United States Senate

WASHINGTON, DC 20510

November 6, 2025

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

The Honorable Martin Makary, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Secretary Kennedy and Commissioner Makary,

We write today with serious concerns about the U.S. Department of Health and Human Services' (HHS or the Department) announcement that it will conduct, through the U.S. Food and Drug Administration (FDA), "its own review of the evidence" on the safety and effectiveness of mifepristone, which has been approved by the FDA since 2000 for the medical termination of pregnancy.[1] Decades of evidence and hundreds of studies prove the safety and efficacy of mifepristone, which is not only the most common method of abortion in the U.S., but is also frequently prescribed to women to help manage early pregnancy loss or miscarriage.[2] We are alarmed by the Department's obvious attempts to politicize the review, regulation, and approval of mifepristone at the FDA, and we write to request more information on the details of the review of mifepristone. We are especially troubled by this administration's clear intent to tee up further restrictions on medication abortion, in light of a recent federal court order holding that the agency has failed to justify its *current* extreme restrictions on mifepristone and must consider lifting them.[3]

In an April 28, 2025 letter, Senator Hawley called on the FDA to revisit its existing restrictions on mifepristone, alleging the "research showing the safety risks" of medication abortion are "far greater than the FDA currently acknowledges."[4] The same day, the avowedly anti-abortion think tank Ethics and Public Policy Center (EPPC) published a junk science "report" that parrots anti-abortion disinformation, was not peer-reviewed or published in any medical journal, and has

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[1] https://www.thegatewaypundit.com/2025/09/trump-admin-rfk-jr-moves-address-assess-safety/.

[2] https://www.ama-assn.org/about/leadership/reducing-access-mifepristone-would-harm-patients; https://www.guttmacher.org/2024/03/medication-abortion-accounted-63-all-us-abortions-2023-increase-53-2020; https://www.acog.org/womens-health/experts-and-stories/the-latest/what-to-know-about-abortion-and-miscarriages-with-or-without-mifepristone.

[3] https://democracyforward.org/wp-content/uploads/2025/09/Fda_Hhs_Letter-1.pdf; https://www.help.senate.gov/hearings/hearing-on-fiscal-year-2026-department-of-health-and-human-services-budget;
Order Granting Pls.' Mot. for Summ. J. & Denying Defs.' Mot. for Summ. J., *Purcell v. Kennedy*, No. 17-00493 (D. Haw. Oct. 30, 2025).

[4] https://www.hawley.senate.gov/hawley-calls-on-fda-to-reinstate-abortion-drug-safety-regulations-the-time-to-act-is-now/.

been widely criticized by reputable health organizations.[5] Based on apparently nothing but the nakedly partisan and easily debunked EPPC report, Commissioner Makary committed to conducting a new review of mifepristone in a June 2, 2025 letter.[6] Secretary Kennedy and Commissioner Makary similarly sent a September 19, 2025 letter to Republican attorneys general, highlighting the EPPC report as alleged evidence of the "potential dangers that may attend offering mifepristone without sufficient medical support or supervision."[7] By elevating the sham EPPC report as rationale for restricting access to mifepristone, HHS is blatantly undermining well-established science and weaponizing disinformation to fit the Trump administration's clear agenda to cut off abortion access in any way possible.

Mifepristone has been proven to be safe and effective in hundreds of studies over more than two decades, and this has been backed up by the American College of Obstetricians and Gynecologists (ACOG)—which represents more than 90% of the nation's OBGYNs, the American Medical Association (AMA), the Society for Maternal-Fetal Medicine, and the Society of Family Planning.[8] While the EPPC report makes unsubstantiated claims about the rate of adverse events following medication abortion, the safety label for mifepristone clearly states that "serious adverse reactions were reported in <0.5% of women" in accordance with the data from 10 clinical trials of more than 30,000 women in settings in the U.S. and abroad.[9] And, the FDA's own website states that "the FDA's periodic reviews of the postmarketing data for Mifeprex and its approved generic have not identified any new safety concerns with the use of mifepristone for medical termination of pregnancy through 70 days."[10]

There are numerous serious methodological issues with the EPPC report, whose analyses cannot be verified or replicated due to EPPC's failure to transparently share its data sources. As the Society of Family Planning stated in a May letter to Commissioner Makary, "this paper is not a methodologically rigorous, evidence-based resource, and does not warrant consideration, particularly in scientific spaces."[11] The FDA should be using gold-standard science and evidence when making decisions about medication access for the American people. Typically, the FDA relies on its Adverse Event Reporting System (FAERS) or other postmarketing surveillance data to consider the safety risk of a particular drug, not unverified claims from a debunked report.

[5] https://eppc.org/publication/insurance-data-reveals-one-in-ten-patients-experiences-a-serious-adverse-event; https://www.kff.org/health-information-trust/flawed-report-aims-to-undercut-established-research-on-abortion-pill-safety-plus-how-a-federal-initiative-to-study-autism-may-overemphasize-environmental-toxins/; https://law.ucla.edu/reproductive-health-researchers-comment-letter-fda.

[6] https://x.com/HawleyMO/status/1929696353010987013?mc_cid=e74f2bdc0d&mc_eid=bce33a25bd.

[7] https://www.statnews.com/2025/09/26/kennedy-abortion-pill-nih-indirect-costs-morning-rounds/.

[8] https://www.regulations.gov/document/FDA-2025-P-0377-0001 ; https://www.supremecourt.gov/DocketPDF/23/23-235/299161/20240130120052623_23-235%20Amicus%20Brief%20of%20American%20College%20of%20Obstetricians%20and%20Gynecologists%20et%20al_.pdf.

[9] https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.

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

[11] https://societyfp.org/wp-content/uploads/2025/05/SFP-Letter-to-Commissioner-Makary_5.2.2025.pdf.

FDA relying on a partisan, sham report as part of the evidence review for *any* drug is deeply concerning—and in this case, it's clear that the Trump administration is downright eager to do away with established science if it helps further their extreme anti-abortion agenda.

It is also important to note that mifepristone is already subject to burdensome Risk Evaluation and Mitigation Strategy (REMS) requirements that must be followed for prescribing and dispensing mifepristone. The REMS already restricts the number of providers who can prescribe or dispense the drug, and the FDA already restricts mifepristone more heavily than 99.5% of the over 20,000 prescription drugs it regulates, making it more difficult for women to receive the timely access to care they need.[12] On January 3, 2023, the FDA approved a modification to the mifepristone REMS, which included permanent removal of the requirement that the drug be dispensed in-person, and the addition of a new pharmacy certification process to allow qualified retail pharmacies to dispense mifepristone to patients with a prescription.[13] These commonsense changes allow for improved access to mifepristone, yet the REMS criteria continues to impose unnecessary restrictions that cause administrative burdens for providers, which may impede their ability to provide the medication, thus impacting patient access.[14]

Leading health experts, including ACOG and the AMA, have long advocated for removal of the mifepristone REMS, given that the restrictions do not make care safer and are not based on medical evidence or need.[15] ACOG argues these restrictions only create further barriers to abortion care and medical management of early pregnancy loss, particularly for communities that already face structural barriers to care.[16]

Abortion opponents are particularly focused on reinstating an "in-person dispensing" requirement for mifepristone. This would force every patient in the country to travel, in some cases hundreds of miles, to pick up the medication in-person at a health center. This mandate would apply even when the patient has been thoroughly evaluated and counseled by a licensed provider via telemedicine and there is no clinical reason to necessitate a health center visit, and even when it would be extremely burdensome or impossible to arrange the transportation, childcare, and time off work necessary for that in-person trip. Yet, as the FDA itself found, "there does not appear to be a difference in adverse events between periods when the in-person dispensing requirement was being enforced and periods when the in-person dispensing

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[12] https://www.regulations.gov/document/FDA-2025-P-0377-0001.

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

[14] https://pmc.ncbi.nlm.nih.gov/articles/PMC9018589/; https://www.regulations.gov/document/FDA-2025-P-0377-0001.

[15] https://www.acog.org/news/news-releases/2024/06/leading-medical-organizations-call-for-fda-to-permanently-remove-restrictions-on-mifepristone.

[16] https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2023/01/updated-mifepristone-rems-requirements#:~:text=Despite%20the%20demonstrated%20safety%20of,professional%203%206%207%208%20.

requirement was not being enforced. This suggests that mifepristone may be safely used without an in-person dispensing requirement."[17]

On October 30, 2025, a federal court ruled in *Purcell v. Kennedy* that the FDA's explanation for its current restrictions on mifepristone is unreasoned, unsupported, and illogical; that the FDA did not engage with the objections of preeminent medical associations like ACOG and AMA that the mifepristone REMS is medically unnecessary and harmful; and that the FDA ignored peer-reviewed research showing both that mifepristone remains extremely safe when regulated like other prescription drugs and that the FDA's restrictions significantly reduce patient access. The court also found that the FDA failed to meaningfully address the guardrails that Congress imposed on the agency's authority to impose a REMS. That court order reinforces that, in conducting this new review, FDA may not cherry-pick junk science serving an anti-abortion agenda, but must instead look at the full body of evidence both confirming mifepristone's safety and underscoring the harms of the FDA's onerous restrictions.

The bottom line is that access to mifepristone allows patients to receive time-sensitive, essential health care, including abortion care and miscarriage management. Medication abortion is a critical option for patients who want to end their pregnancy in a place of their choosing, with access to the medical support and information they need. This option is particularly essential for patients who live in remote or rural areas and those who already face barriers to care due to inequities in our country's health care system. If HHS insists on rejecting the science that clearly proves mifepristone is safe and effective, and instead decides to impose additional restrictions on its use, this will force countless women to carry pregnancies to term against their will—regardless of the consequences for their health or lives.

As you review the evidence regarding the safety and efficacy of mifepristone, we request responses to the following questions by November 28, 2025:

1. Following the March 6, 2025 HELP Committee hearing to consider Dr. Makary's nomination to be FDA Commissioner, he was asked, in a question for the record, if he planned to make any changes to how mifepristone can be prescribed, dispensed, or accessed. He responded: "I have no immediate plans to make changes to regulation of any specific products and would not do so without a fulsome review of safety and efficacy data." What qualifies as a "fulsome review of safety and efficacy data?"
2. What prompted the Department to initiate the recent review of mifepristone?
    a. What studies or data are HHS or FDA relying on to justify restrictions on mifepristone, including but not limited to, initiating a new review of mifepristone?

[17] https://www.accessdata.fda.gov/drugsatfda_docs/summary_review/2023/020687Orig1s025SumR.pdf.

b. Have any mifepristone manufacturers communicated to HHS or FDA any changes in the safety and efficacy data for their products?

3. What process will you use to conduct this review?
    a. Will you solicit unbiased expert review and public comment through advisory committees, expert review panels, public workshops, a request for information, the federal rulemaking process, or other avenues? If utilizing an expert review panel, how will you establish that members have relevant expertise, including recent experience prescribing mifepristone? If utilizing an advisory committee, does HHS commit to following all statutory requirements of the Federal Advisory Committee Act (FACA; 5 U.S.C. Chapter 10)?
    b. Please list all procedural steps you intend to take in the review of mifepristone to ensure public participation and review of all relevant data.
    c. How will you ensure that this review is based on the best available science? For example, will the agency consider only studies that have undergone peer review?
4. How will you ensure that the review is consistent with the court order in *Purcell v. Kennedy* and FDA's limited authority under 21 U.S.C § 355-1(a), (f), and (g)?
5. The FDA Adverse Event Reporting System (FAERS) documents any reported adverse events to specific prescription drugs approved by the FDA. Does the agency have additional unreported data on adverse events that it is considering in initiating its new review of mifepristone? If yes, will the agency release the unreported data to the public and to the signatories of this letter?
6. A recent letter led by Senator Cassidy documented several statements from Secretary Kennedy on mifepristone in a September 4, 2025 Finance Committee hearing. Secretary Kennedy claimed the Biden administration "twisted the data" to bury one of the safety signals for mifepristone and that the signal showed an approximately 11% adverse event risk.[18] Please respond to this letter with the same information you provide in response to Senator Cassidy's letter.
7. Senator Cassidy asked a question regarding a statement by Secretary Kennedy in the same Finance Committee hearing, indicating studies relating to the safety of mifepristone are "progressing and that they're ongoing." Please respond to this letter with the same answer you provide to Senator Cassidy regarding the details of these studies, including the scope, expected timeframe, agencies involved, and type of study.
8. At the close of the same Finance Committee hearing, Ranking Member Wyden inquired about Secretary Kennedy's planned mifepristone review which is "not based on new clinical trials or data from the scientific community," but based on one non-peer-reviewed paper from an anti-abortion political organization. Secretary Kennedy responded by committing to "good science and good scientists" as part of this needless safety review. Please explain how the Secretary intends to meet this commitment and if

[18] https://www.finance.senate.gov/hearings/the-presidents-2026-health-care-agenda.

the preeminent medical professional associations (i.e. ACOG, AMA) will be consulted as part of the review.

The American people need to be able to trust that any reviews, regulations, and approvals of medication by HHS and FDA are based on science and evidence—not on partisan attempts to attack abortion access. We are seriously alarmed by this administration's obvious attempts to interfere with the science and politicize the drug review process in order to restrict abortion access. It is critical that scientific experts and evidence are central to any FDA review or REMS initiative. Mifepristone has long been shown to be safe and effective, and there is no new evidence to justify burdensome restrictions that block women from getting the health care they need.

Thank you for your prompt attention to this matter and we look forward to your response.

Sincerely,

Patty Murray
United States Senator

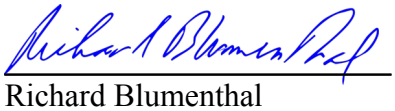
Charles E. Schumer
United States Senator

Jacky Rosen
United States Senator

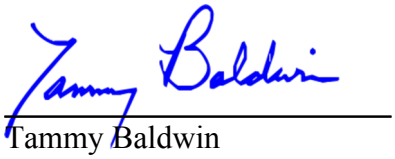
Mazie K. Hirono
United States Senator

Ron Wyden
United States Senator

Adam B. Schiff
United States Senator



Richard Blumenthal
United States Senator

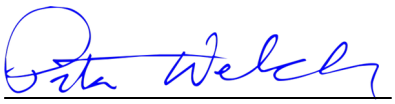


Tammy Baldwin
United States Senator

Christopher A. Coons
United States Senator

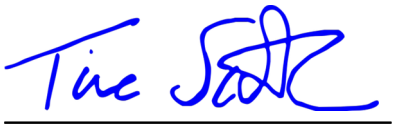
Catherine Cortez Masto
United States Senator

Kirsten Gillibrand
United States Senator



Peter Welch
United States Senator

Ruben Gallego
United States Senator



Tina Smith
United States Senator

Gary C. Peters
United States Senator

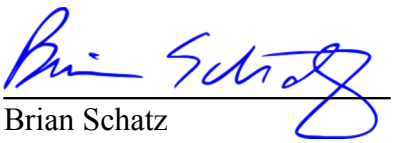
Maria Cantwell
United States Senator

Jeanne Shaheen
United States Senator

Mark R. Warner
United States Senator

Tammy Duckworth
United States Senator

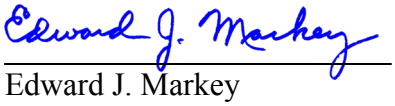
Elissa Slotkin
United States Senator



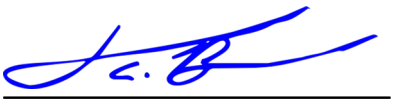
Brian Schatz
United States Senator

Angela D. Alsobrooks
United States Senator

Jack Reed
United States Senator

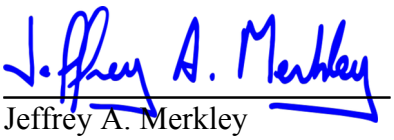


Edward J. Markey
United States Senator



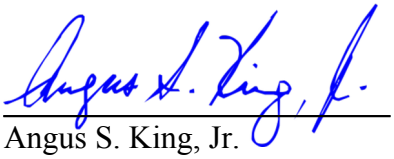
Cory A. Booker
United States Senator

Chris Van Hollen
United States Senator

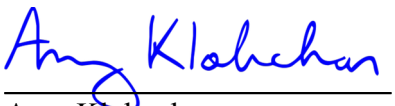


Jeffrey A. Merkley
United States Senator

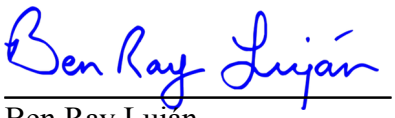
Alex Padilla
United States Senator



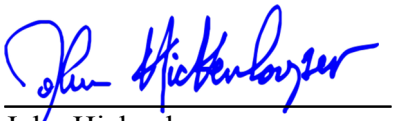
Angus S. King, Jr.
United States Senator



Amy Klobuchar
United States Senator

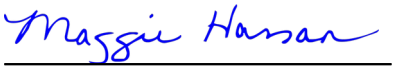


Ben Ray Luján
United States Senator



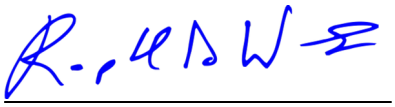
John Hickenlooper
United States Senator

Richard J. Durbin
United States Senator



Margaret Wood Hassan
United States Senator

Bernard Sanders
United States Senator

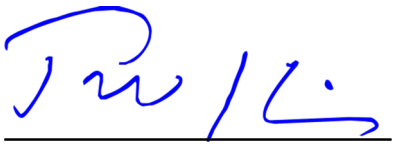


Raphael Warnock
United States Senator

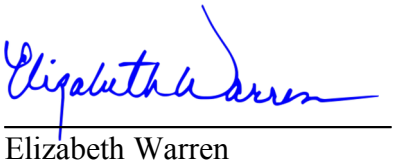
Lisa Blunt Rochester
United States Senator

Sheldon Whitehouse
United States Senator

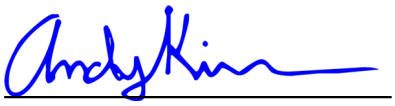
Martin Heinrich
United States Senator



Tim Kaine
United States Senator



Elizabeth Warren
United States Senator



Andy Kim
United States Senator

Michael F. Bennet
United States Senator

Mark Kelly
United States Senator

Christopher S. Murphy
United States Senator

John Fetterman
United States Senator

Jon Ossoff
United States Senator