January XX, 2022

Dear Senator,

We write to you today with profound concerns regarding the nomination of Dr. Robert Califf for Commissioner of the Food and Drug Administration (FDA) – a position he previously held during the Obama presidency. Under Califf's leadership during the Obama Administration, the FDA significantly undermined the reporting and safety requirements on medication abortion, also known as chemical abortion. As the abortion industry continues to push for abortion on demand, the FDA needs a leader who will follow the science and prioritize the health and well-being of women and girls. Based on his past (successful) effort to weaken data and safety requirements for chemical abortion, we must oppose his nomination.

The FDA applies Risk Evaluation and Mitigation Strategies (REMS) to drugs with serious safety concerns "to help ensure the benefits of the medication outweigh its risks."[1] Until 2016, the REMS for chemical abortion required the reporting of severe, life-threatening, and fatal adverse events. Under the direction of Califf, this requirement was altered to require that only fatal adverse events be reported. Califf approved this change despite thousands of adverse event reports already having been submitted to the FDA under the REMS.[2]

Sounding the alarm on these changes to the REMS, 75 members of Congress sent a bipartisan, bicameral letter to Califf expressing disappointment in his decision and calling for greater data transparency.[3] The letter requested additional information related to the decision-making process and an updated summary of the adverse event reporting through March 2016. Califf never responded.

In 2016, approximately one-third of U.S. abortions were reported to be "medical."[4] Now, the most recent data shows chemical abortions constitute 44% of all abortions.[5] In several states, chemical abortion has become the primary method of abortion, and other states are on pace to do the same.[6] With this rapid shift by the abortion industry toward chemical abortion, the weakened reporting requirements for adverse events have obscured the full scope of complications associated with chemical abortion.

An exhaustive report published earlier this year on the FDA's data on deaths and severe adverse events[7] found incomplete data including over 500 "uncodable" events, where women were "lost to follow-up" and there were huge gaps in critical medical information. Still, the existing data within the FDA adverse events reporting (AER) shows evidence of at least 20 deaths, nearly 600 life-threatening events, and over 2,000 severe events, including emergency hysterectomies and ruptured ectopic pregnancies.[8, 9] Another peer-reviewed study of Medicaid claims data has also found that more than 60% of chemical abortion-related emergency room visits were miscoded as miscarriages.[10] Any claims of safety from the FDA without addressing these serious flaws in available data cannot be taken seriously.

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[1] https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems
[2] https://www.aclu.org/sites/default/files/field_document/dkt._140_-_joint_stipulations_of_facts_with_exhibits_april_15_2021.pdf
[3] https://www.lankford.senate.gov/imo/media/doc/smith-lankford_letter_to_fda_on_abortion_drug.pdf
[4] https://www.cdc.gov/mmwr/volumes/68/ss/ss6811a1.htm
[5] https://lozierinstitute.org/us-abortion-trends-2019-and-preliminary-2020/
[6] Ibid.
[7] https://issuesinlawandmedicine.com/wp-content/uploads/2021/01/Deaths-and-Severe-Adverse-Events-after-the-use-of-Mifepristone-as-an-Abortifacient-from-September-2000-to-February-2019-copy5.pdf
[8] https://www.aaplog.org/wp-content/uploads/2011/07/MifeSAEharrison-pdf-copy.pdf
[9] https://issuesinlawandmedicine.com/wp-content/uploads/2021/01/Deaths-and-Severe-Adverse-Events-after-the-use-of-Mifepristone-as-an-Abortifacient-from-September-2000-to-February-2019-copy5.pdf
[10] https://journals.sagepub.com/doi/pdf/10.1177/23333928211053965

In March 2020, at the onset of the COVID-19 pandemic, national and state pro-life leaders warned HHS Secretary Alex Azar of the abortion industry's scheme to use the pandemic as an excuse to expand abortion via telemedicine.[11] The Trump Administration rightly defended these protections to avoid compounding the public health emergency. However, within a month of HHS Secretary Becerra's confirmation, the Biden FDA changed course, allowing abortion pills to be sent through the mail in direct contradiction of existing safety requirements, by using "enforcement discretion" to lift the REMS in-person dispensing requirement.[12] By the following month, the FDA had committed to review data on the REMS for chemical abortion to assess whether the already-insufficient requirements should be continued at all.[13] In a decision driven by pro-abortion pressure, the FDA announced the results of this review, declaring the in-person requirement permanently removed from the REMS on December 16, 2021. The in-person requirement is needed to give physicians the opportunity to accurately confirm and date the pregnancy, rule out an ectopic pregnancy, test the woman's Rh factor, and make certain she is not being coerced into taking the drug regimen.

Failure to identify these risk factors can lead to traumatic, potentially life-threatening complications. The REMS must be strengthened, and accurate reporting reinstated, as called for by an association of OB/GYNs in a Citizen Petition[14] submitted to the FDA in 2019.

In his confirmation hearing before the Senate Health, Education, Labor and Pensions Committee last month, Califf was asked about chemical abortion, and did not address his role in weakening safeguards on the drug. Instead, he told the committee that he trusted that any decision made by the FDA would be based on the best available data. There is a cruel irony in the fact that FDA data is "woefully inadequate"[15] data due to Califf's own decisions while serving as FDA Commissioner during the Obama administration.

Now the Biden administration seeks your consent to return Dr. Robert Califf to the top spot at the FDA where he will be asked to approve mail-order chemical abortion. With a track record of rubber-stamping abortion industry demands and with permanent authorization of unsafe mail-order abortion hanging in the balance, Califf is the wrong choice for FDA Commissioner. We urge you to vote no on his nomination.

Sincerely,

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[11] https://s27319.pcdn.co/wp-content/uploads/2020/03/LETTER-Pro-Life-Concerns-During-Coronavirus-Crisis-FINAL.pdf
[12] https://www.sba-list.org/wp-content/uploads/2021/04/govdoc20210412-226601.pdf
[13] https://www.courtlistener.com/docket/7007501/149/chelius-v-wright/
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[15] https://issuesinlawandmedicine.com/wp-content/uploads/2021/01/Deaths-and-Severe-Adverse-Events-after-the-use-of-Mifepristone-as-an-Abortifacient-from-September-2000-to-February-2019-copy5.pdf