No. 22A901

IN THE

Supreme Court of the United States

DANCO LABORATORIES, L.L.C.,

Applicant,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE; AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS; AMERICAN COLLEGE OF PEDIATRICIANS; CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS; SHAUN JESTER, D.O.; REGINA FROST-CLARK, M.D.; TYLER JOHNSON, D.O.; GEORGE DELGADO, M.D.,

Respondents.

REPLY IN SUPPORT OF EMERGENCY APPLICATION FOR STAY OF PRELIMINARY INJUNCTION PENDING APPEAL

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INTRODUCTION

Eleven days ago, the District Court upended Mifeprex's 23-year-old approval, over FDA's objection and despite FDA's considered view that the drug is safe and effective. This first-in-a-century judicial second-guessing of FDA's scientific judgment prompted immediate chaos and nationwide confusion.

Six days ago, the Fifth Circuit doubled down on the judicial second-guessing of FDA on safety and efficacy, taking an even more rigid and dim view of FDA's authority to analyze data and reach conclusions. This decision was no more narrow in effect: it *equally* precludes lawful distribution of Mifeprex until Danco can obtain FDA approval to implement a now-obsolete dosing regimen involving *higher* doses of mifepristone and unwinding seven years of FDA approvals—a process that would take months even if FDA were not separately enjoined by another court from taking any action related to mifepristone's conditions on distribution. All of this is playing out at breakneck speed, in a stay posture, on an incomplete record. A stay is warranted.

To avoid a stay, Plaintiffs purport to offer a series of truisms in their Opposition that are anything but true. Among others:

- First, Plaintiffs say that a statistical possibility of future harm is sufficient here, unlike in any of this Court's past decisions, because the lower courts said it is. That is ipse dixit reasoning at its strongest.

- Second, Plaintiffs repeatedly posit (at 1, 2, 3, 5, 18, 23, 33, 44) that it was irrational for FDA to strip away safeguards that are "meaningful," "necessary," and "critical," but that framing assumes the answer: *whether* those requirements were in fact meaningful, necessary or critical was the very issue FDA addressed. It concluded the answer was no, based on years of accumulated experience with the drug and a detailed analysis of dozens of studies involving tens of thousands of women. So long as that conclusion

was based on substantial evidence, and it was, that decision stands—like any other agency decision subject to substantial evidence review.

- Third, Plaintiffs assert that mifepristone "remains available" without a stay from this Court because going back to the 2011 regimen and label will "not require FDA to do anything"; FDA can just "sit tight." Opp. 4, 42. That is not how drug approvals and misbranding statute work, for all the reasons explained in the declarations from FDA's Principal Deputy Commissioner and Danco. And this reasoning fails to address the Washington district court injunction that governs in 17 states and the District of Columbia.

- Fourth, Plaintiffs repeatedly invoke concerns about having to violate their conscience without acknowledging the numerous federal and state healthcare conscience laws that undercut the future possibility Plaintiffs might encounter a patient in need of a surgical abortion. Nothing about FDA's approvals in 2016 or 2021 requires anyone to violate their conscience.

If this litigation involved any other drug, there would be no debate that a group of doctors who [1] do not prescribe it and [2] rely on a statistical possibility of encountering a patient in need of follow up care would be found to lack standing. Nor would there be any debate that FDA's consideration of the extensive evidence before it would be viewed as rational. Plaintiffs' arguments, if accepted, would radically rework standing jurisprudence and administrative law, all on an incomplete record.

The Court should stay the District Court's preliminary injunction in full pending resolution of all appellate proceedings, including any petition for a writ of certiorari, leaving in place the current status quo, as is appropriate and proper. In the alternative, the Court should grant certiorari before judgment and set this case for expedited briefing and argument before the summer recess.

ARGUMENT

This Court should stay the portions of the District Court's order that the Fifth Circuit left in place, pending resolution of all appellate proceedings, including a

potential certiorari petition to this Court. The lower courts' approach to this case to date was hardly "orderly," *Certain Named & Unnamed Non-Citizen Child. & Their Parents* v. *Texas*, 448 U.S. 1327, 1331 (1980) (Powell, J., in chambers), as the Government has explained, *see* Gov't Stay Appl. 44-45. It has created "a pressing national problem," as many amici highlighted. *Certain Named & Unnamed Non-Citizen Child.*, 448 U.S. at 1331. Danco meets the "necessary" conditions for a stay, balancing "the relative harms to applicant and respondent, as well as the interests of the public at large." *Barnes* v. *E-Systems, Inc. Grp. Hosp. Med. & Surgical Ins. Plan*, 501 U.S. 1301, 1304 (1991) (Scalia, J., in chambers).

I. THERE IS A REASONABLE PROBABILITY THE COURT WILL GRANT REVIEW.

The decision below accepts a novel view of Article III standing that squarely conflicts with established precedent and disregards the deference owed to federal agencies on complex technical determinations. Many arguments advanced by Plaintiffs and adopted by the lower courts would fundamentally alter the effect of this Court's binding precedent in those jurisdictions, were they allowed to stand unreviewed. Such flouting of settled law functionally creates a circuit split—the courts who follow precedent on one side, and the Fifth Circuit on the other. *Cf.* Opp. 3. Regardless, this Court routinely grants review in cases without a circuit split that are of great importance to fundamental legal principles. *E.g.*, *Trump* v. *Hawaii*, 138 S. Ct. 2392 (2018) (granting certiorari before judgment); *Dep't of Commerce* v. *New York*, 139 S. Ct. 2551 (2019) (same); *Kisor* v. *Wilkie*, 139 S. Ct. 2400 (2019); *Ramos* v.

Louisiana, 140 S. Ct. 1390 (2020); *FCC* v. *Prometheus Radio Project*, 141 S. Ct. 1150 (2021).

II. DANCO IS LIKELY TO PREVAIL ON THE MERITS OF ITS APPEAL.

A. Plaintiffs Failed To Establish Standing To Challenge the 2016 REMS Modification And 2021 Agency Actions That The Fifth Circuit Left Enjoined.

1. No injury to Plaintiffs supports individual or associational standing.

Despite spending over forty percent of their argument on individual and associational standing and disclaiming (at 29) reliance on a theory of "statistical-probability-of-injury-to-a-member," Plaintiffs never answer the most basic questions: *who* is the ER doctor that will be injured, *when* will it happen, *what patient* will they be treating, and *how* would the treatment of that patient have been any different under the 2011 REMS? Plaintiffs do not answer these questions because they do not know and cannot say. That is insufficient for standing under *Clapper* v. *Amnesty Int'l USA*, 568 U.S. 398 (2013) (requiring "certainly impending" injury to specific person without attenuated chain of discretionary third-party actions; "allegations of possible future injury are not sufficient"); *Summers* v. *Earth Island Inst.*, 555 U.S. 488, 495, 497 (2009) ("statistical probability that some [plaintiffs] are threatened with concrete injury" insufficient even if coupled with allegations of past harm); or *TransUnion* v. *Ramirez*, 141 S. Ct. 2190, 2208 (2021) ("plaintiffs must demonstrate standing for each claim that they press and for each form of relief that they seek").

Neither Plaintiffs' opposition nor their declarations supporting their request for injunctive relief identified any "personal stake" of any Plaintiff physician or

association member in whether the FDA-approved regimen extends gestational age for 21 additional days, from 49 to 70 days. Nor do the opposition or declarations show any personal stake in in-person administration of misoprostol; they do not, for example, say that any follow up care in an emergency room—which is where the Plaintiffs' alleged injuries occur—would differ based on whether a patient takes misoprostol at home or in a healthcare provider's office. The same is true for their challenge to the in-person dispensing requirement; they link none of the small number of instances where a patient was treated for follow up care in an emergency room to whether the mifepristone and misoprostol were dispensed in a clinic or through a U.S. pharmacy.

a. Plaintiffs' primary assertion of injury is an inability to abide by their conscience. Opp. 16-17. But no doctor is required to prescribe mifepristone, and federal and state healthcare conscience laws protect Plaintiffs' right to decline to provide medical services to which they have a conscience objection, like a surgical abortion following an incomplete medication abortion—a fact Plaintiffs entirely fail to acknowledge. *See* 42 U.S.C. § 238n, 300a-7(c) & (d) (federal conscience protections); Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, Div. H, Tit. V, §§ 506–507 (similar); Nadia N. Sawicki, *Protections from Civil Liability in State Abortion Conscience Laws*, 322 J. Am. Med. Ass'n 1918, 1918 (2019) ("State conscience laws typically provide additional protections that supplement those established by federal antidiscrimination law."), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6865309/.

Perhaps because of these protections, no declaration that Plaintiffs cite says a Plaintiff was forced to perform a surgical abortion against his or her will. The

Opposition rewrites what a declarant said "may," "could," or "might" happen into a conclusory statement that it did happen, *compare* D. Ct. ECF No. at 9 (FDA's actions "*may* force me to have to [perform an abortion]"), *with* Opp. 16 (describing statement as "FDA's actions 'force me to end the life of a human being in the womb'"); misquotes declarations to attribute surgical abortions performed by *other doctors* to an individual Plaintiff, *compare* Opp. 16, *with* D. Ct. ECF No. 1-8 at 5-6 (colleague performed abortion); D. Ct. ECF No. 15 (no statement that Plaintiff performed surgical abortion for any patient); D. Ct. ECF No. 16 ("the doctors"—not Plaintiff—"had to surgically finish the abortion"); and cites declarations not asserting a conscience injury, *compare* Opp. 16, *with* D. Ct. No. ECF 1-53 at 1-8 (no conscience injury); D. Ct. ECF No. 1-9 at 6 (no assertion declarant had to perform procedure against her will).

Even if these Plaintiffs had asserted that they suffered a conscience injury in the past, they offer no facts rendering that injury fairly traceable to the 2016 REMS modifications or FDA's 2021 actions. No declaration even states that the patients described in the declaration were treated after those FDA actions occurred.

b. Plaintiffs' references to mental and emotional harm and interference with medical practice are also not a cognizable Article III injury caused by FDA's 2016 or 2021 actions. Emergency room doctors regularly face "stress and pressure," Opp. 18, but just as a pulmonologist's grief over a smoker's lung cancer does not grant her standing to sue FDA for stricter tobacco restrictions, Plaintiffs' asserted emotional injuries do not grant them standing to undo FDA's 2016 and 2021 actions. Nor is the fact that they have to "devote significant time and resources" to caring for patients,

Opp. 19, or that they have to treat multiple patients at the same time, Opp. 20, an injury caused by FDA's 2016 and 2021 actions. If it were, any doctor who treated any patient for any "complication" arising from any allegedly dangerous product could sue to ban that product. Doctors do not have the standing superpower Plaintiffs propose.

c. Plaintiffs' concerns about the possible increased risks of medical liability are entirely speculative. No declaration identifies a Plaintiff who was sued, accused of malpractice, or had to pay increased insurance costs since the 2016 REMS modification, or at any other time. That is unsurprising: These physicians do not prescribe medication abortion, and so can hardly be expected to bear whatever risks may be associated with doing so. A bare allegation of "fear [of] greater exposure to liability," Opp. 21, which is entirely dependent on discretionary actions of other doctors and hypothetical patients is not cognizable injury, past or future. *See Lujan* v. *Defenders of Wildlife*, 504 U.S. 555, 567 (1992) (such attenuated theories of standing are "pure speculation and fantasy"). This too would grant doctors a free pass to assert standing with no basis in any precedent.

2. Plaintiffs lack organizational standing.

Plaintiffs' organizational standing argument relies on a misreading of *Havens Realty Corp.* v. *Coleman*, 455 U.S. 363 (1982). Challenging FDA's 2016 and 2021 approvals of mifepristone is not "perceptibly impair[ing]" these organizations' pursuit of their broader goals; it *is part and parcel of* their broader goal to oppose all forms of abortion. *E.g.*, D. Ct. ECF No. 1-4 at 4 ("CMA and its members are morally and ethically opposed to all forms of abortion–chemical or surgical."); D. Ct. ECF No. 1-6

at 3 ("CMDA is opposed to elective abortions * * * ."); D. Ct. ECF No. 1-8 at 3 ("AAP-LOG and its members oppose elective abortions, both surgical and chemical."). And because these organizations have opposed medication abortion "for decades," D. Ct. ECF No. 7 at 7, their actions can hardly be said to have arisen after, and because of, FDA's changes in 2016 or 2021. Plaintiffs' reliance on *Texas State LULAC* v. *Elfant*, 52 F.4th 248, 254 (5th Cir. 2022) is bizarre: that case found no standing where voting rights organizations "fail[ed] to link any diversion of resources specifically to [the challenged law]." Nor are citizen petition expenses (Opp. 31) a diversion of resources; they are prelitigation expenses. *NAACP* v. *City of Kyle*, 626 F.3d 233, 326 (5th Cir. 2010). Were it otherwise, anyone could create standing to challenge FDA by filing a citizen petition. That is not the law.

3. Injunctive relief requires certainly impending future harm.

Standing to seek injunctive relief requires more than past harm; it requires certainly impending or imminent future harm to plaintiffs themselves. But Plaintiffs recite care provided by "colleagues" and others in a "practice group," Opp. 16, 20–22, 24; suggest concerns about ectopic pregnancies or too-late gestational age, even though no Plaintiff's declaration speaks to personal experience with either, Opp. 22, 24; and conflate routine "complications" with serious adverse events. None of this amounts to standing to seek injunctive relief. "[T]he fact of past injury, 'while presumably affording [the plaintiff] standing to claim damages,' " is insufficient to support declaratory or injunctive relief because it " 'does nothing to establish a real and immediate threat that he would again' suffer similar injury in the future." *Adarand*

Constructors, Inc. v. *Pena*, 515 U.S. 200, 210-211 (1995) (quoting *City of Los Angeles* v. *Lyons*, 461 U.S. 95, 105 (1983)).

Plaintiffs claim they are "reasonably certain" to experience a "substantial risk" of future injury. Opp. 14, 28 (quoting *Clapper*, 568 U.S. at 414 n.5). They address none of the multiple levels of errors in the Fifth Circuit's fuzzy math, *see* Stay Appl. 20-21, and cannot reconcile their position with *Summers*. *See* 555 U.S. at 495, 497. Their future-injury claim is nothing more than "a significant degree of guesswork." *Trump* v. *New York*, 141 S. Ct. 530, 536 (2020) (per curiam) (plaintiffs lacked standing to sue because "any prediction about future injury [is] just that—a prediction").

4. Plaintiffs' alleged injuries are not redressable.

Plaintiffs have a redressability problem as well. They do not explain how returning to the 2011 REMS redresses their injuries. *Vermont Agency of Nat. Res.* v. *United States ex rel. Stevens*, 529 U.S. 765, 771 (2000) (redressability requires plaintiff to show "substantial likelihood that the requested relief will remedy the alleged injury in fact") (citation omitted). This is unsurprising, as they also lack any facts showing the 2016 or 2021 actions caused their injury, as opposed to the 2000 approval decision or the 2011 REMS. *See Simon* v. *Eastern Kentucky Welfare Rights Org.*, 426 U.S. 26, 38 (1976) ("Absent" redressability, "exercise of its power by a federal court would be gratuitous and thus inconsistent with the Art. III limitation.").

5. Third-party standing does not help Plaintiffs.

The decision below declined to address third-party standing claims, App. 10a n.4, for good reason. Third-party standing first requires a plaintiff to prove his own

standing, which Plaintiffs have not done here. *See Powers* v. *Ohio*, 499 U.S. 400, 410-411 (1991). It also requires "a 'close' relationship" and a " 'hindrance' to the possessor's ability to protect his own interests"—neither of which are present here. *Kowalski* v. *Tesmer*, 543 U.S. 125, 130 (2004) (internal citations omitted). Plaintiff-physicians lack a close relationship with patients who affirmatively wanted to end their pregnancy and were prescribed mifepristone by another doctor to accomplish that. Their "relationship" is, at worst, antagonistic, and at best, nonexistent. *Id.* at 131 (no third-party standing where litigants and third parties had "no relationship at all").[1] Plaintiffs also offer no facts showing that any patient is hindered in bringing suit. And this Court has long held that third-party standing cannot be based on a relationship between the plaintiff and a "hypothetical" party, such as the unnamed and unknown future patients these Plaintiffs fear they may have to treat. *See id*.

B. The Fifth Circuit's Analysis Of The 2016 REMS Modification And 2021 FDA Actions Ignored FDA's Analysis Of The Substantial Supporting Evidence.

Plaintiffs' defense of the Fifth Circuit's arbitrary-and-capricious ruling misrepresents the record as to the studies and data that FDA analyzed, puts words in FDA's mouth the agency never said, and contradicts the statutory standard governing REMS modifications. Any of these, and certainly all of these together, are a strong reason to grant a stay to permit review of these issues in an orderly fashion, rather

[1] Plaintiffs acknowledge as much in their own Declarations. *E.g.*, D. Ct. ECF No. 1-10 at 6 ("These physicians must treat women * * * without an existing relationship with the patient * * *."); D. Ct. ECF. No 1-4 at 5 ("[E]mergency department doctors do not have a prior relationship with these patients.").

than through the pell mell of a stay application on an unprecedented mandatory injunction that second-guesses FDA's assessment of drug safety and efficacy.

To survive "the APA's deferential arbitrary-and-capricious standard," FDA's decisions in 2016 and 2021 need only be "reasonable and reasonably explained." *Prometheus*, 141 S. Ct. at 1155 (cited at Opp. 33, 36, 38-39; App. 33a-35a). Even on the limited record before the lower courts, FDA's decisions in 2016 and 2021 clear that hurdle.

1. FDA exhaustively reviewed clinical data and carefully explained how that scientific evidence supported each of the changes it adopted in 2016 and 2021.

Plaintiffs parroting the Fifth Circuit's claim that FDA effectively found removing seat belts from cars would be safe by studying cars *with* seat belts. Opp. 33 (citing App. 34a, which cites *Motor Vehicle Mfrs. Ass'n of U.S., Inc.* v. *State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 34-36 (1983)). This analogy fails on the law and the facts.

Begin with the law. The issue in *State Farm* was not that the agency extrapolated from certain studies it was analyzing; it was that the data before the agency *pointed in the opposite direction* from the agency's conclusion and the agency failed to consider, let alone justify, its departure from that data. *State Farm*, 463 U.S. at 51; *see id.* at 52-54.

That is not what happened here. FDA looked at dozens of studies covering tens of thousands of women, including studies that specifically addressed every single one of the changes it was considering. It evaluated:

- 20 studies covering over 35,000 women to alter the dosing regime, D. Ct. ECF No. 28-1 at 33-37;

- seven studies covering 934 women to increase the gestational age, *id.* at 42-43;
- 11 studies covering 30,763 women to allow for the administration of misoprostol at home, *id.* at 45-46;
- four studies covering 3,200 women to permit nonphysicians to prescribe Mifeprex, *id.* at 48-49;[2]
- and one study with over 45,000 women to allow for flexibility regarding follow up appointments, *id.* at 49.

Based on this ample data, FDA reasonably concluded that these additional requirements were no longer necessary to ensure the safety and efficacy of mifepristone. *See* 21 U.S.C. § 355-1(g)(2), (4)(B). If anything, the 2016 changes are akin to relaxing a requirement that passengers must wear a four-point harness *and* a helmet *and* a head restraint to require *only* a standard seat belt based on studies showing no difference in outcomes as between use of a four-point harness, a helmet, a head restraint, or a seat belt.

Other data support that conclusion: As the American Medical Association, the American College of Obstetricians and Gynecologists, and other medical and public health societies document, mifepristone has been discussed to date in *more than 780 medical reviews* and used in more than 630 published clinical trials—more than 420 of which were randomized controlled studies, the gold standard in research design. Medical and Public Health Societies Amicus Br. 11.

[2] All approved REMS programs now universally refer to prescribers and healthcare providers, rather than physicians. FDA, *Approved Risk Evaluation and Mitigation Strategies (REMS)*, https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm. That is consistent with the fact that FDA defers to states on the practice of medicine, including whether and how advanced practice providers can prescribe prescription drugs.

The Fifth Circuit disputed none of this. It did not claim FDA ignored any evidence in the record; as the Government notes, the operative paragraph did not even *cite* the record. *See* App. 34a-35a; Gov't Stay Appl. 31. The FDA's expert analysis of copious statistical and medical evidence simply wasn't to the panel's satisfaction.

Plaintiffs attempt to backfill the reasoning below by attacking two of the dozens of studies FDA reviewed. This is *exactly* the kind of judicial second-guessing this Court has repeatedly admonished against. *E.g.*, *Food & Drug Admin.* v. *Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578, 578-579 (2021) (Roberts, C.J., concurring in grant of application for stay) ("[C]ourts owe significant deference to the politically accountable entities with the 'background, competence, and expertise to assess public health.'"); *Prometheus*, 141 S. Ct. at 1159-60 (agency did not act arbitrarily when it "simply interpreted [studies] differently" than plaintiffs); *cf. Dep't of Commerce* v. *New York*, 139 S. Ct. at 2571 ("second-guessing the Secretary's weighing of risks and benefits * * * substitutes [judge's] judgment for [agency's]").

Plaintiffs first claim that one study (of the seven) FDA relied on to support its change to 70 days gestation contained criteria not part of FDA's approval. Opp. 34. This ignores the "substantial body of literature supporting the proposed dosing regimen," D. Ct. ECF No. 28-1 at 123, that FDA reviewed, including six other studies looking specifically at the gestation between 64-70 days and likewise concluding mifepristone was effective and safe, D. Ct. ECF No. 28-1 at 42-43, 61-62, 123-124.

Plaintiffs' further criticisms fail. To fault the Winikoff study, Plaintiffs excerpt language stating the study "was not powered to detect a difference in safety

outcomes." Opp. 35. The full sentence explains why: "The study was not powered to detect a difference in safety outcomes *because major adverse events attributable to medical abortion* (eg, hospitalizations, emergency department visits, and blood transfusions) *are rare*." D. Ct. ECF No. 1-34 at 6 (emphases added). Put differently, while the study tracked adverse outcomes, there were so few adverse events in a study of 729 women that no statistically significant difference could be shown. And while Smith was aimed at testing efficacy, it notes that only 2.1% of study participants visited another facility for follow up care. Sanhueza Smith et al. 2015.

That Plaintiffs must resort to critiquing studies at this level of granularity underscores how Plaintiffs seek to stretch arbitrary and capricious review beyond recognition. That deferential standard directs courts to assess whether the agency "examine[d] the relevant data and articulate[d] a * * * rational connection between the facts found and the choice made." *Midwest ISO Transmission Owners* v. *FERC*, 373 F.3d 1361, 1368 (D.C. Cir. 2004) (Roberts, J.) (quoting *State Farm*, 463 U.S. at 43). "The question is not what we would have done, nor whether we agree with the agency action. Rather, the question is whether the agency action was reasonable and reasonably explained." *Jackson* v. *Mabus*, 808 F.3d 933, 936 (D.C. Cir. 2015) (Kavanaugh, J.). Agencies need not have "perfect empirical or statistical data;" they can form a "reasonable predictive judgment" based on the evidence before them. *Prometheus*, 141 S. Ct. at 1160.

2. Plaintiffs' arguments about the lower courts' study-match requirement are meritless. This Court has consistently recognized that agencies have discretion to

make changes as new data and circumstances warrant and to exercise reasonable judgment in extrapolating from the data before it. That is because "regulatory agencies do not establish rules of conduct to last forever, and * * * an agency must be given ample latitude to adapt their rules and policies to the demands of changing circumstances." *State Farm*, 463 U.S. at 52 (quotation marks omitted). Indeed, it is not "unusual in day-to-day agency decisionmaking within the Executive Branch" for agencies to make decisions based on imperfect "empirical or statistical data." *Prometheus*, 141 S. Ct. at 1160. As long as FDA made "a reasonable predictive judgment based on the evidence it had" and "reasonably explained" that decision, it clears "the APA's deferential arbitrary-and-capricious standard." *Id.*

FDA's actions cleared that bar here. Nothing in the FDCA or the APA requires FDA have a *single study* evaluating a drug under the precise set of conditions for which it is approved as safe and effective or for REMS modifications. In fact, no clinical trial data are required for REMS modifications. Congress directed only "an adequate rationale," without limiting FDA's discretion on adequacy. FDA can make REMS modifications based on the agency's view of whether modification is appropriate given the benefit-risk balancing for the drug, to minimize the healthcare delivery system's compliance burden, or to accommodate a generic applicant. 21 U.S.C. § 355-1(g)(4)(A), (B); Food & Drug Law Scholars Amicus Br. 12 (FDA "typically modifies and removes" conditions in REMS "and even releases REMS altogether—without data from new clinical trials."). No statute says REMS elements must be supported by clinical investigations. *Compare* 21 U.S.C. § 355-1, *with* 21 U.S.C. § 355(d).

In the absence of any statutory study-match requirement, the Fifth Circuit and District Court erred in concluding it was unreasonable for FDA to have modified the REMS with "zero" studies that considered the exact combination of conditions that would be in the modified REMS. *See Prometheus*, 141 S. Ct. at 1161 (Thomas, J., concurring) (lower court erred in "forcing" agency "to consider" an issue statute did not mandate because "[c]ourts have no authority to impose 'judge-made procedur[es]' on agencies (quoting *Perez* v. *Mortg. Bankers Ass'n*, 575 U.S. 92, 102 (2015)).

It is Plaintiffs—and the Fifth Circuit—who take a head-in-the-sand approach. Plaintiffs flatly ignore the havoc this rigid requirement would wreak on the industry and that it would likely render every single drug's approval and every single REMS modification unlawful—because the agency has never applied this sort of rigid rule. *See* PhRMA Amicus Br. 13; Pharmaceutical Companies, Executives, and Investors Amicus Br. 9-10. "The APA imposes no general obligation on agencies to conduct or commission their own empirical or statistical studies," *Prometheus*, 141 S. Ct. at 1160, and neither does the FDCA. That means the burden to commission a single omnibus study containing every proposed REMS change would fall on the NDA holder. As the leading industry group has explained, such studies will be "expensive [and] resource-intensive," "impose a significant and unnecessary financial burden on pharmaceutical and biotechnology companies, and undermine incentives to pursue approval of products that would require REMS in the first place." PhRMA Amicus Br. 13. And if the NDA holder declines, the REMS would essentially become stagnant–even if the real-world data demonstrates that restrictions are no longer

necessary. *See* Food & Drug Law Scholars Amicus Br. 13-14. That is not what Congress intended. *See, e.g.*, 21 U.S.C. § 355-1(f)(2)(C) (elements to ensure safe use shall "not be unduly burdensome on patient access").

Finally, Plaintiffs resort to rewriting the Fifth Circuit's decision. They claim the Fifth Circuit "went out of its way" to disclaim the idea that its "holding would require an exact 'study match.'" Opp. 38 (citing App. 19a). Their support? A section of the panel majority's *standing* analysis purporting to emphasize the narrowness of that holding. Here is what the panel *actually* said: FDA "failed to consider an important aspect of the problem" when it "relied on zero studies that evaluated the safety-and-effectiveness consequences of the 2016 Major REMS Changes as a whole." App. 35a. It's hard to imagine how the panel could have been clearer.

Plaintiffs also claim the study-match requirement only applies when FDA says that safeguards are "'interrelated,'" and that is why the Fifth Circuit said what it did. Opp. 38. But the Fifth Circuit never used the word "interrelated" in its opinion. And FDA described the requirements as interrelated in the context of saying that data from a single study could "provide evidence to support multiple changes," because several studies examined multiple of the proposed modifications in one study, D. Ct. ECF No. 1-33 at 7, and in explaining that whether to retain a REMS is based on "a complex, drug-specific inquiry, reflecting an analysis of multiple interrelated factors and of how those factors apply in a particular case," D. Ct. ECF No. 1-44 at 23.

3. Plaintiffs' complaint that FDA acted unreasonably when issuing the 2021 non-enforcement decision, App. 35a, ignores the reporting requirements that remained in place following the 2016 changes and the evidence FDA relied on in 2021.

First, the ongoing reporting obligations. The reality is that even after the 2016 REMS revision, mifepristone remains subject to a *more rigorous adverse event reporting regime* than the vast majority of other drugs. The lower courts either ignored or did not understand that fact. The Mifepristone REMS is one of only five REMS programs for which FDA requires prescribers to report any deaths of patients who receive the drug. FDA, *Approved Risk Evaluation and Mitigation Strategies (REMS)*, https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm.

On top of that, Danco is bound by 21 CFR § 314.80 and § 314.81 to report serious, unexpected adverse events to FDA within 15 days, and all others on an annual basis. Relying on a 2021 study that was never presented to FDA, Plaintiffs assert that Danco might be ignoring these mandatory requirements because it might not be in the company's "best interest to report adverse events to those regulating it." Opp. 37 (quoting D. Ct. Dkt. No. 1-46 at 22). It is in Danco's "best interest" to comply with the law, and Danco does so. Plaintiffs' suggestion that Danco could not possibly be fulfilling its legal obligations because the company is not "boots-on-the-ground in emergency rooms to witness adverse events" is even further beyond the pale. *Id.*

Plaintiffs take one more potshot at Danco. Relying on a 2021 paper—which postdates FDA's actions and which Plaintiffs never submitted to the agency—Plaintiffs assert that "[t]here was already a significant disparity between reported adverse

events and FDA's database" even before FDA relaxed the reporting requirement in 2016. Opp. 36. Based on this, Plaintiffs conclude that either Danco purposefully underreported data, or FDA purposefully excluded it. *See id.* But the paper Plaintiffs cite expressly admitted it lacked the full panoply of data necessary to evaluate whether and why any purported mismatch occurred. *See* D. Ct. ECF No. 1-47 at 5. And the co-author of the study the 2021 paper relied on has expressly cautioned against overreading his data in this way.[3]

And providers, like Plaintiffs and the member physicians, can voluntarily report adverse events directly to FDA. 21 C.F.R. § 20.112. FDA's website even includes an online reporting form for providers (FDA Form 3500) and a separate one for consumers and patients (FDA Form 3500B). *See* FDA, *Medwatch Online Voluntary Reporting Form*, https://www.accessdata.fda.gov/scripts/medwatch/. Plaintiffs scoff at this, claiming that many emergency room providers are either too busy or too ignorant to report adverse events. Opp. 36-37. This cannot be serious. No one is stopping medical professionals from reporting adverse events to Danco or FDA. The lack of adverse event reporting is at least equally likely a result of the lack of adverse events.

Moreover, it is not unusual for a REMS to limit the types of adverse events that providers must report. *See supra* p. 18; *FDA, Approved Risk Evaluation and Mitigation Strategies (REMS)*, https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm. If FDA were only permitted to modify a REMS when it had reporting from

[3] Sam Dorman, *FDA data on chemical abortions scrutinized in new study*, Fox News (Jan. 17, 2022), *available at* https://www.foxnews.com/politics/fda-chemical-abortion-data-new-study.

providers about *all* adverse events, FDA would never be able to modify a REMS—especially one that potentially implicated care from emergency room providers given Plaintiffs' position that ER doctors (like themselves) choose not to report adverse events.

Second, the evidence reviewed by the FDA. In adopting the non-enforcement decision, FDA examined actual postmarketing safety data from an eight-month period during which in-person dispensing was not enforced due to the COVID-19 pandemic. D. Ct. ECF. No. 1-44 at 26-28. That data showed "no indication" that relaxing the in-person dispensing requirement "contributed to * * * adverse events." *Id.* at 26-27. Based on this, FDA concluded "that mifepristone may be safely used without in-person dispensing." *Id.* at 28. FDA also examined three studies permitting mail order pharmacy dispensing—in one study, only 0.9% of women had adverse events—and concluded the studies suggest "efficacy of medical abortion is maintained with mail order pharmacy dispensing." D. Ct. ECF No. 1-44, at 31-32. And FDA examined five studies allowing clinic dispensing by mail, again concluding they "support that dispensing by mail from clinic is safe and effective." *Id.* at 34-35.

Plaintiffs invite this Court to join them in second-guessing FDA's scientific judgment. Opp. 37-38. But FDA acknowledged potential shortcomings in these studies and reasonably and extensively explained why they did not undermine—and in fact supported—FDA's conclusion based on the real-world data. D. Ct. ECF No. 1-44 at 27-37. Identifying a potential problem and explaining why the agency would reach the same result anyway is the epitome of reasoned decision-making, particularly

where that analysis involves complex scientific questions within the agency's ken. *See, e.g.*, *Serono Labs., Inc.* v. *Shalala*, 158 F.3d 1313, 1327 (D.C. Cir. 1998) ("Neither we, nor the district judge, are scientists independently capable of assessing the validity of the [FDA's] determination—beyond holding it to the standards of rationality required by the Administrative Procedure Act.").

* * *

Plaintiffs' merits argument, at bottom, reflects a fundamental misunderstanding about how drug approvals and REMS work. Clinical trials are often conducted under conditions more restrictive than approved labeling, which protects participants *before* FDA has concluded a drug is safe and effective. Food & Drug Scholars Amicus Br. 7. Studies can have other limitations, like the inability to ethically give certain participants a placebo. Former FDA Officials Amicus Br. 14. As a result, FDA has significant discretion about how to evaluate a study and extrapolate from it. *Id.* If FDA takes a more conservative approach at first, it can later evaluate whether real-world data or additional trials support lifting certain restrictions. *See* PhRMA Amicus Br. 13 (FDA made nearly 800 modifications to REMS between 2008-2023). Congress entrusted FDA—not the courts—with this power and responsibility. As numerous amici have noted, courts traditionally adhere to these defined lanes; this is the "first time a court has ever second-guessed FDA's scientific judgment by vacating a drug's approval on the ground that FDA got the science wrong"—on an incomplete record and in an emergency posture, no less. Former FDA Officials Amicus Br. 3; *see also* Members of Congress Amicus Br. 6; PhRMA Amicus Br. 3.

C. Plaintiffs Cannot Show *They* Are Likely To Prevail On The Merits Of Their Comstock Argument.

The question of what the Comstock Act does or does not mean is an entirely separate question from the safety and efficacy of mifepristone. And unlike the safety and efficacy of a drug, which is FDA's unique purview, FDA neither implements nor enforces the Comstock Act. FDA's purported failure to structure the mifepristone REMS consistent with this statute, *see* Opp. 39, is not a basis for an injunction.

The only authority Plaintiffs cite for invoking the Comstock Act, *FCC* v. *NextWave Personal Communications, Inc.*, 537 U.S. 293 (2003), shows their folly. The statute there expressly applied to actions any "governmental unit" took, and after a party asked the FCC to comply with it, the Court found the FCC was obliged to do so. *Id.* at 300-301. Comstock is not directed at FDA, Plaintiffs did not raise Comstock in any citizen petition, and FDA regularly approves drugs subject to the concurrent jurisdiction of statutes and regulations administered by other agencies. Former DOJ Officials Amicus Br. 5–8. The existence of such other statutory regimes does not undercut the lawfulness of FDA's scientific determination of safety and efficacy.

To the extent Plaintiffs fasten a Comstock Act claim onto their APA challenge to FDA's modifications of the mifepristone REMS, the claim is not exhausted. The Comstock Act "uncertainty" the Fifth Circuit detected is therefore not properly before the Court. Even if the issue had been properly raised and preserved, the Comstock Act has long been read to restrict only distribution of an item intended for unlawful abortions. Because "statutes should be read where possible to avoid unconstitutionality," *Dobbs* v. *Jackson Women's Health Org.*, 142 S. Ct. 2228, 2276 (2022), the courts

reaching the merits of the question have credited the extensive textual, structural, and historical evidence showing that the Comstock Act cannot bear the weight the District Court placed on it. Former DOJ Officials Amicus Br. 8–21.

D. Plaintiffs Do Not Dispute That The 2023 Changes Were Not Before The Fifth Circuit.

Plaintiffs do not even attempt to defend the Fifth Circuit's decision to reach out and "stay" FDA's 2023 REMS modifications. App. 2a. That's no surprise; it's indefensible. Plaintiffs raised no challenge to the 2023 changes before FDA, never amended their complaint to challenge that action, and the District Court's ruling did not purport to stay the 2023 REMS. Danco Stay Appl. 29-30. At minimum, this Court should stay the Fifth Circuit's order to the extent it purports to "stay" an agency action that was not before it.

Equally important, the fact the 2023 REMS is not properly enjoined means that in this litigation alone there is now both a 2023 *unenjoined* REMS and a Fifth Circuit order to re-implement the outdated and superseded 2011 REMS. Danco and FDA cannot possibly comply with both.

III. THE EQUITIES OVERWHELMINGLY FAVOR A STAY.

The harm to Danco and the public interest from the failure to grant a stay overwhelmingly favor a stay and significantly outweigh any speculative injury to Plaintiffs. Despite Danco seeking a stay of the District Court's full order, the Fifth Circuit crafted an order purporting to require Danco to reimplement the 2011 REMS. That decision creates harm to Danco not presented by the relief ordered by the

District Court, all of which is magnified by the competing injunction issued in Washington, which issued after briefing in the District Court was completed.

A. Danco Faces Substantial, Certain, Unrecoverable Harm.

The rulings below both threaten Danco's very existence. Neither court considered the concrete, substantial, and irreparable harm to Danco that a mandatory injunction blocking Danco's lawful distribution of its sole product for the duration of this case would cause. That reality renders flawed and incomplete the lower courts' analyses of whether a mandatory injunction is warranted.

Plaintiffs' view that Danco is unharmed because the 2011 REMS are instantly back in effect reflects a total misunderstanding of the drug approval process. As FDA and Danco have explained, the order enjoining the 2016 and 2021 FDA actions means that Danco is precluded from distributing Mifeprex without facing civil and criminal penalties because "all extant doses of mifepristone" become immediately misbranded and not marketable until FDA and Danco "sort through the current uncertainty and take steps to bring the drug's labeling and other conditions into compliance with the new legal regime the lower court has abruptly imposed." Gov't Stay Appl. 38.

Plaintiffs suggest the solution is simple: just pull out the old labeling and paperwork. Opp. 43. Wrong. Again, "all extant doses of mifepristone" will become immediately "misbranded" absent this Court's grant of a stay. Gov't Stay Appl. 4, 38. To avoid violating the FDCA while the mandatory injunction remains in effect, Danco would have to prepare a new supplemental New Drug Application (sNDA)—which would need to incorporate currently known clinical data. *See* 21 C.F.R. § 314.50.

Once submitted, FDA would have to review it—and, assuming a new approval is granted, approve revised labels, packaging, and promotional materials, approve revised prescriber agreements, patient agreements, and provider certifications, among other steps—all of which will take months to accomplish. App. 113a ¶ 11-12, 115a ¶¶ 17-19, 118a ¶ 24(d), 119a ¶ 26, 120a ¶ 27; Gov't Stay Appl. 38. Unless and until that process plays out, all lawful manufacturing and distribution in interstate commerce would have to halt.

Plaintiffs' position also ignores the dueling injunction from the Eastern District of Washington which prohibits FDA from approving any changes to the 2023 REMS in 17 states and the District of Columbia. Absent a stay from this Court, at least 33 states will lose immediate access to mifepristone for any use—a drug with lawful uses in every state—which fundamentally threatens Danco's business. Even in the remaining 17 states, any distribution by Danco will be in compliance with one court order (the Washington court's order) and not in compliance with another (the Texas or Fifth Circuit's order). This plainly constitutes irreparable injury. *Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374, 381 (1992) (party's "Hobson's choice" between "expos[ing] themselves to potentially huge liability" or "suffer[ing] the injury of obeying the law during the pendency of the proceedings" was irreparable harm).

B. The Public Interest Favors A Stay.

The public interest favors continued access to a safe and effective drug that is approved for use in 82 countries worldwide;[4] has been on the World Health

[4] *See* Gynuity Health Projects, *Map and Dates of Mifepristone Approvals by Country* (updated Mar. 2023), https://gynuity.org/assets/resources/mapmifelist_en.pdf.

Organization's Model List of Essential Medicines for more than 15 years;[5] and has been relied on by over 5 million women in this country as the standard of care for medication abortions for more than two decades.

As the pharmaceutical industry has explained, the decisions below are wrong on the requirements of the drug approval process and, by eliminating FDA's discretion to make scientific determinations and permitting a non-expert court to radically change the availability of an approved drug regimen over FDA's objection, inject unacceptable instability into that process. "The United States' biopharmaceutical industry is the world leader in the development of new medications, due in no small part to the stability that Congress cultivated through the framework it created in the Federal Food, Drug, and Cosmetic Act." PhRMA Amicus Br. 1. Since Congress gave FDA its REMS authority in 2008, FDA has approved over 300 REMS and made nearly 800 modifications to REMS—*all* of which would be called into question if the Fifth Circuit's rigid study-matching requirement were a prerequisite for FDA approval of a REMS or REMS modification. *Id.* at 11-13. Hundreds of pharmaceutical companies, executives, and investors make clear in their amicus brief that the lower courts' "radical departure" from the scientific and medical discretion and flexibility FDA has to evaluate risks and benefits of drugs eliminates the stability and flexibility that companies depend on when investing in drug development. Pharmaceutical Companies, Executive, and Investors Amicus Br. 5-9. Plaintiffs' only response to this is to

[5] *See* World Health Org., World Health Organization Model List of Essential Medicines – 22nd List (2021), https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2021.02.

say the single-study-match requirement as only applicable to mifepristone. *See* Opp. 48. Hundreds of concerned signatories to the industry amicus brief say otherwise.

Because "all extant doses of mifepristone" will become immediately "misbranded" absent this Court's grant of a stay, *see* Gov't Stay Appl. 4, 38, this means Danco, its suppliers and distributors, and providers in the 17 states who are parties to the Eastern District of Washington injunction have no way of knowing how or to which court order to conform their behavior. Pharmaceutical companies with pending NDAs, sNDAs, or REMS modifications have no way of knowing if their drugs are now unapprovable because the exact clinical trials conditions are not reflected in the proposed conditions of use. Clinicians and providers have no way of knowing if they are still certified Mifeprex providers or whether they need to find outdated versions of the Patient Agreement to give to patients coming in for care *tomorrow*.

The public interest remains where it has been since 1962, when Congress tasked FDA with conducting safety and efficacy reviews for all drugs marketed in the United States: FDA's many doctors, chemists, biologists, pharmacologists, and data scientists (among others) who conduct the various medical, chemistry, pharmacology, statistical, and clinical pharmacology and biopharmaceutics reviews of data submitted by a drug sponsor are not subject to cavalier second-guessing of those scientific judgments and risk-benefit balancing by an inexpert court. *See generally* Former FDA Officials Amicus Br.; FDA Scholars Amicus Br.; Congressional Amicus Br.

Plaintiffs likewise have no response to the injuries to State sovereign authority or the strain that an injunction would impose on health systems by limiting provider

availability for other critical healthcare services, such as pre- and post-natal care, contraceptive care, and cancer screening, and by limiting telemedicine. *E.g.*, New York et al. Amicus Br. 10-12. They ignore the costs of forcing providers, public hospitals, and clinics to pivot to new practices, reallocate resources, and change policies and training—even though the final disposition of this case may render all of that unnecessary. Medical and Public Health Societies Amicus Br. 23; Local Governments Amicus Br. 2, 12; City of New York et al. Amicus Br. 6-7.

Plaintiffs also ignore harms to the many women for whom mifepristone is a complete treatment without complications that will result if the ruling below remains in effect. Opp. 47. The notion that *any* failure rate is "problematic," *id.*, ignores that e*very* drug's approval is a risk-benefit calculus. If a small failure rate mandated denying approval, it is hard to imagine any drug could ever be approved. And Plaintiffs ignore that women will instead be required to use an unapproved misoprostol-only regimen with *more* side effects and a *lower* complete success rate, have more invasive surgical abortions that are less appropriate for some women and be delayed to a later gestational age because of unavailability, or face the psychological and other harms that attend being forced to carry an unwanted or non-viable pregnancy. *E.g.*, City of New York et al. Amicus Br. 7, 14-17; N.Y. et al. Amicus Br. 5, 7-9; Medical and Pub. Health Societies Amicus Br. 19-21; Reproductive Health, Rights, and Justice Orgs. Amicus Br. 13. By rendering mifepristone unavailable, the decision below also eliminates its lawful off-label use for miscarriage management and other pregnancy complications—depriving these women, too, "of an established and effective form of

care." Physicians for Reproductive Health Amicus Br. 7-10; Medical & Public Health Societies Amicus Br. 6-7.

Plaintiffs fall back on their assertion that FDA's data undercounts the number of women harmed by taking mifepristone, Opp. 46-47, but they never assert that in their speculative counter-hypothetical world mifepristone would *not* be successful in the vast majority of cases, or that the women who take the drug *without* experiencing a serious adverse event vastly outnumber those who do experience such an event.

Plaintiffs' remaining two points on harms ring just as hollow. Plaintiffs claim that the public has no interest in allowing FDA's "illegal actions" to persist. Opp. 46. But FDA *did* "abide by the federal laws that govern [its] existence and operations." Opp. 46 (quoting *Texas* v. *Biden*, 40 F.4th 205, 229 (5th Cir. 2022)). Given the significant disruption that would result from flip-flopping between various regulatory states of affairs, even if there is a lack of clarity in this posture, a stay is warranted to hold things in stasis until the Court is sure of its conclusion.

Finally, Plaintiffs are wrong to assert that the remedy here would be remand *with* vacatur. Opp. 49-50. "The decision whether to vacate depends on" two factors: (1) the seriousness of the flaws in the agency's reasoning, and (2) "the disruptive consequences" occasioned by "an interim change that may itself be changed." *Allied-Signal, Inc.* v. *U.S. Nuclear Regul. Comm'n*, 988 F.2d 146, 151 (D.C. Cir. 1993). Both factors point toward remand without vacatur here. Never before has a judicial officer set aside an FDA drug approval after second-guessing the agency's safety determination. And because the agency's medical and scientific judgment is at issue—rather

than, for example, an argument that the agency exceeded its statutory authority—a remand can and will cure any (if indeed there are any) errors in the agency's approach. *Heartland Reg'l Med. Ctr.* v. *Sebelius*, 566 F.3d 193, 198 (D.C. Cir. 2009) ("When an agency may be able readily to cure a defect in its explanation of a decision, the first factor in Allied–Signal counsels remand without vacatur."); *accord Env't Def. Fund, Inc.* v. *EPA*, 898 F.2d 183, 190 (D.C. Cir. 1990). Vacating Mifeprex's approval will be "quite disruptive," to put it mildly, which also makes judicial modesty appropriate. *Allied-Signal*, 988 F.2d at 151.

C. Plaintiffs Face No Irreparable Harm From A Stay.

Plaintiffs' claims of irreparable harm during the appeal of the District Court's ruling are (1) unsubstantiated and (2) undercut by their delay in filing this suit and willingness to consolidate their injunction request with a merits ruling. On the former, Plaintiffs reiterate that they "face imminent, non-speculative harm." Opp. 44. That is wrong for the litany of reasons already established. If Plaintiffs cannot show standing, then they cannot show irreparable harm. Plaintiffs also offer no legally supportable justification to explain away the three years they waited to file their 2019 citizen petition, the eleven-plus months they waited to file suit after its partial denial, or their agreement to a schedule below that would have delayed a merits ruling by months—however "sensible" such an agreement may have been. Opp. 45. The time it took FDA to respond to its citizen petition, Opp. 45, does not show irreparable harm. A lack of diligence in pursuing the remedy they now seek undercuts an assertion of irreparable injury, period. *See Benisek* v. *Lamone*, 138 S. Ct. 1942, 1944 (2018).

CONCLUSION

For the foregoing reasons, and those in Danco's petition, the Court should stay the preliminary injunction pending appeal, including the resolution of any certiorari petition before this Court. Alternatively, the Court should grant certiorari before judgment and set this case for expedited briefing and argument before the summer recess.

Respectfully submitted,

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