

UNITED STATES DISTRICT COURT
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-22-DC

PLAINTIFFS' RESPONSE TO MOTION TO DISMISS

Dobbs v. Jackson Women's Health Org. properly placed the regulation of abortion within the purview of the states and the "people and their elected representatives," not unelected federal agencies. 142 S. Ct. 2228, 2284 (2022). Yet as part of President Biden's government-wide attack on *Dobbs*, Defendants ("HHS") issued a mandate ordering all pharmacies to stock and dispense drugs used to accomplish abortions. This Pharmacy Mandate ("Mandate") threatens Texas's sovereignty by creating conflict with and purporting to preempt its laws, and it threatens the rights of countless individual pharmacies like Mayo Pharmacy, Inc. Although HHS insists the Mandate merely "remind[s] pharmacies of the[ir] nondiscrimination obligations under federal civil rights laws," Dkt. 31 at 20, it says far more. The Mandate promises "vigorous enforcement" against pharmacies that do not dispense drugs given to "halt the pregnancy," by threatening to withhold

federal funds. Dkt. 14-2 at 4. But none of the statutes HHS cites have ever required pharmacies to stock or dispense drugs for abortion purposes.

Plaintiffs have standing because they are the direct targets of this regulation. The Pharmacy Mandate threatens to withhold all federal funding from pharmacies who cannot comply due to State law or religious objections. Plaintiffs' claims are therefore ripe, and they have alleged facts sufficient to support the reasonable inference that the Mandate constitutes final agency action subject to judicial review. Plaintiffs respectfully request the Court deny HHS's Motion to Dismiss.

I. STANDARD OF REVIEW

When reviewing a motion to dismiss under Rule 12(b)(1), the court need only "look to the sufficiency of the allegations in the complaint because they are presumed to be true. If those jurisdictional allegations are sufficient the complaint stands." *Paterson v. Weinberger*, 644 F.2d 521, 523 (5th Cir. 1981). "For standing purposes, [the court must] accept as valid the merits of [plaintiffs'] legal claims." *Fed. Election Comm'n v. Cruz*, 142 S. Ct. 1638, 1647 (2022). "A motion under 12(b)(1) should be granted only if it appears certain that the plaintiff cannot prove *any* set of facts in support of his claim that would entitle him to relief." *Home Builders Ass'n of Miss., Inc. v. City of Madison, Miss.*, 143 F.3d 1006, 1010 (5th Cir. 1998) (emphasis added).

To defeat a motion to dismiss under Rule 12(b)(6), a complaint need only include "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) (internal quotations omitted).

II. ARGUMENTS & AUTHORITIES

A. Plaintiffs have standing.

Standing requires a plaintiff to “prove that he has suffered a concrete and particularized [injury in fact] that is fairly traceable to the challenged conduct, and is likely to be redressed by a favorable judicial decision.” *Hollingsworth v. Perry*, 570 U.S. 693, 704 (2013) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992)). At the motion to dismiss stage, a plaintiff need only “allege facts that give rise to a plausible claim of standing.” *Barilla v. City of Houston, Texas*, 13 F.4th 427, 431 (5th Cir. 2021) (quoting *Cornerstone Christian Schs. v. Univ. Interscholastic League*, 563 F.3d 127, 133 (5th Cir. 2009)). “At the pleading stage, general factual allegations of injury resulting from the defendant’s conduct may suffice, for on a motion to dismiss we ‘presum[e] that general allegations embrace those specific facts that are necessary to support the claim.’” *Lujan*, 504 U.S. at 561 (quoting *Lujan v. National Wildlife Federation*, 497 U.S. 871, 889 (1990)). If the plaintiff is “an object of the action” challenged, there is ordinarily little question that the action [] caused him injury, and that a judgment preventing [] the action will redress it.” *Id.* at 561–62. Plaintiffs clearly allege facts demonstrating each element of Article III standing. *See Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016).

1. Texas has standing to challenge the Pharmacy Mandate.

The Pharmacy Mandate was promulgated in response to *Dobbs* to require retail pharmacies to disregard states’ pro-life laws as a condition of receiving Medicaid and Medicare funding. *See* Dkt.14-1 & 14-2. This “latest step in the HHS’ response to protect reproductive health care” following *Dobbs* conflicts with and purports to preempt Texas’s abortion laws. Dkt. 14-1 at 2. The Mandate threatens the State’s sovereignty by requiring Texas pharmacies to dispense abortion-

inducing drugs even when Texas law would prohibit it. Texas pharmacists, including those at Texas Tech University Health Sciences Center’s retail pharmacies, are faced with an impossible choice: comply with State law and risk losing federal funding, or comply with federal law and risk enforcement proceedings against their State licenses. *See Texas v. United States*, 809 F.3d 134, 163 (5th Cir. 2015) (holding that the “Hobson’s choice of [compliance] or changing [the State’s statutes]” confers the State with standing).

Based on a misinterpretation of federal law and its preemptive effect, the Mandate requires Texas pharmacies and pharmacists to disregard Texas abortion laws. The Mandate leaves no doubt that, under HHS’s view, pharmacists must dispense abortion-inducing drugs. The Mandate asserts that “discrimination against pregnant [women] on the basis of their pregnancy or related conditions . . . is a form of sex discrimination,” and “[p]harmacies, therefore, may not discriminate against pharmacy customers . . . 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.” Dkt. 14-2 at 2.

There is no ambiguity. The Mandate requires dispensing abortion-inducing drugs without regard to State law. HHS boasted that this Mandate is part of a government-wide reaction to *Dobbs*. Dkt. 14-1 at 3; Dkt. 14-2 at 3. HHS cannot avoid judicial review through *post hoc* rationalizations in litigation. *See Dep’t of Homeland Sec. v. Regents of the Univ. of California*, 140 S. Ct. 1891, 1909 (2020). The Mandate repeatedly obliges pharmacies to “ensure access to comprehensive reproductive health care services.” Dkt. 14-1 at 2–3; Dkt. 14-2 at 2. The Mandate specifies that “abortion” is a “form[] of reproductive health care.” Dkt. 14-1 at 3. And its examples specify the requirement to dispense drugs to “halt the pregnancy,” and drugs commonly used for abortion

including methotrexate, misoprostol, and “mifepristone followed by treatment with misoprostol,” a regimen that HHS-FDA has specifically approved for abortion. Dkt. 14-2 at 4. The Pharmacy Mandate is a syllogism: Pharmacies must ensure access to comprehensive reproductive health care services; Dispensing drugs for abortion is a reproductive health care service; Therefore, pharmacies must dispense drugs for abortion.

Texas laws specifically *require* pharmacists to exercise their professional judgment and ensure they do not violate State law. Pharmacists must comply with Texas’s abortion laws, 22 Tex. Admin. Code § 295.3; Tex. Occ. Code § 565.001(a)(12)), and they have “the exclusive authority to determine whether or not to dispense a drug,” Tex. Occ. Code § 551.006. The Mandate injures Texas’s sovereign interest in its “power to create and enforce a legal code” by requiring pharmacies to stock and dispense abortion-inducing drugs even when doing so would violate State law and by prohibiting pharmacists from asking whether abortion-inducing drugs are being used for an illegal purpose. *Tex. Off. of Pub. Util. Couns. v. FCC*, 183 F.3d 393, 449 (5th Cir. 1999) (internal quotation marks omitted).

HHS’s contention that there is no threat of enforcement is belied by the text of the Mandate itself. The Mandate emphasizes that HHS will exercise “vigorous enforcement” of the Mandate’s requirements to ensure that pharmacies who refuse to stock or dispense abortion-inducing drugs will lose all Medicaid and Medicare funding. Dkt. 14-2 at 2–3. HHS contends that the Mandate does not have the force of law and that HHS’s Office of Civil Rights (OCR) has never “tak[en] enforcement action against any pharmacy for refusing to dispense drugs for abortion purposes.” Dkt. 31 at 16. This argument falls apart at the slightest scrutiny.

HHS has launched investigations into two of the nation’s largest retail pharmacies to

ensure their compliance with the terms of the Mandate. In October 2022, HHS announced that it had “received complaints about chain pharmacies across the U.S. for not complying [with] their federal obligations to fill prescriptions. [HHS] has opened investigations into these companies [and] others.”¹ The announcement was accompanied by a news article reporting that national pharmacy chains CVS and Walgreens “could refuse to fill [] prescription[s] if the medication could harm a pregnancy.”² These pharmacies engaged in conduct proscribed by the Mandate and required by Texas law: CVS required its pharmacists to confirm a medication will not be used to terminate a pregnancy and Walgreens “allow[ed] pharmacists to use their discretion when determining the legality of a prescription based on state law.” *See* Exh. 2. HHS’s initiation of enforcement action against these pharmacies based on the Pharmacy Mandate demonstrates the agency’s view that the Mandate is binding, has the force and effect of law, and preempts state laws. HHS cannot claim that the threat of enforcement alleged by Plaintiffs is “speculative” while simultaneously initiating that very enforcement action against two of the largest pharmacy chains in the country, both of which do business within the State of Texas.

The threat of enforcement is further underscored by the Mandate’s invitation for any person to submit a complaint to HHS OCR relating to any perceived violation of the Mandate’s requirements. Dkt. 14-2 at 5. As the Supreme Court has held, a threat of enforcement “is bolstered by the fact that authority to file a complaint with the Commission is not limited to a prosecutor or

¹ Secretary Becerra (@SecBecerra), Twitter (Oct. 14, 2022, 6:55 PM), <https://twitter.com/SecBecerra/status/1581071321814818817> (attached as Exhibit 1).

² *Walgreens, CVS pharmacists are withholding medications for people post-Roe*; USA TODAY (Oct. 14, 2022), <https://www.usatoday.com/story/money/2022/10/13/walgreens-cvs-withholding-medications-post-roe/10476400002/> (last accessed May 30, 2023) (attached as Exhibit 2).

an agency” but that “‘any person’ with knowledge of the purported violation” may file a complaint. *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 164 (2014).

Finally, Texas is entitled to special solicitude in the standing analysis. “States are not normal litigants for the purposes of invoking federal jurisdiction” *Texas v. United States*, 50 F.4th 498, 514 (5th Cir. 2022) (internal quotation marks omitted). To be entitled to special solicitude, the State must allege a procedural right to challenge the agency action, and “the challenged action must affect one of the State’s quasi-sovereign interests.” *Id.* Texas meets both requirements here. Texas challenges HHS’s affirmative decision to preempt Texas’s abortion laws and Texas has a quasi-sovereign interest in “the health and well-being—both physical and economic—of its residents” and in “not being discriminatorily denied its rightful status in the federal system.” *Id.* (internal quotations omitted). The preservation of life is a legitimate and important State interest well within the State’s police powers. *See Dobbs*, 142 S. Ct. at 2284. And Texas warrants special solicitude because of its procedural right under the APA to challenge the Mandate. *See Texas*, 50 F.4th at 517.

2. Mayo Pharmacy has standing.

Mayo Pharmacy has standing as an entity regulated by the Mandate. The Complaint plausibly alleges that the Mandate requires Mayo to stock or dispense drugs for abortion purposes in violation of its religious beliefs as a condition of receiving federal funding. Mayo has established its past practice and intention to continue engaging in conduct the Pharmacy Mandate prohibits, and that it is subject to the Mandate because of its receipt of federal funds. Dkt. 14 at ¶¶ 34–48. Because Mayo is a pharmacy receiving federal funds and therefore the “object” of the mandate, there is “little question” it has standing and redressability. *Lujan*, 504 U.S. at 561–62. Mayo has

pled “an intention to engage in a course of conduct” proscribed by the Mandate, *Driehaus*, 573 U.S. at 159. The mandate itself includes “a credible threat of prosecution,” *id.*, because it insists HHS “plan[s] to” engage in “vigorous enforcement.” Dkt. 14-2 at 3. This makes “the likelihood of future enforcement ... ‘substantial.’” *California v. Texas*, 141 S. Ct. 2104, 2114 (2021).

HHS tries to deny standing by asserting that the Mandate does not require dispensing drugs for abortion purposes. Dkt. 31 at 10. As noted above, the Mandate itself says otherwise. It explicitly requires pharmacies to dispense “methotrexate” “to halt the pregnancy” of a “growing” “fertilized egg.” Dkt. 14-2 at 4. Mayo contends this is an abortion, Dkt. 14 ¶ 43–46, and medical definitions agree, including from HHS.³ And the Mandate requires abortions beyond this example. It repeatedly obliges pharmacies to “ensure access to comprehensive reproductive health care services,” Dkt. 14-2 at 2, and specifies that “abortion” is a “form[] of reproductive health care.” Dkt. 14-1 at 3. The Mandate also requires dispensing the mifepristone-misoprostol drug combination, which HHS-FDA specifically approved for first trimester abortions. Dkt. 14-2 at 4. If HHS wishes to change the Mandate to remove abortion, it cannot do so through *post hoc* rationalizations in legal briefs. *See Dep’t of Homeland Sec.*, 140 S. Ct. at 1909.

HHS then claims that the Mandate’s example requiring pharmacies to dispense “methotrexate” “to halt the pregnancy” of a “growing” “fertilized egg” is not an “abortion”

³ “Abortion,” NIH National Library of Medicine, available at <https://medlineplus.gov/abortion.html> (“An abortion is a procedure to end a pregnancy,” including “Medication abortion, which uses medicines to end the pregnancy. It is sometimes called a ‘medical abortion’ or ‘abortion with pills.’”); see also “Abortion,” Merriam-Webster.com Dictionary, Merriam-Webster, available at <https://www.merriam-webster.com/dictionary/abortion> (“the termination of a pregnancy whether natural or caused artificially that is accompanied by, results in, or follows the death of the fetus”); “Abortion,” Taber’s Medical Dictionary, available at <https://www.tabers.com/tabersonline/view/Tabers-Dictionary/766365/all/abortion?q=abortion> (“The spontaneous or induced termination of pregnancy before the fetus reaches a viable age.”).

requirement because some state laws define the example as not being an abortion. Dkt. 31 at 8. As an initial matter, state pro-life laws define abortion within their four corners, but do not purport to define abortion for all federal sources.⁴ Moreover, the state law definitions have nothing to do with Mayo's standing, which asks whether the agency action injured Mayo. The complaint specifies that Mayo religiously objects to dispensing methotrexate in response to this Mandate, and that Mayo considers the Mandate to require it to assist abortions. Dkt. 14 ¶¶ 43, 46. Mayo's allegations must be read to object to this methotrexate example specifically, because on a motion to dismiss "the complaint is to be liberally construed in favor of the plaintiff." *Voter Info. Project, Inc. v. City of Baton Rouge*, 612 F.2d 208, 210 (5th Cir. 1980). Mayo's allegations clearly parallel the language of the Mandate's methotrexate example and therefore they encompass it. Creative *post hoc* labeling by HHS about what counts as an abortion based on sources not cited in the Mandate and not consistent with medical definitions cannot negate Mayo's allegation that it objects to this Mandate's clear requirement to dispense methotrexate.⁵

HHS claims Mayo lacks a credible threat of enforcement, Dkt. 31 at 10, but one only needs to read the Mandate to find the credible threat of enforcement: HHS says "we plan to" engage in "vigorous enforcement." Dkt. 14-2 at 3. That the federal government has not yet "attempted to enforce the Guidance against [a regulated entity] does not deprive it of standing." *Texas v. Equal Emp. Opportunity Comm'n*, 933 F.3d 433, 449 (5th Cir. 2019); *see also Texas v. Becerra*, No. 5:22-

⁴ *See, e.g.*, Tex. Health & Safety Code § 245.002 (definitions apply "[i]n this chapter"); N.D. Sen. Bill No. 2150, § 1, available at <https://legiscan.com/ND/text/SB2150/2023> (same).

⁵ Notably, if HHS contends that ordering pharmacies to dispense methotrexate to "halt the pregnancy" is not an abortion, then logically HHS would also deny that federal conscience and religious freedom laws protect Mayo when they shield entities from assisting "abortion." *See, e.g.*, 42 U.S.C. § 238n.

CV-185-H, 2022 WL 3639525, at *15–19 (N.D. Tex. Aug. 23, 2022) (obligating regulated parties to act and requiring agency enforcement is not negated by disclaimer that action merely restates existing law and has not yet been enforced). Moreover, the Mandate is less than a year old, and HHS does not publish its ongoing investigations. Limited enforcement history of such a new policy cannot negate the Mandate’s enforcement threat. *See Kay Elec. Co-op. v. City of Newkirk, Okla.*, 647 F.3d 1039, 1045 (10th Cir. 2011) (it is not “the place of a court to say” desuetude applies to a 14-year-old law); *Rhode Island Ass’n of Realtors, Inc. v. Whitehouse*, 199 F.3d 26, 32 (1st Cir. 1999) (rejecting desuetude argument against a law “only twenty years” old).

HHS asks this Court to ignore the Mandate’s own words, but doing so would impermissibly resolve the merits of plaintiffs’ claims in HHS’s favor. *Cruz*, 142 S. Ct. at 1647. “The trial court must assume jurisdiction and proceed to the merits.” *Pickett v. Texas Tech Univ. Health Scis. Ctr.*, 37 F.4th 1013, 1019 (5th Cir. 2022) (quoting *Montez v. Department of the Navy*, 392 F.3d 147, 150 (5th Cir. 2004)) (alteration omitted).

The Mandate is inherently harmful to Mayo whether or not HHS believes that Mayo specifically objects to every action HHS would coerce. To Mayo, all abortions are morally and religiously fraught, and the Mandate pressures Mayo to participate in them. That pressure is itself injury. *See Sherbert v. Verner*, 374 U.S. 398, 404 (1963) (holding that “[g]overnmental imposition” of “pressure” to violate one’s beliefs is a substantial burden on religious exercise); *Equal Emp. Opportunity Comm’n*, 933 F.3d at 446, 449 (finding that “pressure[] . . . to change” is itself injury, even absent enforcement). HHS’s generic assertion that it abides by RFRA does not negate the injury Dkt. 31 at 10. RFRA establishes a balancing test, so HHS can claim to comply with RFRA in the abstract while later claiming in every individual case it can coerce religious objectors because

HHS believes those acts of coercion pass the test. But Mayo objects to any coercion under the Mandate, and that injury cannot be presumed in HHS's favor on a jurisdictional motion. In a related lawsuit, HHS similarly asserted that its specific desires to mandate abortion is not inconsistent with religious freedom laws. Defs' Brief in Supp. of Mot. to Dismiss at 27, *State of Texas v. Becerra*, No. 5:22-cv-00185-H, Doc. No. 39 (N.D. Tex. filed Aug. 15, 2022) (arguing that its view that EMTALA mandates abortions overrides federal conscience laws). HHS's claim to abide by RFRA is simply an assertion that HHS believes it is legal to coerce Mayo. That is a merits question that the Court cannot resolve against Mayo here.

HHS cannot negate its Mandate by implying it might (or might not) respect Mayo's objections later. "Hedging a concrete application of a policy within a disclaimer about hypothetical future contingencies does not insulate regulated entities from the binding nature of the obligations and similarly cannot serve to inoculate the agency from judicial review." *Iowa League of Cities v. E.P.A.*, 711 F.3d 844, 865 (8th Cir. 2013). Nor can disclaimers change the mandatory effect of an agency pronouncement when "[i]t commands, it requires, it orders, it dictates," and gives regulated parties "their 'marching orders.'" *Appalachian Power Co. v. E.P.A.*, 208 F.3d 1015, 1023 (D.C. Cir. 2000); *see also Texas v. United States*, 606 F. Supp. 3d 437, 470 (S.D. Tex. 2022) (agency cannot negate mandatory language through disclaimers); *Neese v. Becerra*, No. 2:21-CV-163-Z, 2022 WL 1265925, at *9 (N.D. Tex. Apr. 26, 2022) (a "settled agency position" that gives "marching orders" is not negated by boilerplate disclaimers); *Regents of the Univ. of California v. U.S. Dep't of Homeland Sec.*, 908 F.3d 476, 516 (9th Cir. 2018) (disclaimers of otherwise mandatory language are not dispositive).

B. Plaintiffs' claims are ripe.

“The standing question [] bears close affinity to [the] question[] of ripeness—whether the harm asserted has matured sufficiently to warrant judicial intervention. . . .” *Warth v. Seldin*, 422 U.S. 490, 499 n.10 (1975). Plaintiffs need not wait for further factual development to challenge the Mandate. Defendants attempt to distance themselves from the terms of the Mandate in their Motion to Dismiss, but they have refused to withdraw the Mandate, and they have already launched investigations into national retail pharmacies for the same actions that Texas law requires. The questions before the Court are legal ones—there is no need to wait for further factual development. *See Choice Inc. v. Texas v. Greenstein*, 691 F.3d 710, 715 (5th Cir. 2012). Plaintiffs need not “wait[] for [the agency] to ‘drop the hammer’ in order to have their day in court.” *U.S. Army Corps of Engineers v. Hawkes Co., Inc.*, 578 U.S. 590, 600 (2016).

C. The Pharmacy Mandate constitutes final agency action that is reviewable by the Court under the APA.

Plaintiffs have plausibly alleged that the Pharmacy Mandate is binding final agency action, is contrary to federal and state law, and is threatening Mayo and Texas’s pharmacies and pharmacists. The APA provides for judicial review of a “final agency action.” 5 U.S.C. § 704. Agency action is “final” when the action (1) “mark[s] the consummation of the agency’s decisionmaking process” and (2) is “one by which rights or obligations have been determined, or from which legal consequences will flow.” *Bennett v. Spear*, 520 U.S. 154, 178 (1997). The Pharmacy Mandate satisfies both conditions and is appropriate for review by this Court.

The Mandate is not “tentative or interlocutory” but marks the consummation of HHS’s decisionmaking process. *Bennett*, 520 U.S. at 178. “When reviewing finality, the Court must take a “pragmatic” approach.” *Becerra*, 2022 WL 3639525 at *32 (quoting *Abbott Labs v. Gardner*, 387

U.S. 136, 149 (1967)). The Fifth Circuit has held that “guidance letters can mark the ‘consummation’ of an agency’s decision-making process.” *National Pork Producers Council v. EPA*, 635 F.3d 738, 755 (5th Cir. 2011) (citing *Her Majesty the Queen in Right of Ontario v. Env’tl. Prot. Agency*, 912 F.2d 1525, 1532 (D.C. Cir. 1990) (holding that the EPA’s guidance letters constitute final agency actions because they “serve[d] to confirm a definitive position that has a direct and immediate impact on the parties. . .”)). When an agency action is not “subject to further Agency review,” it is final. *Sackett v. EPA*, 566 U.S. 120, 127 (2012); *Data Mktg. P’ship, LP v. U.S. Dep’t of Lab.*, No. 20-11179, 2022 WL 3440652, at *3–4 (5th Cir. Aug. 17, 2022).

The Mandate was published on the agency’s website as the announced position of HHS and was issued to put all pharmacies on notice that they are responsible for taking this new interpretation into account, lest they incur liability. Dkt. 14-2 at 2–3 (issuing a warning in mandatory terms that “pharmacies, therefore, may not discriminate against pharmacy customers on the bases prohibited by Section 1557 and Section 504;” “The Department is committed to improving maternal health . . . and vigorous enforcement of our civil rights laws is one way in which we plan to do so.”).

HHS treats the Mandate as binding. As discussed above, HHS has launched investigations into national retail pharmacies that refused to fill prescriptions to terminate a pregnancy. Secretary Becerra noted that pharmacies’ “federal obligations” to fill prescriptions for abortion-inducing drugs preempts state laws and this preemption prompted HHS’s investigations into pharmacies. *See* Exh. 1. In light of these enforcement actions, Defendants’ contention that the Mandate “does not impose legal consequences or conclusively determine rights or obligations” strains credulity. Dkt. 31 at 20.

The Pharmacy Mandate articulates a new legal position that is intended to have immediate effect on “the roughly 60,000 retail pharmacies in the United States” and is not subject to further agency review. Dkt. 14-2 at 2. The Mandate does not merely summarize or restate existing law; the Mandate conflicts with the plain language of the federal laws it purports to interpret. None of the statutes the Mandate cites as authority require pharmacies to stock or dispense drugs for abortion purposes. Indeed, while Defendants rely on the Affordable Care Act for their authority to promulgate the Mandate, that statute precludes the preemptive effect Defendants contend the Mandate has. 42 U.S.C. § 18023(c)(1) (“Nothing in this Act shall be construed to preempt or otherwise have any effect on State laws regarding the prohibition of (or requirement of) coverage, funding, or procedural requirements on abortions.”).

“In determining whether agency action binds the agency, courts look for mandatory language, actions that restrict the agency’s discretion to adopt a different view of the law, and the creation of safe harbors from legal consequences.” *Becerra*, 2022 WL 3639525 at 33 (citing *Equal Emp. Opportunity Comm’n*, 933 F.3d 441–43). The relevant inquiry is “whether the document ‘ha[s] practical binding effect’ such that ‘affected private parties are reasonably led to believe that failure to conform will bring adverse consequences.’” *Equal Emp. Opportunity Comm’n*, 933 F.3d at 442.

The language of the Mandate prohibits pharmacists from advising or asking patients about abortion-inducing drugs, in contraction with state law. The new legal positions taken by HHS in the Mandate “are not mere recommendations; they are couched in mandatory language and backed by the threat of enforcement action.” *Becerra*, 2022 WL 3639525 at *34. The Mandate “leaves no doubt that [pharmacists] must either comply with HHS’s interpretation . . . or face

serious financial consequences.” *Id.* As discussed above, the Pharmacy Mandate explicitly threatens “vigorous enforcement of our civil rights laws” as interpreted by the Mandate and encourages members of the public to file online complaints against pharmacies who violate HHS’s new interpretation of federal law. Dkt. 14-2 at 3, 5. And while Defendants argue that the Mandate frames its interpretation as a recommendation, the Mandate states in clearly mandatory language that “[p]harmacies . . . 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.” *Id.* at 2. The examples that follow this mandate are not recommendations, but warnings backed by the threat of possible enforcement and loss of federal funds.

D. There is no adequate, alternative remedy for Plaintiffs to obtain judicial review.

Defendants contend Plaintiffs are foreclosed from challenging the Pharmacy Mandate, because they may challenge a later enforcement action through the agency’s internal administrative review process. This argument falls short.

The APA establishes a “basic presumption of judicial review for one suffering legal wrong because of agency action. . . . That presumption can be rebutted by showing that the relevant statute precludes review . . . or that the agency action is committed to agency discretion by law.” *Dep’t of Homeland Sec.*, 140 S. Ct. at 1905 (cleaned up). This exception is read narrowly. *Id.* The Supreme Court has held that the strong presumption favoring judicial review only “fails when a statute’s language or structure demonstrates that Congress wanted an agency to police its own conduct.” *Mach Mining, LLC v. EEOC*, 135 S. Ct. 1645, 1651 (2015). “Establishing

unreviewability is a heavy burden.” *Texas*, 809 F.3d at 164. Defendants do not identify any statute establishing that Congress intended to foreclose judicial review. Where, like here, plaintiffs are unable to initiate an enforcement action themselves and instead must “accrue . . . potential liability” while “wait[ing] for the Agency to drop the hammer,” judicial review under the APA is appropriate. *Sackett*, 566 U.S. at 127; *see also Tennessee v. United States Dept. of Education*, 615 F.Supp.3d 807, 834–35 (E.D. Tenn. 2022) (citing *Sackett* in support of permitting plaintiff States to bring pre-enforcement suit against agency guidance documents). Defendants’ reliance on *Hinojosa v. Horn* for the proposition that “the civil rights statutes and HHS’s regulations thus ‘provide[] a direct and guaranteed path to judicial review’” is misplaced. 896 F.3d 305, 312 (5th Cir. 2018). The *Hinojosa* court itself recognized that the ability of a plaintiff to challenge an agency enforcement action in court was not an adequate alternative remedy because the plaintiff would “risk[] onerous liability” in doing so. *Id.* at 311 (citing *Sackett*, 566 U.S. at 127).

While Defendants contend pharmacies could “raise legal objections during the administrative proceedings,” HHS ignores that pharmacies would be subject to the burden of HHS’s investigation before the administrative proceedings commence. Moreover, the State of Texas could not vindicate its sovereign interest in the enforcement of its laws through administrative proceedings related to investigations of pharmacies not operated by the State of Texas. Precluding the court’s jurisdiction here would foreclose Texas’s ability to obtain relief on its sovereign and administrative procedure injuries.

E. Mayo’s RFRA Claim Should Not Be Dismissed Under Rule 12(b)(6) For Failure to State a Claim.

HHS also seeks to dismiss Mayo’s RFRA claim under Rule 12(b)(6) because “Mayo fails to plausibly allege that the pharmacy guidance and press release burden its exercise of religion.”

Dkt. 31 at 17. But the Complaint contains factual allegations, which must be construed as true, that plausibly allege that the Pharmacy Mandate and the corresponding press release substantially burden Mayo's religious beliefs by requiring Mayo to stock or dispense drugs for abortion purposes as a condition of receiving federal financial assistance.

First, the Complaint alleges that "[a]s a matter of religious faith, . . . Mayo Pharmacy believe[s] that it would be immoral and sinful for Mayo Pharmacy to intentionally dispense or otherwise provide drugs such as methotrexate or misoprostol for abortion purposes, or to stock or restock such drugs for those purposes." Dkt. 14 ¶¶ 42–43.

Second, the Complaint plausibly alleges that the Pharmacy Mandate requires Mayo to stock and dispense drugs for abortion purposes as a condition of receiving federal financial assistance. The Complaint alleges that "[t]he Pharmacy Mandate requires pharmacies" generally and "Mayo Pharmacy to stock and dispense drugs for abortion purposes as a condition of receiving patients who are covered by federally funded programs." *Id.* ¶¶ 19, 46. In support of that allegation, the Complaint asserts that the Pharmacy Mandate prohibits discrimination on the basis of termination of pregnancy under Section 1557, Section 504, and other federal statutes HHS enforces. *Id.* ¶¶ 21, 64.

Moreover, as explained above, the plain text of the Pharmacy Mandate and the corresponding press release, which are attached to the Complaint, requires pharmacies that receive federal financial assistance to stock and dispense methotrexate, misoprostol, and all or part of the mifepristone-misoprostol regimen for abortion purposes, and to ensure access to all forms of reproductive health care, including abortion drugs. *Id.*, Exh. 1 at 1–3; Exh. 2 at 2–4.

Finally, the Complaint plausibly alleges that the Pharmacy Mandate's requirements burden

Mayo's ability to practice its religious beliefs. The Complaint alleges that absent relief from the Court, "Mayo Pharmacy will be forced to either lose customers whose payors receive Medicaid, Medicare, or other federal assistance, or violate Mayo Pharmacy's sincerely held religious beliefs regarding the stocking and dispensing of drugs for abortion purposes," and will be substantially burdened in its religious beliefs. *Id.* ¶¶ 47, 50.

Together, these allegations plausibly allege that the Pharmacy Mandate and corresponding press release impose a substantial burden on Mayo's religious exercise.

F. Mayo's RFRA Claim Should Not Be Dismissed Under Rule 12(b)(3) For Lack of Venue.

HHS seeks to dismiss Mayo's RFRA claim under Rule 12(b)(3) because "[v]enue does not lie in this district for Mayo's RFRA claim." Dkt. 31 at 18. This is incorrect. First, since venue is proper for Texas, Mayo can join this case. "[V]enue is proper as to all plaintiffs if suit is brought in a district where any one or more of the plaintiffs resides." *Crane v. Napolitano*, 920 F. Supp. 2d 724, 746 (N.D. Tex. 2013) (citing cases applying 28 U.S.C. § 1391(e)(1); *see also E. Texas Baptist Univ. v. Sebelius*, No. CIV.A. H-12-3009, 2013 WL 4678016, at *7 (S.D. Tex. Aug. 30, 2013) (same). This is "not only the majority view—it is the only view adopted by the federal courts since 1971." *Sidney Coal Co., Inc. v. Soc. Sec. Admin.*, 427 F.3d 336, 345 (6th Cir.2005). The Fifth Circuit regularly entertains cases against federal agencies with plaintiffs from other states. *See, e.g., Texas v. United States*, 50 F.4th 498, 508 (5th Cir. 2022) (affirming injunction encompassing other plaintiff states); *Franciscan All., Inc. v. Becerra*, 47 F.4th 368, 371 (5th Cir. 2022) (affirming injunction encompassing a plaintiff business from Illinois).

Second, Mayo also joins APA claims 1(A), 2, and 3. Where venue lies for one claim, jurisdiction is proper for that plaintiff's other claims. *See Gen. Foods Corp. v. Carnation Co.*, 411

F.2d 528, 532 (7th Cir. 1969). Contrary to HHS's assertion, the RFRA claim does not involve a separate nucleus of facts from the APA claims, as they all derive from the same mandate.

Third, HHS identifies no prejudice to itself. On the contrary, litigating Mayo's claims here where Texas's APA claims will already proceed cannot be harder than litigating two cases across the country. Fourth, HHS's request to transfer Mayo's claims to D.D.C. is groundless, as Mayo would have venue in D.N.D. as well, and venue is proper here with Texas for the reasons given. *Cf. Utah v. Walsh*, No. 2:23-CV-016-Z, 2023 WL 2663256 (N.D. Tex. Mar. 28, 2023) (denying DOJ motion to transfer venue to D.C.); *Texas v. United States Dep't of Homeland Sec.*, No. 6:23-CV-00007, 2023 WL 2457480, at *4 (S.D. Tex. Mar. 10, 2023) (denying motion to transfer venue).

III. CONCLUSION

For the all the foregoing reasons, Plaintiffs respectfully request the Court deny Defendants' Motion to Dismiss.

Dated May 30, 2023.

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Respectfully submitted.

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CERTIFICATE OF SERVICE

We hereby certify that the foregoing document was served on all counsel of record on May 30, 2023, via the court's electronic filing system.

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ANDREA R. DILL

/s/ Amy Snow Hilton
AMY S. HILTON

UNITED STATES DISTRICT COURT
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-22-DC

EXHIBIT 1

← Tweet



Secretary Xavier Becerra ✓

@SecBecerra

...

Since Dobbs & state laws that have gone into effect, HHS has received complaints about chain pharmacies across the U.S. for not complying w/ their federal obligations to fill prescriptions.

[@HHSOCR](#) has opened investigations into these companies & others.



usatoday.com

Walgreens, CVS pharmacists are withholding medications for people post-R...
If you can become pregnant, a pharmacist at Walgreens or CVS could refuse to fill your prescription if the medication could harm a pregnancy.

6:55 PM · Oct 14, 2022

UNITED STATES DISTRICT COURT
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-22-DC

EXHIBIT 2





Walgreens, CVS pharmacists are withholding medications for people post-Roe. What you need to know.

Amanda Pérez Pintado USA TODAY

Published 12:36 p.m. ET Oct. 13, 2022 | Updated 11:47 a.m. ET Oct. 14, 2022

If you could become pregnant, a pharmacist at Walgreens or CVS could refuse to fill your prescription if the medication could harm a pregnancy.

The companies have policies allowing their pharmacists to use professional discretion to deny medication to people they suspect are trying to circumvent state laws restricting abortion, USA TODAY reported.

The Supreme Court in June overturned *Roe v. Wade*, eliminating the constitutional right to abortion. The decision leaves abortion policy in the hands of individual states, some of which have banned the procedure.

Since the *Dobbs v. Jackson Women's Health Organization* ruling, patients in states that have enacted abortion bans have reported that pharmacies have denied them necessary medications that could be used to induce a miscarriage even though they're not pregnant.

Pharmacists and abortion laws: Post-Roe, non-pregnant people are being denied medications over 'hypothetical' babies

What medications are pharmacists denying?

Pharmacies worried about breaking new abortion restrictions have denied people medication that could cause birth defects or a miscarriage.

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, a Tucson TV station reported.

The medication, methotrexate, can also be used to treat ectopic pregnancies, a potentially fatal condition in which the fertilized egg lodges outside the uterus.



CVS requires its pharmacists to confirm a medication will not be used to terminate a pregnancy before it will fill a drug, said Mike DeAngelis, executive director for corporate communications at the company.

Walgreens, meanwhile, allows pharmacists to use their discretion “when determining the legality of a prescription based on state law,” said Fraser Engerman, a spokesperson for Walgreens Boots Alliance, which owns the pharmacy chain.

What policies do Walgreens, CVS have regarding birth control?

Both of the nation’s largest pharmacies had policies in place before the Dobb decision allowing pharmacists to deny customers birth control if the request conflicted with their religious beliefs.

The policy includes prescriptions for birth control pills and other medication like Plan B, as well as the sale of condoms. (Plan B is an oral emergency contraceptive that can be taken up to five days after unprotected sex to reduce the risk of pregnancy.)

Denied: What to do if CVS, the nation's largest pharmacy, refuses to fill your birth control

“Our policy allows pharmacists to step away from filling a prescription for which they have a moral objection,” Walgreens tweeted in June. “At the same time, they are also required to refer the prescription to another pharmacist or manager on duty to meet the patient's needs in a timely manner.”

What have federal agencies said?

Federal officials warned in July that pharmacists must comply with federal civil rights laws in decisions they make when dispensing medication.



patients about medications and how to take them.”

“As our nation faces another significant health care crisis, this guidance is to remind the roughly 60,000 retail pharmacies in the United States of the unique role pharmacies play in ensuring access to comprehensive reproductive health care services,” according to the guidance.

Contributing: Katie Wedell and Riley Gutiérrez McDermid