Nos. 23-235 & 23-236

IN THE

Supreme Court of the United States

U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,
Petitioners,
v.
ALLIANCE FOR HIPPOCRATIC MEDICINE, *et al.*,
Respondents.

DANCO LABORATORIES, L.L.C.,
Petitioner,
v.
ALLIANCE FOR HIPPOCRATIC MEDICINE, *et al.*,
Respondents.

On Writs of Certiorari to the United States Court of Appeals for the Fifth Circuit

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 PETITIONERS

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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] Amici have long 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 emphasize the many ways that the Fifth Circuit's ruling winding back the regulatory landscape by nearly a decade would harm public hospitals and health-care systems—and impair public health more broadly.

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 8.3 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 eight no- or low-cost health clinics that offer an array of sexual and reproductive health services, including testing and treatment for sexually transmitted infections and providing contraceptives, and three locations that offer 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, five post-acute/long-term care facilities, a home health agency, correctional health services, a health plan, and more than 30 community-based health-care centers. NYC Health +

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[1] Amici are 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.

Hospitals' full-service obstetrics and gynecology departments provide medication and procedural abortions and miscarriage management, and the hospital system also offers patients within New York City the option of getting a medication abortion by having a virtual visit with a clinician via a telehealth platform and then receiving their medication by mail.

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, 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. 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 care centers serving 750,000 patients each year. King County, Washington, serves its 2.2 million residents with 15 public health centers, six of which provide birth control and sexual health care. In addition, King County owns Harborview Medical Center, a world-renowned teaching hospital that is the only Level 1 trauma center serving Alaska, Idaho, Montana, and Washington. The City and County of San Francisco, California, with roughly 800,000 residents, provides direct health services through its Department of Public Health to thousands of insured and uninsured people, including those most socially and medically vulnerable. It serves 125,000 people each year across its clinics and hospitals, including Zuckerberg San Francisco General, the only trauma center serving all of San Francisco and northern San Mateo County. 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

Public health-care systems provide crucial health-care services across the nation. And they are currently experiencing severe and unprecedented challenges. Upholding the lower court's "stay" of the FDA's actions with respect to mifepristone over the last decade would aggravate those challenges, increasing operational costs and creating the potential for confusion and disarray, thereby making it harder for residents to access health care of all kinds and undermining community health.

a. Times are difficult for public hospitals 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 four 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 tremendous stress on scarce public health resources, every measure to provide safe, effective, and resource-efficient care matters. Finding new efficiencies through telehealth, patient at-home care, and other tools is essential to keeping public health-care systems working as they should—and must. And avoiding backsliding on past gains in safety and efficiency is just as important.

b. Nowadays, public health-care providers safely and effectively provide medication abortions through telehealth or a single in-person appointment and by leveraging non-physician medical professionals with independent prescribing authority. But the Fifth Circuit's order upholding a "stay" of the FDA's 2016 and 2021 regulatory actions with respect to mifepristone jeopardizes these practices.

Winding back the FDA's actions to before 2016 would significantly increase costs on already overburdened public hospitals and health-care systems at a time when those costs can least be afforded. If allowed to go into effect, the Fifth Circuit's order would decrease the availability and efficacy of the longstanding two-drug regimen for medication abortion and miscarriage management, leading public hospitals to divert resources to meet the increased demand for procedural abortions and other interventions for miscarriages, and to pivot

to other more resource-intensive protocols to end pregnancies and manage miscarriages.

Turning back the clock would also press hospitals into expending critical resources on in-person appointments that are not medically necessary and burdening their overworked physicians with responsibilities that qualified advanced practice clinicians have been performing capably and independently for years. Additional, immediate harms would flow from the Fifth Circuit's curtailment of health-care providers' ability to prescribe effective medication abortions through telehealth visits, which would strain the ability of public hospitals and health-care systems to provide effective patient care across the board. With public health-care providers still in crisis in the wake of the COVID-19 pandemic, the timing could hardly be worse.

Because public hospitals and clinics operate with limited resources, the impact of the Fifth Circuit's ruling 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.

c. Reducing the ability of public hospitals to provide resource-effective, high-quality care would also erode patients' confidence in the public health-care system as a whole and make the provision of health care to already vulnerable and sometimes hard-to-reach populations even more difficult. If left in place, the Fifth Circuit's ruling will undermine public health across the board.

ARGUMENT

As the Government has shown, it is profoundly harmful to force patients who need abortion or miscarriage care to utilize a medication regimen that may pose greater side effects or be less effective than a regimen that includes mifepristone, or to delay care until an appointment for a procedural abortion is available (if ever) (*see* Brief for U.S. Food and Drug Administration et al. ("FDA Br.") 46-47). We write to emphasize additional ways in which the order would harm the public.

To start, the order throws longstanding health-care practices into turmoil by purporting to limit how, where, and when a much-utilized drug is prescribed, dispensed, and administered. It provides little to no guidance about what practical effect it is meant to have on the behavior of frontline health-care providers today. As a result, the order would leave public hospitals and health-care systems—and the medical professionals who work for them—in the lurch. They would be forced to confront the medical and operational risks of potentially having to abandon longstanding practices that have served them and their patients well. And all of this is compounded by a ruling that misunderstands the regulatory landscape before 2016 and seemingly requires labeling changes out of sync with current-day medical standards (*see* FDA Br. 46; Brief for Danco Laboratories LLC ("Danco Br.") at 39, 53).

Moreover, as explained in more detail below, if affirmed, the Fifth Circuit's order would also impose significant burdens on public hospitals and health-care systems that are already strapped for resources—imposing a critical impact on public health in general, and public hospitals in particular. For patients who prefer to and are able to manage their abortions from

home after a telehealth visit 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 patient autonomy, and efficiently deploy health-care resources.

I. 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.[2] In a 2021 report, the Association of American Medical Colleges projected a nationwide shortage of up to 124,000 physicians by 2034—with shortages of up to roughly 50,000 primary care physicians and 75,000 specialists.[3] Surgical

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[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; 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; *see also* Henry, Tanya Albert, *The Physician Shortage Crisis Is Here—And So Are Bipartisan Fixes*, AM. MED. ASS'N (Nov. 6, 2023), https://perma.cc/EET6-RBVS.

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 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

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[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, 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).

[7] Pearson, Bradford, *Nurses Are Burned Out. Can Hospitals Change in Time to Keep Them?* N.Y. TIMES (Feb. 20, 2023), https://tinyurl.com/y2c37dxt.

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

Health Care Provider Protection Act, signed into law in 2022, was named after a New York City emergency room physician who took her own life early in the pandemic.[9] Pandemic-related challenges also triggered a mass exodus from the medical profession.[10] By late 2021, one in five health-care workers had left their jobs.[11] The outlook for hospitals remains bleak even as the pandemic has receded.[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]

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

[10] *Issue Brief: Impact of the COVID-19 Pandemic on the Hospital and Outpatient Clinician Workforce*, OFF. ASSISTANT SEC'Y FOR PLAN. & EVALUATION, U.S. DEP'T OF HEALTH & HUM. 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.

[12] *Early NFP Hospital Medians Show Expected Deterioration; Will Worsen*, FITCH (Mar. 2, 2023), https://perma.cc/PB8W-9N6K; *see*, *e.g.*, Adcroft, Patrick, *Mount Sinai Beth Israel Hospital to Close Amid Financial Losses*, NY1 (Sep. 14, 2023), https://perma.cc/F9G9-M35P; Dyrda, Laura, *293 Hospitals at Immediate Risk Of Closure*, BECKER HOSPITAL REVIEW (June 2, 2023), https://perma.cc/MHT2-85ZV.

[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.

Likewise, of the 200,000 patients served by the County of Santa Clara's public hospitals and clinics every year, nearly 16,000 are uninsured, 139,000 are insured by Medi-Cal (California's Medicaid health care program), and 32,000 are insured by Medicare.

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, healthcare 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 so long. The nation's 74 million baby boomers will soon be 65 or older; and by 2035 seniors will outnumber children.[19] "[O]lder people see

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[15] 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.

[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.

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

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."[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 new 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, in particular, have felt that strain,

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[20] *Id*.

[21] *Id*.

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

[23] 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.

[24] *Our Vow: No More Closings*, NEW YORK STATE NURSES ASS'N, https://perma.cc/L9BK-SA9K (last visited Apr. 7, 2023).

[25] Rau, Jordan, *Urban Hospitals of Last Resort Cling to Life in Time of COVID*, KHN (Sept. 17, 2020), https://perma.cc/5VRQ-MQTV; *Rural Hospitals At Risk of Closing*, CENTER FOR HEALTHCARE QUALITY & PAYMENT REFORM (Jan. 2023), https://perma.cc/AYF6-9B64 (noting that 631 rural hospitals—over 29% nationwide—were at risk of closing in 2023).

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."[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.

II. Upholding a "Stay" of the FDA's 2016 and 2021 actions relating to mifepristone 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. The FDA's changes to the mifepristone label in 2016 and 2021 increased the indicated gestational age limit from seven to ten weeks; lowered the indicated dosage; and reduced the number of indicated in-person clinical visits. Its modification to the REMS in 2016 and 2021 allowed certain licensed non-physician healthcare providers to become certified

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

[27] *Id.*

prescribers; eliminated a requirement that prescribers be asked to report certain adverse events to the drug's sponsor; and removed the in-person dispensing requirement. The changes gave healthcare providers more flexibility to safely and efficiently provide medication abortions and miscarriage management. A "stay" of even part of the FDA's actions with respect to mifepristone would undercut the ability of public-health systems to meet patient needs more broadly—harms which the Fifth Circuit disregarded.

Reinstating medically unnecessary restrictions on mifepristone would significantly increase the burden on public health-care systems, including by exposing patients to unnecessary risks potentially requiring additional medical treatment. Some patients who would have otherwise been prescribed a two-drug medication abortion would instead undergo a costly procedural abortion. Other patients would be prescribed a single-drug regimen that, though safe and effective, can be associated with more severe side effects, takes longer, and has been found in some studies to be less effective than the two-drug regimen—placing additional strains on public hospitals. 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.[28] Increasing the number of visits required and restricting the ability to leverage non-physician medical professionals would

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[28] 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.

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]

As of 2022, medication abortions accounted for more than half of the country's abortions.[30] Last year, NYC Health + Hospitals' 11 hospitals performed more than 5,000 abortions, over two-thirds of which were medication abortions, and the City's sexual health clinics provided over 600 no- and low-cost medication abortions. 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-

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[29] Schreiber, Courtney A. et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, 378 New ENGL. J. MED. 2161, 2161 (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.

[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.

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 procedures occur. In addition to requiring a specialist or trained clinician to perform the procedure itself, when performed at a hospital a procedural abortion often involves the care of 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 can cost 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 threatens to overburden public hospitals' emergency and surgical facilities and undermine public health across the board.

These are not *necessary* costs. The Fifth Circuit 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 Br. 2-6, 37-44) and eliminating in-person visits is medically appropriate for most patients (*id.* at 8, 42-

43).[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 (*id.* at 46-47). And the regimen is medically required for some patients, such as those with allergies to anesthesia[32] or those who might find a procedure to potentially be traumatic (e.g., because of a history of sexual assault) (*id.*).

The Fifth Circuit counterfactually concluded that the FDA's 2016 modifications "increase the number of women who suffer complications as a result of taking mifepristone," and place "enormous stress and pressure" on doctors forcing them to "divert time and resources away from their regular patients." *Alliance for Hippocratic Med. v. U.S. Food & Drug Admin.*, 78 F.4th 210, 229, 237, 238 (5th Cir. 2023). These are invented harms that have no basis in reality.

Worse than that, the Fifth Circuit has it precisely backwards. It is the court of appeals' roll-back of the FDA's evidence-based regulation of mifepristone that threatens to overwhelm public health-care systems and waste crucial limited resources. If affirmed, the order will lead to the diversion of resources away from an array of critical health-care services, as providers will need to perform time-sensitive procedural abortions and miscarriage management and manage the potential side-effects of a single-drug regimen for patients, some of whom would have opted for a less resource-intensive treatment plan including mifepristone.

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

[32] *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.

In addition to being safe and effective, medication abortions have the added 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 use of medication at home 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, a resource-conserving one—that allows them to control the timing of administration and symptoms. Contrary to the Fifth Circuit's unsupported assumptions about the risk of medical complications, 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. It is for these very reasons that the City of New York's public-health experts recently decided to make medication abortions available through telehealth.

To be clear, the longstanding status quo does not involve a lack of medical oversight —far from it. 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.[33] So, for example, a telehealth abortion provided in New York City by NYC Health + Hospitals connects patients to providers; if in-person care is indicated, the hospital will refer the patient for "physical exam, imaging, and testing," and will facilitate in-person "follow-up after abortion care,

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[33] 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.

both routine and problem-based."[34] Other public health providers use telehealth in conjunction with in-person visits to provide better and more cost-effective patient care. For example, the City's sexual health clinics provide a telehealth service to counsel patients about abortion, assess eligibility, make referrals, and schedule clinical appointments.

This is an approach that benefits everyone. Research has shown that increasing rates of at-home care leads to "demonstrable savings for governments, health systems and households."[35] At-home care is not just preferred by some patients, but also reduces wait times and unnecessary emergency department visits, relieves clinician and staff workloads to allow more efficient resource allocation, and lowers the cost of care for patients and health-care systems.[36] Incorporating telehealth into the provision of care to reduce the number of in-person visits helps public hospitals meet unprecedented recent challenges.

Indeed, telehealth can ease the burden on already overburdened doctors and nurses, while increasing access to care for underserved patients.[37] For example, in 2022 the Texas Comptroller reported that increasing telehealth was needed to alleviate economic pressures facing hospitals; telehealth visits reduce the

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[34] *Abortion Care*, NYC HEALTH + HOSPITALS EXPRESSCARE WEBSITE, https://perma.cc/5BF9-QNNW (last visited Oct. 3, 2023).

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

[36] *Id*.

[37] 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.

time for intake and decrease the length and number of hospital visits, while increasing service through online patient portals and virtual meetings.[38] 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."[39]

The Fifth Circuit's ruling pushes public hospitals and clinics into pivoting to new and unnecessarily resource-intensive practices—which will involve reallocating resources and supplies and changing policies, practices, training, and guidance to medical professionals. The irreparable harm to public health would persist, even if the courts ultimately reversed course in the case's final disposition. 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.

III. The ruling will also threaten to undermine confidence in public health-care systems.

The Fifth Circuit's ruling, if affirmed, would also undermine trust in public health-care systems more broadly, resulting in wide-ranging harms to the health

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[38] 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.

[39] *Id.*

and wellbeing of the entire community. As noted, restricting mifepristone's 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, 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.[40] 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.[41]

These ripple effects carry far beyond one individual's experience, and result in increased public skepticism of medical providers, which correlates with devastating 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

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[40] 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.

[41] 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.

seeking health care, fail to adhere to medical advice, and miss medical appointments.[42] Unsurprisingly, these tendencies can lead to worse individual health outcomes. Thus, reduced trust in health-care professionals and systems will impair 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 multiple ones. Making health care even more difficult to navigate—such as by requiring unnecessary doctor's visits and creating delays in care—would impair individuals' willingness and ability to access healthcare.

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The Fifth Circuit mistakenly concluded that patients suffering from complications from mifepristone are overwhelming the health-care system. *Alliance for*

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[42] 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.

Hippocratic Med., 78 F.4th at 229-39. Speaking from experience, as local governments that operate and support public hospitals from coast to coast, we can say with certainty that the public health crisis faced by emergency departments has nothing to do with mifepristone. Far from it: maintaining the current regulatory regime, including eliminating unnecessary doctor visits and allowing for telemedicine, 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 communities.

CONCLUSION

The court of appeals' judgment should be reversed.

Respectfully submitted,

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