
**UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT**

AMERICAN COLLEGE OF PEDIATRICIANS, on behalf of its members; and
CATHOLIC MEDICAL ASSOCIATION, on behalf of its members,

Plaintiffs-Appellants,

v.

XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; OFFICE FOR CIVIL RIGHTS OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; and LISA J. PINO, in her official capacity as Director of the Office for Civil Rights of the U.S. Department of Health and Human Services,

Defendants-Appellees.

On Appeal from the United States District Court
for the Eastern District of Tennessee (Chattanooga)
Case No. 1:21-cv-00195

**REPLY BRIEF OF APPELLANTS AMERICAN COLLEGE OF
PEDIATRICIANS AND CATHOLIC MEDICAL ASSOCIATION**

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SUMMARY OF THE REPLY

In 2021, American College of Pediatricians (ACPeds) and the Catholic Medical Association (CMA) filed this lawsuit on behalf of their more than 3,000 members in response to the Biden Administration's then-recent announcements that it planned to start enforcing Section 1557 of the Affordable Care Act to prohibit discrimination based on gender identity. That means forcing ACPeds' and CMA's members to participate in 22 different types of controversial practices, procedures, and forms of compelled speech that they object to on medical, ethical, and religious grounds. And if they can't comply, it means forcing them out of the medical profession entirely. Rather than waiting for that to happen, both groups filed suit.

In response, the Government refused to disavow its plans to enforce its gender-identity mandate against ACPeds' and CMA's members. Instead, the Government moved to dismiss on Article III standing and ripeness grounds, arguing that the groups had not plausibly alleged a sufficiently credible threat of enforcement. The district court granted the motion, *twice* misstating the test for Article III standing in pre-enforcement challenges. At the same time, the court distinguished factually all-but-identical cases from two other circuits, both of which had reached the opposite conclusion, by claiming that this Court's caselaw "requires more" to prove standing than the caselaw in those other circuits requires. Op., R.61, PageID 1215.

In its response brief, the Government does not deny any of this. Quite the opposite, the Government concedes that the possibility of enforcement here is real. Response Br. 41–42. It concedes the district court “phrased its inquiry” incorrectly. *Id.* at 31. And it doubles down on the erroneous claim that “there are significant differences between this Circuit’s pre-enforcement standing case law and that of the Fifth and Eighth Circuits.” *Id.* at 33. Plus, it argues that “no sufficiently concrete factual context will exist until the statute is actually enforced.” *Id.* at 45. If the Court were to accept *that* argument, that would mean the end of pre-enforcement challenges.

As the Government’s brief proves, affirming the decision below would create a circuit split. The Fifth and Eighth Circuits have already held that similarly situated plaintiffs faced a sufficiently imminent risk of enforcement to challenge the same mandate. *Franciscan Alliance, Inc. v. Becerra*, 47 F.4th 368, 376–77 (5th Cir. 2022); *Religious Sisters of Mercy v. Becerra*, 55 F.4th 583, 602–06 (8th Cir. 2022). The Government insists those cases were “wrongly decided” and based on a less “rigorous approach to pre-enforcement standing.” Response Br. 32–34. But that’s wrong on both fronts, and the Government chose not to seek Supreme Court review in either of those cases. ACPeds and CMA have standing to challenge a controversial government mandate that threatens to drive their members out of the healthcare profession. And their claims are ripe for review. This Court should reverse.

ARGUMENT

I. The Government’s brief bolsters the conclusion that ACPeds and CMA face a substantial risk that the gender-identity mandate will be enforced against them.

A. *Franciscan Alliance* and *Religious Sisters* are directly on point and consistent with this Court’s caselaw.

To plausibly allege Article III standing based on future injury, a plaintiff must allege facts showing “the threatened injury is certainly impending, or there is a substantial risk that the harm will occur.” *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014) (cleaned up). Here, the Government is trying to force doctors to give puberty blockers and cross-sex hormones to patients identifying as the opposite sex—even to remove healthy organs on demand. Compl., R.15, PageID 147–49. And as the Fifth and Eighth Circuits have held, providers who object to participating in these serious, life-altering, and irreversible surgeries and related activities face a credible threat that the Government will bring an enforcement action against them. *Franciscan Alliance*, 47 F.4th at 376–77; *Religious Sisters*, 55 F.4th at 602–06).

Those two courts listed several factors showing the threat of enforcement is sufficiently imminent, all of which apply here. Opening Br. 22–28. First, Plaintiffs’ members plan to engage in “arguably proscribed” conduct. Op., R.61, PageID 1211–14. The Government does not dispute that it reads Section 1557 to impose a gender-identity mandate, and it has “repeatedly refused to disavow enforcement

against” those who are objects of its regulation. *Franciscan Alliance*, 47 F.4th at 376. Second, HHS refused to import Title IX’s religious exemption into Section 1557. *Religious Sisters*, 55 F.4th at 605. And third, the Government cannot “identify a long history of nonenforcement against the plaintiffs and others like them.” *Id.* at 606.

This Court has found pre-enforcement standing based on similar factors in its own cases. Opening Br. 26–28 (citing *Universal Life Church Monastery Storehouse v. Nabors*, 35 F.4th 1021, 1034 (6th Cir. 2022); *Green Party of Tennessee v. Hargett*, 791 F.3d 684 (6th Cir. 2015)). And the Government’s attempts to distinguish those cases fail.

For example, in *Green Party*, this Court held that the plaintiffs had standing to challenge a ballot-access statute that had never been enforced because the defendants had not “explicitly disavowed enforcing it in the future.” 791 F.3d at 696. The Government tries to distinguish *Green Party* because the statute there was “blatantly unconstitutional.” Response Br. 28 n.2. But that conflates the merits with the standing question, which asks whether the “threatened injury” was sufficiently imminent. *Green Party*, 791 F.3d at 696. The Government also notes the *district court* had invoked the capable-of-repetition-yet-evading-review principle. Response Br. 28 n.2. But that did not factor into *this* Court’s analysis. *Contra id.* And that same concern is present here because, when patients seek these procedures, there will not be enough time to challenge Section 1557 before Plaintiffs’ doctors must respond.

Similarly for *Universal Life Church*. In that case, this Court held that a minister had alleged a sufficiently “imminent prosecution” under a set of statutes that had never been enforced where the minister was “able and ready” to violate them, legislative history “reinforce[d] the inference” that the legislature intended to target ministers like him, and the defendants had failed to provide “clear assurances” that they would *not* prosecute ministers like him. 35 F.4th at 1034–36.

All that is equally true here. Opening Br. 27. And the Government’s efforts to distinguish the Court’s imminent-threat holding all fail. Here, other than a conscious decision *not* to accommodate religious objectors, there is “[n]o explanation” for HHS’s refusal to import Title IX’s religious exemption into Section 1557 in its 2016 rule. *Universal Life Church*, 35 F.4th at 1034. And the other two “features” that the Government argues makes *Universal Life Church* distinguishable only go to the first two prongs of the *SBA List* test, not to whether “there exists a credible threat of prosecution.” 573 U.S. at 159 (quoting *Babbitt v. Farm Workers*, 442 U.S. 289, 298 (1979)). *Green Party* and *Universal Life Church* both demonstrate that this Court should reach the same result applying this Court’s caselaw that the Fifth and Eighth Circuits reached in *Franciscan Alliance* and *Religious Sisters*. Indeed, reaching the opposite conclusion would unnecessarily create a split of authority among the circuits.

Seeking to avoid that result, the Government urges the Court to affirm the district court’s (mistaken) belief that there are “significant differences between this Circuit’s pre-enforcement standing case law and that of the Fifth and Eighth Circuits.” Response Br. 33. Specifically, the Government points to language in two *other* pre-enforcement cases, *Alexis Bailly Vineyard, Inc. v. Harrington*, 931 F.3d 774 (8th Cir. 2019), and *Speech First, Inc. v. Fenves*, 979 F.3d 319 (5th Cir. 2020), and then claims those cases “provided the foundation for the standing analysis in *Religious Sisters* and *Franciscan Alliance*,” while “this Court has taken a more rigorous approach to pre-enforcement standing.” Response Br. at 33–34. But that argument, too, falls apart on closer inspection.

The Government notes that the Fifth and Eighth Circuits in *Religious Sisters* and *Franciscan Alliance* both *cited* the Fifth Circuit’s decision in *Fenves*. Response Br. 34. But both courts cited it for a very different proposition than the one the Government highlights about the “presumption” of enforcement that applies to “non-moribund” statutes that facially restrict speech. Response Br. 33 (quoting *Fenves*, 979 F.3d at 335, 337). *Religious Sisters* and *Franciscan Alliance* cite *Fenves* for the completely separate proposition that vaguely promising to comply with the First Amendment and the Religious Freedom Restoration Act does not negate a credible threat of enforcement. *Religious Sisters*, 55 F.4th at 604; *Franciscan Alliance*, 47 F.4th at 377.

So even assuming this Circuit would *not* apply the presumption of enforcement for non-moribund statutes (an apparently open question), that is irrelevant; *Religious Sisters* and *Franciscan Alliance* did not rely on that presumption. Meanwhile, the principle from *Fenves* that those cases *did* apply—that the Government’s vague promise that it will comply with the law is not enough to defeat standing—fits squarely within this Court’s caselaw. *E.g.*, *Universal Life Church*, 35 F.4th at 1035 (finding pre-enforcement standing where defendants would not give “clear assurances” that they would not prosecute ministers like the plaintiff). And it applies equally here to the Government’s vague assertion “that it will abide by RFRA in any enforcement of Section 1557.” Response Br. 29.

The Government’s invocation of language in the Eighth Circuit’s decision in *Alexis Bailly Vineyard* runs into the same problems. Response Br. 33–34. The Government claims the Eighth Circuit’s statement there that a “credible threat of prosecution exists” when a plaintiff’s “course of action is within the plain text of a statute” makes the Eighth Circuit’s pre-enforcement standing caselaw less “rigorous” than this Court’s. *Id.* (quoting *Alexis Bailly Vineyard*, 931 F.3d at 778). But once again, even if that were true, it is not relevant here.

Notably, neither *Franciscan Alliance* nor *Religious Sisters* even cites *Alexis Bailly Vineyard*, much less relies on the Government’s highlighted language.¹ The district court in *Religious Sisters* cited it. Response Br. 34 (citing *Religious Sisters of Mercy v. Azar*, 513 F. Supp. 3d 1113, 1139 (D.N.D. 2021)). But it played no role in the Fifth Circuit’s analysis. So the Government’s claim that *Alexis Bailly Vineyard* somehow “provided the foundation for the standing analysis in *Religious Sisters* and *Franciscan Alliance*” is puzzling. Response Br. 34. And no “significant differences” between those courts’ and this Court’s caselaw justify creating the clear circuit split that would result if the Court affirms the decision below. Response Br. 33; Op., R.61, Page ID 1214.

B. The Government concedes that it might enforce its mandate against ACPeds’ and CMA’s members.

One important through line in *Franciscan Alliance*, *Religious Sisters*, *Green Party*, and *Universal Life Church* is the government’s refusal to disavow the threat of enforcement in each of those cases. *Franciscan Alliance*, 47 F.4th at 376; *Religious Sisters*, 55 F.4th at 605; *Green Party*, 791 F.3d at 696; *Universal Life Church*, 35 F.4th at 1035. The Government has decided to keep that through line here.

¹ As the Government points out, ACPeds and CMA at least cited *Alexis Bailly Vineyard* in their opening brief. Response Br. 34 (citing Opening Br. 18). But the Government is wrong to imply that they relied on it. ACPeds and CMA merely cited *the district court’s* reliance on it in their Statement of the Case. Opening Br. 18. Nothing more.

Indeed, the Government concedes “it is *possible*” one of Plaintiffs’ members could “potentially be subject to an enforcement action by the federal government.” Response Br. at 42. That’s an even more explicit refusal to disavow than in *Franciscan Alliance* and *Religious Sisters*. There, the Fifth and Eighth Circuits read the Government’s refusal to say whether it would enforce Section 1557 against the plaintiffs as “a concession that it may.” *Religious Sisters*, 55 F.4th at 605 (cleaned up).

In this case, the Government has made that concession even more explicit. And while a refusal to disavow “is just one data point among many on the question whether a credible threat of enforcement exists,” *Davis v. Colerain Township*, 51 F.4th 164, 174 (6th Cir. 2022), the cases cited above prove that it is a powerful point in favor of pre-enforcement standing in cases like this one where—unlike in *Davis*—the plaintiffs plausibly allege they plan to engage in arguably proscribed conduct.

C. The Government concedes that the district court phrased the test for pre-enforcement standing incorrectly, and the court’s overreliance on the so-called *McKay* factors was not harmless error.

The Government also concedes that “the district court phrased its inquiry as whether the alleged injury was ‘certainly impending’ without including a disjunctive acknowledgement that a ‘substantial risk’ of harm also suffices.” Response Br. 31. And that mistake matters. As this Court has made clear, “certainly impending ... does not require literal certainty.” *Kanuszewski v. Mich. Dep’t of Health & Hum. Servs.*, 927

F.3d 396, 410 (6th Cir. 2019) (cleaned up). It only requires “a substantial risk that the harm will occur.” *Id.* (cleaned up). And the rest of the district court’s opinion “reads as though [it] was looking to see whether ACPeds and CMA had established to a ‘literal certainty’ that the harm they alleged would necessarily occur.” Opening Br. 32–33 (quoting *Kanuszewski*, 927 F.3d at 410 (cleaned up)). That is not the test. And the court erred by holding ACPeds and CMA to a mistaken standard.

The Government defends the district court’s misstatement by insisting that the court somehow still “applied the correct test.” Response Br. 31. Just one page over, though, it tacitly concedes that the district court *also* erred in its “assertion that some combination of [the] *McKay* factors was required” to prove a credible threat of enforcement. *Id.* at 32. It just claims “any error” in that assertion “was harmless.” *Id.*

But that’s wrong. Opening Br. 34–35. The district court devoted almost its entire threat-of-enforcement analysis to determining whether ACPeds and CMA could “point to some combination” of the so-called *McKay* factors “to demonstrate a credible threat of enforcement.” Op., R.61, PageID 1216 (cleaned up); *see generally id.*, PageID 1215–22. And the Government repeats that mistake, focusing almost exclusively on whether the district court correctly applied the “so-called *McKay* factors” when it concluded that ACPeds’ and CMA’s members do not face a credible threat of enforcement. Response Br. 21; *see generally id.* at 20–28 (applying the “four factors” mentioned in *McKay*).

As ACPeds and CMA have already explained, “this Court has never said that a plaintiff ‘must’ show ‘some combination’ of the factors listed in *McKay* to state a credible threat of enforcement—at least not in a published opinion.” Opening Br. 35. *But see Plunderbund Media, L.L.C. v. DeWine*, 753 F. App’x 362, 372 (6th Cir. 2018) (faulting plaintiffs for not establishing “any *McKay* factor to substantiate their allegation of subjective chill”). “Quite the opposite, the Court has recognized that ‘a variety of facts can demonstrate a credible threat of enforcement.’” Opening Br. 35 (quoting *Fischer v. Thomas*, 52 F.4th 303, 307 (6th Cir. 2022) (per curiam)). “And the factors listed in *McKay* are merely ‘four commonly recurring factors’ that this Court has highlighted in some,” but certainly not all, of the Court’s pre-enforcement cases. *Id.* (quoting *Fischer*, 52 F.4th at 307); *see, e.g., Kentucky v. Yellen*, 54 F.4th 325, 337 (6th Cir. 2022) (finding credible threat without mentioning so-called *McKay* factors based on the Treasury Secretary’s “letter indicating that Treasury intended to enforce” the challenged provision).

If the Court *did* require “some combination” of the so-called *McKay* factors, the Court would find itself at odds with the Supreme Court and on the wrong side of *another* circuit split. That’s because two of the factors in *McKay* ask whether the plaintiffs have alleged “a history of past enforcement against [them] or others” or “enforcement warning letters sent to the plaintiffs regarding their specific conduct.” *McKay v. Federspiel*, 823 F.3d 862, 869 (6th Cir. 2016). On the other

side of the ledger, “the Supreme Court and at least four other circuits have sustained pre-enforcement standing without a past enforcement action or an overt threat of prosecution directed at the plaintiff.”

Vitagliano v. Cnty. of Westchester, No. 23-30, 2023 WL 4095164, at *7 & n.5 (2d Cir. 2023) (per curiam) (citing *Virginia v. Am. Booksellers Ass’n, Inc.*, 484 U.S. 383, 392–93 (1988); *Babbitt v. United Farm Workers Nat’l Union*, 442 U.S. 289, 302 (1979); *Speech First, Inc. v. Fenves*, 979 F.3d 319, 336–37 (5th Cir. 2020); *Speech First, Inc. v. Schlissel*, 939 F.3d 756, 766 (6th Cir. 2019); *Majors v. Abell*, 317 F.3d 719, 721 (7th Cir. 2003); *Mangual v. Rotger-Sabat*, 317 F.3d 45, 57 (1st Cir. 2003)).

This Court has already placed itself in that majority camp, recognizing that the “lack of discipline ... could just as well indicate” that the protected speech or conduct has “already been chilled.” *Schlissel*, 939 F.3d at 766. And that’s consistent with cases like *Green Party* and *Universal Life Church* where the Court has found standing without prior enforcement or overt threats directed at the plaintiff. Opening Br. 26, 35.

Finally, ACPeds and CMA have plausibly alleged a combination of the four factors identified in *McKay*. Opening Br. 36. In their complaint, Plaintiffs alleged that the Government is already enforcing its gender-identity mandate. Compl., R.15, PageID 140–41. And the Government subsequently confirmed that to be true—a concession during litigation to which they are bound. See *Franciscan Alliance*, 47 F.4th at 374 (quoting *HHS Notice and Guidance on Gender Affirming Care, Civil*

Rights, and Patient Privacy, U.S. Dep’t of Health and Human Servs. (Mar. 2, 2022), perma.cc/LX26-59QR).

Plaintiffs also plausibly alleged that, in addition to the risks posed by the looming threat of government enforcement, they risk being “subjected to private lawsuits for damages under Section 1557’s enforcement mechanisms,” Compl., R.15, PageID 167–68, a point Plaintiffs made in their opening brief by citing to that part of their complaint in support of their argument the third so-called *McKay* factor is “met here,” Opening Br. 36. *Contra* Response Br. 25. And the Government agrees that “private individuals” can “trigger[] a process in which [it] determines whether to initiate an investigation” by submitting complaints. Response Br. 24. These private enforcement options make it “easier [and] more likely” that an investigation will begin—meaning that enforcement will start, *McKay*, 823 F.3d at 869, and Plaintiffs will be forced to endure the burdens, costs, and other injuries of intrusive administrative proceedings, however those proceedings might end.

Most important, the Government has repeatedly refused to disavow that it will enforce its mandate against ACPeds’ and CMA’s members. Opening Br. 15–16, 26; Response Br. 25–27, 41–42. Against this backdrop, neither group should have to stand idly by and wait to see whether that threat will become a reality when their doctors are forced to make on-the-spot decisions whether to honor demands for treatment or instead follow medical judgment, science, and conscience.

* * *

In sum, nothing in this Court’s caselaw requires the Court to relegate itself to the kind of outlier status that the district court and the Government would have the Court resign itself to in pre-enforcement cases like this one. Affirming the decision below would mean reaching a result directly at odds with decisions by the Fifth and Eighth Circuits—thus creating a clear circuit split. It would mean accepting an inflexible standard for alleging a credible threat of enforcement that no other circuit has adopted. It would mean placing the Court at war with its own precedent. And it would mean closing the courthouse doors to plaintiffs even in cases like this one, where the Government concedes that the possibility of enforcement is real.

Instead of doing any of that, the Court should follow the well-reasoned opinions in *Religious Sisters* and *Franciscan Alliance*, apply the Court’s own caselaw that is consistent with those cases, reject the district court’s mistaken approach, hold that ACPeds and CMA have plausibly alleged a credible threat of enforcement, and reverse the decision below.

II. ACPeds and CMA plausibly alleged that their members intend to follow their consciences and medical ethics by declining to perform any of the objectionable practices.

For the first time on appeal, the Government also argues that ACPeds and CMA failed to plausibly allege “a substantial probability that their members will engage in proscribed conduct.” Response Br. 16 (cleaned up). The Government did not advance that argument below. And the district court had no difficulty concluding that ACPeds and CMA *did* plausibly allege an intent to engage in conduct arguably proscribed by Section 1557. Op., R.61, PageID 1211–14. This Court “can affirm on any basis supported by the record.” *BNA Assocs. LLC v. Goldman Sachs Specialty Lending Grp., L.P.*, 63 F.4th 1061, 1064 (6th Cir. 2023). So the issue isn’t waived. But the Government’s failure to make the argument until now underscores the argument’s weakness.

In their complaint, ACPeds and CMA identified 22 types of controversial practices, procedures, and forms of compelled speech their members object to on medical, ethical, and religious grounds. Compl., R.15, PageID 147–49. Due to the Government’s “overreaching interpretation” of Section 1557, their members face an “untenable” choice: “act against their medical judgment and deeply held convictions by performing controversial and often medically dangerous gender interventions, or succumb to huge financial penalties, lose participation in Medicaid and other federal funding, and, as a practical matter, lose the ability to practice medicine in virtually any setting.” *Id.*, PageID 127.

When forced to make that choice, ACPeds’ and CMA’s members will follow their convictions and decline to participate in the objectionable practices. *Id.*, PageID 151–52 (ACPeds members), 155–56 (Dr. Quentin Van Meter), 157–59 (CMA members), 160–62 (Dr. Rachel Kaiser). The Government claims Plaintiffs have not plausibly alleged they have already engaged in proscribed conduct, but they concede that Dr. Kaiser has *already* treated for a prostate issue a man who identified as a woman, and it is reasonable to infer from her allegations that she charted the patient by sex and spoke to the patient about the diagnosis using correct sex-based terms and pronouns regardless of the patient’s identification—as she explains she always did in the past and seeks to continue to do so in the future. *Id.*, PageID 160–62; Response Br. 18.

Despite those allegations, the Government argues ACPeds and CMA failed to plausibly allege a substantial probability that their members will engage in each form of proscribed conduct because, “[i]n cases where the Supreme Court has recognized pre-enforcement standing, plaintiffs generally have shown that they previously engaged in the proscribed behavior and will continue doing so.” Response Br. 16. But “[t]his argument conflicts with century-old law.” *Doster v. Kendall*, 54 F.4th 398, 417 (6th Cir. 2022). “The Supreme Court has long held that parties may raise pre-enforcement challenges to a legal mandate before engaging in the act that will trigger it.” *Id.* And *SBA List*, which the Government cites, proves that to be true.

The Government cites *SBA List* because one of the plaintiff entities there, SBA, had “already” made arguably proscribed statements, and had alleged an intent to make similar statements in the future. Response Br. 16 (quoting *SBA List*, 573 U.S. at 161). But the Government “seems to have not read [*SBA List*] closely enough.” *Franciscan Alliance*, 47 F.4th at 378. The *other* plaintiff entity, an organization called COAST, had *not* previously engaged in proscribed conduct. *SBA List*, 573 U.S. at 161. It merely had “previously intended” to do so, and it wished to make such statements in the future. *Id.* And that was enough under the first prong of the *SBA List* test. *Id.*

Other Supreme Court cases show *SBA List* is not the exception. In *Epperson v. Arkansas*, the Court allowed a schoolteacher to challenge a law against teaching evolution even though she apparently had never taught evolution before. 393 U.S. 97, 100–02 (1968). In *Gratz v. Bollinger*, an aspiring transfer student had standing to challenge a school’s race-based admissions policy even though he had never tried to transfer to the school. 539 U.S. 244, 260–61 (2003).

And just last week, the Supreme Court decided a pre-enforcement case brought by a website designer who had not yet created wedding websites or denied a request for a same-sex wedding website. *303 Creative LLC v. Elenis*, No. 21-476, 2023 WL 4277208, at *13 (U.S. June 30, 2023) (“deciding a pre-enforcement challenge”). As the Tenth Circuit there had correctly held, the website designer had standing to bring her

challenge because, although she had “not yet offered wedding website services,” she had “been employed as a graphic and web designer in the past,” and she had “provided clear examples of the types of websites” that she intended to produce. *303 Creative LLC v. Elenis*, 6 F.4th 1160, 1172 (10th Cir. 2021). That was enough for her “intended course of conduct [to be] at least arguably proscribed” by the relevant statute. *Id.* (cleaned up); *accord Vitagliano*, 2023 WL 4095164, at *6 (“That Vitagliano had not engaged in sidewalk counseling prior to the Act’s passage does not require a different result.”). The Supreme Court exercised jurisdiction based on the Tenth Circuit’s reasoning. *303 Creative*, 2023 WL 4277208 at *5–6. And ACPeds and CMA’s similar showing is enough here.

Moreover, the Government seeks to compel ACPeds’ and CMA’s members’ speech and requires them to adopt nondiscrimination policies that conform with the Government’s view of Section 1557 before the first patient walks in the door. Compl., R.15, PageID 136, 147–49, 186. Plaintiffs’ members have not—and cannot—adopt these policies, and thus they have *already* arguably violated the Government’s mandate. *Id.*, PageID 136–37, 159, 167–68, 185. And the Government’s attempt to compel speech relating to such “core religious and philosophical beliefs” favors pre-enforcement review because it makes the “First Amendment interests [here] especially strong.” *Meriwether v. Hartop*, 992 F.3d 492, 509 (6th Cir. 2021).

III. ACPeds and CMA’s claims are ripe for review under both Article-III-ripeness and prudential-ripeness grounds.

The Government devotes the final ten pages of its brief to defending the district court’s holding—in a footnote—that ACPeds and CMA’s claims are not ripe. Response Br. 40–49; Op., R.61, PageID 1222–23 n.5. As ACPeds and CMA have already noted, though, this Court has held that “[t]here cannot be ‘standing without ripeness in preenforcement challenges.’” Opening Br. 30 (quoting *Winter v. Wolnitzek*, 834 F.3d 681, 687 (6th Cir. 2016)). That’s because a “plaintiff meets the injury-in-fact requirement—and the case is ripe—when the threat of enforcement of that law is ‘sufficiently imminent.’” *Platt v. Bd. of Comm’rs on Grievances & Discipline of Ohio Sup. Ct.*, 769 F.3d 447, 451 (6th Cir. 2014) (cleaned up). So for “all the same reasons” Plaintiffs have standing, their “claims are ripe for review.” Opening Br. 30.

In response, the Government insists that it is still technically possible for a plaintiff to have Article III standing, and for her claims to be ripe for review under Article III, and for her to *still* fail to show “that the *prudential* aspects of ripeness” are sufficiently met to justify a court deciding her case. Response Br. 47–48. To support that claim, the Government notes that even though the Supreme Court has called into question the continuing vitality of the prudential-ripeness doctrine, it has not yet affirmatively overruled it. *Id.* at 48–49. And courts have continued to assess cases for prudential ripeness. *Id.*

Even assuming that to be true, none of it helps the Government’s ripeness argument on the merits. As ACPeds and CMA pointed out in their opening brief, the Eighth Circuit’s decision in *Religious Sisters* shows that their “claims would be ripe even applying all three traditional ripeness factors.” Opening Br. 30 n.7 (citing *Religious Sisters*, 55 F.4th at 608). ACPeds and CMA have plausibly alleged a credible threat the Government will enforce its gender-identity mandate against them if they decline to participate in 22 types of controversial practices, procedures, and forms of compelled speech. Compl., R.15, PageID 147–49. If they can’t comply, they risk “huge financial penalties, [losing] participation in Medicaid and other federal funding, and, as a practical matter, [losing] the ability to practice medicine in virtually any setting.” *Id.*, PageID 127.

The Government also never says why it needs more specific facts showing these doctors will decline to engage in these objectionable practices in specific clinical settings in the future, given that Plaintiffs already have non-compliant policies and given that the Government never disavows that Section 1557 applies to all this conduct. Indeed, the Government seemingly agrees that its mandate *requires* these practices. As a result, Plaintiffs are being harmed now, their case “would not benefit from further factual development,” and it “poses a purely legal question not contingent on future possibilities,” making it “fit for judicial decision.” *Religious Sisters*, 55 F.4th at 608 (cleaned up).

Indeed, this is not the first time the Government has made this argument in a RFRA case, and this would not be the first Court to reject it. Just two weeks ago, the Fifth Circuit rejected an almost identically worded argument that “whether any particular application of Title VII will run afoul of RFRA ... will depend on the precise employment practices applied to particular individual employees,” and that “[u]ntil plaintiffs’ policies and preferences crystalize into particular employment decisions that violate Title VII, there is no way of assessing whether enforcing Title VII as to that decision will impose a substantial burden.” *Braidwood Mgmt., Inc. v. Equal Emp. Opportunity Comm’n*, No. 22-10145, 70 F.4th 914, ___, slip op. at 23–24 (5th Cir. June 20, 2023) (cleaned up) (quoting EEOC’s brief). *Compare* Response Br. 43–44.

Disagreeing, the Fifth Circuit wrote that the Government’s “near talismanic mantra that ‘further factual development’ would ‘significantly advance’ [the] court’s ability to resolve plaintiffs’ claims would be more compelling” if the Government had given “an example of factual development that would be helpful to the court.” *Braidwood*, slip op. at 24. The plaintiffs there sought “declaratory relief, and no further factual investigation [was] required to determine whether, for example, RFRA supersedes Title VII’s requirements as applied to their specific employment policies.” *Id.* And that’s all equally true here, too. This case is fit for review right now, and the Court should decide it now.

Requiring Plaintiffs to wait until after they've been forced to choose between violating their convictions and violating the Government's gender-identity mandate in a specific case would mean forcing them to "bet the farm, so to speak, by taking the violative action." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 129 (2007). "When the government pressures parties to give up intangible rights like those protected by RFRA, courts should not delay review until the time that the parties must rush into court seeking a temporary restraining order to protect these rights." *Doster*, 54 F.4th at 418. That's especially true in cases where, as here, any such last-ditch effort would come far too late to supply meaningful relief. And that type of hardship is exactly what pre-enforcement review is meant to avoid.

Accepting the Government's claim that "no sufficiently concrete factual context will exist until the statute is actually enforced," though, would mean the end of pre-enforcement review. Response Br. 45. And none of the Government's various theories justifies such an extreme result. *Contra* Response Br. 40–46.

The Government suggests that RFRA cannot be raised in a pre-enforcement case and that the possibility of an exemption makes any enforcement too speculative. Response Br. at 43. In support of this novel position, the Government says it cannot determine if RFRA will apply until after the fact because it needs to know all the facts of what happened to analyze a claim under RFRA's balancing test. *Id.* at 43–44.

That is not the law. The Supreme Court resolved a landmark pre-enforcement RFRA case against HHS in *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014). *Franciscan Alliance* and *Religious Sisters* affirmed pre-enforcement injunctions on RFRA claims. And in *Braidwood*, the Fifth Circuit correctly held that a RFRA claim was ripe for pre-enforcement review because the “*in terrorem* effects from the EEOC’s guidance and a credible prosecution risk are sufficient.” Slip. op. at 25. So too here. “Denying prompt judicial review, again, forces plaintiffs to risk practicing their religious beliefs and ... thereby putting themselves in danger of a costly enforcement action.” *Id.* This Court should decline the Government’s invitation to hold for the first time that RFRA claims can never be brought in a pre-enforcement case.

The Government also says that its own mandate is vague, and that for that reason it should be allowed to develop its meaning by enforcing it. Response Br. at 44–45. But such vagueness is a reason to *remove* the sword of Damocles, not a reason to let the Government wield it. Plaintiffs are not guinea pigs for the Government to use to practice enforcing its controversial gender-identity mandate.

Finally, the fact that ACPeds and CMA made the point that they satisfy the traditional ripeness factors in a footnote in their opening brief does not mean they somehow “forfeited any challenge to the district court’s determination that their claims are not ripe under the ‘traditional ripeness factors.’” Response Br. 47 (citing *United States v.*

Johnson, 440 F.3d 832, 846 (6th Cir. 2006)). *Johnson* stands for the proposition that a litigant can waive an entire “issue” by only mentioning it in a single footnote in his initial brief. 440 F.3d at 846. ACPeds and CMA devoted an entire subsection of their opening brief to the ripeness issue. Opening Br. 30. And in arguing that “all the same reasons” they have Article III standing prove that their “claims are ripe for review,” they did not distinguish between Article III ripeness and prudential ripeness. *Id.* Accordingly, the argument is preserved. Their claims are constitutionally and prudentially ripe for review. And this Court should reverse the decision below.

CONCLUSION

This Court should reverse the district court’s decision dismissing claims One through Five of the first amended complaint and remand the case for further proceedings.

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FRAP 32(g)

CERTIFICATE OF COMPLIANCE

This brief complies with the word limit of Fed. R. App. P. 32(a)(7)(B) because this brief contains 5,683 words, excluding parts of the brief exempted by Fed. R. App. P. 32(f) and 6 Cir. R. 32(b).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in Word 365 using a proportionally spaced typeface, 14-point Century Schoolbook.

Dated: July 5, 2023

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CERTIFICATE OF SERVICE

I hereby certify that on July 5, 2023, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Sixth Circuit using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users, and that service will be accomplished by the CM/ECF system.

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