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July 31, 2025

The Honorable Robert F. Kennedy, Jr.
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, N.W.
Washington, D.C. 20201

The Honorable Dr. Martin A. Makary, M.D., M.P.H.
Commissioner of Food and Drugs
United States Food and Drug Administration
FDA White Oak Campus
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Review of Mifepristone

Dear Secretary Kennedy and Commissioner Makary:

Recent comprehensive studies of the real-world effects of the chemical abortion drug mifepristone report that serious adverse events occur 22 times more often than stated on the drug's label, while the drug is less than half as effective as claimed. These facts directly contradict the drug's primary marketing message of "safe" and "effective."

Both of you are to be commended for taking this new information seriously and committing to conduct a full-scale review of mifepristone and its labeling based on objective data.[1] Based on that review, the FDA should consider reinstating safety protocols that it identified as necessary as recently as 2011 in its issuance of a Risk Evaluation and Mitigation Strategy (REMS) for

[1] https://www.nationalreview.com/news/robert-f-kennedy-jr-says-fda-should-change-label-on-abortion-pill-promises-full-review-of-health-effects/.

mifepristone,[2] but which were removed by the Obama and Biden administrations.[3] Alternatively, in light of the serious risks to women who are presently being prescribed this drug without crucial safeguards, and in the event the FDA is unable to reinstate the 2011 safety protocols for mifepristone, the FDA should consider withdrawing mifepristone from the market until it completes its review and can decide on a course of action based on objective safety and efficacy criteria.[4]

The EPPC's studies (collectively, the "EPPC Study"), published in April and May of this year, report that mifepristone abortions result in serious adverse events for more than 1 in 10 women—22 times the rate that currently appears on the drug's label[5]—and have a failure rate that is double the rate on the label.[6] Mifepristone's label states that less than 0.5 percent of patients in clinical trials experienced a serious adverse event,[7] but the real-world rate is actually 10.93 percent, based on the EPPC's review of 2017–2023 data from an all-payer insurance claims database which included over 865,000 mifepristone abortions—the largest-known study of the abortion pill.[8] The EPPC Study analyzed diagnosis and procedure codes and used the official FDA definition of a serious adverse event to identify serious adverse events experienced by women prescribed mifepristone,[9] which included sepsis, infection, hemorrhaging, surgical procedures after failed abortions, and complications from confirmed ectopic pregnancies.[10]

The EPPC Study appears more comprehensive than the clinical trials relied on by the FDA in 2016 when it approved label changes that removed most of the critical safeguards that had previously been included. First, the EPPC's inclusion of 865,727 mifepristone abortions in its analysis was more than 28 times as many as were included in the combined total of the clinical trials relied on by the FDA.[11] Second, the EPPC's 2017–2023 dataset is more recent, whereas the FDA-cited clinical trials occurred at least a decade ago.[12] Third, the patients in the EPPC dataset represent real-world American women who obtain mifepristone abortions, instead of a

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[2] *See* https://www.supremecourt.gov/DocketPDF/23/23-235/298587/20240123210020119_FDA%20v.%20Alliance%20-%20Joint%20Appendix%20Volume%202%20-%20Final.pdf at J.A. 276–77, 296 ("The [2011] REMS for Mifeprex incorporated the restrictions under which the drug was originally approved.").

[3] *See* https://eppc.org/wp-content/uploads/2025/04/25-04-The-Abortion-Pill-Harms-Women.pdf at 2.

[4] *See, e.g.,* https://www.supremecourt.gov/DocketPDF/23/23-235/298587/20240123210020119_FDA%20v.%20Alliance%20-%20Joint%20Appendix%20Volume%202%20-%20Final.pdf at J.A. 227; https://www.cghjournal.org/article/S1542-3565(22)00078-7/fulltext (noting the FDA's temporary withdrawal of prescription drug tegaserod after a Swiss study demonstrated a 0.11% risk of adverse cardiovascular events in patients versus 0.01% in placebo; tegaserod was re-approved under a more restrictive label after additional safety data was generated).

[5] https://eppc.org/wp-content/uploads/2025/04/25-04-The-Abortion-Pill-Harms-Women.pdf at 1.

[6] https://eppc.org/wp-content/uploads/2025/05/25-05-SHW-Insurance-Data-Reveals-Repeated-Abortion-Attempts-Due-to-High-Failure-Rate.pdf at 1.

[7] https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s026lbl.pdf at 7 ("Serious adverse reactions were reported in <0.5% of women.").

[8] https://eppc.org/wp-content/uploads/2025/04/25-04-The-Abortion-Pill-Harms-Women.pdf at 1.

[9] https://eppc.org/wp-content/uploads/2025/05/Frequently-Asked-Questions-About-the-Largest-Study-on-Chemical-Abortion-1.pdf at 1, 3.

[10] https://eppc.org/wp-content/uploads/2025/05/Frequently-Asked-Questions-About-the-Largest-Study-on-Chemical-Abortion-1.pdf at 1, 3.

[11] https://eppc.org/wp-content/uploads/2025/04/25-04-The-Abortion-Pill-Harms-Women.pdf at 2.

[12] https://eppc.org/wp-content/uploads/2025/04/25-04-The-Abortion-Pill-Harms-Women.pdf at 2.

"prescreened group of generally healthy women recruited into various clinical trials conducted at different times around the world."[13] Finally—and importantly—the EPPC Study represents the quality of real-world, pre- and post-abortion care available to women today, not the controlled regimen of care typically provided in clinical trials.[14]

The FDA's removal of important safeguards starting in 2016 may explain in part why the real-world risk of serious adverse events from 2017–2023 is so much higher than the risk identified in clinical trials cited in mifepristone's label, which contained many of the safeguards that were later eliminated.[15] The FDA's mifepristone approval memorandum in 2000 acknowledged the drug's danger, stating "[A]ccess to . . . emergency services is critical for the safe and effective use of the drug."[16] To combat the dangers, the original FDA-approved label required the following safeguards:[17]

1. Three in-person office visits (day 1 administration of mifepristone; day 3 administration of misoprostol, the drug that completes the abortion; and day 14 visit to check for complications)
2. Maximum gestational age of 7 weeks
3. Could only be prescribed by a physician
4. Could be dispensed only in the physician's office
5. Patient had to take the drugs in the physician's office
6. An in-office follow-up (the day 14 visit)
7. Reporting by physicians of adverse events

Yet, by the time the FDA implemented the current REMS in 2023, the FDA, under Presidents Obama and Biden, had increased the gestational age to 10 weeks and eliminated every other one of these requirements.[18] Currently, a woman can obtain a mifepristone abortion by participating in only one telehealth visit with any approved healthcare provider (not necessarily a physician), ordering the drugs through a mail-order pharmacy, and self-administering them.[19] And the prescriber is only required to report an adverse event if he or she becomes aware that the patient has died.[20]

The FDA's removal of these crucial safety protocols in 2016 (and in 2023) that only five years before the FDA considered necessary begs the question of whether the removal was motivated by considerations other than the safety of patients. Now, the EPPC Study reports that in the years since the safeguards have been removed, the risk to women is far higher than was

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[13] https://eppc.org/wp-content/uploads/2025/04/25-04-The-Abortion-Pill-Harms-Women.pdf at 2.
[14] https://eppc.org/wp-content/uploads/2025/04/25-04-The-Abortion-Pill-Harms-Women.pdf at 2.
[15] https://www.supremecourt.gov/DocketPDF/23/23-235/298587/20240123210020119_FDA%20v.%20Alliance%20-%20Joint%20Appendix%20Volume%202%20-%20Final.pdf at J.A. 548–62.
[16] https://www.supremecourt.gov/DocketPDF/23/23-235/298587/20240123210020119_FDA%20v.%20Alliance%20-%20Joint%20Appendix%20Volume%202%20-%20Final.pdf at J.A. 227.
[17] https://eppc.org/wp-content/uploads/2025/04/25-04-The-Abortion-Pill-Harms-Women.pdf at 3.
[18] https://eppc.org/wp-content/uploads/2025/04/25-04-The-Abortion-Pill-Harms-Women.pdf at 3.
[19] https://eppc.org/wp-content/uploads/2025/04/25-04-The-Abortion-Pill-Harms-Women.pdf at 3.
[20] https://eppc.org/wp-content/uploads/2025/04/25-04-The-Abortion-Pill-Harms-Women.pdf at 3.

previously thought and far higher than the label indicates. The current FDA's dedication to the health and wellbeing of all Americans is encouraging, as is the much-needed review of mifepristone that Secretary Kennedy has promised.

Respectfully,

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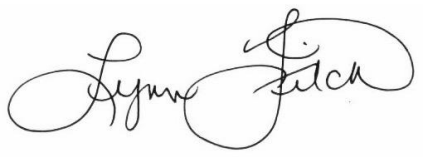

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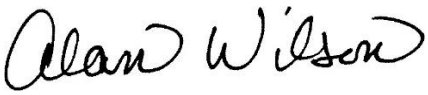

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