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

Alliance for Hippocratic Medicine, *et al.*, Plaintiffs, v. U.S. Food and Drug Administration, *et al.*, Defendants.	Case No. 2:22-cv-00223-Z

Defendants' Opposition To Plaintiffs' Motion For A Preliminary Injunction

OF COUNSEL:

SAMUEL R. BAGENSTOS
General Counsel

MARK RAZA
Associate General Counsel
U.S. Department of Health
and Human Services
Chief Counsel
Food and Drug Administration

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

ARUN G. RAO
Deputy Assistant Attorney General

AMANDA N. LISKAMM
Acting Director

HILARY K. PERKINS
Assistant Director

NOAH T. KATZEN (D.C. Bar. No. 1006053)
Trial Attorney
Consumer Protection Branch
Civil Division
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044-0386
(202) 305-2428
(202) 514-8742 (fax)
Noah.T.Katzen@usdoj.gov

[Additional counsel on next page]

ERIC B. BECKENHAUER
Assistant Director

DANIEL SCHWEI
Special Counsel

JULIE STRAUS HARRIS
Senior Trial Counsel

CHRISTOPHER A. EISWERTH
EMILY NESTLER
KATE TALMOR
Trial Attorneys
Federal Programs Branch
Civil Division
U.S. Department of Justice

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INTRODUCTION

More than twenty-two years ago, the U.S. Food and Drug Administration (FDA) approved the drug mifepristone as safe and effective for the medical termination of intrauterine pregnancy under certain conditions. In this unprecedented action, Plaintiffs ask this Court to upend that longstanding scientific determination based on speculative allegations of harm offered in support of claims and arguments that are untimely, unexhausted, and without merit. Plaintiffs' motion for a preliminary injunction satisfies none of the requirements for the extraordinary relief they seek and should be denied.

Plaintiffs have not shown any likelihood of success on the merits. Their lawsuit relies on speculation to assert novel claims of injury that are not cognizable under Article III and that place Plaintiffs well outside the zone of interests protected by any relevant statute. Plaintiffs are attempting to challenge agency action long after the limitations period has expired and raising claims they did not exhaust with FDA. The only merits issues that possibly could be heard by this Court are those that Plaintiffs presented to FDA in a 2019 citizen petition. That petition challenged particular changes to the conditions of use and restrictions on the distribution of mifepristone. In responding to the 2019 petition, FDA reasonably rejected Plaintiffs' arguments.

Plaintiffs also fail to show that they will suffer imminent and irreparable harm without a preliminary injunction. Plaintiffs' speculative assertions of injury—made months and even decades after the agency actions they challenge—are unsupported by any evidence that Plaintiffs will be harmed by the availability of mifepristone absent an injunction. In contrast, issuance of a preliminary injunction would cause significant harm, depriving patients of a safe and effective drug that has been on the market for more than two decades. Entry of a preliminary injunction here would hardly serve the typical purpose of such relief—maintaining the status quo during the

pendency of litigation. Rather, it would upend the status quo and the reliance interests of patients and doctors who depend on mifepristone, as well as businesses involved with mifepristone distribution. The balance of the equities and the public interest thus also strongly favor denial of Plaintiffs' motion.

BACKGROUND

I. Statutory and Regulatory Background

Congress has entrusted to FDA the responsibility to ensure that "new drugs" are safe and effective. *See* 21 U.S.C. §§ 321(p), 355; *see also id.* § 393(b)(2)(B). The Federal Food, Drug, and Cosmetic Act (FDCA) generally prohibits the interstate distribution of new drugs that have not received FDA approval. *Id.* § 355(a). In deciding whether to approve a new drug, FDA evaluates whether a new drug application contains scientific evidence demonstrating that the drug is safe and effective for its intended uses. *Id.* § 355(d); *see also* 21 C.F.R. §§ 314.50, 314.105(c). Similarly, when a sponsor submits a supplemental new drug application proposing changes to the conditions of approval for a drug (such as changes to a drug's labeling or FDA-imposed restrictions), FDA reviews the scientific evidence to support the changes. *See* 21 C.F.R. § 314.70. To approve a generic version of a previously approved drug, FDA reviews whether an abbreviated new drug application contains information to show that the proposed generic drug is materially the "same" as the approved drug. 21 U.S.C. § 355(j)(2).

In furtherance of its statutory responsibilities, including the responsibility to determine whether to approve drugs as safe and effective for intended uses, FDA issued regulations in 1992 to authorize the imposition of conditions "needed to assure safe use" of certain new drugs that otherwise satisfy the requirements of the FDCA. Final Rule, 57 Fed. Reg. 58,942, 58,958 (Dec. 11, 1992) (codified at 21 C.F.R. § 314.520). The regulations, known as Subpart H, apply to certain new drugs "studied for their safety and effectiveness in treating serious or life-threatening

illnesses" that "provide meaningful therapeutic benefit to patients over existing treatments." 21 C.F.R. § 314.500.

In 2007, Congress enacted the Food and Drug Administration Amendments Act of 2007 (FDAAA), which (among other things) gave FDA authority to require a "risk evaluation and mitigation strategy" (REMS) when it determines that such a strategy is necessary to ensure that the benefits of a drug outweigh the risks. *See* Pub. L. No. 110-85, tit. IX, § 901 (codified at, *inter alia*, 21 U.S.C. § 355-1). This new authority codified and expanded FDA's Subpart H authority to impose restrictions on a manufacturer's distribution of a drug to assure safe use. Under the REMS framework, for certain drugs, FDA may include what are known as "elements to assure safe use," such as a requirement that a drug's prescribers have particular training or experience, that a drug be dispensed only in certain healthcare settings, or that a drug be dispensed only after documentation of safe use conditions is provided. 21 U.S.C. § 355-1(f)(3).

Congress expressly addressed in FDAAA how to incorporate drugs with existing Subpart H restrictions into the new REMS framework. *See* Pub. L. No. 110-85, tit. IX, § 909 (21 U.S.C. § 331 note). Congress "deemed" such drugs to have a REMS in effect upon the effective date of FDAAA, with the REMS imposing the restrictions previously imposed under Subpart H. *Id.* § 909(b). Congress provided that any such restrictions would continue to be required under the new statutory regime unless and until FDA determined that modifications were necessary. *Id.*; *see id.* § 355-1(g)(4)(B), (h) (authorizing FDA to require the sponsor to propose modifications to a drug's REMS). Since the effective date of Title IX of FDAAA, authority that FDA had asserted under the relevant portions of Subpart H has thus rested on the REMS provisions of FDAAA.

II. Factual and Procedural Background

A. FDA Actions Involving Mifepristone

FDA approved the marketing of mifepristone under the brand name Mifeprex in 2000. In

so doing, the agency determined, as to a particular manufacturer's application, that mifepristone is safe and effective for the medical termination of intrauterine pregnancy through 49 days gestation when used in a regimen with an already-approved drug, misoprostol. After following the approved regimen, the patient is expected to experience cramping and bleeding while the contents of the uterus are expelled, similar to a miscarriage. FDA extensively reviewed the scientific evidence and determined that the benefits of mifepristone outweigh any risks. Dkt. No. 8 (App.) 518-25.

When FDA originally approved Mifeprex, the agency relied upon Subpart H to place certain restrictions on the manufacturer's distribution of the drug product to assure its safe use.[1] For example, FDA imposed an in-person dispensing requirement and permitted the drug to be distributed only to prescribers who agreed to dispense it in certain healthcare settings, by or under the supervision of a qualified physician who attested to the ability to accurately date pregnancies and diagnose ectopic pregnancies. App. 523.

These "restrictions to assure safe use" (21 C.F.R. § 314.520) were in effect on the effective date of FDAAA. Accordingly, pursuant to FDAAA, mifepristone was "deemed to have in effect an approved [REMS]" that continued these restrictions. Pub. L. No. 110-85, § 909(b)(1); *see also* 73 Fed. Reg. 16,313 (Mar. 27, 2008); App. 598-602. FDA subsequently granted express approval to the mifepristone REMS after determining that it remained "necessary … to ensure the benefits of [mifepristone] outweigh the risks of serious complications." App. 599.

Later, on March 29, 2016, FDA approved a supplemental new drug application from the sponsor to alter Mifeprex's indication, labeling, and REMS. App. 616. Relying on safety and efficacy data from multiple studies, FDA increased the gestational age limit from 49 to 70 days.

[1] The Subpart H regulations are referred to as FDA's "accelerated approval" regulations. However, FDA's 2000 approval of mifepristone, which occurred more than four years after the new drug application was submitted to the agency, did not involve an "accelerated review," contrary to Plaintiffs' implication. *Compare* Dkt. No. 7 (Mot.) 14, *with* App. 527-29.

App. 631. FDA also reduced the number of required in-person clinic visits to one. The agency determined that at-home administration of misoprostol is safe because multiple studies showed that administration of the drug was "associated with exceedingly low rates of serious adverse events" and because administering misoprostol at home would more likely result in patients being in an "appropriate and safe location" when the cramping and bleeding caused by the drug would begin. App. 640. FDA also found no significant difference in outcomes based on whether patients had follow-up appointments via phone call or in-person or based on the timing of those appointments. App. 641. Additionally, FDA allowed a broader set of healthcare providers, rather than only physicians, to prescribe mifepristone, finding no serious risk to patients from expanding the types of healthcare providers who could become certified under the REMS. App. 641-42.

In 2019, FDA approved a different manufacturer's abbreviated new drug application for a generic version of mifepristone. App. 694-700. That decision did not in any way reevaluate the safety and efficacy of mifepristone. Instead, FDA's approval of the generic drug was based solely on FDA's determination that the generic drug was materially the "same" as brand-name Mifeprex. 21 U.S.C. § 355(j)(2). When it approved the abbreviated new drug application, FDA also approved the Mifepristone REMS Program, which covers both Mifeprex and the generic. App. 703.[2]

In April 2021, FDA decided to exercise enforcement discretion during the public health emergency with respect to the in-person dispensing requirement. App. 713-15. That decision stemmed from the finding that the availability of mifepristone by mail during a six-month period in which the in-person dispensing requirement had been enjoined, *see Am. Coll. of Obstetricians*

[2] For avoidance of doubt, this brief uses "mifepristone" to refer to drug products that are approved for medical termination of early pregnancy, in both branded and generic form. FDA has separately approved another manufacturer's distribution of the brand name drug Korlym, which uses mifepristone in the treatment of Cushing's syndrome. Defendants do not understand Plaintiffs' claims to seek any relief with respect to that separate drug approval.

& Gynecologists v. FDA, 472 F. Supp. 3d 183 (D. Md. 2020), *stayed by FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578, 578 (2021) (mem.), did not appear to show increases in serious safety concerns, according to the literature. App. 713-15.

On January 3, 2023, FDA approved a supplemental application, modifying the REMS by, *inter alia*, removing the in-person dispensing requirement.[3]

B. Plaintiffs' Citizen Petitions

Before asking a court to invalidate FDA's approval of a drug application, a plaintiff must first file a citizen petition raising its arguments to the agency. *See* 21 C.F.R. § 10.45(b); *see also* 21 U.S.C. § 355(e) (setting forth requirements for withdrawal of a drug approval). In 2002, Plaintiffs American Association of Pro-Life Obstetricians and Gynecologists ("AAPLOG") and the Christian Medical Association ("CMA") submitted a citizen petition asking FDA to withdraw the 2000 approval of mifepristone. App. 281-375. FDA denied the petition on March 29, 2016. App. 562-94. FDA addressed the petitioners' arguments and rejected them based on studies and other scientific evidence (including evidence postdating the 2000 approval) that continued to demonstrate that mifepristone was safe and effective for its indicated uses. App. 568-574, 578-89. FDA also rejected petitioners' challenge to the appropriateness of FDA's earlier reliance on Subpart H, explaining that mifepristone satisfied the regulatory prerequisites because it provides a meaningful therapeutic benefit to some patients experiencing a life-threatening condition (because pregnancy can be a serious medical condition for at least some women). App. 565-66.

In 2019, Plaintiffs AAPLOG and American College of Pediatricians ("ACP") submitted another citizen petition, this time challenging several aspects of the 2016 changes to the conditions of approval, including the REMS. App. 668-69, 672, 679. The 2019 petition did not ask FDA to

[3] Plaintiffs do not challenge the 2023 action in this case, but they seek to enjoin all of FDA's approvals of mifepristone, which would, practically, render FDA's recent action inoperative.

withdraw approval of mifepristone. App. 688-93. Rather, it asked FDA to "[r]etain" the REMS and its in-person dispensing requirement, and to "restore and strengthen elements of the [mifepristone] regimen and prescriber requirements approved in 2000" to: (1) limit mifepristone's use to 49 days gestation; (2) require the drug to be administered by or under the supervision of a physically present and certified physician who has ruled out ectopic pregnancy; (3) require three office visits; (4) include a contraindication for patients who do not have convenient access to emergency medical care; (5) require reporting of certain adverse events to FDA; and (6) require additional studies. App. 668-69.

On December 16, 2021, FDA responded to each of petitioners' arguments. App. 729-69. FDA "agree[d]" that, based on the data available at that time, certain of the REMS requirements "continue[d] to be necessary components" of safe distribution of mifepristone. App. 750-51. But FDA declined to make the changes that petitioners had requested. Indeed, FDA determined that the REMS "must be modified to remove" the in-person dispensing requirement because, based on FDA's review of, among other things, the REMS assessment data, postmarketing safety information, and the published literature, the requirement was no longer necessary to ensure the benefits of the drug outweigh the risks and removing it would reduce the burden on the healthcare delivery system. App. 750-64.

C. This Litigation

On November 18, 2022, Plaintiffs filed their complaint, challenging FDA's approval of mifepristone in 2000; FDA's approval of the supplemental new drug application and related changes to the conditions of approval, including the REMS, in 2016; and FDA's denial of the citizen petitions in 2016 and 2021. The complaint also challenges FDA's approval of the generic version of mifepristone in 2019 and FDA's decision in 2021 to exercise its discretion not to enforce the in-person dispensing requirement during the public health emergency. Plaintiffs' claims all

arise under the Administrative Procedure Act. Plaintiffs now seek a preliminary injunction on four grounds and ask this Court, among other things, to order Defendants "to withdraw or suspend *all* of [the] approvals of chemical abortion drugs." Mot. 7.

LEGAL STANDARD

"A preliminary injunction is an extraordinary remedy that should only issue if the movant shows: (1) a substantial likelihood of success on the merits; (2) a substantial threat of irreparable injury if the injunction is not granted; (3) the threatened injury will outweigh any harm that will result to [a] non-movant if the injunction is granted; and (4) the injunction will not disserve the public interest." *Ridgely v. FEMA*, 512 F.3d 727, 734 (5th Cir. 2008); *see also Ladd v. Livingston*, 77 F.3d 286, 288 (5th Cir. 2015). The third and fourth factors merge when the government is the party opposing the motion. *Nken v. Holder*, 556 U.S. 418, 435 (2009). A preliminary injunction "should not be granted unless the movant has clearly carried the burden of persuasion on all four requirements." *Dennis Melancon, Inc. v. City of New Orleans*, 703 F.3d 262, 268 (5th Cir. 2012) (quotation marks and citation omitted); *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008) (requiring a "clear showing"). "[I]f the [p]laintiff fails to satisfy even one" element, "the Court may logically conclude that [the] [p]laintiff fails to meet its burden—regardless of success on the other elements." *Mayo Found. for Med. Educ. & Rsch. v. BP Am. Prod. Co.*, 447 F. Supp. 3d 522, 528 (N.D. Tex. 2020) (Kacsmaryk, J.).

ARGUMENT

I. Plaintiffs' Claims Are Unlikely To Succeed On The Merits

Plaintiffs have not shown a likelihood of success as to any of their claims.

A. Plaintiffs Lack Standing and Are Outside the Zone of Interests

Plaintiffs lack standing to bring any of their claims. To meet the "irreducible constitutional minimum of standing," *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992), Plaintiffs "must show

(i) that [they] suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant[s]; and (iii) that the injury would likely be redressed by judicial relief," *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2203 (2021). An "injury-in-fact" must be "actual" or "certainly impending," *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013), not "conjectural" or "hypothetical," *Lujan*, 504 U.S. at 560. "'[A]llegations of possible future injury' are not sufficient." *Clapper*, 568 U.S. at 409 (quoting *Lujan*, 504 U.S. at 565 n.2). To satisfy the causation requirement, Plaintiffs must also show that their alleged injuries are "fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court." *Lujan*, 504 U.S. at 560. In addition to the requirements of Article III, plaintiffs challenging the actions of federal agencies must demonstrate that they are within the "zone of interests" protected or regulated by the statute in question. *Clarke v. Sec. Indus. Ass'n*, 479 U.S. 388, 395-96 (1987).

1. Plaintiff Physicians Lack Article III Standing

None of the individual Plaintiffs or the organizational Plaintiffs' physician members (collectively, the "complaining physicians") has established an injury-in-fact necessary to satisfy Article III. The complaining physicians are not themselves regulated by FDA, and they do not purport to prescribe mifepristone. *See Grocery Mfrs. Ass'n v. EPA*, 693 F.3d 169, 177 (D.C. Cir. 2012) (explaining that fuel manufacturers lacked standing to challenge EPA approval of a fuel they were not required to distribute). Rather, they contend that they will be injured—in a highly roundabout fashion—because *other* physicians will prescribe mifepristone to patients who will experience adverse events; those patients will seek care from a complaining physician; and the complaining physician will divert time and resources from other patients, subjecting them to "potential liability" exposure and insurance costs, and potentially causing them to suffer grief, distress, and guilt. Mot. 9-10. Plaintiffs also argue that FDA's actions prevent them from practicing

evidence-based medicine, harm the doctor-patient relationship, and deprive them of the opportunity to provide pregnancy care. Mot. 10.

Plaintiffs' allegations of injury to the complaining physicians fail because they depend upon layer after layer of speculation. They require Plaintiffs to establish that, despite the rarity of serious adverse events associated with mifepristone,[4] individuals who are prescribed mifepristone elsewhere will seek out the care of a complaining physician. Those patients then must cause disproportionate burdens, forcing the physician to neglect other patients and somehow exposing the complaining physician to new risks—perhaps because the hypothetical mifepristone users who seek out the complaining physicians after receiving mifepristone from other physicians will entrap their emergency physicians by providing an incomplete medical history and will then sue them for malpractice. *See, e.g.*, App. 865-67, 871-74, 880.

The speculative nature of these claims is self-evident. Courts have consistently rejected such theories of standing based on multi-tiered speculation because they "depend[] on the unfettered choices made by independent actors not before the courts and whose exercise of broad and legitimate discretion the courts cannot presume either to control or to predict." *Lujan*, 504 U.S. at 562 (quoting *ASARCO Inc. v. Kadish*, 490 U.S. 605, 615 (1989)); *see, e.g.*, *Clapper*, 568 U.S. at 414 ("speculative chain of possibilities" does not establish impending constitutional injury and declining to "endorse standing theories that rest on speculation about the decisions of independent actors"); *Little v. KPMG LLC*, 575 F.3d 533, 541 (5th Cir. 2009) (injury based on several layers of decisions by third parties too speculative to confer Article III standing).

Here, Plaintiffs do not even attempt to allege facts supporting the chain of causation. They do not corroborate any of the pecuniary harms that they purport to fear, nor any of the intangible

[4] *See* Katzen Decl., Ex. 1D, at 8, https://perma.cc/2UJ5-8WVF.

concerns that they raise. That omission is particularly telling given the more than two decades that mifepristone has been in use. If Plaintiffs' injuries had an evidentiary basis, then Plaintiffs would be able to marshal allegations grounded in fact rather than conjecture.

For example, Plaintiffs contend that treating patients who experience complications from mifepristone might cause the complaining physicians to divert time and resources from other patients. Mot. 9. Plaintiffs fail to acknowledge that the alternatives to mifepristone—surgical abortion or continued pregnancy—also have rates of complications, with childbirth's being substantially higher than mifepristone's. App. 565 n.6 ("The risk of childbirth related death was therefore approximately 14 times higher than the rate associated with legal abortion."). Even if it were appropriate to focus only on mifepristone, Plaintiffs make allegations only to support the isolated existence of adverse events[5]—but nothing that would remotely support Plaintiffs' sweeping and speculative assertion that adverse events from use of mifepristone will "overwhelm the medical system" and their medical practices in particular (Mot. 9). The declarations nowhere allege facts plausibly showing that such one-off incidents interfere with Plaintiffs' practices or with the treatment of other patients. *Contra* Ex. 5 (Zite Decl.) ¶¶ 10-14.

Plaintiffs' other assertions of injury to individual physicians are likewise based on a series of speculative contingencies. They contend that they will face increased liability exposure and insurance costs from treating patients who experience complications from mifepristone (*see, e.g.*, App. 873), but no Plaintiff or declarant claims to have been sued, threatened with a lawsuit, or required to pay increased insurance premiums. Moreover, Plaintiffs' own explanation for how they

[5] *See, e.g.,* App. 193-94 ¶¶ 2, 10 (Dr. Francis, who has worked at a hospital "for the last six years," but identifies only "several women" who have "present[ed] with complications"); App. 216 ¶ 23 (Dr. Wozniak, one patient over the last six months); App. 880 ¶ 16 (Dr. Delgado, who "expect[s] to see and treat more patients … with complications," but does not identify any past example); App. 886 ¶ 17 (Dr. Jester, citing a purported complication from a medical abortion).

might suffer this purely hypothetical injury depends on speculation about actions of third parties not traceable to FDA, *i.e.*, patients who will not accurately report their medical history—again, citing no concrete evidence in support. *See* App. 89-90. Plaintiffs also express fear that treating hypothetical future patients will cause them distress, grief, or guilt in the unlikely event that they were somehow "force[d]" to "complete an unfinished elective abortion." App. 160-61, Mot. 9. But no complaining physician alleges that he or she has ever been forced to "complete an unfinished elective abortion," nor do Plaintiffs provide any evidence that such injury is likely, much less imminent. Indeed, their own statements confirm that their fears of having to assist in an abortion resulting from mifepristone complications are based on speculation alone. *See, e.g.*, App. 160-61 ("FDA's removal of safeguards *could* force CMA members … to complete an unfinished elective abortion") (emphasis added).

Plaintiffs assert that patients' ability to choose medication abortion deprives them of the "opportunity to provide professional services and care for the woman and child through pregnancy." App. 87, 90. But this assumes—without evidence—that patients seeking medication abortion from a different provider would, in the absence of mifepristone, switch to a complaining physician's practice and opt to carry their pregnancies to term. *Compare* Zite Decl. ¶ 11; Ex. 2 (Lindo Decl.) ¶¶ 47-48 (explaining that, if mifepristone becomes unavailable, individuals prevented from obtaining medication abortions from healthcare providers will seek out surgical abortions or else attempt to self-manage their abortions). Plaintiffs also fail to substantiate their vague assertions that, by not requiring healthcare providers to report non-fatal adverse events, FDA prevents physicians "from practicing evidence-based medicine" and "harms the doctor-patient relationship." Mot. 10.[6] Indeed, no Plaintiff or medical association member claims to

[6] Plaintiffs do not square their objection to having to spend time reporting adverse events with their competing objection that FDA no longer requires healthcare providers to report non-fatal

consult with patients on whether they should take mifepristone.

Even if Plaintiffs could substantiate their standing theories with nonspeculative allegations, those allegations must pertain to a judicially cognizable injury—*i.e.*, one that satisfies the concreteness requirement. Where, as here, a plaintiff claims intangible harm, courts assess whether the asserted harm "has a close relationship to a harm that has traditionally been regarded as providing a basis for a lawsuit in English or American courts." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 340-41 (2016). Plaintiffs do not cite any decision, from any court, endorsing a physician's right to bring suit to advance an interest in evidence-based medicine, or an undefined interest in the physician-patient relationship, or an interest in avoiding adverse events for their patients, or an interest in avoiding new business for themselves. Mot. 10.

Indeed, Plaintiffs' approach to standing would entitle physicians to sue over virtually any FDA action. As Plaintiffs' argument runs, if FDA approved a new heart medication, emergency physicians would have standing to challenge the approval on the theory that some patients would experience adverse events under the new treatment; in contrast, cardiologists would have standing to challenge the approval on the theory that some patients would no longer require their services. This guaranteed pathway to challenge any government action would not be limited to FDA actions. Physicians could sue the National Highway Traffic Safety Administration for agency actions that caused (or prevented) traffic accidents; or pediatricians could sue the U.S. Department of Agriculture for standards that improved (or imperiled) student nutrition. The breathtaking consequences for Plaintiffs' theories of standing, in the absence of historical or statutory support, is a strong indication that Plaintiffs' injuries are not judicially cognizable.[7]

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adverse events. *Contra* App. 82 ("The FDA's elimination of the requirement for abortionists to report all adverse events related to chemical abortion leads to unreliable reporting.").

[7] For similar reasons, Plaintiffs cannot claim third-party standing on behalf of their patients. *See Ass'n of Am. Physicians & Surgeons v. FDA*, 13 F.4th 531, 547 (6th Cir. 2021) (third-party

2. Plaintiff Medical Associations Lack Article III Standing

The medical associations also lack standing. They argue both that they have associational standing based on alleged injuries to their members, and that they have organizational standing because (they allege) FDA's actions have caused them to divert time and resources and have frustrated their ability to provide their members, patients, and the public with accurate information. *See* Mot. 7-8; *OCA-Greater Houston v. Texas*, 867 F.3d 604, 610 (5th Cir. 2017). Plaintiffs' theory of associational standing fails because, as explained in the preceding section, the medical associations have not identified any member with a non-speculative and legally cognizable injury-in-fact. *See OCA-Greater Houston*, 867 F.3d at 610. The medical associations' theory of organizational standing fails because neither their alleged diversion of resources nor their alleged informational injury satisfies Article III.

First, Plaintiffs' allegation that FDA's actions have forced them to divert resources does not establish standing because that injury is self-inflicted and unsubstantiated. Plaintiffs "cannot manufacture standing merely by inflicting harm on themselves based on their fears of hypothetical future harm that is not certainly impending." *Clapper*, 568 U.S. at 416; *see also Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 919-20 (D.C. Cir. 2015); *La Union del Pueblo Entero v. Abbott*, No. 21-CV-0844, 2022 WL 3052489, at *32 (W.D. Tex. Aug. 2, 2022).

Plaintiffs say that they have had to divert their resources away from unspecified priorities in order to "educate and inform their members, their patients, and the public on the dangers of chemical abortion drugs." Mot. 7. But in so alleging, Plaintiffs have failed to identify any Article III injury that their alleged diversion of resources is necessary to avoid. Nor have they sought to

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standing "does not relieve plaintiffs of the need to independently establish their *own* Article III standing") (emphasis added). And notwithstanding Plaintiffs' suggestion, *June Medical Services LLC v. Russo*, 140 S. Ct. 2103 (2020), is not to the contrary. There, physicians had Article III standing to challenge regulations of physician conduct and threats of sanctions. *Id.* at 2119.

substantiate how that alleged diversion has impeded their mission, such as by "identif[ying] … specific projects" harmed by that diversion. *N.A.A.C.P. v. City of Kyle*, 626 F.3d 233, 238 (5th Cir. 2010); *see also Tenth St. Residential Ass'n v. City of Dallas*, 968 F.3d 492, 500 (5th Cir. 2020) (finding no organizational standing because "[c]ritically, [the plaintiff] provided no evidence that its members were required to forego other projects or causes as a result of" challenged conduct).

Second, Plaintiffs' allegations that FDA has "frustrated and complicated" their "ability to educate and inform their members, their patients, and the public" likewise fail to establish standing. Plaintiffs cannot claim injury from FDA's decision not to require broader reporting of adverse events because they are not statutorily entitled to such information. *See U.S. Inventor Inc. v. Vidal*, No. 21-40601, 2022 WL 4595001, at *7 (5th Cir. Sept. 30, 2022) ("An informational injury occurs if a plaintiff fails to obtain information that must be publicly disclosed pursuant to a statute.").[8]

3. Plaintiffs Are Outside the Zone of Interests

Plaintiffs also have not demonstrated that they are within the zone of interests of the FDCA drug approval provisions that they invoke. A plaintiff falls outside the zone of interests when its "interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit." *Clarke*, 479 U.S. at 399. Whether Plaintiffs satisfy "the zone-of-interests test is to be determined not by reference to the overall purpose of the Act in question … but by reference to the particular provision of law upon which the plaintiff relies." *Bennett v. Spear*, 520 U.S. 154, 175-76 (1997).

While Plaintiffs contend that the "legal and regulatory framework" of the FDCA as a whole

[8] In any event, Plaintiffs must demonstrate standing for every claim that they bring. *Ortiz v. Am. Airlines, Inc.*, 5 F.4th 622, 628 (5th Cir. 2021). At most, Plaintiffs' contentions that they have diverted resources to analyze adverse events and have been frustrated in their ability to educate their members, patients, and the public about adverse events would be relevant to FDA's decision to remove the REMS requirement that certified prescribers report non-fatal adverse events. But Plaintiffs do not assert that decision as a basis for a preliminary injunction.

protects physicians' interests, Mot. 10, they identify no particular provision of the FDCA protecting such interests, and physicians cannot satisfy the zone of interests test by generally invoking the overall purposes of the FDCA. *See, e.g., Ass'n of Am. Physicians & Surgeons, Inc. v. FDA*, 539 F. Supp. 2d 4, 18 (D.D.C. 2008) (holding that physicians were not within the zone of interests in challenge to FDA approval of supplemental new drug application), *aff'd*, 358 F. App'x 179 (D.C. Cir. 2009).[9]

B. The Vast Majority of Plaintiffs' Challenges Are Untimely or Unexhausted

1. All of Plaintiffs' Claims Are Untimely or Unexhausted, Except Their Narrow Challenge to FDA's 2021 Response to the 2019 Citizen Petition

All of Plaintiffs' claims are untimely or unexhausted except their challenge to FDA's December 16, 2021, response to the 2019 citizen petition.

First, there is a six-year statute of limitations to challenge each agency action. *See* 28 U.S.C. § 2401(a). FDA approved the new drug application for mifepristone in 2000. FDA responded to Plaintiffs' 2002 citizen petition, which challenged the 2000 approval (*see* App. 280), on March 29, 2016. Both agency actions occurred more than six years before Plaintiffs filed this suit on November 18, 2022. Thus, the statute of limitations plainly bars Plaintiffs' challenge to FDA's underlying approval of mifepristone, including its response to the 2002 citizen petition.

Second, Plaintiffs cannot challenge FDA's approval of the supplemental new drug application for the generic version of mifepristone. Although FDA took that action in 2019, Plaintiffs have not exhausted their administrative remedies to challenge the action. That omission is fatal because "[exhaustion] is required … by agency rule as a prerequisite to judicial review."

[9] Plaintiffs also invoke the Comstock Act, which in some circumstances imposes criminal restrictions on mailing abortion-inducing drugs or sending them by common carrier. *See* 18 U.S.C. §§ 1461, 1462; Mot. 20-21. But Plaintiffs do not explain how they are within the zone of interests of that criminal statute, and they could not plausibly do so.

Darby v. Cisneros, 509 U.S. 137, 153 (1993). As Plaintiffs themselves acknowledge, Mot. 11, FDA regulations explicitly require litigants to file "a [citizen] petition under [21 C.F.R.] § 10.25(a) … before any legal action is filed in a court," 21 C.F.R. § 10.45(b). Because Plaintiffs "filed no such citizen petition with FDA contesting the [2019 generic] approval," their challenge cannot proceed. *Ass'n of Am. Physicians v. FDA*, 358 F. App'x 179, 181 (D.C. Cir. 2009); *see also Cody Labs., Inc. v. Sebelius*, 446 F. App'x 964, 969 (10th Cir. 2011) ("Courts have often dismissed suits against the FDA for failure to utilize the citizen petition procedure.").

2. Review of FDA's December 2021 Petition Response Is Limited to the Narrow Issues Presented in the 2019 Citizen Petition

When FDA denies a petition to rescind an agency action, judicial review of the denial is strictly "limited to the 'narrow issues as defined by the denial of the petition'" and does not otherwise reach "the agency's original action." *NLRB Union v. FLRA*, 834 F.2d 191, 196 (D.C. Cir. 1987) (quoting *Prof'l Drivers Council v. Bureau of Motor Carrier Safety*, 706 F.2d 1216, 1217 n.2 (D.C. Cir. 1983)); *cf. McAfee v. FDA*, 36 F.4th 272, 277 (D.C. Cir. 2022); *DiGiovanni v. FAA*, 249 F. App'x 842, 844 (2d Cir. 2007). This framework applies the usual rule that courts "will not ordinarily consider arguments that a litigant could have raised before an agency but chose not to." *Palm Valley Health Care, Inc. v. Azar,* 947 F.3d 321, 327 (5th Cir. 2020); *see* 21 C.F.R. § 10.45(f) (providing that, in an action under the APA, FDA "shall take the position" that "views" not raised in the administrative record "may not be considered").

Here, Plaintiffs' 2019 citizen petition did not ask FDA to reconsider or revoke the approval of mifepristone or otherwise revisit the agency's 2000 approval decision. App. 667-93. Instead, the petition expressly asked FDA to "restore and strengthen elements of the [mifepristone] regimen and prescriber requirements approved in 2000," specifically concerning the gestational limit for use of mifepristone; requirements for administration under the supervision of a physician; the

number of office visits; contraindication for patients without convenient access to emergency care; adverse-event reporting; and additional studies. App. 668. The petition also asked FDA to "[c]ontinue limiting" dispensing "to patients in clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber" on the sole ground that these measures were necessary for patient safety. App. 681-92. Those are the specific—and the only—claims that were presented to FDA and rejected by the agency in its December 2021 response to the petition, App. 730-31. No other issues can be raised in a challenge to the decision. *See NLRB Union*, 834 F.2d at 196.

Plaintiffs nevertheless seek to use FDA's 2021 response to the 2019 petition as a hook for raising issues to this Court that are wholly absent from both the 2019 petition and FDA's 2021 response to that petition. But Plaintiffs cannot fault FDA for failing to "acknowledge or address" issues that Plaintiffs never raised. Mot. 21. In particular, the response to the 2019 petition provided no mechanism to review FDA's approval of mifepristone in 2000 (Mot. 14-18), which the petition did not ask FDA to reconsider or withdraw. *Contra* App. 668 ("The undersigned submit this petition to request the Commissioner of Food and Drugs to: … retain the Mifeprex Risk Evaluation and Mitigation Strategy (REMS), and continue limiting the dispensing of Mifeprex to patients in clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber."). Nor does the response provide a basis to review Plaintiffs' arguments regarding Subpart H of FDA's regulations or FDA's failure to impose limits allegedly based upon the Comstock Act, none of which was raised in the 2019 petition. *See McAfee*, 36 F.4th at 277 (refusing to reach arguments challenging FDA's statutory authority that were not made in citizen petition); *Koretoff v. Vilsack*, 707 F.3d 394, 398 (D.C. Cir. 2013) (per curiam).

Plaintiffs' reliance on the reopening doctrine, *see* Mot. 11-12, does not alter the analysis. That doctrine applies when "an agency reconsider[s] a previously decided matter," because "if the

agency has opened the issue up anew . . . its renewed adherence is substantively reviewable." *Nat'l Ass'n of Reversionary Prop. Owners v. Surface Transp. Bd.*, 158 F.3d 135, 141 (D.C. Cir. 1998) ("*NARPO*"); *see also, e.g.*, *Sierra Club v. EPA*, 551 F.3d 1019, 1024-25 (D.C. Cir. 2008) (agency revisiting a regulation); *Texas v. Biden*, 20 F.4th 928, 951 (5th Cir. 2021), *rev'd on other grounds sub nom. Biden v. Texas*, 142 S. Ct. 2528 (2022) (agency revisiting termination of a policy). The doctrine is not triggered merely because the agency has responded to a citizen petition; "[a]n agency is normally obliged under the Administrative Procedure Act to issue some sort of explanation when it denies a petition." *Nat'l Mining Ass'n v. U.S. Dep't of Interior*, 70 F.3d 1345, 1352 (D.C. Cir. 1995). "A reopening has occurred only if 'the entire context demonstrates that the agency has undertaken a serious, substantive reconsidering of the existing rule.'" *Texas*, 20 F.4th at 952 (quoting *Growth Energy v. EPA*, 5 F.4th 1, 21 (D.C. Cir. 2021) (per curiam)). Further, only agency action within the limitations period can provide the basis for reopening. *See id.* at 951. The reopening doctrine does not apply here.

In no way did the 2021 petition response reconsider the underlying approval of mifepristone. FDA's "statement of denial of the petition," which merely "responded to assertions in the petition," is not "sufficient to trigger the reopening doctrine." *Nat'l Min. Ass'n*, 70 F.3d at 1351-52. Indeed, far from requesting that the 2000 approval be revisited or withdrawn, the 2019 petition affirmatively urged FDA to "Retain the Mifeprex REMS." App. 669.

FDA also did not reconsider the underlying approval of mifepristone when it modified the REMS in 2016. That decision made targeted alterations to the conditions of approval for mifepristone. The agency never "announc[ed] an intention to reconsider" the underlying approval, "never asked for comments" in relation to that decision, and otherwise left no doubt that the agency intended to "continue[], rather than reopen[]," that decision. *Texas*, 20 F.4th at 954-55; *see also*

NARPO, 158 F.3d at 144 (asking whether the agency conducted a "wholesale review" or intended to "revisit the distinct and settled subject" of the earlier decision). Nor did FDA constructively reopen the earlier approval. Courts have found constructive reopening where the agency made "extensive changes" that "significantly alter[ed] the stakes of judicial review," recognizing that prior to such changes the agency's decision "may not have been worth challenging" on its own. *See Sierra Club*, 551 F.3d at 1025-26 (citing *Kennecott Utah Copper Corp. v. U.S. Dep't of Interior*, 88 F.3d 1191, 1227 (D.C. Cir. 1996)). But here, the 2016 changes to the conditions of approval plainly did not alter Plaintiffs' litigation calculus with respect to the 2000 approval of mifepristone: Plaintiffs challenged the 2000 approval by filing a citizen petition in 2002. But they did not seek judicial review of FDA's denial of that petition during the limitations period.

No other agency action supports Plaintiffs' reopening theory. The approval of the generic version of mifepristone in 2019 did not reopen any issues related to the approval of Mifeprex in 2000. The generic approval simply determined that the generic version of the drug is materially the "same" as the approved version; it did not reconsider whether the approved version met the approval requirements. 21 U.S.C. § 355(j)(2).

Finally, to the extent Plaintiffs seek to challenge FDA's enforcement discretion regarding the in-person dispensing requirement, Mot. 19-20, that challenge would be foreclosed under *Heckler v. Chaney*, 470 U.S. 821, 832 (1985); *see* 5 U.S.C. § 701(a)(2). Such a challenge would, moreover, be moot, given FDA's subsequent approval of supplemental new drug applications to remove the in-person dispensing requirement. *See supra* p. 6 & n.3.

C. Plaintiffs' Claims Are Likely To Fail On The Merits

In any event, each of Plaintiffs' claims is likely to fail on the merits.

1. Plaintiffs' FDCA Challenge to FDA's Response to the 2019 Citizen Petition Should Be Rejected

Plaintiffs' sole timely and exhausted claim is their challenge to FDA's 2021 response to the 2019 citizen petition as allegedly contrary to the FDCA. That claim fails because FDA's rejection of the arguments in the petition was reasonable and not contrary to law. Plaintiffs identify no sound reason for the Court to second-guess FDA's scientific judgments nor any provision of the FDCA that supports their contentions.

Plaintiffs' challenge to the 2021 petition response rests on the contention that FDA relied improperly on certain clinical trials and adverse-event reporting data. *See* Mot. 19-20. In reviewing Plaintiffs' claims, this Court's role is to "simply ensur[e] that the agency has acted within a zone of reasonableness." *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). FDA is due deference "where the parties disagree on the science" because "Congress deemed only the FDA as the scientific expert here—not the federal courts." *Wages & White Lion Invs., L.L.C. v. FDA*, 41 F.4th 427, 436 (5th Cir. 2022).

Here, FDA's decisions were "reasonable and reasonably explained." *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2571 (2019). Each conclusion rested on FDA's expert scientific judgment with respect to the conditions of use. *See* App. 750-51 ("FDA's determination as to whether a REMS is necessary to ensure that the benefits of a drug outweigh its risks is a complex, drug-specific inquiry, reflecting an analysis of multiple, interrelated factors and of how those factors apply in a particular case."). This Court should defer to FDA's "scientific analysis of the evidence before it." *Pharm. Mfg. Research Servs., Inc. v. FDA*, 957 F.3d 254, 262 (D.C. Cir. 2020); *Texas v. EPA*, 690 F.3d 670, 677 (5th Cir. 2012).

Specifically, in affirming its 2016 conclusion that mifepristone can safely be used up to 70 days gestation, FDA's 2021 petition response cited studies that "showed comparable efficacy" and only "rare" serious adverse events from using mifepristone up to 70 days gestation. App. 736-38.

Additionally, FDA determined that "the increase in failure rate with each incremental week of gestation, as described in approved mifepristone labeling, is small," consistent with a published meta-analysis. App. 738. Plaintiffs cite one particular study in arguing that FDA "rel[ied] on studies" that did not "match" the conditions of use described in mifepristone's approved labeling, Mot. 19, but FDA's analysis makes clear that it relied on a multitude of studies, the vast majority of which Plaintiffs do not challenge. *See* App. 736 (discussing 22 studies); *see also* Katzen Decl., Exs. 1A, at 32-38, https://perma.cc/SR23-X9LJ, and 1B, at 15-16, https://perma.cc/5KSW-Q6AF.

Plaintiffs frame their disagreement as an argument that FDA "violated the [FDCA]" by relying on studies that evaluated use of mifepristone in a "drug regimen that did not match" FDA's approved labeling. Mot. 17, 19. But Plaintiffs point to no statutory provision requiring the conditions of use in a drug's approved labeling to duplicate the protocol requirements used in the studies supporting its approval. Instead, the statute instructs FDA to refuse to approve an application (including a supplement to an approved application) if, *inter alia*, considering "the information submitted . . . as part of the application" and "any other information" before the agency regarding the drug, there is "insufficient information to determine whether such drug is safe for use under" the proposed conditions of use, or a "lack of substantial evidence that the drug will have the effect it purports or is represented to have" under such conditions. 21 U.S.C. § 355(d)(4), (5). The FDCA thus requires FDA to apply its scientific expertise in determining whether a drug has been shown to be safe and effective under particular conditions of use, and the application of that expertise is owed substantial deference. 21 C.F.R. §§ 314.105(c), 314.125(b)(2); *see Schering Corp. v. FDA*, 51 F.3d 390, 399 (3d Cir. 1995) ("[J]udgments as to what is required to ascertain the safety and efficacy of drugs falls squarely within the ambit of the FDA's expertise and merit deference from us."). As FDA has explained, "[m]any clinical trial designs are more restrictive

(*e.g.*, additional laboratory and clinical monitoring, stricter inclusion and exclusion criteria, more visits) than will be necessary or recommended in post-approval clinical use; this additional level of caution is exercised until the safety and efficacy of the product is demonstrated." App. 589.

Plaintiffs' challenge to FDA's decision that the REMS should be modified to eliminate the in-person dispensing requirement also fails. Plaintiffs assert that certain studies had limitations (Mot. 20), but the FDCA does not require FDA to consider only data free from limitations in making approval and REMS modification decisions. *See* 21 U.S.C. §§ 355, 355-1(g). *See Huawei Techs. USA, Inc. v. FCC*, 2 F.4th 421, 453 (5th Cir. 2021) (reasoning that an agency's decision was not arbitrary and capricious when "it acted on the imperfect data it had"). In determining that patient safety did not require in-person dispensing in clinics, medical offices, or hospitals, FDA reviewed a wealth of data and concluded that "mifepristone will remain safe and effective if the in-person dispensing requirement is removed, provided all the other requirements of the REMS are met and pharmacy certification is added." App. 754-65. Plaintiffs also fault FDA for relying on adverse-event reporting data (Mot. 20), but the fact that FDA stopped mandating that certified prescribers report non-fatal adverse events to sponsors does not render unlawful the agency's reliance on data that were reported. 21 C.F.R. §§ 314.80, 314.81, 314.98. Plaintiffs offer no explanation for why it was impermissible to rely on the reported data.

In short, each of FDA's judgments was grounded in scientific evidence, reasonably explained, and lawful. There is no basis to remand for reconsideration of any aspect of FDA's petition response (which is the maximum relief that could be available for this claim).

2. Plaintiffs' Untimely FDCA Challenges to the 2000 Approval and 2016 Citizen Petition Response Should Also Be Rejected

As explained above, Plaintiffs' remaining challenges—to the 2000 approval of mifepristone and FDA's 2016 citizen petition response—are untimely. In those challenges,

Plaintiffs assert (1) that FDA violated the FDCA because FDA did not include in the approved conditions of use certain conditions present in the clinical studies on which it relied, and (2) that Subpart H did not authorize FDA's approval. Each claim is likely to fail on the merits.

a. Plaintiffs' Limited Safety and Efficacy Claim Is Likely To Fail

Plaintiffs contend that FDA violated the FDCA by failing to replicate all of the protocol requirements in the U.S. clinical trial in the ensuing conditions of approval. Mot. 17-18. This claim fails on multiple grounds.

Plaintiffs did not raise the claim in their 2019 citizen petition. Had they done so, their otherwise untimely claim would be subject only to "extremely limited" review in district court. *NLRB Union*, 834 F.2d at 196; *see McAfee*, 36 F.4th at 274 ("extremely limited and highly deferential"). Plaintiffs cannot satisfy typical APA review, much less a heightened standard.

As discussed above, FDA's approval of mifepristone in 2000 rested on a comprehensive evaluation of the scientific data, and FDA reasonably determined, in its expert judgment, that the evidence before it demonstrated that the drug was safe and effective for abortions under the specified conditions. *See* App. 518-25, 562-94. As FDA explained in its initial approval memorandum, it reviewed three separate clinical trials involving more than 2,500 pregnant patients, and those trials provided substantial evidence of effectiveness and showed a low rate of serious adverse events. *See* App. 518; *see also* App. 568-75, 585 (citing studies reporting no deaths, very few blood transfusions, and very low rates of surgical intervention). Indeed, when it reviewed the data from the two larger trials (even before the U.S. clinical trial data were available for its review), FDA's Reproductive Health Drugs Advisory Committee voted unanimously (with two abstentions) that mifepristone's benefits outweighed its risks. App. 518.

Plaintiffs' only argument is that the U.S. clinical trial included "safeguards" that were not incorporated into the conditions of use for mifepristone that FDA approved in 2000. Mot. at 18.

But, as explained above, there is no legal basis for Plaintiffs' contention that the approved conditions of use of a drug must duplicate the protocol requirements for the clinical trials supporting its approval. *See supra* pp. 22-23. Here, FDA thoroughly explained why the protocol requirements in the clinical trials were unnecessary for the safe and effective use of mifepristone. *See* App. 579-82; App. 521-22. In any event, Plaintiffs' criticism of the clinical data previously considered by FDA does not present any new evidence that works a "fundamental change in the factual premises" of FDA's findings. *McAfee*, 36 F.4th at 274. Ultimately, Plaintiffs offer no basis for this Court to supplant FDA's considered judgment of the scientific evidence.

b. Plaintiffs' Subpart H Claim Is Likely To Fail

Plaintiffs contend that FDA erred in invoking its Subpart H regulations, 21 C.F.R. §§ 314.500, 314.560 *et seq.*, as part of the 2000 approval of mifepristone. Mot. 14-16. Plaintiffs misconceive of Subpart H as the source of approval authority. *E.g.*, Mot. 4, 14. To the contrary, FDA's authority to approve the marketing of new drug products stems from the FDCA; Subpart H is a regulatory implementation of its statutory authority. In any event, Plaintiffs failed to raise a challenge to compliance with Subpart H in the 2019 citizen petition, so they cannot pursue such a claim here. Moreover, Plaintiffs fail to show any error of law, much less a "plain error" sufficient to overturn FDA's longstanding decision. *McAfee*, 36 F.4th at 274.

As an initial matter, Plaintiffs' arguments about Subpart H have been overtaken by congressional action. In FDAAA, Congress specifically directed that drugs with elements to assure safe use "in effect on the effective date of this Act" (like mifepristone) would be "deemed to have in effect an approved" REMS. Pub. L. No. 110-85, § 909(b)(1). Even if this Court were now to conclude that FDA should not have relied on Subpart H in 2000, that would not change the incontrovertible fact that mifepristone's restrictions were "in effect on the effective date of this Act", *id*., and thus that mifepristone was incorporated into the REMS statutory framework pursuant

to Congress's mandate. Indeed, Congress was well aware that FDAAA would be "deem[ing]" mifepristone to have a REMS.[10]

Moreover, in 2011, FDA approved a proposed REMS that the mifepristone application holder was required to submit under FDAAA. Pub. L. No. 110-85, § 909(b)(3); App. 599. Plaintiffs do not dispute that mifepristone is eligible for approval under the REMS statutory framework (*see* 21 U.S.C. § 355-1(a)(1) (applying the framework to drugs intended to treat "a disease or condition")), so any hypothetical error in the initial reliance on Subpart H would have no continuing impact on mifepristone's current approval under 21 U.S.C. § 355-1 and independently under FDA's 2011 action.

In any event, FDA's reliance on Subpart H was appropriate. FDA promulgated Subpart H as an implementation of its authority, under the FDCA, to (among other things) approve new drugs only if safe for use under the conditions prescribed, recommended, or suggested in their labeling. Subpart H is available for new drugs that (1) "have been studied for their safety and effectiveness in treating serious or life-threatening illnesses," and (2) "provide meaningful therapeutic benefit to patients over existing treatments." 21 C.F.R. § 314.500. Both prongs were satisfied here.

On the first prong, Plaintiffs' contention that "[p]regnancy is not an illness," Mot. 14, ignores FDA's consistent construction of its own regulation. In the final rule, FDA explained that Subpart H was available for serious or life-threatening "conditions," whether or not they were understood colloquially to be "illnesses." 57 Fed. Reg. 58,942, 58,946 (Dec. 11, 1992); *see also* App. 565 (confirming that "the subpart H regulations are intended to apply to serious or life-threatening conditions, as well as to illnesses or diseases"). FDA's contemporaneous use of

[10] *See* 153 Cong. Reg. S5759, 5765 (daily ed. May 9, 2007) (statement of Sen. Coburn) (reflecting congressional awareness that mifepristone would be distributed under a deemed REMS following the enactment of FDAAA); 153 Cong. Rec S5444, 5469 (daily ed. May 2, 2007) (statement of Sen. DeMint) (same).

"condition" in the Subpart H preamble provides "direct insight into what the rule was intended to mean" and "what it was supposed to include." *Kisor v. Wilkie*, 139 S. Ct. 2400, 2412 (2019).[11] Congress subsequently ratified FDA's understanding of its regulation by applying the REMS statutory framework to drugs for treating a "disease or condition" through FDAAA. 21 U.S.C. § 355-1(a)(1).

As to the second prong of § 314.500, Plaintiffs' attempt to second-guess FDA's determination that mifepristone offers a "meaningful therapeutic benefit," Mot. 16, is unavailing. Plaintiffs' assertion that abortion drugs "are not an alternative 'therapy' for patients unresponsive to, or intolerant of, surgical abortion" because some patients require surgical intervention after the medication regimen, *id.*, is belied by the evidence before FDA. As FDA explained in denying the 2002 citizen petition, "medical abortion through the use of Mifeprex provides a meaningful therapeutic benefit to some patients over surgical abortion," because it "avoided an invasive surgical procedure and anesthesia in 92 percent" of patients in the trial. App. 566. Avoidance of surgery provides therapeutic benefits by minimizing the risk of complications from anesthesia or sedation, including "a severe allergic reaction, a sudden drop in blood pressure with cardiorespiratory arrest, death, and a longer recovery time" as compared to medication. *Id.* FDA reasonably found these benefits to support approval—a conclusion plainly not contrary to law.

At a minimum, FDA's authority to approve mifepristone outside of Subpart H—whether under FDAAA's REMS provision or under the agency's preexisting statutory authority, *see* 57 Fed. Reg. 13234, 13237 (Apr. 15, 1992)—means that the appropriate remedy for any improper invocation of Subpart H would be remand without vacatur. No greater relief could be warranted because FDA would have authority to confirm that mifepristone has already been approved outside

[11] Plaintiffs state that the initial sponsor of the Mifeprex NDA argued that pregnancy is not an illness, Mot. 15, but fail to note that the sponsor agreed to approval under Subpart H. App. 523.

of Subpart H, and vacatur would be enormously disruptive as explained below. *See Cent. & S.W. Servs., Inc. v. EPA*, 220 F.3d 683, 692 (5th Cir. 2000). There is thus no basis to enjoin FDA's approval of mifepristone even if the Court were to accept Plaintiffs' Subpart H argument.

3. Plaintiffs' Untimely and Unexhausted Claims Regarding the Comstock Act Fail as a Matter of Law

Plaintiffs suggest that the Comstock Act, 18 U.S.C. §§ 1461, 1462, required FDA to prohibit the manufacturers of mifepristone from distributing it to prescribers by mail or by common carrier. Mot. 21. But Plaintiffs failed to present this argument at any stage of any administrative proceeding. Thus, this argument is unexhausted and barred from review. *See supra* p. 18. Plaintiffs' Comstock argument is also untimely as to the 2000 approval of mifepristone and the 2016 citizen petition denial. *See supra* pp. 16-17.

Plaintiffs' argument also fails on the merits. Plaintiffs provide no reason why FDA was required to consider that Act in deciding whether and under what conditions to approve mifepristone. That is particularly true given that the initial approval occurred in 2000, at a time when the Comstock Act could not constitutionally have been enforced against the mailing of items for abortions. Certainly the Comstock Act does not bear on the safety and efficacy findings at the core of FDA's approval decision, and nothing in the law requires FDA to incorporate into its drug approvals purported criminal-law restrictions on modes of transporting drugs.

More fundamentally, Plaintiffs misconstrue the Comstock Act. They contend that the Comstock Act "expressly prohibit[s] the distribution of chemical abortion drugs by mail, express company, or common carrier." Mot. 20 (citing 18 U.S.C. §§ 1461, 1462). As the Department of Justice's Office of Legal Counsel has explained, however, since the early 20th century the Comstock Act has been understood "not to prohibit all mailing or other conveyance of items that can be used to prevent or terminate pregnancy." Katzen Decl., Ex. 1C (*Application of the Comstock*

Act to the Mailing of Prescription Drugs That Can Be Used for Abortions, 46 Op. O.L.C. ___, at 5 (Dec. 23, 2022)), https://perma.cc/8XHW-32JD. In particular, federal courts of appeals settled upon a consensus view that the Comstock Act did not prohibit the mailing or other conveyance of contraceptives or items designed to produce abortions where the sender does not intend them to be used unlawfully. *See id.* at 5-11 (discussing, *e.g.*, *Davis v. United States*, 62 F.2d 473, 474-75 (6th Cir. 1933); and *United States v. One Package*, 86 F.2d 737, 738-40 (2d Cir. 1936); *Consumers Union of United States, Inc. v. Walker*, 145 F.2d 33, 33 (D.C. Cir. 1944)); *see also United States v. H.L. Blake Co.*, 189 F. Supp. 930, 935 (W.D. Ark. 1960).

Congress was well aware of this judicial interpretation, as well as the Postal Service's acceptance of the courts' settled construction. *See* Katzen Decl., Ex. 1C, at 12-13, 15-16, https://perma.cc/8XHW-32JD. Yet despite re-enacting or amending the Comstock Act several times over the ensuing decades, Congress never modified the relevant statutory text to reject or displace this settled construction. *See id.* at 11-15. Thus, Congress "implicitly adopted that construction of the statute." *Forest Grove Sch. Dist. v. T.A.*, 557 U.S. 230, 244 n.11 (2009); *see also, e.g.*, *Lorillard v. Pons*, 434 U.S. 575, 580 (1978) ("Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change."). Thus even if FDA were required to consider the Comstock Act, because the Comstock Act does not prohibit the mailing or other conveyance of abortion-inducing drugs where the sender does not intend them to be used unlawfully, and given that these drugs may be used lawfully, neither FDA's decisions related to in-person dispensing nor the absence of a prior FDA affirmative prohibition on distribution by mail was inconsistent with the Comstock Act.

Moreover, Plaintiffs' interpretation of the Comstock Act—as requiring FDA to affirmatively prohibit "distribution of mifepristone by mail, express company, and common

carrier," Mot. 21—is foreclosed by the 2007 FDAAA provisions related to REMS. As explained above, FDA initially approved mifepristone pursuant to Subpart H, and in doing so imposed certain restrictions on mifepristone's distribution. *See supra* p. 6; App. 514. In 2007, through FDAAA, Congress created the REMS authority and specifically "deemed" certain Subpart H drugs to have a REMS in effect, with the REMS containing the same distribution restrictions then in effect for each drug. *See* Pub. L. No. 110-85, tit. IX, § 909(b) (codified at note following 21 U.S.C. § 331). In enacting this legislation, Congress was well aware that it was directing mifepristone's preexisting distribution scheme to continue. Indeed, Senators critical of mifepristone's approval specifically noted that result.[12] As Plaintiffs acknowledge, FDA's preexisting restrictions "did not include prohibitions on the upstream distribution of mifepristone . . . by mail, express company, or common carrier." Mot. 21; *cf.* App. 521-23 (discussing the distribution system). Nor did those FDA restrictions prohibit the importation of mifepristone, *cf.* 18 U.S.C. § 1462, despite the understanding of various Members of Congress that the drug was being imported. *See, e.g.*, Staff Report, H. Cmte. Gov't Reform, *The FDA and RU-486: Lowering the Standard for Women's Health* (Oct. 2006), at 3.

Plaintiffs' argument that FDA was required to impose additional distribution restrictions in light of the Comstock Act is therefore foreclosed by FDAAA—because, through that legislation, Congress affirmatively endorsed mifepristone's availability and distribution in the absence of those

[12] *See supra* n.10. One Senate opponent proposed to include a provision in the bill suspending FDA's approval of mifepristone, which was rejected. *See* FDAWeek, *GOP Fails to Narrow Scope of FDA Reform Bill During Senate Mark-Up* (Apr. 20, 2007) ("[Sen. Coburn] also offered an amendment to suspend the approval of RU486 and make FDA review how it was approved. . . . That amendment failed[.]"). The Senate version of the bill then included a different provision targeting mifepristone—requiring the mifepristone manufacturer to submit a revised REMS on a more accelerated schedule than other drugs—which likewise was rejected in favor of requiring proposed REMS submissions from all drug manufacturers on the same timeline. *Compare* S. 1082, 110th Cong., 1st Sess., tit. II, § 214(b)(3)(B) (engrossed in Senate, May 9, 2007), *with* Pub. L. No. 110-85, tit. IX, § 909(b)(3).

restrictions.

II. Plaintiffs Will Not Suffer Irreparable Harm Without An Injunction Against A Drug That Has Been On The Market For More Than Twenty Years

Plaintiffs' motion should be denied for the independent reason that they fail to show irreparable harm. As explained above, *supra* § I.A, Plaintiffs establish no cognizable injury, let alone irreparable harm. Yet they ask this Court for emergency relief in the form of a mandatory injunction that would immediately withdraw approval of a safe and effective drug that has been available in the United States for more than two decades—based on speculative allegations of harm and Plaintiffs' untested assertions (relying for their merits arguments on extra-record evidence not properly before this court) that they know better than FDA whether this drug is safe. That request is extraordinary and unprecedented. Plaintiffs have pointed to no case, and the government has been unable to locate any example, where a court has second-guessed FDA's safety and efficacy determination and ordered a widely available FDA-approved drug to be removed from the market—much less an example that includes a two-decade delay. Nor have Plaintiffs identified any instance in which a court has entered a preliminary injunction suspending or withdrawing approval of a widely available drug on any other ground.

A. Plaintiffs' Own Actions Confirm the Lack of Irreparable Harm

Plaintiffs fail to show the imminent and irreparable harm necessary for injunctive relief. *See Chacon v. Granata*, 515 F.2d 922, 925 (5th Cir. 1975). It is extremely difficult to make that showing in a case like this, where Plaintiffs seek to upend longstanding agency action. Mifepristone has been on the market for more than twenty years, first under restrictions imposed as part of the initial approval and then under a REMS. Even the most recent action Plaintiffs challenge occurred in December 2021, eleven months before Plaintiffs filed suit. "Federal courts in Texas have long recognized" that such a "delay in seeking an injunction" indicates "that the

alleged harm does not rise to a level that merits an injunction." *Texas v. United States*, 328 F. Supp. 3d 662, 738 (S.D. Tex. 2018) (denying a preliminary injunction against Deferred Action for Childhood Arrivals where the policy existed for six years before plaintiffs filed suit); *see also, e.g.*, *Leaf Trading Cards, LLC v. Upper Deck Co.*, No. 17-CV-3200, 2019 WL 7882552, at *2 (N.D. Tex. Sept. 18, 2019) ("[C]ourts generally consider anywhere from a three-month delay to a six-month delay enough to militate against issuing injunctive relief."); *Gonannies, Inc. v. Goupair.Com, Inc.*, 464 F. Supp. 2d 603, 609 (N.D. Tex. 2006) (explaining that delay "demonstrates a lack of urgency and undercuts the need for a preliminary injunction").

Plaintiffs' extreme delay in filing suit undermines their substantive argument for a preliminary injunction because it shows that they face no imminent, irreparable harm. "The purpose of a preliminary injunction is to preserve the status quo and thus prevent irreparable harm until the respective rights of the parties can be ascertained during a trial on the merits." *City of Dallas v. Delta Air Lines, Inc.*, 847 F.3d 279, 285 (5th Cir. 2017). Plaintiffs' dilatory approach to challenging the agency actions at issue here by itself demonstrates that they will not suffer irreparable harm warranting emergency relief while this case is litigated to final judgment—a conclusion only compounded by the fact that the injunction they seek would upend, rather than preserve, the status quo. *See Cherry v. Unidentified Defendants*, No. 19-cv-657, 2019 WL 7838559, at *1 (E.D. Tex. Oct. 16, 2019) ("The purpose of a preliminary injunction is *not* to give a plaintiff the ultimate relief he seeks.").

B. Plaintiffs' Theories of Injury Are Highly Speculative on Their Own Terms

For the reasons explained above, *see supra* § I.A, Plaintiffs' assertions of harm are too speculative to show even standing. It follows *a fortiori* that they are too speculative to show irreparable harm. *Cf. Gbalazeh v. City of Dallas*, 394 F. Supp. 3d 666, 672 (N.D. Tex. 2019) ("[E]stablishing that there is a substantial threat of irreparable injury on a motion for preliminary

injunction is a much taller task than showing injury-in-fact to survive a motion to dismiss.").

C. Contrary to Plaintiffs' Claimed Harms, Serious Complications with Mifepristone Are Rare

In addition, Plaintiffs' alleged harms depend on a shared faulty premise—that mifepristone "inflict[s] severe complications on many women and girls" and "cause[s] more complications than even surgical abortions." Mot. 1-2. Congress authorized FDA to evaluate the safety of new drugs using its scientific expertise. Based on extensive scientific evidence, FDA determined more than two decades ago that mifepristone is safe and effective for its approved use and that its benefits outweigh its risks. *See supra* p. 4. FDA's scientific determination is entitled to significant deference. *See Wages & White Lion Invs.*, 41 F.4th at 436 ("[W]here the parties disagree on the science, we owe the FDA deference."); *see also Sierra Club v. EPA*, 939 F.3d 649, 680 (5th Cir. 2019) ("A reviewing court must be 'most deferential' to the agency where, as here, its decision is based upon its evaluation of complex scientific data within its technical expertise."). FDA's conclusions are amply confirmed by the administrative record here—which is the only relevant record for purposes of the merits in this case. Moreover, for purposes of evaluating whether irreparable harm would result without a preliminary injunction, evidence set forth in the attached declarations further confirms that mifepristone has been demonstrably safe and effective in practice, when considered based on clinicians' real-world experience prescribing the medication. *See* Zite Decl. ¶ 6; Ex. 7 (McHugh Decl.) ¶ 8; Ex. 3 (Ireland Decl.) ¶ 8. Accordingly, Plaintiffs cannot show that they will suffer irreparable injury during the pendency of this litigation (if at all). *See Holland Am. Ins. Co. v. Succession of Roy*, 777 F.2d 992, 997 (5th Cir. 1985).

1. The Agency Record Confirms Mifepristone's Safety and Efficacy

Plaintiffs' claim that women's use of mifepristone imposes greater burdens on Plaintiffs than would be present if mifepristone were removed from the market are belied by the record.

Based on its review of the scientific literature, FDA concluded that "[s]erious adverse events associated with the use of mifepristone through 70 days gestational age are rare." App. 736. More specifically, "the rates of serious adverse events are low: transfusions are 0-0.1 percent, sepsis is less than 0.01 percent, hospitalization related to medical abortion [*i.e.*, medication-induced abortion] is 0-0.7 percent, and hemorrhage is 0.1 percent." *Id.*; *see also* App. 635-36. These conclusions were compiled based on eleven different studies, containing data on "well over 30,000 patients." Katzen Decl., Ex. 1A, at 50, https://perma.cc/SR23-X9LJ; *see also id.* at 51-59 (discussing adverse events on a study-by-study basis). FDA also concluded that mifepristone is highly effective in terminating pregnancy without a need for surgical intervention. App. 736, 767; *see also* App. 736 (discussing rates of "complete medical abortion" across 22 studies, between "93.2 percent to 98.7 percent in the United States studies, and 92 percent to 98 percent in the non-United States studies"); Katzen Decl., Exs. 1A, at 21-47, https://perma.cc/SR23-X9LJ & 1B (Table of Studies for 20-687), at 1-24, https://perma.cc/5KSW-Q6AF.

Notably, as FDA concluded, although medication and surgical abortion each have contraindications and particular risks and benefits for certain patients, the overall safety and efficacy rates are not significantly different. Some patients will benefit, for example, by the avoidance of "an invasive surgical procedure and anesthesia" with medication abortion. App. 566; *see* Ex. 4 (Kieltyka Decl.) ¶¶ 19-22, 30; McHugh Decl. ¶ 7; Ireland Decl. ¶ 10. But averaged across the entire population, FDA highlighted one study "of 30,146 United States women undergoing pregnancy termination before 64 days of gestation from November 2010 to August 2013," which found that "[e]fficacy of pregnancy termination was 99.6 percent and 99.8 percent for medical and surgical abortion, respectively," with "no difference in major adverse events." App. 766-67.

2. Plaintiffs' Submitted Studies Do Not Undermine FDA's Expert Judgments

Rather than confront the significant evidence confirming mifepristone's safety, Plaintiffs

ask this Court to second-guess the agency based on five selected publications. Three are part of the agency record, *see* App. 391-97, 398-40, 421-28, and, as such, were considered by FDA in rendering the challenged decisions. App. 644, 737, 766-67. Two are from outside the record. *See* App. 409-420, 429-33. None purports to conclude that mifepristone is unsafe. Indeed, three of them expressly *endorse* mifepristone as a safe treatment.[13]

Moreover, Plaintiffs misconstrue these studies and their relevant findings. For example, Plaintiffs contend that Niinimaki 2009 (App. 398-408) establishes that "[t]wenty percent (20%) of females will have an adverse event after taking chemical abortion drugs—a rate four times higher than with surgical abortion." Compl. ¶ 65. But that figure includes some instances of uterine bleeding that FDA has described as "an expected and necessary part of the process" that "should only be considered [an] adverse event[] if the amount of bleeding or pain exceeds what would be expected for such a process." Katzen Decl., Ex 1A, at 68-69, https://perma.cc/SR23-X9LJ; *see also* App. 766; Katzen Decl., Ex. 1E, at 11, https://perma.cc/K69R-33EZ and https://perma.cc/RZ2M-9DQH. Indeed, the authors of the cited study recognized that "[u]terine bleeding requiring surgical evacuation probably better reflects the severity of bleeding after termination of pregnancy," and clarified that the rate of *that* complication "was relatively low[.]" App. 403-04.

Plaintiffs also place undue significance on Mentula 2011 (App. 391-97) when they cite a complication rate for women who take mifepristone during the *second* trimester. *See* Compl. ¶ 64. Given that FDA approved mifepristone only for an intended use through 10 weeks, that study is largely irrelevant (and the data were "relatively old"), as FDA explained. *See* App. 737. A similar problem exists with Plaintiffs' reliance on Niinimaki 2011 (App. 421-28), *see* Compl. ¶ 64, which

[13] *E.g.*, App. 407 ("[T]ermination of pregnancy by means of either medical or surgical methods is associated with a low level of serious complications."); *see also* App. 392-97, 422.

included women taking mifepristone up to 20 weeks' gestation—double the time period approved by FDA—and which likewise inflated the complication rate, as the authors acknowledged. *See* App. 425 ("Advanced duration of gestation was strongly related to the risk of incomplete abortion and surgical evacuation."); *see also* App. 644; Katzen Decl., Ex. 1A, at 74-75, https://perma.cc/SR23-X9LJ. In short, FDA independently reviewed all three studies; its determination that the studies comport with FDA's conclusions must be afforded deference. *See Wages & White Lion Invs.*, 41 F.4th at 436.

As for Plaintiffs' extra-record studies—which cannot be considered in connection with the merits of Plaintiffs' underlying claims—Plaintiffs once again mischaracterize their relevance. In particular, Plaintiffs rely on Studnicki 2021 (App. 409-20) to assert that "chemical abortions are over fifty percent (50%) more likely than surgical abortions to result in an emergency department visit within thirty days," Mot. 16. The mifepristone Medication Guide informs patients that cramping and bleeding are an expected part of ending a pregnancy.[14] There are many reasons why patients may seek ER care. *See, e.g.*, App. 172. But serious adverse events are rare, and an ER visit does not mean there has been an adverse event, let alone a serious adverse event. In any event, Plaintiffs' comparison of the relative likelihood of ER visits obscures the fact that Studnicki 2021 reported data showing the rate of emergency room visits is within the range reported in the FDA approved labeling (2.9%-4.6%),[15] which is low for both medication and surgical abortion: 3.6% for medication abortion, and 1.3% for surgical abortion.[16] *Accord* Zite Decl. ¶¶ 8-10, 12-14 (describing, based on experience, low rate of hospital visits due to "adverse events related to mifepristone following FDA's revision of the REMS"); Ireland Decl. ¶ 8. In short, this publication

[14] *See* Katzen Decl., Ex. 1D, at 16, https://perma.cc/2UJ5-8WVF.

[15] *See id.* at 8.

[16] *See* App. 413 (medication abortion: 2,201 abortion-related visits/61,076 total abortions performed; surgical abortion: 4,660/361,924).

does not undermine FDA's scientific determination that mifepristone for the medical termination of intrauterine pregnancy through 70 days gestation is safe for its intended use.

The Studnicki 2021 publication is even less relevant when considered in light of Plaintiffs' second extra-record study, App. 430-33 (Studnicki 2022). Although the Studnicki 2021 publication calculated that medication abortion was more likely than surgical abortion to lead to an emergency room visit, the Studnicki 2022 publication found that the likelihood of being admitted to the hospital was higher for *surgical* abortion (although the overall hospital admission rate for both procedures was quite low). *See* App. 431 ("Women experiencing chemical abortion and a subsequent emergency room (ER) visit within 30 days were less likely . . . to be hospitalized for any reason in that same time period than women who had experienced surgical abortion."). The Studnicki 2022 publication confirms that it is, at best, exceedingly unlikely that removing mifepristone from the market (as Plaintiffs request) would meaningfully decrease the burdens on the medical system, let alone on Plaintiffs in particular. *See also* Lindo Decl. ¶¶ 48 (explaining that individuals would seek surgical abortions); *id.* ¶¶ 49-50 (explaining that removing mifepristone from the market would increase burdens on the medical system as a whole, including with respect to patients seeking healthcare other than abortion); Zite Decl. ¶¶ 11, 15.

In short, none of Plaintiffs' publications undermines FDA's scientific determinations regarding the safety and efficacy of mifepristone. These determinations are entitled to "significant deference," and there is no basis "to compel the FDA to alter the regime for medical abortion" based on Plaintiffs' speculative assertions of harm that contradict the agency's findings. *Am. Coll. of Obstetricians and Gynecologists*, 141 S. Ct. at 578-79 (Roberts, C.J., concurring). Because serious complications with mifepristone are rare, *see, e.g.*, Zite Decl. ¶¶ 8-10, 12-14, Plaintiffs cannot show—despite the drug's two decades on the market—that they face an influx of patients

who (a) experience complications from mifepristone, (b) seek treatment from Plaintiffs, and (c) would not have experienced complications from surgical abortion or childbirth. And without showing such a comparatively larger influx, Plaintiffs cannot show that their practices will be meaningfully affected—or irreparably harmed.

III. A Preliminary Injunction Would Harm The Public Interest And Third Parties

The public interest would be dramatically harmed by effectively withdrawing from the marketplace a safe and effective drug that has lawfully been on the market for twenty-two years. FDA's determination that mifepristone provides a "meaningful therapeutic benefit to patients" over existing treatments, App. 523, 565-66, has been confirmed through decades of experience of thousands of women who, in consultation with their doctors, have determined that mifepristone is the safest and best option for them when compared to surgical abortion or childbirth. *See* Lindo Decl. ¶¶ 30-45; Kieltyka Decl. ¶¶ 18-34; McHugh Decl. ¶ 6; Ireland Decl. ¶¶ 10-13. The public interest is "paramount" where, as here, "an injunction would deprive the public of an important medical benefit." *Pharmacia Corp. v. Alcon Labs., Inc.*, 201 F. Supp. 2d 335, 385 (D.N.J. 2002). Indeed, under these circumstances, relief may be denied on public interest grounds even if a court decides other factors may weigh in Plaintiffs' favor. *Id.* (citing cases).

Removing access to mifepristone would cause worse health outcomes for patients who rely on the availability of mifepristone to safely and effectively terminate their pregnancies. *See* Kieltyka Decl. ¶¶ 19-22; Lindo Decl. ¶ 45; Ex. 6 (Glaser Decl.) ¶ 13. Many patients will likely seek legal access to abortion regardless of any injunction issued in this case—but an injunction would force them to do so through an invasive medical procedure that increases health risks for some patients and that may be otherwise inaccessible to others. *See* Lindo Decl. ¶¶ 47-72 (describing increase in wait times for surgical abortion that would result absent mifepristone, and the far-reaching impacts of such increased wait times on patients, their families, and healthcare

providers); *see also* Kieltyka Decl. ¶¶ 36-45 (explaining that unavailability of mifepristone would force Maine Family Planning to eliminate abortion services at 17 of its 18 clinics across the state of Maine, many in rural areas that lack alternative options); Ireland Decl. ¶ 14; McHugh Decl. ¶ 15. Indeed, as individual providers have explained, a substantial proportion of patients choose medication abortion for a variety of reasons including medical necessity, privacy, and avoiding further trauma, and its sudden absence would be expected to impose real and significant harms on such patients. *See, e.g.*, Kieltkya Decl. ¶¶ 19-31, 40-45; McHugh Decl. ¶ 15; Ireland Decl. ¶¶ 10-14. The effects of a preliminary injunction would be particularly acute for patients for whom mifepristone is the medically indicated treatment because of the patient's pre-existing health condition. For example, surgical abortion involves anesthesia, but people who are allergic to anesthesia can experience "a sudden drop in blood pressure with cardiorespiratory arrest, [and] death." App. 566; *see also* App. 521, 523; Kieltyka Decl. ¶ 20. And as Dr. Ireland explained, patient populations for whom medication abortion is more appropriate than a surgical abortion "include[] patients who are survivors of abuse, including rape and incest, for whom pelvic exams can recreate severe trauma," "[a]dolescent patients, who have not yet had a pelvic exam," and "patients in the intensive care unit or trauma patients who have difficulty with the positioning required for suction D&C." Ireland Decl. ¶ 7; *see also* Kieltyka Decl. ¶ 30; McHugh Decl. ¶¶ 10-14; Glaser Decl. ¶ 11. Notwithstanding these serious implications, the requested relief would deprive patients and their doctors of the opportunity "to decide whether a medical or surgical abortion is preferable and safer in [the patient's] particular situation." App. 566.

A preliminary injunction also would undermine the capacity of state healthcare systems. Taking away patients' option of medication abortion would lead to overcrowding and delays at clinics that provide surgical abortion, including not only dedicated abortion clinics but also general

practitioners. *See* Lindo Decl. ¶¶ 48-50. This would lead to delays for an array of healthcare services as providers and resources are unnecessarily diverted to surgical abortions. *Id*. Even a preliminary injunction with a more limited scope than withdrawal of mifepristone would unduly burden the public and healthcare systems, where FDA, in its scientific judgment, has determined that mifepristone is safe and effective for its intended uses and the benefits outweigh the risks.

Moreover, a preliminary injunction would interfere with the reliance interests of businesses involved in the sale and distribution of mifepristone. These businesses have relied on FDA's approval of mifepristone for the past twenty-two years to invest in the infrastructure to support these pharmaceutical products. These businesses, in turn, have employees whose jobs depend on the continued availability of mifepristone. More generally, if longstanding FDA drug approvals were so easily enjoined, even decades after being issued, pharmaceutical companies would be unable to confidently rely on FDA approval decisions to develop the pharmaceutical-drug infrastructure that Americans depend on to treat a variety of health conditions.

Finally, a preliminary injunction would interfere with Congress's decision to entrust FDA with responsibility to ensure the safety and efficacy of drugs. In discharging this role, FDA applies its technical expertise to make complex scientific determinations about drugs' safety and efficacy, and these determinations are entitled to substantial deference. *See Sierra Club*, 939 F.3d at 680. Allowing Plaintiffs to supplant FDA's considered judgment with cursory and baseless allegations of harm would undermine the administrative framework that Congress designed for the regulation of pharmaceutical drugs.

CONCLUSION

Plaintiffs' Motion for a Preliminary Injunction should be denied.

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Respectfully submitted,

HILARY K. PERKINS
Assistant Director

/s/ Noah T. Katzen
NOAH T. KATZEN (D.C. Bar. No. 1006053)
Trial Attorney
Consumer Protection Branch
Civil Division
U.S. Department of Justice
PO Box 386
Washington, DC 20044-0386
(202) 305-2428
(202) 514-8742 (fax)
Noah.T.Katzen@usdoj.gov

ERIC B. BECKENHAUER
Assistant Director

DANIEL SCHWEI
Special Counsel

JULIE STRAUS HARRIS
Senior Trial Counsel

CHRISTOPHER A. EISWERTH
EMILY NESTLER
KATE TALMOR
Trial Attorneys
Federal Programs Branch
Civil Division
U.S. Department of Justice

CERTIFICATE OF SERVICE

I hereby certify that this document, filed by email according to the Court's Emergency Procedures for the U.S. District Court for the Northern District of Texas, will be sent via electronic mail to all counsel of record.

January 13, 2023

/s/ Noah T. Katzen
NOAH T. KATZEN