Nos. 23-235, 23-236

In the Supreme Court of the United States

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 OF MEDICAL STUDENTS FOR CHOICE AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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TABLE OF AUTHORITIES

CASES

STATUTES

OTHER AUTHORITIES

INTERESTS OF AMICUS CURIAE[1]

Medical Students for Choice ("MSFC") is a non-profit organization with over 10,000 members at nearly 300 chapters in over 30 countries, including 185 chapters across the United States. MSFC seeks to ensure that medical students and trainees have access to comprehensive, evidence-based education on reproductive healthcare. MSFC has a strong interest in protecting evidence-based medical education and training. Accordingly, MSFC submits this brief to outline the concerns of the organization's members concerning judicial interference with evidence-based access to mifepristone.[2]

SUMMARY OF ARGUMENT

Medical education in the United States should be among the best in the world. However, judicial interference with the Food and Drug Administration's ("FDA") evidence-based regulation of mifepristone risks damaging the quality and reputation of medical education and training in this country.

Mifepristone is a safe and effective medication used in nearly 100 countries around the world for

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[1] Pursuant to Supreme Court Rule 37.6, *amicus curiae* states that no counsel for a party authored this brief in whole or in part, and no person or entity, other than *amicus curiae* and its counsel, made a monetary contribution to its preparation or submission.

[2] The statements provided herein express the views of the speaker as a member of MSFC and should not be attributed to any other institutions with which such speakers may be affiliated.

abortion care and miscarriage management.[3] Doctors and patients can trust that mifepristone is safe and effective as distributed, relying on the FDA's evidence-based and scientifically rigorous review and approval process. See 21 U.S.C. § 355(d) (mandating for drug approval "adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling"); 21 U.S.C. § 355-1 (empowering the FDA to implement "risk evaluation and mitigation strategies" (REMS)). The Fifth Circuit's stay of the FDA's changes to mifepristone's label and REMS, after decades of data on its safe and effective use, cannot be squared with science.

There is a grave risk that if courts can supplant their views for those of the FDA, against the weight of scientific evidence and global consensus, then the quality of medical education and training in the United States will suffer. Medical schools would be left to translate policies that are not scientifically supported to students, contrary to their core function of providing an evidence-based education. Meanwhile, clinical and residency programs would be unduly limited in their ability to train future physicians on a globally accepted, evidence-based standard of care.

In short, medical schools and residency programs in the United States cannot provide world-class teaching and training in a healthcare system in which evidence-based medicine is overruled by courts.

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[3] Gynuity Health Projects, *Mifepristone Approved List* (May 2023), https://shorturl.at/eDINX.

ARGUMENT

I. The FDA's evidence-based regulation of mifepristone warrants deference.

Mifepristone is a globally accepted standard of care, championed by the World Health Organization as an essential medicine and available in almost 100 countries.[4] After nearly a quarter-century of mifepristone's safe and effective use in the United States, medication abortions now account for more than half of all abortions in the country.[5] Around the world, the data similarly shows that medication abortions account for approximately half of all abortions in most high-income countries.[6] This Court should defer to the FDA's evidence-based regulation of mifepristone—a drug proven to be safe and effective for medication abortions and miscarriage management.[7]

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[4] *Id.*; World Health Org., *Model List of Essential Medicines* (2019), at 47, https://rb.gy/j5ouh.

[5] See Rachel K. Jones, *Medication Abortion Now Accounts for More Than Half of All US Abortions*, GUTTMACHER INST. (Feb. 24, 2022), https://rb.gy/jf9ey; Jeff Diamant & Besheer Mohamed, *What the data says about abortion in the U.S.*, PEW RSCH. CTR. (Jan. 11, 2023), https://rb.gy/232rl.

[6] Anna Popinchalk & Gilda Sedgh, *Trends in the method and gestational age of abortion in high-income countries*, 45 BMJ SEX REPROD. HEALTH 95 (2019).

[7] E.g., Honor MacNaughton et al., *Mifepristone and Misoprostol for Early Pregnancy Loss and Medication Abortion*, 103 AM. FAM. PHYSICIAN 473 (2021); Marike Lemmers et al., *Medical Treatment for Early Fetal Death (Less Than 24 Weeks)*, 6 COCHRANE DATABASE SYST. REV. 1 (2019); Greer Donley,

A. The FDA is the agency entrusted to decide, based on its scientific expertise, whether mifepristone is safe and effective for distribution and on what terms. The FDA cannot approve a drug for distribution, unless there are "adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use." 21 U.S.C. § 355(d). In 2000, the FDA determined—after a four-year review—that mifepristone was safe and effective for use under specified conditions, including adverse effects reporting and ongoing studies of patient outcomes. J.A. 224–231. In 2007, Congress enacted the FDA's REMS regime. See U.S.C. § 355-1. Mifepristone was deemed to have REMS, in accordance with the restrictions on use set out in the 2000 approval. See 21 U.S.C. § 331 note.

In 2016, after 16 years of reporting and data, the FDA modified mifepristone's label to *inter alia* increase the gestational age limit from 49 days to 70 days, change the dosing from 600 to 200 mg, and reduce in-person visits from three to one. JA. 293–300. The FDA also changed the REMS to permit additional licensed healthcare providers to prescribe mifepristone and remove certain reporting requirements, after 16 years of such data. J.A. 309–310. In 2021, the FDA halted enforcement of the in-person dispensing requirement, J.A. 377, later permanently removing the requirement based on decades of "data and information support[ing]

Medication Abortion Exceptionalism, 107 CORNELL L. REV. 627, 651–52 (2022).

modification of the REMS to reduce burden on the health care delivery system."[8]

B. Judicial interference with the FDA's evidence-based regulation of mifepristone would result in the United States being out of step with global scientific consensus. Decades of data on mifepristone establish that it is safe and effective, and indeed much safer than commonly prescribed drugs like Viagra or Tylenol.[9] Nearly six million Americans have safely used mifepristone to complete an abortion, and nearly 100 countries have approved use of mifepristone, including the United Kingdom, France, Canada, Sweden, Germany, Norway, and Switzerland.[10]

The FDA's gradual reduction of restrictions on mifepristone is in keeping with global scientific consensus based on decades of data. A study in Canada—where mifepristone has been accessible like any other prescription since November 2017—showed that adverse effects and complications remained

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[8] U.S. Food & Drug Admin., *Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (Mar. 23, 2023), https://t.ly/v3aOV.

[9] Univ. of Cal., S.F., *Analysis of Medication Abortion Risk and the FDA Report: Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018,* BIXBY CTR. FOR REPROD. HEALTH (Apr. 2019), http://bit.ly/48MBVnu.

[10] U.S. Food & Drug Admin., *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2022* (Dec. 31, 2022), https://rb.gy/s3zav; Gynuity Health Projects, *supra* note 3.

stable before and after REMS-like restrictions.[11] Another study of over 50,000 patients in the United Kingdom showed no material difference in safety or efficacy using a telemedicine-hybrid model, with ultrasonography performed only when ectopic pregnancy is indicated.[12] Numerous additional studies support the FDA's changes to mifepristone's regulations, including increasing the indicated gestational age from seven to ten weeks and reducing the number of required in-person doctor visits.[13]

C. It is not the role of courts to second-guess the FDA's scientific expertise. Courts, for good reason, "owe significant deference to the politically accountable entities [like the FDA] with the

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[11] Laura Schummers et al., *Abortion Safety and Use with Normally Prescribed Mifepristone*, 386 NEW ENG. J. MED. 57 (2022).

[12] Ara Aiken et al., *Effectiveness, safety and acceptability of no-test medical abortion (termination of pregnancy) provided via telemedicine: a national cohort study*, 128 NAT'L LIBR. MED. 1464 (2021).

[13] E.g., Mette Løkeland et al., *Implementing Medical Abortion with Mifepristone and Misoprostol in Norway 1998–2013*, 46 INT'L J. EPIDEMIOLOGY 643 (2017) (Norwegian study of over 200,000 medication abortions up to 12 weeks' gestation); Jennifer K. Hsia et al., *Medical abortion with mifepristone and vaginal misoprostol between 64 and 70 days' gestation*, 100 CONTRACEPTION 178 (2019) (English study of medical records showing mifepristone-misoprostol abortion is safe up to 70 days' gestation); Helena K. Kallner et al., *Home self-administration of vaginal misoprostol for medical abortion at 50–63 days compared with gestation of below 50 days*, 25 HUMAN REPROD. 1153 (2010) (Swedish study showing mifepristone-misoprostol regimen is safe up to 63 days, with partial at-home use).

'background, competence, and expertise to assess public health.'" *FDA* v. *Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578, 579 (2021) (quoting *South Bay United Pentecostal Church* v. *Newsom*, 140 S. Ct. 1613, 1614 (2020) (Roberts, C. J., concurring)); *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 142 (2000) ("[T]he FDA must determine that there is a reasonable assurance that the product's therapeutic benefits outweigh the risk of harm."); *FDA* v. *Am. Coll. Of Obstetricians & Gynecologists*, 141 S. Ct. 10, 12 (2021) (Alito, J., dissenting, with Thomas, J. joining) (same).

As Sarah McNeilly, a third-year medical student at the Albert Einstein College of Medicine, explains:

> As a future physician, knowing that courts may soon intervene with the evidence-based decisions made by our regulatory bodies like the FDA is gravely concerning. The FDA is meant to be independent, issuing guidance based solely on clinical and scientific evidence. When it comes to mifepristone, the evidence is clear: it is safe and effective.
>
> As physicians, we can and should be able to rely on the FDA to guide our clinical practice. If our faith in our regulatory institutions is eroded, physicians will suffer. This will, in turn, harm patients, who are already struggling to navigate mass medical misinformation. Having such misinformation endorsed by the courts would be extremely harmful to

> patients, public health, and the practice of medicine.

This case reveals the perils of courts supplanting their scientific views for those of the FDA. By way of example, the District Court stayed the FDA's approval of mifepristone based on its own review of "myriad stories and studies brought to the Court's attention," which courts (unlike the FDA) lack the scientific expertise to apply. Pet. App. 177a. Indeed, the District Court cited evidence on deaths and severe adverse events after mifepristone that numerous courts have rejected,[14] as well as studies on the mental health consequences of abortion that have been scientifically discredited.[15]

Similarly, the Fifth Circuit cited the testimony of doctors who treated incomplete medication abortions. Pet. App. 19a–22a. But many of those doctors describe

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[14] Compare Pet. App. 170a (citing Aultman study), with *Little Rock Family Planning Serv.* v. *Rutledge*, 397 F. Supp. 3d 1213, 1302–05 (E.D. Ark. 2019) (rejecting Aultman's evidence on medication abortions), aff'd 984 F.3d 682 (8th Cir.), vacated, 142 S. Ct. 2894 (2022); *Planned Parenthood of Greater Iowa, Inc.* v. *Miller*, 30 F. Supp. 2d 1157, 1165, n. 9 (S.D. Iowa 1998) (holding "[Aultman] has not performed an abortion since 1982 and is not current on the medical aspects of abortion"), aff'd 195 F.3d 386 (8th Cir. 1999).

[15] Compare Pet. App. 123a–124a (citing Coleman and Reardon studies), with *Planned Parenthood of Ind. & Ky., Inc.* v. *Comm'r, Ind. State Dep't of Health*, 896 F. 3d 809, 826 (7th Cir. 2018) (describing Coleman study as "controversial and much maligned"), vacated, 141 S. Ct. 184 (2020); *Planned Parenthood of Wis., Inc.* v. *Schimel*, 806 F. 3d 908, 922 (7th Cir. 2015) (rejecting Reardon and Coleman study).

"adverse effects" such as "very heavy bleeding followed by significant abdominal pain and a fever"—symptoms that are to be expected. Pet. App. 20a. A patient who follows a mifepristone-misoprostol regimen is expected to experience cramping and bleeding, much like a patient who experiences a miscarriage.[16] Some may also require procedural abortions, as the Fifth Circuit found, but that risk is exceedingly rare with an occurrence rate of under 0.01 percent.[17] Contrary to the Fifth Circuit's view, the FDA's impugned actions do not increase that risk.

When courts supplant an agency's scientific analysis with their own, they step beyond their role and risk damaging evidence-based medicine in this country. See *FCC* v. *Prometheus Radio Project*, 592 U.S. 414, 423 (2021) (holding a court cannot "substitute its own policy judgment for that of the agency"); *Kisor* v. *Wilkie*, 139 S. Ct. 2400, 2442 (2019) (Gorsuch J., concurring, with Thomas and Kavanaugh JJ. joining) ("[C]ourts should pay close attention to an expert agency's views on technical questions in its field."). That is why this Court has repeatedly held that during challenges to an agency's expert analysis, "particularly concerning the nature of the data relied upon, the role of courts in reviewing arbitrary and capricious challenges is to 'simply ensur[e] that the agency has acted within a zone of reasonableness.'" *Biden* v. *Missouri*, 595 U.S. 87, 96 (2022) (quoting

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[16] Mitchell D. Creinin et al., *Medication Abortion Up to 70 Days of Gestation*, AM. COLL. OBSTETRICIANS & GYNECOLOGISTS PRAC. BULL. NO. 225 (Oct. 2020), https://shorturl.at/dhI12.

[17] *Id.*

Prometheus Radio Project, 592 U.S. at 423). Otherwise, as occurred here, courts risk undermining the very purpose of empowering agencies to make decisions based on their subject-matter expertise.

II. Medical schools must be permitted to teach evidence-based medicine.

Medical school curricula in the United States are premised on evidence-based medicine, teaching students to use the scientific method combined with clinical experience to arrive at the best medical decisions for their patients.[18] If courts can upend the FDA's evidence-based regulation of medications, the ability of medical schools in the United States to offer evidence-based teaching will be impaired.

A. It is essential that medical schools in the United States offer evidence-based medical curricula. Armed with a strong scientific foundation, medical students must be taught to care for patients based on principles derived from published evidence, national and international guidelines, medical society consensus, and clinical experience, all with the goal of improving medical outcomes based on the highest quality evidence available.[19]

Numerous studies have demonstrated the benefits of an evidence-based medical education on patient

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[18] See Steven Tenny & Matthew Varacallo, *Evidence Based Medicine*, STATPEARLS PUBL'G (Oct. 24, 2022) ("Evidence-based medicine (EBM) uses the scientific method to organize and apply current data to improve healthcare decisions."), https://rb.gy/3nxyo.

[19] *Id.*

care and outcomes.[20] Accordingly, the Association of American Medical Colleges' Medical School Objectives Project concluded that, upon graduation, medical students "must understand the scientific basis and evidence of effectiveness for each of the therapeutic options that are available for patients at different times in the course of the patients' conditions, and be prepared to discuss those options with patients in an honest and objective fashion."[21]

Teaching evidence-based medicine is not only valuable; it is mandatory. The Liaison Committee on Medical Education requires accredited medical schools to select curricular content that teaches students how scientific research "is conducted, evaluated, explained to patients, and applied to patient care," and "provides opportunities for medical students to acquire skills of critical judgment based on evidence and experience, and develops medical students' ability to use those principles and skills

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[20] See Laura Menard et al., *Integrating evidence-based medicine skills into a medical school curriculum: a quantitative outcomes assessment*, 26 BMJ EVIDENCE BASED MED. 249 (2020); Josephine L. Dorsch, et al., *Impact of an evidence-based medicine curriculum on medical students' attitudes and skills*, 92 J. MED. LIBR. ASS'N 397 (2004).

[21] Med. School Objectives Writing Grp., *Learning Objectives for Medical Student Education— Guidelines for Medical Schools: Report I of the Medical School Objectives Project*, 74 ACAD. MED. 13, 16 (1999).

effectively in solving problems of health and disease."[22]

B. Judicial interference with the FDA's regulation of mifepristone—based on rigorous review and scientific consensus—runs counter to the evidence-based curricula that medical schools in this country are entrusted to teach.

Hanna Amanuel, a medical student at Harvard Medical School, fears being restricted in providing evidence-based care to her patients:

> I came to medical school to develop the skills to support people, especially people who are least cared for in the US medical system. At a basic level, this means using the most safe and effective medications and treatments available, and scientific research, to guide healthcare decisions.
>
> Mifepristone is safely used in 96 countries around the world and is safely taken at home. It troubles me that my peers and I might be in a position where we cannot prescribe a medication for use on terms that we know based on the evidence to be safe and effective.

If this Court affirms the Fifth Circuit's decision, thereby reinstating medically unnecessary and outdated restrictions on mifepristone, medical schools

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[22] Liaison Committee on Medical Education, *Functions and Structure of a Medical School* (Nov. 2023), at 10, http://bit.ly/47LxI29.

will be left with the impossible task of teaching students to provide evidence-based care, but to potentially disregard the current scientific evidence when doing so is judicially mandated. See *Weinberger* v. *Bentex Pharms., Inc.*, 412 U.S. 645, 653–54 (1973) (holding that evaluating "reports as to the reputation of drugs among experts in the field is not a matter well left to a court without chemical or medical background").

As Danna Ghafir, a medical student at the University of Texas McGovern Medical School, describes:

> We are expected to learn comprehensive reproductive healthcare, including abortion care, which is tested on our national exams, and most importantly, applied in practice to achieve the best possible patient outcomes.
>
> According to our evidence-based textbooks, which pull from a plethora of peer-reviewed clinical research, medication abortion is most effective when mifepristone and misoprostol are taken in combination. The management of some miscarriages or early pregnancy complications also calls for mifepristone in combination with misoprostol to maximize patient safety during uterine evacuation. When abortion care is restricted, physicians and care teams are prevented from employing best practices

> supported by decades of accumulated scientific evidence.

Medical schools teach students to review clinical studies under controlled conditions (used by the FDA prior to the 2000 approval of mifepristone), as well as data based on real-world use and reporting (used by the FDA to modify mifepristone's label and REMS).[23] As one study of over 40,000 clinical trials and 5.6 million real-world health records showed, evidence-based medicine is greatly benefited by real-world data that more accurately reflects real-world conditions, combinations of drugs, and demographics including clinically vulnerable users.[24]

The Fifth Circuit's preferred scientific method—focused on clinical studies over real-world data—is incompatible with these core principles of evidence-based medicine. For example, the Fifth Circuit faulted the FDA for purportedly failing to require clinical studies of the cumulative effect of the modifications or consider whether to collect clinical data on non-fatal adverse events, notwithstanding that the FDA had collected such data for over a decade from millions of real users of mifepristone. Pet. App. 53–54a.

Reverting to mifepristone's regulations as of 2000, before the FDA had decades of real-world data on the

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[23] Tenny & Varacallo, *supra* note 18.

[24] Yen Yi Tan et al., *Comparing clinical trial population representativeness to real-world populations: an external validity analysis encompassing 43 895 trials and 5 685 738 individuals across 989 unique drugs and 286 conditions in England*, 3 LANCET 674 (2022).

drug's safe and effective use, would undermine the evidence-based curricula that our medical schools are entrusted and required to teach.

C. Judicial interference with evidence-based medicine undermines another central tenet of medical school curricula: to teach medical students to follow principles of medical ethics in caring for patients.[25] Although the precise content of ethical curricula varies among medical schools,[26] the four commonly accepted principles of medical ethics are respect for autonomy (respecting and supporting autonomous decisions); nonmaleficence (avoiding causation of harm); beneficence (relieving, lessening, or preventing harm, providing benefits, and balancing benefits against risks and costs); and justice (fairly distributing benefits, risks, and costs).[27]

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[25] See Liaison Committee on Medical Education, *Functions and Structure of a Medical School*, at 11, https://rb.gy/uur42 (requiring accredited medical schools to "ensure that the medical curriculum includes instruction for medical students in medical ethics and human values both prior to and during their participation in patient care activities and require medical students to behave ethically in caring for patients and in relating to patients' families and others involved in patient care").

[26] See Lisa S. Lehmann et al., *A Survey of Medical Ethics Education at U.S. and Canadian Medical Schools*, 79 ACAD. MED. 682 (2004).

[27] Tom L. Beauchamp & James F. Childress, *Principles of Biomedical Ethics* (8th ed. 2019); Thomas R. McCormick et al., *Principles of Bioethics,* UNIV. OF WASH. MED., DEP'T BIOETHICS & HUMAN. (last visited Jan. 24, 2024), https://rebrand.ly/zs1l6gb.

As Rose Al Abosy, M.D., explains:

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

Similarly, as Ashley Hurd-Jackson, a third-year medical student in Iowa, describes:

> Mifepristone allows patients to have an effective, safe, and non-invasive option for abortion and managing miscarriage. Providing a medication option to patients increases access to care. More than one-third of Iowa's counties are considered rural, where patients face several barriers to receiving in-person care. Mifepristone allows mitigation of both delays and access to care in rural areas with the option of providing this treatment via telemedicine.

> Already, I have encountered several incredibly difficult decisions that women have had to make. These are pregnancies that these women have prayed for, planned for, cried tears of joy for. I have handed tissues to a patient that was recently diagnosed with cervical cancer who had to decide if she wanted to continue her pregnancy while receiving cancer treatment. I helped care for another patient after she was run over by a vehicle and sustained injuries that led to her losing the twins she was pregnant with. Let us start by referring to abortion as what it truly is – healthcare.

Imposing medically unnecessary restrictions on a treatment option that is not only safe and effective, but also one that some patients prefer, conflicts with the principles of evidence-based and ethical care that medical students are taught to uphold.[28]

III. Clinical and residency programs must be permitted to provide evidence-based training.

Clinical and residency programs in the United States must be permitted to train future physicians to provide evidence-based care. Restricting access to mifepristone, contrary to the weight of scientific

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[28] See Basil Varkey, *Principles of Clinical Ethics and Their Application to Practice*, 30 MED. PRINCIPLES & PRAC. 17, 18 (2021); World Health Org., *Medical management of abortion* (2018), at 1–2, https://rb.gy/nmino.

evidence, jeopardizes the quality of evidence-based training that residents, particularly those in obstetrics and gynecology (OB/GYN), can receive in the United States.

A. Imposing medically unnecessary restrictions on mifepristone hinders the ability of clinical and residency programs to train future physicians on all evidence-based standards for abortion care and miscarriage management. Medical students and residents across the country have expressed a strong desire for abortion care training. One study found that 96 percent of medical students indicated that abortion education was appropriate in the preclinical and clinical curricula, and 84 percent found it to be worthwhile or valuable.[29] Numerous studies also show that residents who receive routine abortion training are more skilled in miscarriage management.[30] Without comprehensive reproductive healthcare training, physicians across specialities will be less equipped to care for their patients.

Rose Al Abosy, M.D., describes the importance of her medication abortion training at Boston University School of Medicine as follows:

> The first time I learned about mifepristone was in my pre-clinical courses, which all medical students take

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[29] See Eve Espey et al., *Abortion education in the medical curriculum: a survey of student attitudes*, 77 CONTRACEPTION 205, 206 (2008).

[30] Rachel R. Peachman, *Dobbs Decision Threatens Full Breadth of Ob-Gyn Training*, 328 J. AM. MED. ASS'N 1668, 1668 (2022).

> regardless of the area of medicine they will specialize in. Specifically, I learned about mifepristone during a lecture on abortion options, including both medical and procedural abortion. I continued to learn about mifepristone during my OB/GYN rotation as a third-year medical student, when I saw it administered to a number of patients to manage abortion and miscarriage. Then, as a fourth-year medical student, I completed a rotation in family planning and offered medication and procedural abortion to patients myself as part of options counseling.
>
> This training was absolutely helpful for my practice. Knowing how to talk through medical and procedural options for abortion and miscarriage is a critical skill set, not only for OB/GYN doctors, but for anyone practicing medicine. If a patient comes to you for issues unrelated to reproductive health and has a history of abortion or miscarriage, having reproductive health training is important because your job as a physician is to care for the patient as a whole.

B. Amidst declining access to abortion care training across the country, it is essential that the clinical and residency programs that do provide this training be permitted to teach globally accepted

standards of care based on the best available, up-to-date scientific evidence.

The imposition of medically unnecessary restrictions on mifepristone—such as reducing the label's indicated period of use from ten weeks of pregnancy to only seven weeks and requiring three in-person doctor visits—would make a safe and effective drug less accessible. JA. 293–300. In turn, clinical training opportunities on counseling patients on mifepristone as an option, as well as providing this standard of care, would also become less accessible.

As fourth-year medical student at the University of Texas McGovern Medical School, Danna Ghafir, explains:

> At the time I completed my OB/GYN clinical rotation at a hospital in Texas, several restrictions on abortion care were already in effect in Texas, and access to mifepristone was restricted despite its well-established safety profile. We had patients present to the emergency room with early pregnancy complications and inevitable spontaneous abortions, which we managed with misoprostol alone.
>
> My textbooks taught me that mifepristone in combination with misoprostol has better efficacy in certain cases than misoprostol alone, so I asked my attending why we weren't using mifepristone as well. The attending responded that although it would be

> ideal to give the two medications in combination, the REMS on mifepristone influenced the hospital's decision to stop carrying mifepristone altogether. Even though I was taught a mifepristone-misoprostol management protocol, we were unable to offer that option.
>
> If access to mifepristone is restricted by the courts, trainees nationwide could have less access to experiential learning on the highest quality, evidence-based management protocols involving mifepristone.

Abortion care training is required for the accreditation of OB/GYNs. Currently, the Accreditation Council for Graduate Medical Education ("ACGME") requires OB/GYN residency programs to provide "clinical experience or access to clinical experience in the provision of abortions as part of the planned curriculum," and if doing so would be unlawful, to "provide access to this clinical experience in a different jurisdiction where it is lawful."[31] Further, the ACGME requires specific training on medication abortion methods and management of abortion complications, as well as clinical experience in spontaneous abortion, pregnancy loss, and uterine

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[31] Accreditation Council for Graduate Med. Educ., *ACGME Program Requirements for Graduate Medical Education in Obstetrics and Gynecology* (Sept. 17, 2022), at IV.C.7.a(4), https://bit.ly/4b9hXoP.

evacuation in the operating room and outpatient settings.[32]

Already, residency training on abortion care is in decline. It is predicted that in the aftermath of *Dobbs* v. *Jackson Women's Health Org.*, 597 U.S. 215 (2022)—reversing federal constitutional protection for the right to abortion—available placements for abortion care training will be cut roughly in half.[33] Indeed, the data shows that medical students in abortion-ban states are leaving to study in states without restrictive abortion laws.[34]

As a third-year medical student in Iowa, Alina Beltrami, describes:

> Abortion is healthcare. I am considering moving to another state where I know that I will be able to get the training that I need to provide care to my patients. In Texas, patients effectively need to be septic to receive an abortion. In Idaho, where I completed an OB/GYN clinical rotation, physicians are very afraid that if they do not provide abortions their patients could die or lose their uterus,

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[32] *Id.* at IV.C.7–8.

[33] Sarah McNeilly & Vivian Kim, *A Call to Standardize Abortion Education Across U.S. Medical* Schools, ALBERT EINSTEIN COLL. MED. (Jul. 7, 2022), https://shorturl.at/quFMX.

[34] See Luci Hulsman et al., *Impact of the Dobbs v. Jackson Women's Health Organization decision on retention of Indiana medical students for residency*, 5 AM. J OBSTETRICS & GYNECOLOGY 101164 (Nov. 2023).

> but if they do, they could lose their license, their ability to pay off their medical school loans, and their ability to care for future patients. In Iowa, I would be very hesitant to stay here for residency if there is an abortion ban in place, and I have classmates who will not apply for residency in any states with restrictive abortion laws.

As the data shows, states with restrictive abortion laws have seen the number of residency applications drop across specialties. Applications for OB/GYN residency programs, in particular, have dropped by 10.7 percent in states that ban abortion and 7.1 percent in states with gestational limits on abortion.[35] In 2022, approximately 45 percent of all accredited OB/GYN residency programs across the country were in states certain or likely to ban abortion.[36] Since abortion care training is a requirement for OB/GYN accreditation, residents in abortion-ban states will have to travel out-of-state for this training.[37] As access

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[35] See Kendal Orgera et al., *Training Location Preferences of U.S. Medical School Graduates Post Dobbs v. Jackson Women's Health*, AM. ASS'N AM. MED. COLL. RSCH. ACTION INST. (Apr. 13, 2013), https://rb.gy/0tu9gc.

[36] See Kavita Vinekar et al., *Projected Implications of Overturning* Roe v Wade *on Abortion Training in U.S. Obstetrics and Gynecology Residency Programs*, 140 OBSTETRICS & GYNECOLOGY 146 (2022); see also Peachman, *supra* note 30, at 1668.

[37] The Ryan Residency Training Program in Abortion & Family Planning helps meet the ACGME mandate for routine abortion training in OB/GYN residency programs, including by assisting

to abortion care training declines, there simply is "no guarantee that enough slots would be available to meet demand."[38]

It is therefore critical that the safe havens for abortion care training in the United States be able to offer comprehensive evidence-based training, including on prescribing mifepristone based on the scientific evidence.

C. This case presents a significant risk of harming the reputation of medical training in the United States by setting a new precedent that the FDA's evidence-based actions are subject to judicial second-guessing.

Dango Mwambene, a medical student at the University of Cape Town, describes the following concerns:

> I have considered specialising or subspecialising in obstetrics and gynaecology in the United States, but a ruling restricting mifepristone and that further federally limits access to abortion significantly makes me reconsider this possibility. I'd rather stay in South Africa and specialise here or go elsewhere

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in establishing partnerships between residency programs in abortion-ban states and out-of-state facilities where their residents can complete required training. See Univ. of Cal., S.F., *The Kenneth J. Ryan Residency Training Program in Abortion & Family Planning,* BIXBY CTR. FOR REPROD. HEALTH (last visited Jan. 28, 2024), https://shorturl.at/nvwD7.

[38] See Nick Anderson, *A race to teach abortion procedures, before the bans begin*, WASH. POST (Jun. 20, 2022), https://rb.gy/rz3px0.

> where abortion access is constitutionally protected.

Similarly, Hadiza Thompson, a recent medical school graduate completing clinical training at the University of Nigeria teaching hospital, shared the following concerns:

> The United States is considered a global leader in providing the basic framework for evidence-based medical education and training around the world. I strongly believe that if the United States no longer abides by the evidence-based medicine and ethics that it purports to teach, then it will tarnish its reputation and standing in the global medical community.
>
> I have also seen how restrictive abortion laws impair medical training. In Nigeria, abortion is illegal unless the pregnancy poses an imminent risk of death. The only reason I have training on mifepristone is because I completed it in another country, and I can hardly use my training. When a patient had a miscarriage, I had to collect her payment, go to the pharmacy, pick up mifepristone, and administer it to her at the hospital. Those barriers mean very few patients can access mifepristone, and very few physicians have experience providing this basic and even life-saving care.

In the United States, medical students and graduates are grappling with the uncertainty around their ability to provide evidence-based abortion care in the future. As Rose Al Abosy, M.D., explains:

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

Medical students seeking to practice in the United States and to train in this country's prestigious medical programs should not need to settle for incomplete and scientifically inferior training on reproductive healthcare. As the testimonials of current and former medical students above illustrate, judicial interference with the FDA's regulation of mifepristone would erode evidence-based medicine in this country and have a detrimental impact on medical education and training.

CONCLUSION

It is imperative to the quality and reputation of medical education in the United States that medical schools, clinical programs, and residency programs be permitted to teach evidence-based medicine.

This Court should decline to impose medically unnecessary restrictions on mifepristone, contrary to the FDA's scientific expertise, global consensus, and the evidence-based medicine that our medical schools and training programs are entrusted to teach.

This Court should reverse.

Respectfully submitted,

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