

No. 23-5053

**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

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

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CORPORATE DISCLOSURE STATEMENT

Under Fed. R. App. P. 26.1 and Sixth Circuit R. 26.1(a), Appellants American College of Pediatricians and Catholic Medical Association state that they have no parent corporation, they do not issue stock, they are not a subsidiary or an affiliate of a publicly owned corporation, and there is no publicly owned corporation or its affiliate, not a party to this appeal, that has a financial interest in the outcome of this case.

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STATEMENT IN SUPPORT OF ORAL ARGUMENT

Appellants American College of Pediatricians (ACPeds) and Catholic Medical Association (CMA), each on behalf of its members, respectfully request oral argument in this appeal. ACPeds and CMA challenge HHS and OCR’s (collectively the Government’s) imposition of a federal mandate, through Section 1557 of the Affordable Care Act and its implementing regulations, requiring their members to perform gender-transition surgeries, prescribe gender-transition drugs, and speak and write about patients according to gender identity rather than biological sex—even when doing so violates their medical judgment or their sincerely held religious beliefs. Compl., R.15, PageID 126.

Two circuit courts of appeals—the Fifth and the Eighth Circuits—have already held that similarly situated plaintiffs faced sufficiently imminent threatened enforcement of the same gender-identity mandate to create an ongoing Article III case or controversy. *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).

HHS has repeatedly said it is enforcing its mandate nationwide. Yet the district court here held that ACPeds and CMA lack standing based on its mistaken belief that this circuit’s standing caselaw “requires more” than these other circuits. Op., R.61, PageID 1215. Oral argument is warranted to aid the Court in resolving these important Article III issues while avoiding creating a circuit split.

STATEMENT OF JURISDICTION

The district court had jurisdiction under 28 U.S.C. §§ 1331, 1346, and 1361 because ACPeds and CMA raised claims against the federal government under the Administrative Procedure Act, the First Amendment, the Religious Freedom Restoration Act, and other constitutional provisions and federal laws. Compl., R.15, PageID 178–204.

This Court has jurisdiction under 28 U.S.C. § 1291 and 28 U.S.C. § 1292 because the district court entered its final order dismissing Plaintiffs’ first amended complaint in its entirety on November 18, 2022. Op., R.61, PageID 1229. And because some of the parties are federal officers and agencies, Fed. R. App. P. 4(a)(1)(B), ACPeds and CMA timely filed their notice of appeal on January 13, 2023. Notice, R.63, PageID 1231.

STATEMENT OF ISSUES

Under Article III’s injury-in-fact requirement, an alleged future injury “may suffice if 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). “[C]ertainly impending . . . does not require literal certainty,” just “a substantial risk that the harm will occur.” *Kanuszewski v. Mich. Dep’t of Health & Hum. Servs.*, 927 F.3d 396, 410 (6th Cir. 2019) (cleaned up).

HHS has repeatedly said it is enforcing a nationwide gender-identity mandate. But the district court below failed to ask the substantial-risk question because it thought this Court’s caselaw “requires more,” namely, an injury that is “certainly impending.” Op., R.61, PageID 1215, 1221–22. The Fifth and the Eighth Circuits have already held that similarly situated plaintiffs face a sufficiently imminent risk of injury to challenge the same mandate challenged here. *Franciscan Alliance*, 47 F.4th at 376–77; *Religious Sisters*, 55 F.4th at 602–06. The only difference is that the district court here thought it was required to apply a different Article III test.

This appeal asks whether the district court erred when it ruled that ACPeds and CMA do not have standing and, for similar reasons, have not presented ripe claims for review.¹

¹ ACPeds and CMA do not challenge these rulings as to claims Six and Seven in their first amended complaint. Compl., R.15, PageID 196–204.

STATEMENT OF THE CASE

A. ACPeds and CMA

American College of Pediatricians (ACPeds) is a national organization of pediatricians and other healthcare professionals incorporated in Tennessee. Compl., R.15, PageID 129. It includes more than 600 physicians and other healthcare professionals from 47 different States, including Tennessee. *Id.* Most ACPeds members are board-certified pediatricians with active practices. *Id.*, PageID 149. And as a secular, scientific medical association, its membership includes both religious and non-religious members. *Id.*, PageID 151.

The Catholic Medical Association (CMA) is the largest association of Catholic individuals in healthcare. *Id.*, PageID 130. Its membership includes about 2500 physicians and providers nationwide, including three member guilds in Tennessee. *Id.*, PageID 130, 156. CMA's mission is to inform, organize, and inspire its members to uphold the Catholic faith in the science and practice of medicine. *Id.*, PageID 156.

Members of both groups provide medical treatment for patients who identify as transgender—from setting broken bones, to conducting physicals, to treating acute and chronic illnesses. *Id.*, PageID 150, 159. But members of both groups cannot in good conscience perform gender-transition surgeries, prescribe gender-transition drugs, or speak or write about their patients according to their patients' gender identity as opposed to their biological sex. *Id.*, PageID 126, 150–62.

B. Section 1557 of the Affordable Care Act prohibits discrimination in the provision of healthcare

Section 1557 of the Affordable Care Act (ACA) states that “any health program or activity” receiving federal financial assistance shall not discriminate against an individual in the provision of healthcare based on one of the grounds identified in certain other federal statutes. Compl., R.15, PageID 132 (quoting 42 U.S.C. § 18116(a)). It adds that the “enforcement mechanisms provided for and available under” those other federal statutes “shall apply for purposes of violations of this subsection.” *Id.*, PageID 132–33 (quoting 42 U.S.C. § 18116(a)).

None of the anti-discrimination statutes mentioned in Section 1557 prohibits discrimination based on gender identity. *Id.*, PageID 133. The only one that prohibits discrimination based on sex is Title IX. *Id.* And multiple provisions in both the ACA and Title IX show that Congress understood the word “sex” to mean the biological binary of male and female—not to encompass the broader, *non*-binary concept of gender identity. *Id.*, PageID 133–34. *Accord, e.g., Meriwether v. Hartop*, 992 F.3d 492, 510 n.4 (6th Cir. 2021) (“Title VII differs from Title IX in important respects.”).

C. HHS issues 2016 Rule adding discrimination based on gender identity and sex stereotypes

In 2016, HHS used its rulemaking authority under Section 1557 to promulgate a final rule titled Nondiscrimination in Health Programs and Activities. Compl., R.15, PageID 134 (citing 81 Fed. Reg. 31,375

(May 18, 2016) (codified at 45 C.F.R. pt. 92)). The Rule interprets discrimination “on the basis of sex” to also include discrimination based on gender identity and sex stereotypes, and its preamble specifies multiple ways in which that new interpretation requires medical providers to offer gender-identity interventions and procedures, and to engage in speech that both affirms their patients’ gender identity and affirms that transition-related procedures and interventions are medically necessary and appropriate. *Id.*, PageID 134 (citing 81 Fed. Reg. at 31,467–68 (45 C.F.R. § 92.4)); *id.*, PageID 135–38 (describing specific examples).

D. Federal district court permanently enjoins 2016 Rule’s addition of discrimination based on gender identity

In December 2016, a district court issued a preliminary injunction against the gender-identity mandate under the 2016 Rule. Compl., R.15, PageID 138 (citing *Franciscan Alliance, Inc. v. Burwell*, 227 F. Supp. 3d 660, 695–96 (N.D. Tex. 2016)). Three years later, the same court issued final judgment, declaring that the 2016 Rule violated the Administrative Procedure Act and the Religious Freedom Restoration Act. *Id.*, PageID 139 (citing *Franciscan Alliance, Inc. v. Burwell*, 414 F. Supp. 3d 928, 945 (N.D. Tex. 2019)). The court thus vacated the gender-identity language from the Rule and remanded the rulemaking to HHS. *Id.* (citing *Franciscan Alliance*, 414 F. Supp. 3d at 945).

E. HHS publishes 2020 Rule removing gender-identity mandate

In 2020, HHS published a final rule that substantially revised the partially vacated 2016 Rule by removing its gender-identity language and stating that HHS interprets Section 1557 and Title IX to *not* prohibit discrimination based on gender identity. Compl., R.15, PageID 139 (citing Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority. 85 Fed. Reg. 37,160 (June 19, 2020) (to amend and be codified at 45 C.F.R. pt. 92)). The rule was to go into effect on August 18, 2020.

HHS explained that the 2016 Rule “exceeded its authority under Section 1557, adopted erroneous and inconsistent interpretations of civil rights law, caused confusion, and imposed unjustified and unnecessary costs.” *Id.* (quoting 84 Fed. Reg. 27,846, 27,849 (June 14, 2019)). More specifically, HHS disavowed its “erroneous” prior position that declining to provide transition-related procedures or interventions is “outdated and not based on current standards of care,” explaining that position as lacking a “scientific and medical consensus to support” it. *Id.* (quoting 85 Fed. Reg. at 37,187) (cleaned up).

F. Two federal district courts enjoin 2020 Rule and revive gender-identity mandate

Shortly thereafter, the Supreme Court issued its decision in *Bostock v. Clayton County*, 140 S. Ct. 1731 (June 15, 2020). And before the 2020 Rule’s changes to the 2016 Rule could go into effect, two

district courts enjoined parts of the 2020 Rule while declaring that some of the *2016 Rule*'s gender-identity mandate remains in effect—with one of those courts blocking HHS from adding Title IX's religious exemption to its 1557 regulations. Compl., R.15, PageID 139 (citing *Walker v. Azar*, 480 F. Supp. 3d 417 (E.D.N.Y. Aug. 17, 2020), *modified by* 2020 WL 6363970 (E.D.N.Y. Oct. 29, 2020); *Whitman-Walker Clinic, Inc. v. HHS*, 485 F. Supp. 3d 1 (D.D.C. 2020)).

Both courts said they recognized they had no power to undo the district court's vacatur in *Franciscan Alliance*. See *Whitman-Walker*, 485 F. Supp. 3d at 26; *Walker*, 480 F. Supp. 3d at 427. But as the Fifth Circuit later held, “in effect they did just that.” *Franciscan Alliance*, 47 F.4th at 372. While they “did not directly resurrect the 2016 Rule's prohibition on ‘gender identity’ discrimination, they did reanimate the rule's ‘sex-stereotyping’ prohibition.” *Id.* And both “courts further reasoned that, in light of *Bostock*, sex-stereotyping discrimination encompasses gender identity discrimination.” *Id.* at 372–73. *Accord* Op., R.61, PageID 1212 (interpreting both cases the same way).

As a result of *Walker* and *Whitman-Walker*, the 2016 Rule's gender-identity language, and the implications of that language described in the 2016 Rule's preamble, remained in effect at the time ACPeds and CMA filed their complaint in this case, including the 2016 Rule's failure to incorporate Title IX's religious exemption. Compl., R.15, PageID 139–40.

G. Executive order endorses *Bostock*'s interpretation of sex discrimination; HHS issues Notification announcing plans to enforce Section 1557 accordingly

On January 20, 2021, immediately upon taking office, President Biden signed an executive order purportedly applying *Bostock* and requiring that Section 1557 and Title IX be interpreted to include gender identity as a protected trait, while also requiring similar interpretations of all other federal civil rights laws and promoting related policies. Compl., R.15, PageID 140 (citing Executive Order 13,988, Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation, 86 Fed. Reg. 7023 (Jan. 20, 2021)). (In contrast, the Sixth Circuit has held that “the rule in *Bostock* extends no further than Title VII.” *Pelcha v. MW Bancorp, Inc.*, 988 F.3d 318, 324 (6th Cir. 2021).)

On May 10, 2021, HHS announced that its Office for Civil Rights, effective immediately, “will interpret and enforce Section 1557’s prohibition on discrimination on the basis of sex to include: (1) Discrimination on the basis of sexual orientation; and (2) discrimination on the basis [of] gender identity.” Compl., R.15, PageID 140–41 (quoting 86 Fed. Reg. 27,984, 27,985 (May 25, 2021)). HHS also announced, in the same notice and a press release, that it interprets “sex” in Title IX to include gender identity. *Id.*, PageID 141 (citing Press Release, HHS OCR, HHS Announces Prohibition on Sex Discrimination Includes Discrimination on the Basis of Sexual Orientation and Gender Identity (May 10, 2021),

available at perma.cc/ZM7H-FUBB). The Notification of Interpretation and Enforcement encouraged members of the public to file complaints if they thought their civil rights had been violated. 86 Fed. Reg. at 27,985.

Regarding Section 1557, HHS added that its enforcement activity would comply with RFRA “and all other legal requirements,” including the injunctions related to Section 1557’s regulations, but HHS did not specify how it would respect or accommodate religious or non-religious objections. Compl., R.15, PageID 141 (quoting 86 Fed. Reg. at 27,985).

H. ACPeds and CMA sue to protect their members’ rights

In the wake of *Bostock*, *Walker*, *Whitman-Walker* and President Biden’s and HHS’s announcements, ACPeds and CMA brought suit in federal court to protect their members’ rights under the Constitution, RFRA, and the APA. Compl., R.15, PageID 126–28. As their first amended complaint explains, due to the Government’s “overreaching interpretation” of Section 1557, their members faced “an untenable choice.” *Id.*, PageID 127. They could “either 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.* So injunctive relief was “needed to shield” members “from the federal government’s penalties that threaten to drive thousands of doctors out of practice.” *Id.*, PageID 128.

Based on the announcements and notices described above, and upon information and belief, the complaint alleged that HHS's Office of Civil Rights was "actively investigating, enforcing, and implementing an interpretation of Section 1557 and HHS regulations under which sex discrimination includes gender identity and sex stereotyping." *Id.*, PageID 141. The Government did "not believe that RFRA or other laws require[d] any exemptions from the Section 1557 gender identity mandate." *Id.* HHS had "not publicly recognized any RFRA exemption under its interpretation of Section 1557 except those ordered by a court, and even in some of those cases HHS [had taken] the position that RFRA provides no exemption." *Id.* And HHS had filed a Statement of Interest in one case in which it had "cited its Section 1557 authority as grounds for preempting a state law that protected children from gender interventions and that protected healthcare providers from providing them." *Id.*, PageID 141–42 (citing Statement of Interest of the United States, *Brandt v. Rutledge*, No. 4:21-cv-00450-JM (E.D. Ark. June 17, 2021), ECF. No. 19).

ACPeds and CMA also described how the gender-identity mandate arising out of Section 1557, the 2016 Rule, HHS's May 10, 2021 Notice of Enforcement, and the penalties set out in the 2020 Rule "imposes tangible, concrete harm for ACPeds and CMA members." *Id.*, PageID 141, 147.

Specifically, the complaint lists 22 sets of activities and speech that ACPeds and CMA members object to on medical, ethical, or religious grounds that the Government now requires:

- a. Prescribing puberty blockers off-label from the FDA-approved indication to treat gender dysphoria and initiate or further transition in adults and children;
- b. Prescribing hormone therapies off-label from the FDA-approved indication to treat gender dysphoria in all adults and children;
- c. Providing other continuing interventions to further gender transitions ongoing in both adults and minors;
- d. Performing hysterectomies or mastectomies on healthy women who believe themselves to be men;
- e. Removing the non-diseased ovaries of healthy women who believe themselves to be men;
- f. Removing the testicles of healthy men who believe themselves to be women;
- g. Performing “de-gloving” to remove the skin of a man’s penis to use it to create a faux vaginal opening;
- h. Removing vaginal tissue from women to facilitate the creation of a faux or cosmetic penis;
- i. Performing or participating in any combination of the above mutilating cosmetic procedures, or similar surgeries, to place a patient somewhere along the socially constructed gender identity spectrum;
- j. Offering to perform, provide, or prescribe any and all such interventions, procedures, services, or drugs;
- k. Referring patients for any and all such interventions, procedures, services, or drugs;

- l. Ending or modifying their policies, procedures, and practices of not offering to perform or prescribe these procedures, drugs, and interventions;
- m. Saying in their professional opinions that these gender-intervention procedures are the standard of care, are safe, are beneficial, are not experimental, or should otherwise be recommended;
- n. Treating patients according to their gender identity and not their biological sex;
- o. Stating views on gender interventions they do not share;
- p. Saying that sex or gender is nonbinary or on a spectrum;
- q. Using language affirming self-professed gender identities;
- r. Using patients' preferred pronouns according to their gender identity, rather than using no pronouns or using pronouns based on biological sex;
- s. Creating medical records and coding patients and services according to gender identity and not biological sex;
- t. Providing the government assurances of compliance, providing compliance reports, and posting notices of compliance in prominent physical locations if the 2016 Rule's interpretation of "sex" governs these documents;
- u. Refraining from expressing medical, ethical, or religious views, options, and opinions to patients that disagree with gender-identity theory or transitions; and
- v. Allowing patients to access single-sex programs and facilities, such as mental health therapy groups, breastfeeding support groups, postpartum support groups, educational sessions, changing areas, restrooms, communal showers, and other single-sex programs and spaces, by gender identity and not by biological sex.

Id., PageID 147–49.

The complaint further alleged that the Government “require[s] Plaintiffs to provide” the above-listed “objectionable practices” to the extent the Government deems them to be “within the scope” of ACPeds and CMA members’ medical practice. *Id.*, PageID 149. This follows from the fact that most of their members provide medical care in health programs and activities that receive federal financial assistance from HHS under 42 U.S.C. § 18116, and they also treat patients who are members of federal healthcare programs like Medicaid, Medicare, and CHIP. *Id.*, PageID 129–30, 149, 153–57, 160–62.

As a result, some ACPeds and CMA members were self-censoring out of fear of enforcement. *Id.*, PageID 152, 160. Others were continuing to practice consistent with their views and thus faced the threat of enforcement penalties. *Id.* If ACPeds and CMA members “do not abide by the Section 1557 gender identity mandate, they face losing access to federal healthcare program funds, potential civil lawsuits from plaintiffs, and being investigated by HHS’s Office for Civil Rights or the Attorney General.” *Id.*, PageID 167 (citing 18 U.S.C. § 3486; 45 C.F.R. §§ 80.6 to 80.11; 45 C.F.R. Pt. 81; 45 C.F.R. §§ 92.5, 92.301). Members also face the threat of criminal liability “if they do not comply but have participated or continue to participate in federal programs,” or if they fail to provide evidence of compliance required by an investigation. *Id.*, PageID 167–68 (citing 18 U.S.C. §§ 287, 1001, 1035, 1347, 1516, 1518; 42 U.S.C. §§ 1320a-7b(a), 1320a-7b(c)).

The burdens of being investigated for alleged violations of Section 1557—or being subjected to reviews concerning such compliance—are harsh, imposing significant costs of time, money, attorney fees, and diversion of resources. *Id.* And by the time they filed their complaint, some ACPeds and CMA members had already spent “time and money training staff, issuing guidance, and engaging in public education campaigns to mitigate the confusion caused by the mandate.” *Id.*, PageID 168.

I. The Government moves to dismiss while refusing to disavow intent to enforce gender-identity mandate against Plaintiffs’ members

In response to ACPeds and CMA’s lawsuit, the Government moved to dismiss, arguing that ACPeds and CMA did not have standing (or present a ripe controversy) because they were seeking to “challenge the lawfulness of a position that HHS *has not* taken.” MTD Memo in Supp., R.52, PageID 1108 (emphasis added). Noting that HHS had “taken the consistent position in litigation that the 2016 Rule’s gender identity provisions are no longer in effect,” and had “not taken any action to enforce those provisions since their vacatur,” the Government asserted that ACPeds and CMA could “suffer no injury from a rule that has been vacated and that HHS *is not* enforcing.” *Id.*, PageID 1110 (emphasis added).

As those quotes show, though, throughout their motion-to-dismiss brief, the Government repeatedly couched its position in the past or present tense. *See, e.g., id.* (HHS “has not taken any action”), *id.* (“HHS is not enforcing”), *id.*, PageID 1111–12 (“HHS has not taken the legal position”), *id.*, PageID 1114 (“HHS has not imposed” the mandate). For example, they highlighted the fact that “HHS *has never* enforced Section 1557 to revoke the funding of a provider for failure to provide gender transition services.” *Id.*, PageID 1119 (emphasis added).

At the same time, the Government refused to disavow that it *would* take such enforcement action in the future—effectively conceding that it might. For example, the Government claimed that if it “*were* to decide at some point to pursue action against Plaintiffs, Plaintiffs would still be many steps removed from losing federal funding.” *Id.*, PageID 1117 (emphasis added). It also conceded it had filed motions in other courts asking to modify injunctions to “clarify that HHS would not violate [them] *if it took action* against an entity without knowing that it was a member of the plaintiff organization.” Reply, R.57, PageID 1176 n.2 (emphasis added). Until then, though, the Government insisted that ACPeds and CMA’s “claimed injuries hinge on the contingency that HHS will take a legal position it *has not yet taken* and bring enforcement actions that HHS *has not yet brought*.” MTD Memo in Supp., R.52, PageID 1113 (emphasis added). So ACPeds and CMA lacked standing and had failed to present a ripe controversy. *Id.*, PageID 1108–19.

J. District court grants motion to dismiss, holding ACPeds and CMA failed to allege “certainly impending” threat of enforcement

After canceling oral argument on the Government’s motion to dismiss, Order, R.58, PageID 1184, the district court granted the motion and dismissed ACPeds and CMA’s complaint in its entirety on standing and ripeness grounds. Op., R.61, PageID 1189–1229.

Relevant here, the court applied the Supreme Court’s three-part test for assessing whether a plaintiff bringing a pre-enforcement suit has satisfied Article III’s injury-in-fact requirement. *Id.*, PageID 1211–26. That test asks whether a plaintiff alleges (1) “an intention to engage in a course of conduct arguably affected with a constitutional interest” but (2) arguably “proscribed by a statute,” and (3) “there exists a credible threat of prosecution thereunder.” *Id.*, PageID 1211 (quoting *SBA List*, 573 U.S. at 159).

On the first and second prongs of that test, the district court agreed ACPeds and CMA had plausibly alleged they intend to engage in conduct “arguably protected” by the Constitution and “arguably proscribed” by “HHS’s operative Section 1557 regulations,” which “at least arguably bar discrimination against transgender patients as a form of sex discrimination under the statute,” and by subsequent court decisions interpreting *Bostock* to mean that Title IX’s definition of sex discrimination includes gender-identity discrimination. *Id.*, PageID 1211–14. So the court proceeded to consider the third prong.

The court began its credible-threat-of-prosecution analysis by surveying “other circuits’ jurisprudence” in response to Plaintiffs’ argument that it was “not plausible that [their] doctors lack standing to bring a challenge that was successful in three other courts.” *Id.*, PageID 1214 (cleaned up). The district court noted that three cases in the Fifth and Eighth Circuits found standing in indistinguishable circumstances. *Id.* (citing *Franciscan Alliance*, 227 F. Supp. 3d at 678–80; *Religious Sisters of Mercy v. Azar*, 513 F. Supp. 3d 1113, 1133 (D.N.D. 2021); *Christian Emps. All. v. U.S. Equal Opportunity Comm’n*, No. 1:21-CV-195, 2022 WL 1573689 (D.N.D. May 16, 2022)). But the district court believed that under this Court’s standing jurisprudence, “the issue of whether there exists a credible threat of prosecution[] bears considerable differences from the Fifth and the Eighth Circuit’s.” *Id.*

The Fifth Circuit, for example, recognizes Article III standing based on a “substantial” threat of future enforcement. *Id.*, PageID 1214–15 (citing *Speech First v. Fenves*, 979 F.3d 319, 336–38 (5th Cir. 2020). And the Eighth Circuit has found a credible threat of enforcement “when a course of action is within the plain text of a statute.” *Id.*, PageID 1215 (quoting *Alexis Bailly Vineyard, Inc. v. Harrington*, 931 F.3d 774, 778 (8th Cir. 2019)). Based on the district court’s survey of this Court’s caselaw, it concluded that the “Sixth Circuit requires more.” *Id.*

Partially quoting an unpublished opinion, the court reasoned that, in this circuit, a “plaintiff’s intended course of action falling within the plain text of a non-moribund statute, ‘does not amount to a ‘credible threat’ of prosecution” because “the threat of prosecution must be *certainly impending*.” *Id.* (quoting *Daly v. McGuffey*, No. 21-3266, 2021 WL 7543815, at *2–3 (6th Cir. Nov. 15, 2021)). “In fact,” the court continued, “the Sixth Circuit applies a factor test, first articulated in *McKay v. Federspiel*, 823 F.3d 862 (6th Cir. 2016) and known as the ‘*McKay factors*,’” to decide whether an alleged threat “is credible.” *Id.*

Citing the only two cases from this Court that have ever used the phrase “*McKay factors*,” the court posited that plaintiffs “must” show “some combination” of the factors to prove a credible threat. *Id.*, PageID 1216 (citing and quoting *Online Merchs. Guild v. Cameron*, 995 F.3d 540, 550 (6th Cir. 2021), and *Plunderbund Media, L.L.C. v. DeWine*, 753 F. App’x 362, 366, 372 (6th Cir. 2018)). And because ACPeds and CMA had not made that showing, they failed to show that their alleged injury was “*certainly impending*.” *Id.*, PageID 1221. Finally, HHS had promised to comply with RFRA and similar laws, and the existence of such a “vague exemption” by which ACPeds and CMA were “arguably protected” cut against their standing arguments. *Id.*, PageID 1222–26.²

² For similar and “overlap[ping]” reasons, the court also found in a footnote that Plaintiffs’ “claims are unripe as much as they lack standing.” *Id.*, PageID 1222–23 n.5.

STANDARD OF REVIEW

This Court “review[s] de novo a district court’s grant of a motion to dismiss for lack of subject matter jurisdiction.” *Kiser v. Reitz*, 765 F.3d 601, 606 (6th Cir. 2014). In this appeal, that means the Court “must take the material allegations of the complaint as true and construe them in the light most favorable” to ACPeds and CMA. *Id.* (cleaned up). And because this is an associational-standing case, the Court must accept “as true the complaint’s factual allegations (as opposed to its legal conclusions),” and ask whether ACPeds and CMA have “assert[ed] a plausible claim that one of [their] members has standing.” *Ass’n of Am. Physicians & Surgeons v. U.S. Food & Drug Admin.*, 13 F.4th 531, 544 (6th Cir. 2021) (cleaned up).

SUMMARY OF THE ARGUMENT

This marks the third time in two years that a pre-enforcement challenge to the gender-identity mandate arising out of Section 1557’s ban on sex discrimination has come before a federal court of appeals for a decision on whether plaintiff healthcare-providers face a credible threat that the mandate will be enforced against them. *See Franciscan Alliance*, 47 F.4th at 376–77; *Religious Sisters*, 55 F.4th at 602–06. So far in the Fifth and the Eighth Circuits, the healthcare providers have gone two-for-two. *Franciscan Alliance*, 47 F.4th at 376–77; *Religious Sisters*, 55 F.4th at 605–06.

This appeal asks whether the Sixth Circuit’s standing caselaw “requires more” than these other circuits, requiring a different outcome here. Op., R.61, PageID 1215. It does not. ACPeds and CMA plausibly alleged the same substantial risk of harm that made for justiciable controversies in the Fifth and Eighth Circuits. And under this Circuit’s caselaw, that was enough for Article III standing here, too.

The district court conceded that ACPeds and CMA plausibly alleged that their members intend to engage in conduct “arguably protected” by the Constitution and proscribed by “HHS’s operative Section 1557 regulations.” Op., R. 61, PageID 1211–14. Those regulations do not contain a religious exemption—by design. And the Government has repeatedly refused to disavow an intent to enforce them against ACPeds’ and CMA’s members. By refusing to disavow, they have conceded that they might. And vague promises to comply with RFRA are not enough to negate that threat.

The district court came to a different conclusion by applying a different test. Rather than asking whether ACPeds and CMA had plausibly alleged a “substantial risk” of harm, the court only asked whether they had established that an injury was “certainly impending.” And the court applied that requirement as if it necessitated something close to literal certainty, which this Court and the Supreme Court have both said it does not require. The Court should reject the Government’s invitation to create a circuit split and reverse.

ARGUMENT

- I. **ACPedS and CMA plausibly alleged a substantial risk that the gender-identity mandate will be enforced against them.**
 - A. **As the Fifth and Eighth Circuits have already held, providers covered by the gender-identity mandate face a credible threat of enforcement.**

Just last August, the Fifth Circuit Court of Appeals held that three groups of private religious healthcare providers faced a sufficiently credible and ongoing threat of enforcement from HHS’s gender-identity mandate to prevent the case from becoming moot after the 2020 Rule vacated the only portions of the 2016 Rule that the providers had challenged in their complaint. *Franciscan Alliance*, 47 F.4th at 374 n.26, 376–77.

Though that case was decided on mootness grounds, the court invoked its standing jurisprudence to support its decision. *Id.* at 376–77.³ First, the court affirmed the lower court’s conclusion that the injunctions in *Walker* and *Whitman-Walker*, the 2020 Rule, and the 2021 Notification “combined to threaten [the providers] in the same way that the challenged portions of the 2016 Rule did.” *Id.* at 376. And HHS had doubled down on its expressed intent to enforce the mandate more recently. *Id.* (citing a 2022 Notice warning covered entities that refusing to offer gender-reassignment surgeries violates Section 1557).

³ See also *id.* at 376 n.40 (explaining that “if there is an ongoing dispute giving a plaintiff standing, the case is not moot”).

Second, the court observed that HHS had “repeatedly refused to disavow enforcement against Franciscan Alliance.” *Id.* On appeal, it had simply said that it had “not to date evaluated” whether it would enforce Section 1557 against the providers. *Id.* And the court read that as a concession “that it may.” *Id.* The Fifth Circuit had “repeatedly held that plaintiffs have standing in the face of similar prosecutorial indecision,” including one case where the city had “not yet determined its position” on a charter’s enforceability, and another where the defendant had “vaguely promised to not enforce the challenged policies contrary to the First Amendment.” *Id.* at 376–77 (cleaned up).

In that second case, *Speech First, Incorporated v. Fenves*, the Fifth Circuit had “held that the plaintiffs had standing to bring suit because they were within the ‘class whose [conduct] is arguably restricted,’ and the defendant’s promise was so vague that the scope of liability was both ‘unknown by the [defendant] and unknowable to those regulated by it.’” *Id.* at 377 (quoting *Speech First*, 979 F.3d at 338). So too in *Franciscan Alliance*: the Fifth Circuit found HHS’s promise that it would “comply with the Religious Freedom Restoration Act . . . and all other legal requirements” to be similarly vague and deficient. *Id.* (quoting 86 Fed. Reg. at 27,985). As a result, the court held that the providers’ RFRA claim was not moot, leaving the district court’s vacatur of portions of the 2016 Rule in effect. *Id.*

Four months later, the Eight Circuit Court of Appeals relied on the Fifth Circuit’s reasoning in *Franciscan Alliance* to support its own conclusion that a group of similarly situated healthcare providers had “standing to challenge the government’s interpretation of Section 1557.” *Religious Sisters*, 55 F.4th at 606.

There, the Eighth Circuit began its analysis by laying out two key principles from the U.S. Supreme Court’s decision in *SBA List*: First, an “individual need not be ‘subject to a threat, an actual arrest, prosecution, or other enforcement action to challenge the law.’” *Id.* at 602 (quoting *SBA List*, 573 U.S. at 158) (cleaned up). And second, “[p]re-enforcement review is permissible ‘under circumstances that render the threatened enforcement sufficiently imminent.’” *Id.* at 603 (quoting *SBA List*, 573 U.S. at 159).

Next, the Eighth Circuit discussed and applied the Fifth Circuit’s reasoning in *Franciscan Alliance*, finding it “instructive” and supportive of its own conclusion that the plaintiffs “suffered an injury-in-fact from the government’s interpretation of Section 1557.” *Id.* at 603, 605.

First, the court rejected the government’s argument that the plaintiffs lacked standing because the 2020 Rule “rescinded” the 2016 Rule. *Id.* at 605. The Eighth Circuit “agree[d] with the Fifth Circuit that ‘the district court injunctions, the 2020 Rule, and the 2021 Notification combined to threaten the plaintiffs in the same way that the challenged portions of the 2016 Rule did.’” *Id.* (cleaned up).

Second, the court rejected the government’s argument that the plaintiffs lacked an injury because the government had “not to date taken a position on whether plaintiffs’ conduct violates the relevant statutes and [had] not threatened any enforcement action against plaintiffs.” *Id.* (quoting the government’s brief). Like the Fifth Circuit concluded, that assertion was “actually a concession that it may do so.” *Id.* (cleaned up). And just as in *Franciscan Alliance*, where HHS had repeatedly refused to disavow enforcement against the plaintiffs there, “so, too, [had] it refused in the present case.” *Id.*

Third, the court observed that HHS had declined to import Title IX’s religious exemption into Section 1557 when it issued the 2016 Rule. *Id.* (citing 81 Fed. Reg. at 31,380). *Accord* Compl., R.15, PageID 139–40, 143 (noting same lack of exemption). And though the government claimed it would “comply” with RFRA, that promise was too “vague” and “unknown” and “unknowable” to make a difference. *Religious Sisters*, 55 F.4th at 606 (quoting *Franciscan Alliance*, 47 F.4th at 377).

“Finally, the government [could not] identify a long history of nonenforcement against the plaintiffs and others like them.” *Id.* “To the contrary, the plaintiffs [had] cited enforcement activity in the years prior to the filing of the operative complaint suggesting that the rule [was] likely to be enforced against them.” *Id.* “For these reasons,” the Eighth Circuit held that the plaintiffs had “standing to challenge the government’s interpretation of Section 1557.” *Id.*

B. Sixth Circuit caselaw supports the same result here.

The Fifth and Eighth Circuit’s conclusions apply equally here under this Court’s caselaw. First, as the district court *correctly* held, ACPeds and CMA plausibly alleged that their members intend to engage in conduct “arguably protected” by the Constitution and “arguably proscribed” by “HHS’s operative Section 1557 regulations.” Op., R.61, PageID 1211–14. *Accord Religious Sisters*, 55 F.4th at 605 (agreeing with the Fifth Circuit about the “combined” threat posed).

Second, just like in *Franciscan Alliance* and *Religious Sisters*, the Government here has “repeatedly refused to disavow enforcement against” ACPeds’ and CMA’s members. *Franciscan Alliance*, 47 F.4th at 376; *accord Religious Sisters*, 55 F.4th at 605. And that by itself has been enough to establish standing here in the Sixth Circuit.

For example, in *Green Party of Tennessee v. Hargett*, this Court held that the plaintiffs “sufficiently established that they suffered an injury” due to a loyalty-oath, ballot-access statute. 791 F.3d 684, 696 (6th Cir. 2015). The defendants had argued there was “no evidence that the statute [had] been, or would be, enforced.” *Id.* at 695. But that was not enough to negate the credible threat of enforcement because they had not “explicitly disavowed enforcing it in the future.” *Id.* at 696. “In such situations, the Supreme Court has held that plaintiffs have standing to challenge statutes.” *Id.* So this Court did “the same” and found that the plaintiffs had standing without requiring anything more. *Id.*

Third, HHS’s decision not to import Title IX’s religious exemption into Section 1557 through the 2016 Rule (which it still lacks due to the *Whitman-Walker* injunction) bolsters the credible threat of enforcement. *Religious Sisters*, 55 F.4th at 605; Compl., R.15, PageID 139–40, 143.

This Court has relied on such “surrounding factual circumstances” to “show that a fear of prosecution is plausible.” *Universal Life Church Monastery Storehouse v. Nabors*, 35 F.4th 1021, 1034 (6th Cir. 2022). In *Universal Life Church*, legislative history “reinforce[d] the inference” the legislature had tried to target the plaintiffs. *Id.* at 1034–35. HHS’s refusal to include an exemption supports a similar inference here.

That inference in *Universal Life Church*, combined with (1) the plaintiff being “able and ready” to violate the statutes and (2) the defendants failing to provide “clear assurances” they would *not* prosecute him, was enough to give the minister—and his church—“standing to seek injunctive and declaratory relief.” *Id.* at 1034–36. So too here.

Notably, even if the Government had incorporated a religious exemption into its mandate, ACPeds would still have standing. ACPeds represents doctors who oppose facilitating gender transitions for religious and non-religious reasons. Compl., R.15, PageID 151. So its members with non-religious reasons for objecting to the gender-identity mandate would not be protected by any such religious exemption.⁴

⁴ *Accord* 88 Fed. Reg. 7,236, 7,243 (Feb. 2, 2023) (distinguishing and refusing to honor non-religious objections under a different mandate).

Fourth, the Government here remains unable to “identify a long history of nonenforcement against the plaintiffs and others like them.” *Religious Sisters*, 55 F.4th at 606. That mattered in *Universal Life Church*, too, where the defendants could not show the amendment in question had come anywhere close to “fall[ing] into desuetude” through years of voluntary nonenforcement. 35 F.4th at 1035. Nor was there any evidence showing “that prosecutors [had] deliberately turned a blind eye” to violations. *Id.* at 1036. And that is equally true here.

Finally, the standing analysis is made even easier here by the regulatory context. There “is ordinarily little question” that standing exists where an entity is the “object of the [challenged] action,” such as when an injury arises from the government regulating an entity. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). And so “courts have routinely found sufficient adversity between the parties to create a justiciable controversy when suit is brought by the particular plaintiff subject to the regulatory burden imposed by a statute.” *Nat’l Rifle Ass’n of Am. v. Magaw*, 132 F.3d 272, 282 (6th Cir. 1997).

Entities are the object of a regulation (1) when “the regulation is directed at them in particular”; (2) when “it requires them to make significant changes in their everyday business practices”; and (3) when, “if they fail to observe the [new] rule they are quite clearly exposed to the imposition of strong sanctions.” *Abbott Lab’ys v. Gardner*, 387 U.S. 136, 153–54 (1967). ACPeds’ and CMA’s members satisfy these criteria.

First, as the district court essentially conceded, the Government’s mandate is directed at ACPeds’ and CMA’s members because they provide medical care in health programs that receive federal financial assistance and treat patients who are members of federal healthcare programs. Compl., R.15, PageID 129–30, 149, 153–57, 160–62.

Second, the mandate requires them to make significant changes in their practices. *Id.*, PageID 147–49. And some have spent “time and money training staff, issuing guidance, and engaging in public education campaigns to mitigate the confusion caused by the mandate.” *Id.*, PageID 168. *Accord Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 414 n.5 (2013) (standing can be based on a “substantial risk” of harm that “may prompt plaintiffs to reasonably incur costs to mitigate or avoid” it).

Third, if ACPeds and CMA members cannot in good conscience comply with the mandate, they face losing access to federal funding, and they expose themselves to potential civil lawsuits from plaintiffs and an investigation by HHS’s Office for Civil Rights or the Attorney General. *Id.*, PageID 167 (citing 18 U.S.C. § 3486; 45 C.F.R. §§ 80.6 to 80.11; 45 C.F.R. Pt. 81; 45 C.F.R. §§ 92.5, 92.301). They also could face criminal liability. *Id.*, PageID 167–68 (citing 18 U.S.C. §§ 287, 1001, 1035, 1347, 1516, 1518; 42 U.S.C. §§ 1320a-7b(a), 1320a-7b(c)). “Thus, they are the proper parties to bring suit.” *Magaw*, 132 F.3d at 282.⁵

⁵ See also *Dismas Charities, Inc. v. U.S. Dep’t of Just.*, 401 F.3d 666, 677 (6th Cir. 2005) (finding standing to bring notice-and-comment claim).

C. Because this is a pre-enforcement challenge, all the same factors prove this case is ripe for review.

For all the same reasons, ACPeds and CMA’s claims are ripe for review. There cannot be “standing without ripeness in pre-enforcement challenges.” *Winter v. Wolnitzek*, 834 F.3d 681, 687 (6th Cir. 2016). So the “line between Article III standing and ripeness” in these cases “has evaporated.” *Id.* 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), as it is here.

Stated differently, whether ACPeds and CMA “have standing and whether their claims are ripe come to the same question: Have they established a credible threat of enforcement?” *Winter*, 834 F.3d at 687.⁶ For all the reasons described above, the “answer [here] is yes.” *Id.* So both groups have plausibly alleged both standing and ripeness.⁷

⁶ *Accord Religious Sisters*, 55 F.4th at 608 (addressing ripeness in terms of standing because, in these cases, “standing and ripeness essentially boil down to the same question”) (cleaned up); *Kiser*, 765 F.3d at 607 (taking the same approach while noting that the Supreme Court has “cast into some doubt . . . the long-established prudential aspects of the ripeness doctrine,” specifically “hardship to the parties and fitness of the dispute for resolution”).

⁷ ACPeds and CMA’s claims would be ripe even applying all three traditional ripeness factors. *See Religious Sisters*, 55 F.4th at 608.

II. The district court erred because it incorrectly thought this Court’s caselaw requires more.

A. The district court read “substantial risk” out of the caselaw—and that error infected its entire analysis.

By failing to apply the Sixth Circuit caselaw discussed above, the district court erred in concluding that ACPeds and CMA “have not established standing as to their claims.” Op., R.61, PageID 1226. And that error flowed directly from how it described the test for deciding whether a credible threat of enforcement exists. *Id.*, PageID 1215.

In *Clapper*, the Supreme Court held that a “speculative chain of possibilities [did] not establish that [an] injury based on potential future surveillance [was] certainly impending,” and thus the plaintiffs there did not have standing. 568 U.S. at 414. In a footnote, the Court “clarified that this does not require ‘literal[] certain[ty]’ but at least a ‘substantial risk’ that the harm will occur.” *Kanuszewski*, 927 F.3d at 410 (quoting *Clapper*, 568 U.S. at 414 n.5). And the very next Term, the Supreme Court stated the test in the disjunctive: “An allegation of future injury may suffice if the threatened injury is ‘certainly impending,’ *or* there is a ‘substantial risk’ that the harm will occur.” *SBA List*, 573 U.S. at 158 (emphasis added) (cleaned up) (quoting *Clapper*, 568 U.S. at 414 n.5).

In the years since the Court decided *Clapper*, multiple courts of appeals have made the same point this Court made in *Kanuszewski*. See *In re Equifax Inc. Customer Data Sec. Breach Litig.*, 999 F.3d 1247,

1262 (11th Cir. 2021) (“It need not be ‘literally certain’ that the injury will come about, but there must be a ‘substantial’ risk.”) (quoting *Clapper*, 568 U.S. at 414 n.5); *Nw. Requirements Utils. v. FERC*, 798 F.3d 796, 805 (9th Cir. 2015) (“A future injury need not be ‘literally certain,’ but there must be a ‘substantial risk’ that it will occur.”) (quoting *Clapper*, 568 U.S. at 414 n.5); *Remijas v. Neiman Marcus Grp., LLC*, 794 F.3d 688, 693 (7th Cir. 2015) (explaining that *Clapper* “did not jettison the ‘substantial risk’ standard”).

And the Supreme Court’s more recent “holdings make clear that *certainty* of impending injury is not necessary to establish Article III jurisdiction.” *Citizens for Resp. & Ethics in Wash. v. Trump*, 971 F.3d 102, 140 (2d Cir. 2020) (emphasis added).

But the district court here never asked whether ACPeds and CMA plausibly alleged a “substantial risk” of enforcement. Indeed, the phrase “substantial risk” never appears once in the entirety of the court’s 41-page opinion. The closest the court came was in describing the *Fifth Circuit’s* standing caselaw. Op., R.61, PageID 1214–15 (describing a case in which the threat of future enforcement had been “substantial”). But that was right before the court explained that it thought that “the Sixth Circuit requires more.” *Id.*, PageID 1215.

The rest of the court’s opinion—assessing for an alleged injury that was “certainly impending”—thus reads as though the court was looking to see whether ACPeds and CMA had established to a “literal

certainty” that the harm they alleged would necessarily occur, *Kanuszewski*, 927 F.3d at 410 (cleaned up), contrary to this Court’s and the Supreme Court’s numerous contrary cases and in conflict with multiple circuits.

For example, requiring a plaintiff to point to “some combination” of the factors listed in *McKay* would make more sense under a literal-certainty requirement. Op., R.61, PageID 1216. So too for the court’s assertion that a plaintiff “must allege” that the “*same* conduct” has resulted in prior enforcement. *Id.*, PageID 1217. It also would help explain the court’s belief that a lengthy enforcement process *minimizes* the risk of harm rather than adding to it. *Id.*, PageID 1219. And it might explain the court’s insistence that HHS’s refusal to take “*any* position, whatsoever, on enforcement against these Plaintiffs” somehow “does not amount to a refusal to disavow enforcement.” *Id.*, PageID 1220–21 (cleaned up). Finally, a literal-certainty requirement might justify the court’s position that the existence of a “vague exemption” precludes plaintiffs from having “standing until the exemption has been interpreted so as not to protect them.” *Id.*, PageID 1222.

But none of those conclusions are supported by this Court’s caselaw. And none of the various showings described above that the district court thought ACPeds and CMA were required to make are actually required to plausibly allege a “substantial risk” that the harm will occur. *SBA List*, 573 U.S. at 158.

B. The district court thought some combination of the factors listed in *McKay* was required, but this Court has never required such a showing.

Relatedly, the district court's misreading of this Court's decision in *McKay* also seems to have led the court astray. Op., R.61, PageID 1215–22. The district court thought this Court's use of a “factor test, first articulated in *McKay*,” sets it apart from the other circuits and raises the bar for plaintiffs bringing pre-enforcement suits in the Sixth Circuit. *Id.*, PageID 1215. That's wrong on multiple levels.

For one thing, unlike the district court, *McKay* correctly stated the test for deciding whether a credible threat of enforcement exists: “The Supreme Court has recognized that an allegation of future injury may satisfy the injury-in-fact requirement if the alleged threatened injury is certainly impending, or there is a substantial risk that the harm will occur.” *McKay*, 823 F.3d at 867 (cleaned up). So *McKay* does not justify reading the substantial-risk language out of the caselaw.

For another, *McKay* did not purport to be creating a new required showing of “some combination” of the factors it listed to prove standing in this circuit. *Contra* Op., R.61, PageID 1216. It merely observed that the Court *has* “found a credible threat of prosecution where plaintiffs allege a subjective chill *and* point to some combination” of those factors. *McKay*, 823 F.3d at 869. But merely saying that showing some combination of those factors has been *sufficient* to prove standing is different from saying it's necessary.

In the years since *McKay* was decided, 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. *But see Plunderbund Media*, 753 F. App’x at 372 (“Because Plaintiffs have not established any *McKay* factor to substantiate their allegation of subjective chill, Plaintiffs have not established a credible threat of prosecution.”).

Indeed, the Court has only used the phrase “*McKay* factors” twice, once in a published opinion and once in an unpublished opinion. *See Online Merchants*, 995 F.3d at 550; *Plunderbund Media*, 753 F. App’x at 372. And in *Online Merchants*, the Court used the phrase while explaining that the “factors are not exhaustive, nor must each be established.” 995 F.3d at 550. Quite the opposite, the Court has recognized that “a variety of facts can demonstrate a credible threat of enforcement.” *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 of its cases. *Id.*

As this Court’s decisions in cases like *Universal Life Church* show, the Court does not always use these same factors when it decides whether a plaintiff has shown or plausibly alleged a credible threat of enforcement. The Court in *Universal Life Church* did not even cite *McKay*. Nor did it need to.

None of that is to say the district court was right in concluding ACPeds and CMA failed to plausibly allege “some combination” of the factors in *McKay*. Op., R.61, PageID 1216. Those factors include “(1) a history of past enforcement against the plaintiffs or others; (2) enforcement warning letters sent to the plaintiffs regarding their specific conduct; (3) an attribute of the challenged statute that makes enforcement easier or more likely, such as a provision allowing any member of the public to initiate an enforcement action; and (4) the defendant’s refusal to disavow enforcement of the challenged statute against a particular plaintiff.” *Online Merchants*, 995 F.3d at 550 (cleaned up).

The first, third, and fourth factors are all met here. Compl., R.15, PageID 140–42, 167–68; MTD Memo in Supp., R.52, PageID 1108, 1110–12, 1113–14, 1117, 1119. And HHS has confirmed that the agency “is investigating and, where appropriate, enforcing Section 1557 in ‘cases involving discrimination on the basis of . . . gender identity.’” *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). As for the second factor, this Court “has held there to be standing for a pre-enforcement challenge without any warning letter or similar specific correspondence whatsoever.” *Online Merchants*, 995 F.3d at 551 (citing *Platt*, 769 F.3d at 452). Nothing in this Court’s caselaw justifies creating the circuit split the decision below invites.

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.

Dated: March 30, 2023

Respectfully submitted,

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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 8,231 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: March 30, 2023

s/Christopher P. Schandavel

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CERTIFICATE OF SERVICE

I hereby certify that on March 30, 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.

s/Christopher P. Schandavel

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**DESIGNATION OF RELEVANT
DISTRICT COURT DOCUMENTS**

Under Sixth Circuit Rules 28(b)(1)(A)(i) and 30(g), Appellants American College of Pediatricians and Catholic Medical Association designate the following district court documents as relevant:

Record Entry	Description	Page ID # Range
15	First Amended Complaint	126–210
15-1	Complaint Exhibit 1	211–610
15-2	Complaint Exhibit 2	612–39
51	Motion to Dismiss	1086–87
52	Memorandum in Support of Motion to Dismiss	1088–1125
55	Memorandum in Opposition to Motion to Dismiss	1131–69
56	Plaintiffs’ Notice of Supplemental Authority	1170–71
57	Reply Memorandum in Support of Motion to Dismiss	1172–83
58	Order Canceling Oral Argument	1184
61	Memorandum Opinion Dismissing Case	1189–1229
62	Judgment Order	1230
63	Notice of Appeal	1231–32