Nos. 23-235 and 23-236

In the Supreme Court of the United States

U.S. FOOD AND DRUG ADMINISTRATION, ET AL., PETITIONERS

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.

DANCO LABORATORIES, L.L.C., PETITIONER

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.

ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

REPLY BRIEF FOR THE FEDERAL PETITIONERS

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The lower courts profoundly erred in holding that respondents have Article III standing based on speculative and attenuated injuries; in countermanding FDA's scientific judgments by imposing novel requirements that have "alarmed the entire pharmaceutical industry," Pharmaceutical Cos. Br. 3; and in ordering disruptive preliminary relief. Respondents' attempt to defend those holdings only underscores how far the decisions below strayed from black-letter Article III, administrative law, and equitable principles.

I. RESPONDENTS LACK ARTICLE III STANDING

Respondents acknowledge that bedrock Article III principles require them to establish a "'concrete'" injury that does not rest on "'a highly attenuated chain of possibilities'" and that is "traceable" to FDA's challenged actions. Br. 18, 29, 33 (quoting *Clapper* v. *Amnesty Int'l USA*, 568 U.S. 398, 409, 410 (2013)). Respondents cannot satisfy any of those requirements.

A. Respondents Fail To Identify Any Doctor With A Cognizable Article III Injury

The lower courts held that respondents satisfy Article III based on a loose, statistical approach to associational standing. Gov't Br. 17-20. Respondents do not defend that holding. Instead, they concede they must make a "specific" showing that "at least one identified [association] member" has an Article III injury. Br. 30 (quoting *Summers* v. *Earth Island Inst.*, 555 U.S. 488 (2009)) (brackets in original). But respondents offered evidence related to only seven identified doctors, whose declarations span just a few dozen pages and are often vague or conclusory. J.A. 150-200 (declarations of Drs. Francis, Skop, Wozniak, Johnson, Frost-Clark, Delgado, and Jester). The lower courts did not even purport to find that those barebones declarations establish that any identified doctor satisfies Article III. In seeking to plug that gap in this Court, respondents shift theories, rely on new and unsupported factual assertions, and slip into the probabilistic generalities they purport to disclaim.

We elaborate on those problems below, but the details should not obscure the fundamental point: All of respondents' theories of injury reduce to the assertion that FDA's changes to mifepristone's conditions of use could marginally increase the risk that one of respond-

ents' seven identified doctors may be called upon to treat a woman who has chosen to take mifepristone and experiences an exceedingly rare serious adverse event—a scenario that can occur only at the end of a long chain of contingencies involving independent decisions by third parties. Respondents still have not cited any decision, by any court, endorsing such an attenuated theory. And with good reason: Respondents' theories do not come close to showing that any identified doctor faces a "certainly impending" injury. *Clapper*, 568 U.S. at 401 (citation omitted).[1]

1. Respondents have not identified any member who faces an imminent conscience injury

a. Respondents' primary theory of injury (Br. 18-21) is that FDA's challenged actions increase the risk that one of the seven identified doctors could be forced to provide treatment against the doctor's moral or religious beliefs. But as we explained (Br. 20-21), just two doctors offered any evidence about their beliefs, and both stated only that they oppose "being forced to end the life of a human being in the womb." J.A. 155 (Dr. Francis); see J.A. 167 (Dr. Skop).

Dr. Francis or Dr. Skop could suffer that injury only if all of the following took place: (i) a woman chooses to take mifepristone after consultation with another provider; (ii) she suffers an extremely rare serious adverse event requiring emergency care; (iii) rather than returning to her prescribing provider or another provider she was referred to, she seeks care from Dr. Francis or

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[1] Respondents quibble (Br. 29) with *Clapper*'s formulation. But "to the extent that the 'substantial risk' standard is relevant and is distinct from the 'certainly impending' requirement, respondents fall short of even that standard, in light of the attenuated chain of inferences necessary to find harm." *Clapper*, 568 U.S. at 414 & n.5.

Dr. Skop or presents at a hospital where one of them is working; (iv) when she does so, her pregnancy is still ongoing; (v) the necessary care is termination of the pregnancy; and (vi) Dr. Francis or Dr. Skop is unable to invoke federal conscience protections or otherwise decline to provide care and is instead forced to terminate the pregnancy. Gov't Br. 21-23. That theory is speculative on its face, and respondents have not identified even a *single* doctor among their thousands of members who has ever been required to perform an abortion in the decades mifepristone has been on the market. *Id.* at 23-24.

Respondents do not deny that the conscience injury described by Drs. Francis and Skop is so speculative it has never occurred. Instead, they change their theory. Respondents now assert (Br. 19) that some respondents and members "consider *any* participation in an elective abortion objectionable." But that is not what respondents' declarations say. Respondents quote Dr. Francis's statement that she objects to "completion of an elective chemical abortion," *ibid.* (quoting J.A. 155), but context makes clear that she was describing a procedure that ends an ongoing pregnancy. See J.A. 155 (describing opposition "to 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."). And the organizational declarants on whom respondents rely (Br. 19-20) describe their unidentified members' objections in similar terms. J.A. 121, 136.

b. In any event, respondents' broader conscience-injury theory is likewise speculative. It would require a similarly long chain of contingencies culminating in a woman presenting at a particular doctor's hospital with

an emergency need for care in circumstances where the doctor somehow could not invoke federal conscience protections or otherwise decline to provide treatment. Respondents do not identify any member who has faced that situation. Respondents rely (Br. 20-21, 26-27) on a few doctors' allegations that they have treated women who had taken mifepristone. But none of the declarations states that the declarant objected to providing that care; nor do they identify any employer policies or other circumstances that would have required them to provide care in violation of their consciences.

Respondents emphasize (Br. 20, 31) that some complications from mifepristone involve "emergency situations" and posit that no other doctor may be available if a patient presents to a doctor working in a "healthcare desert," Br. 31 (quoting J.A. 155). But none of respondents' identified doctors claims to work in a healthcare desert or otherwise to practice in a situation where they are the only provider available to provide care in an emergency.

Respondents also dispute (Br. 31-32) their ability to invoke federal conscience protections. They assert (Br. 20, 31) that they "must act *immediately*" and "the doctor hardly has time to invoke her federal rights." But no time-intensive process is required; the Church Amendments, for example, provide that doctors may "refuse[] to perform or assist" in an abortion, and employers may not punish doctors for exercising that right. 42 U.S.C. 300a-7(c)(1)(B); see, *e.g.*, 42 U.S.C. 300a-7(d). Hospitals must accommodate doctors in emergency rooms no less than in other contexts.

It is thus not surprising that respondents fail to identify a single instance of any respondent or member-doctor being required by her employer to provide care

after invoking conscience protections. Instead, respondents quote the government's statement that "treating physicians who violate [the Emergency Medical Treatment and Active Labor Act (EMTALA)] face civil penalties and exclusion from Medicare." Br. 31 (citation and emphasis omitted); see 42 U.S.C. 1395dd(d)(1)(B). But the government did not suggest that EMTALA's general provisions override specific statutory conscience protections. To the contrary, in the separate litigation on which respondents rely, the government has disclaimed the suggestion that "EMTALA would compel individuals to perform abortions contrary to their sincerely held moral or religious beliefs." Reply Br. at 25, *Texas* v. *Becerra*, 89 F.4th 529 (5th Cir. 2024) (No. 23-10246).

c. Respondents next rely (Br. 25-26) on FDA's recognition that in some cases, women who take mifepristone and experience adverse events may rely on "emergency services." Even if such statistics could demonstrate standing, but see Gov't Br. 17-20, serious adverse events associated with the use of mifepristone "are exceedingly rare." J.A. 465; see Gov't Br. 6.

The documents respondents cite prove the point. Danco's 2004 "Dear Emergency Room Director" letter (Resp. Br. 25) states that "[a]bortion, whether medical or surgical, is 'generally very safe and is therefore infrequently associated with complications,'" and that in "rare[]" cases women may "present to an emergency room" due to "infections and bleeding that occur rarely following spontaneous (miscarriage), surgical, and medical abortions, including Mifeprex use, and childbirth." Danco Letter 1, https://perma.cc/734R-LLSQ (citation omitted). Such letters are "not uncommon," and "[t]he fact that Danco and FDA agreed" to the letter's issuance

—years before the FDA actions at issue here—"does not imply" that the approved regimen is "unsafe." J.A. 258.

Respondents also rely (Br. 25) on FDA's statements and labeling from the original 2000 approval of mifepristone. But the current labeling does not list the unavailability of emergency services as a contraindication. J.A. 526, 529-530. Although the labeling continues to instruct patients to seek emergency care if they experience certain symptoms and cannot reach their provider (see Resp. Br. 25-26), drug labeling frequently contains similar statements—including for some commonly prescribed drugs.[2] Far from establishing some risk unique to mifepristone, such language simply reflects that emergency rooms are always the "backstop" (*id.* at 6, 24) for emergencies—even when the risk of emergency is exceedingly slight.

d. Studies involving tens of thousands of women show that the serious adverse events that could give rise to the emergency situations potentially implicating respondents' objections are extremely rare: Hospitalization, serious infections, and bleeding requiring a trans-

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[2] See, e.g., Paxil Medication Guide at 3, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020031s082lbl.pdf; Cialis Labeling (Prescribing Information) at 1, 28, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021368s030lbl.pdf; Eliquis Labeling (Prescribing Information) at 6, https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/202155s034lbl.pdf; Xeljanz Medication Guide at 66, https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/203214 s028,208246s013,213082s003lbl.pdf; Xanax Medication Guide at 22, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/018276s059lbl.pdf; Zelnorm Medication Guide at 1, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021200Orig1s015lbl.pdf.

fusion each occur in between 0% and 0.7% of cases. J.A. 303-304; see Gov't Br. 6. Respondents do not question that overwhelming evidence; instead, they invoke inapposite statistics.

For example, respondents note (Br. 32) that in a small percentage of cases—about 3% at 10 weeks of gestation, J.A. 538—a woman who takes mifepristone requires "a surgical procedure to end the pregnancy." But that statistic goes to mifepristone's effectiveness, not its safety. Respondents provide no support for their implicit assertion that those surgical abortions are *emergency* procedures—much less that any identified doctor would be required to provide such care.

Similarly, respondents emphasize (Br. i, 12, 26, 28, 34) the Medication Guide's statement that in two studies involving about 1,000 women who took mifepristone, 2.9 to 4.6 percent visited an emergency room. J.A. 533. But as the statistics above make clear, most emergency room visits do not involve serious adverse events. The Medication Guide references studies showing a hospitalization rate of only 0.04-0.6%. *Ibid.* As respondents themselves acknowledge, many patients seek care for the cramping and bleeding that are the expected results of mifepristone's approved regimen rather than the sorts of emergencies that respondents focus on. J.A. 132; see ACOG Br. 26 n.44. Respondents have neither asserted that they object to treating women experiencing such symptoms nor explained why they could not decline to provide such non-emergency care.

e. Even giving respondents' conscience theory its broadest understanding, it would not "satisfy the requirement that threatened injury must be certainly impending" because it "relies on a highly attenuated chain of possibilities." *Clapper*, 568 U.S. at 410; see Gov't Br.

21-22. Respondents attempt (Br. 29) to distinguish *Clapper* on the theory that "the government directly imposes the injury here" or somehow "conscript[s]" (Br. 2, 33) respondents into providing care. But the government does no such thing. FDA does not require any doctor to prescribe mifepristone or any woman to take it. And when a woman who chooses to take mifepristone experiences an exceedingly rare serious adverse event, FDA neither requires her to seek emergency care from respondents nor requires respondents to provide it. Respondents' injury will occur, if at all, only because of a series of "unfettered choices made by independent actors not before the courts." *Lujan* v. *Defenders of Wildlife*, 504 U.S. 555, 562 (1992) (citation omitted).

2. Respondents' remaining theories of injury fail

Respondents' remaining theories of injury—which rely on similarly speculative and attenuated causal chains—fail for yet additional reasons.

a. Respondents assert that treating women who have taken mifepristone causes them "distress." Br. 22 (capitalization and emphasis omitted). But as the Fifth Circuit recognized, that argument simply restates their conscience objections. Pet. App. 35a. And to the extent respondents more broadly assert Article III standing for anyone who alleges distress resulting from a government action, they cite no precedent supporting that extravagant theory. Gov't Br. 26-27 & n.3.

b. Respondents next rely on "diverted time and resources" to treat mifepristone patients. Resp. Br. 21 (capitalization and emphasis omitted). That theory is inconsistent with respondents' decisions to practice emergency medicine or serve as hospitalists, which generally requires triaging and treating patients who arrive at the hospital. Gov't Br. 27. And respondents' as-

sertions (Br. 22) that "[t]hey do *not* spend most of their time in the emergency room" refutes their theory of injury. Respondents' central premise is that their provision of "emergency" care exposes them to an imminent threat that they will be forced to treat a woman suffering a rare serious adverse event. Resp. Br. 13, 20, 23, 25-28, 31-35, 40-41. Respondents cannot simultaneously insist that they provide emergency care so infrequently that it is not part of their usual work.

c. Finally, respondents provide no basis for concluding that FDA's actions expose them to "increased liability and insurance costs." Resp. Br. 23 (capitalization and emphasis omitted). Respondents muster (Br. 24) only a single unresolved malpractice complaint—and they do not even suggest it involves a member of a respondent organization.

B. Respondents' Asserted Injuries Are Not Fairly Traceable To FDA's 2016 And 2021 Actions

1. Because respondents' asserted injuries turn on a series of independent choices by third parties, they are not "fairly traceable" to FDA's actions. *Haaland* v. *Brackeen*, 599 U.S. 255, 291 (2023) (citation omitted). Respondents observe that "the independent actions of third parties" do not necessarily "defeat standing where they are 'the predictable effect of Government action.'" Resp. Br. 34 (quoting *Department of Commerce* v. *New York*, 139 S. Ct. 2551, 2566 (2019)). But *Department of Commerce* concerned a challenge to a census question that had "historically" depressed response rates in a manner that would harm the plaintiffs. *Id.* at 2566. Here, by contrast, the causal chain connecting FDA's actions to any harm experienced by any particular doctor is far more attenuated.

2. What is more, respondents have made little effort to isolate the incremental effects of FDA's 2016 and 2021 actions. Three of respondents' declarants each describe treating roughly a "dozen" patients who suffered serious complications from mifepristone over the span of decades. J.A. 163, 179, 184. Such sporadic past injuries would not establish standing to seek prospective relief even if all of those incidents could count. See *City of Los Angeles* v. *Lyons*, 461 U.S. 95, 105-106 (1983). But respondents' burden is much higher: They must show an imminent injury fairly traceable to the *incremental* effect of FDA's 2016 and 2021 actions, which merely revised the conditions of use for a drug that was already widely prescribed.

a. In attempting to carry that burden as to FDA's 2016 changes, respondents focus (Br. 39) on FDA's decision to raise the gestational age limit from 49 to 70 days. But respondents do not claim that mifepristone's safety profile changes after 49 days. Instead, they contend that "the failure rate"—the number of cases in which the approved regimen of mifepristone and misoprostol will not terminate a pregnancy—increases, causing more women to need "surgical intervention." *Ibid.* (brackets and quotation marks omitted). But again, the fact that some women may need non-emergency surgical abortions does not injure respondents or their members. See p. 8, *supra*.

Respondents do not cite any statistics showing that the removal of the second and third in-person visits or permitting prescriptions by licensed non-physician practitioners results in increased complications requiring emergency care. Rather, they cite (Br. 40) one doctor's assertion that a single patient's "situation could have been avoided" with a follow-up visit. J.A. 199-200.

That is plainly insufficient to demonstrate an imminent injury traceable to FDA's 2016 actions.

b. Turning to FDA's 2021 action, respondents focus (Br. 35-36) on the agency's statement that some studies suggest that "there may be more frequent ED/urgent care visits related to the use of mifepristone when dispensed by mail." J.A. 407. But "half of the ED/urgent care visits" in one study "did not entail any medical treatment." J.A. 404-405; see FDA, *REMS Modification Rationale Review* 39 (2021) (*REMS Review*), https://perma.cc/W4U3-L38P (noting that increase in emergency room visits was not associated with an increase in serious adverse events). Moreover, respondents do not explain how any increase in emergency room visits would be significant enough to inflict an imminent injury on any particular doctor.

Respondents further contend (Br. 36-38) that removal of the in-person dispensing requirement "heightens the risk" that women will take mifepristone beyond ten weeks' gestation or present to the emergency room with an undiagnosed ectopic pregnancy. But mifepristone prescribers must have the ability to diagnose ectopic pregnancies and accurately date pregnancies, J.A. 383-384, 395; ectopic pregnancies can be diagnosed and pregnancies can be dated without an in-person visit, *ibid.*; and respondents fail to substantiate their speculation that an in-person visit—which has never been required to include an ultrasound, J.A. 255-256—will better guard against these asserted risks. And once more, even if respondents were correct that FDA's 2021 action will increase the number of women visiting emergency rooms to some unspecified extent, that would not establish that any of their seven identified doctors faces any imminent injury fairly traceable to that action.

C. Respondents' Other Standing Theories Lack Merit

Respondents briefly assert (Br. 42-46) theories of organizational and third-party standing that the Fifth Circuit did not consider. Those theories lack merit.

1. Relying on *Havens Realty Corp.* v. *Coleman*, 455 U.S. 363 (1982), respondent organizations claim (Br. 42) standing on the theory that they have "diverted resources in response to" FDA's actions. But in *Havens*, the organizational plaintiff specifically alleged that the defendants' racial steering made it more costly for the organization to comply with its contractual obligations to identify low-income housing and counsel residents. Resp. Br. at 33, 36, *Havens*, *supra* (No. 80-988). Here, respondents make only vague claims (Br. 43) that FDA's actions "frustrate[] and complicate[]" their "missions to support women's health and educate the public." If those allegations were sufficient, organizations would have standing whenever they allege a "setback to [their] abstract social interests"—an outcome *Havens* disclaimed. 455 U.S. at 379.

Respondents also rely (Br. 44-45) on the cost of preparing their citizen petitions. But respondents cannot bootstrap their way into standing merely by expending resources on a challenge. And contrary to respondents' suggestion (Br. 45), FDA's regulations cannot "confer a right to judicial review that is not authorized by Article III." *Center for Responsible Sci.* v. *Hahn*, 809 Fed. Appx. 10, 13 (D.C. Cir. 2021) (per curiam) (rejecting standing argument based on 21 C.F.R. 10.45(d)(1)(ii)).

Nor can respondents demonstrate standing by asserting that FDA's 2016 removal of heightened reporting requirements led them to "conduct[] their own studies and analyses." Br. 43-44 (quoting J.A. 134, 157). Respondents provide no support for the suggestion that

third parties have standing to challenge the alteration of reporting requirements on *other* providers. And even if that theory were valid, it would support standing to challenge only the change to the reporting requirements, not FDA's other actions.

2. Because respondents have failed to establish their own injury in fact, it is irrelevant whether they could make the *additional* showings required to assert the substantive rights of third parties. Gov't Br. 33 n.7. But they cannot. Among other things, respondents cannot reasonably assert (Br. 46) a "close" relationship with future emergency patients while also claiming injury from their lack of any "existing relationship" with those patients. J.A. 172; see, *e.g.*, J.A. 92, 121, 165, 198-199.

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A straightforward application of this Court's precedents demonstrates that respondents lack standing and that their objections to mifepristone are properly directed "to the Executive and Legislative Branches, not to the Judiciary." *Coalition for Mercury-Free Drugs* v. *Sebelius*, 671 F.3d 1275, 1283 (D.C. Cir. 2012). The Court should put an end to this litigation by holding that respondents cannot satisfy Article III.[3]

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[3] Three States that belatedly intervened in the district court assert that this Court cannot reverse the decisions below without considering whether the States have standing. Missouri Br. 2-4. As we explained in opposing the States' motion to intervene in this Court (at 2, 8-11), that is wrong. The decisions below rest on the lower courts' holding that *respondents* have standing; if this Court disagrees, the decisions must be reversed. And the case would then have to be dismissed because the district court never had jurisdiction to begin with and would not be a proper venue for the States' claims. To avoid prolonging proceedings that cannot properly move forward in the district court, the Court may wish to remand with instructions that the case be dismissed or transferred to an appro-

II. FDA'S ACTIONS WERE LAWFUL

A. In 2016, FDA lawfully increased the gestational age limit from seven to ten weeks, reduced the number of office visits from three to one, and allowed certified non-physicians to prescribe mifepristone. FDA based those changes on "an *enormous* and highly reliable data set," ACOG Br. 20, including dozens of studies involving tens of thousands of women, see J.A. 436-437, 451, 509-516; Gov't Br. 34-36. Respondents do not identify any evidence that FDA overlooked. Instead, they repeat (Br. 59) the Fifth Circuit's criticism that no study examined the "cumulative effect" of the changes. That argument fails for multiple independent reasons.

First, it is telling that respondents themselves failed to raise their current objection in their citizen petition. Gov't Br. 38. Respondents claim (Br. 7, 61) they raised the issue, but the page they cite discusses only one of the three changes; it says nothing about the need for additional studies or any failure to address the changes' cumulative effect. J.A. 328.

Second, FDA must approve an application if the evidence is "adequate" to show that the drug is "safe for use under the conditions prescribed." 21 U.S.C. 355(d)(1). Nothing in the statute limits FDA to particular kinds of evidence; instead, FDA must "exercise its scientific judgment to determine the kind and quantity of data and information" that satisfies the statutory standard. 21 C.F.R. 314.105(c).

Third, demanding a study that exactly matches a drug's approved conditions of use is unprecedented and unworkable. Precisely because they are experimental and intended to gather data, clinical studies frequently

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priate venue for consideration of the States' claims. See, *e.g.*, *Munaf* v. *Geren*, 553 U.S. 674, 691-692 (2008).

include additional measures such as "laboratory and clinical monitoring, stricter inclusion and exclusion criteria, [and] more visits." J.A. 265. Those extra steps—which control variability and maximize data quality, J.A. 255, 265—may not be necessary to ensure safe use. FDA thus routinely approves drugs based on studies that do not exactly mirror the conditions of use. Indeed, a diverse chorus of industry participants has warned that respondents' "impossibly rigid" standard would severely disrupt the Nation's system for developing, approving, and regulating pharmaceuticals. Pharmaceutical Cos. Br. 12-21; see PhRMA Br. 23; Former FDA Comm'rs Br. 22-24; Food and Drug Scholars Br. 10-17.

Fourth, respondents err in asserting (Br. 62) that FDA "ignore[d]" the interaction of the three challenged changes. FDA explained that because the "changes are interrelated," it relied on many studies "to provide evidence to support multiple changes." J.A. 298; see J.A. 479 (observing that "adverse event data typically come from studies or reviews that include multiple changes"). And FDA comprehensively documented its conclusion that mifepristone would continue to be safe and effective under the revised conditions of use—that is, under *all* of them.

Fifth, respondents' focus on studies ignores FDA's consideration of approximately 15 years of post-marketing safety information in evaluating mifepristone's safety profile. That information was compiled during a period when there had been "over 2.5 million uses of Mifeprex by US women since its marketing in 2000, including the use of the proposed dosing regimen and extended gestational age at many clinic/office sites." J.A. 502; see J.A. 456, 459, 465, 485; see also 300 Reproductive Health Researchers Br. 18-19.

Finally, respondents cannot (Br. 59-60) analogize this case to *Motor Vehicle Manufacturers Ass'n* v. *State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983). There, the Court faulted an agency for giving "no consideration" to obvious alternative options and offering "no findings and no analysis" to justify its decision. *Id.* at 47, 49 (citation omitted). Here, in contrast, FDA conducted an exhaustive analysis of post-marketing experience and dozens of studies showing that the changes were safe both individually and in combination. Gov't Br. 34-36, 38-39.

B. In 2016, FDA also lawfully changed the prior requirement that prescribers agree to report certain non-fatal adverse events, such as hospitalizations and blood transfusions, to the drug's sponsor, while maintaining the requirement to report deaths. Gov't Br. 41-42. That action aligned mifepristone with the standard reporting requirements for non-fatal events applicable to all approved prescription drugs. And contrary to respondents' insinuations, those standard requirements constitute "a robust adverse event reporting system." PhRMA Br. 24.

Respondents assert (Br. 63) that FDA could not alter the reporting requirements while also changing other conditions of use. But respondents ignore the extensive evidence supporting the safety of those changes. See pp. 15-16, *supra*. It was not arbitrary and capricious for FDA to change the reporting requirements based on that evidence and 15 years of heightened reporting confirming mifepristone's safety profile.

C. Finally, FDA lawfully decided to eliminate the in-person dispensing requirement in 2021.

1. Respondents fault (Br. 50-51) FDA for relying on adverse event data from FDA's Adverse Event Report-

ing System (FAERS) that was supposedly tainted by the 2016 reporting changes. But it is not plausible to assert that the agency acted arbitrarily by relying on data from the reporting regime that applies to nearly all FDA-approved drugs.

Respondents assert that FDA's reliance on FAERS data contradicts its statement that "[r]ates of occurrence [for adverse events] cannot be established" using FAERS data. Br. 50 (quoting J.A. 417). But that statement simply reflects FDA's recognition that the FAERS data has limits, including that FDA "does not receive reports for every adverse event." J.A. 417. Here, FDA did not use FAERS data to calculate absolute rates of adverse events or assume that every event was captured; instead, it asked whether FAERS showed "any new safety concerns" during "the time when in-person dispensing was not enforced." J.A. 398.

Respondents are also wrong to assert (Br. 50) that FDA gave "dispositive weight" to FAERS data. FDA sought out and considered other evidence, including extensive published literature, data provided by the sponsors, and safety and efficacy information from more than 20 years of experience regulating mifepristone. J.A. 397-408; *REMS Review* 19-42. All of that information supported FDA's conclusion that "mifepristone will remain safe and effective if the in-person dispensing requirement is removed." J.A. 407. And although FDA acknowledged the shortcomings in some of the available studies, it was not required to wait for perfect data; it was entitled to make "a reasonable predictive

judgment based on the evidence it had." *FCC* v. *Prometheus Radio Project*, 592 U.S. 414, 427 (2021).[4]

2. Respondents emphasize (Br. 52-54) that certain studies found lower rates of emergency-room visits when mifepristone was dispensed in person. But those visits are not necessarily evidence of complications. See p. 12, *supra*. And even if there were a minor increase in serious adverse events, that would not preclude FDA from removing the in-person dispensing requirement because neither the cited studies nor any other evidence suggested that change would materially alter mifepristone's well-established safety profile. J.A. 406.

Respondents' focus on a possible increase in the extremely low rate of serious adverse events also misunderstands the governing statutory standard. When deciding whether to modify an existing REMS, FDA must consider not just "risks," but the need to "minimize the burden on the health care delivery system of complying with" the REMS. 21 U.S.C. 355-1(g)(4)(B)(i) and (ii). Here, FDA explained that removing the in-person dispensing requirement would "render the REMS less burdensome," and that the remaining REMS provisions would "continue to ensure that the benefits of mifepristone for medical abortion outweigh the risks." J.A. 407; see also GenBioPro Br. 21-23.

Respondents also overstate the consequences of FDA's decision. Eliminating the in-person dispensing requirement does not result in "unsupervised" abortions (Resp. Br. 49). The REMS still requires patients to obtain a prescription for mifepristone from a certified prescriber who must "[r]eview the Patient Agreement

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[4] Respondents attempt (Br. 54-55) to limit *Prometheus* to the particular statute at issue there, but the Court articulated principles applicable to all "agency decisionmaking." 592 U.S. at 427.

Form with the patient and fully explain the risks of the mifepristone treatment regimen." J.A. 367 (emphasis omitted). That prescriber is "responsible for the well-being of the patient[] regardless of [the] mode of evaluation or dispensing the medication." J.A. 407; see Nurse Practitioners Br. 24-28. And patients who do not receive the drug from their prescriber's office must get it from certified pharmacies that have agreed to meet the REMS requirements. Gov't Br. 7.

3. Respondents note (Br. 48-49) that FDA had previously characterized the in-person dispensing requirement as "necessary" and "minimally burdensome." But the FDCA contemplates that FDA will continue to review an approved REMS and update its requirements as appropriate in light of additional evidence and experience. 21 U.S.C. 355-1(f) and (g). The statements on which respondents rely were made before FDA had the benefit of data and information from periods when, due to a court order and the COVID-19 pandemic, the in-person dispensing requirement was not enforced. J.A. 376-377, 397. Once that actual experience showed that mifepristone could be safely administered without in-person dispensing, it was entirely appropriate for FDA to reconsider its view. And FDA acknowledged its change in position and explained in detail the "good reasons" for its new approach. *FCC* v. *Fox Television Stations, Inc.*, 556 U.S. 502, 514 (2009). Nothing more was required.

4. Respondents briefly assert (Br. 56-58) that the 1873 Comstock Act prohibited FDA from eliminating the in-person dispensing requirement. The Fifth Circuit did not reach that argument, and this Court should not either. See *Cutter* v. *Wilkinson*, 544 U.S. 709, 718 n.7 (2005). In any event, the argument is doubly flawed.

First, respondents misunderstand the Comstock Act. As originally enacted, it prohibited selling drugs for "causing unlawful abortion" in federal territories, Act of Mar. 3, 1873, 17 Stat. 598-599; mailing drugs for "procuring of abortion," *id.* § 2; and importing the "hereinbefore-mentioned articles," *id.* § 3. The next year, Congress clarified that the importation restriction, like the federal-territory restriction, was limited to drugs for "causing unlawful abortion." Rev. Stat. § 2491 (1875) (19 U.S.C. 135 (1925)).

Courts have long recognized that despite "slight distinctions in expression," all the Comstock restrictions should be interpreted to bar only items intended for unlawful use. See, *e.g.*, *United States* v. *One Package*, 86 F.2d 737, 740 (2d Cir. 1936) (Hand, J., concurring); *Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions*, 2022 WL 18273906, at *4-*7 (Op. O.L.C. Dec. 23, 2022) (OLC Op.). Indeed, before the district court decision in this case, not a single court had held that the Comstock Act prohibits the mailing of abortion drugs under all circumstances.

Congress has repeatedly ratified the lower courts' construction by amending the Comstock Act without material change. OLC Op. *6-*8; Former DOJ Officials Br. 12-15. And many of those amendments were made *after* that construction was specifically called to the "attention of Congress" in an unusual Historical and Revision Note set out in the United States Code itself in 1948. See 18 U.S.C. 1461 note.[5]

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[5] Despite that note, respondents deny (Br. 57) that there was a settled construction of the Comstock provisions for Congress to ratify. But the very decision they rely on reflects that consensus by finding it not "reasonable" to suppose Congress intended "the

Second, and in any event, nothing in the FDCA requires FDA to incorporate requirements that other, unrelated laws may impose on a drug's distribution or use. Instead, the FDCA properly leaves enforcement of such laws to the agencies charged with their administration. For example, by 1965, FDA had approved at least seven oral contraceptives, even though contraceptives were then among the Comstock Act's enumerated items. See Lara Marks, *Sexual Chemistry: A History of the Contraceptive Pill* 77-78 (2001). Here, FDA relied on its FDCA authority to require in-person dispensing when it approved mifepristone in 2000. But it decided in 2021 that such a requirement was no longer necessary to "ensure the benefits of [mifepristone] outweigh the risks," 21 U.S.C. 355-1(g)(4)(B), and thus no longer justified by the FDCA provisions authorizing a REMS, J.A. 397-408. Respondents fail to explain how the Comstock Act could require FDA to maintain requirements under the FDCA that the FDCA itself no longer supports.

III. THE DISTRICT COURT'S REMEDY WAS IMPROPER

A. The district court erroneously invoked 5 U.S.C. 705 to "postpone" the effective date of agency actions that had long been in effect. Respondents do not attempt to reconcile that relief with the ordinary meaning of "postpone," pointing instead (Br. 66) to the statute's further authorization for courts to "preserve status or rights pending conclusion of the review proceedings." 5 U.S.C. 705. We acknowledge that Section 705 contemplates preliminary injunctions to preserve the status quo, but the district court's remedy here did not "preserve" the status quo—it upended it. And our point

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statute [to] cover all acts of abortion." *Bours* v. *United States*, 229 F. 960, 964-965 (7th Cir. 1915).

about Section 705 is that it contemplates preliminary injunctions subject to traditional equitable principles, including the principle of party-specific relief. Section 705's "postpone" language does not authorize a novel "interim * * * form of vacatur," Pet. App. 194a, or make such a universal remedy the default in APA cases. Gov't Br. 46.

B. Applying traditional equitable principles, the Fifth Circuit should have given FDA an opportunity to issue a new agency action that could cure any purported failures of explanation. Gov't Br. 48-49. There was no justification for ordering disruptive preliminary relief based on defects that could likely be cured with further explanation—especially where, as here, respondents' own injuries are at best highly attenuated.

Respondents attempt (Br. 67-69) to minimize the disruptive effects of the decision below. But that decision would reinstate an outdated regulatory regime that includes conditions FDA has found unjustified. As FDA's then-Principal Deputy Commissioner explained, staying FDA's 2016 and 2021 actions would "create significant chaos for patients, prescribers, and the health care delivery system" by rendering all extant doses of mifepristone misbranded. 22A902 Appl. App. 116a. The Nation's leading medical organizations have likewise warned that doctors and patients have "come to rely on the FDA's current regulatory approach" and would be seriously harmed by "rewinding the clock." ACOG Br. 19 (emphasis omitted); see *id.* at 19-26.

Respondents assert (Br. 48) that the pre-2016 restrictions are merely "common-sense safety standards." But FDA has determined, based on decades of experience and scientific evidence, that those restrictions are unnecessary and thus unjustified. FDA's cur-

rent conditions of use allow mifepristone to be dispensed only after a woman has consulted with her provider and been informed about the drug's risks. The Fifth Circuit's decision unjustifiably interferes with women's ability to make that intensely personal medical decision for themselves.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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