Nos. 23-235, 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.

and

DANCO LABORATORIES, L.L.C.,
Petitioner,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, *ET AL.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF OF *AMICUS CURIAE* JUDICIAL WATCH, INC. IN SUPPORT OF RESPONDENTS

Meredith L. Di Liberto
JUDICIAL WATCH, INC.
425 Third Street SW
Washington, DC 20024
(202) 646-5172
mdiliberto@judicialwatch.org

Counsel for Amicus Curiae

Dated: February 29, 2024

LEGAL PRINTERS LLC ● Washington, DC ● 202-747-2400 ● legalprinters.com

QUESTION PRESENTED

Whether FDA's 2016 and 2021 actions were arbitrary and capricious.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes and Rules

Miscellaneous

INTERESTS OF THE *AMICUS CURIAE*[1]

Judicial Watch, Inc. ("Judicial Watch") is a non-partisan, public interest organization headquartered in Washington, D.C. Founded in 1994, Judicial Watch seeks to promote accountability, transparency and integrity in government, and fidelity to the rule of law. Judicial Watch regularly files *amicus curiae* briefs and lawsuits related to these goals.

Amicus seeks participation in this case for two reasons. First, this case concerns a subject matter in which Judicial Watch has been involved for over two decades: drugs approved by the federal government that intentionally end pregnancy. *See e.g.*, *Judicial Watch, Inc. v. FDA*, 449 F.3d 141 (D.C. Cir. 2006). Judicial Watch has used the Freedom of Information Act ("FOIA") law and subsequent lawsuits to obtain information vital to this case. *Id.*; *see also Judicial Watch, Inc. v. HHS*, Civil Case No. 1:22-cv-03152 (D.D.C., Mehta, J.). Second, the broader implication of this case extends beyond the specific subject matter into the larger concern of federal executive agency overreach. Throughout its existence, Judicial Watch has championed the constitutional principles of separation of powers and the balance of powers and seeks to assist the Court in analyzing the implications of undue deference given a federal agency –

---

[1] *Amicus curiae* states that no counsel for a party to this case authored this brief in whole or in part; and no person or entity other than *amicus curiae* and their counsel made a monetary contribution intended to fund the preparation or submission of the brief.

particularly when there is evidence of improper political interference.

SUMMARY OF ARGUMENT

The judiciary's default position of bestowing undue deference on federal agencies has led to the rise of an unelected fourth branch of government that touches every aspect of our lives. These federal agencies wield budgets in the hundreds of billions of dollars with little to no oversight. When the agency is protected by the political party in power, it can act with extreme liberality and the American people are powerless to reign it in. The only hope of keeping federal agencies from toppling the balance of powers is for the judiciary to perform its constitutional duty to keep them in check by way of judicial review.

This case is a prime example of the dire consequences of unchecked executive power employed by a federal agency, the Petitioner, Food and Drug Administration ("FDA"). In 2000, the FDA harnessed the executive power from a political administration with a personal agenda bent on approving the drug mifepristone ("Mifeprex") which intentionally ends the life of a prenatal human.[2] In approving Mifeprex, the FDA violated its own unambiguous regulation and relied on pretext. In enacting subsequent major changes to Mifeprex safety restrictions in 2016 and 2021, the FDA laid bare the extent of the pretext used

---

[2] For the purposes of this *amicus curiae* brief, Judicial Watch uses Danco's registered trademark name "Mifeprex" to refer to the abortion drug at issue.

in its original approval by blatantly contradicting most of its previous rationalizations. The FDA's actions in 2016 and 2021 were arbitrary and capricious and violated the Administrative Procedures Act ("APA").[3] This Court should affirm the Fifth Circuit's order.

ARGUMENT

I. The FDA's Decision to Approve Mifeprex and Its Subsequent Changes to the Safety Restrictions Are Subject to the APA

The FDA's decision to approve the use of Mifeprex for the intentional ending of pregnancy and its subsequent decisions to significantly alter the safety restrictions are subject to the APA. Under the APA, the FDA's decisions may be "set aside if found to be 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.* ("*State Farm*"), 463 U.S. 29, 41 (1983) (*quoting* 5 U.S.C. § 706(2)(A)). Commonly referred to as the "arbitrary and capricious standard," courts "must 'hold unlawful and set aside agency action' that is 'arbitrary or capricious' when it fails to 'articulate a satisfactory explanation for its action including a rational connection between the facts found and the choices made.'" *Texas v. Becerra*, 575 F. Supp. 3d 701, 720 (N.

---

[3] *Amicus* maintains that the FDA's initial approval in 2000 was also arbitrary and capricious and respectfully disagrees with the Fifth Circuit's holding that it is most likely time barred. However, *Amicus* recognizes that the Court did not grant review on this issue and therefore, does not address it.

D. Tex. 2021) (*quoting State Farm*, 463 U.S. at 43). In determining whether the FDA's decisions violated the arbitrary and capricious standard, this Court has considered several factors including: (1) whether the FDA's decisions were based on a consideration of the relevant factors at the time each decision was made; (2) whether the FDA made a clear error of judgment; (3) whether the FDA's offered explanation for each decision runs counter to the evidence; and (4) whether the FDA's proffered explanations for its decisions are so implausible that they cannot be explained by a difference of opinion or agency expertise.[4] *State Farm,* 463 U.S. at 43.

The judiciary's role in reviewing the FDA's decisions is clearly rooted in the APA's judicial review. *See* 5 U.S.C. § 706, *et seq*. Whether the FDA violated its own regulations and federal law are legal questions for which the Court, not the FDA, is the expert. The FDA is owed no special deference. Whether the FDA acted arbitrarily and on pretext alone as the basis for its decisions is a legal question for which the Court, not the FDA, is the expert. The FDA is owed no special deference. It is the Court that is granted the constitutional authority to determine whether the FDA violated the APA. Respondents' briefs are replete with references to the deference the FDA is supposedly owed, but they fail to acknowledge or understand the concept of the proper role of the Court. Judicial review is not the Court "second guessing" the science behind the FDA's decisions, as

---

[4] The Court articulated several other factors for consideration, but Amicus is focusing on just a few for the purposes of this brief.

the Respondents claim. *See e.g.*, Brief for the Federal Petitioners at 44. Rather, it is the Court determining – based on the evidence before it – whether the FDA acted arbitrarily, capriciously, abused its discretion, or acted not in accordance with the law. This is quintessentially the role of the Court, and the Court is well equipped to make this determination.

II. The FDA's 2016 Changes to Mifeprex Safety Restrictions Were Arbitrary and Capricious.

In a congressional hearing after the 2000 approval of Mifeprex, the FDA asserted that it chose to approve mifepristone pursuant to Subpart H to maintain more stringent safety restrictions on the drug.[5] This included the requirement that the drug be administered "by or under the supervision of a physician" who met several qualifications. Among these qualifications were: (1) the ability to assess the duration of the pregnancy accurately and diagnose ectopic pregnancies; (2) "the ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through other qualified physicians, and are able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary"; (3) the requirement to provide each

---

[5] *See* RU-486: Demonstrating a Low Standard for Women's Health?: hearing before Subcommittee on Criminal Justice, Drug Policy, and Human Resources, 109 CONG. 202, (2006) (Statement of Janet Woodcock) at 88. A transcript is available in its entirety at: https://www.govinfo.gov/content/pkg/CHRG-109hhrg31397/html/CHRG-109hhrg31397.htm

patient with the Medication Guide, provide the patient with the chance to ask questions, and obtain a patient signature; and (4) the requirement to notify the sponsor of drug failure (an ongoing pregnancy after use of the drug) and to report any hospitalization, transfusion or other serious events to the sponsor. Joint Appendix ("JA") at 235.

Additionally, the 2000 FDA approval was for a specific regimen (600 mg of mifepristone, followed by 400 mg of misoprostol) and for a specific duration: through 49 days' of pregnancy. JA at 234. The FDA approval also included a specific number of doctor visits: one visit for the mifepristone, another for the misoprostol, and a final follow-up visit 14 days after taking the drugs to be certain the abortion was complete. *Id*. In 2004, the FDA increased the black box safety warnings on Mifeprex to include risk of serious bacterial infections, sepsis, bleeding, and death as possible effects of the drug use.[6] And in 2011, the FDA issued a new risk evaluation and mitigation strategy ("REMS") and included the requirement for a medication guide as well as three elements to assure safe use ("ETASU").[7] JA at 272-

---

[6] *See e.g.*, Kate Rawson, "Mifeprex "Black Box" Warning Revised on Reports of Sepsis Deaths," SCRIP (July 20, 2005), https://scrip.pharmaintelligence.informa.com/PS062593/Mifeprex-Black-Box-Warning-Revised-On-Reports-Of-Sepsis-Deaths

[7] Due to the FDA's Amendments Act of 2007, all drugs approved pursuant to Subpart H, including those previously approved, would fall under the risk evaluation and mitigation strategy ("REMS"). Mifeprex was required to participate in REMS and establish elements to assure safe use ("ETASU").

274. This history shows that, in the first decade of post-approval use, the FDA *increased* Mifeprex safety requirements.

The FDA was very clear about the need for Mifeprex safety restrictions as a part of its approval criterion.[8] Yet, despite these very public safety concerns, the FDA significantly revised the Mifeprex labeling and REMS in 2016 and *reduced* the safety requirements. These changes included significantly altered dosage, removal of the follow-up medical visit, removal of the requirement to take the drug in a doctor's office, and expansion of the use through 70 days gestation.[9] Also of significance and concern, the FDA modified the REMS to require reporting of only deaths attributable to the drug. No longer would hospitalizations, transfusions, or other serious adverse events need to be reported.[10]

The FDA's asserted rationalization for these significant changes was that it was "following the science." The FDA has not, however, provided the science it followed that could reasonably explain the changes. For example, the expansion in use from 49 days to 70 days gestation. It was very clearly established that expanding the use of Mifeprex past 49 days decreased the effectiveness – meaning, the

---

8 *See* Subcommittee Hearing, *supra* note 5.

9 *See* Melanie Israel, "Chemical Abortion: A Review," THE HERITAGE FOUNDATION, No. 3603 (March 26, 2021), https://www.heritage.org/life/report/chemical-abortion-review.

10 *Ibid.*

pregnancy was not ended – and increased the adverse events such as hospitalization.[11] Thus, according to the science, by increasing the gestational period of use, the FDA decreased the effectiveness of the drug while increasing the danger. This obvious fact makes the FDA's rationalization implausible as it runs counter to the evidence. *See State Farm*, 463 U.S. at 43; *see also Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221-222 (2016) (agency changes to policy decisions must be explained and a failure to do so is arbitrary and capricious).

The change to in-person medical visits is another example of evidence contrary to the FDA's 2016 decision. Mifeprex was originally approved with three in-person medical visits – the first two to watch for immediate side effects of the drugs following ingestion, and the third, to be certain the abortion was complete. The third visit was absolutely necessary because the delivery of the dead baby most often occurred outside a medical setting, with no one to confirm whether the abortion was medically complete. The potential for a failed or incomplete abortion would run a huge risk for infection, sepsis, a need for surgical intervention and hospitalization. Indeed, "retained products of conception" was the most common cause of maternal morbidity after Mifeprex use.[12] And, as described above, by

---

[11] Irving Spitz, "Early Pregnancy Termination with Mifepristone and Misoprostol in the United States," NEW ENGLAND JOURNAL of MEDICINE, 1998, 338 (18) 1241-47.

[12] Kathi Aultman, Christina Cirucci, *et al.*, "Deaths and Severe Adverse Events after the use of Mifepristone as an

decreasing the effectiveness of the drug with longer gestational usage, the likelihood of incomplete abortions increased, thereby making the follow-up visit even more significant to protect the health of the woman. But rather than "follow the science," the FDA removed the follow-up visit requirement, leaving women more vulnerable to serious adverse events with no medical supervision. The FDA's 2016 Mifeprex changes are arbitrary, capricious, an abuse of discretion, and not in accordance with law.

As with the original approval in 2000, the 2016 changes are steeped in political manipulation.[13] First, by removing critical safety restrictions from the original approval and the subsequent REMS update without rational evidence supporting the decision, the FDA shows its motivation to assuage abortion advocates. Abortion proponents and lobbying groups had a history of challenging safety restrictions in the use and distribution of Mifeprex. Accessibility was key to increasing abortion numbers which had fallen since the 1990's, and the abortion lobby needed Mifeprex expanded to accomplish this goal.[14]

Abortifacient from September 2000 to February 2019," ISSUES IN LAW AND MEDICINE, Volume 36, No. 1 (2021).

[13] For an in-depth investigation of the FDA's corrupt manipulation of international corporations and governments in the pursuance of Mifeprex approval, *see* "A Judicial Watch Special Report: The Clinton RU-486 Files" (April 26, 2006), https://www.judicialwatch.org/archive/2006/jw-ru486-report.pdf

[14] *See e.g.*, Rachel K. Jones and Heather D. Boonstra, "The Public Health Implications of the FDA Update to the Medication Abortion Label," GUTTMACHER INSTITUTE (June 30, 2016),

Increasing the gestational age of use, decreasing doctor involvement and decreasing the dosage all helped to meet the abortion lobby's goal.

Second, the FDA's partnership with another abortion-minded administration, who, like the Clinton administration, sought the political and financial support of the abortion lobby, benefitted greatly from the FDA changes. Facing a critical election, Former President Obama was able to take the credit for increasing the use of Mifeprex, despite that very increase being scientifically unsound.[15] The increased usage would, of course, increase profits for Danco, the manufacturer of Mifeprex.[16] By increasing the gestational age of use to 70 days, the

---

https://www.guttmacher.org/article/2016/06/public-health-implications-fda-update-medication-abortion-label.

[15] *See e.g.*, Sabrina Tavernise, "New F.D.A. Guidelines Ease Access to Abortion Pill," THE NEW YORK TIMES (March 31, 2016), https://www.nytimes.com/2016/03/31/health/abortion-pill-mifeprex-ru-486-fda.html.

[16] Danco is a private company, and intervenor before this Court, which has refused to disclose its investors, but evidence suggests Danco is financially backed by very wealthy, politically connected individuals and foundations that supported abortion rights. *See* Carole Novielli, "The abortion industry's conflicts of interest should concern politicians and media as much as in other industries" LIVE ACTION (Oct. 2, 2020), https://www.liveaction.org/news/abortion-industry-financial-conflicts-interest-politicians-media/; *see also* Sharon Bernstein, "Persistence Brought Abortion Pill to U.S.," LA TIMES (Nov. 5, 2000), https://www.latimes.com/archives/la-xpm-2000-nov-05-mn-47330-story.html (detailing the secretive and questionable business dealings of Danco).

FDA effectively ***doubled*** the number of eligible pregnancies.[17] The FDA's decision certainly improved the market for Mifeprex and Danco, though at the expense of exposing women to increased health risks.

The lack of a rational connection between the evidence (or lack thereof) and the FDA's 2016 decision to change the Mifeprex safety and labeling, and the suggestion of pretext lead to the conclusion that the decision was arbitrary and capricious. *See State Farm*, 463 U.S. at 41; *see also U.S. Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2575-2576.

III. The FDA's 2021 Changes to Mifeprex Restrictions Were Arbitrary and Capricious.

In 2021, using the COVID-19 pandemic as a tool, abortion proponents, led by the American College of Obstetricians and Gynecologists ("ACOG"), sued the FDA to dispense with the REMS in-person medical visit as a prerequisite for obtaining Mifeprex and permit the drug to be mailed.[18] ACOG and the other abortion lobbying groups asserted that the in-patient visit put women at risk of COVID-19 or delayed their

---

17 *See* Tarvernise, *supra* note 15.

18 *See* American College of Obstetricians and Gynecologists, "The FDA's Decision Lifting the Burdensome Restriction on Mifepristone during the Pandemic: What You Need to Know," ACOG ADVOCACY AND HEALTH POLICY (April 21, 2021), https://www.acog.org/news/news-articles/2020/07/courts-order-lifting-burdensome-fda-restriction-what-you-need-to-know.

abortion decision too long to make Mifeprex an option. The FDA accepted ACOG's request and temporarily suspended the in-person medical visit based solely on the COVID-19 pandemic.[19] COVID-19 was, however, just pretext for the FDA's decision.[20] With the pandemic declared over by President Biden on September 18, 2022, the foundation of concern for in-person medical visits should have ended.[21] Instead, the FDA maintained its temporary suspension and continued permitting Mifeprex to be mailed. Then, on December 16, 2022, the FDA permanently removed the REMS requirement for any in-person medical visits.[22]

---

[19] *See* Spitz, *supra* note 11.

[20] Indeed, COVID-19 was just pretext for ACOG as well. ACOG has a long history of fighting for the removal of Mifeprex REMS, including in-person visits. COVID-19 had nothing to do with ACOG's motivations. *See* https://www.acog.org/news/news-releases/2016/03/acog-statement-on-medication-abortion; *see also* American College of Obstetricians and Gynecologists, "Improving Access to Mifepristone for Reproductive Health Indications," ACOG CLINICAL INFORMATION (June 2018), https://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2018/improving-access-to-mifepristone-for-reproductive-health-indications.

[21] *See e.g.*, Zachary B. Wolf, "Biden declares pandemic over. People are acting like it too." CNN (Sept. 19, 2022), https://www.cnn.com/2022/09/19/politics/biden-covid-pandemic-over-what-matters/index.html.

[22] *See e.g.*, Anne Flaherty, "FDA lifts restriction on abortion pill, permanently allowing delivery by mail," ABC NEWS (Dec. 16. 2021), https://abcnews.go.com/Politics/fda-women-obtain-abortion-pill-mail/story?id=81798959.

Removing any in-person medical visit and permitting Mifeprex to be mailed do not allow the prescriber to ascertain the gestational age of the baby or determine whether there is an ectopic pregnancy – two essential pieces of information in the Mifeprex safety approval.[23] The FDA's rationalization for permanently removing in-person medical visits was:

> [T]he FDA analyzed postmarketing data to determine if there was a difference in adverse events between periods when in-person dispensing was and was not enforced. Based on this review, the agency concluded that there did not appear to be a difference in adverse events between periods when in-person

[23] Ectopic pregnancies occur in approximately 1-2% of pregnancies, though that percentage can rise significantly due to certain factors like smoking, IVF treatments, or IUD usage. Erin Hendricks, MD, Rachel Rosenberg, MD, and Linda Prine, MD, "Ectopic Pregnancy: Diagnosis and Management," AM FAM PHYSICIAN 2020: 101 (10): 599-606, https://www.aafp.org/pubs/afp/issues/2020/0515/p599.html. Fatal ectopic pregnancies account for roughly 2.7% of maternal deaths. *Id*. ACOG's own website states that ectopic pregnancies can be life-threatening and recommends the involvement of a health care professional. American College of Obstetricians and Gynecologists, "Ectopic Pregnancy," ACOG (Feb 2018), https://www.acog.org/womens-health/faqs/ectopic-pregnancy; *see also* Virginia Allen, "FDA Has Made Abortion 'Wild West' With Rule Change on Drugs, OB-GYN Says," DAILY SIGNAL (Jan. 18, 2023), https://www.dailysignal.com/2023/01/18/fda-has-made-abortion-wild-west-rule-change-drugs-ob-gyn-says.

dispensing was and was not enforced.[24]

The FDA made this public assertion despite the FDA Commissioner acknowledging that the study designs it relied on were "limited" and "do not appear to show increases in serious safety concerns." JA at 363. And critically missing from this rationalization is the admission that the FDA's 2016 REMS changes dispensed of the reporting requirement for any nonfatal adverse events.[25] The "serious safety concerns" the Commissioner was "reviewing" had not been routinely reported in nearly ***five years***. What reporting data was the FDA comparing? Pre-2016 data, which required ***all*** adverse events as well as failed abortions compared to post-2016 data, which required ***only*** reports of death? This defies all logic and reason and demonstrates that the 2021 decision was not rationally related to the facts, but, rather, was arbitrary and capricious. *See State Farm*, 463 U.S. at 41.

Bolstering this assessment is more evidence of political manipulation. President Biden's affinity for the abortion lobby is widely known and

---

[24] U.S. Food & Drug Administration, "Questions and Answers on Mifepristone for Medical Termination on Pregnancy Through Ten Weeks Gestation," FDA (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.

[25] *See* Israel, *supra* note 9.

acknowledged.[26] The Acting FDA Commissioner, Robert Califf, was the FDA Commissioner during the 2016 Mifeprex changes.[27] The FDA's decision to permanently dispense with in-person medical visits occurred just days after Califf's Senate nomination hearing. Lobbying by ACOG and other abortion lobbyists is at an all-time high, emboldened by an administration bent on forcing states to accept the President's abortion agenda.[28] It is reported that lobbying spending by these abortion lobbyists increased by 107% in the first few months of 2021 – prompted by the possibility of *Roe v. Wade* being overturned.[29] In fact, the President issued a response to the U.S. Supreme Court's *Dobbs v. Jackson Women's Health Organization* decision in which he

---

[26] *See* Alice Miranda Ollstein and Darius Tahir, "FDA lifts curbs on dispensing abortion pills during pandemic," POLITICO (April 12, 2021), https://www.politico.com/news/2021/04/12/abortion-pills-481092.

[27] As FDA Commissioner in 2016, Dr. Califf refused to respond to a congressional inquiry into the 2016 REMS changes for Mifeprex. James Lankford, "Lankford Opposes Controversial Pro-Abortion FDA Nominee," Lankford Press Release (Feb. 15, 2022), https://www.lankford.senate.gov/news/press-releases/lankford-opposes-controversial-pro-abortion-fda-nominee.

[28] *See e.g.*, Lankford, *supra* note 27; *see also Texas v. Becerra*, 2024 U.S. App. LEXIS 35 (5th Cir. 2024) (changing the meaning of a 1986 statute without notice and consent).

[29] *See* Julia Forest, "Abortion rights advocates up their lobbying with Roe under threat," OPEN SECRETS (May 19, 2021), https://www.opensecrets.org/news/2021/05/abortion-rights-up-lobbying-with-roe-threatened.

clearly supported mail-order Mifeprex and made no mention of the COVID-19 pretext.[30] Appendix at 112-113. The FDA desired to alter the Mifeprex REMS and used COVID-19 to do so. Evidence shows this was pretext and the decision was arbitrary and capricious. S*ee Dep't of Commerce,* 139 S. Ct. at 2575-2576.

IV. The FDA's History of Political Ideology over Science Is Dangerous and Cannot Be Granted Blanket Deference.

From disingenuously forcing pregnancy into a "serious illness" category to ensure accelerated approval under 21 C.F.R. § 314.520, to using a pandemic to irresponsibly ship a dangerous drug to individuals under no doctor's professional supervision, the FDA's approval of Mifeprex and subsequent removal of key safety features were accomplished through political force at the expense of science. This alone is reason enough for the Court to question the agency's decisions and reign in agency deference. However, Mifeprex is far from the first politically motivated dangerous drug approval. The FDA has a history of elevating political ideology over science that is becoming increasingly frightening. A brief look at the FDA's history in the past few decades shows a federal agency fraught with corruption, conflicts of interest, and an immense amount of professional negligence that has cost millions of human lives.[31]

---

30 142 S. Ct. 2228 (2022).

31 *See e.g.*, *Alliance for Hippocratic Medicine, et al. v.*

For example, OxyContin (oxycodone), first approved by the FDA in 1995, is seen now by many in the medical field as a the spark that created the opioid crisis in the United States.[32] In records obtained by ProPublica, it is now known that the drug was originally meant to treat short term, severe or end-of--life pain, but the manufacturer, Purdue Pharma, recognized the market value of a more widely accessible pain killer. Therefore, despite lacking any scientific evidence supporting broad use, the FDA approved OxyContin much more broadly for moderate and chronic pain.[33] Purdue's only clinical trial began with 133 elderly osteoarthritis patients, 70 of whom did not complete the trial.[34] Of the 63 participants who completed the trial, 82% had an adverse reaction.[35] The FDA also approved Purdue's

---

U.S. Food & Drug Admin., et al., 78 F.4th 210, 270-271 (5th Cir. 2023) (Ho, J., dissenting).

[32] *See e.g.*, Andrew Kolodny, M.D., "How FDA Failures Contributed to the Opioid Crisis," AMA Journal of Ethics, Vol. 22, 8:E743-750 (August 2020), https://journalofethics.ama-assn.org/sites/journalofethics.ama-assn.org/files/2020-08/joe-2008_0.pdf.

[33] Gerald Posner, "FDA's Janet Woodcock failed to stop the opioid epidemic," USA TODAY (Feb. 3, 2021), https://www.usatoday.com/story/opinion/2021/02/03/janet-woodcocks-failure-fda-opioid-epidemic-column/4352787001/.

[34] Shraddha Chakradhar and Casey Ross, "The history of OxyContin, told through unsealed Purdue document," Stat (Dec. 3, 2019), https://www.statnews.com/2019/12/03/oxycontin-history-told-through-purdue-pharma-documents/.

[35] *Ibid.*

medication insert assertion that claimed OxyContin had a "delayed absorption" that reduced the drug's addictiveness.[36] The label stated unequivocally that addiction was "rare."[37] But this claim was not based on any clinical trials.[38] None. Science had nothing to do with the claim. Janet Woodcock, former FDA Commissioner, oversaw approval of OxyContin as the Director of the Center for Drug Evaluation and Research ("CDER:"), admitted in 2022 that there was a "miscalculation about projected harms" when she led the OxyContin approval.[39] A miscalculation would require a calculation and an error of said calculation. But the FDA approved OxyContin without *any* scientific calculation of projected harms and more than a million people are dead because of it.[40] In addition to the vast amounts of money Purdue made on OxyContin sales, two of the principal reviewers of Purdue's Oxycontin application took high-paying jobs

---

36 *See* Posner, *supra* note 32.

37 *Ibid*.

38 *Ibid*.

39 Celine Castronuovo, "OxyContin Decision Involved FDA 'Miscalculation,' Woodcock Says," Bloomberg Health Law & Business (June 15, 2022), https://news.bloomberglaw.com/health-law-and-business/fdas-woodcock-admits-to-miscalculation-in-oxycontin-decision.

40 Centers for Disease Control, "The Drug Overdose Epidemic: Behind the Numbers," CDC OPIOIDS (Aug. 8, 2023), https://www.cdc.gov/opioids/data/index.html.

at Purdue after leaving the FDA.[41]

Another example is Nuplazid, a drug approved by the FDA for Parkinson's patients in 2016. Nuplazid failed to show any benefit in its first two clinical trials, and, in fact, more patients died or experienced serious side effects from the medication than having no treatment at all.[42] Acadia Pharmaceuticals, Nuplazid's manufacturer, requested that the study scale be revised, thereby making it statistically more probable that a benefit would result in the third clinical trial.[43] The FDA acquiesced then agreed to grant Nuplazid's "breakthrough therapy" designation, consequently requiring only one positive trial.[44] Nuplazid's third trial produced a small benefit in participants who took the drug versus the placebo.[45] The FDA advisory committee would vote 12-2 in favor of accelerated approval after hearing from 15 members of the public.[46] It did not seem to trouble the FDA committee that three speakers were paid Acadia

---

41 *See* Kolodny, *supra* note 31.

42 Caroline Chen, "FDA increasingly approves drugs without conclusive proof they work," PBS NEWSHOUR (June 26, 2018), https://www.pbs.org/newshour/health/fda-increasingly-approves-drugs-without-conclusive-proof-they-work.

43 *Ibid*.

44 *Ibid*.

45 *Ibid*.

46 *Ibid.*

consultants, four worked with an advocacy organization funded by Acadia, three were family members of Parkinson's patients whose travel was paid for by Acadia, and one became a paid "ambassador" for Acadia following the hearing.[47] In the two years following Nuplazid's FDA approval, 887 deaths were attributed to the drug.[48] Altering the study scale was not based on science or clinical evidence.

Yet another example is Aduhelm, a drug purporting to treat Alzheimer's disease. Biogen, the manufacturer, conducted two trials of over 3,200 patients.[49] One trial assessed no statistical difference in the groups and the second showed a difference, but not one that was "clinically significant."[50] Biogen submitted Aduhlem for approval based on the second trial. An FDA advisory committee met and expressed concern that the first trial, which was nearly identical to the second, did not show any benefit and 40% of the participants developed abnormalities.[51] Ten of the 11 committee members voted against approval, but the

---

47 *Ibid.*

48 *Ibid.*

49 Stephanie Diu, "Slowing Down Accelerated Approval: Examining the Role of Industry Influence, Patient Advocacy Organizations, and Political Pressure of FDA Drug Approval," 90 Fordham L. Rev. 2303, 2323(2022).

50 *Id.* at 2324-2325.

51 *Id.* at 2325-2326.

FDA granted approval anyway in 2021.[52] Several FDA committee members resigned following this rogue approval, criticizing Aduhelm as lacking evidence of a benefit while having significant adverse effects on patients.[53] After the FDA granted accelerated approval, it was revealed that the FDA and Biogen had a very close relationship which has caught the attention of the U.S. Department of Health and Human Services ("HHS") Office of Inspector General ("OIG") and members of Congress.[54] Meanwhile, Aduhelm remains on the market without clinical evidence of benefit, giving false hope to Alzheimer's patients and potentially harming them.

These are just a few examples of the FDA's questionable decisions in approving drugs. The approvals themselves, however, are not the only concerning issue at hand. The FDA's approval process is rife with disturbing trends of trading in speed and political favors for safety. For instance, the flow of money from the pharmaceutical industry and patient advocacy groups to the FDA is astounding. The pharmaceutical industry and patient advocacy groups contributed 75% or $905 million of the FDA's scientific review budget in 2017.[55] Additionally, there is the "revolving door" of employment between the pharmaceutical industry and the FDA. In 2018, a

---

52 *Id.* at 2326.

53 *Id.* at 2327.

54 *Id.* at 2330.

55 *See* Chen, *supra* note 41.

study revealed that in 28 product approvals, 11 of the 16 FDA medical reviewers who approved the products worked for the companies whose product they reviewed.[56]

Also concerning is the dramatic increase in the FDA's use of the accelerated approval path and "breakthrough therapy" label.[57] Increasing accelerated approval decreases the stringent pre-market testing required and sets up a "partial end run" around the once gold standard for safety testing.[58] In the mid-90's 80.6% of new drugs were backed by at least two trials.[59] Roughly 20 years later, only 52.8% were so supported.[60] And the FDA has seemingly turned a blind eye to overseeing the completion of post-marketing studies. In 2022, HHS' OIG reported that, of the 278 drugs approved under the accelerated approval label, 104 had not yet completed the required post-marketing trials and more than half of the trials are submitted late.[61] Yet, the FDA has never penalized a single manufacturer with a monetary penalty.[62] Will the FDA determine

---

56 *See* Kolodny, *supra* note 31 at 746.

57 *See* Chen, *supra* note 41.

58 Daniel A. Aaron, "The fall of FDA Review," 22 Yale J. Health Pol'y L. & Ethics 95, 129 (2023).

59 *Id.* at 132.

60 *Ibid.*

61 *Id.* at 129.

62 *Ibid.*

in the future that some of these drugs involved a "miscalculation of projected harms" like the OxyContin approval? How many patients will experience adverse effects or even death while the FDA plays protector of the public health with its eyes closed? How many families will go bankrupt on treatments that offer no real medical benefit but line the pockets of the drug industry and politicians? The FDA has demonstrated that it is not immune from politicization and elevating ideology over science and clinical data. Its approval decisions should be carefully reviewed, and deference regarded at a minimum.

CONCLUSION

For the foregoing reasons, *Amicus* respectfully requests that the Court affirm the Fifth Circuit.

Respectfully submitted,

Meredith L. Di Liberto
Counsel of Record
JUDICIAL WATCH, INC.
425 Third Street SW
Washington, DC 20024
(202) 646-5172
mdiliberto@judicialwatch.org

Counsel for Amicus Curiae

February 29, 2024