

**Statement of the Center for Reproductive Rights**  
**1600 K Street NW, Washington, DC, 20006**  
**for**  
**Senate Committee on Health, Education, Labor, and Pensions (HELP)**  
**Hearing Titled “Protecting Women: Exposing the Dangers of Chemical Abortion Drugs”**  
**January 14, 2026**

**Protecting Women’s Access to Medication Abortion**

Chair Cassidy, Ranking Member Sanders, and Members of the Committee:

Thank you for the opportunity to submit testimony on the robust safety record of mifepristone. The Center for Reproductive Rights (“the Center”) is a global legal advocacy organization that uses the power of the law to advance reproductive rights as fundamental human rights. Since our founding in 1992, the Center’s game-changing litigation, legal policy, and advocacy work—combined with unparalleled expertise in constitutional, international, and comparative human rights law—has transformed how reproductive rights are understood by courts, governments, and human rights bodies around the world.

The United States has one of the highest maternal mortality rates among wealthy democracies.<sup>1</sup> Women in states with severe abortion restrictions are twice as likely to die during pregnancy, childbirth, or shortly after giving birth.<sup>2</sup> For example, in Louisiana, a state with a total abortion ban, mothers are three times as likely as mothers in states without severe abortion restrictions to die during this time period in their lives.<sup>3</sup> Research shows that restrictive abortion laws, including laws that restrict access to medication abortion, force women to carry unwanted or dangerous pregnancies to term, which can profoundly impact their lifelong physical, mental, and economic wellbeing.<sup>4</sup> For high-risk pregnancies, restricting access to necessary abortion care results in higher rates of overall pregnancy-related mortality and morbidities.<sup>5</sup> For these people and others, medication abortion is life-saving, essential medication.<sup>6</sup>

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<sup>1</sup> See generally, Eugene Declercq and Laurie C. Zephyrin, *Maternal Mortality in the United States, 2025*, THE COMMONWEALTH FUND, Jul. 29, 2025, available at <https://www.commonwealthfund.org/publications/issue-briefs/2025/jul/maternal-mortality-united-states-2025>; Donna L. Hoyert, *Maternal Mortality Rates in the United States, 2021*, Ctr. for Disease Control and Prevention Nat’l Ctr. for Health Stat., Mar. 2023, available at <https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2021/maternal-mortality-rates-2021.pdf>; Donna L. Hoyert, *Maternal Mortality Rates in the United States, 2019*, Ctr. for Disease Control and Prevention Nat’l Ctr. for Health Stat, Apr. 2021, available at <https://www.cdc.gov/nchs/data/hestat/maternalmortality-2021/E-Stat-Maternal-Mortality-Rates-H.pdf>.

<sup>2</sup> See *Maternal Mortality in the United States After Abortion Bans*, GENDER EQUITY POL’Y INST., Apr. 2025, available at <https://thegepi.org/maternal-mortality-abortion-bans/>.

<sup>3</sup> See *id.*

<sup>4</sup> See *id.*, see also Eugene Declercq, et al., *The U.S. Maternal Health Divide: The Limited Maternal Health Services and Worse Outcomes of States Proposing New Abortion Restrictions*, THE COMMONWEALTH FUND, Dec. 14, 2022, available at <https://www.commonwealthfund.org/publications/issue-briefs/2022/dec/us-maternal-health-divide-limited-services-worse-outcomes>.

<sup>5</sup> See *id.*

<sup>6</sup> See e.g., *About the Plaintiffs: Texas Women Denied Abortion Care*, CTR. FOR REPROD. RTS., Nov. 14, 2023, available at <https://reproductiverights.org/news/zurawski-v-texas-plaintiffs-stories-remarks/> (sharing Kaitlyn Kash’s story of her inability to access medication abortion in Texas).

## I. Medication abortion is safe and effective.

Medication abortion is a safe and effective method for ending a pregnancy. In many countries, including in the United States, it is the most popular method of abortion.<sup>7</sup> Access to medication abortion gives patients greater privacy and flexibility to make their own health care decisions. Additionally, the availability of medication abortion expands access to this essential health care for patients with lower incomes, health inequities, and disabilities, and those without access to health care providers, including in rural communities. Studies show that the provision of medication abortion through the mail is statistically as safe as in-clinic provision, and the provision of telehealth medication abortion is responsible for preserving abortion access across the United States in the wake of the *Dobbs* decision and subsequent state actions to restrict abortion care.<sup>8</sup>

A two-drug regimen is most commonly used for medication abortion in the United States: mifepristone, which blocks the action of the hormone (progesterone) that supports the pregnancy; and misoprostol, which causes the cervix to dilate and the uterus to contract. The mifepristone and misoprostol regimen is effective at ending pregnancy more than 95% of the time, with even higher efficacy rates at earlier gestational ages.

Mifepristone is one of the most studied and scrutinized medications. In the 25 years since mifepristone's approval by the Food and Drug Administration ("FDA"), its safety and efficacy have been confirmed numerous times through the agency's repeated, rigorous review of the underlying scientific data and literature; the real-world clinical experience of millions of women who have safely used the mifepristone regimen; and FDA's own safety monitoring systems. According to FDA, in the last 25 years, more than 7.5 million women in the United States have used mifepristone safely.<sup>9</sup>

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<sup>7</sup> See *New Poll Shows Strong Support in the U.S. for Medication Abortion*, CTR. FOR REPROD. RTS., Apr. 4, 2024, available at <https://reproductiverights.org/news/axios-ipsos-poll-medication-abortion/> (highlighting Axios/Ipsos polling data which found that 72% of Americans say they support women obtaining medication abortion from their doctor or a clinic, and 45% say they strongly support it.); Rachel K. Jones and Amy Friedrich-Karnik, *Medication Abortion Accounted for 63% of All US Abortions in 2023—An Increase from 53% in 2020*, GUTTMACHER INST., Mar. 19, 2024, available at <https://www.guttmacher.org/2024/03/medication-abortion-accounted-63-all-us-abortions-2023-increase-53-2020> (finding that in 2023, medication abortions accounted for 63% of all abortions in the formal health care system in the United States).

<sup>8</sup> See Victoria Colliver, *Telehealth is as Safe as a Visit to the Clinic for Abortion Pills*, UNIV. OF CALIF. SAN FRANCISCO, Feb. 15, 2024, available at <https://www.ucsf.edu/news/2024/02/427111/telehealth-safe-visit-clinic-abortion-pills>; #WeCount report, *April 2022 to June 2025*, SOC'Y OF FAM. PLANNING, Dec. 9, 2025, available at <https://societyfp.org/research/wecount/wecount-june-2025-data/>. In the first half of 2025, 27% of all abortions within the United States health care system were provided via telehealth and this number has continued to increase.

<sup>9</sup> See U.S. Food & Drug Admin., TTT #2022-2468, NDA 020687, ANDA 091178, Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2024, available at <https://www.fda.gov/media/185245/download>.

## II. FDA has repeatedly found that mifepristone is safe and effective based on robust scientific data, clinical studies, and post-marketing safety surveillance.

FDA’s original approval of mifepristone in 2000 and each subsequent update to its labeling and safety requirements have been based on high-quality research, analyzing tens of thousands of patient experiences that conclusively demonstrate the safety and effectiveness of mifepristone.

Mifepristone was first approved by FDA under the brand name Mifeprex in 2000.<sup>10</sup> This approval was based on FDA’s nearly five-year scientific review of extensive scientific studies and data substantiating mifepristone’s safety and effectiveness, including multiple clinical studies involving thousands of patients.<sup>11</sup> At the time, mifepristone had already been approved in multiple countries across the world, and FDA’s review included extensive evidence from those countries.<sup>12</sup> Based on this review, FDA concluded that there is substantial evidence of Mifeprex’s safety and efficacy and allowed the drug to be marketed in the United States with some distribution restrictions.<sup>13</sup>

In 2011, after Congress enacted the Risk Evaluation and Mitigation Strategy (“REMS”) framework, FDA reviewed mifepristone to evaluate whether the distribution restrictions initially imposed in 2000 were still valid and sufficient to comply with the REMS framework; FDA concluded that they were.<sup>14</sup>

In 2016, FDA approved modifications to the mifepristone REMS to increase gestational limits on its use from 49 days to 70 days gestation, reduce the dosage, permit at-home use of misoprostol, and expand the type of health care provider authorized to prescribe the drug.<sup>15</sup> This decision was based on extensive data from dozens of clinical studies about mifepristone and a multidisciplinary review.<sup>16</sup> FDA found that the safety of mifepristone was “well-characterized over 15 years of experience, with known risks occurring rarely; the safety profile has not

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<sup>10</sup> See U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., NDA Approval Letter, NDA 020687, Sept. 28, 2000, available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/appltr/2000/20687appltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appltr/2000/20687appltr.pdf) (hereinafter “NDA Approval Letter”); U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., Medical Review Part 1, Sept. 28, 2000, available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2000/20687\\_Mifepristone\\_medr\\_P1.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20687_Mifepristone_medr_P1.pdf); U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., Medical Review Part 2, Sept. 28, 2000, available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2000/20687\\_Mifepristone\\_medr\\_P2.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20687_Mifepristone_medr_P2.pdf).

<sup>11</sup> See *id.*

<sup>12</sup> U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., Medical Officer’s Review of NDA 20-687, at 2, Nov. 1999, available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2000/20687\\_Mifepristone\\_medr\\_P1.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20687_Mifepristone_medr_P1.pdf); see also Laura Schummers, et al., *Abortion Safety and Use with Normally Prescribed Mifepristone in Canada*, 386 NEW ENG. J. MED. 57, Dec. 8, 2021, available at <https://www.nejm.org/doi/full/10.1056/NEJMsa2109779>.

<sup>13</sup> See NDA Approval Letter, *supra* n 10.

<sup>14</sup> See U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., Supplement Approval Letter, NDA 020687/S-014, Jun. 8, 2011, available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/appltr/2011/020687s014ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appltr/2011/020687s014ltr.pdf).

<sup>15</sup> See U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., NDA 020687 MIFEPREX® (mifepristone) Tablets, 200 mg, Risk Evaluation and Mitigation Strategy (REMS), Mar. 2016, available at <https://www.fda.gov/media/164649/download?attachment>.

<sup>16</sup> See generally, U.S. Gov’t Accountability Off., GAO-18-292, Food and Drug Administration: Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts, Mar. 2018, available at <https://www.gao.gov/assets/gao-18-292.pdf> (hereinafter “2018 GAO Report”).

changed over the period of surveillance.”<sup>17</sup> FDA also found that mifepristone “has been increasingly used as its efficacy and safety have become well-established by both research and experience, and serious complications have proven to be extremely rare.”<sup>18</sup> Lastly, FDA found that the rates of serious adverse events associated with the mifepristone-misoprostol regimen were “exceedingly low.”<sup>19</sup>

In 2019, FDA approved a generic version of mifepristone.<sup>20</sup> This approval again noted that FDA found that scientific evidence and ongoing medical studies since the original approval in 2000 consistently showed the safety and efficacy of mifepristone.<sup>21</sup>

During the COVID-19 public health emergency, it became a necessity to use telehealth more generally to ensure that people could continue to safely access health care and medication. In July 2020, a court ordered FDA to suspend the in-person dispensing requirement for mifepristone due to the constraints on accessing in-person health care.<sup>22</sup> In April 2021, FDA itself suspended the in-person dispensing requirement during the COVID-19 public health emergency because, during the six-month period in which the in-person dispensing requirement had been enjoined, the availability of telehealth medication abortion showed no increases in serious patient safety concerns.<sup>23</sup> In coming to this decision, FDA cited four separate studies, including one which was launched in 2016, which all found that the use of telemedicine to provide medication abortion in the United States did not appear to show increases in serious safety concerns.<sup>24</sup>

In 2023, FDA decided to formalize the removal of the in-person dispensing requirements through the REMS process. Additional REMS changes included expanding the definition of certified providers and other important changes that broadly expanded national access. FDA reached this decision following a robust and thorough scientific review by agency experts who evaluated relevant information, including clinical outcomes data, extensive literature review, and adverse event reports.<sup>25</sup> Subsequently, a large prospective cohort study confirmed that telehealth

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<sup>17</sup> See U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., Medical Review at 88, Mar. 29, 2016, available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2016/020687Orig1s020MedR.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf); see also U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., Full Prescribing Information for Mifeprex 7–8, tbls.1 & 2, Mar. 29, 2016, available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2016/020687s020lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf).

<sup>18</sup> *Id.* at 12.

<sup>19</sup> *Id.* at 62.

<sup>20</sup> See U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., ANDA Approval Letter, ANDA 091178, Apr. 11, 2019, available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/applletter/2019/091178Orig1s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/091178Orig1s000ltr.pdf).

<sup>21</sup> See *id.*

<sup>22</sup> *Am. Coll. of Obstetricians & Gynecologists v. FDA*, 472 F. Supp. 3d 183, 233 (D. Md. 2020), stayed by *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578, 578 (2021) (mem.).

<sup>23</sup> Letter from Janet Woodcock, Acting Comm’r, U.S. Food & Drug Admin., to Maureen G. Phipps, Chief Exec. Officer, Am. Coll. Of Obstetricians & Gynecologists, and William Grobman, President, Soc’y for Maternal-Fetal Med. Apr. 12, 2021, available at <https://x.com/ACOGAction/status/1381781110980501512>.

<sup>24</sup> See *id.*; *Gynuity’s Research is Primary Source Cited in the U.S. Food and Drug Administration’s Decision to Suspend In-Person Mifepristone Dispensing Requirement*, GYNUITY, Apr. 13, 2021, available at <https://gynuity.org/news/gynuitys-research-is-primary-source-cited-in-the-food-and-drug-administrations-decision-to-suspend-in-person-mifepristone-dispensing-requirements>.

<sup>25</sup> U.S. Food & Drug Admin., Response Letter from FDA CDER to American Association of Pro-Life Obstetricians and Gynecologists and American College of Pediatricians, Dec. 17, 2021, available at <https://www.regulations.gov/document/FDA-2019-P-1534-0016>; U.S. Food & Drug Admin., Ctr. for Drug

prescription of mifepristone was still safe and effective, with similar results to previous large U.S. studies of in-person access to mifepristone.<sup>26</sup>

Ongoing research shows that mifepristone continues to be safe and effective with rare adverse events. *Hundreds* of high-quality studies conducted since mifepristone’s 2000 approval show the same. Mifepristone has been used in over 600 published clinical trials and discussed in nearly 800 medical reviews.<sup>27</sup> In fact, these studies collectively prove that FDA’s current REMS restrictions on mifepristone are likely overly burdensome and neither scientifically necessary nor warranted for patient safety. As such, both the Center and the American Civil Liberties Union have brought litigation seeking judicial clarity as to whether the remaining REMS exceed the FDA’s authority.<sup>28</sup> In October 2025, a federal district court found that FDA acted improperly when it assumed, without citing evidence, that mifepristone’s established safety record depended on FDA’s burdensome REMS restrictions on access to the drug.<sup>29</sup> It is imperative that the FDA continues to follow a scientific process to review clinical outcomes and adverse event data to make mifepristone more accessible to the patients that need this essential health care.

### **III. FDA’s decision making should be transparent and free from political interference to ensure that patients are able to access and trust life-saving medication.**

The integrity of FDA’s regulatory process is paramount to ensure that the public is able to trust FDA’s decisions as a credible scientific regulatory agency and that patients are able to access life-saving medication, such as mifepristone.

As noted above, FDA’s reviews of mifepristone’s safety have been anchored in decades of scientific data, clinical studies, and post-marketing safety surveillance. In 2008, and again in 2018, at the request of several members of Congress, the U.S. Government Accountability Office (“GAO”) independently reviewed FDA’s approval of mifepristone and the agency’s oversight and safety monitoring of the drug since its approval.<sup>30</sup> Repeatedly, GAO found that the approval of mifepristone and the subsequent changes in the REMS, as well as the agency’s post-market oversight of mifepristone, were all consistent with the agency’s own scientific processes, peer-reviewed scientific literature, clinical data, and safety monitoring information.<sup>31</sup>

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Evaluation & Rsch., NDA and ANDA Summary Review, Dec. 16, 2021, available at

[https://www.accessdata.fda.gov/drugsatfda\\_docs/summary\\_review/2023/020687Orig1s025SumR.pdf#page=41](https://www.accessdata.fda.gov/drugsatfda_docs/summary_review/2023/020687Orig1s025SumR.pdf#page=41).

<sup>26</sup> Ushma D. Upadhyay, et al., *Effectiveness and safety of telehealth medication abortion in the USA*, NATURE MED., Feb. 15, 2024, available at <https://www.nature.com/articles/s41591-024-02834-w>.

<sup>27</sup> Based on a review of publications on PubMed. See generally PubMed, NAT’L LIBRARY OF MED., <https://pubmed.ncbi.nlm.nih.gov/?term=mifepristone> (last visited Jan. 6, 2026).

<sup>28</sup> *Whole Woman’s Health Alliance v. FDA*, Case No. 3:23-cv-00019 (W.D. Va 20023). Additional information about this litigation is available at <https://reproductiverights.org/cases/whole-womans-health-alliance-v-fda/>; *Purcell, et al., v. Kennedy*, Case 1:17-cv-00493-JAO-RT, (D. Haw. 2025).

<sup>29</sup> *Purcell, et al., v. Kennedy*, Case 1:17-cv-00493-JAO-RT, (D. Haw. 2025), available at [https://litigationtracker.law.georgetown.edu/wp-content/uploads/2024/10/Purcell\\_2025.10.30\\_ORDER-ON-MOTION-FOR-SUMMARY-JUDGMENT.pdf](https://litigationtracker.law.georgetown.edu/wp-content/uploads/2024/10/Purcell_2025.10.30_ORDER-ON-MOTION-FOR-SUMMARY-JUDGMENT.pdf).

<sup>30</sup> U.S. Gov’t Accountability Off., GAO-08-751, *Food and Drug Administration: Approval and Oversight of the Drug Mifeprex*, Aug. 2008, available at <https://www.gao.gov/assets/gao-08-751.pdf>; 2018 GAO Report, *supra* n 16.

<sup>31</sup> See *id.*

In the last year, scientists, medical professionals, and FDA-regulated industry have expressed serious concerns that FDA may now be considering unreliable and politically-motivated sources of information rather than peer-reviewed scientific research in its decision making regarding mifepristone.<sup>32</sup> It is clear that the Trump Administration is under political pressure from anti-abortion interest groups to take action on mifepristone. The Department of Health and Human Services (“HHS”) Secretary Robert F. Kennedy Jr. specifically stated, “President Trump has asked me to study the safety of mifepristone. He has not yet taken a stand on how to regulate it. Whatever he does, I will implement those policies.”<sup>33</sup> FDA should not regulate necessary medication based on a president’s wishes.

To influence this decision, anti-abortion organizations and advocates appear to be attempting to interfere in FDA’s decisions regarding mifepristone.<sup>34</sup> Specifically, a heavily publicized, self-published position paper masquerading as scientific research has become the basis of the campaign by anti-abortion organizations and politicians to repeatedly politically pressure FDA to take action to restrict mifepristone access.<sup>35</sup> This paper has been thoroughly debunked; specifically, the paper uses methods inconsistent with strong scientific standards and does not meet the rigor, integrity, or transparency necessary to contribute to evidence-based regulatory decision making about mifepristone.<sup>36</sup>

Based on President Trump’s request to study mifepristone’s safety, and external pressure from anti-abortion advocates and politicians, HHS Secretary Kennedy has asked FDA Commissioner Marty Makary to review the latest data on mifepristone.<sup>37</sup> Reporting in December 2025

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<sup>32</sup> See e.g., Citizen Petition from American College of Obstetricians and Gynecologists, FDA-2025-P-0377-0001, Feb. 4, 2025, available at <https://www.regulations.gov/document/FDA-2025-P-0377-0001>; Comment from Ushma Upadhyay, FDA-2025-P-0377-0017, May 9, 2025, available at <https://www.regulations.gov/comment/FDA-2025-P-0377-0017> (hereinafter “Upadhyay Comment”); Comment from Grace Colón, FDA-2025-P-0377-0019, Jul. 1, 2025, available at <https://www.regulations.gov/comment/FDA-2025-P-0377-0019>.

<sup>33</sup> Cheyenne Haslett, et al., *5 takeaways after RFK Jr. is grilled by senators during confirmation hearings*, ABC NEWS, Jan. 30, 2025, available at <https://abcnews.go.com/Politics/4-takeaways-rfk-jr-senate-hearing/story?id=118213176>.

<sup>34</sup> See e.g., Kelly Baden, Joerg Dreweke, Rachel K. Jones, *The War on Mifepristone: How Junk Science and False Narratives Threaten US Abortion Access*, GUTTMACHER INST., Oct. 22, 2025, available at <https://www.guttmacher.org/2025/10/war-mifepristone-how-junk-science-and-false-narratives-threaten-us-abortion-access>.

<sup>35</sup> See e.g., *Hawley Calls on FDA to Reinstate Abortion Drug Safety Regulations: ‘The Time to Act is Now,’* Apr. 28, 2025, available at <https://www.hawley.senate.gov/hawley-calls-on-fda-to-reinstate-abortion-drug-safety-regulations-the-time-to-act-is-now/>.

<sup>36</sup> See Upadhyay Comment, *supra* n 32; see also Science Unpacked Series, *False serious adverse events claims with medication abortion*, SOC’Y FOR FAM. PLAN., Oct. 12, 2025, available at [https://societyfp.org/wp-content/uploads/2025/10/SFP\\_Science\\_Unpacked-FalseSeriousAdverseEvents-f.pdf](https://societyfp.org/wp-content/uploads/2025/10/SFP_Science_Unpacked-FalseSeriousAdverseEvents-f.pdf).

<sup>37</sup> See Sara Moniuszko, *FDA to “review the latest data” on mifepristone. What could it mean for access to the abortion pill?*, CBS NEWS, Jun. 5, 2025, available at <https://www.cbsnews.com/news/fda-review-mifepristone-abortion-pill-access/>; Alejandra O’Connell-Domenech, *FDA commissioner pledges to investigate mifepristone*, THE HILL, Jun. 3, 2025, available at <https://thehill.com/policy/healthcare/5330774-marty-makary-fda-mifepristone-review/>; *Trump Admin., RFK Jr., Moves to Address, Assess, Safety of Abortion Pill After Years of FDA Negligence*, THE GATEWAY PUNDIT, Sept. 22, 2025, available at <https://www.thegatewaypundit.com/2025/09/trump-admin-rfk-jr-moves-address-assess-safety/>; David Lim, *Abortion pill faces multi-agency scrutiny*, POLITICO, Dec. 9, 2025, available at <https://www.politico.com/newsletters/prescription-pulse/2025/12/09/abortion-pill-faces-multi-agency-scrutiny-00682416>; Elizabeth Mitchell, *EXCLUSIVE: Makary Responds to Report Saying He Slow-Walked Abortion Pill Safety Review*, THE DAILY SIGNAL, Dec. 9, 2025, available at

highlighted that Commissioner Makary was trying to “slow walk” whatever mifepristone review is being conducted at FDA to not be completed until after the 2026 mid-term elections,<sup>38</sup> which resulted in several anti-abortion organizations calling for his removal.<sup>39</sup> This request to delay an internal review as well as the resulting fallout clearly demonstrate the politically-motivated nature of HHS and FDA leadership’s decision making and the pressure campaign against FDA. This supposed review, with the clearly political goal of further restricting mifepristone access, is baseless.

To date, neither HHS nor FDA has provided any clarity or transparency regarding the basis of agency review of mifepristone, despite repeated calls from the public, including from the Center and other advocacy organizations, as well as Congress.<sup>40</sup> In fact, in response to this Committee’s request for information on FDA’s current review of mifepristone, the agency provided only a high-level and cursory response.<sup>41</sup>

Political considerations which result in imposing unnecessary restrictions on mifepristone undermine the fundamental right for people to make health care choices for themselves. No other essential medication with such a substantial, established, and sustained record of safety and efficacy has faced such hostility and political interference. It is neither rational nor sustainable.

## Conclusion

Mifepristone is safe and effective; FDA has made that determination numerous times under administrations of both political parties. FDA’s authority and legitimacy depend on its reputation as a credible scientific regulatory agency. Political interference from anti-abortion organizations, advocates, and politicians weakens the agency’s legitimacy in the public eye. It is imperative that Congress exercise its oversight powers to assure that FDA continues to be steadfast in its mission to promote and protect public health on the basis of rigorous scientific research and data that is free from partisan pressure and political bias. We urge Congress to ensure that FDA continues to follow the science when it comes to safety reviews of all drugs, including mifepristone; removes

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<https://www.dailysignal.com/2025/12/09/exclusive-makary-responds-report-saying-he-slow-walked-abortion-pill-safety-review>.

<sup>38</sup> See Rile Griffin, *FDA Slow Walking a Long-Awaited Abortion Pill Safety Study*, BLOOMBERG, Dec. 9, 2025, available at <https://news.bloomberglaw.com/health-law-and-business/fda-slow-walking-a-long-awaited-abortion-pill-safety-study>.

<sup>39</sup> See Joseph Choi and Nathaniel Weixel, *Anti-abortion hard-liners want FDA’s Makary out*, THE HILL, Dec. 09, 2025, available at <https://thehill.com/newsletters/health-care/5641418-anti-abortion-hardliners-want-fdas-makary-out/>.

<sup>40</sup> See *Center Sues Trump Administration for Withholding Records on Abortion Pill*, CTR. FOR REPROD. RTS., Sept. 5, 2025, available at <https://reproductiverights.org/cases/center-sues-trump-administration-for-withholding-records-on-abortion-pill/>; Letter to The Honorable Martin A. Makary, M.D., M.P.H., Comm’r of Food and Drugs, U.S. Food & Drug Admin. from Honorable Bill Cassidy, M.D., Chairman, Comm. on Health, Education, Labor, and Pensions, et al., Oct. 16, 2025, available at [https://www.help.senate.gov/imo/media/doc/cassidy\\_et\\_al\\_letter\\_to\\_commissioner\\_makary\\_re\\_mifepristone\\_generic\\_approval\\_finalpdf.pdf](https://www.help.senate.gov/imo/media/doc/cassidy_et_al_letter_to_commissioner_makary_re_mifepristone_generic_approval_finalpdf.pdf).

<sup>41</sup> See Letter to Honorable Bill Cassidy, M.D., Chairman, Comm. on Health, Education, Labor, and Pensions from the U.S. Food & Drug Admin., Dec. 11, 2025, available at [https://www.help.senate.gov/imo/media/doc/fda\\_response\\_to\\_cassidy\\_letter.pdf](https://www.help.senate.gov/imo/media/doc/fda_response_to_cassidy_letter.pdf).

barriers to medication abortion access; and remains free of political interference in its regulatory decision making.

Thank you again for the opportunity to contribute the Center's expertise to the record about the robust safety record of mifepristone.