IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its member organizations, their members, and these members' patients, et al., Plaintiffs, v. **U.S. FOOD AND DRUG ADMINISTRATION**, et al., Defendants.	**Case No. 2:22-cv-00223-Z**

PLAINTIFFS' BRIEF IN SUPPORT OF THEIR MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

The U.S. Food and Drug Administration (FDA) must protect the health, safety, and welfare of all Americans by rejecting or limiting the use of dangerous drugs. But the FDA failed America's women and girls when it approved chemical abortion drugs for use in the United States.[1] And it has repeatedly failed them by removing even the most basic precautionary requirements associated with their use.

The *only* way the FDA could have approved chemical abortion drugs was to call pregnancy an "illness" and argue that these dangerous drugs provide a "meaningful therapeutic benefit" over surgical abortions. Both of those conclusions are transparently false. What's more, in approving these drugs, the FDA chose politics over science because the FDA never studied the safety of the drugs under the labeled conditions of use, ignored the potential impacts of this hormone-blocking regimen on the developing bodies of adolescent girls, and disregarded the substantial evidence that chemical abortions cause more complications than even surgical abortions.

Since approving chemical abortion drugs, the FDA has not followed the science, reversed course, or fixed its mistakes—all to the detriment of women and girls. Instead, the FDA has repeatedly removed the few safeguards that were in place to protect women and girls who undergo this dangerous drug regimen. And just last year, it removed even the most rudimentary requirement that women and girls have at least one in-person visit with an abortionist during the course of the drug regimen.

[1] The FDA's approval of chemical abortion lacks an age restriction and thus permits the use of the drug regimen by a pregnant girl of any age under 18 years.

While that has accomplished the current administration's goal of facilitating a "mail-order" abortion economy, it has jeopardized the health and safety of women and girls.

The FDA took these actions by running roughshod over the laws and regulations that govern the agency and, more importantly, protect the public from harmful drugs. Chemical abortion drugs inflict severe complications on many women and girls, requiring critical and avoidable treatment by doctors. The FDA's unlawful actions have caused, and will continue to cause, irreparable harm to Plaintiffs.

Because the FDA has refused to withdraw these dangerous drugs and evaded responsibility for decades, Plaintiffs Alliance for Hippocratic Medicine, American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG), American College of Pediatricians (ACPeds), Christian Medical & Dental Associations (CMDA), Dr. Shaun Jester, Dr. Regina Frost-Clark, Dr. Tyler Johnson, Dr. George Delgado, and their patients seek a preliminary injunction: (1) ordering Defendants to withdraw or suspend the approvals of chemical abortion drugs, and remove them from the list of approved drugs; (2) ordering Defendants to withdraw or suspend their actions to deregulate chemical abortion drugs; and (3) enjoining Defendants from taking actions inconsistent with the Court's orders while they remain in effect.

BACKGROUND

The FDA's chemical abortion drug regimen requires the use of two drugs: (1) mifepristone (also known as "RU-486" and "Mifeprex") and (2) misoprostol. App. 017. As an endocrine disruptor, mifepristone is a synthetic steroid that works to block the hormone progesterone, stop nutrition to the unborn baby, and ultimately starve

the baby to death in the mother's womb. *Id*. Because mifepristone alone will not always work to complete the abortion, the FDA mandates the use of a second drug—misoprostol—to induce cramping and contractions to try to expel the dead baby from the mother's womb. *Id.* 017–18.

During 1993 and 1994, the Clinton administration negotiated for the Population Council—a nonprofit that John Rockefeller III founded to address world "overpopulation"—to obtain the U.S. patent rights to mifepristone from its French manufacturer. *Id.* 033–34. The Population Council then conducted clinical trials of the drug and filed a new drug application (NDA) with the FDA. *Id.* 034–35. It later granted Danco Laboratories, LLC, a Cayman Islands-based company with no other pharmaceutical products, an exclusive license to manufacture, market, and distribute mifepristone in the United States. *Id*. 042.

Shortly before the 2000 presidential election, on September 28, 2000, the FDA approved chemical abortion drugs (2000 Approval) under its regulation entitled "Subpart H – Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses" (Subpart H). *Id.* 527. Subpart H authorizes the FDA to provide accelerated approval of new drugs "that have been studied for their safety and effectiveness in treating serious or life-threatening *illnesses* and that provide *meaningful therapeutic benefit to patients over existing treatments* (e.g., ability to treat patients unresponsive to, or intolerant of, available therapy, or improved patient response over available therapy)." 21 C.F.R. § 314.500 (emphasis added).

Given the dangers of chemical abortion drugs, Subpart H was the *only* possible regulatory pathway available to the FDA to push approval of these drugs. Only under Subpart H could the FDA have imposed post-approval restrictions on the drugs' distribution and use "to assure safe use." *See* 21 C.F.R. § 314.520. Indeed, without improperly relying on Subpart H and applying its post-approval restrictions, the FDA would have been left with no choice but to reject these drugs.

The FDA's 2000 Approval thus placed several restrictions on the use of chemical abortion drugs. It limited them to women and girls with babies ages 49 days' gestation or younger. App. 527. The FDA required three in-person office visits: (1) the Day 1 in-person dispensing and administration of mifepristone; (2) the Day 3 in-person dispensing and administration of misoprostol; and (3) the Day 14 office visit to confirm no fetal parts or tissue remain. *Id.* 519–20, 523. The FDA also required chemical abortionists to be physicians, and these abortionists needed to report *all* adverse events from the drugs. *Id.* 523. The FDA's approved distribution system for mifepristone neither acknowledged nor attempted to comply with the federal laws that prohibit the upstream distribution of these drugs—from the manufacturer to the abortionists—by mail, express company, or common carrier. *Id.* 040.

In 2002, under the FDA's regulations that require the filing of a citizen petition before seeking judicial relief, Plaintiffs AAPLOG and CMDA filed a citizen petition with the FDA challenging the 2000 Approval (2002 Citizen Petition). *Id.* 281–372. *Fourteen years later*, on March 29, 2016—close to another presidential election—the FDA rejected the 2002 Citizen Petition (2016 Petition Denial). *Id.* 562–94.

On the *same day* in March 2016, the FDA approved "major changes" to the chemical abortion drug regimen, eviscerating crucial safeguards for women and girls (2016 Major Changes). *Id.* 616–23. For example, the agency increased the maximum gestational age of a baby for which a pregnant woman or girl may have a chemical abortion from 49 days' gestation to 70 days' gestation. *Id.* 627. The FDA also (1) changed the dose and regimen for chemical abortion, (2) reduced the number of required in-person office visits from three to one, (3) allowed non-doctors to prescribe and administer chemical abortions, and (4) eliminated the requirement for prescribers to report non-fatal adverse events from chemical abortion. *Id*. The FDA once again neither acknowledged nor attempted to comply with the federal laws that prohibit the upstream distribution of these drugs—from the manufacturer to the abortionists—by mail, express company, or common carrier. *Id.* 627–51.

In March 2019, Plaintiffs AAPLOG and ACPeds filed a citizen petition challenging the 2016 Major Changes (2019 Citizen Petition). *Id.* 668–93.

On April 11, 2019, the FDA approved GenBioPro, Inc.'s abbreviated new drug application for a generic version of mifepristone, relying on Mifeprex's safety data (2019 ANDA Approval). *Id.* 695. GenBioPro's generic version of mifepristone has the same labeling and postmarketing restrictions as does Danco's Mifeprex. *Id.* 702.

On April 12, 2021, in the early days of the Biden administration, the FDA stated that it would "exercise enforcement discretion" and allow "dispensing of mifepristone through the mail . . . or through a mail-order pharmacy" during the COVID pandemic (2021 Non-Enforcement Decision). *Id.* 715. The FDA took this

action even though federal statutes expressly prohibit distribution of chemical abortion drugs by mail, express company, or common carrier. Then, on December 16, 2021, the FDA denied almost all of the 2019 Citizen Petition (2021 Petition Response). *Id.* 769. In particular, the FDA expressly rejected the 2019 Citizen Petition's request to keep the in-person dispensing requirements and announced that the agency would permanently allow abortion by mail. *Id.* 735. Major news outlets proclaimed that FDA's move would "permanently . . . [allow abortion] by mail."[2]

LEGAL STANDARD

A court may issue a preliminary injunction when a movant satisfies the following four factors: (1) a substantial likelihood of success on the merits; (2) a substantial threat of irreparable harm if the injunction does not issue; (3) the threatened injury outweighs any harm that will result if the injunction is granted; and (4) the grant of an injunction is in the public interest. *See Louisiana v. Becerra*, 20 F.4d 260, 262 (5th Cir. 2021). "The purpose of a preliminary injunction is always to prevent irreparable injury so as to preserve the court's ability to render a meaningful decision on the merits." *Canal Auth. of State of Fla. v. Callaway*¸ 489 F.2d 567, 576 (5th Cir. 1974). The same standards apply "to prevent irreparable injury" under the Administrative Procedure Act (APA). 5 U.S.C. § 705. *Wages & White Lion Investments, L.L.C. v. U.S. Food & Drug Admin.*, 16 F.4d 1130, 1143 (5th Cir. 2021).

[2] Christal Hayes, FDA makes abortion pills permanently available through mail and telehealth by removing in-person restriction, USA TODAY (Dec. 16, 2021), https://www.usatoday.com/story/news/health/2021/12/16/fda-abortion-pills-permanently-available-mail/8931338002/.

ARGUMENT

Plaintiff medical associations, doctors, and their patients seek a preliminary injunction ordering Defendants to: (1) withdraw or suspend their September 30, 2000, Approval of Mifeprex and their April 11, 2019, approval of Mifepristone Tablets, 200 mg, and remove them from the list of approved drugs; (2) withdraw or suspend their March 29, 2016, Approval of Danco Laboratories' supplemental new drug application for Mifeprex; (3) withdraw or suspend their April 12, 2021, Non-Enforcement Decision letter, and December 16, 2021, Response to the 2019 Citizen Petition concerning the in-person dispensing requirement for mifepristone; and (4) enjoining Defendants from taking actions inconsistent with these orders.

I. This Court has jurisdiction over Plaintiffs' challenge to the FDA's actions on chemical abortion drugs.

A. Plaintiffs individually and collectively have standing to sue.

Plaintiff medical associations have standing to sue in their own right because the FDA's actions on chemical abortion have injured these associations. App. 090–93. The FDA's actions have frustrated and complicated Plaintiff medical associations' ability to educate and inform their members, their patients, and the public on the dangers of chemical abortion drugs. *Id.* 091. These associations have also been challenging the FDA's actions to legalize and deregulate these drugs for decades. *Id.* 091–93. In response to the FDA's actions on chemical abortion, Plaintiff medical associations have needed to divert limited time, energy, and resources away from their other priorities and functions, and will continue to do so. *Id.* Such injuries confer organizational standing. *OCA-Greater Houston v. Texas*, 867 F.3d 604, 610–12 (5th

Cir. 2017) (holding nonprofit had standing after spending "additional time and effort" explaining the new law, which "frustrate[d] and complicate[d] its routine community outreach activities"); s*ee also* 21 C.F.R. § 10.45(d)(1)(ii) (requiring FDA to concede that anyone who files a citizen petition "is affected by, and thus has standing to obtain judicial review of final agency action").

Plaintiff medical associations also have standing to bring claims on behalf of their members, who are medical professionals who treat women and girls harmed by chemical abortion drugs, and on behalf of their members' patients. *See Tex. Ass'n of Mfrs. v. U.S. Consumer Prod. Safety Comm'n*, 989 F.3d 368, 377 (5th Cir. 2021); *Pa Psychiatric Soc. v. Green Spring Health Servs., Inc.*, 280 F.3d 278, 283–293 (3d Cir. 2002). Similarly, Plaintiff doctors also have standing to sue on behalf of themselves and their patients. *June Med. Servs. LLC v. Russo*, 140 S. Ct. 2103, 2118–20 (2020).

Plaintiffs have standing because the FDA legalized an unsafe drug regimen that has caused, and will continue to cause, Plaintiffs' past and future patients to endure many intense side effects and suffer significant complications requiring medical attention. App. 074–79. Because the FDA has created an inaccurate and false safety profile of chemical abortion, Plaintiffs' patients cannot give informed consent before going through the regimen. *Id.* 078–79. Many do not fully understand the nature and risks of these drugs. *Id.* 078. As a result, many suffer distress and regret after undergoing chemical abortion. *Id.* 079.

The harms that the FDA has wreaked on women and girls have also injured, and will continue to injure, Plaintiff doctors and their medical practices. *Id.* 074, 080,

090. The FDA's actions have caused medical professionals, including Plaintiffs, to treat women and girls suffering complications from chemical abortion drugs—the rate of which has increased and will continue to increase over time. *Id.* 076–78, 080–82. The adverse events from chemical abortion drugs can overwhelm the medical system and consume crucial limited medical resources, including blood for transfusions, physician time and attention, space in hospitals and medical centers, and other equipment and medicines. *Id*. 081–83. The more patients suffering emergency complications from chemical abortion drugs or seeking to reverse the effects of the drug regimen, the less time and attention Plaintiff doctors have to treat their other patients. *Id.* 077–84. Plaintiff doctors need to take additional time out of their busy schedules to learn how to report adverse events and then submit adverse event reports to the FDA, the state, or drug manufacturer. *Id.* 088–89. The FDA's actions on chemical abortion directly injure the well-being and practices of Plaintiff doctors who care for pregnant patients and their babies through pregnancy. *Id.* 088, 087–90.

The FDA's actions have placed enormous pressure and stress on Plaintiff doctors during these emergency situations. *Id.* 085. Some of these emergency situations force pro-life doctors, including Plaintiffs, into situations in which they feel complicit in the elective chemical abortion by needing to remove a baby with a beating heart or fetal remains as the only means to save the life of the woman or girl. *Id.* 085–86. This feeling of complicity causes great emotional suffering, mental anguish, and spiritual distress for these doctors. *Id*. 086. It also grieves Plaintiffs to treat women

and girls harmed by chemical abortion drugs, including those who regret their decision to have a chemical abortion. *Id*. 087.

There are other costs to Plaintiffs. The FDA's actions prevent Plaintiff doctors from practicing evidence-based medicine. *Id.* 087. The lack of accurate information on adverse events also harms the doctor-patient relationship. *Id.* 089. The FDA has caused Plaintiff doctors to face increased exposure to allegations of malpractice and potential liability, along with higher insurance costs. *Id.* 089–90.

Plaintiffs are also within the zone of interests of the Federal Food, Drug, and Cosmetic Act (FFDCA) and federal laws that restrict the distribution of chemical abortion drugs. *See Texas v. United States*, 809 F.3d 134, 162 (5th Cir. 2015) (stating that the interest that plaintiffs assert for APA claims "must be arguably within the zone of interests to be protected or regulated by the statute that they say was violated") (citations and quotations omitted). This test is not meant to be demanding. *Id*. The FFDCA establishes a legal and regulatory framework to protect the public from harmful drugs, to prevent dangerous situations requiring emergency medical attention, and to inform doctors and the public about the risks of approved drugs. Federal laws restricting the distribution of chemical abortion drugs protect women, girls, and their doctors from these harmful drugs by limiting access to them.

Plaintiffs' injuries in fact are thus "concrete and particularized," "actual or imminent, not conjectural or hypothetical," fairly traceable to the challenged actions, and likely to be redressed by the relief requested. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992). The Complaint and its attached declarations show that the harms

that the FDA's actions inflict on these associations, doctors, and their patients are real, significant, and ongoing. App. 075–93.

B. Plaintiffs' claims are ripe for review.

"Before the Court may reach the merits, it must also address whether [the challenged agency action] is a final agency action subject to the Court's review." *State of Texas v. Becerra,* 2022 WL 3639525, 15 (N.D. Tex. Aug. 23, 2022). Under the APA, courts may review "final agency action." *See id.* (citing 5 U.S.C. § 704). "[A]n agency action is 'final' for purposes of the APA where the action (1) 'mark[s] the consummation of the agency's decision making process' and (2) is 'one by which rights or obligations have been determined, or from which legal consequences will flow.'" *Id.* at *15 (citing *Bennett v. Spear*, 520 U.S. 154, 178 (1997)).

The FDA's regulations require the submission of a citizen petition requesting the agency to take or refrain from taking any form of administrative action before suing. 21 C.F.R. §§ 10.30; 10.45(b). The FDA's final decision on a citizen petition constitutes a final agency action for the underlying FDA action and the related citizen petition, and both are reviewable in the courts under the APA. 21 C.F.R. § 10.45(c). The 2016 Major Changes and the related 2021 Petition Response are thus ripe for review as they represent the consummation of the agency's decision-making process.

The FDA's 2016 Major Changes and 2021 Petition Response reopened the 2000 Approval and 2016 Petition Denial, thereby making these earlier FDA actions also ripe for review. "The reopening doctrine . . . create[s] an exception to statutory limits on the time for seeking review [of an agency decision]." *Nat'l Ass'n of*

Reversionary Prop. Owners v. Surface Transp. Bd., 158 F.3d 135, 141 (D.C. Cir. 1998) (quotations and citation omitted). "Under the reopening doctrine, the time for seeking review starts anew where the agency reopens an issue." *Sierra Club v. EPA*, 551 F.3d 1019, 1024 (D.C. Cir. 2008). An agency reopens an underlying regulatory action where the agency's later actions "*completely* changed the regulatory context," "created a different regulatory construct," or "removed . . . necessary safeguards." *Id.* at 1025 (emphasis in original). The Fifth Circuit has adopted the "reopening doctrine." *See Texas v. Biden*, 20 F.4th 928, 951–55 (5th Cir. 2021) (noting "[o]ur holding . . . is dictated by the well-established reopening doctrine").

The FDA's 2000 Approval and 2016 Petition Denial are ripe for judicial review because the FDA's 2016 Major Changes and the 2021 Petition Response reopened the underlying approval. App. 093, 103. At the request of Danco, the FDA agreed to reopen, reexamine, and revise the conditions upon which the 2000 Approval was based. When reviewing this request, the FDA acknowledged that Danco asked for "major changes" to the chemical abortion drug regimen. *Id.* 630. The FDA's 2016 Major Changes then gutted the crucial safeguards that the FDA believed were necessary for the agency to approve chemical abortion drugs in 2000. *Id.* 100–01. Ultimately, the FDA—through its 2016 Major Changes and later affirmed in its 2021 Petition Response—completely changed the regulatory context and created a different regulatory construct for chemical abortion drugs by removing these necessary safeguards. *Id.*

II. Plaintiffs have a substantial likelihood of success on the merits.

"To satisfy the first element of likelihood of success on the merits," Plaintiffs "must present a prima facie case but need not show that [they are] certain to win." *Janvey v. Alguire*¸ 647 F.3d 585, 595–96 (5th Cir. 2011) (quotations and citation omitted). Indeed, Plaintiffs are "not required to prove [their] entitlement to summary judgment." *Id.* at 596. Because Plaintiffs claim the FDA has violated the APA, this Court should look to the "standards provided by the [APA]." *Id.* (quotations and citation omitted). In addition, distinct from the APA, courts of equity have the power to set aside ultra vires federal actions. *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689–90, 693 (1949).

Under the APA, courts must "hold unlawful and set aside agency action, findings, and conclusions to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C); *see also FCC v. Next Wave Pers. Commc'ns Inc.*, 537 U.S. 293, 300 (2003) ("The Administrative Procedure Act requires federal courts to set aside federal agency action that is 'not in accordance with law,' 5 U.S.C. § 706(2)(A)—which means, of course, any law, and not merely those laws that the agency itself is charged with administering.") (citation omitted). "In a challenge to agency action under the APA, part of the court's task involves 'reviewing agency action to determine whether the agency conformed with controlling statutes.'" *Am. Stewards of Liberty v. Dep't of Interior*, 370 F. Supp. 3d 711, 725 (W.D. Tex. 2019) (citing *Baltimore Gas & Elec. Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 97 (1983)). Moreover, "an agency must comply with its own

regulations, and the court must review an agency's actions to ensure conformity with relevant regulations." *Id.* at 725–26 (citations omitted).

Plaintiffs' motion focuses on four specific legal infirmities associated with the FDA's actions to approve and deregulate chemical abortion drugs: (1) the 2000 Approval and the 2016 Petition Denial violated Subpart H because mifepristone does not treat an illness or provide meaningful comparative therapeutic benefits; (2) the 2000 Approval, the 2016 Petition Denial, the 2016 Major Changes, 2021 Non-Enforcement Decision, and the 2021 Petition Response all failed to meet the requirements for showing safety and effectiveness under the FFDCA; (3) the 2000 Approval, the 2016 Major Changes, the 2021 Non-Enforcement Decision, and the 2021 Petition Response all violated federal laws that restrict the distribution of chemical abortion drugs; and (4) the 2019 ANDA Approval lacked the requirements for approval and demands withdrawal under the FFDCA.

A. The FDA's 2000 Approval and 2016 Petition Denial violated Subpart H.

The 2000 Approval and the 2016 Petition Denial conflicted with law and the FDA's own regulations under 21 C.F.R. § 314, Subpart H. This accelerated review authority applies only to "certain new drugs that . . . treat[] serious or life-threatening *illnesses* and that provide *meaningful therapeutic benefit to patients over existing treatments*." 21 C.F.R. § 314.500 (emphasis added).

Pregnancy is not an illness. App. 003, 043–44. Indeed, it is a normal physiological state that many females experience one or more times during their childbearing years. *Id.* 012. Before the 2000 Approval, the Population Council

actually agreed that "[n]either pregnancy nor unwanted pregnancy is an illness, and Subpart H is therefore inapplicable for that reason alone." *Id.* 036. Even the FDA conceded that pregnancy is not an "illness." *Id.* 050. The Court's inquiry should end here and find that the 2000 Approval violated Subpart H.

Not surprisingly, the FDA has attempted to justify its illicit approval of chemical abortion drugs under Subpart H by looking beyond the unambiguous regulatory text. *Id*. 050. The FDA has asserted that, according to the preamble of the Subpart H final rule, the regulations are "intended to apply to serious or life-threatening *conditions*, as well as to illnesses or diseases." *Id*. 050. (emphasis added). But this interpretation defies the plain text of Subpart H. And the FDA's interpretation of an unambiguous regulation is entitled to no deference whatsoever. *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019); *see also Univ. of Texas M.D. Anderson Cancer Ctr. v. HHS*, 985 F.3d 472, 476 (5th Cir. 2021) (applying *Kisor* when holding that HHS's interpretation of an unambiguous regulation was invalid and actions under that interpretation were arbitrary and capricious). Nor is this interpretation reasonable. If the FDA wanted to include "conditions" in Subpart H, the agency knew how to draft such language. *See, e.g.*, 21 C.F.R. § 312.300(a) (defining scope of the FDA's "Subpart I" regulations for use of certain investigational drugs "when the primary purpose is to diagnose, monitor, or treat a patient's *disease or condition*") (emphasis added).

The FDA's argument also contradicts the fundamental principle of administrative law that the text of a codified regulation controls its scope and terms;

a preamble cannot override regulatory text. *See Cuomo v. Clearing House Ass'n*, 557 U.S. 519, 533 (2009) (invalidating an agency's interpretation of a regulation inconsistent with the regulation's text and the statute); *Texas Child.'s Hosp. v. Azar*, 315 F. Supp. 3d 322, 334 (D.D.C. 2018) (holding preamble to a final rule cannot be used to contradict the unambiguous text of the rule at issue).

The FDA's 2000 Approval and 2016 Petition Denial also violate Subpart H because chemical abortion drugs do not provide a "meaningful therapeutic benefit" to patients over existing treatments, in particular surgical abortion. App. 003, 015, 037, 051. The U.S. clinical trial failed to compare chemical abortion drugs with the existing "therapy," surgical abortion, to support a finding of a "meaningful therapeutic benefit over existing treatments." *Id.* 044. Because surgical intervention is required after many chemical abortions, these drugs are not an alternative "therapy" for patients unresponsive to, or intolerant of, surgical abortion—as contemplated by Subpart H. *Id*. Nor do these drugs provide an improved patient response over surgical abortion—also as contemplated by Subpart H. Indeed, especially when compared to surgical abortion, chemical abortion drugs have potential serious and life-threatening adverse effects on women and girls. *Id.* 019. For example, chemical abortions are over fifty percent (50%) more likely than surgical abortions to result in an emergency department visit within thirty days, affecting one in twenty females who take the chemical abortion drugs. *Id.*

Despite these facts, the FDA offered only one "meaningful therapeutic benefit" of chemical abortion: "the avoidance of a surgical procedure." *Id.* 038. But this

specious "justification" is not even a benefit as it creates additional health risks and cannot satisfy the requirements of Subpart H to approve chemical abortion drugs.

B. FDA's 2000 Approval, 2016 Petition Denial, 2016 Major Changes, 2021 Non-Enforcement Decision, and 2021 Petition Response Violated the FFDCA.

The FDA's actions to approve and deregulate chemical abortion drugs failed to satisfy the FFDCA's strict safety and effectiveness requirements. The FFDCA requires companies seeking to market any new drug in the United States to obtain the FDA's approval by filing a new drug application (NDA). 21 U.S.C. § 355(a), (b). The NDA must contain extensive scientific data showing the safety and effectiveness of the drug. 21 U.S.C. § 355(d). The FDA must reject the NDA if the clinical investigations "do not include adequate tests . . . to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof." *Id.* The FDA must also reject the NDA if "the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions." *Id.* (emphasis added). The FDA must deny the NDA if the agency "has insufficient information to determine whether such drug is safe for use under such conditions." *Id.* Finally, the FDA must deny the NDA if "there is a lack of substantial evidence that the new drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." *Id.*

If a sponsor of an approved drug later seeks to change the label, market a new dosage or strength of the drug, or changes the way it manufactures a drug, the

company must submit a supplemental new drug application (sNDA) seeking FDA's approval of such changes. 21 U.S.C. § 355(b); 21 C.F.R. §§ 314.54, 314.70. The sNDA must also show that the drug is safe and effective for use under the conditions of use prescribed, recommended, or suggested in the proposed labeling. 21 U.S.C. § 355(d).

The FDA's 2000 Approval and 2016 Petition Denial violated the FFDCA because the U.S. clinical trial on which the FDA relied failed to evaluate the conditions of use under the approved label. For example, the clinical trial included these requirements: (1) each woman had to receive an ultrasound to confirm gestational age and exclude an ectopic pregnancy; (2) physicians were required to have experience in performing surgical abortions and have admitting privileges at medical facilities that could provide emergency care and hospitalization; (3) all patients needed to be within one hour of emergency facilities or the facilities of the principal investigator; and (4) the women needed to be monitored over the course of four hours to check for adverse events after taking misoprostol. App. 045.

The FDA included *none* of these crucial safeguards in the 2000 Approval. *Id.* 046. By not requiring the clinical trial to evaluate whether chemical abortion drugs are safe and effective without these safeguards, the FDA's approach conflicted with the requirements of the FFDCA and defied sound scientific policy. *See, e.g.*, *United States v. An Article of Device . . . Diapulse*, 768 F.2d 826, 832–33 (7th Cir. 1985) (upholding FDA's rejection of labeling because "the proposed labeling for the devices must specify conditions of use that are similar to those followed in the studies").

Similarly, the 2016 Major Changes violated the FFDCA because *none* of the studies on which the FDA relied were designed to evaluate the safety and effectiveness of chemical abortion drugs for use under the conditions prescribed, recommended, or suggested in the proposed labeling. App. 055–56. Not only did the FDA rely on studies that evaluated a drug regimen that did not match the labeling in the 2016 Major Changes, but the agency also took a piecemeal approach to evaluating the safety and effectiveness of its removal of necessary safeguards—despite acknowledging that "these major changes are interrelated." *Id.* 055–56.

For example, the FDA relied on a study to support extending the maximum gestational age to 70 days, changing the dosing regimen, and authorizing a repeat dose of misoprostol if the first dose fails. *Id.* 055–56. In this study, the abortionists (1) confirmed gestational age "based on routine ultrasound practices," (2) required the participants to return to the study site after the chemical abortion "for clinical assessment, which included ultrasonography," and (3) "intervened surgically if they deemed it medically necessary or at the patient's request." *Id.* 655. But the labeling that the FDA approved in the 2016 Major Changes did not require (1) an ultrasound to confirm gestational age, (2) an in-person follow-up exam using ultrasonography, and (3) an ability of abortionists to personally perform surgical abortion if necessary. *Id.* 055–56. The FDA's approved labeling needed to be at least as protective as the studies on which the agency purportedly relied to determine safety and effectiveness.

The FDA's 2021 Non-Enforcement Decision and 2021 Petition Response suffer similar infirmities. In removing the in-person dispensing requirement for

mifepristone, the FDA impermissibly relied on data from the FDA Adverse Event Reporting System (FAERS)—despite the agency's decision in 2016 to eliminate the requirement for abortionists to report non-fatal adverse events. *Id.* 066, 070–71. What's more, the FDA also cited certain studies to support the 2021 Petition Response, even though the agency conceded that "the ability to generalize the results of these studies to the United States population is hampered," "the usefulness of the studies is limited in some instances by small sample sizes and lack of follow-up information on outcomes with regard to both safety and efficacy," and the FDA "did not find any large clinical studies that were designed to collect safety outcomes in healthcare systems similar to the United States." *Id.* 072. These studies and the FAERS data cannot even conceivably meet the FFDCA's strict standards for showing a drug's safety and effectiveness.

C. The FDA's 2000 Approval, 2016 Major Changes, 2021 Non-Enforcement Decision, and 2021 Petition Response permit the distribution of chemical abortion drugs through means prohibited by certain federal laws.

The FDA's actions to approve chemical abortion drugs and subsequently eliminate necessary safeguards—the FDA's 2000 Approval, 2016 Major Changes, 2021 Non-Enforcement Decision, and 2021 Petition Response—all permit the distribution of these drugs through means that federal laws prohibit.

These federal laws expressly prohibit the distribution of chemical abortion drugs by mail, express company, or common carrier. Specifically, 18 U.S.C. § 1641 prohibits the mailing or delivery by any letter carrier of "[e]very article or thing designed, adapted, or intended for producing abortion" and "[e]very article,

instrument, substance, drug, medicine, or thing, which is advertised or described in a manner calculated to lead another to use or apply it for producing abortion." And 18 U.S.C. § 1462 forbids the use of "any express company or other common carrier" to transport chemical abortion drugs "in interstate or foreign commerce."

But the FDA's unlawful actions allow distribution of mifepristone by mail, express company, and common carrier. For example, the FDA's 2000 Approval contained certain restrictions on the distribution of mifepristone, *see* App. 523, but the FDA did not include prohibitions on the upstream distribution of mifepristone—from the manufacturer or importer to the abortionist—by mail, express company, or common carrier, nor did the FDA acknowledge and address these laws. *Id.* 040. The 2016 Major Changes suffered from the same shortcomings. *Id.* 055. The FDA's 2021 Non-Enforcement Decision and 2021 Petition Response further violated these laws when expressly allowing the "dispensing of mifepristone through the mail . . . or through a mail-order pharmacy." *Id.* 066. Neither of these 2021 decisions, however, acknowledged or addressed the federal laws expressly prohibiting such downstream distribution. *Id.* 066, 073.

D. The FDA's 2019 ANDA Approval for a generic version of mifepristone should be withdrawn.

The FDA also violated these federal laws and the FFDCA when it approved a generic version of mifepristone. The FFDCA allows a generic drug manufacturer to submit an abbreviated new drug application (ANDA) for premarket review and approval. 21 U.S.C. § 355(j); 21 C.F.R. § 314.94. The generic company must show that (a) the conditions of use prescribed, recommended, or suggested in the labeling

proposed for the new drug have been previously approved for a drug listed and (b) the drug product is chemically the same as the already approved drug, allowing it to rely on the FDA's previous finding of safety and effectiveness for the approved drug. *Id*. The route of administration, dosage form, and strength must also be the same. *Id*.

If the FDA withdraws the listed drug on which the ANDA-approved generic drug is based, the FFDCA and the FDA's implementing regulations generally require the FDA to withdraw the generic drug as well. 21 U.S.C. § 355(j)(6); 21 C.F.R. § 314.151. The grounds for withdrawing both the underlying drug and the generic drug include clinical or other experience, tests, or other scientific data that show that the drug is unsafe under the conditions of use upon the basis of which the application was approved. *Id*. Or the FDA can withdraw the drugs if new information shows that there is a lack of substantial information that the drugs will have the effect they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof. *Id*.

The 2019 ANDA Approval violated the FFDCA because the FDA relied on the unlawful 2000 Approval and 2016 Major Changes to approve GenBioPro's generic chemical abortion drug. Because the 2000 Approval and the 2016 Major Changes must be withdrawn for the reasons stated above, the 2019 ANDA must meet the same fate. Unable to rely on the unlawful 2000 Approval and 2016 Major Changes, the 2019 ANDA Approval violated the FFDCA because it lacked its own clinical

investigations, adequate testing, sufficient information, and substantial evidence to show the generic drug's safety and effectiveness.

III. There is a substantial threat that irreparable harm will result if the preliminary injunction is not granted.

"To satisfy the second element of the preliminary injunction standard, [Plaintiffs] must demonstrate that if the district court denied the grant of a preliminary injunction, irreparable harm would result." *Janvey*, 647 F.3d at 600. "Harm is irreparable where there is no adequate remedy at law, such as monetary damages." *Id.* (cleaned up). The injury must not be "speculative. . . . [T]here must be more than an unfounded fear on the part of the applicant." *Id.* (cleaned up). "If the currently existing status quo itself is causing one of the parties irreparable injury, it is necessary to alter the situation so as to prevent the injury . . . by the issuance of a mandatory injunction." *Canal Auth. of State of Fla.*, 489 F.2d at 576. Indeed, "[t]he focus always must be on prevention of injury by a proper order, not merely on preservation of the status quo." *Id.*

The FDA's actions on chemical abortion drugs cause real, significant, and ongoing harm to Plaintiffs. App. 016, 018, 075–80. Without a preliminary injunction, these injuries will continue. *Id.* 074, 076, 080. The physical and emotional trauma that chemical abortion inflicts on women and girls cannot be reversed or erased. The crucial time that doctors need to treat these injured women and girls cannot be replaced. The mental and monetary costs to these doctors cannot be repaid. And the time, energy, and resources that Plaintiff medical associations expend in response to the FDA's actions on chemical abortion drugs cannot be recovered.

IV. Plaintiffs' injuries and the harm threatened to the public outweighs the possible harm to Defendants, and injunctive relief will serve the public interest.

"The third and fourth requirements for issuance of a preliminary injunction—the balance of harms and whether the requested injunction will serve the public interest—'merge when the Government is the opposing party.'" *State of Texas v. Becerra*, 2022 WL 3639525, at *29 (N.D. Tex. Aug. 23, 2022) (citations omitted). Courts must "balance the harm that would be suffered by the public if the preliminary injunction were denied against the possible harm that would result to [Defendant] if the injunction were granted." *Miss. Power & Light Co. v. United Gas Pipe Line Co.*, 760 F.2d 618, 626 (5th Cir. 1985). "[P]ublic interest weighs strongly in favor of preventing unsafe drugs from entering the market." *Hill Dermaceuticals, Inc. v. U.S. Food & Drug Admin.*, 524 F. Supp. 2d 5, 12 (D.C. 2007). A preliminary injunction is appropriate where the "irreparable harm asserted is the adverse impact . . . on the public," and the "dominant presence of the public interest" is a "central issue in th[e] case." *Miss. Power & Light*, 760 F.2d at 623.

The public interest favors protecting women and girls from the harms of chemical abortion drugs. The FDA's actions have exposed women and girls to suffering physical pain, medical complications, and emotional trauma—and continue to do so. In addition, these actions harm doctors and their medical associations by causing them to respond to the FDA's failure to protect women and girls. The vital public interest in protecting women, girls, and their doctors from the harmful effects of chemical abortion warrant preliminary injunctive relief. *See id.* This interest is particularly strong where the unlawful actions likely were undertaken with the

unlawful purposes of bringing into being an illegal market—in this case, a nationwide mail-order abortion industry.

"[T]here is a strong public interest in meticulous compliance with the law by public officials," particularly by the FDA. *Fund for Animals, Inc. v. Espy*¸ 814 F. Supp. 142, 152 (D.C. 1993). The FDA's repeated disregard for federal law and evisceration of crucial safeguards for women and girls warrant immediate relief—before more women, girls, and their doctors suffer the consequences.

CONCLUSION

For the foregoing reasons, the Court should issue a preliminary injunction, without bond, ordering Defendants to: (1) withdraw or suspend its September 30, 2000, Approval of Mifeprex and its April 11, 2019, approval of Mifepristone Tablets, 200 mg, and remove them from the list of approved drugs; (2) withdraw or suspend its March 29, 2016, Approval of Danco Laboratories, LLC's supplemental new drug application for Mifeprex (Application Number: 020687Orig1s020); (3) withdraw or suspend its April 12, 2021, Non-Enforcement Decision letter, and December 16, 2021, Response to the 2019 Citizen Petition concerning the in-person dispensing requirement for mifepristone; and (4) enjoin Defendants from enforcing the Federal Food, Drug, and Cosmetic Act inconsistent with these orders while they remain in effect.[3]

[3] Because the injunctive relief requested would serve the public interest, Plaintiffs ask the Court to exercise its discretion to not require a security or bond under Fed. R. Civ. P. 65(c). *See City of Atlanta v. Metro. Atlanta Rapid Transit Auth.*, 636 F.2d 1084, 1094 (5th Cir. 1981).

Respectfully submitted this November 18, 2022.

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CERTIFICATE OF SERVICE

I certify that this document will be served on all defendants via USPS Priority Mail Express to the addresses listed in the complaint and on the summonses. In addition, I will cause courtesy copies of all filings in this case to be sent via USPS Priority Mail Express and via email to General Counsel Samuel R. Bagenstos, U.S. Department of Health and Human Services, 200 Independence Ave., S.W., Room 713-F, Washington, D.C. 20201, Samuel.Bagenstos@hhs.gov, and Isaac Belfer, U.S. Department of Justice, Civil Division, Consumer Protection Branch, 950 Pennsylvania Avenue, N.W., Washington, D.C. 20530, isaac.c.belfer@usdoj.gov.

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