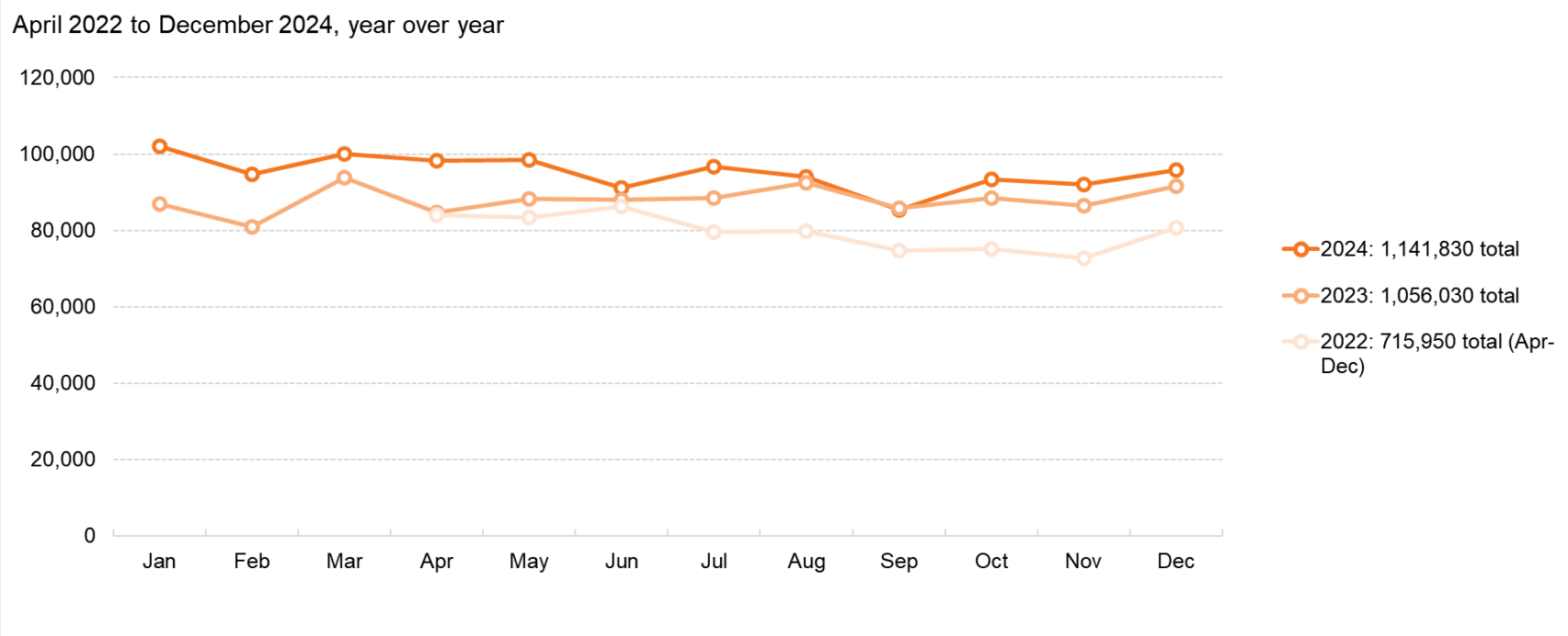
In 2024, 1.14 million abortions occurred in the US, the largest number of abortions in the US in recent years. The monthly total peaked in January 2024, reaching over 102,000 abortions in a single month.

Monthly average number of abortions increased each year



The monthly average number of abortions climbed from around 80,000 in 2022, to 88,000 in 2023, to 95,000 in 2024. Note that the 2022 monthly average is less precise because it reflects only April to December of that year; we did not collect data in January to March, which, in subsequent years, had higher volume of abortions. In addition, these months were pre-*Dobbs*, before abortion bans were enacted.

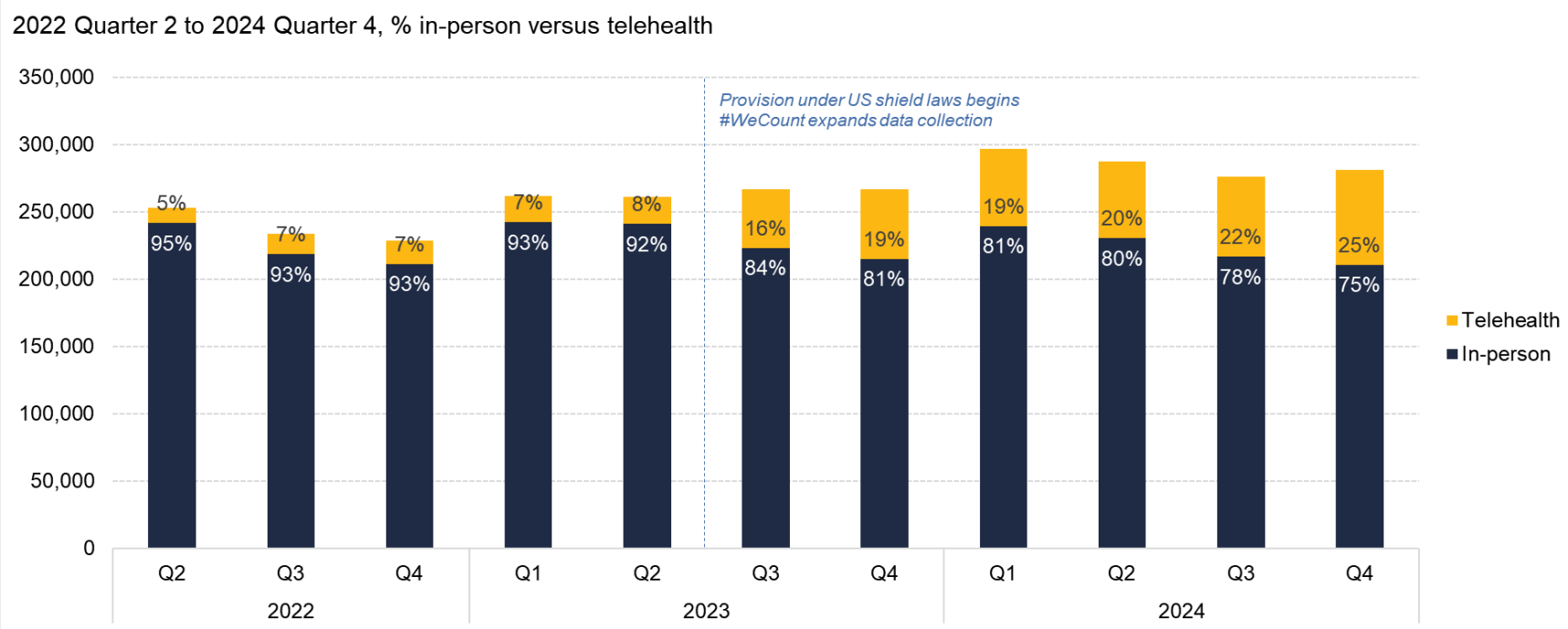
The monthly number of abortions increased each year



Comparisons of year over year show that for most months the number of abortions in 2024 was higher than the number of abortions in the same month of 2023 or 2022.

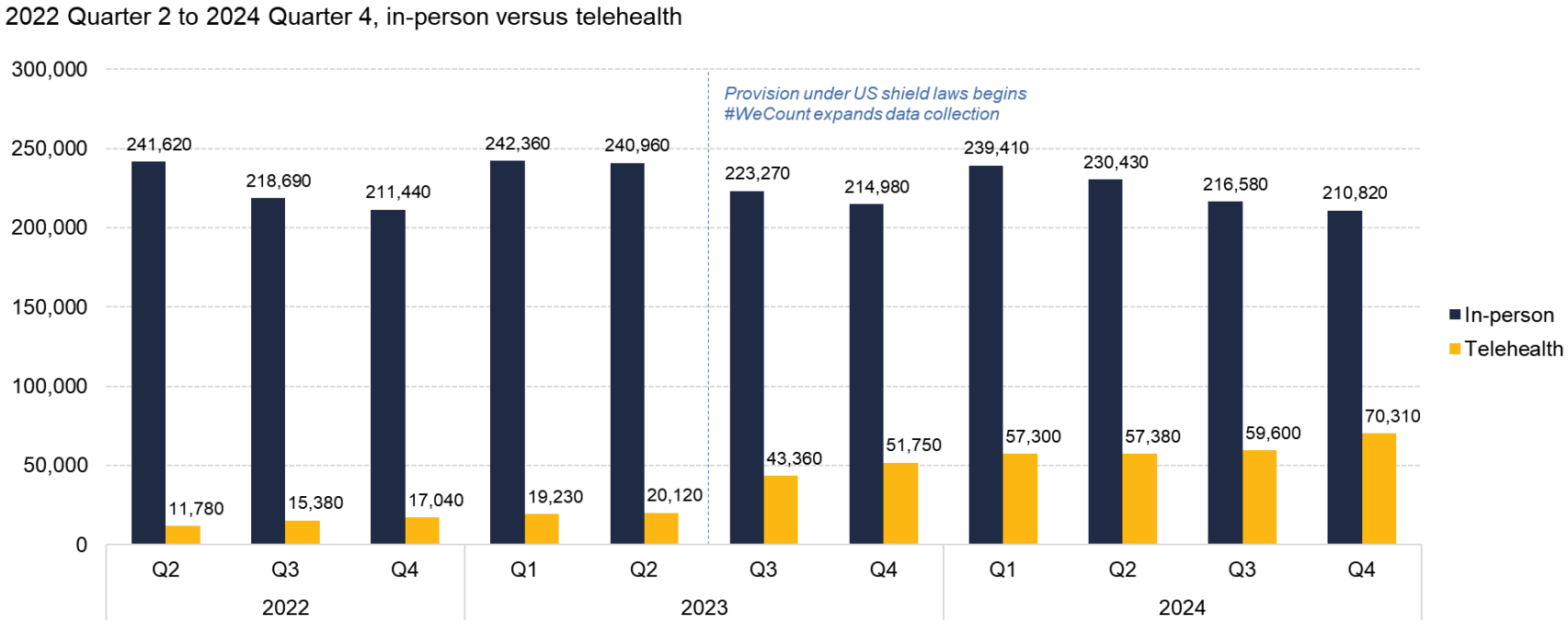
Telehealth findings

By Q4 of 2024, 1 in 4 abortions were provided via telehealth



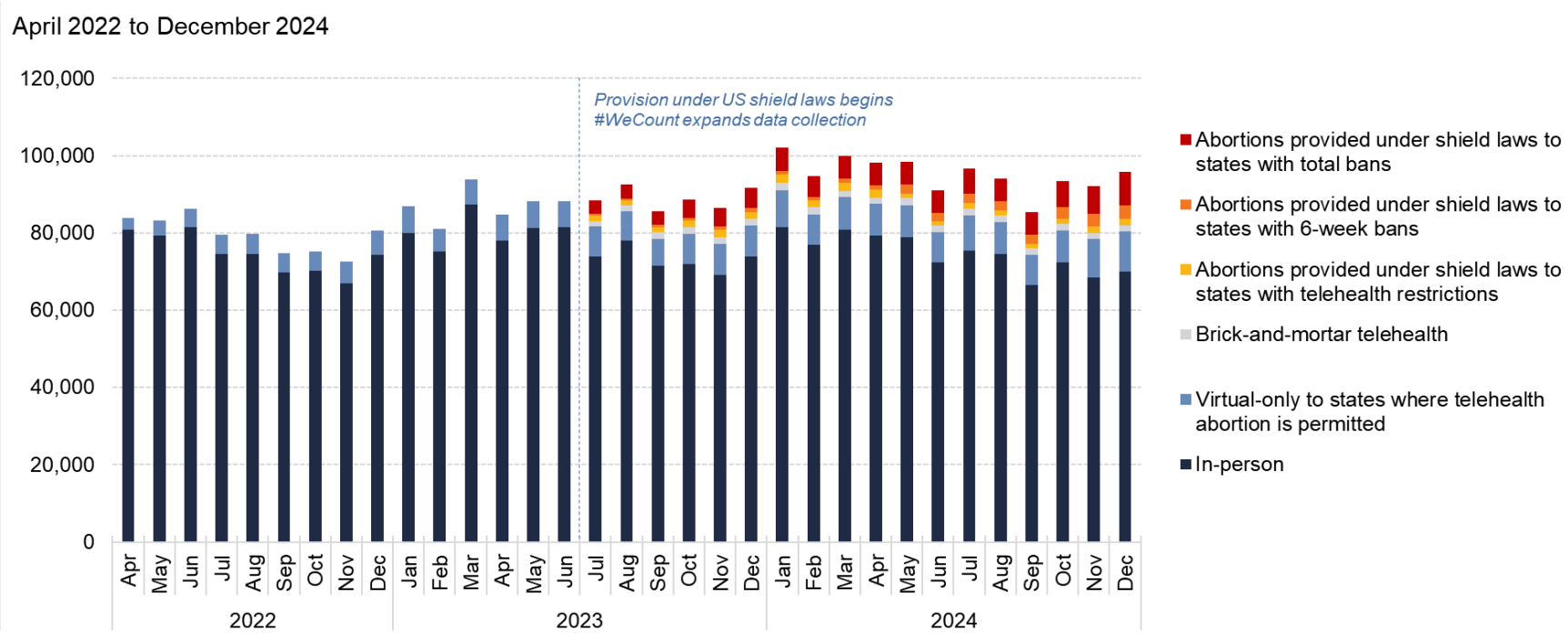
The proportion of abortions that were provided via telehealth increased over time from 5% in April-June of 2022 to 25% by the end of December 2024.

In-person abortion care declined slightly, while telehealth grew



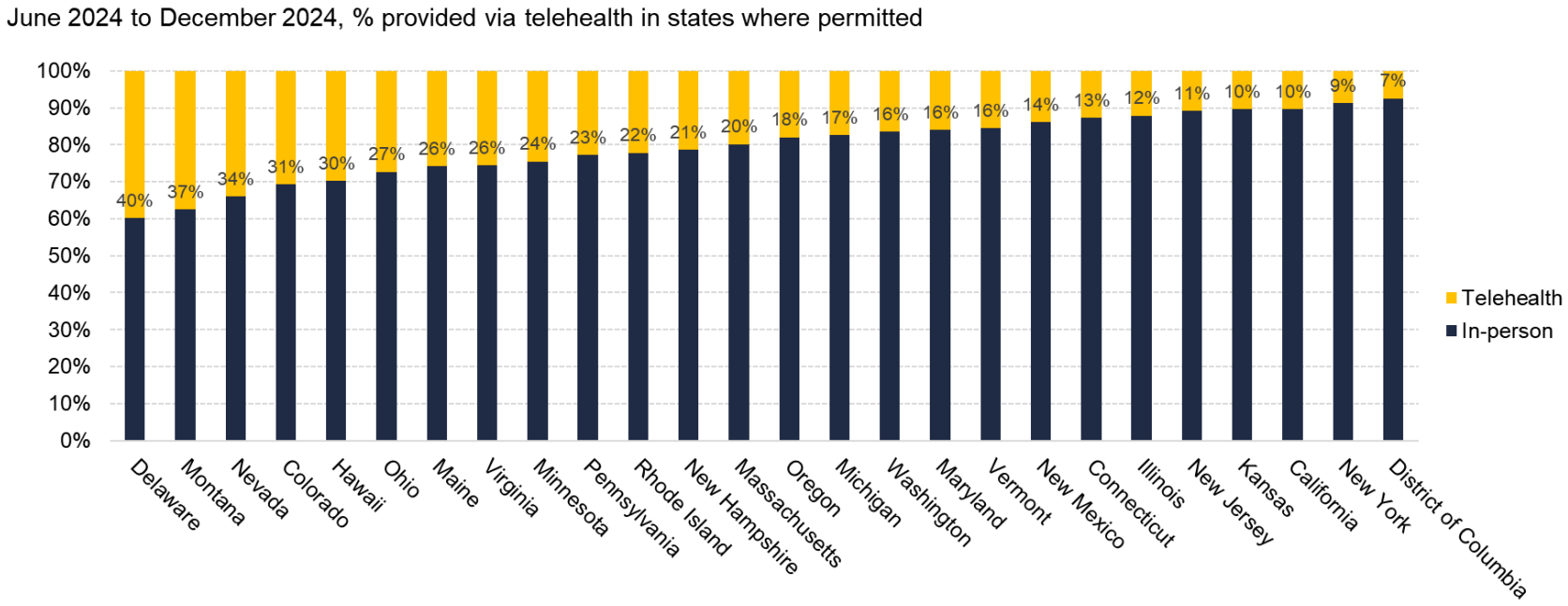
Telehealth abortion care (which involves mailing medication abortion pills) increased both in proportion and in absolute numbers over the study period. In-person abortion care (which includes both procedural abortions and medication abortion pills dispensed in person), was much more common than telehealth abortions. As telehealth has grown, the number of in-person abortions has not declined commensurately. The number of in-person abortions was lower in the second half of each year compared to the first half.

The majority of abortions still take place in-person



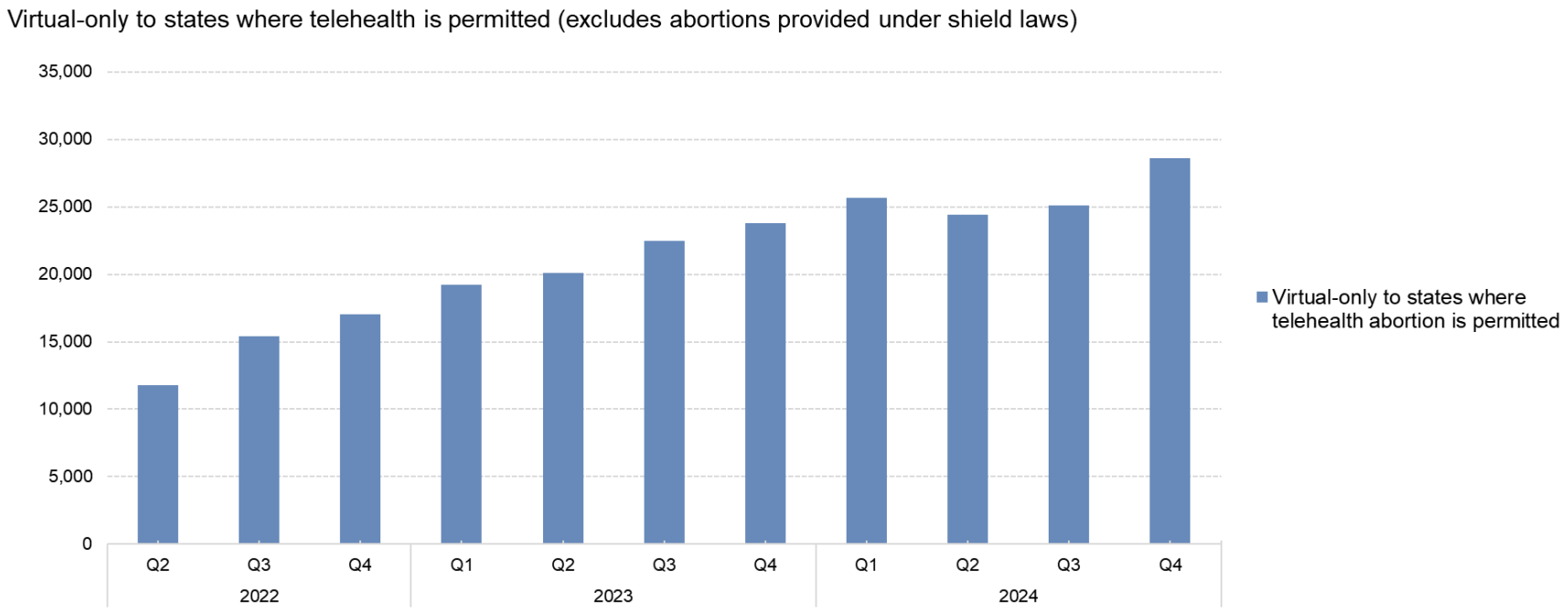
In the US, in-person provision continues to represent the majority of abortion care.

The proportion of abortions provided via telehealth varied by state, 2024



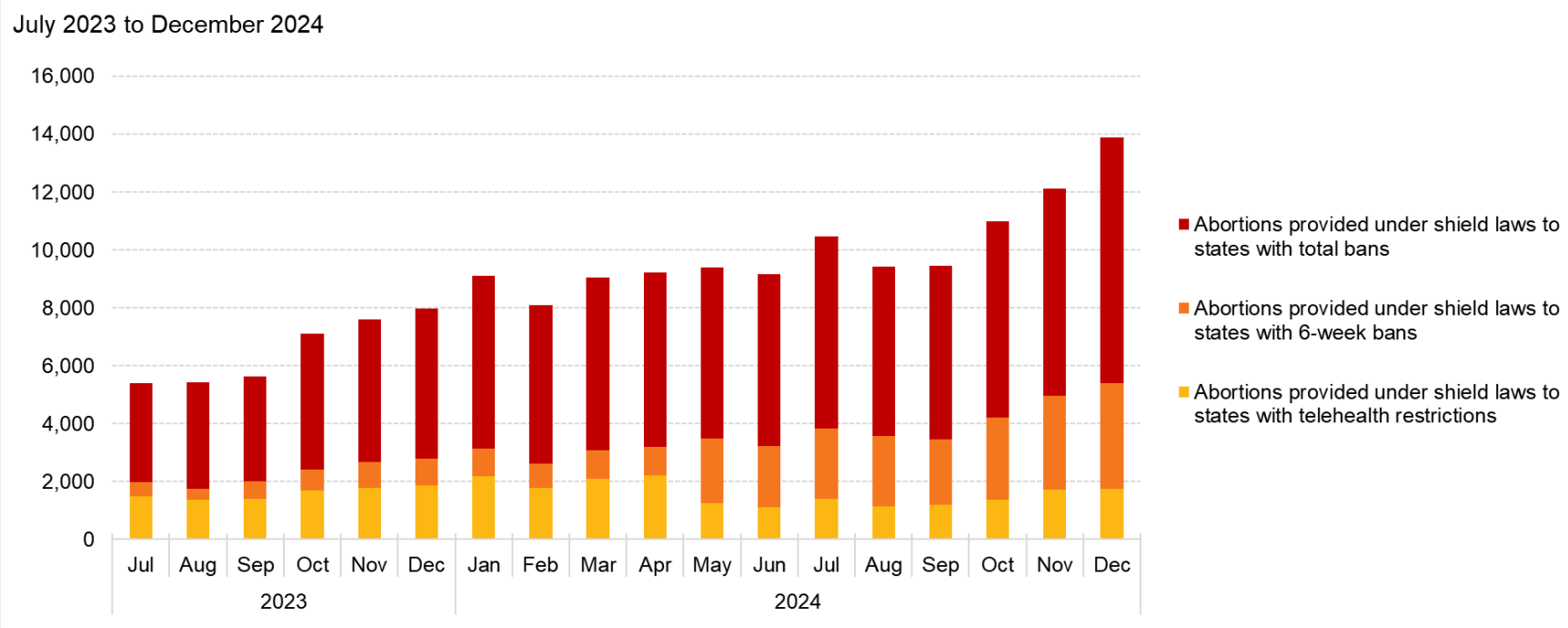
Across the US, in states that permit abortion and telehealth provision of abortion, there is substantial variation in the proportion of abortions provided via telehealth, ranging from 7% to 40%. In several larger states, telehealth is a smaller share of the abortions, at about 9-12% of all abortions.

Abortions provided by virtual-only clinics have increased since *Dobbs*



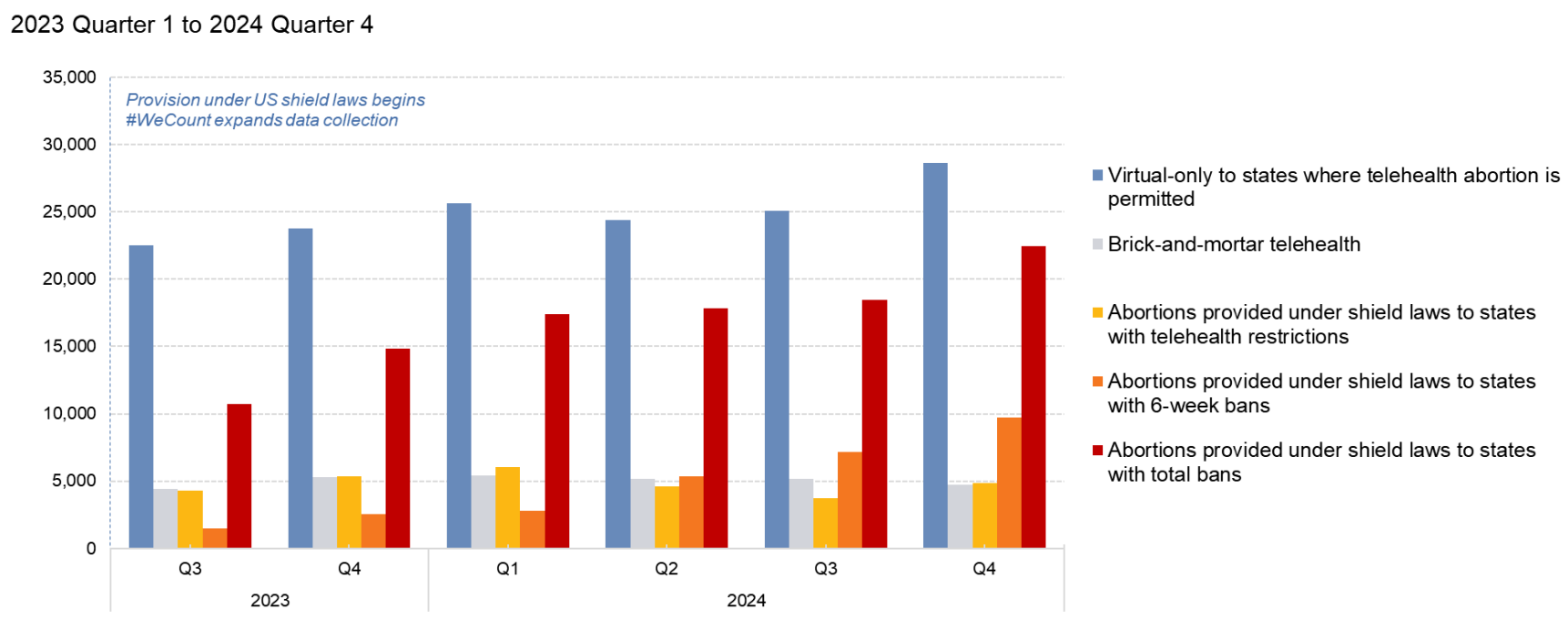
Virtual clinics (those that that are online only and have no brick-and mortar clinic) in states that permit abortion and telehealth abortion have provided an increasing number of abortions since 2022.

Abortions provided under shield laws have increased since this route to care became available



Providing abortions under shield laws involves mailing medication abortion pills to people in states with telehealth restrictions, 6-week bans, or total abortion bans. The number of abortions provided under shield laws has increased since providers began to offer abortion under shield laws in July 2023, with notable increases in provision to states with 6-week bans and total abortion bans. Some of the increase into states with 6-week bans is due to the states switching categories, when the states transitioned from having telehealth restrictions to having 6-week bans during this time period. By December 2024, abortions provided under shield laws totaled nearly 14,000 that month.

Legal climates appear to play an important role in telehealth use



Telehealth abortions provided by virtual clinics (those that that are online only and have no brick-and mortar clinic) to states that permit abortion and telehealth abortion have increased since 2023. Telehealth abortions provided by brick-and-mortar clinics have remained steady. Telehealth abortions provided into states with telehealth restrictions also remained relatively steady. Telehealth abortions provided into states with 6-week bans have increased; some of the increase into states with 6-week bans was due to the states switching from having telehealth restrictions to having 6-week bans during this time period. Telehealth abortions provided into states with total bans increased substantially by the end of 2024.

Half of abortions provided via telehealth in 2024 were facilitated by shield laws

2024 monthly average number of abortions		
	In-person	Telehealth
Abortion and telehealth permitted	60,780	10,360
Abortion permitted, telehealth restricted	8,610	1,610
6-week abortion ban, telehealth restricted	5,350	2,080
Abortion is totally banned	30	6,350

Disaggregating in-person and telehealth and summing up across states by legal climate in 2024, there were stark differences in mode of provision, with a larger proportion of abortions provided by telehealth with each restrictiveness category. In states where abortion and telehealth were permitted, on average, 15% of abortions were provided via telehealth each month. In states where abortion was permitted but telehealth was restricted, on average 16% of abortions were provided via telehealth each month. In states with 6-week bans, on average 28% of abortions were provided via telehealth each month. In states where abortion was totally banned, there was a monthly average of only 30 abortions provided in-person, under so-called exceptions, and over 99% of abortions were provided by telehealth. In 2024, the monthly average number of abortions provided under shield laws was about 10,000 per month. Abortions provided under shield laws accounted for 49% of all abortion provided via telehealth in 2024.

Background

#WeCount is a national effort that aims to report the monthly number of abortions in the US, by state and month starting in April 2022. #WeCount data include clinician-provided abortions, defined in this report as medication or procedural abortions completed by a licensed clinician within the US in a clinic, private medical office, hospital, or virtual-only clinic. This report does not reflect any self-managed abortions, defined as ending a pregnancy outside the formal healthcare system. These data reflect the status of abortion provision in the US and can be used by healthcare systems, public health practitioners, and policymakers so that their decisions can be informed by evidence.

Terminology

Delivery settings

- **Brick and mortar clinic:** A physical clinic where a patient can go to receive care
- **Virtual-only clinic:** An online-only provider

Delivery methods

- **Brick-and-mortar telehealth:** Telehealth abortions offered by a brick-and-mortar clinic
- **In-person care:** Abortions in which a clinician meets with the patient face-to-face; can be procedural or medication abortions
- **Self-managed abortion:** Abortion using medications, herbs, or something else, or obtaining pills from friends or online without clinician assistance
- **Telehealth abortion:** Medication abortion offered by a clinician through remote consultation with the patient, resulting in remote dispensing of medications by mail

Types of care

- **Medication abortion:** Abortion performed with medications, including mifepristone, misoprostol, and misoprostol alone
- **Procedural abortion:** Abortion performed with instrumentation, including uterine aspiration (manual or electric), dilation and curettage, dilation and evacuation, or dilation and extraction

Legal context

- **Shield laws:** Legal protections put in place by some states to reduce legal risk for clinicians who offer abortions to patients in states where abortion is prohibited or severely restricted

Methods

In early 2022, #WeCount developed a database of all clinics, private medical offices, hospitals, and virtual clinic providers in the US known to offer abortion care. We started with the Abortion Facility Database from Advancing New Standards in Reproductive

Health (ANSIRH) at University of California, San Francisco. Throughout the study period, we added new providers to our database as we became aware of them, using AbortionFinder.org and INeedanA.com to conduct regular searches in all 50 states and the District of Columbia. This report also includes abortions provided under shield laws by US-based licensed providers who are following their own state law. The Society provided compensation to participating facilities for each monthly submission.

The data in this report includes the monthly counts reported by providers for April 2022 through December 2024. In total, 83% of the abortions across the study period were based on data obtained from providers or health departments, while the remaining 17% of the data were imputed. The magnitude of imputation in each state is noted with symbols in the data tables. In 18 states, all known providers reported to #WeCount; we imputed any months not reported by these providers. For these imputations, we calculated the average percent change in abortion volume in the state and imputed values for providers with missing months. In the remaining 33 states and Washington, DC, some providers never reported to #WeCount; for these providers we imputed all months of data. To develop our imputations, we used information from news articles, contacts known to the non-reporting clinics, knowledge of the abortion volumes by state, or the median #WeCount number for the clinic or hospital type. To compute medians, we categorized reporters to #WeCount into five types of facilities and calculated the median for April and May 2022 for each category: 1) small abortion clinics, 2) large abortion clinics, 3) primary care clinics, 4) low volume hospitals, and 5) high volume hospitals. In ten states we also used publicly available state administrative data to supplement our estimates. We developed separate imputations for virtual clinics that did not submit data to us, using the median number of abortions that were provided by other virtual clinics in the state.

We reported the number of abortions by state and by restrictiveness level using three categories: states that banned abortion, states that restricted abortion to before detection of embryonic cardiac activity, also referred to as a “6-week bans” because detection of such activity usually occurs around that point, and states that permitted abortion. These categories were based on the abortion policy in each state on the 15th of each month as reported by the New York Times. For a legal analysis of restrictions that prevent explicitly ban telehealth or implicitly preclude telehealth abortion, we rely on the RHITES map. Monthly state totals were rounded to the nearest 10.

#WeCount was deemed exempt by Advarra IRB. All major decisions were guided by a Research Steering Committee listed below. This research was sponsored by the Society of Family Planning.

Limitations

Counts are an underrepresentation of all abortions in the US. #WeCount has a comprehensive count of abortions provided by licensed clinicians, with more than 83% of all abortions reported and about 17% imputed. Abortions provided by individual

hospitals and private practice clinicians may be underreported. These counts also do not include abortions that take place in the US outside of the formal health care system.

We do not have estimates of the proportion of people who did not take the medications sent to them. These data show telehealth abortions as the providers documented mailing them. Some people may not have taken the pills, and we do not have an estimate of that. Use of shield laws to provide abortion via telehealth into states with total or 6-week abortion bans or with telehealth abortion restrictions started in July 2023, and #WeCount began to count abortions provided under shield laws at that time. Because of this transition in abortion provision, #WeCount does not have a comparator for previous months.

#WeCount cannot estimate the unmet needs for abortion. Research has yet to accurately capture the underlying need for abortion. We don't have any counts of the number of people who needed an abortion and didn't get it.
#WeCount is designed to describe changes in abortion access and provision, rather than to explain why these changes are taking place.

Contributors

#WeCount is made possible by the many abortion providers who generously reported their data in support of this effort. This report was prepared by the #WeCount Co-Chairs and Society of Family Planning staff, with guidance from the Research Steering Committee, as well as many members of the Society of Family Planning community.

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EXHIBIT 94

Society of Family Planning, *#WeCount Report April 2022 to March 2024* (August 7, 2024)

Data Table

State	Month	Total abortions	In-person	Total telehealth	Virtual-only	Brick-and-morta
_All US states	4/1/2022	83,930	80,790	3,140	3,140	0
_All US states	5/1/2022	83,320	79,380	3,940	3,940	0
_All US states	6/1/2022	86,150	81,450	4,700	4,700	0
_All US states	7/1/2022	79,610	74,480	5,130	5,130	0
_All US states	8/1/2022	79,750	74,510	5,240	5,240	0
_All US states	9/1/2022	74,710	69,700	5,010	5,010	0
_All US states	10/1/2022	75,250	70,110	5,140	5,140	0
_All US states	11/1/2022	72,600	67,020	5,580	5,580	0
_All US states	12/1/2022	80,630	74,310	6,320	6,320	0
_All US states	1/1/2023	86,810	79,890	6,920	6,920	0
_All US states	2/1/2023	80,970	75,220	5,750	5,750	0
_All US states	3/1/2023	93,810	87,250	6,560	6,560	0
_All US states	4/1/2023	84,730	78,090	6,640	6,640	0
_All US states	5/1/2023	88,240	81,310	6,930	6,930	0
_All US states	6/1/2023	88,110	81,560	6,550	6,550	0
_All US states	7/1/2023	88,430	73,910	14,520	13,250	1,270
_All US states	8/1/2023	92,500	77,930	14,570	13,080	1,490
_All US states	9/1/2023	85,700	71,430	14,270	12,630	1,640
_All US states	10/1/2023	88,570	71,930	16,640	14,910	1,730
_All US states	11/1/2023	86,570	69,200	17,370	15,570	1,800
_All US states	12/1/2023	91,590	73,850	17,740	16,000	1,740
_All US states	1/1/2024	102,040	81,480	20,560	18,670	1,890
_All US states	2/1/2024	94,720	77,010	17,710	15,880	1,830
_All US states	3/1/2024	99,950	80,920	19,030	17,330	1,700
_All US states	4/1/2024	98,280	79,290	18,990	17,390	1,600
_All US states	5/1/2024	98,410	78,830	19,580	17,700	1,880
_All US states	6/1/2024	91,120	72,310	18,810	17,100	1,710
_All US states	7/1/2024	96,740	75,490	21,250	19,410	1,840
_All US states	8/1/2024	94,020	74,560	19,460	17,700	1,760
_All US states	9/1/2024	85,420	66,530	18,890	17,330	1,560
_All US states	10/1/2024	93,360	72,410	20,950	19,220	1,730
_All US states	11/1/2024	92,060	68,520	23,540	22,030	1,510
_All US states	12/1/2024	95,710	69,890	25,820	24,340	1,480
_Permitted	4/1/2022	80,800	77,640	3,160	3,160	0
_Permitted	5/1/2022	80,360	76,420	3,940	3,940	0
_Permitted	6/1/2022	83,540	78,850	4,690	4,690	0
_Permitted	7/1/2022	78,520	73,380	5,140	5,140	0
_Permitted	8/1/2022	76,630	71,400	5,230	5,230	0
_Permitted	9/1/2022	71,740	66,740	5,000	5,000	0
_Permitted	10/1/2022	72,840	67,680	5,160	5,160	0
_Permitted	11/1/2022	69,890	64,330	5,560	5,560	0
_Permitted	12/1/2022	78,230	71,880	6,350	6,350	0
_Permitted	1/1/2023	84,160	77,240	6,920	6,920	0

_Permitted	2/1/2023	78,580	72,830	5,750	5,750	0
_Permitted	3/1/2023	90,760	84,230	6,530	6,530	0
_Permitted	4/1/2023	82,140	75,510	6,630	6,630	0
_Permitted	5/1/2023	85,780	78,860	6,920	6,920	0
_Permitted	6/1/2023	85,670	79,120	6,550	6,550	0
_Permitted	7/1/2023	81,890	71,230	10,660	9,370	1,290
_Permitted	8/1/2023	86,040	75,520	10,520	9,020	1,500
_Permitted	9/1/2023	79,080	68,990	10,090	8,440	1,650
_Permitted	10/1/2023	80,750	69,510	11,240	9,510	1,730
_Permitted	11/1/2023	78,290	66,690	11,600	9,780	1,820
_Permitted	12/1/2023	82,850	71,180	11,670	9,920	1,750
_Permitted	1/1/2024	92,430	78,760	13,670	11,770	1,900
_Permitted	2/1/2024	86,020	74,610	11,410	9,560	1,850
_Permitted	3/1/2024	90,160	78,080	12,080	10,370	1,710
_Permitted	4/1/2024	88,780	76,720	12,060	10,450	1,610
_Permitted	5/1/2024	82,730	71,270	11,460	9,560	1,900
_Permitted	6/1/2024	76,300	65,570	10,730	9,010	1,720
_Permitted	7/1/2024	80,880	68,710	12,170	10,340	1,830
_Permitted	8/1/2024	78,940	67,680	11,260	9,480	1,780
_Permitted	9/1/2024	70,890	60,250	10,640	9,070	1,570
_Permitted	10/1/2024	76,880	65,510	11,370	9,610	1,760
_Permitted	11/1/2024	75,130	62,020	13,110	11,590	1,520
_Permitted	12/1/2024	77,210	63,500	13,710	12,210	1,500
_Gestational lin	4/1/2022	3,190	3,190	0	0	0
_Gestational lin	5/1/2022	2,990	2,990	0	0	0
_Gestational lin	6/1/2022	2,600	2,600	0	0	0
Gestational lin	7/1/2022	990	990	0	0	0
_Gestational lin	8/1/2022	3,110	3,110	0	0	0
_Gestational lin	9/1/2022	2,260	2,260	0	0	0
_Gestational lin	10/1/2022	2,380	2,380	0	0	0
_Gestational lin	11/1/2022	2,690	2,690	0	0	0
_Gestational lin	12/1/2022	2,420	2,420	0	0	0
_Gestational lin	1/1/2023	2,640	2,640	0	0	0
_Gestational lin	2/1/2023	2,390	2,390	0	0	0
_Gestational lin	3/1/2023	2,980	2,980	0	0	0
_Gestational lin	4/1/2023	2,590	2,590	0	0	0
_Gestational lin	5/1/2023	2,440	2,440	0	0	0
_Gestational lin	6/1/2023	2,470	2,470	0	0	0
_Gestational lin	7/1/2023	3,080	2,590	490	490	0
_Gestational lin	8/1/2023	2,740	2,370	370	370	0
_Gestational lin	9/1/2023	3,020	2,410	610	610	0
_Gestational lin	10/1/2023	3,130	2,390	740	740	0
_Gestational lin	11/1/2023	3,310	2,420	890	890	0
_Gestational lin	12/1/2023	3,530	2,610	920	920	0

_Gestational lin	1/1/2024	3,640	2,670	970	970	0
_Gestational lin	2/1/2024	3,220	2,370	850	850	0
_Gestational lin	3/1/2024	3,810	2,820	990	990	0
_Gestational lin	4/1/2024	3,480	2,490	990	990	0
_Gestational lin	5/1/2024	9,770	7,520	2,250	2,250	0
_Gestational lin	6/1/2024	8,880	6,770	2,110	2,110	0
_Gestational lin	7/1/2024	9,230	6,790	2,440	2,440	0
_Gestational lin	8/1/2024	9,250	6,820	2,430	2,430	0
_Gestational lin	9/1/2024	8,480	6,210	2,270	2,270	0
_Gestational lin	10/1/2024	9,680	6,830	2,850	2,850	0
_Gestational lin	11/1/2024	9,760	6,530	3,230	3,230	0
_Gestational lin	12/1/2024	9,980	6,350	3,630	3,630	0
_Banned	4/1/2022	0	0	0	0	0
_Banned	5/1/2022	0	0	0	0	0
_Banned	6/1/2022	0	0	0	0	0
_Banned	7/1/2022	120	100	20	20	0
_Banned	8/1/2022	10	0	10	10	0
_Banned	9/1/2022	730	710	20	20	0
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_Banned	11/1/2022	30	10	20	20	0
_Banned	12/1/2022	20	0	20	20	0
_Banned	1/1/2023	30	10	20	20	0
_Banned	2/1/2023	20	0	20	20	0
_Banned	3/1/2023	60	10	50	50	0
_Banned	4/1/2023	20	10	10	10	0
_Banned	5/1/2023	20	10	10	10	0
Banned	6/1/2023	10	0	10	10	0
_Banned	7/1/2023	3,440	20	3,420	3,420	0
_Banned	8/1/2023	3,720	40	3,680	3,680	0
_Banned	9/1/2023	3,650	40	3,610	3,610	0
_Banned	10/1/2023	4,690	10	4,680	4,680	0
_Banned	11/1/2023	4,980	50	4,930	4,930	0
_Banned	12/1/2023	5,220	20	5,200	5,200	0
_Banned	1/1/2024	5,990	30	5,960	5,960	0
_Banned	2/1/2024	5,480	20	5,460	5,460	0
_Banned	3/1/2024	6,000	30	5,970	5,970	0
_Banned	4/1/2024	6,040	40	6,000	6,000	0
_Banned	5/1/2024	5,920	20	5,900	5,900	0
_Banned	6/1/2024	5,970	10	5,960	5,960	0
_Banned	7/1/2024	6,650	20	6,630	6,630	0
_Banned	8/1/2024	5,850	20	5,830	5,830	0
_Banned	9/1/2024	6,050	40	6,010	6,010	0
_Banned	10/1/2024	6,810	30	6,780	6,780	0
_Banned	11/1/2024	7,190	10	7,180	7,180	0

_Banned	12/1/2024	8,550	30	8,520	8,520	0
_Abortions prov	4/1/2022	0		0	0	
_Abortions prov	5/1/2022	0		0	0	
_Abortions prov	6/1/2022	0		0	0	
_Abortions prov	7/1/2022	0		0	0	
_Abortions prov	8/1/2022	0		0	0	
_Abortions prov	9/1/2022	0		0	0	
_Abortions prov	10/1/2022	0		0	0	
_Abortions prov	11/1/2022	0		0	0	
_Abortions prov	12/1/2022	0		0	0	
_Abortions prov	1/1/2023	0		0	0	
_Abortions prov	2/1/2023	0		0	0	
_Abortions prov	3/1/2023	0		0	0	
_Abortions prov	4/1/2023	0		0	0	
_Abortions prov	5/1/2023	0		0	0	
_Abortions prov	6/1/2023	0		0	0	
_Abortions prov	7/1/2023	1,500		1,500	1,500	
_Abortions prov	8/1/2023	1,380		1,380	1,380	
_Abortions prov	9/1/2023	1,410		1,410	1,410	
_Abortions prov	10/1/2023	1,690		1,690	1,690	
_Abortions prov	11/1/2023	1,790		1,790	1,790	
_Abortions prov	12/1/2023	1,870		1,870	1,870	
_Abortions prov	1/1/2024	2,180		2,180	2,180	
_Abortions prov	2/1/2024	1,770		1,770	1,770	
_Abortions prov	3/1/2024	2,090		2,090	2,090	
_Abortions prov	4/1/2024	2,220		2,220	2,220	
_Abortions prov	5/1/2024	1,250		1,250	1,250	
_Abortions prov	6/1/2024	1,110		1,110	1,110	
_Abortions prov	7/1/2024	1,400		1,400	1,400	
_Abortions prov	8/1/2024	1,150		1,150	1,150	
_Abortions prov	9/1/2024	1,200		1,200	1,200	
_Abortions prov	10/1/2024	1,370		1,370	1,370	
_Abortions prov	11/1/2024	1,730		1,730	1,730	
_Abortions prov	12/1/2024	1,760		1,760	1,760	
_Abortions prov	4/1/2022	0		0	0	
_Abortions prov	5/1/2022	0		0	0	
_Abortions prov	6/1/2022	0		0	0	
_Abortions prov	7/1/2022	0		0	0	
_Abortions prov	8/1/2022	0		0	0	
_Abortions prov	9/1/2022	0		0	0	
_Abortions prov	10/1/2022	0		0	0	
_Abortions prov	11/1/2022	0		0	0	
_Abortions prov	12/1/2022	0		0	0	
_Abortions prov	1/1/2023	0		0	0	

_Abortions prov	2/1/2023	0	0	0
_Abortions prov	3/1/2023	0	0	0
_Abortions prov	4/1/2023	0	0	0
_Abortions prov	5/1/2023	0	0	0
_Abortions prov	6/1/2023	0	0	0
_Abortions prov	7/1/2023	490	490	490
_Abortions prov	8/1/2023	370	370	370
_Abortions prov	9/1/2023	610	610	610
_Abortions prov	10/1/2023	740	740	740
_Abortions prov	11/1/2023	890	890	890
_Abortions prov	12/1/2023	920	920	920
_Abortions prov	1/1/2024	970	970	970
_Abortions prov	2/1/2024	850	850	850
_Abortions prov	3/1/2024	990	990	990
_Abortions prov	4/1/2024	990	990	990
_Abortions prov	5/1/2024	2,250	2,250	2,250
_Abortions prov	6/1/2024	2,110	2,110	2,110
_Abortions prov	7/1/2024	2,440	2,440	2,440
_Abortions prov	8/1/2024	2,430	2,430	2,430
_Abortions prov	9/1/2024	2,270	2,270	2,270
_Abortions prov	10/1/2024	2,850	2,850	2,850
_Abortions prov	11/1/2024	3,230	3,230	3,230
_Abortions prov	12/1/2024	3,630	3,630	3,630
_Abortions prov	4/1/2022	0	0	0
_Abortions prov	5/1/2022	0	0	0
_Abortions prov	6/1/2022	0	0	0
_Abortions prov	7/1/2022	0	0	0
_Abortions prov	8/1/2022	0	0	0
_Abortions prov	9/1/2022	0	0	0
_Abortions prov	10/1/2022	0	0	0
_Abortions prov	11/1/2022	0	0	0
_Abortions prov	12/1/2022	0	0	0
_Abortions prov	1/1/2023	0	0	0
_Abortions prov	2/1/2023	0	0	0
_Abortions prov	3/1/2023	0	0	0
_Abortions prov	4/1/2023	0	0	0
_Abortions prov	5/1/2023	0	0	0
_Abortions prov	6/1/2023	0	0	0
_Abortions prov	7/1/2023	3,420	3,420	3,420
_Abortions prov	8/1/2023	3,680	3,680	3,680
_Abortions prov	9/1/2023	3,610	3,610	3,610
_Abortions prov	10/1/2023	4,680	4,680	4,680
_Abortions prov	11/1/2023	4,930	4,930	4,930
_Abortions prov	12/1/2023	5,200	5,200	5,200

_Abortions prov	1/1/2024	5,960		5,960	5,960	
_Abortions prov	2/1/2024	5,460		5,460	5,460	
_Abortions prov	3/1/2024	5,970		5,970	5,970	
_Abortions prov	4/1/2024	6,000		6,000	6,000	
_Abortions prov	5/1/2024	5,900		5,900	5,900	
_Abortions prov	6/1/2024	5,960		5,960	5,960	
_Abortions prov	7/1/2024	6,630		6,630	6,630	
_Abortions prov	8/1/2024	5,840		5,840	5,840	
_Abortions prov	9/1/2024	6,000		6,000	6,000	
_Abortions prov	10/1/2024	6,760		6,760	6,760	
_Abortions prov	11/1/2024	7,160		7,160	7,160	
_Abortions prov	12/1/2024	8,500		8,500	8,500	
Alabama	4/1/2022	650	650	0	0	0
Alabama	5/1/2022	620	620	0	0	0
Alabama	6/1/2022	520	520	0	0	0
Alabama	7/1/2022	0	0	0	0	0
Alabama	8/1/2022	0	0	0	0	0
Alabama	9/1/2022	0	0	0	0	0
Alabama	10/1/2022	0	0	0	0	0
Alabama	11/1/2022	0	0	0	0	0
Alabama	12/1/2022	0	0	0	0	0
Alabama	1/1/2023	0	0	0	0	0
Alabama	2/1/2023	0	0	0	0	0
Alabama	3/1/2023	0	0	0	0	0
Alabama	4/1/2023	0	0	0	0	0
Alabama	5/1/2023	0	0	0	0	0
Alabama	6/1/2023	0	0	0	0	0
Alabama	7/1/2023	220	0	220	220	0
Alabama	8/1/2023	250	0	250	250	0
Alabama	9/1/2023	250	0	250	250	0
Alabama	10/1/2023	300	0	300	300	0
Alabama	11/1/2023	340	0	340	340	0
Alabama	12/1/2023	360	0	360	360	0
Alabama	1/1/2024	390	0	390	390	0
Alabama	2/1/2024	410	0	410	410	0
Alabama	3/1/2024	420	0	420	420	0
Alabama	4/1/2024	420	0	420	420	0
Alabama	5/1/2024	440	0	440	440	0
Alabama	6/1/2024	440	0	440	440	0
Alabama	7/1/2024	530	0	530	530	0
Alabama	8/1/2024	450	0	450	450	0
Alabama	9/1/2024	450	0	450	450	0
Alabama	10/1/2024	470	0	470	470	0
Alabama	11/1/2024	530	0	530	530	0

Alabama	12/1/2024	660	0	660	660	0
Alaska	4/1/2022	120	110	10	10	0
Alaska	5/1/2022	130	120	10	10	0
Alaska	6/1/2022	140	120	20	20	0
Alaska	7/1/2022	110	90	20	20	0
Alaska	8/1/2022	140	110	30	30	0
Alaska	9/1/2022	150	120	30	30	0
Alaska	10/1/2022	130	110	20	20	0
Alaska	11/1/2022	130	110	20	20	0
Alaska	12/1/2022	150	120	30	30	0
Alaska	1/1/2023	130	100	30	30	0
Alaska	2/1/2023	140	120	20	20	0
Alaska	3/1/2023	140	120	20	20	0
Alaska	4/1/2023	110	90	20	20	0
Alaska	5/1/2023	160	130	30	30	0
Alaska	6/1/2023	140	120	20	20	0
Alaska	7/1/2023	170	140	30	30	0
Alaska	8/1/2023	170	140	30	30	0
Alaska	9/1/2023	150	110	40	40	0
Alaska	10/1/2023	180	140	40	40	0
Alaska	11/1/2023	150	120	30	30	0
Alaska	12/1/2023	140	100	40	40	0
Alaska	1/1/2024	130	110	20	20	0
Alaska	2/1/2024	140	120	20	20	0
Alaska	3/1/2024	140	110	30	30	0
Alaska	4/1/2024	160	130	30	30	0
Alaska	5/1/2024	160	130	30	30	0
Alaska	6/1/2024	170	130	40	40	0
Alaska	7/1/2024	150	120	30	30	0
Alaska	8/1/2024	140	110	30	30	0
Alaska	9/1/2024	130	100	30	30	0
Alaska	10/1/2024	130	100	30	30	0
Alaska	11/1/2024	160	120	40	40	0
Alaska	12/1/2024	150	100	50	50	0
Arizona	4/1/2022	1,320	1,320	0	0	0
Arizona	5/1/2022	1,470	1,470	0	0	0
Arizona	6/1/2022	1,170	1,170	0	0	0
Arizona	7/1/2022	210	210	0	0	0
Arizona	8/1/2022	720	720	0	0	0
Arizona	9/1/2022	610	610	0	0	0
Arizona	10/1/2022	420	420	0	0	0
Arizona	11/1/2022	790	790	0	0	0
Arizona	12/1/2022	820	820	0	0	0
Arizona	1/1/2023	1,120	1,120	0	0	0

Arizona	2/1/2023	990	990	0	0	0
Arizona	3/1/2023	1,250	1,250	0	0	0
Arizona	4/1/2023	1,000	1,000	0	0	0
Arizona	5/1/2023	1,150	1,150	0	0	0
Arizona	6/1/2023	1,090	1,090	0	0	0
Arizona	7/1/2023	1,280	1,030	250	250	0
Arizona	8/1/2023	1,350	1,120	230	230	0
Arizona	9/1/2023	1,410	1,120	290	290	0
Arizona	10/1/2023	1,310	1,020	290	290	0
Arizona	11/1/2023	1,230	950	280	280	0
Arizona	12/1/2023	1,260	1,010	250	250	0
Arizona	1/1/2024	1,570	1,250	320	320	0
Arizona	2/1/2024	1,480	1,190	290	290	0
Arizona	3/1/2024	1,580	1,230	350	350	0
Arizona	4/1/2024	1,470	1,110	360	360	0
Arizona	5/1/2024	1,430	1,120	310	310	0
Arizona	6/1/2024	1,310	1,050	260	260	0
Arizona	7/1/2024	1,420	1,080	340	340	0
Arizona	8/1/2024	1,350	1,050	300	300	0
Arizona	9/1/2024	1,280	950	330	330	0
Arizona	10/1/2024	1,290	960	330	330	0
Arizona	11/1/2024	1,350	960	390	390	0
Arizona	12/1/2024	1,480	1,010	470	470	0
Arkansas	4/1/2022	290	290	0	0	0
Arkansas	5/1/2022	340	340	0	0	0
Arkansas	6/1/2022	260	260	0	0	0
Arkansas	7/1/2022	0	0	0	0	0
Arkansas	8/1/2022	0	0	0	0	0
Arkansas	9/1/2022	0	0	0	0	0
Arkansas	10/1/2022	0	0	0	0	0
Arkansas	11/1/2022	0	0	0	0	0
Arkansas	12/1/2022	0	0	0	0	0
Arkansas	1/1/2023	0	0	0	0	0
Arkansas	2/1/2023	0	0	0	0	0
Arkansas	3/1/2023	0	0	0	0	0
Arkansas	4/1/2023	0	0	0	0	0
Arkansas	5/1/2023	0	0	0	0	0
Arkansas	6/1/2023	0	0	0	0	0
Arkansas	7/1/2023	130	0	130	130	0
Arkansas	8/1/2023	140	0	140	140	0
Arkansas	9/1/2023	140	0	140	140	0
Arkansas	10/1/2023	180	0	180	180	0
Arkansas	11/1/2023	200	0	200	200	0
Arkansas	12/1/2023	180	0	180	180	0

Arkansas	1/1/2024	230	0	230	230	0
Arkansas	2/1/2024	230	0	230	230	0
Arkansas	3/1/2024	260	0	260	260	0
Arkansas	4/1/2024	220	0	220	220	0
Arkansas	5/1/2024	240	0	240	240	0
Arkansas	6/1/2024	260	0	260	260	0
Arkansas	7/1/2024	280	0	280	280	0
Arkansas	8/1/2024	220	0	220	220	0
Arkansas	9/1/2024	240	0	240	240	0
Arkansas	10/1/2024	260	0	260	260	0
Arkansas	11/1/2024	300	0	300	300	0
Arkansas	12/1/2024	330	0	330	330	0
California	4/1/2022	13,920	13,210	710	710	0
California	5/1/2022	13,910	13,040	870	870	0
California	6/1/2022	14,530	13,500	1,030	1,030	0
California	7/1/2022	14,180	13,050	1,130	1,130	0
California	8/1/2022	14,370	13,210	1,160	1,160	0
California	9/1/2022	12,640	11,620	1,020	1,020	0
California	10/1/2022	12,690	11,640	1,050	1,050	0
California	11/1/2022	12,830	11,750	1,080	1,080	0
California	12/1/2022	14,900	13,680	1,220	1,220	0
California	1/1/2023	15,900	14,470	1,430	1,430	0
California	2/1/2023	14,210	13,010	1,200	1,200	0
California	3/1/2023	16,300	15,000	1,300	1,300	0
California	4/1/2023	15,040	13,760	1,280	1,280	0
California	5/1/2023	15,750	14,360	1,390	1,390	0
California	6/1/2023	15,400	14,170	1,230	1,230	0
California	7/1/2023	14,290	12,790	1,500	1,310	190
California	8/1/2023	15,560	14,040	1,520	1,260	260
California	9/1/2023	14,130	12,810	1,320	1,110	210
California	10/1/2023	14,380	12,780	1,600	1,270	330
California	11/1/2023	13,720	12,160	1,560	1,200	360
California	12/1/2023	14,960	13,380	1,580	1,260	320
California	1/1/2024	17,260	15,420	1,840	1,500	340
California	2/1/2024	15,350	13,840	1,510	1,120	390
California	3/1/2024	15,990	14,460	1,530	1,190	340
California	4/1/2024	15,450	13,930	1,520	1,260	260
California	5/1/2024	15,840	14,330	1,510	1,240	270
California	6/1/2024	14,590	13,190	1,400	1,170	230
California	7/1/2024	15,830	14,350	1,480	1,230	250
California	8/1/2024	14,990	13,560	1,430	1,140	290
California	9/1/2024	13,820	12,410	1,410	1,130	280
California	10/1/2024	14,940	13,400	1,540	1,190	350
California	11/1/2024	13,930	12,310	1,620	1,370	250

California	12/1/2024	15,550	13,830	1,720	1,460	260
Colorado	4/1/2022	1,620	1,380	240	240	0
Colorado	5/1/2022	1,700	1,380	320	320	0
Colorado	6/1/2022	1,810	1,440	370	370	0
Colorado	7/1/2022	1,980	1,470	510	510	0
Colorado	8/1/2022	2,160	1,610	550	550	0
Colorado	9/1/2022	1,940	1,440	500	500	0
Colorado	10/1/2022	1,900	1,370	530	530	0
Colorado	11/1/2022	1,910	1,400	510	510	0
Colorado	12/1/2022	2,060	1,530	530	530	0
Colorado	1/1/2023	2,340	1,830	510	510	0
Colorado	2/1/2023	2,090	1,620	470	470	0
Colorado	3/1/2023	2,410	1,930	480	480	0
Colorado	4/1/2023	2,200	1,700	500	500	0
Colorado	5/1/2023	2,400	1,920	480	480	0
Colorado	6/1/2023	2,280	1,770	510	510	0
Colorado	7/1/2023	2,230	1,680	550	540	10
Colorado	8/1/2023	2,300	1,740	560	520	40
Colorado	9/1/2023	1,990	1,430	560	530	30
Colorado	10/1/2023	2,140	1,610	530	490	40
Colorado	11/1/2023	2,140	1,580	560	510	50
Colorado	12/1/2023	2,060	1,510	550	510	40
Colorado	1/1/2024	2,320	1,750	570	530	40
Colorado	2/1/2024	2,080	1,570	510	490	20
Colorado	3/1/2024	2,150	1,610	540	510	30
Colorado	4/1/2024	2,110	1,540	570	540	30
Colorado	5/1/2024	2,110	1,550	560	530	30
Colorado	6/1/2024	2,000	1,470	530	510	20
Colorado	7/1/2024	2,080	1,470	610	600	10
Colorado	8/1/2024	2,070	1,480	590	570	20
Colorado	9/1/2024	1,800	1,240	560	530	30
Colorado	10/1/2024	1,990	1,440	550	520	30
Colorado	11/1/2024	1,920	1,290	630	600	30
Colorado	12/1/2024	1,920	1,250	670	650	20
Connecticut	4/1/2022	920	860	60	60	0
Connecticut	5/1/2022	950	890	60	60	0
Connecticut	6/1/2022	970	910	60	60	0
Connecticut	7/1/2022	1,000	940	60	60	0
Connecticut	8/1/2022	930	850	80	80	0
Connecticut	9/1/2022	850	760	90	90	0
Connecticut	10/1/2022	860	780	80	80	0
Connecticut	11/1/2022	880	770	110	110	0
Connecticut	12/1/2022	960	830	130	130	0
Connecticut	1/1/2023	1,120	970	150	150	0

Connecticut	2/1/2023	1,000	890	110	110	0
Connecticut	3/1/2023	1,230	1,100	130	130	0
Connecticut	4/1/2023	1,250	1,100	150	150	0
Connecticut	5/1/2023	1,320	1,180	140	140	0
Connecticut	6/1/2023	1,290	1,140	150	150	0
Connecticut	7/1/2023	1,400	1,250	150	150	0
Connecticut	8/1/2023	1,240	1,100	140	140	0
Connecticut	9/1/2023	1,130	1,000	130	130	0
Connecticut	10/1/2023	1,260	1,110	150	150	0
Connecticut	11/1/2023	1,140	970	170	170	0
Connecticut	12/1/2023	1,260	1,090	170	170	0
Connecticut	1/1/2024	1,310	1,150	160	160	0
Connecticut	2/1/2024	1,110	990	120	120	0
Connecticut	3/1/2024	1,280	1,120	160	150	10
Connecticut	4/1/2024	1,160	1,010	150	140	10
Connecticut	5/1/2024	1,220	1,060	160	150	10
Connecticut	6/1/2024	1,110	990	120	110	10
Connecticut	7/1/2024	1,280	1,120	160	150	10
Connecticut	8/1/2024	1,190	1,030	160	140	20
Connecticut	9/1/2024	1,110	990	120	110	10
Connecticut	10/1/2024	1,180	1,040	140	120	20
Connecticut	11/1/2024	1,160	1,020	140	130	10
Connecticut	12/1/2024	1,160	980	180	170	10
Delaware	4/1/2022	220	190	30	30	0
Delaware	5/1/2022	230	190	40	40	0
Delaware	6/1/2022	270	230	40	40	0
Delaware	7/1/2022	250	210	40	40	0
Delaware	8/1/2022	270	200	70	70	0
Delaware	9/1/2022	300	240	60	60	0
Delaware	10/1/2022	300	240	60	60	0
Delaware	11/1/2022	310	250	60	60	0
Delaware	12/1/2022	350	290	60	60	0
Delaware	1/1/2023	270	200	70	70	0
Delaware	2/1/2023	240	180	60	60	0
Delaware	3/1/2023	300	240	60	60	0
Delaware	4/1/2023	260	180	80	80	0
Delaware	5/1/2023	270	210	60	60	0
Delaware	6/1/2023	310	230	80	80	0
Delaware	7/1/2023	310	220	90	90	0
Delaware	8/1/2023	280	190	90	80	10
Delaware	9/1/2023	270	190	80	70	10
Delaware	10/1/2023	300	200	100	90	10
Delaware	11/1/2023	320	220	100	90	10
Delaware	12/1/2023	300	190	110	100	10

Delaware	1/1/2024	360	230	130	110	20
Delaware	2/1/2024	320	210	110	100	10
Delaware	3/1/2024	310	190	120	110	10
Delaware	4/1/2024	340	240	100	90	10
Delaware	5/1/2024	350	240	110	100	10
Delaware	6/1/2024	290	200	90	80	10
Delaware	7/1/2024	330	180	150	140	10
Delaware	8/1/2024	310	180	130	120	10
Delaware	9/1/2024	310	190	120	110	10
Delaware	10/1/2024	310	210	100	90	10
Delaware	11/1/2024	330	200	130	120	10
Delaware	12/1/2024	340	200	140	130	10
District of Colur	4/1/2022	920	890	30	30	0
District of Colur	5/1/2022	880	850	30	30	0
District of Colur	6/1/2022	870	830	40	40	0
District of Colur	7/1/2022	870	810	60	60	0
District of Colur	8/1/2022	930	870	60	60	0
District of Colur	9/1/2022	820	780	40	40	0
District of Colur	10/1/2022	890	860	30	30	0
District of Colur	11/1/2022	810	780	30	30	0
District of Colur	12/1/2022	830	790	40	40	0
District of Colur	1/1/2023	900	860	40	40	0
District of Colur	2/1/2023	870	840	30	30	0
District of Colur	3/1/2023	1,080	1,030	50	50	0
District of Colur	4/1/2023	920	870	50	50	0
District of Colur	5/1/2023	1,000	940	60	60	0
District of Colur	6/1/2023	730	680	50	50	0
District of Colur	7/1/2023	770	720	50	50	0
District of Colur	8/1/2023	760	690	70	70	0
District of Colur	9/1/2023	610	570	40	40	0
District of Colur	10/1/2023	630	560	70	70	0
District of Colur	11/1/2023	610	530	80	80	0
District of Colur	12/1/2023	590	520	70	70	0
District of Colur	1/1/2024	710	610	100	100	0
District of Colur	2/1/2024	740	670	70	70	0
District of Colur	3/1/2024	800	710	90	90	0
District of Colur	4/1/2024	750	670	80	80	0
District of Colur	5/1/2024	830	750	80	80	0
District of Colur	6/1/2024	770	700	70	70	0
District of Colur	7/1/2024	910	830	80	80	0
District of Colur	8/1/2024	1,000	930	70	70	0
District of Colur	9/1/2024	890	830	60	60	0
District of Colur	10/1/2024	980	920	60	60	0
District of Colur	11/1/2024	870	810	60	60	0

District of Colur	12/1/2024	880	800	80	80	0
Florida	4/1/2022	5,400	5,400	0	0	0
Florida	5/1/2022	5,430	5,430	0	0	0
Florida	6/1/2022	5,980	5,980	0	0	0
Florida	7/1/2022	5,950	5,950	0	0	0
Florida	8/1/2022	6,410	6,410	0	0	0
Florida	9/1/2022	6,050	6,050	0	0	0
Florida	10/1/2022	6,530	6,530	0	0	0
Florida	11/1/2022	5,990	5,990	0	0	0
Florida	12/1/2022	7,000	7,000	0	0	0
Florida	1/1/2023	6,940	6,940	0	0	0
Florida	2/1/2023	6,760	6,760	0	0	0
Florida	3/1/2023	7,790	7,790	0	0	0
Florida	4/1/2023	6,930	6,930	0	0	0
Florida	5/1/2023	6,900	6,900	0	0	0
Florida	6/1/2023	6,850	6,850	0	0	0
Florida	7/1/2023	7,320	6,830	490	490	0
Florida	8/1/2023	7,170	6,720	450	450	0
Florida	9/1/2023	7,190	6,670	520	520	0
Florida	10/1/2023	7,130	6,510	620	620	0
Florida	11/1/2023	6,680	6,030	650	650	0
Florida	12/1/2023	7,040	6,330	710	710	0
Florida	1/1/2024	8,030	7,260	770	770	0
Florida	2/1/2024	7,550	6,900	650	650	0
Florida	3/1/2024	7,920	7,140	780	780	0
Florida	4/1/2024	9,680	8,790	890	890	0
Florida	5/1/2024	5,890	4,700	1,190	1,190	0
Florida	6/1/2024	5,320	4,230	1,090	1,090	0
Florida	7/1/2024	5,830	4,570	1,260	1,260	0
Florida	8/1/2024	5,630	4,530	1,100	1,100	0
Florida	9/1/2024	5,320	4,230	1,090	1,090	0
Florida	10/1/2024	5,550	4,190	1,360	1,360	0
Florida	11/1/2024	5,850	4,300	1,550	1,550	0
Florida	12/1/2024	5,840	4,190	1,650	1,650	0
Georgia	4/1/2022	4,540	4,390	150	150	0
Georgia	5/1/2022	4,230	4,080	150	150	0
Georgia	6/1/2022	4,450	4,290	160	160	0
Georgia	7/1/2022	4,430	4,370	60	60	0
Georgia	8/1/2022	1,970	1,970	0	0	0
Georgia	9/1/2022	2,260	2,260	0	0	0
Georgia	10/1/2022	2,380	2,380	0	0	0
Georgia	11/1/2022	2,690	2,690	0	0	0
Georgia	12/1/2022	2,420	2,420	0	0	0
Georgia	1/1/2023	2,640	2,640	0	0	0

Georgia	2/1/2023	2,390	2,390	0	0	0
Georgia	3/1/2023	2,980	2,980	0	0	0
Georgia	4/1/2023	2,590	2,590	0	0	0
Georgia	5/1/2023	2,440	2,440	0	0	0
Georgia	6/1/2023	2,470	2,470	0	0	0
Georgia	7/1/2023	2,770	2,400	370	370	0
Georgia	8/1/2023	2,740	2,370	370	370	0
Georgia	9/1/2023	2,670	2,250	420	420	0
Georgia	10/1/2023	2,690	2,190	500	500	0
Georgia	11/1/2023	2,870	2,250	620	620	0
Georgia	12/1/2023	3,050	2,410	640	640	0
Georgia	1/1/2024	3,060	2,370	690	690	0
Georgia	2/1/2024	2,700	2,090	610	610	0
Georgia	3/1/2024	3,220	2,510	710	710	0
Georgia	4/1/2024	2,970	2,240	730	730	0
Georgia	5/1/2024	3,310	2,520	790	790	0
Georgia	6/1/2024	3,050	2,310	740	740	0
Georgia	7/1/2024	2,840	1,980	860	860	0
Georgia	8/1/2024	2,870	1,980	890	890	0
Georgia	9/1/2024	2,440	1,690	750	750	0
Georgia	10/1/2024	3,280	2,290	990	990	0
Georgia	11/1/2024	3,000	1,890	1,110	1,110	0
Georgia	12/1/2024	3,210	1,910	1,300	1,300	0
Hawaii	4/1/2022	260	250	10	10	0
Hawaii	5/1/2022	220	210	10	10	0
Hawaii	6/1/2022	280	260	20	20	0
Hawaii	7/1/2022	230	210	20	20	0
Hawaii	8/1/2022	300	260	40	40	0
Hawaii	9/1/2022	280	260	20	20	0
Hawaii	10/1/2022	260	240	20	20	0
Hawaii	11/1/2022	280	270	10	10	0
Hawaii	12/1/2022	270	240	30	30	0
Hawaii	1/1/2023	320	280	40	40	0
Hawaii	2/1/2023	280	250	30	30	0
Hawaii	3/1/2023	300	260	40	40	0
Hawaii	4/1/2023	330	290	40	40	0
Hawaii	5/1/2023	330	280	50	50	0
Hawaii	6/1/2023	280	250	30	30	0
Hawaii	7/1/2023	300	230	70	40	30
Hawaii	8/1/2023	340	270	70	50	20
Hawaii	9/1/2023	290	220	70	50	20
Hawaii	10/1/2023	300	230	70	50	20
Hawaii	11/1/2023	300	210	90	70	20
Hawaii	12/1/2023	280	200	80	60	20

Hawaii	1/1/2024	340	250	90	70	20
Hawaii	2/1/2024	290	200	90	60	30
Hawaii	3/1/2024	330	240	90	60	30
Hawaii	4/1/2024	330	230	100	70	30
Hawaii	5/1/2024	280	200	80	60	20
Hawaii	6/1/2024	280	200	80	60	20
Hawaii	7/1/2024	320	240	80	70	10
Hawaii	8/1/2024	290	210	80	50	30
Hawaii	9/1/2024	280	200	80	50	30
Hawaii	10/1/2024	310	220	90	50	40
Hawaii	11/1/2024	270	190	80	60	20
Hawaii	12/1/2024	310	190	120	90	30
Idaho	4/1/2022	220	200	20	20	0
Idaho	5/1/2022	220	190	30	30	0
Idaho	6/1/2022	230	190	40	40	0
Idaho	7/1/2022	190	140	50	50	0
Idaho	8/1/2022	130	100	30	30	0
Idaho	9/1/2022	0	0	0	0	0
Idaho	10/1/2022	10	10	0	0	0
Idaho	11/1/2022	0	0	0	0	0
Idaho	12/1/2022	0	0	0	0	0
Idaho	1/1/2023	0	0	0	0	0
Idaho	2/1/2023	0	0	0	0	0
Idaho	3/1/2023	0	0	0	0	0
Idaho	4/1/2023	0	0	0	0	0
Idaho	5/1/2023	0	0	0	0	0
Idaho	6/1/2023	0	0	0	0	0
Idaho	7/1/2023	30	0	30	30	0
Idaho	8/1/2023	30	0	30	30	0
Idaho	9/1/2023	40	0	40	40	0
Idaho	10/1/2023	60	0	60	60	0
Idaho	11/1/2023	50	0	50	50	0
Idaho	12/1/2023	50	0	50	50	0
Idaho	1/1/2024	70	0	70	70	0
Idaho	2/1/2024	50	0	50	50	0
Idaho	3/1/2024	40	0	40	40	0
Idaho	4/1/2024	60	0	60	60	0
Idaho	5/1/2024	60	0	60	60	0
Idaho	6/1/2024	50	0	50	50	0
Idaho	7/1/2024	80	0	80	80	0
Idaho	8/1/2024	60	0	60	60	0
Idaho	9/1/2024	70	0	70	70	0
Idaho	10/1/2024	60	0	60	60	0
Idaho	11/1/2024	70	0	70	70	0

Idaho	12/1/2024	80	0	80	80	0
Illinois	4/1/2022	5,590	5,270	320	320	0
Illinois	5/1/2022	5,550	5,140	410	410	0
Illinois	6/1/2022	6,170	5,660	510	510	0
Illinois	7/1/2022	6,780	6,290	490	490	0
Illinois	8/1/2022	7,090	6,650	440	440	0
Illinois	9/1/2022	6,530	6,090	440	440	0
Illinois	10/1/2022	6,510	6,080	430	430	0
Illinois	11/1/2022	6,200	5,720	480	480	0
Illinois	12/1/2022	7,040	6,490	550	550	0
Illinois	1/1/2023	7,840	7,210	630	630	0
Illinois	2/1/2023	7,310	6,880	430	430	0
Illinois	3/1/2023	8,470	7,970	500	500	0
Illinois	4/1/2023	7,650	7,190	460	460	0
Illinois	5/1/2023	7,850	7,350	500	500	0
Illinois	6/1/2023	7,930	7,470	460	460	0
Illinois	7/1/2023	7,650	6,680	970	540	430
Illinois	8/1/2023	8,320	7,320	1,000	530	470
Illinois	9/1/2023	7,520	6,630	890	470	420
Illinois	10/1/2023	7,520	6,590	930	560	370
Illinois	11/1/2023	7,650	6,690	960	520	440
Illinois	12/1/2023	7,810	6,840	970	490	480
Illinois	1/1/2024	8,120	7,150	970	490	480
Illinois	2/1/2024	8,100	7,210	890	430	460
Illinois	3/1/2024	8,350	7,410	940	470	470
Illinois	4/1/2024	8,090	7,200	890	460	430
Illinois	5/1/2024	8,530	7,570	960	480	480
Illinois	6/1/2024	8,110	7,220	890	420	470
Illinois	7/1/2024	8,330	7,310	1,020	480	540
Illinois	8/1/2024	8,480	7,450	1,030	450	580
Illinois	9/1/2024	7,020	6,140	880	390	490
Illinois	10/1/2024	7,660	6,770	890	460	430
Illinois	11/1/2024	7,590	6,670	920	520	400
Illinois	12/1/2024	7,560	6,640	920	550	370
Indiana	4/1/2022	920	920	0	0	0
Indiana	5/1/2022	850	850	0	0	0
Indiana	6/1/2022	860	860	0	0	0
Indiana	7/1/2022	1,100	1,100	0	0	0
Indiana	8/1/2022	1,060	1,060	0	0	0
Indiana	9/1/2022	710	710	0	0	0
Indiana	10/1/2022	480	480	0	0	0
Indiana	11/1/2022	670	670	0	0	0
Indiana	12/1/2022	550	550	0	0	0
Indiana	1/1/2023	510	510	0	0	0

Indiana	2/1/2023	690	690	0	0	0
Indiana	3/1/2023	730	730	0	0	0
Indiana	4/1/2023	610	610	0	0	0
Indiana	5/1/2023	640	640	0	0	0
Indiana	6/1/2023	700	700	0	0	0
Indiana	7/1/2023	880	720	160	160	0
Indiana	8/1/2023	180	20	160	160	0
Indiana	9/1/2023	170	20	150	150	0
Indiana	10/1/2023	220	10	210	210	0
Indiana	11/1/2023	220	20	200	200	0
Indiana	12/1/2023	240	20	220	220	0
Indiana	1/1/2024	290	20	270	270	0
Indiana	2/1/2024	240	20	220	220	0
Indiana	3/1/2024	290	20	270	270	0
Indiana	4/1/2024	240	10	230	230	0
Indiana	5/1/2024	250	10	240	240	0
Indiana	6/1/2024	230	10	220	220	0
Indiana	7/1/2024	290	10	280	280	0
Indiana	8/1/2024	280	10	270	270	0
Indiana	9/1/2024	270	20	250	250	0
Indiana	10/1/2024	340	20	320	320	0
Indiana	11/1/2024	360	10	350	350	0
Indiana	12/1/2024	380	10	370	370	0
Iowa	4/1/2022	380	360	20	20	0
Iowa	5/1/2022	370	360	10	10	0
Iowa	6/1/2022	390	380	10	10	0
Iowa	7/1/2022	360	340	20	20	0
Iowa	8/1/2022	280	260	20	20	0
Iowa	9/1/2022	320	300	20	20	0
Iowa	10/1/2022	310	280	30	30	0
Iowa	11/1/2022	350	310	40	40	0
Iowa	12/1/2022	370	330	40	40	0
Iowa	1/1/2023	370	340	30	30	0
Iowa	2/1/2023	300	270	30	30	0
Iowa	3/1/2023	390	330	60	60	0
Iowa	4/1/2023	250	160	90	90	0
Iowa	5/1/2023	270	170	100	100	0
Iowa	6/1/2023	290	230	60	60	0
Iowa	7/1/2023	310	190	120	120	0
Iowa	8/1/2023	370	260	110	110	0
Iowa	9/1/2023	330	240	90	90	0
Iowa	10/1/2023	390	270	120	120	0
Iowa	11/1/2023	350	190	160	160	0
Iowa	12/1/2023	360	190	170	170	0

Iowa	1/1/2024	360	160	200	200	0
Iowa	2/1/2024	350	210	140	140	0
Iowa	3/1/2024	410	230	180	180	0
Iowa	4/1/2024	380	240	140	140	0
Iowa	5/1/2024	420	280	140	140	0
Iowa	6/1/2024	370	250	120	120	0
Iowa	7/1/2024	320	180	140	140	0
Iowa	8/1/2024	200	100	100	100	0
Iowa	9/1/2024	190	80	110	110	0
Iowa	10/1/2024	240	110	130	130	0
Iowa	11/1/2024	250	100	150	150	0
Iowa	12/1/2024	220	50	170	170	0
Kansas	4/1/2022	970	970	0	0	0
Kansas	5/1/2022	950	950	0	0	0
Kansas	6/1/2022	930	930	0	0	0
Kansas	7/1/2022	930	930	0	0	0
Kansas	8/1/2022	1,280	1,280	0	0	0
Kansas	9/1/2022	1,150	1,150	0	0	0
Kansas	10/1/2022	1,260	1,260	0	0	0
Kansas	11/1/2022	1,130	1,130	0	0	0
Kansas	12/1/2022	1,310	1,300	10	10	0
Kansas	1/1/2023	1,660	1,580	80	80	0
Kansas	2/1/2023	1,560	1,450	110	110	0
Kansas	3/1/2023	1,700	1,550	150	150	0
Kansas	4/1/2023	1,740	1,600	140	140	0
Kansas	5/1/2023	1,820	1,690	130	130	0
Kansas	6/1/2023	2,020	1,890	130	130	0
Kansas	7/1/2023	1,710	1,530	180	180	0
Kansas	8/1/2023	1,810	1,680	130	130	0
Kansas	9/1/2023	1,620	1,510	110	110	0
Kansas	10/1/2023	1,720	1,570	150	150	0
Kansas	11/1/2023	1,820	1,660	160	160	0
Kansas	12/1/2023	1,830	1,670	160	160	0
Kansas	1/1/2024	2,060	1,860	200	200	0
Kansas	2/1/2024	2,020	1,870	150	150	0
Kansas	3/1/2024	2,220	2,060	160	160	0
Kansas	4/1/2024	1,960	1,790	170	170	0
Kansas	5/1/2024	2,010	1,850	160	160	0
Kansas	6/1/2024	1,710	1,540	170	170	0
Kansas	7/1/2024	1,650	1,440	210	210	0
Kansas	8/1/2024	2,110	1,950	160	160	0
Kansas	9/1/2024	1,660	1,510	150	150	0
Kansas	10/1/2024	1,900	1,710	190	190	0
Kansas	11/1/2024	1,820	1,640	180	180	0

Kansas	12/1/2024	1,660	1,430	230	230	0
Kentucky	4/1/2022	310	310	0	0	0
Kentucky	5/1/2022	380	380	0	0	0
Kentucky	6/1/2022	300	300	0	0	0
Kentucky	7/1/2022	280	280	0	0	0
Kentucky	8/1/2022	0	0	0	0	0
Kentucky	9/1/2022	0	0	0	0	0
Kentucky	10/1/2022	0	0	0	0	0
Kentucky	11/1/2022	0	0	0	0	0
Kentucky	12/1/2022	0	0	0	0	0
Kentucky	1/1/2023	0	0	0	0	0
Kentucky	2/1/2023	0	0	0	0	0
Kentucky	3/1/2023	0	0	0	0	0
Kentucky	4/1/2023	0	0	0	0	0
Kentucky	5/1/2023	0	0	0	0	0
Kentucky	6/1/2023	0	0	0	0	0
Kentucky	7/1/2023	140	0	140	140	0
Kentucky	8/1/2023	130	10	120	120	0
Kentucky	9/1/2023	150	0	150	150	0
Kentucky	10/1/2023	180	0	180	180	0
Kentucky	11/1/2023	190	10	180	180	0
Kentucky	12/1/2023	180	0	180	180	0
Kentucky	1/1/2024	230	0	230	230	0
Kentucky	2/1/2024	180	0	180	180	0
Kentucky	3/1/2024	220	0	220	220	0
Kentucky	4/1/2024	220	10	210	210	0
Kentucky	5/1/2024	220	10	210	210	0
Kentucky	6/1/2024	210	0	210	210	0
Kentucky	7/1/2024	240	0	240	240	0
Kentucky	8/1/2024	210	0	210	210	0
Kentucky	9/1/2024	230	10	220	220	0
Kentucky	10/1/2024	260	0	260	260	0
Kentucky	11/1/2024	290	0	290	290	0
Kentucky	12/1/2024	300	0	300	300	0
Louisiana	4/1/2022	760	760	0	0	0
Louisiana	5/1/2022	810	810	0	0	0
Louisiana	6/1/2022	540	540	0	0	0
Louisiana	7/1/2022	310	310	0	0	0
Louisiana	8/1/2022	0	0	0	0	0
Louisiana	9/1/2022	0	0	0	0	0
Louisiana	10/1/2022	0	0	0	0	0
Louisiana	11/1/2022	0	0	0	0	0
Louisiana	12/1/2022	0	0	0	0	0
Louisiana	1/1/2023	0	0	0	0	0

Louisiana	2/1/2023	0	0	0	0	0
Louisiana	3/1/2023	0	0	0	0	0
Louisiana	4/1/2023	0	0	0	0	0
Louisiana	5/1/2023	0	0	0	0	0
Louisiana	6/1/2023	0	0	0	0	0
Louisiana	7/1/2023	310	0	310	310	0
Louisiana	8/1/2023	380	0	380	380	0
Louisiana	9/1/2023	320	0	320	320	0
Louisiana	10/1/2023	480	0	480	480	0
Louisiana	11/1/2023	470	0	470	470	0
Louisiana	12/1/2023	520	0	520	520	0
Louisiana	1/1/2024	560	0	560	560	0
Louisiana	2/1/2024	540	0	540	540	0
Louisiana	3/1/2024	600	0	600	600	0
Louisiana	4/1/2024	610	0	610	610	0
Louisiana	5/1/2024	620	0	620	620	0
Louisiana	6/1/2024	620	0	620	620	0
Louisiana	7/1/2024	630	0	630	630	0
Louisiana	8/1/2024	560	0	560	560	0
Louisiana	9/1/2024	530	0	530	530	0
Louisiana	10/1/2024	670	0	670	670	0
Louisiana	11/1/2024	740	0	740	740	0
Louisiana	12/1/2024	830	0	830	830	0
Maine	4/1/2022	200	190	10	10	0
Maine	5/1/2022	230	220	10	10	0
Maine	6/1/2022	240	220	20	20	0
Maine	7/1/2022	240	220	20	20	0
Maine	8/1/2022	230	210	20	20	0
Maine	9/1/2022	220	190	30	30	0
Maine	10/1/2022	190	170	20	20	0
Maine	11/1/2022	180	140	40	40	0
Maine	12/1/2022	200	160	40	40	0
Maine	1/1/2023	240	190	50	50	0
Maine	2/1/2023	220	190	30	30	0
Maine	3/1/2023	260	230	30	30	0
Maine	4/1/2023	220	180	40	40	0
Maine	5/1/2023	230	200	30	30	0
Maine	6/1/2023	250	210	40	40	0
Maine	7/1/2023	230	170	60	50	10
Maine	8/1/2023	220	150	70	40	30
Maine	9/1/2023	230	130	100	70	30
Maine	10/1/2023	220	140	80	60	20
Maine	11/1/2023	220	140	80	50	30
Maine	12/1/2023	220	140	80	60	20

Maine	1/1/2024	280	210	70	50	20
Maine	2/1/2024	250	190	60	40	20
Maine	3/1/2024	250	190	60	50	10
Maine	4/1/2024	250	170	80	60	20
Maine	5/1/2024	270	210	60	40	20
Maine	6/1/2024	230	180	50	40	10
Maine	7/1/2024	260	190	70	60	10
Maine	8/1/2024	260	190	70	50	20
Maine	9/1/2024	250	190	60	50	10
Maine	10/1/2024	260	190	70	50	20
Maine	11/1/2024	210	160	50	40	10
Maine	12/1/2024	230	170	60	50	10
Maryland	4/1/2022	2,880	2,840	40	40	0
Maryland	5/1/2022	2,860	2,810	50	50	0
Maryland	6/1/2022	2,890	2,820	70	70	0
Maryland	7/1/2022	2,770	2,680	90	90	0
Maryland	8/1/2022	2,860	2,790	70	70	0
Maryland	9/1/2022	2,940	2,850	90	90	0
Maryland	10/1/2022	3,000	2,920	80	80	0
Maryland	11/1/2022	2,980	2,880	100	100	0
Maryland	12/1/2022	3,460	3,330	130	130	0
Maryland	1/1/2023	3,580	3,450	130	130	0
Maryland	2/1/2023	3,590	3,500	90	90	0
Maryland	3/1/2023	3,570	3,440	130	130	0
Maryland	4/1/2023	3,480	3,370	110	110	0
Maryland	5/1/2023	3,810	3,630	180	180	0
Maryland	6/1/2023	3,820	3,680	140	140	0
Maryland	7/1/2023	3,780	3,270	510	180	330
Maryland	8/1/2023	3,660	3,140	520	180	340
Maryland	9/1/2023	3,190	2,660	530	200	330
Maryland	10/1/2023	3,320	2,780	540	200	340
Maryland	11/1/2023	3,580	3,030	550	200	350
Maryland	12/1/2023	3,410	2,870	540	170	370
Maryland	1/1/2024	3,860	3,210	650	230	420
Maryland	2/1/2024	3,450	2,900	550	160	390
Maryland	3/1/2024	3,550	2,990	560	200	360
Maryland	4/1/2024	3,470	2,940	530	180	350
Maryland	5/1/2024	3,610	3,030	580	190	390
Maryland	6/1/2024	3,240	2,730	510	170	340
Maryland	7/1/2024	3,650	3,040	610	210	400
Maryland	8/1/2024	3,370	2,850	520	180	340
Maryland	9/1/2024	3,000	2,560	440	170	270
Maryland	10/1/2024	3,430	2,910	520	220	300
Maryland	11/1/2024	3,230	2,690	540	250	290

Maryland	12/1/2024	3,470	2,880	590	290	300
Massachusetts	4/1/2022	1,670	1,590	80	80	0
Massachusetts	5/1/2022	1,550	1,450	100	100	0
Massachusetts	6/1/2022	1,650	1,530	120	120	0
Massachusetts	7/1/2022	1,670	1,530	140	140	0
Massachusetts	8/1/2022	1,640	1,510	130	130	0
Massachusetts	9/1/2022	1,600	1,480	120	120	0
Massachusetts	10/1/2022	1,560	1,400	160	160	0
Massachusetts	11/1/2022	1,520	1,320	200	200	0
Massachusetts	12/1/2022	1,730	1,510	220	220	0
Massachusetts	1/1/2023	1,880	1,670	210	210	0
Massachusetts	2/1/2023	1,640	1,480	160	160	0
Massachusetts	3/1/2023	2,080	1,840	240	240	0
Massachusetts	4/1/2023	1,720	1,550	170	170	0
Massachusetts	5/1/2023	1,860	1,660	200	200	0
Massachusetts	6/1/2023	1,910	1,690	220	220	0
Massachusetts	7/1/2023	1,800	1,520	280	270	10
Massachusetts	8/1/2023	1,990	1,700	290	270	20
Massachusetts	9/1/2023	1,760	1,490	270	240	30
Massachusetts	10/1/2023	1,830	1,540	290	250	40
Massachusetts	11/1/2023	1,920	1,580	340	290	50
Massachusetts	12/1/2023	2,150	1,830	320	280	40
Massachusetts	1/1/2024	2,130	1,770	360	310	50
Massachusetts	2/1/2024	2,030	1,710	320	270	50
Massachusetts	3/1/2024	2,090	1,750	340	280	60
Massachusetts	4/1/2024	1,860	1,520	340	290	50
Massachusetts	5/1/2024	2,050	1,680	370	310	60
Massachusetts	6/1/2024	1,760	1,420	340	290	50
Massachusetts	7/1/2024	1,910	1,540	370	320	50
Massachusetts	8/1/2024	1,840	1,510	330	290	40
Massachusetts	9/1/2024	1,760	1,460	300	250	50
Massachusetts	10/1/2024	1,810	1,470	340	270	70
Massachusetts	11/1/2024	1,910	1,490	420	360	60
Massachusetts	12/1/2024	1,710	1,300	410	310	100
Michigan	4/1/2022	2,610	2,610	0	0	0
Michigan	5/1/2022	2,570	2,450	120	120	0
Michigan	6/1/2022	2,910	2,720	190	190	0
Michigan	7/1/2022	3,030	2,830	200	200	0
Michigan	8/1/2022	2,930	2,720	210	210	0
Michigan	9/1/2022	2,770	2,540	230	230	0
Michigan	10/1/2022	2,750	2,530	220	220	0
Michigan	11/1/2022	2,630	2,390	240	240	0
Michigan	12/1/2022	2,720	2,430	290	290	0
Michigan	1/1/2023	2,990	2,700	290	290	0

Michigan	2/1/2023	2,920	2,670	250	250	0
Michigan	3/1/2023	3,380	3,120	260	260	0
Michigan	4/1/2023	3,080	2,820	260	260	0
Michigan	5/1/2023	3,000	2,760	240	240	0
Michigan	6/1/2023	2,950	2,780	170	170	0
Michigan	7/1/2023	2,990	2,680	310	310	0
Michigan	8/1/2023	3,200	2,840	360	360	0
Michigan	9/1/2023	2,970	2,640	330	330	0
Michigan	10/1/2023	2,980	2,650	330	330	0
Michigan	11/1/2023	2,920	2,560	360	360	0
Michigan	12/1/2023	3,030	2,730	300	300	0
Michigan	1/1/2024	3,490	3,030	460	460	0
Michigan	2/1/2024	3,230	2,880	350	350	0
Michigan	3/1/2024	3,340	2,990	350	350	0
Michigan	4/1/2024	3,090	2,740	350	350	0
Michigan	5/1/2024	3,190	2,840	350	350	0
Michigan	6/1/2024	2,990	2,630	360	360	0
Michigan	7/1/2024	3,140	2,710	430	430	0
Michigan	8/1/2024	3,200	2,790	410	400	10
Michigan	9/1/2024	2,740	2,260	480	460	20
Michigan	10/1/2024	3,140	2,670	470	450	20
Michigan	11/1/2024	2,970	2,310	660	620	40
Michigan	12/1/2024	3,260	2,500	760	710	50
Minnesota	4/1/2022	940	760	180	180	0
Minnesota	5/1/2022	930	730	200	200	0
Minnesota	6/1/2022	1,040	840	200	200	0
Minnesota	7/1/2022	1,180	940	240	240	0
Minnesota	8/1/2022	1,200	1,000	200	200	0
Minnesota	9/1/2022	1,210	990	220	220	0
Minnesota	10/1/2022	1,240	1,000	240	240	0
Minnesota	11/1/2022	1,270	1,050	220	220	0
Minnesota	12/1/2022	1,200	980	220	220	0
Minnesota	1/1/2023	1,240	990	250	250	0
Minnesota	2/1/2023	1,110	870	240	240	0
Minnesota	3/1/2023	1,430	1,110	320	320	0
Minnesota	4/1/2023	1,220	1,000	220	220	0
Minnesota	5/1/2023	1,400	1,100	300	300	0
Minnesota	6/1/2023	1,360	1,100	260	260	0
Minnesota	7/1/2023	1,320	970	350	320	30
Minnesota	8/1/2023	1,410	1,080	330	290	40
Minnesota	9/1/2023	1,280	1,010	270	250	20
Minnesota	10/1/2023	1,250	960	290	260	30
Minnesota	11/1/2023	1,240	940	300	270	30
Minnesota	12/1/2023	1,180	840	340	320	20

Minnesota	1/1/2024	1,380	1,020	360	330	30
Minnesota	2/1/2024	1,300	930	370	350	20
Minnesota	3/1/2024	1,320	970	350	320	30
Minnesota	4/1/2024	1,350	990	360	330	30
Minnesota	5/1/2024	1,370	1,030	340	310	30
Minnesota	6/1/2024	1,340	980	360	330	30
Minnesota	7/1/2024	1,390	1,070	320	290	30
Minnesota	8/1/2024	1,450	1,110	340	320	20
Minnesota	9/1/2024	1,250	980	270	250	20
Minnesota	10/1/2024	1,430	1,090	340	320	20
Minnesota	11/1/2024	1,380	1,010	370	360	10
Minnesota	12/1/2024	1,430	1,030	400	380	20
Mississippi	4/1/2022	350	350	0	0	0
Mississippi	5/1/2022	350	350	0	0	0
Mississippi	6/1/2022	470	470	0	0	0
Mississippi	7/1/2022	0	0	0	0	0
Mississippi	8/1/2022	0	0	0	0	0
Mississippi	9/1/2022	0	0	0	0	0
Mississippi	10/1/2022	0	0	0	0	0
Mississippi	11/1/2022	0	0	0	0	0
Mississippi	12/1/2022	0	0	0	0	0
Mississippi	1/1/2023	0	0	0	0	0
Mississippi	2/1/2023	0	0	0	0	0
Mississippi	3/1/2023	0	0	0	0	0
Mississippi	4/1/2023	0	0	0	0	0
Mississippi	5/1/2023	0	0	0	0	0
Mississippi	6/1/2023	0	0	0	0	0
Mississippi	7/1/2023	200	0	200	200	0
Mississippi	8/1/2023	210	0	210	210	0
Mississippi	9/1/2023	220	0	220	220	0
Mississippi	10/1/2023	280	0	280	280	0
Mississippi	11/1/2023	300	0	300	300	0
Mississippi	12/1/2023	360	0	360	360	0
Mississippi	1/1/2024	390	0	390	390	0
Mississippi	2/1/2024	380	0	380	380	0
Mississippi	3/1/2024	420	0	420	420	0
Mississippi	4/1/2024	390	0	390	390	0
Mississippi	5/1/2024	400	0	400	400	0
Mississippi	6/1/2024	380	0	380	380	0
Mississippi	7/1/2024	400	0	400	400	0
Mississippi	8/1/2024	370	0	370	370	0
Mississippi	9/1/2024	360	0	360	360	0
Mississippi	10/1/2024	450	0	450	450	0
Mississippi	11/1/2024	450	0	450	450	0

Mississippi	12/1/2024	560	0	560	560	0
Missouri	4/1/2022	10	10	0	0	0
Missouri	5/1/2022	10	10	0	0	0
Missouri	6/1/2022	10	10	0	0	0
Missouri	7/1/2022	0	0	0	0	0
Missouri	8/1/2022	0	0	0	0	0
Missouri	9/1/2022	0	0	0	0	0
Missouri	10/1/2022	0	0	0	0	0
Missouri	11/1/2022	0	0	0	0	0
Missouri	12/1/2022	0	0	0	0	0
Missouri	1/1/2023	0	0	0	0	0
Missouri	2/1/2023	0	0	0	0	0
Missouri	3/1/2023	0	0	0	0	0
Missouri	4/1/2023	10	10	0	0	0
Missouri	5/1/2023	0	0	0	0	0
Missouri	6/1/2023	0	0	0	0	0
Missouri	7/1/2023	110	0	110	110	0
Missouri	8/1/2023	120	0	120	120	0
Missouri	9/1/2023	110	10	100	100	0
Missouri	10/1/2023	150	0	150	150	0
Missouri	11/1/2023	150	10	140	140	0
Missouri	12/1/2023	160	0	160	160	0
Missouri	1/1/2024	160	0	160	160	0
Missouri	2/1/2024	140	0	140	140	0
Missouri	3/1/2024	160	0	160	160	0
Missouri	4/1/2024	180	0	180	180	0
Missouri	5/1/2024	160	0	160	160	0
Missouri	6/1/2024	160	0	160	160	0
Missouri	7/1/2024	220	0	220	220	0
Missouri	8/1/2024	160	0	160	160	0
Missouri	9/1/2024	210	10	200	200	0
Missouri	10/1/2024	190	0	190	190	0
Missouri	11/1/2024	230	0	230	230	0
Missouri	12/1/2024	280	10	270	270	0
Montana	4/1/2022	170	130	40	40	0
Montana	5/1/2022	180	150	30	30	0
Montana	6/1/2022	170	130	40	40	0
Montana	7/1/2022	160	120	40	40	0
Montana	8/1/2022	220	180	40	40	0
Montana	9/1/2022	170	130	40	40	0
Montana	10/1/2022	200	160	40	40	0
Montana	11/1/2022	190	160	30	30	0
Montana	12/1/2022	170	140	30	30	0
Montana	1/1/2023	210	170	40	40	0

Montana	2/1/2023	170	140	30	30	0
Montana	3/1/2023	190	150	40	40	0
Montana	4/1/2023	190	160	30	30	0
Montana	5/1/2023	190	150	40	40	0
Montana	6/1/2023	200	170	30	30	0
Montana	7/1/2023	210	140	70	40	30
Montana	8/1/2023	240	170	70	30	40
Montana	9/1/2023	210	130	80	30	50
Montana	10/1/2023	220	140	80	40	40
Montana	11/1/2023	230	140	90	50	40
Montana	12/1/2023	220	140	80	30	50
Montana	1/1/2024	230	140	90	40	50
Montana	2/1/2024	200	130	70	30	40
Montana	3/1/2024	210	130	80	30	50
Montana	4/1/2024	200	130	70	30	40
Montana	5/1/2024	220	140	80	20	60
Montana	6/1/2024	200	120	80	30	50
Montana	7/1/2024	250	140	110	50	60
Montana	8/1/2024	260	180	80	60	20
Montana	9/1/2024	140	60	80	50	30
Montana	10/1/2024	270	180	90	60	30
Montana	11/1/2024	220	150	70	60	10
Montana	12/1/2024	250	160	90	60	30
Nebraska	4/1/2022	200	200	0	0	0
Nebraska	5/1/2022	190	190	0	0	0
Nebraska	6/1/2022	210	210	0	0	0
Nebraska	7/1/2022	210	210	0	0	0
Nebraska	8/1/2022	260	260	0	0	0
Nebraska	9/1/2022	230	230	0	0	0
Nebraska	10/1/2022	240	240	0	0	0
Nebraska	11/1/2022	200	200	0	0	0
Nebraska	12/1/2022	170	170	0	0	0
Nebraska	1/1/2023	320	320	0	0	0
Nebraska	2/1/2023	280	280	0	0	0
Nebraska	3/1/2023	250	250	0	0	0
Nebraska	4/1/2023	280	280	0	0	0
Nebraska	5/1/2023	180	180	0	0	0
Nebraska	6/1/2023	240	240	0	0	0
Nebraska	7/1/2023	180	130	50	50	0
Nebraska	8/1/2023	270	230	40	40	0
Nebraska	9/1/2023	210	170	40	40	0
Nebraska	10/1/2023	190	140	50	50	0
Nebraska	11/1/2023	210	150	60	60	0
Nebraska	12/1/2023	290	220	70	70	0

Nebraska	1/1/2024	270	200	70	70	0
Nebraska	2/1/2024	260	200	60	60	0
Nebraska	3/1/2024	270	190	80	80	0
Nebraska	4/1/2024	280	210	70	70	0
Nebraska	5/1/2024	300	220	80	80	0
Nebraska	6/1/2024	310	240	70	70	0
Nebraska	7/1/2024	300	230	70	70	0
Nebraska	8/1/2024	310	240	70	70	0
Nebraska	9/1/2024	300	220	80	80	0
Nebraska	10/1/2024	340	250	90	90	0
Nebraska	11/1/2024	340	240	100	100	0
Nebraska	12/1/2024	350	250	100	100	0
Nevada	4/1/2022	1,140	1,020	120	120	0
Nevada	5/1/2022	1,090	940	150	150	0
Nevada	6/1/2022	1,320	1,140	180	180	0
Nevada	7/1/2022	1,220	1,030	190	190	0
Nevada	8/1/2022	1,430	1,210	220	220	0
Nevada	9/1/2022	1,290	1,040	250	250	0
Nevada	10/1/2022	1,340	1,110	230	230	0
Nevada	11/1/2022	1,290	1,050	240	240	0
Nevada	12/1/2022	1,440	1,150	290	290	0
Nevada	1/1/2023	1,540	1,230	310	310	0
Nevada	2/1/2023	1,440	1,140	300	300	0
Nevada	3/1/2023	1,580	1,270	310	310	0
Nevada	4/1/2023	1,370	1,080	290	290	0
Nevada	5/1/2023	1,360	1,050	310	310	0
Nevada	6/1/2023	1,390	1,150	240	240	0
Nevada	7/1/2023	1,260	970	290	290	0
Nevada	8/1/2023	1,420	1,100	320	320	0
Nevada	9/1/2023	1,300	900	400	310	90
Nevada	10/1/2023	1,360	960	400	340	60
Nevada	11/1/2023	1,320	940	380	360	20
Nevada	12/1/2023	1,410	990	420	390	30
Nevada	1/1/2024	1,680	1,160	520	500	20
Nevada	2/1/2024	1,520	1,070	450	440	10
Nevada	3/1/2024	1,660	1,160	500	490	10
Nevada	4/1/2024	1,410	970	440	430	10
Nevada	5/1/2024	1,500	1,070	430	410	20
Nevada	6/1/2024	1,460	990	470	440	30
Nevada	7/1/2024	1,450	940	510	490	20
Nevada	8/1/2024	1,410	950	460	450	10
Nevada	9/1/2024	1,310	880	430	400	30
Nevada	10/1/2024	1,460	1,000	460	450	10
Nevada	11/1/2024	1,280	800	480	470	10

Nevada	12/1/2024	1,410	920	490	470	20
New Hampshire	4/1/2022	230	230	0	0	0
New Hampshire	5/1/2022	200	200	0	0	0
New Hampshire	6/1/2022	220	220	0	0	0
New Hampshire	7/1/2022	210	200	10	10	0
New Hampshire	8/1/2022	220	200	20	20	0
New Hampshire	9/1/2022	210	200	10	10	0
New Hampshire	10/1/2022	180	160	20	20	0
New Hampshire	11/1/2022	190	160	30	30	0
New Hampshire	12/1/2022	230	200	30	30	0
New Hampshire	1/1/2023	210	190	20	20	0
New Hampshire	2/1/2023	230	210	20	20	0
New Hampshire	3/1/2023	270	240	30	30	0
New Hampshire	4/1/2023	250	220	30	30	0
New Hampshire	5/1/2023	250	220	30	30	0
New Hampshire	6/1/2023	240	220	20	20	0
New Hampshire	7/1/2023	240	180	60	50	10
New Hampshire	8/1/2023	270	220	50	40	10
New Hampshire	9/1/2023	250	210	40	30	10
New Hampshire	10/1/2023	230	190	40	30	10
New Hampshire	11/1/2023	280	230	50	50	0
New Hampshire	12/1/2023	280	230	50	40	10
New Hampshire	1/1/2024	290	240	50	40	10
New Hampshire	2/1/2024	290	210	80	70	10
New Hampshire	3/1/2024	310	240	70	60	10
New Hampshire	4/1/2024	310	260	50	40	10
New Hampshire	5/1/2024	320	240	80	60	20
New Hampshire	6/1/2024	260	210	50	50	0
New Hampshire	7/1/2024	270	220	50	50	0
New Hampshire	8/1/2024	250	210	40	40	0
New Hampshire	9/1/2024	250	200	50	50	0
New Hampshire	10/1/2024	250	200	50	50	0
New Hampshire	11/1/2024	300	230	70	70	0
New Hampshire	12/1/2024	270	190	80	80	0
New Jersey	4/1/2022	4,020	3,860	160	160	0
New Jersey	5/1/2022	3,980	3,790	190	190	0
New Jersey	6/1/2022	4,070	3,890	180	180	0
New Jersey	7/1/2022	4,100	3,850	250	250	0
New Jersey	8/1/2022	4,300	4,000	300	300	0
New Jersey	9/1/2022	3,730	3,450	280	280	0
New Jersey	10/1/2022	3,850	3,540	310	310	0
New Jersey	11/1/2022	4,020	3,650	370	370	0
New Jersey	12/1/2022	4,190	3,750	440	440	0
New Jersey	1/1/2023	4,370	3,840	530	530	0

New Jersey	2/1/2023	4,140	3,700	440	440	0
New Jersey	3/1/2023	4,780	4,310	470	470	0
New Jersey	4/1/2023	4,400	3,910	490	490	0
New Jersey	5/1/2023	4,920	4,400	520	520	0
New Jersey	6/1/2023	4,710	4,200	510	510	0
New Jersey	7/1/2023	4,480	3,960	520	520	0
New Jersey	8/1/2023	4,690	4,190	500	500	0
New Jersey	9/1/2023	4,130	3,690	440	440	0
New Jersey	10/1/2023	4,070	3,510	560	560	0
New Jersey	11/1/2023	3,900	3,380	520	520	0
New Jersey	12/1/2023	4,560	4,000	560	560	0
New Jersey	1/1/2024	4,780	4,040	740	740	0
New Jersey	2/1/2024	4,120	3,550	570	570	0
New Jersey	3/1/2024	4,630	4,000	630	630	0
New Jersey	4/1/2024	4,380	3,850	530	530	0
New Jersey	5/1/2024	4,830	4,290	540	540	0
New Jersey	6/1/2024	4,790	4,220	570	570	0
New Jersey	7/1/2024	5,190	4,650	540	540	0
New Jersey	8/1/2024	4,990	4,480	510	510	0
New Jersey	9/1/2024	4,760	4,300	460	460	0
New Jersey	10/1/2024	5,060	4,520	540	540	0
New Jersey	11/1/2024	4,950	4,350	600	600	0
New Jersey	12/1/2024	4,830	4,270	560	560	0
New Mexico	4/1/2022	1,230	1,150	80	80	0
New Mexico	5/1/2022	1,200	1,110	90	90	0
New Mexico	6/1/2022	1,430	1,290	140	140	0
New Mexico	7/1/2022	1,460	1,290	170	170	0
New Mexico	8/1/2022	1,510	1,360	150	150	0
New Mexico	9/1/2022	1,650	1,510	140	140	0
New Mexico	10/1/2022	1,700	1,540	160	160	0
New Mexico	11/1/2022	1,790	1,610	180	180	0
New Mexico	12/1/2022	1,890	1,720	170	170	0
New Mexico	1/1/2023	2,070	1,890	180	180	0
New Mexico	2/1/2023	1,850	1,700	150	150	0
New Mexico	3/1/2023	2,150	2,000	150	150	0
New Mexico	4/1/2023	1,890	1,730	160	160	0
New Mexico	5/1/2023	1,870	1,690	180	180	0
New Mexico	6/1/2023	1,980	1,810	170	170	0
New Mexico	7/1/2023	1,770	1,600	170	140	30
New Mexico	8/1/2023	1,650	1,510	140	120	20
New Mexico	9/1/2023	1,650	1,490	160	140	20
New Mexico	10/1/2023	1,520	1,360	160	140	20
New Mexico	11/1/2023	1,520	1,380	140	120	20
New Mexico	12/1/2023	1,630	1,470	160	140	20

New Mexico	1/1/2024	1,890	1,680	210	190	20
New Mexico	2/1/2024	1,650	1,510	140	120	20
New Mexico	3/1/2024	1,790	1,610	180	150	30
New Mexico	4/1/2024	1,560	1,370	190	150	40
New Mexico	5/1/2024	1,650	1,470	180	140	40
New Mexico	6/1/2024	1,560	1,350	210	130	80
New Mexico	7/1/2024	1,480	1,290	190	130	60
New Mexico	8/1/2024	1,500	1,300	200	140	60
New Mexico	9/1/2024	1,270	1,090	180	130	50
New Mexico	10/1/2024	1,260	1,090	170	120	50
New Mexico	11/1/2024	1,350	1,130	220	140	80
New Mexico	12/1/2024	1,270	1,100	170	140	30
New York	4/1/2022	8,770	8,370	400	400	0
New York	5/1/2022	9,190	8,690	500	500	0
New York	6/1/2022	9,790	9,240	550	550	0
New York	7/1/2022	9,410	8,860	550	550	0
New York	8/1/2022	9,920	9,300	620	620	0
New York	9/1/2022	9,080	8,540	540	540	0
New York	10/1/2022	9,120	8,540	580	580	0
New York	11/1/2022	7,300	6,680	620	620	0
New York	12/1/2022	8,620	7,850	770	770	0
New York	1/1/2023	8,610	7,760	850	850	0
New York	2/1/2023	8,030	7,350	680	680	0
New York	3/1/2023	9,980	9,160	820	820	0
New York	4/1/2023	9,010	8,110	900	900	0
New York	5/1/2023	9,380	8,560	820	820	0
New York	6/1/2023	9,530	8,740	790	790	0
New York	7/1/2023	9,160	8,280	880	880	0
New York	8/1/2023	10,060	9,230	830	830	0
New York	9/1/2023	9,110	8,380	730	730	0
New York	10/1/2023	9,630	8,840	790	790	0
New York	11/1/2023	8,930	8,140	790	790	0
New York	12/1/2023	9,720	8,900	820	820	0
New York	1/1/2024	10,790	9,890	900	900	0
New York	2/1/2024	9,940	9,250	690	690	0
New York	3/1/2024	10,210	9,460	750	750	0
New York	4/1/2024	10,320	9,530	790	790	0
New York	5/1/2024	11,020	10,130	890	890	0
New York	6/1/2024	9,780	9,010	770	770	0
New York	7/1/2024	10,510	9,540	970	970	0
New York	8/1/2024	9,980	9,170	810	810	0
New York	9/1/2024	9,200	8,440	760	760	0
New York	10/1/2024	9,840	9,090	750	750	0
New York	11/1/2024	9,440	8,520	920	920	0

New York	12/1/2024	9,800	8,900	900	900	0
North Carolina	4/1/2022	3,280	3,280	0	0	0
North Carolina	5/1/2022	3,270	3,270	0	0	0
North Carolina	6/1/2022	3,230	3,230	0	0	0
North Carolina	7/1/2022	3,930	3,930	0	0	0
North Carolina	8/1/2022	4,390	4,390	0	0	0
North Carolina	9/1/2022	4,090	4,090	0	0	0
North Carolina	10/1/2022	3,870	3,870	0	0	0
North Carolina	11/1/2022	3,770	3,770	0	0	0
North Carolina	12/1/2022	4,070	4,070	0	0	0
North Carolina	1/1/2023	4,510	4,510	0	0	0
North Carolina	2/1/2023	4,120	4,120	0	0	0
North Carolina	3/1/2023	4,730	4,730	0	0	0
North Carolina	4/1/2023	4,210	4,210	0	0	0
North Carolina	5/1/2023	4,560	4,560	0	0	0
North Carolina	6/1/2023	4,730	4,730	0	0	0
North Carolina	7/1/2023	3,390	3,140	250	250	0
North Carolina	8/1/2023	3,570	3,340	230	230	0
North Carolina	9/1/2023	4,190	3,950	240	240	0
North Carolina	10/1/2023	4,130	3,790	340	340	0
North Carolina	11/1/2023	3,540	3,190	350	350	0
North Carolina	12/1/2023	3,960	3,600	360	360	0
North Carolina	1/1/2024	4,310	3,800	510	510	0
North Carolina	2/1/2024	4,250	3,890	360	360	0
North Carolina	3/1/2024	4,410	3,990	420	420	0
North Carolina	4/1/2024	4,730	4,310	420	420	0
North Carolina	5/1/2024	4,530	4,130	400	400	0
North Carolina	6/1/2024	4,390	4,020	370	370	0
North Carolina	7/1/2024	4,250	3,760	490	490	0
North Carolina	8/1/2024	4,340	3,880	460	460	0
North Carolina	9/1/2024	3,730	3,260	470	470	0
North Carolina	10/1/2024	3,970	3,440	530	530	0
North Carolina	11/1/2024	4,520	3,790	730	730	0
North Carolina	12/1/2024	3,950	3,240	710	710	0
North Dakota	4/1/2022	90	90	0	0	0
North Dakota	5/1/2022	110	110	0	0	0
North Dakota	6/1/2022	130	130	0	0	0
North Dakota	7/1/2022	100	100	0	0	0
North Dakota	8/1/2022	20	20	0	0	0
North Dakota	9/1/2022	0	0	0	0	0
North Dakota	10/1/2022	0	0	0	0	0
North Dakota	11/1/2022	0	0	0	0	0
North Dakota	12/1/2022	0	0	0	0	0
North Dakota	1/1/2023	0	0	0	0	0

North Dakota	2/1/2023	0	0	0	0	0
North Dakota	3/1/2023	0	0	0	0	0
North Dakota	4/1/2023	0	0	0	0	0
North Dakota	5/1/2023	0	0	0	0	0
North Dakota	6/1/2023	0	0	0	0	0
North Dakota	7/1/2023	10	0	10	10	0
North Dakota	8/1/2023	10	0	10	10	0
North Dakota	9/1/2023	30	0	30	30	0
North Dakota	10/1/2023	20	0	20	20	0
North Dakota	11/1/2023	20	0	20	20	0
North Dakota	12/1/2023	10	0	10	10	0
North Dakota	1/1/2024	20	0	20	20	0
North Dakota	2/1/2024	20	0	20	20	0
North Dakota	3/1/2024	10	0	10	10	0
North Dakota	4/1/2024	20	0	20	20	0
North Dakota	5/1/2024	20	0	20	20	0
North Dakota	6/1/2024	20	0	20	20	0
North Dakota	7/1/2024	30	0	30	30	0
North Dakota	8/1/2024	30	0	30	30	0
North Dakota	9/1/2024	20	0	20	20	0
North Dakota	10/1/2024	20	0	20	20	0
North Dakota	11/1/2024	40	0	40	40	0
North Dakota	12/1/2024	30	0	30	30	0
Ohio	4/1/2022	2,040	2,040	0	0	0
Ohio	5/1/2022	1,990	1,990	0	0	0
Ohio	6/1/2022	1,830	1,830	0	0	0
Ohio	7/1/2022	810	810	0	0	0
Ohio	8/1/2022	780	780	0	0	0
Ohio	9/1/2022	1,070	1,070	0	0	0
Ohio	10/1/2022	1,500	1,500	0	0	0
Ohio	11/1/2022	1,510	1,510	0	0	0
Ohio	12/1/2022	1,860	1,860	0	0	0
Ohio	1/1/2023	1,950	1,950	0	0	0
Ohio	2/1/2023	1,920	1,920	0	0	0
Ohio	3/1/2023	2,110	2,110	0	0	0
Ohio	4/1/2023	1,860	1,860	0	0	0
Ohio	5/1/2023	1,970	1,970	0	0	0
Ohio	6/1/2023	1,970	1,970	0	0	0
Ohio	7/1/2023	1,970	1,720	250	250	0
Ohio	8/1/2023	2,220	1,920	300	300	0
Ohio	9/1/2023	1,970	1,680	290	290	0
Ohio	10/1/2023	2,290	1,940	350	350	0
Ohio	11/1/2023	2,180	1,750	430	430	0
Ohio	12/1/2023	2,280	1,880	400	400	0

Ohio	1/1/2024	2,340	1,760	580	580	0
Ohio	2/1/2024	2,300	1,810	490	490	0
Ohio	3/1/2024	2,590	2,090	500	500	0
Ohio	4/1/2024	2,470	1,940	530	530	0
Ohio	5/1/2024	2,620	2,100	520	520	0
Ohio	6/1/2024	2,410	1,900	510	510	0
Ohio	7/1/2024	2,430	1,810	620	620	0
Ohio	8/1/2024	2,480	1,900	580	580	0
Ohio	9/1/2024	2,440	1,810	630	630	0
Ohio	10/1/2024	2,610	1,980	630	630	0
Ohio	11/1/2024	2,580	1,790	790	790	0
Ohio	12/1/2024	2,700	1,790	910	910	0
Oklahoma	4/1/2022	480	480	0	0	0
Oklahoma	5/1/2022	140	140	0	0	0
Oklahoma	6/1/2022	0	0	0	0	0
Oklahoma	7/1/2022	0	0	0	0	0
Oklahoma	8/1/2022	0	0	0	0	0
Oklahoma	9/1/2022	0	0	0	0	0
Oklahoma	10/1/2022	0	0	0	0	0
Oklahoma	11/1/2022	0	0	0	0	0
Oklahoma	12/1/2022	0	0	0	0	0
Oklahoma	1/1/2023	0	0	0	0	0
Oklahoma	2/1/2023	0	0	0	0	0
Oklahoma	3/1/2023	0	0	0	0	0
Oklahoma	4/1/2023	0	0	0	0	0
Oklahoma	5/1/2023	0	0	0	0	0
Oklahoma	6/1/2023	0	0	0	0	0
Oklahoma	7/1/2023	120	0	120	120	0
Oklahoma	8/1/2023	150	0	150	150	0
Oklahoma	9/1/2023	140	0	140	140	0
Oklahoma	10/1/2023	190	0	190	190	0
Oklahoma	11/1/2023	180	0	180	180	0
Oklahoma	12/1/2023	200	0	200	200	0
Oklahoma	1/1/2024	220	0	220	220	0
Oklahoma	2/1/2024	190	0	190	190	0
Oklahoma	3/1/2024	220	0	220	220	0
Oklahoma	4/1/2024	260	0	260	260	0
Oklahoma	5/1/2024	240	0	240	240	0
Oklahoma	6/1/2024	250	0	250	250	0
Oklahoma	7/1/2024	240	0	240	240	0
Oklahoma	8/1/2024	250	0	250	250	0
Oklahoma	9/1/2024	250	0	250	250	0
Oklahoma	10/1/2024	300	0	300	300	0
Oklahoma	11/1/2024	310	0	310	310	0

Oklahoma	12/1/2024	340	0	340	340	0
Oregon	4/1/2022	850	820	30	30	0
Oregon	5/1/2022	800	740	60	60	0
Oregon	6/1/2022	920	840	80	80	0
Oregon	7/1/2022	880	800	80	80	0
Oregon	8/1/2022	1,030	950	80	80	0
Oregon	9/1/2022	920	840	80	80	0
Oregon	10/1/2022	930	850	80	80	0
Oregon	11/1/2022	910	810	100	100	0
Oregon	12/1/2022	960	850	110	110	0
Oregon	1/1/2023	1,050	950	100	100	0
Oregon	2/1/2023	890	800	90	90	0
Oregon	3/1/2023	1,140	1,070	70	70	0
Oregon	4/1/2023	940	840	100	100	0
Oregon	5/1/2023	1,060	960	100	100	0
Oregon	6/1/2023	1,080	990	90	90	0
Oregon	7/1/2023	1,020	880	140	140	0
Oregon	8/1/2023	1,110	990	120	90	30
Oregon	9/1/2023	970	850	120	100	20
Oregon	10/1/2023	1,030	880	150	120	30
Oregon	11/1/2023	980	830	150	130	20
Oregon	12/1/2023	1,000	860	140	130	10
Oregon	1/1/2024	1,070	890	180	160	20
Oregon	2/1/2024	1,100	940	160	140	20
Oregon	3/1/2024	1,040	890	150	130	20
Oregon	4/1/2024	1,060	890	170	150	20
Oregon	5/1/2024	1,020	860	160	140	20
Oregon	6/1/2024	970	790	180	150	30
Oregon	7/1/2024	1,090	920	170	150	20
Oregon	8/1/2024	1,090	920	170	130	40
Oregon	9/1/2024	960	800	160	130	30
Oregon	10/1/2024	1,050	890	160	130	30
Oregon	11/1/2024	1,090	820	270	220	50
Oregon	12/1/2024	1,130	910	220	200	20
Pennsylvania	4/1/2022	2,950	2,950	0	0	0
Pennsylvania	5/1/2022	2,690	2,690	0	0	0
Pennsylvania	6/1/2022	2,970	2,960	10	10	0
Pennsylvania	7/1/2022	3,350	3,310	40	40	0
Pennsylvania	8/1/2022	3,140	3,090	50	50	0
Pennsylvania	9/1/2022	3,080	3,030	50	50	0
Pennsylvania	10/1/2022	2,760	2,700	60	60	0
Pennsylvania	11/1/2022	2,570	2,520	50	50	0
Pennsylvania	12/1/2022	3,170	3,100	70	70	0
Pennsylvania	1/1/2023	2,940	2,940	0	0	0

Pennsylvania	2/1/2023	3,050	3,050	0	0	0
Pennsylvania	3/1/2023	3,530	3,530	0	0	0
Pennsylvania	4/1/2023	3,110	2,980	130	130	0
Pennsylvania	5/1/2023	3,140	3,020	120	120	0
Pennsylvania	6/1/2023	3,300	3,130	170	170	0
Pennsylvania	7/1/2023	3,270	2,810	460	370	90
Pennsylvania	8/1/2023	3,450	3,050	400	380	20
Pennsylvania	9/1/2023	3,210	2,640	570	360	210
Pennsylvania	10/1/2023	3,110	2,500	610	410	200
Pennsylvania	11/1/2023	3,090	2,420	670	440	230
Pennsylvania	12/1/2023	3,340	2,760	580	450	130
Pennsylvania	1/1/2024	3,550	2,810	740	570	170
Pennsylvania	2/1/2024	3,640	3,000	640	460	180
Pennsylvania	3/1/2024	3,640	3,030	610	480	130
Pennsylvania	4/1/2024	3,180	2,570	610	460	150
Pennsylvania	5/1/2024	3,450	2,730	720	500	220
Pennsylvania	6/1/2024	3,050	2,450	600	440	160
Pennsylvania	7/1/2024	3,240	2,530	710	550	160
Pennsylvania	8/1/2024	3,240	2,590	650	510	140
Pennsylvania	9/1/2024	2,770	2,160	610	490	120
Pennsylvania	10/1/2024	3,200	2,490	710	530	180
Pennsylvania	11/1/2024	3,140	2,350	790	670	120
Pennsylvania	12/1/2024	3,170	2,380	790	690	100
Rhode Island	4/1/2022	330	310	20	20	0
Rhode Island	5/1/2022	300	270	30	30	0
Rhode Island	6/1/2022	280	250	30	30	0
Rhode Island	7/1/2022	290	260	30	30	0
Rhode Island	8/1/2022	300	280	20	20	0
Rhode Island	9/1/2022	290	270	20	20	0
Rhode Island	10/1/2022	320	290	30	30	0
Rhode Island	11/1/2022	210	170	40	40	0
Rhode Island	12/1/2022	240	210	30	30	0
Rhode Island	1/1/2023	280	240	40	40	0
Rhode Island	2/1/2023	250	210	40	40	0
Rhode Island	3/1/2023	330	270	60	60	0
Rhode Island	4/1/2023	220	190	30	30	0
Rhode Island	5/1/2023	240	190	50	50	0
Rhode Island	6/1/2023	250	200	50	50	0
Rhode Island	7/1/2023	220	150	70	70	0
Rhode Island	8/1/2023	240	180	60	60	0
Rhode Island	9/1/2023	250	200	50	50	0
Rhode Island	10/1/2023	260	210	50	50	0
Rhode Island	11/1/2023	300	240	60	60	0
Rhode Island	12/1/2023	270	210	60	60	0

Rhode Island	1/1/2024	310	240	70	60	10
Rhode Island	2/1/2024	280	200	80	70	10
Rhode Island	3/1/2024	290	240	50	40	10
Rhode Island	4/1/2024	300	250	50	50	0
Rhode Island	5/1/2024	300	220	80	70	10
Rhode Island	6/1/2024	310	240	70	60	10
Rhode Island	7/1/2024	320	240	80	70	10
Rhode Island	8/1/2024	340	280	60	50	10
Rhode Island	9/1/2024	290	230	60	50	10
Rhode Island	10/1/2024	310	260	50	40	10
Rhode Island	11/1/2024	340	260	80	70	10
Rhode Island	12/1/2024	340	240	100	80	20
South Carolina	4/1/2022	690	690	0	0	0
South Carolina	5/1/2022	630	630	0	0	0
South Carolina	6/1/2022	490	490	0	0	0
South Carolina	7/1/2022	180	180	0	0	0
South Carolina	8/1/2022	360	360	0	0	0
South Carolina	9/1/2022	790	790	0	0	0
South Carolina	10/1/2022	830	830	0	0	0
South Carolina	11/1/2022	830	830	0	0	0
South Carolina	12/1/2022	850	850	0	0	0
South Carolina	1/1/2023	990	990	0	0	0
South Carolina	2/1/2023	1,000	1,000	0	0	0
South Carolina	3/1/2023	1,090	1,090	0	0	0
South Carolina	4/1/2023	950	950	0	0	0
South Carolina	5/1/2023	890	890	0	0	0
South Carolina	6/1/2023	930	930	0	0	0
South Carolina	7/1/2023	1,060	870	190	190	0
South Carolina	8/1/2023	960	760	200	200	0
South Carolina	9/1/2023	350	160	190	190	0
South Carolina	10/1/2023	440	200	240	240	0
South Carolina	11/1/2023	440	170	270	270	0
South Carolina	12/1/2023	480	200	280	280	0
South Carolina	1/1/2024	580	300	280	280	0
South Carolina	2/1/2024	520	280	240	240	0
South Carolina	3/1/2024	590	310	280	280	0
South Carolina	4/1/2024	510	250	260	260	0
South Carolina	5/1/2024	570	300	270	270	0
South Carolina	6/1/2024	510	230	280	280	0
South Carolina	7/1/2024	560	240	320	320	0
South Carolina	8/1/2024	550	210	340	340	0
South Carolina	9/1/2024	530	210	320	320	0
South Carolina	10/1/2024	610	240	370	370	0
South Carolina	11/1/2024	660	240	420	420	0

South Carolina	12/1/2024	710	200	510	510	0
South Dakota	4/1/2022	20	20	0	0	0
South Dakota	5/1/2022	40	40	0	0	0
South Dakota	6/1/2022	30	30	0	0	0
South Dakota	7/1/2022	0	0	0	0	0
South Dakota	8/1/2022	0	0	0	0	0
South Dakota	9/1/2022	0	0	0	0	0
South Dakota	10/1/2022	0	0	0	0	0
South Dakota	11/1/2022	0	0	0	0	0
South Dakota	12/1/2022	0	0	0	0	0
South Dakota	1/1/2023	0	0	0	0	0
South Dakota	2/1/2023	0	0	0	0	0
South Dakota	3/1/2023	0	0	0	0	0
South Dakota	4/1/2023	0	0	0	0	0
South Dakota	5/1/2023	0	0	0	0	0
South Dakota	6/1/2023	0	0	0	0	0
South Dakota	7/1/2023	10	0	10	10	0
South Dakota	8/1/2023	10	0	10	10	0
South Dakota	9/1/2023	10	0	10	10	0
South Dakota	10/1/2023	20	0	20	20	0
South Dakota	11/1/2023	20	0	20	20	0
South Dakota	12/1/2023	20	0	20	20	0
South Dakota	1/1/2024	30	0	30	30	0
South Dakota	2/1/2024	20	0	20	20	0
South Dakota	3/1/2024	20	0	20	20	0
South Dakota	4/1/2024	20	0	20	20	0
South Dakota	5/1/2024	30	0	30	30	0
South Dakota	6/1/2024	30	0	30	30	0
South Dakota	7/1/2024	30	0	30	30	0
South Dakota	8/1/2024	30	0	30	30	0
South Dakota	9/1/2024	20	0	20	20	0
South Dakota	10/1/2024	40	0	40	40	0
South Dakota	11/1/2024	40	0	40	40	0
South Dakota	12/1/2024	40	0	40	40	0
Tennessee	4/1/2022	1,190	1,190	0	0	0
Tennessee	5/1/2022	1,220	1,220	0	0	0
Tennessee	6/1/2022	1,040	1,040	0	0	0
Tennessee	7/1/2022	280	280	0	0	0
Tennessee	8/1/2022	250	250	0	0	0
Tennessee	9/1/2022	0	0	0	0	0
Tennessee	10/1/2022	0	0	0	0	0
Tennessee	11/1/2022	0	0	0	0	0
Tennessee	12/1/2022	0	0	0	0	0
Tennessee	1/1/2023	0	0	0	0	0

Tennessee	2/1/2023	0	0	0	0	0
Tennessee	3/1/2023	0	0	0	0	0
Tennessee	4/1/2023	0	0	0	0	0
Tennessee	5/1/2023	0	0	0	0	0
Tennessee	6/1/2023	0	0	0	0	0
Tennessee	7/1/2023	230	0	230	230	0
Tennessee	8/1/2023	270	0	270	270	0
Tennessee	9/1/2023	260	0	260	260	0
Tennessee	10/1/2023	310	0	310	310	0
Tennessee	11/1/2023	390	0	390	390	0
Tennessee	12/1/2023	360	0	360	360	0
Tennessee	1/1/2024	420	0	420	420	0
Tennessee	2/1/2024	380	0	380	380	0
Tennessee	3/1/2024	440	0	440	440	0
Tennessee	4/1/2024	460	0	460	460	0
Tennessee	5/1/2024	470	0	470	470	0
Tennessee	6/1/2024	450	0	450	450	0
Tennessee	7/1/2024	530	0	530	530	0
Tennessee	8/1/2024	400	0	400	400	0
Tennessee	9/1/2024	460	0	460	460	0
Tennessee	10/1/2024	550	0	550	550	0
Tennessee	11/1/2024	640	0	640	640	0
Tennessee	12/1/2024	670	0	670	670	0
Texas	4/1/2022	3,190	3,190	0	0	0
Texas	5/1/2022	2,990	2,990	0	0	0
Texas	6/1/2022	2,600	2,600	0	0	0
Texas	7/1/2022	70	70	0	0	0
Texas	8/1/2022	0	0	0	0	0
Texas	9/1/2022	0	0	0	0	0
Texas	10/1/2022	0	0	0	0	0
Texas	11/1/2022	10	10	0	0	0
Texas	12/1/2022	0	0	0	0	0
Texas	1/1/2023	10	10	0	0	0
Texas	2/1/2023	0	0	0	0	0
Texas	3/1/2023	10	10	0	0	0
Texas	4/1/2023	0	0	0	0	0
Texas	5/1/2023	10	10	0	0	0
Texas	6/1/2023	0	0	0	0	0
Texas	7/1/2023	1,780	10	1,770	1,770	0
Texas	8/1/2023	1,690	10	1,680	1,680	0
Texas	9/1/2023	1,780	10	1,770	1,770	0
Texas	10/1/2023	2,260	0	2,260	2,260	0
Texas	11/1/2023	2,410	10	2,400	2,400	0
Texas	12/1/2023	2,540	0	2,540	2,540	0

Texas	1/1/2024	2,920	10	2,910	2,910	0
Texas	2/1/2024	2,650	0	2,650	2,650	0
Texas	3/1/2024	2,850	10	2,840	2,840	0
Texas	4/1/2024	2,880	20	2,860	2,860	0
Texas	5/1/2024	2,720	0	2,720	2,720	0
Texas	6/1/2024	2,820	0	2,820	2,820	0
Texas	7/1/2024	3,100	10	3,090	3,090	0
Texas	8/1/2024	2,780	10	2,770	2,770	0
Texas	9/1/2024	2,870	0	2,870	2,870	0
Texas	10/1/2024	3,150	10	3,140	3,140	0
Texas	11/1/2024	3,150	0	3,150	3,150	0
Texas	12/1/2024	4,000	10	3,990	3,990	0
Utah	4/1/2022	320	320	0	0	0
Utah	5/1/2022	400	400	0	0	0
Utah	6/1/2022	360	360	0	0	0
Utah	7/1/2022	270	270	0	0	0
Utah	8/1/2022	310	310	0	0	0
Utah	9/1/2022	320	320	0	0	0
Utah	10/1/2022	280	280	0	0	0
Utah	11/1/2022	320	320	0	0	0
Utah	12/1/2022	340	340	0	0	0
Utah	1/1/2023	360	360	0	0	0
Utah	2/1/2023	340	340	0	0	0
Utah	3/1/2023	400	400	0	0	0
Utah	4/1/2023	340	340	0	0	0
Utah	5/1/2023	310	310	0	0	0
Utah	6/1/2023	330	330	0	0	0
Utah	7/1/2023	410	360	50	50	0
Utah	8/1/2023	390	330	60	60	0
Utah	9/1/2023	400	350	50	50	0
Utah	10/1/2023	380	310	70	70	0
Utah	11/1/2023	440	350	90	90	0
Utah	12/1/2023	380	300	80	80	0
Utah	1/1/2024	450	360	90	90	0
Utah	2/1/2024	420	340	80	80	0
Utah	3/1/2024	420	350	70	70	0
Utah	4/1/2024	440	330	110	110	0
Utah	5/1/2024	460	370	90	90	0
Utah	6/1/2024	400	320	80	80	0
Utah	7/1/2024	510	420	90	90	0
Utah	8/1/2024	420	340	80	80	0
Utah	9/1/2024	430	350	80	80	0
Utah	10/1/2024	470	360	110	110	0
Utah	11/1/2024	490	350	140	140	0

Utah	12/1/2024	470	360	110	110	0
Vermont	4/1/2022	120	100	20	20	0
Vermont	5/1/2022	140	120	20	20	0
Vermont	6/1/2022	130	110	20	20	0
Vermont	7/1/2022	130	110	20	20	0
Vermont	8/1/2022	150	130	20	20	0
Vermont	9/1/2022	130	110	20	20	0
Vermont	10/1/2022	120	100	20	20	0
Vermont	11/1/2022	130	110	20	20	0
Vermont	12/1/2022	120	90	30	30	0
Vermont	1/1/2023	150	130	20	20	0
Vermont	2/1/2023	120	100	20	20	0
Vermont	3/1/2023	150	120	30	30	0
Vermont	4/1/2023	140	120	20	20	0
Vermont	5/1/2023	200	180	20	20	0
Vermont	6/1/2023	140	130	10	10	0
Vermont	7/1/2023	120	90	30	20	10
Vermont	8/1/2023	160	130	30	20	10
Vermont	9/1/2023	130	100	30	20	10
Vermont	10/1/2023	140	120	20	10	10
Vermont	11/1/2023	140	110	30	20	10
Vermont	12/1/2023	150	120	30	20	10
Vermont	1/1/2024	150	120	30	20	10
Vermont	2/1/2024	160	130	30	20	10
Vermont	3/1/2024	160	120	40	30	10
Vermont	4/1/2024	160	120	40	30	10
Vermont	5/1/2024	160	130	30	20	10
Vermont	6/1/2024	140	120	20	20	0
Vermont	7/1/2024	170	150	20	20	0
Vermont	8/1/2024	130	110	20	20	0
Vermont	9/1/2024	150	130	20	20	0
Vermont	10/1/2024	170	140	30	30	0
Vermont	11/1/2024	140	110	30	30	0
Vermont	12/1/2024	140	120	20	20	0
Virginia	4/1/2022	2,180	1,990	190	190	0
Virginia	5/1/2022	2,230	2,030	200	200	0
Virginia	6/1/2022	2,430	2,200	230	230	0
Virginia	7/1/2022	2,650	2,330	320	320	0
Virginia	8/1/2022	2,210	1,900	310	310	0
Virginia	9/1/2022	2,260	1,880	380	380	0
Virginia	10/1/2022	2,320	1,940	380	380	0
Virginia	11/1/2022	1,980	1,530	450	450	0
Virginia	12/1/2022	2,050	1,570	480	480	0
Virginia	1/1/2023	3,130	2,610	520	520	0

Virginia	2/1/2023	2,860	2,420	440	440	0
Virginia	3/1/2023	3,110	2,630	480	480	0
Virginia	4/1/2023	3,030	2,540	490	490	0
Virginia	5/1/2023	3,000	2,510	490	490	0
Virginia	6/1/2023	2,960	2,370	590	590	0
Virginia	7/1/2023	2,720	1,970	750	670	80
Virginia	8/1/2023	3,050	2,270	780	660	120
Virginia	9/1/2023	2,950	2,200	750	620	130
Virginia	10/1/2023	2,840	2,010	830	700	130
Virginia	11/1/2023	2,750	1,920	830	710	120
Virginia	12/1/2023	3,030	2,140	890	740	150
Virginia	1/1/2024	3,720	2,690	1,030	880	150
Virginia	2/1/2024	3,460	2,650	810	680	130
Virginia	3/1/2024	3,730	2,940	790	710	80
Virginia	4/1/2024	3,390	2,580	810	730	80
Virginia	5/1/2024	3,900	3,040	860	710	150
Virginia	6/1/2024	3,580	2,740	840	700	140
Virginia	7/1/2024	3,630	2,710	920	750	170
Virginia	8/1/2024	3,620	2,740	880	790	90
Virginia	9/1/2024	3,210	2,390	820	740	80
Virginia	10/1/2024	3,380	2,640	740	630	110
Virginia	11/1/2024	3,230	2,340	890	800	90
Virginia	12/1/2024	3,260	2,320	940	860	80
Washington	4/1/2022	1,790	1,640	150	150	0
Washington	5/1/2022	1,740	1,550	190	190	0
Washington	6/1/2022	1,960	1,680	280	280	0
Washington	7/1/2022	1,760	1,510	250	250	0
Washington	8/1/2022	1,910	1,650	260	260	0
Washington	9/1/2022	1,960	1,730	230	230	0
Washington	10/1/2022	1,950	1,710	240	240	0
Washington	11/1/2022	1,770	1,510	260	260	0
Washington	12/1/2022	1,880	1,560	320	320	0
Washington	1/1/2023	2,060	1,730	330	330	0
Washington	2/1/2023	1,920	1,670	250	250	0
Washington	3/1/2023	2,100	1,840	260	260	0
Washington	4/1/2023	1,880	1,570	310	310	0
Washington	5/1/2023	2,020	1,710	310	310	0
Washington	6/1/2023	2,010	1,720	290	290	0
Washington	7/1/2023	1,920	1,520	400	400	0
Washington	8/1/2023	2,060	1,670	390	370	20
Washington	9/1/2023	1,840	1,520	320	310	10
Washington	10/1/2023	2,030	1,650	380	350	30
Washington	11/1/2023	1,940	1,580	360	340	20
Washington	12/1/2023	1,950	1,610	340	320	20

Washington	1/1/2024	2,250	1,860	390	370	20
Washington	2/1/2024	2,080	1,760	320	300	20
Washington	3/1/2024	2,070	1,720	350	340	10
Washington	4/1/2024	2,040	1,720	320	290	30
Washington	5/1/2024	2,120	1,810	310	290	20
Washington	6/1/2024	1,880	1,610	270	250	20
Washington	7/1/2024	2,090	1,800	290	280	10
Washington	8/1/2024	1,970	1,650	320	300	20
Washington	9/1/2024	1,840	1,590	250	250	0
Washington	10/1/2024	1,840	1,540	300	280	20
Washington	11/1/2024	1,910	1,550	360	350	10
Washington	12/1/2024	2,020	1,620	400	390	10
West Virginia	4/1/2022	90	90	0	0	0
West Virginia	5/1/2022	120	120	0	0	0
West Virginia	6/1/2022	110	110	0	0	0
West Virginia	7/1/2022	30	30	0	0	0
West Virginia	8/1/2022	80	80	0	0	0
West Virginia	9/1/2022	20	20	0	0	0
West Virginia	10/1/2022	0	0	0	0	0
West Virginia	11/1/2022	0	0	0	0	0
West Virginia	12/1/2022	0	0	0	0	0
West Virginia	1/1/2023	0	0	0	0	0
West Virginia	2/1/2023	0	0	0	0	0
West Virginia	3/1/2023	0	0	0	0	0
West Virginia	4/1/2023	0	0	0	0	0
West Virginia	5/1/2023	0	0	0	0	0
West Virginia	6/1/2023	0	0	0	0	0
West Virginia	7/1/2023	40	10	30	30	0
West Virginia	8/1/2023	30	0	30	30	0
West Virginia	9/1/2023	30	0	30	30	0
West Virginia	10/1/2023	40	0	40	40	0
West Virginia	11/1/2023	40	0	40	40	0
West Virginia	12/1/2023	40	0	40	40	0
West Virginia	1/1/2024	60	0	60	60	0
West Virginia	2/1/2024	50	0	50	50	0
West Virginia	3/1/2024	50	0	50	50	0
West Virginia	4/1/2024	60	0	60	60	0
West Virginia	5/1/2024	50	0	50	50	0
West Virginia	6/1/2024	50	0	50	50	0
West Virginia	7/1/2024	50	0	50	50	0
West Virginia	8/1/2024	50	0	50	50	0
West Virginia	9/1/2024	70	0	70	70	0
West Virginia	10/1/2024	70	0	70	70	0
West Virginia	11/1/2024	80	0	80	80	0

West Virginia	12/1/2024	80	0	80	80	0
Wisconsin	4/1/2022	580	580	0	0	0
Wisconsin	5/1/2022	720	700	20	20	0
Wisconsin	6/1/2022	480	470	10	10	0
Wisconsin	7/1/2022	20	0	20	20	0
Wisconsin	8/1/2022	10	0	10	10	0
Wisconsin	9/1/2022	20	0	20	20	0
Wisconsin	10/1/2022	10	0	10	10	0
Wisconsin	11/1/2022	20	0	20	20	0
Wisconsin	12/1/2022	20	0	20	20	0
Wisconsin	1/1/2023	20	0	20	20	0
Wisconsin	2/1/2023	20	0	20	20	0
Wisconsin	3/1/2023	50	0	50	50	0
Wisconsin	4/1/2023	10	0	10	10	0
Wisconsin	5/1/2023	10	0	10	10	0
Wisconsin	6/1/2023	10	0	10	10	0
Wisconsin	7/1/2023	110	0	110	110	0
Wisconsin	8/1/2023	120	0	120	120	0
Wisconsin	9/1/2023	170	60	110	110	0
Wisconsin	10/1/2023	380	250	130	130	0
Wisconsin	11/1/2023	470	340	130	130	0
Wisconsin	12/1/2023	420	260	160	160	0
Wisconsin	1/1/2024	550	400	150	150	0
Wisconsin	2/1/2024	490	350	140	140	0
Wisconsin	3/1/2024	600	460	140	140	0
Wisconsin	4/1/2024	570	410	160	160	0
Wisconsin	5/1/2024	590	420	170	170	0
Wisconsin	6/1/2024	470	330	140	140	0
Wisconsin	7/1/2024	670	460	210	210	0
Wisconsin	8/1/2024	480	290	190	190	0
Wisconsin	9/1/2024	460	280	180	180	0
Wisconsin	10/1/2024	530	300	230	230	0
Wisconsin	11/1/2024	600	340	260	260	0
Wisconsin	12/1/2024	630	390	240	240	0
Wyoming	4/1/2022	50	10	40	40	0
Wyoming	5/1/2022	50	10	40	40	0
Wyoming	6/1/2022	60	20	40	40	0
Wyoming	7/1/2022	60	20	40	40	0
Wyoming	8/1/2022	50	20	30	30	0
Wyoming	9/1/2022	70	20	50	50	0
Wyoming	10/1/2022	50	10	40	40	0
Wyoming	11/1/2022	50	20	30	30	0
Wyoming	12/1/2022	60	20	40	40	0
Wyoming	1/1/2023	60	20	40	40	0

Wyoming	2/1/2023	50	20	30	30	0
Wyoming	3/1/2023	60	20	40	40	0
Wyoming	4/1/2023	60	20	40	40	0
Wyoming	5/1/2023	80	40	40	40	0
Wyoming	6/1/2023	80	40	40	40	0
Wyoming	7/1/2023	60	30	30	30	0
Wyoming	8/1/2023	80	50	30	30	0
Wyoming	9/1/2023	70	40	30	30	0
Wyoming	10/1/2023	80	50	30	30	0
Wyoming	11/1/2023	80	40	40	40	0
Wyoming	12/1/2023	80	50	30	30	0
Wyoming	1/1/2024	90	40	50	50	0
Wyoming	2/1/2024	70	30	40	30	10
Wyoming	3/1/2024	100	60	40	40	0
Wyoming	4/1/2024	80	40	40	40	0
Wyoming	5/1/2024	70	30	40	30	10
Wyoming	6/1/2024	70	30	40	30	10
Wyoming	7/1/2024	60	30	30	30	0
Wyoming	8/1/2024	80	50	30	20	10
Wyoming	9/1/2024	80	50	30	30	0
Wyoming	10/1/2024	90	40	50	40	10
Wyoming	11/1/2024	70	30	40	30	10
Wyoming	12/1/2024	80	30	50	40	10