IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT CHATTANOOGA

AMERICAN COLLEGE OF PEDIATRICIANS, on behalf of itself and its members;
CATHOLIC MEDICAL ASSOCIATION, on behalf of itself and its members; and
JEANIE DASSOW, M.D.,

Plaintiffs,

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**; **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; and **OFFICE FOR CIVIL RIGHTS OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**,

Defendants.

No. 1:21-cv-00195-TRM-SKL

REPLY MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS FIRST AMENDED COMPLAINT

ARGUMENT

I. The Court Lacks Jurisdiction Over Plaintiffs' Section 1557 Claims

A. Plaintiffs Lack Standing To Bring Their Section 1557 Claims

Plaintiffs' opposition confirms that they seek to challenge the lawfulness of positions that HHS has not adopted. Plaintiffs assert that HHS has adopted a Section 1557 "gender identity mandate" that "require[s]" each of the thousands of members of ACPeds and CMA to perform each of 22 "specific objectional practices" related to gender-affirming care, "regardless of" any objections based on "faith." Plaintiffs' Memorandum in Opposition to Defendants' Motion to Dismiss, ECF No. 55, 6-7 & n.14 ("Opp.") (citing First Am. Compl. ¶ 131). Plaintiffs primarily read this purported mandate into the provisions concerning gender identity in HHS's 2016 Rule implementing Section 1557 ("2016 Rule"). *See* Opp. 3 (2016 Rule imposes "this mandate").

However, as Defendants showed, the 2016 Rule's gender identity provisions were vacated in *Franciscan Alliance v. Azar*, 414 F. Supp. 3d 928 (N.D. Tex. 2019), and are no longer in effect. *See* Memorandum in Support of Motion to Dismiss, ECF No. 52, at 14-15 ("Mem."). Plaintiffs argue that two subsequent district court decisions, *Walker v. Azar*, 480 F. Supp. 3d 417 (E.D.N.Y. 2020), and *Whitman-Walker Clinic, Inc. v. HHS*, 485 F. Supp. 3d 1 (D.D.C. 2020), revived the vacated portions of the 2016 Rule, Opp. 4, but that is incorrect. Both decisions acknowledged the courts lacked the power to revive a rule vacated by another district court. *Walker*, 480 F. Supp. 3d at 427 (the court "has no power to revive a rule vacated by another district court"); *Whitman-Walker*, 485 F. Supp. 3d. at 26 ("no authority . . . would permit either this Court or HHS to disregard the final order of a district court vacating part of a regulation").

Plaintiffs cite a statement in *Walker* that the 2016 Rule's definition of gender identity "will remain in effect." *Walker*, 480 F. Supp. 3d at 430. That statement, when read in light of *Walker*'s "predict[ion] that either the district court [in *Franciscan Alliance*] or some higher

authority will revisit the vacatur," *id.* at 427, is best read as stating that because the *Walker* court enjoined the 2020 Rule's repeal of the 2016 Rule's gender identity definition, that definition would be in effect if the *Franciscan Alliance* vacatur were set aside as the *Walker* court (erroneously) predicted. But this Court should not read *Walker* as having revived the vacated portions of the 2016 Rule when the court explicitly acknowledged that it had "no power" to do so. *Id.*

Although Plaintiffs cite three district court decisions that concluded that *Walker* and *Whitman-Walker* revived the vacated portions of the 2016 Rule, Opp. 4 n.6, those decisions are incorrect because they ignore the express acknowledgment by the *Walker* and *Whitman-Walker* courts that they could do no such thing. Indeed, the Fifth Circuit's recent *Franciscan Alliance* decision found an APA challenge to the 2016 Rule's gender identity provisions moot because such provisions have been vacated. *Franciscan All., Inc. v. Becerra*, --- F. 4th ---, 2022 WL 3700044, at *3-*4 (5th Cir. Aug. 26, 2022).[1] Moreover, because HHS has consistently taken the position that the gender identity provisions from the 2016 Rule are not in effect and has not enforced them, Plaintiffs face no "substantial" threat that HHS will enforce the 2016 Rule against them, as required for a preenforcement challenge. *California v. Texas*, 141 S. Ct. 2104, 2114 (2021).

Failing to locate the "gender identity mandate" in the 2016 Rule, Plaintiffs attempt to locate it in HHS guidance documents interpreting Section 1557 to prohibit discrimination on the

[1] Defendants disagree with the Fifth Circuit's statement that "in effect," the *Walker* and *Whitman-Walker* injunctions "und[id] the [*Franciscan Alliance*] district court's vacatur" by enjoining the repeal of a prohibition on discrimination on the basis of sex stereotypes. *Id.* at *2. Although *Walker* and *Whitman-Walker* noted that some overlap exists between the concepts of sex stereotypes and gender identity, *Walker*, 480 F. Supp. 3d at 427; *Whitman-Walker*, 485 F. Supp. 3d at 38, neither court held that discrimination on the basis of sex stereotypes is identical to discrimination on the basis of gender identity.

basis of gender identity, or in Section 1557 itself. Opp. 14-15. But a statute prohibiting gender identity discrimination is not the same thing as a mandate that all health care providers perform all types of gender-affirming care, regardless of the circumstances or religious objections.

Indeed, HHS's recently issued Notice of Proposed Rulemaking setting forth a proposed rule implementing Section 1557, Dep't of Health & Human Servs., Nondiscrimination in Health Programs and Activities, Notice of Proposed Rulemaking, 87 Fed. Reg. 47,824 (Aug. 4, 2022) ("NPRM"), shows that HHS's interpretation of Section 1557 differs from Plaintiffs' portrayal of HHS's position. Although the proposed rule would interpret discrimination on the basis of sex to "include[] . . . discrimination on the basis of . . . gender identity," *id.* at 47,916 (proposed 45 C.F.R. § 92.101(a)(2)), it further states that the proposed rule would not "require[] the provision of any health service where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting that service," *id.* at 47,918 (proposed 45 C.F.R. § 92.206(c)). For example, the proposed rule would "not require health care professionals to perform services outside of their normal specialty area," and further would "not compel a provider to prescribe a specific treatment that the provider decides not to offer after making a nondiscriminatory bona fide treatment decision." *Id.* at 47,867. Perhaps most pertinent here, the NPRM acknowledges that statutes protecting religious exercise such as the Religious Freedom Restoration Act (RFRA) may require exemptions from Section 1557's nondiscrimination provisions, and it accordingly proposes a process for covered entities to assert claims for religious exemptions. *Id.* at 47,885-86, 47,911, 47,918-19. Of course, the NPRM sets forth a proposed rule, and HHS will not issue a final rule until after a comment period during which any member of the public (including Plaintiffs) can submit comments, but that only underscores that Plaintiffs' challenge to HHS's

interpretation of Section 1557 is premature when HHS is still developing that interpretation through the notice-and-comment rulemaking process.

Plaintiffs misunderstand or mischaracterize HHS's positions, but federal courts lack jurisdiction to issue advisory opinions on the lawfulness of positions that the government has not actually taken. *Vonderhaar v. Vill. of Evendale, Oh.*, 906 F.3d 397, 399 (6th Cir. 2018). Rather, Plaintiffs must show that HHS's actions cause them "imminent injury," which means a "certainly impending" injury, rather than a mere "allegation 'of *possible* future injury.'" *Id.* at 401 (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013)). In the context of a preenforcement challenge, Plaintiffs "must show that the likelihood of future enforcement is 'substantial.'" *California*, 141 S. Ct. at 2114. This they fail to do. Plaintiffs do not dispute that Defendants have never enforced Section 1557 to require any provider to perform gender transition services, nor have Defendants threatened any Plaintiff or Member with enforcement. Mem. 16. Plaintiffs point to HHS's generalized May 2021 guidance that it will interpret and enforce Section 1557 to prohibit discrimination on the basis of gender identity, Opp. 21, but "'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) (quoting *United Pub. Workers of Am. v. Mitchell*, 330 U.S. 75, 88 (1947)).[2]

[2] Plaintiffs attempt to demonstrate a credible threat of enforcement by citing motions HHS filed to clarify three injunctions issued by other district courts. Opp. 22-23. In each case, the district court enjoined HHS from enforcing Section 1557 against any member of a large membership organization, where the organizations did not publicize their member lists. HHS filed motions asking the courts to modify the injunctions to clarify that HHS would not violate the injunction if it took action against an entity without knowing that it was a member of the plaintiff organization, arguing that such a modification was necessary to comply with the requirement of Federal Rule of Civil Procedure 65(d) that an injunction "state its terms specifically" and "describe in reasonable detail . . . the act or acts restrained or required." *See*, *e.g.*, *Franciscan*

In addition, the fact that most Members (including all Members identified by Plaintiffs) have religious objections to performing gender transition services further shows the lack of substantial threat of enforcement. As noted, the NPRM proposes a process in which a covered entity can raise a claim with HHS, either preemptively or in response to an investigation or enforcement action, that it is entitled to an exemption from one or more of Section 1557's requirements under RFRA or other conscience laws. 87 Fed. Reg. at 47,885, 47,918. HHS would then "h[o]ld in abeyance" "[a]ny relevant ongoing investigation or enforcement activity regarding the recipient . . . until a determination has been made" about the entity's entitlement to a religious exemption. *Id.* at 47,919. In other words, under this proposal, HHS could not take any adverse action against a covered entity, or even conduct an investigation, unless and until HHS resolved the entity's claim for a religious exemption. Again, while this is a proposed rule, it underscores HHS's commitment to respecting the religious protections afforded by federal law, which further renders Plaintiffs' alleged injury speculative.

Plaintiffs miss the mark in arguing that considering RFRA in the standing analysis would "negate RFRA's text." Opp. 24. It is true that RFRA authorizes a party to bring "a claim" against the federal government. 42 U.S.C. § 2000bb-1(c). But RFRA's cause of action does not override the limits of Article III standing. *See Spokeo, Inc. v. Robins*, 578 U.S. 330, 341 (2016) ("Article III standing requires a concrete injury even in the context of a statutory violation."); 42 U.S.C. § 2000bb-1(c) (standing to assert RFRA claim "governed by the general rules of standing under article III"). In determining whether Plaintiffs face the substantial threat of enforcement

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All., No. 7:16-cv-00108-O, ECF No. 208 at 2 (filed Sept. 13, 2021). Contrary to Plaintiffs' assertion, HHS never stated in any of those motions that it planned to enforce Section 1557 against anyone. HHS's efforts in separate cases to ensure that injunctions entered against it were sufficiently clear to comply with the Federal Rules of Civil Procedure do not show a credible threat that HHS will enforce Section 1557 against Plaintiffs.

that Article III requires, it is relevant that HHS has consistently stated that it will abide by RFRA in any enforcement of Section 1557, has never enforced Section 1557 to require a provider with a religious objection to perform gender transition services, and has recently proposed a robust procedural mechanism to protect providers' rights under RFRA and other religious freedom laws. The contraceptive coverage requirement cases cited by Plaintiffs, Opp. 25, are distinguishable. For example, in *Autocam Corp. v. Sebelius*, 730 F.3d 618 (6th Cir. 2013), the Sixth Circuit concluded that a company had standing to challenge the contraceptive coverage requirement because it found that the plaintiff "face[d] an imminent loss of money." *Id.* at 622. For the reasons stated above, Plaintiffs do not face such an imminent threat here.

Plaintiffs correctly point out that three district courts have allowed challenges to HHS's actions concerning Section 1557 to go forward. But while Plaintiffs summarize those courts' opinions, Opp. 9-11, Plaintiffs fail to respond to Defendants' showing that those opinions contained several legal errors, Mem. 22-24. A recent Eighth Circuit decision illustrates the error in those courts' analysis. In *School of the Ozarks, Inc. v. Biden*, 41 F.4th 992 (8th Cir. 2022), a federal agency (the Department of Housing and Urban Development, or HUD) had issued a memorandum interpreting a federal statute (the Fair Housing Act) as prohibiting discrimination on the basis of sexual orientation and gender identity, but it had not taken any enforcement action against the plaintiff. *Id.* at 996. The plaintiff brought a preenforcement challenge to this memorandum, but the Eighth Circuit ruled that the plaintiff lacked standing, holding that its "alleged injury . . . lacks imminence because it is speculative that HUD will file a charge of discrimination against the College in the first place." *Id.* at 998. Noting the lack of relevant enforcement history or a specific enforcement threat against the plaintiff, the court concluded that the plaintiff's "alleged injury is too speculative to establish Article III standing" because any

future injury depended on "the kind of 'highly attenuated chain of possibilities' that 'does not satisfy the requirement that threatened injury must be certainly impending.'" *Id.* at 1000 (quoting *Clapper*, 568 U.S. at 410). So too, here, the threat of enforcement against Plaintiffs is speculative, rather than imminent. The decisions cited by Plaintiffs strayed from Article III's limitations by adjudicating a preenforcement challenge despite the lack of a credible threat of enforcement. The Court should instead follow the analysis of *School of the Ozarks*, which faithfully applies Article III.

B. Plaintiffs' Section 1557 Claims Are Unripe

Plaintiffs' claims are unripe because they depend on facts that have not yet been developed and because they challenge legal positions HHS has not taken. Mem. 18-22. Plaintiffs attempt to distinguish *Kentucky Press Association, Inc v. Kentucky*, 454 F.3d 505, 507 (6th Cir. 2006), in which the Sixth Circuit found a challenge to a Kentucky law unripe when it was not clear how Kentucky courts would interpret the law, by arguing that there is "nothing unclear about whether HHS is imposing a ban on gender identity discrimination." Opp. 28. But while HHS has taken the position that Section 1557 prohibits discrimination on the basis of gender identity, the recent NPRM shows that the agency has not made a final determination regarding the contours and limitations of such a prohibition. And Plaintiffs have no answer to *Walmart, Inc. v. U.S. Department of Justice*, 21 F.4th 300 (5th Cir. 2021), in which the court held that "[b]ecause [Walmart] challenge[d] a series of positions that the government does not quite take, Walmart fail[ed] to show the 'actual controversy' that is needed for a declaratory judgment to be fit for judicial decision." *Id.* at 312. Adjudicating Plaintiffs' challenge to positions HHS has not taken, while HHS is still developing its positions through the rulemaking

progress, would "entangle [this Court] in abstract debates," *Warshak v. United States*, 532 F.3d 521, 525 (6th Cir. 2008), in violation of Article III's ripeness requirement.

Plaintiffs further argue that the facts are sufficiently clear for a ripe controversy because they categorically oppose providing gender transition services. Opp. 28-29. But in any potential dispute over RFRA, a court would need to consider the "application of [Section 1557] 'to the person'—the particular claimant whose sincere exercise of religion is being substantially burdened," *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 430-431 (2006), to determine whether requiring a particular provider to perform a particular procedure is the least restrictive means of advancing a compelling government interest. RFRA's fact-specific nature does not allow a court to determine, in one fell swoop, that it could never comply with RFRA for HHS to require any provider to provide any gender transition service in any situation.

Plaintiffs cite Judge Atchley's decision in *Tennessee v. United States Department of Education*, No. 3:21-CV-308, 2022 WL 2791450 (E.D. Tenn. July 15, 2022), for the proposition that "a long line of precedent allowing pre-enforcement judicial review of agency actions" exists. *Id.* at *9. But no one disputes that pre-enforcement judicial review is *sometimes* available; the question is whether an Article III controversy exists here. *Tennessee* did not address HHS's interpretation of Section 1557, which HHS is still developing through the rulemaking process. And the fact-specific nature of the RFRA analysis was not relevant in *Tennessee* because the plaintiffs were states who cannot assert a RFRA claim.[3]

II. Plaintiffs Lack Standing Or A Ripe Controversy For Their Grants Rule Claims

Plaintiffs lack standing or a ripe controversy to challenge the 2016 Grants Rule because HHS issued a Notice of Nonenforcement stating that HHS will not enforce the regulation. Mem.

[3] The federal government also respectfully disagrees with Judge Atchley's decision, and litigation in that case is ongoing.

24-28. Plaintiffs' primary response is to assert that the Notice of Nonenforcement is "defunct and obsolete" because a court has vacated the 2021 Grants Rule, which would have amended the challenged provisions, Opp. 17, but that is wrong. The Notice of Nonenforcement states that the 2016 Grants Rule "will not be enforced pending repromulgation." Notification of Nonenforcement of Health and Human Services Grants Regulation, 84 Fed. Reg. 63,809, 63,811 (Nov. 19, 2019). Given the vacatur, HHS has not yet promulgated a new grants rule. Therefore, the Notice of Nonenforcement remains applicable.

Plaintiffs cast aspersions at HHS for moving to vacate the 2021 Grants Rule in *Facing Foster Care*, but HHS moved to vacate the 2021 Grants Rule because it determined that its contractor's review of comments on the proposed rule — which consisted of reviewing a small percentage of comments without a valid sampling methodology — did not allow HHS to comply with the APA's requirements to respond to any significant comments when issuing a final rule. *See Facing Foster Care in Alaska*, No. 1:21-cv-00308, ECF No. 41, at 3-8. HHS's appropriate action to ensure compliance with the APA does not indicate bad faith. In any event, it has no bearing on whether there is a substantial threat that HHS will enforce the 2016 Grants Rule.

Plaintiffs also erroneously argue that HHS declared its intent to enforce the 2016 Grants Rule in a press release announcing HHS's rescission of religious waivers to the 2016 Grants Rule. Opp. 19-20. In fact, in that press release, HHS announced that the religious waivers were "unnecessary" *because* HHS had issued the "Notice of Nonenforcement for the 2016 Grants Rule."[4] And HHS has continued to adhere to the Notice of Nonenforcement in the nine months since that press release.

[4] HHS, *HHS Takes Action to Prevent Discrimination and Strengthen Civil Rights* (Nov. 18, 2021), https://www.hhs.gov/about/news/2021/11/18/hhs-takes-action-to-prevent-discrimination-and-strengthen-civil-rights.html.

Plaintiffs' efforts to distinguish *Texas Department of Family and Protective Services v. Azar*, 476 F. Supp. 3d 570 (S.D. Tex. 2020), and *Vita Nuova, Inc. v. Azar*, 458 F. Supp. 3d 546 (N.D. Tex. 2020) are unpersuasive. Those cases found a lack of justiciability because the Notice of Nonenforcement "expressly disavowed enforcement," *Vita Nuova*, 458 F. Supp. 3d at 558, and "unequivocally states that [HHS] will not enforce" the 2016 Grants Rule, *Texas Dep't*, 476 F.3d at 578. Plaintiffs' assertion that "[t]here is a credible threat of enforcement now that was not present in either Texas case," Opp. 20, is wrong: HHS has continued to abide by the Notice of Nonenforcement. Although Plaintiffs cite several cases that adjudicated challenges to statutes that had never or rarely been enforced, Opp. 20, none of those cases involved an officially published statement of nonenforcement such as HHS's Notice of Nonenforcement.

In light of HHS's consistent history of nonenforcement and HHS's publication of the Notice of Nonenforcement, no "substantial" threat exists that HHS will enforce the 2016 Grants Rule against Plaintiffs. *California*, 141 S. Ct. at 2114. Accordingly, Plaintiffs' challenge to the rule does not present an Article III case or controversy.

CONCLUSION

The Court should grant Defendants' Motion to Dismiss and dismiss the First Amended Complaint for lack of subject-matter jurisdiction.

Dated: August 31, 2022

Respectfully submitted,

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

MICHELLE R. BENNETT
Assistant Branch Director

/s/ Jeremy S.B. Newman
Jeremy S.B. Newman
Trial Attorney
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, NW
Washington, DC 20005
Tel: (202) 532-3114
Email: jeremy.s.newman@usdoj.gov

Counsel for Defendants