Nos. 23-235, 23-236

In the Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, ET AL., *Petitioners*,
v.
ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL., *Respondents*.

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

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

AMICI CURIAE BRIEF OF ADVANCING AMERICAN FREEDOM; ANGLICAN CHURCH IN NORTH AMERICA; AFA ACTION; ALASKA FAMILY COUNCIL; AMAC ACTION; AMERICAN VALUES; ANGLICANS FOR LIFE; CATHOLICS COUNT; CATHOLICVOTE; CENTER FOR POLITICAL RENEWAL (CPR); CENTER FOR URBAN RENEWAL AND EDUCATION (CURE); CITIZENS UNITED; CITIZENS UNITED FOUNDATION; COMMITTEE FOR JUSTICE; CONCERNED WOMEN FOR AMERICA; EAGLE FORUM; FAMILY COUNCIL IN ARKANSAS; FAMILY INSTITUTE OF CONNECTICUT; 40 DAYS FOR LIFE; CHARLIE GEROW;
(*Brief Title continued on inside cover*)

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INTEREST OF AMICI CURIAE[1]

Advancing American Freedom (AAF) promotes and defends policies that elevate traditional American values, including the rights to life, liberty, and the pursuit of happiness. In April 2023, AAF, joined by twenty-nine other pro-life groups,[2] sent a Freedom of Information Act (FOIA) request regarding the approval of mifepristone for abortifacient use to the Food and Drug Administration (FDA) because the women whose health and safety were jeopardized by chemical abortion deserve answers about the approval process for this chemical abortion drug.[3] As of

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[1] All parties received timely notice and have consented to the filing of this brief. No counsel for a party authored this brief in whole or in part. No person other than *Amicus Curiae* and its counsel made any monetary contribution intended to fund the preparation or submission of this brief.

[2] Those fellow requesters were Able Americans, American Cornerstone Institute, American Principles Project, Americans United for Life, Anglicans for Life, Care Net, Catholic Vote, Center for Medical Progress, Center for Political Renewal, Center for Urban Renewal and Education (CURE), Concerned Women for America, Delegate Elias Coop-Gonzalez (WV-67th), Democrats for Life, Eagle Forum, Ethics and Public Policy Center, Family Research Council, Frederick Douglass Foundation, Global Liberty Alliance, Good Counsel, Inc., Heartbeat International, International Conference of Evangelical Chaplain Endorsers, Lifeline Children's Services, Men for Life, My Faith Votes, National Center for Public Policy Research, New Jersey Family Policy Center, Phyllis Schlafly's Eagles, Students for Life of America, Susan B. Anthony Pro-Life America, and Young America's Foundation.

[3] Freedom of Information Act Request: Mifepristone (April 27, 2023), https://advancingamericanfreedom.com/wp-content/uploads/2023/04/AAF-FOIA-Request-to-FDA-Re-Mifepristone-4-27-23.pdf

February 2024, the FDA has failed to respond to AAF's FOIA request. The FDA must base its decisions on evidence established by research conducted with integrity. Public disclosure of the FDA's rationale for approving mifepristone is essential to ensure accountability in the drug approval process. AAF believes this case permits this Court to clearly articulate 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).

Amicus curiae the Anglican Church in North America ("ACNA") unites some 100,000 Anglicans in nearly 1,000 congregations and twenty-eight dioceses across the United States and Canada into a single Church. It is a Province in the Fellowship of Confessing Anglicans, initiated at the request of the Global Anglican Future Conference (GAFCon) and formally recognized by the GAFCon Primates – leaders of Anglican Churches representing 70 percent of active Anglicans globally. The ACNA is determined with God's help to maintain the doctrine, discipline, and worship of Christ as the Anglican Way has received them. Because "God, and not man, is the creator of human life," the ACNA and all of its "members and clergy are called to promote and respect the sanctity of every human life from conception to natural death." (ACNA Canon II:8:3)

Amici curiae AFA Action; Alaska Family Council; AMAC Action; American Values; Anglicans For Life; Catholics Count; CatholicVote; Center for Political Renewal (CPR); Center for Urban Renewal and Education (CURE); Citizens United; Citizens United Foundation; Committee For Justice; Concerned Women

for America; Eagle Forum; Family Council in Arkansas; Family Institute of Connecticut; 40 Days for Life; Charlie Gerow; Global Liberty Alliance; Congresswoman Vicky Hartzler ((MO-4), 2011-2023); Healing the Culture; Idaho Family Policy Center; International Conference of Evangelical Chaplain Endorsers; James Dobson Family Institute; Tim Jones, Fmr. Speaker, Missouri House & Chairman, Missouri Center-Right Coalition; Louisiana Family Forum; Men for Life; National Center for Public Policy Research; National Religious Broadcasters; New Jersey Family Foundation; Project 21 Black Leadership Network; Roughrider Institute; Samaritan's Purse; Setting Things Right; The Family Foundation (Virginia); Tradition, Family, Property, Inc.; Wisconsin Family Council; and Young America's Foundation are concerned about the Food and Drug Administration's political abuse of power and the harm it has caused and will continue to cause vulnerable women if left unchecked.

INTRODUCTION

Quis custodiet ipsos custodes? (Juvenal, *Satire VI*, lines 347–348). For some 2000 years, the problem of "who guards the guardians" has posed a challenge for good governance. What happens when the FDA, entrusted with basing decisions on sound science, trucks in junk science and maneuvers to achieve a desired political outcome? In 2006, the United States House of Representatives Government Reform Committee's Subcommittee on Criminal Justice, Drug Policy, and Human Resources culminated a year-long investigation with a hearing on mifepristone entitled *RU-486: Demonstrating a Low Standard for Women's*

Health?[4] ("Congressional Hearing") at which Janet Woodcock, M.D., defendant in the lower court, served as a witness on behalf of the FDA. A witness to the danger of this drug was Monty Patterson, father of Holly Patterson, who was killed by mifepristone just after her eighteenth birthday.[5] Congressional Hearing

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[4] *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 and https://advancingamericanfreedom.com/mifepristone-resource-congressional-hearing-ru-486-demonstrating-a-low-standard-for-womens-health/ Video available at https://www.c-span.org/video/?192580-1/ru-486-health-safety-standards#.

[5] "I said I wanted to show you a picture of my daughter so at least you see what I have lost and actually what she lost. I owe and dedicate my presence here to those who have no voice and particularly to my daughter, Holly, who died at 18, and the other women who have died or have been seriously hurt by taking the RU-486 medical abortion drug regimen as a solution to their unplanned pregnancy. I am here to testify about my personal experience as the father of a victim of this drug and my consequent knowledge, experiences, and views pertaining to RU-486, the drug... Twelve days after Holly's 18th birthday, on September 10, 2003, she walked into a Planned Parenthood clinic to be administered an RU-486 medical abortion regimen. By the 4thday, she was admitted to the emergency room of a local hospital. She was examined. She was given pain killers. She complained of bleeding, cramping, constipation, and pain, but subsequently, she was sent home. Seven days after taking RU-486, Holly returned to the same emergency room hospital complaining of weakness, vomiting, abdominal pain. Hours later, I was called to the hospital, where I found her surrounded by doctors and nurses, barely conscious and struggling to breathe. Holly was so weak she could barely hold onto my hand. Feeling utter disbelief and desperation, I watched Holly succumb to a

at 117-121. Subcommittee staff issued a subsequent report entitled *The FDA and RU-486: Lowering the Standard for Women's Health*[6] ("Congressional Report"). This report summarized the congressional investigation into the scandalous flaws in the FDA's September 28, 2000 approval of RU-486 ("mifepristone") as a chemical abortifacient,[7] which was clearly a political rather than scientific decision. Following years of political pressure from Democratic congressional chairmen Ron Wyden, Ted Weiss, and Henry Waxman in the early 1990s,[8] the Congressional Report made publicly known the deep Clinton White House political involvement, beginning just hours

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massive bacterial infection as a result of a drug-induced abortion with RU-486." Congressional Hearing at 120.

[6] *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 and Mifepristone Resource: Congressional staff report "The FDA and RU-486: Lowering the Standard for Women's Health" - Advancing American Freedom (last visited Feb. 26, 2024).

[7] Hannah Levintova, "The Abortion Pill's Secret Money Men: The untold story of the private equity investors behind Mifeprex—and their escalating legal battle to cash in post-Dobbs," *Mother Jones*, (March/April 2023), available at https://www.motherjones.com/politics/2023/01/abortion-pill-mifepristone-mifeprex-roe-dobbs-private-equity/ .

[8] Lawrence Lader, *RU 486: The Pill That Could End the Abortion Wars and Why American Women Don't Have It* (1991) at 114. Available at https://archive.org/details/ru486pillthatcou00lade

after President Clinton's inauguration[9] in pushing FDA to find a way to introduce mifepristone into America even before a new drug application could be received.[10] The Congressional Report details the uncontroverted safety concerns that exceeded alternatives at the time of FDA's abusive approval of mifepristone as an abortifacient under the Subpart H approval process.

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 staff attorney Michelle Powers Gress identifying the FDA problems detailed in the Congressional Report. I write today on behalf of

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[9] President Clinton to the Secretary of the U.S. Department of Health and Human Services, January 22, 1993: "In addition, I direct that you promptly assess initiatives by which the Department of Health and Human Services can promote the testing, licensing, and manufacturing in the United States of RU-486 or other antiprogestins." Mifepristone Resource: Judicial Watch Special Report: The Clinton RU-486 Files at https://advancingamericanfreedom.com/mifepristone-resource-judicial-watch-special-report-the-clinton-ru-486-files/ (last visited Feb. 28, 2024), part of the Congressional Hearing at 20.

[10] Donna Shalala, Secretary of the U.S. Department of Health and Human Services in a confidential memo to the Clinton White House, November 19, 1993: "Hoechst has historically refused to permit Roussel Uclaf to seek marketing approval for RU-486 as an abortifacient in the United States. Both Dr. Kessler [FDA Commissioner] and I have taken steps to persuade Roussel Uclaf and Hoechst to change their position." Mifepristone Resource: Judicial Watch Special Report: The Clinton RU-486 Files at https://advancingamericanfreedom.com/mifepristone-resource-judicial-watch-special-report-the-clinton-ru-486-files/ (last visited Feb. 28, 2024), part of the Congressional Hearing at 6.

Advancing American Freedom and *amici* because the findings in the Congressional Report remain today, even as the FDA blinds itself by declining to collect adverse event reports associated with chemical abortions and arbitrarily and capriciously decreases protective protocols.[11]

Finally, after years of stonewalling Congress and complainants, the FDA is being called to account as another Administration seeks to bend the FDA to abandon all reasonable protections, even in States that exercise their inherent authority to safeguard the safety of both mothers and their preborn children by restricting use of chemical or surgical abortion.[12] The district court's stay of the FDA's approval of mifepristone as an abortifacient must be upheld because the clear legal deficiencies of mifepristone's approval process is not entitled to deference.

The FDA's decades-long avoidance of public review must end. Just as mifepristone partisans tried to withhold FDA documents for months from Congress and just as Danco declined to testify under oath (Congressional Hearing, 68), FDA senior bureaucrats have manipulated the agency to extend a 180-day

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[11] See, Mifepristone Resource: Mifepristone Safety Fact Sheet at https://advancingamericanfreedom.com/mifepristone-resource-mifepristone-safety-fact-sheet/ (last visited Feb. 26, 2024).

[12] 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 mifepristone 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).

review to nearly two decades, a Dickensian *Bleak House*-testing of the outer limits of *Chevron* and *Auer* deference. Clearly, the "FDA [has] stonewalled judicial review," *Alliance for Hippocratic Medicine v. FDA*, ---F. Supp. 3d ----, 2023 WL 2325871, 1 (N.D. Tex. 2023) because it knows that approving mifepristone for abortifacient use violated its own rules in 2000. If the FDA were confident in its 2000 determination, especially in a past legal environment so obsequious to FDA decisions under *Chevron v. NRDC*, 467 U.S. 837 (1984) and *Auer v. Robbins*, 519 U.S. 452 (1997), it would have allowed judicial review to proceed long ago. Too many victims, named and unnamed, have been harmed or destroyed by this illegally approved chemical abortion drug. This Court should rule for Respondents.

SUMMARY OF THE ARGUMENT

In October 2006, a yearlong Congressional investigation culminated in a report outlining the significant scientific and legal shortcomings of the FDA's approval in 2000 of the drug mifepristone for use as a chemical abortifacient. The FDA approved mifepristone under Subpart H, which was designed to allow the agency to approve drugs that would provide meaningful therapeutic benefits over existing treatments for serious and life-threatening illnesses such as AIDS. Because abortion is not a treatment, and pregnancy is neither an illness nor, itself, serious or life-threatening, and because mifepristone is more dangerous and less effective than the alternative, surgical abortion, the FDA abused its own regulation in approving mifepristone in 2000.

When reviewing this agency action, this Court should not defer to FDA's interpretations; rather, this Court should exercise independent judgment as to the legality of FDA's actions. Judicial deference permits Federal agencies like the FDA to expand their power, undermining the separation of powers and the freedoms that constitutional principle exists to protect. The power to legislate belongs to Congress alone and the power to interpret belongs to the courts. Federal agencies, part of the executive branch, may only apply existing law. Agency power does not include changing the plain meaning of those regulations outside the laws that govern the regulatory process.

Chemical abortions were and are more dangerous and less effective than surgical abortion. Unlawful expansion of chemical abortion undermines States' efforts to protect their legitimate interests. The FDA's increasingly lax reporting and use requirements for the drugs make it almost impossible to determine the true scope of the danger posed by chemical abortion drugs. For all these reasons, this Court should uphold the Fifth Circuit's order staying the FDA's unlawful 2016 and 2021 Non-enforcement decisions, reverse the Fifth Circuit's decision with regard to the FDA's initial approval of mifepristone for use as an abortifacient in both its name-brand and generic forms, and grant all of Respondents' other prayers for relief.

ARGUMENT

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

The FDA approved mifepristone for use as an abortifacient under Subpart H. To be approved under Subpart H, a drug must 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 dangers of mifepristone when used as an abortifacient. Those trials resulted in two unsuccessful abortions out of eleven attempts. Two additional women required 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 prostaglandin alongside mifepristone, though it remained significantly lower than the ninety-nine

percent (99%) success rate of surgical abortion at the time.[13] *Id*.

After mifepristone was approved in France,[14] 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 mifepristone'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

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

[14] A French manufacturer handed over the technologies and patent rights to Population Council. The plan for this donation was first recommended to president-elect Clinton by Ron Weddington (co-counsel with his wife Sarah in *Roe v Wade*) in a 1992 letter where he proposed expanding access to cheap chemical abortions "to eliminate the barely educated, unhealthy and poor segment of our country" since "26 million food stamp recipients is more than the economy can stand."[54] Weddington JR. Letter to President-To-Be Clinton, Jan 6 1992. In: Rasco C, editor. OA/Box OA7455, File Folder: RU-486 [Internet]. Clinton Library; 1992. p. 54–8. Available from: https://clinton.presidentiallibraries.us/files/original/f8977047aefa0c1f90a24665cabf95bc.pdf

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, greater frequency of symptoms including cramping, nausea and vomiting, and increased blood loss associated with chemical as opposed to surgical abortions. Congressional Report at 29-30.

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 between eight and nine weeks. Congressional Report at 31.

Because these failure rates were higher, the symptoms associated were more frequent, and 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 may have 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 if 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 (however that may have come about), 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 regulation promulgated to address the AIDS crisis and entitled *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 a "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 patients whose illnesses are serious and who need better treatment options. The FDA, in approving the mifepristone 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 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,[15] 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 plain meaning of Subpart H is clear as is the FDA's rank violation of the requirements of Subpart H.

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

Subpart H requires that new drugs approved through its process "provide [a] meaningful therapeutic benefit to patients over existing treatments." 21 CFR § 314.500. The regulation gives examples of such therapeutic benefits as the "ability

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[15] "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/ As pro-abortion activist Lawrence Ladar noted, "In a larger sense, each woman who decides whether or not a fetus should become a child affects the population charts." (Lawrence Lader, Abortion. Indianapolis, Indiana: Bobbs-Merrill; 1966, at 2. Available at https://archive.org/details/abortion0000unse_b0t6)

to treat patients unresponsive to, or intolerant of, available therapy, or improved patient response over available therapy." *Id*. Even if abortion may constitute a treatment with therapeutic benefits, it was clear from the evidence at the time of approval in 2000 that chemical abortion was both more dangerous for the woman and less effective than surgical abortion.

The Congressional 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 Congressional Report identifies four problems with this idea.

First, the report clarifies that mifepristone was not approved only for use for women intolerant of surgical abortions, as would be expected for a less safe, less effective form of abortion. Congressional Report at 22. 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 to induce an abortion ultimately required surgical intervention thus casting doubt on the supposed benefit of chemical abortions 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 highlights 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 comparing chemical to surgical abortions. "Given these comments," the report summarizes, "it is impossible to conclude that [mifepristone] medical abortions provide a meaningful therapeutic benefit over surgical abortion." Congressional Report at 23.

C. Approval of Mifepristone as an abortifacient 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) says, "Uncontrolled 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 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 (defendant in the case below), 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, 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 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 issues, but the FDA acknowledged that the historical data, 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." *Id*. 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." *Id.*

Finally, the report notes that using historical data rather than a concurrent control group results in

"defining the clinical endpoint too restrictively." *Id*. In other words, surgical abortions and miscarriage are not binary, they do not "produce only simple zero or one outcomes." *Id.* 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)." *Id.*

In sum, the FDA only claimed that its studies were controlled after approval, the American cherry-picked 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, it is not entitled to *Auer* deference and thus this Court should interpret and apply Subpart H for itself and rule for Respondents.

III. 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 mifepristone before approving it for abortifacient use in the United States. Despite the continued danger of chemical abortion since its approval, the FDA has

simultaneously removed limitations designed to protect women on the prescription of chemical abortion drugs and weakened the reporting requirements for adverse events caused by those drugs, casting doubt on its claims about the safety of mifepristone.

A. The FDA's slackened reporting standards and removal of safety measures for the prescription of chemical abortion drugs put women at further risk and smack of politics rather than healthcare.

Today, adverse events are widely underreported because the FDA only requires prescribers to report maternal deaths, not other less-than-lethal adverse events associated with mifepristone. In 2000, the FDA approved mifepristone with certain safeguards and requirements to decrease the dangers mifepristone could pose to women, consistent with Subpart H. *See* 21 C.F.R. § 314.520. Although compliance with those requirements was insufficient to prevent adverse events, they were much more stringent than the requirements imposed today. In 2000, prescribers were obligated to report non-fatal but serious adverse events to the drug manufacturer.[16] Shockingly, beginning in 2016, prescribers need only report deaths associated with the drug, not other serious adverse

[16] Food and Drug Administration, Approved Labeling Text for Mifeprex (Sept. 28, 2000), https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.htm. (last visited Feb. 26, 2024).

events.[17] Imposing ignorance of adverse event reporting requirements and then claiming the drug is safe because there are so few reports of adverse events is a Through-The-Looking-Glass approach to public health that intentionally obscures the true dangers of mifepristone. Such reckless disregard of data collection on women's well-being smacks more of political maneuver than medical science.

The FDA's inexplicable slackening of adverse event reporting requirements forces researchers to look overseas for data on mifepristone's harm to women. Even recent experience with mifepristone bears out the fact that it continues to be more dangerous than surgical abortion, contrary to the requirements of Subpart H. As British researcher and medical doctor Calum Miller explains:

> During the COVID-19 pandemic, a small minority of countries permitted abortion providers to send abortion pills—usually mifepristone and misoprostol—by post to women after a remote consultation by video or telephone (hereafter, "telemedicine" refers to either)—that is, without any in-person contact throughout the process. This was an unprecedented move since

[17] Food and Drug Administration, Risk Evaluation and Mitigation Strategy (March 2016), https://www.fda.gov/media/164649/download. (last visited Feb. 26, 2024). Food and Drug Administration, Risk Evaluation and Management Strategy (May 2021), https://www.fda.gov/media/164651/download. (last visited Feb. 26, 2024).

> full telemedicine had not been studied in legal, experimental conditions prior to this… In the United Kingdom… ambulance calls and responses relating to medical abortion also increased dramatically between 2018 and 2021, following the introduction of [chemical abortion] at home and then full telemedicine.[18]

Further, British researchers

> [U]sing [their] rights under the Freedom of Information Act… asked each of the ten [National Health Service] Ambulance Trusts in England to provide data related to the number of emergency ambulance responses made when the caller indicated complications arising from the use of abortion pills, a combination treatment of mifepristone and misoprostol. Data was requested for three time periods: A – during 2018, when all medical abortions were

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[18] Calum Miller, "Telemedicine Abortion: Why It Is Not Safe for Women," in Nicholas Colgrove, ed., *Agency, Pregnancy and Persons : Essays in Defense of Human Life* at 288, 296 (forthcoming, 2023). ProQuest Ebook Central, http://ebookcentral.proquest.com/lib/wfu/detail.action?docID=6998328.
Even the most zealous advocates for mifepristone did not countenance that: "Prescribing RU 486 will maintain the same doctor-patient relationship that accompanies the use of an antibiotic or any drug." Lawrence Lader, *A Private Matter: RU 486 and the Abortion Crisis* (1995) at 17. Available at https://archive.org/details/privatematterru400lade.

> provided in a clinic; B – during 2019, when women were able to self-administer misoprostol (the second part of the combined treatment) at home, after having received the mifepristone (the first part of the combined treatment) at an abortion clinic; C – from April 2020, when women were able to self-administer both mifepristone and misoprostol at home… Data obtained from five NHS Ambulance Trusts in England, show that emergency ambulance responses for complications arising after a medical abortion are three times higher for women using pills-by-post at home, compared to those who have their medical abortion in a clinic." Duffy at 1. "In a related freedom of information investigation, we found that complications arising from the failure of medical abortion treatment result in 590 women presenting at the emergency department of their local NHS hospital in England every month. The treatment failure rate is 5.9%, 1-in-17.[19]

Not only did the FDA remove the adverse event reporting requirement, but it also removed the in-person doctor assessment that had previously been required. At the time of the FDA's initial approval, a woman seeking a chemical abortion was required to visit the doctor three times to receive a chemical abortion prescription. In 2016, that number of visits

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[19] *Id.*

dropped to one.[20] Then in 2021 the FDA removed the in-person visit requirement altogether, meaning that a woman can obtain mifepristone through the mail without in-person examination, sonogram, or laboratory analysis.[21]

Prescribing chemical abortion drugs via telemedicine exposes women to several risks. One of the most significant of these is a ruptured ectopic pregnancy. Despite the fact that only 2% of pregnancies are determined to be ectopic, these pregnancies contribute to 13% of maternal deaths. When a woman chooses to abort with mifepristone, she is 30% more likely to face death from an undiscovered ectopic pregnancy than if she had decided against an abortion. This is because the woman is likely to mistake bleeding and pain as a sign of the chemical abortion taking place although her life is actually in jeopardy.[22] Ultrasounds, which require an in-person assessment, are critical in identifying gestational age and in ruling out ectopic pregnancies. Chemical abortion is ineffective in cases of ectopic pregnancy. As the district court put it, "there is simply *no requirement* that *any* procedure is done to rule out

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[20] Information on Mifeprex Changes and Ongoing Monitoring Efforts, Government Accountability Office at 7 (Mar. 2018) https://www.gao.gov/assets/gao-18-292.pdf.

[21] Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation, U.S. Food and Drug Administration (Mar. 2023) https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

[22] ACOG Practice Bulletin No. 193 Summary: Tubal Ectopic Pregnancy. Obstet Gynecol. 2018;131(3):613–5.)

an ectopic pregnancy—which *is* a serious and life-threatening situation." Joint App. at 176A. The current REMS require only that the prescriber have the "[a]billity to diagnose ectopic pregnancies," not that a doctor actually assess whether the patient has one.[23]

Finally, telemedicine may not allow for a thorough discussion of the patient's medical history or assessment of her needs, potentially missing important details that could impact the procedure's safety. Telemedicine also leads to uncertainty and the inability to confirm that a woman is not being coerced into performing an abortion against her will. Further, "We can expect that 1-in-17 women using the abortion pills at home, will subsequently need hospital treatment for complications arising from the medical abortion treatment failure, presenting with retained products of conception and/or hemorrhage."[24] Thus, the FDA's loosening of standards puts women at greater risk harm without a counterbalancing interest to justify that increased risk.

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[23] Risk Evaluation and Mitigation Strategy (REMS) Singla Shared System for Mifepristone 200MG, Food and Drug Administration at 1 https://www.fda.gov/media/164651/download?attachment.

[24] FOI Investigation into Medical Abortion Treatment Failure, Percuity at 4 (Oct. 2021) https://percuity.files.wordpress.com/2021/10/foi-ma-treatment-failure-211027.pdf. (last visited Feb. 26, 2024).

B. 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 2006, Dr. Donna Harrison (a Plaintiff in the lower court) 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. Dr. Harrison 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 effort to push mifepristone over the past 23 years.

Information that has become available since the Congressional Report was published in 2006 is no more encouraging. Several studies have shown the medical risk associated with the use of chemical abortion. One study found that ten percent (10%) of women, after use of chemical abortion, require follow-up medical treatment for failed or incomplete

abortion,[25] and twenty percent (20%) of women who use mifepristone to induce abortions will have an adverse event, including hemorrhaging and infections.[26] This rate of adverse events is four times greater than the adverse event rate of surgical abortion. *Id*.

Abortion, including chemical abortion, also risks harm to the woman's mental health. A comprehensive review of the literature on abortion and mental health found that at least some women experienced negative mental health outcomes as a result of their abortions and that "[t]he ability to identify women who are at greater risk of negative reactions has resulted in numerous recommendations for abortion providers to screen for these risk factors in order to provide additional counseling both before an abortion, including decision-making counseling, and after an abortion."[27] A 2016 analysis of data from the National Longitudinal Study of Adolescent to Adult Health shows that each exposure to abortion increases the risk of mental disorders by 23 percent, even after controlling for 25 other factors, including

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[25] Maarit Niinimaki et al., *Comparison of rates of adverse events in adolescent and adult women undergoing medical abortion: population register based study*, BMJ, April 20, 2011, at 4

[26] Maarit Niinimaki et al., *Immediate complications after medical compared with surgical termination of pregnancy*, 114 Obstetrics & Gynecology 795 (2009).

[27] David C. Reardon, *The abortion and mental health controversy: A comprehensive literature review of common ground agreements, disagreements, actionable recommendations, and research opportunities*, 6 Sage Open Medicine 1, http://journals.sagepub.com/doi/10.1177/2050312118807624.

prior mental health issues. *Id*. A recent peer-reviewed CLI analysis of state Medicaid data showing that, compared to women who give birth, women who have an abortion in their first pregnancy are 3.4 times more likely to experience an increase in outpatient mental health visits and 5.7 times more likely to experience an increase in inpatient admissions.[28] Among the most vulnerable women, those dependent on Medicaid, women with a history of pregnancy loss, including abortion, are about 35 percent more likely to require mental health treatment following their subsequent first live birth.[29]

The dangers to women posed by chemical abortion are legion, and they should not face them alone without the care of a physician. A 2011 study published in the British Journal of Psychiatry reported that there were dramatic changes in mental health in women who had an abortion. "Based on data extracted from 22 studies, the results of this meta-analytic review of the abortion and mental health literature indicate quite consistently that abortion is associated with moderate to highly increased risks of

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[28] Studnicki J, Longbons T, Fisher J, Reardon DC, Skop I, Cirucci CA, Harrison DJ, Craver C, Tsulukidze M, Ras Z. *A Cohort Study of Mental Health Services Utilization Following a First Pregnancy Abortion or Birth*. Int J Womens Health. 2023;15:955-963
https://doi.org/10.2147/IJWH.S410798

[29] Reardon DC, Craver C. *Effects of Pregnancy Loss on Subsequent Postpartum Mental Health: A Prospective Longitudinal Cohort Study*. Int J Environ Res Public Health. 2021 Feb 23;18(4):2179. doi: 10.3390/ijerph18042179. PMID: 33672236; PMCID: PMC7926811.

psychological problems subsequent to the procedure."[30] The meta-study examined medical information from 877,000 women, of which 164,000 had an abortion; the women who had an abortion were 81 percent more likely to experience mental health struggles. They were:

- 34% more likely to develop an anxiety disorder
- 37% more likely to experience depression
- 110% more likely to abuse alcohol
- 155% more likely to commit suicide
- 220% more likely to abuse marijuana

The study found that 10 percent of these issues could be linked to the woman's abortion. *Id*.

Yet the FDA, despite consistent evidence of these dangers, has repeatedly reduced the safety measures it had initially put in place to protect against those harms. Because these dangers remain significant, and because the FDA's initial approval of mifepristone for abortifacient use was illegal, this Court should rule for Respondents.

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[30] Coleman PK. *Abortion and mental health: quantitative synthesis and analysis of research published 1995–2009*. British Journal of Psychiatry. 2011;199(3):180-186. doi:10.1192/bjp.bp.110.077230

CONCLUSION

For the forgoing reasons, this Court should rule for Respondents and find that mifepristone was illegally approved under Subpart H because it is more dangerous than surgical abortion and that the FDA's loosening of the protections around the prescription of mifepristone was arbitrary and capricious.

Respectfully submitted,

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