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NOTE

STANDING BEYOND REASON: AFFIRMING THE SUPREME COURT'S DECISION IN *ALLIANCE FOR HIPPOCRATIC MEDICINE V. FDA*[*]

I. INTRODUCTION

There is a lot to be said about the Supreme Court's 2022 decision in *Dobbs v. Jackson Women's Health Organization*; it is, after all, a 226-page decision that revokes a woman's right to bodily autonomy—a right that the Court itself recognized as fundamental for nearly half a century.[1] One sentence of particular note, buried in Justice Brett Kavanaugh's concurrence, applauds the decision as an example of "judicial neutrality" and one that "returns the issue of abortion to the people and their elected representatives in the democratic process."[2] The suggestion that *Dobbs* effectively removed the judiciary from the nation's ongoing abortion debate was wildly naïve. Less than six months after *Dobbs* was decided, the question of abortion—more specifically, the safety of abortion pills—was again presented to the federal court system.[3]

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1. *See* Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228, 2284–85 (2022); *cf.* Roe v. Wade, 410 U.S. 113, 152–54 (1973) ("[O]nly personal rights that can be deemed 'fundamental' or 'implicit in the concept of ordered liberty'. . . are included in this guarantee of personal privacy. . . . We, therefore, conclude that the right of personal privacy includes the abortion decision . . . ." (citations omitted) (quoting Palko v. Connecticut, 302 U.S. 319, 325 (1937))).

2. *Dobbs*, 142 S. Ct. at 2310 (Kavanaugh, J., concurring).

3. All. for Hippocratic Med. v. FDA, 668 F. Supp. 3d 507, 520 (N.D. Tex. 2023).

In November 2022, a lawsuit was filed in the Northern District of Texas, Amarillo Division,[4] by a band of antiabortion advocacy groups called the Alliance for Hippocratic Medicine, as well as a handful of emergency room doctors, many of whom were also avowed antiabortion advocates.[5] The lawsuit was brought against the Food and Drug Administration (FDA), challenging the way the FDA approved and regulated the abortion-inducing drug mifepristone.[6] The district court found in favor of the plaintiffs in a ruling that would have removed mifepristone from the market entirely but for an interlocutory appeal.[7] The FDA appealed to the Fifth Circuit, which determined that mifepristone's initial approval was lawful[8] but that the FDA's subsequent regulatory actions—which loosened restrictions on the drug and thus made it easier to access and use—were unlawful.[9] Finally, the case arrived at the Supreme Court, which held that the antiabortion plaintiffs lacked standing.[10] The Supreme Court determined that the plaintiffs did not experience concrete, particularized injuries, nor did they sufficiently establish that they were at risk of future harm such that prospective relief was warranted.[11] As the Supreme Court rightly noted,[12] the Fifth Circuit's grant of unwarranted standing was a harmful expression of judicial overreach and the Supreme Court was correct in reversing its decision.

II. FACTS

A. Background: Mifepristone

Mifepristone is an abortion-inducing drug that was approved by the FDA in 2000.[13] The pill, which is the first of a two-drug regimen, chemically induces an abortion by blocking the hormone progesterone, thereby terminating a pregnancy's progression.[14] Mifepristone has been on the market for over two decades and is widely

4. *Id.*

5. FDA v. All. for Hippocratic Med., 144 S. Ct. 1540, 1559 (2024) ("[T]he plaintiffs say that they are pro-life, oppose elective abortion, and have sincere legal, moral, ideological, and policy objections to mifepristone being prescribed and used by others." (emphasis omitted)).

6. All. for Hippocratic Med. v. FDA, 668 F. Supp. 3d at 520.

7. Danco Lab'ys, LLC v. All. for Hippocratic Med., 143 S. Ct. 1075 (2023) (staying the decision of the district court until the end of the appeal process).

8. The court determined that the plaintiff's challenge to the initial approval was time-barred and thus could not reach the merits of whether the approval process was legal. All. for Hippocratic Med. v. FDA, 78 F.4th 210, 222 (5th Cir. 2023).

9. *Id.* at 256–57.

10. FDA v. All. for Hippocratic Med., 144 S. Ct. at 1552.

11. *Id.* at 1563.

12. *Id.* at 1555 ("By limiting who can sue, the standing requirement implements 'the Framers' concept of the proper—and properly limited—role of the courts in a democratic society.").

13. *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/A3FY-JSKV] (Jan. 17, 2025).

14. *Id.*

regarded as safe, reliable, and effective.[15] Indeed, the FDA reports that of the approximately six million people who have used mifepristone since 2000, only thirty-two have died, which means that the drug has a 0.0005% fatality rate.[16] Many widely used drugs—like Viagra, which treats erectile dysfunction—have higher fatality rates.[17] Studies also indicate that abortion generally is safer than pregnancy and childbirth.[18]

To understand the legal battle over mifepristone, it is valuable to understand the process by which the drug was approved. Mifepristone was approved by the FDA pursuant to the agency's Subpart H regulations,[19] "Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses," developed largely in response to the HIV/AIDS epidemic of the 1980s and 1990s.[20] Subpart H regulations allowed the agency to accelerate approval for certain drugs if the drug provided a substantial therapeutic benefit to patients over existing treatments.[21] It is critically important to note, however, that Subpart H contains two approval provisions. One provision allows for accelerated approval of drugs like those created to fight HIV/AIDS.[22] The second provision allows the FDA to impose restrictions on the use and distribution of the drug once the agency has approved it.[23] Mifeprex, the brand name version of mifepristone, was approved via the latter provision of Subpart H, thereby allowing the FDA to

15. *See* U.S. FOOD & DRUG ADMIN., TTT No. 2022-2468, MIFEPRISTONE U.S. POST-MARKETING ADVERSE EVENTS SUMMARY THROUGH 12/31/2022 (2022) [hereinafter MIFEPRISTONE ADVERSE EVENTS SUMMARY], https://www.fda.gov/media/164331/download [https://perma.cc/EQ5R-BAGX] (explaining that the "estimated number of women who have used mifepristone in the U.S. for medical termination of pregnancy through the end of December 2022 is approximately 5.9 million women" and including a table which states that only 32 of the 5.9 million women have died, and only 4,218 have experienced any type of adverse event); Amy Schoenfeld Walker, Johnathan Corum, Malika Khurana & Ashley Wu, *Are Abortion Pills Safe? Here's the Evidence.*, N.Y. TIMES (Apr. 7, 2023), https://www.nytimes.com/interactive/2023/04/01/health/abortion-pill-safety.html ("More than 100 scientific studies, spanning continents and decades, have examined the effectiveness and safety of mifepristone and misoprostol, the abortion pills that are commonly used in the United States. All conclude that the pills are a safe method for terminating a pregnancy.").

16. MIFEPRISTONE ADVERSE EVENTS SUMMARY, *supra* note 15.

17. Mike Mitka, *Some Men Who Take Viagra Die—Why?*, 283 JAMA 590, 593 (2000) (noting that Viagra is associated with forty-nine deaths per one million prescriptions).

18. *E.g.*, Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 OBSTETRICS & GYNECOLOGY 215, 215 (2012) ("The pregnancy-associated mortality rate among women who delivered live neonates was 8.8 deaths per 100,000 live births. The mortality rate related to induced abortion was 0.6 deaths per 100,000 abortions. In the one recent comparative study of pregnancy morbidity in the United States, pregnancy-related complications were more common with childbirth than with abortion.").

19. U.S. GOV'T ACCOUNTABILITY OFF., GAO-08-751, FOOD AND DRUG ADMINISTRATION: APPROVAL AND OVERSIGHT OF THE DRUG MIFEPREX 5 (2008).

20. Jessica Holden Kloda & Shahza Somerville, *FDA's Expedited Review Process: The Need for Speed*, APPLIED CLINICAL TRIALS (Mar. 11, 2015), https://www.appliedclinicaltrialsonline.com/view/fda-s-expedited-review-process-need-speed [https://perma.cc/KB2Y-JWWJ] ("In 1992, in response to a push by AIDS advocates to make the investigational anti-AIDS drug azidothymidine (AZT) accessible, the FDA enacted 'Subpart H' commonly referred to as Accelerated Approval; giving rise to expedited review of drugs by the FDA.").

21. U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 19, at 1 n.2.

22. 21 C.F.R. § 314.510 (2023).

23. *Id.* § 314.520.

impose restrictions on how mifepristone was prescribed and distributed even after it received FDA approval.[24] The Food and Drug Administration Amendments Act of 2007 (FDAAA) codified the FDA's ability to impose post-approval restrictions on the use and distribution of drugs.[25] These measures are referred to as Risk Evaluation and Mitigations Strategies (REMS).[26]

There were several REMS initially imposed on mifepristone.[27] Generally speaking, the REMS dictated when mifepristone could be taken during a pregnancy, who could prescribe mifepristone, and how many in-person office visits were required to receive a prescription.[28] In 2016, relying on robust clinical data, the FDA loosened the REMS that were in place for mifepristone, making it easier to prescribe and obtain the drug.[29] In 2019, the FDA approved the generic version of Mifeprex and applied the same (loosened) REMS to generic mifepristone as Mifeprex.[30] Finally, in the wake of the COVID-19 pandemic, the FDA enacted a handful of other changes to the REMS, loosening in-person prescription and distribution requirements.[31] All of these agency actions were being challenged by the plaintiffs in the *Hippocratic Medicine* lawsuit.[32]

B. Background: Plaintiffs

The plaintiffs in this case were a coalition of antiabortion medical groups, known collectively as the Alliance for Hippocratic Medicine, as well as a handful of emergency room doctors.[33] Two member organizations of the Alliance are also separately named as plaintiffs: the Christian Medical and Dental Association (CMDA) and the American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG).[34] AAPLOG was originally a special interest group within the American College of Obstetricians and Gynecologists (ACOG), the primary professional membership organization for obstetricians and gynecologists in the nation.[35] In 2013, ACOG ended the practice of maintaining special interest groups, which led to

24. U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 19, at 6.

25. U.S. DEP'T HEALTH & HUM. SERVS., FOOD & DRUG ADMIN., REMS: FDA'S APPLICATION OF STATUTORY FACTORS IN DETERMINING WHEN A REMS IS NECESSARY 2 (2019), https://www.fda.gov/media/100307/download [https://perma.cc/3WCN-2ELH].

26. 21 U.S.C. § 355-1.

27. All. for Hippocratic Med. v. FDA, 78 F.4th 210, 224–25 (5th Cir. 2023).

28. *Id.*

29. *Id.* at 222.

30. *Id.*

31. *Id.* at 226; *see also Updated Mifepristone REMS Requirements*, AM. COLL. OBSTETRICIANS & GYNECOLOGISTS: PRAC. ADVISORY (Jan. 2023), https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2023/01/updated-mifepristone-rems-requirements [https://perma.cc/G8PQ-W52F].

32. All. for Hippocratic Med. v. FDA, 668 F. Supp. 3d 507, 520 (N.D. Tex. 2023).

33. All. for Hippocratic Med. v. FDA, 78 F.4th at 222; *see also Our Partnering Organizations*, ALL. HIPPOCRATIC MED., https://allianceforhippocraticmedicine.org/ [https://perma.cc/89PY-HLNC] (last visited Feb. 2, 2025).

34. All. for Hippocratic Med. v. FDA, 78 F.4th at 222.

35. *About*, AM. COLL. OBSTETRICIANS AND GYNECOLOGISTS, https://www.acog.org/about [https://perma.cc/DH3Y-6XUV] (last visited Feb. 2, 2025) [hereinafter *About* ACOG]; *About Us*, AM. ASSOC. PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS, https://aaplog.org/about-us/ [https://perma.cc/3384-XZJR] (last visited Jan. 14, 2025) [hereinafter *About* AAPLOG].

AAPLOG splitting off into a distinct organization.[36] ACOG, which has roughly 60,000 members, has long been supportive of increasing abortion access.[37] Its current policy statement, which was adopted in 1993 and has been regularly reaffirmed throughout the past thirty years, emphasizes that "[a]bortion is an essential component of comprehensive, evidence-based health care. . . . [ACOG] supports the availability of high-quality reproductive health services for all people and is committed to protecting and increasing access to abortion."[38]

AAPLOG, meanwhile, has vocally opposed abortion and advocated for restrictions on access to abortion.[39] It has far fewer members than ACOG[40] but has been involved in numerous lawsuits implicating reproductive healthcare.[41] In addition to the suit challenging the FDA over mifepristone, which is the subject of this Note, AAPLOG joined in a lawsuit brought by the state of Texas. This lawsuit sought to invalidate federal regulations requiring hospitals to provide abortion services if necessitated by a patient's medical emergency.[42]

III. PRIOR LAW

A. Article III Standing

Article III of the Constitution dictates that courts can oversee "[c]ases" and "[c]ontroversies."[43] Over time, the Supreme Court has established certain parameters that dictate whether a federal court can adjudicate a case, often referred to as "justiciability."[44] One element of justiciability is standing.[45] The standing doctrine limits who is able to bring a case into court by requiring that litigants are personally connected to the controversy and have a personal stake in the outcome of the case.[46]

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36. *About* AAPLOG, *supra* note 35.

37. *About* ACOG, *supra* note 35.

38. *Abortion Policy*, AM. COLL. OBSTETRICIANS AND GYNECOLOGISTS, https://www.acog.org/clinical-information/policy-and-position-statements/statements-of-policy/2022/abortion-policy [https://perma.cc/4T7Y-JR3E] (last visited Feb. 2, 2025).

39. *See Latest News*, AM. ASS'N PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS, https://aaplog.org/latest-news/ [https://perma.cc/V7TC-JDTC] (last visited Jan. 14, 2025) (listing pro-life op-eds that AAPLOG published and amici briefs submitted in abortion cases).

40. Christina Francis, *Written Testimony of Christina Francis, MD for the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce Hearing on "Roe Reversal: The Impacts of Taking Away the Constitutional Right to Abortion"*, AM. ASS'N. PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS (July 16, 2022), https://docs.house.gov/meetings/IF/IF02/20220719/114995/HHRG-117-IF02-Wstate-FrancisMDC-20220719.pdf [https://perma.cc/L83U-S5MD] (according to written testimony provided to Congress by an AAPLOG board member, it has a membership of "nearly 7,000 members across the country and internationally").

41. *See, e.g.*, All. for Hippocratic Med. v. FDA, 78 F.4th 210, 222 (5th Cir. 2023); Texas v. Becerra, 623 F. Supp. 3d 696, 703–04 (N.D. Tex. 2022).

42. *Becerra*, 623 F. Supp. 3d at 703–04.

43. U.S. CONST. art. III, § 2.

44. WILSON C. FREEMAN & KEVIN M. LEWIS, CONG. RSCH. SERV., R45636, CONGRESSIONAL PARTICIPATION IN LITIGATION: ARTICLE III AND LEGISLATIVE STANDING 2 (2019).

45. *Id.*

46. James L. Buchwalter, Annotation, *Supreme Court Jurisprudence on Article III Standing*, 41 A.L.R. Fed. 3d Art. 5, § 3.5 (2019).

In *Lujan v. Defenders of Wildlife*, the Supreme Court laid out a three-pronged test for a plaintiff to establish standing.[47] The essential elements that a plaintiff must prove are (1) an injury in fact, (2) that the injury was caused by the challenged action, and (3) that the injury will be redressed by the proposed relief.[48] Although all three elements must be proven, scholars note that demonstrating an injury in fact is often the focal point of a standing analysis because neither the second nor the third prong can be met without first establishing a cognizable injury.[49]

So, what is an injury in fact? The Court in *Lujan* elaborated that an injury in fact requires "an invasion of a legally protected interest which is . . . concrete and particularized."[50] "Concrete" in this sense does not mean tangible, for the invasion of a legally protected interest can often be intangible.[51] For example, the Court in *Lujan* wrote that "the desire to use or observe an animal species, even for purely esthetic purposes, is undeniably a cognizable interest for purpose of standing."[52] Although the Court ultimately held that the environmental conservation organization plaintiffs did not have standing to sue the Secretary of the Interior, the "cognizable interest" validated by the Court was undeniably intangible.[53] A concrete injury can instead be understood as an injury that is real, as opposed to one that is abstract.[54]

A general principle of standing is that a plaintiff must have standing for each claim brought and for each form of relief sought.[55] Therefore, when a plaintiff seeks injunctive relief, she must demonstrate that there is a threat of an injury, and "the threat must be actual and imminent, not conjectural or hypothetical."[56] "Imminent" is an imprecise word, but various Supreme Court decisions offer examples of when a future injury is insufficiently imminent to establish standing.[57]

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47. Lujan v. Defs. of Wildlife, 504 U.S. 555, 560–61 (1992).

48. *Id.*

49. FREEMAN & LEWIS, *supra* note 44, at 3.

50. *Lujan*, 504 U.S. at 560 (citing City of Los Angeles v. Lyons, 461 U.S. 95 (1983)).

51. FREEMAN & LEWIS, *supra* note 44, at 3.

52. *Lujan*, 504 U.S. at 562–63.

53. *Id.* at 562, 578.

54. *See* 13A CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE § 3531.4 (3d ed. 2023) ("One common practice is to distinguish between the mere 'abstract injury' that is not sufficient to confer standing and the 'concrete injury' that is sufficient."); *Lyons*, 461 U.S. at 101–02 ("Abstract injury is not enough. The plaintiff must show that he 'has sustained or is immediately in danger of sustaining some direct injury' as the result of the challenged official conduct and the injury or threat of injury must be both 'real and immediate' . . . .").

55. FREEMAN & LEWIS, *supra* note 44, at 2 ("Further, a litigant must demonstrate standing for each claim he seeks to press and each form of relief that he seeks to obtain.").

56. Summers v. Earth Island Inst., 555 U.S. 488, 493 (2009).

57. *See, e.g.*, *Lyons*, 461 U.S. at 105 ("Lyons' standing to seek the injunction requested depended on whether he was likely to suffer future injury from the use of the chokeholds by police officers. . . . The additional allegation in the complaint that the police in Los Angeles routinely apply chokeholds in situations where they are not threatened by the use of deadly force falls far short of the allegations that would be necessary to establish a case or controversy between these parties."); *Summers*, 555 U.S. at 496 ("This vague desire to return is insufficient to satisfy the requirement of imminent injury: 'Such "some day" intentions—without any description of concrete plans, or indeed any specification of *when* the some day will be—do not support a finding of the "actual or imminent" injury that our cases require.'" (quoting *Lujan*, 504 U.S. at 564)); Clapper v. Amnesty Int'l USA, 568 U.S. 398, 410 (2013) ("[R]espondents' theory of standing,

A seminal case in this regard is *City of Los Angeles v. Lyons*.[58] In that case, the plaintiff, Lyons, had been placed in a harmful (but legal) chokehold by the police.[59] In addition to monetary damages, he sought injunctive relief to ban the use of police chokeholds in the city.[60] The Court ultimately held that, while he was entitled to damages, Lyons had failed to prove that the threatened injury—namely, the Los Angeles police's use of chokeholds—was actual and imminent, and thus, he lacked standing.[61] In reversing the finding of the Ninth Circuit, the Supreme Court wrote that it "[could not] agree that the 'odds' . . . that Lyons would not only again be stopped for a traffic violation but would also be subjected to a chokehold without any provocation whatsoever are sufficient to make out a federal case for equitable relief."[62]

In a more recent case brought by environmentalists, the Supreme Court again considered whether an injury was sufficiently imminent to confer standing.[63] The conservationist organization plaintiffs in *Summers v. Earth Island Institute* sought injunctive relief to prevent the United States Forest Service from allowing small-scale fire rehabilitation and timber salvage projects to proceed without the same public notice and appeals process as is usually applied to larger-scale projects.[64] Plaintiffs argued that they had organizational standing because their members had a recreational interest in the National Forest Service lands, and so the challenged regulations threatened an injury in fact to the organization.[65] Although the Court recognized the legitimacy of the injury, it rejected that the injury was imminent enough to confer standing because no proof was offered that members of the plaintiff organization had any specific plans to visit any specific sites implicated in the Forest Service regulations.[66] The majority opinion soundly rejected using "statistical probability" to determine that an injury in fact was imminent, even given the number of members in the organization and the amount of forest land affected by the regulations.[67] The Court wrote that to embrace such an approach to organizational standing "would make a mockery of our prior cases, which have required plaintiff-organizations to make specific allegations establishing that at least one identified member had suffered or would suffer harm."[68]

A third case, decided by the Supreme Court in 2013, provides the most helpful articulation of the imminence requirement in cases seeking injunctive relief.[69] Plaintiffs

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which relies on a highly attenuated chain of possibilities, does not satisfy the requirement that threatened injury must be certainly impending.").

58. *Lyons*, 461 U.S. at 101–02.

59. *Id.*

60. *Id.* at 97–98.

61. *Id.* at 108 ("[I]t may be that among the countless encounters between the police and the citizens of a great city such as Los Angeles, there will be certain instances in which strangleholds will be illegally applied and injury and death unconstitutionally inflicted on the victim. . . . [However,] it is surely no more than speculation to assert . . . that Lyons himself will again be involved in one of those unfortunate instances . . . .").

62. *Id.*

63. Summers v. Earth Island Inst., 555 U.S. 488, 493 (2009).

64. *Id.* at 490–91.

65. *Id.* at 494.

66. *Id.* at 495.

67. *Id.* at 497.

68. *Id.* at 498.

69. Clapper v. Amnesty Int'l USA, 568 U.S. 398, 401 (2013).

in *Clapper v. Amnesty International USA* were journalists, attorneys, and human rights workers whose work involved conducting sensitive and occasionally privileged communications with clients and sources living abroad.[70] Plaintiffs challenged a law authorizing the surveillance of certain non-American individuals, asserting that the law violated their constitutional rights because the communications between them and their foreign clients were likely to be surveilled.[71] Plaintiffs argued there was "an objectively reasonable likelihood" that their sensitive communications would be spied upon because of the challenged statute.[72] However, the standard required to establish the imminence of an injury is not "objectively reasonable likelihood," but rather that the "threatened injury [be] certainly impending."[73] To come to this decision, the Court relied on *Summers* and noted that a "theory of standing, which relies on a highly attenuated chain of possibilities, does not satisfy the requirement that threatened injury must be certainly impending."[74] Taken together, *Lyons*, *Summers*, and *Clapper* provide a framework for conducting a standing analysis when a plaintiff seeks prospective relief.[75] The threatened injury cannot be "conjectural,"[76] nor can it rely on a "highly attenuated chain of possibilities."[77] Instead, it must be "certainly impending."[78]

This Note focuses primarily on the injury in fact prong of Article III standing analysis, along with the imminence requirement for injunctive relief, because the Supreme Court in *Hippocratic Medicine* held that these were the necessary standing elements that the plaintiffs failed to establish.[79] However, for standing, a plaintiff must also establish causation (that the challenged action is the cause of the injury) and redressability (that a favorable disposition will redress the asserted injury).[80] There is a complex body of case law that addresses the interwoven issues of causation and redressability,[81] but that is mostly outside the scope of this Note. Suffice it to say, for a plaintiff to establish standing, all three elements of the test laid out in *Lujan* must be met.[82]

B. Federal Conscience Protections

Individual doctors are protected by numerous federal laws against being compelled to participate in procedures, like abortion, which violate their conscience.[83]

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70. *Id.* at 406.

71. *Id.* at 406–07.

72. *Id.* at 401.

73. *Id.*

74. *Id.* at 410.

75. *See generally* City of Los Angeles v. Lyons, 461 U.S. 95 (1983); Summers v. Earth Island Inst., 555 U.S. 488 (2009); *Clapper*, 568 U.S. 398.

76. *Lyons*, 461 U.S. at 102.

77. *Clapper*, 568 U.S. at 410.

78. *Id.*

79. FDA v. All. for Hippocratic Med., 144 S. Ct. 1540, 1552 (2024).

80. FREEMAN & LEWIS, *supra* note 44, at 3.

81. WRIGHT & MILLER, *supra* note 54.

82. FREEMAN & LEWIS, *supra* note 44, at 2–3.

83. *Conscience and Religious Nondiscrimination*, U.S. DEP'T OF HEALTH & HUM. SERVS. (Jan. 10, 2023), https://www.hhs.gov/conscience/conscience-protections/index.html [https://perma.cc/JX9Z-RZXH].

Collectively, these laws are referred to as "Federal Health Care Provider Conscience Protection Laws."[84] One especially relevant set of provisions instituted in the 1970s, the Church Amendments, contains broad conscience protections for doctors.[85] One provision within the Church Amendments reads:

> No individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services if his performance or assistance in the performance of such part of such program or activity would be contrary to his religious beliefs or moral convictions.[86]

This provision provides especially broad conscience protection because the protection emanates from the subjective belief of the individual doctor, rather than being tied to any particular medical procedure.[87]

More recent federal laws have reaffirmed doctors' conscience protections.[88] The Public Health Service Act Section 245, which was enacted in 1996, prevents federal, state, and local governments receiving federal assistance from discriminating against any health entity for refusing abortion-related trainings, refusing to make abortion referrals, or refusing to perform abortions.[89] Even more recently, the Affordable Care Act also contains conscience protections for doctors unwilling to participate in abortion or abortion-related procedures.[90] The robust set of federal conscience protection laws in place in this country further undermine the plaintiffs' averments of alleged injury in *Hippocratic Medicine*, as will be discussed more fully below.

For the sake of brevity, this Note does not address in depth another federal law that plays a minor role in this case: the Emergency Medical Treatment and Active Labor Act (EMTALA). This law essentially requires hospitals to provide emergency services to any patient who presents to the emergency room.[91] Plaintiffs argued that EMTALA requires emergency room doctors to provide abortion as lifesaving medical treatment, even if doing so violates the doctor's sincerely held moral beliefs against abortions.[92] The FDA argued that EMTALA compelled *hospitals*, not *individual doctors* to provide lifesaving abortion treatment.[93] Ultimately, the Supreme Court was persuaded that EMTALA does not override the federal conscience protection laws

84. Off. for Civ. Rts., *Fact Sheet: Your Rights Under the Federal Health Care Provider Conscience Protection Laws*, U.S. DEP'T OF HEALTH & HUM. SERVS. (May 2012), https://www.hhs.gov/sites/default/files/ocr/civilrights/provider_conscience_factsheet.pdf [https://perma.cc/FX7G-HH2W].

85. 42 U.S.C. § 300a-7.

86. 42 U.S.C. § 300a-7(d).

87. *Id.*

88. *See, e.g.*, *id.*; *id.* § 238n; *id.* § 18023(c).

89. Id. § 238n.

90. Id. § 18023(c).

91. Joseph Zibulewsky, *The Emergency Medical Treatment and Active Labor Act: What It Is and What It Means for Physicians*, 14 BAYLOR UNIV. MED. CTR. PROC. 339, 339 (2017).

92. FDA v. All. for Hippocratic Med., 144 S. Ct. 1540, 1560 (2024).

93. *Id.*

described above, nor does it compel antiabortion medical providers to provide medical treatment that violates their conscience.[94]

IV. COURT'S ANALYSIS

The Supreme Court correctly determined that the plaintiffs in *Hippocratic Medicine* do not have standing, reversing the decision of the Fifth Circuit.[95] The Court considered and rejected three categories of injury presented by the plaintiffs: economic, conscience, and associational.[96] This Note looks specifically at the alleged economic and conscience injuries in order to elaborate on the Supreme Court's well-reasoned decision to deny the legitimacy of those injuries and ultimately deny standing to the plaintiffs.

A. Economic Injuries

The Supreme Court identified the same distinct economic harms that the Fifth Circuit identified. However, unlike the Fifth Circuit, the Court rejected all of those harms as being "highly speculative" and not causally related to the challenged FDA actions.[97] The first purported economic injury was that plaintiffs "sustain a concrete injury when they are forced to divert time and resources away from their regular patients."[98] This assertion begs a question the lower courts failed to engage with: How specifically is such a diversion an economic harm experienced by an individual doctor?

In order to legitimize this claim, the Fifth Circuit relied on several testimonial accounts contained within the plaintiffs' complaint.[99] One plaintiff, Dr. Donna Harrison, testified that "[w]hen women suffer complications from chemical abortions, it can overwhelm the medical system and consume crucial limited medical resources, including blood for transfusions, physician time and attention, space in hospital and medical centers, and other equipment and medicines."[100] While the burdening of the medical system is undoubtedly concerning for the general public welfare, it is not clear how any individual doctor experiences a "particularized" harm because of that. In rejecting this claim, the Supreme Court wrote that "the law has never permitted doctors to challenge the government's loosening of general public safety requirements simply because more individuals might then show up at emergency rooms or in doctors' offices with follow-on injuries."[101]

Recognizing this as a cognizable injury would have presented a nearly limitless theory of standing, as the Supreme Court pointed out.[102] Using this reasoning, any doctor could bring suit over any law or regulatory action that caused more patients to

94. *Id.* at 1561.

95. *Id.* at 1552.

96. *Id.* at 1559. A discussion of associational standing is outside the scope of this Note.

97. *Id.* at 1561.

98. All. for Hippocratic Med. v. FDA, 78 F.4th 210, 235 (5th Cir. 2023).

99. *Id.* at 232–33.

100. Complaint, Exhibit 4 ¶ 28, All. for Hippocratic Med. v. FDA, 668 F. Supp. 3d 507 (N.D. Tex. 2023) (No. 2:22-CV-223-Z).

101. FDA v. All. for Hippocratic Med., 144 S. Ct. at 1561.

102. *Id.* at 1562.

require hospital treatment or caused patients to require more complicated treatment. The Court offered these hypotheticals:

> A local school district starts a middle school football league—does a pediatrician have standing to challenge its constitutionality because she might need to spend more time treating concussions? A federal agency increases a speed limit from 65 to 80 miles per hour—does an emergency room doctor have standing to sue because he may have to treat more car accident victims?[103]

As the Supreme Court made plain, the theory of standing that was accepted by the district and circuit courts is wildly overexpansive and would thereby undermine well-established standing jurisprudence.[104]

Another testimonial proffered by the Fifth Circuit (and subsequently rejected by the Supreme Court) as proof of injury was no more legitimate. The court cited Dr. Ingrid Skop, who wrote in her testimonial: "When I am called to the operating room to address an emergency resulting from chemical abortion, this necessarily means I may not be immediately available if an emergency should occur with one of my laboring patients."[105] Again, this is not obviously an economic injury. More significantly, a close read of the language employed by Dr. Skop reveals that this assertion is, in fact, a purely hypothetical scenario. She noted that she "*may* not be immediately available if an emergency *should occur* with one of [her] laboring patients."[106] The Supreme Court also observed that this assertion was an imagined, rather than actual, scenario. The Court wrote:

> [T]he claim that the doctors will incur those [economic] injuries as a result of FDA's 2016 and 2021 relaxed regulations lacks record support and is highly speculative. The doctors have not offered evidence tending to suggest that FDA's deregulatory actions have both caused an increase in the number of pregnant women seeking treatment from the plaintiff doctors *and* caused a resulting diversion of the doctors' time and resources from other patients.[107]

The Court noted that there was no *actual* evidence supporting the plaintiffs' claims and objected to the highly speculative nature of the proffered injuries.[108]

The second economic harm the Fifth Circuit described when it found standing in this case was that the FDA's regulatory scheme for mifepristone exposed doctors to increased liability costs.[109] The Supreme Court rightly rejected this claim, because the plaintiffs failed to offer any tangible proof that it was true.[110] The Court wrote:

> Moreover, the doctors have not identified any instances in the past where they have been sued or required to pay higher insurance costs because they have treated pregnant women suffering mifepristone complications. Nor

103. *Id.* at 1561.

104. *Id.* at 1562.

105. Complaint, Exhibit 8 ¶ 32, All. for Hippocratic Med. v. FDA, 668 F. Supp. 3d 507 (N.D. Tex. 2023) (No. 2:22-CV-223-Z).

106. *Id.* (emphasis added).

107. FDA v. All. for Hippocratic Med., 144 S. Ct. at 1561–62.

108. *Id.*

109. All. for Hippocratic Med. v. FDA, 78 F.4th 210, 233 (5th Cir. 2023).

110. FDA v. All. for Hippocratic Med., 144 S. Ct. at 1562.

> have the plaintiffs offered any persuasive evidence or reason to believe that the future will be different.[111]

Precedent suggests that when a quantifiable claim such as this one is made by a party in order to demonstrate standing, it is incumbent upon the Court to verify its validity.[112]

The Supreme Court's earlier decision not to confer standing in *Summers* is particularly revelatory. In *Summers*, the Court not only rejected the plaintiffs' legal theory of standing, but also declined to grant standing because the plaintiffs had failed to prove their claims. The Court wrote:

> A major problem with the dissent's approach is that it accepts the organizations' self-descriptions of their membership, on the simple ground that "no one denies" them. But it is well established that the court has an independent obligation to assure that standing exists, regardless of whether it is challenged by any of the parties.[113]

The Court in *Summers* considered whether the plaintiffs successfully proved the imminence prong required to obtain prospective relief, rather than the injury prong. Regardless, the Court in *Summers* cautioned against accepting "organizations' self-descriptions of their memberships."[114] Similarly, in *Hippocratic Medicine*, the plaintiffs offered a description of their alleged liability costs without any proof.[115] Under *Summers*, the onus is placed upon the court itself to verify the validity of plaintiffs' standing claims.[116] In *Hippocratic Medicine*, the Supreme Court took on that responsibility and reasonably rejected the alleged injury because it determined that the plaintiffs had not, in fact, provided any evidence to support their averments.[117]

B. Conscience Injury

In addition to economic harms, the Fifth Circuit held that the plaintiff doctors experienced a conscience harm when treating mifepristone patients, because treating the patients forced the doctors to participate in elective abortions in violation of their conscience.[118] The Supreme Court acknowledged the validity of conscience injuries as a cognizable injury sufficient to confer Article III standing.[119] However, the Supreme Court accurately observed that the plaintiffs in *Hippocratic Medicine* were already legally protected against being compelled to perform elective abortions.[120] The Court explained:

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111. *Id.*

112. *See, e.g.*, Summers v. Earth Island Inst., 555 U.S. 488, 499 (2009).

113. *Id.*

114. *Id.*

115. FDA v. All. for Hippocratic Med., 144 S. Ct. at 1562.

116. *Summers*, 555 U.S. at 499.

117. FDA v. All. for Hippocratic Med., 144 S. Ct. at 1563.

118. All. for Hippocratic Med. v. FDA, 78 F.4th 210, 232 (5th Cir. 2023).

119. *Id.* at 236–37. ("FDA and Danco do not dispute that the Medical Organizations and Doctors' conscience injury is cognizable.").

120. *See* 42 U.S.C. §§ 238n, 300a-7(c)–(d) ("No individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services if his performance or assistance in the

> Not only as a matter of law but also as a matter of fact, the federal conscience laws have protected pro-life doctors ever since FDA approved mifepristone in 2000. The plaintiffs have not identified any instances where a doctor was required, notwithstanding conscience objections, to perform an abortion or to provide other abortion-related treatment that violated the doctor's conscience. Nor is there any evidence in the record here of hospitals overriding or failing to accommodate doctors' conscience objections.[121]

The Court identified two flaws with the plaintiffs' conscience injury claims. It noted that, as a matter of law, the plaintiff doctors are already insulated from providing the care they deem morally objectionable.[122] The plaintiffs also failed to offer any proof that the conscience injuries they described had ever occurred or were likely to occur in the future.[123] In its decision, the Supreme Court showed a great deal of deference to the *idea* of such a conscience injury but noted that the reality of the federal conscience protections and the lack of legitimate evidence to support the plaintiffs' claims precluded a grant of standing.

V. PERSONAL ANALYSIS

The Supreme Court rejected the plaintiffs' arguments and declined to grant Article III standing. So why talk about this case at all? Simply put, the fact that the Fifth Circuit granted standing in the first place, when the justification to do so was so slim, is a reflection of that court's willingness to assert its own power. As the Supreme Court explained in its *Hippocratic Medicine* decision, standing serves as a bulwark against judicial overreach.[124] Granting standing when it is inappropriate to do so allows a court, like the Fifth Circuit, to wield more control than it is legally allowed to possess. Although the Supreme Court reversed the Fifth Circuit's decision in this one case, it is important to recognize such a threat of judicial overreach because it can easily happen again.

A. Horizontal Overreach: Unelected Judiciary Above the Executive

The Fifth Circuit's inappropriate grant of standing is dangerously self-aggrandizing because it grants more power to the court than is constitutionally prescribed or institutionally warranted. The American government is predicated on a system of checks and balances; it is generally appropriate for a court to review regulations issued by executive agencies like the FDA.[125] But, when a court does not have a legitimate basis to check the power of a particular agency, doing so amounts to

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performance of such part of such program or activity would be contrary to his religious beliefs or moral convictions.").

121. FDA v. All. for Hippocratic Med., 144 S. Ct. at 1560.

122. *Id.*

123. *Id.*

124. *Id.* at 1555 ("By limiting who can sue, the standing requirement implements 'the Framers' concept of the proper—and properly limited—role of the courts in a democratic society.'" (quoting John G. Roberts, *Article III Limits on Statutory Standing*, 42 DUKE L.J. 1219, 1220 (1993))).

125. JARED P. COLE, CONG. RSCH. SERV., R44699, AN INTRODUCTION TO JUDICIAL REVIEW OF FEDERAL AGENCY ACTION 1 (2016).

judicial overreach against the executive branch.[126] Furthermore, the Fifth Circuit supplanted its own judgment regarding the safety and efficacy of mifepristone for that of the FDA.[127] This is deeply troubling because the judges of the Fifth Circuit are not nearly as well-situated to assess scientific data as the scientists, researchers, and medical professionals of the FDA.[128]

The plaintiffs in *Hippocratic Medicine* did not experience a legally cognizable injury that was concrete, particularized, or imminent.[129] Therefore, the injunctive relief they sought against the FDA was not warranted. The Fifth Circuit should not have had the power to restrict the FDA's mifepristone decisions because the plaintiffs lacked standing and the court therefore lacked jurisdiction. Not only did the court seize more power than it should have in this particular case, but by embracing the plaintiffs' limitless conception of standing, the court empowered itself to do so again.

In *Hippocratic Medicine*, the Fifth Circuit upheld the plaintiffs' attack against the FDA by affirming that their generalized grievances were, instead, particularized harms.[130] It is easy to imagine that other advocacy groups might try similar strategies to achieve their policy goals, even when they do not have legally recognized claims against executive agencies or institutions.[131] When a court issues a decision in such a case, it is acting as an unelected rulemaker, guided by its own judges' political and moral beliefs. Instead of showing deference to the other two branches of government—both of which are more immediately accountable to the electorate—the court is granting itself power it does not rightfully have to challenge mandates and regulations proffered by the legislative and executive branches.

This is even more troubling in cases like *Hippocratic Medicine* where the presiding court lacks the relevant scientific or technical knowledge to sufficiently assess the dubious claims being brought by overtly politically motivated plaintiffs. The FDA conducted numerous studies over decades and extensively reviewed scientific literature to arrive at the conclusion that mifepristone was and continues to be safe and effective.[132] No federal court has the requisite scientific background to assert that its own assessment of the scientific literature is more correct than that of the FDA. In fact,

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126. *See* Clapper v. Amnesty Int'l USA, 568 U.S. 398, 408–09 (2013) ("Relaxation of standing requirements is directly related to the expansion of judicial power . . . ." (quoting United States v. Richardson, 418 U.S. 166, 188 (1974) (Powell, J., concurring))).

127. *See* All. for Hippocratic Med. v. FDA, 78 F.4th 210, 256 (5th Cir. 2023).

128. *See Scientific Careers at FDA*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/jobs-and-training-fda/scientific-careers-fda [https://perma.cc/AVZ6-L3VV] (Oct. 29, 2024) ("[The] FDA employs scientists in a wide variety of fields and disciplines, including biologists, chemists, epidemiologists, nurses, pharmacists, pharmacologists, physicians, social or behavioral scientists, statisticians, veterinarians, engineers, and others.").

129. *See supra* Section IV.

130. *See* All. for Hippocratic Med. v. FDA, 78 F.4th at 235–38; *supra* Section IV.

131. Indeed, many of the seminal standing cases discussed in Part III.A originated as disputes between environmental advocacy groups challenging the agencies that regulate the environment like the Environmental Protection Agency and the Department of the Interior.

132. *See, e.g.*, MIFEPRISTONE ADVERSE EVENTS SUMMARY, *supra* note 15; U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 19, at 5; CTR. DRUG EVAL. RSCH., 020687Orig1s020, SUMMARY REVIEW 14–16 (2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020SumR.pdf [https://perma.cc/97RH-ACKR].

two key studies claiming to prove the harms of mifepristone, which the district court relied upon to make its decision in *Hippocratic Medicine*, were subsequently retracted from their scientific journals because of questionable methodology.[133] The lower court also relied upon statistics gleaned from anonymous blog posts from a website titled AbortionChangesYou.com, which is a far cry from the rigorous scientific standard applied to FDA research.[134] Although these are two concerning examples from the district court, rather than the Fifth Circuit, it is evident that there are significant perils and concerns about allowing members of the judiciary to supplant their judgment for that of the professionals employed by the FDA.

Hippocratic Medicine bucks the principle of judicial neutrality that Justice Kavanaugh cheered for in his *Dobbs* concurrence.[135] The abortion debate has not been "returned to the people and their elected representatives"[136] but has instead been fed to a power-hungry, unelected federal court. Regardless of how one might feel about the specific question of abortion, empowering the courts to legislate in this way is harmful to the nation's carefully constructed political and administrative system.

VI. CONCLUSION

Despite the averments of Justice Kavanaugh,[137] the federal court system has not removed itself from abortion regulation. On the contrary, politically motivated abortion lawsuits are being brought by plaintiffs who do not have the standing to bring these cases.[138] *Hippocratic Medicine* is a prime example of this phenomenon. Avowed antiabortion doctors and advocacy groups brought a lawsuit against the FDA to challenge the regulation of the abortion pill mifepristone.[139] Although the plaintiffs failed to prove that they had suffered an injury or that a risk of future harm was "certainly impending," the case nevertheless wound its way all the way up to the Supreme Court.

The Supreme Court made the correct, well-reasoned decision to deny the plaintiffs in *Hippocratic Medicine* standing.[140] Because of this decision, mifepristone—a drug that is safe, reliable, and effective[141]—remains accessible to the hundreds of thousands

133. Liz Szabo, *Flimsy Antiabortion Studies Cited in Case To Ban Mifepristone Are Retracted*, SCI. AM. (Feb. 23, 2024), https://www.scientificamerican.com/article/flimsy-antiabortion-studies-cited-in-case-to-ban-mifepristone-are-retracted/ [https://perma.cc/X3KQ-SSPL].

134. *See* All. for Hippocratic Med. v. FDA, 668 F. Supp. 3d 507, 524 (N.D. Tex. 2023); Lauren Weber, Laurie McGinley, David Ovalle & Frances Stead Sellers, *Unpacking the Flawed Science Cited in the Abortion Pill Ruling*, WASH. POST (Apr. 13, 2023), https://www.washingtonpost.com/health/2023/04/13/abortion-pill-safety/.

135. Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228, 2304 (2022) (Kavanaugh, J., concurring).

136. *Id.* at 2279 (majority opinion).

137. *See id.* at 2304 (Kavanaugh, J., concurring).

138. *See supra* Part II.B.

139. All. for Hippocratic Med. v. FDA, 78 F.4th 210, 222 (5th Cir. 2023).

140. FDA v. All. for Hippocratic Med., 144 S. Ct. 1540, 1552 (2024).

141. MIFEPRISTONE ADVERSE EVENTS SUMMARY, *supra* note 15; *see also* Schoenfeld et al., *supra* note 15.

of Americans who rely upon it.[142] However, the fact that two lower courts not only found standing in this case but actually ruled in favor of the plaintiffs suggests that the threat of judicial overreach is still cause for concern. The Fifth Circuit still wields immense judicial power and seems, from its erroneous decision in *Hippocratic Medicine*, eager to grant itself still more power. The Supreme Court must continue to uphold well-established judicial principles that recommend *against* judicial overreach and self-aggrandizement. Only time will tell whether the Supreme Court rises to such a challenge.

142. *See* Laura Ungar, *More than Six in 10 US Abortions in 2023 Were Done by Medication — a Significant Jump Since 2020*, AP NEWS, https://apnews.com/article/abortion-pills-mifepristone-supreme-court-27d18f91242eb08c4d805880ddb5bb60 [https://perma.cc/FS3D-9476] (Mar. 19, 2024, 5:18 PM).