No. 23-10362

IN THE UNITED STATES COURT
OF APPEALS FOR THE FIFTH CIRCUIT

Alliance for Hippocratic Medicine, et al.,
Plaintiffs-Appellees

v.

Food & Drug Administration, et al.,
Defendants-Appellants
Danco Laboratories, LLC,
Intervenor Defendant-Appellant

On Appeal from the United States District Court for the Northern District of Texas, Amarillo Division, No. 2:22-cv-00223

BRIEF OF MEDICAL STUDENTS FOR CHOICE AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANTS-APPELLANTS

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SUPPLEMENTAL CERTIFICATE OF INTERESTED PARTIES

No. 23-10362, *Alliance for Hippocratic Medicine, et al. v. U.S. Food and Drug Administration, et al.*

Amicus curiae certify that they have no outstanding shares or debt securities in the hands of the public, and they have no parent companies. No publicly held company has a 10% or greater ownership interest in the *amicus curiae*. *Amicus curiae* is unaware of any persons with any interest in the outcome of this litigation other than the signatories to this brief and their counsel, and those identified in the party and *amicus* briefs filed in this case.

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INTEREST OF *AMICUS CURAE* AND SUMMARY OF ARGUMENT

When federal courts impose medically unnecessary restrictions on healthcare in the United States, medical schools are left to translate inaccurate and scientifically flawed policies to students. This is contrary to the core function of medical schools: to provide an evidence-based medical education. Clinical programs, too, are unable to train future physicians on best practices unfettered by medically unnecessary restrictions, undermining their provision of comprehensive evidence-based training. In short, medical schools and clinical programs in the United States cannot provide world-class teaching and training in a healthcare system in which evidence-based medicine is outlawed or restricted by courts.

Medical Students for Choice ("MSFC") is a non-profit organization with nearly 300 chapters in over 30 countries, including 185 chapters across the United States, seeking to ensure that medical students and trainees have access to comprehensive, evidence-based education on all aspects of reproductive healthcare. MSFC was formed by a group of medical students in 1993 in response to the lack of abortion and family planning education in their medical training, and it has since grown to a global organization with over 10,000 members. MSFC works to bring family planning and abortion education to medical students through medical training, conferences, meetings, community organizing, and education. As such, MSFC has a strong interest in protecting evidence-based medical care and

training. MSFC submits this brief to underscore the ways in which the reversal of mifepristone's approval could disrupt medical education and training nationwide.

Mifepristone is safe and effective. Indeed, mifepristone combined with misoprostol has been the most common regimen used for medication abortions in the United States for decades. It is also commonly used to treat miscarriages. There is no scientific justification to reverse the Food & Drug Administration's ("FDA") determination that mifepristone is safe and effective. The district court's decision is contrary to the weight of scientific evidence demonstrating the safety of mifepristone, a drug that has been used by over five million individuals in this country and is available in over 90 countries around the world.

Barring or restricting access to mifepristone denies medical students and trainees in the United States evidence-based teaching and training on a safe and effective method of healthcare. If judges can supplant the scientific judgment of FDA that a medication is safe and effective—contrary to hundreds of high-quality scientific studies, over two decades of extensive research, safe use by millions of Americans, and scientific consensus around the world—the quality of American healthcare, along with training for future healthcare providers, will be in peril. The district court's order thus jeopardizes the quality of American medical education.

Accordingly, MSFC urges this Court to reverse the district court's order.

ARGUMENT

I. Adverse Impact on Medical School Curricula

The unprecedented reversal of FDA's approval of mifepristone undermines the ability of medical schools to offer comprehensive, evidence-based curricula. As many courts have warned, judicial orders such as the one at issue herein carry a significant risk of having nationwide consequences not adequately developed in the record before a single court.[1] Here, one such consequence is the adverse impact on medical education.

A. *Medical School Curricula is Based on Evidence-Based Medicine*

The foundation of medical school curricula in the United States is evidence-

[1] *See U.S. v. Mendoza*, 464 U.S. 154, 160 (1984) (Rehnquist, J.) (holding that nationwide relief can "substantially thwart the development of important questions of law by freezing the first final decision rendered on a particular legal issue" and "deprive[s] this Court of the benefit it receives from permitting several courts of appeals to explore a difficult question before this Court grants certiorari."); *Dep't of Homeland Sec. v. New York*, 140 S. Ct. 599, 600 (2020) (Gorsuch, J., concurring) ("By their nature, universal injunctions tend to force judges into making rushed, high-stakes, low-information decisions."); *Trump v. Hawaii*, 201 L. Ed. 2d 775, 138 S. Ct. 2392, 2424–25 (2018) (Thomas, J., concurring) (holding that nationwide relief is "beginning to take a toll on the federal court system—preventing legal questions from percolating through the federal courts, encouraging forum shopping, and making every case a national emergency for the courts and for the Executive Branch."); *Louisiana v. Becerra*, 20 F.4th 260, 263–64 (5th Cir. 2021) (per curiam) (holding that "an issue of great significance currently being litigated throughout the country . . . will benefit from 'the airing of competing views' in our sister circuits.") (internal citation omitted); *see also L.A. Haven Hospice, Inc. v. Sebelius*, 638 F.3d 644, 664–65 (9th Cir. 2011) ("The Supreme Court has also suggested that nationwide injunctive relief may be inappropriate where a regulatory challenge involves important or difficult questions of law, which might benefit from development in different factual contexts and in multiple decisions by the various courts of appeals."); *Va. Soc'y for Human Life, Inc. v. FEC*, 263 F.3d 379, 393 (4th Cir. 2001) (holding that "an injunction that prevents the FEC from enforcing the regulation against any party anywhere in the United States . . . encroaches on the ability of other circuits to consider the [issue]"), overruled on other grounds by *Real Truth About Abortion, Inc. v. FEC*, 681 F.3d 544 (4th Cir. 2012).

based medicine, which teaches students to use the scientific method combined with clinical experience to arrive at the best medical decisions for their patients.[2] Rose Al Abosy, a medical student at Boston University School of Medicine, explains the importance of studying the rich body of medical knowledge that has arisen from scientific research and evidence-based teaching:

> For me, the point of medical school is to learn from the centuries of knowledge and practice in this field so that I can effectively offer patients options and provide counseling informed by my medical training. My job as a future physician is to work together with my patients to decide what care is best for them and their unique circumstances.

Indeed, numerous studies have demonstrated the benefits of an evidence-based medical education on patient care and outcomes.[3]

In January 1996, the Association of American Medical Colleges established the Medical School Objectives Project to develop a consensus within the medical education community on the attributes that medical students should possess at the time of graduation and to set forth learning objectives to guide medical schools in

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[2] *See* Steven Tenny and Matthew Varacallo, *Evidence Based Medicine* 1 (Treasure Island FL, StatPearls Publishing 2022) ("Evidence-based medicine (EBM) uses the scientific method to organize and apply current data to improve healthcare decisions. Thus, the best available science is combined with the healthcare professional's clinical experience and the patient's values to arrive at the best medical decision for the patient.").

[3] *See, e.g.,* Laura Menard et al., *Integrating Evidence-Based Medicine Skills Into a Medical School Curriculum: A Quantitative Outcomes Assessment*, 26(5) BMJ EVID. BASED MED. 249, 249-250 (2021); Josephine L. Dorsch, Meenakshy K. Aiyer, Lynne E. Meyer, *Impact of an Evidence-Based Medicine Curriculum on Medical Students' Attitudes and Skills*, 92(4) JOURNAL OF THE MEDICAL LIBRARY ASSOCIATION 397, 397-406 (2004).

developing curricula.[4] The Medical School Objectives Project concluded that, upon graduation, medical students "must understand the scientific basis and evidence of effectiveness for each of the therapeutic options that are available for patients at different times in the course of the patients' conditions, and be prepared to discuss those options with patients in an honest and objective fashion."[5]

To prepare medical students to provide evidence-based patient care, the Liaison Committee on Medical Education (the "LCME") requires accredited medical schools to select curricular content based on the scientific method, including the ways in which scientific research "is conducted, evaluated, explained to patients, and applied to patient care."[6] Armed with a strong scientific foundation, medical students at accredited medical schools must also be taught critical judgment skills through curricular content that "incorporates the fundamental principles of medicine, provides opportunities for medical students to acquire skills of critical judgment based on evidence and experience, and develops medical students' ability to use those principles and skills effectively in solving

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[4] The Medical School Objectives Writing Group, *Learning Objectives for Medical Student Education— Guidelines for Medical Schools: Report I of the Medical School Objectives Project*, 74(1) ACADEMIC MEDICINE 13, 13-18 (1999).

[5] *Id.* at 16.

[6] *See* Liaison Committee on Medical Education, *Functions and Structure of a Medical School* 10 (March 2023), https://rb.gy/qojyp.

problems of health and disease."[7]

Accordingly, medical students are taught to care for patients based on principles derived from published evidence, national and international guidelines, medical society consensus, and clinical experience, all with the goal of providing the best possible care for their patients.

B. *Restricting Mifepristone Threatens Evidence-Based Medical Education in the United States*

When courts impose medically unnecessary restrictions on the treatment options available in the United States, medical school deans and faculty must navigate how to teach students scientifically flawed policies. This state of affairs threatens a central tenet of any medical school curriculum: to teach future physicians how to provide their patients with the most safe and effective standard of care backed by science.

The overwhelming scientific evidence shows that mifepristone, followed by misoprostol, is safe and effective.[8] By 2020, medication abortions accounted for

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[7] *Id.*

[8] Rachel K. Jones et al., *Medication Abortion Now Accounts for More Than Half of All US Abortions*, GUTTMACHER INST. (Dec. 1, 2022), https://rb.gy/jf9ey; The National Academies of Sciences Engineering & Medicine, *The Safety and Quality of Abortion Care in the United States* 152 (Washington D.C, The National Academies Press 2018); Courtney A. Schreiber, M.D., M.P.H. et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, 378(23) NEW ENG. J. MED. 2161 (2018); Honor MacNaughton, MD et al., *Mifepristone and Misoprostol for Early Pregnancy Loss and Medication Abortion*, 108(8) AM. FAMILY PHYSICIAN 473 (2018); American College of Obstetricians and Gynecologists, *Early Pregnancy Loss*, Practice Bulletin No. 200, e197, e203 (Nov. 2018, *aff'd* 2021); American College of

the majority of abortions in America.[9] Over the past 23 years, more than five million Americans have safely used mifepristone to complete an abortion.[10] And for miscarriage management, the American College of Obstetricians and Gynecologists recommends a dose of mifepristone 24 hours before misoprostol based on studies showing that "a combined mifepristone–misoprostol regimen was superior to misoprostol alone for the management of early pregnancy loss," "significantly increased rates of complete expulsion," and "decreased [the] risk of surgical intervention with uterine aspiration to complete treatment."[11]

Restricting mifepristone access despite its proven safety and efficacy would therefore contravene a core principle of medical training, as fourth-year medical student Rose Al Abosy explains:

> Taking away the option of mifepristone would seriously undermine my medical training. Medical school teaches us to use rigorously defined

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Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine, *Obstetric Care Consensus*, Practice Bulletin No. 10, 135(3), e110, e122 (2020); Marike Lemmers et al., *Medical Treatment for Early Fetal Death (Less Than 24 Weeks)*, COCHRANE DATABASE SYSTEMATIC REVIEWS, June 2019, at 25; Greer Donley, *Medication Abortion Exceptionalism*, 107(627) CORNELL L. REV. 627, 651-52 (2022).

[9] Jeff Diamant and Besheer Mohamed, *What the Data Says About Abortion in the U.S.*, PEW RESEARCH CENTER (Jan. 11, 2023), https://rb.gy/232rl; World Health Organization, *Medical Management of Abortion* 1 (2018), https://rb.gy/nmino.

[10] U.S. Food & Drug Admin., *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 06/30/2022* (June 30, 2022), https://rb.gy/s3zav.

[11] American College of Obstetricians and Gynecologists, *Early Pregnancy Loss*, Practice Bulletin No. 200, e197, e203 (Nov. 2018, *aff'd* 2021). *See also* Schreiber, *supra* note 8, at 2161 (finding that "[p]retreatment with mifepristone followed by treatment with misoprostol resulted in a higher likelihood of successful management of first-trimester pregnancy loss than treatment with misoprostol alone").

> evidence-based practice along with compassionate counseling to decide with our patients the treatment that works best for them. If mifepristone is no longer available, then I can no longer offer my patients this accepted standard of care, even though my medical training teaches that mifepristone is an extremely safe and effective option, and even though many patients prefer medical abortions over procedural abortions. This outcome would contradict the basic principles of my medical training.

Because mifepristone is a critical component of abortion and miscarriage care, eliminating it from the curriculum would deprive medical students of a comprehensive reproductive healthcare education. Danna Ghafir, a medical student at the University of Texas McGovern Medical School, elaborates:

> We are expected to understand comprehensive reproductive healthcare, including abortion care, which is tested on our national exams, and most importantly, applied in practice to achieve the best possible patient outcomes. According to our evidence-based textbooks, which pull from a plethora of peer-reviewed clinical research, medication abortion is most effective when mifepristone and misoprostol are taken in combination. Further, the management of some miscarriages or early pregnancy complications also calls for the use of mifepristone in combination with misoprostol to maximize patient safety during uterine evacuation. When abortion care is restricted, through state-level bans or politically-driven attacks on mifepristone's availability, physicians and care teams are precluded from employing best practices supported by decades of accumulated scientific evidence.

Courts, for good reason, "owe significant deference to the politically accountable entities [like FDA] with the background, competence, and expertise to assess public health."[12] The lower court's decision, if allowed to stand, would

[12] *Food and Drug Administration v. American College of Obstetricians and Gynecologists*, 141 S.Ct. 578 (Mem), *579 (2021) (Roberts, C.J., concurring in stay of injunction against FDA enforcement of in-person dispensing requirement for mifepristone) (internal quotation marks

trample such deference. As medical student Rose Al Abosy describes, such a result would prevent her from providing a "remarkably safe" drug to her patients:

> For patients seeking to medically terminate a pregnancy, mifepristone followed by misoprostol is the accepted standard of care. Mifepristone is remarkably safe; it is safer than many drugs, even those offered over-the-counter. I remember one of the medical fellows I worked with telling me that when mifepristone is administered appropriately, the biggest risk is accidentally choking on the pill.
>
> Even the fact that mifepristone has been under REMS for so long is an example of a lack of reproductive justice in this country. For patients seeking to medically terminate a pregnancy, mifepristone followed by misoprostol is the accepted standard of care and it is unprecedented that a federal judge, with no medical training at all, could unilaterally diminish the quality of care I am trained to provide to my patients.

A world-class, modern medical school curriculum should teach future physicians the best available treatment options for terminating a pregnancy through both a procedural and a medication abortion. A reproductive healthcare education that teaches medical students the best standard of care for procedural abortions, but not medication abortions (*i.e.*, a mifepristone-misoprostol regimen), is incomplete

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omitted) (citing *South Bay United Pentecostal Church v. Newsom*, 140 S.Ct. 1613, 1614 (2020) (Roberts, C. J., concurring in denial of application for injunctive relief)), *Kisor v. Wilkie*, 139 S.Ct. 2400, 2442 (2019) (Gorsuch J., concurring, with Thomas and Kavanaugh JJ. joining) ("[N]o one doubts that courts should pay close attention to an expert agency's views on technical questions in its field. Just as a court 'would want to know what John Henry Wigmore said about an issue of evidence law [or] what Arthur Corbin thought about a matter of contract law,' so too should courts carefully consider what the Food and Drug Administration thinks about how its prescription drug safety regulations operate." (quoting Paul J. Larkin, Jr. and Elizabeth H. Slattery, *The World After Seminole Rock and Auer*, 42(2) HARV. J. L. & PUB. POL'Y 625, 647 (2020)); *Carson Products Co. v. Califano*, 594 F. 2d 453, 460 (5th Cir. 1979) (holding that FDA's decision under review was "primarily a matter of technical judgment" and "[t]he court is not empowered to substitute its judgment for that of the agency.") (internal citation and quotation marks omitted).

and inadequate. By analogy, an oncology education would be incomplete and inadequate if medical students learned the best standard of care for radiation, but not chemotherapy, because a single judge pulled the best available chemotherapy drugs from the market after decades of safe and effective use.[13]

Mifepristone is a globally accepted drug used in reproductive healthcare treatments, championed by the World Health Organization as an "essential medicine," and available in over 90 countries.[14] Eliminating or restricting access to a treatment option deemed safe and effective by the global scientific community not only lowers the quality of healthcare in the United States, but also of the medical education that our institutions can offer. Accordingly, upholding the district court's medically unnecessary restriction on mifepristone would damage the quality of medical education in this country.

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[13] American Cancer Society, *History of Cancer Treatments: Chemotherapy* (Jun. 12, 2014), https://rb.gy/xw3bw (noting that methotrexate was first used to cure cancer in 1956).

[14] World Health Organization, *Model List of Essential Medicines* 47 (2019), https://rb.gy/j5ouh; Gynuity Health Projects, *Mifepristone Approved List* (March 2023), https://rb.gy/uluf3; Sarah Munro et al., *Perspectives Among Canadian Physicians on Factors Influencing Implementation of Mifepristone Medical Abortion: A National Qualitative Study*, 18(5) ANNALS OF FAM. MED. 414 (2020) ("Mifepristone is on the World Health Organization's list of essential medicines and is considered the gold standard for medical abortion."); Kurt Barnhart, *Medical Management of Miscarriage With Mifepristone*, 396(10253) THE LANCET 737, 737-739 (2020) (finding that "mifepristone pretreatment is the optimal medical approach to women with missed miscarriage").

C. *Limiting Safe and Effective Treatment Options Undercuts Students' Medical Ethics Education*

Judicial interference with access to mifepristone undermines another central tenet of medical school curricula: to teach medical students to follow principles of medical ethics in caring for patients.[15]

Though the precise content of ethical curricula varies among medical schools,[16] the four commonly accepted principles of medical ethics are respect for autonomy (respecting and supporting autonomous decisions); nonmaleficence (avoiding causation of harm); beneficence (relieving, lessening, or preventing harm, providing benefits, and balancing benefits against risks and costs); and justice (fairly distributing benefits, risks, and costs).[17] Eliminating a treatment option that is not only safe and effective, but also often the option that many

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[15] *See* Liaison Committee on Medical Education, *Functions and Structure of a Medical School* 11 (March 2023), https://rb.gy/uur42 (requiring accredited medical schools to "ensure that the medical curriculum includes instruction for medical students in medical ethics and human values both prior to and during their participation in patient care activities and require medical students to behave ethically in caring for patients and in relating to patients' families and others involved in patient care"); Association of American Medical Colleges, *Core Entrustable Professional Activities for Entering Residency* 16-17 (2017), https://rb.gy/09q4r (required competencies for medical school graduates include "adherence to ethical principles," including "a commitment to ethical principles pertaining to provision or withholding of care…").

[16] Lisa Soleymani Lehmann M.D., Ph.D., M.Sc, et al., *A Survey of Medical Ethics Education at U.S. and Canadian Medical Schools*, 79(7) ACADEMIC MEDICINE 682, 682 (2004) (while all responding institutions offered formal instruction in medical ethics, the curricular content of ethical instruction varied among institutions).

[17] Tom L. Beauchamp & James F. Childress, *Principles of Biomedical Ethics* 13 (7th ed. 2013); Thomas R. McCormick et al., *Principles of Bioethics*, UNIVERSITY OF WASHINGTON MEDICINE (Apr. 30, 2023), https://rb.gy/ajavf (Beauchamp and Childress's four principles of medical ethics are commonly accepted).

patients prefer over a more burdensome and invasive procedural abortion, contravenes these core principles.[18] This is particularly the case for patients for whom procedural abortions may lead to physical and/or psychological harm, and for whom a mifepristone-misoprostol regimen is thus the best treatment plan that accounts for the patient's unique circumstances.

Medical student Danna Ghafir fears that further restrictions on abortion care may violate her ethical obligation to "do no harm":

> As part of our education, we are taught to act in the best interests of our patients and abide by the tenet to "do no harm." When abortion care is restricted, we are forced to make decisions in violation of these professional principles.

Hanna Amanuel, a medical student at Harvard Medical School, shares similar concerns that she may one day be unable to offer her patients a safe and effective treatment option despite her ethical obligations:

> I came to medical school to develop the skills to really support people, especially people who are least cared for in the US medical system. At a super basic level, this means using the most safe and effective medications and treatments available, and rigorous scientific research, to guide healthcare decisions. We know that mifepristone is safely used across the world (in at least 94 countries) and is safely taken at home. A ban on mifepristone is a ban on an essential medicine.
>
> It deeply troubles me that my peers and I might be in a position where we cannot offer a medication to people that we know is safe and effective. Not offering the best treatment available is unethical and

[18] World Health Organization, *Medical Management of Abortion* 1-2 (2018), https://rb.gy/nmino ("Medical abortion plays a crucial role in providing access to safe, effective and acceptable abortion care.").

> harmful. People who are denied access to abortions still seek them out because they need them, and unsafe abortion is one of the leading causes of maternal mortality globally.

In summary, failing to offer patients the option of mifepristone for abortion care or to treat miscarriages despite its safety and efficacy conflicts with the ethical obligations that medical students are taught to uphold.[19]

II. Adverse Impact on Clinical and Residency Training

The potential ramifications of this case extend beyond medical students' academic careers to their careers as practicing physicians. As the testimonials of medical students below illustrate, restricting mifepristone in the United States impairs reproductive healthcare training and access to increasingly competitive obstetrics and gynecology ("OB/GYN") residency and clinical programs.

A. *Future Healthcare Providers Should Receive Training on Administering Mifepristone*

If FDA's approval of mifepristone is overturned, medical students and residents throughout the country are unlikely to receive any training on how mifepristone is provided. To understand why this is so, one need look no further than the changes in medical education and training wrought by the United States

[19] *See* Basil Varkey, *Principles of Clinical Ethics and Their Application to Practice*, 30(1) MEDICAL PRINCIPLES AND PRACTICE 17 (2021) (explaining that, in regards to one of four guiding ethics principles, "[t]he practical application of nonmaleficence is for the physician to weigh the benefits against burdens *of all interventions and treatments*, to eschew those that are inappropriately burdensome, and to choose the best course of action for the patient.") (emphasis added).

Supreme Court's decision in *Dobbs*: The Journal of the American Medical Association reports that residents in an estimated 45% of OB/GYN residency programs located in states banning or severely restricting abortions now lack in-state abortion education and training.[20] The damage inflicted by *Dobbs* will be greatly exacerbated if training on medication abortion and miscarriage management is impaired by a restriction on mifepristone, and this damage will be felt even in states where abortion remains legal.[21]

Numerous studies show that residents who receive routine abortion training are ultimately more skilled in miscarriage management.[22] By the same token, depriving medical trainees of that education would impair more than just their ability to provide medication abortions. While eliminating training on mifepristone would be particularly consequential for medical students and residents planning to practice as OB/GYN doctors given the frequency with which mifepristone is

[20] Rachel Rabkin Peachman, Dobbs *Decision Threatens Full Breadth of Ob-Gyn Training*, 328(17) THE JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION 1668, 1668 (2022).

[21] In the first 100 days after the *Dobbs* decision, at least 66 clinics in 15 states stopped offering abortion care, and only one of those 15 states retained any clinics offering abortion care, creating geographic areas of insufficient or completely absent abortion care in the United States. Marielle Kirstein et al., *100 Days Post-Roe: At Least 66 Clinics Across 15 U.S. States Have Stopped Offering Abortion Care*, GUTTMACHER INST. (Oct. 6, 2022), https://rb.gy/mhqzn. *See also* Society of Family Planning, *#WeCount Report* (April 11, 2023), https://rb.gy/54pgy (reporting shifts in abortion access since the *Dobbs* decision).

[22] Peachman, *supra* note 20, at 1668, citing Jody Steinauer, MD, PhD, professor of obstetrics and gynecology and director of the Bixby Center for Global Reproductive Health at the University of California, San Francisco.

administered for abortion procedures, medical students planning to practice in other fields would also be disadvantaged. Without the adequate training, physicians—regardless of whether they specialize in OB/GYN—will be unable to provide the highest standard of care for their patients.

Medical student Rose Al Abosy's first-hand account illuminates the importance of medication abortion training for both students like her seeking to specialize in the OB/GYN field as well as other medical students:

> The first time I learned about mifepristone was in my pre-clinical courses, which all medical students take regardless of the area of medicine they will specialize in. Specifically, I learned about mifepristone during a lecture on abortion options, including both medical and procedural abortion. I continued to learn about mifepristone during my OB/GYN rotation as a third-year medical student, when I saw it administered to a number of patients to manage abortion and miscarriage. Then, as a fourth-year medical student, I completed a rotation in family planning and offered medical and procedural abortion to patients myself as part of options counseling.
>
> My training during medical school was absolutely helpful for my future practice as a physician and the patients I will serve. Knowing how to talk through medical and procedural options for abortion and miscarriage is a critical skill set. It is important not only for people like me who want to become OB/GYN doctors, but for anyone practicing medicine generally. If a patient comes to you for issues unrelated to reproductive health and has a history of abortion or miscarriage, having reproductive health training is important because your job as a physician is to care for the patient as a whole. This issue is not only relevant to me because I am going into obstetrics and gynecology; it is relevant to any medical student or physician who wants to provide the best care for their patients.

Moreover, setting the precedent that FDA approval is subject to judicial

scrutiny and overruling would cause instability in all fields of medical training. Medical students would be faced with a future where their training is adequate one day, only to become inadequate the next, depending on the latest court ruling.

B. *Restricting Mifepristone Access Will Detrimentally Impact Residency Placement and Clinical Experience*

Restricting access to mifepristone would exacerbate the harm to medical residents seeking to obtain clinical abortion training at a time when access to such training is already limited. The Accreditation Council for Graduate Medical Education ("ACGME") requires all OB/GYN training programs to provide access to clinical experience on abortion and comprehensive family planning.[23] But the Supreme Court's decision in *Dobbs* has made it exceedingly difficult for medical students and residents to obtain this hands-on training, particularly in states with greater abortion restrictions.[24] ACGME has made clear that OB/GYN training programs in states where clinical abortion experience is legally restricted are not exempt from the clinical experience requirement, mandating that those programs

[23] *Id.* Following the *Dobbs* decision, ACGME proposed revised requirements clarifying that abortion education and clinical training is essential for OB/GYN physicians and that simulation exercises are not a substitute for hands-on experience with patients. *See id.*

[24] *Id.* ("An estimated 45% of accredited US obstetrics and gynecology residency programs are located in the more than half of states that ban or severely restrict abortions," and consequently, "current and future medical students and residents attending those programs will lack in-state abortion education and training.").

support their residents to obtain the required training in another state.[25]

Consequently, OB/GYN residents in restricted states must secure a training position with an out-of-state program offering clinical abortion experience (programs which are growing increasingly competitive and oversubscribed) and coordinate logistics to complete this weeks-long clinical rotation—all to receive training that is required for their practice and critical to providing quality patient care.[26] Even if residents can secure placement in out-of-state training programs, they face significant logistical challenges, including acquiring the funds to travel to and live in another state for weeks, and for residents with families, coordinating the necessary child care. At the same time, programs offering clinical abortion experience have experienced a tremendous strain both from patients seeking care that they cannot obtain in their home states and from future healthcare providers seeking the full spectrum of abortion training.[27]

Fourth-year medical student and future OB/GYN resident Rose Al Abosy shares her experience applying to OB/GYN residencies and her predictions on the

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[25] *Id.*

[26] Dr. Amanda P. Williams, MD, MPH, an OB/GYN and clinical innovation advisor for Stanford University's California Maternal Quality Care Collaborative, has noted that lack of hands-on abortion care training would be "a loss of a critical skill to be an excellent obstetrician-gynecologist." *Id.*

[27] *Id.* (Many medical educators have expressed concerns that "medical students who want the full spectrum of training will apply in greater numbers to residency programs in nonrestricted states").

future obstacles to clinical training:

> Based on my own experience and understanding of data on this topic, getting a residency position in a state with greater access to abortions has become more competitive since the *Dobbs* decision. When I was applying to residency programs, many of the decisions that I made were influenced by *Dobbs*. Whether I would be able to obtain abortion training in a particular residency program was constantly on my mind.
>
> In my opinion, removing access to mifepristone would certainly make clinical abortion training more competitive and harder for medical students and residents to access. Limiting medical abortion would leave procedural abortion as the only option, so programs in states still offering procedural abortion training would become more competitive. Those states would also face an even greater influx of both patients seeking abortion care and healthcare providers who want to continue offering full-scope reproductive care. Further, many physicians themselves want to live and work in states where they can access abortions. In short, restrictions on mifepristone would make an already terrible situation for clinical abortion training even worse.
>
> Further, I understand that many residency programs do not have a clear plan for how to provide abortion training to their residents. Some programs are discussing partnering with clinics and programs in other states, but that option presents complications, including obtaining medical licenses for residents to practice in other states.

Without access to mifepristone, some patients will be forced to obtain a procedural abortion. Eliminating or restricting access to mifepristone could therefore only intensify competition for access to clinical abortion training and aggravate the burden on programs in states that still permit procedural abortions.

III. Adverse Impact on the Quality and Reputation of Medical Programs in the United States

Not surprisingly, future OB/GYNs have expressed concerns about the quality of an American medical education on reproductive healthcare in light of

judicial interventions such as the district court's decision in the case at bar.[28] Deprived of the opportunity to receive comprehensive abortion training in the United States, medical students and residents may foreseeably seek such training internationally where it can still be obtained.

For instance, medical students in Sweden typically spend eight weeks on OB/GYN coursework and training, which includes education on all methods of abortion.[29] And in the United Kingdom, the Royal College of Obstetricians and Gynecologists ("RCOG") core curriculum for post-graduate OB/GYN training requires education on both medical and procedural abortion methods.[30] Further, as discussed above, mifepristone is classified as an "essential medicine" by the World Health Organization and is available in over 90 countries around the world.[31] Presumably, many of those countries likewise offer their future healthcare

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[28] Susan E. W. Spencer, *Panel Calls Out Health and Medical Education Impacts of Overturning Roe v. Wade,* UMASS CHAN MEDICAL SCHOOL, (Jul. 28, 2022), https://rb.gy/4j42e. *See also* Alyssa Stephenson-Famy, MD et al., *The* Dobbs *Decision and Undergraduate Medical Education: The Unintended Consequences and Strategies to Optimize Reproductive Health and a Competent Workforce for the Future*, 98(4) ACADEMIC MEDICINE 431 (2023).

[29] Kristina Gemzell-Danielsson and Amanda Cleeve, *Abortion Training Models in Sweden, in* ADVANCING WOMEN'S HEALTH THROUGH MEDICAL EDUCATION: A SYSTEMS APPROACH IN FAMILY PLANNING AND ABORTION 331, 333 (Ulta Landy, Philip D. Darney, & Jody Steinauer eds., 2021).

[30] Patricia A. Lohr and Lesley Regan, *Abortion Training and Integration in the United Kingdom, in* ADVANCING WOMEN'S HEALTH THROUGH MEDICAL EDUCATION: A SYSTEMS APPROACH IN FAMILY PLANNING AND ABORTION 336, 339 (Ulta Landy, Philip D. Darney, & Jody Steinauer eds., 2021).

[31] World Health Organization, *Model List of Essential Medicines* 47 (2019), https://rb.gy/j5ouh; Gynuity Health Projects, *Mifepristone Approved List* (March 2023), https://rb.gy/uluf3.

providers with education and training on mifepristone.

The availability of such comprehensive reproductive healthcare educational opportunities is a real consideration for medical students deciding where to continue their training. In fact, after the *Dobbs* decision, residency programs in states that enacted abortion restrictions saw a 10.5% drop in OB/GYN residency applications compared to the period preceding *Dobbs.*[32] If comprehensive abortion training can no longer be offered in the United States, this trend may extend to a loss of OB/GYN residents nationwide.

Further, if medical professionals in this country can no longer prescribe mifepristone, the United States risks falling behind the international standard for abortion care and training recommended by international medical and healthcare organizations that have been recognized as "set[ting] professional standards for reproductive health care."[33] Medical student Danna Ghafir harbors related concerns that if mifepristone approval is revoked, medical trainees in the United States would be relegated to receiving second-rate training:

Even in states like Texas, where abortion care is inaccessible, medical

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[32] Kendal Orgera, M.P.H., M.P.P., et al., *Training Location Preferences of U.S. Medical School Graduates Post* Dobbs v. Jackson Women's Health Organization *Decision*, THE AAMC RESEARCH AND ACTION INSTITUTE (April 13, 2023), https://rb.gy/tufte.

[33] The National Academies of Sciences Engineering & Medicine, *The Safety and Quality of Abortion Care in the United States* 19-20 (Washington D.C, The National Academies Press 2018). This group of international healthcare organizations includes the World Health Organization, RCOG in the United Kingdom, and—currently—the American College of Obstetricians and Gynecologists, among others.

> students and residents have the opportunity to travel to other states for comprehensive family planning training. If mifepristone's FDA approval were revoked, trainees nationwide would not have access to experiential learning opportunities that entail the highest quality, evidence-based management protocols involving mifepristone.

Ms. Ghafir also fears that such circumstances would harm the reputation of the medical profession in the United States, opining:

> Under these circumstances [where teaching decisions are informed by political opinion rather than scientific research], medical education institutions in the US would be failing to fulfill their duty to train and graduate the best possible physicians, harming not only the reputation of the medical profession in the US, but more importantly, bringing undue harm to patients themselves.

Similarly, medical student Rose Al Abosy has serious concerns about the status of abortion training and care in this country. Below, Ms. Al Abosy shares her reflections on her medical education and future medical career in the United States in light of recent uncertainty surrounding abortion care training:

> I have higher expectations for what my medical education should provide as far as training in abortion care. Now that the situation around abortion training and access in this country is growing increasingly dire, when I think about my future practice as an OB/GYN, I think about what it would be like to practice in a different country. If abortion options become very limited in the United States and I am not permitted to practice medicine here in the way that I was trained, I would consider my options for practicing elsewhere.

Dango Mwambene, a medical student at the University of Cape Town in South Africa, also reconsidered where she intends to practice given the potential reversal of mifepristone approval:

> I have considered specialising or subspecialising in obstetrics and

> gynaecology in the United States but a ruling that supports the banning of [m]ifepristone and further federally limits access to abortion significantly makes me reconsider this possibility. I'd rather stay in South Africa and specialise here or go elsewhere where abortion access is constitutionally protected.

Medical students seeking to practice in the United States and to train in this country's prestigious medical programs should not need to settle for incomplete and scientifically inferior training on reproductive healthcare. And, as the testimonies of medical students and future residents above illustrate, the reversal of FDA's approval of mifepristone against the weight of the overwhelming scientific evidence would cause substantial harm to medical education in the United States.

CONCLUSION

For the foregoing reasons, this Court should reverse the decision below.

Respectfully submitted,

<u>/s/ Jayme Jonat</u>

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CERTIFICATE OF SERVICE

I hereby certify that on this 1st day of May, 2023 a true and correct copy of the foregoing Brief was served via the Court's CM/ECF system.

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Fed. R. App. P. 32(a)(7)(B) because it contains 6,109 words, excluding the parts of the document exempted by Fed. R. App. P. 32(f).

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