No. 23-10362

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Plaintiffs-Appellees,
v.
U.S. FOOD AND DRUG ADMINISTRATION, ET AL.,
Defendants-Appellants
and
DANCO LABORATORIES, LLC,
Intervenor-Appellant

On Appeal from the United States District Court
for the Northern District of Texas
No. 2:22-cv-00223-Z

PLAINTIFFS' OPPOSITION TO AN EMERGENCY STAY PENDING APPEAL

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Alliance for Hippocratic Medicine, et al. v. U.S. Food and Drug Administration, et al.

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

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INTRODUCTION AND SUMMARY OF ARGUMENT

The FDA and Danco—mifepristone's main purveyor—ask this Court to set aside a meticulously considered administrative stay the district court found necessary to prevent irreparable harm. That court's order paints an alarming picture of decades-long agency lawlessness—all to the detriment of the women and girls FDA is charged to protect. It describes an agency that has repeatedly put politics above women's health, demonstrating callous disregard for women's well-being, unborn life, and statutory limits. Across decades, FDA has persisted in its unlawful activity, continually removing necessary safeguards.

Ignoring all these harms and their own stonewalling of judicial review for nearly 20 years, Defendants ask this Court to award them emergency equitable relief that would perpetuate FDA's unlawful mail-order abortion regime and result in further harms from a dangerous drug the district court found should never have been approved. But Defendants meet no requirements for emergency relief.

At the outset, Defendants have not made the requisite "strong showing" of success on the merits. *Nken v. Holder*, 556 U.S. 418, 426 (2009). As the district court concluded, it is Plaintiffs, not Defendants,

who are likely to prevail. Defendants admit that pregnancy is not an illness and cannot prove mifepristone provides a therapeutic benefit—the two prerequisites for FDA's approval here. And FDA's mail-order approval flagrantly violates the Comstock Act.

Nor have Defendants shown irreparable harm absent a stay. The public has no interest in maintaining unlawful agency action. And the order merely removes mifepristone from the mails and the market; abortion will still be available in states that permit it.

Conversely, a stay would perpetuate substantial harm on the public. The district court determined that chemical abortions: (1) "are over fifty percent more likely than surgical abortion to result in an emergency room visit within thirty days," (2) increased emergency room visits attributable to abortion "by over *five hundred percent* between 2002 and 2015," (3) caused a "fourfold higher" incidence of adverse events when compared to surgical abortions, and (4) resulted in 53% of women taking the drug reporting "a *negative* change" in their well-being. FDA.Add.45–47. And those statistics do not reflect thousands of harmed women who were never counted because FDA inexplicably discontinued reporting for mifepristone's non-fatal adverse effects.

Finally, the equities weigh heavily in favor of continuing the district court's stay. The district court found that the government has engaged in decades' long obfuscation and delay. And FDA's failure to abide by federal law has resulted in the death of "many" women and a serious physical and emotional toll—a toll minimized by FDA's "systematic" concealment. FDA.Add.29 n.22, 58–59.

For all these reasons, the district court did not abuse its discretion in entering an administrative stay under Section 705 of the Administrative Procedure Act, and it is the government's stay request that is "extraordinary and unprecedented," not the district court's ruling. FDA.Mot.8. This Court should deny Defendants' motions for stay of the district court's April 7 Order (Dkt.137) ("Order") pending appeal.

JURISDICTION

Defendants assume this Court has jurisdiction to review the district court's order under 42 U.S.C. § 1292(b). But that provision applies to orders granting preliminary injunctions. The lower court here did not grant an injunction but an administrative stay. As explained in Appellees' concurrently filed motion to dismiss, this Court lacks jurisdiction to hear an appeal as of right or Defendants' motion for stay.

BACKGROUND

The FDA's chemical abortion regimen requires two drugs: mifepristone (also known as "RU-486" and "Mifeprex") and misoprostol. FDA.Add.84. Mifepristone is a synthetic steroid that blocks nutrition to the unborn baby, starving the baby to death. *Id*. Misoprostol induces contractions to expel the dead baby from the mother's womb. FDA.Add.84–85.

During the early 1990s, the Population Council—a nonprofit founded to address world "overpopulation"—obtained mifepristone's U.S. patent rights. FDA.Add.100–01. After the Council filed a new drug application (NDA) with FDA, it granted to Defendant Danco Laboratories—a Cayman Islands-based company with no other pharmaceutical products—an exclusive license to manufacture, market, and distribute mifepristone in the U.S. FDA.Add.109.

The FDA fast-tracked mifepristone's approval under Subpart H, a regulation that authorizes accelerated approval of new drugs that safely and effectively treat "serious or life-threatening illnesses" and "provide [a] meaningful therapeutic benefit to patients over existing treatments." 21 C.F.R. § 314.500. To mitigate acknowledged, serious, and adverse

complications, the FDA's 2000 Approval imposed a seven-week gestational limit, limited prescribing authority to physicians, and 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. FDA.Add.182–83, 186, 189. Abortion providers were required to report all adverse events. FDA.Add.186.

In 2002, Plaintiffs AAPLOG and CMDA timely filed a citizen petition with FDA challenging the 2000 Approval (2002 Citizen Petition). Alliance.Add.151–246. *Fourteen years later*, FDA rejected the 2002 Citizen Petition (2016 Petition Denial). FDA.Add.804–36. The same day, FDA approved "major changes" to the chemical abortion drug regimen, eviscerating crucial safeguards (2016 Major Changes). FDA.Add.768–75. The agency increased the maximum gestational age from seven to ten weeks gestation; reduced the number of required in-person office visits from three to one; allowed non-doctors to prescribe and administer chemical abortions; and eliminated non-fatal adverse event reporting. FDA.Add.778.

In March 2019, Plaintiffs AAPLOG and ACPeds timely filed another citizen petition challenging the 2016 Major Changes (2019 Citizen Petition). FDA.Add.192–218.

In April 2021, FDA stated 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). Alliance.Add.249. The FDA took this action even though the Comstock Act expressly prohibits distribution of chemical abortion drugs by mail, express company, or common carrier. Then, on December 16, 2021, FDA denied almost all the 2019 Citizen Petition (2021 Petition Response). FDA.Add.876. The FDA rejected the 2019 Citizen Petition's request to keep the in-person dispensing requirements and announced it would permanently allow abortion by mail. FDA.Add.842.

STANDARD OF REVIEW

An emergency stay is an "extraordinary remedy." *Texas v. United States*, 40 F.4th 205, 215 (5th Cir. 2022) (per curiam) (cleaned up). A party is not entitled to a stay as a "matter of right, even if irreparable injury might otherwise result." *Tex. Democratic Party v. Abbott*, 961

F.3d 389, 397 (5th Cir. 2020) (cleaned up). Rather, an applicant for an emergency stay pending appeal must convince the reviewing court to exercise its equitable power based on four factors: "(1) whether the applicant has made a strong showing of likelihood to succeed on the merits; (2) whether the movant will be irreparably harmed absent a stay; (3) whether issuance of a stay will substantially injure other interested parties; and (4) where the public interest lies." *Vote.Org v. Callanen*, 39 F.4th 297, 302–03 (5th Cir. 2022) (cleaned up). The last two factors merge when the Government is the appealing party. *Id*. at 309. This Court reviews a grant of equitable relief for an "abuse of discretion." *Sepulvado v. Jindal*, 729 F.3d 413, 417 (5th Cir. 2013). "The district court's findings of fact are reviewed for clear error and its legal conclusions *de novo*." *Texas*, 40 F.4th at 215.

As noted, because the district court granted an administrative stay, *not* a preliminary injunction, this Court lacks interlocutory appellate jurisdiction and should leave in place the district court's ruling.

ARGUMENT

I. Plaintiffs' claims satisfy Article III and are properly before this Court.

A. Plaintiffs satisfy Article III.

The FDA and Danco recycle *Clapper v. Amnesty Int'l USA*, 568 U.S. 398 (2013), to argue that Plaintiffs have not shown a sufficiently concrete injury. But the district court correctly determined that Plaintiffs satisfy Article III's injury-in-fact requirement in multiple ways.[1]

1. The district court correctly held that Plaintiff Medical Associations have organizational standing because, in response to FDA's approval and deregulation of mifepristone, they "diverted valuable resources away from [their] advocacy and educational efforts" to inform their members, patients, and the public about the dangers of chemical abortion drugs "to the detriment of other priorities and functions." FDA.Add.13; *accord OCA-Greater Houston v. Texas*, 867 F.3d 604, 610–12 (5th Cir. 2017) (nonprofit had organizational standing after

[1] Danco suggests that the lower court broadly applied the wrong standard. Danco.Mot.6. Not so. In the organizational standing section, the court noted that allegations were viewed liberally. FDA.Add.12. But viewed liberally or strictly, Plaintiffs' allegations satisfy Article III.

spending "additional time and effort" explaining the new law, which "frustrate[d] … its routine … activities"). Additionally, Plaintiffs spent significant amounts of time on their citizen petitions. FDA.Add.70–74, 109–15, 127–30, 157–59.

The FDA takes issue with organizational standing writ large. FDA.Mot.8. But this Court's cases clearly teach that an organization has standing if it has "proven a drain on its resources resulting from counteracting the effects of the defendant's actions." *La. ACORN Fair Hous. v. LeBlanc*, 211 F.3d 298, 305 (5th Cir. 2000).

Danco complains Plaintiffs cannot claim organizational standing because they oppose abortion—and thus all its current efforts are on "mission." Danco.Mot.8. But by this logic, none of the organizations devoted to promoting voting rights would have been allowed to challenge alleged voting restrictions—that too would have been on mission. *See*, *e.g.*, *Tex. State LULAC v. Elfant*, 52 F.4th 248 (5th Cir. 2022). Here, *because of FDA's lawless actions,* the organizations diverted resources from their routine functions to educate the public about the dangers of chemical abortion, and to advocate for protecting conscience rights, and promoting the value of human life. FDA.Add.158.

2. The district court also correctly held that Plaintiff Medical Associations have associational standing to sue on behalf of their members because they allege that: (1) "adverse events from chemical abortion drugs can overwhelm the medical system"; (2) these emergencies "consume crucial limited resources, including blood for transfusions, physician time and attention, space in hospital and medical centers, and other equipment and medicines"; (3) force doctors into situations "in which they feel complicit in the elective chemical abortion by needing to remove a baby with a beating heart or pregnancy tissue as the only means to save the life of the woman or girl"; (4) and "prevent Plaintiff doctors from practicing evidence-based medicine," which harms the doctor-patient relationship and causes "Plaintiffs to face increased exposure to allegations of malpractice and potential liability, along with higher insurance costs." FDA.Add.7–8.

The FDA discounts Plaintiffs' allegations about treating women harmed by mifepristone as "a handful of alleged incidents … none of which meaningfully interfered with a member's medical practice." FDA.Mot.7. The FDA is wrong. Plaintiffs' declarations attest that they "often" treat patients suffering adverse complications from chemical

abortions—several doctors treating emergency medical conditions caused by chemical abortion a dozen times, or more. Alliance.Add.006–07, 014–19, 026–27, 033–34. And Defendants concede the existence of adverse events related to chemical abortion drugs. Alliance.Add.055. In a dozen different cases, Dr. Skop has been required to perform emergency surgery to remove embryos, fetuses, and pregnancy tissue. Alliance.Add.012–20. Several doctors detail interference with their medical practice and the need to call in an additional doctor to cover other patients while they treated emergency complications from mifepristone. Alliance.Add.006, 019, 025–28, 091–92, 106. And three doctors state that they were faced with emergency situations and forced to complete elective abortions because women were suffering life-threatening conditions from mifepristone, even though this violated their most deeply held beliefs.[2] Alliance.Add.005–007, 016–019, 111.

3. The lower court also correctly held that Plaintiffs can assert third-party standing because their physician–members' patients:

[2] This case is unlike one where a doctor refuses to treat an asthmatic child because of objections to environmental regulations. Danco.Mot.8. Rather, Plaintiff Medical Associations' members "oppose being forced to end the life of a human being in the womb for no medical reason, including by having to complete an incomplete elective chemical abortion." FDA.Add.153.

(1) have "endure[d] many intense side effects," "suffer[ed] significant complications requiring medical attention," and "suffer[ed] distress and regret"; (2) have a "close relation" to the physician–members; and (3) are hindered from "protect[ing] their [own] interests." FDA.Add.9.

Defendants do not contest that women sometimes suffer injuries and might be hindered from bringing suit. Instead, Danco suggests that Plaintiff doctors disavowed a "close relationship" with their emergency patients. Danco.Mot.6–7. Not so. Plaintiffs simply explained that they often had no *previous* relationship with a patient suffering emergency and often life-threatening complications from a chemical abortion. As this Court's abortion jurisprudence makes clear, a previous relationship is not the *sine qua non* of a close relationship. *Jackson Women's Health Org. v. Dobbs*, 945 F.3d 265, 275 (5th Cir. 2019), *rev'd and remanded*, 142 S. Ct. 2228 (2022) (allowing abortion facility to pursue claims on behalf of patients); 13A Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 3531.9.3 (3d ed. 2022) ("Doctors regularly achieve standing to protect the rights of patients and their own related professional rights.").

4. Plaintiffs' claims are sufficiently concrete and imminent. As the district court held, *Clapper* is distinguishable because no plaintiff there had *ever* suffered an injury. FDA.Add.14–15. Here, as the lower court found, FDA's mail-order abortion regime all but guarantees Plaintiffs will again treat women suffering complications from chemical abortion.

Recent cases make clear what *Clapper* explained in footnote five, that a material risk of future harm can suffice "so long as the risk of harm is sufficiently imminent and substantial." *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2210 (2021); *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014) ("An allegation of future injury may suffice if the threatened injury is 'certainly impending,' or there is a 'substantial risk' that the harm will occur.") (cleaned up); *Massachusetts v. EPA*, 549 U.S. 497, 525 n.23 (2007).

B. Plaintiffs' claims are reviewable.

The FDA does not dispute that Plaintiffs' challenge to the 2000 Approval is timely if the district court correctly held that the 2016 Major Changes and the 2021 Petition Denial reopened that decision. FDA.Mot.10. FDA argues that all the 2016 Major Changes did was "relax[ ]" REMS ("risk evaluation and mitigation strategies") conditions.

But those changes altered nearly every requirement—each one having been determined to be a *precondition for approval*. FDA.Add.21–22. The 2016 changes—self-described by FDA as major—affected a "sea change" in the regulatory scheme, thus reopening the matter and restarting the limitations period.[3] *See Sierra Club v. EPA*, 551 F.3d 1019, 1025 (D.C. Cir. 2008). So too for the "2021 Actions" which removed the "in-person dispensing requirement," dramatically reducing the chance a prescriber can "confirm gestational age, discover ectopic pregnancies, and identify a victim of abuse or human trafficking being coerced into having a chemical abortion." FDA.Add.22.

The district court also correctly found that equitable tolling was appropriate given FDA's decades-long pattern of delay and obfuscation. FDA.Add.24. As the court explained, "[i]t took FDA 13 years, 7 months, and 9 days to respond to the 2002 Petition. The FDA then moved the goalposts by substantially changing the regulatory scheme on the *same day*." *Id.*

[3] The FDA protests that Plaintiffs did not challenge the 2000 Approval in its 2019 Citizen Petition. But exhaustion would have been "futile because the administrative agency w[ould] clearly reject the claim." *Gulf Restoration Network v. Salazar*, 683 F.3d 158, 176 (5th Cir. 2012).

For similar reasons, Plaintiffs' efforts to exhaust would surely have been "futile because the administrative agency will clearly reject the claim." FDA.Add.28 (quoting *Gulf Restoration Network v. Salazar*, 683 F.3d 158, 176 (5th Cir. 2012); *accord Gardner v. Sch. Bd. Caddo Par.*, 958 F.2d 108, 112 (5th Cir. 1992). Exhaustion was also excused because the agency was acting contrary to public policy, patently contrary to law, and in a way likely to result in individual injustice. FDA.Add.28–30.

II. Defendants have not made a strong showing that they are likely to succeed on the merits.

To obtain a stay pending appeal, Defendants must make "a strong showing of likelihood to succeed on the merits." *Vote.Org*, 39 F.4th at 302. This is "arguably the most important factor." *Robinson v. Ardoin*, 37 F.4th 208, 227 (5th Cir. 2022) (per curiam) (cleaned up). Defendants cannot meet their heavy burden merely by showing "a substantial case alone." *Tex. Democratic Party*, 961 F.3d at 397 (cleaned up). Rather, the district court correctly held that Plaintiffs are likely to succeed on the merits.

A. The FDA violated Subpart H's requirements.

The FDA justified accelerated approval of the chemical abortion drugs under 21 C.F.R. § 314, Subpart H. That provision required FDA to find that pregnancy was a "serious or life-threatening illness," and that the chemical abortion drugs would give women a "meaningful therapeutic benefit" over surgical abortion. Both conclusions were wrong.

1. Pregnancy is not an illness.

Subpart H applies only to drugs that "treat[ ] serious or life-threatening illnesses." But pregnancy is *not* an illness. As the district court concluded, pregnancy is "a *natural* process essential to perpetuating human life" that "most women experience one or more times during their childbearing years." FDA.Add.40 (emphasis added). Even Defendants concede that. FDA.Add.117–18; FDA.Mot.20.

The agency argues that Subpart H also applies to "life-threatening conditions," a category to which FDA contends pregnancy belongs. But nowhere does the final rule list "life-threatening conditions." That language instead comes from Subpart H's preamble, and language in a

preamble cannot override the final rule's unambiguous text. *Cuomo v. Clearing House Ass'n*, 557 U.S. 519, 533 (2009).

Nor can agency deference stretch that language to cover what Subpart H plainly says. Courts defer to agencies' interpretations of their own regulations only when those regulations are "genuinely ambiguous" and cannot be resolved using "all the traditional tools of construction." *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019). Yet Subpart H is "plain and unambiguous." FDA.Add.43. "Illness" has an ordinary meaning denoting "sickness," an "unhealthy condition," or "a particular abnormal condition." *Id.* Pregnancy is none of those things. In fact, pregnancy is the *opposite*: a "natural process" that "most women experience." FDA.Add.40.

The FDA's interpretation is also unreasonable. As the district court noted, sometimes complications arise during pregnancy that may be serious or life-threatening. FDA.Add.44. "But that does not make pregnancy *itself* an illness." *Id.*

2. Chemical abortion drugs offer no "meaningful therapeutic benefit" over surgical abortion.

Subpart H's accelerated approval process also applies only to drugs that provide a "meaningful therapeutic benefit" to patients over

"existing treatments." For two reasons, chemical abortion drugs fail to qualify.

First, those drugs do not provide a "therapeutic" benefit. "Therapeutic" has an ordinary meaning relating to the healing of a disease. FDA.Add.44. Since pregnancy is not a disease, mifepristone cannot be therapeutic.

Second, whatever their efficacy, chemical abortion drugs do not provide a benefit *over* "existing treatments"—i.e., surgical abortions. Compared to surgical abortion, chemical abortion drugs have potential serious and life-threatening adverse effects on women and girls. Chemical abortion drugs are 50% more likely to result in an emergency room visit within 30 days than surgical abortion. FDA.Add.45. The overall incident of adverse events is "fourfold higher" in chemical abortions. *Id.* And chemical abortion patients "reported significantly higher levels of pain, nausea, vomiting and diarrhea during the actual abortion than did surgical patients." *Id.* at 45–46. "Post-abortion pain occurred in 77.1% of mifepristone patients compared with only 10.5% of surgical patients." *Id.* at 46.

Before the 2000 Approval, an FDA medical officer conceded that chemical abortion drugs have "*more* adverse events, particularly bleeding, than did surgical abortion." FDA.Add.46. That same officer noted that "[f]ailure rates" for chemical abortion drugs "exceeded those for surgical abortion." *Id.*

The FDA argued in 2000 and again today that the chemical abortion drugs have the benefit of avoiding "a surgical procedure." FDA.Add.105; FDA.Mot.20. That logic is circular. "By defining the 'therapeutic benefit' solely as the avoidance of the current standard of care's delivery mechanism, FDA effectively guarantees that a drug will satisfy this second prong of Subpart H as long as it represents a different method of therapy." FDA.Add.45.

3. Congress did not cure the FDA's misapplication of Subpart H.

Defendants argue that Congress cured these defects in the Food and Drug Administration Amendments Act. The FDAAA requires FDA to approve REMS for certain dangerous drugs (including the chemical abortion drugs). For drugs with safety requirements already in place before the FDAAA's effective date, Congress "deemed" those preexisting safety requirements to be a sufficient REMS until a new REMS was

approved. Defendants maintain that this effectively adopted FDA's approval of chemical abortion drugs.

Congress did no such thing. The FDAAA created a new regulatory framework for dangerous drugs. To help ease the regulatory transition, Congress deemed prior safeguards for dangerous drugs generally adequate—but only *until* FDA could comply with the new regulatory guidelines. This grace period says nothing about the specific approval for chemical abortion drugs.

B. The FDA also violated the FDCA.

The 2000 Approval, 2016 Major Changes, 2021 Non-Enforcement Decision, and 2021 Petition Response all violated the Food, Drug, and Cosmetic Act. The FDCA demands that FDA reject any NDA if there is not substantial evidence, adequate tests, and sufficient information demonstrating the safety and effectiveness of a drug "for use *under the conditions prescribed, recommended, or suggested in the proposed labeling*." 21 U.S.C. § 355(d) (emphasis added).

To start, FDA approved mifepristone's NDA without a clinical investigation evaluating the safety and effectiveness of chemical abortion drugs under the conditions of use in the proposed labeling.

FDA.Add.111–13, 162–64. The clinical trials that FDA relied on in its 2000 Approval used crucial safeguards—such as ultrasounds to confirm gestational age and to exclude ectopic pregnancies—that FDA omitted from the approved label. *Id.* So not a single study or trial evaluated the *actual* label that FDA approved. FDA.Add.162–64; 21 C.F.R. § 312.21 ("Phase 3 studies … are intended … to provide an adequate basis for physician labeling."); Glossary, Weill Cornell Medicine, https://research.weill.cornell.edu/compliance/human-subjects-research/institutional-review-board/glossary-faqs-medical-terms-lay-3 (last visited Feb. 23, 2023) ("In Phase 3 studies, the drug is used the way it would be administered when marketed.").

These omitted safeguards matter. If a woman with an ectopic pregnancy takes mifepristone, she could interpret warning signs like cramping and severe bleeding as mere side effects from mifepristone, when in reality her "life is in danger." FDA.Add.53. Yet FDA did not impose an ultrasound requirement in its final approval. That violated the FDCA.

The 2016 Major Changes suffered from similar pitfalls. With these changes, FDA eliminated crucial safeguards. Yet not one study

evaluated the safety and effectiveness of chemical abortion drugs under the new regimen. FDA.Add.122–124, 170–71. Rather, the only data FDA relied on featured the very safeguards omitted. FDA.Add.59. Worse, FDA "shirked any responsibility for the consequences of its actions by eliminating any requirement that non-fatal adverse events be reported." *Id*. This action effectively gives FDA cover to tout its regimen as "safe." *E.g.*, FDA.Mot.14–15. The FDA's 2021 Non-Enforcement Decision and 2021 Petition Response, for instance, relied heavily on FDA's Adverse Event Reporting System (FAERS). Given that FDA *abandoned* reporting requirements for nonfatal adverse events, this was stacking the deck. And such chicanery cannot constitute reasoned decision-making.

Defendants contend that these decisions were within the agency's discretion. FDA.Mot.17. But whatever discretion is afforded FDA, it cannot continually fail to "cogently explain" why it deviated from safeguards in place in the clinical trials it evaluated. *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1491 (D.C. Cir. 1995). This Court need not defer to FDA's lawless actions.

C. The FDA's actions violate longstanding federal criminal laws.

The Comstock Act prohibits the mailing or delivery of "[e]very article or thing designed, adapted, or intended for producing abortion" and "[e]very article … which is advertised or described in a manner calculated to lead another to use or apply it for producing abortion." 18 U.S.C. §§ 1461–62.

Both FDA's 2000 Approval and 2016 Major Changes ignored these laws. FDA.Add.107, 122. Moreover, the 2021 Non-Enforcement Decision and 2021 Petition Response went further by *authorizing* the mailing of chemical abortion drugs. The district court correctly found that "Defendants' decision to allow the dispensing of chemical abortion drugs through mail violates unambiguous federal criminal law." FDA.Add.38. By violating the Comstock Act, FDA also violated the APA, which requires federal agencies to follow all laws. *FCC v. NextWave Pers. Commc'ns Inc.*, 537 U.S. 293, 300 (2003).

Defendants' scattershot defenses fail. First, they contend that the FDCA requires FDA to assess only safety and effectiveness, not the Comstock Act. But the APA requires agencies to follow "*any* law, and

not merely those laws that the agency itself is charged with administering." *Id.*

Second, Defendants say that historically the Comstock Act "never prohibited the distribution of abortion drugs for *lawful* uses." FDA.Mot.23 (emphasis added). But the Comstock Act's text controls over any such history.[4] *N.Y. State Rifle & Pistol Ass'n v. Bruen*, 142 S. Ct. 2111, 2137 (2022). When FDA acted, the Comstock Act plainly prohibited the mailing of chemical abortion drugs. "Defendants cannot immunize the illegality of their actions by pointing to a small window in the past where those actions might have been legal." FDA.Add.38.

Defendants also say Congress implicitly repealed the Comstock Act. But "repeals by implication are not favored," and exist only when "Congress' intention to repeal is clear and manifest." *Me. Cmty. Health Options v. United States*, 140 S. Ct. 1308, 1323 (2020) (cleaned up). For the same reasons that the FDAAA did not cure the 2000 Approval's deficiencies, it did not silently repeal the Comstock Act. And the meager floor statements that Defendants point to do not amount to a "clear and

[4] And as the district court rightly noted, this Court should be skeptical of the Defendants' newfound history. Until *Roe*, most jurisdictions overwhelmingly made abortions illegal. FDA.Add.37–38.

manifest" intent. If anything, these statements show the opposite, calling into question the legality and danger of mifepristone's original approval. 153 Cong. Rec. S5759, 5765 (daily ed. May 9, 2007); 153 Cong. Rec. S5444, 5469 (daily ed. May 2, 2007).

Finally, Defendants argue that "when all the FDA action occurred, *Roe v. Wade* was governing law making the Comstock Act constitutionally unenforceable." Danco.Mot.12. But "*Roe* did not prohibit *all* restrictions on abortions." FDA.Add.38. Surgical abortions were readily available and no court had found that a prohibition on mailing chemical abortion drugs constituted an "undue burden" on abortion overall.

III. The equitable factors weigh decisively against an appellate stay.

1. Defendants cannot demonstrate irreparable injury caused by their own failure to follow the law. "[S]elf-inflicted wounds are not irreparable injury." *Texas v. Biden*, 10 F.4th 538, 558 (5th Cir. 2021) (per curiam) (citation omitted), *rev'd and remanded on other grounds*, 142 S. Ct. 2528 (2022). "The doctrine of 'unclean hands' [similarly] allows a court to refuse to grant equitable relief sought by one whose conduct in connection with the same matter or transaction has violated

the principles of equity and righteous dealing." *Binh Hoa Le v. Exeter Fin. Corp.*, 990 F.3d 410, 416 (5th Cir. 2021) (cleaned up).

In any event, Defendants' asserted harms do not justify a stay. FDA insists that the district court's order harms women. FDA.Mot.25–26. But as noted above and below, the harm runs the opposite way—chemical abortions cause greater harm to women than alternatives.

In a post-hoc justification, FDA claims that mifepristone can sometimes be used as an alternative for miscarriage management. FDA.Mot.26. But that off-label use is not at issue in this case. In any event, FDA itself has rejected miscarriage management as a new indication for mifepristone. FDA, *Agency Response Letter to ACOG*, (Jan. 3, 2023), https://perma.cc/24HJ-K6SF.

Danco claims economic harm if it cannot distribute mifepristone. Danco.Mot.18–19. But Danco has been complicit in FDA's unlawful actions at issue in this case since the beginning. Danco and its allies pressured FDA not to require ultrasounds as part of the 2000 Approval. Alliance.Add.115–21. It was Danco that lobbied FDA to remove several crucial safeguards and completely revise the regimen in the 2016 Major Changes. Alliance.Add.122–50. Danco also continues to distribute

chemical abortion drugs in violation of the Comstock Act. And any economic harm to a company that has financially benefitted from its own unlawful behavior is far outweighed by the harms to women and their doctors.

2. The district court found numerous irreparable harms that mifepristone causes women and Plaintiffs who represent them, and those findings warrant deference. As noted, chemical abortions increase exponentially the number of emergency room visits and adverse events compared to surgical abortions, including "higher rates of hemorrhaging, incomplete abortion," "unplanned surgical evacuation," "pain, nausea, vomiting and diarrhea." FDA.Add.45–47; *accord* Charlotte Lozier Amicus.Br. 15–19, Dist.Ct.ECF103 (collecting studies). All this, even though FDA "systematically" concealed mifepristone's true harms by eliminating reporting for all non-lethal complications. FDA.Add.59.

There are also serious mental health impacts unique to chemical abortions. FDA.Add.46. Unlike surgical abortions, "a mother sees the remains of her aborted child. These factors add to the psychological pain that is unique to medication abortion," a pain compounded by the reality that "women are often alone when they experience the effects of

the medication abortion," isolated even "from in-person physician interaction." Human Coalition.Amicus.Br.19–22, Dist.Ct.ECF.51-1 (citing medical studies and collecting women's stories when, following a chemical abortion, they saw their intact, fully formed babies dead and covered in blood). And it is well documented that human sex traffickers use chemical abortions to coerce and force women to have abortions. *Id.* at 22–25.

Like their patients, Plaintiffs will also endure irreparable harm. These medical associations and doctors will continue to spend their limited time, energy, and resources dealing with the tragic effects of these dangerous drugs, and suffer spiritual and emotional distress from these tragic events. FDA.Add.147–159.

3. Finally, the balance of harms and the public interest weigh decisively against an appellate stay. To begin, "the public interest weighs strongly in favor of preventing unsafe drugs from entering the market." *Hill Dermaceuticals, Inc. v. FDA*, 524 F. Supp. 2d 5, 12 (D.D.C. 2007). "[T]here is generally no public interest in the perpetuation of unlawful agency action." *Louisiana v. Biden*, 55 F.4th 1017, 1035 (5th Cir. 2022) (citation omitted). Allowing illegal actions by government

agencies to stand "*undermine[s]*" the public interest. *Valley v. Rapides Par. Sch. Bd.*, 118 F.3d 1047, 1056 (5th Cir. 1997) (emphasis added). Indeed, "there is a substantial public interest in having governmental agencies abide by the federal laws that govern their existence and operations." *Texas*, 40 F.4th at 229 (cleaned up). And that's before considering the additional physical and emotional trauma that chemical abortion drugs inflict on women or the irreparable mental, monetary, and temporal harms the district court recognized Plaintiff doctors and medical associations will continue to suffer. FDA.Add.61–62. These harms substantially outweigh any supposed economic interests or other harms Defendants assert.

CONCLUSION

The Court should deny Defendants' motion for stay pending appeal.

Respectfully submitted,

/s/ Erik C. Baptist

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CERTIFICATE OF COMPLIANCE

This response complies with the word limit of Fed. R. App. P. 27(d)(2)(A) because it contains 5,156 words.

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in Word 365 using a proportionally spaced typeface, 14-point Century Schoolbook.

Dated: April 11, 2023

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CERTIFICATE OF SERVICE

I hereby certify that on April 11, 2023, I electronically filed the foregoing response in opposition with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

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