FACTS ON TRIAL: *ALLIANCE FOR HIPPOCRATIC MEDICINE V. FDA* AND THE BATTLE OVER MAILED MEDICATION ABORTION

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INTRODUCTION

Is medication abortion, the regimen commonly administered through two drugs before ten to twelve weeks of pregnancy, safe? The answer, according to a federal agency, researchers, lawyers, and more recently two federal courts, is yes. That answer has remained the same for decades, culminating in the U.S. Food & Drug Administration (FDA), the federal agency in charge of assessing drug safety, easing restrictions since 2016. Medication abortion's safety record, however, is under attack in federal courts. At the time of the writing of this Essay, the Fifth Circuit had issued an opinion that would suspend FDA policies relaxing restrictions on medication abortion, stating that "it was not reasonable for the

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FDA to depend on the published literature to support its decision" to revise restrictions.[1]

This Essay endeavors to capture a moment in the present abortion wars after the Supreme Court, in *Dobbs v. Jackson Women's Medical Center*, overturned the constitutional right to abortion first set out in *Roe v. Wade*. It details the arguments put forward in recent litigation surrounding the FDA's approval of the first drug in a medication abortion, mifepristone. Medication abortion is the most common method of abortion in the United States, and most medication abortions are completed with a regimen of mifepristone, the only drug approved to terminate a pregnancy, and a second drug, misoprostol, prescribed off label with mifepristone.[2] This Essay details this litigation to showcase the deep-seated, longstanding contestation of facts and science in abortion law and policy. At its heart, the current litigation seeks to undermine evidence of the safety and efficacy of mailed abortion pills. This is a case that will test the application of standing and administrative review doctrines, but it is also litigation that could determine the future distribution of medication abortion.[3]

The broader aim of this Essay is to consider how evidence of safety, health, and efficacy has been marshaled by courts and to interrogate the methods by which facts are asserted and repeated by research collectives in support of their respective causes. To be sure, some evidence is better than other evidence; but this Essay reflects on the infrastructure that has made the present contestation possible, and what could change about how evidence is deployed in the wake of *Roe v. Wade*'s reversal.[4]

This Essay proceeds as follows. The first Part provides a background for FDA regulation of mifepristone. Part II reviews the evidence of mifepristone's safety as advanced by the district

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1. All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 23-10362, 2023 WL 5266026, at *1, *27 (5th Cir. Aug. 16, 2023).

2. Rachel K. Jones et al., *Medication Abortion Now Accounts for More Than Half of All US Abortions*, GUTTMACHER INST. (Feb. 24, 2022), https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions [https://perma.cc/7JNN-YYTH] (demonstrating that medication abortions constitute almost 60 percent of the nation's abortions); *see also* Complaint at 17, All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 2:22-CV-00223 (N.D. Tex. Nov. 18, 2022), ECF No. 1 [hereinafter ECF No. 1].

3. *See infra* Part IV (describing a prior case on mailed medication abortion).

4. In *Dobbs v. Jackson Women's Health Organization*, the Supreme Court overturned *Roe v. Wade* and granted states broad leeway to ban abortion at any stage of pregnancy. 142 S. Ct. 2228, 2242–43 (2022).

court decision in *Alliance for Hippocratic Medicine v. FDA*. The next Part assesses the Fifth Circuit's review of that decision. Finally, Part IV examines what is at stake in battles of safety evidence, and how that evidence has been generated by well-resourced movement actors. The whiplash from conflicting accounts of important, public matters, such as a drug's safety, erodes people's faith in courts to discern fact from fiction. A loss of faith in courts is palatable and significant, but also important is the willingness of courts to target mailed medication abortion under the guise of protecting safety. This moment may be an opportunity to pursue strategies that are less tied to judicial opinions and respond to means by which people can gain access to medication abortion.

I. FDA REGULATION OF MIFEPRISTONE

To put mifepristone on the market, a nonprofit organization, the Population Council, sponsored a New Drug Application ("NDA") for mifepristone sold under the name Mifeprex and manufactured by Danco Laboratories, L.L.C. (the brand pharmaceutical producer of mifepristone).[5] The FDA approved the marketing of mifepristone in September 2000 after concluding that it was safe and effective for medical termination of pregnancy through forty-nine days of gestation when used with misoprostol, a drug approved to treat ulcers.[6] The NDA defined effectiveness as the "complete expulsion of products of conception without the need for surgical intervention," and, before approval in 2000, the FDA reviewed a U.S. clinical trial and two French clinical trials to determine the safety and efficacy of mifepristone.[7]

The U.S. clinical trial studied the effectiveness of mifepristone in 859 patients and the safety of mifepristone in

5. ECF No. 1, *supra* note 2, at 17; Approval Memorandum from U.S. Food & Drug Admin. to Sandra P. Arnold, Vice President of Corp. Affairs, Population Council, (Sept. 28, 2000) [hereinafter FDA Approval Memorandum]; *Clinical Review: NDA 020687/S-020- Mifeprex*, CTR. FOR DRUG EVALUATION AND RSCH. 5 (2015) [hereinafter *Clinical Review: Mifeprex*], https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf [https://perma.cc/Y23X-XEW9].

6. FDA Approval Memorandum, *supra* note 5. In 2019, the FDA approved an abbreviated NDA for a generic version of mifepristone manufactured by GenBioPro. That decision was also contested in the litigation this Essay describes.

7. *Clinical Review: Mifeprex*, *supra* note 5, at 28.

827 patients, all with pregnancies with less than forty-nine days of gestation.[8] This clinical study found that

> [m]edical abortion was complete in 92.1% of the 827 subjects[; s]urgical intervention was performed in 7.9% of subjects (1.6% had medically indicated interventions and 1.2% for heavy bleeding), 4.7% had incomplete abortions, 1.0% had ongoing pregnancies, and 0.6% had intervention at the patient's request[; and o]ne of the 859 patients received a blood transfusion.[9]

The two French clinical trials studied the effectiveness of mifepristone in 1,681 patients and the safety of mifepristone in 1,800 patients.[10] The French clinical trials found that "[m]edical abortion was complete in 95.5% of the 1,691 subjects[; s]urgical intervention was performed in 4.5% of subjects: 0.3% for bleeding, 2.9% for incomplete abortions, and 1.3% for ongoing pregnancies[; and o]f the 1,800 women, 2 patients received blood transfusions."[11] The FDA also considered data from other European trials from the 1980s and 1990s in which mifepristone was studied alone or in combination with misoprostol or other similar drugs, as well as relied on manufacturing and chemistry data on mifepristone.[12] The FDA concluded that "the data from these three clinical trials . . . constitute substantial evidence that Mifeprex is safe and effective for its approved indication

8. *Id.* at 32 (noting also that the racial demographic makeup of the subjects reflected the racial demographic of the overall U.S. population). FDA, *MIFEPREX™ (mifepristone) Tablets, 200 mg for Oral Administration Only,* https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.htm [https://perma.cc/6VJE-4C2E].

9. FDA, *supra* note 8.

10. *Id.*

11. *Id.*

12. U.S GOV'T ACCOUNTABILITY OFF., GAO-08-751, FOOD AND DRUG ADMINISTRATION: APPROVAL AND OVERSIGHT OF THE DRUG MIFEPREX 16 (2008), https://www.gao.gov/assets/gao-09-751.pdf [https://perma.cc/3QH6-C2LZ].

. . . ."[13] In 2002, anti-abortion groups submitted a petition to the FDA challenging that approval, which the FDA denied.[14]

When the FDA approved mifepristone, it imposed restrictions on its dispensation and distribution. Until 2016, those restrictions included a gestational limit of seven weeks, physicians-only prescription, a higher dosage, and in-person collection and use—in other words, patients had to pick up and take the medicine at a healthcare facility.[15] But by 2016, a new program, the Risk Evaluation Mitigation Strategies ("REMS"), had taken effect.[16] As described by the FDA, the REMS "is a drug safety program that the [FDA] can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks." While all medications have labeling that informs healthcare stakeholders about medication risks, only a few medications require a REMS.[17] The FDA issued the REMS with Elements to Assure Safe Use ("ETASU"), which can circumscribe distribution and limit who can prescribe a drug and under what conditions.[18] In the consultation over mifepristone's REMS, the FDA received letters from more than forty medical experts, researchers, advocacy groups, and professional associations, all of which asked the agency to completely abandon the REMS for

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13. Letter from Janet Woodcock, Dir. of Ctr. for Drug Evaluation & Rsch., to Am. Ass'n of Pro-Life Obstetricians & Gynecologists, Christian Medical & Dental Ass'ns, and Concerned Women for Am. 8 (Mar. 29, 2016) (denying 2002 Citizen Petition, FDA-2002-P0464).

14. All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 23-10362, at 7 (5th Cir. Apr. 12, 2023) (order granting the motion in part to stay pending appeal).

15. Changes made in 2016 were prompted by a supplemental NDA submitted by Danco, which proposed to update mifepristone's label. ECF No. 1, *supra* note 2, at 52.

16. Brief for Federal Defendant-Appellants at 36, All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 23-10362 (5th Cir. Apr. 26, 2023). The petition denial was the final agency action in the 2000 approval process. The six-year statute of limitations to challenge that approval was tolled when the petition was denied in March of 2016. *Id.* at 35.

17. *Risk Evaluation and Mitigation Strategies | REMS*, FDA, https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems [https://perma.cc/AZN7-WUWK].

18. FDA, RISK EVALUATION AND MITIGATION STRATEGY (REMS) SINGLE SHARED SYSTEM FOR MIFEPRISTONE 200 MG (2019) [hereinafter FDA, RISK EVALUATION & MITIGATION], https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_REMS_Full.pdf [https://perma.cc/76GZ-6LVG]. The REMS, along with ETASU, is a tool Congress created to help the FDA regulate particularly risky products. By statute, a REMS can only be imposed if necessary to ensure that the drug's benefits outweigh its risks. *Id.*

mifepristone because none of the restrictions protected patient health or reflected the drug's safety record.[19]

The agency, however, imposed restrictions while revising and removing others that had existed since mifepristone's approval. Enacting significant changes, the FDA (1) increased the maximum gestational age at which mifepristone could be used from seven to ten weeks, (2) lifted the requirement that patients take the medication in a provider's presence, (3) allowed non-physicians to prescribe mifepristone, and (4) eliminated the requirement to report non-fatal adverse events.[20] The original restrictions that remained after 2016 included a signed Patient Agreement Form,[21] the requirement that providers seek certification to prescribe mifepristone, and that patients pick up mifepristone at a healthcare facility, such as a clinic.[22]

In making these changes, the FDA based these decisions on the outcomes of the 2.5 million users of medication abortion since the drug's 2000 approval, which reflected a very strong record of safety.[23] The agency also relied on major studies and articles that covered 45,000 women who had a medication abortion through seventy days, beyond the originally approved forty-nine days, of gestation.[24] The FDA found that mifepristone

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19. *Id.* Signatories included the American College of Obstetricians and Gynecologists, the American Public Health Organization, the Director at Stanford University School of Medicine's Division of Family Planning Services and Research, the Chair of the Department of Obstetrics and Gynecology at the University of New Mexico School of Medicine, and the Senior Research Demographer in the Office of Population Research at Princeton University.

20. FDA, CTR. FOR DRUG EVALUATION & RSCH., 020687ORIG1S020, MIFEPREX RISK ASSESSMENT AND RISK MITIGATION REVIEW(S), REMS MODIFICATION REVIEW 15–17 (2016) [hereinafter FDA, REMS MODIFICATION REVIEW]. In the litigation described in the next part, anti-abortion groups assert that there are no studies conducted that feature all four of the changes working together. Brief of Plaintiff-Appellees at 52, All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 23-10362 (5th Cir. May. 8, 2023). However, "[n]either the district court nor the stay panel suggested that FDA ignored any study in the administrative record. Nor did they identify any evidence that combining the proposed changes would lead to unsafe outcomes. Indeed, neither court's analysis on this point cited the record at all. Instead, both courts effectively required that studies be conducted to produce evidence that would meet a legal requirement that does not exist." Brief for Federal Defendant-Appellants at 49, All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 23-10362 (5th Cir. Apr. 26, 2023).

21. FDA, REMS MODIFICATION REVIEW, *supra* note 20, at 24.

22. *Id.* at 3.

23. *Clinical Review: Mifeprex*, *supra* note 5, at 12.

24. *Id.* at 18–19 (citing the following studies: Mary Gatter et al., *Efficacy and Safety of Medical Abortion Using Mifepristone and Buccal Misoprostol Through 63 Days*, 91 CONTRACEPTION 269 (2015); Karmen S. Louie et al., *Acceptability and*

is safe and effective, resulting in exceedingly rare serious complications.[25] The FDA observed that "[m]ajor adverse events . . . are reported rarely in the literature on over 30,000 patients. The rates, when noted, are exceedingly rare, *generally far below 0.1%* for any individual adverse event."[26] The FDA stated that "[t]he safety profile of Mifeprex is well-characterized and its risks well-understood after more than 15 years of marketing."[27] In 2018, the Government Accountability Office concluded that

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Feasibility of Mifepristone Medical Abortion in the Early First Trimester in Azerbaijan, 19 EUR. J. CONTRACEPTION & REPROD. HEALTH CARE 4 (2014); Luu Doan Ireland et al., *Medical Compared with Surgical Abortion for Effective Pregnancy Termination in the First Trimester*, 126 OBSTETRICS & GYNECOLOGY 22 (2015); Nguyen Thi Nhu Ngoc et al., *Acceptability and Feasibility of Phone Follow-Up After Early Medical Abortion in Vietnam: A Randomized Controlled Trial,* 123 OBSTETRICS & GYNECOLOGY 88 (2014); Erica Chong et al., *A Prospective, Non-Randomized Study of Home Use of Mifepristone for Medical Abortion in the US*, 92 CONTRACEPTION 215 (2015); Elizabeth G. Raymond et al., *First-Trimester Medical Abortion with Mifepristone 200 mg and Misoprostol: A Systematic Review*, 87(1) CONTRACEPTION 26 (2013); Beverly Winikoff et al., *Extending Outpatient Medical Abortion Services Through 70 Days of Gestational Age*, 120 OBSTETRICS & GYNECOLOGY 1070 (2012); Philip Goldstone et al., *Early Medical Abortion Using Low-Dose Mifepristone Followed by Buccal Misoprostol: A Large Australian Observational Study*, 197 MED. J. AUSTL. 282 (2012); Lisa K. Perriera et al., *Feasibility of Telephone Follow-Up After Medical Abortion*, 81 CONTRACEPTION 143 (2010); Adriana A. Boersma et al., *Mifepristone Followed by Home Administration of Buccal Misoprostol for Medical Abortion Up to 70 Days of Amenorrhea in a General Practice in Curacao*, 16 EUR. J. CONTRACEPTION & REPROD. HEALTH CARE 61 (2011); Beverly Winikoff et al., *Two Distinct Oral Routes of Misoprostol in Mifepristone Medical Abortion: A Randomized Controlled Trial*, 112(6) OBSTETRICS & GYNECOLOGY 1303 (2008); Tamer Middleton et al., *Randomized Trial of Mifepristone and Buccal or Vaginal Misoprostol for Abortion Through 56 Days of Last Menstrual Period*, 72 CONTRACEPTION 328 (2005); Mitchell D. Creinin et al., *Medical Abortion at the Same Time (MAST Study Trial Group). Mifepristone and Misoprostol Administered Simultaneously Versus 24 Hours Apart for Abortion a Randomized Controlled Trial*, 109 OBSTETRICS & GYNECOLOGY 885 (2007); Irving M. Spitz et al., *Early Pregnancy Termination with Mifepristone and Misoprostol in the United States*, 338 NEW ENG. J. MED. 1241 (1998)).

25. FDA, *supra* note 8.

26. ECF No. 1, *supra* note 2, at 30, citing Exhibit B at 47, Exhibit M at 8; and Kelly Cleland et al., *Significant Adverse Events and Outcomes After Medical Abortion*, 121 OBSTETRICS & GYNECOLOGY, 166, 166 (2013) ("Medical research has consistently demonstrated that mifepristone is safe and effective and that adverse events and outcomes are exceedingly rare, occurring in less than a fraction of 1% of cases.").

27. FDA, REMS MODIFICATION MEMORANDUM, *supra* note 20, at 3.

the FDA followed its standard review process and based its approval on peer-reviewed published research.[28]

In 2021, the FDA announced that it would change the REMS again. The FDA lifted the in-person pick-up requirement, and also, for the first time, allowed pharmacies to stock mifepristone after becoming certified.[29] Following litigation which suspended the in-person pick-up requirement during the COVID-19 public health emergency, and investigational studies of telehealth for medication abortion, the FDA found that the evidence on safety or efficacy did not support requiring a patient to pick up mifepristone from a healthcare facility.[30] Additionally, alternatives to in-person mifepristone dispensing had been studied in several countries with research demonstrating its safety and efficacy.[31] As a result of this

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28. U.S. GOV'T ACCOUNTABILITY OFF., GAO-18-292, FOOD AND DRUG ADMINISTRATION: INFORMATION ON MIFEPREX LABELING CHANGES AND ONGOING MONITORING EFFORTS 6 (2018), https://www.gao.gov/assets/gao-18-292.pdf [https://perma.cc/79C5-37CG].

29. FDA, RISK EVALUATION & MITIGATION, *supra* note 18, at 2–3.

30. Center for Drug Evaluation and Research, NDA 0202687 (Dec. 16, 2021) at 37.

31. FDA, Letter to Am. Ass'n of Pro-Life Obstetricians & Gynecologists and Am. Coll. Of Pediatricians, denying in part and granting in part 2019 Citizen Petition, Docket No. FDA-2019-P-1534 (Dec. 16, 2021) at 38; *see also* Daniel Grossman et al., *Mail-Order Pharmacy Dispensing of Mifepristone for Medication Abortion After In-Person Clinical Assessment*, 107 CONTRACEPTION 36 (2022); Daniel Grossman et al., *Medication Abortion with Pharmacist Dispensing of Mifepristone*, 137 OBSTETRICS & GYNECOLOGY 613 (2021); Erica Chong et al., *Expansion of a Direct-to-Patient Telemedicine Abortion Service in the United States and Experience During the COVID-19 Pandemic*, 104 CONTRACEPTION 43 (2021); Courtney Kerestes et al., *Provision of Medication Abortion in Hawai'i During COVID-19: Practical Experience with Multiple Care Delivery Models*, 104 CONTRACEPTION 49 (2021); Abigail R.A. Aiken et al., *Effectiveness, Safety and Acceptability of No-Test Medical Abortion (Termination of Pregnancy) Provided via Telemedicine: A National Cohort Study*, 128 BJOG 1464 (2021); Corinne H. Rocca et al., *Effectiveness and Safety of Early Medication Abortion Provided in Pharmacies by Auxiliary Nurse-Midwives: A Non-inferiority Study in Nepal*, 13 PLOS ONE (2018), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0191174 [https://perma.cc/U92V-6DBC]; Ellen R. Wiebe et al., *Comparing Telemedicine to In-Clinic Medication Abortions Induced with Mifepristone and Misoprostol*, 2 CONTRACEPTION: X 100023 (2020); Ushma D. Upadhyay et al., *Safety and Efficacy of Telehealth Medication Abortion in the US During the COVID-19 Pandemic*, 4 JAMA NETWORK OPEN (2021); Paul Hyland et al., *A Direct-to-Patient Telemedicine Abortion Service in Australia: Retrospective Analysis of the First 18 Months*, 58 AUSTL. & N.Z. J. OBSTETRICS & GYNAECOLOGY 335 (2018); Elizabeth G. Raymond et al., *TelAbortion: Evaluation of a Direct to Patient Telemedicine Abortion Service in the United States*, 100 CONTRACEPTION 173 (2019); Holly A. Anger et al., *Clinical and Service Delivery Implications of Omitting Ultrasound Before Medication Abortion Provided via Direct-to-Patient*

change, patients can meet with a certified provider, either in-person or online, then receive the pills for their medication abortion via mail.[32] This development—mailed abortion pills—is revolutionizing abortion care and has been a focus of abortion-related litigation and advocacy.[33]

II. FACTS REWRITTEN: THE DISTRICT COURT'S DECISION

Less than a year after the U.S. Supreme Court overturned *Roe v. Wade*, the U.S. District Court for the Northern District of Texas in Amarillo heard a case to suspend the FDA's approval of mifepristone in *Alliance for Hippocratic Medicine v. FDA*.[34] On April 7, 2023, the court issued an order suspending the FDA's 2000 approval of mifepristone and threatening access to the drug nationwide.[35] The court held that the drug approval process the FDA used to approve mifepristone two decades ago, as well as the decisions it made after in 2016 and 2021 (and its approval of the generic version of mifepristone in 2019) were arbitrary and capricious in violation of the Administrative Procedure Act.[36]

Telemedicine and Mail, 28 CONTRACEPTION 659 (2021); John J. Reynolds-Wright et al., *Telemedicine Medical Abortion at Home Under 12 Weeks' Gestation: A Prospective Observational Cohort Study During the COVID-19 Pandemic*, 47 BMJ SEXUAL & REPROD. HEALTH 246 (2021); Abigail R.A. Aiken et al., *Self-Reported Outcomes and Adverse Events After Medical Abortion Through Online Telemedicine: Population Based Study in the Republic of Ireland and Northern Ireland*, 357 BMJ (2017), https://www.bmj.com/content/357/bmj.j2011 [https://perma.cc/C4KQ-L5RG]; Hanna Norten et al., *10-Year Evaluation of the Use of Medical Abortion Through Telemedicine: A Retrospective Cohort Study*, 129 BJOG 151 (2021); Margit Endler et al., *Safety and Acceptability of Medical Abortion Through Telemedicine After 9 Weeks of Gestation: A Population-Based Cohort Study*, 126 BJOG 609 (2019).

32. For a summary of the litigation that suspended the in-person pick-up requirement, see Rachel Rebouché, *The Public Health Turn in Reproductive Rights*, 78 WASH. & LEE L. REV. 1355, 1361–65 (2021).

33. For the ramifications of this development, see David S. Cohen, Greer Donley & Rachel Rebouché, *Abortion Pills,* 76 STAN. L. REV. __, *1–4 (forthcoming 2024).

34. All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 2:22-CV-223-Z, 2023 WL 2825871, at *32 (N.D. Tex. Apr. 7, 2023).

35. *Id.* at *28–29.

36. The District Court held that the FDA unlawfully approved of mifepristone under its "Subpart H" authority, the precursor to the REMS program, because it erroneously categorized pregnancy as an "illness." *All. for Hippocratic Med.*, 2023 WL 2825871, at *19. Defendants countered that "Subpart H" authority allowed FDA to approve drugs that had meaningful therapeutic benefits for serious diseases, illnesses, and conditions, and that while pregnancy is not an "illness," it is a "serious medical condition," thereby supporting the use of "Subpart H"

Among other holdings, the district court rejected the notion that a medication abortion (or as the court called it, "chemical abortion") provides a meaningful therapeutic benefit and adopted contested claims that mifepristone is unsafe.[37]

To justify those conclusions, the court drew on a wide variety of medical journal articles, FDA statements, and data about the regulatory process governing mifepristone, declarations from plaintiff medical providers, and several dozen anonymous blog posts linked to anti-abortion advocates as sources.[38] The plaintiff medical providers are comprised of three medical associations, four individual doctors, and the Alliance for Hippocratic Medicine—an amalgamation of five anti-abortion medical groups.[39] Collectively, they alleged that the FDA exceeded its regulatory authority in approving mifepristone and has repeatedly "chose[n] politics over science," "all to the detriment of women and girls."[40]

Alliance for Hippocratic Medicine cited the experiences of these plaintiff providers, which were included as exhibits to their complaint, as well as various amicus briefs to advance three arguments: (1) mifepristone is unsafe and causes physical harm to patients, especially as related to misdiagnosed gestational age and ectopic pregnancy, putting a strain on emergency rooms; (2) people experience regret and suffer mental health consequences after a medication abortion; and (3) the

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authority. Brief for Federal Defendant-Appellants, All. for Hippocratic Med., No. 23-10362, at 45–46 (5th Cir. Apr. 26, 2023).

37. All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 23-10362, at 11 (5th Cir. Apr. 12, 2023).

38. *Id.*

39. Sabrina Talukder, Alliance for Hippocratic Medicine v. FDA*: Legal Standing and the Impact on Abortion Access*, CTR. FOR AM. PROGRESS (May 19, 2023), https://www.americanprogress.org/article/alliance-for-hippocratic-medicine-v-fda-legal-standing-and-the-impact-on-abortion-access [https://perma.cc/U92Z-PSTJ].

40. ECF No. 1, *supra* note 2, at 2–3.

FDA relied on flawed evidence when approving mifepristone and revising the REMS.[41]

A. Gestational Age, Ectopic Pregnancy, and Strain on Providers

The court recounted the testimonials offered by plaintiff medical providers. "Heavy bleeding," "unstable vital signs," "significant abdominal pain," and "other adverse side effects" were among the afflictions the plaintiffs alleged that patients suffer.[42] One doctor described having cared for "several dozen women . . . who were totally unprepared for the pain and bleeding they experienced due to chemical abortion" as well as seeing at least twelve patients who needed surgery to remove pregnancy tissue and five patients who needed blood transfusions or IV antibiotics.[43] Relying on plaintiffs' accounts discussed below, the court stated that "at least two women died from chemical abortion drugs last year," a statistic attributed to an anti-abortion news website.[44]

The court seemed particularly concerned with examples demonstrating "the error in FDA's judgment [through] myriad stories and studies" of what happens when gestational age and ectopic pregnancies are diagnosed incorrectly.[45] At one point, the court's decision referred to a woman who was mistakenly given mifepristone "during an ectopic pregnancy because her

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41. All. for Hippocratic Med. v. U.S. Food and Drug Admin., No. 2:22-CV-00223, 2023 WL 2825871, at *22–23, *26 (N.D. Tex. Nov. 18, 2022).

42. *Id.* at *1, *7 (citing ECF No. 1-8, Compl. Ex. 7, Declaration of Dr. Cristina Francis, at 5–6; ECF No. 1-10, Compl. Ex. 9, Declaration of Dr. Nancy Wozniak, at 6–7).

43. *Id.* at *7 (quoting ECF No. 1-9, Compl. Ex. 8, Declaration of Dr. Ingrid Skop, at 4–9).

44. *Id.* at *25 (citing ECF No. 120, Plaintiffs' Reply Brief In Support of Their Motion For Preliminary Injunction, at 30 n.5). The plaintiffs collected this story from an anti-abortion website: Carole Novielli, *Abortion Pill Deaths, Infant Born Alive Linked to Indiana Abortionist Suing to End State's Pro-life Law*, LIVE ACTION (Jan. 26, 2023, 8:43 AM), https://www.liveaction.org/news/reported-abortion-pill-deaths-tied-indiana- abortionist [https://perma.cc/8XSZ-U8HY].

45. *All. for Hippocratic Med.*, 2023 WL 2825871, at *25 (citing ECF No. 1, Compl., at 21–22, quoting a recent case from a New York state court: Doe v. Shah, No. 501531/2021 (Sup. Ct. N.Y., Cnty. Of Kings Jan. 20, 2021)) ("One woman alleged she did not receive an ultrasound or any other physical examination before receiving chemical abortion drugs from Planned Parenthood. The abortionist misdated the baby's gestational age as six weeks, resulting in the at-home delivery of a 'lifeless, fully-formed baby in the toilet,' later determined to be around 30-36 weeks old.").

ultrasound 'was not even that of a uterus but was of a bladder.' The resulting rupture 'led to massive infection and a collapse of her vital systems.'"[46] That particular account was part of an amicus brief submitted by the Chattanooga National Memorial for the Unborn, which relied on a lawyer's account, not the patient's, in a malpractice suit.[47] In addition, the court cited several journal articles, many of which were published approximately twenty to thirty years ago. The first batch of journal articles addressed incorrect assessments of gestational age. The court focused on two studies that sought to demonstrate that women frequently miscalculate the length of their pregnancy.[48] The court discounted another study that found that clinicians rarely underestimate gestational age, suggesting the FDA wrongly relied upon it.[49] Nowhere in the court's decision are the more recent studies, cited by the defendants, showing that patients' self-reporting of approximate gestational age, based on the last missed menstrual cycle, was generally accurate.[50]

The second batch of studies relates to ectopic pregnancies. The court cited research published ten years before mifepristone

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46. *Id.* (citing ECF No. 31, Amicus Brief on Behalf of The Chattanooga National Memorial for the Unborn, at 5).

47. *Id.* (citing ECF No. 31, Amicus Brief on Behalf of The Chattanooga National Memorial for the Unborn, at 1).

48. *Id.* at *25 n.50 (citing Pekka Taipale & Vilho Hiilesmaa, *Predicting Delivery Date by Ultrasound and Last Menstrual Period in Early Gestation*, 97 OBSTETRICS & GYNECOLOGY 189 (2001) and David A. Savitz et al., *Comparison of Pregnancy Dating by Last Menstrual Period, Ultrasound Scanning, and Their Combination*, 187 AM. J. OBSTETRICS & GYNECOLOGY 1660 (2002). *But see* Lauren Ralph et al. *Accuracy of Self-Assessment of Gestational Duration Among Adolescents Seeking Abortion Using Information in Addition to Date of Last Menstrual Period*, 177 JAMA PEDIATRICS 642 (2023), https://doi.org/10.1001/jamapediatrics.2023.0483 [https://perma.cc/5ED3-9D3S] (noting that adolescents, like adults, typically correctly assess the gestational age of their pregnancies).

49. *All. for Hippocratic Med.*, 2023 WL 2825871, at *25 (citing ECF No. 1-28, Compl. Ex. 27, "2016 Petition Denial," at 19 n.49 and a study found therein). *See also* Steven L. Fielding et al., *Clinicians' Perception of Sonogram Indication for Mifepristone Abortion up to 63 Days*, 66 CONTRACEPTION 27 (2002), https://pubmed.ncbi.nlm.nih.gov/12169378 [https://perma.cc/GG65-EJST] (discussing the results of a prospective study of 1,016 women in a medical abortion trial at 15 sites that concluded that "clinicians correctly assessed gestational age as no more than 63 days in 87% of women. In only 1% (14/1013) of their assessments did clinicians underestimate gestational age. We conclude that the clinicians felt confident in not using ultrasound in most cases.").

50. Abigail R.A. Aiken et al., Safety and Effectiveness of Self-Managed Medication Abortion Provided Using Online Telemedicine in the United States: A Population Based Study, 10 Lancet Reg'l Health-Ams. (June 2022), https://www.sciencedirect.com/science/article/pii [https://perma.cc/EGF2-J55R].

was approved, stating that "women are thirty percent more likely to die from a ruptured ectopic pregnancy while seeking abortions if the condition remains undiagnosed."[51] The court cited another, more recent, study "of 5,619 chemical abortion visits, 452 patients had a pregnancy of 'unknown location' and thirty-one were treated for ectopic pregnancy — including four that were ruptured."[52] The court relied on data from the results synopsis without engaging with the entire study. Standing alone and out of context, that quotation appears to support the idea that a significant number of people who seek medication abortions are erroneously prescribed mifepristone by medical providers who fail to accurately diagnose ectopic pregnancies. However, the study compared people who tested for ectopic pregnancies and those who did not.[53] Ultimately, researchers found that people who used mifepristone without testing for an ectopic pregnancy had lower abortion efficacy, but patients also ruled out ectopic pregnancies more quickly thus ending pregnancies earlier.[54] Researchers also "found no evidence of an increase in the rates of serious adverse events, emergency department visits, or nonadherence with follow-up" between the two groups of patients, concluding that "health care professionals may now consider using mifepristone and misoprostol in a similar diagnostic and therapeutic way."[55] Rather than supporting the plaintiffs' position that medication abortion is dangerous, this study appears to establish the opposite.

The *Alliance for Hippocratic Medicine* plaintiffs not only alleged harm to patients but also to medical practitioners and hospital systems. The court cited the plaintiffs' examples of the pressure medication abortion puts on emergency care: "These emergencies 'consume crucial limited resources, including blood for transfusions, physician time and attention, space in hospital and medical centers, and other equipment and medicines' . . .

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51. *All. For Hippocratic Med.*, 2023 WL 2825871, at *26 (citing Hani Khalil Atrash et al., *Ectopic Pregnancy Concurrent with Induced Abortion: Incidence and Mortality*, 162 AM. J. OBSTETRICS & GYNECOLOGY 726 (1990)).

52. *Id.* (citing Alisa B. Goldberg et al., *Mifepristone and Misoprostol for Undesired Pregnancy of Unknown Location*, 139 OBSTETRICS & GYNECOLOGY 771, 775 (2022)). Throughout the district court and Fifth Circuit's litigation, the courts refer to medication abortion as chemical abortion.

53. *See* Alisa B. Goldberg et al., *Mifepristone and Misoprostol for Undesired Pregnancy of Unknown Location*, 139 OBSTETRICS & GYNECOLOGY 771, 771 (2022).

54. *Id.*

55. *Id.* at 778–79.

This is especially true in maternity-care 'deserts' – geographical areas with limited physician availability."[56] The plaintiffs claimed that providers "often spend several hours treating post-abortive women, even hospitalizing them overnight or providing treatment throughout several visits."[57]

To further support claims that mifepristone puts a strain on hospitals, the court relied on a study that has since been the source of methodological critique. The court stated that "ER visits following mifepristone abortion grew from 3.6% of all postabortion visits in 2002 to 33.9% of all postabortion visits in 2015. The trend toward increasing use of mifepristone abortion requires all concerned with health care utilization to carefully follow the ramifications of ER utilization."[58] The lead author of the study is a researcher at the Charlotte Lozier Institute, a Virginia-based organization that "advises and leads the pro-life movement" with research used "to educate policymakers, the media, and the public."[59] Yet the Lozier ER study's findings are missing important context. For instance, "the study captures emergency room visits broadly and does not distinguish between routine medical care and adverse events"; "the study's findings appear in line with increased use of the FDA's medication abortion protocol between its approval in 2000 and 2015 . . . [and the] amount of patients on Medicaid also grew toward the end of that time frame, reflecting Medicaid expansion following the Affordable Care Act"; "the researchers do not offer an estimated total of emergency department visits among Medicaid patients to contextualize the estimated abortion-related visits."[60]

B. Mental Health Harms

Turning again to declarations from plaintiff medical providers, the court embraced the argument that medication

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56. *All. for Hippocratic Med.*, 2023 WL 2825871, at *4 (quoting ECF No. 1-5, Compl. Ex. 4, Declaration of Dr. Donna Harrison, at 9).

57. *Id.* at *5 (citing ECF No. 1-8, Compl. Ex. 7, Declaration of Dr. Cristina Francis, at 5–6).

58. *Id.* at *4 (citing James Studnicki et al., *A Longitudinal Cohort Study of Emergency Room Utilization Following Mifepristone Chemical and Surgical Abortions, 1999-2015*, 8 HEALTH SERVS. RSCH. & MGMT. EPIDEMIOLOGY 8 (2021)).

59. Charlotte Lozier Institute, *About Lozier*, LOZIER INST., https://lozierinstitute.org/about [https://perma.cc/7UKM-3VTY].

60. Sofia Resnick, *Study Cited by Texas Judge in Abortion-Pill Case Under Investigation*, FLA. PHOENIX (Aug. 3, 2023), https://floridaphoenix.com/2023/08/03/study-cited-by-texas-judge-in-abortion-pill-case-under-investigation [https://

abortion damages patients' mental health. One exhibit discussed treating "several women for abortion-pill reversal,"[61] whom the doctor claimed "experience[d] mental anguish over the experience of having chosen chemical abortion."[62] The court then referred to several studies discussed in an amicus brief from the Human Coalition, a nonprofit organization with the mission "to remove the stain of abortion from America."[63] Those studies described "intense psychological trauma" caused by abortion and noted that women who choose medication abortion "often experience shame, regret, anxiety, depression, drug abuse, and suicidal thoughts because of the abortion."[64] The assertion that abortion results in regret has been the subject of decades-long critique, with numerous studies demonstrating that abortion does not lead to mental health and substance abuse conditions.[65]

The court concluded that the "FDA 'entirely failed to consider an important aspect of the problem by omitting any

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perma.cc/7ARW-EY99]*; see also* Ushma Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 OBSTETRICS & GYNECOLOGY 175 (2015) (finding that less than 1 percent of medication abortion patients have major complications).

61. Abortion pill reversal includes taking a high-dose progesterone after taking mifepristone but before administration of misoprostol. Khadijah Z. Bhatti et al., *Medical Abortion Reversal: Science and Politics Meet*, 218 AM. J. OBSTETRICS & GYNECOLOGY 317 (2018). The American Medical Association and ACOG stated the practice lacks credible medical evidence of its efficacy. *Id.*

62. All. for Hippocratic Med. v. U.S. Food and Drug Admin., No. 2:22-CV-00223, 2023 WL 2825871, at *7 (N.D. Tex. Nov. 18, 2022) (citing ECF No. 1-11, Compl. Ex. 10, Declaration of Dr. Steven A. Foley, at 4–5).

63. *Our Story*, HUM. COAL. (June 26, 2023), https://www.humancoalition.org/who-we-are [https://perma.cc/3Y8B-QMT8].

64. *All. for Hippocratic Med.*, 2023 WL 2825871, at *5, *14 (citing ECF No. 96, Amicus Brief for Human Coalition, and several scientific studies discussed therein). David C. Reardon et al., *Deaths Associated with Pregnancy Outcome: A Record Linkage Study of Low Income Women*, 95 S. MED. J. 834, 834–41 (2002) (stating that women who receive abortions have a 154 percent higher risk of death from suicide than if they gave birth, with persistent tendencies over time and across socioeconomic boundaries, indicating "self-destructive tendencies, depression, and other unhealthy behavior aggravated by the abortion experience"); Priscilla K. Coleman, *Abortion and Mental Health: Quantitative Synthesis and Analysis of Research Published 1995–2009*, 199 BRITISH J. PSYCHIATRY 180, 180–86 (2011); Pauline Slade et al., *Termination of Pregnancy: Patient's Perception of Care*, J. FAM. PLANNING & REPROD. HEALTH CARE Vol. 27, No. 2, 72–77 (2001) ("Seeing the foetus, in general, appears to be a difficult aspect of the medical termination process which can be distressing, bring home the reality of the event and may influence later emotional adaptation.").

65. M. Antonia Biggs et al., *Women's Mental Health and Well-being 5 Years After Receiving or Being Denied an Abortion: A Prospective, Longitudinal Cohort*

evaluation of the psychological effects of the drug or an evaluation of the long-term medical consequences of the drug" in its 2000 approval process.[66] But the FDA considered these issues and concluded the evidence was on the side of mifepristone's safety, both short-term and long-term, and that studies did not show that patients suffered mental health problems post-abortion.[67]

The court's evidence in this vein tracks the reasoning of a February 2022 report by the Family Research Council entitled *The Next Abortion Battleground: Chemical Abortion*.[68] The report referred to medication abortion as a "violent regimen" that results in "profound dangers" to people.[69] Specifically, the report asserted medication abortion was "uniquely traumatic."[70] But in relying on reports like the Council's, the court repeats claims refuted by major medical organizations, including the American Psychological Association.[71] As noted, significant research has undermined the claim that abortion leads to mental health problems; moreover, the court ignored the research presented by the defendants and amici that denial of

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Study, 74 JAMA PSYCHIATRY (2018) (finding that women who received a wanted abortion had similar or better mental health than those who were denied a wanted abortion).

66. *All. for Hippocratic Med.*, 2023 WL 2825871, at *25 (citing ECF No. 84, Brief *Amici Curiae* of 67 Members of Congress in Support of Plaintiff's Motion for a Preliminary Injunction, at 12). This page of the amicus brief quotes from the FDA Commissioner Jane Henney's congressional testimony: "These clinical studies did not include an evaluation of the psychological effects of the drug in women or an evaluation of the long-term medical consequences of the drug in women." It also quotes from several medical journal articles that say essentially the same thing: "Pregnancy loss (natural or induced) is associated with an increased risk of mental health problems," and notes that "recent research indicates an increased correlation [of elective abortion] to the genesis or exacerbation of substance abuse and affective disorders including suicidal ideation."

67. Lauren Weber et al., *Unpacking the Flawed Science Cited in the Texas Abortion Pill Ruling*, WASH. POST (Apr. 13, 2023), https://www.washingtonpost.com/health/2023/04/13/abortion-pill-safety [https://perma.cc/XGN9-7RMR].

68. MARY SZOCH, THE NEXT ABORTION BATTLEGROUND: CHEMICAL ABORTION, FAM. RSCH. COUNCIL, (2022), https://link.gale.com/apps/doc/A745356086/AONE?u=temple_main&sid=bookmark-AONE&xid=d048e1fa [https://perma.cc/P77L-XU3C].

69. *Id.*

70. *Id.*

71. *Restricting Access to Abortion Likely to Lead to Mental Health Harms, APA Asserts*, AM. PYSCH. ASS'N (April 20, 2023), https://www.apa.org/news/press/releases/2022/05/restricting-abortion-mental-health-harms [https://perma.cc/25LL-5JX4].

abortion correlates with decreased mental, social, and economic health.[72]

C. Gaps in FDA Data

The court concentrated on purported discrepancies between clinical trial requirements for mifepristone and the FDA's 2000 approval of the drug, highlighting what it viewed as lax regulatory decisions by the agency. For example, it discussed four trial requirements to ensure drug safety, which the FDA ultimately included in its approval.[73] In one footnote, the court stated that "at least 4,213 adverse events from chemical abortion drugs have been reported," a statistic that the Human Coalition pulled from an FDA report and cited in its amicus brief.[74] The court continued that the number is likely far higher due to issues with reporting procedures.[75] But the court omitted another important piece of data from that same FDA report, which puts the number of adverse events, a broad category, into perspective. Only 4,213 adverse events have been reported out of the 5.6 million women who have taken mifepristone over the twenty-

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72. DIANA GREENE FOSTER, THE TURNAWAY STUDY: TEN YEARS, A THOUSAND WOMEN, AND THE CONSEQUENCES OF HAVING—OR BEING DENIED—AN ABORTION (2020); *see also* Sarah Miller et al., *The Economic Consequences of Being Denied an Abortion* (Nat'l Bureau of Econ. Rsch., Working Paper Series, Working Paper No. 26662, 2020).

73. All. for Hippocratic Med. v. U.S. Food and Drug Admin., No. 2:22-CV-00223, 2023 WL 2825871, at *24 (N.D. Tex. Nov. 18, 2022) ("Here, the U.S. trials the FDA relied upon when approving mifepristone required that: (1) each woman receive an ultrasound to confirm gestational age and exclude an ectopic pregnancy; (2) physicians have experience in performing surgical abortions and admitting privileges at medical facilities that provide emergency care; (3) all patients be within one hour of emergency facilities or the facilities of the principal investigator; and (4) women be monitored for four hours to check for adverse events after taking misoprostol. However, FDA included *none* of these requirements — which were explicitly stated in the clinical trial FDA relied on most — in the 2000 Approval.") (citing ECF No. 7, Plaintiffs' Brief in Support of Their Motion For Preliminary Injunction, at 23–24).

74. *Id.* at *14 n.22 (citing ECF No. 96, Amicus Brief for Human Coalition, at 12 n.16 [citing FDA, MIFEPRISTONE U.S. POST-MARKETING ADVERSE EVENTS SUMMARY THROUGH 6/30/2022]).

75. *Id.* at 23.

three-year life of the drug on the U.S. market.[76] That amounts to 0.075 percent, or three out of 4,000.

From the same FDA report, the court noted that at least ninety-seven women with ectopic pregnancies took mifepristone from 2000 to 2022.[77] The court again suggested, "these data are likely incomplete because the FDA now only requires reporting on deaths."[78] Though the agency requires reporting only on deaths, the FDA report also included data on "cases with any adverse event," hospitalizations, infections, and blood loss requiring transfusions.[79] Additionally, of the twenty-eight deaths reported to the FDA since mifepristone's approval in 2000, more than half were not related to the drug's use: "fatal cases are included regardless of causal attribution to mifepristone."[80] The causes of death for many of the women who took mifepristone included various drug overdoses and intoxication as well as homicide, or pulmonary emphysema.[81]

The FDA countered with copious data supporting its decision to approve mifepristone and to remove or modify restrictions on the drug. The FDA's brief took a close look at the Center for Drug Evaluation and Research's Team Leader Review and detailed several studies that assessed mifepristone use at a later gestational age (as well as studies comparing the efficacy of mifepristone when administered by doctors as opposed to nurse practitioners), finding the efficacy and safety rates to be consistently high.[82]

When the court issued its decision, it stayed the applicability of its holding for seven days to allow the defendants time to appeal.[83] The FDA and Danco Laboratories submitted a

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76. FDA, MIFEPRISTONE U.S. POST-MARKETING ADVERSE EVENTS SUMMARY THROUGH 12/31/2022, https://www.fda.gov/media/164331/download [https://perma.cc/BND9-WWSL].

77. *Id.*

78. *All. for Hippocratic Med.*, 2023 WL 2825871, at *26 (citing FDA, MIFEPRISTONE US. POST-MARKETING ADVERSE EVENTS SUMMARY THROUGH 6/30/2022; ECF No. 1, Compl., at 4).

79. FDA, MIFEPRISTONE U.S. POST-MARKETING ADVERSE EVENTS SUMMARY THROUGH 6/30/2022, https://www.fda.gov/media/164331/download [https://perma.cc/83T8-YQ6G].

80. *Id.* (noting deaths related to homicides, for example).

81. *Id.*

82. Defendant's Opposition to Plaintiff's Motion for a Preliminary Injunction, Exhibit 1B at 13–15, All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 2:22-CV-002233-Z (N.D. Tex. Jan. 13, 2023).

83. All. for Hippocratic Med. v. U.S. Food & Drug Admin., 78 F.4th 210, 254 (5th Cir. 2023) ("We hold that the district court entered an appropriate form of

motion for stay pending a full appeal to the Court of Appeals for the Fifth Circuit, and in April 2023, the Fifth Circuit granted that motion in part. In August 2023, issuing a decision on the merits, the Fifth Circuit essentially repeated its earlier decision.[84] Thus, at the time of the writing of this Essay, the Fifth Circuit has issued two decisions: one in response to an injunction request and the other on the merits. The next Part of this Essay examines the evidence considered by the Fifth Circuit.

III. FACTS ON APPEAL: THE FIFTH CIRCUIT'S REVIEW

A gateway question in the litigation was whether the plaintiffs had standing to challenge the FDA's approval of mifepristone, and that answer depended on whether the plaintiffs suffered injury.[85] In the first of two decisions concerning a request to stay the district court's ruling, the Fifth Circuit outlined the legal standard that governs the principle of standing: "[t]o allege an injury in fact, these doctors must show they have suffered an 'invasion of a legally protected interest' that is both 'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical.'"[86] The court further noted "the Supreme Court has emphasized that 'threatened injury must be *certainly impending* to constitute injury in fact, and that allegations of *possible* future injury are not sufficient.'"[87] The District Court found four premises of standing on which the plaintiffs could present their claims,[88] but the Fifth Circuit validated only two of those theories: first, that doctors had been compelled to care for patients who presented to the ER after taking mifepristone, and the stress of caring for these women, personally and institutionally, was an injury; and second, that medical associations had standing because the

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relief. To begin, consider the nature of a 'stay' under § 705. In the same way that a preliminary injunction is the temporary form of a permanent injunction, a stay is the temporary form of vacatur.").

84. *See* Unpublished Order at 2, All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 23-10362, (5th Cir. Apr. 12, 2023) (order granting the motion in part to stay pending appeal).

85. *Id.* at 10.

86. *Id.* at 11 (citing Spokeo, Inc. v. Robins, 578 U.S. 330, 339 (2016)).

87. *Id.* at 11 (citing Clapper v. Amnesty Int'l USA, 568 U.S. 398, 409 (2013)) (emphasis in original).

88. All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 2:22-CV-223-Z, 2023 WL 2825871, at *3–*9 (N.D. Tex. Apr. 7, 2023).

FDA's approval of mifepristone forced the organizations to divert resources away from other projects.[89] The Fifth Circuit relied upon the testimonials of seven emergency-care doctors in the plaintiffs' complaint.[90] Although the particulars of each declaration differed, the overarching theme was that plaintiff doctors had cared for patients who had experienced negative side effects after taking mifepristone.[91] The declarations claimed that the doctors were thus forced to participate in elective abortions in violation of their beliefs and that medication abortion patients drew resources away from other patients, thereby injuring the medical system writ large.[92]

The FDA and Danco offered evidence, as they had done at the lower court level, that contradicted claims of ER strain or personal injury—evidence that the appellate court found unpersuasive[93]—and highlighted several flaws with plaintiffs' declarations.[94] To start, the use of passive voice coupled with references to third parties obfuscated how or whether the doctors writing the testimonials personally participated in the activities they described.[95] For example, Dr. Ingrid Skop wrote in her declaration about three patients who required medical care after taking mifepristone. However, she prefaced the statement by saying: "in one month while covering the emergency room, my group practice admitted three women to the hospital,"[96] making it unclear whether Dr. Skop was involved in these patients' care.[97] Similarly, Dr. Christina Francis described an incident of her partner physician being

89. Unpublished Order at 10, *All. for Hippocratic Med.*, No. 23-10362.

90. *Id.* at 13–18.

91. Plaintiff's Complaint, Exhibits 4, 7–9, 51, 52, All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 2:22-CV-002233-Z (N.D. Tex. Nov. 18, 2022).

92. *Id.*

93. *See* Brief for Federal Defendant-Appellants at 19–21, All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 23-10362 (5th Cir. Apr. 26, 2023); Reply Brief for Intervenor-Appellant Danco Laboratories, LLC at 4–8, All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 23-10362 (5th Cir. May 12, 2023).

94. *See* Brief for Federal Defendant-Appellants at 26, All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 23-10362 (5th Cir. Apr. 26, 2023); Reply Brief for Intervenor-Appellant Danco Laboratories, LLC at 4–5, *All. for Hippocratic Med.*, No. 23-10362.

95. Reply Brief for Intervenor-Appellant Danco Laboratories, LLC at 3, *All. For Hippocratic Med.*, No. 23-10362.

96. Plaintiff's Complaint, Exhibit 8 para. 22, All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 2:22-CV-002233-Z (N.D. Tex. Nov. 18, 2022).

97. Reply Brief for Intervenor-Appellant Danco Laboratories, LLC at 8, *All. for Hippocratic Med.*, No. 23-10362.

required to complete an abortion for a patient who had taken mifepristone, although her partner was not a plaintiff in the case.[98] To the extent that a physician is asked to deliver care, laws protect providers from being forced to participate personally in medical procedures (such as elective abortions) that violate their beliefs.[99]

Moreover, defendants argued that even if the alleged injuries occurred, FDA approval of mifepristone was not the cause of the injury. Danco highlighted that, in one of the plaintiffs' testimonials, a patient who required care had taken medication abortion drugs ordered from India, circumventing the FDA's protocol for mifepristone in the United States.[100] Another testimonial described a patient whose doctor specifically instructed her *not* to take mifepristone because of other medications she was using, but the patient proceeded to obtain mifepristone from another provider and then needed emergency care.[101]

The Fifth Circuit also cited mifepristone's Patient Agreement Form to underscore mifepristone's danger to patients.[102] The court highlighted paragraph six of the form, which reads:

> I know that, in some cases, the treatment will not work. This happens in about 2 to 7 out of 100 women who use this treatment. If my pregnancy continues after treatment with

98. Plaintiff's Complaint, Exhibit 7 para. 13, *All. for Hippocratic Med.*, No. 2:22-CV-002233-Z.

99. "In response, the Fifth Circuit points to a government guidance document that allegedly requires doctors to perform emergency care, including abortion care notwithstanding conscience objections (p. 28). The government says the Fifth Circuit is misinterpreting the guidance document, the Fifth Circuit points to statements in a government brief allegedly saying otherwise (p. 28). The funny thing here is that a different district court in Texas *enjoined* that guidance, yet the Fifth Circuit still relies on it to substantiate the purported conscience injury." Adam Unikowsky, *The Fifth Circuit's Mifepristone Opinion Is Wrong*, ADAM'S LEGAL NEWSL. (Aug. 17, 2023), https://adamunikowsky.substack.com/p/the-fifth-circuits-mifepristone-opinion [https://perma.cc/CJ33-C3DV].

100. Reply Brief for Intervenor-Appellant Danco Laboratories, LLC at 6–7, *All. For Hippocratic Med.*, No. 23-10362.

101. Plaintiff's Complaint, Exhibit 9 para. 24, *All. for Hippocratic Med.*, No. 2:22-CV-002233-Z.

102. All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 23-10362, 2023 WL 2913725, at *5–6 (5th Cir. Apr. 12, 2023).

> mifepristone and misoprostol, I will talk with my provider about a surgical procedure to end my pregnancy.[103]

Defendants responded that the statement "treatment will not work" does not mean that patients are likely to experience "serious complications" that would necessitate an ER visit.[104] Rather, an ineffective treatment means that either the pregnancy was not terminated or that material in the uterus was not fully expelled within the specified time frame, not that a medical or health complication arose.[105] Defendants further emphasized that the Agreement informs patients to speak to their healthcare provider if the treatment is ineffective.[106] Since the plaintiffs did not prescribe mifepristone, they are likely not the healthcare providers people would contact with concerns about an incomplete abortion.[107] As before in the district court, defendants highlighted the FDA research indicating that "serious complications," such as the ones being described in the testimonials, are quite rare.[108]

After the Supreme Court returned the case to the Fifth Circuit (described next), a new panel of judges issued a decision on the merits in August 2023. The decision tracked the result of the first opinion of the appellate court. After holding that the plaintiffs had standing, the court reversed the suspension of the 2000 approval based on the statute of limitations but suspended FDA actions after 2011. On the merits, the panel found that

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103. *Patient Agreement Form: Mifepristone Tablets, 200mg*, FDA (2023), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_Patient_Agreement_Form.pdf [https://perma.cc/8LD7-G6G7].

104. Brief for Federal Appellants at 25, All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 23-10362 (5th Cir. Apr. 26, 2023).

105. Oral Arguments at 38:47, All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 23-10362 (5th Cir. May 17, 2023), https://www.ca5.uscourts.gov/OralArgRecordings/23/23-10362_5-17-2023.mp3 [https://perma.cc/P6F3-NNNY].

106. Moreover, most incomplete abortions are effectively treated with another dose of misoprostol, requiring no ER visit or surgical intervention. Reply Brief for Intervenor-Appellant Danco Laboratories, LLC at 9, All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 23-10362 (5th Cir. May 12, 2023).

107. Brief for Federal Appellants at 25, All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 23-10362 (5th Cir. Apr. 26, 2023).

108. *Id.* at 28. According to the "Post-Marketing Adverse Events Summary," which includes data from September of 2000 through June of 2022, there have been 4,207 reported cases with any adverse event out of the approximately 4.9 million patients or adverse events occur in .086 percent of patients. FDA, MIFEPRISTONE U.S. POST-MARKETING ADVERSE EVENTS SUMMARY THROUGH 06/30/2021 [hereinafter FDA, POST-MARKETING THROUGH 6/30/2021], https://www.fda.gov/media/154941/download [https://perma.cc/2TM6-EFNH].

lifting restrictions taking effect in 2016 and 2021 (the 2021 changes were issued in final form in January 2023) was arbitrary and capricious and thus unlawful because the FDA "failed to consider an important aspect of the problem."[109] The court held that the FDA did not assess the cumulative effects of the 2016 changes, even though the agency had no duty to do so, and erred in removing the requirement that prescribers report all serious adverse effects (rather than only fatal effects).[110] While the FDA considered the cumulative effect of the 2016 changes and decided that they were safe, it appears the agency did not use the Fifth Circuit's preferred wording.[111]

At the core of these conclusions is skepticism about the safety record of mifepristone. Numerous studies that supported mifepristone's safety record were not believed despite, as cataloged above, the substantial evidence to the contrary. Specifically, the court took issue with studies that the FDA had criticized in pandemic-related litigation described below.[112] The court gave significant weight to a passage from a 2021 FDA letter discussing the limitations of research about the safety of telehealth for mifepristone. It noted that the agency "candidly acknowledged" that available studies were not dispositive of safety of telehealth for abortion but rather are consistent with it.[113] But the possibility of gathering dispositive evidence once a safety determination is made is not required of agencies or by

109. Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). In addition, the court vacated the portion of district court order that suspended the 2019 approval of a generic "because the Medical Organizations and Doctors have not shown that they are injured by that particular action." All. for Hippocratic Med. v. U.S. Food & Drug Admin., 78 F.4th 210 (5th Cir. 2023).

110. All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 23-10362, 2023 WL 5266026, at *1, *27 (5th Cir. Aug. 16, 2023). The court suggests that it was inappropriate for the FDA to rely on a voluntary reporting system of adverse effects. The court quoted one plaintiff who testified that, "Many doctors likely do not know about the need to report adverse events related to chemical abortion to the FDA." *Id.* (citing Dr. Harrison Declaration ¶¶ 33–34).

111. Unikowsky notes that the FDA stated at the time: "After 15 years of reporting serious adverse events, the safety profile of Mifeprex is essentially unchanged. Therefore, I agree that reporting of labeled serious adverse events other than deaths can be collected in the periodic safety update reports and annual reports to the Agency." Adam Unikowsky, *The Fifth Circuit's Mifepristone Opinion Is Wrong, Part 2*, ADAM'S LEGAL NEWSL. (Aug. 20, 2023) [hereinafter Unikowsky, *Wrong Part 2*], https://adamunikowsky.substack.com/p/the-fifth-circuits-mifepristone-opinion-157 [https://perma.cc/PY8D-A93Y].

112. *Id.*

113. *Id.*

law. Adam Unikowsky, an appellate lawyer and former judicial law clerk to Justice Antonin Scalia,[114] opined, "When a federal agency decides that something is safe, a federal court shouldn't overturn that decision because the agency could, theoretically, have collected more safety data. It's *always* possible to collect more safety data."[115]

This commentary illustrates has made plain the problems with the Fifth Circuit's analysis. The next Part does not add to that commentary by further refuting the facts as set forth by the appellate court, although more could be said on that score. Instead, the next Part assesses how such contestation of fact is possible and how competing evidence has long characterized the abortion debate.

IV. FACTS REVISITED: WHAT IS AT STAKE

The Fifth Circuit's decision was stayed by the Supreme Court until the Court decided whether to grant certiorari and until the Court issues a decision.[116] This stay maintains the status quo for mifepristone and keeps at bay the potential upheaval of the current regulations. The Court granted certiorari and will weigh the same evidence when it hands down a judgment in 2024.

With that in mind, contrast the district court's decision in *Alliance for Hippocratic Medicine* with another opinion issued the same day. In *Washington v. FDA*, the attorneys general of Washington, Oregon, Arizona, Colorado, Connecticut, Delaware, Illinois, Nevada, New Mexico, Rhode Island, Vermont, Pennsylvania, Hawaii, Maine, Maryland, Minnesota, Michigan, and the District of Columbia sued the FDA in defense of mifepristone's availability. The plaintiffs asked the U.S. District Court of the Eastern District of Washington to affirm the FDA's original conclusion that mifepristone is safe and effective, to

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114. *Adam Unikowsky*, FEDERALIST SOC'Y, https://fedsoc.org/contributors/adam-unikowsky.

115. Unikowsky, *Wrong Part 2*, *supra* note 111 (emphasis in original).

116. Justice Alito dissented from the Supreme Court's order granting a stay in the *Alliance for Hippocratic Medicine* case. He was particularly critical of the applicants' irreparable harm argument, which was largely based on a claim that the manufacturer of mifepristone would be forced to cease marketing the drug. Justice Alito argued that any such harm would likely never occur because the FDA could decline to exercise its enforcement discretion on mifepristone's manufacturer. Danco Laboratories, LLC v. Alliance for Hippocratic Medicine, No. 22A901, 2–4 (US 2023) (dissenting, Alito, J.).

preserve the status quo by enjoining any actions by defendants to remove mifepristone from the market, and to remove the remaining mifepristone restrictions.[117] The court issued an order that enjoined the FDA from "altering the status quo and rights as it relates to the availability of Mifepristone under the current operative January 2023 Risk Evaluation and Mitigation Strategy . . . in Plaintiff States."[118] But the court denied the plaintiffs' request that the FDA be ordered to lift the remaining REMS.

The *Washington* opinion is the opposite image of the Texas decisions. The court cited the scientific and medical evidence offered by the FDA on mifepristone's safety and efficacy—the same evidence the *Alliance* courts ignored or claimed was flawed.[119] Citing the numerous studies on safety that included thousands of participants,[120] the court relied on over twenty years of data gathered since mifepristone's approval in 2000.[121]

Similarly, in *GenBioPro, Inc. v. Sorsaia*, a case decided by a federal district court in West Virginia, the generic drug manufacturer of mifepristone sued the state to repeal the state's restrictions on mifepristone use.[122] The plaintiff alleged that

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117. *See* Complaint at 110–11, All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 2:22-CV-223-Z, 2023 WL 2825871, at *25 (N.D. Tex. Apr. 7, 2023).

118. Washington v. U.S. Food & Drug Admin., No. 1:23-cv-03026-TOR, at 30 (D. Wa. Apr. 7, 2023) (order granting preliminary injunction).

119. Weber et al., *supra* note 67.

120. Defendant's Opposition to Plaintiffs' Motion For a Preliminary Injunction, Exhibit 1B, All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 2:22-CV-002233-Z (N.D. Tex. Jan. 13, 2023).

121. *Id.* FDA, POST-MARKETING THROUGH 6/30/2021, *supra* note 108.

122. GenBioPro, Inc. v. Sorsaia, No. CV 3:23-0058, 2023 WL 3451688, at *1 (S.D. W.Va. Apr. 21, 2023). Plaintiffs argued that West Virginia's restrictions were preempted by FDA regulations under the Supremacy Clause. The court quickly disposed of the possibility of express preemption under *Dobbs* but considered implied conflict and field preemption. It held that neither the UCPA nor West Virginia's other prior abortion restrictions posed an "unacceptable 'obstacle to the accomplishment and execution of the full purposes and objectives of Congress'" because there is no evidence in the FDCA or FDAAA amendments of congressional intent to preempt state laws like the ones challenged in this suit. Wyeth v. Levine, 555 U.S. 555, 563 (2009) (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941). The defendants' motion to dismiss as to the UCPA and other prior restrictions was granted. However, the court denied defendants' motion to dismiss as to West Virginia's prior restriction on telemedicine prescriptions of mifepristone, writing that it is "unambiguously preempted by the 2023 REMS." *Id.* at 26 ("Under this standard, if plaintiff can demonstrate that the challenged law burdens interstate commerce, then the Court determines 'whether the State's interest is legitimate and whether the burden on interstate commerce clearly exceeds the local benefits.'") (quoting Pike v. Bruce Church, 397 U.S. 137 (1970)). The court also granted the

these barriers to prescribing its product violated both the Supremacy and Commerce Clauses of the U.S. Constitution. The defendants moved to dismiss the complaint, and like in the Washington decision, the court granted in part and denied in part. Like its Washington counterpart, the court highlighted the safety of mifepristone as established by the evidence, opening the door to a preemption challenge to the state's ban on telehealth for abortion. [123] Noting that "[d]efendants have not disputed the safety of the mifepristone REMS, nor could they,"[124] the court relied not only on FDA studies but also on comments from an amicus brief to suggest it was absurd to question the drug's safety.[125] The decision to lift the in-person pick-up requirement, according to the court, was the result of a "rigorous agency and pharmaceutical industry review process,"[126] "which unambiguously assures the safety of the drug without any additional safeguards from the States."[127]

How can courts review the same evidence and come to contrary conclusions about mifepristone's safety?

Since *Roe* was decided, abortion debates have been waged on the terrain of contested expertise and facts.[128] And in the last twenty years, abortion opponents have sought to generate evidence that abortion correlates with negative health effects, leading to breast cancer or mental health problems, for example.[129] Mary Ziegler highlights that "abortion opponents had tried to expand their capacity for research. In 2011, the Susan B. Anthony List founded the Charlotte Lozier Institute as an alternative to abortion-rights research groups, but as many abortion opponents realized, supporters of abortion-rights had

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defendants' motion to dismiss on arguments grounded in the Commerce Clause and based on the Major Questions Doctrine. *Id.* at 29–34.

123. *Id.* at 5–6.

124. *Id.* at 6.

125. *See id.* at 5 ("As summarized by Food and Drug Law and Health Law Scholar *amici*, 'mifepristone has been subject to more regulatory and congressional scrutiny than perhaps any other prescription drug.'") (quoting ECF No. 40-1, at 5).

126. *Id.*

127. *Id.* at 5–6.

128. *See* Rebouché, *supra* note 32; *see also* Aziza Ahmed, *Feminist Legal Theory and Praxis after Dobbs: Science, Politics, and Expertise*, 34 YALE J.L. & FEMINISM 48 (2023).

129. *See*, *e.g.*, *Myths About Abortion and Breast Cancer*, PLANNED PARENTHOOD (Mar. 2013), https://www.plannedparenthood.org/uploads/filer_public/af/1a/af1ae95f-de81-43dd-91a3-470043b06dce/myths_about_abortion_and_breast_cancer.pdf [https://perma.cc/HS3T-8C9B].

an advantage in research funding and access to data."[130] Anti-abortion research efforts have been dwarfed by the research that supports abortion access, in part because of a reliance on credible, rigorous research methods but also because of a better infrastructure.[131] For instance, there has been a substantial investment in rigorous research on the regulation of abortion facilities and providers.[132] This investment has yielded an increasing number of experts and researchers who study the health and social consequences of abortion restrictions and who have found that scarcity of abortion services compounded by abortion restrictions has both short-term and long-term negative effects.[133] Indeed, this generation of peer-reviewed studies helped shape the application of constitutional tests before the Court overturned *Roe* in *Dobbs v. Jackson Women's Health Organization*.[134]

Yet evidence of the connection between abortion restrictions and negative effects on people's lives, health, and finances has not been enough for some courts.[135] In cases leading up to *Roe*'s

130. MARY ZIEGLER, ABORTION AND THE LAW IN AMERICA: *ROE V. WADE* TO THE PRESENT 124 (2020).

131. *Id.* at 199.

132. The investment in research hubs is a product of concentrated, coordinated funding by one of the largest private foundations in the country. *See* Nina Martin, *How One Abortion Research Megadonor Forced the Supreme Court's Hand*, MOTHER JONES (July 14, 2016), https://www.motherjones.com/politics/2016/07/abortion-research-buffett [https://perma.cc/2XXF-FP9L] (reporting that private donors poured at least 200 million dollars into the research cited by the Supreme Court); Kelsey Piper, *How Billionaire Philanthropy Provides Reproductive Health Care When Politicians Won't*, VOX (Sept. 17, 2019), https://www.vox.com/future-perfect/2019/9/17/20754970/billionaire-philanthropy-reproductive-health-care-politics [https://perma.cc/B4EH-SMUB] (stating that reproductive health care "would suffer greatly if billionaire philanthropy was reduced in scale or ceased to exist tomorrow"); GUTTMACHER INST., ANN. REPORT (2019), https://www.guttmacher.org/sites/default/files/page_files/guttmacher_2019_annual_report.pdf [https://perma.cc/YN92-G9TM] (showing that 65 percent of the organization's funding is from private U.S. foundations, and listing "anonymous" and the Gates Foundation as foundation-based donors).

133. *See* ZIEGLER, *supra* note 130, at 199. *See also* Daniel Grossman, *The Use of Public Health Evidence in* Whole Woman's Health v. Hellerstedt, 177 JAMA INTERNAL MED. 155 (2016); *TxPEP Fact Sheet*, UNIV. TEX., https://sites.utexas.edu/txpep/files/2017/07/TxPEP-Fact-Sheet.pdf [https://perma.cc/V34S-RYMF] (TxPEP "began in the fall of 2011 with the purpose of documenting and evaluating the impact of reproductive health legislation passed by the 82nd Texas Legislature.").

134. *See* Martin, *supra* note 132, (demonstrating that the purpose of funding centers and studies like those identified in this Part was to provide evidence offering courts certainty).

135. *See* Jessie Hill, *The Geography of Abortion Rights*, 109 GEO. L.J. 1081, 1111–12 (2021) (explaining that courts do not consider how various laws reduce

reversal, a number of courts accepted states' arguments that the difficulties clinics experience in implementing regulations, such as a requirement that clinics have admitting privileges to nearby hospitals, reflect "neutral, pre-existing states of affairs unrelated to the legislation itself."[136] And if there was contestation of fact, even if evidence heavily weighed to one side or one side presented dubious evidence, contestation alone was reason to defer to anti-abortion evidence.[137]

States no longer need to amass evidence of abortion's harm to ban it.[138] Even so, the litigation in Texas and Washington showcases the evolving role of experts and evidence in the present and future regulation of medication abortion. The litigation discussed in this Essay encapsulates the struggle over mailed pills: will the avenues the FDA opened for "no-touch abortions"—terminating a pregnancy without a single visit to a clinic—stay open? The successful proliferation of virtual services and mailed pills belies the claims of those services' opponents. And abortion untethered to a physical space is changing how abortion care is practiced and advanced. Shutting down those providers and networks is a project that has little to do with how safe the services are. The Supreme Court's decision in *Alliance for Hippocratic Medicine* will pave the way, post-*Dobbs*, to assess what harms should matter to courts. The *Alliance* litigation asks courts to view abortion as harm to potential life, to physicians who do not provide abortion services, and to the integrity of the medical profession. Those who support abortion will pursue research that demonstrates the harmful short-term and long-term consequences of abortion restrictions. One question the

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abortion access); *The Turnaway Study*, ANSIRH, https://www.ansirh.org/research/ongoing/turnaway-study [https://perma.cc/M8H2-9G62] (finding that women denied abortions are four times more likely to live in poverty and are more likely to experience serious health complications from pregnancy).

136. Hill, *supra* note 135, at 1111. *See also* Mary Ziegler, *The Jurisprudence of Uncertainty: Knowledge, Science, and Abortion*, 2018 WIS. L. REV. 317, 355, 357 (noting that *Whole Woman's Health* turned on a question about the Texas statute's causal effects).

137. Ahmed, *supra* note 128, at 50.

138. *Id.* at 51. After *Dobbs,* states can ban abortion for a wide range of state interests without legislative findings that abortion is unsafe. Those state interests, according to the *Dobbs* majority, include "respect for and preservation of prenatal life at all stages of development; the protection of maternal health and safety; the elimination of particularly gruesome or barbaric medical procedures; the preservation of the integrity of the medical profession; the mitigation of fetal pain; and the prevention of discrimination on the basis of race, sex, or disability…" Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228, 2284 (2022).

Supreme Court will answer is which set of harms matters more and why.

CONCLUSION

The *Alliance for Hippocratic Medicine* litigation is a striking example of how evidence can be marshaled by a court to undermine a federal agency. But abortion advocates also have used evidence in contemporary cases to undermine agency decision-making. *FDA v. American College of Obstetricians and Gynecologists*, a 2020 case, similarly involved a challenge to the FDA's mifepristone regulations. The district court suspended the FDA's in-person dispensation restriction for the duration of the COVID-19 pandemic and because of the absence of safety justifications for the rule.[139] It did not defer to the agency (which had a different position on the matter under the Trump Administration), and abortion advocates counted this as a victory for evidence. On appeal, however, the Supreme Court deferred to the FDA and supported the use of agency expertise to retain then-existing mifepristone restrictions.

This example matters because it tests the assumptions that evidence is apolitical, neutral, or settled; that evidence is separate from law; and that healthcare policy will be better if based only on evidence and not on politics, as if the two could be untangled.[140] Neither side of the abortion debate should bank on having facts—or courts—to advance their agendas. Instead, as the uptake of mailed medication pills shows, what matters is real-time abortion access through telehealth and through organizations like Aid Access, which ship medication abortion to every state in the country. That is not to argue that all facts and evidence are equal; the *Alliance* litigation makes that point clear. But what that litigation also makes clear is that some courts may not care or may not believe that the evidence supports abortion's safety. And rather than creating research agendas reactive to that reality, research needs to pioneer new pathways tethered to political and strategic goals. The last

139. *See* Am. Coll. of Obstetricians & Gynecologists v. U.S. Food & Drug Admin., 472 F. Supp. 3d 183, 218 (D. Md. 2020) (noting that ACOG and other medical associations had formally requested FDA's approval for non-enforcement of the in-person requirement because of the COVID-19 pandemic but they did not receive a response from the FDA).

140. Aziza Ahmed, *A Critique of Expertise for Health Law*, 50 J.L. MED. & ETHICS 682, 682 (2023).

sentence is not a call for the dilution of evidentiary or scientific standards. Rather, this Essay offers an example of the contemporary will of some courts to undermine those standards and asks, what will abortion-supportive forces do about it?