23-10362

United States Court of Appeals for the Fifth Circuit

ALLIANCE FOR HIPPOCRATIC MEDICINE, *et al.*,

Plaintiffs-Appellees,

against

U.S. FOOD AND 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
No. 2:22-cv-223

BRIEF FOR AMICI CURIAE THE CITY OF NEW YORK AND NYC HEALTH + HOSPITALS, THE COUNTY OF SANTA CLARA, AND FOUR OTHER LOCAL JURISDICTIONS IN SUPPORT OF DEFENDANTS-APPELLANTS' EMERGENCY STAY APPLICATIONS

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The County of Los Angeles, California
The City and County of San Francisco, California
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CERTIFICATE OF INTERESTED PARTIES

1. Case No. 23-10362, *Alliance for Hippocratic Medicine v. FDA*.
2. Pursuant to Federal Rule of Appellate Procedure 26.1(a), Federal Rule of Appellate Procedure 29(a)(4)(A), and Fifth Circuit Rule 28.2.1, Amici Curiae cities and counties need not furnish a certificate of interested persons because they are governmental entities.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Statutes

Other Authorities

TABLE OF AUTHORITIES (cont'd)

Page(s)

TABLE OF AUTHORITIES (cont'd)

Page(s)

TABLE OF AUTHORITIES (cont'd)

Page(s)

TABLE OF AUTHORITIES (cont'd)

Page(s)

INTERESTS OF AMICI AND SUMMARY OF ARGUMENT

Amici, the City of New York and NYC Health + Hospitals, the County of Santa Clara, Los Angeles County, City and County of San Francisco, King County, and Cook County, are on the front lines of protecting the public health. Amici write to highlight how the district court's interim "stay" of the FDA's more than two-decades-old approval of mifepristone would cause broad harm to the nation's largest public hospital systems by disrupting their long-settled use of the safe, effective, and resource-efficient two-drug regimen for carrying out medication abortions, at a time when it can least be afforded.

Amici speak from experience. NYC Health + Hospitals is the largest municipal hospital and health care system in the country, operating 11 public hospital sites and providing essential inpatient, outpatient, and home-based services to over one million New Yorkers every year in more than 70 locations across the city's five boroughs. Separately, the City's Department of Health and Mental Hygiene oversees public health policy in the city by, among other things, tracking infectious diseases and conditions and operating

clinics offering patients sexual health services, immunizations, and tuberculosis testing at no or low cost.

The County of Santa Clara, which is the most populous of the San Francisco Bay Area's nine counties, operates the second largest major public health and hospital system in California. Alongside its Public Health Department, Behavioral Health Services Department, Custody Health Services Department, Homeless Healthcare Program, and a County-run health insurance plan, the County of Santa Clara Health System includes three public hospitals and a network of clinics that offer emergency, urgent, acute, preventative, and specialized care as well as pharmacy services. The County's three public hospitals and clinics serve more than 200,000 unique patients per year and serve as a critical health care safety net provider, providing care to anyone in the County who needs it, regardless of financial circumstances.

America's public health-care systems provide crucial health-care services to those who need them most. And they are currently experiencing severe and unprecedented challenges. We write to highlight how the district court's decision will aggravate those

challenges, generating confusion and disarray, making it harder for residents to access health care of all kinds and undermining community health—the very harms that the district court mistakenly suggested its "stay" of mifepristone's FDA approval would avert.

Times are difficult for public hospital systems. It has never been easy to provide low-cost, high-quality health care to vulnerable populations that depend on public health-care systems and suffer many acute ailments at above-average rates. Even before the COVID-19 pandemic, public hospitals faced significant staffing and resource shortages. But the last three years have pushed public hospitals to a crisis point. Burnout has contributed to an exodus of medical professionals, while the demand for care is swelling.

In these times of unmatched stress on scarce public health resources, every measure matters. Finding new efficiencies through telehealth, patient self-management, and other tools is essential to keeping public health-care systems working as they should—as they must. And avoiding backsliding on past gains is just as important. If medication abortion using the safe and effective two-

drug regimen is suddenly removed as an option for health-care professionals and their patients, that will increase demands placed on public hospitals. Public hospitals, in turn, will have to divert resources to meet the increased demand for procedural abortions from their existing patients and from new patients who otherwise would have secured care from other community-based providers.

Because public hospitals operate with limited resources, the impact of the district court's decision will not be confined to patients seeking abortions, or even those seeking reproductive health care. Thousands of patients in need of all kinds of non-emergency surgical care could find themselves facing significant delays in obtaining procedures, and some may forgo care altogether, as health system resources are diverted to address the needs of patients requiring time-sensitive abortion and miscarriage treatment. Reducing the ability of public hospitals to provide resource-effective, high-quality care will erode patients' confidence in care and make the provision of health care to already vulnerable and sometimes hesitant populations even more difficult. If left in

place, the district court's decision will undermine public health services across the board.

ARGUMENT

THE DISTRICT COURT'S ORDER IS PREDICATED ON A SERIES OF FALSE ASSUMPTIONS AND WILL DAMAGE PUBLIC HEALTH

As the Government has shown, forcing patients to opt for less effective health-care options or delay until a procedural abortion is feasible is itself profoundly harmful, and reason alone to deny petitioners a preliminary injunction or interim relief under 5 U.S.C. § 705 (*see* Brief for U.S. Food and Drug Administration in Support of Emergency Motion Under Circuit Rule 27.3 for a Stay Pending Appeal ("FDA Brief") at 25-26). There is no threat of irreparable harm to plaintiffs, and any harm is outweighed by the damage done to the public interest by the district court's interim stay.

We write to emphasize additional ways in which the order harms the public. The order will cause significant harm to already overburdened public health-care systems by decreasing the efficacy of medication abortion as compared to the long preferred two-drug regimen that has been used for more than two decades, which will

in turn increase demand for procedural abortions. And additional, immediate harms will flow from the district court's curtailment of health-care providers' ability to prescribe effective medication abortions through telehealth.

The claim that mifepristone is unsafe or ineffective is entirely refuted by the drug's well-documented safety and efficacy record spanning more than two decades, as the FDA and the Intervenor Danco Laboratories have shown in their briefs (FDA Brief at 14-15; Brief in Support of Intervenor-Appellant's Emergency Motion to Stay Preliminary Injunction Pending Appeal and for a Temporary Administrative Stay Pending Consideration of Motion ("Danco Brief") at 17-18). Yet, the district court concluded that patients presenting with mifepristone-related complications threaten to "overwhelm the medical system" and "place 'enormous pressure and stress' on doctors during emergencies and complications," which "consume crucial limited resources" (Decision at 7, 63). These are invented harms that have no basis in reality. Meanwhile, the court effectively ignored the strong public interests in ensuring that the

20-year-long status quo is not upended based on a judge's medically unsupported belief that mifepristone is unsafe (*see id.* at 14).

Worse than that, the district court has it precisely backwards. It is the suspension of mifepristone's 20-year-old approval—not its continuance—that would threaten to overwhelm public health-care systems and waste crucial limited resources. If it goes into effect, the district court's decision will lead, at a minimum, to delays in the provision of an array of critical health-care services as providers and resources must be diverted to provide time-sensitive procedural abortions and miscarriage management for patients, some of whom would have opted for a less resource-intensive treatment plan including mifepristone.

This will critically impact public health, in general, and public hospitals, in particular. For patients who prefer to manage their abortions from home and without a procedure, public hospitals depend on the availability of the less resource-intensive two-drug abortion regimen that starts with mifepristone to provide the best patient care, respect patients' autonomy, and efficiently deploy health-care resources.

A. It is a uniquely difficult time to operate a public health network.

Local governments stand on the front lines of protecting public health, and amici can report that these are particularly challenging times to do this work. The City of New York—tasked with protecting the health of the city's 8.5 million residents and 60 million annual visitors—operates five no- or low-cost health clinics, together offering testing and treatment for sexually transmitted infections, contraceptives, and medication abortions. And NYC Health + Hospitals, the nation's largest municipal healthcare system, operates 11 public hospital campuses with full-service obstetrics and gynecology departments, as well as five post-acute/long-term care facilities, a home health agency, correctional health services, a health plan, and more than 50 community-based health-care centers—employing 40,000 people and serving more than 1.2 million New Yorkers annually.

The County of Santa Clara, California—home to over 1.9 million people—operates the County of Santa Clara Health System, which is the second-largest county-owned health and hospital system in California. The County's three public hospitals and

clinics serve more than 200,000 unique patients per year, including indigent patients, patients who comes from the 53% of Santa Clara County households that do not speak English as a first language[1], and rural community members who would otherwise need to travel 30 or more miles to receive care. The County Health System offers comprehensive reproductive health services, including routine screenings, labor and delivery, miscarriage management, and medication and procedural abortions. Other amici likewise operate major public health systems. For example, the County of Los Angeles, California—with more than 10 million residents—operates the nation's second largest municipal health-care system, with four acute-care hospitals and 26 health centers serving 750,000 patients each year.

Public hospitals are facing unprecedented hurdles to delivering high-quality care to patients. Even before the pandemic, acute staffing and resource shortages loomed for over a decade.[2] In

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[1] *QuickFacts Santa Clara County, California*, U.S. CENSUS BUREAU, https://perma.cc/MK8E-BV85.

[2] Daily Briefing: *America deliberately limited its physician supply—now it's facing a shortage*, ADVISORY BD. (Feb. 16, 2022), https://perma.cc/5XJK-U887;

(cont'd on next page)

a June 2021 report, the Association of American Medical Colleges projected a nationwide shortage of nearly 124,000 physicians by 2034—shortages of up to 47,000 primary care physicians and 77,000 specialists.[3] Surgical specialists[4] and anesthesiologists,[5] in particular, are already in short supply. Staffing shortages force hospitals to take beds and operating rooms offline, which reduces health-care access and compounds hospitals' financial problems.[6]

The pandemic intensified these problems. Hospital staff worked in grueling conditions around the clock, logging significant

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Carmichael, Mary, *Primary-Care Doctor Shortage Hurts Our Health*, NEWSWEEK (Feb. 25, 2010), https://perma.cc/2UUS-NSK3.

[3] *The Complexities of Physician Supply and Demand: Projections From 2019 to 2034,* ASS'N OF AM. MED. COLL. (June 2021), https://perma.cc/3WD7-5ACY; Robezneiks, Andis, *Doctor shortages are here—and they'll get worse if we don't act fast,* AM. MED. ASS'N (Apr. 13, 2022), https://perma.cc/BP8M-3T8P.

[4] Darves, Bonnie, *Physician shortage spikes demand in several specialties*, NEW ENGL. J. MED., CAREER CENTER (Nov. 30, 2017), https://perma.cc/QF8R-DNX3.

[5] *White Paper: Anesthesiology: Supply, Demand and Recruiting Trends*, MERRITT HAWKINS (2021), https://perma.cc/WAH4-9KSB.

[6] Muoio, Dave, *'Unsustainable' losses are forcing hospitals to make 'heart-wrenching' cuts and closures, leaders warn*, FIERCE HEALTHCARE (Sept. 16, 2022), https://perma.cc/MSD2-E5UH (reporting that, due to shortage of 3,900 nurses and 14% of clinical support staff, Trinity Health, which operates 88 hospitals, has had to take 12% of its beds, 5% of operating rooms, and 13% of emergency departments offline); Glatter, Dr. Robert, et ano., *The Coming Collapse of the U.S. Health Care System*, TIME (Jan. 10, 2023), https://perma.cc/3CXV-DEBP (explaining that hospital beds are "browned out" due to lack of staff, leading to overcrowding).

overtime, to respond to an unprecedented disaster. They dealt with staggering patient mortality rates, full beds, and shortages of ventilators for patients and personal protective equipment for themselves—and experienced illness, burnout, exhaustion, and trauma.[7] Front-line medical professionals have suffered from depression and PTSD—in some cases committing suicide.[8] The federal Dr. Lorna Breen Health Care Provider Protection Act, recently signed into law, was named after a New York City emergency room physician who took her own life early in the pandemic.[9] Pandemic-related challenges triggered a mass exodus from the medical profession.[10] By November 2021, one in five health-care workers had left their jobs.[11]

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[7] Pearson, Bradford, *Nurses Are Burned Out. Can Hospitals Change in Time to Keep Them?* N.Y. TIMES (Feb. 20, 2023), https://www.nytimes.com/2023/02/20/well/nurses-burnout-pandemic-stress.html.

[8] *Id.;* Belluz, Julia, *The doctors are not all right,* VOX (Jun. 23, 2021), https://perma.cc/9JB2-4N26.

[9] Robezneiks, *supra* n.3.

[10] *Issue Brief: Impact of the COVID-19 Pandemic on the Hospital and Outpatient Clinician Workforce*, Office of the Assistant Secretary for Planning and Evaluation, Office of Health Policy, U.S. DEP'T OF HEALTH AND HUMAN SERV., (May 3, 2022), https://perma.cc/U6VA-XJ2M.

[11] Yong, Ed, *Why Health-Care Workers Are Quitting in Droves*, THE ATLANTIC (Nov. 16, 2021), https://perma.cc/47LT-8RRF.

The challenges facing public hospitals, as compared with private hospitals, are deepened by the demographics of public hospitals' patient populations. Of the over one million patients New York City's public health-care system serves every year, nearly 400,000 are uninsured, equating to more than $1.1 billion in uncompensated care, while the majority of the patients are insured by public payers, primarily Medicaid,[12] which reimburse providers at below-cost rates.[13] Likewise, of the 200,000 patients served by the County of Santa Clara's public hospitals and clinics every year, nearly 17,000 are uninsured, 134,700 are insured by Medi-Cal, and 31,500 are insured by Medicare. Low-income individuals have historically suffered from a range of acute ailments at higher rates than their higher-income counterparts.[14] The communities served by public hospitals are disproportionately susceptible to "chronic conditions, such as hypertension and diabetes, that are by far the

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[12] *Metropolitan Anchor Hospital (MAH) Case Study, NYC Health + Hospitals | New York*, AM. HOSPITAL ASS'N (June 2022), https://perma.cc/6Q6P-QR8U.

[13] *Fact Sheet: Underpayment by Medicare and Medicaid*, AM. HOSPITAL ASS'N (Feb. 2022), https://perma.cc/6D5D-A3M5.

[14] Madara, Dr. James, *America's health care crisis is much deeper than COVID-19,* AM. MED. ASS'N (Jul. 22, 2020), https://perma.cc/KD4L-P6MU.

largest drain on our health system."[15] With a greater insured population following the passage of the Affordable Care Act finally seeking out long-delayed care, health-care demand has grown among historically underserved populations, just as the ability of public hospitals to meet that demand has plummeted.[16]

Add to all this an aging population, and demand for medical care is at an all-time high.[17] Never before have so many people lived so long.[18] The nation's 74 million baby boomers will soon be 65 or older; by 2025, seniors will outnumber children.[19] "[O]lder people see a physician at three or four times the rate of younger people and account for a highly disproportionate number of surgeries,

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[15] *Id*.

[16] Howley, Elaine, *The U.S. Physician Shortage Is Only Going to Get Worse. Here Are Potential Solutions,* TIME (JUL. 25, 2022), https://perma.cc/6MNC-FDCB; Zhang X, et al., *Physician workforce in the United States of America: forecasting nationwide shortages*. HUM RESOUR. HEALTH (Feb. 6, 2020), https://perma.cc/8BQV-4TMW.

[17] Zhang, *supra* n.16.

[18] Recent reports of a dramatic and troubling drop in life expectancy across the country is largely due to the pandemic, which is reaching its close, and does not cancel out the staggering number of aging Americas who are anticipated to put unprecedented strain on the health-care industry in the coming years. *NYC Life Expectancy Plunged Amid COVID, New Stats Show. See How Much It Shaved Off*, NBC N.Y. (Apr. 7, 2023), https://perma.cc/V2EW-2DEP.

[19] Howley*, supra* n.16.

diagnostic tests, and other medical procedures."[20] And this aging population includes physicians and nurses, themselves. "We're facing a physician retirement cliff"—with many actively licensed physicians in the U.S. age 60 or older, and not enough newly minted doctors taking their places.[21]

Public hospitals face a perfect storm. The massive shortfall of staff and resources creates acute financial pressures.[22] Since 2010, an astounding number of hospitals across the country have closed—an average of 21 per year, with 47 closures in 2019 alone[23]—including more than two dozen in New York State.[24] This includes both rural and inner-city hospitals, and has put significant strain on surviving hospitals.[25] Public hospitals have particularly felt that

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[20] *Id*.

[21] *Id*.

[22] *The Current State of Hospital Finances: Hospital Finance Report, Fall 2002 Update*, KAUFMAN HALL, https://perma.cc/327Z-3CHP.

[23] Saghafian, S., et al., *Towards a more efficient healthcare system: Opportunities and challenges caused by hospital closures amid the COVID-19 pandemic*. HEALTH CARE MANAG. SCI. 25, at 187–190 (Mar. 16, 2022), https://perma.cc/868E-6E5U.

[24] *Our Vow: No More Closings*, NEW YORK STATE NURSES ASS'N, https://perma.cc/L9BK-SA9K.

[25] Rau, Jordan, *Urban Hospitals of Last Resort Cling to Life in Time of COVID*, KHN (Sept. 17, 2020), https://perma.cc/5VRQ-MQTV.

strain, and at times have taken action to respond to or prevent closures. In 2019, for example, the County of Santa Clara stepped in to purchase two local hospitals in bankruptcy that were at risk of imminent closure, thereby ensuring uninterrupted access to care to residents in an underserved area of the county.

Many other hospitals and clinics have survived only by shutting down select vital services. "It is not uncommon to hear that health care systems have shut down Pediatrics, Psychiatry, Obstetrics, and ICU."[26] And inpatient beds and operating rooms taken offline due to staffing shortages lead to longer wait times for admission from emergency rooms. The problem is compounded by corresponding shortages in outpatient and rehabilitation facilities, which delay patient discharge.[27] In all, these are exceptionally challenging times in which to operate a public hospital or health-care system.

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[26] Glatter, *sura* n.6.

[27] *Id.*

B. Removal of mifepristone from the market will undermine public health.

Removal of mifepristone from the market will result in an inevitable increase in the need for procedural abortions and emergency care from patients who otherwise could have been prescribed the two-drug regimen. Some patients who would have otherwise preferred a medication abortion will forgo the single-drug regimen that, though safe and effective, is associated with more severe side effects, takes longer, and has been found in some studies to be less effective than the two-drug regimen. Others will opt for the single-drug regimen, and will experience more intense pain, increased bleeding, and additional side effects, such as nausea, diarrhea, and vomiting, and turn to emergency departments for care. And hospitals will also need to expend additional resources in miscarriage management, because mifepristone is used to medically manage miscarriage.[28] These patient harms and

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[28] Schreiber, Courtney A. et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, N. ENGL. J. MED. 2018 (June 7, 2018), https://perma.cc/BBB2-7GRE; Macnaughton, Honor MD et al., *Mifepristone and Misoprostol for Early Pregnancy Loss and Medication Abortion*, 103 AM. FAMILY PHYSICIAN 473 (Apr. 15, 2018), https://perma.cc/NJE3-HFC9.

systemwide costs are currently avoided. The change would undercut public-health systems' ability to efficiently meet patient demands more broadly—harms of which the district court took no account.

Last year, medication abortions accounted for more than half of the country's abortions.[29] NYC Health + Hospitals' 11 hospitals performed nearly 3,000 abortions, over two-thirds of which were medication abortions, and this does not account for the no- and low-cost medication abortions provided by the City's sex health clinics. And in 2020, Los Angeles County's four public hospitals performed more than 450 abortions, with medication abortions accounting for roughly half. With the country returning to a patchwork of jurisdictions where abortions are lawful, we anticipate increased

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[29] Jones, Rachel, *Medication Abortion Now Accounts for More Than Half of All US Abortions*, GUTTMACHER INST. (Feb. 2022), https://perma.cc/2R5Z-EGY9. Guttmacher Institute estimates that there were 930,160 abortions in 2020. *See* Jones, Rachel, et al., *Abortion incidence and service availability in the United States, 2020*, GUTTMACHER INST. (Nov. 2022), https://perma.cc/G4NN-TDFE. In 2019, 886,000 pregnancies ended in abortion. *Fact Sheet: Global and Regional Estimates of Unintended Pregnancy and Abortion*, GUTTMACHER INST. (Mar. 2022), https://perma.cc/Y79N-DWA7.

pressure on public health systems' abortion services, where available.

A shift towards procedural abortions would only heighten public hospitals' present challenges, because procedural abortions are significantly more resource-intensive than medication abortions. In both New York City's and the County of Santa Clara's public hospitals, procedural abortions are commonly performed in the same operating theaters where other surgeries occur. In addition to requiring an OB/GYN, a procedural abortion often requires a patient to receive care from an anesthesiologist, who administers either a local or general anesthetic and places the patient in either moderate or deep sedation with intravenous medication. It also often requires the presence of general nursing and specialized surgical nursing staff. And while a procedural abortion is relatively quick, patients require aftercare before being discharged. The additional staffing and support requirements lead to additional costs: NYC Health + Hospitals estimates that providing a procedural abortion costs five times as much as a medication abortion.

As explained, public hospitals confront a national shortage of anesthesiologists and certified registered nurse anesthetists, as well as surgical specialists and nurses, and a shortage of hospital beds. Increasing the number of procedural abortions will decrease hospitals' surgical and post-operative care capacity, just as the demands from the country's aging population are expected to surge.

These are not *necessary* costs. A two-drug regimen of mifepristone and misoprostol is the long-prevailing approach to ending an early pregnancy in the United States.[30] And for good reason: it is a safe and effective option, as safe as ibuprofen, and about as effective as procedural abortions, as the FDA has shown (FDA Brief at 15).[31] This regimen is advantageous for patients who prefer to manage the termination of a pregnancy from outside of a clinical setting, and in a manner that is less physically invasive—and is medically required for some patients, such as those with

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[30] Schreiber, *supra* n.28; Macnaughton, *supra* n.28; *see also* Declaration of Dr. Courtney Schreiber, MD, MPH in Support of Danco's Brief at 4-11.

[31] *Medication Abortion*, GUTTMACHER INST. (Feb. 1, 2021), https://perma.cc/FH4S-3XJX.

allergies to anesthesia.[32] And because misoprostol-only abortions present hurdles associated with more significant side effects than occur under the two-drug regimen,[33] the use of misoprostol alone will put additional strains on public hospitals and will not be an adequate alternative for a sizeable share of our patient populations.

Medication abortions have the additional advantage that patients can take the prescribed medications at home, rather than being treated in an operating room. Promoting, rather than vilifying, safe and effective self-care is essential to prudent use of public hospitals' scarce resources. Where the risks of complication and likelihood of error are low, patients should be empowered to choose a safe and comfortable option—and, critically from a public health perspective, the least resource-intensive one—that allows

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[32] FDA Brief at 25; Danco Brief at 19-20; Declaration of Dr. Alisa Goldberg, MD, MPH in Support of Danco's Brief at 4-5; *see also The Safety and Quality of Abortion Care in the United States*, NAT'L ACADS. OF SCIS., ENG'G, & MED. (2018), https://perma.cc/9PR7-73WF.

[33] Declaration of Dr. Courtney Schreiber, MD, MPH in Support of Danco's Brief at 10; Raymond, Elizabeth, *Efficacy of Misoprostol Alone for First-Trimester Medical Abortion: A Systematic Review*, OBSTET. GYNECOL. 133(1): 137-47 (Jan. 2019), https://perma.cc/F8MY-TYQ6; Ngoc NT, et al., *Comparing two early medical abortion regimens: mifepristone+misoprostol vs. misoprostol alone*, CONTRACEPTION 83(5):410-7 (May 2011), https://perma.cc/8S42-QEEW.

them to control the timing of administration and symptoms. Contrary to the district court's unsupported assumptions about risk (Decision at 46), medication abortion can safely be completed at home, because patients can easily take the two-drug regimen without direct supervision and serious side-effects are exceedingly rare.

And medication abortion is not solo care. To the contrary, patients taking the two-drug regimen have access to information and support, including virtual or in-person consultation and medical care if necessary or preferred at any stage.[34] Research has shown that increasing rates of self-care leads to "demonstrable savings for governments, health systems and households."[35] Self-care is not just preferred by some patients, but also reduces wait times and unnecessary emergency department visits, relieves

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[34] Donovan, Megan, *Self-Managed Medication Abortion: Expanding the Available Options for U.S. Abortion Care*, GUTTMACHER INST. (OCT. 17, 2018), https://perma.cc/LPQ5-6BFD.

[35] *The Economic and Social Value of Self-Care*, AESGP (Nov. 26, 2021), https://perma.cc/6C9L-F4M5.

physician workloads to allow more efficient resource allocation, and lowers the cost of care for patients and health-care systems.[36]

In short, eliminating access to effective medication abortions will compromise public health and undermine public hospitals during a particularly dire time for our nation's public health-care systems. The decision will overburden public hospitals' emergency and surgical facilities and undermine public health across the board—the very harm that the district court mistakenly believed it was averting by "staying" mifepristone's FDA approval 20-plus years after the fact.

Other aspects of the order compound these harms. Incorporating telehealth into the provision of care helps public hospitals meet unprecedented recent challenges. The district court was deeply mistaken in reasoning that health-care resources have been strained by the FDA's elimination of the requirement that the two-drug regimen be administered in a doctor's office, on the theory that doctors must "spend several hours treating post-abortive

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[36] *Id.*

women, even hospitalizing them overnight or providing treatment throughout several visits" (Decision at 4, 10).[37]

The opposite is true. Telehealth can ease the burden on already overburdened doctors and nurses, while increasing access to care for underserved patients.[38] The Texas Comptroller reports that increasing telehealth is needed to alleviate economic pressures facing hospitals; telehealth visits reduce the time for intake and decrease the length and number of hospital visits, while increasing service through online patient portals and virtual meetings.[39] Telehealth "can increase patient engagement by creating new or additional ways of communicating with patients' physicians," increasing patient and primary-care provider access to specialists, assisting with "on-going monitoring and support for patients with

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[37] Donovan, Megan, *Self-Managed Medication Abortion: Expanding the Available Options for U.S. Abortion Care*, GUTTMACHER INST. (OCT. 17, 2018), https://perma.cc/LPQ5-6BFD.

[38] Howley, *supra* n.16; Alvandi, Maryam, *Telemedicine and its Role in Revolutionizing Healthcare Delivery,* AM. J. OF ACCOUNTABLE CARE Vol.5(1), at e1-e5 (Mar. 10, 2017), https://perma.cc/E66Z-W8GH.

[39] Falconnier, Jamie, et ano., *A Review of the Texas Economy from the Office of Glenn Hegar, Texas Comptroller of Public Accounts: Rural Counties Face Hospital Closures, The Economics of Medical Care Outside of Cities*, FISCAL NOTES (Oct. 2022), https://perma.cc/3LMA-72LC.

chronic conditions," and reducing expenses "by maximizing the use of specialists without the need to duplicate coverage in multiple locations."[40]

Indeed, given the preliminary posture of this case, the district court's "stay"—which would radically disrupt the long-prevailing status quo during the pendency of litigation—will compound these harms and cause additional confusion. Public hospitals would be forced to immediately pivot to a new approach—rapidly reallocating resources and supplies and providing updated training and guidance to professionals, even though the courts may reverse course in the case's final disposition. Swings of that nature are particularly troubling in the context of public health—another dynamic of which the district court took no account.

C. By prohibiting the often-preferred course of treatment and adding to strains on public hospitals, the order will also undermine confidence in public health-care systems.

The district court's decision will also undermine trust in public health-care systems more broadly, resulting in wide-ranging

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[40] *Id.*

harms to the health and wellbeing of the entire community. As noted, removing mifepristone from the market will not only impact people seeking medication abortions and miscarriage management, but also put an unnecessary strain on limited resources and cause delays in treatment for an array of other conditions. This, in turn, will erode public confidence in the ability of public health-care systems to provide quality services, with effects that will reverberate across our communities.

Research shows that patients who have negative medical experiences, or who feel betrayed by their medical institutions—for example, a woman who is denied proper care for her miscarriage, or an individual whose much-needed surgery is delayed due to lack of space in the operating room—are more likely to distrust and disengage from their health care providers.[41] Critically, negative experiences make people less likely to follow medical advice in the future. And loss of faith in health-care providers reaches beyond the individual: research also shows that people who feel that a relative

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[41] Carly Parnitzke Smith, *First, do no harm: institutional betrayal and trust in health care organizations*, 10 J. MULTIDISC. HEALTHCARE 133, 137, 140-42 (2017), https://perma.cc/4F93-3MK5.

has experienced poor medical care are likely to lose trust in health-care providers in general.[42]

These ripple effects carry far beyond one individual's experience, and result in increased public skepticism of medical providers, which, in amici's experience, correlates with devasting consequences for local governments' ability to ensure their communities' health and welfare. For instance, research shows that individuals who mistrust health-care systems are also more likely to delay seeking healthcare, fail to adhere to medical advice, and fail to keep medical appointments.[43] Unsurprisingly, these tendencies can lead to worse individual health outcomes. Thus, reduced trust in healthcare professionals and systems will negatively affect local governments' ability to carry out one of their core functions: ensuring the safety and wellbeing of their residents.

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[42] Oguro, Nao, et al., *The impact that family members' health care experiences have on patients' trust in physicians*, BMC HEALTH SERV. RSCH., at 2, 9-10 (Oct. 19, 2021), https://perma.cc/AA8E-LPU4.

[43] LaVeist, Thomas A. et al., *Mistrust of Health Care Organizations is Associated with Underutilization of Health Services*, 44 HEALTH SERVS. RSCH., 2093, 2102-03 (2009), https://perma.cc/A3GV-PNZW.

Finally, restricting access to mifepristone will adversely affect the public health by imposing another barrier for underserved communities, who already face multiple barriers to accessing basic and critical healthcare. As local governments who provide safety-net care for underserved communities—including individuals who face poverty, lack health insurance, or do not speak English as a first language—amici have experienced firsthand the hurdles that underserved communities face in accessing healthcare. Patients who are struggling to make ends meet, for example, may face difficulties in finding time off work, arranging for substitute childcare, or locating rides to and from healthcare facilities for even one visit, let alone multiple ones. Making healthcare even more difficult to navigate—here, by requiring additional doctor's visits and creating delays in care—will impair individuals' willingness and ability to access healthcare.

* * *

Speaking from experience, as local governments that operate and support public hospitals from coast to coast, we can say for certain that the public health crisis faced by emergency

departments is not due to emergency side effects caused by mifepristone, as the district court found (Decision at 7, 29). Far from it: mifepristone is a critical tool for combatting the mounting supply and demand crisis that is already imperiling local governments' ability to protect the health and safety of their residents.

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CONCLUSION

This Court should grant the FDA's and Danco Laboratories' applications for an emergency stay of the district court's ruling "staying" the FDA's 2000 approval of mifepristone and subsequent FDA actions regarding the drug.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that this document complies with the type-volume limitation set forth in the Federal Rules of Appellate Procedure 27(d)(2)(A) and 32(a)(7)(B) because it contains 4,963 words, exclusive of the portions of the brief that are exempted by Rule 32(f). In their motion for leave, amici curiae have included a request for leave to submit an amici curiae brief of up to 5,200 words—the same number of words permitted for motions under Rule 27(d)(2)(A). I hereby certify that this brief was prepared using Microsoft Word, and according to that software, it contains 4,963 words, not including the table of contents, table of authorities, this certificate, and the cover.

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STATEMENT UNDER FRAP 29(a)(4)(E)

(i) No counsel for a party authored this brief in whole or in part;

(ii) No party or a party's counsel contributed money that was intended to fund preparing or submitting the brief; and

(iii) No person – other than the amici curiae or their counsel – contributed money that was intended to fund preparing or submitting the brief.

CERTIFICATE OF SERVICE

I hereby certify that, on April 11, 2023, the foregoing document was filed with the Clerk of the Court, using the CM/ECF system, causing it to be served on all counsel of record.

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