REPRODUCTIVE FREEDOM Alliance

October 14th, 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 Martin Makary, MD, MPH
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Secretary Kennedy and Commissioner Makary,

On September 19, 2025, your offices sent a response letter to twenty-two State Attorneys General who had requested a review of the drug mifepristone's safety.[1] Your letter informed them and the public that the U.S. Department of Health and Human Services (HHS), through the Food and Drug Administration (FDA), intends to "review . . . mifepristone" as well as specifically "study ... the safety of the current REMS [Risk Evaluation and Mitigation Strategy]."[2] If you conduct this unnecessary review, the Reproductive Freedom Alliance (RFA),[3] a nonpartisan coalition of 23 Governors committed to protecting access to reproductive health care, urges you to adhere to the careful, rigorous and extensive scientific analysis that the FDA has already undertaken to conclude that mifepristone is safe and effective.[4]

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[1] Letter from Kris Kobach, Attorney General of Kansas, and 21 other Attorneys General to Department of Health and Human Services Secretary Robert F. Kennedy and FDA Commissioner Martin Makary, July 31, 2025, *available at* https://www.catholicnewsagency.com/pdfs/mifepristoneletter081325.pdf, The Attorneys General of the following states also signed this letter: Alabama, Alaska, Arkansas, Florida, Georgia, Idaho, Indiana, Iowa, Kentucky, Mississippi, Missouri, Montana, Nebraska, North Dakota, Oklahoma, Ohio, South Carolina, South Dakota, Texas, Utah, Wyoming.

[2] Letter from Department of Health and Human Services Secretary Robert F. Kennedy to Attorneys General, September 19, 2025, *available at* https://democracyforward.org/wp-content/uploads/2025/09/Fda_Hhs_Letter-1.pdf.

[3] The following Governors are members of the Reproductive Freedom Alliance: Arizona Governor Katie Hobbs, California Governor Gavin Newsom, Colorado Governor Jared Polis, Connecticut Governor Ned Lamont, Delaware Governor Matt Meyer, Guam Governor Lou Leon Guerrero, Hawai'i Governor Josh Green, Illinois Governor JB Pritzker, Kentucky Governor Andy Beshear, Maine Governor Janet Mills, Maryland Governor Wes Moore, Massachusetts Governor Maura Healey, Michigan Governor Gretchen Whitmer, Minnesota Governor Tim Walz, New Jersey Governor Phil Murphy, New Mexico Governor Michelle Lujan Grisham, New York Governor Kathy Hochul, North Carolina Governor Josh Stein, Oregon Governor Tina Kotek, Pennsylvania Governor Josh Shapiro, Rhode Island Governor Daniel McKee, Washington Governor Bob Ferguson, and Wisconsin Governor Tony Evers.

[4] Advancing New Standards in Reprod. Health, Analysis of Medication Abortion Risk and the FDA report "Mifepristone US Post-Marketing Adverse Events Summary through 6/30/2021" 3 (Nov. 2022).

Experts at FDA have reviewed mifepristone safety data regularly over more than twenty-five years, through five Presidential Administrations, and consistently found that complications and serious adverse events arising from mifepristone use are rare.[5] Indeed, there are pending requests asking the FDA to review and remove existing restrictions based on extensive safety and efficacy findings over decades.[6]

Over time, as a result of extensive, peer-reviewed research, the FDA has modified mifepristone's labeling and removed certain REMS requirements that its experts have concluded were no longer necessary and were unnecessarily limiting access.[7] Your letter states that "HHS and FDA remain committed to protecting the health and safety of pregnant women" and that FDA decisions will continue to be "grounded in . . . rigorous, transparent and objective evidence."[8] All existing peer-reviewed research has concluded that mifepristone is safe and effective, including when provided through telehealth, and that the medication is associated with low rates of serious adverse events.[9]

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[5] U.S. Food and Drug Administration/Center for Drug Evaluation and Research ("FDA/CDER"). (2016, Mar. 29) Application No. 020687Orig1s020 Medical Review(s), at p. 12. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf (concluding medication abortion's "efficacy and safety have become well-established by both research and experience, and serious complications have proven to be extremely rare"); *id.* at p. 47 (serious adverse events "exceedingly rare"): U.S. Food and Drug Administration ("FDA"). (2024). Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2024, at p. 1. https://www.fda.gov/media/185245/download (discussing rarity of serious adverse events, that there is no established causal relationship between those events and medication abortion and that, rather, the "critical risk factor" is pregnancy itself); *see also* Kulier et al., 2011, *supra* note 4 (systematic review finding "serious adverse events are rare"); GenBioPro Petition, *supra* note 4, at pp. 12-14 (summarizing evidence on serious adverse events).

[6] *See, e.g.*, Citizen's Petition to the FDA, State of Massachusetts et al., June 5, 2025, *available at* https://www.mass.gov/doc/rems-mifepristone-citizen-petition/download.

[7] *See* U.S. Food and Drug Administration, Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation (as the website appeared on October 5, 2025); *see also* U.S. Food and Drug Administration/Center for Drug Evaluation and Research ("FDA/CDER") (2016, Mar. 29) Application No. 020687Orig1s020 Medical Review(s), at p. 12. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf (concluding medication abortion's "efficacy and safety have become well-established by both research and experience, and serious complications have proven to be extremely rare"); id. at p. 47 (serious adverse events "exceedingly rare"); Letter from Janet Woodcock, Acting Commissioner of Food & Drugs, to Maureen Phipps, Chief Executive Official, American College of Obstetricians & Gynecologists, and William Grobman, President, Society for Maternal Fetal Medicine, (Apr. 12, 2021), *available at* https://www.aclu.org/sites/default/files/field_document/fda_acting_commissioner_letter_to_acog_april_12_2021.pdf; U.S. Food and Drug Administration ("FDA"). (2024). Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2024, at p. 1. https://www.fda.gov/media/185245/download (discussing rarity of serious adverse events, that there is no established causal relationship between those events and medication abortion and that, rather, the "critical risk factor" is pregnancy itself).

[8] Letter from Department of Health and Human Services Secretary Robert F. Kennedy to 22 Attorneys General, September 19, 2025, *available at* https://democracyforward.org/wp-content/uploads/2025/09/Fda_Hhs_Letter-1.pdf, in response to the letter *supra* note 1.

[9] *See supra* notes 3 *and* 4.

Since 1906, when the agency was created, the FDA's role in reviewing medications for sale in the United States has been of paramount importance to our nation's health.[10] The FDA's mission statement notes that:

> FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, [and] our nation's food supply [and] cosmetics. FDA is also responsible for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health.[11]

We understand that several Attorneys General have requested that your agencies review the safety of mifepristone once again, relying on a single, self-published, non-peer reviewed paper released in April 2025 by the Ethics and Public Policy Center (EPPC).[12] Further, on October 9, 2025, a number of Senators wrote to your agencies to urge you to take action to restrict access to mifepristone based entirely on that same, non-scientific report.[13] However, this paper should not inform your agencies' scientific analysis of the safety of mifepristone, as it does not meet the core standards of the FDA. The American College of Obstetricians and Gynecologists (ACOG) publicly stated that these "findings are based on faulty methodology and do not supplant years of studies indicating the medication is safe when used as prescribed".[14] The request appears to be driven by the goal of making it more difficult for people to access care, rather than being

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[10] *See, e.g.* Margaret A. Hamburg, M.D., *Remarks at the Annual Conference of the Food and Drug Law Institute*, 68 Food & Drug L.J. 217, 222 (2013).

[11] FDA, Report of the Science Looking Forward Subcommittee, Mission Possible: How FDA Can Move at the Speed of Science, Sept. 2015, *available at* https://www.fda.gov/files/about%20fda/published/Report--Mission-Possible--How-FDA-Can-Move-at-the-Speed-of-Science.pdf.

[12] *See supra* note 1.

[13] Letter from Senators to FDA Commissioner and HHS Secretary, October 9, 2025, *available at* https://justthenews.com/sites/default/files/2025-10/2025.10.09%20-%20Letter%20from%20Senator%20Graham%20et%20al%20to%20HHS%20and%20FDA%20re%20Mifepristone.pdf. The following Senators signed this letter: Sen. Lindsey Graham (R-S.C.), Sen. John Barrasso (R-WY), Sen. Shelley Moore Capito (R–W.V.), Sen. Tim Scott (R-S.C.), Sen. James E. Risch (R-ID), Sen. Jim Justice (R–W.V.), Sen. Ted Budd (R-N.C.), Sen. Cindy Hyde-Smith (R- MS), Sen. Tim Sheehy (R-MT), Sen. Kevin Cramer (R-N.D.), Sen. Todd Young (R-IN), Sen. Tom Cotton (R-AR), Sen. James Lankford (R-OK), Sen. Jim Banks (R-IN), Sen. John Cornyn (R-TX), Sen. Pete Ricketts (R-NE), Sen. Steve Daines (R-MT), Sen. Roger Mashall (R-KS), Sen. Rick Scott (R-FL), Sen. Bernie Moreno (R-OH), Sen. Bill Hagerty (R-TN) , Sen. Deb Fischer (R-NE), Sen. Mike Lee (R-UT), Sen. Roger F. Wicker (R-MS), Sen. Josh Hawley (R-MO). Sen. Joni Ernst (R-IA), Sen. Jon Husted (R-OH), Sen. Charles Grassley (R-IA), Sen. Rand Paul (R-KY), Sen. Katie Boyd Britt (R-AL), Sen. Jerry Moran (R-KS), Sen. Ron Johnson (R-WI), Sen. Marsha Blackburn (R-TN), Sen. Ted Cruz (R-TX), Sen. Markwayne Mullin (R-OK), Sen. Mike Rounds (R-S.D.), Sen. John Boozman (R-AR), Sen. Ashley Moody (R-FL), Sen. John Hoeven (R-N.D.), Sen. Tommy Tuberville (R-AL), Sen. John Kennedy (R-LA), Sen. Cynthia Lummis (R-WY), Sen. Bill Cassidy (R-LA), Sen. Mike Crapo (R-ID), Sen. Eric Schmitt (R-MO), Sen. Dan Sullivan (R-AK), Sen. David McCormick (R-PA), Sen. Thom Tillis (R-NC), Sen. John Curtis (R-UT), and Sen. Mitch McConnell (R-KY).

[14] Marisha Goldhamer, 'Flawed' paper overstates health risks of abortion pills, Agence France-Presse (AFP), May 5, 2025, https://factcheck.afp.com/doc.afp.com.444Z863 (last visited Oct. 14, 2025).

informed by the science. In responding to this request, the Reproductive Freedom Alliance urges the FDA and HHS to continue to rely on scientific and clinical data that has been documented in peer-reviewed research over many decades and is relied on by public health institutions and health care providers around the world.[15]

The World Health Organization recognizes the medications used for medication abortion as "'core' essential medications for basic healthcare systems, a category comprised of 'the most efficacious, safe, and cost-effective medicines.'"[16] Decades of research have demonstrated the safety and efficacy of mifepristone, both in the US and around the world. The Reproductive Freedom Alliance calls on you to uphold the core mission of the FDA to improve health using accurate, science-based information, including by ensuring ongoing access to safe, effective, essential medications like mifepristone.

Sincerely,

Christina Chang

Executive Director

Reproductive Freedom Alliance

[15] *See supra* notes 3 – 4, 6-7.
[16] WHO Expert Comm. on Selection and Use of Essential Medicines, World Health Org., *The Selection and Use of Essential Medicines* 17, 635 (2019).