

# THE FEDERAL FUTURE OF MEDICATION ABORTION

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## ABSTRACT

A majority of Americans believe that there should be a right to abortion, at least in some cases. Yet a vocal and determined minority has its sights set on a complete ban on all abortions everywhere in the United States. In many states, these anti-abortion activists have achieved their goal through new laws and limitations enacted in the wake of the Supreme Court's 2022 decision in *Dobbs*. Anti-abortion advocates are also challenging the Food and Drug Administration's regulatory approval of mifepristone, one of the drugs used in medication abortion (also known as medical abortion). The FDA had initially approved mifepristone in 2000. During the COVID-19 pandemic, the FDA also relaxed various dispensing requirements and permitted the medication to be prescribed via telemedicine and delivered by mail. In August 2023, the Fifth Circuit ruled in *Alliance for Hippocratic Medicine v. FDA* that challenges to mifepristone's approval were likely time-barred, but that access to the medication should be restricted to those who make in-person visits to a doctor, among other limitations. The case will be appealed to the United States Supreme Court.

This Article makes three contributions to the national conversation about reproductive rights. First, it evaluates the arguments raised by both sides in *Alliance for Hippocratic Medicine*. Second, it recommends that mifepristone's defenders focus on standing arguments if they wish to maintain the status quo. Third, the Article predicts that even if mifepristone's defenders could persuasively argue that the plaintiffs were not entitled to rely on associational standing, there will be future plaintiffs with standing who are willing to take their place. In a future case, the Court might well find that challenges to the FDA's initial approval of mifepristone are time-barred, but that the agency unlawfully relaxed dispensing and other requirements. It is almost certain that access to mifepristone will be restricted in the foreseeable future.

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INTRODUCTION

With the 2022 decision in *Dobbs v. Jackson Women's Health Organization*, the Supreme Court of the United States set aside a right that Americans have enjoyed for the last 50 years.<sup>1</sup> The decision impacted the heart of what the vast majority of Americans believed to be secure, including the importance of precedent and stare decisis, the belief that the Supreme Court protects constitutional rights regardless of political pressure, and the treatment of women as equal citizens. The Court's assault on reproductive autonomy shattered the confidence of many, and yet the *Dobbs* decision marks only the beginning of a much more comprehensive attack on reproductive rights. The stated ultimate objective of pro-life advocates is a country where abortion is banned everywhere and at any point in pregnancy.<sup>2</sup> The advocates want to prevent pregnant people in states where abortion is illegal from traveling to other states to obtain care, and to force anyone who seeks the procedure anywhere in the United States to leave the country or be subject to criminal penalties.<sup>3</sup>

This attack on reproductive rights continued on April 7, 2023, in *Alliance for*

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1. *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228 (2022).

2. See, e.g., *U.S. Repro Watch*, August 9, CTR. FOR REPROD. RTS. (Aug. 9, 2023), <https://reproductiverights.org/u-s-repro-watch-8-9-23/> [<https://perma.cc/63Z3-JGT7>]; *Where Abortion Laws Stand in Every State a Year After the Supreme Court Overturned Roe*, ASSOC. PRESS (June 22, 2023), <https://apnews.com/article/abortion-status-list-state-protection-ban-4466aefe6141745b71c824522aac47b9> [<https://perma.cc/66SX-SVML>] (listing states that enacted laws post-*Dobbs* banning abortion throughout pregnancy: Alabama, Arkansas, Idaho, Kentucky, Louisiana, Mississippi, Missouri, North Dakota, Oklahoma, South Dakota, Tennessee, Texas, West Virginia, and Wisconsin).

3. See Shefali Luthra, *Abortion Opponents are Trying to Deter People From Traveling Out of State for Care*, THE 19TH (Oct. 12, 2023, 6:00 AM), <https://19thnews.org/2023/10/abortion-opponents-out-of-state-care/> [<https://perma.cc/KD4H-VZCT>].

*Hippocratic Medicine v. FDA*.<sup>4</sup> In that case, a federal judge in the Northern District of Texas issued a 67-page decision that threatened to unwind the FDA's approval of mifepristone, a drug used in more than half of all abortions performed in the United States.<sup>5</sup> That judge concluded that the FDA had exceeded its authority by initially approving mifepristone in 2000 under its accelerated program, violated the Comstock Act by allowing mifepristone to be dispensed via mail, and "stonewalled" timely judicial review of its regulatory decisions related to mifepristone.<sup>6</sup> The district court ultimately stayed the effective date of the FDA's approval of the drug in 2000, and as a result, stayed all of the challenged actions related to that approval.<sup>7</sup>

The FDA, along with Danco Laboratories, the company that distributes the name-brand version of the drug, quickly appealed<sup>8</sup> and the United States Supreme Court fully blocked the order, sending the case back to the Fifth Circuit.<sup>9</sup> The Fifth Circuit heard oral arguments in the case on May 17, 2023, and released its opinion on August 16, 2023.<sup>10</sup> The three-judge panel vacated the district court's decision that had effectively halted the use of mifepristone, finding that the challenge of the approval by the FDA in 2000 is "likely barred" by the statute of limitations, and that the plaintiffs did not demonstrate that they were actually injured by the 2019 approval of generic mifepristone.<sup>11</sup> However, the circuit court affirmed the district court's reinstatement of the restrictions on access to mifepristone, i.e., that the FDA's 2016 and 2021 changes, which allowed the drug to be mailed, allowed medical professionals other than doctors to prescribe the drug, allowed the medication to be prescribed by telemedicine, and allowed patients to take the drug up to ten weeks of pregnancy, are unlawful.<sup>12</sup> It is anticipated that the decision will be appealed to the Supreme Court.<sup>13</sup> Until such time, mifepristone remains on the market without court-imposed restrictions and the fate of mifepristone lies with that decision.<sup>14</sup>

Both the initial District Court decision and the subsequent actions by the Fifth

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4. 668 F. Supp. 3d 507, 545-56 (N.D. Tex. 2023).

5. 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/EBF7-92ZG>].

6. *All. for Hippocratic Med.*, 668 F. Supp. 3d at 520, 539, 548.

7. *Id.* at 559-60.

8. Food & Drug Admin. v. All. for Hippocratic Med., No. 22A902, 2023 WL 2996931, at \*1 (Apr. 19, 2023) (Mem.) (seeking full stay of District Court order).

9. *See id.*

10. *All. for Hippocratic Med. v. U.S. Food & Drug Admin.*, 78 F.4th 210 (5th Cir. 2023).

11. *Id.* at 222-23.

12. *Id.*

13. Tierney Sneed, *Takeaways from the 5th Circuit Arguments Over Abortion Drug Access*, CNN (May 17, 2023, 8:26 PM), <https://www.cnn.com/2023/05/17/politics/abortion-drug-mifepristone-5th-circuit-hearing-takeaways/index.html> [<https://perma.cc/GK8Z-WPPV>].

14. *See id.*

Circuit were met with instant and strong reactions.<sup>15</sup> Pro-choice advocates immediately raised concerns about forum shopping.<sup>16</sup> Judge Kacsmaryk is a Trump-appointed conservative judge and the only judge in the Amarillo Division, meaning any case filed in that district is necessarily assigned to him.<sup>17</sup> The decision was also criticized on the grounds that it ignored science, diminished FDA authority, posed a threat to other drug approvals, and created regulatory uncertainty.<sup>18</sup> Finally, the decision has been decried for its lack of understanding of substantive law such as the standing requirement, the tolling of the statute of limitations, and its reliance on the 1873 Comstock Act, a nineteenth-century anti-vice law adopted in an era when women were prohibited from voting or practicing law.<sup>19</sup>

When the draft opinion in *Dobbs* was leaked, many pro-choice voters continued to hold out hope that the Court would reconsider its decision in light of the national outcry.<sup>20</sup> It did not.<sup>21</sup> Yet even though the final *Dobbs* opinion was not a complete surprise, the opinion still created shock waves throughout the country.<sup>22</sup> The Court essentially erased a constitutional right that citizens had

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15. See Maggie Astor & David W. Chen, *Reaction to Texas Abortion Pill Ruling: Outrage, and Muted Praise*, N.Y. TIMES (Apr. 7, 2023), <https://web.archive.org/web/20230408051506/https://www.nytimes.com/2023/04/07/us/abortion-pill-ruling-reaction.html> [https://perma.cc/CYB3-6HB7]. Senator Cindy Hyde-Smith, Republican of Mississippi, tweeted “that the abortion ruling was ‘a victory for pregnant mothers and their unborn children’ . . . [d]emocratic senators and representatives called the ruling ‘outrageous,’ ‘extreme’ and ‘devastating.’” *Id.* Erik Babbitt, a lawyer for the Alliance Defending Freedom, told reporters that the decision was a “significant victory for the doctors and medical associations we represent and, more importantly, the health and safety of women and girls.” *Id.*

16. See Caroline Kitchener & Ann E. Marimow, *The Texas Judge Who Could Take Down the Abortion Pill*, WASH. POST (Feb. 25, 2023), <https://www.washingtonpost.com/politics/2023/02/25/texas-judge-abortion-pill-decision/> [https://perma.cc/YM9D-2AKZ]; Melissa Quinn, *Meet the Federal Judge Set to Rule in a Case That Could Disrupt Access to the Abortion Pill*, CBS NEWS (Mar. 2, 2023), <https://www.cbsnews.com/news/matthew-kacsmaryk-medication-abortion-mifepristone-abortion-pill-judge-texas/> [https://perma.cc/X4QM-EA8E].

17. See *id.*

18. See Lauren Weber et al., *Unpacking the Flawed Science Cited in the Texas Abortion Pill Ruling*, WASH. POST (Apr. 13, 2023), <https://archive.is/8B8ID> (“A Texas judge’s decision to invalidate federal approval of a key abortion drug cites research based on anonymous blog posts, cherry picks statistics that exaggerate the negative physical and psychological effects of mifepristone, and ignores hundreds of scientific studies attesting to the medication’s safety.”).

19. See 18 U.S.C. § 1461.

20. See Caroline Kitchener, *After Leak of Draft Abortion Decision, Advocates React with Emotion*, WASH. POST (May 3, 2022, 7:29 AM), <https://www.washingtonpost.com/politics/2022/05/03/abortion-reaction-alito-decision/> [https://perma.cc/P459-F56J].

21. See John Keefe et al., *Track Changes Between the Abortion Decision and the Leaked Draft*, CNN (June 27, 2022), <https://www.cnn.com/interactive/2022/06/us/supreme-court-abortion-dobbs-decision-changes/> [https://perma.cc/P7Q5-KRL4].

22. See Jennifer Rubin, *A Year After Dobbs, the Pro-Choice Movement Has Never Been*

relied on for 50 years.<sup>23</sup> A year later, stories abounded of people denied medical care and abortion bans threatening women's lives.<sup>24</sup>

The current efforts to ban an FDA-approved drug used for not only abortion but also treatment after miscarriage continues the effort to intrude into a person's right to make decisions about their own health care.<sup>25</sup> If the plaintiffs prevail, mifepristone may be pulled from the market or at the very least, be much less accessible.<sup>26</sup> With millions of people relying on the medicine for abortion access in the post-*Dobbs* world,<sup>27</sup> such an imprudent decision would cause short-term turmoil and set a perilous long-term precedent.

It is important not to be shocked again. This Article provides an in-depth analysis of the implications of *Alliance for Hippocratic Medicine v. FDA*, including the availability and use of mifepristone going forward as well as the potential impact on the FDA's broader authority. Part I reviews what the drug mifepristone is used for and how it works. Part II charts the history of the drug's approval by examining the regulatory process and the authority of the FDA. Part III takes a close look at the complicated and politically wrought approval of mifepristone, and the various milestones that led to the current litigation. Part IV examines the procedural history of the case, from the time it was brought in Texas district court, through the various stays, up until the Fifth Circuit decision in August 2023. Finally, Part V evaluates the various arguments that have been

*Stronger*, WASH. POST (June 26, 2023, 7:45 AM), <https://www.washingtonpost.com/opinions/2023/06/26/dobbs-ruling-anniversary-health-political-fallout/>. [<https://perma.cc/KE2C-MWL5>].

23. *See id.*

24. *See* HUM. RTS. WATCH, *Human Rights Crisis: Abortion in the United States After Dobbs* (Apr. 18, 2023, 12:01 AM), <https://www.hrw.org/news/2023/04/18/human-rights-crisis-abortion-united-states-after-dobbs> [<https://perma.cc/8VLE-MUH4>] (“The consequences of the Dobbs decision are wide-ranging. Restrictions on access to healthcare places women’s lives and health at risk, leading to increased maternal mortality and morbidity, a climate of fear among healthcare providers, and reduced access to all forms of care. Dobbs also enables penalization and criminalization of healthcare, with providers, patients, and third parties at risk of prosecution or civil suit for their involvement in private healthcare decisions. Relatedly, the decision opens the door to widespread infringement of privacy rights as digital surveillance is expanded to detect violations of new regulations. New bans also infringe on freedom of thought, conscience and religion or belief, restricting the ability of physicians to counsel patients and clergy to provide pastoral care to their congregants. Finally, the harms of Dobbs violate principles of equality and non-discrimination; they fall disproportionately on marginalized populations including Black, indigenous, and people of color; people with disabilities; immigrants; and those living in poverty.”).

25. *See* Jennifer Dalven, *What to Know About the Abortion Case that Could Ban Mifepristone*, ACLU (Feb. 10, 2023), <https://www.aclu.org/news/reproductive-freedom/abortion-case-lawsuit-ban-mifepristone> [<https://perma.cc/7WB5-QWPU>].

26. *See* Mark Sherman & Jessica Gresko, *What to Expect from the Supreme Court Battle Over Mifepristone*, PBS: PBS NEWS HOUR (Apr. 20, 2023, 9:58 AM), <https://www.pbs.org/newshour/politics/what-to-expect-from-the-supreme-court-battle-over-mifepristone#>. [<https://perma.cc/RPY7-JH9E>].

27. *See id.*

raised by the plaintiffs and the defendants, and analyzes their strengths and weaknesses, especially in light of recent decisions by the Supreme Court. The Article concludes that, while there are some issues that fall by the wayside, there are others that will be attractive to this conservative Court. Only by fully understanding the arguments can pro-choice advocates prepare a more powerful response.

### I. WHAT IS MIFEPRISTONE?

Mifepristone<sup>28</sup> is the first of two medications used in medication abortion (also called medical abortion or “abortion with pills”).<sup>29</sup> Along with a second medication, misoprostol,<sup>30</sup> it is used to end an early pregnancy.<sup>31</sup> Mifepristone works by blocking the hormone progesterone.<sup>32</sup> Thus, this antiprogestin drug interferes with the flow of the hormone progesterone to a developing embryo, essentially causing a miscarriage.<sup>33</sup> Without progesterone, the lining of the uterus breaks down and the pregnancy can no longer continue.<sup>34</sup>

Misoprostol, the second medication, is taken up to 48 hours later and causes the uterus to empty.<sup>35</sup> Once mifepristone is used to pause the pregnancy, misoprostol simulates contractions and expels the embryo from the uterus.<sup>36</sup> This prostaglandin drug triggers contractions that help expel the uterine lining and gestational sac.<sup>37</sup>

In addition to the expected cramping, some patients experience significant

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28. The brand name is Mifeprex and is also approved in generic form as mifepristone. *See Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation> [<https://perma.cc/W8BR-T6DS>] (last visited June 11, 2023).

29. *See The Availability and Use of Medication Abortion*, KFF (June 1, 2023), <https://www.kff.org/womens-health-policy/fact-sheet/the-availability-and-use-of-medication-abortion/> [<https://perma.cc/R3ZV-CJCG>].

30. *Id.*

31. In general, it is used up to 70 days, or 10 weeks, after the first day of the last menstrual period. *Id.*

32. *Id.*

33. *See* Etienne-Emile Baulieu, *RU-486 as an Antiprogestosterone Steroid*, 262 JAMA 1808 (1989); Beatrice Couzinet et al., *Termination of Early Pregnancy by the Progesterone Antagonist RU 486 (Mifepristone)*, 315 NEW ENG. J. MED. 1565 (1986).

34. *See* Laurah J. Samuels, *Mifepristone Protocol Legislation—The Anti-Choice Movement’s Disingenuous Method of Attack on the Reproductive Rights of Women and How Courts Should Respond*, 26 COLUM. J. GENDER & L. 316 (2014).

35. *Id.*

36. *Id.*

37. *See* Remi Peyron et al., *Early Termination of Pregnancy with Mifepristone (RU 486) and the Orally Active Prostaglandin Misoprostol*, 328 NEW ENG. J. MED. 1509 (1993); André Ulmann et al., *RU 486*, 262 SCI. AM. 42 (1990).

hemorrhaging and may require medical attention, and, in a small percentage of cases the procedure fails and necessitates a surgical abortion.<sup>38</sup> Mifepristone is also used for evidence-based indications in the medical management of miscarriage, cervical preparation for later second-trimester abortion, and management of second and third-trimester pregnancies when the fetus has died before birth.<sup>39</sup>

## II. THE REGULATORY AUTHORITY AND PROCESS OF THE FDA

### *A. Establishing the FDA's Regulatory Authority*

The FDA's regulatory authority was originally based on the 1906 Pure Food and Drugs Act,<sup>40</sup> which prohibited manufacturing or shipping of any adulterated or misbranded food or drugs.<sup>41</sup> While the statute tasks the Bureau of Chemistry (later renamed the Food and Drug Administration) with preventing the "manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious food, drugs, medicines, and liquors,"<sup>42</sup> it did not cover how to ensure the safety or efficacy of regulated products.<sup>43</sup> As a result, many drugs continued to be sold without any clinical testing before being approved.<sup>44</sup>

In 1938, Congress passed the Federal Food, Drug, and Cosmetic Act (FDCA), largely in response to public outcry after more than 100 people, mostly children, died after ingesting a drug used to treat streptococcal infections that

38. See Louise Silvestre et al., *Voluntary Interruption of Pregnancy with Mifepristone (RU 486) and a Prostaglandin Analogue: A Large-Scale French Experience*, 322 *NEW ENG. J. MED.* 645, 647-48 (1990); Robin Herman, *The Politics of the Abortion Pill*, *WASH. POST*, Oct. 3, 1989, at Z12; see also Janice G. Raymond et al., *RU 486: Misconceptions, Myths and Morals* (1991) (discussing potential side effects); Peter Coles, *French Government Approves Abortion Pill for Commercial Use*, 335 *NATURE* 486 (1988) (noting concerns about delivering a child when the abortion is not successful); Jane E. Norman, *Uterine Rupture During Therapeutic Abortion in the Second Trimester Using Mifepristone and Prostaglandin*, 102 *BRITISH J. OBSTETRICS & GYNAECOLOGY* 332 (1995) (reporting a serious complication).

39. *Id.*

40. Pure Food and Drugs Act, ch. 3915, 34 Stat. 768, 769 (1906).

41. The purpose was to regulate the use of over-the-counter medications that included ingredients such as opium, alcohol, and cocaine. See Jonathan J. Darrow et al., *FDA Approval and Regulation of Pharmaceuticals, 1983-2018*, 323 *JAMA* 164, 165 (2020).

42. Pure Food and Drugs Act § 1.

43. See Clinton Lam & Preeti Patel, *Food, Drug, and Cosmetic Act*, *NAT'L LIBR. MED.* (July 31, 2023), <https://www.ncbi.nlm.nih.gov/books/NBK585046/> [<https://perma.cc/9ZUJ-NEFC>].

44. See *Part II: 1938, Food, Drug, Cosmetic Act*, U.S. FOOD & DRUG ADMIN. (Nov. 27, 2018), <https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-ii-1938-food-drug-cosmetic-act> [<https://perma.cc/T75Y-UJXN>] (explaining that the 1906 law allowed dangerous products to remain on the market, including an eyelash dye that caused permanent blindness and a radium-containing tonic that killed purchasers).

contained a chemical similar to antifreeze.<sup>45</sup> The 1938 law contained a comprehensive regulatory scheme for marketing new drugs in the United States<sup>46</sup> and required companies to prove to the Food and Drug Administration (FDA) that a drug was safe before it could be sold.<sup>47</sup> The new Act focused on safety rather than effectiveness, and required drug manufacturers to submit new drug applications (NDA) for FDA approval to demonstrate the drug was safe before the drug could be shipped.<sup>48</sup> The FDA was also given the power to exempt new drugs from the ban in order to allow research and investigation of the drug's safety.<sup>49</sup> This statute remains the basis for FDA regulation today.<sup>50</sup>

### *B. Proving Safety and Effectiveness*

In 1961, another drug tragedy occurred when thousands of infants in Europe were born with severe deformities after pregnant mothers took a drug called thalidomide, which was marketed to cure morning sickness.<sup>51</sup> Although thalidomide never gained FDA approval in the United States,<sup>52</sup> Congress passed the Kefauver-Harris Drug Amendments<sup>53</sup> to the FDCA in 1962. These new amendments required that drug manufacturers provide “substantial evidence” that drugs were effective through “adequate and well-controlled investigations . . . on the basis of which it could fairly and responsibly be concluded . . . that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.”<sup>54</sup> Thus, drugs had to be proven both safe and effective before being

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45. See Carol Ballentine, *Taste of Raspberries, Taste of Death: The 1937 Elixir Sulfanilamide Incident*, FDA CONSUMER MAG. (1981), <https://www.fda.gov/files/about%20fda/published/The-Sulfanilamide-Disaster.pdf> [<https://perma.cc/9XXE-LKS3>].

46. See 21 U.S.C. § 355.

47. See *id.* § 355(e) (allowing the FDA to withdraw approval of a drug if “clinical or other experience, tests, or other scientific data show that such drug is unsafe for use.”).

48. *Id.*

49. *Id.*

50. See *Part III: Drugs and Foods Under the 1938 Act and Its Amendments*, U.S. FOOD & DRUG ADMIN. (Feb. 1, 2018), <https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-iii-drugs-and-foods-under-1938-act-and-its-amendments> [<https://perma.cc/G9K9-FM6W>].

51. Adam Bernstein & Patricia Sullivan, *Frances Oldham Kelsey, FDA Scientist Who Kept Thalidomide Off U.S. Market, Dies at 101*, WASH. POST (Aug. 7, 2015, 12:53 PM), [https://www.washingtonpost.com/national/health-science/frances-oldham-kelsey-heroine-of-thalidomide-tragedy-dies-at-101/2015/08/07/ae57335e-c5da-11df-94e1-c5afa35a9e59\\_story.html](https://www.washingtonpost.com/national/health-science/frances-oldham-kelsey-heroine-of-thalidomide-tragedy-dies-at-101/2015/08/07/ae57335e-c5da-11df-94e1-c5afa35a9e59_story.html) [<https://perma.cc/JP3S-ZUV8>] (detailing the severe deformities and causalities of children resulting from the commercial sales of thalidomide in Europe and Australia).

52. See *Part III: Drugs and Foods Under the 1938 Act and Its Amendments*, *supra* note 50.

53. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (codified as amended in scattered sections of 21 U.S.C.).

54. 21 U.S.C. § 355(d).



given FDA approval. Although safety is not defined, effectiveness must be shown by “substantial evidence,”<sup>55</sup> which includes data from clinical trials.<sup>56</sup>

Under this process, a sponsor<sup>57</sup> (generally, the pharmaceutical company) submits an Investigational New Drug Application (IND) that summarizes the trial data and other information about the drug’s effects on animals.<sup>58</sup> The sponsor must also establish protocols for three phases of human trials.<sup>59</sup> Phase I trials are conducted on a small number of humans to gather basic safety information, identify side effects, and determine basic dosing.<sup>60</sup> Phase II testing is done on larger pools of patients who have the condition “that the drug is intended to prevent, diagnose, or treat.”<sup>61</sup> The focus in Phase II trials shifts to “evaluat[ing] the effectiveness of the drug” and “determin[ing] the common or short-term side effects and risks[.]”<sup>62</sup> The evidence gathered during Phase I and Phase II trials becomes part of the NDA submitted to the FDA.<sup>63</sup> The FDA then reviews the data to determine whether the sponsor can proceed.<sup>64</sup> Sometimes the FDA and the sponsor will meet throughout this process to discuss the safety of proceeding to the next phase or the best way to analyze data.<sup>65</sup>

Phase III tests are conducted on large amounts of patients who have the target disease to “gather additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship” of the drug in conditions similar to marketing for the general public.<sup>66</sup> Phase III trials monitor side effects and attempt to discover rarer issues that only become apparent when tested on a large population.<sup>67</sup> The FDA normally requires at least two controlled Phase III

55. *Id.*

56. *Id.* § 355(b).

57. A sponsor is “a person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization.” Definitions and Interpretations, 21 C.F.R. § 312.3 (2022).

58. *See* IND Content and Format, 21 C.F.R. § 312.23 (2022); *see also* Darrow et al., *supra* note 41, at 166.

59. *Id.*; *see also* *Clinical Outcome Assessments (COAs) in Medical Device Decision Making*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/about-fda/cdrh-patient-science-and-engagement-program/clinical-outcome-assessments-coas-medical-device-decision-making> [<https://perma.cc/PC99-XAR6>] (last visited June 11, 2023).

60. *See* Colin Scott, *Principles and Practice of Clinical Drug Development*, in *DRUG DISCOVERY AND DEVELOPMENT*, VOL. 2: DRUG DEVELOPMENT 370-71 (Mukund S. Chorghade ed., 2007).

61. *Id.* at 371.

62. *Id.*

63. *See id.*

64. *See* Darrow et al., *supra* note 41, at 167.

65. *See* Erin E. Kepplinger, *FDA’s Expedited Approval Mechanisms for New Drug Products*, 34 *BIOTECHNOLOGY L. REP.* 15, 21 (2015).

66. 21 C.F.R. § 321.21(c).

67. *See* Kevin M. Fain et al., *An Analysis of FDA’s Drug Safety Authorities: Challenges and*

studies to demonstrate that there is substantial evidence of the drug's safety and effectiveness before allowing marketing of the drug.<sup>68</sup>

### C. Evaluating and Approving New Drugs

Once all three phases are complete, manufacturers submit an NDA to the Center for Drug Evaluation and Research (CDER), the branch of the FDA responsible for evaluating new drugs.<sup>69</sup> NDAs include all clinical data gathered during testing, any other information on safety and effectiveness, and details of the methods and quality controls used in manufacturing.<sup>70</sup> The CDER conducts an investigation of all the clinical studies before deciding whether to approve or reject the drug, or to request more information.<sup>71</sup> This traditional drug development process takes an average of twelve years from concept creation to market authorization.<sup>72</sup>

Concerns about this lengthy process led to the creation of an accelerated pathway to expedite approval of drugs for the most serious diseases.<sup>73</sup> The Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (HIV/AIDS) epidemic dramatically increased pressure on the FDA to streamline the drug approval process.<sup>74</sup> In response, the FDA established several reforms to the drug approval process,<sup>75</sup> including the accelerated approval pathway in 1992.<sup>76</sup>

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*Opportunities Under a New Regulatory Framework*, 17 N.Y.U. J. LEG. & PUB. POL'Y 1, 3 n.7 (2014).

68. See Scott, *supra* note 60, at 372.

69. See Gail A. Van Norman, *Drugs, Devices, and the FDA: Part I: An Overview of Approval Processes for Drugs*, 1 JACC: BASIC TO TRANSLATIONAL SCI. 170, 176 (2016); *Center for Drug Evaluation and Research | CDER*, U.S. FOOD & DRUG ADMIN. (Aug. 14, 2023), <https://www.fda.gov/about-fda/fda-organization/center-drug-evaluation-and-research-cder>.

70. Van Norman, *supra* note 69, at 176; *New Drug Application (NDA)*, U.S. FOOD & DRUG ADMIN. (Jan. 21, 2022), <https://www.fda.gov/drugs/types-applications/new-drug-application-nda>.

71. See Van Norman, *supra* note 69, at 176-77.

72. See *id.* at 170.

73. See *infra* Part I.B.

74. See Joanne Silberner, *Accelerated Approval, the Path Used to Greenlight Biogen Alzheimer's Drug, Has a Checkered Track Record, Critics Say*, STAT (July 21, 2021), <https://www.statnews.com/2021/07/21/biogen-alzheimers-accelerated-approval-confirmatory-trials/> [<https://perma.cc/24DU-DN26>].

75. Besides accelerated approval, the FDA established three other mechanisms to hasten the availability of drugs for serious diseases: fast-track designation, breakthrough therapy, and priority review. See *Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review*, U.S. FOOD & DRUG ADMIN., (Feb. 23, 2018), <https://www.fda.gov/patients/learn-about-drug-and-device-approvals/fast-track-breakthrough-therapy-accelerated-approval-priority-review> [<https://perma.cc/Q8CJ-JZUM>].

76. See Kepplinger, *supra* note 65, at 21. Also called Subpart H. New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval; Final Rule 57 Fed. Reg. 58942, 58958 (proposed Dec. 11, 1992) (codified at 21 C.F.R. § 314.520).

Under this program, drugs designed for serious and life-threatening diseases can be “fast-tracked” so that Phase II and III trials are combined.<sup>77</sup> Also called Subpart H, this process allows the FDA to approve drugs for marketing if clinical studies show the drug has an effect on a “surrogate endpoint,” which is a factor “reasonably likely, based on epidemiologic, therapeutic, pathophysiologic, or other evidence, to predict clinical benefit[.]”<sup>78</sup> After the drug is granted accelerated approval, to compensate for the compression of clinical phases and the lack of effectiveness data, the pharmaceutical company must perform post-marketing studies, also called Phase IV trials, to further monitor effects and risks and to supplement information on dosage.<sup>79</sup> The FDA evaluates evidence from Phase IV post-marketing trials “to ensure that any remaining doubts about the relationship of the effect on the surrogate to clinical benefit are resolved.”<sup>80</sup> Accelerated approval permits approval of a drug earlier in the drug development process.

If the post-marketing trials confirm the surrogate endpoints and clinical benefit, accelerated approvals are converted to traditional approvals.<sup>81</sup> If, however, the Phase IV trials fail to show a clinical benefit, the FDA may remove the drug from the market or impose additional labeling requirements.<sup>82</sup> Unless withdrawal procedures are initiated, drugs may continue to be marketed as accelerated approval drugs.<sup>83</sup>

When this accelerated process went into effect, many sponsors failed to comply with the required Phase IV trials<sup>84</sup> or only conducted small, inconclusive trials.<sup>85</sup> Because the drug was already on the market, it was difficult to recruit

77. See Kepplinger, *supra* note 65, at 21.

78. 21 C.F.R. § 314.510 (2024); see Emil D Kakkis et al., *Recommendations for the Development of Rare Disease Drugs Using the Accelerated Approval Pathway and for Qualifying Biomarkers as Primary Endpoints*, 10 ORPHANET J. RARE DISEASES 1, 1 (2015) (A surrogate endpoint is an outcome image or related physical sign that is expected to predict patient survival or symptom improvement but that is not itself a direct measure of clinical benefit).

79. See Kepplinger, *supra* note 65.

80. *Battle of the Regulators: Comparing FDA’s Accelerated Approval and EMA’s Conditional Marketing Authorisation*, PROPHARMA (Feb. 22, 2022), <https://www.propharmagroup.com/thought-leadership/comparing-fdas-accelerated-approval-and-emas-conditional-marketing-authorisation> [<https://perma.cc/CY4S-ELNY>] [hereinafter PROPHARMA].

81. See *id.*; King & Spalding, *Not Quite the Titanic: The Food and Drug Omnibus Reform Act Rescues Some FDA Policy Initiatives*, JDSUPRA (Jan. 10 2023), <https://www.jdsupra.com/legalnews/not-quite-the-titanic-the-food-and-drug-5317183/> [<https://perma.cc/ZW8J-EWHN>].

82. See PROPHARMA, *supra* note 80; King & Spalding, *supra* note 81.

83. See PROPHARMA, *supra* note 80; King & Spalding, *supra* note 81.

84. See, e.g., Michael S. Sinha & Stephen Latham, *Patient Advocacy Organizations and FDA Drug Approval: Lessons from Aduhelm*, STAT (July 23, 2021), <https://www.statnews.com/2021/07/23/patient-advocacy-organizations-lessons-from-aducanumab/> [<https://perma.cc/737T-QRLS>] (noting that the drug Exondys 51 remains on the market even after missing its post-marketing trial deadline in May 2021).

85. See Silberner, *supra* note 74.

patient participants, who were afraid to risk being given a placebo when the drug was already available.<sup>86</sup> As a result, some drugs that had no proven clinical benefit stayed on the market and were used by patients without the benefit of the FDA's assessment of the drug's efficacy and safety.<sup>87</sup>

Thus, as the FDA began implementing these accelerated procedures to spur the development of beneficial therapies and expedite the drug approval process, there were several market withdrawals that caused the public to respond with distrust and fear.<sup>88</sup> Although the FDA successfully reduced its approval time from an average of thirty months down to eleven,<sup>89</sup> many blamed the FDA for those market withdrawals, alleging that its review was perfunctory and catered to the industry that funded it.<sup>90</sup> In 1998, the Public Citizen Health Research Group conducted a provocative survey of FDA reviewers, finding many who felt the industry, FDA senior officials, and Congress were pressuring them to approve questionable drugs.<sup>91</sup>

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86. See Stephanie Cajjigal, *What FDA's Controversial Accelerated Approval of Aducanumab Means for Other Neurology Drugs*, NEUROLOGY TODAY (Aug. 5, 2021), [https://journals.lww.com/neurotodayonline/fulltext/2021/08050/what\\_fda\\_s\\_controversial\\_accelerated\\_approval\\_of.1.aspx](https://journals.lww.com/neurotodayonline/fulltext/2021/08050/what_fda_s_controversial_accelerated_approval_of.1.aspx) [<https://perma.cc/XP5S-9W5F>]; see also Robert A. Bohrer, *Drug Prices, Dying Patients, and the Pharmaceutical Marketplace: A New Conditional Approval Pathway for Critical Unmet Medical Needs*, 12 DREXELL. REV. 1, 18 (2019) (“[F]or those drugs that go through the accelerated approval . . . there is a lower standard of evidence for approval and, as a result, even less certainty provided to doctors and patients that the benefits of the drugs do in fact exceed their risks.” (footnotes omitted)).

87. See Bishal Gyawali et al., *Regulatory and Clinical Consequences of Negative Confirmatory Trials of Accelerated Approval Cancer Drugs: Retrospective Observational Study* 374 BRIT. MED. J. 1, 7 (2021).

88. See Arthur A. Levin, *RxNews: FDA Finds Safety of New Drugs Not Compromised*, HEALTHFACTS, June 1, 1999 (presenting public's negative reaction and FDA's defense).

89. *Id.*

90. See *FDA Hearing Considers the Future of User Fees*, CHAIN DRUG REV., <https://www.thefreelibrary.com/FDA+Hearing+Considers+The+Future+of+User+Fees-a066458995> [<https://perma.cc/PXF2-HX78>] (last accessed Aug. 22, 2023) (discussing positives and negatives of PDUFA). John Gaas, the Executive Vice President of the American Pharmaceutical Association, postulated that “as the percentage of funding for the drug and biological review processes from user fees increases, the risk for an undue influence on speed of review—rather than quality of review—also increases.” *Id.*; see also Levin, *supra* note 88 (commenting on conflict of interest resulting from FDA's dependence on user fees). The article indicates that in 1998, FDA review costs exceeded \$ 253 million. *Id.*; see also Levin, *supra* note 88. Funding forty percent of these excessive costs, PDUFA has made the FDA more dependent on industry and disturbed its once “arms-length regulatory relationship.” *Id.*; see also Levin, *supra* note 88.

91. See *Is the FDA Approving Drugs Too Easily?*, BUS. & HEALTH, Jan. 1999 (estimating one-third of 172 physicians overseeing FDA's evaluation process participated in survey). A reviewer protested, “we are shifting the burden of proof on safety onto ourselves. Instead of asking the drug companies to prove the drug safe, we are trying to prove the drug dangerous. If we cannot show that the drug is dangerous, then it is assumed safe.” Peter Lurie & Sidney M. Wolfe, *FDA Medical Officers Report Lower Standards Permit Dangerous Drug Approvals*, PUBLIC CITIZEN (Dec. 2,

#### *D. Addressing New Safety Concerns*

Reacting to the criticism, the FDA created three administrative mechanisms to guarantee the safer use of drugs that posed greater risks.<sup>92</sup> These administrative remedies included medication guides, communication plans, and RiskMAPs.<sup>93</sup> The FDA concentrated on providing safety information directly to patients and doctors and imposing additional conditions on the prescribing and dispensing of drugs.<sup>94</sup> These administrative mechanisms allowed a drug to remain on the market and prevented additional reports of new adverse reactions.<sup>95</sup>

However, while those administrative mechanisms were limited to addressing new safety concerns that arose after a drug's approval,<sup>96</sup> the FDA lacked any statutory authority to require the drug sponsor to give specific information to patients and healthcare providers or place conditions on the continued distribution of the drug.<sup>97</sup> Before marketing began, the FDA could condition a drug's approval upon certain indications, warnings, and directions in the product labeling, but after approval, there was no clear statutory authority for the FDA to require a drug sponsor to amend the drug's labeling with new safety information.<sup>98</sup> Instead, the FDA could only resort to more extreme legal measures, such as withdrawing a drug's approval through administrative procedures or enjoining marketing with

1998), <https://www.citizen.org/article/fda-medical-officers-report-lower-standards-permit-dangerous-drug-approvals/> [<https://perma.cc/ZK3L-C6YB>]. Although the FDA knew that some prevalent bacteria were resistant to Cedax, a drug for treating children's ear infections, the agency nonetheless approved the drug and merely required the manufacturer to apply a warning label stating this fact. See Rochelle Sharpe, *Some Restrictions on Drug Makers' Ability to Promote Off-Label Uses Are Overruled*, WALL ST. J., July 31, 1998 (noting FDA approved antibiotic ineffective against some pathogens).

92. See Fain et al., *supra* note 67, at 5.

93. See *id.* at 5-8.

94. See Deborah B. Leiderman, *Risk Management of Drug Products and the U.S. Food and Drug Administration: Evolution and Context*, 105 DRUG & ALCOHOL DEPENDENCE S9, S10-S12 (2009).

95. See *id.*; see Fain et al., *supra* note 67.

96. See INST. OF MED. OF THE NAT'L ACADS., THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC 157 (2007) ("FDA relies on firms to withdraw drugs from the market voluntarily when safety issues are revealed.") [hereinafter INST. OF MED.].

97. See Fain et al., *supra* note 67, at 9.

98. U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: SAFETY LABELING CHANGES - IMPLEMENTATION OF SECTION 505(O)(4) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (2013) ("In the past, FDA has requested that holders of applications for approved products make labeling changes related to safety after approval to address serious risks . . . In most cases, application holders responded to these requests for labeling changes by negotiating appropriate language with FDA staff to address the concerns and then submitting a supplement or amended supplement to obtain approval of the changes. Negotiations were often protracted, and FDA had few tools at its disposal to end negotiations and require the changes."); see also INST. OF MED., *supra* note 96, at 157.

a federal enforcement action.<sup>99</sup> Because these extreme measures were not warranted, the FDA typically negotiated additional safety steps directly with the drug sponsor; and, unfortunately, this approach often resulted in a compromise agreement and further delay.<sup>100</sup>

As a result, the FDA asked the Institute of Medicine (IOM) to assess these problems and revisit the FDA's regulatory system for ensuring drug safety.<sup>101</sup> The IOM issued its findings in a 2007 report, *The Future of Drug Safety*, which included recommendations for statutory changes to strengthen the FDA's drug safety authorities.<sup>102</sup> Following the report, Congress recognized the legal challenges faced by the FDA in requiring post-approval safety conditions for prescription drugs and, in 2007, enacted the Food and Drug Administration Amendments Act (FDAAA) to address this problem.<sup>103</sup>

The FDAAA supplied the FDA with new procedures to allow the continued marketing of drugs through the accelerated program, but with additional requirements to help decrease adverse risks.<sup>104</sup> The FDA could condition the initial approval or continued marketing of a drug on compliance with certain stipulations.<sup>105</sup> It allowed the FDA to require a drug sponsor to conduct post-marketing studies, make labeling changes, and implement Risk Evaluation and Mitigation Strategies (REMS) for a drug.<sup>106</sup>

The FDAAA therefore provides statutory authority for the FDA to condition a drug's approval and continued marketing on the development of and adherence to a REMS, which is a plan to ensure the drug's safe use through written communications to patients and/or healthcare providers, as well as restricted distribution conditions for more serious risks.<sup>107</sup> The Amendment also mandates that a drug shall not be distributed in interstate commerce if its sponsor fails to satisfy any REMS requirements.<sup>108</sup> The failure to comply with any of these required conditions is a prohibited act and is subject to enforcement action by the FDA, including civil or criminal proceedings.<sup>109</sup>

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99. See 21 C.F.R. § 314.200 (2013); 21 U.S.C. §§ 331-332, 334 (2012).

100. See INST. OF MED., *supra* note 96, at 157; see also U.S. FOOD & DRUG ADMIN., *supra* note 98.

101. See INST. OF MED., *supra* note 96, at 21-24 ("In response to growing public concern with health risks posed by prescription drugs, FDA requested that the Institute of Medicine . . . convene an ad hoc committee of experts to conduct an independent assessment of the current system for evaluating and ensuring drug safety and to make recommendations to improve risk assessment, surveillance, and the safe use of drugs.").

102. *Id.* at 167-76.

103. See Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2008).

104. See 21 U.S.C. §§ 355-1, 355(o)(3)-(4) (2012).

105. See *id.*

106. See *id.*

107. See *id.* § 355-1.

108. *Id.* § 355(p).

109. See *id.* §§ 331(d), 332-334, 355(o)-(p) ("A drug's distribution in violation of this provision

The FDAAA also establishes important parameters for the development and implementation of a REMS.<sup>110</sup> A REMS may be required both for the initial approval of a drug or after the drug has been approved if there is new safety information.<sup>111</sup> The FDA takes into account certain elements in requiring a REMS, such as the size of the population likely to use the drug, the seriousness of the disease, and the expected benefit of the drug.<sup>112</sup> In order to trigger a REMS for a drug that is already being marketed, there must be “new safety information,” which is defined as information derived from a clinical trial, an adverse event report, a post-approval study, peer-reviewed medical literature, FDA’s post-market risk identification and analysis system, or other scientific data.<sup>113</sup> The FDAAA also requires a REMS to address a drug’s “serious risks,” which are adverse drug experiences resulting in death, risk of death, hospitalization, incapacity, or a congenital anomaly or birth defect.<sup>114</sup>

With respect to the conditions for the content of a REMS, the FDA can require that a REMS include a Medication Guide for patients about a drug’s risks.<sup>115</sup> The FDA can also require that a REMS include a communication plan to health care providers about a drug’s risks.<sup>116</sup> Finally, the FDA can require additional limitations such as restricted distribution<sup>117</sup> if it finds the drug to be harmful.<sup>118</sup> The FDA can impose an “implementation system”<sup>119</sup> to ensure that these requirements are monitored and implemented by health care providers and pharmacists.<sup>120</sup>

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constitutes a prohibited act under the FDC Act, which is subject to civil actions, such as seizures and injunctions, and criminal proceedings initiated by the United States Department of Justice and FDA.”); *see* Fain et al., *supra* note 67, at 11.

110. *See* Fain et al., *supra* note 67, at 11.

111. *See* § 355-1(a).

112. *See id.*

113. *Id.* § 355-1(b)(3) (this information can pertain to a known serious risk or an unexpected serious risk (i.e., one not included in the drug’s labeling), as well as the effectiveness of a current REMS).

114. *Id.* § 355-1(b)(4) (to trigger a REMS, the adverse drug experiences must occur in the course of the drug’s professional practice use, or result from the drug’s abuse, misuse, withdrawal, or failure); *see also id.* § 355-1(b)(1).

115. *See* 21 U.S.C. § 355-1(e)(2).

116. *See id.* § 355-1(e)(3) (this can be accomplished by sending letters to physicians or disseminating information to professional societies).

117. *See id.* § 355-1(f)(3) (elements to assure safe use may include health care provider education and training, pharmacy certification, restrictions on use settings, specific patient monitoring, and patient registry enrollment).

118. *See id.* § 355-1(f)(1).

119. *Id.* § 355-1(f)(4).

120. *See id.*

## III. THE APPROVAL OF MIFEPRISTONE: A LONG AND WINDING ROAD

As a political hot potato from the time it was introduced, mifepristone's approval process has been filled with twists and turns. Its voyage began in 1980, when French researchers first introduced the drug and began clinical trials.<sup>121</sup> It was ultimately approved by the French government in 1988,<sup>122</sup> and subsequently approved by several other countries before it finally reached the United States market.<sup>123</sup>

Against that backdrop, in 1989, the FDA adopted a policy that authorized the importation of a three-month supply of drugs for personal use that had not yet been approved for sale in the United States.<sup>124</sup> Patients could not, however, use this exemption for any drugs that the FDA regarded as unsafe or fraudulent and were, therefore, the subject of an "import alert."<sup>125</sup> Shortly thereafter, apparently responding to pressure from members of Congress, the FDA issued an "import alert" that prevented the importation of mifepristone for personal use.<sup>126</sup>

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211. See Sheldon J. Segal, *Editorial, Mifepristone (RU 486)*, 322 *NEW ENG. J. MED.* 691 (1990); see also Steven Greenhouse, *A New Pill, a Fierce Battle*, *N.Y. TIMES MAG.*, Feb. 12, 1989, at 23; Megan Rosenfeld, *Conception of a Controversy: The French Doctor and His Pill to Prevent Pregnancy*, *WASH. POST*, Dec. 18, 1986, at C1.

212. See Judy Foreman, *France OK's Use of New "Abortion Pill"*, *BOSTON GLOBE*, Sept. 24, 1988, at 1; see also Gina Kolata, *France and China Allow Sale of a Drug for Early Abortion*, *N.Y. TIMES*, Sept. 24, 1988, at A1 (the manufacturer, Roussel-Uclaf, discontinued sales of the drug, under the brand name Mifegyne, just one month later because of protests and misgivings expressed by the CEO of Hoechst A.G., the German company that owned Roussel-Uclaf, but it relented after French officials ordered a resumption in sales); Alexander Dorozynski, *Boycott Threat Forces French Company to Abandon RU486*, 314 *BMJ* 1150 (1997).

213. See Katharine Q. Seelye, *Accord Opens Way for Abortion Pill in U.S. in 2 Years*, *N.Y. TIMES* (May 17, 1994), <https://www.nytimes.com/1994/05/17/us/accord-opens-way-for-abortion-pill-in-us-in-2-years.html?&pagewanted=all> [<https://perma.cc/Q3P5-LV3Q>] (China authorized the use of mifepristone in 1988, the United Kingdom followed in 1991, Sweden approved the drug in 1992, and a dozen other European countries did so in 1999); see also S. Wu, *Medical Abortion in China*, 55 *J. AM. MED. WOMENS ASSOC.* 197 (2000); W. Smith, *Great Britain Second Country to Allow Use of RU-486*, 20 *PLANNED PARENTHOOD EUR.* (1991); *RU 486 Licensed in Sweden*, 26 *IPPF MED. BULL.* (1992); S. Christin-Maitre et al., *Medical Termination of Pregnancy*, 342 *NEW ENG. J. MED.* 946, 946-56 (2000).

214. See U.S. FOOD & DRUG ADMIN., *Regulatory Procedures Manual*, Ch. 9-71-30(C) (1997); see also Peter S. Reichertz & Melinda S. Friend, *Hiding Behind Agency Discretion: The Food and Drug Administration's Personal Use Drug Importation Policy*, 9 *CORNELL J.L. & PUB. POL'Y* 493 (2000).

215. U.S. FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., *Policy on Importing Unapproved Aids Drugs for Personal Use*, FDA Talk Paper Pub. No. T88-51 (1988).

216. See U.S. FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., *Automatic Detention of Abortifacient Drugs*, FDA Import Alert No. 66-47 (June 6, 1989); see also Robin Herman, *The Politics of the Abortion Pill*, *WASH. POST*, Oct. 3, 1989, at Z12; Philip J. Hilts, *Abortion Pills Are Confiscated by U.S. Agents*, *N.Y. TIMES*, July 2, 1992, at A12.



The FDA's decision to exclude the drug from the importation policy resulted in unfavorable reactions by congressional committees still chaired at the time by members of the Democratic party.<sup>127</sup> In 1992, it led to a judicial challenge by a woman who traveled to England for a prescription of mifepristone.<sup>128</sup> The district court issued a preliminary injunction in that case, ordering the FDA to release the drug to the plaintiff.<sup>129</sup> The district court judge opined that "the decision to ban the drug was based not [on] any bona fide concern for the safety of users of the drug, but on political considerations having no place in FDA decisions on health and safety."<sup>130</sup> The Second Circuit Court of Appeals stayed the preliminary injunction pending appeal, however, and the Supreme Court ultimately denied the petition to vacate the stay.<sup>131</sup>

On his third day in office, President Clinton ordered a review of the FDA's import alert,<sup>132</sup> and remarked during the accompanying press conference that "RU-486 has been held hostage to politics."<sup>133</sup> While the usual process is for the FDA to review whatever new drug applications happen to come in, it occasionally asks companies to apply for approval for a product that the agency wants to see

127. See *RU 486: The Import Ban and Its Effect on Medical Research: Hearing Before the Subcomm. on Regulation, Bus. Opportunities, and Energy of the House Comm. on Small Bus.*, 101st Cong. 1 (1990); see also *The Safety and Effectiveness of the Abortifacient RU486 in Foreign Markets: Opportunities and Obstacles to U.S. Commercialization: Hearing Before the Subcomm. on Regulation, Bus. Opportunities, and Energy of the House Comm. on Small Bus.*, 102d Cong. 1 (1991).

128. See *Benten v. Kessler*, 799 F. Supp. 281, 281-92 (E.D.N.Y. 1992).

129. See *id.* at 290 (granting a preliminary injunction because of the petitioner's likelihood of success on the merits of her claim); see also Lars Noah, *The FDA's New Policy on Guidelines: Having Your Cake and Eating It Too*, 47 CATHOLIC UNIV. L. REV. 113, 136-37 (1997); Debora C. Fliegelman, Comment, *The FDA and RU486: Are Politics Compatible with the FDA's Mandate of Protecting Public Health and Safety?*, 66 TEMP. L. REV. 143, 157-67 (1993); Elizabeth A. Silverberg, Note, *Looking Beyond Judicial Deference to Agency Discretion: A Fundamental Right of Access to RU 486?*, 59 BROOK. L. REV. 1551, 1580-94 (1994).

130. *Benten*, 799 F. Supp. at 286; see also Kate Michelman & Marcy Wilder, *The RU 486 Dilemma; Abortion Drug Must Be Legal*, NAT'L L.J., Sept. 7, 1992, at 13.

131. See *Benten v. Kessler*, 505 U.S. 1084, 1085 (1992) (per curiam).

132. See Memorandum of January 22, 1993, Importation of RU-486, 58 Fed. Reg. 7459 (Feb. 5, 1993); see also Actions Regarding Family Planning Service Projects, Transplantation of Human Fetal Tissue, and Importation of the Drug Mifepristone, 58 Fed. Reg. 7468 (Feb. 5, 1993); see also Robin Toner, *Settling In: Easing Abortion Policy; Clinton Orders Reversal of Abortion Restrictions Left by Reagan and Bush*, N.Y. TIMES, Jan. 23, 1993, at 1.

133. See Administration of William J. Clinton, 1993, *President's Remarks on Signing Memorandums on Medical Research and Reproductive Health and an Exchange with Reporters*, 29 WEEKLY COMP. PRES. DOC. 85, 86 (Jan. 22, 1993), <https://www.govinfo.gov/content/pkg/WCPD-1993-01-25/pdf/WCPD-1993-01-25-Pg85.pdf> [<https://perma.cc/EMW2-NBZ7>] [hereinafter *President's Remarks*]; see also REPROD. HEALTH ACCESS PROJECT, *The History of Mifepristone* (Apr. 18, 2023), <https://www.reproductiveaccess.org/2023/04/history-of-mifepristone/>[<https://perma.cc/F2W9-YPSD>].

brought to market.<sup>134</sup> Pressured by the Clinton administration, the FDA proceeded to put substantial force on the French company to apply for marketing approval in the United States.<sup>135</sup>

The French company initially resisted the Clinton administration's overtures, as it was concerned about the prospect of boycotts orchestrated by anti-abortion groups<sup>136</sup> as well as worries about potential tort claims brought by patients who had bad reactions to the drug.<sup>137</sup> After lengthy negotiations, in May 1994, the company agreed to donate a license to sell the drug in the United States to the Population Council,<sup>138</sup> which was a non-profit organization that promotes family planning.

In March 1996, after assembling the data from extensive overseas experience and newly conducted clinical trials, the Population Council submitted an application for NDA.<sup>139</sup> Instead of the regular approval process, the NDA for mifepristone underwent the administrative accelerated approval process, which had been established in 1992 under subpart H.<sup>140</sup> As part of this expedited procedure, the pharmaceutical company had to agree to accept the administrative mechanisms that had been put in place as a result of public concern, including medication guides, communication plans, and RiskMAPs.<sup>141</sup> These post-marketing restrictions included limited distribution only through certain medical facilities or physicians, conditions relating to the performance of specified

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134. *President's Remarks*, *supra* note 133; *Reprod. Health Access Project*, *supra* note 133.

135. See Philip J. Hilts, *Door May Be Open for Abortion Pill to Be Sold in U.S.*, N.Y. TIMES, Feb. 25, 1993, at A1 (reporting that the FDA's Commissioner met with Roussel-Uclaf's CEO); see also *Hoechst Seeks Firm for U.S. Marketing of Its Abortion Pill*, WALL ST. J., Mar. 24, 1993, at C10 (other countries were also exerting pressure on the French company); Reed Boland, *RU 486 in France and England: Corporate Ethics and Compulsory Licensing*, 20 L. MED. & HEALTH CARE 226, 229 (1992) ("One of the most striking features of the process of licensing of RU 486 in France and England is the fashion in which the governments of both countries became actively involved in bringing the drug to market.").

136. See Warren E. Leary, *Maker of Abortion Pill Reaches Licensing Pact with U.S. Group*, N.Y. TIMES, Apr. 21, 1993, at A18; see also Tamar Lewin, *Plans for Abortion Pill Stalled in U.S.*, N.Y. TIMES, Oct. 13, 1993, at A17; Elyse Tanouye & Rose Gutfeld, *U.S. Companies Seek to Market Abortion Pill*, WALL ST. J., Apr. 26, 1993, at B1 (simultaneously, pro-choice groups attempted to exert countervailing pressures against the company); Susan Jenks, *Feminist Group Plans "Economic Pressure Campaign" for Access to RU 486*, 84 J. NAT'L CANCER INST. 562, 562 (1992).

137. See Leslie A. Rubin, Note, *Confronting a New Obstacle to Reproductive Choice: Encouraging the Development of RU-486 Through Reform of Products Liability Law*, 18 N.Y.U. REV. L. & SOC. CHANGE 131, 141-48 (1991).

138. See Seelye, *supra* note 123 (describing high-level pressure exerted by the Clinton administration on the French manufacturer of RU-486 to apply for FDA approval, and the manufacturer's eventual decision to grant a license to the Population Council).

139. See U.S. GOV'T ACCOUNTABILITY OFF., REPORT TO CONGRESSIONAL REQUESTERS, FOOD AND DRUG ADMINISTRATION: APPROVAL OF THE DRUG MIFEPREX 4 (2008).

140. *Id.*

141. *Id.*

medical procedures, and advance submission of all promotional materials for FDA review.<sup>142</sup> The FDA also required that NDA applicants waive their statutory right to demand an evidentiary hearing in the event that the agency chooses to withdraw an approval.<sup>143</sup>

Mifepristone's eligibility to undergo the accelerated approval process remains something of a mystery. The drug did not provide the type of benefit over existing treatments for a serious illness that the regulations envisioned as justifying an accelerated review process.<sup>144</sup> Pregnancy is not an "illness," and is certainly not a "serious" one.<sup>145</sup> William Hubbard, who served as the FDA's Associate Commissioner for Policy throughout the Clinton administration, made the following remark shortly before joining the agency: "RU-486 [Mifepristone] is intended for convenience use by healthy young women rather than as a therapy for an incapacitating or life-threatening disease."<sup>146</sup> Nevertheless, the FDA reviewed the drug under its accelerated approval regulations.<sup>147</sup>

In September 1996, after initially reviewing mifepristone and soliciting the advice of an advisory committee,<sup>148</sup> the FDA issued an "approvable" letter to the Population Council.<sup>149</sup> Although the FDA identified several issues that still required resolution pending further information from the Population Council, this conditional approval letter did not contain any information about specific

142. See 21 C.F.R. §§ 314.520(a), 314.550 (2024).

143. See *id.* § 314.530 (providing the applicant with only an informal hearing prior to revocation).

144. See Seelye, *supra* note 123.

145. See § 314.500 (although not specifically defined in connection with the accelerated approval regulations, elsewhere in the rules applicable to NDAs (in connection with the obligation to report adverse reactions), the FDA provided that "serious means an adverse drug experience that is fatal or life-threatening, is permanently disabling, requires inpatient hospitalization, or is a congenital anomaly, cancer, or overdose."); see also *id.* §§ 314.500, 314.80(a) (the preamble to the proposed accelerated approval rule provided illustrations of potentially qualifying diseases or conditions); see also New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval, 57 Fed. Reg. 13,234 (1992) (codified at 21 C.F.R. §§ 314, 601 (2024)) (none of which can be compared to pregnancy).

146. William Hubbard, *Commentary*, in BIOMEDICAL POLITICS, 94 (Kathi E. Hanna, ed., 1991).

147. See Sydney Lupkin, *Here's What Really Happened During the Abortion Drug's Approval 23 Years Ago*, NPR (Apr. 14, 2023, 5:01 AM), <https://www.npr.org/sections/health-shots/2023/04/14/1169859888/heres-what-really-happened-during-the-abortion-drugs-approval-23-years-ago> [<https://perma.cc/9SV7-CWVV>] (discussing how "mifepristone's approval and oversight were in line with the other eight drugs approved [by the FDA] with similar subpart H safety requirements").

148. See *Mifepristone (RU-486) Proposed Distribution System Is Acceptable, but Abortion Training Process Raises "Serious Concerns," Advisory Committee Concludes*, THE PINK SHEET (FDA/F-D-C Reports), July 29, 1996, at 13.

149. See Gina Kolata, *Pill for Abortion Clears Big Hurdle to Its Sale in U.S.*, N.Y. TIMES (Sept. 19, 1996), <https://archive.nytimes.com/www.nytimes.com/specials/issues/rights/rigdepth/0919abortion-drug.html> [<https://perma.cc/ZMR5-XHWG>].

administrative requirements post-distribution.<sup>150</sup> The Population Council did not provide the information requested by the FDA until almost three years after it received the letter because of difficulties it faced in finding a company to manufacture and distribute the drug.<sup>151</sup>

While this was going on, David Kessler stepped down as Commissioner of the FDA, and it took two years before the Senate confirmed Jane Henney as his permanent replacement.<sup>152</sup> She was confirmed in 1994, after Senate Republican leaders received assurances that Dr. Henney would not actively facilitate the final approval of mifepristone.<sup>153</sup> During the same time, the House twice passed an appropriations rider designed to prevent the FDA from expending any further resources to review mifepristone, though the Senate declined to enact these budget measures.<sup>154</sup> When Population Council finally filed the requested information in August 1999, it confronted an FDA that was no longer as enthusiastic about the drug.<sup>155</sup>

In February 2000, after reviewing the information from the Population Council, the FDA issued a second approvable letter for mifepristone.<sup>156</sup> This time the FDA suggested several distribution restrictions, including a restriction that the

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150. *Id.*

151. See Marc Kaufman, *Abortion Pill Inches Closer to Production; American Marketer Hopeful That Drug Will Be Available By the End of the Year*, WASH. POST (Mar. 23, 1999), <https://www.washingtonpost.com/archive/lifestyle/wellness/1999/03/23/abortion-pill-inches-closer-to-production/d2424ac4-a365-4d13-a2ca-70eff8a10fa4/> [<https://perma.cc/27U5-87EN>] (adding that one new clinical trial enrolling thousands of subjects continued during the interim).

152. See Sheryl Gay Stolberg, *Woman in the News: Jane Ellen Henney; For F.D.A., an Old Hand*, N.Y. TIMES (June 24, 1998), <https://www.nytimes.com/1998/06/24/us/woman-in-the-news-jane-ellen-henney-for-fda-an-old-hand.html> [<https://perma.cc/787A-83VX>].

153. See 144 Cong. Rec. S12688-89 (Oct. 20, 1998) (statement of Sen. Nickles); see also *FDA Commissioner Negotiations Focus on Non-FDA Abortion Issues*, THE PINK SHEET (FDA/F-D-C Reports), Oct. 19, 1998, at 3 (“Sen. Nickles (R-Okla.) is using his 11th-hour hold on the confirmation of Jane Henney as FDA Commissioner to win concessions from the Clinton Administration on the abortifacient RU-486 . . . pushing for assurances from Henney that, as commissioner, she would not take a proactive role in finding a manufacturer for the product.”). Republican members of the Senate also expressed concerns about Henney’s plans to continue Kessler’s controversial initiative to assert FDA jurisdiction over tobacco products. See *Clinton Admin. Recruits Republican Sens. to Free Henney Nomination Block*, THE PINK SHEET (FDA/F-D-C Reports), Oct. 12, 1998, at 3; see also Eric Schmitt, *Nomination for FDA Post Nears Approval in Senate*, N.Y. TIMES (Oct. 21, 1998), <https://www.nytimes.com/1998/10/21/us/nomination-for-fda-post-nears-approval-in-senate.html>.

154. See Judy Mann, *We Need the Abortion Pill Now*, WASH. POST (June 23, 2000), <https://www.washingtonpost.com/archive/lifestyle/2000/06/23/we-need-the-abortion-pill-now/d5190008-9de6-4d77-acd5-71af382e8b73/> [<https://perma.cc/AL6U-M2W6>]; see also Katherine Q. Seelye, *House Votes to Block FDA on Approval of Abortion Pill*, N.Y. TIMES, June 25, 1998, at A20, <https://www.nytimes.com/1998/06/25/us/house-votes-to-block-fda-on-approval-of-abortion-pill.html>.

155. See *Mifepristone*, THE PINK SHEET (FDA/F-D-C Reports), Feb. 21, 2000.

156. See *id.* at 36.

drug would only be available from physicians who performed surgical abortions and who agreed to register with the manufacturer.<sup>157</sup> This was the type of oversight that had been imposed on controlled substances such as methadone.<sup>158</sup> Mifepristone is not a narcotic subject to the Controlled Substances Act, and there was nothing in the FDA's enabling statute that authorized the imposition of these types of restrictions on access to the drug.<sup>159</sup>

In its response to the FDA's second approvable letter, the Population Council objected to these newly proposed requirements, arguing that the conditions would render the drug essentially unmarketable.<sup>160</sup> The FDA issued its final approval letter on September 28, 2000, removing some of the most onerous of the proposed restrictions.<sup>161</sup> The final approval did include numerous restrictions, such as the drug's labeling must specify that a physician should administer mifepristone within 49 days of the patient's last menstrual period, followed by a dose of misoprostol in the physician's office two days later, and a third office visit for a check-up more than one week later.<sup>162</sup> In addition, physicians could not dispense mifepristone for home use,<sup>163</sup> and the manufacturer could not supply mifepristone to pharmacists.<sup>164</sup>

157. See Marie McCullough, *FDA Rules Would Limit Use of Abortion Pill, Doctors Say in a Letter, Two Groups of Physicians Asked Whether the Proposal was Based on Good Science or Politics*, PHILA. INQUIRER, Aug. 5, 2000, at A04.

158. See 21 U.S.C. §§ 812, 822-828, 829(a) (2000); see generally Noah Lars, *Challenges in the Regulation of Pain Management Technologies*, 31 J.L. MED. & ETHICS 55 (2003) (the FDA may impose certain limitations on the distribution of "restricted" medical devices); see 21 U.S.C. § 360j(e).

159. See Greer Donley, *Medication Abortion Exceptionalism*, 107 CORNELL L. REV. 627, 639 (2022) (discussing controls that the FDA has put on the distribution of drugs that do not qualify as a controlled substance.).

160. See *RU-486 Action Date Is Sept. 30; Allen Named Reproductive Division Director*, THE PINK SHEET (FDA/F-D-C Reports), June 12, 2000, at 14.

161. For the FDA's approval letter and related agency documents, see *Drug Approval Package: Mifeprex (Mifepristone) Tablet*, U.S. FOOD & DRUG ADMIN. (June 18, 2001), [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2000/20687\\_mifepristone.cfm](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20687_mifepristone.cfm).

162. Both drugs come in tablet form and do not require any special skill to take. See Sandee LaMotte, *How a Medication Abortion, Also Known as an 'Abortion Pill,' Works*, CNN HEALTH (May 11, 2023, 4:57 AM), <https://www.cnn.com/2023/01/06/health/medication-abortion-process-wellness/index.html> [<https://perma.cc/E7G8-UHC9>] (discussing how "[a] growing body of research indicates that self-managed abortion is safe and effective.").

163. See U.S. FOOD & DRUG ADMIN., MIFEPREX TABLETS LABEL, [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2016/020687s020lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf) (last visited Aug. 21, 2023).

164. See *Questions and Answers on Mifepristone for Medical Termination of Pregnancy through Ten Weeks Gestation*, U.S. FOOD & DRUG ADMIN. (Sept. 1, 2023), <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation#:~:text=Is%20mifepristone%20available%20at%20retail,be%20dispensed%20from%20retail%20pharmacies>. Retail pharmacies may dispense mifepristone as of January 2023. *Id.* Healthcare providers routinely

Contrary to its normal policy,<sup>165</sup> in approving mifepristone the FDA also required that physicians and patients sign an agreement to adhere to a precise regimen of three office visits, and it required that the distributor enforce this requirement by refusing to continue supplying the drug to any physicians who fail to comply.<sup>166</sup> As an acknowledgment of the distributor's legitimate fears that pro-life protestors would try to interfere with the production of the drug and threaten the distributor's employees, the FDA agreed not to disclose the distributor's address or the name and address of the manufacturing facility.<sup>167</sup> The FDA allowed Population Council to designate a manufacturing facility in China as the supplier of the bulk drug substance in order to minimize the risk that protestors would disrupt production.<sup>168</sup>

The FDA's final approval was issued on September 28, 2000.<sup>169</sup> As previously discussed, while the FDA had crafted administrative mechanisms to address safety concerns that arose after a drug's approval for drugs in the accelerated program, the FDA lacked any statutory authority to require that information.<sup>170</sup> These procedures were first authorized by Congress in the FDAAA in 2007.<sup>171</sup> The FDA's letter approving the NDA for mifepristone makes it clear, however, that the 1992 administrative rule and not the subsequently amended legislation governed this license.<sup>172</sup> This, however, formed the basis for one of the Plaintiffs' arguments in *Alliance for Hippocratic Medicine v. FDA*.<sup>173</sup>

Since mifepristone's approval in 2000, the FDA has increasingly restricted its distribution.<sup>174</sup> Following the passage of the amendments in 2007, the FDA

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deviate from labeling approved by the FDA. One month after the FDA announced its decision to approve mifepristone, pro-choice groups sent letters to physicians recommending a more manageable treatment regimen in an effort to expand use. Pro-life groups sent letters to physicians requesting them to provide patients with more risk information.

165. See *MKB Mgmt. Corp. v. Burdick*, No. 09-2011-CV-02205, at \*13 (D.N.D. Feb. 16, 2012), [https://reproductiverights.org/sites/crr.civicactions.net/files/documents/MKB%20v%20Burdick%20Order%2021612%20\(2\).pdf](https://reproductiverights.org/sites/crr.civicactions.net/files/documents/MKB%20v%20Burdick%20Order%2021612%20(2).pdf) [<https://perma.cc/55R6-BL9D>] (finding that “[o]ff-label use is neither prohibited nor discouraged by the FDA.”).

166. See *All. for Hippocratic Med. v. U.S. FDA*, 668 F. Supp. 3d 507, 522-23 (N.D. Tex. 2023).

167. *Id.*

168. *Id.*

169. U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., Letter Approving Mifeprex (Mifepristone) Tablet (Sept. 28, 2000), [https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2000/20687appltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.pdf).

170. *Id.*

171. See Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 112, 111 Stat. 2296, 2309-10 (codified at 21 U.S.C. § 356 (2000)); see also Deborah G. Parver, Comment, *Expediting the Drug Approval Process: An Analysis of the FDA Modernization Act of 1997*, 51 ADMIN. L. REV. 1249, 1261-62 (1999).

172. *Id.*

173. *Id.*

174. See *Am. Coll. of Obstetricians & Gynecologists v. U.S. FDA*, 472 F. Supp. 3d 183 (D. Md. 2020).

gave mifepristone a REMS designation, imposing additional restrictions on the drug's distribution and administration.<sup>175</sup> The FDA incorporated more stringent restrictions to the drug's distribution in 2011 by adding Elements to Assure Safe Use (ETASU) components to the REMS.<sup>176</sup> ETASU is a "special category of REMS . . . [that] can be imposed on a drug that has been 'shown to be effective' but is 'associated with a serious adverse drug experience' such that it can be approved only in the condition that the designated elements are satisfied."<sup>177</sup> Three ETASU components in the mifepristone REMS required that: (1) "health care providers who prescribe the drug have particular training or experience or are specially certified";<sup>178</sup> (2) "mifepristone may be dispensed only in a hospital, clinic, or medical office, by or under the supervision of a certified healthcare provider";<sup>179</sup> and (3) mifepristone is only "dispensed to patients with evidence or other documentation of safe-use conditions."<sup>180</sup> The ETASU also requires that patients sign a Patient Agreement Form in the presence of the provider acknowledging that the patient reviewed the risks associated with mifepristone and received adequate counseling.<sup>181</sup> This in-person requirement was part of the FDA's REMS protocols for mifepristone<sup>182</sup> and mirrored requirements for high-risk medications such as injectable schizophrenia drugs.<sup>183</sup>

The FDA re-examined mifepristone's ETASU and REMS requirements in 2013 and 2016.<sup>184</sup> In 2016, the mifepristone drug regimen was re-approved with

175. *See id.*

176. *See id.* at 191-97.

177. *Id.* at 191-95.

178. *See* 21 U.S.C. § 355-1(f)(3)(A).

179. *See id.* § 355-1(f)(3)(C).

180. *See id.* § 355-1(f)(3)(D).

181. *See Am. Coll. of Obstetricians & Gynecologists*, 472 F. Supp. 3d at 195.

182. *See* U.S. FOOD & DRUG ADMIN., RISK EVALUATION AND MITIGATION STRATEGY (REMS) SINGLE SHARED SYSTEM FOR MIFEPRISTONE 200MG (2021), <https://www.fda.gov/media/164651/download?attachment> [hereinafter REMS FOR MIFEPRISTONE].

183. *See Risk Evaluation and Mitigation Strategies: REMS*, U.S. FOOD & DRUG ADMIN. (Dec. 17, 2021), <https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rem> [<https://perma.cc/A35D-EGNH>] (Mifeprex REMS are likely politically motivated by anti-abortion bias); *see also Recent Guidance: Reproductive Rights, Medication Abortion, FDA Lifts In-Person Dispensing Requirement for Mifepristone Abortion Pill. Update to FDA's Risk Evaluation and Mitigation Strategy for Mifepristone on Dev. 16, 2021, Eliminating IN-Person Dispensing Requirement*, 135 HARV. L. REV. 2235, <https://harvardlawreview.org/wp-content/uploads/2022/06/135-Harv.-L.-Rev.-2235.pdf> [<https://perma.cc/M3KD-DXL8>] [hereinafter *Recent Guidance*]; Sarah Christopherson & Olivia Snavely, *The FDA's Convoluted Stance on Abortion Pills Doesn't Protect Patients—It Endangers Them*, NAT'L WOMEN'S HEALTH NETWORK (May 8, 2020), <https://nwhn.org/the-fdas-convoluted-stance-on-abortion-pills-doesnt-protect-patients-it-endangers-them> [<https://perma.cc/L3HP-3LDA>].

184. *See Am. Coll. of Obstetricians & Gynecologists*, 472 F. Supp. 3d at 190-92. (in both 2013 and 2016, the FDA did not consider the applicability of telemedicine when reviewing of mifepristone REMS).

additional guidance on dose, administration, and labeling, along with some minor modifications.<sup>185</sup> The modifications were made in light of a determination by the FDA that: “no new safety concerns [regarding mifepristone] have arisen in recent years;” “the known serious risks occur rarely;” and “[g]iven that the numbers of . . . adverse events appear to be stable or decreased over time, it is likely that . . . serious adverse events will remain acceptably low.”<sup>186</sup> The changes included increasing the maximum gestational age from forty-nine to seventy days, allowing non-physicians to prescribe the drug, eliminating the prescriber’s obligation to report non-fatal adverse results, and changing the dose of the drug.<sup>187</sup>

No changes were made, however, to mifepristone’s In-Person Requirements. As a result, because patients seeking mifepristone had to visit certified clinics, they often had to travel long distances or cross state lines.<sup>188</sup> During the COVID-19 pandemic, the FDA exercised enforcement discretion to relax the in-person dispensing requirement for many riskier drugs subject to REMS, reasoning that making these medicines mailable reduced coronavirus transmission risks.<sup>189</sup> Still, the agency continued enforcing stringent in-person dispensing protocols for mifepristone for another year, incurring accusations of political bias based on mifepristone’s use as an abortifacient.<sup>190</sup> This revision to the in-person requirement formed the basis of another of the Plaintiff’s arguments in *Alliance for Hippocratic Medicine v. FDA*.<sup>191</sup>

In 2019, the FDA also approved an abbreviated new drug application for a generic version of mifepristone.<sup>192</sup> In determining that the drug was safe, the agency used the same data it had relied on in 2000 and 2016.<sup>193</sup> This, again, became a pressure point for the Plaintiffs’ recent lawsuit.<sup>194</sup>

On April 20, 2020, the American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine sent a letter to the FDA, urging the

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185. *Id.* at 193-95

186. *Id.* at 190-91 (citations omitted).

187. *Id.* at 191.

188. *See id.* at 190-95; *see also* Christopherson & Snavely, *supra* note 183.

189. *See Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency*, U.S. FOOD & DRUG ADMIN. 7 (March 2020), [https://www.supremecourt.gov/opinions/URLs\\_Cited/OT2020/20A34/20A34-5.pdf](https://www.supremecourt.gov/opinions/URLs_Cited/OT2020/20A34/20A34-5.pdf).

190. *See* Carolyn B. Maloney & Ayanna Pressley, *Why the FDA Must Lift Unnecessary Restrictions on Medication Abortion Care Now*, ELLE (Feb. 17, 2021), <https://www.elle.com/culture/career-politics/a35534458/fda-restrictions-medication-abortion> [<https://perma.cc/6CHA-8VRS>].

191. *See id.*

192. U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., Letter Approving Mifepristone Tablet, 200 mg (Apr. 11, 2019), [https://www.accessdata.fda.gov/drugsatfda\\_docs/applletter/2019/091178Orig1s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/091178Orig1s000ltr.pdf).

193. *Id.*

194. *See id.*



agency to lift the in-person dispensing requirement for mifepristone.<sup>195</sup> The two organizations pointed out that the requirement put patients and doctors at unnecessary risk of COVID-19 while seeking a time-sensitive medical service.<sup>196</sup> The FDA commissioner at the time, appointed by Trump, never acknowledged this letter.<sup>197</sup> On May 27, 2020, the organizations brought a lawsuit in the U.S. District Court for the District of Maryland, seeking to enjoin enforcement of the FDA's in-person dispensing requirement during the pandemic.<sup>198</sup> The court granted a preliminary injunction, allowing mifepristone to be dispensed by mail.<sup>199</sup> The court held that the in-person dispensing requirement imposed "a 'substantial obstacle'" to patients' free exercise of the fundamental right of choice.<sup>200</sup>

The FDA moved for an emergency stay of the injunction.<sup>201</sup> The case was remanded to and reaffirmed by the district court.<sup>202</sup> The FDA then renewed its stay application,<sup>203</sup> and the Supreme Court granted the stay, reinstating in-person dispensing requirements on January 12, 2021,<sup>204</sup> finding that there was "a need for agency deference during the pandemic."<sup>205</sup>

On April 12, 2021, a few months after President Biden's inauguration, the FDA Commissioner, now a Biden appointee, responded to the original letter and stated that it would not enforce the in-person dispensing requirement.<sup>206</sup> The letter authorized mail distribution of mifepristone via "enforcement discretion" regarding pandemic-context in-person protocols.<sup>207</sup>

Shortly thereafter, on May 7, 2021,<sup>208</sup> the FDA announced that it would

195. See *Recent Guidance*, *supra* note 183.

196. *Id.*

197. *Id.*

198. See Complaint at 39, *Am. Coll. of Obstetricians & Gynecologists v. U.S. FDA*, 472 F. Supp. 3d 183 (D. Md. 2020) (No. 8:20-CV-01320-TDC).

199. See *Am. Coll. of Obstetricians & Gynecologists v. U.S. FDA*, 472 F. Supp. 3d 183, 233 (D. Md. 2020).

200. See *id.* at 217 (quoting *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292 at 2317-18 (2016)).

201. See *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578 (2020) (mem.).

202. See *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 10 (2020); *Am. Coll. of Obstetricians & Gynecologists v. U.S. FDA*, 506 F. Supp. 3d 328, 347 (D. Md. 2020) (applying the undue burden test from *Whole Woman's Health v. Hellerstedt* and *June Med. Servs. v. Russo*).

203. See *Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. at 581 (Sotomayor, J., dissenting from grant of application for stay).

204. *Id.* at 578-79 (mem.).

205. *Id.* at 579 (Roberts, C.J., concurring in the grant of application for stay).

206. See Letter from Janet Woodcock, Acting Comm'r, FDA, to Maureen G. Phipps, Chief Exec. Officer, *Am. Coll. of Obstetricians & Gynecologists*, and William Grobman, President, Soc'y for Maternal-Fetal Med. (Apr. 12, 2021) (on file with the Harvard Law School Library).

207. *Id.* (noting the COVID-19 health risks imposed by in-person dispensing).

208. See Joint Motion to Stay Case Pending Agency Review at 2, *Chelius v. Becerra*, CV No. 1:17-00493 JAO-RT (D. Haw. May 7, 2021), <https://www.aclu.org/wp-content/uploads/legal->

review whether the mifepristone REMS program should be modified.<sup>209</sup> FDA released a REMS update following the review.<sup>210</sup> In another letter to a group of medical professionals who had challenged the constitutionality of the REMS,<sup>211</sup> the FDA announced that it would allow certified pharmacies to mail mifepristone pills.<sup>212</sup> The Medication Guide and informational materials were subsequently revised to reflect these changes.<sup>213</sup> On December 16, 2021, the agency removed the federal in-person dispensing requirement for medication abortion REMS,<sup>214</sup> allowing individuals in thirty-one states to access mifepristone through the mail.<sup>215</sup> In January 2023, the FDA approved the removal of the in-person dispensing requirement, kept the prescriber and patient agreement form requirements, and added a pharmacy certification requirement.<sup>216</sup> This was the end of the journey of mifepristone at the time of the latest attacks.

#### IV. THE CURRENT CRISIS: OVERVIEW OF *ALLIANCE FOR HIPPOCRATIC MEDICINE V. FDA*

##### A. *The District Court Opinion*

On November 18, 2022, a group of medical organizations and doctors led by the Alliance for Hippocratic Medicine filed a complaint in the United States District Court for the Northern District of Texas.<sup>217</sup> The plaintiffs were seeking

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documents/Chelius\_v.\_Becerra\_-\_Joint\_Motion\_for\_Stay\_Pending\_Agency\_Review\_\_May\_7,\_2021\_.pdf [https://perma.cc/J2UD-N239]; see also *FDA Announces Long Sought-After Review of Harmful Restrictions on Medication Abortion*, ACLU (May 7, 2021), https://www.aclu.org/press-releases/fda-announces-long-sought-after-review-harmful-restrictions-medication-abortion [https://perma.cc/7P5E-Z4LF].

209. See *Recent Guidance*, *supra* note 183, at 2238.

210. *Id.*

211. *Id.*

212. See *id.*

213. See REMS FOR MIFEPRISTONE, *supra* note 182.

214. See *id.*

215. See *id.* “Medication by mail” entails a tele-meeting with a clinician followed by a pharmacy mailing the abortifacient pills to the patient. Nineteen states have banned telemedicine visits for abortion, so the in-person requirement exists at the state level. Federal policy sets the baseline for access to mifepristone as an abortifacient. State laws can impose greater (but not lesser) restrictions. *State Laws and Policies: Medication Abortion*, GUTTMACHER INST. (Apr. 1, 2022), https://www.guttmacher.org/state-policy/explore/medication-abortion [https://perma.cc/3ZB4-AEMR]; Pam Belluck, *F.D.A. Will Permanently Allow Abortion Pills by Mail*, N.Y. TIMES (Dec. 16, 2021), https://www.nytimes.com/2021/12/16/health/abortion-pills-fda.html [https://perma.cc/YPT3-LNCN].

216. See *Updated Mifepristone REMS Requirements*, AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS (Jan. 2023), https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2023/01/updated-mifepristone-rems-requirements [https://perma.cc/Y94B-M54H].

217. See *All. for Hippocratic Med. v. U.S. FDA.*, 668 F. Supp. 3d 507 (N.D. Tex. 2023), *aff'd*

an injunction to withdraw the FDA's 2000 approval of mifepristone and to hold unlawful and set aside numerous regulatory decisions the FDA made over the years, including removing mifepristone from the REMS program and allowing the medication to be dispensed by pharmacists and through the mail.<sup>218</sup> The plaintiffs alleged that the FDA's actions violated the Administrative Procedure Act because the Agency's initial approval of the mifepristone in 2000 should not have been granted through the accelerated regulatory pathway, that the FDA's subsequent regulatory decisions including the decision to revise the REMS designation were not based on appropriate information and data, that the regimen is not safe, and that the FDA's decision to allow mifepristone to be sent via mail violated the Comstock Act.<sup>219</sup>

In its January 13, 2023, response, the Department of Justice on behalf of the FDA urged the court to dismiss the case on several grounds.<sup>220</sup> The Defendant argued that the plaintiffs lacked standing, that the claims were untimely because they were brought after the six-year statute of limitations to challenge an agency action, that the FDA's regulatory actions were proper and within its statutory authority, and that the Comstock Act does not prohibit the mailing of abortion medications as long as the sender does not intend for the items to be used unlawfully.<sup>221</sup>

The Plaintiffs then moved for a preliminary injunction, seeking an order that the FDA withdraw or suspend its 2000 approval of mifepristone, its 2016 amendments to the REMS, its approval in 2019 of the generic brand, and its 2021 amendments removing the in-person dispensing requirements.<sup>222</sup> The Defendant argued that a preliminary injunction was inappropriate because the drug had been on the market for decades and therefore it is not possible to demonstrate "imminent and irreparable harm."<sup>223</sup> Instead, a preliminary injunction would harm the public interest by removing a medication that is safe and effective and that patients and doctors have relied upon for many years.<sup>224</sup>

Danco Laboratories, the manufacturer of Mifeprex, the branded version of mifepristone,<sup>225</sup> also intervened in the case to oppose the plaintiffs' motion for a

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*in part, vacated in part*, 78 F.4th 210 (5th Cir. 2023), *cert. granted sub nom.* Danco Lab'ys, L.L.C. v. All. for Hippocratic Med., No. 23-236, 2023 WL 8605744 (U.S. Dec. 13, 2023), *cert. granted sub nom.* FDA v. All. for Hippocratic Med., No. 23-235, 2023 WL 8605746 (U.S. Dec. 13, 2023), *cert. denied sub nom.* All. for Hippocratic Med. v. FDA, No.23-395, 2023 WL 8605749 (U.S. Dec. 13, 2023).

218. *See id.* at 520.

219. *See id.* at 522-23.

220. *See* Defendants' Opposition to Plaintiffs' Motion for a Preliminary Injunction at 38-40, All. for Hippocratic Med. v. FDA, 668 F. Supp. 3d 507 (N.D. Tex. 2023) (No. 2:22-cv-00223-Z).

221. *See id.* at 8, 16, 27, 28.

222. *Id.* at 8.

223. *Id.* at 31.

224. *See id.* at 38.

225. *See* All. for Hippocratic Med. v. U.S. FDA., 668 F. Supp. 3d 507 (N.D. Tex. 2023).

preliminary injunction.<sup>226</sup> Danco underscored many of the government’s arguments, affirming the safety, efficacy, and proper FDA approval and regulation of mifepristone, and added that, because it is a small pharmaceutical company whose sole product is Mifeprex, a preliminary injunction would have existential consequences.<sup>227</sup> “Danco also highlighted that the Government Accountability Office was asked by Congress on two occasions (once in 2008 and 2018) to review the FDA’s approval and regulatory oversight of Mifeprex, and concluded on both occasions that the FDA’s regulatory decisions were appropriate and consistent with the Agency’s approval and oversight of similarly situated drugs.”<sup>228</sup>

“On March 15, 2023, Judge Kacsmaryk held a four-hour hearing to hear arguments from the parties before issuing his 67 page opinion on April 7, 2023.”<sup>229</sup> He concluded that the FDA exceeded its authority by initially approving mifepristone in 2000 under its accelerated program, violated federal law by allowing mifepristone to be dispensed via mail during the COVID-19 pandemic, and “stonewalled” timely judicial review of its regulatory decisions related to mifepristone.<sup>230</sup> Rather than issuing a preliminary injunction, however, he issued a section 705 stay,<sup>231</sup> which stayed the effective date of the FDA’s 2000 approval of the drug.<sup>232</sup>

In his opinion, Judge Kacsmaryk first held that the plaintiffs had standing and therefore satisfied the case or controversy requirement of Article III of the Constitution.<sup>233</sup> He determined that the Medical Associations had “associational standing,” where an association can bring suit on behalf of its members when its members would have standing to sue in their own right.<sup>234</sup> Because the members of the association allege adverse events from the medication and that the drugs “place enormous pressure and stress” on physicians, the court concluded that the injury requirement was satisfied.<sup>235</sup> In addition, the court found that there was

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226. *See id.*

227. Defendants’ Opposition to Plaintiffs’ Motion for a Preliminary Injunction, *All. for Hippocratic Med.*, 668 F. Supp. 3d 507 (No. 2:22-cv-00223-Z).

228. *See* Samantha Jandl et al., *A Tale of Two Lawsuits: Federal Court in Texas Suspends FDA Approval of Medication Abortion Drug Mifepristone Nationwide, While Federal Court in Washington Orders FDA to Not Alter Availability of Mifepristone in 17 States and D.C.*, GOODWIN (Apr. 12, 2023), <https://www.jdsupra.com/legalnews/a-tale-of-two-lawsuits-federal-court-in-7692937> [<https://perma.cc/V7NX-8EP2>]. Over twenty states filed a brief supporting the plaintiffs’ motion for a preliminary injunction. *Id.* Twenty-one states and the District of Columbia filed briefs supporting the defendants and opposing the motion for a preliminary injunction. *Id.* Nineteen food and drug law scholars filed briefs urging the court to deny the plaintiffs’ request. *Id.*

229. *Id.*

230. *See All. for Hippocratic Med.*, 668 F. Supp. 3d at 520.

231. *See id.* at 559-60; *see* 5 U.S.C. § 705.

232. *See All. for Hippocratic Med.*, 668 F. Supp. 3d at 559-60.

233. *See id.* at 522-23.

234. *Id.* at 523-24.

235. *Id.*

“associational standing” because of the Associations’ members could sue on behalf of their patients.<sup>236</sup> The district court determined that there could be third party standing because the patients had endured side effects and complications, have a relationship with their doctors, and could have difficulty protecting their own interests.<sup>237</sup> The court also determined that the Association has “organizational standing” because it was able to demonstrate a drain on its resources as a result of counteracting the effects of the Defendant’s actions.<sup>238</sup> The court concluded that the medical association’s alleged injuries were both concrete and redressable because there are fewer safety restrictions as a result of the FDA’s actions, and thus future emergency care is not speculative.<sup>239</sup>

The court also held that the plaintiffs’ claims were timely.<sup>240</sup> While challenges to an FDA action have a six-year statute of limitations period, the court held that the agency’s 2016 and 2021 changes reopened the limitation period and therefore the Association’s claims are not time-barred.<sup>241</sup> Alternatively, the court also held that the claims were not time-barred under the equitable tolling doctrine, because the FDA was unreasonable when it delayed responding to the Plaintiff’s 2002 and 2019 requests.<sup>242</sup> The court also found that the FDA’s decision to do away with the in-person dispensing requirement did not fall within the FDA’s discretionary powers, and therefore is reviewable.<sup>243</sup> Finally, the court determined that the plaintiff’s failure to present its objections during the administrative proceedings did not preclude judicial review as its failure to exhaust its claims was excusable.<sup>244</sup>

The court then addressed the requirements of the preliminary injunction. In order to issue a preliminary injunction, the moving party must demonstrate that (1) there is a substantial likelihood of success on the merits; (2) there is a substantial threat of irreparable harm if the injunction is not granted; (3) the threatened injury outweighs any harm that will result if the injunction is not granted, and (4) the grant of the injunction is in the public interest.<sup>245</sup> The purpose of a preliminary injunction is to prevent irreparable injury so that the court has time to render a meaningful decision on the merits of the case.<sup>246</sup>

With respect to the first requirement, that the plaintiff’s challenges to the FDA 2021’s actions have a substantial likelihood of success, the court held that

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236. *Id.*

237. *See id.*

238. *See id.* at 527-36.

239. *See id.* at 537.

240. *See id.* at 524-48.

241. *See id.*

242. *See id.* at 548.

243. *See id.* at 550-54.

244. *See id.* at 553-58.

245. *See id.* at 526.

246. *See id.*

the Comstock Act<sup>247</sup> prohibits the mailing of mifepristone.<sup>248</sup> While the Defendants argued that the Comstock Act does not prohibit the mailing of medications where the sender did not intend to use them unlawfully, the court found that argument unpersuasive.<sup>249</sup> Instead, it held that it is not appropriate for courts to interpret a statute contrary to its plain language even when they have settled on a consensus interpretation that has never been modified by Congress.<sup>250</sup> In addition, the court determined that the FDA's actions in 2021 were unlawful not only because they violated the Comstock Act, but also because they violated the Administrative Procedure Act.<sup>251</sup>

The court also held that the pre-2021 actions also have a substantial likelihood of success on the merits because the FDA inappropriately approved mifepristone through the accelerated approval process in 2020, that it was not entitled to the deference given to agencies' readings of ambiguous regulations, that the drug trials were insufficient, and that it was under political pressure to forego its proposed safety precautions.<sup>252</sup> Similarly, the changes in 2016 were arbitrary and capricious because none of the studies that the FDA relied on evaluated the safety and effectiveness of mifepristone.<sup>253</sup>

With respect to the second requirement of a preliminary injunction, the court held that there is a substantial threat of irreparable harm if the court denies the preliminary injunction because women are dying and suffering from the effects of mifepristone.<sup>254</sup> The court also held that the third and fourth requirements, assessing the harm to the opposing party and weighing the public interest, merge when the government is the opposing party.<sup>255</sup> By ensuring that women and girls are protected from unnecessary harm and that the defendants do not disregard federal law, a preliminary injunction serves the public interest.<sup>256</sup>

Ultimately, instead of granting an injunction to remove mifepristone from the list of approved drugs, the court issued a section 705 stay<sup>257</sup> where it stayed the effective date of the FDA's 2000 approval of the drug. As a result, all of the challenged actions related to that approval were also stayed.<sup>258</sup> The court also stayed the applicability of the opinion and order for seven days to allow the federal government to seek emergency relief from the Fifth Circuit.<sup>259</sup> The

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247. See 18 U.S.C. § 1461.

248. See *All. for Hippocratic Med.*, 668 F. Supp. 3d at 525, 559-60.

249. See *id.*

250. See *id.*

251. See *id.*

252. See *id.*

253. See *id.*

254. See *id.*

255. See *id.*

256. See *id.*

257. See 5 U.S.C. § 705.

258. See *All. for Hippocratic Med.*, 668 F. Supp. 3d at 525, 559-60.

259. See Ann O'Leary et al., *What's Next For Mifepristone?*, MONDAQ (Apr. 26, 2023), <https://www.mondaq.com/unitedstates/healthcare/1308266/whats-next-for-mifepristone>

Department of Justice filed a notice of appeal that same evening.<sup>260</sup>

In addition, GenBioPro, the manufacturer of the generic version of mifepristone that is marketed in the United States, brought a lawsuit to enjoin the FDA from treating its drug as misbranded under the Texas district court's ruling.<sup>261</sup> This suit, which was brought in the district court in Maryland, further complicates an already fluid situation that also includes a range of state and federal action, legislation and litigation.<sup>262</sup>

*B. The Conflicting District Court Opinion: Washington v. U.S.  
Food and Drug Administration*

Shortly after Judge Kacsmaryk's decision, on the same day, Judge Thomas O. Rice of the US District Court for the Eastern District of Washington issued a decision in a second lawsuit, *Washington v. U.S. Food and Drug Administration*.<sup>263</sup> In that case, several states' attorneys general sought a preliminary injunction, asking the court to affirm the FDA's conclusion that mifepristone is safe and effective, to preserve the status quo by enjoining any actions to remove the drug from the market, and to enjoin the burdensome restrictions added in January 2023.<sup>264</sup> The court granted the Plaintiffs' requests in part and preliminarily enjoined the FDA from "altering the status quo and rights as it relates to the availability of mifepristone" in the seventeen Plaintiff states and the District of Columbia.<sup>265</sup> Judge Rice declined the Plaintiffs' request for a nationwide injunction.<sup>266</sup>

In its opinion, the court addressed the requirements of a preliminary injunction, finding that the Plaintiffs had standing both on behalf of itself as a state and also as *parens patriae* in protecting the health and welfare of its residents.<sup>267</sup> While the court declined to address the applicability of standing through *parens patriae*, it determined that the plaintiffs had standing as a result of its alleged direct injuries and allegations that the 2023 REMS violated the

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[<https://perma.cc/GMD9-PRMR>].

260. *See id.*

261. *See* Complaint at 1, GenBioPro, Inc., v. U.S. FDA, No. 1:23-cv-1057-SAG (Apr. 19, 2023), <https://democracyforward.org/wp-content/uploads/2023/04/GenBioPro-v.-FDA-Complaint-4.19.pdf> [<https://perma.cc/RET3-JBCZ>].

262. *See id.*

263. *See generally* *Washington v. U.S. FDA*, No. 1:23-cv-3026-TOR, 2023 WL 2825861 (E.D. Wash. Apr. 7, 2023) *opinion clarified*, No. 1:23-CV-3026-TOR, 2023 WL 2941567 (E.D. Wash. Apr. 13, 2023).

264. *See generally* Plaintiff States' Reply in Support of Motion for Preliminary Injunction, *Washington v. U.S. FDA*, No. 1:23-cv-3026-TOR, 2023 WL 2825861 (E. D. Wash. Mar. 24, 2023) (No. 1:23-cv-03026-TOR).

265. *Washington*, 2023 WL 2825861, at \*10.

266. *Id.*

267. *See id.* at \*5.

Administrative Procedure Act.<sup>268</sup>

On April 13, 2023, the Defendants moved for clarification regarding their obligations in light of the contradictory order out of the Texas district court and the pending Fifth Circuit opinion.<sup>269</sup> Because the order was stayed and was not in effect at the time of the Washington court's preliminary injunction, the Washington district court determined because it had limited its preliminary injunction only to the Plaintiff States and the District of Columbia, its preliminary injunction was effective as of April 7, 2023, and must be followed by Defendants pursuant to FRCP 65(a).<sup>270</sup> The Defendants filed an appeal to the Ninth Circuit on May 1, 2023.<sup>271</sup> That appeal is pending.<sup>272</sup> Having the Northern District of Texas purport to invalidate FDA approvals and risk evaluation and mitigation strategies for mifepristone, while the Eastern District of Washington has enjoined the FDA from changing the status quo takes us into uncharted territories.

### *C. Fifth Circuit's Order on Motion to Stay Pending Appeal*

The Defendants moved to stay the district court's order in *Alliance for Hippocratic Medicine v. FDA* pending appeal.<sup>273</sup> On April 12, 2023, a motions panel of the Fifth Circuit issued an order finding that the Plaintiff physicians had standing to challenge the FDA's actions approving mifepristone because they provided emergency care to women who took the drug and had harmful effects and that the Association had standing to challenge the FDA actions because the decisions of the FDA frustrating their efforts to educate the public, and that the challenges were not barred by exhaustion.<sup>274</sup> While it concluded that the Plaintiff's challenges to the FDA's approval in 2000 were barred by the statute of limitations, it held that the FDA's actions in 2016 and after were timely.<sup>275</sup>

### *D. Application for a Full Stay to the Supreme Court*

On April 14, 2023, the Defendants submitted an application for a full stay of the district court's order to Justice Alito,<sup>276</sup> who covers the Fifth Circuit. Justice

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268. *See id.* at \*6-8.

269. *See* Washington v. U.S. FDA, No. 1:23-cv-3026-TOR, 2023 WL 2941567, at \*1 (E.D. Wash. Apr. 13, 2023).

270. *See id.* at \*2.

271. *See* Washington v. U.S. FDA, No. 1:23-cv-3026, 2023 WL 3035380 (E.D. Wash. Apr. 21, 2023), *appeal docketed* (9th Cir. 2023).

272. *Id.*

273. *See* All. for Hippocratic Med. v. FDA, No. 23-10362, 2023 WL 2913725, at \*1 (5th Cir. Apr. 12, 2023).

274. *See id.* at \*5, 11, 16.

275. *See id.* at \*1.

276. U.S. FDA v. All. for Hippocratic Med., No. 22A902, 2023 WL 2942266, at \*1 (U.S. Apr. 14, 2023) (mem.) (granting Alliance for Hippocratic Medicine's motion for stay); Danco Lab'ys, LLC v. All. for Hippocratic Med., No. 22A901, 2023 WL 2942264, at \*1 (U.S. Apr. 14, 2023) (mem.) (granting Danco Laboratories' motion for stay).



Alito ordered that the district court's order be temporarily stayed until April 19, 2023,<sup>277</sup> and then on April 19 he extended it until April 21, 2023.<sup>278</sup> On April 21, 2023, the Supreme Court issued a stay that lasts until either the denial of a petition for certiorari or a ruling from the Supreme Court if it accepts certiorari.<sup>279</sup> That stay is still in effect today. Although the Supreme Court's stay decision provided no reasoning, it did contain two dissents,<sup>280</sup> one from Justice Alito—the author of the *Dobbs v. Jackson Women's Health Organization* decision that overturned *Roe v. Wade* and its progeny<sup>281</sup>—and Justice Thomas—author of a concurrence in *Dobbs* that urged severe restrictions on substantive due process rights.<sup>282</sup> These dissents, along with the partial stay ruling from the Fifth Circuit, help to provide some tea leaves about what the Fifth Circuit and ultimately the Supreme Court will do on the merits.

#### *E. The Fifth Circuit Opinion*

The Fifth Circuit heard oral arguments in the case on May 17, 2023.<sup>283</sup> Many watching the argument reported that the court appeared sympathetic to the plaintiffs.<sup>284</sup> On August 16, 2023, the Fifth Circuit released its opinion.<sup>285</sup> The three-judge panel, in a 93 page opinion, vacated the district court's decision that effectively ordered a halt to the use of mifepristone, finding that the challenge of the approval by the FDA in 2000 is “likely barred” by the statute of limitations, and that the plaintiffs did not demonstrate that they were actually injured by the 2019 approval of generic mifepristone.<sup>286</sup> However, the court did affirm the district court's reinstatement of restrictions on access to mifepristone concluding that the FDA's 2016 and 2021 changes, which allowed the drug to be mailed, allowed medical professionals other than doctors to prescribe the drug, allowed the medication to be prescribed by telemedicine, and allowed patients to take the drug up to ten weeks of pregnancy, are likely unlawful.<sup>287</sup> The court determined that by “loosening . . . safety restrictions, FDA failed to address . . . important concerns about whether the drug would be safe for the women who use it.”<sup>288</sup> Thus, while the court rejected the district court's blanket suspension of the FDA's

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277. See *U.S. FDA*, 2023 WL 2942266, at \*1; *Danco Lab's, LLC*, 2023 WL 2942264, at \*1.

278. *U.S. FDA v. All. for Hippocratic Med.*, No. 22A902, 2023 WL 2996931, at \*1 (U.S. Apr. 19, 2023); *Danco Lab's, LLC v. All. for Hippocratic Med.*, No. 22A901, 2023 WL 2996932, at \*1 (U.S. Apr. 19, 2023) (mem.).

279. See *Danco Lab's, LLC v. All. for Hippocratic Med.*, 143 S. Ct. 1075, 1075 (2023) (mem.).

280. See *id.* at 1075-76 (Alito, J., dissenting); see *id.* at 1075 (Thomas, J., dissenting).

281. See *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228 (2022).

282. See *id.* at 2300-04 (Thomas, J., concurring).

283. See Sneed, *supra* note 13.

284. *Id.*

285. See *All. for Hippocratic Med. v. U.S. FDA*, 78 F.4th 210 (5th Cir. 2023).

286. *Id.* at 222.

287. See *id.* at 256.

288. *Id.*

approval, it did agree with Judge Kacsmaryk's conclusion that the modifications exceeded the FDA's authority.<sup>289</sup> Because of the Supreme Court's stay ruling in April, however, none of these changes can go into effect at this time. Therefore, the approval and relaxed restrictions all remain in effect for now.

In reaching its decision, the three-judge panel held that the Plaintiffs had satisfied the injury requirement to establish standing.<sup>290</sup> In an analysis similar to the district court, the Fifth Circuit determined that the injury prong is satisfied because the doctors are forced to provide a treatment that conflicts with their moral beliefs, treating mifepristone patients diverts time, resources, and energy away from other patients, and mifepristone patients involve greater risks of complications than the average patient.<sup>291</sup> The Fifth Circuit ruled, however, that Plaintiffs' challenge to FDA's initial approval in 2000 is time-barred by the six-year statute of limitations and rejected Plaintiffs' argument that the later modifications to the drug protocol invoked the "reopening doctrine",<sup>292</sup> an exception that restarts the time for seeking review when an "agency has undertaken a serious, substantive reconsideration of the existing rule."<sup>293</sup> The Court noted that there was neither evidence that demonstrated that the FDA undertook a serious and substantial reconsideration of its approval nor that the FDA's basic assumption that mifepristone is safe and effective was changed in any way.<sup>294</sup> The Court did find that the claims challenging the 2016 and 2021 changes were timely, and ruled that they should be set aside as arbitrary and capricious under the Administrative Procedure Act.<sup>295</sup> By failing to consider the cumulative effects of the changes, the FDA departed from its rulemaking authority.<sup>296</sup>

Judge Ho concurred with the majority's rejection of the 2016 and 2021 amendments, but dissented regarding the FDA's approval of the drug in 2000.<sup>297</sup> He stated that the FDA's initial approval of mifepristone violated the agency's own rules and therefore the initial approval of mifepristone should be invalidated as well.<sup>298</sup> In his concurrence, Judge Ho also presented another theory through which the Plaintiffs can establish Article III standing: a showing of aesthetic injury.<sup>299</sup> While the concept of aesthetic injury has typically been applied in cases

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289. *Id.*

290. *Id.* at 227-28.

291. *Id.* at 256.

292. *Id.* at 242-43.

293. *Growth Energy v. Env't Prot. Agency*, 5 F.4th 1, 24 (D.C. Cir. 2021). That doctrine holds that when an agency reconsiders a settled rule, aggrieved parties may contest the agency's decision not to change the rule. *See Kennecott Utah Copper Corp. v. U.S. Dep't of Interior*, 88 F.3d 1191, 1214 (D.C. Cir. 1996).

294. *All. for Hippocratic Med.*, 78 F.4th at 242-44.

295. *Id.* at 248.

296. *Id.* at 245-46.

297. *See id.* at 257 (Ho, J., concurring in part and dissenting in part).

298. *See id.* at 262.

299. *Id.* at 258-59.

seeking to protect plants and wildlife,<sup>300</sup> Judge Ho opined that “[d]octors delight in working with their unborn patients and experience an aesthetic injury when they are aborted.”<sup>301</sup> He was also the only judge on the panel to agree with anti-abortion groups’ argument that mail delivery of abortion pills is illegal under the Comstock Act—a century-plus-old, rarely enforced anti-vice law.<sup>302</sup>

It is expected that the decision will be appealed to the Supreme Court.<sup>303</sup> Until then, mifepristone remains on the market without court-imposed restrictions.<sup>304</sup> If this ruling were permitted to take effect, it would have a huge impact on the availability of abortion nationwide.<sup>305</sup> In our post-*Roe* world, the Supreme Court’s action is the next fight for reproductive freedom.

#### V. EVALUATION OF THE ISSUES RAISED BY THE CASES: WHAT CAN WE EXPECT?

The case raises numerous jurisdictional, procedural, and substantive issues. As soon as the district court’s decision was announced, there were concerns about whether the choice of that forum constituted unlawful forum shopping.<sup>306</sup> In spite of the Fifth Circuit’s ruling, it is not clear whether there is Article III standing, or

300. *See id.*

301. *Id.* at 259.

302. *Id.* at 267-70, 272.

303. The White House issued the following statement on Aug. 16, 2023, by Press Secretary Karine Jean-Pierre on the 5th Circuit Court of Appeals’ decision in *Alliance for Hippocratic Medicine vs. Food and Drug Administration*: “We strongly disagree with today’s ruling from the Fifth Circuit Court of Appeals in *Alliance for Hippocratic Medicine v. FDA*, which undermines FDA’s scientific, independent judgment and reimposes onerous restrictions on access to safe and effective medication abortion. The Department of Justice announced that it will be seeking Supreme Court review of the Fifth Circuit’s contrary decision.” Press Release, Karine Jean-Pierre, Press Secretary, The White House, Statement from Press Secretary Karine Jean-Pierre on Fifth Circuit Court of Appeals Decision in *Alliance for Hippocratic Medicine v. FDA* (Aug. 16, 2023), <https://www.whitehouse.gov/briefing-room/statements-releases/2023/08/16/statement-from-press-secretary-karine-jean-pierre-on-fifth-circuit-court-of-appeals-decision-in-alliance-for-hippocratic-medicine-v-fda/> [<https://perma.cc/VNV4-ZPB9>].

304. Tierney Sneed, *Appeals Court Says Abortion Pill Mifepristone Should Remain on the Market but Rules in Favor of Limiting Access*, CNN (Aug. 16, 2023, 9:33 PM), <https://www.cnn.com/2023/08/16/politics/abortion-pill-mifepristone-5th-circuit/index.html> [<https://perma.cc/BZ4U-XY8X>].

305. Press Release, Deirdre Schifeling, Spokesperson, ACLU, ACLU Comment on Court Decision Blocking Approval of Mifepristone, a Medication Used in Half of Abortions in the United States (Apr. 7, 2023, 8:28 PM), <https://www.aclu.org/press-releases/aclu-comment-on-court-decision-blocking-approval-of-mifepristone-a-medication-used-in-half-of-abortions-in-the-united-states> [<https://perma.cc/2P4J-XAPW>] [hereinafter ACLU Press Release].

306. *See* Kevin Breuninger, *Abortion Pill Ruling Puts ‘Judge Shopping’ Concerns Back in Spotlight*, CNBC (Apr. 12, 2023, 9:36 AM), <https://www.cnbc.com/2023/04/12/abortion-pill-ruling-puts-judge-shopping-concerns-back-in-spotlight.html> [<https://perma.cc/S75X-DKVA>].

whether the lawsuit is ripe because the Plaintiffs failed to exhaust available administrative remedies prior to seeking judicial review.<sup>307</sup> Judge Ho's concurrence continues to raise the issue of whether the challenge to the FDA's 2000 decision to approve mifepristone is precluded by the six-year statute of limitations.<sup>308</sup>

With respect to the substance of the lawsuit, the issues involve the deference that should be given to the decisions of the FDA, including its regulatory decision to use Subpart H and its reliance on expert scientific judgments with respect to the conditions of use.<sup>309</sup> Finally, the issue remains about whether the Comstock Act prohibits the mailing of items that are designed to produce abortions.<sup>310</sup>

Although the final outcome of the case remains to be determined, it is difficult to overstate the potentially sweeping impact of the rulings in *Alliance for Hippocratic Medicine*. The ultimate decision of the Supreme Court could undermine access to mifepristone nationwide by impacting the foundation of the drug's manufacturing, marketing, and distribution throughout the United States. A drug that has been a basis of evidence-based care for over 20 years would no longer be available.<sup>311</sup> This would lead to a huge disruption for both people needing abortion care and their healthcare providers.<sup>312</sup> The case also raises urgent questions about the stability and integrity of the FDA's drug approval process. This is the first time we are seeing physicians and an association seek and obtain judicial relief to overturn a drug that has been approved by the FDA.<sup>313</sup> It is crucial that we fully understand the issues and are prepared to respond to the ones that are viable and are likely to be successful.

#### A. Forum Shopping

*Alliance for Hippocratic Medicine v. FDA* was filed in the United States District Court for the Northern District of Texas, Amarillo division.<sup>314</sup> All of the civil cases that are filed in that division are heard by Judge Kacsmaryk,<sup>315</sup> who was appointed by President Trump, and had previously ruled against pro-choice arguments.<sup>316</sup> Consequently, the lawsuit has resulted in accusations of unlawful

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307. See *All. For Hippocratic Med. v. U.S. FDA*, 668 F. Supp. 3d 507, 522-23, 535-36 (N.D. Tex. 2023).

308. See *All. for Hippocratic Med. v. U.S. FDA*, 78 F.4th 210, 260 (5th Cir. 2023) (Ho, J., concurring in part and dissenting in part).

309. See O'Leary et al., *supra* note 259.

310. See *id.*

311. See *id.*

312. See ACLU Press Release, *supra* note 305.

313. See O'Leary et al., *supra* note 259.

314. *All. For Hippocratic Med. v. U.S. FDA*, 668 F. Supp. 3d 507 (N.D. Tex. 2023).

315. See Steve Vladeck, *A Federal Judge Couldn't Handle My Criticism. So He Made Fun of My Tweets.*, SLATE (Mar. 29, 2023, 11:04 AM), <https://slate.com/news-and-politics/2023/03/trump-judge-matthew-kacsmaryk-steve-vladeck-tweets.html> [<https://perma.cc/V8MW-JP5N>].

316. For a list of decisions by Judge Kacsmaryk that are anti-choice, see O'Leary et al., *supra*

forum or judge shopping.<sup>317</sup>

Because different judges might decide the same case differently, forum-shopping can influence the outcome of a case in a way that is unfair to the non-shopping party.<sup>318</sup> Judge-shopping also creates a perception of partiality that undermines the legitimacy and credibility of the courts.<sup>319</sup> In an atmosphere where the public is already questioning the judiciary's reputation for impartiality and nonpartisanship, the authority of the court is further diminished.<sup>320</sup> Both of those concerns are raised by the decision in *Alliance for Hippocratic Medicine v. FDA*. However, while these issues certainly deserve exploration, concerns about forum shopping will not help resolve this case. While judge-shopping is frequently viewed as harmful,<sup>321</sup> courts have generally found that the unfairness created by judge-shopping does not rise to the level of a violation of constitutional due process.<sup>322</sup>

A lawsuit can frequently be brought in more than one forum.<sup>323</sup> While “forum shopping” might sound pejorative, lawyers often have a choice between federal court and state court, or between a court in one state (either federal or state) or a court in another state (either federal or state).<sup>324</sup> Lawyers may choose one forum over another because of the differences in the substantive law depending on where the lawsuit is filed, the procedural law followed by one court or another, or the subjective factors, such as the convenience of the forum, where the lawyer is admitted, or the reputations of prospective judges.<sup>325</sup>

Of all of these options, the only type of forum shopping that is prohibited falls under the principles set forth in *Erie Railroad Co. v. Tompkins* and its progeny.<sup>326</sup> Because of concerns about the lack of fairness applying different substantive law as between a federal court and a state court located within the

note 259, at n.29.

317. See O’Leary et al., *supra* note 259; see also Caroline Kitchener & Ann E. Marimow, *The Texas Judge Who Could Take Down the Abortion Pill*, WASH. POST (Feb. 25, 2023, 6:00 AM), <https://www.washingtonpost.com/politics/2023/02/25/texas-judge-abortion-pill-decision/> [<https://perma.cc/7DGU-T7A7>].

318. For discussions of judge-shopping, see Alex Botoman, *Divisional Judge-Shopping*, 49 COLUM. HUM. RTS. L. REV. 297 (2018), Kimberly Jade Norwood, *Shopping for a Venue: The Need for More Limits on Choice*, 50 U. MIAMI L. REV. 267, 300 (1996), and Jonas Anderson, *Judge Shopping in the Eastern District of Texas*, 48 LOY. U. CHI. L.J. 539, 550-55 (2016).

319. See Botoman, *supra* note 318; see Norwood, *supra* note 318; see Anderson, *supra* note 318.

320. See Botoman, *supra* note 318; see Norwood, *supra* note 318; see Anderson, *supra* note 318.

321. See Botoman, *supra* note 318; see Norwood, *supra* note 318; see Anderson, *supra* note 318.

322. For a list of cases (including *Francolino v. Kuhlman*, 365 F.3d 137, 141-42 (2d Cir. 2004)) where the courts have rejected the argument that judge shopping violates due process, see Botoman, *supra* note 318, at 16-18.

323. See Debra Lyn Basset, *The Forum Game*, 84 N.C. L. REV. 333 (2006).

324. See *id.* at 336 (“Congressional efforts to limit forum shopping have portrayed the practice as abusive, devious, and unethical”).

325. See *id.* at 343.

326. *Erie R.R. Co. v. Tompkins*, 304 U.S. 64 (1938).

same state, the Supreme Court has held that when dealing with state issues, federal courts have to apply the substantive law of the state in which they sit.<sup>327</sup> Thus, the Supreme Court has only denounced forum shopping in the context presented by *Erie*—in order to prevent different results between a federal court and a state court within the same state because of the application of different substantive law.<sup>328</sup> The Supreme Court has never prohibited choices involving different substantive laws beyond the narrow *Erie* context, including choosing one forum over another because the substantive law is different, or because a judge is perceived to be helpful to the plaintiff.

In the early part of our history, district courts had only one judge, so there was no need for judge-assignment procedures.<sup>329</sup> That is no longer true today; almost all of the federal district courts have multiple judgeships.<sup>330</sup> As a result, even the smallest district courts have several judges available to hear each case, and those judges are assigned to a particular case through a case assignment system.

The district courts have a lot of latitude in creating their own procedures for assigning cases. The relevant statute only states that “[t]he business of the court . . . shall be divided among the judges as provided by the rules and orders of the court.”<sup>331</sup> As a result, district courts across the country all use different case assignment procedures.<sup>332</sup> Consequently, some district courts, including those in Texas, have been able to gain significantly more control over the judges selected to hear certain cases.<sup>333</sup>

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327. *See id.* at 78.

328. *See, e.g.*, *Guar. Trust Co. v. York*, 326 U.S. 99, 109 (1945); *Hanna v. Plumer*, 380 U.S. 460, 472-73 (1965) (holding Congress has the power to prescribe procedural rules that differ from state law rules, such as Federal Rules of Civil Procedure, even at the expense of altering the outcome of litigation).

329. The Judiciary Act of 1789 created the first federal district courts and authorized a single judgeship for each district. 1 Stat. 73 (1789). It was not until the early 1900s that Congress began to regularly authorize multiple permanent judgeships for district. *See Chronological History of Authorized Judgeships—District Courts*, ADMIN. OFF. U.S. COURTS, <http://www.uscourts.gov/judges-judgeships/authorized-judgeships/chronological-history-authorized-judgeships-district-courts> [<https://perma.cc/KYF7-FDZX>]; *see also* Botoman, *supra* note 318.

330. *See* 28 U.S.C. § 133(a) (establishing the number of authorized judgeships per district). The Eastern District of Oklahoma is the only Article III district court with a single authorized judgeship, but it shares an additional judge with the two other districts in the state. *Id.* The district courts for the Northern Mariana Islands and Guam, which are Article I courts with the same subject matter jurisdiction as the other federal district courts, also have only one judgeship each. 48 U.S.C. §§ 1424, 1424b, 1821, 1822; *see* Botoman, *supra* note 318. Most district courts have judges on senior status who hear a significant number of cases. And many district courts assign a percentage of their docket to magistrate judges. 48 U.S.C. §§ 1424, 1424b, 1821, 1822; *see* Botoman, *supra* note 318.

331. 28 U.S.C. § 137. Only if the judges of the district court cannot agree will the supervising circuit court step in to create the district’s assignment procedures. *Id.*

332. *See* Botoman, *supra* note 318, at 312.

333. The original purpose of divisions was to provide litigants with a convenient local forum

It is clear that the Plaintiffs in *Alliance for Hippocratic Medicine* specifically chose to file the case in the district court where it would be heard by Judge Kacsmaryk, a conservative judge appointed by President Trump.<sup>334</sup> Alliance for Hippocratic Medicine incorporated itself in Amarillo, Texas shortly before filing the case in the Northern District of Texas, where Judge Kacsmaryk is the only judge.<sup>335</sup> Judge Kacsmaryk has already issued nationwide injunctions on immigration and laws protecting transgender workers from discrimination, so naturally it made sense to choose this court.<sup>336</sup> While the concern about judge-shopping was raised by the public following the decision and has now become part of a bigger movement to address this issue in the future, it is not a part of the case going forward and is not a viable argument.

### B. Standing

A court can only hear a claim if it has jurisdiction. Standing has requirements that are mandated by the Constitution under Article III case or controversy and also what we call prudential requirements: criteria that the Supreme Court has developed but are not constitutionally compelled.<sup>337</sup> Under the Constitution, there must be injury-in-fact, causation, and redressability in order for the plaintiff to bring a cause of action.<sup>338</sup> The plaintiffs must demonstrate that they have suffered

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in the days when travel was arduous. The Judiciary Act of 1789, which established the first lower federal courts, required the single district judge in ten of the original thirteen districts to hold court in multiple locations. *See* Botoman, *supra* note 318, at 315. Some district courts still use those divisions when making judge assignments. Until 1988, the federal venue statute provided that “any civil action . . . against a single defendant in a district containing more than one division must be brought in the division where he resides.” 28 U.S.C. § 1393. The statute was amended, and no longer refers to divisions, only districts. 28 U.S.C. § 1393. District courts remain free to create and enforce their own divisional venue rules through local rules and standing orders, and many do; therefore, if there are no local court rules, as long as venue is proper, plaintiffs are free to file in any of the district’s divisions. *See id.* at 315-16. While divisional venue only determines the courthouse where the case will be heard, many courts use divisions to assign judges as well. Rather than requiring judges to travel to different locations, judges remain in their home courthouse and hear cases only from the division that the courthouse serves. When there is only one judge who is assigned to a division, that judge generally hears all of the division’s cases. In districts with relaxed divisional venue rules, it is easy for plaintiffs to judge-shop. *See id.* at 317.

334. *Matthew Kacsmaryk*, BALLOTPEdia, [https://ballotpedia.org/Matthew\\_Kacsmaryk](https://ballotpedia.org/Matthew_Kacsmaryk) [https://perma.cc/4RLX-5WPU] (last visited Mar. 20, 2024).

335. *See* Kelcie Moseley-Morris, *Legislators in 49 States Ask SCOTUS to Preserve Access to Abortion Pill*, OHIO CAP. J., <https://ohiocapitaljournal.com/2023/10/16/legislators-in-49-states-ask-scotus-to-preserve-access-to-abortion-pill/> [https://perma.cc/YH3J-S5JC] (last visited Mar. 20, 2024).

336. *See* BALLOTPEdia, *supra* note 334.

337. *See* Tacy F. Flint, *A New Brand of Representational Standing*, 70 U. CHI. L. REV. 1037, 1042 (2003).

338. *See id.* at 1037.

personal injury traceable to the defendant and that can be redressed by the court.<sup>339</sup> Even if the court finds that the injury is real and can be redressed, the plaintiffs must show “causation”—that the injury is linked to the defendant’s conduct.<sup>340</sup> Finally, the plaintiffs must demonstrate redressability—they must identify some form of relief that will alleviate the injury the defendant has caused.<sup>341</sup>

The Supreme Court has added prudential requirements to the constitutional requirements: the plaintiffs must assert their own particularized rights, and the plaintiffs’ complaint must fall “within the zone of interests to be protected or regulated by the statute or constitutional guarantee in question.”<sup>342</sup> The Court has established two exceptions to that requirement.<sup>343</sup> First, under associational standing, an association has standing to bring its members’ claims rather than the association’s own claims.<sup>344</sup> As a result, the association need not suffer injury in its own right as long as its members have suffered an injury.<sup>345</sup> Second, in third-party standing, a plaintiff has standing to bring the claims of a third party rather than its own; however, the plaintiffs themselves must also have suffered some injury, and the third party must be somehow unable to bring the lawsuit on their own behalf.<sup>346</sup> Finally, an organization or association can assert Article III standing in its own right where it establishes that the defendant’s behavior has frustrated its mission and caused it to divert resources in response to that frustration of purpose.<sup>347</sup> Although organizations cannot “manufacture the injury by incurring litigation costs or simply choosing to spend money fixing a problem that otherwise would not affect the organization at all,” they can establish standing by showing that they “would have suffered some other injury’ had they ‘not diverted resources to counteracting the problem.’”<sup>348</sup> The purpose of Article III standing under any of these methods is to “maintain the limited role of courts by ensuring they protect against only concrete, non-speculative injuries.”<sup>349</sup>

The district court held that the Plaintiff Medical Association had “associational standing” to bring suit on behalf of its physician members because the physicians would have standing to sue in their own right as a result of the

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339. *See id.*

340. *See id.*

341. *See id.* at 1042.

342. *Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 474-75 (1982) (internal quotation marks omitted).

343. *See Flint, supra* note 337, at 1037.

344. *See id.*

345. *See id.*

346. *See id.*

347. *See E. Bay Sanctuary Covenant v. Biden*, 993 F.3d 640, 663 (9th Cir. 2021) (citing *Fair Hous. of Marin v. Combs*, 285 F.3d 899, 905 (9th Cir. 2002)).

348. *Id.*

349. *Id.* at 662 (citing *La Asociacion de Trabajadores de Lake Forest v. Lake Forest*, 624 F.3d 1083, 1088 (9th Cir. 2010)).



pressure placed on them from adverse effects of the drug on their patients.<sup>350</sup> This also gave the physicians “third party standing” to protect the interests of their patients because the patients would allegedly have difficulty protecting their own interests.<sup>351</sup> The court also concluded that the medical association had “organizational standing” because it was able to demonstrate a drain on its resources as a result of counteracting the effects of the defendant’s actions.<sup>352</sup> Finally, the court determined that the Medical Association’s alleged injuries were both concrete and redressable because the FDA’s actions resulted in fewer safety restrictions, and thus future emergency care was not speculative.<sup>353</sup>

In its order for a stay, the Fifth Circuit also held that there was “associational standing” on behalf of the physicians because the physicians provided emergency care to women who took the drug and experienced harmful effects, and that the Association had “organizational standing” to challenge the FDA actions because the decisions of the FDA frustrated their efforts to educate the public.<sup>354</sup> The Fifth Circuit reiterated that finding in its recent decision, holding that the Defendants do not dispute that a significant percentage of women who take mifepristone experience adverse effects.<sup>355</sup> The Court concluded that the Medical Organization and Doctors made a clear showing of associational standing and that caring for women who suffer complications results in a substantial risk of future injury.<sup>356</sup>

Standing is determined at the time the lawsuit is brought.<sup>357</sup> Here, the standing of the physicians was based on their alleged injuries that were the result of the weakening of the REMS requirements over time.<sup>358</sup> The physicians’ injuries were not linked to the approval of the new drug application in 2000 or the approval of the abbreviated new drug application in 2019.<sup>359</sup> Instead, the Fifth Circuit relied on the 2023 change to the REMS that removed the requirement of in-person dispensing of the drug, even though this occurred after the lawsuit was brought.<sup>360</sup> The Fifth Circuit tried to limit its analysis, stating:

We do not hold that doctors necessarily have standing to raise their patients’ claims. We do not hold that doctors have constitutional standing whenever they’re called upon to do their jobs. And we do not hold that doctors have standing to challenge FDA’s actions whenever the doctor

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350. *See All. for Hippocratic Med. v. U.S. FDA*, 668 F. Supp. 3d 507, 526-36 (N.D. Tex. 2023).

351. *See id.* at 529.

352. *See id.* at 526-36.

353. *See id.* at 526-29.

354. *See id.* at 523-26.

355. *All. for Hippocratic Med. v. FDA*, 78 F.4th 210, 229 (5th Cir. 2023), *cert. granted*, 2023 WL 8605744 (U.S. Dec. 13, 2023) (No. 23-236).

356. *Id.* at 233.

357. *See Cook v. Bennett*, 792 F.3d 1294, 1298 (11th Cir. 2015) (holding that standing is determined when the plaintiff files its complaint).

358. *See All. for Hippocratic Med.*, 78 F.4th at 228-29.

359. *See id.* at 228, 241.

360. *See id.* at 229, 247-49.

sees a patient experiencing complications from an FDA-approved drug. Rather, we hold that on the record before us applicants know that hundreds of thousands of women *will*—with applicants’ own statistical certainty—need emergency care on account of applicants’ actions.<sup>361</sup>

Thus, the Fifth Circuit determined that some percentage of patients experience complications.<sup>362</sup> Some of those patients might seek care from the plaintiff doctors, who might struggle to reconcile their religious or moral objections to abortion with their duties to patients.<sup>363</sup> That all of this was conjecture did not matter: The court held the plaintiffs had standing anyway.<sup>364</sup> And Judge Ho went even further, finding that doctors could suffer “aesthetic injury” as a result of having to reconcile their enjoyment of taking care of pregnant patients with taking care of someone who was suffering from post-abortion complications.<sup>365</sup>

Unlike arguments about forum selection, there is a good argument that there is no standing here. To satisfy Article III, “threatened injury must be ‘certainly impending’” or “sufficiently imminent and substantial.”<sup>366</sup> A theory that relies on a chain of possibilities or speculation is not sufficient.<sup>367</sup> There must be “a real and immediate threat” of future harm to have standing for injunctive relief.<sup>368</sup> All of the facts asserted by the plaintiffs are speculation, and there is some evidence that the studies relied on by the court are flawed.<sup>369</sup> There is nothing to demonstrate that an unidentified physician will treat an unidentified patient sometime in the future for some unidentified injury as a result of that patient using mifepristone for a medical abortion.<sup>370</sup> These vague allegations do not satisfy the standing requirements of the physicians and destroy the associational standing argument, as association members must have standing in their own right. There is nothing to demonstrate that there is a past injury as a result of an overwhelmed medical system, and because these physicians do not themselves prescribe mifepristone,<sup>371</sup> there is nothing to support the assertion that they cannot practice evidence-based medicine.<sup>372</sup>

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361. *See* All. for Hippocratic Med. v. FDA, No. 23-10362, 2023 WL 2913725, at \*9 (5th Cir. Apr. 12, 2023) (granting defendants’ motion to stay in part and denying in part).

362. *All. for Hippocratic Med.*, 78 F.4th at 234.

363. *Id.*

364. *Id.* at 241.

365. *Id.* at 241 (Ho, J., concurring).

366. *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 410 (2013) (internal citations omitted); *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2210 (2021).

367. *See Clapper*, 568 U.S. at 410, 414 n.5.

368. *City of Los Angeles v. Lyons*, 461 U.S. 95, 105 (1983).

369. *See* Emergency Application for Stay of Preliminary Injunction Pending at 19, *Danco Lab’ys v. All. for Hippocratic Med.*, 2023 WL 3122097 (2023) (No. 22A901) (S. Ct. filed Apr. 10, 2023).

370. *See id.*

371. *See id.* at 18.

372. *See* Opening Brief for Intervenor-Appellant Danco Lab’ys, LLC at 13, *All. for Hippocratic*

All of the injuries claimed by the physicians to establish standing are based on the difference between the current REMS requirements and the original approval of the drug. The Plaintiffs claim that the physicians are injured because they would have to provide emergency care for some number of women because of “unsuccessful chemical abortions.”<sup>373</sup> That does not take into account the fact that they would also be likely to provide emergency care for complications as a result of unintended pregnancies, abortions not conducted under medical supervision, or the use of mifepristone under no REMS or a pre-2023 REMS.<sup>374</sup> The second injury was “stress” to physicians from “treating these women.”<sup>375</sup> The third and most questionable injury was “the irreconcilable choice between performing their jobs and abiding by their consciences.”<sup>376</sup> Those injuries were not contrasted with the stress or internal conflicts the physician plaintiffs would likely experience under no REMS or a pre-2023 REMS, which would be the appropriate considerations for standing.<sup>377</sup>

To claim third-party standing, Plaintiff physicians must first establish their own injury, which they cannot. In addition, physicians who fundamentally oppose medical abortions and patients who seek medical abortions have interests that do not align. Even if a woman suffers an adverse effect from a medical abortion, she does not have a close, aligned interest with a physician whose interests are diametrically opposed. Without a close, aligned relationship there can be no third-party standing.

Plaintiff Medical Association’s organizational standing theory is that it diverted resources from disseminating information that disagreed with abortion to disagreeing with abortion.<sup>378</sup> In *Texas State LULAC v. Elfant*, the Fifth Circuit denied organizational standing where plaintiffs made similarly vague assertions that they diverted resources.<sup>379</sup> In addition, pre-litigation expenses cannot provide organizational standing for injunctive relief because otherwise, an organization could manufacture standing just by preparing to sue.<sup>380</sup>

In his concurrence, Judge Ho also presented another theory through which the Plaintiffs can establish Article III standing: a showing of aesthetic injury.<sup>381</sup> While the concept of aesthetic injury has typically been applied in cases seeking to protect plants and wildlife,<sup>382</sup> Judge Ho opined that “[d]octors delight in working

Med. v. FDA, No. 23-10362, 2023 WL 2913725 (5th Cir. Apr. 12, 2023) (No. 23-10362).

373. *All. for Hippocratic Med.*, 2023 WL 2913725, at \*5.

374. *See id.*

375. *Id.* at \*7.

376. *Id.* at \*8.

377. *See id.* at \*1-21.

378. *See All. for Hippocratic Med. v. U.S. FDA*, 668 F. Supp. 3d 507, 526-27 (N.D. Tex. 2023).

379. *See Texas LULAC v. Elfant*, 52 F.4th 253, 255-56 (5th Cir. 2022).

380. *See NAACP v. City of Kyle*, 626 F.3d 233, 236 (5th Cir. 2010).

381. *All. for Hippocratic Med. v. U.S. FDA*, 78 F.4th 210, 259 (Ho, J., concurring).

382. *Id.* at 259 (citing *Humane Soc’y v. Hodel*, 840 F.2d 45, 52 (D.C. Cir. 1988); *Am. Bottom Conservancy v. Army Corps of Eng’rs*, 650 F.3d 652, 657 (7th Cir. 2011); *Ctr. for Biological Diversity v. EPA*, 861 F.3d 174, 183 (D.C. Cir. 2017)).

with their unborn patients and experience an aesthetic injury when they are aborted.”<sup>383</sup> This outlandish and unprecedented theory was not adopted by the rest of the Fifth Circuit panel.

The FDA is charged by Congress with advancing public health. Its job is to balance risks and benefits on a population basis.<sup>384</sup> Prescription drugs always have risks, and their benefits are often measured in the risk of complications and the medical care that will result if the patient’s condition is left untreated.<sup>385</sup> Clearly, the FDA took this into consideration when it approved the new drug application and abbreviated new drug application for mifepristone because it does this calculus each time it considers imposing or updating a REMS for any drug.<sup>386</sup> The basis for the Plaintiffs’ lawsuit is that they do not agree with the actions of the FDA.<sup>387</sup> Should the Supreme Court agree with the determination of the Fifth Circuit, it will create a dangerous precedent that goes against all of the principles of the standing requirement.

### *C. Judicial Deference to the FDA’s Decisions*

The Plaintiff’s lawsuit relies heavily on the conclusion that mifepristone should not have been approved pursuant to the accelerated framework, and that the FDA did not rely on a comprehensive scientific analysis when it approved the drug, amended the REMS in 2016, approved the generic version, and changed the REMS in 2020.<sup>388</sup> In addition to undermining the FDA’s statutory authority to evaluate and determine the safety and efficacy of drugs through its established regulatory approval methods, it could also have an impact on agency deference more generally. The Fifth Circuit order solely invoked a constraint on agency decision-making authority: the arbitrary and capricious standard under the Administrative Procedure Act, which instructs courts to set aside agency decisions found to be unsupported by sufficient data.<sup>389</sup>

Both the Administrative Procedure Act and the FDCA afford private parties the opportunity to challenge FDA actions and decisions in court.<sup>390</sup> Because a

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383. *All. for Hippocratic Med.*, 78 F.4th at 259 (Ho, J., concurring).

384. *See About FDA*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/about-fda> [https://perma.cc/PF54-6WY6] (last visited June 25, 2023).

385. *See id.*

386. *See Risk Evaluation and Mitigation Strategies: REMS*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems> [https://perma.cc/KY7Z-CFHU] (last updated May 16, 2023).

387. *See All. for Hippocratic Med. v. U.S. FDA*, 668 F. Supp. 3d 507 (N.D. Tex. 2023).

388. *See id.*

389. *All. for Hippocratic Med. v. FDA*, 78 F.4th 210 (5th Cir. 2023).

390. *See* 5 U.S.C. § 704 (“Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review . . . Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section whether or not there has been presented or determined an application for a declaratory order, for any form of reconsideration, or, unless the agency otherwise requires by rule and provides that

great deal of the FDA's decision-making is a matter of judgment,<sup>391</sup> there can be substantial litigation over FDA's drug classification and reclassification decisions.

While judicial oversight is an essential aspect of administrative law, courts have been reluctant to substitute their own judgment for that of an agency acting within its area of expertise, especially with respect to technical or scientific matters.<sup>392</sup> Federal courts may only set aside FDA decisions that are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.”<sup>393</sup> A decision is arbitrary and capricious if the agency “has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or product of agency expertise.”<sup>394</sup>

As such, “there is a presumption in favor of the validity of administrative action,” and courts do not “substitute [their] judgment for that of the agency.”<sup>395</sup> The FDA thus historically wields “considerable discretion” when deciding

the action meanwhile is inoperative, for an appeal to superior agency authority.”).

391. See Jonas Zajac Hines et al., *Left to Their Own Devices: Breakdowns in United States Medical Device Premarket Review*, 7 PLOS MED. 1, 6 (2010).

392. See *United States v. Alpine Land & Reservoir Co.*, 887 F.2d 207, 213 (9th Cir. 1989) (holding that “[d]eference to an agency’s technical expertise and experience is particularly warranted with respect to questions involving engineering and scientific matters”); *Greenpeace v. Nat’l Marine Fisheries Serv.*, 55 F. Supp. 2d 1248, 1260 (W.D. Wash. 2021) (finding that a court must afford deference to an agency’s scientific expertise, but this is not unlimited in nature).

393. Administrative Procedure Act of 1946, 5 U.S.C. § 706(2)(A); see also *Breeze Smoke, LLC v. FDA*, 18 F.4th 499, 503 (6th Cir. 2021) (finding that the marketer of electronic nicotine delivery systems had “not made a strong showing that it would likely succeed on its claim that the FDA’s review of its application was arbitrary or capricious.”); *Melinta Therapeutics, LLC v. FDA*, No. CV 22-2190 (RC), 2022 WL 6100188, at \*4 (D.D.C. Oct. 7, 2022) (holding that “a court will find an [a]gency acted arbitrarily or capriciously ‘if it has relied on factors Congress did not intend it to consider, entirely failed to consider an important aspect of the problem, or offered an explanation either contrary to the evidence before the agency or so implausible as to not reflect either a difference in view or agency expertise.’”) (quoting *Taylor Made Software v. Cuccinelli*, 453 F. Supp. 3d 237, 242 (D.D.C. 2020)).

394. *United States v. Snoring Relief Labs Inc.*, 210 F.3d 1081, 1085 (9th Cir. 2000) (quoting *O’Keeffe’s, Inc. v. U.S. Consumer Prod. Safety Comm’n*, 92 F.3d 940, 942 (9th Cir. 1996)); see also *Pharm. Rsch. & Mfg. of Am. v. FTC*, 44 F. Supp. 3d 95, 113-14 (D.D.C. 2014) (finding that “when an agency has acted in an area in which it has special expertise, the court must be particularly deferential to the agency’s determinations . . . [d]eferring as appropriate to the agency’s expertise and looking only for a rational connection between the facts found and the choice made.” (internal citations omitted)).

395. *Ethicon, Inc. v. FDA*, 762 F. Supp. 382, 386 (D.D.C. 1991) (citing *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971), *abrogated in part by Califano v. Sanders*, 430 U.S. 99 (1977)).

whether and how to reclassify a drug.<sup>396</sup>

When the court is reviewing the FDA's decisions about NDA, the FDA must "articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'"<sup>397</sup> The court will only look further if there is evidence that its judgment was the result of "arbitrariness, expansion of power, or improper influences."<sup>398</sup> Courts have thus demonstrated a willingness to more closely intervene in FDA decision-making if the decision seems to be the product of political forces rather than scientific judgment.<sup>399</sup> As a result, agencies may attempt to justify their decisions as entirely founded on science, even when those decisions could be the product of both scientific and political motives.<sup>400</sup>

When examining the history of the approval of mifepristone, it is clear that the FDA experienced both social and political pressures, including political interference from several administrations<sup>401</sup> that commingled with its regulatory decision-making.<sup>402</sup> As a result, the REMS requirements reflect the political controversy surrounding abortion. This could create a situation where the Court will more closely intervene in the FDA's decision making. Additionally, it is interesting that the Fifth Circuit did not reference Chevron deference. Nearly forty years ago, the Supreme Court held in *Chevron v. Natural Resources Defense Council, Inc.* that courts should give deference to an agency's interpretation of an

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396. Stephanie P. Fekete, Comment, *Litigating Medical Device Premarket Classification Decisions for Small Businesses: Have the Courts Given the FDA Too Much Deference? The Case for Taking the Focus Off Efficacy*, 65 CATH. U. L. REV. 605, 616 (2016) (citing *Ethicon, Inc.*, 762 F. Supp. at 386).

397. See Mara Sanders, *Sex, Drugs, and Advisory Committees: An Analysis of Pharmaceutical Industry Manipulations of FDA Vulnerability to Sociopolitical Influences on Matters of Women's Health*, 48 COLUM. HUM. RTS. L. REV. 149, 158 (2017).

398. Gillian Metzger, *Abortion, Equality, and Regulation*, 56 EMORY L.J. 865, 900 (2007); see Sanders, *supra* note 397, at 159.

399. See Gillian Metzger, *The Interdependent Relationship Between Internal and External Separation of Powers*, 59 EMORY L.J. 423, 445 (2009) [hereinafter Metzger, *Separation of Powers*]; see also James T. O'Reilly, *Losing Deference in the FDA's Second Century: Judicial Review, Politics, and a Diminished Legacy of Expertise*, 93 CORNELL L. REV. 939, 953-55, 973-76 (2008).

400. See Sanders, *supra* note 397, at 160.

401. See Aziza Ahmed, *Abortion Experts*, 2022 U. CHI. LEGAL F. 1 (2022) ("the Trump administration encouraged the FDA to hold its ground on the enforcement [of its REMS and ETASU restrictions.]"); see also John Fielder, *Ethics and FDA*, 61 FOOD & DRUG L.J. 809, 810 (2009) (arguing that the George W. Bush administration attempted "to hijack the FDA approval process and use it for their own ethical views and political goals").

402. See *infra* Section III.B (discussing the long and challenging process Mifepristone faced while seeking FDA approval); see generally UNION OF CONCERNED SCIENTISTS, INTERFERENCE AT THE EPA: SCIENCE AND POLITICS AT THE U.S. ENVIRONMENTAL AGENCY (2008) (describing the political influence present over EPA decisions making during the Bush Administration and the Administration's "direct abuse of science."); Vladeck, *supra* note 315; Ahmed, *supra* note 401.

ambiguous statute so long as that interpretation is reasonable.<sup>403</sup> On May 1, 2023, the Supreme Court agreed to hear a case this coming term that explicitly challenges Chevron deference.<sup>404</sup> The Fifth Circuit’s silence regarding the application of the Chevron doctrine may indicate a broader impending retreat from agency deference. Expanding judicial authority at the expense of the authority of agencies has the potential of undermining the balance of power and weaken political accountability.

#### D. The Comstock Act

One of the substantive arguments raised by the Plaintiffs is that the FDA’s decision for all mifepristone to be sent through the mail violated the Comstock Act.<sup>405</sup> While the district court agreed with that interpretation, the Fifth Circuit majority did not.<sup>406</sup> However, in his concurrence, Judge Ho agreed with the Plaintiff’s argument that mail delivery of mifepristone is illegal under the Act.<sup>407</sup> Thus, this continues to be a live issue that could be addressed by the Supreme Court.

In 1873, Congress passed the Comstock Act.<sup>408</sup> It was enacted as part of a nationwide “purity campaign.”<sup>409</sup> Images that promoted contraception or abortion were considered to have the ability to cause sexual excitement, and therefore they were considered obscene.<sup>410</sup> When it was introduced, the bill included a health exception, that allowed prescriptions issued by “a physician in good standing, given in good faith.”<sup>411</sup> The bill was then amended and the exception deleted.<sup>412</sup>

403. *Chevron v. Nat’l Res. Def. Council, Inc.*, 467 U.S. 837, 865 (1984).

404. *Loper Bright Enters. v. Raimondo*, 45 F.4th 359 (D.C. Cir. 2022), *cert. granted*, 143 S. Ct. 2429 (2023).

405. *See All. for Hippocratic Med. v. U.S. FDA*, 668 F. Supp. 3d 507 (N.D. Tex. 2023)

406. *See id.*

407. *All. for Hippocratic Med. v. FDA*, 78 F.4th 210 (5th Cir. 2023) (Ho, J., concurring).

408. Comstock Act, ch. 258, § 2, 17 Stat. 598 (1873).

409. For a further discussion, see Priscilla J. Smith, *Contraceptive Comstockery: Reasoning from Immorality to Illness in the Twenty-First Century*, 47 CONN. L. REV. 971, 993 (2015) (The phrase “purity campaign” described a campaign to stop the distribution of offensive materials.), and Margaret A. Blanchard, *The American Urge to Censor: Freedom of Expression Versus the Desire to Sanitize Society—From Anthony Comstock to 2 Live Crew*, 33 WM. & MARY L. REV. 741, 747 (1992).

410. *See Judicial Regulation of Birth Control Under Obscenity Laws*, 50 YALE L.J. 682 (1941) (“By forbidding the mailing, importation, and interstate transportation of indecent articles and obscene publications and ‘contraceptives,’ Congress hoped to check the moral degeneration that followed the Civil War.”); *see* Peter Smith, *The History and Future of the Legal Battle over Birth Control*, 49 CORNELL L.Q. 275, 275-76 (1964) (section two of the Comstock Act “prohibited the use of the mails for the sending of any of the materials or articles outlawed in section one.”).

411. Cong. Globe, 42d Cong., 3d Sess. 1436 (1873).

412. *See id.* at 1571 (approving the bill without the exemption); Comstock Act, ch. 258, 17 Stat. 598 (1873) (failing to provide a good faith medical exception in the final act). There was very limited debate and some members of Congress admitted that they did not understand the bill or the

The inclusion of a ban on contraceptive devices and abortifacients in the obscene literature bill was advocated by Anthony Comstock, a well-known member of the New York Committee on the Suppression of Vice.<sup>413</sup> He argued that contraception and abortion promoted sex for pleasure rather than for procreation.<sup>414</sup> Just as obscene literature caused desires to be “inflame[d],”<sup>415</sup> contraceptives and abortion enabled people to have sex while escaping the fear of procreation.<sup>416</sup> Although the Act primarily impacted access to contraception with abortion as a secondary feature, it has now become significant in shaping the abortion conversation.

Attempts to repeal or modify the Comstock Act in the late nineteenth and early twentieth centuries were unsuccessful.<sup>417</sup> Eventually, birth control advocates and a small group of sex reformers began to change societal acceptance of contraceptives.<sup>418</sup> As medical knowledge about reproductive functions developed, the Comstock Act’s connection between obscenity and immorality on the one hand and contraceptives on the other resulted in the repeal of the Act’s contraceptive ban.<sup>419</sup> However, even though Congress recodified the Comstock Act in the 1940s and repealed the restrictions on contraceptives, the Act’s language on abortion remained in place.<sup>420</sup>

Section 1461 of the Act currently states that “[e]very article or thing designed, adapted, or intended for producing abortion,” as well as “[e]very article, instrument, substance, drug, medicine, or thing which is advertised or

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amendment. See *Judicial Regulation of Birth Control Under Obscenity Laws*, *supra* note 410; see also Smith, *supra* note 410 (highlighting that very little debate or discussion accompanied the amendment removing the physician exemption from the act).

413. Margaret A. Blanchard & John E. Semonche, *Anthony Comstock and His Adversaries: The Mixed Legacy of This Battle for Free Speech*, 11 COMM. L. & POL’Y 317, 320, 323 (2006).

414. *Id.*; see Cong. Globe, 42d Cong., 3d Sess. App. at 168.

415. Blanchard & Semonche, *supra* note 413.

416. *Id.*

417. See Smith, *supra* note 410, at 276-77 (stating there were “unsuccessful attempts to repeal or modify the Comstock Act” in 1878, 1919, 1923, and many times between 1930 and 1936).

418. See *Judicial Regulation of Birth Control Under Obscenity Laws*, *supra* note 410, at 685-86 n.35 (describing poll results which indicated public opposition to birth control laws).

419. *Id.*

420. “The last time the act was amended, in 1996, Patricia Schroeder, then a Democratic representative from Colorado, fought to remove the provision about mailing abortion materials, but the effort fell short. ‘Comstockery has been given a new lease on life by this Congress,’ Ms. Schroeder, who died in March, mourned at the time in a floor speech. Barney Frank, a Massachusetts Democrat, was involved in the 1996 effort. The repeal failed, he said in a recent interview, because at that time, ‘abortion was overwhelmingly unpopular among Republicans and also seen as a wedge issue that could be used against Democrats.’ Newt Gingrich, the Republican Speaker of the House in 1996, said that then and now, ‘both parties face the challenge of avoiding being the extremist’ on abortion. He distinguished between narrowing the Comstock Act and repealing it entirely, saying repeal ‘would be a different kind of fight.’” Emily Bazelon, *Why a 150-Year-Old Lewdness Law is Key to the Abortion Pill Battle*, N.Y. TIMES, May 17, 2023, at A14.



described in a manner calculated to lead another to use or apply it for producing abortion,” is “nonmailable matter” that the United States Postal Service may not lawfully deliver.<sup>421</sup> The federal government has long understood the Act only to forbid the mailing of items that may be used in an abortion where the sender possesses the “intent that the recipient . . . will use them unlawfully.”<sup>422</sup> The Justice Department issued a legal memo in December 2022 concluding that the Comstock Act does not prevent the mailing of abortion medication when the sender believes the drug will be used lawfully in states where abortion is permitted.<sup>423</sup>

When Alliance Defending Freedom brought its action against the FDA’s approval of the mifepristone, however, it cited the 150-year-old Act to support its argument.<sup>424</sup> Then, when Judge Kacsmaryk ruled to suspend the Food and Drug Administration’s approval of mifepristone, he relied in part on the Comstock Act, finding that the meaning of the law was clear from the text, an appealing argument to other conservative judges who consider themselves “textualists” with a focus on the original wording of the statute.<sup>425</sup> During oral argument, the Fifth Circuit indicated that it might be open to arguments that the Comstock Act applies, when Judge Walker Elrod noted that there was “some disagreement” over the Justice department’s conclusion that the Act does not prohibit the mailing of abortion drugs.<sup>426</sup>

In its written decision, the Fifth Circuit panel stopped short of “a conclusive exploration of the topic,” but opined that the text of the Comstock Act favors the anti-abortion medical groups seeking to limit the drug’s access.<sup>427</sup> The majority of the panel stated, “we hesitate to find ‘clear and manifest’ intention to repeal a 150-year-old statute that Congress has otherwise repeatedly declined to alter in the far reaches of a single section of the cavernous FDAAA.”<sup>428</sup>

Up until recently, the Comstock Act has not been part of the abortion debate.<sup>429</sup> It has now reemerged. Those supporting the ban of abortions and are modeling their arguments on Anthony Comstock<sup>430</sup> by claiming that abortion is

421. 18 U.S.C. § 1461.

422. Application of the Comstock Act to the Mailing of Prescription Drugs that Can Be Used for Abortions, 2022 WL 18273906 (O.L.C. Dec. 23, 2022).

423. *See id.*

424. *See* Amber Phillips, *How an Old, Anti-Porn Law Could Be Used to End Medication Abortion*, WASH. POST (Apr. 19, 2023, 3:33 PM), <https://www.washingtonpost.com/politics/2023/04/19/comstock-act-explained/> [<https://perma.cc/5EDC-34MJ>].

425. *See* Dan Diamond & Ann E. Marimow, *A 150-Year-Old Law Could Help Determine the Fate of U.S. Abortion Access*, WASH. POST (May 16, 2023, 6:00 PM), <https://www.washingtonpost.com/health/2023/05/16/comstock-act-abortion-access/> [<https://perma.cc/NDL8-VEDX>].

426. *See id.*

427. *See id.*

428. *See* All. for Hippocratic Med. v. FDA, 78 F.4th 210 (5th Cir. 2023).

429. *See* Phillips, *supra* note 424.

430. *See* Diamond & Marimow, *supra* note 425 (“While Comstock is often portrayed as an arch-critic of abortion, his views on the procedure appear to be nuanced and not fully known. His

immoral and leads to obscenity and that it poses a danger to women's health.<sup>431</sup> As illustrated in the recent cases, it has now become part of the effort to ban all abortions nationwide.<sup>432</sup> Thus, the impact of the Act is still felt, especially in light of the recent developments in abortion litigation.

If the Fifth Circuit has signaled the importance of the Comstock Act to the Supreme Court, the Court will have the opportunity to interpret the language to find that it only applies to the mailing of items if the sender knows the items are intended to be used "illegally" for abortions. In that case, little or nothing would change in states where abortion is legal. If the Court decides that the Comstock Act bars mailing mifepristone even when used legally or that the Act prohibits the shipping of all abortion medication, that will create a huge problem with access to healthcare.

More broadly, if the Court determines that the Comstock Act applies to mifepristone, the language could also apply to any other item or tool that is used to terminate a pregnancy. This view of the Comstock Act would have "potentially boundless effects on medical care delivery"<sup>433</sup> by preventing the distribution of all medical equipment used in obstetrics and gynecology. It would have the effect of compelling a nationwide ban on abortions, even in states where it is legal. While it might seem outlandish to base a decision on an Act that was enacted over 150 years ago, when women could not vote, could not practice law, and were not a part of the political process, it is consistent with the decision in *Dobbs*, where the Court overturned *Roe v. Wade* based on the law as it stood in 1868.<sup>434</sup>

#### CONCLUSION

For now, it appears that the Supreme Court is not completely convinced by

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knowledge of conception and pregnancy—shaped in part by witnessing his mother die from childbirth—was limited, biographer Amy Sohn writes in her book, *The Man Who Hated Women*. 'The man who did more to curtail women's rights than anyone else in American history had nearly no understanding of reproduction; he believed a fetus could form seconds after unprotected sex,' Sohn writes.').

431. "Allan Carlson, President of The Howard Center for Family, Religion, and Society, draws on this nineteenth century history in an article that appears as a sort of strategic blueprint for contemporary opponents of contraceptives. The article celebrates the role of Evangelical Protestants in general, and Anthony Comstock in particular, in enacting the 'only effective laws suppressing birth control information and devices.' According to Carlson, opposition to contraception for Anthony Comstock was grounded in 'a natural law that encompassed human sexuality.' Carlson grounds Comstock's success in two strategies. The first was connecting contraceptives and abortion to obscenity and immorality. As reported by Carlson, Comstock argued to his backers that the 'availability of contraceptives encouraged immoral behavior,' i.e., non-procreative sex." See Priscilla J. Smith, *Contraceptive Comstockery: Reasoning from Immorality to Illness in the Twenty-First Century*, 47 CONN. L. REV. 971, 993 (2015).

432. See Diamond & Marimow, *supra* note 425.

433. *Id.*

434. *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2238, 2267 (2022).

the position taken by the Plaintiffs in *Alliance for Hippocratic Medicine*. In order to grant the stay, the Court had to analyze who was likely to prevail on the merits of the case.

Because the Court granted the stay, a majority of justices must be of the view that the FDA will ultimately prevail. There are many reasons for the Court to come to that conclusion. While problematic, the selection of the conservative forum was not inappropriate. That being said, the case was filed over twenty years after the drug was approved, creating serious problems with the statute of limitations. There are critical issues with standing. On the merits, the 150-year-old Comstock Act is clearly being used in a way that would have a boundless effect on the delivery of health care. All of this may seem like too much for a Court that many say already overstepped its bounds in *Dobbs*.

On the other hand, the Fifth Circuit's decision may signal how this conservative Supreme Court will rule. If the Supreme Court follows the lead of the Fifth Circuit, mifepristone would again require three visits to a doctor to receive the two-pill regimen, decrease the number of weeks after conception that the drug can be prescribed from ten to seven, and lower the dosage which could lead to more side effects. While the Fifth Circuit opinion might seem muted compared to the district court's opinion, if the Supreme Court eventually embraces its reasoning and rationales, abortion access will further contract with the elimination of virtual clinics, increased costs, and a transformed experience for patients. Furthermore, many court observers—perhaps relieved that Judge Ho's extreme position did not carry the day—underestimate the sweeping and broad changes that the Fifth Circuit's majority opinion makes to the standing doctrine. The legal battles over medication abortion are far from over. If *Dobbs* has taught equality advocates anything, it is this: Watch carefully because nothing should be taken for granted.