Robert Califf

Taking Health and Safety Out of Drug Regulations

Robert Califf, President Biden's nominee to be the next commissioner of the U.S. Food and Drug Administration (FDA), has a troubling record of prioritizing partisan interests over the health and safety of Americans when it comes to abortion. Therefore, he is unsuitable to lead the regulatory body primarily responsible for legalizing and administering the chemical abortion regimen.

Califf previously served as FDA commissioner for nearly a year towards the end of the Obama administration. Under his leadership, several modifications were made to weaken the FDA's safety precautions for administering chemical abortion pills. If confirmed to the commissioner position for a second time, Califf could potentially oversee even more dramatic changes to how chemical abortion drugs are regulated in the United States—making this already incredibly risky procedure even more dangerous for women, not to mention their unborn children.

The Dangers of Chemical Abortion

- Chemical abortion (often called by the more palliative name "medication abortion") is a two-step regimen consisting of the drugs mifepristone and misoprostol. Mifepristone (Mifeprex®; also known as RU-486 or simply "the abortion pill") was approved by the FDA in September 2000 to chemically induce abortions. Misoprostol is taken 24 to 48 hours after mifepristone to induce uterine contractions intended to expel the unborn child.

- Because mifepristone carries health-threatening risks such as hemorrhage, infection, incomplete pregnancy, retained fetal parts, the need for emergency surgery, and death, it has been subject to the FDA's drug safety program known as the Risk Evaluation and Mitigation Strategies (REMS).
- There are over 4,000 documented cases of abortion pills endangering the lives and health of women. The full extent of the damage that abortion pills have inflicted on women's health is unknown, because reporting of adverse events is voluntary. The FDA states that it "does not receive reports for every adverse event or medication error that occurs with a product."
- A 2021 study by the Charlotte Lozier Institute found that "chemical abortion is consistently and progressively associated with more postabortion ER visit morbidity than surgical abortion."
- Most states do not require abortion complication data to be broken down based on abortion type. However, in 2019, Arkansas recently passed legislation requiring this breakdown. The 2020 data shows that 88.9 percent of abortion complications in Arkansas are the result of chemical abortions.

Califf's Changes While FDA Commissioner

- During his first stint as FDA commissioner (2016–2017), Califf oversaw the first changes made to the mifepristone regulations since the drug was approved in 2000. Even though it was the pro-abortion Clinton administration that first approved the drug for use in the United States, strict health and safety protocols were nevertheless put into place. The changes brought about under Califf's leadership were a break with precedent. Furthermore, the changes were made at the request of the abortion industry, not the scientific community.
- The FDA approval in 2000 prohibited the use of the mifepristone-misoprostol regimen to after the 49th day of pregnancy. In 2016, the FDA approved a patient's starting the regimen as late as 70 days into pregnancy (as determined by gestational age). Studies show that the more

developed the child is, the greater the failure rate for the regimen and the greater the risk to the woman.

- The 2016 changes also eliminated the requirement for a follow-up office visit to check on the patient. Furthermore, the second step in the two-part regimen (misoprostol) could be self-administered by the patient. This puts the woman at greater risk since she is not being monitored for sepsis (infection), hemorrhage, ectopic pregnancy, and other complications.
- With these modifications, the FDA accepted the "off-label" regimen being used by abortion providers like Planned Parenthood, not a regimen backed by clinical trials and safety protocols.

The Rise of Chemical Abortion Use

- Chemical abortion pill usage has increased sharply in recent years. According to the Guttmacher Institute, chemical abortions increased by 73 percent between 2008 and 2017, even as overall abortion numbers declined over that same period.
- Planned Parenthood, a main proponent of the 2016 regulation changes, has a lot to gain from chemical abortion becoming less regulated. Chemical abortion significantly lowers the overhead costs for facilities or staff. Additionally, chemical abortion and other forms of "self-managed abortion" allow the abortion industry to shift the burden of this barbaric practice away from their staff and onto the women themselves. This would also make it easier to skirt state laws if *Roe* is overturned and the question of abortion legality returns to the individual states.
- In the past 15 years, the number of Planned Parenthood facilities performing chemical abortions has increased dramatically. In 2005, there were 57 facilities that performed chemical abortions only. By 2020, that number increased to 213 facilities that perform chemical abortions only.
- In April of 2021, the Biden FDA temporarily enabled abortion pill distribution by mail during the COVID-19 pandemic. Then, days before Califf's nomination was made public, the agency

coincidentally announced its intention to finalize a review of the REMS on the chemical abortion pill, signaling a further weakening of health and safety protocols.

Conclusion

Califf has already proven that he is willing to put partisan interests above the health and safety of Americans. During his first stint as FDA commissioner, he allowed changes to chemical abortion pill regulations that severely increased the risk of complications for women. Given that the Biden administration has already made it clear that it plans to listen to abortion businesses like Planned Parenthood over clear scientific evidence that shows chemical abortion can lead to severe complications, Califf cannot be trusted to neutrally review any proposed changes to the existing chemical abortion regimen. Now is the time to consider increased health and safety protocols, not weaken them.