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

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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.

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TABLE OF AUTHORITIES

Page(s)

Secondary Authorities

Alvandi, Maryam, *Telemedicine and Its Role in Revolutionizing Revolutionizing Healthcare Delivery,* AM. J. OF ACCOUNTABLE CARE Vol.5(1), (Mar. 10, 2017), https://perma.cc/E66Z-W8GH 27

Belluz, Julia, *The Doctors Are Not All Right,* VOX (Jun. 23, 2021), https://perma.cc/9JB2-4N26 14

Carmichael, Mary, *Primary-Care Doctor Shortage Hurts Our Health*, NEWSWEEK (Feb. 25, 2010), https://perma.cc/2UUS-NSK3 13

Daily Briefing: America Deliberately Limited Its Physician Supply—Now It's Facing a Shortage, ADVISORY BD. (Feb. 16, 2022), https://perma.cc/5XJK-U887 13

Darves, Bonnie, *Physician Shortage Spikes Demand in Several Specialties*, NEW ENGL. J. OF MED., CAREER CENTER (Nov. 30, 2017), https://perma.cc/QF8R-DNX3 13

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 25, 26

Falconnier, Jamie, et al., *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 27

Fact Sheet: Global and Regional Estimates of Unintended Pregnancy and Abortion, GUTTMACHER INST. (Mar. 2022), https://perma.cc/Y79N-DWA7 21

TABLE OF AUTHORITIES (cont'd)

Page(s)

Fact Sheet: Underpayment by Medicare and Medicaid, AM. HOSPITAL ASS'N (Feb. 2022), https://perma.cc/6D5D-A3M5 15

Glatter, Robert, et al., *The Coming Collapse of the U.S. Health Care System*, TIME (Jan. 10, 2023), https://perma.cc/3CXV-DEBP 14, 18, 19

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 16, 17, 27

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 15

Jones, Rachel, *Medication Abortion Now Accounts for More Than Half of All US Abortions*, GUTTMACHER INST. (Feb. 2022), https://perma.cc/2R5Z-EGY9 21

Jones, Rachel, et al., *Abortion Incidence and Service Availability in the United States, 2020,* GUTTMACHER INST. (Nov. 2022), https://perma.cc/G4NN-TDFE 21

LaVeist, Thomas A., et al., *Mistrust of Health Care Organizations is Associated with Underutilization of Health Services*, 44 HEALTH SERVS. RSCH. 2093 (2009), https://perma.cc/A3GV-PNZW 30

Madara, James, *America's Health Care Crisis Is Much Deeper Than COVID-19*, AM. MED. ASS'N (Jul. 22, 2020), https://perma.cc/KD4L-P6MU 16

TABLE OF AUTHORITIES (cont'd)

Page(s)

MacNaughton, Honor 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 .... 20, 23

Medication Abortion, GUTTMACHER INST. (Feb. 1, 2021), https://perma.cc/FH4S-3XJX 23

Metropolitan Anchor Hospital (MAH) Case Study, NYC Health + Hospitals | New York, AM. HOSPITAL ASS'N (June 2022), https://perma.cc/6Q6P-QR8U 15

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 13, 14

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 17

Ngoc, Nguyen Thi Nhu, 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 24

Oguro, Nao et al., *The Impact That Family Members' Health Care Experiences Have on Patients' Trust in Physicians*, BMC HEALTH SERV. RSCH. (Oct. 19, 2021) https://perma.cc/AA8E-LPU4 29

Our Vow: No More Closings, NEW YORK STATE NURSES ASS'N, https://perma.cc/L9BK-SA9K 18

TABLE OF AUTHORITIES (cont'd)

Page(s)

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 14

Rau, Jordan, *Urban Hospitals of Last Resort Cling to Life in Time of COVID*, KHN (Sept. 17, 2020), https://perma.cc/5VRQ-MQTV 18

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 24

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 13, 14

Saghafian, Soroush, 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 (Mar. 16, 2022), https://perma.cc/868E-6E5U 18

Schreiber, Courtney A. et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, New ENGL. J. MED. 2018 (June 7, 2018), https://perma.cc/BBB2-7GRE 20, 23

Smith, Carly Parnitzke, *First, Do No Harm: Institutional Betrayal and Trust in Health Care Organizations,* 10 J. MULTIDISC. HEALTHCARE, 133 (2017), https://perma.cc/4F93-3MK5 29

TABLE OF AUTHORITIES (cont'd)

Page(s)

The Current State of Hospital Finances: Hospital Finance Report, Fall 2022 Update, KAUFMAN HALL, https://perma.cc/327Z-3CHP 17

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 13, 18

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 24

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

White Paper: Anesthesiology: Supply, Demand and Recruiting Trends, MERRITT HAWKINS (2021), https://perma.cc/WAH4-9KSB 13

Yong, Ed, *Why Health-Care Workers Are Quitting in Droves*, THE ATLANTIC (Nov. 16, 2021), https://perma.cc/47LT-8RRF 15

Zhang, Xiaoming, et al., *Physician Workforce in the United States of America: Forecasting Nationwide Shortages*, HUM. RESOUR. HEALTH (Feb. 6, 2020), https://perma.cc/8BQV-4TMW 16

INTERESTS OF AMICI CURIAE

Amici are local governments on the front lines of protecting the public health and include the operators of some of the largest municipal public hospital and health-care systems in the nation.[1] For many years, amici have relied on a safe, effective, and resource-efficient drug regimen using mifepristone for medication abortions up to roughly 10 weeks of pregnancy.

We write to highlight how the district court's preliminary injunction "staying" the FDA's more than two-decades-old approval of mifepristone would cause broad harm to the nation's public health, including by significantly increasing costs to public health-care systems at a time those costs can least be afforded, thereby straining the ability of public healthcare systems to provide effective patient care. And an order like the one issued by the

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[1] Amici consist of the City of New York, New York and NYC Health + Hospitals; the County of Santa Clara, California; the County of Los Angeles, California; the City and County of San Francisco, California; King County, Washington; and Cook County, Illinois. No counsel for a party authored this brief in whole or in part, and no party or counsel for a party made a monetary contribution intended to fund its preparation or submission. No person other than the amici or their counsel made a monetary contribution to the preparation or submission of this brief.

motions panel, winding back the FDA's actions to before 2016, would likewise be tremendously damaging, forcing health-care systems to pivot to more resource-intensive protocols that are not medically indicated, if they can even obtain the medication at all.

The U.S. Supreme Court stayed the district court's order pending disposition of this appeal and any timely petition for writ of certiorari, injecting stability into these proceedings for the time being. But any injunction prior to the consideration of the underlying merits of this case threatens to inject profound uncertainty and chaos into an area of great public significance. Until this case has been finally resolved, public health-care systems should not be forced to take on uncertain legal risks or consider abruptly abandoning longstanding practices that have served them and their patients well for years. With public health-care providers at a crisis point in the wake of the COVID-19 pandemic, the timing could not be worse.

Amici's views on public health are shaped by their deep and unique experience in the area. The City of New York, with more than 8.4 million residents and tens of millions of annual visitors,

has been at the forefront of public health for centuries. Today, through its Department of Health and Mental Hygiene, the City operates five no- or low-cost health clinics that offer an array of sexual and reproductive health services, including testing and treatment for sexually transmitted infections, contraceptives, and medication abortions. NYC Health + Hospitals is the country's largest municipal hospital and health-care system, serving more than 1.2 million people annually through its 11 public hospital campuses, which have 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.

The County of Santa Clara, which is the most populous of the San Francisco Bay Area's nine counties with roughly 1.9 million residents, operates the second-largest 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, including indigent patients, patients who come from the 53% of Santa Clara County households that do not speak English as a first language, and rural community members who would otherwise need to travel great distances 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 roughly 10 million residents, operates the nation's second largest municipal health-care system, with four acute-care hospitals and 26 health centers care serving 750,000 patients each year. And Cook County,

Illinois, serves more than 600,000 people each year through its health system, which includes two hospitals, more than a dozen community health centers, and a Medicaid managed care health plan.

SUMMARY OF ARGUMENT

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. Enjoining all or part of the FDA's actions with respect to mifepristone over the last several decades would aggravate those challenges, creating the potential for 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 avoid.

Times are difficult for public hospital and health care systems. It has never been easy to provide low-cost, high-quality health care to vulnerable populations who 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 to provide effective, safe, and resource-efficient care matters. Finding new efficiencies through telehealth, patient self-care, 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 two-drug regimen is suddenly removed as an option for patients, public hospitals will face substantially increased demands on their resources. And if those portions of the district court's order purporting to "stay" the FDA's actions on mifepristone beginning in 2016 are sustained, it would require many public hospitals to needlessly expend critical resources on in-person appointments that are not medically necessary, and to burden their overworked physicians with responsibilities that qualified advanced practice clinicians have

been capably doing independently for years. Further, sustaining all or part of the district court's order would require public hospitals to divert resources to meet the increased demand for procedural abortions from existing patients and from new patients who otherwise would have seen other community-based providers.

Because public hospitals and clinics operate with limited resources, the impact of the district court's decision would 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 would also erode patients' confidence in the public health-care system 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 across the board.

ARGUMENT

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

As the Government has shown, forcing patients seeking abortion or miscarriage care to utilize a medication regimen that may pose greater side effects or be less effective, or to delay care until an appointment for a procedural abortion is available and accessible (if ever), is itself profoundly harmful, and reason alone to vacate the preliminary injunction (*see* Brief for Federal Appellants ("FDA Brief") at 63-65). There is no threat of irreparable harm to plaintiffs, who have no standing in any event, and any speculative harm is outweighed by the real damage done to the public interest by the district court's order.

We write to emphasize additional ways in which the order would harm the public. To start, the district court's order threatens to throw longstanding health-care practices into turmoil by purporting to stay FDA approval of a much-utilized drug. And,

what's more, the order provides little to no guidance about what effect it's meant to have on the behavior of frontline health-care providers today. As a result, public health-care providers are left in the lurch, forced to confront the medical and operational risks of potentially having to abandon longstanding practices that have best served them and their patients and the legal risks that follow from attempting to comply with a court order that fails to provide necessary guidance. The quandary is only compounded by the conflicting order from a district court in another circuit.[2]

The ruling below further threatens to corner public hospitals and clinics into immediately pivoting to new practices—rapidly reallocating resources and supplies and changing policies, practices, training, and guidance to medical 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—a dynamic of which the district court took no account.

[2] Two amici—Cook County, Illinois and King County, Washington—are in states covered by the conflicting order of the district court.

An order affirming in part and reversing in part, along the lines of reasoning of this Court's partial stay, would also be deeply troubling. Such an order would force public hospitals and health-care systems—and the medical professionals who work for them—to work under a cloud of potential liability unless they take the drastic approach of attempting to conform their practices to a misperception of the pre-2016 regulatory landscape.

Even putting immediate implementation concerns to one side, the district court's order will cause significant harm to already overburdened public health-care systems by potentially decreasing the efficacy of medication abortion and medical management of miscarriage as compared to the long-preferred two-drug regimen, which will in turn increase demand for procedural abortions and necessary procedures in the event of an incomplete miscarriage. And additional, immediate harms will flow from the district court's limits on who can prescribe medication abortion and 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 40-44, 47-51; Brief in Support of Intervenor-Appellant ("Danco Brief") at 43-48). 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" (NDTX ECF Dkt. 22-cv-223, No. 137 ("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 affirmed, the

district court's decision would 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 procedures for abortions and miscarriage management for patients, some of whom would have opted for a less resource-intensive treatment plan including mifepristone.

This would critically impact public health, in general, and public hospitals, in particular. For patients who prefer to manage their abortions from home with one or no in-person visits 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-care system.

Local governments stand on the front lines of protecting public health, and amici—who operate some of the nation's largest public hospital and health-care systems—can report that these are particularly challenging times to do this work.

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.[3] In 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.[4] Surgical specialists[5] and anesthesiologists,[6] 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.[7]

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[3] *Daily Briefing: America Deliberately Limited Its Physician Supply—Now It's Facing a Shortage*, ADVISORY BD. (Feb. 16, 2022), https://perma.cc/5XJK-U887; Carmichael, Mary*, Primary-Care Doctor Shortage Hurts Our Health*, NEWSWEEK (Feb. 25, 2010), https://perma.cc/2UUS-NSK3.

[4] *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.

[5] Darves, Bonnie, *Physician Shortage Spikes Demand in Several Specialties*, NEW ENGL. J. MED., CAREER CENTER (Nov. 30, 2017), https://perma.cc/QF8R-DNX3.

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

[7] 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

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The pandemic intensified these problems. Hospital staff worked in grueling conditions around the clock, logging significant 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.[8] Front-line medical professionals have suffered from depression and PTSD—in some cases committing suicide.[9] 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.[10] Pandemic-related challenges triggered a mass exodus

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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, Robert, et al., *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).

[8] 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.

[9] *Id.;* Belluz, Julia, *The Doctors Are Not All Right,* VOX (Jun. 23, 2021), https://perma.cc/9JB2-4N26.

[10] Robezneiks, *supra* n.4.

from the medical profession.[11] By November 2021, one in five health-care workers had left their jobs.[12]

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 billion in uncompensated care, while the majority of the patients are insured by public payers, primarily Medicaid,[13] which reimburse providers at below-cost rates.[14] 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.

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[11] *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.

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

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

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

Low-income individuals have historically suffered from a range of acute ailments at higher rates than their higher-income counterparts.[15] The communities served by public hospitals are disproportionately susceptible to "chronic conditions, such as hypertension and diabetes, that are by far the largest drain on our health system."[16] And with a greater insured population following the implementation 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.[17]

Add to all this an aging population, and demand for medical care is at an all-time high.[18] Never before have so many people lived

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[15] Madara, James, *America's Health Care Crisis Is Much Deeper Than COVID-19,* AM. MED. ASS'N (Jul. 22, 2020), https://perma.cc/KD4L-P6MU.

[16] *Id.*

[17] 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, Xiaoming, et al., *Physician Workforce in the United States of America: Forecasting Nationwide Shortages*, HUM RESOUR. HEALTH (Feb. 6, 2020), https://perma.cc/8BQV-4TMW.

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

so long.[19] The nation's 74 million baby boomers will soon be 65 or older; by 2025, seniors will outnumber children.[20] "[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, diagnostic tests, and other medical procedures."[21] 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.[22]

Public hospitals face a perfect storm. The massive shortfall of staff and resources creates acute financial pressures.[23] Since 2010, an astounding number of hospitals across the country have closed—

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[19] 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 Americans 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.

[20] Howley, *supra* n.17.

[21] *Id.*

[22] *Id.*

[23] *The Current State of Hospital Finances: Hospital Finance Report, Fall 2022 Update*, KAUFMAN HALL, https://perma.cc/327Z-3CHP.

an average of 21 per year, with 47 closures in 2019 alone[24]—including more than two dozen in New York State.[25] This includes both rural and inner-city hospitals, and has put significant strain on surviving hospitals.[26] Public hospitals have particularly felt that 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 take on 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."[27] And inpatient beds and operating rooms taken offline due to staffing shortages lead to longer wait times for

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[24] Saghafian, Soroush, 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.

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

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

[27] Glatter, *supra* n.7.

admission from emergency rooms. The problem is compounded by corresponding shortages in outpatient and rehabilitation facilities, which delay patient discharge.[28] In all, these are exceptionally challenging times in which to operate a public hospital or health-care system.

B. "Staying" the FDA's approval of mifepristone or its 2016, 2019, and 2021 actions relating to the drug will undermine public health.

Public hospitals should not have to shoulder additional and unnecessary systemwide costs during what is a dire time for our nation's public health-care systems. A "stay" of all or part of the FDA's actions with respect to mifepristone would undercut the ability of public-health systems to efficiently meet patient needs more broadly—harms which the district court disregarded.

Eliminating the availability of mifepristone or reinstating medically unnecessary restrictions on this medication would significantly increase the burden on public health-care systems. Some patients who would have otherwise preferred a two-drug

[28] *Id.*

medication abortion would opt for a costly procedural abortion. Other patients would choose a 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. Some patients opting for the single-drug regimen would experience more intense pain, increased bleeding, and additional side effects, such as nausea, diarrhea, and vomiting, and turn to emergency departments for care. Increasing the number of visits required and restricting the ability to leverage non-physician medical professionals would, of course, also increase health-care costs. And hospitals may also need to expend additional resources on miscarriage management because mifepristone is used to medically manage miscarriage.[29]

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[29] Danco Brief at 59; 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 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.

Last year, medication abortions accounted for more than half of the country's abortions.[30] 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 sexual health clinics. As another example, 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 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

[30] 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.

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 a specialist or trained clinician to perform the procedure itself, 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 currently costs more than 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. The order below, if affirmed in whole or in part, would threaten to overburden public hospitals' emergency and surgical facilities and undermine public health across the board—the very kinds of harms that courts typically aim to avert by preserving the status quo during the pendency of litigation.

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.[31] The district court ignored that public health experts—chief among them, the FDA—have studied the medical evidence and concluded that mifepristone is safe and effective (*see* FDA Brief at 40-44), and that reducing the number of doctor visits or eliminating in-person visits altogether is medically appropriate for most patients (*id.* at 46-48, 50-56).[32] This regimen is advantageous for patients who prefer to manage the

[31] Schreiber, *supra* n.29; MacNaughton, *supra* n.29.

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

termination of a pregnancy from outside of a clinical setting, and in a manner that is less physically invasive—and this regimen is medically required for some patients, such as those with allergies to anesthesia (*id*. at 62-63)[33] or those who might find a procedure to potentially be traumatic (e.g., because of a history of sexual assault). And because misoprostol-only abortions present hurdles associated with more significant side effects than occur under the two-drug regimen,[34] the use of misoprostol alone will put additional strains on public hospitals and will not be an adequate alternative for a sizeable share of public hospitals' 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 or other clinical setting. Promoting, rather than vilifying, safe and effective self-care is

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[33] *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.

[34] 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, Nguyen Thi Nhu, 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.

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 them to control the timing of administration and symptoms. Contrary to the district court's unsupported assumptions about the risk of medical complications (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.

To be clear, the longstanding status quo 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.[35] Research has shown that increasing rates of self-care leads to "demonstrable savings for governments, health systems and

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[35] 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.

households."[36] Self-care is not just preferred by some patients, but also reduces wait times and unnecessary emergency department visits, relieves physician workloads to allow more efficient resource allocation, and lowers the cost of care for patients and health-care systems.[37]

Reducing the number of in-person visits and incorporating telehealth into the provision of care helps public hospitals meet unprecedented recent challenges. The district court was deeply mistaken in concluding that mifepristone puts a strain on resources, because doctors must "spend several hours treating post-abortive women, even hospitalizing them overnight or providing treatment throughout several visits" (Decision at 4, 7-8, 10, 13-14).[38]

The opposite is true. Telehealth can ease the burden on already overburdened doctors and nurses, while increasing access

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

[37] *Id.*

[38] Donovan, *supra* n.35.

to care for underserved patients.[39] For example, 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.[40] 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 chronic conditions," and reducing expenses "by maximizing the use of specialists without the need to duplicate coverage in multiple locations."[41]

The district court's sweeping "stay" is particularly harmful given the preliminary posture of this case. The irreparable harm to

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[39] Howley, *supra* n.17; 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.

[40] Falconnier, Jamie, et al., *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.

[41] *Id.*

public health would persist, even if the courts ultimately reversed course in the case's final disposition.

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

The district court's decision, if affirmed, would also undermine trust in public health-care systems more broadly, resulting in wide-ranging harms to the health and wellbeing of the entire community. As noted, removing mifepristone from the market or restricting its use would 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, would 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.[42] 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 has experienced poor medical care are likely to lose trust in health-care providers in general.[43]

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 health care, fail to adhere to medical advice, and

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[42] Smith, Carly Parnitzke, *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.

[43] 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.

fail to keep medical appointments.[44] Unsurprisingly, these tendencies can lead to worse individual health outcomes. Thus, reduced trust in health-care 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.

Finally, restricting access to mifepristone or discouraging use of the two-drug regimen would 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 health care. 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 health-care facilities for even one visit, let alone

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[44] 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.

multiple ones. Making health care even more difficult to navigate—here, by requiring additional doctor's visits and creating delays in care—would impair individuals' willingness and ability to access healthcare.

* * *

The district court mistakenly concluded that patients suffering from complications from mifepristone are overwhelming the health-care system (Decision at 7, 29). 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 has nothing to do with mifepristone. Far from it: maintaining the current regulatory regime is critical 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 reverse the district court's order "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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I hereby certify that, on May 1, 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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