IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, *et al*.,	)	
Plaintiffs,	)	
v.	)	Case No. 2:22-cv-00223-z
U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,	)	
Defendants.	)	

***AMICUS CURIAE BRIEF* OF JUDICIAL WATCH, INC. IN SUPPORT OF PLAINTIFFS' COMPLAINT AND MOTION FOR TEMPORARY INJUNCTION**

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STATEMENT OF INTEREST OF *AMICUS CURIAE*

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 in both state and federal courts.

Judicial Watch 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*. 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 – particularly when there is evidence of improper political interference.

SUMMARY OF THE ARGUMENT

The 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.

The events described in Plaintiff's complaint are a prime example of the dire consequences of unchecked executive power employed by a federal agency, the Defendant, 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.[1] 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 in its original approval by blatantly contradicting most of its previous rationalization. The FDA's actions in 2000, 2016, and 2021 violate the Administrative Procedures Act ("APA"). The Court should grant Plaintiffs motion for a temporary injunction and grant the relief requested in Plaintiffs' Complaint.

ARGUMENT

I. Legal Standards

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.[2] Under the APA, the FDA's decisions may be "set aside if found to be 'arbitrary,

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[1] 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.

[2] By reexamining its original decision to approve Mifeprex in both 2016 and 2021, the FDA reopened review of approval decision. *See Texas v. Biden*, 20 F.4th 928, 952 (5th Cir. 2021), *rev'd on other grounds*, *Biden v. Texas*, 142 S. Ct. 2528 (2022); *see also Nat'l Ass'n of Reversionary Prop. Owners v. Surface Transp. Bd*., 158 F.3d 135, 141 (D.C. Cir. 1998); *Public Citizen v. Nuclear Regulatory Com.,* 901 F.2d 147, 150-51 (D.C. Cir. 1990).

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. D. Tex. 2021) (*quoting State Farm*, 463 U.S. at 43). In determining whether the FDA's decisions violated the arbitrary and capricious standard, courts consider 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.[3] *State Farm,* 463 U.S. at 43.

This Court'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 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. Defendants' 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

[3] The U.S. Supreme Court articulated several other factors for consideration, but Judicial Watch is focusing on just a few for the purposes of this brief.

the Court. Judicial review is not the Court "second guessing" the science behind the FDA's decisions, as the Defendants' claim. 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 Approval of Mifeprex Was Arbitrary, Capricious, an Abuse of Discretion, and Not in Accordance with Law.

In reviewing the FDA's process for granting approval for Mifeprex as well as the contemporaneous evidence related to the decision, it is clear that the FDA's decision was arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law.[4] It is uncontested that the FDA approved Mifeprex pursuant to the accelerated approval procedure provided in 21 C.F.R. § 314.500. Referred to as Subpart H, the agency rule provides for the accelerated approval of new drugs for:

> [C]ertain new drug products that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments (e.g., ability to treat patients unresponsive to, or intolerant of, available therapy, or improve patient response over available therapy).

21 C.F.R. § 314.500.

The summary of the final rule issued by the FDA clearly defines the purpose as providing an alternative and accelerated path to approval for certain drugs needed for serious or life-threatening illnesses. 57 FR 58942. This accelerated path to approval requires additional study and restrictions on use. *Id*. This requirement balances the potential for harm from the new drugs

[4] Defendants' APA violations are plentiful but Judicial Watch, Inc.'s focus is on two primary violations: (1) the violation of the FDA's own regulation; and (2) the FDA's reliance on pretext.

with the need for a drug that provides a "therapeutic benefit" to individuals suffering from a serious or life-threatening illness. *See id*. The FDA determined there were two situations in which this accelerated approval could be met. Mifeprex was approved under the second as a "drug, effective for the treatment of a disease, [that] can be used safely only if distribution or use is modified or restricted." *Id*.

For Subpart H to legally apply to the approval of Mifeprex, the FDA would have needed to demonstrate that, (1) pregnancy was a "serious or life-threatening illness" or a "disease," and (2) that the drug "provided a meaningful therapeutic benefit to patients over existing treatments." The FDA did neither. More to the point, the FDA *could* not. The plain language of the final rule shows that Subpart H was written for drugs that treat diseases. The scope of the final rule reads:

> The new procedures [accelerated approval] apply to certain new drugs, antibiotic, and biological products used in the treatment of serious or life-threatening ***diseases***, where the products provide a meaningful therapeutic advantage over existing treatment.

57 FR 58942 (emphasis added). In 2000, pregnancy was not classified as a "disease" by the FDA. The FDA's decision to apply Subpart H to pregnancy was arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law.

The FDA's historical usage of Subpart H solidifies the conclusion that Mifeprex did not qualify for Subpart H approval. Prior to the 2000 approval of Mifeprex, the FDA granted accelerated approval pursuant to Subpart H 37 times. *See* Appendix at 2-19.[5] Of these 37 accelerated approvals, 21 related to HIV drugs and 10 related to cancer drugs. *Id*. The remaining accelerated approvals were related to chronic low blood pressure, tuberculosis,

[5] This information is also available at: https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/accelerated-and-restricted-approvals-under-subpart-h-drugs-and-subpart-e-biologics.

leprosy, and bacterial infections. *Id.* Unlike pregnancy, each one of these drugs treats a condition widely considered a "disease" by both the medical community as well as the FDA. Since the 2000 approval of Mifeprex, the FDA has granted accelerated approval pursuant to Subpart H 26 times. *Id*. Of these 26 accelerated approvals, 9 related to HIV drugs, 10 related to cancer drugs, 3 related to hypertension, and 2 to blood disorders.[6] *Id*. The remaining accelerated approvals were related to hypogonadotropic hypogonadism (pituitary problem) and narcolepsy. *Id*. Unlike pregnancy, each one of these drugs treats a condition widely considered a "disease" by both the medical community as well as the FDA. In 64 instances of granting accelerated approval pursuant to Subpart H, there is exactly one drug that targets something non-disease related: Mifepristone. This shows the FDA's decision was arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law.

The plain language of Subpart H, as well as the unambiguous synopsis and scope of the final rule, run counter to the FDA's decision to approve Mifeprex pursuant to Subpart H. Subpart H was clearly designed to approve drugs for serious and life-threatening diseases. Referring to pregnancy as a disease is implausible based on the FDA's own understanding of pregnancy at the time of approval and the understanding of pregnancy by the wider medical community. *See e.g., State Farm*, 463 U.S. at 43 (an explanation counter to evidence is too implausible to accept). The FDA simply cannot demonstrate that pregnancy was a condition that fit the purpose or meaning of Subpart H. Similarly, the FDA's historical use of accelerated approval pursuant to Subpart H runs counter to the FDA's decision to approve Mifeprex pursuant to Subpart H. *See id*. (Evidence contrary to the agency decision is not a satisfactory explanation). Mifeprex is the exception to Subpart H regulation, and the FDA's decision is implausible. The FDA's decision

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[6] *Ibid*. (The FDA's website states that it is current as of August 26, 2014.)

was arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law. *See State Farm*, 463 U.S. at 41.

The FDA's approval of mifepristone violates the APA for another reason: the FDA's reliance on pretext. While the FDA publicly asserted that the rationale for approving Mifeprex was for the health of American women, the evidence shows that the true motivation was political.

Former President Clinton was not shy about his personal interest in having mifepristone approved in the U.S. In fact, directing the approval of an abortion drug was his first official act as President of the United States. Appendix at 38. In his May 16, 1994 letter to the Chairman of Roussel Uclaf, the French pharmaceutical group which created and owned the abortion pill, President Clinton wrote that, "it is important for the health of women in the United States that they have access to the widest possible range of safe and effective medical treatments."[7] Appendix at 77. He then thanked the Chairman "on behalf of the government of the United States and for the women in America." *Id*. Roussel Uclaf would reply that same month to confirm that President Clinton's request was being granted and the abortion pill would be given the U.S. as an "unconditional gift" with "nothing in return." Appendix at 72. Only after the approval would it be discovered that President Clinton's very letter was a bargained-for part of a backroom deal between the President, the FDA, U.S. Department of Health and Human Services ("HHS"), and Population Council to approve Mifeprex in the U.S. for the express purpose of

[7] Neither the Clinton administration nor Defendants have ever rationally explained what therapeutic benefit to women's "health" was being addressed by the abortion pill. This relates back to Defendant's arbitrary and capricious use of Subpart H – they utterly failed to articulate what "therapeutic benefit" Mifeprex provided that was not already available or addressed by the medical field. Even pretending that pregnancy can be legitimately categorized as a "serious or life-threatening illness," is of no avail. The maternal medical conditions that can give rise to serious or life-threatening situations like ectopic pregnancies or placenta previa cannot be treated with Mifeprex. In fact, using Mifeprex in those situations will most likely place the woman's life in immediate danger.

intentionally ending prenatal lives. *See* Appendix at 54. (Roussel demanded that President Clinton write the letter requesting the abortion drug "on behalf of women in America.")

The evidence uncovered of Defendants' true motivation for their decision to approve Mifeprex is eye-opening and shows the administration and FDA applying political pressure on not only international corporations, but on international governments – all for a drug to kill prenatal human beings. The evidence also shows the intricate political and corporate machinations spent in the service of promoting a drug that has nothing to do with women's health. Defendants pressured both Roussel, a French company, and Hoechst AG, the German pharmaceutical company and majority shareholder of Roussel, to bring the abortion pill to the U.S. *See* Appendix at Tab B, pp. 21-34. Hoechst was opposed to producing the drug for the U.S. and in fact, ordered Roussel to cease producing the abortion drug altogether.[8] The government of France exerted its legal and economic powers and forced Hoechst to continue producing the abortion drug.[9] This created a serious international rift for which Hoechst would respond by demanding complete indemnity for any future production of the abortion drug in the U.S. Hoechst would find an avenue to satisfy that indemnity desire – an American venture capitalist group, but Defendant-Intervenor Population Council refused to work with the group. *See* Appendix at 43.

Instead, the FDA became the deal-broker between Roussel and Population Council. This was not a simple negotiation, however, as Defendant admitted it needed to apply "pressure on Roussel Uclaf/Hoechst." Appendix at 43. In fact, Defendant wrote that political pressure was

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[8] *See* Melanie Israel, "Chemical Abortion: A Review," THE HERITAGE FOUNDATION, No. 3603, March 26, 2021 available at: https://www.heritage.org/life/report/chemical-abortion-review.

[9] *Ibid*; *see also* Appendix at 50.

the "only way to get RU-486 [Mifeprex] onto the U.S. market." Appendix at 50. In a November 15, 1993 letter from Donna Shalala, HHS Secretary to the White House, she states that "Dr. Kessler [FDA Commissioner] and I have taken steps to persuade Roussel Uclef and Hoechst to change their position." Appendix at 40. This same letter shows the FDA offering to discuss the possibility of offering Roussel federal legislative immunity as part of the deal despite that discussion "far exceed[ing] FDA's appropriate role." Appendix at 42.

Roussel's preference for satisfying its demand for federal legislative immunity was for the U.S. to exercise its eminent domain powers and take the patent for the abortion drug.[10] *Id.* However, neither the President, nor the FDA would agree to this proposal because it was a decision subject to congressional checks and balances and it put the President's personal quest for the abortion drug at risk of rejection. *See* Appendix at 44. The FDA did not want to incur the burden of having to convince Congress that the abortion drug was actually a medical benefit. It was absolutely necessary to close the deal between Roussel and Population Council, and Defendant was willing to pressure other governments to accomplish its goal.

This can be seen in a September 30, 1993 letter from the HHS Commissioner, Dr. Kessler, to the FDA Secretary Donna Shalala in which Secretary Shalala states:

> It may be that France and Germany would be unhappy to learn that their companies were not accommodating a request made by the United States Government. The U.S. Ambassadors to France and Germany will need to be consulted on these issues, and your counterparts in France and Germany may also need to be involved.

[10] It is significant to note that Roussel's primary liability concern related to women harmed by taking its abortion pill as well as the potential for delivery of a "deformed fetus." Appendix at 41. Roussel's concern about liability was so great that it offered to give Population Council the license royalty-free, foregoing all profits. It absolutely refused to manufacture the abortion drug for Population Council to distribute however, and demanded a new manufacturer be found. *Id*. at 48.

Appendix at 50-51.

The Administration and the FDA were willing to place political pressure on two foreign governments to accomplish the task of approving an abortion pill. This was not a life-saving medication or a drug that cured cancer. This was a drug which was being sought for one purpose and one purpose alone: the intentional death of prenatal humans. And for what reason? The ability to satisfy a financially and politically powerful group of abortion advocates.

In a May 11, 1994 memo from the HHS Chief of Staff to the White House, the true motivation of the FDA's decision is illuminated. The memo describes the political significance of closing the abortion pill deal:

> Because of the situation with the Health Security Act, the introduction of RU 486 [the abortion pill] will be of greater significance to the pro-choice and women's groups. If the Administration is viewed as closing the door or rejecting an apparently reasonable offer on RU 486, then the path toward reaching a non-confrontational agreement with the advocates on the Health Security Act could become much more difficult. ***It is, therefore, extremely important that the decision concerning RU 486 be placed in the context of promoting women's health and maintaining the close relationship of the Administration to these groups.***

Appendix at 64 (emphasis added).[11]

This extraordinary admission conclusively demonstrates that the Defendant's rationale for approving Mifeprex was nothing more than pretext. Defendant's pretextual rationale is "substantively invalid" and therefore, arbitrary and capricious. *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2575-76 (2019). "We are presented, in other words, with an explanation for agency action that is incongruent with what the record reveals about the agency's priorities and

[11] In fact, to this day, the rationalization of abortion as a woman's health matter has become a permanent justification and rallying cry of pro-abortion groups and their political and cultural allies.

decisionmaking process." *Id*. at 2575. Courts are not required to accept "contrived reasons" by an agency for its actions. *Id*. at 2576.

The FDA's decision to approve Mifeprex was arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law. The decision violated the unambiguous meaning of Subpart H and was based on nothing more than political manipulation. The dire consequences cannot be overstated: the very the agency responsible for brokering the transfer of the drug at the personal request of the sitting President of the United States was then tasked with performing an unbiased review of the approval. Even the Secretary of the Defendant federal agency admitted in writing that their political interference was running the risk of bias and "compromising its [FDA's] role as objective reviewers of the safety and efficacy of the drug." Appendix at 50. Indeed, that role was fatally compromised and continues to be as the FDA permits Mifeprex to be recklessly distributed based on an arbitrary and capricious approval decision. *See State Farm*, 463 U.S. at 41.

III. The FDA's 2016 Changes to Mifeprex Safety Restrictions Were Arbitrary, Capricious, an Abuse of Discretion, and Not in Accordance with Law.

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. Appendix at 87.[12] 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

[12] A transcript of the U.S. House of Representatives Subcommittee on Criminal Justice, Drug Policy, and Human Resources May 17, 2006 Hearing on RU-486 [Mifeprex] is available in its entirety at: https://www.govinfo.gov/content/pkg/CHRG-109hhrg31397/html/CHRG-109hhrg31397.htm

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 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. Appendix at 89-91.

Additionally, the 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' pregnancy. Appendix at 93-103. 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.[13] 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").[14] Appendix at 105-107. This history shows that in the first decade of post-approval use, the FDA *increased* Mifeprex safety requirements.

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[13] *See e.g.*, https://scrip.pharmaintelligence.informa.com/PS062593/Mifeprex-Black-Box-Warning-Revised-On-Reports-Of-Sepsis-Deaths

[14] 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").

The FDA was very clear about the need for Mifeprex safety restrictions and its approval criterion. *See e.g*., Appendix at 87. 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.[15] 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.[16]

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 pregnancy was not ended – and increased the adverse events such as hospitalization.[17] 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.

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 –

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15 *See supra* note 8.

16 *Ibid.*

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

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.[18] And, as described above, by 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. 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.[19] Increasing the gestational age of use,

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[18] Kathi Aultman, Christina Cirucci, *et al*., "Deaths and Severe Adverse Events after the use of Mifepristone as an Abortifacient from September 2000 to February 2019," ISSUES IN LAW AND MEDICINE, Volume 36, No. 1, 2021 report to South Carolina General Assembly State Medical Affairs Committee.

[19] *See e.g*., https://www.guttmacher.org/article/2016/06/public-health-implications-fda-update-medication-abortion-label

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.[20] The increased usage would, of course, increase profits for Danco, the manufacturer of Mifeprex.[21] By increasing the gestational age of use to 70 days, the FDA effectively ***doubled*** the number of eligible pregnancies.[22] 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 Dep't of Commerce*, 139 S. Ct. at 2575-2576.

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[20] *See e.g.*, https://www.nytimes.com/2016/03/31/health/abortion-pill-mifeprex-ru-486-fda.html

[21] Danco is a private company 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* https://www.liveaction.org/news/abortion-industry-financial-conflicts-interest-politicians-media/; *see also* https://www.latimes.com/archives/la-xpm-2000-nov-05-mn-47330-story.html (detailing the secretive and questionable business dealings of Danco)

[22] *See supra* note 20

IV. The FDA's 2021 Changes to Mifeprex Restrictions Were Arbitrary, Capricious, an Abuse of Discretion, and Not in Accordance with Law.

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.[23] ACOG and the other abortion lobbying groups asserted that the in-patient visit put women at risk of COVID-19 or delayed their abortion decision too long to make Mifeprex an option.[24] The FDA accepted ACOG's request and temporarily suspended the in-person medical visit based solely on the COVID-19 pandemic.[25] COVID-19 was, however, just pretext for the FDA's decision.[26] With the pandemic declared over by President Biden on September 18, 2022, the foundation of concern for in-person medical visits should have ended.[27] Instead, the FDA maintained its temporary suspension and continued permitting Mifeprex to be mailed. Then, on

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[23] *See* https://www.acog.org/news/news-articles/2020/07/courts-order-lifting-burdensome-fda-restriction-what-you-need-to-know.

[24] Appendix at ??; also available at:/https://www.aafp.org/dam/AAFP/documents/advocacy/prevention/women/LT-WH-Mifepristone-030121.pdf

[25] *See supra* note 17

[26] 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* https://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2018/improving-access-to-mifepristone-for-reproductive-health-indications

[27] *See e.g.*, https://www.cnn.com/2022/09/19/politics/biden-covid-pandemic-over-what-matters/index.html

December 16, 2022, the FDA permanently removed the REMS requirement for any in-person medical visits.[28]

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.[29] 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 dispensing was and was not enforced.[30]

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." Appendix at 109-110. 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.[31] The "serious safety

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[28] *See e.g.*, https://abcnews.go.com/Politics/fda-women-obtain-abortion-pill-mail/story?id=81798959

[29] 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. 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. https://www.acog.org/womens-health/faqs/ectopic-pregnancy; *see also* https://www.dailysignal.com/2023/01/18/fda-has-made-abortion-wild-west-rule-change-drugs-ob-gyn-says

[30] https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation

[31] *See supra* note 8.

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 acknowledged.[32] The Acting FDA Commissioner, Robert Califf, was the FDA Commissioner during the 2016 Mifeprex changes.[33] The FDA's decision to permanently dispense with in-person medical visits occurred just days after Califf's Senate 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.[34] 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 overtured.[35] In fact, the President issued a response to the U.S. Supreme Court's *Dobbs v. Jackson Women's Health Organization* decision which clearly supported mail-order Mifeprex and made no

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[32] *See* https://www.politico.com/news/2021/04/12/abortion-pills-481092

[33] As FDA Commissioner in 2016, Dr. Califf refused to respond to a congressional inquiry into the 2016 REMS changes for Mifeprex. https://www.lankford.senate.gov/news/press-releases/lankford-opposes-controversial-pro-abortion-fda-nominee;

[34] *See e.g.*, *supra* note 32

[35] *See* https://www.opensecrets.org/news/2021/05/abortion-rights-up-lobbying-with-roe-threatened

mention of the COVID-19 pretext.[36] 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, capricious, an abuse of discretion, and not in accordance with law. S*ee Dep't of Commerce*, 138 S. Ct. at 2575-2576.

CONCLUSION

The evidence is clear. The FDA had one goal: approval of an abortion drug. The FDA's arbitrary and capricious decisions in 2000, 2016, and 2021 demonstrate that the "how" was unimportant. Each of these decisions violate the APA and should be set aside.

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Respectfully submitted,

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[36] 142 S. Ct. 2228 (2022)

CERTIFICATE OF SERVICE

This is to certify that a true and correct copy of the foregoing was served, pursuant to the Federal Rules of Civil Procedure, on all counsel of record appearing herein via ECF on this 10th day of February, 2023 by the filing of this pleading with the Clerk of Court for the U.S. District Court for the Northern District of Texas using the Court's ECF system.

/s/ *Meredith Di Liberto*
Meredith Di Liberto