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.,
Respondents.

DANCO LABORATORIES, L.L.C.,
Petitioner,
v.
ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.
Respondents.

On Writs of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF FOR FORMER U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, U.S. FOOD AND DRUG ADMINISTRATION, AND WHITE HOUSE OFFICIALS AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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TABLE OF CONTENTS

TABLE OF CONTENTS—CONTINUED

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

TABLE OF AUTHORITIES—CONTINUED

Page(s)

TABLE OF AUTHORITIES—CONTINUED

Page(s)

TABLE OF AUTHORITIES—CONTINUED

Page(s)

INTEREST OF *AMICI CURIAE*[1]

Amici Curiae are former officials at the U.S. Department of Health and Human Services (HHS), U.S. Food and Drug Administration (FDA), and the White House. Like all Americans, they have an interest in the administration of federal laws by HHS agencies like FDA. While these officials have diverse perspectives on abortion, they share the view that while agency experts deserve respect, their decisions, which impact hundreds of millions of people, demand judicial scrutiny. *Amici* are:

- **Brian Harrison**, who served as Chief of Staff at HHS from 2019 to 2021.

- **Catherine Hoyer**, who served as Principal Deputy Assistant Secretary for Administration at HHS.

- **Kelley Smith James, Ph.D., LMSW**, who served at HHS for more than fourteen years in various capacities, most recently as a Senior Social Scientist in the Office of the Assistant Secretary of Health.

- **Darcie Johnston**, Director of Intergovernmental Affairs at HHS from 2017 to 2021.

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[1] Counsel for *amici curiae* certifies that no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amici* made such a monetary contribution.

- **James R. Lawrence, III**, who served as a Deputy General Counsel at HHS, and as outgoing FDA Chief Counsel in 2021.

- **Anna Pilato**, who served as Deputy Assistant Secretary and Senior Advisor for External Affairs in the Administration for Families Children at HHS from 2017 to 2021.

- **Katy Talento, N.D., Sc.M.**, who served as Special Assistant to the President for Domestic Policy at the White House from 2017 to 2019.

INTRODUCTION AND SUMMARY OF ARGUMENT

FDA regulates "about 21 cents of every dollar spent by U.S. consumers," a wide scope which includes drugs, medical devices, and televisions. FDA, *FDA at a Glance* (Jan. 2024), https://www.fda.gov/media/175664/download. Drug companies operate under regulations governing all aspects of product manufacturing, distribution, labeling, and marketing. A company's fortunes can pivot—for better or worse—as much on finding space to operate within those regulatory constraints as on positive clinical trial results.

Where many companies have found their clinical and commercial ambitions quelled by FDA regulatory requirements, Petitioner Danco Laboratories LLC found flexibility. In 2015, Danco asked FDA to revisit eleven different restrictions on mifepristone, a drug previously approved "for the medical termination of intrauterine pregnancy"—more commonly known as abortion. Even though Danco did not

present FDA with data on the cumulative impact of implementing all of those changes simultaneously, the company essentially ran the table, winning a wider label and relaxed restrictions from the agency in 2016. Later, in 2021, Danco got further relief from the agency after FDA lifted mifepristone's in-person dispensing requirement.

The Fifth Circuit correctly set these actions aside as arbitrary and capricious under the Administrative Procedure Act (APA). FDA's evidentiary justifications for deregulating mifepristone fail scrutiny. Further, FDA, Danco, and their *amici* advance the notion that the cumulative effects evidence the Fifth Circuit was looking for was too demanding. But FDA expects similar evidence in related contexts, including when a drug sponsor wants to change its manufacturing process.

The decisions at issue here were less the product of reasoned agency decision making, and more an artifact of *Roe v. Wade*, 410 U.S. 113 (1973), and the since-discarded notion that the Constitution contains an unenumerated right to an abortion. Affirming FDA's actions in this case will embolden commercial entities disappointed by FDA's actions to demand the Danco treatment—to have the agency apply the same weights and measures to them and their products that FDA applied to Danco and mifepristone to achieve similar ends.

ARGUMENT

I. In FDA's Selective Deregulation of the Abortifacient Mifepristone, the Agency Failed to Consider the Cumulative Effects of the Changes Proposed, Even Though the Agency Does So in Similar and Related Circumstances.

A. The Regulatory Framework for Drug Development and Approval

FDA exists to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner." 21 U.S.C. § 393(b)(1). Relevant here, Congress directed the agency to "protect the public health by ensuring that . . . human and veterinary drugs are safe and effective." *Id.* § 393(b)(2)(B).

Under the Federal Food, Drug, and Cosmetic Act (FDCA), FDA's enabling statute, any new drug must be approved by FDA pursuant to a new drug application (NDA) before the product is introduced into interstate commerce. 21 U.S.C. § 355(a). Among other things, these applications include clinical trial reports, proposed labeling, and details about the manufacturing process for the drug at issue. *Id.* § 355(b)(1)(A). Once an NDA is approved, an applicant can change the existing approval by filing a supplemental new drug application (SNDA). According to one treatise, "[a] supplemental new drug application (SNDA) modifies an existing product approval to permit a significant change or new indication to be used

for an existing new drug." JAMES T. O'REILLY & KATHARINE A. VAN TASSEL, 1 FOOD AND DRUG ADMIN. § 13:135 (2023-2) [hereinafter O'REILLY & VAN TASSEL].[2]

FDA regulations distinguish between major, moderate, and minor changes to approved NDAs. 21 C.F.R. § 314.70. Major changes such as alterations to labeling and certain changes to the manufacturing process require a company to submit and for FDA to approve an SNDA. *Id.* § 314.70(b). As Danco points out, SNDAs are held to the same evidentiary standard as NDAs. Danco Br. 5; *see also* O'REILLY & TASSEL, § 13:135 (noting that "[e]fficacy and safety data of the same quality as the original NDA will be expected" to accompany an SNDA).

B. FDA Approves the Abortifacient Mifepristone with Multiple Restrictions to Ensure Safety.

The Population Council filed an NDA for mifepristone with FDA in 1996. Pet. App. 6a. The two-step drug regimen requires a pregnant woman to take mifepristone to block production of progesterone, "a hormone needed for . . . pregnancy to continue." J.A. 542. Next the pregnant woman takes misoprostol "to cause the pregnancy to be passed from [her] uterus." *Id.* Around the time of mifepristone's NDA filing, one medical professor described this "passing" in more specific terms, noting that, unlike with suction

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[2] The same treatise calls SNDAs "a purely administrative creation" which "meet a need not discussed at all in the statute." O'REILLY & VAN TASSEL, § 13:135 n.1.

abortions, "one of the features of this kind of termination is that a patient may actually see the products of conception and may actually see the tiny, tiny fetus." Carlyle Murphy, *RU 486: Abortion By Pill Is Not As Simple As It Seems*, WASH. POST (Feb. 3, 1997), https://www.washingtonpost.com/archive/lifestyle/wellness/1997/02/04/ru-486-abortion-by-pill-is-not-as-simple-as-it-seems/50fc9192-4c98-4e74-bf57-7a6cd442da33/.

In its coverage of mifepristone, *The Washington Post* reported on the drug's clinical protocol. "That protocol recommends three visits to the physician or clinic providing mifepristone," while also "verify[ing] that a woman is within the first 49 days of her pregnancy by asking her the date of her last menstrual period, doing a physical exam of the uterus or, if there is still doubt, doing a sonogram." *Id.* "This is really a regimen," one of the physicians studying the drug explained to *The Post*. "This is not a simple matter of one thing you do," the doctor said. *Id.*[3]

When FDA approved the NDA for mifepristone in 2000, the controls the agency placed on the drug were consistent with this prior reporting.[4] FDA limited the drug to pregnancies with "a gestational age of forty-nine days or less," required physicians capable of assessing gestational age and diagnosing ectopic pregnancies to prescribe the drug in-person to the

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[3] The physician *The Post* quoted, Paul Blumenthal, M.D., M.P.H., signed onto a brief in support of Petitioners. Br. Over 300 Reproductive Health Researchers 4a.

[4] The 2000 approval of mifepristone and the various legal issues related to that approval are not at issue in this appeal.

patient, and report adverse events to the drug sponsor. Pet. App. 8.a. The patient was required to take mifepristone in-office, and then return three days later to take misoprostol. *Id.* A third and final visit was required "to determine whether the drug has successfully terminated the pregnancy and to screen for any adverse effects." *Id.*

C. In 2015, Danco Proposes Major and Interrelated Labeling Changes to Its Abortifacient Product and Obtains Relief From FDA on Substantially All the Proposed Changes. Later, in 2021, FDA Lifts the In-Person Dispensing Requirement for Mifepristone.

Danco asked FDA to lift many of the restrictions on its product in 2015. J.A. 294–95. In FDA's review of these requests, the agency noted that "these major changes are interrelated," and that "in some cases data from a given study were relied on to provide evidence to support multiple changes." J.A. 298. In 2016, the agency granted the company's requests, "[i]ncreasing the maximum gestational age from forty-nine days to seventy days," "[a]llowing non-physicians to prescribe mifepristone," eliminating the requirement of in-person administration of misoprostol while changing the drug's route of administration and altering the dosing schedule for both mifepristone and misoprostol. Pet. App. 10a. The agency also eliminated the requirement that prescribers "report non-fatal adverse events" to Danco. *Id.*

In April 2021, citing the COVID-19 pandemic, FDA eliminated the in-person dispensing

requirement for mifepristone. Pet. App. 11a.[5] In December 2021, the agency concluded, "based in part on its experience in the pandemic," that in-person dispensing of mifepristone "was not necessary to assure [the drug's] safe use." FDA Br. 7.

D. The Fifth Circuit Correctly Set Aside FDA's Actions on Mifepristone as Arbitrary and Capricious.

1. The 2016 Amendments

The Fifth Circuit set aside FDA's deregulation of mifepristone as arbitrary and capricious under the APA and this Court's decision in *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983). Regarding the agency's 2016 actions, the Fifth Circuit determined that FDA failed to consider the "cumulative effect" of the amendments. Pet. App. 53a. Specifically, none of the studies FDA cited in its decision "examined the effect of implementing all of those changes together." *Id.* FDA "neither considered the effects [of the amendments] as a whole, nor explained why it declined to do so." *Id.* FDA also "failed to consider" the impact of eliminating the adverse event reporting requirement in view of the various major changes the agency approved. Pet. App. 54a.

FDA defends the 2016 amendments, contending that the Fifth Circuit faulting the agency's failure to consider the changes "as a whole" "ignored the

[5] This move occurred after COVID-19 vaccines became available in the United States.

realities of the drug-approval process." FDA Br. 37. Concurring with the pharmaceutical industry, FDA complains that "[r]equiring sponsors to provide a single study exactly matching all of the approved conditions of use would impose . . . an impossibly rigid new standard." FDA Br. 38 (internal quotation marks omitted).

This justification for the 2016 amendments fails for at least two reasons. First, the Fifth Circuit faulted FDA for "fail[ing] to address the cumulative effect at all." Pet. App. 54a. There might be an explanation as to why study of the various, interrelated changes to mifepristone's protocol "as a whole" was unnecessary, but "the agency needed to acknowledge the question, determine if the evidence before it adequately satisfied the concern, and explain its reasoning." *Id.* When it did not do so, the agency "entirely failed to consider an important aspect of the problem," rendering the actions arbitrary and capricious. *State Farm*, 463 U.S. at 43; *see also Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1913 (2020) (setting aside as arbitrary and capricious agency's termination of Deferred Action for Childhood Arrivals for failing to consider "the option of forbearance or the option of retaining forbearance without benefits").

Second, FDA overstates the practical impact of requiring cumulative effects evidence. Over time, a drug manufacturer may wish to change its manufacturing process. The FDCA requires drug manufacturers to obtain FDA approval prior to implementing certain manufacturing changes. *See* 21 U.S.C. § 356a. This regulatory oversight of drug production protects

patients by ensuring "the manufacturing process will produce the same result each time." FDA, *Generic Drugs: Questions & Answers* (Mar. 16, 2021), https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers.

Under existing FDA guidance, a drug company is "responsible for validating the effects of any postapproval manufacturing change on the identity, strength, quality, purity, and potency of the drug as these factors may relate to the safety or effectiveness of the drug before distribution of the drug made with the change." FDA, *Guidance for Industry, Comparability Protocols for Postapproval Changes to the Chemistry, Manufacturing, and Controls Information in an NDA, ANDA, or BLA*, at 3 (Dec. 2022), https://www.fda.gov/media/162263/download. Among other things, the sponsor is expected to submit a "risk assessment" of the proposed changes. *Id.* at 8. Relevant here, "[i]f multiple changes are proposed for simultaneous implementation or if a specified type of change will be made repeatedly over the life cycle of the product, the risk assessment should also address *the potential for cumulative effects* of these changes on product quality." *Id.* (emphasis added). These are the same kind of "cumulative effects" the Fifth Circuit determined FDA failed to consider when the agency deregulated mifepristone in 2016. Pet. App. 53a–54a.

FDA also maintains the Fifth Circuit "was wrong on the record," citing to three studies the agency argues "closely mirrored challenged aspects of the 2016 conditions." FDA Br. 38. But none of those studies considered all the changes together, nor does

FDA cite to how the agency extrapolated from those studies to support changes to the entire mifepristone regimen.

The studies themselves provide an uncertain foundation for approval. For example, FDA points to a 2015 study which the agency maintains "evaluat[ed] prescribing by nurses versus physicians" as support for the decision to lift the requirement that only physicians prescribe mifepristone. FDA Br. 39. But that study evaluated the differences in outcomes between nurse and physician prescribing *in Mexico*, not in the United States. Claudia Diaz Olvarrieta et al., *Nurse versus physician-provision of early medical abortion in Mexico: a randomized controlled non-inferiority trial*, BULL WORLD HEALTH ORGAN. 249 (2015). Regulation of the health care profession, including nursing, varies among the States. *See Nurses' Authority to Prescribe or Dispense*, GUTTMACHER INST. (Sept. 1, 2023), https://www.guttmacher.org/state-policy/explore/nurses-authority-prescribe-or-dispense. Given these State-by-State variations, controlling for the different regulatory environments governing prescribers would be a challenge within the United States, much less a foreign country where there are still more distinct regulatory and educational requirements applicable to nursing. And that is not to mention other physician extenders like physician assistants.

The Fifth Circuit also determined FDA's removal of the requirement that prescribers report adverse events to Danco was arbitrary and capricious. Pet. App. 54a. FDA rejects this conclusion in part because the agency "had already found that the 2016

changes *would not* affect mifepristone's safety profile." FDA Br. 42. That does not excuse the agency's apparent disinterest in getting real-world data from a source that is, second the patient herself, closest to the point of care. That Danco, which has no care relationship with patients, may receive an adverse event report, which the company then passes along to FDA, does not fill this information gap.

2. FDA's Elimination of Mifepristone's In-Person Dispensing Requirement in 2021.

The Fifth Circuit also set aside FDA's 2021 elimination of the in-person dispensing requirement for mifepristone. The court found that "FDA gave dispositive weight to adverse-event data in FAERS," the FDA Adverse Event Reporting System, "despite the uncontested limitations in doing so." Pet. App. 59a. Because FDA had previously lifted the requirement that prescribers report adverse event data in 2016, the court deemed FDA "responsible for its own inability to obtain probative data," preventing the agency from "citing its lack of information as an argument in favor of removing further safeguards." *Id.*

FDA attempts to justify its 2021 deregulation of mifepristone on the grounds that the 2016 changes "left undisturbed the reporting requirements governing mifepristone's sponsors." FDA Br. 43. Again though, the choice to eliminate reporting by previously included prescribers created a gap in reporting which cannot be filled by the passive collection of adverse events by the drug's sponsor.

The agency also cites its conclusion "that non-enforcement of the in-person dispensing requirement during much of 2020 and 2021 . . . did not appear to affect adverse events." FDA Br. 43. To reach that conclusion, FDA relied on "the FAERS database and the published medical literature to identify U.S. postmarketing adverse events that reportedly occurred from January 27, 2020 through September 30, 2021." J.A. 398. From its review of FAERS data, FDA found "that there does not appear to be a difference in adverse events when in-person dispensing was not enforced and that mifepristone may be safely used without in-person dispensing." J.A. 399. In the Fifth Circuit's words, "FDA gave dispositive weight to adverse-event data in FAERS—despite the uncontested limitations of doing so." Pet. App. 59a.

The agency did not accord such weight to adverse event data in at least one other context. During the COVID-19 pandemic, FDA did not require premarket notification prior to marketing of certain surgical gloves. FDA, *Guidance for Industry, Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19 Public Health Emergency*, at 10 (Mar. 2020), https://web.archive.org/web/20201206031141/https://www.fda.gov/media/136540/download. In reversing an HHS decision to make that change permanent, FDA rejected reliance on adverse event reporting. "Although adverse event reports are a valuable source of information, the reports have limitations . . . including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data," the agency explained. 86 Fed. Reg. 20167, 20170 (Apr. 16, 2021).

"The incidence or prevalence of an event cannot be determined from adverse event reports alone, due to underreporting of events, inaccuracies in reports, lack of verification that the device caused the reported event, and lack of information about frequency of device use." *Id.* at 20170–71. Because FDA eliminated the prescriber reporting requirement in 2016, the logic of these limitations on adverse event reporting applies even more forcefully to mifepristone, but the abortifacient received less, not more regulatory oversight.

FDA also cites its reliance on published literature to justify relaxing its oversight of mifepristone. FDA Br. 43–44. But the agency acknowledged that "the studies we reviewed are not adequate on their own to establish the safety of the model of dispensing mifepristone by mail." J.A. 407. The agency prefaced its conclusion "that mifepristone will remain safe and effective if the in-person dispensing requirement was not being enforced" by invoking "REMS assessment data, FAERS data from the time period when the in-person dispensing requirement was not being enforced, and our review of the literature." *Id.* In other words, the literature in and of itself was insufficient to justify the decision. This Court should reject FDA's attempt to proffer the literature as a standalone justification for deregulating mifepristone.

II. Failing to Curb FDA's Arbitrary and Capricious Actions Related to Mifepristone Will Spur Additional Litigation.

Danco warns that the Fifth Circuit's "merits analysis threatens to destabilize the pharmaceutical industry." Danco Br. 3. The Pharmaceutical Research

and Manufacturers of America (PhRMA) similarly advises that this case "could discourage biopharmaceutical companies from making the necessary investments to advance new and approved medicines that benefit patients." PhRMA Br. 5.

If the Fifth Circuit imposed new requirements on FDA in this case, that would be one thing. Applying the APA and this Court's 1983 *State Farm* decision to require an agency like FDA to consider the important aspects of a problem is quite another. The Fifth Circuit did not so much as second-guess agency experts here as require those experts to consider issues like "the cumulative effect" of Danco's 2015 proposed changes in the first instance. Pet. App. 54a.

To the extent the Fifth Circuit's decision is destabilizing, consider the impact of affirming FDA's actions in this case. "A fundamental norm of administrative procedure requires an agency to treat like cases alike. If the agency makes an exception in one case, then it must either make an exception in a similar case or point to a relevant distinction between the two cases." *Westar Energy, Inc. v. Federal Energy Regulatory Com'n*, 473 F.3d 1239, 1241 (D.C. Cir. 2007). Further, while "[a]n agency is by no means required to distinguish every precedent cited to it by an aggrieved party," it "must do more than simply ignore that argument" when "a party makes a significant showing that analogous cases have been decided differently." *LeMoyne-Owen Coll. v. N.L.R.B.*, 357 F.3d 55, 61 (D.C. Cir. 2004) (Roberts, J.). As one member of this Court put it previously, quoting a celebrated nineteenth century thinker, "Emerson's advice to preachers—'emphasize your choice by utter ignoring

of all that you reject'—will not do for administrative agencies." *Id.* (quoting RALPH WALDO EMERSON, *The Preacher*, *reprinted in* 10 LECTURES AND BIOGRAPHICAL SKETCHES 215, 235 (1904)).

If FDA is not required to consider the cumulative effects of changes to mifepristone, then drug sponsors have every reason to insist, and likely will demand, that they receive the same treatment from the agency. The possibility of such questions arising is not mere speculation. As noted above, when drug manufacturers submit requests to FDA to approve changes in drug production processes, the agency expects manufacturers to assess the cumulative effects of those changes. Part I.D.1 *supra*.

Or consider FDA and their *amici*'s related contention that demanding "a single study exactly matching all of the approved conditions of use" for a product would create an impossible standard. FDA Br. 38. In 2018, FDA rejected an NDA for a nitric oxide delivery system. The agency took issue with "confounding variables" in the sponsor's study, including "incorrect system set-up for the testing scenarios, moderator error, and missing device components." FDA, *GeNOsyl Delivery System (Nitric Oxide) NDA 202860 Response*, at 4 (2018), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/202860Orig1s000OtherActionLtrs.pdf. Relevant here, the agency also rejected the sponsor's human factors study, concluding that the sponsor did "not provide sufficient evidence to demonstrate that your proposed product can be used safely and effectively for its intended uses and use environments." *Id.*

FDA regulates medical devices. The agency is responsible for ensuring "there is reasonable assurance of the safety and effectiveness of devices intended for human use." 21 U.S.C. § 393(b)(2)(C). There are two principal pathways to market for medical devices: premarket approval and regulatory clearance. Unless FDA exempts a class I or class II device from the premarket notification requirement, the device must be cleared by the agency pursuant to section 510(k) of the FDCA, 21 U.S.C. § 360(k).

Over time, a medical device company, like a drug manufacturer, may decide to change certain features of a product. When it does, the firm must consider whether to submit a new section 510(k) notice for the modified device. As part of that process, FDA advises companies to "conduct a risk-based assessment" of the modified device to the one that was previously cleared. FDA, *Guidance for Industry, Deciding When to Submit a 510(k) for a Change to an Existing Device*, at 10 (Oct. 25, 2017) https://www.fda.gov/media/99812/download. As with drug manufacturing changes, these alterations are not viewed in isolation. Instead, companies are to consider "[w]hen the cumulative effect of individual changes triggers the regulatory threshold for submission," which would mean "the manufacturer should submit a new 510(k). *Id.*

These commercial considerations aside, consider the plight of a parent seeking treatment for a child suffering from a rare disease. Judy Stecker, *The FDA Could Help Save My Son From a Rare Disease*, WALL. ST. J. (Feb. 27, 2024), https://www.wsj.com/articles/the-fda-could-help-save-my-son-from-a-rare-

disease-bureaucracy-efficacy-7090ac82. As one mother explains, FDA recently doubled down on the agency's "outdated interpretation of efficacy criteria" while "insist[ing] that" a foundation engaged in finding therapies for a rare genetic disease "conduct substantially more scientific and clinical development" work, tacking on "additional complex requirements that significantly expanded the geographic footprint and cost of the Phase III clinical trial." *Id.* All this while mifepristone receives less regulation.

FDA insists that "[t]he same standards are applied to the drug applications for Mifeprex and the approved generic Mifepristone Tablets, 200 mg, as are applied to all drug applications." FDA, *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (Sept. 1, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation. While there may be a way to distinguish specific cases, at the very least, when FDA determines a company failed to provide requisite cumulative effects evidence, mifepristone's deregulation will provide a basis to complain, as companies press for FDA to grant them the same flexibility Danco received for its abortifacient.

From a historical standpoint, mifepristone's treatment makes sense. As far back as 1989, before the drug ever made it to America, commentators observed that "the pill would fit neatly within the federal law of abortion announced in *Roe v. Wade*." Sarah Ricks, *The New French Abortion Pill: The Moral Property of Women*, 1 YALE J.L. & FEMINISM 75, 76 (1989).

Mifepristone was originally approved in 2000, and later deregulated in 2016 and 2021 in an America in which *Roe* and its judicially-invented right to an abortion was still on the books. This Court has since ruled that "*Roe* was egregiously wrong from the start," while "return[ing] the issue of abortion to the people's elected representatives." *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2243 (2022).

In *Dobbs*, this Court "observed that its abortion rights cases "led to the distortion of many important but unrelated legal doctrines." *Id.* at 2275. Upholding *Roe* and its progeny meant compromise in at least six different areas, including rules on third-party standing, "standard res judicata principles," and "ordinary rules on the severability of unconstitutional provisions." *Id.* at 2275-76. *Stare decisis*, this Court explained, does not require upholding a "doctrinal innovation" like a constitutional right to an abortion when such "requires courts to engineer exceptions to longstanding background rules." *Id.* at 2276.

Similar *Roe*-induced innovations are at issue here. At Danco's request, FDA lifted multiple restrictions on the previously approved abortifacient mifepristone. The agency deregulated the drug, failing to consider the cumulative effects of implementing those changes at the same time, even though the agency requires that kind of evidence in similar situations. The Fifth Circuit was correct to hold those decisions were arbitrary and capricious.

CONCLUSION

For the reasons above, the decision below should be affirmed.

Respectfully submitted,

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