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

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its member organizations, their members, and these members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his Patients,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION; **ROBERT M. CALIFF, M.D.**, in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; **JANET WOODCOCK, M.D.**, in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration; **PATRIZIA CAVAZZONI, M.D.**, in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**; and **XAVIER BECERRA**, in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

Case No. 2:22-cv-00223-z

MOTION OF ADVANCING AMERICAN FREEDOM TO FILE A BRIEF AS AMICUS CURIAE IN SUPPORT OF PLAINTIFF'S COMPLAINT AND MOTION FOR TEMPORARY INJUNCTION

Pursuant to Fed. R. Civ. P. 7, movant, Advancing American Freedom ("AAF") respectfully seeks this Court's leave to file the accompanying brief as an amicus curiae in support of Plaintiff's Complaint (Doc. 1) and Plaintiff's Motion for Preliminary Injunction (Doc. 6). Consistent with Fed. R. App. P. 29(a)(4)(E), counsel for amicus authored its brief in whole; no counsel for a party authored this brief in any respect; and no person or entity – other than amicus, its members, and its counsel – contributed monetarily to this brief's preparation or submission.

IDENTITY AND INTERESTS OF MOVANT

Movant, Advancing American Freedom (AAF) is a nonprofit organization that promotes and defends policies that elevate traditional American values, including the uniquely American idea that all men are created equal and endowed by their Creator with unalienable rights to life, liberty, and the pursuit of happiness. This case is important to AAF because it presents an opportunity for this court to demonstrate that the FDA does not merit judicial deference under *Chevron v. NRDC*, 467 U.S. 837 (1984) nor under *Auer v. Robbins*, 519 U.S. 452 (1997), two lines of cases that for too long have permitted the confusion of powers of the several branches of the Federal government. The genius of the Constitution is its structure, dividing power against itself into three coequal branches and thereby protecting the liberties of its citizens from usurpers of delegated and limited governmental power.

REASONS TO GRANT MOVANT'S AMICUS CURIAE STATUS

Although no federal or local rule provides for *amicus curiae* briefs here, this Court allows the filing of amicus briefs in appropriate cases. *See e.g., United States v. Texas Educ. Agency*, 138 F.R.D. 503, 508 (N.D. Tex. 1991); *Kinard v. Dish Network Co.*, 228 F. Supp. 3d 771, 777 (N.D. Tex. 2017). Given the absence of applicable rules, movant AAF looks to the appellate rules' criteria for granting leave to file amicus briefs to support its motion here.

The Advisory Committee Note to the 1998 amendments to Rule 29 explains that "[t]he amended rule . . . requires that the motion state the relevance of the matters asserted to the disposition of the case" as "ordinarily the most compelling reason for granting leave to file." Fed. R. App. P. 29, Advisory Committee Notes, 1998 Amendment. Now-Supreme Court Justice Samuel Alito once wrote "I think that our court would be well advised to grant motions for leave to file amicus briefs unless it is obvious that the proposed briefs do not meet Rule 29's criteria as broadly interpreted. I believe that this is consistent with the predominant practice in the courts of appeals." *Neonatology Assocs., P.A. v. Comm'r*, 293 F.3d 128, 133 (3d Cir. 2002) (citing Michael E. Tigar and Jane B. Tigar, *Federal Appeals – Jurisdiction and Practice* 181 (3d ed. 1999) and Robert L. Stern, *Appellate Practice in the United States* 306, 307-08 (2d ed. 1989)). With that background, movant AAF respectfully submits that its proffered brief will bring at least two relevant and important matters to the Court's attention:

1. In October of 2006, the United States House of Representatives Government Reform Committee's Subcommittee on Criminal Justice, Drug Policy, and Human Resources conducted a hearing entitled *RU-486: Demonstrating a Low Standard for Women's Health?* ("Congressional Hearing"), and committee staff issued a subsequent report entitled *The FDA and RU-486: Lowering the Standard for Women's Health* ("Congressional Report"). This congressional report addressed the significant flaws in the FDA's approval of RU-486, or mifepristone, for use in conjunction with misoprostol as a chemical abortifacient. The report details the significant safety concerns that existed at the time of approval and the FDA's abuse of the Subpart H new drug approval process despite those concerns. The undersigned counsel for movant served as Staff Director and Senior Counsel for this Subcommittee.
2. The problems apparent in 2006 at the time of the report remain today, even as the FDA introduces laxity in the safety requirements associated with chemical abortions.

Respectfully submitted, this 10th day of February 2023.

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CERTIFICATE OF SERVICE

I certify that this document will be served on all defendants via ECF and via first class United States mail and email to:

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This 10th day of February 2023.

ADVANCING AMERICAN FREEDOM

By: /s/J. Marc Wheat
Darald J. Schaffer

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

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its member organizations, their members, and these members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his Patients, Plaintiffs, v. **U.S. FOOD AND DRUG ADMINISTRATION**; **ROBERT M. CALIFF, M.D.**, in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; **JANET WOODCOCK, M.D.**, in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration; **PATRIZIA CAVAZZONI, M.D.**, in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**; and **XAVIER BECERRA**, in his official capacity as Secretary, U.S. Department of Health and Human Services, Defendants.	**Case No. 2:22-cv-00223-z**

BRIEF OF AMICUS CURIAE ADVANCING AMERICAN FREEDOM IN SUPPORT OF PLAINTIFFS

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INTEREST OF AMICUS CURIAE

Movant, Advancing American Freedom ("AAF"), is a nonprofit organization that promotes and defends policies that uphold traditional American values, including the uniquely American idea that all men are created equal and endowed by their Creator with unalienable rights to life, liberty, and the pursuit of happiness. This case is important to AAF because it presents an opportunity for this Court to reaffirm the import of the Constitution, by holding that the actions of the U.S Food and Drug Administration ("FDA") do not merit judicial deference under *Chevron v. NRDC*, 467 U.S. 837 (1984) nor under *Auer v. Robbins*, 519 U.S. 452 (1997), two lines of cases that for too long have permitted the confusion of powers of the several branches of the Federal government. The genius of the Constitution is its structure, dividing power against itself into three coequal branches and thereby ensuring a balance that protects the liberties of its citizens from usurpers of delegated and limited governmental power.

SUMMARY OF THE ARGUMENT

In October of 2006, the United States House of Representatives Government Reform Committee's Subcommittee on Criminal Justice, Drug Policy, and Human Resources released a report outlining the significant problems with the FDA's approval of the drugs mifepristone and misoprostol for use as a chemical abortifacient. The FDA had previously approved this regimen of drugs under regulatory language originally designed to allow the agency flexibility to approve drugs that would provide meaningful therapeutic benefits over existing treatments

when used to fight serious and life-threatening illnesses. However, because abortion is not classified as a treatment, because pregnancy is not classified as an illness and is not, itself, serious or life-threatening, and because chemical abortion was more dangerous and less effective than the alternative, surgical abortion, the FDA misused its authority, disregarded its own regulation, and approved dangerous new chemical abortion drugs.

When reviewing agency action such as this, whether justified on the basis of statutory or regulatory authority, this Court should not defer to agency interpretations. Rather, this Court should exercise independent judgment as to the legality of the agency action. When courts defer to agencies, they allow them to unjustifiably expand their power, undermining the separation of powers and the freedoms that constitutional principle exists to protect. The power to legislate belongs to the people vested through Congress, but the power to interpret belongs to the courts alone. Agencies, as members of the executive branch, have neither power and may only apply existing law. While it is true that the Supreme Court has held that agencies may create regulations through delegated congressional authority, these holdings and their subsequent applications do not allow an agency to change the meaning of those regulations outside of established regulatory process.

Here the studies have shown that the use of mifepristone and misoprostol to perform chemical abortions is a more dangerous and less effective form of abortion. Yet the FDA's increasingly lax reporting and use requirements for these drugs conceal the true scope of the danger posed by these chemical abortion drugs. Thus,

the health and safety of women are not served by chemical abortions, which can unknowingly cause significant harm to the mother. States have a legitimate interest in protecting the health and safety of the mother as well as the life of the unborn. The FDA's approval of and the Biden administration's effort to expand the grasp of chemical abortion both undermine states' efforts to protect their legitimate interests and oversteps the FDA's power. For all of these reasons, the FDA's approval of the mifepristone/misoprostol regimen must be preliminarily and permanently enjoined.

ARGUMENT

In October of 2006, the United States House of Representatives Government Reform Committee's Subcommittee on Criminal Justice, Drug Policy, and Human Resources conducted a hearing entitled *RU-486: Demonstrating a Low Standard for Women's Health?* [1] ("Congressional Hearing"), and committee staff issued a subsequent report entitled *The FDA and RU-486: Lowering the Standard for Women's Health*[2] ("Congressional Report"). This report addressed the significant flaws in the FDA's approval of RU-486 ("mifepristone") for use in conjunction with misoprostol as a chemical abortifacient. The report details the significant safety concerns that

[1] *RU-486: Demonstrating a Low Standard for Women's Health? Hearing before the House Subcommittee on Criminal Justice, Drug Policy and Human Res., Committee on Government Reform*, 109th Cong. (May 17, 2006), available at https://archive.org/details/gov.gpo.fdsys.CHRG-109hhrg31397.

[2] *The FDA and RU-486: Lowering the Standard for Women's Health*, House of Representatives Government Reform Committee; Subcommittee on Criminal Justice, Drug Policy, and Human Resources (Oct. 2006), available at https://www.liveaction.org/news/wp-content/uploads/2020/08/SouderStaffReportonRU-486.pdf.

existed at the time of approval and the FDA's abuse of the Subpart H new drug approval process despite those concerns.

As Staff Director and Senior Counsel of the Subcommittee on Criminal Justice, Drug Policy, and Human Resources from 2003-2007, I supervised the investigatory team led by Michelle Powers Gress identifying the problems detailed in our report. I write today on behalf of Advancing American Freedom in support of the Alliance for Hippocratic Medicine, the American Association of Pro-Life Obstetricians and Gynecologists, the American College of Pediatricians, the Christian Medical and Dental Associations, and the physicians suing on behalf of themselves and their patients, Dr. Shaun Jester, Dr. Regina Frost-Clark, Dr. Tyler Johnson, and Dr. George Delgado, because the problems apparent in 2006 at the time of the report remain today, yet the FDA ignores those blatant issues and continues to diminish the protective protocols associated with chemical abortions.

While plaintiffs are challenging the FDA's approval of those drugs on these grounds, the Biden Administration and others ignore their potentially dangerous side effects and seek to expand access to chemical abortions despite the risks, particularly in states that have exercised their legislative authority to restrict this type of legal abortion pursuant to their legitimate interest in the safety of both mothers and their preborn children.[3] The FDA's approval of the mifepristone/misoprostol regimen must

[3] The states' legitimate interest in protecting the life of the unborn and the safety and health of the mother are recognized by the Court today and were recognized at the time of the FDA's approval. *See Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228, 2284 (2022); *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 846 (1992).

be enjoined because of the clear legal deficiencies of its approval process and because the agency's action in this case is not entitled to deference. Further, the current dangers of chemical abortions provide a strong justification as a matter of policy, to halt the distribution and use of the chemical abortion drugs.

I. The FDA Approved Mifepristone Without Regard for the Significant Safety Concerns Apparent at the Time of Approval.

As will be discussed in greater detail below, the FDA regulation under which it approved the mifepristone/misoprostol regimen for use as an abortifacient requires that new drugs approved through that process provide a "meaningful therapeutic benefit over existing treatments." 21 CFR § 314.500. There was ample evidence prior to the FDA's approval of mifepristone in 2000 that chemical abortions provided no such benefit over the existing procedure, surgical abortions.

In 1981, human trials of mifepristone took place in Geneva, Switzerland after seventeen months of animal research. Congressional Report at 10. Even those initial human trials indicated the potential dangers of the drug when used as an abortifacient. Those trials resulted in two unsuccessful abortions out of eleven attempts with two of the eleven women requiring further medical intervention including, in one case, emergency surgery and a blood transfusion. Congressional Report at 10. The next round of trials, conducted in several different countries, produced widely varied success rates from as low as fifty-four percent (54%) to as high as ninety percent (90%). Congressional Report at 10-11. That success rate increased to ninety-four percent (94%) in one trial when doctors in Sweden began to administer

misoprostol in combination with mifepristone, though it remained significantly lower than the ninety-nine percent (99%) success rate of surgical abortion at the time.[4] *Id*.

After mifepristone was approved in France, a committee of experts reviewed data on 30,000 women who had used mifepristone as an abortifacient and found numerous significant risks associated with use of the drug. Congressional Report at 11-12. Further, the World Health Organization released a study in 1991 in which just under three percent (3%) of women with completed abortions and almost thirty percent (30%) of those with incomplete abortions "had to be given 'antibiotic therapy to prevent or cure suspected genitourinary infection' during the six-week follow-up period." Congressional Report at 12, n. 63.

Writing before the drug's approval, the FDA's medical reviewer found that chemical abortions were of limited value given the short time period during which they were available, the need for three visits to a medical facility during the process, the need for a follow-up visit to ensure that surgical intervention is not required, and because of specific problems with chemical abortion in comparison to surgical abortion. Congressional Report at 29-30. In particular, the reviewer noted the higher failure rates of chemical abortion, the greater frequency of symptoms including cramping, nausea, and vomiting, and the increased blood loss associated with chemical as opposed to surgical abortions. Congressional Report at 29-30.

[4] Success was defined as fetal death without the need for further medical intervention.

Further, the FDA Medical Officer's review found that for women with pregnancies up to seven weeks, the original gestational limit approved by the FDA, the failure rate was almost eight percent (8%), with the percentage increasing at longer gestational periods, up to twenty-three percent (23%) for pregnancies at 57-63 days. Congressional Report at 31.

Because these failure rates were higher and the symptoms associated more frequent, and because chemical abortion provided no other significant benefits over the alternative, surgical abortion, improved efficacy and safety could not have justified the FDA's approval of mifepristone for abortifacient use under its own regulation.

II. The FDA's Approval of Mifepristone for Use as an Abortifacient is Not Entitled to *Auer* Deference Because it Violated the Plain Language of Subpart H of CFR Part 314.

Federal executive agencies derive whatever power they have from Congressional authority. They receive that authority from Congress by legislation empowering them to exercise legal control over a particular policy domain. When an agency's interpretation of that legislation is challenged in court, courts will often accept the agency's interpretation if the language of the statute is ambiguous, and the agency's interpretation of that statute is reasonable. *See Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984).

In *Auer v. Robbins*, 519 U.S. 452 (1997), the Supreme Court established a similar doctrine that applies to an agency's interpretation of its own regulations. When an agency interprets one of its own regulations, and that regulation is genuinely

ambiguous, the agency's interpretation may be entitled to deference. *See Kisor v. Wilkie*, 139 S. Ct. 2400, 2414 (2019). This judicial approach, called *Auer* deference, has not been overturned, but its future is uncertain. *Id*. at 2425 (Gorsuch, J. concurring) (Justice Gorsuch, joined by Justices Thomas, Alito, and Kavanaugh in relevant parts, arguing that it is time to overrule *Auer*) Regardless, as explained below, it does not apply here because the language of Subpart H is clear and was flagrantly violated by the FDA's approval of mifepristone as an abortifacient.

Subpart H, an FDA promulgated regulation titled *Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses*, allows the FDA to approve new drugs to treat "serious or life-threatening illnesses" and "that provide meaningful therapeutic benefit to patients over existing treatments." 21 CFR § 314.500. Further, the FDA may approve the new drug only "on the basis of adequate and well-controlled clinical trials." 21 CFR § 314.510. Thus, its purpose is to allow for expedited approval of new drugs when doing so would allow for improved treatment of people whose illnesses are serious and who need better treatment options. The FDA, in approving the mifepristone/misoprostol regimen for chemical abortions, acted outside of this clear purpose and violated the plain requirements of the regulation's text.

Auer deference only applies "to an agency's reasonable interpretation of its own regulations when the regulation's text is 'genuinely ambiguous,' and the 'character and context of the agency's interpretation entitles it to controlling weight.'" *Johnson v. BOKF Nat'l Ass'n*, 15 F.4th 356, 362 (5th Cir. 2021) (quoting *Kisor v. Wilkie*, 139 S. Ct. 2400, 2414, 2416 (2019)). Genuine ambiguity is a requirement the U.S.

Supreme Court takes seriously. "When we use that term, we mean it—genuinely ambiguous, even after a court has resorted to all the standard tools of interpretation." *Kisor v. Wilkie*, 139 S. Ct. 2400, 2414 (2019). In this case, the language of Subpart H is unambiguous, and the FDA's interpretation of that language is just as clearly contrary to that language in several ways.

A. Pregnancy is not a serious or life-threatening illness, and thus is not the type of condition Subpart H is intended to address, and so Auer *deference should not apply.*

Subpart H exists to allow for the approval of new drugs for the treatment of "serious or life-threatening illnesses." 21 CFR § 314.500. Most importantly, pregnancy is not an illness. As noted by the Subcommittee report, the FDA's letter to the Population Council,[5] mifepristone's sponsor for FDA approval in the United States, referred to "the termination of an unwanted pregnancy" as the "serious condition" to be addressed by the approval of mifepristone. (Congressional Report 19, n. 99). However, the language of the regulation does not provide for approval of drugs for serious conditions but rather for illnesses. Although pregnancy may occasionally result in serious or life-threatening conditions, pregnancy itself is neither serious nor life-threatening. Because *Auer* deference only applies to ambiguous regulatory language, it is inapplicable here because the language of Subpart H is clear as is the FDA's violation of the requirements of that language.

[5] "The Population Council is a nonprofit founded in 1952 by John D. Rockefeller III to address supposed world overpopulation." Population Council, https://www.influencewatch.org/non-profit/population-council/ (last visited Feb. 9, 2023).

B. Chemical abortion does not provide a "meaningful therapeutic benefit over existing treatments" because chemical abortion is neither safer nor more effective than surgical abortions.

Subpart H also requires that new drugs approved through its process "provide meaningful therapeutic benefit to patients over existing treatments." 21 CFR § 314.500. The regulation provides an example of such therapeutic benefits: the "ability to treat patients unresponsive to, or intolerant of, available therapy, or improved patient response over available therapy." *Id*. Even assuming that abortion constitutes a treatment with therapeutic benefits, it was clear from the evidence at the time of approval that chemical abortion was both more dangerous for the woman and less effective than surgical abortion.

The report quotes the FDA's Approval Memo to the Population Council as describing the supposed therapeutic benefit of chemical over surgical abortions as being the "avoidance of a surgical procedure." Congressional Report at 21, n. 106 (internal quotation marks omitted). The report identifies four problems with this idea.

First, the report notes that mifepristone was not approved for use <u>only</u> for women intolerant of surgical abortions, which would be expected if the FDA followed Subpart H's requirements of only offering the drug to women for whom it would be a safer, more effective form of abortion. Congressional Report at 22. Instead, the report says, "[the] FDA baldly asserted that there was a clinical benefit for chemical abortion and made no effort to produce statistical evidence of an actual benefit." Congressional Report at 22.

Second, the report points to the fact that a substantial portion of women using mifepristone and misoprostol to induce an abortion ultimately required surgical intervention, therein calling into question its necessity and benefit because "women must be able to tolerate the surgical procedure" if they are going to attempt a chemical abortion. Congressional Report at 22. As the report notes, the FDA must show that there is, in fact, some clinical benefit to an approved drug, which they did not do in this case. *Id*.

Third, the report notes that the fact that some patients may prefer one form of treatment over another is not itself a clinical benefit.

Finally, the report notes that the FDA medical officer, prior to approval of mifepristone, made comments to the effect that bleeding was a significantly more prevalent and serious issue in multiple studies examining chemical as compared to surgical abortions. "Given these comments," the report says, "it is impossible to conclude that [mifepristone] medical abortions provide a meaningful therapeutic benefit over surgical abortion." Congressional Report at 23.

C. Approval of the Mifepristone/Misoprostol Regimen was not based on "adequate and well-controlled studies."

Subpart H also requires that the FDA's approval of a drug be "on the basis of well-controlled clinical trials." Further, 21 CFR 314.126(e) states, "[u]ncontrolled studies or partially controlled studies are not acceptable as the sole basis for the approval of claims of effectiveness." In this case, the data relied on by the FDA was not concurrently controlled. *See* Congressional Report at 15-19. As the Congressional Report notes, the trials the FDA relied on were not concurrently controlled against

either a placebo or first trimester surgical abortion. Congressional Report at 14. As part of the investigation for the report, the subcommittee held a hearing in which the FDA Deputy Commissioner for Operations, Dr. Janet Woodcock, said that a historical control was used in assessing the trials of mifepristone. Congressional Hearing at 92. In other words, the trials were controlled against the existing data on pregnancy, miscarriage, and abortion.

The Congressional Report points out three problems with the FDA's assertion of non-concurrent control as a basis for the approval of mifepristone. First, while the FDA reviewed multiple studies from various countries, the "FDA's assertion that the French and U.S. trials were historically controlled appears to be a *post hoc* assertion." Congressional Report at 17. The study that reported on the American trials did not mention a control group and a statement from an FDA statistician who reviewed the French trials suggested a lack of concurrent control groups in those trials as well. Congressional Report at 17.

Second, the American studies of mifepristone excluded women with numerous medical or other issues but the FDA acknowledged that the historical data, which they claimed to be the control group, was data from the general population and thus did not exclude women with those health problems. Congressional Report at 18. As a result, the apparent safety of mifepristone relative to surgical abortion was likely inflated because the data on chemical abortions was gathered from relatively healthy women, while the data on surgical abortions included women with health problems who would have been excluded from the studies of chemical abortion. Regardless,

because the trial and control groups were not matched in terms of their health background, they are not a "meaningful control." Congressional Report at 18. As the report concludes, "If it was not possible to match the populations with the historical data set, then a concurrent control should have been used." Congressional Report at 18.

Finally, the report notes that using historical data rather than a concurrent control group results in "defining the clinical endpoint too restrictively." Congressional Report at 18. In other words, surgical abortions and miscarriage are not binary; they do not "produce only simple zero or one outcomes." Congressional Report at 18. As the report notes, "A control should have been used in the [mifepristone] trial that compared different methods of producing the experimental outcome – first-trimester pregnancy termination – while assessing each method's ability to manage highly predictable, regular complications of medical abortion (i.e., hemorrhage, incomplete abortion)." Congressional Report at 18.

In sum, the FDA only claimed that its studies were controlled after approval, the American studies of mifepristone excluded women with numerous medical issues potentially inflating the appearance of safety of chemical as opposed to surgical abortion, and the historical data used as a non-concurrent control provided, at best, a low-resolution picture of the safety and effectiveness of chemical as opposed to surgical abortions. Thus, because the FDA violated the clear language of Subpart H intended to impart safety, it is not entitled to *Auer* deference and the approval of the mifepristone/misoprostol regimen should be enjoined.

III. *Auer* Deference, Like *Chevron* Deference, Undermines the Constitutional Balance of Powers Between the Branches and should not be applied in this case.

The 1780 Massachusetts state constitution, drafted by John Adams, prohibited each of its government's three branches from exercising the powers of the other two so that, "it may be a government of laws and not of men." Mass. Const. pt. 1, art. XXX. When Congress delegates its authority to executive agencies, the risk increases that we will have a government of men, namely bureaucrats, and not of laws. This case is a perfect example of agency officials flagrantly disregarding the rule of law to advance their political goals.

A. Both the constitutional balance of power between the branches and the express language of the Administrative Procedure Act require the judicial branch to interpret the law.

Both *Chevron* and *Auer* deference require courts to yield to agency interpretations of law. When the courts defer in this way, they are abandoning their constitutional responsibility. As Chief Justice John Marshall recognized, "It is emphatically the province and duty of the judicial department to say what the law is." *Marbury v. Madison*, 5 U.S. 137, 177 (1803). Similarly, Justice Thomas has noted, "Those who ratified the Constitution knew that legal texts would often contain ambiguities. . .The judicial power was understood to include the power to resolve these ambiguities over time. *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 119 (2015) (Thomas, J. concurring) (citations omitted). When executive agencies' interpretations of statutes or regulations are granted deference, they are exercising the judicial power of final interpretation. Thus, both *Chevron* and *Auer*, in effect, allow agencies to supersede

both Article III of the Constitution and the constitutional principle of separation of powers.

The Administrative Procedure Act ("APA") is a statute enacted by Congress to govern administrative agencies. For example, it requires that in most cases, for an agency to promulgate a new regulation, it must issue public notice of its intent to regulate and must allow for and respond to public comments on the proposed regulation. 5 U.S.C. § 553. If an agency fails to comply with those requirements, the courts on review must strike down the regulation. As Justice Gorsuch notes, "some have even described it as a kind of constitution for our 'administrative state.'" *Kisor v. Wilkie*, 139 S. Ct. 2400, 2432 (2019) (Gorsuch, J. concurring). The APA echoes Chief Justice Marshall's sentiment above. It requires "reviewing courts to 'decide all relevant questions of law' and 'set aside agency action ... found to be ... not in accordance with law.'" *Kisor v. Wilkie*, 139 S. Ct. 2400, 2432 (2019) (Gorsuch, J. concurring) (quoting 5 U.S.C. § 706). Thus, agencies and reviewing courts are bound by the requirements of the APA. When courts defer to agency interpretation, whether of a statute under *Chevron* or a regulation under *Auer*, they supply executive agencies with greater authority than intended by Congress and allowed by the Constitution.

B. Both Chevron *and* Auer *undermine the constitutional principle of separation of powers and allow executive agencies to abuse their authority to the detriment of freedom and the rule of law.*

Courts should consider *Auer* and *Chevron* together because of the doctrines' significant similarities both in their application and in their shortcomings. The fundamental problems of *Chevron*, its deference to agencies to the detriment of those

challenging an agency interpretation of statutory law, is well illustrated by *Buffington v. McDonough*, 143 S. Ct. 14 (2022). There, the Court denied the petition for certiorari of a veteran who had certain retroactive disability benefits payments withheld because of a Department of Veterans Affairs statutory interpretation. *Buffington*, 143 S. Ct. at 14 (Gorsuch, J. dissenting). The lower "courts invoked '*Chevron* deference,' bypassed any independent review of the relevant statutes, and allowed the agency to continue to employ its rules to the detriment of veterans." *Id.* Although not every case that invokes *Chevron* deference is so dramatic, every court that does so by necessity violates both the APA and Article III, as well as the constitutional principle of separation of powers.

Auer deference, similarly, "creates a 'systematic judicial bias in favor of the federal government, the most powerful of parties, and against everyone else.'" *Kisor v. Wilkie*, 139 S. Ct. 2400, 2425 (2019) (Gorsuch, J. concurring) (quoting Larkin & Slattery, The World After *Seminole Rock* and *Auer*, 42 Harv. J. L. & Pub. Pol'y 625, 641 (2019)). Justice Gorsuch argued in *Kisor* that the majority was "keeping *Auer* on life support" and that it emerged from the majority's whittling, "maimed and enfeebled—in truth, zombified." *Id.* Even in its zombified state, *Auer* can wreak havoc. One of the most significant is the means it gives usurpatious agencies to overturn judicial precedent and change federal law without following the notice and comment requirements of the APA. Depending on the type of decision, a court's holding in a case creates precedent which can be overturned or made inapplicable by a future case, congressional action, changes in regulation pursuant to the

requirements of the APA, or, in some cases, a constitutional amendment. However, under *Auer*, if a court defers to an agency interpretation and the agency later changes its interpretation of that regulation without going through the notice and comment process, and a court then defers to that new interpretation, the agency has effectively been allowed to change the law outside of the congressionally established regulatory process. *See Kisor*, 139 S. Ct. at 2433 (Gorsuch, J., concurring) (citing *National Cable & Telecommunications Assn. v. Brand X Internet Services*, 545 U.S. 967 (2005)).

The plain language of Subpart H, binding on the FDA, is unambiguous. To the extent that the FDA relies on *Auer* to justify its interpretation here, it demonstrates the danger of that doctrine. If this Court defers to the FDA's interpretation of Subpart H, it will signal to agencies that their powers are not limited by the language of their regulations or statutes but only by the bottomless imagination of the bureaucratic mind. The FDA's willingness to ignore the significant safety concerns of mifepristone at the time it approved it for use as an abortifacient, as well as the agency's willingness to flout the clear text of its own regulation, is exactly the type of agency mischief that demands independent judicial review.

C. The Supreme Court's major questions doctrine jurisprudence supports rejecting deference in this case.

The Supreme Court applies the major questions doctrine in cases of potential *Chevron* deference "when an agency claims the power to resolve a matter of great 'political significance' or end an 'earnest and profound debate across the country.'" *West Virginia v. EPA*, 142 S. Ct. 2587, 2620 (2022) (quoting *NFIB v. OSHA*, 142 S. Ct. 661, 665 (2022) (internal quotation marks omitted); *Gonzales v. Oregon*, 546 U.S.

243, 267 (2006)). "The major questions doctrine seeks to protect against 'unintentional, oblique, or otherwise unlikely' intrusions," on the interest of "self-government, equality, fair notice, federalism, and the separation of powers." *Id.* (quoting *NFIB v. OSHA*, 142 S. Ct. at 669).

In the same year that the FDA approved the mifepristone/misoprostol regimen, the Supreme Court issued one of its most important major questions decisions, by striking down another instance of overreach by the FDA. In *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), the Court denied the FDA's claimed authority to regulate or even ban tobacco products based on Congress's grant of authority to regulate "drugs" and "devices." *West Virginia*, 142 S. Ct. at 2608 (citing *Brown & Williamson Tobacco Corp.*, 529 U.S. at 126-27). The Court, "rejected that 'expansive construction of the statute,' concluding that 'Congress could not have intended to delegate' such a sweeping and consequential authority 'in so cryptic a fashion.'" *Id.* (quoting *Brown & Williamson Tobacco Corp.*, 529 U.S. at 160). The FDA was apparently busy at the start of the new millennium testing the limits of its power.

The same rationale applies here, where the FDA, rather than reaching beyond its Congressionally approved power, tried to reach beyond the limits it had established for itself through the regulatory process. Abortion is today, and has been since at least 1973, one of the most hotly contested issues in American life. Chemical abortion is no less controversial. Federal executive agencies are not empowered to end such debates unilaterally. Here, the FDA sought to expand abortion access by its approval of

chemical abortion, disregarding both the significant safety issues of the drug and the political process that could have resolved this issue.

Chevron and *Auer* allow federal agencies and their bureaucrats to exercise expanded government power. Through its major questions doctrine jurisprudence, the Supreme Court has sought to hem in such excesses to protect the separation of powers and the freedoms that constitutional principle was designed to protect. This case is a striking example of the need for such judicial protection.

IV. Chemical abortion continues to pose a significant safety risk for women, made worse by the lax reporting requirements approved by the FDA.

As discussed above, the FDA knew about the significant, negative health consequences of the mifepristone/misoprostol regimen before approving it for abortifacient use in the United States. Despite the continued danger of chemical abortion since its approval, the FDA has weakened the reporting requirements, casting doubt on its claims about the safety of the mifepristone/misoprostol regimen.

A. The danger to women posed by chemical abortions has not abated in the 23 years since its approval by the FDA.

By 2006, the dangers of chemical abortion had become even more evident than they were when the FDA approved the drugs for that use in 2000. In her testimony in the Congressional Hearing in May of 2006, Dr. Donna Harrison said,

> In my experience as an ob-gyn, the volume of blood loss seen in the life-threatening cases is comparable to that observed in major surgical trauma cases like motor-vehicle accidents. This volume of blood loss is rarely seen in early surgical abortion without perforation of the uterus, and it is rarely seen in spontaneous abortion.

Congressional Hearing at 142. She added that no risk factors predicted such hemorrhage, and that it was life threatening for women without access to immediate medical care. *Id*. Such dangers have been ignored by the FDA in its politically motivated effort to expand abortion numbers over the past 23 years.

The information that has become available since the Congressional Report was published is no more encouraging. Several studies have shown the medical risk associated with the use of chemical abortion. Ten percent (10%) of women, after use of chemical abortion, will need follow up medical treatment for failed or incomplete abortion, Maarit Niinimaki et al., *Comparison of rates of adverse events in adolescent and adult women undergoing medical abortion: population register based study*, BJM, April 20, 2011, at 4, and twenty percent (20%) of women who use mifepristone and misoprostol to induce abortions will have an adverse event, including hemorrhaging and infections. Maarit Niinimaki et al., *Immediate complications after medical compared with surgical termination of pregnancy*, 114 Obstetrics & Gynecology 795 (2009). This rate of adverse events is four times greater than the adverse event rate of surgical abortion. *Id*. Further, five percent (5%) of women who undergo a chemical abortion will need to visit the emergency room within thirty days; a rate fifty percent (50%) higher than those who undergo surgical abortions. James Studnicki et al., *A Longitudinal Cohort Study of Emergency Room Utilization Following Mifepristone Chemical and Surgical Abortions*, 1999-2015, Health Serv. Rsch. & Managerial Epidemiology, Nov. 9, 2021.

B. The FDA's slackened reporting standards put women at further risk and smack of politics rather than healthcare.

Today, adverse events are likely to be widely underreported because the FDA only requires prescribers to report deaths, not other less-than-lethal adverse events associated with the drugs. In 2000, the FDA approved the mifepristone/misoprostol regimen with certain restrictions and requirements to assure safe use, with an eye to consistency with Subpart H. *See* 21 C.F.R. § 314.520. Although compliance with those restrictions was insufficient to render use of the regimen safe, they were much more stringent than the requirements imposed today. Among those requirements in 2000, prescribers were obligated to report non-fatal but serious adverse events to the drug manufacturer. Food and Drug Administration, Approved Labeling Text for Mifeprex (Sept. 28, 2000), https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.htm. Shockingly, beginning in 2016, prescribers need only report deaths associated with the drug, not other serious adverse events. Food and Drug Administration, Risk Evaluation and Mitigation Strategy (March 2016), https://www.fda.gov/media/164649/download. Food and Drug Administration, Risk Evaluation and Management Strategy (May 2021), https://www.fda.gov/media/164651/download. Such lax reporting requirements obscure the true dangers of chemical abortion in the United States today.

The data relied upon by the FDA when it approved the mifepristone/misoprostol regimen in 2000 was insufficient to support its finding that chemical abortion was a safe alternative to surgical abortion. In the ensuing two decades, even the

deliberately narrow range of adverse event information collected by the FDA on the safety of chemical abortion continues to manifestly demonstrate significant dangers for women using these drugs. Despite this data suggesting significant danger, the FDA continues to slacken requirements both for use of the drugs and for reporting the dangerous consequences of their use. Such reckless disregard of data collection on women's well-being smacks of political maneuvering more than medical science.

CONCLUSION

For the forgoing reasons, we urge the Court to preliminarily and permanently enjoin the FDA's unlawful approval of the mifepristone/misoprostol regimen as an abortifacient in both its name-brand and generic forms and to grant all of the plaintiff's other prayers for relief.

Respectfully submitted,

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