IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
MIDLAND / ODESSA DIVISION

STATE OF TEXAS, AND MAYO PHARMACY INC., A NORTH DAKOTA CORPORATION, *Plaintiffs*; v. XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE FOR CIVIL RIGHTS, *Defendants*.	No. 7:23-cv-00022-DC

DEFENDANTS' MOTION TO DISMISS AMENDED COMPLAINT

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INTRODUCTION

Pursuant to Federal Rules of Civil Procedure 12(b)(1), 12(b)(6), and 12(b)(3), defendants Xavier Becerra, in his official capacity as Secretary of Health and Human Services, the United States Department of Health and Human Services ("HHS"), and the United States Department of Health and Human Services Office for Civil Rights ("OCR," and collectively "defendants") hereby move to dismiss the First Amended Complaint.

Plaintiffs Texas and Mayo Pharmacy, Inc. ("Mayo," and collectively, "plaintiffs") challenge a guidance document (and accompanying press release) that OCR issued last year to assist pharmacies in complying with federal civil rights laws, but plaintiffs' claims rest on a fundamental misunderstanding of the pharmacy guidance. Plaintiffs contend that the guidance violates the Administrative Procedure Act ("APA") and Mayo's rights under the Religious Freedom Restoration Act ("RFRA") because it purportedly requires pharmacies to dispense drugs for abortion purposes. But the pharmacy guidance—which in any event is non-binding and imposes no legal requirements—does not address the issue of dispensing drugs for purposes of abortion. Rather, it addresses dispensing drugs for other, non-abortion purposes. For example, the pharmacy guidance states that it may constitute discrimination on the basis of disability to refuse to fill a patient's prescription for a rheumatoid arthritis medication because of the medication's alternative uses, including that it can also be used to induce an abortion.

In large part because of plaintiffs' misunderstanding of the pharmacy guidance, they have failed to allege a plausible basis for the Court's subject-matter jurisdiction. Neither plaintiff has alleged standing, because each plaintiff's claimed injury stems from the purported requirement to dispense drugs for abortion purposes, which the pharmacy guidance does not impose. Similarly, no ripe controversy exists because plaintiffs seek to challenge a legal position that defendants have not taken. Furthermore, judicial review under the APA is unavailable because the pharmacy guidance

(which imposes no legal obligations and merely states OCR's view that certain types of behavior "may" constitute discrimination) is not final agency action, and Congress and HHS have established an adequate, alternative remedy for regulated parties to challenge OCR's enforcement of civil rights laws through an administrative process subject to judicial review.

Mayo's RFRA claim is independently subject to dismissal for failure to state a claim and improper venue. Mayo fails to allege a substantial burden on its religious exercise, as required for a RFRA claim, because the pharmacy guidance does not, as Mayo contends, require Mayo to dispense drugs for abortion purposes. And Mayo, which is based in North Dakota, fails to allege a basis for venue in this district for the RFRA claim it alone brings.

BACKGROUND

A. HHS Office for Civil Rights ("OCR") and the Laws It Enforces

OCR is a law enforcement agency within HHS. It enforces federal civil rights laws; conscience and religious freedom laws; Health Insurance Portability and Accountability Act ("HIPAA") rules regarding health privacy and security; and the confidentiality requirements of the Patient Safety Act. These laws together protect Americans' fundamental rights of nondiscrimination, conscience, religious freedom, and health information privacy.

Among the laws enforced by OCR are two statutes particularly relevant here prohibiting recipients of federal financial assistance from discriminating based on certain protected grounds. Section 504 of the Rehabilitation Act ("Section 504") prohibits funding recipients and HHS from discriminating on the basis of disability. 29 U.S.C. § 794(a); *see also* 45 C.F.R. pt. 84. Section 1557 of the Affordable Care Act ("Section 1557") prohibits health programs and activities that receive federal financial assistance from discriminating on the basis of grounds prohibited under other civil rights laws, including on the basis of race, color, national origin, age, disability, or sex. 42 U.S.C.

§ 18116(a); *see also* 45 C.F.R. pt. 92.[1]

B. OCR's Enforcement Procedures and Investigatory Process[2]

Individuals who believe themselves or a specific class of individuals to be subjected to discrimination prohibited by the statutes within OCR's purview may submit a complaint to OCR. 45 C.F.R. § 80.7(b). OCR initially reviews the complaint to see if it falls within OCR's subject matter jurisdiction and is timely. *See id.* If so, OCR will conduct an investigation, reviewing the pertinent practices and policies of the funding recipient, the circumstances under which the alleged noncompliance with the statutes and regulations occurred, and other factors relevant to a determination as to whether the recipient has failed to comply with its legal obligations. *Id.* § 80.7(c). OCR may determine that no violation has occurred, and will so inform both the complainant and the recipient, and close the case. *Id.* § 80.7(d)(2). If an investigation indicates a failure to comply with the law, "the matter will be resolved by informal means whenever possible." *Id.* § 80.7(d)(1); *see also id.* § 80.8(a). If informal means cannot correct the issue, OCR may take various actions within its discretion to effect compliance, including but not limited to referral to the Department of Justice for enforcement. *Id.* § 80.8. If OCR determines that suspension or termination of a recipient's federal financial assistance may be warranted, it may not do so without first providing notice and a formal administrative hearing. *Id.* § 80.8(c); *id.* § 80.9. Additionally, OCR must file reports with appropriate House and Senate committees, providing a "full written report of the circumstances and

[1] HHS has issued a proposed rule to revise OCR's current regulations implementing Section 1557. *See Nondiscrimination in Health Programs & Activities*, 87 Fed. Reg. 47,824 (Aug. 4, 2022).

[2] The enforcement procedures described in this section are outlined in HHS's regulations implementing Title VI of the Civil Rights Act of 1964 ("Title VI"), which prohibits discrimination on the basis of race, color, or national origin by recipients of federal financial assistance. *See* 45 C.F.R. §§ 80.1–80.13. Except for claims of age discrimination, *see* 45 C.F.R. § 91.46, OCR uses the same Title VI procedures to enforce other civil rights laws, including Section 504 and Section 1557. *See* 45 C.F.R. § 84.61 (procedures for HHS's Section 504 regulations); 45 C.F.R. § 92.5 (providing that "[t]he enforcement mechanisms provided for, and available under, Title VI" and other civil rights laws, "shall apply" corresponding to violations of the statutory grounds laid out in 45 C.F.R. § 92.2, which is within 45 C.F.R. pt. 92—HHS's regulations implementing Section 1557).

the grounds" for any determination to suspend or terminate funding, and then wait at least thirty days before such order becomes effective. *Id.* § 80.8(c). Administrative determinations revoking funding are subject to judicial review in district court, *id.* § 80.11, and are also subject to post-termination administrative proceedings to restore funding, *id.* § 80.10(g).

HHS's regulations also authorize OCR to conduct compliance reviews. *Id.* § 80.7(a). If OCR initiates a compliance review, it follows the same procedures outlined above, including appropriate notifications to the funding recipient regarding the opening of the investigation and its resolution. *Id.* § 80.7(c), (d).

OCR also carries out its enforcement responsibilities by providing technical assistance and guidance to funding recipients to help them comply with the civil rights laws. *Id.* § 80.6.

C. The Pharmacy Guidance

On July 13, 2022, OCR issued a guidance document to retail pharmacies that receive federal financial assistance. Am. Compl. Ex. 2. The guidance is now posted on OCR's website along with other educational materials.[3] The guidance reviews the nondiscrimination obligations of covered pharmacies under civil rights laws—and particularly Section 504 and Section 1557[4]—with respect to supplying medications, making determinations regarding the suitability of a prescribed medication for a patient, or advising patients about medications and how to take them. *Id.* at 1.

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[3] *See* Am. Compl. ¶ 17 n.9; https://www.hhs.gov/civil-rights/for-individuals/special-topics/reproductive-healthcare/pharmacies-guidance/index.html.

[4] As recipients of federal financial assistance, including Medicare and Medicaid, covered pharmacies are prohibited from discriminating on the basis of race, color, national origin, sex, age, and disability in their programs and activities under a range of federal civil rights laws, including Section 504 and Section 1557.

The guidance also includes a footnote referencing Title IX of the Education Amendments of 1972 ("Title IX"). Am. Compl. Ex. 2 at 1 n.3. Title IX prohibits sex-based discrimination in educational institutions and education programs and activities of recipients of federal financial assistance. 20 U.S.C. § 1681(a) *et seq.*; *see also* 45 C.F.R. pt. 86. The footnote reminded covered entities that pharmacies affiliated with a covered education program or activity are also subject to Title IX nondiscrimination requirements. Am. Compl. Ex. 2 at 1 n.3.

The pharmacy guidance lists several examples of circumstances in which a pharmacy "may be discriminating" on the basis of sex or disability if it refuses to dispense certain drugs for certain purposes. For instance, one of the examples states that a pharmacy may be discriminating on the basis of disability if it refuses to dispense methotrexate as an immunosuppressive treatment for rheumatoid arthritis, because of its alternate uses. *Id.* at 3. Although the pharmacy guidance discusses reproductive health issues including pregnancy, miscarriage, and contraception, *id.* at 2–3, it does not address dispensing drugs for purposes of abortion. Instead, the guidance covers the refusal to dispense drugs for purposes *other than abortion*. *Id.* at 2–4.

D. HHS's Press Release

On the same day that OCR issued the pharmacy guidance, the HHS press office issued a short press release announcing and summarizing the pharmacy guidance:

> Today, following President Biden's Executive Order on ensuring access to reproductive health care, the U.S. Department of Health and Human Services (HHS) is issuing guidance to roughly 60,000 U.S. retail pharmacies, reminding them of their obligations under federal civil rights laws. The guidance makes clear that as recipients of federal financial assistance, including Medicare and Medicaid payments, pharmacies are prohibited under law from discriminating based on race, color, national origin, sex, age, and disability in their programs and activities.

Am. Compl. Ex. 1 at 1. After summarizing the pharmacy guidance, the press release included "a list of actions HHS ha[d] taken in the days following the Supreme Court's ruling [in *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228 (2022)] to ensure access to reproductive health care." *Id.* at 2–3.

E. Procedural History

Texas initially filed this action on February 7, 2023. On February 28, 2023, Texas filed an amended complaint, adding co-plaintiff Mayo, a privately owned pharmacy located in Bismarck, North Dakota. Am. Compl. ¶ 34. Plaintiffs construe the pharmacy guidance and press release collectively, Am. Compl. at 1—and insist that the two documents constitute a "mandate" "requir[ing] pharmacies to dispense drugs for abortions as a condition of receiving Medicare and

Medicaid payments," *id.* at 1, ¶ 19. Plaintiffs assert several claims under the APA, alleging that the guidance document and press release: (a) exceed statutory authority and are not in accordance with law, specifically the Affordable Care Act, Title IX, the Hyde Amendment, the Department of Justice's appropriation act, and the Constitution's Spending Clause, *id.* ¶¶ 54–75;[5] (b) were not issued pursuant to notice-and-comment rulemaking procedures, *id.* ¶¶ 76–81; and (c) are arbitrary and capricious, *id.* ¶¶ 82–90. Additionally, plaintiff Mayo brings a claim that the guidance document and press release violate its rights under RFRA. *Id.* ¶¶ 91–103.

Defendants now move to dismiss.

MOTION TO DISMISS STANDARDS

Rule 12(b)(1) requires dismissal of a complaint where the court "lacks the statutory or constitutional power to adjudicate the case." *Home Builders Ass'n of Miss., Inc. v. City of Madison*, 143 F.3d 1006, 1010 (5th Cir. 1998) (citation omitted). As the parties asserting federal jurisdiction, plaintiffs bear the burden of proving that it exists. *See Choice Inc. v. Greenstein*, 691 F.3d 710, 714 (5th Cir. 2012). Where, as here, defendants raise a "facial attack" on the Court's jurisdiction, the Court takes as true the plaintiffs' factual allegations and "'look[s] and see[s] if plaintiff[s] ha[ve] sufficiently alleged a basis of subject matter jurisdiction.'" *Cell Science Sys. Corp. v. La. Health Serv.*, 804 F. App'x 260, 263 (5th Cir. 2020) (quoting *Menchaca v. Chrysler Credit Corp.*, 613 F.2d 507, 511 (5th Cir. 1980)).

To survive a motion to dismiss under Rule 12(b)(6) for failure to state a claim, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The court must accept the factual allegations of the complaint as true, but is "not bound to accept as true a legal conclusion couched as a factual allegation." *Twombly*, 550 U.S. at 555.

[5] Texas alone brings the Spending Clause claim. Am. Compl. ¶¶ 69–75.

Additionally, the court may consider factual matter in the complaint's exhibits, and matters for which judicial notice may be taken. *Petersen v. Johnson*, 57 F.4th 225, 229 n.1 (5th Cir. 2023).

A Rule 12(b)(3) motion challenges the complaint—or specific causes of action therein—for improper venue. Well-pleaded factual allegations are "viewed in the light most favorable to the plaintiff"; the court may also consider facts outside the complaint. *See Ambraco, Inc. v. Bossclip B.V.*, 570 F.3d 233, 237–38 (5th Cir. 2009). "While there is a split of authority among federal courts and in the Fifth Circuit [regarding] which party shoulders the burden of establishing venue . . . it appears the majority place the burden with the plaintiff," and this is "the better view." *Broadway Nat'l Bank v. Plano Encryption Techs., LLC*, 173 F. Supp. 3d 469, 473 n.2 (W.D. Tex. 2016) (quotation omitted).

ARGUMENT

I. The Court Should Dismiss Plaintiffs' Claims for Lack of Subject-Matter Jurisdiction Pursuant to Rule 12(b)(1)

A. Plaintiffs lack standing

To establish standing under Article III, a plaintiff must demonstrate that it has suffered a concrete injury, or that such an injury is "imminent" or "certainly impending." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013). Plaintiffs challenging a law or government policy when no enforcement action has been taken against them satisfy the injury-in-fact requirement by alleging "'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.'" *Susan B. Anthony List v. Driehaus* ("*SBA List*"), 573 U.S. 149, 159 (2014) (quoting *Babbitt v. Farm Workers*, 442 U.S. 289, 298 (1979)). But "[i]n the absence of contemporary enforcement, . . . a plaintiff claiming standing must show that the likelihood of future enforcement is 'substantial.'" *California v. Texas*, 141 S. Ct. 2104, 2114 (2021). Neither plaintiff alleges an injury-in-fact that meets this standard.

1. Texas lacks standing

Texas asserts an injury to its "'sovereign interest in the power to create and enforce a legal

code,'" because the pharmacy guidance purportedly "preempt[s] its laws by requiring pharmacies to *stock and dispense drugs for abortions* even if doing so would violate state law." Am. Compl. ¶ 29 (quoting *Texas v. United States*, 809 F.3d 134, 153 (5th Cir. 2015)) (emphasis added). But Texas's asserted injury lacks a basis in the pharmacy guidance which, by its terms, does not address dispensing drugs for purposes of abortions. Rather, the guidance addresses situations in which a pharmacy would fail to fill a prescription for *non-abortion* purposes (such as rheumatoid arthritis or severe and chronic stomach ulcers) because the drug at issue can also be used for abortion. For example, the guidance states that it may constitute discrimination to refuse to fill a prescription for methotrexate to treat rheumatoid arthritis "because of its alternate uses." Am. Compl. Ex. 2, at 3. In discussing medication used for reproductive health care, the guidance addresses miscarriages, ectopic pregnancies, and contraception, not abortion.[6] Texas cannot point to any language in the guidance that purports to require pharmacies to dispense drugs for abortion purposes. Accordingly, the pharmacy guidance does not conflict with, or purport to preempt, Texas laws that restrict abortion.

Texas also claims standing based on speculation that HHS will enforce the pharmacy guidance against pharmacies operated by Texas Tech University Health Sciences Center ("TTUHSC"). Am. Compl. ¶¶ 30, 33. But Texas does not allege that HHS has taken any action against TTUHSC, and Texas does not meet any of the requirements for pre-enforcement standing. First, Texas does not identify any constitutional interest with which TTUHSC's "course of conduct"

[6] For instance, one of the examples in the pharmacy guidance addresses refusal to dispense methotrexate to treat ectopic pregnancy, which occurs when a fertilized egg grows outside of the uterus, such as in a fallopian tube. Am. Compl. Ex. 2, at 3 & n.13. Texas law specifically excludes "remov[ing] an ectopic pregnancy" from the definition of abortion. Tex. Health & Safety Code § 245.002(1)(C). The same is true of a recently enacted North Dakota law. *See* N.D. Sen. Bill No. 2150, § 1, *available at* https://legiscan.com/ND/text/SB2150/2023 (signed into law April 24, 2023) ("use, sale, prescription, or means is not an abortion if done with the intent to . . . [t]reat a woman for an ectopic pregnancy").

is "arguably affected" and which would allow a pre-enforcement challenge. *SBA List*, 573 U.S. at 159. Second, Texas fails to show that TTUHSC intends to engage in conduct Texas claims is "proscribed by" the pharmacy guidance. *Id.* Texas points to the TTUHSC pharmacies' refusal "to dispense drugs for abortions," Am. Compl. ¶ 30, but as explained, the pharmacy guidance does not address dispensing drugs for purposes of abortion.[7] Third, Texas has not established a "credible threat" that OCR will rely on the pharmacy guidance to justify enforcement against Texas. *SBA List*, 573 U.S. at 159. As an initial matter, there is no likelihood of "enforcement" of the pharmacy guidance, let alone a "substantial" likelihood, *California*, 141 S. Ct. at 2114, because the pharmacy guidance "do[es] not have the force and effect of law," Am. Compl. Ex. 2, at 4, and merely describes a pharmacy's nondiscrimination obligations under existing civil rights laws.

Moreover, Texas fails to cite a single instance of OCR taking enforcement action against any pharmacy for refusing to dispense drugs for abortion purposes. Nor does Texas allege any specific threat of enforcement directed at the TTUHSC pharmacies. The notion that OCR will rely on the pharmacy guidance to require TTUHSC pharmacies to dispense drugs for abortion purposes, even though OCR has never done so and the pharmacy guidance does not on its face address dispensing drugs for abortion purposes, rests on the sort of "speculative chain of possibilities" that is insufficient for pre-enforcement standing. *Barber v. Bryant*, 860 F.3d 345, 357 (5th Cir. 2017).

Finally, Texas lacks standing to challenge the press release. Texas articulates no basis on which to conclude that a press release, which simply announces and summarizes the pharmacy guidance, *see* Am. Compl. Ex. 1, causes it any injury.

[7] Because the pharmacy guidance does not state that pharmacies are required to dispense drugs for abortion purposes, it does not "require[] Texas Tech to choose between violating State law or jeopardizing its ability to participate in Medicare and Medicaid." Am. Compl. ¶ 33.

2. Mayo lacks standing

Mayo lacks standing largely for the same reasons that Texas lacks standing to sue on behalf of TTUHSC pharmacies. Mayo alleges that it is injured by the purported "require[ment] . . . to stock and dispense drugs for abortion purposes," Am. Compl. ¶ 46, but the pharmacy guidance does not impose such a requirement. *See supra*, pp. 4–5, 8. Mayo lacks pre-enforcement standing because its intended conduct of not dispensing drugs for abortion purposes is not addressed by the pharmacy guidance, and HHS has never relied on the guidance to require dispensing drugs for abortion purposes. Further, as the guidance does not have the force of law, it cannot be enforced.

Mayo also fails to show a credible threat of enforcement for an additional reason: Under RFRA, the federal government cannot substantially burden a person's exercise of religion unless it shows that doing so is the least restrictive means of advancing a compelling government interest. 42 U.S.C. § 2000bb-1. HHS has consistently maintained that it will abide by RFRA in its enforcement of civil rights laws. *See*, *e.g.*, *Nondiscrimination in Health Programs & Activities*, 81 Fed. Reg. 31,376, 31,466 (May 18, 2016) ("application" of requirements of rule implementing Section 1557 "shall not be required" where it "would violate applicable Federal statutory protections for religious freedom and conscience"); *Nondiscrimination in Health & Health Educ. Programs or Activities, Delegation of Auth.*, 85 Fed. Reg. 37,160, 37,207 (June 19, 2020) (HHS "is bound to enforce Section 1557 in compliance with RFRA").[8] Mayo has not cited any examples of HHS taking enforcement action to require a pharmacy to dispense a drug for the purpose of abortion (or any other drug for any other purpose) over a religious objection. That underscores that Mayo has failed to show a credible threat of enforcement.

[8] Further, the agency's recent notice of proposed rulemaking implementing Section 1557 proposes a procedure under which, if a covered entity asserts rights under a federal conscience or religious freedom law, HHS will not take action unless and until HHS makes a determination on the entity's entitlement to an exemption. *See* 87 Fed. Reg. at 47,918-19.

B. Plaintiffs' claims are unripe

Plaintiffs' claims are unripe because they challenge a legal position that HHS has not taken, and any speculation that HHS may take such a position in the future is too abstract and hypothetical to generate a ripe controversy. "At its core, ripeness is a matter of timing that serves to prevent courts from entangling themselves in cases prematurely." *Walmart Inc. v. U.S. Dep't of Justice*, 21 F.34th 300, 312 (5th Cir. 2021). Under ripeness principles, courts must "dismiss a case for lack of 'ripeness' when the case is abstract or hypothetical." *Monk v. Huston*, 340 F.3d 279, 282 (5th Cir. 2003) (quotation omitted). The "key considerations" in making that determination "are the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Id.* (quotation omitted).

Plaintiffs' "failure to contradict a definite government position means that it has not demonstrated the existence of a ripe case or controversy, as required by Article III." *Walmart*, 21 F.4th at 305. In *Walmart*, Walmart sued the Department of Justice ("DOJ"), seeking a series of declarations about the obligations of pharmacists when dispensing opioids, but Walmart could not point to any "public document setting forth the positions it seeks to contest." *Id.* at 305–06. DOJ later expressed legal positions that were different from those that Walmart sought to ascribe to DOJ and oppose. *Id.* at 312. Because 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.* The same is even more true here. Plaintiffs ask this Court to rule that it would be unlawful "to impose a legal duty on pharmacies . . . to dispense drugs for abortion purposes." Am. Compl. ¶ 57. But the pharmacy guidance does not purport to impose such a duty. It does not address the issue of dispensing drugs for purposes of abortion, but rather addresses dispensing drugs for purposes other than abortion. *See supra*, pp. 4–5, 8. Because HHS's position expressed in the guidance is "materially different from the one [plaintiffs] challenge[]"

Walmart, 21 F.4th at 312, plaintiffs fail to present a ripe controversy fit for judicial resolution. Furthermore, because the pharmacy guidance does not require plaintiffs to dispense drugs for abortion purposes against their wishes or otherwise, "withholding court consideration" would not cause "hardship." *Monk*, 340 F.3d at 282 (quotation omitted).

To the extent plaintiffs speculate that HHS may in the future take the position that pharmacies are required to dispense drugs for abortion purposes, such a claim is unripe because it is "abstract [and] hypothetical." *Id.* "A claim is not ripe for adjudication" where, as here, "it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas v. United States*, 523 U.S. 296, 300 (1998) (quotations omitted); *see also Walmart*, 21 F.4th at 312 (challenge is "premature" absent a "clear position on the part of the government" opposing plaintiff's position).

C. Plaintiffs fail to challenge agency action that is reviewable under the APA

1. Neither the pharmacy guidance nor the press release is final agency action

Judicial review under the APA is generally limited to "final agency action." 5 U.S.C. § 704. Such action must (1) represent "the consummation of the agency's decisionmaking process," and (2) conclusively determine legal "rights or obligations." *Bennett v. Spear*, 520 U.S. 154, 178 (1997) (quotation omitted). The pharmacy guidance and press release meet neither of these requirements.

First, the pharmacy guidance is not the consummation of HHS's decisionmaking process. "Agency action may mark the consummation of the agency's decisionmaking process if the agency action is not subject to further agency review, which occurs when the agency has asserted its final position on the factual circumstances underpinning the agency action." *La. State v. U.S. Army Corps of Eng'rs*, 834 F.3d 574, 581 (5th Cir. 2016) (quotations omitted). The guidance does not assert HHS's "final position" on any "factual circumstances." *Id.* Instead, it provides several general examples of conduct before stating that pharmacies engaged in such conduct "may be

discriminating." Am. Compl. Ex. 2, at 3–4. That tentative language underscores that "further agency review," *La. State*, 834 F.3d at 581—including a series of investigative steps and administrative procedures, *see supra*, pp. 3–4—would be necessary for HHS to make any definitive determinations about whether any specific course of conduct constituted discrimination. *See U.S. Army Corps of Eng'rs v. Hawkes Co.*, 578 U.S. 590, 597 (2016) (distinguishing a preliminary determination that "there may be waters of the United States on a parcel of property" from an approved determination that "clearly marks the consummation of the [agency's] decisionmaking on that question"). For example, to determine whether a pharmacy's conduct was discriminatory, HHS would need to analyze the factual circumstances, including the pharmacy's reasons for not dispensing a drug, and the application of any invoked federal conscience or religious freedom laws.

Second, the pharmacy guidance does not impose legal consequences or conclusively determine rights or obligations. The guidance "remind[s]" pharmacies of "the nondiscrimination obligations of pharmacies under federal civil rights laws," Am. Compl. Ex. 2, at 1, such as Section 504 and Section 1557, but it creates no "new obligation or legal consequence" beyond those the statutes already imposed, *State v. Rettig*, 987 F.3d 518, 530 (5th Cir. 2021), *cert. denied*, 142 S. Ct. 1308 (2022); *see also id.* at 529; *Nat'l Pork Producers Council v. EPA*, 635 F.3d 738, 756 (5th Cir. 2011) ("guidance letters" that describe existing legal obligations but "have no effect on a party's rights or obligations are not reviewable final actions"). The pharmacy guidance further states that "[t]he contents of this document do not have the force and effect of law and are not meant to bind the public in any way." Am. Compl. Ex. 2, at 4. That is not mere boilerplate but reflects that in future enforcement actions, HHS could not establish a legal violation by relying on the pharmacy guidance, but rather would need to show a violation of the underlying statutes described in the guidance. Such "disclaimers," while not dispositive, are "relevant to the conclusion that a guidance document is non-binding," particularly where there is no "evidence—or practice—to the contrary." *Cement Kiln*

Recycling Coal. v. EPA, 493 F.3d 207, 228 (D.C. Cir. 2007). Here, no contrary evidence or practice exists. The disclaimer is entirely consistent with the preliminary nature of the pharmacy guidance's analysis that certain conduct "may" constitute discrimination. Am. Compl. Ex. 2, at 3–4.

Plaintiffs' reliance on *Texas v. Equal Employment Opportunity Commission*, 933 F.3d 433, 441 (5th Cir. 2019), in support of the proposition that the pharmacy guidance is final agency action, Am. Compl. ¶ 55, is misplaced. In that case, the Fifth Circuit determined that an EEOC Notice of Interpretation was final agency action reviewable under the APA where it was binding on EEOC staff, limited their discretion, and, by its terms, "le[ft] no room for EEOC staff *not* to" take certain action. *EEOC*, 933 F.3d at 443. The court thus concluded that the guidance "carrie[d] legal consequences and dictate[d] employers' rights and obligations." *Id.* at 443. Here, the pharmacy guidance does not direct HHS staff to take any action and does not limit the staff's discretion. Rather, in stating that certain behavior "may" constitute discrimination, Am. Compl. Ex. 2, at 3–4, the guidance leaves HHS's staff with discretion to make appropriate investigatory and enforcement decisions based on the circumstances of each case. Moreover, plaintiffs' allegation that the guidance "is being 'applied . . . in a way that indicates it is binding,'" Am. Compl. ¶ 55 (quoting *EEOC*, 933 F.3d at 441), is conclusory. The Amended Complaint does not allege any instances of HHS applying the pharmacy guidance at all, let alone in a manner that treats it as binding.

Finally, the press release is also not final agency action. It merely announces and summarizes the pharmacy guidance and, accordingly, does not and could not determine legal "rights or obligations." *Bennett*, 520 U.S. at 178. *See* Am. Compl. Ex. 1.

2. Judicial review is unavailable here because Congress provided an adequate, alternative remedy for plaintiffs to obtain judicial review

Judicial review under the APA is also unavailable because the APA limits judicial review to "those agency actions which otherwise lack an 'adequate remedy in a court.'" *Hinojosa v. Horn*, 896 F.3d 305, 310 (5th Cir. 2018) (*per curiam*) (quoting *Bowen v. Mass.*, 487 U.S. 879, 903 (1988)); 5 U.S.C.

§ 704 (review available for "final agency action for which there is no other adequate remedy in a court"). Here, an adequate remedy in a court is available. If HHS wished to terminate federal funding on the basis of any of the civil rights laws referenced in the pharmacy guidance, HHS would first need to give notice of a potential violation, attempt to resolve the issue through voluntary means, and provide the recipient with a formal administrative hearing, with the administrative determination subject to judicial review. *See* 45 C.F.R. §§ 80.8–80.10; *supra*, pp. 3–4. Or HHS could choose to refer the matter to the Department of Justice to bring appropriate enforcement proceedings (after notice, findings, and attempts at voluntary compliance failed). *See* 45 C.F.R. § 80.8(a), (d). In any hypothetical enforcement action, plaintiffs would be able to raise legal objections during the administrative proceedings and again on judicial review. The civil rights statutes and HHS's regulations thus "provide[] a direct and guaranteed path to judicial review." *Hinojosa*, 896 F.3d at 312.

For similar reasons, judicial review is barred by the doctrine of *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200 (1994). Under *Thunder Basin*, where it is "fairly discernible" that an elaborate statutory review scheme for administrative enforcement proceedings was intended to create an exclusive remedy, parallel jurisdiction outside that scheme is precluded. *Id.* at 207, 216 (quotation omitted). In determining whether a plaintiff's claim is "'of the type Congress intended to be reviewed within this statutory structure,'" courts consider three factors: (1) "could precluding district court jurisdiction 'foreclose all meaningful judicial review' of the claim?", (2) "is the claim 'wholly collateral to [the] statute's review provisions'?", and (3) "is the claim 'outside the agency's expertise'?" *Axon Enter., Inc. v. FTC*, 143 S. Ct. 890, 900 (2023) (quoting *Thunder Basin*, 510 U.S. at 212–13).

Here, each *Thunder Basin* factor weighs in favor of the conclusion that Congress intended legal challenges to HHS's interpretation of the civil rights laws described in the pharmacy guidance to be brought within the procedural scheme for administrative enforcement proceedings that

culminates in the opportunity for judicial review. First, precluding judicial review at this time for plaintiffs' claims would not foreclose meaningful judicial review. As explained above, in a hypothetical enforcement proceeding, plaintiffs could raise the legal arguments they raise here, both before the agency and on judicial review of the agency's determination in the district court. *See supra*, p. 15; 20 U.S.C. § 1683; 29 U.S.C. § 794a(a)(2); 42 U.S.C. § 2000d-2. Second, plaintiffs' claims are not "wholly collateral" to the administrative review scheme. *Bank of La. v. Federal Deposit Ins. Corp.*, 919 F.3d 916, 928 (5th Cir. 2019). Instead, their claims are "inextricably intertwined" with the issue that would be at the heart of a future enforcement proceeding: whether certain conduct constitutes unlawful discrimination under Section 504 and Section 1557. *Id.* Third, plaintiffs' claims, which concern the obligations of pharmacies under civil rights laws administered by OCR, are within the heartland of OCR's expertise. *See Thunder Basin*, 510 U.S. at 214 (1994) (claims that require interpretation of a statute enforced by an agency "fall squarely" within that agency's expertise, and lead to the conclusion that "exclusive review before the [agency] is appropriate"); *see also Bank of La.*, 919 F.3d at 929 ("[T]here are precious few cases involving interpretations of statutes authorizing agency action in which our review is not aided by the agency's statutory construction.") (quoting *Jarkesy v. SEC*, 803 F.3d 9, 29 (D.C. Cir. 2015)).

For these reasons, this Court lacks jurisdiction to review plaintiffs' claims outside the context of the regulatory scheme created by Congress for administrative enforcement and judicial review under the civil rights statutes.

II. The Court Should Dismiss Mayo's RFRA Claim Pursuant to Rule 12(b)(6) Because Mayo Does Not Plausibly Allege That the Pharmacy Guidance Violates RFRA

Rule 12(b)(6) provides a separate basis to dismiss Mayo's RFRA claim.[9] Under RFRA, the

[9] The Court need not reach either this argument or defendants' Rule 12(b)(3) argument below if it concludes it lacks subject matter jurisdiction over plaintiffs' claims. *See, e.g.*, *U.S. ex rel. King v. Univ. of Texas Health Sci. Ctr.*, 907 F. Supp. 2d 846, 856 n.8 (S.D. Tex. 2012), *aff'd*, 544 F. App'x 490 (5th Cir. 2013); *Painter v. Whitley*, 686 F. Supp. 150, 151 (E.D. La. 1988).

federal government may not "substantially burden a person's exercise of religion" unless application of that burden to the person is the least restrictive means of furthering a compelling governmental interest. 42 U.S.C. § 2000bb-1(b). A burden is substantial under RFRA where the government "demands" that a plaintiff "engage in conduct that seriously violates their religious beliefs" or face "severe" consequences. *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 720 (2014).

Mayo fails to plausibly allege that the pharmacy guidance and press release burden its exercise of religion at all, let alone substantially. Mayo alleges that it "holds sincerely held religious beliefs that prohibit Mayo Pharmacy and its owner, [Kevin] Martian, [PharmD,] from stocking or dispensing drugs for abortion purposes." Am. Compl. ¶ 93. Mayo further alleges that "[w]hile [it] does stock and dispense the drugs methotrexate and misoprostol for non-abortion purposes, Mayo does not dispense such drugs for abortion purposes and seeks to continue not to do so." *Id.* ¶ 45. This approach is not inconsistent with the pharmacy guidance. The pharmacy guidance addresses situations in which a pharmacy fails to fulfill a prescription for non-abortion purposes. It does not state that a pharmacy is required to dispense drugs for abortion purposes. Am. Compl. Ex. 2.

Mayo's allegation that the pharmacy guidance and press release "require" Mayo "to stock and dispense drugs for abortion purposes as a condition of receiving patients who are covered by federally funded programs such as Medicare and Medicaid," Am. Compl. ¶ 46, contains no well-pleaded facts to support that contention, which is a "legal conclusion couched as a factual allegation." *Twombly*, 550 U.S. at 555. Moreover, it is at variance with the actual text of the guidance and press release, which on their face do not state any such requirement. *See* Am. Compl. Ex. 1; *id.* Ex. 2; *Smit v. SXSW Holdings, Inc.*, 903 F.3d 522, 528 (5th Cir. 2018) ("[W]hen an allegation is contradicted by the contents of an exhibit attached to the pleading, then indeed the exhibit and not the allegation controls." (quotation omitted)). This Court should not credit the statement.

Mayo's factual allegations regarding its practices—both religious and business—establish no

conflict between those practices and the pharmacy guidance. Thus, Mayo fails to state a claim that the pharmacy guidance causes a burden on Mayo's religious exercise. Nor does Mayo assert any allegations that would allow the Court to conclude that the press release substantially burdens the pharmacy. The Court should dismiss Mayo's RFRA claim pursuant to Rule 12(b)(6).

III. The Court Should Dismiss Mayo's RFRA Claim Pursuant to Rule 12(b)(3) Because This District Is Not a Proper Venue for That Claim

Rule 12(b)(3) provides another basis for dismissing Mayo's RFRA claim. Venue must be proper for each cause of action. *Tucker v. U.S. Dep't of Army*, 42 F.3d 641 (5th Cir. 1994) (*per curiam*). Venue does not lie in this district for Mayo's RFRA claim.[10]

Venue in this case is governed by 28 U.S.C. § 1391(e), the general venue statute for actions against the United States and its agencies. Section 1391(e) allows venue "in any judicial district in which (A) a defendant in the action resides, (B) a substantial part of the events or omissions giving rise to the claim occurred, … or (C) the plaintiff resides if no real property is involved in the action." 28 U.S.C. § 1391(e)(1).

Venue does not lie under the residency prongs of Section 1391(e). Mayo resides in Bismarck, North Dakota, not in this district. Am. Compl. ¶ 2; *cf.* 28 U.S.C. § 1391(e)(1)(C). Defendants do not reside in this district either. They reside in Washington, D.C., where HHS and OCR are headquartered and where Secretary Becerra maintains his principal office and performs his official duties. *See Holloway v. Gunnell*, 685 F.2d 150, 153 n.3 (5th Cir. 1982); *U.S. Dep't of Agric. v. Hunter*, 171 F.2d 793, 795 (5th Cir. 1949); *cf.* 28 U.S.C. § 1391(e)(1)(A).

Nor can Mayo show that any—let alone "a substantial part"—of "the events or omissions giving rise to" its RFRA claim "occurred" in this district. 28 U.S.C. § 1391(e)(1)(B). Defendants issued the pharmacy guidance and press release from their offices in Washington, D.C. And to the

[10] Defendants do not contest venue over the APA claims in this district.

extent the Court may properly consider the location where Mayo alleges it feels the effects of the pharmacy guidance or press release,[11] that place is in North Dakota.

Mayo does not assert that the Court should exercise its discretion under the "pendent venue" doctrine, *see* Am. Compl. ¶ 9, but if it were to do so, the Court should reject application of that doctrine here. "Pendent venue" is a judge-made doctrine through which some courts, as a matter of discretion, exercise pendent venue over a claim that shares a "common nucleus of operative fact" with a different claim for which venue properly lies. *See Seamon v. Upham*, 563 F. Supp. 396, 389–99 (E.D. Tex. 1983). As far as defendants are aware, neither the Supreme Court nor the Fifth Circuit have adopted or applied the pendent venue doctrine under analogous circumstances. "[C]ourts in the Fifth Circuit typically reject opportunities to apply" the doctrine. *Gremillion v. Lockheed Martin Corp. Grp. Benefits Plan*, No. 14-cv-2987, 2015 WL 3863375, at *2 (E.D. La. June 22, 2015). And there is good reason to reject it here: "The structure of the federal venue provisions confirms that they alone define whether venue exists in a given forum." *Atl. Marine Const. Co. v. U.S. Dist. Ct. for W. Dist. of Tex.*, 571 U.S. 49, 56 (2013); *see also Olberding v. Ill. Cent. R. Co.*, 346 U.S. 338, 340 (1953) ("The requirement of venue is specific and unambiguous; it is not one of those vague principles which, in the interests of some overriding policy, is to be given a 'liberal' construction."); *Leroy v. Great W. United Corp.*, 443 U.S. 173, 183–84 (1979) ("The purpose of statutorily specified venue is to protect the *defendant* against the risk that a plaintiff will select an unfair or inconvenient place of trial." (emphasis in original)).

The pendent venue doctrine utilizes "the same factors that [a court] would consider in

[11] The Fifth Circuit "has not ruled upon" whether the transactional venue inquiry may consider a plaintiff's activities, *ENTU Auto Servs., Inc. v. PicMyRide.Biz, LLC*, No. 15-cv-77, 2015 WL 1638179, at *4 (E.D. La. Apr. 13, 2015), but "many district courts in the … Circuit have held that the focus of the … inquiry is on the actions or omissions of the defendant, and not where the plaintiff … feels the … effects of those actions," *id.*; *see also*, *e.g.*, *Gault v. Yamunaji, LLC*, No. 09-cv-78, 2009 WL 10699952, at *5 (W.D. Tex. Apr. 17, 2009).

deciding whether to exercise pendent jurisdiction … [i.e.,] considerations of judicial economy, convenience, and fairness." *Seamon*, 563 F. Supp. at 399. Those factors militate against pendent venue here. The RFRA claim would ultimately turn on whether the pharmacy guidance and press release: (a) substantially burden Mayo's exercise of religion, (b) further a compelling government interest, and (c) are the least restrictive means of furthering that interest. These are separate inquiries—and would involve different witnesses, none of which are located in this district—than the administrative-record-based adjudication that would be required for the plaintiffs' APA claims. Mayo has already bootstrapped itself into this district for its APA claims by joining Texas's suit. Mayo would be unable to establish venue here on its own for *any* of its claims. Further bootstrapping should not be allowed. The interests of justice—including fairness to the litigants and convenience for the witnesses—would best be served by declining to exercise pendent venue.

To the extent Mayo's RFRA claim survives defendants' Rule 12(b)(1) and 12(b)(6) motions—which for the reasons discussed above it does not—the Court should either dismiss Mayo's RFRA claim for improper venue pursuant to Rule 12(b)(3), or transfer it to the District of Columbia, where it could have been brought. *See* 28 U.S.C. § 1406.

CONCLUSION

For the foregoing reasons, the First Amended Complaint should be dismissed in its entirety under Rule 12(b)(1). Alternatively, Mayo's RFRA claim should be dismissed pursuant to Rule 12(b)(6) or Rule 12(b)(3).

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Respectfully submitted,

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