



# Americans United for Life

## *Food & Drug Administration v. Alliance for Hippocratic Medicine:* Legal Implications for the Pro-life Movement

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The Supreme Court issued its decision in *Food and Drug Administration v. Alliance for Hippocratic Medicine*,<sup>1</sup> the case that challenges the Food and Drug Administration’s (FDA) removal of patient safeguards for chemical abortion drugs, on June 13, 2024. In a unanimous decision, the Court held that Alliance for Hippocratic Medicine does not have standing to bring this case in federal court. Although the holding is a setback, litigation will continue in the district court where three states—Missouri, Idaho, and Kansas—have intervened to challenge FDA’s actions. And even though Alliance for Hippocratic Medicine lost on the standing issue, the case sets a robust precedent for the defense of conscience rights. Accordingly, the fight to protect women, adolescents, and unborn children from the harms of chemical abortion will continue, but we now have stronger caselaw defending medical rights of conscience.

### Background of the Case

The Fifth Circuit aptly described the *FDA* case as a “complicated administrative law appeal,” and like all such appeals, the case started with a federal agency action.<sup>2</sup> In 2000, FDA initially approved mifepristone for, in their words, “medical termination of pregnancy,” but with safeguards in place to guard against mifepristone’s serious and common side effects.<sup>3</sup>

In 2016, FDA loosened those safeguards considerably, which allowed non-physicians to prescribe mifepristone, removed mandatory reporting for non-lethal adverse events, and eliminated the requirement for an in-person follow-up examination to check for complications and retained fetal remains.<sup>4</sup> In 2019, FDA approved a generic version of mifepristone.<sup>5</sup> In 2021, FDA announced it would stop enforcing the in-person dispensing requirement for mifepristone entirely, effectively allowing abortionists to prescribe mifepristone through the mail.<sup>6</sup> This is in spite of federal laws

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<sup>1</sup> No. 23-235 (U.S. June 13, 2024).

<sup>2</sup> *All. for Hippocratic Med. v. U.S. Food & Drug Admin.*, 78 F.4th 210, 222 (5th Cir. 2023), *rev’d*, No. 23-235.

<sup>3</sup> *Food & Drug Admin.*, slip op. at 2.

<sup>4</sup> *Id.* at 2–3.

<sup>5</sup> *Id.* at 3.

<sup>6</sup> *Id.*

which prohibit mailing abortifacients through the United States Postal Service or shipping these drugs through common carriers.<sup>7</sup>

Alliance for Hippocratic Medicine—a group of five associations comprised of pro-life doctors—and healthcare practitioners sued FDA in the Northern District of Texas.<sup>8</sup> Specifically, Alliance for Hippocratic Medicine argued that both FDA’s initial approval and later deregulation of mifepristone were “arbitrary and capricious” and “not in accordance with the law” under the Administrative Procedure Act (APA).<sup>9</sup> Indeed, FDA approved mifepristone using the Subpart H accelerated approval process by labeling pregnancy as “a serious or life threatening illness,” and deregulated mifepristone without examining the cumulative effects these actions would have upon patient safety.<sup>10</sup>

The Northern District of Texas sided with Alliance for Hippocratic Medicine on all issues, halting both FDA’s initial approval of mifepristone and its later deregulation with a Section 705 stay,<sup>11</sup> but the Supreme Court stayed the district court’s ruling pending appeal.<sup>12</sup> The Fifth Circuit reversed on the issue of FDA’s initial approval of mifepristone, determining that Alliance for Hippocratic Medicine did not sue within the statute of limitations.<sup>13</sup> However, the Fifth Circuit upheld the stay against FDA’s 2016 and 2021 deregulation of mifepristone, finding that FDA’s actions did not align with FDA’s stated rationale or with FDA’s standard drug approval process.<sup>14</sup> As such, according to the Fifth Circuit, FDA’s deregulation of mifepristone was “arbitrary and capricious” under the APA.<sup>15</sup>

The Supreme Court only chose to review FDA’s 2016 and 2021 deregulation of mifepristone; it left the initial 2000 approval and the 2019 generic approval in place.<sup>16</sup> And the only significant issue the Supreme Court opinion discussed was procedural: whether Alliance for Hippocratic Medicine has standing to sue FDA in federal court.<sup>17</sup>

### Supreme Court’s Opinion

Justice Kavanaugh authored the Supreme Court’s opinion, joined by a unanimous Court. The opinion did not reach the merits of the case and whether FDA unlawfully deregulated mifepristone. Rather, it exclusively focused on “[t]he threshold question [of]

<sup>7</sup> 18 U.S.C. §§ 1461–62.

<sup>8</sup> *All. for Hippocratic Med. v. U.S. Food & Drug Admin.*, 668 F. Supp. 3d 507 (N.D. Tex. 2023), *aff’d in part & vacated in part*, 78 F.4th 210, *rev’d*, No. 23-235.

<sup>9</sup> *All. for Hippocratic Med.*, 78 F. 4th at 245 (citing 5 U.S.C. § 706(2)(A)).

<sup>10</sup> *Id.* at 224, 246.

<sup>11</sup> *All. for Hippocratic Med.*, 668 F. Supp. at 559. A Section 705 stay refers to a remedy under the APA. 5 U.S.C. § 705 (“[T]he reviewing court . . . may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings.”)

<sup>12</sup> *Food & Drug Admin.*, slip op. at 4–5.

<sup>13</sup> *All. for Hippocratic Med.*, 78 F. 4th at 242.

<sup>14</sup> *Id.* at 245–46, 249.

<sup>15</sup> *Id.*

<sup>16</sup> *Food & Drug Admin.*, slip op. at 5.

<sup>17</sup> *Id.* at 24–25.

whether the plaintiffs have standing to sue under Article III of the Constitution.”<sup>18</sup> Ultimately, the Court held the pro-life doctors do not have standing to bring this case in federal court.<sup>19</sup>

Article III enumerates the judicial power of the United States and extends to certain “Cases” or “Controversies.”<sup>20</sup> Standing stems from the Cases or Controversy Clause, and “determine[s] *who* is entitled to invoke the power of the federal courts to decide cases.”<sup>21</sup> Quoting Justice Scalia, the Court in the *FDA* opinion noted, “Article III requires a plaintiff to first answer a basic question: ‘What’s it to you?’”<sup>22</sup> As the Court wrote, “[f]or a plaintiff to get in the federal courthouse door and obtain a judicial determination of what the governing law is, the plaintiff cannot be a mere bystander, but instead must have a ‘personal stake’ in the dispute.”<sup>23</sup> “And the standing requirement means that the federal courts may never need to decide some contested legal questions,” but rather leave those issues to the political branches.<sup>24</sup>

There is a three-prong test to determine standing: “a plaintiff must demonstrate (i) that she has suffered or likely will suffer an injury in fact, (ii) that the injury likely was caused or will be caused by the defendant, and (iii) that the injury likely would be redressed by the requested judicial relief.”<sup>25</sup> The Court noted, “[t]he second and third standing requirements—causation and redressability—are often ‘flip sides of the same coin.’”<sup>26</sup> Accordingly, the decision focused on the injury in fact and causation prongs.<sup>27</sup> Here, the Court described, “the causation requirement and the imminence element of the injury in fact requirement can overlap. Both target the same issue: Is it likely that the government’s regulation or lack of regulation of someone else will cause a concrete and particularized injury in fact to the unregulated plaintiff?”<sup>28</sup>

The Supreme Court was skeptical of the causal link between Alliance for Hippocratic Medicine’s alleged injuries and FDA’s actions. As the decision detailed:

Here, the plaintiff doctors and medical associations are unregulated parties who seek to challenge FDA’s regulation *of others*. Specifically, FDA’s regulations apply to doctors prescribing mifepristone and to pregnant women taking mifepristone. But the plaintiff doctors and medical

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<sup>18</sup> *Id.* at 5.

<sup>19</sup> *Id.* at 1.

<sup>20</sup> U.S. CONST. art. III § 2.

<sup>21</sup> RICHARD H. FALLON ET AL., HART AND WECHLER’S THE FEDERAL COURTS AND THE FEDERAL SYSTEM 101 (7th ed. 2015) (emphasis in original).

<sup>22</sup> *Food & Drug Admin.*, slip op. at 6 (citing Antonin Scalia, *The Doctrine of Standing as an Essential Element of the Separation of Powers*, 17 SUFFOLK U. L. REV. 881, 882 (1983)).

<sup>23</sup> *Id.* at 6 (citing *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423 (2021)).

<sup>24</sup> *Id.* at 7.

<sup>25</sup> *Id.* at 7–8 (citations omitted).

<sup>26</sup> *Id.* at 8 (citing *Spring Commc’ns Co. v. APCC Servs., Inc.*, 554 U.S. 269, 288 (2008)).

<sup>27</sup> *Id.* at 8–12.

<sup>28</sup> *Id.* at 12 n.2.

associations do not prescribe or use mifepristone. And FDA has not required the plaintiffs to do anything or to refrain from doing anything.<sup>29</sup>

Although “the 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* . . . those . . . concerns do not suffice on their own to confer Article III standing to sue in federal court.”<sup>30</sup>

The decision then addressed, and rejected, Alliance for Hippocratic Medicine’s three causation theories. According to the Court, “[t]he first set of causation theories contends that FDA’s relaxed regulation of mifepristone may cause downstream conscience injuries to the individual doctor plaintiffs and the specified members of the plaintiff medical associations, who are also doctors.”<sup>31</sup> Under this theory, the:

FDA’s 2016 and 2021 actions will cause more pregnant women to suffer complications from mifepristone, and those women in turn will need more emergency abortions by doctors. The plaintiff doctors say that they therefore may be required—against their consciences—to render emergency treatment completing the abortions or providing other abortion-related treatment.<sup>32</sup>

The Justices recognized “that a conscience injury of that kind constitutes a concrete injury in fact for purposes of Article III. So doctors would have standing to challenge a government action that likely would cause them to provide medical treatment against their consciences.”<sup>33</sup> However, “the plaintiff doctors have not shown that they could be forced to participate in an abortion or provide abortion-related medical treatment over their conscience objections.”<sup>34</sup>

Federal conscience protections are robust, and “definitively protect doctors from being required to perform abortions or to provide other treatment that violates their consciences.”<sup>35</sup> These protections “encompass ‘the doctor’s beliefs rather than particular procedures,’ meaning that doctors cannot be required to treat mifepristone complications in any way that would violate the doctors’ consciences.”<sup>36</sup> “[S]trong protection for conscience remains true even in a so-called healthcare desert, where other doctors are not readily available.”<sup>37</sup> Even in the emergency context, “EMTALA [the Emergency Medical Treatment and Active Labor Act] does not require doctors to perform abortions or provide abortion-related medical treatment over their conscience objections because EMTALA does not impose obligations on individual doctors.”<sup>38</sup>

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<sup>29</sup> *Id.* at 13.

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> *Id.* at 14.

<sup>33</sup> *Id.* (citations omitted).

<sup>34</sup> *Id.*

<sup>35</sup> *Id.* at 14–15 (citations omitted).

<sup>36</sup> *Id.* at 15 (citing Transcript of Oral Argument 18, *Food & Drug Admin.*, No. 23-235).

<sup>37</sup> *Id.* (citation omitted).

<sup>38</sup> *Id.* at 16 (citation omitted).

Likewise, there is no “time-intensive procedure to invoke federal conscience protections. A doctor may simply refuse; federal law protects doctors from repercussions when they have ‘refused’ to participate in an abortion.”<sup>39</sup> With “the broad and comprehensive conscience protections guaranteed by federal law, the plaintiffs have not shown—and cannot show—that FDA’s actions will cause them to suffer any conscience injury.”<sup>40</sup>

The Court then turned to Alliance for Hippocratic Medicine’s “second set of causation theories [which] asserts that FDA’s relaxed regulation of mifepristone may cause downstream economic injuries to the doctors.”<sup>41</sup> Alliance for Hippocratic Medicine particularly asserted economic injuries from “diverting resources and time from other patients to treat patients with mifepristone complications; increasing risk of liability suits from treating those patients; and potentially increasing insurance costs.”<sup>42</sup> The Court, however, found “[t]he causal link between FDA’s regulatory actions and those alleged injuries is too speculative or otherwise too attenuated to establish standing.”<sup>43</sup>

The Court described that “there is no Article III doctrine of ‘doctor standing’ that allows doctors to challenge general government safety regulations.”<sup>44</sup> The Justices expressed concern that general doctor standing would open the floodgates to litigation, “[a]llowing doctors or other healthcare providers to challenge general safety regulations as unlawfully lax would be an unprecedented and limitless approach and would allow doctors to sue in federal court to challenge almost any policy affecting public health.”<sup>45</sup> However, the opinion noted that “the causal link at least would be substantially less attenuated” if the doctors were challenging a health and safety law that directly regulates their medical practice.<sup>46</sup> Accordingly, the Court rejected this causation theory.

Finally, the decision analyzed “[t]he third set of causation theories [which] maintains that FDA’s relaxed regulation of mifepristone causes injuries to the medical associations themselves, who assert their own organizational standing.”<sup>47</sup> Alliance for Hippocratic Medicine argued that the “FDA has ‘impaired’ their ‘ability to provide services and achieve their organizational missions.’”<sup>48</sup> But, as the Court detailed, “[a] plaintiff must show ‘far more than simply a setback to the organization’s abstract social interests.’”<sup>49</sup> Consequently, Alliance for Hippocratic Medicine “contend[s] that FDA has ‘forced’ the associations to ‘expend considerable time, energy, and resources’ drafting citizen petitions to FDA, as well as engaging in public advocacy and public

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<sup>39</sup> *Id.* at 17 (citations omitted).

<sup>40</sup> *Id.*

<sup>41</sup> *Id.* at 13–14.

<sup>42</sup> *Id.* at 18.

<sup>43</sup> *Id.*

<sup>44</sup> *Id.* at 18–19.

<sup>45</sup> *Id.* at 19.

<sup>46</sup> *Id.* at 19 n.4.

<sup>47</sup> *Id.* at 14.

<sup>48</sup> *Id.* at 21 (citing Brief for Respondents 43, *Food & Drug Admin.*, 23-235).

<sup>49</sup> *Id.* (citing *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982)).

education. And all of that has caused the associations to spend ‘considerable resources’ to the detriment of other spending priorities.”<sup>50</sup>

The Supreme Court indicated *Havens Realty Corp. v. Coleman*<sup>51</sup> is distinguishable from the present case. In *Havens Realty*, the Supreme Court held that “a housing counseling organization, HOME, had standing to bring a claim under the Fair Housing Act against Havens Realty, which owned and operated apartment complexes.”<sup>52</sup> Havens had engaged in racial steering by “provid[ing] HOME’s black employees false information about apartment availability.”<sup>53</sup> But as the Supreme Court noted in the *FDA* decision, “[c]ritically, HOME not only was an issue-advocacy organization, but also operated a housing counseling service,” which meant that “Havens’s actions directly affected and interfered with HOME’s core business activities” unlike Alliance for Hippocratic Medicine’s situation.<sup>54</sup> Consequently, *Havens Realty* does not support Alliance for Hippocratic Medicine’s theory of organizational standing.

Concluding its discussion of standing, the Supreme Court noted that “it has been suggested that the plaintiffs here must have standing because if these plaintiffs do not have standing, then it may be that no one would have standing to challenge FDA’s 2016 and 2021 actions.”<sup>55</sup> The Court, however, indicated “it is not clear that no one else would have standing to challenge FDA’s relaxed regulation of mifepristone,” but regardless, the absence of another potential plaintiff is not a reason to confer standing.<sup>56</sup>

The Supreme Court recognized that “[t]he plaintiffs have sincere legal, moral, ideological, and policy objections to elective abortion and to FDA’s relaxed regulation of mifepristone. But under Article III of the Constitution, those kinds of objections alone do not establish a justiciable case or controversy in federal court.”<sup>57</sup> Although “the federal courts are the wrong forum for addressing the plaintiffs’ concerns about FDA’s actions,” Alliance for Hippocratic Medicine can turn to the political branches or “express their views about abortion and mifepristone to fellow citizens, including in the political and electoral processes.”<sup>58</sup> Accordingly, the Supreme Court reversed the Fifth Circuit’s judgment and remanded the case for further proceedings consistent with its opinion.<sup>59</sup>

### Justice Thomas’ Concurrence

Justice Thomas concurred in the opinion, fully agreeing with the unanimous opinion’s reasoning.<sup>60</sup> However, he wrote a separate concurrence to encourage the Court to do away with the doctrine of associational standing entirely, which has

<sup>50</sup> *Id.* at 22 (citing Brief for Respondents 44, *Food & Drug Admin.*, 23-235).

<sup>51</sup> 455 U.S. 363.

<sup>52</sup> *Food & Drug Admin.*, slip op. at 22–23 (citing *Havens Realty*, 455 U.S. at 368, 378).

<sup>53</sup> *Id.* at 23 (citing *Havens Realty*, 455 U.S. at 366 & n.1, 368).

<sup>54</sup> *Id.*

<sup>55</sup> *Id.*

<sup>56</sup> *Id.* at 23–24.

<sup>57</sup> *Id.* at 24.

<sup>58</sup> *Id.*

<sup>59</sup> *Id.* at 24–25.

<sup>60</sup> *Food & Drug Admin.*, slip op. at 1 (Thomas, J., concurring).

implications for pro-life organizations and other public interest groups hoping to sue on behalf of their members.<sup>61</sup>

The Justice began his concurrence by criticizing the separate doctrine of third-party standing.<sup>62</sup> First, he noted that Alliance for Hippocratic Medicine does not have third-party standing under the current Supreme Court's precedents, which the unanimous opinion also explains.<sup>63</sup> Specifically, he wrote that “doctors cannot establish third-party standing to sue for violations of their patients’ rights without showing an injury of their own.”<sup>64</sup>

Then, Justice Thomas went further: he argued, “as I have previously explained,” that “our third-party standing doctrine is mistaken.”<sup>65</sup> The Justice referred to *June Medical Services*, citing his own dissent<sup>66</sup> to a plurality opinion that held “the State’s strategic waiver and a long line of well-established precedents foreclose[d] its belated challenge to the plaintiffs’ [third-party] standing” on behalf of patients to challenge a health and safety law.<sup>67</sup> He noted that “just as abortionists lack standing to assert the rights of their clients, doctors who oppose abortion cannot vicariously assert the rights of their patients.”<sup>68</sup>

From there, Justice Thomas framed his associational standing argument by first outlining the Court’s current doctrine.<sup>69</sup> He quoted *Hunt v. Washington State Apple Advertising Commission*, a controlling precedent in this area, which states that:

. . . an association has standing to bring suit on behalf of its members when: (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization’s purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.<sup>70</sup>

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<sup>61</sup> *Id.* at 2.

<sup>62</sup> *Id.* at 1–2.

<sup>63</sup> *Id.*

<sup>64</sup> *Id.* at 2 (citing *id.*, slip op. at 21 n.5 (unanimous opinion)).

<sup>65</sup> *Id.*

<sup>66</sup> *Id.* (citing *June Med. Servs. L. L. C. v. Russo*, 591 U.S. 299, 366, 140 S. Ct. 2103, \_\_\_ (2020) (Thomas, J., dissenting)).

<sup>67</sup> *June Med. Servs.*, 140 S. Ct. at 2120 (plurality opinion). Under the *Marks* rule, the opinion that supplied the determining vote on the narrowest grounds is regarded as the controlling opinion. *Marks v. United States*, 430 U.S. 188, 193 (1977). Accordingly, Chief Justice Roberts’ *June Medical Services* concurrence provided the deciding vote, in which he limited abortionists’ third-party standing holding to the facts of the case. *June Med. Servs.*, 140 S. Ct. at 2139 n.4 (“I agree that the abortion providers in this case have standing to assert the constitutional rights of their patients”). For further analysis of the *June Medical Services* decision, see Memorandum from Ams. United for Life to State Legal Officers, Lawmakers, and Policy Advocates (July 31, 2020), <https://aul.org/wp-content/uploads/2020/08/2020-07-31-AUL-on-JMS-Disappointment-and-Opportunity.pdf>.

<sup>68</sup> *Id.*

<sup>69</sup> *Id.*

<sup>70</sup> *Id.* (citing *Hunt v. Wash. State Apple Advert. Comm’n*, 432 U.S. 333, 343 (1977)).

He also called associational standing “simply another form of third-party standing” and noted that “the Court has never explained or justified either doctrine’s expansion of Article III standing.”<sup>71</sup>

Justice Thomas expressed three main concerns about how associational standing is incompatible with Article III. First, the Justice asserted that the “traditional understanding of the judicial power” means Article III’s “case or controversy” requirement only allows courts to “decide on the rights of individuals,” and that associational understanding “run[s] roughshod” over this.<sup>72</sup> Justice Thomas specifically expressed discomfort with the fact that an organization with millions of members could sue on behalf of only one of them, using the American Association of Retired People with its “almost thirty-eight million members” as an example.<sup>73</sup> He also disagreed with allowing an association that represents other associations like Alliance for Hippocratic Medicine to bring a lawsuit on behalf of its members, who are “two degrees removed from the party before us pursuing those injuries.”<sup>74</sup>

The second main concern Justice Thomas expressed with associational standing is redressability, or the principle that “a court must be able to ‘provid[e] a remedy that can redress *the plaintiff’s* injury.’”<sup>75</sup> Associational standing makes redressability problematic because the party in the suit—the association—has no injury to redress, so courts do not have a clean remedy.<sup>76</sup> This encourages courts to use universal injunctions, which “prohibit the Government from enforcing a policy with respect to anyone” rather than addressing the claims of the parties at hand. In Justice Thomas’s view, this is “legally and historically dubious.”<sup>77</sup> The Justice also expressed concern that associational standing “subverts the class-action mechanism,” which is specifically designed to address the claims of a group of plaintiffs at once.<sup>78</sup>

Justice Thomas’s third and final concern with associational standing was that it evolved “without explanation, seemingly by accident,” and that “the Court has yet to explain how the doctrine comports with Article III.”<sup>79</sup> He noted that associational standing is ahistorical, only coming into existence in the late 1950s and slowly expanding from there.<sup>80</sup> On top of that, associational standing seems to exist only because of “considerations of practical judicial policy [which] cannot overcome the Constitution’s mandates” seemingly to the contrary.<sup>81</sup>

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<sup>71</sup> *Id.* at 3.

<sup>72</sup> *Id.* at 3–4 (citing *Acheson Hotels, LLC v. Laufer*, 601 U.S. 1, 10 (2023) (Thomas, J., concurring in judgment) (citing *Marbury v. Madison*, 1 Cranch 137, 170 (1803))).

<sup>73</sup> *Id.* at 4 (citing Brief for Professor F. Andrew Hessick as *Amicus Curiae* 28, *Food & Drug Admin.*, No. 23-235).

<sup>74</sup> *Id.*

<sup>75</sup> *Id.* (citing *Uzuegbunam v. Preczewski*, 592 U.S. 279, 291 (2021)) (alteration and emphasis in original).

<sup>76</sup> *Id.* at 5.

<sup>77</sup> *Id.* at 6 (citations omitted).

<sup>78</sup> *Id.* at 6–7.

<sup>79</sup> *Id.* at 8–9.

<sup>80</sup> *Id.*

<sup>81</sup> *Id.* at 9.



Justice Thomas ended his concurrence with an invitation for litigants to challenge the Court’s associational standing doctrine in the future:

No party challenges our associational-standing doctrine today. That is understandable; the Court consistently applies the doctrine, discussing only the finer points of its operation. In this suit, rejecting our associational-standing doctrine is not necessary to conclude that the plaintiffs lack standing. In an appropriate case, however, the Court should address whether associational standing can be squared with Article III’s requirement that courts respect the bounds of their judicial power.<sup>82</sup>

### States’ Intervention in the District Court Case

The Supreme Court’s decision does not end litigation. Three states—Missouri, Idaho, and Kansas—are intervening in the district court case, *Alliance for Hippocratic Medicine v. Food & Drug Administration*.<sup>83</sup> The Supreme Court sent the case back down to the lower courts for further proceedings. Even though Alliance for Hippocratic Medicine does not have standing, the three states are continuing to litigate the case in the district court.

The states are alleging different theories of standing than the theories put forward by Alliance for Hippocratic Medicine. Specifically, they are arguing they have standing because, first, “they have suffered traditional economic injury . . . including (1) increased public insurance costs for emergency medical procedures and mental health support for women who experience complications from chemical abortions; and (2) diversion of resources by public hospitals to care for those who experience complications.”<sup>84</sup> Second, “FDA’s actions also harm the States’ ‘sovereign interests’ in ‘the power to create and enforce a legal code.’”<sup>85</sup> For example, FDA’s actions threaten “Missouri’s prohibition on abortions ‘except in cases of medical emergency,’ . . . and [] Missouri’s requirement that chemical abortion drugs be dispensed in-person, not through the mail.”<sup>86</sup> Third, “[t]he States have quasi-sovereign injuries because FDA’s actions put countless women and girls in these States at risk.”<sup>87</sup> This argument is based on *parens patriae*, in which a state “has a paternal and protective role over its citizens or others subject to its jurisdiction.”<sup>88</sup>

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<sup>82</sup> *Id.* (citation omitted).

<sup>83</sup> Order, *All. for Hippocratic Med. v. U.S. Food & Drug Admin.*, No. 2:22-cv-223 (N.D. Tex. Jan. 12, 2024). They also had tried to intervene in the Supreme Court case, but the Court denied their motion. Order Denying the Motion of Missouri, et al. for Leave to Intervene, *Food & Drug Admin. v. All. for Hippocratic Med.*, No. 23-235 (U.S. Feb. 20, 2024).

<sup>84</sup> Brief of Missouri, Idaho, & Kansas in Support of Alliance for Hippocratic Medicine, et. al. 6–7, *Food & Drug Admin.*, No. 23-235.

<sup>85</sup> *Id.* at 11 (citing Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez, 458 U.S. 592, 601 (1982)).

<sup>86</sup> *Id.* (citations omitted).

<sup>87</sup> *Id.* at 20.

<sup>88</sup> *Parens Patriae*, CORNELL L. SCH. LEGAL INFO. INST. (May 2022), [https://www.law.cornell.edu/wex/parens\\_patriae](https://www.law.cornell.edu/wex/parens_patriae).

Missouri, Idaho, and Kansas are not challenging FDA’s 2000 approval of mifepristone. According to the states, “[a]lthough Plaintiff States do not challenge the 2000 approval in light of concerns expressed by the Fifth Circuit in the *Alliance for Hippocratic Medicine* case that the statute of limitations may have run, the 2000 approval was arbitrary and capricious and otherwise unlawful.”<sup>89</sup> Instead, the states are focusing their challenge on the (1) 2016 major changes that removed patient safeguards, (2) 2019 generic drug approval (which FDA based on the 2000 approval of mifepristone, so the states’ challenge does implicate legal questions surrounding the 2000 approval), (3) 2021 non-enforcement decision of the in-person dispensing requirement, and (4) 2023 formalization of the removal of the in-person dispensing requirement.<sup>90</sup> Among other theories, the states are contending FDA’s actions violated the Food, Drug, and Cosmetic Act (FDCA),<sup>91</sup> Pediatric Research Equity Act (PREA),<sup>92</sup> and federal laws that prohibit mailing abortifacients through the United States Postal Service or shipping these drugs through common carriers.<sup>93</sup> Accordingly, litigation in this case will continue over whether FDA unlawfully deregulated chemical abortion drugs.

### Legal and Pro-life Implications of the Decision

Although the *FDA* decision was a disappointing outcome for the pro-life movement, the Justices delivered an even-handed decision in which they sought to align standing doctrine with Article III of the Constitution. This decision affects all federal court litigation, not just abortion-related cases, since standing is a constitutional requirement. The decision provides guidance for future litigation, especially clarifying the injury in fact and causation prongs of standing. The decision also gives a roadmap for how a plaintiff could go into federal court to challenge FDA’s actions.<sup>94</sup> Notably, the Court said, “it is not clear that no one else would have standing to challenge FDA’s relaxed regulation of mifepristone,” which indicates a different plaintiff may be able to bring a similar case.

The Justices were critical of creating a rule that generally confers standing for doctors. As the opinion held, “[s]tated otherwise, there is no Article III doctrine of ‘doctor standing’ that allows doctors to challenge general government safety regulations.”<sup>95</sup> Yet, the unanimous opinion indicated “[a] safety law regulating hospitals or the doctors’ medical practices obviously would present a different issue—either such a law would directly regulate doctors, or the causal link at least would be substantially less attenuated.”<sup>96</sup> Accordingly, it is an open question whether abortionists have direct (or first-party) standing to challenge health and safety laws protecting women from the

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<sup>89</sup> Intervenor Complaint ¶ 409, *All. for Hippocratic Med. v. U.S. Food & Drug Admin.*, 2:22-cv-223 (N.D. Tex. Jan. 12, 2024).

<sup>90</sup> *Id.* ¶¶ 393–427.

<sup>91</sup> 21 U.S.C. § 301 *et seq.*

<sup>92</sup> 21 U.S.C. § 355c.

<sup>93</sup> 18 U.S.C. §§ 1461–62.

<sup>94</sup> *See Food & Drug Admin.*, slip op. at 13 (discussing the types of injuries FDA’s actions could inflict upon a hypothetical plaintiff).

<sup>95</sup> *Id.* at 18–19.

<sup>96</sup> *Id.* at 19 n.4

abortion industry.<sup>97</sup> Regardless, even if the abortionist had first-party standing, he or she still would need to prove the case on the merits, such as showing a regulatory action is arbitrary and capricious<sup>98</sup> or a statute fails under the rational basis standard for a constitutional challenge.<sup>99</sup>

The *FDA* decision reins in third-party standing, which is a positive outcome for the pro-life movement. Prior to *Dobbs v. Jackson Women’s Health Organization*,<sup>100</sup> abortionists often brought challenges to pro-life laws under the theory of third-party standing, *i.e.*, they sued on behalf of women to vindicate women’s constitutional rights to abortion. Abortionists asserted third-party standing to receive a more favorable standard of review, the undue burden standard.<sup>101</sup> The unanimous *FDA* opinion notes that “third-party standing doctrine does not allow doctors to shoehorn themselves into Article III standing simply by showing that their patients have suffered injuries or may suffer future injuries.”<sup>102</sup> Five Justices previously had critiqued abortionists’ *carte blanche* to have third-party standing to challenge pro-life laws in *Dobbs*.<sup>103</sup> In his *FDA* concurrence, Justice Thomas repeated that “abortionists lack standing to assert the rights of their clients.”<sup>104</sup> Accordingly, the *FDA* decision adds precedent that cuts against abortionists’ third-party standing.

Since the Supreme Court ruled on a procedural issue (*i.e.*, standing), it did not reach the merits of the case. This means it remains an open question whether *FDA* unlawfully removed patient safeguards in 2016 and 2021. During oral argument, two Justices identified federal laws that prohibit mailing abortifacients,<sup>105</sup> but the *FDA* decision did not mention these laws. As noted above, Missouri, Idaho, and Kansas will continue litigation in the district court over these questions. Litigation also will raise subsidiary questions of federalism, administrative law, and the health and safety risks of mifepristone.

The *FDA* decision was a resounding win for conscience rights. The Supreme Court discussed the robust federal protections for conscientious objectors, “agree[ing] with the Solicitor General’s representation that federal conscience protections provide ‘broad coverage’ and will ‘shield a doctor who doesn’t want to provide care in violation of those protections.’”<sup>106</sup> A unanimous Supreme Court opinion, backed by the United States (as represented by the Solicitor General), is the strongest caselaw precedent

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<sup>97</sup> *But see June Med. Servs.*, 140 S. Ct. 2103 (plurality opinion).

<sup>98</sup> 5 U.S.C. § 706(2)(A).

<sup>99</sup> *Dobbs v. Jackson Women’s Health Org.*, 142 S. Ct. 2228, 2284 (2022).

<sup>100</sup> 142 S. Ct. 2228.

<sup>101</sup> *See Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992), *overruled by Dobbs*, 142 S. Ct. at 2242 (devising the undue burden standard). Today, it is uncertain why the abortionist simply would not assert first-party standing since the litigation standard—rational basis—likely would be the same if he or she showed either first- or third-party standing.

<sup>102</sup> *Food & Drug Admin.*, slip op. at 21 n.5.

<sup>103</sup> *Dobbs*, 142 S. Ct. at 2275.

<sup>104</sup> *Food & Drug Admin.*, slip op. at 2.

<sup>105</sup> Transcript of Oral Argument 26–27, 48–49, 90–91, *Food & Drug Admin.*, No. 23-235.

<sup>106</sup> *Food & Drug Admin.*, slip op. at 16–17 (citing Transcript of Oral Argument 18, 36, *Food & Drug Admin.*, No. 23-235).

possible. The *FDA* opinion has positive implications for medical professionals who conscientiously object to taking a human life through abortion.

The Justices also referenced the other abortion case before the Court this term, *Moyle v. United States*. *Moyle* presents the issue of whether the Emergency Medical Treatment and Active Labor Act (EMTALA) imposes an abortion mandate upon emergency rooms. In the *FDA* case, the Court unanimously pointed out that “EMTALA does not require doctors to perform abortions or provide abortion-related medical treatment over their conscience objections because EMTALA does not impose obligations on individual doctors.”<sup>107</sup> Quoting the Solicitor General, the Court noted “[h]ospitals must accommodate doctors in emergency rooms no less than in other contexts.”<sup>108</sup> Accordingly, the *FDA* case resolved the issue of whether EMTALA overrides individual conscience rights in favor of medical professionals who conscientiously object to abortion.

One notable aspect of the opinion is the descriptive language. It used the words “pro-life” and “elective abortion.” The unanimous opinion noted, “the 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.”<sup>109</sup> These descriptions align with caselaw, which holds that conscientious objections are from the perspective of the objector.<sup>110</sup> These words also show that we are in a post-*Roe* world, in which the Court takes a neutral stance on abortion.<sup>111</sup> However, Justice Thomas goes further in his concurrence, using the word “abortionists” to describe medical professionals that perform abortions.<sup>112</sup>

The Supreme Court ruled that Alliance for Hippocratic Medicine does not have standing, but that doctors may bring their concerns and objections to the political branches and public square.<sup>113</sup> It is important that the pro-life movement continue to advocate for patient safeguards for women and adolescents seeking chemical abortions, and support pregnancy resource centers, which provide life-affirming alternatives to abortion. The *FDA* decision was a setback, but the pro-life movement will continue to defend women, adolescents, and unborn children from the dangers of chemical abortion.

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<sup>107</sup> *Id.* at 16 (citing Brief for United States 23 n.3, *Food & Drug Admin.*, No. 23-235).

<sup>108</sup> *Id.* at 17 (citing Reply Brief for United States 5, *Food & Drug Admin.*, No. 23-235).

<sup>109</sup> *Id.* at 13 (emphasis omitted).

<sup>110</sup> See *Thomas v. Rev. Bd. of the Ind. Emp. Sec. Div.*, 450 U.S. 707, 714–15 (1981).

<sup>111</sup> *Cf. Casey*, 505 U.S. 833 (devising the undue burden standard, which was favorable to pro-abortion litigants).

<sup>112</sup> *Food & Drug Admin.*, slip op. at 2 (Thomas, J., concurring) (“So, just as abortionists lack standing to assert the rights of their clients, doctors who oppose abortion cannot vicariously assert the rights of their patients.”); see also *June Med. Servs.*, 140 S. Ct. at 2142–53 (Thomas, J., dissenting) (using “abortionist” throughout his dissent).

<sup>113</sup> *Food & Drug Admin.*, slip op. at 24.