How the New FDA Chief Helped to Hide Abortion Pill Dangers

How often have the pro-life movement and Senator Bernie Sanders been united on an issue? It happened last month when President Biden's nomination of Dr. Robert Califf to become commissioner of the Food and Drug Administration (FDA) sparked something exceedingly rare in modern Washington: bipartisan opposition.

The roots of conservative and liberal opposition to Califf, who is a respected cardiologist, professor of medicine and expert in clinical research at Duke University, had common outlines but different objects. Senators like Sanders (D-Vt.), Maggie Hassan (D-Vt.) and Edward Markey (D-Ma.) registered opposition over Califf's role in FDA opioid regulation and, at least in Sanders' case, his ties to what some call "the revolving door" between the FDA and the drug industry. For right-to-life advocates, it was Califf's role in the unscientific, near-eradication of reporting requirements for abortion pill complications during the Obama administration, where he served as FDA commissioner from February 2016 to January 2017.

To fully understand that role, it's important to know the FDA's checkered—which is to say not evidence-driven—history with the abortion regimen of mifepristone and misoprostol. FDA's approval in late 2000 came with significant safeguards for women's health. But over the next two decades, the FDA, an agency with a notoriously closed process for evaluating drugs and devices, proceeded (some would argue "receded") from robust patient safeguards to what has become a brisk, mail-order trade with little or no medical support for women and girls consuming these dangerous abortion drugs.

Pro-life activist Dr. Alveda King told Charisma News Friday

that Califf's callous attitude toward the abortion pill and its side effects is extremely dangerous for women.

"Surely, Dr. Califf is aware of the harmful impact of the abortion pill," King says. "If he is not, someone please remind him that abortion pills hurt women. Studies show the side effects are sometimes permanent. Women need to know about those side effects, which include nausea, weakness, fever and chills, vomiting, headaches, diarrhea and dizziness.

"Added to the risk of the abortion pill, this process leaves the woman alone and vulnerable at perhaps the most critical moments of her life. This is women's history month,. Shame on Joe Biden for choosing someone for that position that cares so little for women's health."

In December 2021, just before Califf's confirmation hearing, the FDA stripped away the better part of the remaining REMS—risk evaluation and mitigation strategies—for abortion pills. Califf had helped pave the way for erosion of safety standards (the abortion pill is never safe for the unborn life it kills) in 2016 when he led the FDA's decision to end the REMS requirement for any health harms short of death to be reported to the agency. Hemorrhage, need for follow-up surgical abortion, infection, ectopic pregnancy, near-death experience? No need to tell the FDA.

Conveniently, this non-reporting regime now allows the FDA and abortion industry to claim the abortion pill poses no serious risks. See no evil, hear no evil, report no data on evil.

Yet robust Medicaid data from 17 states, which publicly fund elective abortion, was ignored by the FDA but was analyzed by respected public health scientists and showed the real-world impact. The rate of abortion pill-related emergency room visits increased more than 500 percent from 2000 through 2015.

On top of laying the asphalt for mail-order abortion, the FDA's treatment of mifepristone had other unique features. The

manufacturers of the drug—Danco Laboratories and the generic-maker GenBioPro — make no other drugs. The abortion pill is all they have. This makes the companies invulnerable even to collateral pressure that they act responsibly with the FDA because they will have future products come before the agency. {eoa}

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