No. 21-11174

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

FRANCISCAN ALLIANCE, INCORPORATED; CHRISTIAN MEDICAL AND DENTAL SOCIETY; SPECIALTY PHYSICIANS OF ILLINOIS, L.L.C.,

Plaintiffs-Appellees,

v.

XAVIER BECERRA, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants-Appellants

AMERICAN CIVIL LIBERTIES UNION OF TEXAS; RIVER CITY GENDER ALLIANCE,

Intervenor Defendants-Appellants.

On Appeal from the United States District Court
for the Northern District of Texas

REPLY BRIEF FOR DEFENDANTS-APPELLANTS

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INTRODUCTION

The district court erred in entering permanent injunctive relief against the government based on positions that the government has not actually adopted and in the absence of an Article III case or controversy. The court's permanent injunction and plaintiffs' arguments are based on the premise that the Department of Health and Human Services (HHS) currently interprets and will enforce Section 1557 to mandate that "Christian [p]laintiffs[] … perform and provide insurance coverage for gender-transition procedures and abortions." ROA.5065; *see also* ROA.5062-5063; Pls. Br. 41-42, 46-51. But this premise is fundamentally incorrect. HHS has not taken a position on whether Section 1557 could in any specific circumstance require the provision or coverage of gender-transition procedures or abortions by entities with religious objections to providing or covering those procedures, or how the Religious Freedom Restoration Act (RFRA) interacts with Section 1557's general prohibition on sex discrimination. *See Bostock v. Clayton County*, 140 S. Ct. 1731, 1754 (2020) (specifically reserving question of how RFRA and other "doctrines protecting religious liberty interact with Title VII" and explaining that these "are questions for future cases"). Whether viewed as a problem of mootness, an Article III standing defect, a lack of ripeness, and/or an absence of irreparable harm to support an injunction, the district court erred and its permanent injunction should be vacated.

First, this case is moot. As presented in the operative complaint and consistently litigated by plaintiffs for the first four years of this long-running litigation,

this lawsuit involves a RFRA challenge to HHS's 2016 Rule implementing Section 1557. Plaintiffs suffer no ongoing harm from the 2016 Rule because the district court vacated its challenged provisions and HHS rescinded and replaced them. The district court cannot grant plaintiffs any additional effective relief against the 2016 Rule.

Second, even if the case were not moot, plaintiffs have not established a concrete case or controversy with respect to their challenge to HHS's hypothetical future enforcement of Section 1557, and their RFRA claims are not ripe. Plaintiffs have not demonstrated any imminent injury, as they have not shown that HHS has ever brought or threatened an enforcement action against plaintiffs or *any* objecting religious entity for declining to provide or cover gender-transition procedures or abortions. Plaintiffs' RFRA claims are not ripe for review, as they cannot properly be evaluated in the abstract and instead require a factual record in which HHS is actually requiring plaintiffs to do something specific. For similar reasons, plaintiffs have not made the necessary showing of imminent irreparable harm sufficient to justify permanent injunctive relief.

ARGUMENT

I. This Case Is Moot Because Plaintiffs Only Challenged the 2016 Rule.

A. As explained in our opening brief (at 25-28), plaintiffs brought this case solely as a challenge to HHS's 2016 Rule, and the vacatur, recission, and replacement

of that rule rendered that challenge moot. Plaintiffs' various assertions of a live controversy are unpersuasive.

1. Plaintiffs first assert that the case is not moot because the 2016 Rule's vacated portions have been "revived by other district courts." Pls. Br. 46. Not so. As explained in our opening brief (at 42), the district courts in *Whitman-Walker* and *Walker* lacked authority to reverse the district court's vacatur of the 2016 Rule, and they did not purport to do so. The *Walker* court explicitly stated that it "agrees [with HHS] that it has no power to revive a rule vacated by another district court." *Walker v. Azar*, 480 F. Supp. 3d 417, 427 (E.D.N.Y. 2020). The *Whitman-Walker* court explained that the plaintiffs in that case had "identif[ied] no authority that would permit either this Court or HHS to disregard the final order of [the *Franciscan Alliance*] district court vacating part of a regulation," and thus the court was "powerless to revive it." *Whitman-Walker Clinic, Inc. v. HHS*, 485 F. Supp. 3d 1, 26 (D.D.C. 2020). In any event, to the extent there is any ambiguity in the *Walker* and *Whitman-Walker* orders, they should be read to avoid a conflict with the district court's prior order here for reasons of comity. *Cf. Feller v. Brock*, 802 F.2d 722, 727-28 (4th Cir. 1986) ("Prudence requires that whenever possible, coordinate courts should avoid issuing conflicting orders."); *Colby v. J.C. Penney Co.*, 811 F.2d 1119, 1124 (7th Cir. 1987) (same).

Plaintiffs' attempted "analogy to the contraceptive-mandate cases" (Br. 48) is unavailing. In that context, there was no underlying vacatur rendering it impossible

for a court's subsequent injunction of a replacement rule to restore a previous rule. *See Little Sisters of the Poor v. Pennsylvania*, 140 S. Ct. 2367, 2373-79 (2020). More generally, the government largely consented to injunctions in the contraceptive-coverage cases, *see, e.g.*, *Christian Emps. All. v. Azar*, No. 3:16-cv-309, 2019 WL 2130142, at *1 (D.N.D. May 15, 2019), which further undercuts plaintiffs' attempt to draw parallels here.

2. Plaintiffs' reliance (Br. 35-36) on *Federal Election Commission v. Cruz*, 142 S. Ct. 1638 (2022), is likewise misplaced. Contrary to plaintiffs' argument, *Cruz* does not suggest that all challenges to implementing regulations must also be understood as challenging the underlying statute. That case did not involve a mootness challenge, and the plaintiffs there specifically sought relief against *both* the regulation and the underlying statute. Joint Appendix at 26-27, *Cruz*, 142 S. Ct. 1638 (No. 21-12).

3. Plaintiffs' attempt to invoke Federal Rule of Civil Procedure 54(c) and the possibility of broader injunctive relief to circumvent mootness also fails. Plaintiffs contend that "'being able to imagine an alternative form of relief is all that's required to keep a case alive,'" Pls. Br. 54, emphasizing that their complaint "requested all relief that is 'equitable and just,'" Pls. Br. 37. But plaintiffs fail to grapple with *New York State Rifle & Pistol Association v. City of New York*, 140 S. Ct. 1525 (2020) (*NYSRPA*) (per curiam). There, an alternative form of relief was not merely imaginable, it was actually put forward, *id.* at 1526; and the operative complaint had included a general prayer for all "'just and proper'" relief. *See id.* at 1535 (Alito, J., dissenting) (asserting

that case was live based on prayer for relief in conjunction with Rule 54(c)). Rather than find either of these points sufficient to permit merits consideration, the Supreme Court determined that the case was moot. *See id.* at 1526 (per curiam).

Because *NYSRPA* became moot while on appeal and "'mootness [wa]s attributable to a change in the legal framework governing the case,'" the Supreme Court remanded for the lower courts to consider whether the complaint could be amended to add a claim for the new relief then sought. 140 S. Ct. at 1526-27. Plaintiffs had the same opportunity in this case following remand from this Court on the previous appeal. But instead of attempting to amend their complaint to add a claim for the new injunctive relief now sought,[1] plaintiffs attempted to recast the nature of their challenge nearly five years later by relying on Rule 54(c). Plaintiffs cannot plausibly claim that they are invoking Rule 54(c) to rectify "'omissions' in a 'prayer for relief.'" Pls. Br. 55. Rather, they seek to use that rule to plug a glaring hole in their core theory of this case, as it had been understood by all parties and the district court and consistently litigated for almost half a decade–that is, that plaintiffs

[1] Plaintiffs' failure to seek to amend the complaint distinguishes this case from *Religious Sisters of Mercy*, in which plaintiffs' counsel—representing other litigants—filed an amended complaint after the issuance of the 2020 Rule, specifically seeking relief from HHS's current interpretation of Section 1557 and not merely the 2016 Rule. *See Religious Sisters of Mercy v. Azar*, 513 F. Supp. 3d 1113, 1134 (D.N.D. 2021); Amended Complaint at 41-45, 69, *Religious Sisters of Mercy*, 513 F. Supp. 3d 1113 (No. 3:16-cv-386), ECF 95.

challenged only the 2016 Rule. The Court should reject this attempt to circumvent the limits of Article III.

B. Unable to demonstrate that their challenge to a long-rescinded regulation presents a live controversy, plaintiffs shift gears and insist that this lawsuit never merely challenged the 2016 Rule. But this belated attempt to recharacterize their claims—now almost six years into this litigation—likewise fails.

1. Plaintiffs insist that their RFRA challenge was not merely to the 2016 Rule because they sought injunctive relief beyond just that rule in proposed orders accompanying their motions for summary judgment. Pls. Br. 35, 37-38. But that broad characterization of the relief sought is inconsistent with plaintiffs' operative complaint. *See, e.g.*, ROA.311; ROA.352, ¶ 121; ROA.379, ¶ 295; ROA.393-394. It is also unsupported by the actual content of plaintiffs' summary-judgment briefing. *See, e.g.*, ROA.3307; ROA.3354; ROA.4504; ROA.4516. And it is irreconcilable with the understanding the district court evinced in issuing final judgment on plaintiffs' RFRA claims in October 2019. *See* ROA.4799. Merely inserting a broad request for relief in a proposed injunction order—extending beyond the scope of anything otherwise sought or justified throughout the course of long-running litigation—cannot retroactively transform a focused challenge to discrete agency action into a wide-ranging assault on any hypothetical future enforcement actions.

2. Plaintiffs further suggest that their RFRA claim cannot be construed as challenging only the 2016 Rule because a RFRA claim is never "aimed at a law or

regulation" but rather challenges "government action." Pls. Br. 36 (emphasis omitted). But promulgating a regulation *is* a government action. Indeed, it is the only government action that plaintiffs identified in the RFRA claims in their operative complaint. *See* ROA.311-312; ROA.378-381. When HHS rescinded and replaced that regulation—the 2016 Rule—plaintiffs were no longer subject to any burden from the "rule of general applicability" that they had challenged. 42 U.S.C. § 2000bb-1(a). This litigation challenging that agency action under RFRA thus became moot. *See Alaska v. U.S. Dep't of Agric.*, 17 F.4th 1224, 1226 (D.C. Cir. 2021) (describing "'well-settled principle of law'" regarding mootness of litigation challenging rescinded regulations).[2]

Plaintiffs nonetheless contend that the government action their RFRA claim challenges must now be understood more broadly as HHS's "threat to require them, on pain of penalties under Section 1557, to perform and insure gender transitions and abortions in violation of conscience." Pls. Br. 36. But plaintiffs' preferred reframing of their RFRA claim only underscores that this case is long-dead.

Under Article III's case-or-controversy requirement, "'an actual controversy [must] be extant at all stages of review.'" *Campbell-Ewald Co. v. Gomez*, 577 U.S. 153, 160 (2016) (ellipsis omitted). "'[A]ny set of circumstances that eliminates actual controversy after the commencement of a lawsuit renders that action moot.'" *Environmental Conservation Org. v. City of Dallas*, 529 F.3d 519, 527 (5th Cir. 2008).

[2] Plaintiffs do not dispute the basic rule that challenges to a regulation become moot upon the regulation's rescission. *See* Pls. Br. 52-53.

Accordingly, parties must "maintain a 'concrete interest in the outcome'" throughout the litigation. *Id.* With respect to plaintiffs' reframed RFRA claim, this means the Court must determine that HHS has consistently imposed this "threat" on plaintiffs from the filing of the operative complaint in October 2016 through the present. However, plaintiffs have not identified *any* agency action after the 2016 Rule was preliminarily enjoined in December 2016 that could plausibly be understood to impose such a "threat."

Any controversy that might have existed when this lawsuit was filed in 2016 was eliminated by the proposal and promulgation of the 2020 Rule, which made clear that objecting religious entities like plaintiffs were under no threat of government enforcement for failing to provide and cover gender-transition procedures or abortions. *See* 85 Fed. Reg. 37,160, 37,188 (June 19, 2020) ("The Department sees no compelling interest [under RFRA] in forcing the provision, or coverage, of [gender-transition] services by covered entities[] …."); *id.* at 37,192-93 ("This final rule ensures that the Department's Section 1557 regulations are implemented consistent with the abortion neutrality and statutory exemptions in Title IX."); *see also id.* at 37,206; 84 Fed. Reg. 27,846, 27,849, 27,864 (June 14, 2019).[3]

At that point, no agency action could be said to be imposing any "threat" of enforcement burdening plaintiffs' religious exercise. And there can be no credible

[3] The absence of any threat of enforcement was clear regardless of the existence or scope of any religious exemption in the 2020 Rule. *Contra* Pls. Br. 53.

assertion that HHS's then-expressed position was a mere act of "'litigation posturing.'" *Yarls v. Bunton*, 905 F.3d 905, 910-11 (5th Cir. 2018). Accordingly, plaintiffs' RFRA claim for injunctive relief became (and remains) moot, and the district court lost any jurisdiction to grant additional relief. *See Empower Texans, Inc. v. Geren*, 977 F.3d 367, 369 (5th Cir. 2020) ("[F]ederal courts have no authority to hear moot cases.").

C. Plaintiffs further assert that this case is not moot because HHS currently "impose[s] the same RFRA-violating burden" through the agency's interpretation of "Section 1557 itself." Pls. Br. 46; *see* Pls. Br. 48-51.

1. As an initial matter, even if HHS were now imposing the alleged threat of enforcement that plaintiffs purport to challenge in their reframed RFRA claim, that would not reanimate a challenge to the 2016 Rule that has long been moot. *See*, *e.g.*, *Hirschfeld v. ATF*, 14 F.4th 322, 325 (4th Cir. 2021) (rejecting attempts to revive case after it became moot); *Gayle v. Warden Monmouth County Corr. Inst.*, 838 F.3d 297, 304 n.8 (3d Cir. 2016) (observing that subsequent event "does not 'unmoot' the case and retroactively confer jurisdiction"); *Robertson v. Biby*, 719 F. App'x 802, 804 (10th Cir. 2017) (similar).

The various mootness cases that plaintiffs cite (Br. 51-52) are distinguishable on this basis. Those cases involve defendants immediately replacing a challenged action with a new action and arguing that the new action simultaneously mooted the case. *See Northeastern Fla. Chapter of Associated Gen. Contractors of Am. v. City of*

Jacksonville, 508 U.S. 656, 660-61 (1993) (arguing that challenge to ordinance was mooted by repeal and immediate replacement); *Texas v. Biden*, 20 F.4th 928, 946 (5th Cir. 2021) (arguing that new memoranda mooted appeal); *Opulent Life Church v. City of Holly Springs*, 697 F.3d 279, 284-86 (5th Cir. 2012) (arguing that amendment to zoning ordinance mooted challenge to original ordinance). These decisions rejecting mootness thus stand for the limited proposition that a case does not become moot where a defendant "ha[s]n't really ceased anything" and continuously "perpetuat[es] the very same injury that brought the [parties] into court." *Texas*, 20 F.4th at 959-60 (emphasis omitted).

Here, even under plaintiffs' framing of their RFRA claim, HHS had ceased imposing any threat of enforcement on plaintiffs (assuming one ever existed) as of June 2020 at the latest, when HHS rescinded the 2016 Rule and replaced it with the 2020 Rule. Indeed, plaintiffs assert that HHS's May 2021 "[n]otification by its terms *restores* the same interpretation of Section 1557 that was embodied in the 2016 Rule." Pls. Br. 52 (emphasis added). Plaintiffs are thus incorrect to characterize this as a case in which challenged conduct consistently continued through other means, keeping the case alive notwithstanding the repeal and replacement of the initially challenged action. Pls. Br. 52-53. That HHS took a new action to allegedly reimpose the

challenged harm almost a full year (at least) after that alleged harm ceased does not retroactively save plaintiffs' claim from mootness.[4]

Plaintiffs appear to take issue with this outcome as a matter of policy. *See* Pls. Br. 32 (objecting to "play[ing] whack-a-mole every time HHS concocts another method" of imposing a similar burden); *see also* Pls. Br. 52. But this objection amounts to a request to pursue broad claims for injunctive relief based on free-floating fears of future enforcement, untethered to any actual agency actions or continuous burdens imposed throughout the course of litigation. Article III forecloses this novel request.

2. In any event, plaintiffs mischaracterize HHS's current position regarding Section 1557's interpretation and enforcement. In its May 2021 notification, HHS explained that, "[c]onsistent with … *Bostock* and Title IX," it would "interpret and enforce Section 1557's prohibition on discrimination on the basis of sex to include … discrimination on the basis of gender identity." 86 Fed. Reg. 27,984, 27,985 (May 25, 2021). The agency made clear, however, that this interpretation "does not itself determine the outcome in any particular case or set of facts." *Id.* And HHS further emphasized that in enforcing Section 1557, it would "comply with the Religious Freedom Restoration Act … and all other legal requirements." *Id.*

[4] Similarly, HHS's forthcoming Notice of Proposed Rulemaking regarding Section 1557 could not revive an otherwise moot case, regardless of its contents.

More recently, in its March 2022 notice, HHS addressed how the prohibition on gender-identity discrimination relates to gender-affirming care. *See* HHS, Office for Civil Rights, *HHS Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy* (Mar. 2, 2022), https://go.usa.gov/xzGbp. However, that document did not specifically address the provision of such care by objecting religious entities, or otherwise undermine HHS's commitment to respect such entities' religious exercise through a faithful application of RFRA.

HHS's recent statements thus do not establish that the agency currently interprets and will enforce Section 1557 to require entities raising religious objections to nonetheless perform and cover gender-transition services or abortions. Nor do the various district-court decisions that plaintiffs point to in litigation between *private parties* under Section 1557 support plaintiffs' characterization regarding how *the government* currently interprets and will enforce Section 1557. *See* Pls. Br. 49-50. In short, the district court could not properly continue to exercise jurisdiction in this case based on positions that HHS has not actually adopted.

II. In the Alternative, Plaintiffs Failed to Demonstrate Standing, Ripeness, and Imminent Irreparable Harm Sufficient to Support a Permanent Injunction.

A. Plaintiffs Lack Standing.

1. Plaintiffs argue that they have demonstrated an injury-in-fact because their conduct is "'arguably proscribed'" by the 2016 Rule and Section 1557. Pls. Br. 23. However, "plaintiffs must demonstrate standing for each claim that they press and for

each form of relief that they seek." *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2208 (2021). Under their reframed RFRA claim, plaintiffs purport to seek an injunction against enforcement of Section 1557, not the 2016 Rule. Accordingly, whatever indication the 2016 Rule might have given with respect to the permissibility of plaintiffs' conduct based on their religious objections is now irrelevant.[5]

Plaintiffs also miss the point in arguing that Section 1557 itself arguably proscribes their conduct. Pls. Br. 23-24. Plaintiffs ignore Article III's requirements that an injury must be "concrete and particularized" and "actual or imminent, not 'conjectural' or 'hypothetical.'" *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014) (*SBA List*) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)). Plaintiffs' allegations of harm rest entirely on their speculation that HHS will one day interpret Section 1557 to require them to provide or cover gender-transition services or abortions over their religious objections, despite RFRA's protections. But this speculative "allegation of future injury" cannot establish standing where plaintiffs have not demonstrated that the threatened injury is "certainly impending" or that there is a "substantial risk" that it will occur. *Id.* (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 & n.5 (2013)).

[5] Regardless, HHS recognized that the 2016 Rule did not displace "the protections afforded by provider conscience laws" and RFRA, and explained that "application of RFRA" on a case-by-case basis "is the proper means to evaluate any religious concerns about the application of Section 1557 requirements." 81 Fed. Reg. 31,375, 31,379-80 (May 18, 2016).

As explained in our opening brief (at 41-42), in assessing this prong of the pre-enforcement standing analysis, the relevant question is whether plaintiffs' conduct is proscribed under Section 1557 and RFRA, as viewed together. Plaintiffs suggest (Br. 28-29) that the Court should consider only Section 1557 at this step of its inquiry. But plaintiffs provide no justification for ignoring a critical part of the statutory interpretation analysis that pre-enforcement standing requires. The Court can no more disregard RFRA in addressing whether plaintiffs' conduct is proscribed than it could ignore a subsection of Section 1557. *See Bostock*, 140 S. Ct. at 1754 ("RFRA operates as a kind of super statute, displacing the normal operation of other federal laws ….").

At best, plaintiffs can only demonstrate uncertainty about how Section 1557 and RFRA interact, and how HHS might act with respect to potential enforcement, in each situation involving an objecting religious entity. Such uncertainty does not confer standing. *See, e.g.*, *City of Los Angeles v. Lyons*, 461 U.S. 95, 107 n.8 (1983).

2. Plaintiffs further argue that they face a credible threat of prosecution and thus have demonstrated an injury-in-fact. Pls. Br. 24-26. But plaintiffs have pointed to *no* instances of HHS revoking federal funding from, or bringing enforcement actions in court against, religious providers for declining to provide or cover gender-transition procedures or abortions in the twelve years since Section 1557 was enacted. *Cf. SBA List*, 573 U.S. at 164 (substantial threat of future enforcement demonstrated

where enforcement agency had already found probable cause that plaintiffs had violated challenged statute in the past).

Plaintiffs attempt to rely on HHS's general statements that it will enforce Section 1557's prohibition of sex discrimination, including the fact that HHS did not "'disavow[] enforcement'" against plaintiffs. Pls. Br. 24-25. But the prospect that HHS might bring an enforcement action against a provider who refuses to treat a transgender patient's broken bone based on the patient's gender identity provides no basis for concluding that HHS will bring an enforcement action against providers who decline to provide gender-transition services due to their religious beliefs. The type of religious objections that could be asserted in those two scenarios would be quite different, and the likelihood of government enforcement activity would likewise vary.

Plaintiffs declare that there is a "'history of past enforcement'" (Br. 25), but the examples they cite do not support this assertion. That HHS (1) received a complaint against a Catholic hospital for denying birth control to a cis gender woman, *see* ROA.1722 & n.3; (2) indicated that it would initiate an investigation against a provider for denying gender-transition services, *see* Complaint, *Conforti v. St. Joseph's Healthcare Sys., Inc.*, No. 2:17-cv-50, 2017 WL 67114 (D.N.J. Jan. 5, 2017)[6]; and (3) investigated a

[6] Indeed, this example underscores the lack of any credible threat of enforcement. HHS halted its investigation when the provider in *Conforti* invoked religious protections; once a private lawsuit was filed, HHS did not proceed with the investigation; and the administrative complaint was ultimately withdrawn after the private lawsuit was settled.

state, which cannot assert a RFRA defense, for declining to cover gender-transition procedures in its Medicaid program, *see* ROA.1773 & n.15, does not show that HHS has brought enforcement actions in court or initiated funding-termination proceedings against religious providers who decline to provide gender-transition services or abortions. Nor does it show a "substantial" likelihood of future enforcement sufficient to support standing. *See California v. Texas*, 141 S. Ct. 2104, 2114 (2021).

Plaintiffs further assert that they need not actually demonstrate a credible threat of enforcement, because such a threat is "'assumed'" whenever a "'recently enacted'" law proscribes plaintiffs' conduct. Pls. Br. 24 (alteration omitted). As the case plaintiffs cite demonstrates when quoted in full, however, any such assumption only applies when dealing with "'statutes that facially restrict *expressive activity* by the class to which the plaintiff belongs.'" *Speech First, Inc. v. Fenves*, 979 F.3d 319, 335 (5th Cir. 2020) (emphasis added). In other contexts, such as here, the ordinary requirement applies whereby challengers "must show that the likelihood of future enforcement is 'substantial.'" *California*, 141 S. Ct. at 2114. Plaintiffs have failed to do so.

3. Plaintiffs' reliance on private lawsuits is similarly misplaced. Pls. Br. 4, 23-24. Private lawsuits under Section 1557 have no bearing on whether *defendant HHS* will bring enforcement actions against plaintiffs for declining to provide or cover gender-transition services, and an injunction against HHS has no effect on private litigants. *See Balogh v. Lombardi*, 816 F.3d 536, 544 (8th Cir. 2016) (plaintiff did not

have standing despite threat of private lawsuits because the "'injury is "fairly traceable" only to the private civil litigants"').

Nor do the private lawsuits plaintiffs cited (Br. 24 n.1) demonstrate that plaintiffs' conduct—declining to perform and cover gender-transition services and abortions based on religious objections—is arguably proscribed. Plaintiffs identify only three district-court decisions in Section 1557 lawsuits that purportedly involve religious entities with objections to gender-transition procedures. Two of those decisions do not discuss RFRA at all. *See Scott v. St. Louis Univ. Hosp.*, No. 4:21-cv-1270, 2022 WL 1211092 (E.D. Mo. Apr. 25, 2022); *Hammons v. University of Md. Med. Sys. Corp.*, 551 F. Supp. 3d 567 (D. Md. 2021). The third does not address the merits of the RFRA claim or otherwise discuss whether an entity with a religious objection and a valid RFRA claim would nonetheless be required to perform or cover gender-transition services under Section 1557. *See C.P. ex rel. Pritchard v. Blue Cross Blue Shield of Ill.*, 536 F. Supp. 3d 791, 797 (W.D. Wash. 2021).

4. As explained in our opening brief (at 44-45), plaintiffs have failed to demonstrate any likelihood that they will be subject to an enforcement action. Plaintiffs contend (Br. 30) that a declaration from Dr. Robert Hoffman, a CMDA member who does not prescribe hormones for gender transitions, demonstrates that he is "one patient away from a complaint" being filed against him. But the cited declaration undermines any claim to standing based on this individual: Dr. Hoffman specifically explains that his hospital "has always accommodated [his] beliefs" and

"[t]hat accommodation is quite easy[]" because he "work[s] with other pediatric endocrinologists who are able to perform gender transition procedures for children, and so there is no need for [him] to do so." ROA.976-977.

Plaintiffs also assert (Br. 30) that a complaint is unnecessary, because HHS could learn about potential Section 1557 violations from the failure to certify compliance with Section 1557. Although HHS can initiate an investigation through means other than the receipt of a complaint, *see* 45 C.F.R. § 80.7(c), that is beside the point. The fact that HHS could receive complaints alleging violations of Section 1557, or could assess compliance otherwise, does not demonstrate a likelihood that HHS will bring enforcement actions against objecting religious entities. *See AT&T Co. v. EEOC*, 270 F.3d 973, 976 (D.C. Cir. 2001) (explaining that even "law enforcement agencies rarely have the ability, or for that matter the need, to bring a case against each violator").

Nor does the motion to modify the injunction in this case support plaintiffs' claim that they face a credible threat of prosecution. Pls. Br. 26. HHS sought to clarify that it would not violate the injunction "by taking any action under Section 1557 as to any entities that Defendants are unaware are covered by the scope of the Order, given that Plaintiffs' members are not known to Defendants." ROA.5072. That HHS may enforce Section 1557 against non-religious entities and cannot identify

all of plaintiffs' members[7] without further information does not demonstrate that HHS intends to bring enforcement actions against plaintiffs or any other religious entities, or that plaintiffs suffer imminent injury sufficient to support standing. The motion to modify simply reflects an understandable desire by HHS to avoid risking contempt by taking enforcement action against a seemingly non-religious entity.

5. The various standing cases plaintiffs cited only confirm that this suit is not justiciable.

First, plaintiffs cite *Barilla v. City of Houston*, 13 F.4th 427 (5th Cir. 2021), for the proposition that "all Plaintiffs need to show is that it's 'plausible' their conduct is proscribed." Pls. Br. 18-19. In *Barilla*, this Court held at the motion-to-dismiss stage that plaintiffs had standing because under a "plausible reading" of the challenged statute their conduct was arguably proscribed. *See* 13 F.4th at 433. Because this case was resolved on summary judgment, however, plaintiffs have a higher burden to demonstrate standing, and plaintiffs have not met it. *See Clapper*, 568 U.S. at 411-12 ("The party invoking federal jurisdiction bears the burden of establishing standing—and, at the summary judgment stage, such a party … must set forth by affidavit or other evidence specific facts." (quotation marks omitted)).

Second, plaintiffs cite *Contender Farms, LLP v. U.S. Department of Agriculture*, 779 F.3d 258 (5th Cir. 2015), for the principle that objects of a regulation generally have

[7] CMDA alone has "around 19,000" members. Christian Med. & Dental Ass'ns, *About Us* (2022), https://perma.cc/5QU3-96GJ.

standing to challenge that regulation because "[a]n 'increased regulatory burden' itself 'satisfies the injury in fact requirement.'" Pls. Br. 29. This is correct as a general principle of administrative law, and perhaps would have applied in the context of plaintiffs' Administrative Procedure Act challenge to the 2016 Rule. But under their reframed RFRA claim, plaintiffs no longer challenge the 2016 Rule; instead, they challenge hypothetical future enforcement actions by HHS of which plaintiffs may never be the object and upon which they thus cannot establish standing under this principle.

Third, plaintiffs' invocation (Br. 26-27) of *Federal Election Commission v. Cruz* is irrelevant. The issue in *Cruz* was whether an injury caused by a live regulation was traceable to, and could be redressed by the invalidation of, the underlying statute. 142 S. Ct. at 1649. Here, by contrast, the relevant question is whether plaintiffs have demonstrated a credible threat of enforcement of Section 1557 alone (and thus an injury-in-fact) at the time of filing this lawsuit, given that they now seek to enjoin the enforcement of the statute and not the rescinded 2016 Rule.

Finally, in two cases on which plaintiffs rely (Br. 28), the injury sufficient to support standing was chilled speech under the First Amendment. *See Speech First*, 979 F.3d at 330-31 (highlighting evidence in record that speech was deterred by challenged university policies concerning speech); *Pool v. City of Houston*, 978 F.3d 307, 312-13 (5th Cir. 2020) (holding that plaintiff had "standing to seek an injunction that would guard against continued chilling of his speech" based on history of attempted

enforcement of challenged requirement). Plaintiffs do not attempt to argue on appeal that HHS's interpretation of Section 1557 has chilled their speech or religious exercise, much less point to any support in the record for such a finding. To the contrary, their brief makes clear that plaintiffs have not provided or covered gender-transition procedures or abortions against their religious beliefs despite their alleged fear of enforcement actions. *See* Pls. Br. 8 ("In accordance with its … religious beliefs, [Franciscan Alliance] does not perform gender-transition procedures …. Also according to its Catholic beliefs, Franciscan does not perform abortions."); Pls. Br. 29 ("Plaintiffs are already engaged in the relevant conduct."); *see also* Pls. Br. 3, 30, 32.

B. Plaintiffs' Claim Is Not Ripe.

Plaintiffs' argument that their RFRA claim is ripe also fails. Plaintiffs assert that this case presents a "purely legal question" of "whether the challenged interpretation of Section 1557 violates RFRA." Pls. Br. 55 (cleaned up). But as we have explained, *supra* pp. 11-12; Gov't Br. 36-38, HHS has not actually adopted the interpretations that plaintiffs challenge, rendering any analysis purely hypothetical. Plaintiffs are thus asking the Court to broadly declare that a wide range of hypothetical future HHS enforcement actions all violate RFRA such that plaintiffs are entitled to an anticipatory permanent injunction divorced from the specific context necessary to evaluate a RFRA claim.

In any event, courts have long recognized that even a "purely legal" question is unfit for adjudication where a concrete factual context would facilitate a court's

"'ability to deal with the legal issues presented.'" *National Park Hosp. Ass'n v. Department of Interior*, 538 U.S. 803, 812 (2003); *see, e.g.*, *Texas v. United States*, 523 U.S. 296, 301 (1998); *California Bankers Ass'n v. Shultz*, 416 U.S. 21, 56 (1974); *Toilet Goods Ass'n v. Gardner*, 387 U.S. 158, 163-64 (1967); *Zemel v. Rusk*, 381 U.S. 1, 18-20 (1965); *United Pub. Workers of Am. v. Mitchell*, 330 U.S. 75, 89-90 (1947); *Pennzoil Co. v. FERC*, 645 F.2d 394, 398 (5th Cir. 1981). Judicial review is thus properly deferred if "[t]he operation of [a] statute" would be "better grasped when viewed in light of a particular application." *Texas*, 523 U.S. at 301.

The issues that plaintiffs raise would much better be resolved in the context of a fully-developed factual record where HHS actually requires plaintiffs to do something specific. Gov't Br. 46-47; *see also American Fed'n of Gov't Emps. v. O'Connor*, 747 F.2d 748, 755-56 (D.C. Cir. 1984) ("Courts customarily deal in specific facts or circumstances drawn with some precision and legal questions trimmed to fit those facts or circumstances; they are not in the business of deciding the general without reference to the specific."). One example of a concrete dispute would be if HHS brought an enforcement action against an objecting religious hospital for denying use of an operating room to perform a hysterectomy for a transgender man, where the treating physician has indicated that the procedure was intended to treat severe endometriosis but the hospital denied the surgery, arguing that it constituted a gender-transition procedure. Among other things, a court would have to determine, based on the evidence in the record, whether the procedure was deemed medically necessary to

treat severe endometriosis, how the hospital treats other patients with similar conditions, whether performing the procedure would substantially burden the hospital's religious exercise, whether there is a compelling government interest, and whether the government satisfied RFRA's least-restrictive-means requirement. This highly fact-specific inquiry underscores why plaintiffs' RFRA claims cannot be evaluated in the abstract.

Plaintiffs do not dispute that RFRA requires consideration of "'the specific factual context of the religious exemption requested by a particular plaintiff.'" Pls. Br. 57. For good reason: The Supreme Court and this Court have repeatedly made clear that "RFRA, and the strict scrutiny [standard] it adopted [from First Amendment jurisprudence]," requires "'a case-by-case, fact-specific inquiry.'" *Brown v. Collier*, 929 F.3d 218, 230 (5th Cir. 2019); *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 430-31 (2006); *see also Ramirez v. Collier*, 142 S. Ct. 1264, 1283 (2022). That is true at every stage of the RFRA analysis. *See Brown*, 929 F.3d at 230 (substantial-burden analysis is fact-specific); *U.S. Navy Seals 1-26 v. Biden*, 27 F.4th 336, 350 (5th Cir. 2022) (per curiam) (compelling interest must be focused on "'particular claimant'").

Instead, plaintiffs contend (Br. 57) that HHS was required to raise this issue below as a partial defense to the RFRA claim on the merits. That response misses the point: HHS is not contesting merely the scope of relief awarded, but rather that *any* relief could be awarded in the absence of sufficiently-concrete factual circumstances

required to properly assess every element in the RFRA analysis. This is appropriately framed as an issue of ripeness because it demonstrates that plaintiffs' reframed RFRA claim is not currently fit for judicial resolution.

Moreover, plaintiffs face little, if any, cognizable harm from deferring judicial review. Although plaintiffs may prefer to press broad RFRA claims divorced from any government enforcement activity compelling any specific action, and to obtain broad injunctive relief as soon as possible, that preference does not constitute hardship justifying premature judicial review. Plaintiffs do not contest (Br. 56) that "mere uncertainty" does not "constitute[] a hardship for purposes of the ripeness analysis." *National Park Hosp. Ass'n*, 538 U.S. at 811. Their only response is that HHS's actions also cause "practical harm" by forcing plaintiffs to either change their behavior or risk financial consequences, including losing federal funding. Pls. Br. 56 (cleaned up); *see* Pls. Br. 1, 37.[8] But as explained in our opening brief (at 51), HHS has not evaluated whether Section 1557 could in any specific circumstance require the provision or coverage of gender-transition procedures or abortions by objecting religious entities, and thus plaintiffs are not being forced to do anything.

[8] Plaintiffs claim that HHS requires them to "immediately revise their policies," Pls. Br. 56 (cleaned up)—but this alleged directive comes from the regulatory impact analysis section of the 2016 Rule. Ripeness is assessed as of the time of this Court's decision. *See Walmart Inc. v. U.S. Dep't of Justice*, 21 F.4th 300, 313 (5th Cir. 2021). Plaintiffs' assertion of current hardship cannot depend on a statement in the discussion of costs imposed by a rule that was rescinded over two years ago. In any event, it does not appear that plaintiffs revised their policies. *See supra* p. 21.

Even if HHS were to determine at some point that Section 1557 requires plaintiffs to provide or cover gender-transition procedures or abortions, plaintiffs would still be many steps removed from losing federal funding. *See Colwell v. HHS*, 558 F.3d 1112, 1128 (9th Cir. 2009). First, HHS would be required to attempt to achieve informal or voluntary compliance. 45 C.F.R. § 80.8(c); *see id.* § 92.5(a). Second, there must be a formal adjudication and an administrative hearing. *Id.* § 80.8(c). Third, HHS must wait thirty days after providing a full written report to Congressional committees. *Id.* Moreover, "[j]udicial review of any funding termination is available in an Article III court." *Colwell*, 558 F.3d at 1128. Plaintiffs make no effort to explain why they would be harmed by waiting to bring their RFRA claims in the context of a factual record, at the outset of an investigation by HHS, if HHS were to ever initiate an investigation of them.

C. The District Court Erred in Concluding that Plaintiffs Demonstrated Imminent Irreparable Harm Sufficient to Justify Permanent Injunctive Relief.

For many of the same reasons discussed above and in our opening brief (at 52-53), plaintiffs have not demonstrated imminent irreparable harm sufficient to justify permanent injunctive relief against HHS. Plaintiffs argue that the "'loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury.'" Pls. Br. 31. Similarly, plaintiffs assert that they have been irreparably harmed by being made to "choose between violating their consciences and harming their patients, or suffering crippling penalties destroying their ministries."

Pls. Br. 32. But as explained above, *supra* pp. 21, 24, plaintiffs do not actually argue that their religious exercise has been chilled; nor have they faced any such choice.

Plaintiffs attempt to invoke other cases in which injunctive relief was rewarded for successful RFRA claims. Pls. Br. 31, 34-35. But just because such relief is often appropriate does not mean that it is automatic. *See, e.g.*, ROA.4798-4799 (declining to grant injunctive relief in issuing final judgment on RFRA claim). Plaintiffs must still satisfy the ordinary requirements to establish entitlement to such relief. They have not done so here. Plaintiffs' speculation about enforcement positions that HHS might take at some unspecified future time does not demonstrate irreparable harm.

CONCLUSION

For the foregoing reasons, this Court should vacate the district court's permanent injunction and remand with instructions to dismiss for lack of jurisdiction.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 1, 2022, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system.

/s/ McKaye L. Neumeister
McKaye L. Neumeister

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 6,458 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 Microsoft Word 2016 in Garamond 14-point font, a proportionally spaced typeface.

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