No. 23-5053

IN THE 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*; UNITED STATES 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

BRIEF FOR APPELLEES

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STATEMENT REGARDING ORAL ARGUMENT

Appellants have requested oral argument. The government believes this is an appropriate case to resolve on the briefs, but we stand ready to offer oral argument if the Court determines that it would facilitate consideration of the issues.

STATEMENT OF JURISDICTION

Plaintiffs invoked the district court's jurisdiction under 28 U.S.C. §§ 1331, 1346(a), and 1361. Am. Compl., R. 15, PageID 128. The district court granted defendants' motion to dismiss on November 18, 2022. Op., R. 61, PageID 1229. Plaintiffs timely appealed on January 13, 2023. Notice of Appeal, R. 63, PageID 1231. This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUE

This case concerns a pre-enforcement challenge brought by two medical associations seeking to enjoin the hypothetical future enforcement of Section 1557 of the Affordable Care Act (ACA) against their members by the Department of Health and Human Services (HHS). The question presented is whether the district court properly dismissed plaintiffs' claims for lack of jurisdiction.

STATEMENT OF THE CASE

A. Statutory and Regulatory Background

1. Statutory Prohibition and Enforcement Mechanisms

Section 1557 of the ACA prohibits "any health program or activity" "receiving Federal financial assistance" from discriminating against an individual based on "ground[s] prohibited under" several other statutes. 42 U.S.C. § 18116(a). One of the specified statutes is Title IX of the Education Amendments of 1972, which prohibits discrimination "on the basis of sex." 20 U.S.C. § 1681(a).

HHS's enforcement under Section 1557 through its Office of Civil Rights (OCR) is typically a complaint-driven process, though OCR also has authority to initiate investigations on its own. *See* 45 C.F.R. § 80.7; *see also id.* §§ 86.71, 92.5(a). As part of an investigation, OCR considers all "factors relevant to a determination as to whether the recipient has failed to comply" with Section 1557, *id.* § 80.7(c), including any religious, conscience, or legal objections the recipient may raise to the statute's application to the relevant conduct. If an investigation finds a "failure to comply," OCR must attempt to secure voluntary compliance through informal means. *Id.* § 80.7(d)(1). If such efforts fail, OCR makes a written finding that the recipient is in violation of Section 1557 and makes further attempts at voluntary resolution. *Id.* § 80.8(d). If these prove unsuccessful, OCR can either refer the matter to the Department of Justice with a recommendation that appropriate proceedings be brought to enforce Section 1557 or begin administrative proceedings to suspend or terminate federal financial assistance. *Id.* § 80.8(a), (c).

To terminate federal funding, OCR must conduct a formal administrative hearing and provide 30 days' advance notice to the relevant congressional committees, including "a full written report of the circumstances and the grounds for such action." 45 C.F.R. § 80.8(c); *see id.* § 80.9 (hearing requirements). A final decision to suspend or terminate funding resulting from these administrative proceedings is subject to judicial review. *Id.* § 80.11; *see* 20 U.S.C. § 1683 (incorporated by 42 U.S.C. § 18116(a)).

2. The 2016 Rule and Subsequent Litigation

In 2016, HHS promulgated a rule implementing the anti-discrimination requirements of Section 1557. *See* 81 Fed. Reg. 31,376 (May 18, 2016) (2016 Rule). As relevant here, the 2016 Rule defined discrimination "on the basis of sex" to include gender-identity discrimination. *See id.* at 31,467. Although Title IX contains a religious exemption, the 2016 Rule did not incorporate that exemption. *Id.* at 31,380; *see* 20 U.S.C. §§ 1681(a)(3), 1687. The 2016 Rule made clear, however, that other "statutory protections for religious freedom" applied, including the Religious Freedom Restoration Act (RFRA). 81 Fed. Reg. at 31,379-80.

Several lawsuits by religious entities followed. In December 2016, a district court in the Northern District of Texas issued a nationwide preliminary injunction barring enforcement of the challenged parts of the 2016 Rule. *See Franciscan All., Inc. v. Burwell*, 227 F. Supp. 3d 660, 670 (N.D. Tex. 2016). Three years later, the same district court issued a final judgment vacating the 2016 Rule "insofar as the Rule define[d] '[o]n the basis of sex' to include gender identity." Order at 2, *Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d 928 (N.D. Tex. 2019) (No. 7:16-cv-00108), Dkt. No. 182 (emphasis omitted).

3. The 2020 Rule and Subsequent Litigation

a. In June 2020, HHS finalized a new rule implementing Section 1557. *See* 85 Fed. Reg. 37,160 (June 19, 2020) (2020 Rule). As relevant here, the 2020 Rule rescinded the 2016 Rule's provisions defining sex discrimination, including the

portion regarding gender-identity discrimination. *See id.* at 37,162-65. In place of those provisions, the 2020 Rule paraphrased the statutory language without adopting a new regulatory definition of sex discrimination. *See id.* at 37,178 (codified at 45 C.F.R. § 92.2). In the 2020 Rule's preamble, HHS explained that it did not believe that either Section 1557 or Title IX prohibited gender-identity discrimination. *See id.* at 37,162, 37,168, 37,183-86, 37,207. In addition, the 2020 Rule did not expressly import the Title-IX religious exemption, but stated that HHS interpreted the exemption to be incorporated into Section 1557, along with RFRA and other conscience statutes whose application the 2016 Rule had recognized. *See id.* at 37,204-09; *see also* 45 C.F.R. § 92.6(b).

b. Three days after HHS submitted the 2020 Rule for publication in the Federal Register, the Supreme Court decided *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020). The Court held that Title VII's prohibition against discrimination "because of" sex encompasses discrimination because of sexual orientation and transgender status. *Id.* at 1737-41. However, the Court specifically reserved the question of how RFRA and other "doctrines protecting religious liberty interact with Title VII," explaining that these "are questions for future cases." *Id.* at 1754. The Court noted in dicta that "RFRA operates as a kind of super statute, displacing the normal operation of other federal laws" and that "it might supersede Title VII's commands in appropriate cases." *Id.*

c. Following *Bostock*, plaintiffs in several district courts challenged the 2020 Rule as substantively and procedurally unlawful under the Administrative Procedure Act (APA). Two district courts issued preliminary injunctions barring HHS from enforcing its repeal of the 2016 regulatory definition of sex discrimination as including discrimination on the basis of sex stereotyping, and one court enjoined HHS from enforcing the 2020 Rule's incorporation of Title IX's religious exemption. *See Whitman-Walker Clinic, Inc. v. HHS*, 485 F. Supp. 3d 1, 64 (D.D.C. 2020) (2016 regulatory definition and Title-IX religious exemption); *Walker v. Azar*, 480 F. Supp. 3d 417, 427 (E.D.N.Y. 2020) (2016 regulatory definition); *Walker v. Azar*, No. 20-cv-2834, 2020 WL 6363970 (E.D.N.Y. Oct. 29, 2020) (related provision). Both district courts acknowledged that their orders did not affect the vacatur of the 2016 Rule by the *Franciscan Alliance* court insofar as the Rule defined sex discrimination to include gender-identity discrimination. *See Whitman-Walker*, 485 F. Supp. 3d at 26 (acknowledging vacatur); *Walker*, 480 F. Supp. 3d at 427 (same).

d. On January 20, 2021, President Biden issued Executive Order No. 13,988, which acknowledges *Bostock* and directs agencies to "consider whether to" take any actions "necessary to fully implement statutes that prohibit sex discrimination," "consistent with applicable law" (which includes RFRA). 86 Fed. Reg. 7023, 7024 (Jan. 25, 2021).

In May 2021, HHS issued a notification to inform the public that, consistent with *Bostock* and Title IX, HHS would interpret and enforce Section 1557's

prohibition of sex discrimination as including discrimination based on sexual orientation and gender identity. 86 Fed. Reg. 27,984 (May 25, 2021) (2021 Notice of Interpretation). This 2021 Notice of Interpretation emphasizes that it "will guide OCR in processing complaints and conducting investigations, but does not itself determine the outcome in any particular case or set of facts." *Id.* at 27,985. Additionally, the Notice explicitly states that HHS "will comply with [RFRA] and all other legal requirements." *Id.* (cleaned up).

In July 2022, HHS issued a Notice of Proposed Rulemaking (NPRM), which proposed to interpret Section 1557's prohibition against sex discrimination to include discrimination based on gender identity and sexual orientation. 87 Fed. Reg. 47,824 (Aug. 4, 2022). The NPRM proposed that covered entities must not "[d]eny or limit health services, including those that are offered exclusively to individuals of one sex, to an individual based upon the individual's sex assigned at birth, gender identity, or gender otherwise recorded." *Id.* at 47,918 (proposed 45 C.F.R. § 92.206(b)(1)). The NPRM explained that "[n]othing in this section requires the provision of any health service where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting that service." *Id.* (proposed 45 C.F.R. § 92.206(c)). The NPRM also acknowledged that statutes protecting religious exercise such as RFRA may require exemptions from Section 1557's nondiscrimination provisions, and it accordingly proposed a process for covered entities to assert claims for religious exemptions. *Id.* at 47,885-86, 47,911, 47,918-19.

B. Factual Background

Plaintiffs-Appellants—the American College of Pediatricians (ACP) and Catholic Medical Association (CMA) (collectively, plaintiffs)—are "two medical associations, which together represent approximately three thousand physicians and health professionals." Am. Compl., R. 15, PageID 127. Plaintiffs allege that their members have "medical, ethical, or religious objections" to a list of 22 "objectionable practices," which includes performing various gender-affirming health care services. *Id.*, PageID 147-149; Opening Br. 12-13. And plaintiffs allege that HHS has imposed a "Section 1557 gender identity mandate" through the 2016 Rule, 2020 Rule, and 2021 Notice of Interpretation, which allegedly requires their members to engage in these 22 practices. *See* Am. Compl. ¶¶ 87, 133, R. 15, PageID 141, 149.

C. Prior Proceedings

1. In August 2021, plaintiffs filed suit on behalf of their members challenging this purported "Section 1557 gender identity mandate." *See* Compl., R. 1, PageID 1-81. Plaintiffs allege that this "mandate" violates the APA; First Amendment rights to freedom of speech and association; RFRA; the Free Exercise Clause; and structural principles of federalism, the Spending Clause, and the Tenth Amendment. Am. Compl., R. 15, PageID 178-195. The complaint asserts in the alternative that, to the extent the source of this "mandate" is "Section 1557 itself," the statute and its enforcement violate RFRA and those constitutional provisions. *See id.* ¶¶ 420, 441, 447, 459, 461, 473, PageID 188, 191, 193, 195.

Plaintiffs' complaint requested injunctive relief on behalf of their members "against implementation, enforcement, or application of a gender identity nondiscrimination mandate under Section 1557 of the ACA"—and against the enforcement of Section 1557 itself—"because of the failure to perform, offer, endorse, pr[e]scribe, or refer for gender interventions." Am. Compl., R. 15, PageID 205-206. Plaintiffs further requested vacatur of the 2016 Rule's "gender identity language" and the 2021 Notice of Interpretation, and the 2020 Rule to the extent it can be "interpreted to prohibit gender identity discrimination," as well as various forms of declaratory relief. *Id.*, PageID 205-206.

2. The government filed a motion to dismiss for lack of subject-matter jurisdiction, arguing that plaintiffs lacked standing and their challenge was not ripe. Mem., R. 52, PageID 1108-1117. The district court granted the motion on both standing and ripeness grounds. Op., R. 61, PageID 1229.

a. The district court first explained that, to satisfy the injury-in-fact requirement "[i]n a pre-enforcement suit" such as this, a plaintiff must allege "an intention to engage in a course of conduct arguably affected with a constitutional interest, but [arguably] proscribed by a statute," and "a credible threat of prosecution thereunder." Op., R. 61, PageID 1211 (second alteration in original) (quoting *Susan B. Anthony List v. Driehaus* (*SBA List*), 573 U.S. 149, 159 (2014)). The court observed that the refusal of plaintiffs' members to engage in "the twenty-two 'objectionable practices' related to medical gender-transition services" is "arguably affected with a

constitutional interest." *Id.* The court also concluded that "HHS's operative Section 1557 regulations" and Section 1557 itself "at least arguably bar discrimination against transgender patients as a form of sex discrimination," and that the "refusal to engage in the 'objectionable practices'" by plaintiffs' members "would arguably amount to such sex discrimination." *Id.*, PageID 1212-1214.

The district court concluded, however, that plaintiffs had not demonstrated that their members faced a sufficiently credible threat of enforcement under Section 1557. Op., R. 61, PageID 1214-1226. Plaintiffs urged the court to follow district courts in the Fifth and Eighth Circuits, which had permitted other plaintiffs to proceed to the merits on similar pre-enforcement challenges. Mem., R. 55, PageID 1146-1148. The court declined this invitation, noting that "[t]he Sixth Circuit's jurisprudence on standing, in particular, the issue of whether there exists a credible threat of prosecution, bears considerable differences from the Fifth and Eighth Circuit's." Op., R. 61, PageID 1214. The court explained that this Circuit looks to four non-exhaustive factors to determine "whether there is a credible threat of prosecution sufficient to confer [pre-enforcement] standing":

> (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.

Id., PageID 1215-1216 (quotation marks omitted) (quoting *Online Merchs. Guild v. Cameron*, 995 F.3d 540, 550 (6th Cir. 2021)). The court concluded that "[p]laintiffs can point to no facts relating to any of these factors to support their contention that they face a credible threat of prosecution under Section 1557." *Id.*, PageID 1216.

The district court determined that plaintiffs did not plausibly allege any history of enforcement against their members or others, much less enforcement for the same type of conduct in which their members wish to engage. Op., R. 61 PageID 1216-1217. Nor did they allege that members "received any enforcement warning letters from HHS regarding their refusal to perform gender-transition services." *Id.*, PageID 1217. Additionally, the court observed that Section 1557 does not contain "a citizen-enforcement provision" and has a "length[y]" enforcement process that "offers regulated entities many procedural protections," during which "[p]laintiffs would be able to raise the same claims they now raise." *Id.*, PageID 1218-1220. Finally, the court explained that "HHS has not taken *any* position, whatsoever, on enforcement against these [p]laintiffs," and emphasized the fact-specific nature of the inquiry into whether the statute has been violated. *Id.*, PageID 1220-1221. Accordingly, the court concluded that these four factors "weigh against [p]laintiffs' standing," *id.*, PageID 1221, and that the complaint had "not allege[d] any other feature of Section 1557 that would render [plaintiffs'] injuries 'certainly impending,'" *id.*, PageID 1222.

b. The district court also found plaintiffs' claims to be unripe. Op., R. 61, PageID 1222-1223 n.5. Consistent with its credible-threat analysis, the court noted

"the unlikelihood that the injury would ever come to pass in light of the RFRA exemption and the lack of threatened or actual enforcement." *Id.*, PageID 1223 n.5. The court further explained that "the factual record is [not] sufficiently developed to produce a fair adjudication of the merits of the parties' respective claims[] … because there are no facts alleged regarding a particular patient, seeking a particular medical procedure, with their medical provider giving particular reasons, whether discriminatory or nondiscriminatory, for their refusal to perform the procedure." *Id.* (quotation marks omitted). Moreover, the court determined that there would be "little to no hardship to the parties" from postponing judicial review, because plaintiffs' members "could raise these exact same claims, albeit in a more developed factual context, at any point after HHS initiated some kind of enforcement proceeding against them." *Id.*

SUMMARY OF ARGUMENT

I. The district court correctly held that plaintiffs lack standing to bring this challenge to HHS's hypothetical, future enforcement of Section 1557. Pre-enforcement standing is the exception, not the norm. Here, plaintiffs cannot show that any enforcement action against their members is sufficiently imminent to create a concrete injury. The operative complaint fails to plausibly allege a substantial probability that any of plaintiffs' identified members will actually engage in proscribed conduct. Plaintiffs have also failed to demonstrate that their members face a credible threat of enforcement. The district court properly evaluated the relevant factors to

conclude that none supports plaintiffs' assertion of standing on behalf of their members. The Fifth and Eighth Circuits' decisions in cases raising distinct challenges to possible enforcement of Section 1557—raised by different plaintiffs, based on different factual allegations in different complaints, and resolved under different standing precedents—do not compel a different result here.

II. The district court also correctly concluded that plaintiffs' claims are unripe. Any potential future enforcement action against plaintiffs' members depends on a series of speculative contingencies that may never come to pass. And the specific claims raised in the operative complaint cannot be properly evaluated in the absence of a concrete factual context. Moreover, postponing judicial review would not harm plaintiffs' members, given their ability to raise these same claims in the context of HHS administrative proceedings.

Accordingly, this Court should affirm the district court's dismissal for lack of subject-matter jurisdiction.

STANDARD OF REVIEW

This Court reviews de novo the dismissal of a suit for lack of standing or ripeness. *Mosley v. Kohl's Dep't Stores, Inc.*, 942 F.3d 752, 756 (6th Cir. 2019); *Doe v. Oberlin Coll.*, 60 F.4th 345, 351 (6th Cir. 2023).

ARGUMENT

"[N]o principle is more fundamental to the judiciary's proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual

cases or controversies." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 408 (2013) (quotation marks omitted). The case-or-controversy inquiry is "especially rigorous when reaching the merits of the dispute would force [a court] to decide whether an action taken by one of the other two branches of the Federal Government was" unlawful. *Raines v. Byrd*, 521 U.S. 811, 819-20 (1997); *see Crawford v. U.S. Dep't of Treasury*, 868 F.3d 438, 457 (6th Cir. 2017) (citing *Raines*); *see also Flast v. Cohen*, 392 U.S. 83, 96 (1968) (observing that in this context "the rule against advisory opinions implements the separation of powers prescribed by the Constitution and confines federal courts to the role assigned them by Article III").

Several Article-III doctrines are implicated when plaintiffs bring suit in the absence of any enforcement action against them, including standing and ripeness. Adherence to those principles ensures that federal courts remain within their assigned role in our system of separated powers. A plaintiff cannot sue to obtain an anticipatory injunction based on its speculative predictions about what policies or positions an agency may adopt in the future. *See Miller v. City of Wickliffe*, 852 F.3d 497, 503 (6th Cir. 2017) ("The 'case or controversy' requirement prohibits all advisory opinions, not just some advisory opinions and not just advisory opinions that hold little interest to the parties or the public." (quotation marks omitted)). Nor may a plaintiff sue to compel the Executive Branch to formulate an enforcement position and thereby create a dispute that does not otherwise exist. *Cf. Linda R.S. v. Richard D.*, 410 U.S. 614, 619 (1973). Article-III courts are limited to "real, earnest and vital

controvers[ies]" requiring immediate resolution. *Valley Forge Christian Coll. v. Americans United for Separation of Church & State, Inc.*, 454 U.S. 464, 471 (1982) (quotation marks omitted).

Pre-enforcement review is thus the exception, not the rule. *See Whole Woman's Health v. Jackson*, 142 S. Ct. 522, 537-38 (2021) (making clear that there is no "unqualified right to pre-enforcement review" and that many statutory and constitutional rights "are as a practical matter asserted typically as defenses," not in "pre-enforcement cases"). Although plaintiffs may prefer to seek broad relief against government agencies through such an action, a "case-by-case approach" challenging "further agency action" that "more immediately harm[s] the plaintiff" "is the traditional, and remains the normal, mode of operation of the courts." *Lujan v. National Wildlife Fed'n*, 497 U.S. 871, 892-94 (1990); *see Warshak v. United States*, 532 F.3d 521, 529 (6th Cir. 2008) (en banc) (citing *National Wildlife Fed'n*). Plaintiffs have not satisfied the requirements for invoking pre-enforcement review in this case.

I. The District Court Correctly Held That Plaintiffs Lack Standing.

The district court correctly concluded that plaintiffs lack standing to challenge HHS's hypothetical future enforcement of Section 1557.

Under the doctrine of standing, a court must ensure that "the plaintiff has alleged such a personal stake in the outcome of the controversy as to warrant his invocation of federal-court jurisdiction and to justify exercise of the court's remedial powers on his behalf." *Warth v. Seldin*, 422 U.S. 490, 498-99 (1975) (quotation marks

omitted). A plaintiff must, *inter alia*, show he has suffered an injury that is "actual or imminent, not 'conjectural' or 'hypothetical.'" *SBA List*, 573 U.S. at 158 (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)). An alleged future injury satisfies that requirement only "if the threatened injury is certainly impending, or there is a substantial risk that the harm will occur." *Id.* (quotation marks omitted). A plaintiff pursuing pre-enforcement review can demonstrate a sufficiently imminent injury "where he alleges 'an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute, and there exists a credible threat of prosecution thereunder.'" *Id.* at 159 (quoting *Babbitt v. Farm Workers*, 442 U.S. 289, 298 (1979)).

Where organizational plaintiffs proceed on behalf of their members, they must demonstrate injury-in-fact consistent with the associational-standing doctrine, which requires "that [an organization's] members have Article III standing in their own right." *Association of Am. Physicians & Surgeons v. U.S. Food & Drug Admin.* (*AAPS*), 13 F.4th 531, 543 (6th Cir. 2021). At the motion-to-dismiss stage, the factual allegations in an organization's complaint specifically with respect to at least one identified member must support a plausible claim that this identified member had standing at the time the relevant complaint was filed. *See id.* at 543-45; *see also Barber v. Charter Twp. of Springfield*, 31 F.4th 382, 390, 392 n.7 (6th Cir. 2022) (observing that, in "assessing standing," this Court "look[s] only to the facts existing when the

complaint" adding the relevant plaintiff to the action "[wa]s filed" (quotation marks omitted)).

To establish a sufficiently imminent future injury, plaintiffs were thus required to plausibly plead that one of their identified members (1) possessed an intent to engage in arguably-constitutional-but-proscribed conduct and (2) would suffer a credible threat of prosecution for doing so. *See SBA List*, 573 U.S. at 158, 159. Neither component is satisfied here.

A. Plaintiffs Have Not Established a Substantial Probability that Their Members Will Engage in Proscribed Conduct.

To satisfy the first component of "standing to bring a pre-enforcement challenge to a federal statute, there must be a *substantial probability* that the plaintiff actually will engage in conduct that is arguably affected with a constitutional interest" but proscribed by statute. *Crawford*, 868 F.3d at 455 (emphasis omitted); *accord Daly v. McGuffey*, No. 21-3266, 2021 WL 7543815, at *2 (6th Cir. Nov. 15, 2021). Plaintiffs have not met this standard.

In 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. *See SBA List*, 573 U.S. at 161 ("SBA has already" made arguably proscribed statements, "and it has alleged an intent to engage in substantially similar activity in the future." (cleaned up)); *see also id.* at 159-61 (observing same for plaintiffs in *Holder v. Humanitarian Law Project*, 561 U.S. 1 (2010);

Babbitt, 442 U.S. 289; and *Steffel v. Thompson*, 415 U.S. 452 (1974)). This Circuit's pre-enforcement cases are similar. *See, e.g.*, *Berry v. Schmitt*, 688 F.3d 290, 296 (6th Cir. 2012) (intent to re-engage in proscribed speech); *Online Merchs. Guild*, 995 F.3d at 549-50 (intent to "continue" engaging in arguably proscribed "online sales"); *Kiser v. Reitz*, 765 F.3d 601, 608 (6th Cir. 2014) (advertised in arguably proscribed manner "in the past and … intends to do so in the future"). Because those plaintiffs previously engaged in the proscribed conduct, it was substantially probable, as opposed to merely speculative, that they would engage in similar conduct in the future.

It is more difficult for plaintiffs to establish pre-enforcement standing, however, where they cannot allege previous engagement in proscribed conduct that can be resumed at will. For instance, in *Crawford*, this Court held that individuals challenging a law that imposed reporting requirements for funds in foreign accounts lacked standing because none "claim[ed] to hold enough foreign assets to be subject to the individual-reporting requirement" and thus they were not actually "subject to" the law. *Crawford*, 868 F.3d at 443, 458. And in *Daly*, this Court found no pre-enforcement standing to challenge firearms laws where the plaintiffs "d[id] not allege that they have engaged in any conduct prohibited by statute, nor d[id] they put forth facts that would allow a court to infer that they are substantially likely to do so." *Daly*, 2021 WL 7543815, at *2.

The instant suit falls into this latter category. Here, the complaint identifies five specific ACP members. *See* Am. Compl., R. 15, PageID 153-156. The complaint

does not allege that any of these five has ever treated a transgender patient or declined to perform—or even been asked to perform—one of the "objectionable practices." *Id.* Nor does the complaint allege any specific facts making it likely that these members will treat or be asked to treat a transgender patient in future. *Id.* Unlike the successful pre-enforcement cases discussed above, these members do not allege that they previously engaged in proscribed conduct—discriminating against a patient on the basis of their gender identity—or provide any factual basis to support a substantial probability that they will do so in future.

Similarly, CMA identifies only three members. *See* Am. Compl., R. 15, PageID 160-162. Of the three, the complaint alleges only that Dr. Rachel Kaiser, an emergency-room doctor, "has encountered patients who have said that their gender identity differs from the patient's sex." *Id.* ¶¶ 226, 232, PageID 160-161. But the complaint identifies just one instance in which Dr. Kaiser actually "cared for" such a patient, and it does not allege that she was required to engage in any "objectionable practices" in doing so. *Id.* ¶ 232, PageID 161. Nor does the complaint allege facts to plausibly establish that Dr. Kaiser will likely have occasion to refuse gender-affirming care to a transgender patient in the future. On the contrary, the complaint specifically alleges that another doctor at Dr. Kaiser's emergency room *provided* care to a transgender patient to which Dr. Kaiser would object. *Id.* The availability of other physicians to perform objected-to services underscores the uncertainty that Dr. Kaiser herself would ever be required to engage in an "objectionable practice."

For plaintiffs' members to engage in proscribed conduct by refusing to perform gender-affirming health care, a series of contingencies must occur: a transgender patient seeks care at their practice and, specifically, from the member; in the course of treating the patient, the member is asked or obligated to perform gender-affirming care; the care falls within the scope of the member's objections; the member's refusal to provide the care does not rest on a legitimate, non-discriminatory justification (such as a bona fide treatment decision); and the member cannot raise a valid RFRA claim. Plaintiffs have not established a "substantial probability" that this string of occurrences will come to pass such that their members "actually will engage in [proscribed] conduct." *Crawford*, 868 F.3d at 455 (emphasis omitted). This kind of "'highly conjectural'" and "'speculative'" "chain of events is simply too attenuated to establish the injury in fact required to confer standing." *Fieger v. Michigan Supreme Court*, 553 F.3d 955, 967 (6th Cir. 2009).

B. Plaintiffs Have Not Demonstrated that Their Members Face a Substantial Likelihood of Enforcement.

Plaintiffs have also failed to demonstrate the second component of pre-enforcement standing: the existence of a credible threat of enforcement.

A plaintiff may establish a credible threat by showing that the plaintiff was subject to past enforcement or has received a targeted threat of future enforcement. *See, e.g.*, *Steffel*, 415 U.S. at 459 (plaintiff twice instructed that unless he ceased challenged conduct, he would be prosecuted); *SBA List*, 573 U.S. at 164 ("threat of

future enforcement of the [challenged] statute is substantial" as "there is a history of past enforcement here"). A plaintiff cannot, however, satisfy Article III merely by alleging that the plaintiff will engage in conduct that it fears may violate federal law. *See, e.g.*, *Clapper*, 568 U.S. at 410; *Vonderhaar v. Village of Evendale*, 906 F.3d 397, 402 (6th Cir. 2018) (observing that "speculative" "fear of an unconstitutional search" does not "permit[] a pre-enforcement action"). Likewise, "'general threat[s] by officials to enforce those laws which they are charged to administer' do not create the necessary injury in fact" absent a more particularized basis for the plaintiff to fear enforcement. *Lopez v. Candaele*, 630 F.3d 775, 787 (9th Cir. 2010) (alteration in original) (quoting *United Pub. Workers of Am. (C.I.O.) v. Mitchell*, 330 U.S. 75, 88 (1947)).

Because plaintiffs here offer nothing more than generalized, speculative fears, they have failed to plausibly plead "that the likelihood of future enforcement" against their members "is 'substantial.'" *See California v. Texas*, 141 S. Ct. 2104, 2114 (2021).

1. The district court correctly held that plaintiffs did not establish a credible threat of enforcement.

This Circuit has identified four factors that generally "inform [its] analysis of whether there is a credible threat of prosecution sufficient to confer standing": (1) "a history of past enforcement"; (2) "warning letters sent to the plaintiffs"; (3) "an attribute of the challenged statute that makes enforcement easier or more likely"; and (4) the "defendant's refusal to disavow enforcement" against the plaintiff. *Online Merchs. Guild*, 995 F.3d at 550 (quoting *McKay v. Federspiel*, 823 F.3d 862, 869 (6th Cir.

2016)). Although "not exhaustive," *id.*, the Court's "cases have highlighted [these] four commonly recurring factors to consider" under this inquiry, *Fischer v. Thomas*, 52 F.4th 303, 307 (6th Cir. 2022) (per curiam). The district court correctly applied these so-called *McKay* factors and concluded that plaintiffs' members did not face a credible threat of enforcement.

This Court has recognized that "[a] threat of future enforcement may be 'credible' when the same conduct has drawn enforcement actions or threats of enforcement in the past." *Kiser*, 765 F.3d at 609; *see Fischer*, 52 F.4th at 308 (involving "past enforcement against others" for "similar conduct"). As the district court observed, here "there is no history of enforcement" of Section 1557 "against the plaintiffs or others." Op., R. 61, PageID 1216.

In their complaint, plaintiffs merely allege that "OCR is now actively investigating, enforcing, and implementing an interpretation of Section 1557 and HHS regulations under which sex discrimination includes gender identity and sex stereotyping." Op., R. 61, PageID 1216 (quoting Am. Compl. ¶ 88, R. 15, PageID 141). Although prior enforcement is only relevant to this inquiry if it involves conduct "similar" to a plaintiff's proposed conduct, *see Fischer*, 52 F.4th at 308, the complaint makes "no allegations regarding what type of conduct has drawn or is drawing enforcement actions under Section 1557, much less that the refusal to perform gender-transition services for medical, ethical, and religious reasons has precipitated enforcement actions," Op., R. 61, PageID 1217. And plaintiffs did not

dispute the government's representation that "HHS has never enforced Section 1557 to revoke the funding of a provider for failure to provide gender-transition services." *Id.*, PageID 1217 n.4 (quoting Mem., R. 52, PageID 1119).[1]

Plaintiffs offer no real response to the district court's assessment of this factor. Instead, they merely assert that the factor is "met here," citing a March 2022 guidance document which stated generally that OCR "is investigating and, where appropriate, enforcing Section 1557" against gender-identity discrimination. Opening Br. 36 (quotation marks omitted). As an initial matter, plaintiffs cannot invoke this document—or any other facts arising after August 2021—because standing is evaluated based on allegations "at the time the [original] complaint was filed." *Crawford*, 868 F.3d at 460; *Barber*, 31 F.4th at 392 n.7.

In any event, the generic statement reflected in that guidance document does not amount to "past enforcement against others" "for similar conduct." *Fischer*, 52 F.4th at 308. There is a great deal of conduct that might violate Section 1557 but clearly falls outside plaintiffs' list of "objectionable practices," such as refusing to treat a patient's broken arm because the patient is transgender. Enforcement in those scenarios would not make it any more likely that HHS would enforce Section 1557

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[1] Plaintiffs briefly suggest that the district court incorrectly required that the "'*same* conduct' has resulted in prior enforcement" under this factor. Opening Br. 33. But the court was merely quoting language used by this Court. *See Kiser*, 765 F.3d at 609. In any event, plaintiffs fail to identify any enforcement actions against the same or meaningfully similar conduct.

against physicians who decline to provide gender-affirming care based on ethical or religious objections of the sort asserted by plaintiffs here.

In lieu of affirmatively attempting to demonstrate a history of enforcement in similar circumstances, plaintiffs instead fault the government for being "unable to identify a long history of nonenforcement." Opening Br. 28 (quotation marks omitted). This argument improperly inverts the burden of proof. It is black-letter law that "the burden … falls squarely on the plaintiff," *Crawford*, 868 F.3d at 460, with respect to "[e]ach element" of standing. *Lujan*, 504 U.S. at 561. This Circuit does not assign the burden of proving a history of *non*-enforcement to defendants. *See, e.g.*, *AAPS*, 13 F.4th at 545 ("The complaint[] … did not allege any prior enforcement actions …."); *Daly*, 2021 WL 7543815, at *3 ("[T]he plaintiffs have not made such specific factual allegations [of a history of past enforcement] here."). And *Universal Life Church Monastery Storehouse v. Nabors*, 35 F.4th 1021 (6th Cir. 2022), is not to the contrary. *See id.* at 1033, 1035 (recognizing that "plaintiffs have the burden" with respect to standing, and noting merely that "desuetude" can provide a basis for finding that "no case or controversy exists").

The district court also correctly held that the second *McKay* factor—"enforcement warning letters sent to the plaintiffs regarding their specific conduct," *Online Merchs. Guild*, 995 F.3d at 550 (quoting *McKay*, 823 F.3d at 869)—provides no support for plaintiffs. *See* Op., R. 61, PageID 1217-1218. Indeed, plaintiffs concede (Br. 36) that this second factor does not support standing here.

The third *McKay* factor looks to "attribute[s] of the challenged statute that make[] enforcement easier or more likely, such as a provision allowing any member of the public to initiate an enforcement action." *Online Merchs. Guild*, 995 F.3d at 550 (quoting *McKay*, 823 F.3d at 869). As the district court explained, "HHS's enforcement process under Section 1557 is lengthier than those of commonly challenged state civil and criminal statutes that are often examined for standing," Op., R. 61, PageID 1218, and "offers regulated entities many procedural protections prior to any funding loss," *id.*, PageID 1219. Indeed, any entity subject to an OCR investigation for potential violations of Section 1557 "would be able to raise the same claims [plaintiffs] now raise" before the agency, "well before any enforcement action has been taken." *Id.*, PageID 1220. The robustness of this administrative process makes the prospect of enforcement more uncertain.

If private individuals submit complaints to OCR, 45 C.F.R. § 80.7(b), this merely triggers a process in which OCR determines whether to initiate an investigation. And although there is a private right of action under Section 1557, plaintiffs' challenge is to the *federal government's* unique enforcement scheme under Section 1557. *See* Opening Br. 10 (emphasizing that "'the federal government's penalties'" and potential loss of "'federal funding'" are the crucial threatened harms at issue). There is no "citizen-enforcement provision," Op., R. 61, PageID 1218, akin to that employed in other statutory schemes such as *qui tam* actions, wherein a private individual could enforce Section 1557 on behalf of the federal government or seek to

terminate an entity's federal funding. Only the federal government can initiate the process to terminate federal funding, not private parties. The district court was thus correct to conclude that this third factor "weigh[s] against [p]laintiffs' standing." Op., R. 61, PageID 1221.

Again, plaintiffs advance no real argument that they satisfy this factor. Instead, they offer a bare assertion, devoid of any explanation, that the third factor is "met here." Opening Br. 36. Because plaintiffs failed to develop any argument that the district court erred in concluding that the attributes of Section-1557 enforcement do not "support [plaintiffs'] contention that they face a credible threat of prosecution under Section 1557," Op., R. 61, PageID 1216, they have forfeited any argument on this point. *See Glennborough Homeowners Ass'n v. U.S. Postal Serv.*, 21 F.4th 410, 414 (6th Cir. 2021) ("[A] party can forfeit its argument for why it has standing to sue." (emphasis omitted)); *United States v. Phinazee*, 515 F.3d 511, 520 (6th Cir. 2008).

The fourth *McKay* factor considers a "defendant's refusal to disavow enforcement of the challenged statute against a particular plaintiff." *Online Merchs. Guild*, 995 F.3d at 550 (quoting *McKay*, 823 F.3d at 869). Whether a disavowal exists, and the extent to which it supports finding a credible threat of enforcement, can be a "nuanced" question. *See McKay*, 823 F.3d at 870. Even when a defendant does not expressly disavow enforcement against a plaintiff, the particular circumstances surrounding enforcement can make a threat "less immediate." *See id.*

Here, the district court reasoned that plaintiffs had "not alleged HHS's 'refusal to disavow enforcement' against" their members; rather, "HHS has not taken *any* position, whatsoever, on enforcement against these [p]laintiffs." Op., R. 61, PageID 1220. The court emphasized that "HHS's consistent position has been that any enforcement would depend on the particular facts of the action, including the nondiscriminatory reasons for refusing to offer a specific service and the applicability of RFRA and other legal requirements." *Id.*, PageID 1221. Given plaintiffs' "allegations that [their members] have nondiscriminatory scientific and medical concerns regarding the objectionable practices and that RFRA protects them from engaging in the objectionable practices," the court concluded that "HHS's position can hardly be construed as a 'refusal to disavow enforcement' against [p]laintiffs." *Id.*

The district court's conclusion that this fourth factor does not support plaintiffs' standing thus correctly evaluates the nuance of the government's enforcement position in light of the case-specific nature of Section-1557 enforcement. Until faced with sufficiently concrete facts from which to evaluate the circumstances of a physician's refusal to treat a transgender patient—including the treatment sought, the nature of the physician's practice, the reasons for denying treatment, and any religious exemption that could be sought—it is impossible for the government to take a definitive enforcement position with respect to a hypothetical future refusal. As the district court recognized, that does not mean HHS plans to take any enforcement action against plaintiffs' members; nor does it mean HHS must categorically refuse to

disavow future enforcement in certain circumstances. *Cf.* 87 Fed. Reg. at 47,885-86, 47,918-19 (NPRM).

The multifaceted and fact-specific inquiry into whether conduct violates Section 1557—and the current lack of concrete factual circumstances in which to undertake the inquiry—distinguishes this case from cases where this Court has relied on a defendant's refusal to disavow enforcement to support standing. *See Fischer*, 52 F.4th at 308 (enforcement body already determined it had sufficient "basis" to investigate conduct); *Online Merchs. Guild*, 995 F.3d at 550 (Attorney General asserted he had "reason to believe" the defendant "is engaging in[] … unlawful acts" through subpoena (quotation marks omitted)); *Platt v. Board of Comm'rs on Grievances & Discipline of Ohio Supreme Court*, 769 F.3d 447, 452 (6th Cir. 2014) (challenged law clearly restricted intended speech).

Plaintiffs contend (Br. 26) that the government's purported "refusal" to categorically disavow enforcement against all of their individual members without any fact-specific analysis should, by itself, be "enough to establish standing." That argument is both factually and legally flawed. As discussed, HHS's position cannot properly be understood as an absolute refusal to disavow enforcement, and it does not subject plaintiffs' members to any greater risk of enforcement than any other covered medical provider in the country for whom HHS has likewise not issued a personalized statement of enforcement intentions.

In any event, the disavowal factor is not dispositive of the credible-threat inquiry. As this Court has recognized, it "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); *see also AAPS*, 13 F.4th at 545 (finding no credible threat without discussing disavowal).[2] This Court generally relies upon refusals to disavow enforcement to support standing where at least one other factor is implicated as well, such as a warning letter to the plaintiff. *See, e.g.*, *Online Merchs. Guild*, 995 F.3d at 550-551; *Kiser*, 765 F.3d at 609; *Fischer*, 52 F.4th at 308. Overall, the district court properly concluded that this factor did not support plaintiffs' standing.

Beyond the four *McKay* factors, the district court correctly determined that there were no other facts that could support plaintiffs' claimed threat of enforcement. *See* Op., R. 61, PageID 1222.[3] Instead, as the district court explained, "the availability

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[2] Plaintiffs point to a single case where they contend this Court found pre-enforcement standing based on a refusal to disavow alone. *See* Opening Br. 26 (citing *Green Party of Tenn. v. Hargett*, 791 F.3d 684 (6th Cir. 2015)). But the extreme circumstances of that case render it the exception that proves the rule. There, a blatantly unconstitutional state law required political parties to file a loyalty-oath affidavit in order to place their nominees on the ballot, but the State would not disavow future enforcement. And if the law were ever enforced, there would be insufficient time to challenge it in advance of an impending election. *See Green Party of Tenn. v. Hargett*, 7 F. Supp. 3d 772, 790 (M.D. Tenn. 2014) (invoking "capable of repetition, yet evading review" principle in support of standing).

[3] With respect to First Amendment claims, this Court also considers "whether the challenged action chills speech." *Fischer*, 52 F.4th at 307. However, plaintiffs have not alleged that their identified members are self-censoring, Am. Compl., R. 15, PageID 153-156, 160-162, and they do not advance any argument regarding allegations of chilled speech in support of standing.

of a religious exemption to protect [plaintiffs' members] from enforcement" further "cuts against any argument that they face a credible threat of prosecution." *Id.*

HHS has consistently affirmed that it will abide by RFRA in any enforcement of Section 1557. *See* 81 Fed. Reg. at 31,466 (2016 Rule); 86 Fed. Reg. at 27,985 (2021 Notice of Interpretation); *see also* 87 Fed. Reg. at 47,828 (NPRM). Here, plaintiffs allege that the sincerely held religious beliefs of their members "prohibit them from engaging in or facilitating in the 'objectionable practices,'" that their "exercise of religion" would be "substantially burden[ed]" by requiring them to do so, and that their members' "provision of healthcare in accord with their religious beliefs prevents no one from obtaining gender transition interventions from other providers." Am. Compl. ¶¶ 428, 433, 438, R. 15, PageID 189-190. The possibility that at least some of plaintiffs' members may be able to successfully invoke RFRA adds yet another link to the attenuated "chain of events necessary for the plaintiffs in this case to suffer false prosecution," which had already "veer[ed] into the area of speculation and conjecture." *White v. United States*, 601 F.3d 545, 554 (6th Cir. 2010) (quotation marks omitted)); *see supra* p. 19.

Plaintiffs contend (Br. 27), that ACP should be deemed to have standing on behalf of its non-religious members even if its religious members would be protected by a religious exemption. However, ACP has not identified a specific, non-religious member who objects to providing the same services (on non-religious grounds) and faces a substantial risk of enforcement. *See AAPS*, 13 F.4th at 543 ("The organization

must … identify a member who has suffered (or is about to suffer) a concrete and particularized injury from the defendant's conduct."). ACP alleges that, in addition to medical and ethical objections to the listed practices, "[s]ome [ACP] members also have religious objections." Am. Compl. ¶¶ 146-147, R. 15, PageID 151. But its anonymous individual members merely claim that they "oppose[] engaging in the objectionable practices," without specifying whether their opposition is religious in nature. *See id.* ¶¶ 162, 168, 174, 180, PageID 153-155. And Dr. Van Meter is a member of CMA and has religious objections to the listed practices. *Id.* ¶¶ 189, 219, 222, PageID 156, 159-160. Accordingly, ACP has not clearly identified a non-religious member to whom RFRA would not apply and thus undermine any credible threat of enforcement. *See Crawford*, 868 F.3d at 457 ("Standing cannot be inferred argumentatively from averments in the pleadings, … but rather must affirmatively appear in the record." (cleaned up)).

2. Plaintiffs' various attacks on the district court's standing analysis lack merit.

Plaintiffs challenge the district court's holding that they lack standing on a variety of grounds. None has any merit.

First, plaintiffs contend that the district court improperly required "a 'literal certainty' that the harm they alleged would necessarily occur," as distinct from a "substantial risk." Opening Br. 31-33. Not so. The district court applied this Circuit's accepted mode of analysis for evaluating "whether there is a credible threat

of prosecution sufficient to confer standing," *i.e.*, to demonstrate a "sufficiently imminent injury." *Online Merchs. Guild*, 995 F.3d at 549-50.

Although 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, the court applied the correct test. Indeed, this Court has employed similar terminology, describing the requirement of a "certainly impending" future injury, without expressly referencing "substantial risk." *See, e.g.*, *AAPS*, 13 F.4th at 545; *Davis*, 51 F.4th at 172; *see also Jackson*, 142 S. Ct. at 539 n.1 (Thomas, J., concurring in part and dissenting in part). This simplified phraseology does not suggest that either this Court or the district court was applying an incorrect standard. Moreover, the district court relied on cases that clearly invoked the correct standard for assessing the imminence of a threatened injury, belying any suggestion that the court misapprehended the inquiry. *See McKay*, 823 F.3d at 867; *Kiser*, 765 F.3d at 607-09.[4]

Second, plaintiffs contend that the district court erred in requiring "some combination of the factors listed in *McKay*," to establish pre-enforcement standing, as opposed to other potentially relevant factors. Opening Br. 34 (emphasis omitted).

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[4] In speculating that the district court applied a "literal-certainty requirement," plaintiffs list several aspects of the opinion below that they claim would "make more sense" under their theory. Opening Br. 33. But the court's discussion of those points, within the context of the relevant factors, was reasonable and consistent with this Court's precedents. *See supra* pp. 20-28.

But there can be no doubt that the court applied the correct analysis. The court recognized that these "*McKay* factors" were "not exhaustive, nor must each be established." Op., R. 61, PageID 1216 (quotation marks omitted). Thus, after assessing the four factors and concluding that all four "weigh against [p]laintiffs' standing," *id.*, PageID 1221, the court "review[ed] … the amended complaint" for other potential "feature[s] of Section 1557 that would" support the credibility of the claimed threat of enforcement, *id.*, PageID 1222. The court concluded that plaintiffs had not alleged any such additional relevant factors. *Id.* Accordingly, any error in the court's assertion that some combination of *McKay* factors was required was harmless.[5]

Plaintiffs also argue that the district court's conclusion that they lack standing must be wrong because it is inconsistent with decisions by the Fifth and Eighth Circuits in similar cases. *See* Opening Br. 22-25 (citing *Religious Sisters of Mercy v. Becerra*, 55 F.4th 583 (8th Cir. 2022), and *Franciscan Alliance, Inc. v. Becerra*, 47 F.4th 368 (5th Cir. 2022)). Plaintiffs warn (Br. 21, 36) that affirming the district court would create a circuit split. That concern is both mistaken and irrelevant. This Court has an obligation to apply its own circuit precedent to the allegations presented in this case; it

[5] Plaintiffs also imply that the district court was wrong "in concluding [that plaintiffs] failed to plausibly allege 'some combination'" of the *McKay* factors. Opening Br. 36. But plaintiffs' conclusory assertion that "[t]he first, third, and fourth factors are all met here," *id.*, is insufficient to preserve an argument that the district court erred in evaluating those factors. *See Phinazee*, 515 F.3d at 520.

should not be swayed by out-of-circuit decisions that are factually distinct and were wrongly decided.

Standing is a fact-bound inquiry that relies on the allegations established by a particular plaintiff as of the time it filed its complaint. A case-specific outcome with respect to standing as to one set of plaintiffs in one circuit cannot dictate the outcome of the standing inquiry with respect to a different complaint, filed by different plaintiffs, in a different circuit, at a different stage in the proceedings. That courts might reach different results under these circumstances is not properly characterized as a circuit split.

As the district court recognized, there are significant differences between this Circuit's pre-enforcement standing case law and that of the Fifth and Eighth Circuits. Op., R. 61, PageID 1214-1215. The Eighth Circuit has categorically stated that "when a course of action is within the plain text of a statute, a 'credible threat of prosecution' exists." *Alexis Bailly Vineyard, Inc. v. Harrington*, 931 F.3d 774, 778 (8th Cir. 2019). Similarly, the Fifth Circuit has stated that the existence of a "non-moribund" policy that "causes self-censorship among those who are subject to it," where the speech at issue "is arguably regulated by the policy," is enough for pre-enforcement standing. *Speech First, Inc. v. Fenves*, 979 F.3d 319, 337 (5th Cir. 2020); *see id.* at 335 (suggesting that *defendants* must offer "'compelling contrary evidence'" to refute a presumption of credible threat).

These cases provided the foundation for the standing analysis in *Religious Sisters* and *Franciscan Alliance*. *See Religious Sisters*, 55 F.4th at 604 (citing *Fenves*); *Franciscan All.*, 47 F.4th at 377 (same); *Religious Sisters of Mercy v. Azar*, 513 F. Supp. 3d 1113, 1139 (D.N.D. 2021) (citing *Alexis Bailly Vineyard*); *see also* Opening Br. 18, 23 (citing *Fenves* and *Alexis Bailly Vineyard*). But this Court has taken a more rigorous approach to pre-enforcement standing. *See, e.g.*, *Speech First, Inc. v. Schlissel*, 939 F.3d 756, 764 (6th Cir. 2019) ("[A] litigant alleging chill must still establish that a concrete harm—i.e., enforcement of a challenged statute—occurred or is imminent." (quotation marks omitted)); *Davis*, 51 F.4th at 173 ("[W]e have repeatedly rejected ... claims that concerns about 'chilling' speech allow us to water down Article III's core constitutional components."); *Crawford*, 868 F.3d at 454 ("The mere *possibility* of prosecution, however—no matter how strong the plaintiff's intent to engage in forbidden conduct may be—does not amount to a 'credible threat' of prosecution.").

Moreover, as plaintiffs acknowledge (Br. 22), *Franciscan Alliance* was "decided on mootness grounds," not standing. "Standing and mootness, albeit related, are distinct doctrines with separate tests to evaluate their existence at different times of the litigation." *Memphis A. Philip Randolph Inst. v. Hargett*, 2 F.4th 548, 559 (6th Cir. 2021). Significantly, those doctrines impose different burdens on different parties. *See Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 190 (2000) (contrasting defendant's "formidable burden of showing" mootness with "plaintiff's burden to establish standing"). And although the Fifth Circuit alluded to standing

concepts in its mootness decision, it did not engage in a full-blown standing analysis with respect to all the factors that this Circuit deems relevant to the inquiry.

In *Religious Sisters*, the Eighth Circuit then "applied the Fifth Circuit's reasoning in *Franciscan Alliance*," Opening Br. 24, without properly accounting for its mootness context. For instance, although the Fifth Circuit concluded that "prosecutorial indecision" was enough to show that the *government* had not carried its high burden to demonstrate mootness, *see Franciscan All.*, 47 F.4th at 376, the Eighth Circuit departed from fundamental Article-III principles in concluding that similar uncertainty in that case was sufficient for plaintiffs to carry *their* burden of demonstrating standing. *See Religious Sisters*, 55 F.4th at 605.

In sum, *Religious Sisters* and *Franciscan Alliance* are both wrong on their own terms and inconsistent with this Circuit's long-standing pre-enforcement standing precedents. Plaintiffs' invocation of those decisions ultimately amounts to a request to "relax" "Article III's normal rules" in a way that violates the "critical separation-of-powers check" that "Article III's case-or-controversy requirement" places on the judiciary. *Davis*, 51 F.4th at 173 (cleaned up).

Plaintiffs also contend that standing is "made … easier" in this case because their members are the "'object of the challenged action.'" Opening Br. 28 (alteration omitted). The Supreme Court has made clear, however that even a plaintiff that *is* the object of a challenged statute or regulation cannot establish standing based on future enforcement unless it shows "that the likelihood of future enforcement is

'substantial,'" *California*, 141 S. Ct. at 2114. As plaintiffs recognize, this is a pre-enforcement challenge. *See* Opening Br. 20, 30. They must therefore satisfy the requirements for demonstrating an Article-III injury-in-fact under this doctrine.

Moreover, plaintiffs are incorrect in claiming (Br. 28) that HHS has imposed a regulation "'requir[ing] them to make significant changes in their everyday business practices.'" Plaintiffs have not identified any currently operative regulatory provision that clearly requires them to engage in their listed practices contrary to their medical, ethical, and religious beliefs. The 2016 Rule's prohibition on gender-identity discrimination was vacated in *Franciscan Alliance*, before the rest of the rule was rescinded and replaced through the 2020 Rule. Although the *Walker* and *Whitman-Walker* injunctions against the 2020 Rule revived the 2016 Rule's prohibition of sex-stereotyping discrimination,[6] those district courts recognized that they lacked the power to revive a rule vacated by another district court. *See Walker*, 480 F. Supp. 3d at 427; *Whitman-Walker*, 485 F. Supp. 3d. at 26; *see also* Op., R. 61, PageID 1196 n.2, 1197. Accordingly, the government has consistently recognized that the 2016 Rule's gender-identity provisions are no longer in effect, and HHS has not taken any action to enforce those provisions since their vacatur.

[6] Plaintiffs also have not demonstrated that HHS has brought or threatened any enforcement action against any entity for objecting to performing gender-affirming care based on the sex-stereotyping provision.

Plaintiffs are similarly incorrect to suggest (Br. 11) that the 2021 Notice of Interpretation is a source for their purported regulatory "mandate." The Notice merely expresses the general point that sex discrimination includes discrimination on the basis of "gender identity," 86 Fed. Reg. at 27,984, following directly from *Bostock*'s reasoning. *See* 140 S. Ct. at 1741. The Notice did not define what gender-identity discrimination means in the context of specific treatment decisions, nor did it conclude that providers were required to perform any specific procedure. *See* 86 Fed. Reg. at 27,985.

The closest that plaintiffs come to identifying a concrete regulatory source for their supposed "mandate" is to point to the preamble of the 2016 Rule, suggesting that the "implications" of "the 2016 Rule's gender-identity language … described in the 2016 Rule's preamble" were resurrected by the *Walker* and *Whitman-Walker* injunctions. Opening Br. 6, 8. But plaintiffs have not attempted to demonstrate that this preamble was ever binding on regulated parties independent from the regulatory text. *See AT&T Corp. v. FCC*, 967 F.3d 840, 847 (D.C. Cir. 2020) (per curiam). And the relief in *Walker* and *Whitman-Walker* focused on specific, codified regulatory provisions; neither purported to enjoin the preamble to the 2020 Rule or otherwise revive the preamble to the 2016 Rule. *See Walker*, 2020 WL 6363970, at *4; *Whitman-Walker*, 485 F. Supp. 3d at 64.

Plaintiffs thus cannot show that, as of August 2021—when the relevant complaint was filed—their members were under a regulatory mandate to make

specific "changes in their practices." Opening Br. 29. Any resources spent doing so based on a subjective fear of future enforcement cannot support standing. *See Shelby Advocates for Valid Elections v. Hargett*, 947 F.3d 977, 983 (6th Cir. 2020) (per curiam) ("[P]laintiffs may not bootstrap their way into standing by 'inflicting harm on themselves based on their fears of a hypothetical future harm.'" (quoting *Clapper*, 568 U.S. at 416)). In any event, plaintiffs nowhere allege that any specifically identified members actually changed their practices or incurred any compliance costs. *See* Am. Compl. ¶¶ 164, 170, 176, 181, 192, 235, 244, PageID 153-156, 161-162.

Plaintiffs also contend for the first time on appeal that the failure to "import Title IX's religious exemption into Section 1557 through the 2016 Rule … bolsters the credible threat of enforcement" because it "supports a[n] … inference" that HHS was "tr[ying] to target the plaintiffs." Opening Br. 27. The Court should reject this implausible inference. The preamble to the now-rescinded 2016 Rule reveals no animus against plaintiffs' religious members. HHS justified the decision not to incorporate the Title-IX religious exemption based on the text and context of the respective statutes, and explained that "application of RFRA is the proper means to evaluate any religious concerns about the application of Section 1557 requirements." 81 Fed. Reg. at 31,380. And the final rule adopted a provision stating that the application "of any requirement" under the rule "shall not be required" insofar as it "would violate applicable Federal statutory protections for religious freedom,"

including RFRA. *Id.* at 31,466. Plaintiffs offer no basis for concluding that RFRA will be inadequate protection for their religious members. *See supra* p. 29.

The case that plaintiffs rely on for this targeting theory—*Universal Life Church*, 35 F.4th 1021—is easily distinguishable. There, "[n]o explanation" for the challenged law was "provided other than to target [the plaintiff's organization]." *Id.* at 1034-35. Moreover, the ban on the plaintiff's specific conduct was "explicit[]," and the plaintiff offered concrete allegations that he had previously violated the law and modified his behavior to avoid doing so again. *Id.* at 1034. All three of those features are missing in this case.

* * *

Ultimately, plaintiffs' members fear harm not from any extant regulatory mandate, but from HHS's potential future enforcement of Section 1557 against them. But plaintiffs have not plausibly alleged a substantial probability that their members will actually be asked to perform gender-affirming care and consequently will engage in proscribed conduct, or that their members will not be protected under a religious exemption. Nor have plaintiffs pleaded any basis for finding a substantial likelihood that future enforcement actions will ever be brought against their members. Instead, the possibility of enforcement against plaintiffs' members rests on a hypothetical chain of uncertain contingencies. Their wholly speculative, subjective fears about possible future HHS enforcement activity do not establish a sufficiently imminent injury for purposes of Article III.

II. The District Court Correctly Held that Plaintiffs' Claims Are Unripe.

Beyond standing, lawsuits filed when there has been no enforcement action against plaintiffs implicate the doctrine of ripeness. The ripeness doctrine seeks to "'avoid premature adjudication' of legal questions and to prevent courts from 'entangling themselves in abstract' debates that may turn out differently in different settings." *Warshak*, 532 F.3d at 525 (alterations omitted) (quoting *National Park Hosp. Ass'n v. Department of Interior*, 538 U.S. 803, 807 (2003)). "In ascertaining whether a claim is ripe for judicial resolution," this Court evaluates its "fit[ness] for judicial decision" and "the hardship to the parties of withholding court consideration." *Id.* (alteration omitted) (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967)). Ripeness is motivated in part by concerns that "'the proper exercise of the judicial function' avoids deciding abstract and speculative questions." *Id.* at 528 (quoting *Texas v. United States*, 523 U.S. 296, 301 (1998)). Under these principles, the district court correctly held that plaintiffs' claims challenging HHS's possible future enforcement of Section 1557 fail because they are not ripe.

This Court considers three factors in evaluating ripeness: "(1) the likelihood that the harm alleged by the plaintiffs will ever come to pass"; "(2) whether the factual record is sufficiently developed to produce a fair adjudication of the merits"—which both go to the fitness of the issues for immediate judicial decision—and "(3) the hardship to the parties if judicial relief is denied at this stage in the proceedings."

Berry, 688 F.3d at 298 (quotation marks omitted). The district court correctly determined that all three factors "weigh against finding [p]laintiffs' claims to be ripe." Op., R. 61, PageID 1223 n.5.

Under the first factor, "[a] claim is not ripe if it turns on 'contingent future events that may not occur as anticipated, or indeed may not occur at all.'" *OverDrive Inc. v. Open E-Book Forum*, 986 F.3d 954, 957-58 (6th Cir. 2021) (quoting *Trump v. New York*, 141 S. Ct. 530, 535 (2020) (per curiam)). As the district court recognized, plaintiffs' claims rest on a highly speculative chain of future events.

For one of plaintiffs' members to face an enforcement action by the federal government, numerous actions would likely have to occur: a transgender patient seeks treatment from the member; the treatment involves providing gender-affirming care (or performing related practices) identified as "objectionable"; the member declines to perform the care or related practice; the patient submits a complaint about the member's conduct to OCR (or OCR otherwise becomes aware of the conduct); OCR initiates an investigation; if the member raises a religious objection, OCR adjudicates the availability of an exemption or modification based on the application of RFRA and rejects it; OCR elects to proceed with the investigation; OCR evaluates whatever reason the member provided for their conduct, within the relevant circumstances, and determines that it does not amount to a legitimate, non-discriminatory reason, that discrimination has occurred, and that Section 1557 was violated; and any efforts at informal, voluntary compliance that OCR offers are deemed unacceptable by the

member. Then, and only then, would the person potentially be subject to an enforcement action by the federal government. For any given member of ACP or CMA, each of these steps may not occur as anticipated or at all. To be sure, it is *possible* that they might. "But these possibilities are just that—possibilities" which "mak[e] it eminently unpredictable whether, when or why the government would" enforce Section 1557 against plaintiffs' members. *See Warshak*, 532 F.3d at 526.

As the district court explained, plaintiffs' claims are thus unripe given the "unlikelihood that the injury would ever come to pass in light of the RFRA exemption and the lack of threatened or actual enforcement." Op., R. 61, PageID 1223 n.5. Plaintiffs fear the loss of federal funding or other federal penalties that could drive their members "'out of practice.'" Opening Br. 10. But "we have no idea whether or when such a sanction will be ordered," and thus "the issue is not fit for adjudication." *Texas*, 523 U.S. at 300 (cleaned up).

For many of the same reasons, plaintiffs' speculative claims are also not fit for review at this time. "Claims are fit for review if they present purely legal issues that will not be clarified by further factual development." *Oberlin Coll.*, 60 F.4th at 356 (quotation marks omitted). However, where "[t]he operation of the statute," would be "better grasped when viewed in light of a particular application," the claim is unripe. *Warshak*, 532 F.3d at 528 (quoting *Texas*, 523 U.S. at 301). Particularly with respect to "constitutional questions," this Court has recognized that it is "more likely" to "decid[e them] correctly[] … on a case-by-case basis in the context of a concrete

factual setting." *Id.* at 533; *id.* at 526 ("Answering difficult legal questions before they arise and before the courts know how they will arise is not the way we typically handle constitutional litigation."). Additionally, this Court has recognized that where a plaintiff "is not challenging a specific rule or finding … but rather the general applicability of a statutory scheme to its conduct," a court's analysis of legal issues "would benefit from knowledge of just what was forbidden by the [statute], and what the effects of the [agency's] regulation would be." *Ammex, Inc. v. Cox*, 351 F.3d 697, 707-08 (6th Cir. 2003).

Those conditions apply here. Plaintiffs assert a variety of claims under the APA, RFRA, the First Amendment, and the Tenth Amendment. *See* Am. Compl., R. 15, PageID 178-195. All of these claims require fact-specific inquiries grounded in an actual controversy. Indeed, the Supreme Court has emphasized that "RFRA, and the strict scrutiny test it adopted" from First Amendment jurisprudence, "contemplate[s] an inquiry more focused than [a] categorical approach." *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 430 (2006). "[S]trict scrutiny at least requires a case-by-case determination of the question, sensitive to the facts of each particular claim." *Id.* at 431 (quotation marks omitted).

At every turn, plaintiffs' RFRA and First Amendment claims call for factual development that simply has not yet occurred and may never occur. Whether any particular application of Section 1557 will run afoul of RFRA, the Free Exercise Clause, or the freedom of speech will depend on the precise "objectionable practice"

that an individual medical professional refuses to engage in, and their particular reason for refusing. Until those objections translate into specific refusals to provide gender-affirming treatment or engage in related practices with respect to specific patients, there is no way to assess whether enforcing the statute as to that refusal will impose a substantial burden on the members or regulate their speech based on content or viewpoint. Am. Compl. ¶¶ 405, 433, 447, R. 15, PageID 186, 190-192. And there is likewise no way to evaluate whether the government has a compelling interest in enforcing Section 1557 in that particular context, or whether there is a less restrictive means of doing do. *Id.* ¶¶ 411-412, 439, 453-454, PageID 187, 190, 192; *see also id.* ¶¶ 365-366, PageID 181 (incorporating constitutional and RFRA claims into APA claim).[7]

Plaintiffs challenge an amorphous "gender-identity mandate," which they purport to locate in the penumbras of the 2016 Rule and 2021 Notice of Interpretation, and, alternatively, in "Section 1557" itself. Opening Br. 11. As explained, *supra* pp. 36-38, plaintiffs are not challenging a specific regulatory directive, but rather "the general applicability of [the Section 1557] statutory [and regulatory]

[7] The Tenth Amendment claim likewise depends on fact-specific analysis of whether States knew or "'clearly underst[oo]d' that the ACA would impose on [them] … a new 'gender identity' requirement, let alone a requirement that applies in the objectionable ways described above." Am. Compl. ¶ 471, R. 15, PageID 195. This claim can only be assessed in the factual context of Section 1557's application to a specific State.

scheme to [their members'] conduct," *see Ammex*, 351 F.3d at 707-08. As their complaint makes clear, resolving their challenge to this vague "mandate" will require evaluating how the prohibition on gender-identity discrimination operates against plaintiffs' members. *See* Am. Compl. ¶¶ 362-363, 373, 394-395, 400, 405-407, 410, R. 15, PageID 180, 182, 185-187. But no sufficiently concrete factual context will exist until the statute is actually enforced. Accordingly, the district court correctly held that the factual record was not "sufficiently developed to produce a fair adjudication of the merits of the parties' respective claims[] … because there are no facts alleged regarding a particular patient, seeking a particular medical procedure, with their medical provider giving particular reasons, whether discriminatory or nondiscriminatory, for their refusal to perform the procedure." Op., R. 61, PageID 1223 n.5 (quotation marks omitted).

In assessing a claim's fitness for judicial decision, this Court also considers "the extent to which the enforcement authority's legal position is subject to change before enforcement." *Ammex*, 351 F.3d at 706; *accord CBA Pharma, Inc. v. Perry*, No. 22-5358, 2023 WL 129240, at *3 (6th Cir. Jan. 9, 2023). HHS is currently engaging in a new Section-1557 rulemaking that may change the agency's approach to the types of issues raised by plaintiffs, which further underscores the impropriety of entertaining a pre-enforcement action at this time. *See Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 733 (1998) (considering "whether judicial intervention would inappropriately interfere with further administrative action" in concluding case was not justiciable).

The district court's holding that plaintiffs' claims are not ripe also finds support in the third ripeness factor, because postponing judicial review would cause no hardship to plaintiffs' members. As this Court has explained, hardship cannot be premised on a "long list of speculative assumptions." *Warshak*, 532 F.3d at 533. Nor does "mere uncertainty" "constitute[] a hardship for purposes of the ripeness analysis." *National Park*, 538 U.S. at 811; *see also Ammex*, 351 F.3d at 710. And hardship can be "difficult to maintain" where plaintiffs have "alternatives short of a pre-enforcement" challenge in which to bring their claims. *Warshak*, 532 F.3d at 531-32.

Withholding premature review of plaintiffs' claims would impose little, if any, hardship on plaintiffs' members because they are not currently suffering any concrete injury. *See supra* pp. 14-39. The district court was thus correct to conclude that plaintiffs' claims are unripe given that their members would experience "little to no hardship" because they could "raise these exact same claims, albeit in a more developed factual context, at any point after HHS initiated some kind of enforcement proceeding against them." Op., R. 61, PageID 1223 n.5. Indeed, the members could raise these same arguments in HHS's administrative proceedings if any discrimination charge is ever filed against them and if any enforcement action is ever brought against them. *See Ohio Forestry Ass'n*, 523 U.S. at 729-30, 733-34 (holding that case was not ripe where plaintiff "will have ample opportunity later to bring its legal challenge at a

time when harm is more imminent and more certain," and noting that there would be an administrative process before plaintiffs would face any "practical harm").

Plaintiffs do not offer any meaningful challenge to the district court's assessment of the ripeness factors. Instead, they simply assert in a footnote that their claims would be ripe even applying "all three traditional ripeness factors." Opening Br. 30 n.7. They have thus forfeited any challenge to the district court's determination that their claims are not ripe under the "traditional ripeness factors." *See United States v. Johnson*, 440 F.3d 832, 846 (6th Cir. 2006) (observing that argument subject to only "perfunctory" reference "limited to the single footnote and … not otherwise developed" is considered forfeited).

According to plaintiffs, the standing and ripeness inquiries wholly overlap for pre-enforcement challenges, such that if they demonstrated Article-III standing, they have also demonstrated ripeness. Opening Br. 30. This assertion is premised on a misreading of this Court's precedents.

In *Winter v. Wolnitzek*, 834 F.3d 681 (6th Cir. 2016), the Court relied on *SBA List* to conclude that, because *Article-III* standing and *Article-III* ripeness "originate from the same Article III limitation," they can be "analyzed together" in pre-enforcement challenges. *Id.* at 687 (quotation marks omitted).[8] *Winter* did not hold

[8] That Article-III ripeness and standing are capable of being analyzed together—and generally lead to the same result—does not necessarily mean that the

Continued on next page.

that the *prudential* aspects of ripeness are subsumed within the pre-enforcement standing inquiry. To the contrary, after explaining in *SBA List* that "the *Article III* standing and ripeness issues in this case 'boil down to the same question,'" 573 U.S. at 157 n.5 (emphasis added), the Supreme Court separately concluded that the "prudential ripeness" factors—"'fitness' and 'hardship'"—were satisfied, *id.* at 167-68. *See also Kiser*, 765 F.3d at 607 & n.2 (following *SBA List* by "address[ing] the constitutional component of ripeness in terms of standing," while noting separately that the "'prudential' ripeness factors[] ... []are also satisfied"). *Platt*—which assessed ripeness only in the context of raising the issue of "Article III jurisdiction" sua sponte—is consistent with those decisions. *See* 769 F.3d at 451, 453 (citing *SBA List*, 573 U.S. at 157 n.5, 158; *Kiser*, 765 F.3d 606-07).

To the extent plaintiffs mean to suggest (Br. 30 n.6), that courts are now free to disregard the prudential aspects of ripeness, they are incorrect. As this Court has recognized, neither the Supreme Court's (nor this Court's) precedents "affirmatively

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inquires are identical, however. *See Doster v. Kendall*, 54 F.4th 398, 415 (6th Cir. 2022) ("[Constitutional ripeness] *largely* duplicates Article III's separate 'standing' test." (emphasis added)). There appears to be some disagreement regarding which elements of the ripeness inquiry are properly considered constitutional. *Compare OverDrive*, 986 F.3d at 957-58, *with Kiser*, 765 F.3d at 607 n.2. And the Court has previously stated that "analysis of [a] standing challenge applies equally and interchangeably to [a] ripeness challenge" where the "ripeness arguments concern only the requirement that the injury be imminent." *Thomas More Law Ctr. v. Obama*, 651 F.3d 529, 537-38 (6th Cir. 2011) (quotation marks omitted), *abrogated on other grounds by NFIB v. Sebelius*, 567 U.S. 519 (2012).

state that the prudential-standing doctrine is dead, and we cannot predict its future." *Miller*, 852 F.3d at 503 n.2; *see id.* at 507-08 (Rogers, J., concurring). Indeed, "the Supreme Court continues to look at both [components of ripeness]," including "most recently in" *Trump v. New York*, 141 S. Ct. at 536. *OverDrive*, 986 F.3d at 958. Accordingly, this Court has also continued to evaluate prudential ripeness, including in the context of pre-enforcement review. *See Oberlin Coll.*, 60 F.4th at 348, 355-57; *OverDrive*, 986 F.3d at 957-58; *Hill v. Snyder*, 878 F.3d 193, 213-15 (6th Cir. 2017). Applying this prudential component, the district court correctly held that plaintiffs' claims are not ripe for review.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 12,227 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Word for Microsoft 365 in Garamond 14-point font, a proportionally spaced typeface.

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CERTIFICATE OF SERVICE

I hereby certify that on May 31, 2023, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Sixth Circuit by using the appellate CM/ECF system.

s/ McKaye L. Neumeister
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DESIGNATION OF RELEVANT DISTRICT COURT DOCUMENTS

Pursuant to Sixth Circuit Rule 28(b)(1)(A)(i), the government designates the following district court documents as relevant:

Record Entry	**Description**	**Page ID # Range**
R. 15	First Amended Complaint	126-210
R. 51	Motion to Dismiss	1086-1087
R. 52	Memorandum in Support of Motion to Dismiss	1088-1125
R. 55	Memorandum in Opposition to Motion to Dismiss	1131-1169
R. 57	Reply Memorandum in Support of Motion to Dismiss	1172-1183
R. 61	Memorandum Opinion	1189-1229
R. 62	Judgment Order	1230
R. 63	Notice of Appeal	1231-1232

ADDENDUM

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42 U.S.C. § 18116

§ 18116. Nondiscrimination

(a) In general

Except as otherwise provided for in this title (or an amendment made by this title), an individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section 794 of Title 29, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments). The enforcement mechanisms provided for and available under such title VI, title IX, section 794, or such Age Discrimination Act shall apply for purposes of violations of this subsection.

* * * *

42 U.S.C. § 2000bb-1

§ 2000bb-1. Free exercise of religion protected

(a) In general

Government shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability, except as provided in subsection (b).

(b) Exception

Government may substantially burden a person's exercise of religion only if it demonstrates that application of the burden to the person--

(1) is in furtherance of a compelling governmental interest; and

(2) is the least restrictive means of furthering that compelling governmental interest.

(c) Judicial relief

A person whose religious exercise has been burdened in violation of this section may assert that violation as a claim or defense in a judicial proceeding and obtain appropriate relief against a government. Standing to assert a claim or defense under this section shall be governed by the general rules of standing under article III of the Constitution.