

Nos. 22A901 & 22A902

In the
Supreme Court for the United States

DANCO LABORATORIES, L.L.C,
Applicants,

against

ALLIANCE FOR HIPPOCRATIC MEDICINE ET AL.,
Respondents.

—
U.S. FOOD AND DRUG ADMINISTRATION et al.,
Applicants,
against

ALLIANCE FOR HIPPOCRATIC MEDICINE ET AL.,
Respondents.

**BRIEF FOR LOCAL GOVERNMENTS OPERATING PUBLIC
HOSPITAL AND HEALTH CARE SYSTEMS IN SUPPORT OF THE
GOVERNMENT'S AND DANCO LABORATORIES' STAY APPLICATIONS**

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TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	ii
INTEREST OF AMICI CURIAE.....	1
SUMMARY OF ARGUMENT	3
ARGUMENT.....	5
THE ORDER BELOW THREATENS TO UNDERMINE PUBLIC HEALTH	5
A. It is a uniquely difficult time to operate a public health-care network.	7
B. The continuing “stay” of the FDA’s 2016, 2019, and 2021 actions will undermine public health.	13
C. By discouraging the often-preferred course of treatment and adding to strains on public hospitals, the order will also undermine confidence in public health-care systems.	18
CONCLUSION.....	21

TABLE OF AUTHORITIES

Page(s)

Other Authorities

<p>Alvandi, Maryam, <i>Telemedicine and its Role in Revolutionizing Revolutionizing Healthcare Delivery</i>, AM. J. OF ACCOUNTABLE CARE Vol.5(1), (Mar. 10, 2017), https://perma.cc/E66Z-W8GH</p>	19
<p>Belluz, Julia, <i>The doctors are not all right</i>, VOX (Jun. 23, 2021), https://perma.cc/9JB2-4N26</p>	9
<p>Carmichael, Mary, <i>Primary-Care Doctor Shortage Hurts Our Health</i>, NEWSWEEK (Feb. 25, 2010), https://perma.cc/2UUS-NSK3</p>	8
<p>Daily Briefing: <i>America deliberately limited its physician supply—now it’s facing a shortage</i>, ADVISORY BD. (Feb. 16, 2022), https://perma.cc/5XJK-U887</p>	8
<p>Darves, Bonnie, <i>Physician shortage spikes demand in several specialties</i>, NEW ENGL. J. OF MED., CAREER CENTER (NOV. 30, 2017), https://perma.cc/QF8R-DNX3</p>	8
<p>Donovan, Megan, <i>Self-Managed Medication Abortion: Expanding the Available Options for U.S. Abortion Care</i>, GUTTMACHER INST. (Oct. 17, 2018), https://perma.cc/LPQ5-6BFD</p>	17
<p><i>Fact Sheet: Global and Regional Estimates of Unintended Pregnancy and Abortion</i>, GUTTMACHER INST. (Mar. 2022), https://perma.cc/Y79N-DWA7</p>	10
<p>Falconnier, Jamie, et ano., <i>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</i>, FISCAL NOTES (Oct. 2022), https://perma.cc/3LMA-72LC</p>	18
<p>Glatter, Dr. Robert, et ano., <i>The Coming Collapse of the U.S. Health Care System</i>, TIME (Jan. 10, 2023), https://perma.cc/3CXV-DEBP</p>	8, 12
<p>Howley, Elaine, <i>The U.S. Physician Shortage Is Only Going to Get Worse. Here Are Potential Solutions</i>, TIME (Jul. 25, 2022), https://perma.cc/6MNC-FDCB</p>	10, 11, 18

TABLE OF AUTHORITIES (cont'd)

	Page(s)
<i>Issue Brief: Impact of the COVID-19 Pandemic on the Hospital and Outpatient Clinician Workforce</i> , 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	9
Jones, Rachel et al., <i>Abortion incidence and service availability in the United States, 2020</i> , GUTTMACHER INST. (Nov. 2022), https://perma.cc/G4NN-TDFE	13
Jones, Rachel, <i>Medication Abortion Now Accounts for More Than Half of All US Abortions</i> , GUTTMACHER INST. (Feb. 2022), https://perma.cc/2R5Z-EGY9	13
LaVeist, Thomas A. et al., <i>Mistrust of Health Care Organizations is Associated with Underutilization of Health Services</i> , 44 HEALTH SERVS. RSCH., 2093 (2009), https://perma.cc/A3GV-PNZW	20
MacNaughton, Honor MD et al., <i>Mifepristone and Misoprostol for Early Pregnancy Loss and Medication Abortion</i> , 103 AM. FAMILY PHYSICIAN 473 (Apr. 15, 2018), https://perma.cc/NJE3-HFC9	6, 16
Madara, Dr. James, <i>America's health care crisis is much deeper than COVID-19</i> , AM. MED. ASS'N (Jul. 22, 2020), https://perma.cc/KD4L-P6MU	10
<i>Metropolitan Anchor Hospital (MAH) Case Study, NYC Health + Hospitals New York</i> , AM. HOSPITAL ASS'N (June 2022), https://perma.cc/6Q6P-QR8U	10
Muoio, Dave, <i>'Unsustainable' losses are forcing hospitals to make 'heart-wrenching' cuts and closures, leaders warn</i> , FIERCE HEALTHCARE (Sept. 16, 2022), https://perma.cc/MSD2-E5UH	8
Ngoc NT et al., <i>Comparing two early medical abortion regimens: mifepristone+misoprostol vs. misoprostol alone</i> , CONTRACEPTION 83(5):410-7 (May 2011), https://perma.cc/8S42-QEEW	14
<i>NYC Life Expectancy Plunged Amid COVID, New Stats Show. See How Much It Shaved Off</i> , NBC N.Y. (Apr. 7, 2023), https://perma.cc/V2EW-2DEP	11

TABLE OF AUTHORITIES (cont'd)

	Page(s)
Oguro, Nao et al., <i>The impact that family members' health care experiences have on patients' trust in physicians</i> , BMC HEALTH SERV. RSCH. (Oct. 19, 2021) https://perma.cc/AA8E-LPU4	19
<i>Our Vow: No More Closings</i> , NEW YORK STATE NURSES ASS'N, https://perma.cc/L9BK-SA9K	12
Raymond, Elizabeth, <i>Efficacy of Misoprostol Alone for First-Trimester Medical Abortion: A Systematic Review</i> , OBSTET GYNECOL. 133(1): 137-47 (Jan. 2019), https://perma.cc/F8MY-TYQ6	14
Pearson, Bradford, <i>Nurses Are Burned Out. Can Hospitals Change in Time to Keep Them?</i> N.Y. TIMES (Feb. 20, 2023), https://www.nytimes.com/2023/02/20/well/nurses-burnout-pandemic-stress.html	9
Rau, Jordan, <i>Urban Hospitals of Last Resort Cling to Life in Time of COVID</i> , KHN (Sept. 17, 2020), https://perma.cc/5VRQ-MQTV	12
Robezneiks, Andis, <i>Doctor shortages are here—and they'll get worse if we don't act fast</i> , AM. MED. ASS'N (Apr. 13, 2022), https://perma.cc/BP8M-3T8P	8, 11
Saghafian, S. et al., <i>Towards a more efficient healthcare system: Opportunities and challenges caused by hospital closures amid the COVID-19 pandemic</i> , HEALTH CARE MANAG. SCI. 25, at 187–190 (Mar. 16, 2022), https://perma.cc/868E-6E5U	12
Schreiber, Courtney A. et al., <i>Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss</i> , NEW ENGL. J. MED. 2018 (June 7, 2018), https://perma.cc/BBB2-7GRE	6, 16
<i>The Complexities of Physician Supply and Demand: Projections From 2019 to 2034</i> , ASS'N OF AM. MED. COLL. (June 2021), https://perma.cc/3WD7-5ACY ;.....	8
<i>The Current State of Hospital Finances: Hospital Finance Report, Fall 2002 Update</i> , KAUFMAN HALL, https://perma.cc/327Z-3CHP	11

TABLE OF AUTHORITIES (cont'd)

	Page(s)
<i>The Safety and Quality of Abortion Care in the United States</i> , NAT'L ACADS. OF SCIS., ENG'G, & MED. (2018), https://perma.cc/9PR7-73WF	16
<i>The Economic and Social Value of Self-Care</i> , AESGP (Nov. 26, 2021), https://perma.cc/6C9L-F4M5	17
<i>White Paper: Anesthesiology: Supply, Demand and Recruiting Trends</i> , MERRITT HAWKINS (2021), https://perma.cc/WAH4-9KSB	8
Yong, Ed, <i>Why Health-Care Workers Are Quitting in Droves</i> , THE ATLANTIC (Nov. 16, 2021), https://perma.cc/47LT-8RRF	9
Zhang X. et al., <i>Physician workforce in the United States of America: forecasting nationwide shortages</i> , HUM. RESOUR. HEALTH (Feb. 6, 2020), https://perma.cc/8BQV-4TMW	10, 11

INTEREST OF AMICI CURIAE

Amici are local governments on the front lines of protecting the public health and include the operators of the largest municipal public hospital and health-care systems in the nation.¹ For several years now, amici have relied on the safe, effective, and resource-efficient drug regimen that starts with mifepristone and is supervised through one appointment to provide their patients with medication abortions up to roughly 10 weeks of pregnancy. We write to highlight how the order below threatens to inject profound uncertainty and chaos into an area of great public significance, pressuring public health-care providers to take on uncertain legal risks or consider abruptly abandoning—perhaps only until the next order in the case—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 8.5 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

¹ Amici include 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.

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 over 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 more than 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. The order of the court of appeals threatens to 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.

Times are difficult for public hospitals and health-care systems. As public hospital and health departments attest, it has never been easy to provide low-cost, high-quality health care to vulnerable populations who depend on public health care 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 health 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. For years now, public health-care providers have been safely and effectively providing medication abortions beyond seven weeks of pregnancy by administering the two-drug regimen with a single appointment with a medical professional and leveraging the value of non-physician medical professionals.

Purporting to roll back the clock on the FDA’s regulation of mifepristone after nearly seven years, the court of appeals’ order casts a shadow over these longstanding practices. And on matters of great significance to health-care providers, their patients, and many others, the order both misapprehends the past regulatory landscape and threatens to create confusion about what is required in the real world. The court of appeals’ order threatens to create confusion for public health-care systems about how they should approach, on an interim basis, providing mifepristone at a single appointment for abortions under seven weeks of pregnancy, medically managing miscarriage, prescribing generic mifepristone, resuming reporting non-fatal adverse events, and utilizing independent, non-physician medical professionals to prescribe the drug, if authorized under state law. These issues, and others raised by the decisions below, are critical to ascertaining the impact of the court of appeals’ middle-of-the-night redrafting of the medication’s labeling and REMS.

The court of appeals' failure to provide clarity on these and other key points has the potential to create significant confusion in public health-care settings, putting pressure on public health-care providers to choose between taking on perceived legal risks or abruptly changing their longstanding practices in this area. Indeed, the order threatens to upend public health-care providers' 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.

Because public hospitals and clinics operate with limited resources, the impact of the order 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 treatment. Reducing the ability of public hospitals to provide resource-effective, high-quality care will erode patients' confidence in the 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 decision will undermine public health across the board.

ARGUMENT

THE ORDER BELOW THREATENS TO UNDERMINE PUBLIC HEALTH

As the Government has shown, making health care more difficult to access and limiting patients' access to preferable or needed care is profoundly harmful, and provides more than enough reason to stay the entirety of the district court's order,

not just the small piece carved out by the court of appeals. 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.

We write to emphasize additional ways in which the order harms the public. To start, the court of appeals provided little to no guidance about what effect its order partially “staying” a “stay” of long-past administrative determinations is 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.² The quandary is only compounded by the conflicting order from a district court in another circuit.³

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

² The decision risks creating uncertainty outside of the abortion field too, because it does not address whether mifepristone is authorized to medically manage miscarriage—another of its longstanding uses. 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>.

³ Two amici—Cook County, Illinois and King County, Washington—are in states covered by the conflicting order of the district court.

that nature are particularly troubling in the context of public health—another dynamic of which the lower courts took no account.

Indeed, the court of appeals' order forces 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 the court of appeals' apparent misapprehension of the regulatory landscape that existed before 2016. But pressuring public health-care providers to abruptly shift toward procedural abortions or misoprostol-only medication abortions out of fear of legal liability could overwhelm public health-care systems and waste crucial limited resources, causing delays in the provision of an array of critical health-care services as providers and resources are diverted to new and unnecessary ends.

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

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

Local governments stand on the front lines of protecting the public health, and amici 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.⁴ 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.⁵ Surgical specialists⁶ and anesthesiologists,⁷ 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.⁸

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

⁴ 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>.

⁵ *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>.

⁶ Darves, Bonnie, *Physician shortage spikes demand in several specialties*, NEW ENGL. J. MED., CAREER CENTER (Nov. 30, 2017), <https://perma.cc/QF8R-DNX3>.

⁷ *White Paper: Anesthesiology: Supply, Demand and Recruiting Trends*, MERRITT HAWKINS (2021), <https://perma.cc/WAH4-9KSB>.

⁸ 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).

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.⁹ Front-line medical professionals have suffered from depression and PTSD—in some cases committing suicide.¹⁰ 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.¹¹ Pandemic-related challenges triggered a mass exodus from the medical profession.¹² By November 2021, one in five health-care workers had left their jobs.¹³

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

⁹ 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>.

¹⁰ *Id.*; Belluz, Julia, *The doctors are not all right*, VOX (Jun. 23, 2021), <https://perma.cc/9JB2-4N26>.

¹¹ Robezneiks, *supra* n.5.

¹² *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>.

¹³ Yong, Ed, *Why Health-Care Workers Are Quitting in Droves*, THE ATLANTIC (Nov. 16, 2021), <https://perma.cc/47LT-8RRF>.

care, while the majority of the patients are insured by public payers, primarily Medicaid,¹⁴ which reimburse providers at below-cost rates.¹⁵ 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.¹⁶ 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.”¹⁷ 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.¹⁸

¹⁴ *Metropolitan Anchor Hospital (MAH) Case Study, NYC Health + Hospitals | New York*, AM. HOSPITAL ASS’N (June 2022), <https://perma.cc/6Q6P-QR8U>.

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

¹⁶ 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>.

¹⁷ *Id.*

¹⁸ 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>.

Add to all this an aging population, and demand for medical care is at an all-time high.¹⁹ Never before have so many people lived so long.²⁰ The nation’s 74 million baby boomers will soon be 65 or older; by 2025, seniors will outnumber children.²¹ “[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.”²² 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.²³

Public hospitals face a perfect storm. The massive shortfall of staff and resources creates acute financial pressures.²⁴ Since 2010, an astounding number of hospitals across the country have closed—an average of 21 per year, with 47 closures

¹⁹ Zhang, *supra* n.18.

²⁰ 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>.

²¹ Howley, *supra* n.18.

²² *Id.*

²³ *Id.*

²⁴ *The Current State of Hospital Finances: Hospital Finance Report, Fall 2002 Update*, KAUFMAN HALL, <https://perma.cc/327Z-3CHP>.

in 2019 alone²⁵—including more than two dozen in New York State.²⁶ This includes both rural and inner-city hospitals, and has put significant strain on surviving hospitals.²⁷ 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.”²⁸ 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.²⁹ In all, these are exceptionally challenging times in which to operate a public hospital or health-care system.

²⁵ 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>.

²⁶ *Our Vow: No More Closings*, NEW YORK STATE NURSES ASS’N, <https://perma.cc/L9BK-SA9K>.

²⁷ Rau, Jordan, *Urban Hospitals of Last Resort Cling to Life in Time of COVID*, KHN (Sept. 17, 2020), <https://perma.cc/5VRQ-MQTV>.

²⁸ Glatter, *supra* n.8.

²⁹ *Id.*

B. The continuing “stay” of the FDA’s 2016, 2019, and 2021 actions will undermine public health.

Using the cloud of potential legal liability to pressure public health-care providers to move toward multiple appointments, physician-supervised in-person dispensing, and often less-preferable methods for abortions after the 49-day gestational window would harm public hospitals and health-care systems. Such shifts would undercut public-health systems’ ability to efficiently meet patient needs more broadly—harms of which the lower courts took no account.

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. 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 pressure on public-health systems’ abortion services, where available.

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>.

Most obviously, to the extent the court of appeals believed it was reimposing a set of strictures for dispensing medication abortion—ones that never actually existed and that the FDA, the expert on medication safety, efficacy, and administration, deemed medically unnecessary many years ago—the order would only drain resources so desperately needed elsewhere. The Court should not cast aside—in the preliminary stages of an administrative challenge—an expert agency’s determinations on what is medically indicated, especially where it, to the extent it is effectual at all, would disrupt settled practices and waste limited public resources.

And the potential waste of resources does not stop there. If the order results in shifts in practices, some patients who would have otherwise preferred or needed a medication abortion may forgo the two-drug regimen if required to attend three appointments, and may opt instead for 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. The single-drug regimen is associated with more intense pain, increased bleeding, and additional side effects, such as nausea, diarrhea, and vomiting, and these patients may as a result turn to emergency departments for care.³¹ The court of appeals, however, ignored these avoidable patient harms and systemwide costs.

³¹ 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>.

Other patients who are unwilling or unable to attend three appointments over a number of weeks are likely to request procedural abortions. But 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 a specialist 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.

Public hospitals should not have to shoulder additional systemwide costs associated with misoprostol-only and procedural abortions during what is a dire time for our nation's public health-care systems, when a longstanding, safe and effective alternative would be available, but for the decision below. 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—the very kinds of harms that the 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.³² And for good reason: it is a safe and effective option. 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 allergies to anesthesia.³³

And 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 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

³² Schreiber, *supra* n.2; MacNaughton, *supra* n.2.

³³ FDA Stay Application at 23-26, 38-39; *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>.

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

The court of appeals also ignored that public health experts—chief among them, the FDA—have concluded that reducing the number of doctor visits or eliminating in-person visits altogether by incorporating telehealth into the provision of care is safe and effective. But further, telehealth is vital to public hospitals being able to meet unprecedented, looming challenges. Telehealth can ease the burden on already overburdened doctors and nurses, while increasing access to care for

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>.

³⁶ *Id.*

underserved patients.³⁷ 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.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

C. By discouraging 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 order below also threatens to undercut trust in public health-care systems more broadly, resulting in wide-ranging harms to the health and wellbeing of the entire community. Not only does it pose a risk of confusion and potential backsliding on safe, effective, and resource-efficient abortion treatment, but it also risks putting

³⁷ Howley, *supra* n.18; 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>.

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.*

an unnecessary strain on limited resources and causing 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.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, in amici’s experience, correlates with devastating consequences for local governments’ ability to ensure their communities’ health and welfare. For instance, research shows that individuals who

⁴⁰ 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>.

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>.

mistrust health-care systems are also more likely to delay seeking healthcare, fail to adhere to medical advice, and fail to keep medical appointments.⁴² 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.

Finally, discouraging use of the two-drug regimen, or making the drug harder to obtain, 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 will impair individuals' willingness and ability to access healthcare.

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>.

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The court of appeals' decision describes a culture of chaos in emergency departments that is supposedly due to emergency side effects caused by mifepristone (at 17-19). 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.

CONCLUSION

The applications should be granted.

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Respectfully submitted,

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