AAF LEGAL & AAF POLICY DEPARTMENT

SENATORS SHOULD QUESTION FDA-NOMINEE HEIDI OVERTON ABOUT ABORTION DRUGS

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TOPLINE: As Commissioner of the United States Food and Drug Administration, Heidi Overton would be responsible for overseeing the abortion industry's favorite tool – the chemical abortion pill, also known as Mifepristone. In a February 2023 paper titled "Risking Two Lives – The Dangerous Rise of Chemical Abortion," FDA Commissioner nominee Heidi Overton wrote, "Abortion is corrosive to children, women, and society broadly because it devalues and extinguishes innocent human life," and that "[e]ffective policies should prioritize quality care for women by providing safeguards from the known dangers of chemical abortion." These comments and others like them are encouraging. But Congress must ensure Overton will be true to her words if confirmed as the FDA Commissioner.

EXECUTIVE SUMMARY: AAF calls on Senators to ask Overton the following questions about Mifepristone (additional information on each of these questions is provided below):

1. In a 2023 paper, you wrote that, "Dangerous chemical abortion drugs…are a serious threat to women's health and deserve greater medical scrutiny." What role do you see for the Commissioner of the FDA to revisit FDA decisions that were based on junk science and in giving chemical abortion drugs the medical scrutiny they deserve?
2. In a 2022 op-ed, you said "Americans should reject abortion radicalism and require policies informed by 21st century science and medicine. Then, indeed, we would all be 'Following the Science!'" Will you review the approval of any drug that was introduced to the U.S. market under White House or Congressional pressure, bypassing the normal new drug application process and following politics rather than the science?
3. If confirmed, will you produce the documents Congress requested years ago and that are the subject of litigation with HHS and the FDA? Will you make available all the Mifepristone documents, including adverse event reports?
4. In 2024, you co-authored a *Townhall* article saying that "we cannot forget" that the effects of bad abortion policies "are measured in unborn children *killed.*" Mifepristone was approved under an accelerated review process that was reserved for new therapies that were safer and more effective than the

alternative, two hurdles that Mifepristone failed. Will you commit to right a wrong by subjecting Mifepristone to the regular drug review process?

5. Do you believe that the FDA erred when it treated pregnancy as a serious or life-threatening illness?
6. Which has a higher probability for an adverse event for the mother: a chemical abortion or a surgical abortion?
7. Would you agree or disagree that drug approvals should be based on well-controlled clinical trials? If a drug were approved based on flawed clinical trials, would you direct the agency to reconsider the drug's approval?
8. In a 2023 paper, you said, "Unfortunately, federal policymakers have recently expanded access to abortion pills, also called chemical abortions, which are far more dangerous to women, enabling rapid access to abortion." If you were confirmed to be Commissioner of the FDA, would you work diligently to fully restore the requirement for accurate adverse event reporting on Mifepristone so that scientists investigating the drug can do so with accurate data?
9. As FDA Commissioner, would you restore the protections initially mandated by the FDA on the use of Mifepristone that were implemented to protect women from the real dangers of chemical abortion and were removed for political reasons? Would you follow through on the pro-life policy proposals for which you previously advocated, including "ensur[ing] in-person ultrasounds are completed before women undergo an abortion for accurate pregnancy dating" and requiring "mandatory three-day waiting periods to allow women to process their options following counseling and ultrasound appointments"?
10. In your 2024 *Townhall* article, you said, "Ending *Roe* was just the start," and that "the real goal, the destination toward which we indefatigably strive, is protecting a woman and child's shared right to 'Life, Liberty and the pursuit of happiness.'" Would protecting the health and safety of women and their unborn children from the dangers of chemical abortions be your top priority if you were confirmed as head of the FDA?

BOTTOMLINE: The FDA has repeatedly loosened safety requirements for Mifepristone's prescription. It's time for the government to prioritize safety and science over politics.

SOURCED & FOOTNOTED QUESTIONS:

Q1: In a 2023 paper, you wrote that, "Dangerous chemical abortion drugs…are a serious threat to women's health and deserve greater medical scrutiny." What role do you see for the Commissioner of the FDA to revisit FDA decisions that were based on junk science and in giving chemical abortion drugs the medical scrutiny they deserve?

Quis custodiet ipsos custodes? (Juvenal, *Satire VI*, lines 347–348). For some 2000 years, the problem of "who guards the guardians" has challenged good governance. What happens when the Food and Drug Administration (FDA), entrusted with basing decisions on sound science, relies on junk science to achieve a desired political outcome?[1] In short, women are harmed. The deaths of young mothers like Candi Miller,

[1] The FDA's approval of Mifepristone for abortifacient use demonstrates the danger of bureaucracy and its tendency to hide politics behind a veil of supposed expertise. Advancing American Freedom (AAF) has repeatedly drawn attention to the danger. This testimony summarizes AAF's work on this issue and the work of others to call attention to the FDA's prioritization of politics over women's safety. AAF's own work and other important resources on this issue can be found at the links below. The Judicial Watch Special Report provides some of the most striking evidence that the approval of Mifepristone for abortifacient use was a political, not a scientific, decision.

AAF Amicus Briefs

- *Louisiana v. FDA* (Fifth Circuit) (June 2026): https://tinyurl.com/mr24634e
- *Louisiana v. FDA* (Supreme Court) (May 2026): https://tinyurl.com/24xz9eh7
- *Missouri v. FDA* (District Court) (March 2026): https://tinyurl.com/3zm9nzfd
- *Louisiana v. FDA* (District Court) (February 2026): https://tinyurl.com/2n8j6cb6
- *Bryant* v. *Moore* (Fourth Circuit) (August 2024): https://tinyurl.com/52k345f6
- *GenBioPro Inc. v. Kristina Raynes* (Fourth Circuit) (April 2024): https://tinyurl.com/bd4yhzuh
- *FDA v. Alliance for Hippocratic Medicine* (Supreme Court) (February 2024): https://tinyurl.com/599bn29e
- *FDA v. Alliance for Hippocratic Medicine* (Fifth Circuit) (May 2023): https://tinyurl.com/35sf857s
- *Alliance for Hippocratic Medicine v. FDA* (Supreme Court) (April 2023): https://tinyurl.com/4fh98c47
- *Alliance for Hippocratic Medicine v. FDA* (Fifth Circuit) (April 2023): https://tinyurl.com/mpwsjc7u
- *Alliance for Hippocratic Medicine v. FDA* (District Court) (February 2023): https://tinyurl.com/bdcjjcnt

AAF FOIA Requests & AAF Lawsuit

- AAF Foundation Files FOIA Lawsuit Against HHS on Mifepristone (October 2024): https://tinyurl.com/4uy73n8z
- FOIA Request for FDA Records on Mifepristone (May 2024): https://tinyurl.com/2n85njv6
- FOIA on FDA Approval of Mifepristone (April 2023): https://tinyurl.com/3p8uju2y

AAF Memos

- It's Time for the FDA to Put Science over Politics (April 2025): https://tinyurl.com/y353cvja
- The Truth About the Georgia Abortion Death (Sept 2024): https://tinyurl.com/yc5ftebj
- How Chemical Abortion Harms American Women and Children (Feb 2024): https://tinyurl.com/4xsy9ybr

AAF Letter to Congress on Mifepristone

- Restore Safeguards on Mifepristone in Agriculture Appropriations Bill (Sept 2023): https://tinyurl.com/5acjw2rr

AAF Letter to FDA on Mifepristone

Amber Thurman[2] and Alyona Dixon[3] are among the tragic consequences of the FDA's reckless approval of chemical abortion drugs.[4] The danger those drugs pose to women's health was clear at the time of their approval by the FDA and has not abated in the intervening decades, as the agency has repeatedly reduced the restrictions it had once implemented as a way of mitigating some of the risk.

Q2: In a 2022 op-ed, you said "Americans should reject abortion radicalism and require policies informed by 21st century science and medicine. Then, indeed, we would all be 'Following the Science!'" Will you review the approval of any drug that was introduced to the U.S. market under White House or Congressional pressure, bypassing the normal new drug application process and following politics rather than the science?

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?*[5] ("Congressional Hearing"). One of the witnesses was Monty Patterson, the father of Holly Patterson who was killed by Mifepristone just after her eighteenth birthday.[6] Congressional Hearing at 117-121.

- AAF Urges FDA for Transparency on Mifepristone for Women's Safety (July 2025): https://tinyurl.com/6d3bpp8v

AAF Comments in the Federal Register

- AAF Urges FDA to Review Mifepristone Regulations (August 2025): https://tinyurl.com/39wjwudn

Online Resources

- Judicial Watch Special Report: The Clinton RU-486 Files: https://tinyurl.com/3f8dmjav
- Congressional staff report "The FDA and RU-486: Lowering the Standard for Women's Health": https://tinyurl.com/46ehb98s
- Congressional Hearing "RU-486: Demonstrating A Low Standard for Women's Health?": https://tinyurl.com/yu852jmp

[2] Kavitha Surana, *Abortion Bans Have Delayed Emergency Medical Care. In Georgia, Experts Say This Mother's Death Was Preventable*, ProPublica (Sept. 16, 2024) https://www.propublica.org/article/georgia-abortion-ban-amber-thurman-death.

[3] Carole Novielli, *Woman's Death from 'Septic Abortion' Days After Obtaining Abortion Pill Sparks Lawsuit*, Live Action (September 25, 2023) https://www.liveaction.org/news/womans-death-septic-abortion-pill-lawsuit/.

[4] The Truth About the Georgia Abortion Death: https://advancingamericanfreedom.com/aaf-the-truth-about-the-georgia-abortion-death/.

[5] *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. Video available at https://www.c-span.org/video/?192580-1/ru-486-health-safety-standards#.

[6] "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

Subcommittee staff issued a subsequent report entitled *The FDA and RU-486: Lowering the Standard for Women's Health*[7] ("Congressional Report"). This report summarized the congressional investigation into the scandalous scientific flaws in the FDA's clearly political September 28, 2000 approval of RU-486 ("Mifepristone") as a chemical abortifacient.[8] Following years of political pressure from Democratic congressional chairmen Ron Wyden, Ted Weiss, and Henry Waxman in the early 1990s, the Congressional Report showed the deep Clinton White House involvement in pushing the FDA to find a way to get Mifepristone introduced into the American market even before a new drug application was received. Congressional Hearing at 3-66. The Congressional Report details the uncontroverted dangers of chemical abortion at the time of the FDA's abusive approval of Mifepristone as an abortifacient under the Subpart H approval process.

Q3: If confirmed, will you produce the documents Congress requested years ago and that are the subject of litigation with HHS and the FDA? Will you make available all the Mifepristone documents, including adverse event reports?

The House Commerce Committee Subcommittee on Oversight and Investigations sent two letters to the FDA seeking documents on the data integrity in clinical trials of the safety and efficacy of Mifepristone sponsored by the Population Council, and a third letter related to the FDA's unusual consideration of Mifepristone. There appears to be no record that the FDA or HHS ever responded to these oversight letters, and neither agency has produced them under FOIA. Judicial Watch is representing Advancing American Freedom in a FOIA lawsuit in federal court to obtain copies of these records first requested by Congress in 1996. As of August 31, 2026, Advancing American Freedom has received 300 redacted pages of the 125,000 pages that the FDA identified as potentially responsive to the FOIA request.[9] If the FDA

RU-486 medical abortion regimen. By the 4th day, 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 massive bacterial infection as a result of a drug-induced abortion with RU-486." Congressional Hearing at 120.

[7] *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. Also available at https://advancingamericanfreedom.com/legal-filings/mifepristone-resource-congressional-staff-report-the-fda-and-ru-486-lowering-the-standard-for-womens-health

[8] 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/ .

[9] Copy of the lawsuit and the Congressional oversight letters are available at https://advancingamericanfreedom.com/legal-filings/aaf-foundation-files-foia-lawsuit-against-hhs-on-mifepristone.

continues producing 300 pages per month, Advancing American Freedom would not receive all of the documents *for twenty-five years*.

Finally, after years of stonewalling Congress and complainants, the FDA is being called to account just as another Administration seeks to bend the FDA to abandon all reasonable protections, even as Pro-Life states attempt to safeguard the wellbeing of both mothers and their preborn children by restricting the use of chemical or surgical abortion.[10]

Q4: ***In 2024, you co-authored a Townhall article saying that "we cannot forget" that the effects of bad abortion policies "are measured in unborn children killed." Mifepristone was approved under an accelerated review process that was reserved for new therapies that were safer and more effective than the alternative, two hurdles that Mifepristone failed. Will you commit to right a wrong by subjecting Mifepristone to the regular drug review process?***

The FDA has spent decades avoiding judicial review. Just as pro-Mifepristone partisans tried to withhold FDA documents over months from Congress and just as chemical abortion manufacturer Danco declined to testify under oath, Congressional Hearing at 68, FDA senior bureaucrats have manipulated the agency to extend a 180-day review to nearly two decades. Clearly, the "FDA [has] stonewalled judicial review," *Alliance for Hippocratic Medicine v. FDA*, 668 F. Supp. 3d 507, 520 (N.D. Tex. 2023) because it knows that approving Mifepristone for abortifacient use violated its own rules.

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

[10] 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). See AAF amicus briefs defending State laws to restore FDA protections on Mifepristone in West Virginia (https://advancingamericanfreedom.com/legal-filings/genbiopro-inc-v-kristina-raynes) and North Carolina (https://advancingamericanfreedom.com/legal-filings/bryant-v-moore).

alongside Mifepristone, though it remained significantly lower than the ninety-nine percent (99%) success rate of surgical abortion at the time.[11] *Id*.

After Mifepristone was approved in France,[12] 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 intervention is not required, and the 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 and the symptoms associated more frequent, and because chemical abortion provided no 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.

Q5: *Do you believe that the FDA erred when it treated pregnancy as a serious or life-threatening illness?*

Federal executive agencies derive whatever power they may have from Congress by legislation empowering them to exercise legal control over a particular policy domain. Subpart H, an FDA regulation promulgated to address the AIDS crisis and entitled *Accelerated Approval of New Drugs for Serious or Life-Threatening*

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

[12] 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.

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. The language of Subpart H is unambiguous, and the FDA's interpretation of Subpart H is unambiguously wrong.

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,[13] 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.

Q6: *Which has a higher probability for an adverse event for the mother: a chemical abortion or a surgical abortion?*

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 to treat patients unresponsive to, or intolerant of, available therapy, or improved patient response over available therapy." *Id*. Even if abortion constituted 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.

[13] "The Population Council was formed in New York State in 1952" by John D. Rockefeller III. "The group was originally founded as an expressly eugenicist organization and in 1969 published a controversial journal article that discussed involuntary fertility controls, including forced abortions, sterilizing drugs in the food and water supply, and requirements for government permission to have a child." Population Council, https://www.influencewatch.org/non-profit/population-council/ (last visited Sep. 9, 2026). 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. 212 p.

First, the report notes 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." *Id.*

Second, the report points to the fact that a substantial portion of women using Mifepristone to induce an abortion ultimately required surgical intervention, 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. *Id.* 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 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." *Id.* at 23.

Q7: *Would you agree or disagree that drug approvals should be based on well-controlled clinical trials? If a drug were approved based on flawed clinical trials, would you direct the agency to reconsider the drug's approval?*

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 upon which the FDA relied 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. *Id.* 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. *Id.* 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." *Id.* 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. *Id.* 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. *Id.* 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.* 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." *Id.*

Finally, the report notes that using historical data rather than a concurrent control group results in "defining the clinical endpoint too restrictively." *Id.* at 18. 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's approval of the abortion drug violated the plain language of Subpart H.

Q8: ***In a 2023 paper, you said, "Unfortunately, federal policymakers have recently expanded access to abortion pills, also called chemical abortions, which are far more dangerous to women, enabling rapid access to abortion." If you were confirmed to be Commissioner of the FDA, would you work diligently to fully restore the requirement for accurate adverse event reporting on Mifepristone so that scientists investigating the drug can do so with accurate data?***

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 protective limitations 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.

In 2024, adverse events are widely underreported because the FDA only requires prescribers to report 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 did not prevent adverse events, the requirements were much more stringent than those imposed today. Among those requirements in 2000, prescribers were obligated

to report non-fatal but serious adverse events to the drug manufacturer.[14] But since 2016, prescribers need only report deaths associated with the drug, not other serious adverse events.[15] The FDA's intentional blinding of itself and the public along with its claims that chemical abortion 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 is politics, not science.

The FDA's inexplicable removal of most 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 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.[16]

Further, according to British researchers:

> "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."[17]

Q9: ***As FDA Commissioner, would you restore the protections initially mandated by the FDA on the use of Mifepristone that were implemented to protect women from the real dangers of chemical abortion and were removed for political reasons? Would you follow through on the pro-life policy proposals for which you previously***

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

[15] 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.

[16] 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 (July 2022). ProQuest Ebook Central.
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." Lader 1995 at 17.

[17] *Id*.

***advocated*, including "ensur[ing] in-person ultrasounds are completed before women undergo an abortion for accurate pregnancy dating," preventing access to chemical abortion through telemedicine, and requiring "mandatory three-day waiting periods to allow women to process their options following counseling and ultrasound appointments"?**

Not only did the FDA remove the adverse event reporting requirement; 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 dropped to one.[18] 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.[19]

Prescribing chemical abortion drugs via telemedicine exposes women to several risks, one of the most significant of which is a ruptured ectopic pregnancy. Ultrasounds, which require an in-person assessment, are critical in identifying gestational age and ruling out ectopic pregnancies. Chemical abortion is ineffective in cases of ectopic pregnancy, yet "there is simply *no requirement* that *any* procedure is done to rule out an ectopic pregnancy—which *is* a serious and life-threatening situation." *Alliance for Hippocratic Medicine*, 668 F. Supp. 3d at 551. The current REMS require only that the prescriber have the "[a]bility to diagnose ectopic pregnancies," not that a doctor actually assess whether the patient has one.[20]

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."[21] Thus, the FDA's loosening of standards puts women at greater risk of harm without a counterbalancing interest to justify that increased risk.

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 a Congressional Hearing in May of 2006, Dr. Donna Harrison said,

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

[19] 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.

[20] 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.

[21] 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.

> 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*. The FDA has ignored such dangers in its effort to push Mifepristone over the past 25 years.

Information that has become available since the publication of the Congressional Report 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,[22] and twenty percent (20%) of women who use Mifepristone to induce abortions will have an adverse event, including hemorrhaging and infections.[23] This rate of adverse events is four times greater than the adverse event rate of surgical abortion. *Id*. Additionally, a 2025 Ethics & Public Policy report based on insurance data found that adverse events were at least 22 times as common as the 0.5 percent adverse event rate listed on the chemical abortion drug's label.[24]

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." [25] The dangers to women posed by chemical abortion are many. 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.

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[22] 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

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

[24] The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event (April 28, 2025) https://eppc.org/stop-harming-women/.

[25] 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.

Q10: ***In your 2024 Townhall article, you said, "Ending Roe was just the start" and that "the real goal, the destination toward which we indefatigably strive, is protecting a woman and child's shared right to 'Life, Liberty and the pursuit of happiness.'" Would protecting the health and safety of women and their unborn children from the dangers of chemical abortions be your top priority if you were confirmed as head of the FDA?***

The regulation of chemical abortion should be about one thing: the health and safety of women and the unborn. Yet many regulators and politicians have prioritized "access" over the wellbeing of women and children. Surgical abortion is safer than chemical abortion, at least for the mother. Yet the FDA has repeatedly loosened safety requirements for Mifepristone's prescription. It's time for the government to prioritize safety and science over politics. Until it does so, women like Amber Thurman and Candi Miller will continue to suffer the consequences.