



December 15, 2021

Dear Senator,

I write to advise you that Susan B. Anthony List, on behalf of our more than 900,000 members from all 50 states, strongly opposes the confirmation of Robert Califf to the position of Commissioner of the Food and Drug Administration (FDA). Although he enjoyed bipartisan support when he was confirmed under President Obama, his current nomination must be considered in light of his actions in that role. In 2016, he showed a blatant disregard for the unborn and for the health of women and girls when he loosened safety and reporting requirements on the abortion drug, mifepristone. In 2016, he was a nominee without a record; now he is a nominee with a track record of disregarding life. The Biden FDA is currently considering the pleas of the abortion industry to allow mail-order abortion drugs. With so much at stake, Dr. Califf is the wrong choice to lead the FDA.

As FDA Commissioner under President Obama, Dr. Califf loosened the Risk Evaluation and Mitigation Strategy (REMS) protocols¹ on mifepristone, the first of the two-drug regimen involved in medication abortion, also known as chemical abortion. One of the most alarming changes Dr. Califf oversaw was ending the requirement for reporting nonlethal adverse events caused by mifepristone. Instead, he only maintained reporting for those complications ending in death. With over 2000 severe complications and over 500 life-threatening complications having been reported to the FDA, removal of this reporting requirement under Dr. Califf's leadership is in itself grounds for opposition to his current confirmation. Faced with questions on chemical abortion at his nomination hearing before the HELP Committee, Califf said nothing to allay any concerns about this subject. He gave no indication that he would change course and choose to protect the health of women and girls despite pressure from the abortion lobby. In fact, when asked how he would handle the REMS, Califf merely said he trusts that the staff at the FDA would make the right decision based on the best available evidence. ***However, he failed to mention that the best evidence is no longer available due to his own actions obscuring the risks to women and girls during his tenure under Obama.***

An in-depth report published earlier this year on the FDA's data on deaths and severe adverse events² found that the FDA's data is "woefully inadequate" in assessing the risks or safety of mifepristone. Incomplete and inaccurate data with miscoded events have left huge gaps in critical information. Still, with the data that could be found within the FDA adverse events reporting (AERs), there is evidence of at least 20 deaths, 529 life threatening events, and nearly 2000 severe events, including emergency hysterectomies and ruptured ectopic pregnancies. Equally concerning, the study indicated severe underreporting of a significant number of complications.

¹ https://www.lankford.senate.gov/imo/media/doc/smith-lankford_letter_to_fda_on_abortion_drug.pdf

² <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>

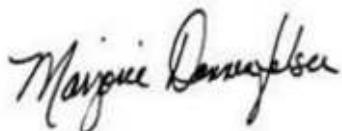
Another peer-reviewed study, this one reviewing Medicaid claims data, showed the rate of abortion-related emergency room visits following chemical abortions increased over 500% from 2002-2015, a greater increase than the rate of emergency room visits following surgical abortions. Additionally, more than 60% of chemical abortion-related emergency room visits were miscoded as miscarriages, obscuring the true impact of the abortion pill.³ The FDA cannot afford to ignore these staggering numbers.

The next FDA Commissioner should be a person willing to go where the science and the data lead—and willing to demand data where it is lacking—in order to protect pregnant women and girls who are being lied to about the safety of chemical abortion. Califf has already proven he is not up for this challenge and in fact is willing to obscure the data by limiting reporting of adverse events.

Under the Biden administration, the FDA informed the Court in *Chelius v. Azar*⁴ proceedings that it intends to revisit the REMS on mifepristone, including potentially removing the requirement for in-person distribution of these dangerous drugs, which further imperils women's health and safety. Among other reasons, the in-person requirement gives physicians the opportunity to accurately date the pregnancy, to ensure that she is not carrying an ectopic pregnancy, to test her Rh factor, and to make certain she is not being coerced into taking these drugs. Failure to identify any of these risk factors can lead to traumatic, potentially life-threatening complications.

Under Califf's leadership, the FDA would be poised to further weaken the REMS, needlessly endangering countless women and girls, while pandering to an extreme pro-abortion agenda. I urge your strong opposition to Califf's confirmation. Susan B. Anthony List intends to score against votes related to his confirmation.

Sincerely,



Marjorie Dannenfelser
President
Susan B. Anthony List

³ <https://journals.sagepub.com/doi/full/10.1177/23333928211053965>

⁴ <https://www.courtlistener.com/docket/7007501/149/chelius-v-wright/>