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REPRODUCTIVE HEALTH AND EQUITY FACT SHEET

# MEDICATION ABORTION: A FEDERAL-STATE LEGAL TUG-OF-WAR

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<u>Medication abortion</u> (or the "abortion pill") generally refers to the use of two medications—mifepristone and misoprostol—to safely end an early pregnancy. Importantly, it does *not* refer to the use of Plan B emergency contraceptive; in <u>December 2022</u>, FDA updated Plan B's packaging insert to <u>expressly acknowledge</u> that it functions to prevent conception, not to end a pregnancy. In 2020, medication abortion was used for <u>53 percent</u> of all U.S. abortions. However, since the <u>Dobbs v. Jackson Women's Health Organization</u> decision on June 24, 2022, <u>14 states</u> have implemented near-total abortion bans (though bans in select states are <u>currently blocked</u> by <u>state courts</u>). Consequently, requests for medication abortion through <u>Aid Access</u> (an international telemedicine service) increased in the month following <u>Dobbs</u>, particularly in states with near-total bans. In fact, the increase in requests for medication abortion <u>helped offset</u> the effect of state abortion bans in the first two months immediately post-Dobbs.

Abortion-hostile states have taken substantial <u>steps to inhibit medication abortion access</u> while the Biden administration has implemented measures to expand it. The resulting federal-state "tug-of-war" has created confusion about the legality and availability of medication abortion. According to a <u>January 2023 Kaiser Family</u> <u>Foundation (KFF) poll</u>, 45 percent of adults are unsure whether medication abortion is legal in their state. Even in states legalizing abortion, 49 percent of adults are unsure whether a prescription is required. This Memo analyzes ongoing federal-state conflicts over medication abortion accessibility and public health ramifications.

#### I. STATE RESTRICTIONS

Several abortion-hostile states have restricted distribution of medication abortion, limiting its accessibility. Perhaps the most notable restriction is Wyoming's law <u>explicitly banning pills</u> that can end pregnancies. Passed in March 2023, Wyoming is currently the only state that prohibits medication abortions separately from its prohibition on surgical abortions.

As of April 13 2023, <u>15 states</u> require medication abortion be administered by a licensed physician and <u>5 states</u> prohibit the use of telemedicine for prescribing the abortion pill. Additionally, <u>32 states</u> mandate counseling for patients before abortion, <u>15</u> of which require in-person counseling prior to a statutorily-mandated waiting period. In states that also prohibit telemedicine use for obtaining medication abortion, in-person counseling requirements necessitate 2 trips to the clinic. In <u>16 states</u>, abortion providers are required to perform an ultrasound on patients seeking abortions; in <u>6 of those states</u>, providers are further required to show and describe the ultrasound image to the patient. All these requirements are stricter than what has been deemed necessary by the U.S. Food and Drug Administration (FDA) for the safe administration of medication abortions (see **Part II.a** below).

Multiple state attorneys general have indicated they would prosecute users and providers of abortion pills. <u>Alabama</u> Attorney General Steve Marshall suggested on January 10, 2023 that he would prosecute individuals who undergo medication abortion under Alabama's <u>child chemical endangerment law</u>, which has been used to prosecute pregnant people using controlled substances. It was not until 2016 that Alabama law <u>excluded use of drugs as prescribed</u> by a doctor from this law—between 2006 and 2015, <u>479 women were prosecuted</u> under it.

On February 6, 2023, <u>Kansas</u> Attorney General Kris Kobach threatened to prosecute Walgreens<sup>®</sup> if it offers mifepristone by mail, despite a <u>court-ordered block</u> on the state's prohibition of administering medication abortions via telemedicine. Walgreens' executive vice president <u>responded</u> that "Walgreens does not intend to dispense Mifepristone within [Kansas] and does not intend to ship Mifepristone into [Kansas] from any of our pharmacies." Following the response from Walgreens, on February 21, Attorney General Kobach also <u>urged</u> <u>CVS</u> to not distribute Mifepristone in Kansas. CVS has yet to respond.

### **II. FEDERAL ATTEMPTS TO EXPAND ACCESS**

In contrast to states' attempts to restrict medication abortion access, the Biden administration has taken steps to expand access to the abortion pill. Specifically, FDA and the U.S. Department of Justice (DOJ) have recently addressed accessibility of medication abortions.

**a.** Food and Drug Administration. FDA <u>approved Mifeprex</u> in 2000 and its generic version, mifepristone, in 2019. In 2019, FDA also approved a shared <u>Risk Evaluation and Mitigation Strategy (REMS) for all mifepristone products</u> used to end a pregnancy ("Mifepristone REMS Program"). A <u>REMS</u> is "a drug safety program that the [FDA] can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks." In 2021, FDA <u>reviewed the Mifepristone REMS Program</u> and determined that it could be modified "to reduce burden on the health care delivery system."

On January 3, 2023, FDA modified the Mifepristone REMS Program primarily to (1) include certified pharmacies (including retail pharmacies) as dispensers, and (2) remove in-person dispensing requirements, permitting mifepristone to be dispensed by mail. However, a January 2023 KFF poll found that 73 percent of adults were unaware that retail pharmacies (such as Walgreens<sup>®</sup> and CVS<sup>®</sup>) may now dispense abortion pills. Notably, the Mifepristone REMS Program does not require patients to see a health care provider in-person before having a medication abortion, nor does it require that abortion pill prescribers be licensed physicians. Rather, the abortion pill may be prescribed by certified health care providers (which need not always be M.D.s).

While FDA has taken clear action to make mifepristone more accessible, it has retained the Mifepristone REMS Program. Questions have arisen as to whether the Mifepristone REMS Program <u>should instead be entirely eliminated</u> to further increase accessibility. On February 23, 2023, <u>numerous state attorneys general sued FDA</u>, alleging that it is "improper and discriminatory" to subject mifepristone to a REMS. Specifically, the complaint states that the REMS "only serves to make mifepristone harder for doctors to prescribe, harder for pharmacies to fill, harder for patients to access, and more burdensome for the Plaintiff States and their health care providers to dispense." On April 7, 2023, <u>the district court blocked FDA</u> from taking any actions that would reduce

accessibility of mifepristone in the Plaintiff States. Notably, the Washington court's decision was published <u>on</u> <u>the same day</u> as a contrary decision from a Texas federal district court (see **Part III.b** below). At least one other lawsuit like the Washington REMS challenge has been filed <u>by abortion clinics in Virginia, Montana, and Kansas</u> urging increased mifepristone access.

**b.** Department of Justice. Shortly after the *Dobbs* decision was released, the U.S. Postal Service (USPS) requested legal guidance from DOJ regarding delivery of abortion pills in states imposing strict abortion bans. USPS was specifically interested in the impact of the Comstock Act on mail delivery of abortion pills. <u>Section</u> 1461 of the Comstock Act states:

Every article or thing designed, adapted, or intended for producing abortion . . . and [e]very article, instrument, substance, drug, medicine, or thing which is advertised or described in a manner calculated to lead another to use or apply it 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.

On December 23, 2022, DOJ <u>issued a Memorandum Opinion</u> ("Memo") responding to USPS, stating that the Comstock Act "does not prohibit the mailing of certain drugs that can be used to perform abortions where the sender lacks the intent that the recipient of the drugs will use them unlawfully." Specifically, <u>"longstanding judicial construction</u>" of the Comstock Act supports its narrow interpretation. DOJ demonstrates via a series of pre-<u>Griswold</u> and -<u>Roe</u> cases that convicting someone under Section 1461 requires proof beyond a reasonable doubt that they shipped abortifacient devices with the *intent* that such devices be used for an *illegal* abortion (see, e.g., <u>United States v. One Package</u> (2nd Cir., 1936)). Further, there are legal justifications for mailing abortion medications in all states (e.g., use of such drugs for legal lifesaving abortions, miscarriages, gastric ulcers, etc.).

The Memo also explains that Congress and USPS <u>have since adopted</u> the narrow judicial construction of Section 1461. Congress amended the Comstock Act four times since the above-mentioned judicial interpretation of Section 1461 was issued in 1945. None of those amendments changed the statutory language to suggest Congress disagreed with the narrow interpretation. Moreover, prior to Congress' 1971 amendment of the Comstock Act, the USPS Postmaster General submitted a statement to Congress that USPS understood Section 1461 as narrowly construed by the judiciary. On May 19, 1970, the U.S. House Committee on Ways & Means specifically included the Postmaster General's statement as support for its recommendation that Congress adopt the drafted amendment.

## III. EMERGING FEDERAL-STATE LEGAL TUG-OF-WAR

As explained in **Parts I** and **II**, some states are actively trying to limit medication abortion access while the federal government is trying to expand it. Three noteworthy cases evince this tug-of-war, as explicated below:

**a.** Federal Preemption. A predominant legal argument addressing medication abortion relates to preemption, specifically whether federal law overrides conflicting state law. Whether FDA's national authority to approve drugs and devices preempts state laws is not a novel question—the U.S. Supreme Court has heard <u>multiple cases on the subject</u>. Courts typically apply <u>conflict preemption principles</u>, determining (1) whether it is possible to comply with both state and federal laws, or (2) whether the state law poses an obstacle to the purposes of the federal Food, Drug, and Cosmetic Act (FDCA).

In <u>Wyeth v. Levine</u> (2009), the Supreme Court held that FDA approval of a brand-name drug label did not preempt state law failure-to-warn claims based on inadequate labeling because the drug manufacturer could comply with both state and federal law, and state law claims did not frustrate FDCA's purposes. Justice Samuel Alito (author of the <u>Dobbs</u> majority opinion) dissented, <u>stating that</u>:

Congress made its 'purpose' plain in authorizing the FDA—not state tort juries—to determine when and under what circumstances a drug is 'safe.' . . . Where the FDA determines, in accordance with its statutory mandate, that a drug is on balance 'safe,' our conflict pre-emption cases prohibit any State from countermanding that determination.

However, two years later, the Supreme Court decided inappositely in <u>PLIVA, Inc. v. Mensing</u> (2011). This time, the Court held that FDA approval of a generic drug label preempted state failure-to-warn claims. It found the drug manufacturer could not comply with both state and federal law; if the manufacturers had changed the label to satisfy state law duties, the label would no longer match the brand-name drug label, violating federal law.

The most relevant case on this issue is arguably *Zogenix, Inc. v. Patrick*, decided by a Massachusetts district court. In 2014, the Massachusetts Department of Public Health Commissioner banned prescribing and dispensing FDA-approved Zohydro ER, a hydrocodone pain medicine lacking an <u>"abuse-resistant formulation,"</u> in response to an opioid-based state public health emergency. The drug's manufacturer, Zogenix, argued FDA's approval of its drug preempted the Commissioner's order. The court agreed, <u>stating</u>, "[i]f the Commonwealth were able to countermand the FDA's determinations and substitute its own requirements, it would undermine the FDA's ability to make drugs available to promote and protect the public health." Moreover, the court distinguished *Zogenix* from *Wyeth*: *Wyeth* was a drug labeling case which did not as clearly frustrate the purposes of the FDCA as *Zogenix's* full drug prohibition.

In their article, <u>The New Abortion Battleground</u>, Professors David Cohen, Greer Donley, and Rachel Rebouché analyze how Wyeth, PLIVA, Zogenix, and other FDA preemption cases could affect lawsuits over medication abortion. They further assess in a subsequent article, <u>Abortion Pills</u>, whether FDA should get involved in this preemption debate. Their analyses are unfolding in the courts—on January 25, 2023, <u>two separate lawsuits</u> were filed alleging that FDA's approval of mifepristone preempts state mifepristone restrictions, as discussed below.

**Bryant v. Stein.** North Carolina requires that medication abortion be provided by a physician and that patients have an in-person physician visit prior to receiving a prescription. The state also mandates a <u>72-hour waiting</u> period after patients receive abortion counseling before they can undergo an abortion procedure. As noted in **Part II.a** above, the Mifepristone REMS Program does not require an in-person physician visit before having a medication abortion, nor does the abortion pill need to be provided by a licensed physician. Plaintiff, a North Carolina health care provider, <u>filed a complaint</u> in a federal district court arguing that North Carolina's mifepristone restrictions are inconsistent with FDA's approval and thus preempted. Plaintiff has asked the court to block enforcement of the state's restrictions and prohibit "any other action to restrict the ability of a provider to provide, or patient to access, mifepristone in accordance with federal law."

**GenBioPro, Inc. v. Sorsaia.** Like North Carolina's mifepristone restrictions, West Virginia's mifepristone requirements are stricter than FDA's requirements. West Virginia mandates a <u>24-hour waiting period</u> after patients receive abortion counseling before they can undergo an abortion procedure. It also prohibits prescription of the abortion pill <u>via telemedicine</u>. GenBioPro, a mifepristone manufacturer, <u>sued</u> in a federal district court arguing in part that FDA's approval preempts these restrictions. Although West Virginia has implemented a <u>near-total ban</u> on abortions (including medication abortions), GenBioPro asserts that the mifepristone restrictions will immediately become effective <u>upon any court ruling</u> that the abortion ban is unconstitutional. On May 2, 2023, the <u>district court found that GenBioPro met the requirements for standing</u>, allowing the suit to go forward.

**b.** Federal Agency Authority. The predominant medication abortion argument challenges FDA's authority to approve mifepristone at all, based primarily on challenges to its <u>administrative powers</u>.

Alliance for Hippocratic Medicine v. FDA. On November 18, 2022, various anti-abortion entities <u>filed a</u> <u>complaint</u> against FDA in the Northern District of Texas, alleging FDA exceeded its statutory authority in initially

approving Mifeprex and later when it extended approval to mifepristone and modified the Mifepristone REMS Program (see **Part II.a** above). Plaintiffs asked the court to order FDA to withdraw approval of mifepristone and rescind the agency's authority to deregulate it. The case specifically challenges mifepristone's approval, not misoprostol's; while mifepristone is FDA-approved for abortion use, misoprostol is FDA-approved <u>as a non-steroidal anti-inflammatory drug</u> often used for gastric ulcers and is prescribed off-label by providers for abortion/miscarriage management. <u>Nearly every state</u> weighed in on the case—22 Democrat-led states filed an <u>amicus brief</u> supporting FDA, while 22 Republican-led states filed an <u>amicus brief</u> supporting Plaintiffs. California, Massachusetts, and Washington <u>stockpiled dosages of mifepristone</u> in anticipation of an adverse ruling.

On April 7, 2023, Texas District Judge Matthew Kacsmaryk <u>ruled in Plaintiffs' favor</u>, blocking FDA's approval of mifepristone in an <u>unprecedented manner</u>. The judge delayed his ruling from taking effect for seven days to enable the Biden administration to seek emergency relief from the Fifth Circuit, which <u>the government did</u> on April 10, 2023. On April 12, the <u>Fifth Circuit issued an order</u> finding the drug's initial approval in 2000 could not be blocked, but that changes made to REMS from 2016 and onward could be. This ruling <u>would have rewound</u> <u>mifepristone back to its 2011 REMS</u>, effectively blocking GenBioPro from selling generic mifepristone (as it was not approved until 2019) and eliminating access to abortion medications by mail. On April 14, the <u>FDA filed an</u> <u>emergency appeal</u> and the <u>U.S. Supreme Court issued a temporary stay</u> effective until April 19 and subsequently extended until <u>April 21</u>. This temporary stay blocked the lower court orders from taking effect. On <u>April 21</u>, the <u>Fifth Circuit heard oral arguments</u>, but its ultimate decision will remain paused by the U.S. Supreme Court until the Court either declines to take up the case, or agrees to take it on and resolves it.

**c. Statutory Interpretation.** Despite the DOJ's Memo addressing the Comstock Act (see **Part II.b** above), state attorneys general have indicated their <u>willingness to bring lawsuits</u> against retail pharmacies for dispensing abortion pills. Following FDA's modifications to the Mifepristone REMS Program, Walgreens<sup>®</sup> and CVS<sup>®</sup> stated that they <u>plan to become certified</u> to dispense the abortion pill. In response to this announcement, 20 Republican AGs wrote to <u>Walgreens<sup>®</sup></u> and <u>CVS<sup>®</sup></u>, warning them of the legal consequences that could arise under the <u>Comstock Act</u>. Republican AGs explicitly rejected <u>DOJ's Memo</u> (see **Part II.b** above), arguing that "the text [of the Comstock Act], not the Biden administration's view, is what governs."

On February 16, 2023, 23 Democratic AGs <u>wrote a separate letter</u> to the pharmacies stating that Republican AGs' assertions are "misguided and disregard[] over a century's worth of legal precedent." Democratic AGs reiterated the points made in DOJ's Memo to reassure retail pharmacies that they are complying with state and federal law in dispensing the abortion pill. Nonetheless, Walgreens<sup>®</sup> confirmed that <u>it will not dispense abortion</u> pills in the Republican AGs' states. California Governor Gavin Newsom <u>attempted to cut ties</u> with Walgreens<sup>®</sup> over the retail pharmacy's decision not to dispense mifepristone in some states, but federal law <u>prevented him</u> from doing so.

Notably, the <u>Fifth Circuit's decision</u> in *Alliance* hinges on the Comstock Act as a potential justification for blocking FDA's updates to the mifepristone REMS post-2011. The Fifth Circuit explained that while it did not need to assess the Comstock Act to resolve the case at this point in time, "under a plain view of the Act," mifepristone manufacturers would be violating the law each time they ship abortion medication. Conversely, the <u>district court</u> in *GenBioPro* agreed with DOJ's assessment that only "[the] use of the mails in an illegal manner" is unlawful. Additionally, that court found no need to address the Comstock Act's application because DOJ, the body with enforcement power under the Comstock Act, had itself pronounced that it would not enforce the Act. These two contrasting judicial approaches indicate that analyses relating to the Comstock Act are quite distinct depending on which court is performing the analysis, and that the Comstock Act continues to represent a threat to medication abortion access. If the Comstock Act is not repealed, a final interpretation, likely from the U.S.

Supreme Court, would determine the future of mail-order medication abortion access. Still, DOJ ultimately retains the power to enforce the law, not the Supreme Court.

#### **IV. PUBLIC HEALTH IMPACTS**

This legal tug-of-war over medication abortion has tangible public health impacts. Restrictions on medication abortion in certain states (see **Part I** above) may create insurmountable obstacles to obtaining abortion care, <u>particularly for communities that have been marginalized</u>. As a <u>January 2023 Guttmacher report</u> aptly states, "Latina, Black and Indigenous women . . . are [] less likely than other groups to be able to overcome the egregious, unnecessary web of barriers to abortion care, both because they are less likely to have the money to do so and because they are more likely to experience racism in health care." In states like Alabama that may prosecute people under state criminal laws for having medication abortions, Black and Indigenous people and people of color are <u>more likely to be prosecuted</u>. A 2013 study by Pregnancy Justice (formerly known as National Advocates for Pregnant Women) analyzed cases in which pregnant women were arrested or detained because of their pregnancy status (i.e., under circumstances in which law enforcement and/or health care providers believed the women endangered the fetus), finding that 59 percent of the women were Black, Latina, Indigenous, or Asian, and 71 percent were unable to afford legal counsel and represented by public defenders.

People with disabilities also face heightened impacts of medication abortion restrictions. <u>Methotrexate</u> is a drug primarily prescribed to treat psoriasis, rheumatoid arthritis, and certain cancers, specifically among patients with chronic health conditions or autoimmune diseases. However, it <u>can also be used off-label</u> to end a pregnancy. Consequently, patients seeking the drug for non-abortion treatments are <u>being denied methotrexate</u>, despite it being the <u>standard of care</u>. According to a recent <u>Arthritis & Rheumatology study</u>, 53 percent of people receiving methotrexate for a chronic condition resided in states where abortion is banned or restricted by September 2022. Additionally, misoprostol, the second drug used for medication abortions, <u>is also used</u> to treat severe and chronic stomach ulcers. Whether it be on moral grounds or out of fear of legal liability, health care providers have been <u>denying patients access</u> to methotrexate and misoprostol. In response, the U.S. Department of Health and Human Services (HHS) issued its <u>Guidance to Nation's Retail Pharmacies</u> in July 2022, specifically identifying failures to dispense misoprostol or methotrexate as discrimination on the basis of sex and/or disability.

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