STATE OF ALABAMA
OFFICE OF THE ATTORNEY GENERAL

STEVE MARSHALL
ATTORNEY GENERAL

501 WASHINGTON AVENUE
MONTGOMERY, AL 36130
(334) 242-7300
ALABAMAAG.GOV

January 13, 2023

Dr. Robert Califf, Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-002

Dear Commissioner Califf:

The Food and Drug Administration's decision to abandon commonsense restrictions on remotely prescribing and administering abortion-inducing drugs is both illegal and dangerous. In direct contravention of longstanding FDA practice and congressional mandate, the FDA's rollback of important safety restrictions ignores both women's health and straightforward federal statutes. We urge you to reverse your decision.

The authority to regulate abortion lies with the people and their elected representatives. In our states, we prioritize the health and safety of women and children and our laws reflect this. And in many states, including Alabama, elective abortion is illegal. For example, in Alabama, abortion is permitted only when a pregnancy poses a "serious health risk" to a woman, Ala. Code § 26-23H-4. In the rare and unfortunate circumstance in which abortion could occur legally, it must be under the close supervision of a qualified physician, Ala. Code § 16-23E-7. Alabama's law carries criminal penalties for providers and, as you seem to acknowledge, your recent change in policy does nothing to dilute the strength of state laws. Our States will not yield to the Administration's radical pro-abortion policies.

As you know, mifepristone is an abortion drug that causes an abortion by blocking the body's receptors for the hormone necessary to carry an unborn child to term. As you also know, the drug is risky. When the FDA first approved it in 2000, the agency recognized that the drug carried serious risks for women, including infection and bleeding. To mitigate the risk of harm to women, the FDA imposed several restrictions, which it began issuing as part of a Risk Evaluation Mitigation Strategy ("REMS") in 2007. According to the REMS, mifepristone could only be prescribed by a qualified physician and administered in a hospital, clinic, or medical office and only by or under the supervision of such a physician. Until recently, the FDA adhered to the judgment that these requirements—which prohibited remotely prescribing mifepristone—are necessary to mitigate the serious health risks to women who take the drug.

Many states have rightly recognized that drugs like mifepristone are dangerous, especially when prescribed and administered remotely. As part of the Women's Health and Safety Act, the Alabama Legislature recognized the risk of "failure and complications from medical abortion" and provided that "[o]nly a physician may … administer[] or otherwise prescribe an abortion-inducing drug," which can only be prescribed after an in-person examination. Ala. Code § 16-23E-7; *see also, e.g.*, Ind. Code § 16-34-2-1 ("A physician must dispense the abortion inducing drug in person and have the pregnant woman consume the drug in the presence of the physician."). It is not seriously disputed that provisions like these are lawful and necessary to protect women's health.

These laws to protect women's health and safety comport with longstanding federal law. Congress mandated that "[e]very article or thing designed, adapted, or intended for producing abortion" is "nonmailable matter and shall not be conveyed in the mails or delivered from any post office or by any letter carrier." 18 U.S.C. 1461; *see also* 18 U.S.C. 1462 (criminalizing "tak[ing] or receiv[ing]" such nonmailable matter). Though Congress repealed this provision's application to contraceptives in 1971, *see* Pub. L. No. 91-662, 84 Stat. 1973 (1971), the provision prohibiting post offices from delivering abortion-related drugs remains intact. No court—and certainly not the United States Supreme Court—ever purported to strike down these abortion-related provisions.

About six months after *Dobbs* was decided, the FDA announced a wholesale change to the REMS for mifepristone that purports to authorize its remote prescription and administration. This change isn't the result of an analysis on how to help promote women's health. Instead, the FDA explains that "the REMS must be modified to reduce burden on the health care delivery system and to ensure the benefits of the product outweigh the risks."[1] At the same time, the Office of Legal Counsel of the Department of Justice issued a creative opinion asserting that, contrary to the plain text of 18 U.S.C. § 1461, federal law "does not prohibit the mailing, or the delivery or receipt by mail, of" abortion-inducing drugs. 46 Op. O.L.C. __ (Dec. 23, 2022) (slip op. at 1-2).

The problems with this change in policy are legion. Most importantly, the FDA has ignored its responsibility to protect health and safety by prioritizing a reckless pro-abortion policy over women's health. Though there are risks to a woman of using these drugs at any point in pregnancy, abortion-inducing drug are riskiest when used later in pregnancy. This means that accurately determining the date of pregnancy is critical for women's safety. And that determination will be accurate only if made in-person via ultrasound. Even the American College of Obstetricians and Gynecologists—a pro-abortion group that unsuccessfully sued the FDA to try to achieve the result you now marshal in—admits that an ultrasound

[1] *Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, U.S. Food & Drug Admin. (Jan. 3, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and- providers/ questions-and- answers-mifepristone- medical-termination-pregnancy-through-ten-weeks-gestation.

is needed to accurately determine gestational age.[2] By permitting and promoting the remote use of abortion drugs, you are endangering the lives of women. Of course, your policy enthusiastically endangers the lives of unborn children who may be even older and more developed than could be known without an in-person examination.

Aside from ignoring the health of women and the lives of unborn children, your decision ignores the plain text of federal law. Federal law has long provided that: "***Every*** article or thing designed, adapted, or intended for producing abortion … [i]s declared to be nonmailable matter and shall not be conveyed in the mails or delivered from any post office or by any letter carrier." 18 U.S.C. § 1461. To be sure, the Biden Justice Department recently tried to invent an exception to the law, opining that the law "is narrower than a literal reading might suggest." 46 Op. O.L.C. __ (slip op. at 5). But the statute couldn't be plainer, and it is no suggestion: a violation is a felony that carries five years' imprisonment. And yet, you now encourage physicians to facilitate remote abortions and pharmacies to order and provide abortion drugs.

The Biden DOJ's conclusion is implausible on its face, and a closer look makes the conclusion even more farcical. It relies on a series of lower-court decisions from about 100 years ago, all of which concerned contraceptives, not abortion.[3] While Congress *removed* the statutory references to contraceptives in response to those decisions, Congress has never taken steps to loosen restrictions on abortion-inducing drugs. Somehow, the Opinion reaches the strained conclusion that old court decisions disfavoring restrictions on contraceptives can now be used to speak for Congress on abortion. It should be obvious that this conclusion is exactly backwards: Congress decided *not* to remove statutory restrictions on abortion. The argument that Congress, by removing references to *contraception*, meant to remove references to abortion but failed to say so, is unserious. Furthermore, post-*Dobbs*, there is no credible legal argument that state laws could so easily be usurped.

Though the FDA has abdicated its responsibility to protect women's health, we have not. To be crystal clear, you have not negated any of our laws that forbid the remote prescription, administration, and use of abortion-inducing drugs. The health and safety of our citizens—women and children included—is of paramount concern. Nothing in the FDA's recent changes affects how we will protect our people.

Sincerely,

---

[2] Am. Coll. of Obstetricians and Gynecologists, *Committee Opinion No. 700: Methods for Estimating Due Date*, 129 Obstetrics & Gynecology 5 (2017) (https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/05/ methods-for-estimating-the-due-date).

[3] Slip op. at 11 n.11 (admitting that "[t]he leading cases … each involved items that could be used to prevent conception rather than to produce abortion").

Steve Marshall
Alabama Attorney General

Treg Taylor
Alaska Attorney General

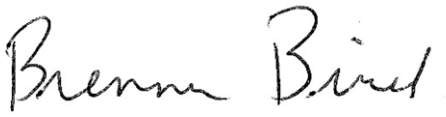
Tim Griffin
Arkansas Attorney General

Ashley Moody
Florida Attorney General

Chris Carr
Georgia Attorney General

Raúl Labrador
Idaho Attorney General

Todd Rokita
Indiana Attorney General



Brenna Bird
Attorney General of Iowa

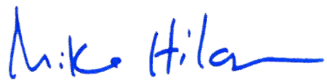
Daniel Cameron
Kentucky Attorney General

Jeff Landry
Louisiana Attorney General

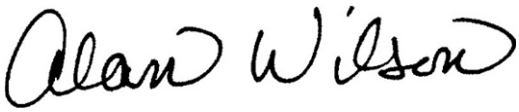
Lynn Fitch
Mississippi Attorney General

Andrew Bailey
Missouri Attorney General

Austin Knudsen
Montana Attorney General



Mike Hilgers
Nebraska Attorney General



Alan Wilson
South Carolina Attorney General

Jonathan Skrmetti
Tennessee Attorney General

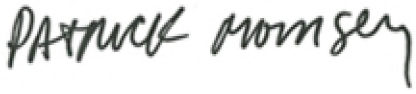
Sean D. Reyes
Utah Attorney General

Bridget Hill
Wyoming Attorney General

Dave Yost
Ohio Attorney General

Marty Jackley
South Dakota Attorney General

Ken Paxton
Attorney General of Texas



Patrick Morrisey
West Virginia Attorney General