

**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

**REPLY IN SUPPORT OF DEFENDANTS'  
MOTION TO DISMISS AMENDED COMPLAINT**

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**TABLE OF ACRONYMS AND ABBREVIATIONS**

Am. Compl.	Amended Complaint, ECF No. 14
AAPLOG	American Association of Pro-Life Obstetricians and Gynecologists
APA	Administrative Procedure Act
HHS	United States Department of Health and Human Services
Mayo	Mayo Pharmacy, Inc.
Mot.	Defendants' Motion to Dismiss Amended Complaint, ECF No. 31
OCR	United States Department of Health and Human Services Office for Civil Rights
Opp.	Plaintiffs' Response to Motion to Dismiss, ECF No. 37
RFRA	Religious Freedom Restoration Act, 42 U.S.C. § 2000bb-1
Section 504	Section 504 of the Rehabilitation Act, 29 U.S.C. § 794(a)
Section 1557	Section 1557 of the Affordable Care Act, 42 U.S.C. § 18116(a)
TTUHSC	Texas Tech University Health Sciences Center

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Defendants respectfully submit this reply brief in support of their motion to dismiss the Amended Complaint pursuant to Federal Rules of Civil Procedure 12(b)(1), 12(b)(6), and 12(b)(3).

## ARGUMENT

### I. Plaintiffs Mischaracterize the Pharmacy Guidance

Plaintiffs mischaracterize the pharmacy guidance as requiring pharmacies to stock and dispense drugs for abortion purposes. It does not. The guidance reviews the nondiscrimination obligations of covered pharmacies (i.e., pharmacies that receive federal financial assistance) under federal civil rights laws—and particularly the prohibitions on disability and sex discrimination in Section 504 of the Rehabilitation Act and Section 1557 of the Affordable Care Act—with “regard 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.” Am. Compl. Ex. 2 at 1. The guidance covers reproductive health care issues including maternal health, miscarriage management, and contraception (and non-reproductive health care issues such as stomach ulcers), *id.* at 2–3, but it does not address, let alone require, dispensing of drugs for purposes of abortion. On the contrary, the guidance addresses the refusal to dispense drugs for purposes *other than abortion*.<sup>1</sup> *Id.* at 2–4.

Plaintiffs rely on three strategies to mischaracterize the guidance as “mandat[ing]” pharmacies to dispense drugs for abortions. First, plaintiffs selectively quote language from the pharmacy guidance—completely out of context—to misleadingly suggest that the pharmacy guidance requires

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<sup>1</sup> Certain drugs like methotrexate or misoprostol, which can be used for medication abortions, are often prescribed for non-abortion purposes such as the treatment of rheumatoid arthritis (methotrexate) or to manage early pregnancy loss (misoprostol). HHS issued the pharmacy guidance following the Supreme Court’s decision in *Dobbs v. Jackson Women’s Health Org.*, 142 S. Ct. 2228 (2022), at a time when “patients in states that ha[d] enacted abortion bans ha[d] reported that pharmacies [were denying] them necessary medications [to treat such conditions] even though” the patients were “not pregnant.” Opp. Ex. 2 at 1. The pharmacy guidance is directed largely at this issue, explaining that refusing to dispense a medication for a non-abortion purpose, because that medication could also be used for purposes of abortion, may constitute discrimination on the basis of disability or sex. Am. Compl. Ex. 2 at 3.

pharmacies to dispense drugs for abortion purposes.<sup>2</sup>

Plaintiffs repeatedly quote the phrase “halt the pregnancy,” without ever acknowledging that the guidance language is referring to medication treatment of an ectopic pregnancy—not medication abortions. Opp. 1, 4, 8, 9; Am. Compl. Ex. 2 at 3. “An ectopic pregnancy is a form of pregnancy in which implantation of the fertilized egg occurs outside of the uterus, oftentimes in one of the fallopian tubes.” *Gaydar v. Sociedad Instituto Gineco-Quirurgico y Planificacion*, 345 F.3d 15, 19 n.2 (1st Cir. 2003). An ectopic pregnancy cannot lead to a live birth, and it can cause severe and life-threatening bleeding in the pregnant person if not promptly treated. See, e.g., Antonette T. Dulay, M.D., *Ectopic Pregnancy*, Merck Manual, <https://www.merckmanuals.com/home/women-s-health-issues/complications-of-pregnancy/ectopic-pregnancy>. Treating an ectopic pregnancy is not an “abortion” under Texas or North Dakota law, see Mot. 8 n.6, and leading medical organizations as well as major pro-life groups do not consider treatment of ectopic pregnancy to be abortion.<sup>3</sup> Thus, the pharmacy guidance’s example of “halt[ing]” an ectopic pregnancy does not equate to abortion.<sup>4</sup>

Plaintiffs also repeatedly quote the phrase “vigorous enforcement”—insisting that the agency has promised “vigorous enforcement” against pharmacies that do not dispense drugs for abortions.

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<sup>2</sup> Attached as Ex. 1 is a copy of the pharmacy guidance in which the sentences that plaintiffs partially quote are highlighted, to assist the Court in viewing the context in which they appear.

<sup>3</sup> Am. College of Obstetricians & Gynecologists, *Facts Are Important: Understanding Ectopic Pregnancy*, <https://www.acog.org/advocacy/facts-are-important/understanding-ectopic-pregnancy> (“indication and treatment for ectopic pregnancies is distinct from the indication and provision of induced abortion”); Am. Assoc. of Pro-Life Obstetricians & Gynecologists, *What is AAPLOG’s Position on Treatment of Ectopic Pregnancy?*, <https://aaplog.org/what-is-aaplogs-position-on-treatment-of-ectopic-pregnancy> (“[We] recognize[] the unavoidable loss of human life that occurs in an ectopic pregnancy, but do[] not consider treatment of ectopic pregnancy by standard surgical or medical procedures to be the moral equivalent of elective abortion, or to be the wrongful taking of human life.”).

<sup>4</sup> Similarly, plaintiffs point to an example in the pharmacy guidance about “mifepristone followed by treatment with misoprostol,” which they note is a regimen that the FDA has approved for abortion, Opp. 5, but plaintiffs ignore that the guidance discusses using this regimen “to assist with the passing of the miscarriage,” specifically first-trimester miscarriage and early pregnancy loss. Am. Compl. Ex. 2, at 3. The example states that it may be discriminatory to deny “medications needed to manage a miscarriage or complications from pregnancy loss, because these medications can also be used to terminate a pregnancy.” *Id.*



Opp. 1, 5, 8, 9. In the pharmacy guidance, however, this phrase appears in a sentence about improving maternal health—it is not referring to abortion. Am. Compl. Ex. 2 at 2 (HHS “is committed to improving maternal health—including for individuals who experience miscarriages—and vigorous enforcement of our civil rights laws is one way in which we plan to do so.”).

Second, plaintiffs use faulty logic. They argue that because the pharmacy guidance recognizes and addresses pharmacies’ “unique role ... in ensuring access to comprehensive reproductive health care services,” Am. Compl. Ex. 2 at 1, the guidance necessarily requires covered pharmacies to provide access to medication abortion. *See, e.g.*, Opp. 5 (describing supposed “syllogism”). Not so. It is true that the guidance uses the phrase “comprehensive reproductive health care services” in its title and acknowledges that “pharmacies play” a “unique role” in providing reproductive health care services, Am. Compl. Ex. 2 at 1, but it never purports to require covered pharmacies to provide access to every form of reproductive health care service.<sup>5</sup> Rather, the guidance outlines what may be considered discrimination under federal civil rights laws. *Id.* at 2–4. It addresses the refusal to dispense drugs for *non-abortion* purposes, describing scenarios where refusing to dispense a drug because of its alternate abortion uses may be considered discrimination. *Id.* at 3. It does not mandate abortion. *Id.*

Third, plaintiffs characterize the pharmacy guidance in a conclusory manner unsupported by the guidance’s language. For example, plaintiffs say that the guidance “purports to preempt Texas’s abortion laws.” Opp. 3. It does not. Am. Compl. Ex. 2 at 1–4. They contend that the pharmacy guidance “requires dispensing abortion-inducing drugs without regard to State law.” Opp. 4. Again, not so. Am. Compl. Ex. 2 at 1–4. And plaintiffs assert that “[t]he language of the [pharmacy guidance] prohibits pharmacists from advising or asking patients about abortion-inducing drugs, in contraction [sic] with state law.” Opp. 14. But plaintiffs cite no such language in the pharmacy guidance, nor

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<sup>5</sup> As a practical matter, it is not possible for pharmacies to furnish all reproductive health care services, many of which necessarily must be provided in a doctor’s office or hospital (e.g., delivering babies).

could they; nothing in the guidance prohibits a pharmacy from engaging in reasonable inquiry about the purpose for which a drug is being used. Am. Compl. Ex. 2 at 1–4.

At the motion to dismiss stage, “when an ‘allegation is contradicted by the contents of an exhibit attached to the pleading, then indeed the exhibit and not the allegation controls.’” *Smit v. SXSX Holdings, Inc.*, 903 F.3d 522, 528 (5th Cir. 2018) (quoting *U.S. ex rel. Riley v. St. Luke’s Episcopal Hosp.*, 335 F.3d 370, 377 (5th Cir. 2004)). That principle is directly applicable here. The pharmacy guidance speaks for itself, and it does not mandate dispensing drugs for abortion purposes.

## II. The Court Lacks Subject Matter Jurisdiction Over Plaintiffs’ Challenge

### A. Plaintiffs Lack Standing

#### 1. *Texas lacks standing*

Texas’s opposition confirms its lack of standing. Texas argues that the pharmacy guidance and press release “threaten[] the State’s sovereignty” by “requir[ing] dispensing abortion-inducing drugs without regard to state law,” *i.e.* that “pharmacies must dispense drugs for abortion.” Opp. 3–5. But the premise on which Texas bases its claimed injury is wrong. The pharmacy guidance does not address dispensing drugs for purposes of abortion or purport to require pharmacies to do so, *see supra*, Part I, and the press release simply summarizes the pharmacy guidance along with a few other HHS initiatives, *see* Am. Compl. Ex. 1; Mot 5, 9. Therefore, the pharmacy guidance and press release do not interfere with Texas’s enforcement of its abortion laws or purport to require pharmacies in Texas (including TTUHSC’s pharmacies) to facilitate abortions in contravention of Texas law. *See* Mot. 8–9.<sup>6</sup> Because Texas is incorrect that the pharmacy guidance requires Texas pharmacies to dispense drugs for abortion in violation of Texas law, Texas fails to show any injury to its “quasi-sovereign interests,” so Texas fails to show that it “is entitled to special solicitude in the standing

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<sup>6</sup> Texas does not dispute that treatment of ectopic pregnancy with methotrexate does not violate Texas abortion laws. Mot. 8 n.6 (citing Tex. Health & Safety Code § 245.002(1)(C)); Opp. 9 (“some state laws define the [ectopic pregnancy] example as not being an abortion”).

analysis.” Opp. 7; *Texas v. United States*, 50 F.4th 498, 514 (5th Cir. 2022).

Because the pharmacy guidance does not purport to require dispensing drugs for purposes of abortion, no credible threat of enforcement exists based on TTUHSC pharmacies refusing to do so. Mot. 8–9. As defendants stated, “OCR has never” “rel[ied] on the pharmacy guidance to require” “pharmacies to dispense drugs for abortion purposes.” Mot. 9. In an attempt to discredit this statement and show a credible threat of enforcement, Texas cites a tweet from Secretary Becerra regarding pending investigations of pharmacy companies. *See* Opp. 5–6; Opp. Ex. 1. But nothing in the tweet states that any pharmacy is being investigated on the theory that it is violating the law by failing to dispense drugs for abortion purposes. Indeed, the article linked in the tweet notes that “[a] 14 year old girl in Arizona was refused a refill on a drug she had been taking for years to manage her rheumatoid arthritis and osteoporosis just two days after the state’s new abortion law took effect.” Opp. Ex. 2, at 3. This example is consistent with defendants’ explanation that the pharmacy guidance addresses dispensing drugs for non-abortion purposes.

## **2. *Mayo Lacks Standing***

Mayo lacks standing for largely the same reasons that Texas does. It claims injury from being required “to stock or dispense drugs for abortion purposes in violation of its religious beliefs.” Opp. 7. But the pharmacy guidance does not require pharmacies to dispense drugs for abortion purposes.<sup>7</sup>

Much of Mayo’s standing argument centers on the guidance’s example about dispensing methotrexate to treat an “ectopic pregnancy.” Am. Compl. Ex. 2, at 3. Mayo claims to object to the “methotrexate example,” Opp. 9, but Mayo misconstrues this example to require pharmacies generally to dispense methotrexate to halt pregnancies. Opp. 8. Mayo never specifically alleges or argues that

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<sup>7</sup> Mayo claims injury because it feels “pressure[]” to dispense drugs for purposes of abortion, Opp. 10, citing *Sherbert v. Verner*, 374 U.S. 398, 404 (1963). But *Sherbert* held that the economic pressure from the government denying unemployment benefits to a person who refused to work on her faith’s Sabbath burdened her religious exercise. *Id.* at 403–04. *Sherbert* does not support standing based on subjective pressure derived from Mayo’s misinterpretation of the guidance. *See Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 418 (2013) (“subjective fear” of unlawful conduct “does not give rise to standing”).

it objects to dispensing methotrexate to treat an ectopic pregnancy.

Even assuming *arguendo* that Mayo did object to dispensing methotrexate to treat an ectopic pregnancy, Mayo would have at most a narrow religious objection to the guidance specific to the context of ectopic pregnancy. To meet the test for pre-enforcement standing, Mayo would need to show a “credible threat,” *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 159 (2014), that HHS would penalize Mayo for refusing to dispense methotrexate to treat ectopic pregnancy on the basis of religious objection. Mayo fails to make that showing in light of HHS’s consistent acknowledgment that the agency must abide by RFRA when enforcing civil rights laws. Mot. 10 (citing HHS pronouncements across three administrations). Mayo argues that “HHS’s claim to abide by RFRA is simply an assertion that HHS believes it is legal to coerce Mayo,” Opp. 11. But HHS’s repeated commitment to following RFRA, most recently by proposing a rule granting robust procedural protections to those asserting religious conscience rights, *Nondiscrimination in Health Programs & Activities*, 87 Fed. Reg. 47,824, 47,918–19 (Aug. 4, 2022), is not mere litigation posturing. Indeed, Mayo does not dispute that HHS has never penalized any pharmacy for declining to dispense a drug for religious reasons, Mot. 10; Opp. 10 (acknowledging “[l]imited enforcement history”).

#### **B. Plaintiffs’ Claims Are Unripe**

Plaintiffs do not dispute that challenges to a legal position an agency has not adopted are not ripe. *See* Mot. 11–12. Accordingly, if the Court agrees with defendants that plaintiffs are misinterpreting the pharmacy guidance to require dispensing drugs for abortion purposes, then it follows that plaintiffs’ claims are unripe. Moreover, plaintiffs are wrong that the Court faces only “legal” questions that do not “need to wait for further factual development.” Opp. 12. The pharmacy guidance merely stated that certain types of conduct “may” constitute discrimination, Am. Compl. Ex. 2, at 3–4, but whether any particular pharmacy is actually engaged in discrimination will depend on specific factual circumstances, including the pharmacy’s reasons for not dispensing a drug. Mot. 13.

If a pharmacy asserts a religious objection, then RFRA demands application of a fact-specific balancing test “to the person” claiming a religious burden. *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 430 (2006). This necessary factual development shows that the case is not “fit[] . . . for judicial decision.” *Monk v. Huston*, 340 F.3d 279, 282 (5th Cir. 2003).

### **C. Plaintiffs Fail to Challenge Final Agency Action**

The pharmacy guidance is not final agency action reviewable under the APA because it neither represents “the consummation of the agency’s decisionmaking process,” nor does it determine legal “rights or obligations.” *Bennett v. Spear*, 520 U.S. 154, 178 (1997); Mot. 12–14. In arguing otherwise, plaintiffs ignore the fact that the guidance states that pharmacies engaged in certain types of conduct “may be discriminating,” Am. Compl. Ex. 2, at 3–4, underscoring that OCR would need to conduct further review of specific circumstances to determine whether pharmacies violated the law. That distinguishes the guidance from actions that are final because they are “not ‘subject to further agency review.’” Opp. 13 (quoting *Sackett v. EPA*, 566 U.S. 120, 127 (2012)). Such tentative language also makes this case distinguishable from decisions cited by plaintiffs finding agency actions final because their language was deemed sufficiently mandatory. See, e.g., *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1023 (D.C. Cir. 2000) (guidance document final where “[i]t commands, it requires, it orders, it dictates”); *Texas v. Becerra*, 623 F. Supp. 3d 696, 721 (N.D. Tex. 2022), *appeal pending*, No. 23-10246 (5th Cir.) (finding guidance final based on conclusion it was “couched in mandatory language”).<sup>8</sup> Finally, contrary to plaintiffs’ argument, Opp. 13, Secretary Becerra’s tweet does not indicate that HHS

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<sup>8</sup> In arguing that the pharmacy guidance contains mandatory language, plaintiffs point to language that “[p]harmacies . . . may not discriminate against pharmacy customers on the bases prohibited by Section 1557 and Section 504.” Opp. 15 (quoting Am. Compl. Ex. 2, at 1). But the statement that statutorily prohibited discrimination is prohibited is a mere tautology. The guidance’s examples of what *may* constitute prohibited discrimination are general illustrations that are described conditionally because OCR’s ultimate determination would rely on any relevant facts, not just those it used to sketch out examples. The guidance’s conditional language is consistent with the disclaimer that the guidance lacks the force of law. Am. Compl. Ex. 2, at 4. Therefore, this is not an example, as plaintiffs assert, of a “disclaimer[] . . . chang[ing] the mandatory effect of an agency pronouncement.” Opp. 11.

is treating the pharmacy guidance as binding. That tweet states that HHS has received complaints about violations of “federal obligations,” Opp. Ex. 1, but does not mention the pharmacy guidance, or indicate that HHS is investigating any company for violating the pharmacy guidance (as opposed to the federal civil rights statutes enforced by OCR) or is treating the pharmacy guidance as binding.

**D. Congress Provided an Adequate, Alternative Remedy for Plaintiffs to Obtain Judicial Review**

This lawsuit is barred under the APA because the process, set forth in statutes and regulations, for administrative proceedings followed by judicial review provides an “adequate remedy in a court.” 5 U.S.C. § 704; *see* Mot. 3–4, 15 (describing this process). Plaintiffs neither acknowledge the extensive procedural protections embedded in this process nor explain why the process is inadequate. *See* Opp. 16. Plaintiffs argue that a “strong presumption favoring judicial review” applies, Opp. 15, but their cited cases involve the question, not at issue here, whether Congress has wholly precluded judicial review under 5 U.S.C. § 701(a). *See Dep’t of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1905 (2020); *Mach Mining, LLC v. EEOC*, 135 S. Ct. 1645, 1651 (2015). Here, the question is not *whether* judicial review is available but *when* and *how* that review will take place, through the administrative process established by Congress that culminates in federal court review or through a lawsuit that short-circuits that process.

Defendants separately showed that this lawsuit is barred by the doctrine of *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200 (1994), which holds that the existence of a statutory review scheme for administrative enforcement can preclude lawsuits outside that scheme. Mot. 15–16. The Opposition ignores and makes no mention of *Thunder Basin*, and it does not even attempt to dispute that all three *Thunder Basin* factors weigh against review here. *See* Mot. 15–16.

**III. Mayo Does Not Plausibly Allege That the Pharmacy Guidance Violates RFRA**

Instead of pointing to well-pleaded facts, Mayo’s opposition brief repeats the same mistake as the Amended Complaint: it relies on “legal conclusion[s] couched as ... factual allegation[s],” *Bell Atl.*

*Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Mayo contends that the pharmacy guidance “requires Mayo to stock and dispense drugs for abortion purposes as a condition of receiving federal financial assistance,” Opp. 17, but this is a legal conclusion—and a mischaracterization at odds with the pharmacy guidance itself, *see* Am. Compl. Ex. 2. Mayo claims to object to the “methotrexate example,” Opp. 9, but Mayo misconstrues this example as generally requiring dispensing of methotrexate to terminate pregnancies, rather than explaining how the civil rights laws might apply to a patient seeking treatment for an ectopic pregnancy. The Amended Complaint does not mention ectopic pregnancy, let alone allege that Mayo has a religious objection to treating ectopic pregnancy. *See* Am. Compl. ¶¶ 34–45.

Moreover, Mayo fails to show that the pharmacy guidance<sup>9</sup> burdens its ability to practice its religious beliefs. The pharmacy guidance does not purport to override RFRA. To the contrary, by devoting an entire paragraph to the Church Amendments,<sup>10</sup> the pharmacy guidance explicitly recognizes that a pharmacist’s religious beliefs must be considered, and makes clear that religious objections shall be assessed on a case-by-case basis, Am. Compl. Ex. 2 at 4, which is consistent with RFRA, *see O Centro*, 546 U.S. at 418; *Tagore v. United States*, 735 F.3d 324, 331 (5th Cir. 2013).

#### **IV. This District Is Not a Proper Venue for Mayo’s RFRA Claim**

Mayo fails to meaningfully respond to defendants’ contention that venue must be proper for each cause of action. *See* Opp. 18–19; Mot. 18 (citing *Tucker v. U.S. Dep’t of Army*, 42 F.3d 641 (5th Cir. 1994) (*per curiam*)); *see also Guajardo v. State Bar of Texas*, 803 F. App’x 750, 755 (5th Cir. 2020).

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<sup>9</sup> Mayo states in conclusory fashion that the press release also imposes requirements on it, without explaining how. Opp. 16, 17, 18. But the press release merely announces and summarizes the guidance; it imposes no requirements. Am. Compl. Ex. 1 at 1.

<sup>10</sup> Among other things, the Church Amendments, codified at 42 U.S.C. § 300a-7, contain a provision stating: “No individual shall be required to perform or assist in the performance of any part of a health service program ... funded ... under a program administered by the Secretary of Health and Human Services if his performance or assistance in the performance of such part of such program or activity would be contrary to his religious beliefs or moral convictions.” 42 U.S.C. § 300a-7(d).

Instead, Mayo cites an out-of-circuit case, *General Foods Corp. v. Carnation Co.*, 411 F.2d 528, 532 (7th Cir. 1969). But *General Foods* analyzes the special venue statute for patent infringement, 28 U.S.C. § 1400(b), which provides that venue in a patent case lies “where the defendant has committed acts of infringement and has a regular and established place of business.” *Gen. Foods*, 411 F.2d at 530–32 (7th Cir. 1969). *General Foods* uses the term “claim” to refer to a “patent claim”<sup>11</sup>—not to a plaintiff’s cause of action. *Id.* at 531. *General Foods* holds that where a plaintiff alleges infringement of more than one “claim in a patent,” *id.*, if venue properly lies in a district for one patent claim, it necessarily lies in that district for all of the patent’s claims, *id.* at 532. Contrary to Mayo’s assertion, *General Foods* does not stand for the proposition that a plaintiff establishes venue for each cause of action merely by establishing venue for one cause of action.

Mayo makes no attempt to refute defendants’ showing that under 28 U.S.C. § 1391(e), the venue statute applicable *to this case*, Mayo’s RFRA claim does not belong in this Court. *See* Mot. 18–19; Opp. 18–19. Nor does Mayo’s opposition mention the concept of “pendent venue” or urge the Court to adopt it here. Opp. 18–19; *cf.* Mot. 19–20. Mayo contends that defendants “identif[y] no prejudice” to themselves of allowing venue to lie in this district. Opp. 18. But it is plaintiff’s burden—not defendants’—to establish venue—a point that Mayo does not counter. *See* Mot. 7; Opp. 2, 18–19. As discussed in defendants’ opening brief, Mot. 18–20, Mayo fails to meet that burden here.

### CONCLUSION

For the reasons discussed above and in defendants’ opening brief, 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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<sup>11</sup> A patent claim is a “formal statement describing the novel features of an invention and defining the scope of the patent’s protection.” *Patent Claim*, Black’s Law Dictionary (11th ed. 2019). A single patent application can have multiple claims. *Id.*



Dated: June 13, 2023

Respectfully submitted,

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# Exhibit 1



## U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Office for Civil Rights

### Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services

Pharmacies—and the pharmacists they employ—play a critical role in the American health care system. This has never been more apparent than the efforts taken to administer vaccines during the COVID-19 pandemic, for which your continued partnership has been crucial.<sup>1</sup> As our nation faces another significant health care crisis, this guidance is to remind the roughly 60,000 retail pharmacies in the United States<sup>2</sup> of the unique role pharmacies play in ensuring access to comprehensive reproductive health care services. This guidance covers the nondiscrimination obligations of pharmacies under federal civil rights laws.

Under Section 1557 of the Affordable Care Act (Section 1557), 42 U.S.C. § 18116, and its implementing regulation, 45 C.F.R. part 92, recipients of federal financial assistance are prohibited from excluding an individual from participation in, denying them the benefits of, or otherwise subjecting them to discrimination on the basis of sex and disability, among other bases, in their health programs and activities.<sup>3</sup> Under Section 504 of the Rehabilitation Act of 1973 (Section 504), 29 U.S.C. 794, recipients of federal financial assistance are prohibited from discriminating in all programs and activities, on the basis of disability. Pharmacies, therefore, may not discriminate against pharmacy customers on the bases prohibited by Section 1557 and Section 504—including with regard 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.

The United States has the highest maternal mortality rate among developed nations; though most maternal deaths in the United States are preventable, they have been rising over the last two decades.<sup>4</sup> Maternal deaths are especially high among Black women and Native American

<sup>1</sup> See, e.g., *The Federal Retail Pharmacy Program for COVID-19 Vaccination*, U.S. Dep't of Health & Human Servs., Ctrs. for Disease Control & Prevention (last updated June 24, 2022), <https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/index.html>.

<sup>2</sup> IQVIA, *U.S. National Pharmacy Market Summary 2021: Market Insights Report* (2021), [https://www.onekeydata.com/downloads/reports/2021\\_US\\_Pharmacy\\_Market\\_Report.pdf](https://www.onekeydata.com/downloads/reports/2021_US_Pharmacy_Market_Report.pdf).

<sup>3</sup> Covered entities should also note that Title IX of the Education Amendments of 1972 (Title IX), 20 U.S.C. § 1681 *et seq.*, prohibits discrimination on the basis of sex in education programs and activities of recipients of federal financial assistance. Pharmacies that are affiliated with a covered education program or activity are also subject to Title IX nondiscrimination requirements. See also 45 C.F.R. part 86 (HHS Title IX implementing regulations).

<sup>4</sup> Roosa Tikkanen et al., *Issue Brief: Maternal Mortality and Maternity Care in the United States Compared to 10 Other Developed Countries*, Commonwealth Fund (Nov. 18, 2020),

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women—regardless of their income or education levels.<sup>5</sup> The Supreme Court’s decision in *Dobbs v. Jackson Women’s Health Organization*, No. 19-1392, 2022 WL 2276808 (U.S. June 24, 2022), will exacerbate these inequities and disparities for women across the country. Further, the early loss of pregnancy (before 13 completed weeks) is extremely common, experienced by about 10 percent of those who know they are pregnant.<sup>6</sup> **The Department is committed to improving maternal health—including for individuals who experience miscarriages—and vigorous enforcement of our civil rights laws is one way in which we plan to do so.**

Pharmacies are often the most accessible health care provider for millions of Americans, with most Americans living within five miles of a pharmacy.<sup>7</sup> It is estimated that more than 131 million people (66 percent of adults) in the United States use prescription medication,<sup>8</sup> and therefore come into contact with pharmacies. Of the 7.6 billion retail prescription drugs filled by pharmacies in 2019, 44 percent were paid for either by Medicare or Medicaid health coverage.<sup>9</sup> As recipients of federal financial assistance, including Medicare and Medicaid payments, 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.

Among its civil rights enforcement responsibilities, the Department of Health and Human Services’ (HHS or Department) Office for Civil Rights (OCR) is responsible for protecting the rights of women and pregnant people in their ability to access care that is free from discrimination. This includes their ability to access reproductive health care, including prescription medication from their pharmacy, free from discrimination. A recent study by the Centers for Disease Control and Prevention showed that nearly 25 percent of women aged 15–49 in the United States who use contraception use some form of prescribed method (e.g., oral contraception pill, contraceptive ring).<sup>10</sup>

Furthermore, **discrimination against pregnant people on the basis of their pregnancy or related conditions (examples below) is a form of sex discrimination.** Such discrimination can have significant health consequences from denial of medication or treatment which can have negative health impacts on a patient. Under federal civil rights law, pregnancy discrimination

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<https://www.commonwealthfund.org/publications/issue-briefs/2020/nov/maternal-mortality-maternity-care-us-compared-10-countries>.

<sup>5</sup> Emily Petersen et al., *Racial/Ethnic Disparities in Pregnancy-Related Deaths — United States, 2007–2016*, 68 *Morbidity & Mortality Wkly. Rep.* 762 (2019), <https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6835a3-H.pdf>.

<sup>6</sup> *FAQs: Early Pregnancy Loss*, Am. Coll. of Obstetricians & Gynecologists (last updated Jan. 2022), <https://www.acog.org/womens-health/faqs/early-pregnancy-loss>.

<sup>7</sup> *Federal Retail Pharmacy Program*, U.S. Dep’t of Health & Human Servs., Ctrs. for Disease Control & Prevention (last updated June 24, 2022), <https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/index.html>.

<sup>8</sup> *Prescription Drugs*, Georgetown Univ., Health Pol’y Inst., <https://hpi.georgetown.edu/rxdrugs> (last visited June 29, 2022).

<sup>9</sup> *Number of Retail Prescription Drugs Filled at Pharmacies by Payer*, Kaiser Fam. Found., <https://www.kff.org/health-costs/state-indicator/total-retail-rx-drugs/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D> (last visited June 29, 2022).

<sup>10</sup> Kimberly Daniels & Joyce C. Abma, U.S. Dep’t of Health & Human Servs., Ctrs. for Disease Control & Prevention, Nat’l Ctr. for Health Stats., *Data Brief: Current Contraceptive Status Among Women Aged 15–49: United States, 2015–2017* (2018), <https://www.cdc.gov/nchs/data/databriefs/db327-h.pdf>.

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includes discrimination based on current pregnancy, past pregnancy, potential or intended pregnancy, and medical conditions related to pregnancy or childbirth.<sup>11</sup>

**Examples:**

- An individual experiences an early pregnancy loss (first-trimester miscarriage) and their health care provider prescribes pretreatment with mifepristone followed by treatment with misoprostol to assist with the passing of the miscarriage.<sup>12</sup> If a pharmacy refuses to fill the individual's prescription—including medications needed to manage a miscarriage or complications from pregnancy loss, because these medications can also be used to terminate a pregnancy—the pharmacy may be discriminating on the basis of sex.
- An individual experiences severe and chronic stomach ulcers, such that their condition meets the definition of a disability under civil rights laws. Their gastroenterologist prescribes misoprostol to decrease risk of serious complications associated with ulcers. If the pharmacy refuses to fill the individual's prescription or does not stock misoprostol because of its alternate uses, it may be discriminating on the basis of disability.
- An individual presents to a hospital emergency department with chills, fever, and vaginal bleeding. The treating physician diagnoses a miscarriage complicated by a uterine infection (known medically as a septic abortion) and orders an antibiotic. If the hospital pharmacy refuses to provide the antibiotic required for treatment because of concern that subsequent care may include uterine evacuation (via medical or surgical abortion), the pharmacy may be discriminating on the basis of sex.
- An individual who has been undergoing fertility treatments receives a positive pregnancy test. After the individual expresses concern with symptoms associated with an ectopic pregnancy,<sup>13</sup> their medical provider performs an ultrasound to determine where the pregnancy is developing. The ultrasound indicates the fertilized egg is growing in a fallopian tube. The medical provider orders methotrexate to halt the pregnancy. If a pharmacy refuses to fill the prescription because it will halt the growing of cells and end the pregnancy, it may be discriminating on the basis of sex.
- An individual with rheumatoid arthritis, such that their condition meets the definition of a disability under civil rights laws, is prescribed methotrexate by their physician's assistant as a standard immunosuppressive treatment. If the pharmacy refuses to fill the individual's prescription or does not stock methotrexate because of its alternate uses, it may be discriminating on the basis of disability.

<sup>11</sup> Covered entities should also note that, while pregnancy itself is not a disability, medical issues resulting from pregnancy can qualify as a disability under Section 504 of the Rehabilitation Act of 1973 (Section 504), 29 U.S.C. § 794, which prohibits discrimination on the basis of disability in programs and activities of recipients of federal financial assistance. *Webster v. U.S. Dep't of Energy*, 267 F. Supp. 3d 246, 267 (D.D.C. 2017).

<sup>12</sup> Am. Coll. of Obstetricians and Gynecologists, *Practice Bulletin: Pregnancy Loss* (2018), <https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2018/11/early-pregnancy-loss>.

<sup>13</sup> An ectopic pregnancy is a pregnancy that occurs when fertilized egg grows outside of the uterus. *FAQs: Ectopic Pregnancy*, Am. Coll. of Obstetricians and Gynecologists (last updated Feb. 2018), <https://www.acog.org/womens-health/faqs/ectopic-pregnancy>.

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- An individual presents a prescription for an emergency contraceptive at their local pharmacy after a sexual assault to prevent pregnancy. If the pharmacy otherwise provides contraceptives (e.g., external and internal condoms) but refuses to fill the emergency contraceptive prescription because it can prevent ovulation or block fertilization, the pharmacy may be discriminating on the basis of sex.
- An individual's health care provider sends the individual's prescription for hormonal contraception (e.g., oral contraceptive pill, emergency contraception, a patch placed on the skin, a contraceptive ring, or any other FDA-approved contraceptive product) to a pharmacy. If the pharmacy otherwise provides contraceptives (e.g., external and internal condoms) but refuses to fill a certain type of contraceptive because it may prevent a pregnancy, the pharmacy may be discriminating on the basis of sex.

In addition to the aforementioned civil rights laws, OCR also enforces the Church Amendments, codified at 42 U.S.C. § 300a-7, which protect health care personnel from discrimination related to their employment because they refused to perform or assist in the performance of abortion or sterilization because of their religious beliefs or moral convictions. It also protects health care personnel from discrimination related to their employment because they performed or assisted in the performance of abortion or sterilization. This guidance does not address how the Church Amendments would apply in a given case. OCR will evaluate and apply the Church Amendments on a case-by-case basis. To learn more about OCR's enforcement of this statutory protection, see HHS's [\*Guidance on Nondiscrimination Protections under the Church Amendments\*](#).

For additional information, contact the Office for Civil Rights at (800) 368-1019 or [OCRMail@hhs.gov](mailto:OCRMail@hhs.gov). If you believe that your or another person's civil rights, conscience rights, or health information privacy rights have been violated, visit the OCR complaint portal to file a complaint online at: <https://www.hhs.gov/ocr/complaints/index.html>.

To obtain this information in an alternate format, contact the HHS Office for Civil Rights at (800) 368-1019, TDD toll-free: (800) 537-7697, or by emailing [OCRMail@hhs.gov](mailto:OCRMail@hhs.gov). Language assistance services for OCR matters are available and provided free of charge.

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