TESTIMONY

BEFORE THE UNITED STATES SENATE

HEALTH, EDUCATION, LABOR, AND PENSIONS (HELP) COMMITTEE

ON

PROTECTING WOMEN: EXPOSING THE DANGERS OF CHEMICAL ABORTION DRUGS

BY

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Dobbs Returned to the States the Ability to Protect Life, but the Biden FDA Thwarted that Promise by Allowing Mail-Order Abortion Drugs.

The United States Supreme Court "return[ed] the issue of abortion to the people's elected representatives" in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215, 232 (2022). That landmark decision empowered Louisiana, and every state, to decide how to address the issue of abortion.

Louisiana made its decision declaring that— "every unborn child is a human being from the moment of conception"—and reaffirming the longstanding policy of the state to protect the right to life of every child–born and unborn. See La. R.S. 40:1061.1. Louisiana prohibits abortion except in cases of fatal fetal anomalies or when "medically necessary to prevent the death or substantial risk of death" or the permanent impairment of a life-sustaining organ of the mother. La. Stat. Ann. § 40:1061; La. Stat. Ann. § 40:1061.1.2; *see also Louisiana v. EEOC*, 784 F.Supp.3d 886, 895 n.10 (W.D. La. 2025) (citing La. R.S. 40:1061, 14:87.7, 14:87.8.1). But even then, physicians must preserve the dignity of the unborn child by "mak[ing] reasonable medical efforts under the circumstances to preserve both the life of the mother and the life of her unborn child." La. Stat. Ann. § 40.1061 (emphasis added). Louisiana's protection for life includes a prohibition on abortion "by means of an abortion-inducing drug." La. R.S. 14:87.9, And likewise it prohibits aiding and abetting in the procurement or distribution of such drugs.

That should have been the end of it. But the Biden Food and Drug Administration (FDA) had long been planning to circumvent *Dobbs*. When oral argument in that case indicated *Roe v. Wade* might be overturned,[1] the Biden FDA promptly announced it would remove the in-person dispensing requirement for abortion pills, thereby authorizing mifepristone to be shipped nationwide.[2] This was not a legal or medically-informed decision, but a purely political one.

President Biden called *Dobbs* "an extreme decision"[3] by "not a normal Court"[4] and recommitted to "doing everything in his power" to "protect access" to abortion.[5] He noted: "Some states are saying that they'll try to ban or severely restrict access to

[1] Ian Millhiser, *It sure sounds like* Roe v. Wade *is doomed*, Vox (Dec. 1, 2021), perma.cc/M4EU-DSC2.
[2] Center for Drug Evaluation and Research, Application Number: 020687Orig1s025 Summary Review at 3, 12-13 (Jan. 3, 2023) ("FDA 2023 Summary Review").
[3] White House, Remarks by President Biden Before Meeting with His Task Force on Reproductive Healthcare Access (Jan. 22, 2024), perma.cc/N9KR-TKX9.
[4] White House, Remarks by President Biden on the Supreme Court's Decision on Affirmative Action (June 29, 2023), perma.cc/7XU8-3KL4.
[5] White House, FACT SHEET: President Biden to Sign Executive Order Protecting Access to Reproductive Health Care Services (July 8, 2022), perma.cc/F5ZZ-XGL8.

these medications."[6] To that end, President Biden issued multiple executive orders purporting to mandate access to abortion.[7]

Within hours of the Supreme Court handing down its decision in *Dobbs*, notwithstanding a prohibition on mailing abortion pills under the federal Comstock Act, the President directed Health and Human Services Secretary Xavier Becerra to identify "ways to ensure that mifepristone is as widely accessible as possible . . . including when prescribed through telehealth and *sent by mail*."[8] The same day, Secretary Becerra announced HHS's "commitment to ensure *every American* has access to … medication abortion,"[9] trampling upon the recognized authority of states to ensure medical ethics are properly observed and to protect their citizens from these harmful drugs. President Biden then issued a follow-up executive order directing HHS "to protect and expand access to abortion care, including medication abortion."[10]

These directives culminated in the revised Risk Evaluation and Mitigation Strategy (REMS) protocols for mifepristone. The 2023 REMS permanently removed restrictions under REMS that previously required in-person dispensing, which for health and safety reasons mandated that mifepristone "be dispensed only in certain healthcare settings, specifically clinics, medical offices, and hospitals[.]"[11] That requirement was the only thing standing between the Biden Administration and nationwide abortion access. Its elimination has facilitated widespread "dispensing of mifepristone through the mail."[12] This is medically dangerous, unethical, and illegal in many states.

The Biden Administration identified the FDA's 2023 permanent removal of the in-person dispensing requirement as one of its primary responses to *Dobbs*[13] and the culmination of President Biden's July 8, 2022, executive order directing HHS to

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[6] White House, Remarks by President Biden on the Supreme Court Decision to Overturn *Roe v. Wade* (June 24, 2022), perma.cc/B8Y3-EWUZ.

[7] Exec. Order No. 14076, Protecting Access to Reproductive Healthcare Services, 87 Fed. Reg. 42053 (July 8, 2022); Exec. Order No. 14079, Securing Access to Reproductive and Other Healthcare Services, 87 Fed. Reg. 49505 (Aug. 3, 2022); *see also*, Presidential Memorandum, Further Efforts To Protect Access to Reproductive Healthcare Services, 88 Fed. Reg. 4895 (Jan. 22, 2023) ("My Administration remains committed to supporting safe access to mifepristone...").

[8] White House, FACT SHEET: President Biden Announces Actions In Light of Today's Supreme Court Decision on *Dobbs v. Jackson Women's Health Organization* (June 24, 2022), perma.cc/66T6-BL87 (emphasis added).

[9] Press Release, HHS, HHS Secretary Becerra's Statement on Supreme Court Ruling in *Dobbs v. Jackson Women's Health Organization* (June 24, 2022), perma.cc/89AZ-RFL4 (emphasis added).

[10] Exec. Order No. 14076.

[11] FDA 2023 Summary Review at 3.

[12] 2021 FDA Letter to ACOG and SMFM About Mifepristone REMS at 2 (Apr. 12, 2021).

[13] HHS, Marking the 50th Anniversary of *Roe*: Biden-Harris Administration Efforts to Protect Reproductive Health Care (Jan. 19, 2023), perma.cc/8EB4-P7US (HHS "continue[s] to activate all divisions of the Department in service to [its] commitment to ensuring" access to abortion).

"protect and expand access to abortion care, including medication abortion."[14] The 2023 REMS were in fact necessary component of the Biden Administration's plan to "protect and expand access" to abortion post-*Dobbs*.[15]

The 2023 REMS revision worked as planned. The removal of the in-person dispensing requirement rendered Louisiana and other states' pro-life laws nearly meaningless. Aid Access—perhaps most well-known among the abortion-drug drug distribution facilitators—unabashedly credits removal of in-person dispensing for its ability to mail FDA-approved abortion drugs "to people in all 50 states, even those that have banned it."[16] To be clear, removing the pre-existing protections under REMS did not legalize distribution of these pills in states that ban them or legalize sending them by mail, which is prohibited by the Comstock Act, so the Biden Administration's objectives – as directly stated by the President – were to *facilitate* illegal drug distribution in violation of state and federal law as a means of facilitating abortion. The Biden Administrations political objectives entirely subsumed medical ethics as well.

Indeed, abortions have tragically *increased* in Louisiana since *Dobbs*, despite its pro-life laws. The pro-abortion Society of Family Planning reports that, from April to June 2024 alone, mail-order abortion drugs—sent *illegally* into Louisiana from doctors and activists in other states—accounted for an average of 617 abortions in Louisiana per month.[17] That number topped 800 abortions in December 2024[18] and continues to trend upward eclipsing 900 abortions per month in Louisiana in 2025.[19]

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[14] White House, FACT SHEET: The Biden-Harris Administration's Record on Protecting Access to Medication Abortion (Apr. 12, 2023), perma.cc/78TT-3J2G (citing Exec. Order No. 14076, Protecting Access to Reproductive Healthcare Services, 87 Fed. Reg. 42053 (July 8, 2022)); HHS, Secretary's Report, Health Care Under Attack: An Action Plan to Protect and Strengthen Reproductive Care (Aug. 2022), perma.cc/WWV5-CSFY.

[15] Press Release, HHS, HHS Releases Report Detailing Biden-Harris Administration Efforts to Protect Reproductive Health Care Since *Dobbs* (Jan. 19, 2023), perma.cc/6CE3-J7DD.

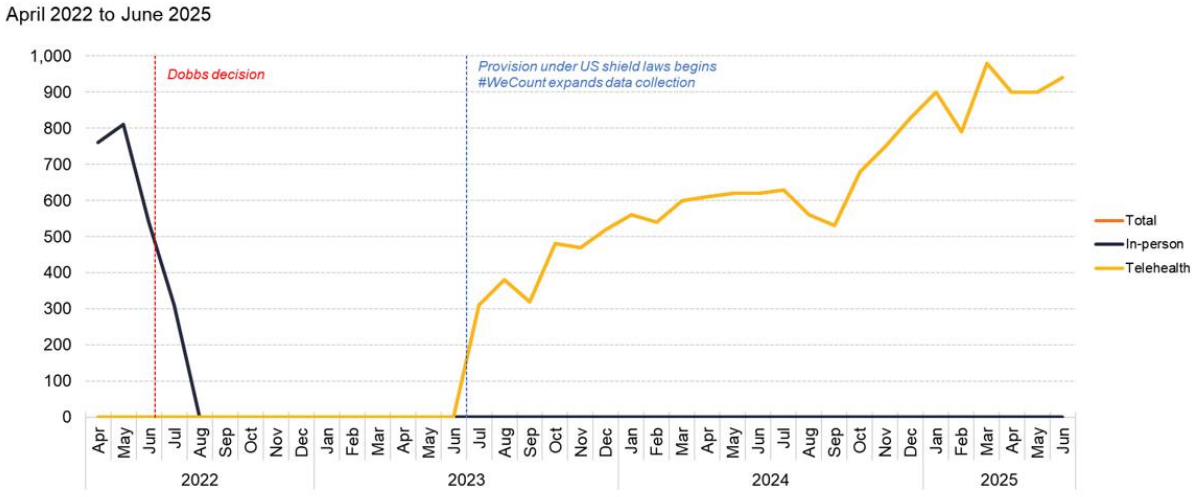
[16] Rebecca Grant, *Group Using 'Shield Laws' to Provide Abortion Care in States That Ban It*, The Guardian (July 23, 2023), perma.cc/49J6-3CZS; Ex. 71, Aid Access, *Get Abortion Pill Online in Louisiana*, perma.cc/J65J-M5LF.

[17] Society of Family Planning, #WeCount Report April 2022 to June 2024 at 10 (Oct. 22, 2024), perma.cc/WRW3-PMWK.

[18] Society of Family Planning, #WeCount Report April 2022 to December 2024 at PowerPoint slide 35 (Jun. 23, 2025), perma.cc/RM6F-H2Q9.

[19] Society of Family Planning, #WeCount Report April 2022 to June 2025 (Dec. 9, 2025), perma.cc/AYJ2-FYJ2; Society of Family Planning, #WeCount Report Summary Slides with National and 51 State-Level Findings April 2022 to June 2025 at PowerPoint slide 35 (Dec. 9, 2025), perma.cc/83U9-TC79; Abigail R. A. Aiken et al., *Research Letter, Provision of Abortion Medications Using Online Asynchronous Telemedicine Under Shield Laws in the US*, Vol. 334 No. 15, JAMA 1388 (Oct. 21, 2025), https://doi.org//10.1001/jama.2025.11420; Declaration of Michael J. New, Ph.D, *Louisiana v. FDA*, No. 25-cv-01491 (W.D. La. Dec. 15, 2025), Dkt. No. 20-22 at 1–2.

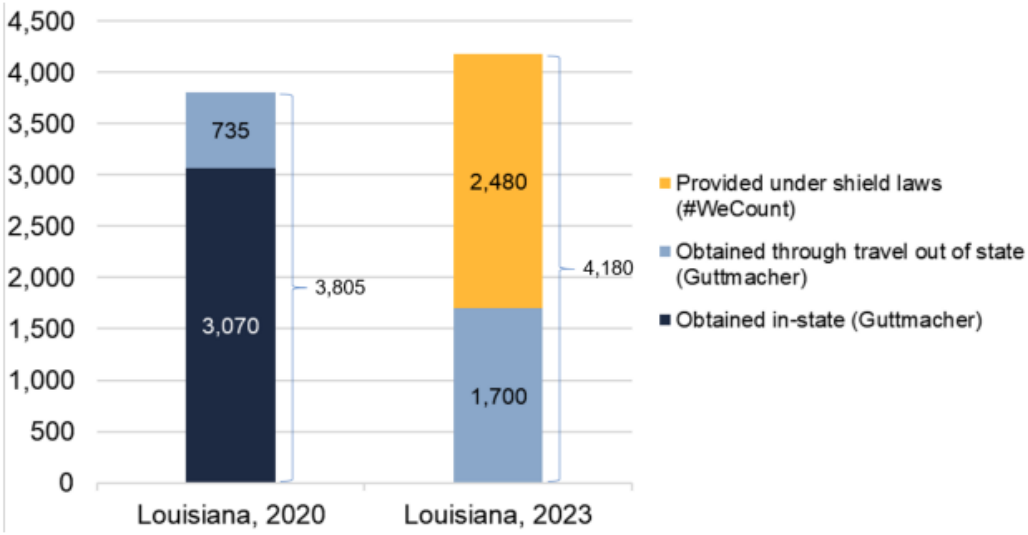
Louisiana



Source: Society of Family Planning, December 2025

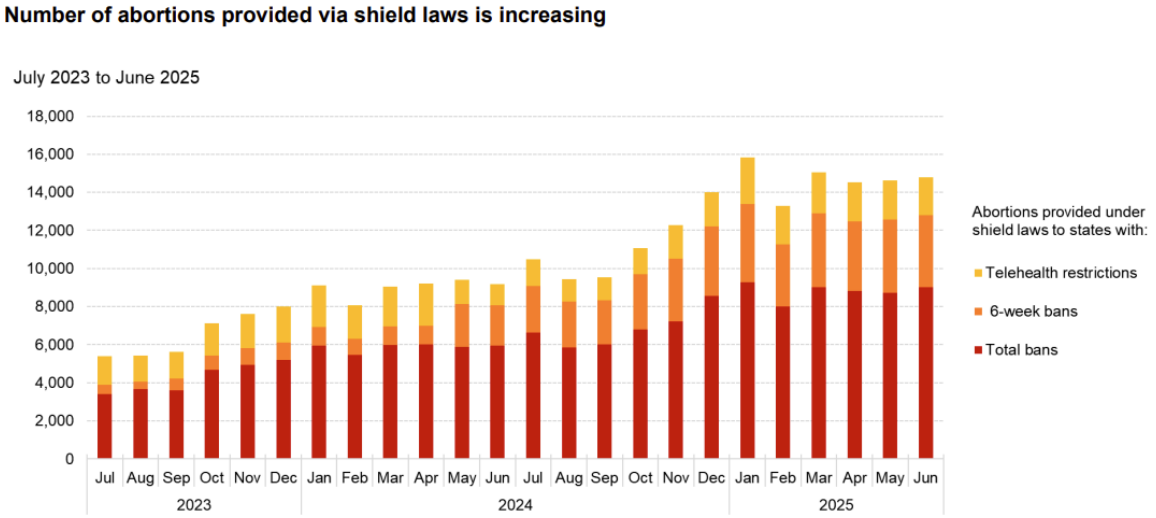
FDA's approval of mifepristone-by-mail increased the number of abortions Louisiana residents obtained—even after Louisiana's abortion prohibition took effect.[20]

Figure 13. Louisiana, six months of 2020 and 2023, respectively



[20] Society of Family Planning, #WeCount Report April 2022 to June 2024 at 16.

That trend coincides with national reported data, which shows that the mailing of mifepristone under the 2023 REMS accounts for thousands of abortions every month in pro-life states:[21]



These are not mere statistics – behind them is a woman or girl injured by this dangerous, illegal, and medically un-supervised distribution and use of abortion pills. Here are a few examples:

- In one parish, a 16-year-old teenager was coerced by her mother to abort her wanted child because the mother did not want the added burden of a baby. The mother had a prior history of domestic violence against the daughter. The daughter had been planning a "gender reveal" for her baby but instead ended up alone, scared, and bleeding on the floor of a hotel room, abandoned by to abort her baby alone by the mother who coerced her into taking pills *the mother* was able to obtain. The girl had no medical supervision and never requested the pills. That matter has resulted in the indictment by West Baton Rouge District Attorney Tony Clayton of the mother, NY doctor XX Carpenter who prescribed the pills without any communication whatsoever with the pregnant girl and Carpenter's so-called clinic in New York.

- In Caddo Parish, a young man drove his hemorrhaging girlfriend to an emergency room for treatment after she took pills obtained online. She took these pills at 20 weeks even though they are not safe to use at that time

[21] Society of Family Planning, #WeCount Report April 2022 to June 2025 at 12.

and the likelihood of serious and life-threatening complications dramatically increases at this time. A doctor in the hospital asked where the baby was and learned the couple had placed the deceased child in a dumpster. The boyfriend retrieved the baby, and the matter was referred to law enforcement. These pills also came from the same New York doctor.

- In yet another parish, a woman again reported to an emergency room. Those pills came from California – no doctor or pharmacy is identified on the pill bottle. A box containing mifepristone tablets identifies GenBioPro as the manufacturer and the box states the pills are manufactured in India.

- Louisiana has conducted a controlled buy of pills from California. Aid Access has no human interaction to request pills – only a form to fill out. If you state that you cannot pay the $150 charge, the charge is reduced to $20. There is no human interaction and no access to medical personnel. The return address on a package of pills was traced to an unoccupied storage facility in California.

The weakening of the mifepristone REMS rendered Louisiana's pro-life laws nearly unenforceable. Emboldened by shield laws that inhibit the ability of law enforcement officers to hold out-of-state actors culpable for violations of state law, doctors and activists have blanketed Louisiana and other pro-life states with mail-order abortion drugs. In 2022, for example, Dr. Margaret Carpenter and Dr. Linda Prine launched the Abortion Coalition for Telemedicine (ACT)—a group that is dedicated to facilitating abortion "in all 50 states."[22] It works with healthcare providers to "launch shielded practices" to ship FDA-approved abortion drugs to women "across state lines."[23] ACT partners with several notorious out-of-state abortion-drug peddlers, including Aid Access.[24] And Dr. Carpenter is upfront about her desire to "facilitate access to abortion drugs *in states where it's illegal*."[25] In other words, they have created a coordinated network of individuals who are using the mail to facilitate an illegal scheme of drug dealing where it is illegal under state and federal law.

Dr. Carpenter's actions reveal a dark consequence of remote dispensing: bad actors intending to coerce or force a woman to abort her child can order and obtain abortion drugs by mail with ease and the facilitators of this illegal scheme area protected by Governors in New York and California. In the case where a Louisiana

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[22] ACT, *Who We Are*, perma.cc/EX5M-RFUX.
[23] ACT, *What We Do*, perma.cc/E3CM-SLYC.
[24] ACT, *Resources*, perma.cc/A9ND-USQL.
[25] Alaa Elassar, *New York Doctor Indicted in Louisiana Abortion Case Recognized as a Leader in Women's Reproductive*[25] *Health*, CNN (Feb. 23, 2025), perma.cc/8F88-6BYA (emphasis added).

grand jury indicted Dr. Carpenter and the Louisiana woman who forced her teenage daughter to take abortion drugs that the woman had obtained from Dr. Carpenter, the teenage girl suffered a medical emergency alone at home, called 911, and was rushed to the hospital in an ambulance after delivering a dead fetus. This young woman had no medical oversight whatsoever until she entered an emergency room. There are not medical standards in any state that sanction such irresponsible actions by a licensed medical professional, and political preferences for access to abortion do not justify placing women at such medical risk.

But not even criminal charges have deterred Dr. Carpenter's coalition or its allies. Despite the Louisiana indictment, New York Governor Kathy Hochul has refused to extradite Dr. Carpenter, citing New York's shield law: "I'm respecting the laws of New York. Am I supposed to make those subservient to laws of another state?"[26] For its part, ACT issued a press release touting its resolve "to stand behind New York and other shield laws across the country that enable the distribution" of mail-order abortion drugs.[27] To be clear, New York's law is not designed or intended to protect New York residents or New York women seeking access to abortions in New York – it, like other state shield laws – is intended to shield individuals like Dr. Carpenter from being brought to justice for their knowing, intentional, criminally illegal conduct that is directed to and carried out in other states. In other words, Governor Hochul is shielding and facilitating an illegal drug distribution operation.

In response to Dr. Carpenter's indictment, New York enacted a law further shielding abortion-drug prescribers from liability. The law allows prescribers to list only the name of their clinic on prescription labels—an attempt to make it even more difficult to prosecute out-of-state doctors who dispense abortion drugs to states that prohibit them.[28] Other states—including Colorado, Maine, Massachusetts, Rhode Island, Vermont, and Washington—have passed similar laws. California has gone further, authorizing prescriptions to not identify either the provider *or* the recipient. This not only shields abortion drug providers,[29] but makes it more difficult for women coerced into taking abortion drugs to bring their abusers to justice. It is important to note, again, that all of this violates the Comstock Act, which prohibits sending abortion pills through the mail.

In a second case Louisiana is investigating against Dr. Carpenter, she has allegedly mailed mifepristone to a woman who was 20 weeks pregnant—*twice* the

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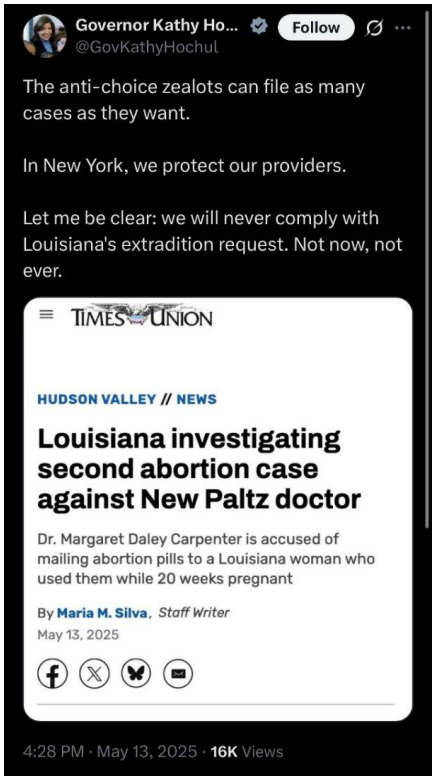
[26] Donlevy, *supra* note 27.
[27] Press Release, ACT, Statement on Governor Hochul's Response to Louisiana Extradition Order (Feb. 13, 2025), perma.cc/S7PG-NNAM.
[28] Press Release, Protecting Reproductive Freedom: Governor Hochul Signs Legislation Affirming New York's Status as a Safe Haven for Reproductive Health Care (Feb. 3, 2025), perma.cc/ZSH6-J6HW.
[29] Pam Belluck, *California Passes Bill Allowing Omission of Patients' Names from Abortion Pill Bottles*, N.Y. Times (Sept. 11, 2025), perma.cc/U25B-S4M2.

FDA-approved gestational age.[30] The woman wrapped the aborted baby's remains in a towel and threw the baby in a garbage can.[31] Governor Hochul responded to the investigation by doubling down on her defiance of Louisiana law[32]:



The Biden FDA's removal of the in-person dispensing requirement in the 2023 REMS has had its intended effect. But for the 2023 REMS, activists in New York and California could not blanket pro-life states like Louisiana with mifepristone by mail.

The 2023 REMS must be vacated. Until then, Louisiana's efforts to protect mothers and unborn children—and to hold out-of-state abortion pill traffickers accountable for the harm they inflict—will be all but futile.

The Biden FDA's Mail-Order Abortion Scheme Destroys Lives and Endangers Women.

The harm of abortion-by-mail to Louisiana's unborn children is obvious: *death*—at a rate of nearly 1,000 children every month, according to the abortion

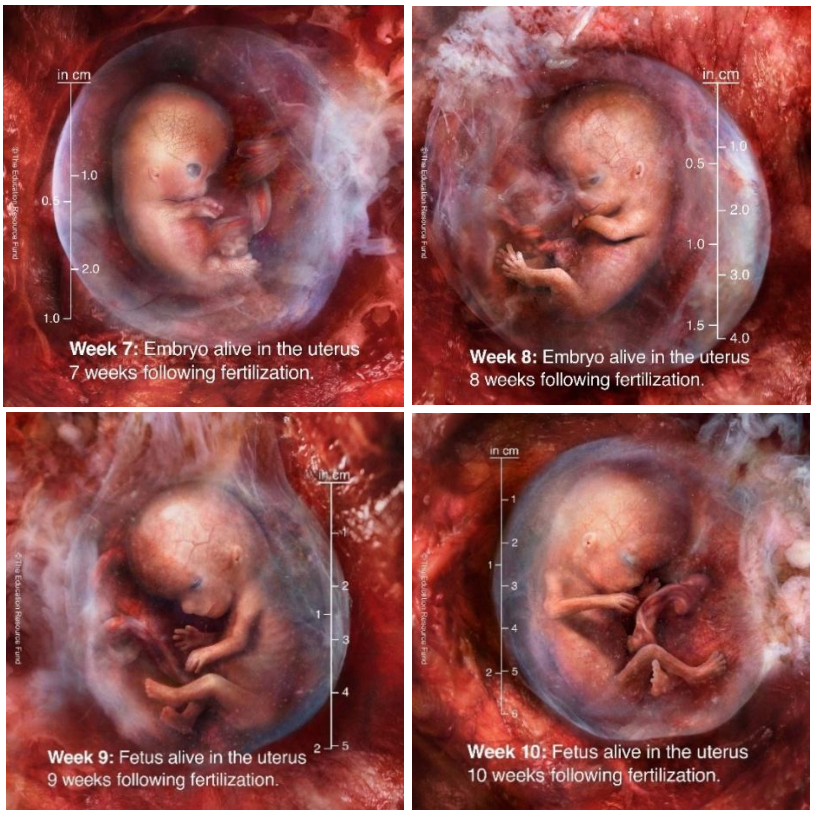
[30] Complications increase substantially with increasing gestational age. *See infra* p. 12.

[31] Rosemary Westwood, *Louisiana Investigates Second Case Against New York Doctor Over Mailing Abortion Pills*, La. Illuminator (May 13, 2025), perma.cc/D4BR-RKFC.

[32] Governor Kathy Hochul (@GovKathyHochul), X (May 13, 2025, 4:28 PM), perma.cc/ZA4U-G2CY.

industry.[33] And this, despite our State's promise to protect "every unborn child [as] a human being from the moment of conception."[34] The creation of illegal abortion pill drug distribution networks, with Governor of other states shielding these illegal actors from the consequences of their actions, has demonstrably harmed women not helped them.

Endoscopic video footage[35] of embryos and fetuses in the womb by the Education Resource Fund extoll the humanity of the unborn at all stages, even from conception through ten weeks—FDA's approved gestational limit for a mifepristone abortion.[36] Anatomically accurate embryonic and fetal color images recount the same:[37]



[33] Society of Family Planning, #WeCount Report Summary Slides with National and 51 State-Level Findings April 2022 to June 2025 at PowerPoint slide 35.
[34] La. R.S. 40:1061.1.
[35] Education Resource Fund, *The Science of Life Before Birth*, perma.cc/6L5V-Z3TP.
[36] FDA-Approved Label for Mifepristone (Mifeprex) at 17 (Jan. 2023), perma.cc/2UJ58WVF ("Mifeprex 2023 Label").
[37] Education Resource Fund, *Weeks 1-12 and Months 4-9 Embryonic & Fetal Color Images*, perma.cc/86HC-Q98M.

Louisiana wants to protect these children, and we were promised after the fall of *Roe v. Wade* that we could. Not so under the Biden FDA's 2023 REMS.

Our women are suffering. Rosalie Markezich[38] did not want an abortion. Her boyfriend knew that. She told him repeatedly. But that did not stop him from ordering and obtaining abortion drugs online using Rosalie's information. It did not stop him from cornering Rosalie in a speeding car, abruptly stopping in a location unknown to her friends, and berating her for ruining his life by wanting to keep the baby. And it certainly did not stop him from becoming so angry that Rosalie felt she had no other option to secure her safety than to swallow the drugs in front of him.

Those drugs killed Rosalie's child.

Despite her best efforts to throw them up as soon as she could escape the car, Rosalie ended her night on a blood-soaked towel on the garage floor, in physical and emotional anguish. She mourns her child still. And the California doctor who sent her boyfriend the abortion drugs did so without knowing or caring who he was sending them to or how, when, and by whom they would be used. How could he know? He never even spoke with Rosalie. Far from empowering Rosalie, mail-order abortion drugs took away her choice and destroyed the life within her.

This is the regime the Biden FDA created. Notably, the recent approval of generic abortion pills will increase this problem.

No woman should have to experience this tragedy—and yet Rosalie is not alone. The internet is littered with disturbing accounts from women who assert they were coerced into taking mail-ordered abortion drugs or even poisoned by their partners with them.[39] These results are tragic, but they are also the predictable result of removing the in-person dispensing requirement for mifepristone. At the click of a few buttons, *anyone* can access abortion drugs—even abusers, traffickers, and unwilling fathers. Plus, thanks to anonymous dispensing in many pro-abortion states,[40] women like Rosalie have no recourse against the individuals who recklessly mail unlawful drugs to strangers residing in pro-life states.

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[38] *See generally* Declaration of Rosalie Markezich, *Louisiana v. FDA*, 25-cv-01491 (W.D. La. Oct. 6, 2025), Dkt. No. 1-92.

[39] *E.g.*, Minyvonne Burke, *Texas attorney who poisoned pregnant wife with abortion medication sentenced to 180 days in jail*, NBC News (Feb. 9, 2024), perma.cc/8GTA-T7SM; Landon Mion, *Illinois man accused of drugging girlfriend with abortion pills to cause miscarriage*, Fox News (Aug. 27, 2025), perma.cc/A5BK-WSFL; Kimberlee Speakman, *Surgeon Indicted on Felony Charges After Allegedly Attempting to Give His Girlfriend Abortion Pills Against Her Will*, People (Dec. 9, 2025), perma.cc/R5CP-V5VX.

[40] *E.g.*, Press Release, Protecting Reproductive Freedom: Governor Hochul Signs Legislation Affirming New York's Status as a Safe Haven for Reproductive Health Care; Belluck, *supra* note 31.

The Biden FDA's mail-order scheme predictably imperils women, all while protecting abusers and empowering prescribers who recklessly send life-ending, high-risk drugs in the mail without confirming who consumes them.

In fact, abortion-drug peddlers like Abuzz tout on their websites that recipients need only fill out a short form to obtain discreetly packaged, FDA-approved mail-order abortion drugs in just a couple of days—no phone call or telehealth consultation required.[41] Activists throw "pill-packing parties," drinking "Chardonnay in red plastic cups" while they package their unlawful contraband for shipment into pro-life states:[42]

And providers brazenly admit that they discourage women from seeking emergency care for complications,[43] or prompt them to conceal from emergency staff that they took chemical abortion drugs.[44] *In no other context would this be considered healthcare.*

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[41] Abuzz, *Abortion Pill Access in Louisiana*, perma.cc/BDY4-5MX9; Abuzz, *Need abortion care at home?*, perma.cc/ERK3-D97B; A Safe Choice, *Home*, perma.cc/HCQ7-WYC6; A Safe Choice, *Online Consultation Form*, perma.cc/NSA6-HGPQ; Choices Rising, *Abortion Pill*, perma.cc/7NKQ-BYRU; MAP, *Frequently asked questions*, perma.cc/3HNJ-ZFTC.

[42] Scott Calvert, *The Parties Where Volunteers Pack Abortion Pills for Red-State Women*, Wall St. J. (Aug. 12, 2024), perma.cc/57KX-MD3V.

[43] Caroline Kitchener, *Alone in a bathroom: The fear and uncertainty of a post-*Roe *medication abortion*, Wash. Post (April 11, 2024), perma.cc/N66P-FTWU.

[44] *Id.*; *see also* Pam Belluck, *A day with one abortion pill prescriber*, N.Y. Times (Jun. 9, 2025), perma.cc/8Y85-E7UJ; Abuzz, *FAQs*, perma.cc/9LQ7-QZVL.

But that's not all. By permitting mail-order abortions, the Biden FDA not only put women at a heightened risk of coercion but recklessly increased the risks of the drug to women who voluntarily take it. We cannot forget the grave consequences mifepristone—the drug at the heart of chemical abortion trafficking—causes to both mother and child. Mifepristone is a synthetic steroid and endocrine disruptor that blocks progesterone receptors in the uterus. By blocking progesterone receptors, mifepristone causes the uterine lining to deteriorate, starving the baby of oxygen and nutrition and eventually killing the baby. The harm to Louisiana's children is obvious.

The mother faces potentially life-threatening complications. To start, FDA's mifepristone label features a black box warning stating that mifepristone can cause "[s]erious and sometimes fatal infections and bleeding."[45] Further, as the Fifth Circuit Court of Appeals already recognized, FDA's "own documents" show that "emergency room care is statistically certain" in mifepristone cases.[46] Mifepristone's FDA label warns that roughly 1 in 25 of women who take the drug *as directed* will end up in the emergency room, and up to 7% will require a "surgical procedure because the pregnancy did not completely pass from the uterus or to stop bleeding."[47] And these complication rates existed *before* the Biden Administration removed the in-person dispensing requirement—all while conceding that dispensing by mail increases emergency room visits. In the real world, there is good reason to believe that emergency room visits and hospitalization rates are as high as 11%.[48]

Why is that? For one, remote dispensation precludes prescribers from confirming the gestational age of the baby or detecting an ectopic pregnancy—with potentially fatal consequences. The risks of complications and emergency surgeries increase with gestational age.[49] And abortion drugs will not end an ectopic pregnancy. Instead, mifepristone is contraindicated for ectopic pregnancies because it causes symptoms similar to a ruptured ectopic pregnancy and may mask that life-threatening condition, preventing women from seeking emergency medical care.[50] For

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[45] Mifeprex 2023 Label at 1.

[46] *All. for Hippocratic Med. v. FDA*, No. 23-10362, 2023 WL 2913725, at *10 (5th Cir. Apr. 12, 2023) (*Alliance I*).

[47] Mifeprex 2023 Label at 7 ("Uterine bleeding and cramping are expected consequences of the action of MIFEPREX and misoprostol as used in the treatment procedure. Most patients can expect bleeding more heavily than they do during a heavy menstrual period.").

[48] Jamie Bryan Hall & Ryan T. Anderson, *The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event, Ethics & Pub. Pol'y Ctr.* at 1 (Apr. 28, 2025), perma.cc/YH5F-9R6C.

[49] 2021 FDA Letter to AAPLOG and Am. Coll. of Pediatricians denying in part and granting in part 2016 Citizen Petition, Docket No. FDA-2019-P-1534 at 9 (Dec. 16, 2021) ("We agree that the failure rate of medical abortion regimens, including the currently approved regimen, generally increases with increasing gestational age.")

[50] Declaration of Christina Francis, M.D., *Louisiana v. FDA*, No. 25-cv-01491 (W.D. La. Dec. 17, 2025), Dkt. No. 20-21 at ¶ 23.

another, women with an untreated Rh-negative blood type also risk a 14% chance that a future baby will be stillborn and a 50% chance that a future baby will suffer neonatal death or a brain injury.[51]

These risks are why FDA long required in-person dispensing with pre-and post-termination medical supervision, finding it necessary to "ensure that the benefits of the drug outweigh[ed] the risks[.]"[52] Even as other restrictions were pulled from the mifepristone REMS, FDA recognized that in-person dispensing remained "minimally burdensome" and "necessary" to preserve the safety of women who take abortion drugs[53]—until the Biden FDA permanently reversed course post-*Dobbs*.

FDA's own data establishes that a harrowing number of women who take remotely dispensed abortion drugs wind up in emergency rooms. Even before the in-person dispensation was stripped, roughly 40 of those women would have ended up in the emergency room.[54] FDA concedes that the number for remote dispensing is higher and the actual number of emergency room visits and hospitalizations may be as high as 110 (11%).[55] Even this data is likely under-counting the actual numbers.

These numbers are not just hypothetical. In 2025, one Louisiana woman took mifepristone she received in the mail from Aid Access and tragically delivered her dead child in a Louisiana emergency room.[56] Another took mifepristone from the same source in the same year and later arrived at a Louisiana emergency room with severe abdominal pain. She delivered her child there, and because of the heroic efforts of emergency personnel, that child survived.[57]

Unfortunately, these stories are not unique. Many Louisiana women have sought help from OB/GYNs for complications arising from chemical abortion drugs they received in the mail. Declarants in our ongoing case out of the Western District of Louisiana[58] have highlighted some of these instances.

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[51] *Id.* at ¶ 24.
[52] 21 U.S.C. § 3551(a); *See also* 2011 FDA Supplemental Approval Letter to Danco Laboratories, LLC at 1 (June 8, 2011) ("2011 Approval Letter").
[53] Appl. for Stay, *FDA v. Am. Coll. of Obstetricians & Gynecologists*, No. 20A34 at 4, 13 (U.S. Aug. 26, 2020).
[54] Mifeprex 2023 Label at 8, 17.
[55] Hall & Anderson, *supra* note 49.
[56] Declaration of Kathleen Willis, M.D., *Louisiana v. FDA*, No. 25-cv-01491 (W.D. La. Dec. 17, 2025), Dkt. No. 20-20 at ¶ 11.
[57] *Id.* ¶ 12. These two women were recipients of Louisiana Medicaid. The combined cost to the State for just these two instances was nearly $90,000.
[58] *Louisiana v. FDA*, No. 25-cv-01491 (W.D. La. filed Oct. 6, 2025).

One New Orleans OB/GYN testified[59] that, since 2022 (when FDA temporarily waived in-person dispensation), she has personally treated roughly fourteen Louisiana women who suffered incomplete abortions or infections from primarily mail-ordered mifepristone. These complications required emergency medical intervention, including dilation and curettage (D&C), supportive management, ultrasounds, and antibiotics.

One patient, for example, was bleeding and was septic. The patient initially claimed to be having a miscarriage. The doctor performed a suction D&C and later discovered that the patient had taken mifepristone at 19 weeks gestation. A second patient had been bleeding for three weeks and was experiencing lightheadedness after taking mail-ordered mifepristone from Abuzz. The doctor's partner performed a suction D&C and a blood transfusion. In the operating room, the woman started hemorrhaging.

From April through May 2025, the doctor's team treated at least 30 women who suffered mifepristone complications requiring blood transfusions, D&Cs, and hospital stays.[60] She is aware of women seeking treatment for mifepristone complications in her hospital every day—and she testified that these women often do not know the gestational ages of their children.[61]

Another Lafayette OB/GYN performed a D&C procedure last year on a patient who was 5 weeks gestation to treat an incomplete abortion and severe bleeding caused by abortion drugs she likely received in the mail.[62]

Pregnancy care centers throughout Louisiana routinely see women suffering from abortion drug complications. Some women bring abortion drugs with them to the centers, and others request follow-up ultrasounds after taking mifepristone.[63] One center, for instance, needed to send a woman to the emergency room with excessive bleeding after she passed out. Her abortion-drug provider irresponsibly and unethically told her not to tell doctors that she had taken mifepristone.[64]

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[59] Declaration of Angela Parise, M.D., *Louisiana v. FDA*, No. 25-cv-01491 (W.D. La. Dec. 17, 2025), Dkt. No. 20-23 at ¶¶ 9-11.
[60] *Id*. at ¶ 13.
[61] *Id*. at ¶ 19.
[62] Declaration of John Voltz, M.D., *Louisiana v. FDA*, No. 25-cv-01491 (W.D. La. Dec. 17, 2025), Dkt. No. 20-18 at ¶ 10.
[63] Declaration of Kathleen Richard, LMSW, *Louisiana v. FDA*, No. 25-cv-01491 (W.D. La. Dec. 17, 2025), Dkt. No. 20-19 at ¶ 6; Declaration of Lyndsey Sikes, *Louisiana v. FDA*, No. 25-cv-01491 (W.D. La. Dec. 17, 2025), Dkt. No. 20-24 at ¶ 7.
[64] Decl. of Kathleen Richard, LMSW, Dkt. No. 20-19 at ¶ 7.

FDA anticipated the reality that emergency rooms would backstop abortion drug complications,[65] yet it removed the in-person dispensing requirement even though its own data suggested that the need for emergency medical care would increase.[66] That was both medically unethical and irresponsible. FDA's remote dispensing regime prioritizes and facilitates a radical political ideology over women's health and safety and ethical standards that apply under virtually any other circumstances.

The Biden FDA's Mail-Order Abortion Scheme is Unlawful.

There is no serious question that the 2023 REMS is unlawful.

Secretary Robert F. Kennedy, Jr., and FDA Commissioner Martin A. Makary both admit that there was a "lack of adequate consideration" of the safety risks "underlying the prior REMS approvals," including the decision to "remov[e] the in-person dispensing requirement.[67] And five Fifth Circuit judges have already held the action unlawful under the Administrative Procedure Act (APA).[68]

FDA relied on two sources for its 2023 REMS, but neither source supports the removal of the in-person dispensing requirement, rendering its removal arbitrary and capricious under the APA (5 U.S.C. § 706(2)(A)). Specifically, FDA relied on (1) adverse events reported to the agency via FDA's Adverse Event Reporting System (FAERS) database and the drug's sponsors, and (2) published literature.[69]

First, FDA's reliance on the FAERS data was arbitrary and capricious. The agency itself recognizes that "the FAERS data by themselves are not an indicator of the safety profile of the drug" and that "[t]he number of suspected reactions in FAERS

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[65] And FDA knew that these emergency room doctors would bear a heavy burden for its recklessness. When it began stripping away safeguards from the mifepristone REMS in 2016, FDA said it would continue to rely on emergency rooms as a backstop to "ensure that women have access to medical facilities for emergency care" to manage expected complications. 2016 FDA Letter to AAPLOG, Christian Medical & Dental Associations, and Concerned Women for America denying 2002 Citizen Petition, Docket No. FDA2002-P-0364, at 21 (Mar. 29, 2016).

[66] 2021 FDA Letter to AAPLOG at 35.

[67] Letter from Robert F. Kennedy, Secretary of Health and Human Services, to Attorneys General at 1 (Sept. 19, 2025).

[68] *See Alliance I*, 2023 WL 2913725, at *17 (5th Cir. Apr. 12, 2023) (Judges Oldham and Engelhardt); *See also All. for Hippocratic Med. v. FDA*, 78 F.4th 210, 249–51 (5th Cir. 2023) (*Alliance II*) (Judges Elrod, Ho, and Wilson).

[69] The "assessment data" that FDA also purportedly considered (concerning healthcare provider certification, program utilization, and noncompliance) does not help. FDA admitted that the *eight* reported cases of adverse events from this data set were duplicates of those already reported in the FAERS database. Center for Drug Evaluation and Research, Application Numbers: 020687 and 91178 Rationale Review at 21–23, 38–39 (Dec. 16, 2021) ("FDA 2021 Rationale Review").

should not be used to determine the likelihood of a side effect occurring."[70] That fact alone renders FDA's reliance on the database to "determine the likelihood of [mifepristone] side effect[s] occurring" arbitrary.

As FDA acknowledges, since "FDA does not receive reports for every adverse event ... that occurs with a product," FAERS data "cannot be used to calculate the incidence of an adverse event ... in the U.S."[71] Commissioner Makary recently agreed, stating: "So there are studies that are done using adverse events, self-reported data, but that data's not very good .... When you do a study based on self-reported data, you're not capturing a lot of the data that you wanna know in a study."[72]

As scholars have recognized, the FAERS database is "woefully inadequate to determine the post-marketing safety of mifepristone due to its inability to adequately assess the frequency or severity of adverse events," and the adverse events reported to FDA "represent a fraction of the actual adverse events occurring in American women."[73] The database's unreliability is rivaled only by its impenetrability: it takes FDA a whopping 48 pages just to explain how a doctor is supposed to report an adverse event.[74] Hardly conducive to encouraging voluntary reporting. In the realm of Covid vaccine research, Dr. Makary has long been openly critical about the manipulation of data to facilitate a political objective. The same degree of rigor is due here.

As Judges Elrod, Ho, and Wilson previously found: "considerable evidence shows that FAERS data is insufficient to draw general conclusions about adverse events." *Alliance II*, 78 F.4th at 249.

What's more, the deficiencies in the FAERS data *are of FDA's own making*. It was FDA that removed the requirement that abortion prescribers report serious adverse events other than death to the Agency—stripping the FAERS database of actual reporting of non-fatal adverse events.[75] Faced with that fact, the Fifth Circuit expressed disbelief that "[a]fter eliminating th[e] adverse-event reporting requirement [in 2016], FDA turned around in 2021 and declared the absence of non-fatal adverse-event reports means mifepristone is 'safe.'" *Alliance I*, 2023 WL

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[70] FDA Adverse Events Reporting System (FAERS) Public Dashboard, *Frequently Asked Questions (FAQs),* perma.cc/CZ2G-4S75 (under question "What points should I consider while viewing the dashboard content?").

[71] *Id.* (under question "Does FAERS data have limitations?").

[72] Video posted by Elizabeth Troutman Mitchell (@TheElizMitchell), X, at 02:02–2:19 (Dec. 9, 2025 at 17:56 ET), perma.cc/Q9CV-8FDN.

[73] Kathi A. Aultman et al., *Deaths and Severe Adverse Events After the Use of Mifepristone as an Abortifacient from September 2000 to February 2019*, 26 Issues in L. & Med., no. 1, Nov. 1, 2021, at 25-26.

[74] Specifications for Preparing and Submitting Electronic ICSRs and ICSR Attachments (Apr. 2021), perma.cc/CAD8-N4EM.

[75] *Louisiana v. FDA*, No. 25-cv-01491 (W.D. La. Dec. 17, 2025), Dkt. No. 1-11 at 5–10, 28.

2913725, at *17. "This ostrich's-head-in-the-sand approach is deeply troubling," it said, "especially on a record that, according to [FDA's] own documents, necessitates a REMS program, a 'Patient Agreement Form,' and a 'Black Box' warning." *Id.* "And it suggests FDA's actions are well outside the zone of reasonableness." *Id.* (citation modified).

Judges Oldham and Englehardt concluded, "[i]t's unreasonable for an agency to eliminate a reporting requirement for a thing and then use the resulting absence of data to support its decision." *Id.* And as Judges Elrod, Ho, and Wilson found, "[t]he agency is responsible for its own inability to obtain probative data; it cannot then cite its lack of information as an argument in favor of removing further safeguards." *Alliance II*, 78 F.4th at 249.

Second, FDA's reliance on published literature it admitted had limited value was arbitrary and capricious.

FDA conceded that it was unable to "generalize" the results of its cited studies to the United States population and that "the usefulness of the studies is limited in some instances by small sample sizes and lack of follow-up information on outcomes."[76] It thus acknowledged that "[t]he studies [FDA] reviewed are *not adequate on their own* to establish the safety of the model of dispensing mifepristone by mail."[77] Rather, the studies were, at most, "not inconsistent with" FDA's conclusion that removing the in-person dispensing requirement would be safe.[78] Once again, FDA's own conclusions about the published literature render its reliance on it to remove the in-person dispensing safeguard arbitrary.

In addition to their "limited" usefulness due to design flaws, the studies do not establish the safety of dispensing mifepristone by mail. Much the reverse. The studies show that emergency room incidents *increase* with remote dispensing.

FDA reviewed three studies for "mail-order pharmacy dispensing"[79]:

- *Hyland*: reporting that 3% of the participants needed to be hospitalized—a 330% increase over the rate on the approved label.[80] FDA disregarded this dramatic increase, saying it could make no "conclusions about [that study's] safety findings."[81]

[76] FDA 2021 Rationale Review at 38.
[77] *Id.* at 39 (emphasis added); *cf.* 21 U.S.C. § 355(d)(1) (directing FDA to reject drug applications that "do not include adequate tests").
[78] *Id.*
[79] *Id.* at 28.
[80] *Id.* at 27–28.
[81] *Id.* at 28.

- *Upadhyay*: exhibiting "numerous deviations" from abortion practices in the United States, "limited follow-up information, and small sample size"—all of which "limit[ed] [its] usefulness."[82]
- *Grossman*: evaluating outcomes for "dispens[ing] by mail-order pharmacy *after* in-person clinical assessment,"—the very safeguard stripped away by the 2023 REMS.[83]

FDA also cited five studies that "evaluated clinic dispensing by mail"[84]:

- *Raymond*: reporting that 7% of participants "had clinical encounters in [emergency department (ED)] and urgent care centers."[85]
- *Chong*: reporting that "(6%) [of] participants had unplanned clinical encounters in ED/urgent care," and "[s]urgical interventions were required in … 4.1[%] to complete abortion."[86]
- *Anger*: reporting that 12.5% of participants "had an unplanned clinical encounter."[87] FDA acknowledged that this "suggests a pre-abortion examination may decrease the occurrence of procedural intervention and decrease the number of unplanned visits for postabortion care."[88]
- *Kerestes*: reporting that 5.8% of participants in the "telemedicine [plus] mail group" had "ED visits," a rate exceeding the range on the label (2.9% to 4.6%) and almost three times higher than the 2.1% for women who had an "in-person" visit.[89]
- *Aiken*: exhibiting "limitations" because "investigators were unable to verify the outcomes" and "the study's design did not capture all serious safety outcomes."[90]

Every one of these studies was performed by abortion activists and none warrant removing the in-person dispensing requirement.

Indeed, FDA conceded that "the literature suggests there may be more frequent ED/urgent care visits related to the use of mifepristone when dispensed by mail from the clinic[.]"[91] Yet it *still* concluded that, while the studies "suggest more frequent encounters with healthcare providers, they generally support a conclusion

[82] *Id.* at 27.
[83] *Id.* at 26 (emphasis added).
[84] *Id.* at 28.
[85] *Id.* at 29.
[86] *Id.* at 30.
[87] *Id.* at 31.
[88] *Id.* at 34.
[89] *Id.* at 31–32.
[90] *Id.* at 33–34.
[91] *Id.* at 34.

that dispensing by mail is safe"[92] and that mifepristone will "remain safe and effective for medical abortion if the in-person dispensing requirement is removed[.]"[93]

As Judges Elrod, Ho, and Wilson determined, "[e]specially in light of the unreliability of the adverse-event data, it was not reasonable for FDA to depend on the published literature to support its decision."[94]

In addition, FDA had previously argued to the U.S. Supreme Court that in-person dispensing was "minimally burdensome" and "necessary" for safety.[95] In that same filing, FDA added that it had reviewed "thousands of adverse events resulting from the use of Mifeprex," determined that abortion drugs continue to cause "serious risks for up to seven percent of patients," and concluded that in-person dispensing was "necessary to mitigate [those] serious risks."[96]

Third, the 2023 REMS is "otherwise not in accordance with law" under the APA because the plain text of the Comstock Act expressly prohibits the mailing of abortion-inducing drugs, and a federal agency cannot permit what federal law expressly prohibits.

As Judge Ho noted in his concurring opinion in *Alliance II*, the 2023 REMS "violates the Comstock Act" because it "authorizes the dispensing of mifepristone through the mail … or through a mail-order pharmacy."[97] "But using the mails for the mailing of a drug ... for producing abortion is precisely what the Comstock Act prohibits."[98]

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Through the 2023 REMS, the Biden Administration knowingly and intentionally undermined *Dobbs* by facilitating the criminally-culpable mailing of mifepristone into every pro-life state, thus harming states like Louisiana and causing women like Rosalie immense suffering. The Fifth Circuit has twice recognized what FDA and HHS's leadership now publicly admit: that the 2023 REMS is almost certainly unlawful.

The solution is simple. Louisiana's pro-life laws are meaningless if they can be bypassed through the mail, especially where the FDA is facilitating this criminal

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[92] *Id.* at 39.
[93] *Id.*
[94] *Alliance II*, 78 F.4th at 250.
[95] Appl. for Stay, *FDA v. Am. Coll. of Obstetricians & Gynecologists*, No. 20A34 at 4, 13 (U.S. Aug. 26, 2020).
[96] *Id.* at 4, 7, 21.
[97] *Alliance II*, 78 F.4th at 267 (Ho., J., concurring) (citation modified).
[98] *Id*. at 267–268 (citation modified).

conduct. And women's health shouldn't be sacrificed on the altar of politics. It's time to end the reckless dispensing of abortion drugs through the mail once and for all.