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Clarke D. Forsythe

Donna Harrison M.D.

CLARKE D. FORSYTHE & DONNA HARRISON, M.D.

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ABSTRACT

Roe v. Wade legalized abortion in all 50 states for any reason, at any time of pregnancy, and thereby paved the way for the development of new abortifacients. Chemical abortion, also referred to as RU-486, is a two-drug regimen. The first, mifepristone (brand name, Mifeprex), is an antiprogesterone, which starves the pregnancy. The second, misoprostol (brand name, Cytotec), a prostaglandin, causes the uterus to contract, which mechanically expels the fetus and placenta. The United States Food & Drug Administration (FDA) approved chemical abortion for the U.S. medical market in September 2000 and, since then, it has steadily and significantly increased as a percentage of all abortions.

Abortion advocates are now prioritizing chemical abortion to replace surgical abortion, which necessarily involves doctors, in order to de-medicalize abortion and exclude doctors entirely. The inherent risks of mifepristone and misoprostol include incomplete abortion, septic infection, and excessive hemorrhage. The inherent risks, combined with lax federal protection of women's health and a U.S. healthcare system that does not reliably track abortions or their complications, demonstrate that the states have compelling interests within their traditional police powers to protect women's health by prohibiting or regulating chemical abortion. The active promotion and proliferation of chemical abortion will be a significant challenge for state officials who wish to protect women's health and prenatal human beings after *Dobbs*.

AUTHOR

Senior Counsel, Americans United for Life. We are grateful to Ryan Desrosiers, Hugh Phillips, and Carolyn McDonnell, Esq. for excellent research assistance, to Regina Maitlen, Esq. for her review, and to Katie Glenn, Esq. for inspiration and encouragement. We thank Christopher Horton and numerous

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M.D. (University of Michigan). Dr. Harrison is a diplomate of the American Board of Obstetrics and Gynecology. She is currently CEO of the American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG). Dr. Harrison was a co-author of the 2002 Citizen Petition cited herein and filed by AAPLOG.

ARTICLE

STATE REGULATION OF CHEMICAL ABORTION AFTER *DOBBS*

Clarke D. Forsythe[†] & *Donna Harrison*, M.D.[††]

I. INTRODUCTION

Stories about pessaries, potions, herbs, or chemicals to *attempt* abortion, whether effective or not, have a long social and legal history.[1] Since the U.S. Food and Drug Administration (FDA) approved RU-486 for the medical marketplace in September 2000,[2] chemical or drug-induced abortion has reportedly become a greater percentage of all abortions in the United States.[3] Although named RU-486 by the French pharmaceutical company Roussel Uclaf, the FDA approved it in the U.S. as a two-drug regimen involving mifepristone (brand name, Mifeprex) and misoprostol (brand name, Cytotec).[4] Abortion advocates have long promoted a shift from surgical to

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[1] JOSEPH W. DELLAPENNA, DISPELLING THE MYTHS OF ABORTION HISTORY 37–51 (2006).

[2] *Mifeprex (mifepristone) Information* (Dec. 16, 2021), FDA, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information.

[3] *See* Katherine Kortsmit et al., *Abortion Surveillance—United States, 2019*, CTRS. FOR DISEASE CONTROL & PREVENTION MORBIDITY & MORTALITY WKLY. REP., Nov. 26, 2021, at 1, 1. The CDC estimated that, as of 2019, 43.7 percent of all abortions in the U.S. were chemical abortions. *See id.* at 6 (reporting that the number of chemical abortions increased by 12.5 percent between 2018 and 2019).

[4] Mary Davenport et al., *Embryo Survival After Mifepristone: A Systematic Review of the Literature*, 32 ISSUES L. & MED. 3, 4–7 (2017) (reviewing the history of development). Since RU-486 was named by Roussel Uclaf, numerous brand names, generic names, and labels have been used. We use the term "chemical" abortion for several practical and medical reasons. First, it clearly distinguishes the method from surgical abortion and allows that there may be additional chemical forms now or in the future. Second, both surgical and RU-486 abortion has some "medical" aspect, so "medical abortion" is not a clear descriptor. Third, RU-486 involves a two-drug regimen with two chemicals, mifepristone, an anti-progestin, and misoprostol, a prostaglandin, each of which has unique properties, effects, and risks. The risks of each need to be specifically examined as fully as possible if women are

chemical abortion.[5] Some are now promoting a misoprostol-only abortion.[6] Some are attempting to de-medicalize chemical abortion entirely and make it over-the-counter (OTC), do-it-yourself (DIY), or by mail-order, thereby eliminating physician involvement.

Mail-order and DIY abortions have obvious risks, as exemplified by the 2013 case of *Patel v. State*.[7] The Indiana Court of Appeals described the case:

> Thirty-two-year-old Purvi Patel managed her father's restaurant in Mishawaka[, Indiana]. A relationship with a restaurant employee resulted in her pregnancy. In June 2013, she purchased mifepristone and misoprostol online from a Hong Kong pharmacy and used those drugs to terminate the pregnancy at home. On the evening of July 13, she delivered a live baby of approximately twenty-five to thirty weeks gestation who died shortly after birth. She drove to the restaurant, put the baby in a nearby dumpster, and drove herself to the emergency room.[8]

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to give fully informed consent and if legislators are going to be sufficiently informed to adopt effective policy. Fourth, if the current plans of many abortion advocates to de-medicalize chemical abortion are realized, mifepristone and/or misoprostol may become over-the-counter (OTC) or do-it-yourself (DIY), doctors will be excluded, and "medical abortion" will no longer be meaningful. *See* VICE News, *Inside Texas's Underground Abortion Pill Network*, YOUTUBE (Feb. 9, 2022), https://www.youtube.com/watch?v=CR3uexqGgXo (discussing the use of misoprostol without physician involvement and the trafficking of misoprostol between Texas and Mexico). Some states also employ the term "chemical abortion." IDAHO CODE § 18-617(1)(b) (2022) (defining "chemical abortion").

[5] *See, e.g.*, Carrie N. Baker, *Self-Managed Abortion is Medically Very Safe. But is it Legally Safe?*, MS. (Apr. 1, 2020), https://msmagazine.com/2020/04/01/self-managed-abortion-is-medically-very-safe-but-is-it-legally-safe/. *See infra* notes 54, 132.

[6] *See* VICE News, *supra* note 4.

[7] Patel v. State, 60 N.E.3d 1041 (Ind. Ct. App. 2016).

[8] *Id.* at 1043. Indiana prosecutors charged Patel with violating two Indiana laws: a statute criminalizing the neglect of a dependent and a "feticide" statute, and the court stated that the "feticide" statute was not intended to regulate the unique legal and medical aspects of chemical abortion. *Id.* at 1044. The neglect statute had existed for decades. IND. CODE ANN. § 35-46-1-4 (2021). The "feticide" statute was first enacted in 1979, years before RU-486 was developed. *Patel*, 60 N.E.3d at 1058. A jury found Patel guilty of violating both statutes. *Id.* at 1044. At trial, there was evidence that Patel's baby was born alive. *Id.* at 1047–48, 1050. The question was whether Patel caused the death, and the appeals court held that the state did not prove beyond a reasonable doubt that Patel caused the death by failing to secure medical care for the baby. *Id.* at 1044. Since there was sufficient evidence of neglect, but not enough to prove it as the cause of death, the appeals court reduced the neglect charge. *Id.* at 1055. The court also held that the "feticide" statute could not be used against a woman for her own abortion because the Indiana legislature never intended the statute to apply to self-abortion, and the appeals court vacated Patel's "feticide" conviction. *Id.* at 1044.

State authority to specifically regulate and address the unique risks of chemical abortion has been tied up in litigation challenging the constitutionality of such regulations based on *Roe v. Wade*[9] and *Planned Parenthood v. Casey*.[10] The constitutionality of abortion regulations may change with the outcome of *Dobbs v. Jackson Women's Health Organization*, a case challenging the constitutionality of Mississippi's fifteen-week limit on abortion,[11] because the State of Mississippi has pressed the overruling of *Roe* and *Casey* in both briefs and oral argument. After *Dobbs*, the states may have greater authority to regulate or prohibit chemical abortion.

In this Article, we will start by providing an overview of chemical abortion, its nature, and its risks, as reflected in medical literature and governmental reports. Next, we will examine the lack of adequate federal governmental oversight since 2000. The FDA approved mifepristone and misoprostol in 2000 with limited restrictions, and the FDA loosened those restrictions in 2016, enabling doctors to prescribe abortion later in pregnancy and eliminating the reporting requirements for complications less than death.[12] In 2021, the FDA rescinded the in-person administration requirement that the FDA had required since 2000.[13] Given the vacuum of federal oversight, we will address the prospects for state regulation. As of 2022, few states have comprehensive regulations that specifically address the unique nature and risks of chemical abortion. Given the inherent medical risks of mifepristone and misoprostol and the history of inadequate federal oversight, the states have compelling interests in regulating mifepristone and misoprostol. These interests are strengthened by the prospect that chemical abortion will be increasingly available by mail-order for DIY abortions.

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[9] Roe v. Wade, 410 U.S. 113 (1973).

[10] Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833 (1992); *see* FDA v. Am. Coll. of Obstetricians & Gynecologists, 141 S. Ct. 10, 10–11 (2020) (granting stay of district court injunction). The unconstitutionality of federal in-person administration would obviously apply to similar state regulations. *See e.g.*, Planned Parenthood of the Heartland, Inc. v. Iowa Bd. of Med., 865 N.W.2d 252, 262–69 (Iowa 2015).

[11] Jackson Women's Health Org. v. Dobbs, 945 F.3d 265 (5th Cir. 2019), *cert. granted*, 141 S. Ct. 2619 (2021).

[12] Kathi A. Aultman et al., *Death and Severe Adverse Events After the Use of Mifepristone as an Abortifacient From September 2000 to February 2019*, 36 ISSUES L. & MED. 3, 23 (2021) ("In March 2016, the FDA substantially reduced the prescribing requirements and changed the drug protocol and yet at the same time eliminated reporting requirements except for deaths. With the later relaxation of reporting requirements, the ability to perform any relevant post-marketing evaluation of mifepristone was lost.").

[13] *See* Letter from Patrizia Cavazzoni, M.D., Dir. Ctr. Drug Evaluation & Rsch., FDA, to Graham Chelius, M.D., Soc'y. Fam. Plan. (Dec. 16, 2021), https://s3.documentcloud.org/documents/21155575/fda_letter_to_chelius.pdf.

II. THE DEVELOPMENT OF CHEMICAL ABORTION IN THE U.S.

A. *The Anglo-American Legal Heritage Protecting Prenatal Human Beings*

Evaluating state policy on abortion after *Dobbs* requires an understanding of the history of abortion law. The American colonies inherited and adopted the English common law protecting prenatal human lives from abortion and homicide.[14] Two common law rules governed: the quickening rule and the born alive rule.[15] The common law quickening rule was an evidentiary rule intended to establish sufficient proof that a woman was pregnant with a living child.[16] Under the rule, until a woman felt fetal movement (quickening), there was insufficient proof of a living child (and pregnancy).[17] Proof of a live pregnancy was necessary for a charge of abortion (terminating a pregnancy), but not sufficient to prove homicide of a prenatal child.

That was the purpose of the common law born alive rule, also an evidentiary rule.[18] Live birth was required for sufficient proof of homicide, the killing of a human being.[19] At a time of primitive medical understanding and a high infant mortality rate, if an infant was stillborn, the born alive rule prevented a charge of homicide because the law deemed there to be insufficient proof to distinguish between natural and criminal (human) causes of prenatal death.[20] An individual could be prosecuted for homicide only if the infant was born alive (observed outside the womb at any stage of pregnancy showing signs of life) and died thereafter from injuries inflicted while in utero (prenatal injuries).[21] A critical element of the born alive rule was that there was no gestational limit.[22] Neither

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[14] DELLAPENNA, *supra* note 1, at 211–28 (2006). Dellapenna stated: "We are left then with the conclusion that the English law regard ing [sic] abortion was fully received in the colonies, and that the purported 'common law liberty' to abort is a myth." *Id.* at 228. S*ee also* 2 JAMES WILSON, THE COLLECTED WORKS OF JAMES WILSON 1068 (Kermit L. Hall & Mark David Hall eds., 2007) ("With consistency, beautiful and undeviating, human life, from its commencement to its close, is protected by the common law. In the contemplation of law, life begins when the infant is first able to stir in the womb. By the law, life is protected not only from immediate destruction, but from every degree of actual violence, and, in some cases, from every degree of danger.").

[15] Clarke D. Forsythe, *Homicide of the Unborn Child: The Born Alive Rule and Other Legal Anachronisms*, 21 VAL. U. L. REV. 563, 567 (1987).

[16] *Id.* at 568.

[17] *Id.* at 567–68.

[18] *Id.* at 567.

[19] *Id.* at 575–76, 576 nn.59–60.

[20] *Id.* at 575.

[21] Forsythe, *supra* note 15, at 575–76.

[22] *Id.* at 591 & nn.132–34; *see* Regina v. West, 2 C. & K. 784, 175 Eng. Rep. 329 (1848) (allowing a homicide charge where an infant aborted alive died from prematurity); *see also* DELLAPENNA, *supra* note 1, at 464.

viability nor quickening limited the born alive rule.[23] Hence, the prosecution could bring a homicide charge if the child was injured at any time during pregnancy and then born alive before dying of injuries inflicted while in the womb.[24] This was equally true if the child was born alive early in gestation from a prenatal assault and then died from prematurity.[25] The born alive rule was a rule of location, not gestation.[26] And if the child was born alive, quickening was obsolete and no longer relevant. These common law rules protected the life of the developing prenatal human being from the earliest point that it could be determined to be alive.[27] By the time of *Roe*, state courts and legislatures had enhanced this common law protection through prenatal injury, wrongful death, and fetal homicide laws.[28]

These common law rules demonstrate that the law was dependent on the medical understanding at the time the law developed. Abortion law and medicine have always been inextricably intertwined. Medicine and technology affected the law's ability to prove a live pregnancy or the *corpus delicti* of homicide.[29] Contrary to folk tales, during the years of the common law there were no means of abortion that were both effective and safe.[30] Common law decisions and literature provide evidence that abortion providers attempted

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[23] DELLAPENNA, *supra* note 1, at 464 & n.85; Forsythe, *supra* note 15, at 591 & nn.132–37.

[24] *See* Forsythe, *supra* note 15, at 591 & nn.132–36.

[25] *Id.* The prenatal application of the born alive rule is confirmed by numerous authorities. *Id.* at 584, 583–84 n.92, 585, 586 n.106 (first quoting R. v. Sims (1600) 75 Eng. Rep. 1075, 1076; then quoting EDWARD COKE, THE THIRD PART OF THE INSTITUTES OF THE LAWS OF ENGLAND 50 (Garland Publ'g. 1979) (1628); then quoting 1 WILLIAM BLACKSTONE, COMMENTARIES *126; and then quoting 1 WILLIAM HAWKINS, A TREATISE OF THE PLEAS OF THE CROWN § 16 (Garland Publ'g. 1978) (1716)).

[26] *See id.* at 591 n.134 ("If a person intending to procure abortion causes a child to be born so soon that it cannot live, and it does in consequence, this is murder, though no bodily injury be inflicted on the child." (quoting 2 WILLIAM RUSSELL, A TREATISE ON CRIMES AND MISDEMEANORS 670–72 (Garland Publ'g. 1979) (1865))).

[27] *See id.* at 591 & nn.132–37.

[28] Paul Benjamin Linton, *The Legal Status of the Unborn Child Under State Law*, 6 U. ST. THOMAS J.L. & PUB. POL'Y 141, 143–50 (2011); William J. Maledon, Note, *The Law and the Unborn Child: The Legal and Logical Inconsistencies*, 46 NOTRE DAME LAW. 349, 356–58, 365–66 (1971).

[29] Forsythe, *supra* note 15, at 565–80.

[30] *See* DELLAPENNA, *supra* note 1, at 3–56. "[T]he ingestion and insertion techniques, if effective, appear to have been nearly as deadly as the batterings and other injury techniques." *Id.* at 31. "Ingestion techniques were nearly as painful and deadly as the worst injury techniques until well into the nineteenth century . . . ." *Id.* at 37. "American courts in [the] nineteenth century were well aware of the limited effectiveness of such 'potions' unless taken in doses dangerous to the health or the life of the mother." *Id.* at 49. "As we saw in chapter 1, abortion techniques were so crude before 1800 as virtually to amount to suicide . . . ." *Id.* at 57.

three types of abortion techniques—injury (battery), intrusion (an instrument), and ingestion (a potion or substance).[31] But there is no reliable evidence that any of the techniques were effective (producing a completed abortion) or safe (not killing the mother).[32] Abortion could not be considered safe if it killed the mother, as many potions and devices did.[33] Thus, most states enacted legislation prohibiting abortion with the intent to protect both mother and unborn child.[34]

Abortion techniques before the nineteenth century were both dangerous to the mother and minimally effective.[35] Then, with the distribution and wider usage of antibiotics after World War II—another example of technological change—and the introduction of new techniques, induced abortion became *less dangerous* for the mother around mid-century.[36] As Mary Calderone, then Medical Director for Planned Parenthood, noted in 1960, only 260 abortion-related deaths were reported in 1957.[37] Although virtually all states prohibited abortion except to save the life of the mother until 1966, several states loosened their abortion laws between 1967 and 1973.[38] Still, in the 1973 case of *Roe v. Wade*, the Supreme Court struck down the laws of all fifty states and legalized

[31] DELLAPENNA, *supra* note 1, at 31.

[32] *See id.*

[33] *See id.*

[34] *Id.* at 286 & n.198 (collecting cases explaining the purpose of nineteenth century state abortion laws). *See generally* James S. Witherspoon, *Reexamining* Roe*: Nineteenth Century Abortion Statutes and the Fourteenth Amendment*, 17 ST. MARY'S L.J. 29 (1985) (showing the protective purposes of nineteenth century abortion statutes).

[35] DELLAPENNA, *supra* note 1, at 454. *See also* Anita Bernstein, *Common Law Fundamentals of the Right to Abortion*, 63 BUFF. L. REV. 1141, 1193 (2015) ("Dellapenna argues persuasively that this combination [safety and effectiveness] did not come together until the nineteenth century.").

[36] DELLAPENNA, *supra* note 1, at 454.

[37] Mary Steichen Calderone, *Illegal Abortion as a Public Health Problem*, 50 AM. J. PUB. HEALTH 948, 949 (1960).

[38] *See* Roe v. Wade, 410 U.S. 113, 117–18, 140 & n.37 (1973).

abortion in every state, at every stage of gestation, for virtually any reason.[39] The States then had the burden to fill the legal vacuum created by *Roe v. Wade*.[40]

B. *The Concept of Elective Abortion & Informed Consent*

The Supreme Court in *Roe* assumed that legal abortion would involve a woman's regular physician in a medical decision about whether to have an abortion and that a medical judgment was always involved in deciding whether an abortion should be done.[41] But elective abortion in the U.S. has not turned out that way.[42] Elective abortion is significantly different from medically-

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[39] *See id.* at 162–64 (holding that the state has no interest in prohibiting abortion until the "compelling" point of viability and that abortion may be prohibited at viability unless abortion is necessary to preserve the life or health of the mother); Doe v. Bolton, 410 U.S. 179, 192 (1973) ("[A]ll factors -- physical, emotional, psychological, familial, and the woman's age -- [are] relevant to the well-being of the patient. All these factors may relate to health."); Laurence H. Tribe, *Foreword: Toward a Model of Roles in the Due Process of Life and Law*, 87 HARV. L. REV. 1, 2 (1973) ("And in *Roe v. Wade* and *Doe v. Bolton*, when the Court had its most dramatic opportunity to express its supposed aversion to substantive due process, it carried that doctrine to lengths few observers had expected, imposing limits on permissible abortion legislation so severe that no abortion law in the United States remained valid.").

[40] *See* CLARKE D. FORSYTHE, ABUSE OF DISCRETION: THE INSIDE STORY OF *ROE V. WADE* 217–18 (2013) ("The Public Health Vacuum the Justices Created").

[41] *See Roe*, 410 U.S. at 163 ("[F]or the period of pregnancy prior to this 'compelling' point, the attending physician, in consultation with his patient, is free to determine, without regulation by the State, that, in his medical judgment, the patient's pregnancy should be terminated."); *id.* at 165–66 ("The decision vindicates the right of the physician to administer medical treatment according to his professional judgment up to the points where important state interests provide compelling justifications for intervention. Up to those points, the abortion decision in all its aspects is inherently, and primarily, a medical decision, and basic responsibility for it must rest with the physician."); *Doe*, 410 U.S. at 208 (Burger, C.J., concurring) ("[T]he vast majority of physicians observe the standards of their profession, and act only on the basis of carefully deliberated medical judgments relating to life and health.").

[42] *See* City of Akron v. Akron Ctr. for Reprod. Health, 462 U.S. 416, 473 (1983) (O'Connor, J., dissenting) ("It is certainly difficult to understand how the Court believes that the physician-patient relationship is able to accommodate any interest that the State has in maternal physical and mental well-being in light of the fact that the record in this case shows that the relationship is non-existent."); Planned Parenthood of Cent. Mo. v. Danforth, 428 U.S. 52, 91 (1976) (Stewart, J., concurring) ("It seems unlikely that she [a pregnant minor] will obtain adequate counsel and support from the attending physician at an abortion clinic, where abortions for pregnant minors frequently take place."). *See generally* Mary Anne Wood & W. Cole Durham, Jr., *Counseling, Consulting, and Consent: Abortion and the Doctor-Patient Relationship*, 1978 BYU L. REV. 783, 793–802 (1978) (identifying as part of the doctor-patient relationship: screening, informing the patient as to the nature and consequences of the procedure, consideration of alternatives, and the conscious exercise of medical judgment).

indicated procedures. Elective abortion does not treat any illness or disease, and there is no *medical* reason to interrupt a healthy pregnancy in a healthy mother with surgery or drugs.[43] Elective abortion's primary objective is the death of the prenatal child, as evidenced by the testimony of abortion providers during the *Gonzales v. Carhart*[44] litigation.[45]

As with any medical intervention, there are both short-term and long-term risks and consequences. Any surgical procedure involves the risk of bleeding, infection, and damage to the organ being worked on or the organs nearby. A surgical abortion can damage any of the woman's reproductive organs. Because nearly one out of twenty women require surgery after a chemical abortion done at the earliest gestational ages (sometimes emergently), the risks of reproductive

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[43] *See, e.g.*, *Elective abortion*, BRITANNICA, https://www.britannica.com/science/elective-abortion (last visited Mar. 6, 2022) ("An elective abortion is the interruption of a pregnancy before the 20th week of gestation at the woman's request for reasons other than maternal health or fetal disease. Most abortions in the United States are performed for this reason."); *Elective abortion*, FARLEX, INC., https://medical-dictionary.thefreedictionary.com/elective+abortion (last visited Mar. 6, 2022) ("[E]lective abortion [is an] induced abortion done at the request of the mother for other than therapeutic reasons."); *Elective abortion*, FERTILITYPEDIA, https://fertilitypedia.org/edu/risk-factors/elective-abortion (last visited Mar. 6, 2022) ("An abortion is referred to as an elective or voluntary abortion when it is performed at the request of the woman for non-medical reasons.").

[44] *See* Gonzales v. Carhart, 550 U.S. 124, 168 (2007) (upholding the constitutionality of the federal Partial Birth Abortion Ban Act (PBABA)).

[45] *See id.* at 167–68. As the Court recorded in its opinion in *Gonzales*:

> Yet one doctor would not allow delivery of a live fetus younger than 24 weeks because "the objective of [his] procedure is to perform an abortion," not a birth. The doctor thus answered in the affirmative when asked whether he would "hold the fetus' head on the internal side of the [cervix] in order to collapse the skull" and kill the fetus before it is born. Another doctor testified he crushes a fetus' skull not only to reduce its size but also to ensure the fetus is dead before it is removed. For the staff to have to deal with a fetus that has "some viability to it, some movement of limbs," according to this doctor, "[is] always a difficult situation."

Id. at 139–40 (alterations in original) (citations omitted); *see also* Planned Parenthood Ass'n of Kan. City, Mo., Inc. v. Ashcroft, 462 U.S. 476, 483 n.7 (1983). The Court noted:

> His disinterest in protecting fetal life is evidenced by his agreement "that the abortion patient has a right not only to be rid of the growth, called a fetus in her body, but also has a right to a dead fetus." He also agreed that he "[never] [has] any intention of trying to protect the fetus, if it can be saved," and finally that "as a general principle" "[there] should not be a live fetus."

Id. (alterations in original) (citations omitted). *See generally* 18 U.S.C. § 1531.

organ damage from surgical intervention pertain to chemical abortions as well.[46] Worse, the risks of chemical abortions rise rapidly after ten weeks gestation so that abortions after thirteen weeks of pregnancy result in one out of every three women needing surgery for hemorrhage or tissue left inside.[47]

Elective abortion is not medical care but rather the use of surgery or drugs to end a pregnancy for social reasons.[48] The social reasons displace necessary medical analysis which examines the abnormal medical condition that requires treatment and medical indications for the intervention, compares the various alternative interventions, and discusses these with the patient.[49] It skews and short-cuts the decision-making and informed consent process.[50] Abortion providers often assume that the client has made the decision before walking into the clinic.[51] Because elective abortion is not medically necessary for anything, no discussion of alternatives are necessary, and no discussion of risks are relevant. By skewing and short cutting the decision-making process, elective abortion cannot produce fully informed consent for the woman.

1. The Discovery & Development of RU-486

Medical technology has long shaped the efficacy of abortion techniques, the enforceability of abortion law, and the language of abortion statutes.[52] Medical technology for terminating pregnancy has evolved from primitive methods to the development in France of the curved blade (curette) in the nineteenth century to the development in the 1960s of the flexible plastic suction curettage cannula.[53] This has led increasingly toward chemical

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[46] Maarit J. Mentula et al., *Immediate Adverse Events After Second Trimester Medical Termination of Pregnancy: Results of a Nationwide Registry Study*, 26 HUM. REPROD. 927, 929, 931 tbl. II (2011).

[47] *Id.*

[48] *See supra* note 43. And the presumed empirical evidence that abortion is good for women is, to say the least, thin. *See generally* Helen M. Alvare, *Nearly 50 Years Post-*Roe v. Wade *and Nearing its End: What is the Evidence that Abortion Advances Women's Health and Equality?*, 34 REGENT U. L. REV. 165 (2022).

[49] *See* Wood & Durham, *supra* note 42, at 793–800.

[50] *See id.*

[51] *See, e.g.*, *Government-Mandated Delays Before Abortion*, ACLU, https://www.aclu.org/other/government-mandated-delays-abortion (last updated Jan. 2003) ("In reality, almost all women, by the time they arrive at a clinic, are very clear about their reasons for wanting an abortion.").

[52] *See generally* DELLAPENNA, *supra* note 1, chs. 1, 5, 6, 12; Joseph W. Dellapenna, *The History of Abortion: Technology, Morality, and Law*, 40 U. PITT. L. REV. 359 (1979).

[53] Danielle B. Cooper & Gary W. Menefee, *Dilation and Curettage*, NCBI BOOKSHELF, https://www.ncbi.nlm.nih.gov/books/NBK568791/ (last updated Dec. 16, 2021) ("History documents the first cervical dilators available in the early 19th century. Joseph-Claude-

abortion, which abortion providers hope will increase access, eliminate the need for doctors, and allow DIY abortions.[54]

In the 1980s, a French chemist, Etienne-Emile Baulieu, worked at the pharmaceutical company Roussel Uclaf on a drug named RU-38486—later shortened to RU-486, generic name, mifepristone.[55] The drug blocked a specific cellular receptor called the glucocorticoid receptor.[56] This receptor blockade is important in treating Cushing's syndrome, the initial reason for pharmaceutical interest.

Mifepristone also blocks a second cellular receptor called the progesterone receptor, by binding with a woman's progesterone receptors on the nuclear membranes of cells in the uterus, ovary, brain, breast, and immune system.[57] Progesterone is the natural hormone which changes a woman's body to allow her to carry and nurture a pregnancy. With mifepristone blocking the connection of progesterone to progesterone receptors in the uterus of a pregnant woman, the mother's cells in the placenta stop functioning, which eventually leads to the death of the embryo through, in essence, starvation.[58]

Anthelme Récamier (6 November 1774–28 June 1852) is credited with the invention of the first curette in 1843, which resembled a small scoop or spoon with a long handle."); World Health Org. Task Force on Sequelae of Abortion, *Comparison of Rigid and Flexible Cannulae for Early Abortion without Cervical Dilatation*, 15 STUD. FAM. PLAN. 79, 79 (1984); Tanfer Emin Tunc, *Designs of Devices: The Vacuum Aspirator and American Abortion Technology*, 28 DYNAMIS 353, 370 (2008), https://scielo.isciii.es/pdf/dyn/v28/15.pdf.

[54] *See infra* notes 128, 129; *see also, e.g.*, Anastasia Toufexis, *Abortions Without Doctors*, TIME, Aug. 28, 1989, at 66; DELLAPENNA, *supra* note 1, at 831 & n.422 ("Despite all the hype, however, the approval of the abortion pill initially made little difference because few doctors were enthusiastic about using it."); *id.* at 670 (referring to "'underground' groups for performing abortions" in the 1960s; "'Jane' reached its stride when the women involved decided they could do the abortions themselves and dispense with physicians except as a backup. At its peak, between 1969 and 1973, 'Jane' was doing 3,000 abortions a year . . . .").

[55] *See* THE ANTIPROGESTIN STEROID RU 486 AND HUMAN FERTILITY CONTROL (Etienne-Emile Baulieu & Sheldon J. Segal eds., 1985) [hereinafter BAULIEU & SEGAL].

[56] Ralph P. Miech, *Pathophysiology of Mifepristone-induced Septic Shock Due to* Clostridium Sordellii, 39 ANNALS PHARMACOTHERAPY 1483, 1484 (2005), https://pubmed.ncbi.nlm.nih.gov/16046483/.

[57] *See generally* Katherine M. Scarpin et al., *Progesterone Action in Human Tissues: Regulation by Progesterone Receptor (PR) Isoform Expression, Nuclear Positioning and Coregulator Expression*, NUCLEAR RECEPTOR SIGNALING, Dec. 31, 2009, at 1 ("Progesterone is an essential regulator of normal human female reproductive function in the uterus, ovary, mammary gland and brain, and also plays an important role in non-reproductive tissues such as the cardiovascular system, bone and the central nervous system, highlighting the widespread role of this hormone in normal physiology.").

[58] U.S. H.R. GOV'T REFORM COMM., SUBCOMM. ON CRIM. JUST., DRUG POL'Y, & HUMAN RES., THE FDA AND RU-486: LOWERING THE STANDARD FOR WOMEN'S HEALTH 4 (2006)

When progesterone is insufficient, the woman loses the pregnancy. Baulieu realized that this new drug might be able to be developed as an abortifacient.[59] However, the blockade of glucocorticoid receptors also induces an unexpected immune blockade, suppressing the immune system, which can result in increased susceptibility to overwhelming infection.[60]

In the drug development process, Baulieu's report included a study which graphed the rate at which RU-486 could be removed from the progesterone receptor, in the presence of high concentrations of progesterone.[61] This pharmacokinetic study clearly shows that mifepristone's blockade of progesterone receptors is reversible—not permanent—and that high concentrations of progesterone will reverse the binding of mifepristone at the progesterone receptor.[62]

Scientists conducted additional animal model experiments to test the reversibility of mifepristone binding and to determine if natural progesterone could overcome the abortifacient effects in animal models. In 1989, Yamabe conclusively determined that, in rats, the administration of additional natural progesterone could overcome the mifepristone blockage of progesterone

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[hereinafter House Subcommittee Staff Report] ("RU-486 terminates pregnancy by blocking progesterone receptors in the uterus, a hormone necessary for the maintenance of pregnancy. This leads to degeneration of the uterine lining, blocking nutrition to the prenate, thus resulting in its death.").

[59] BAULIEU & SEGAL, *supra* note 55, at 14–15. *See generally* Etienne-Emile Baulieu, *Updating RU 486 Development*, 20 L. MED. & HEALTH CARE 154, 155–56 (1992).

[60] Jeanette I. Webster & Ester M. Sternberg, *Role of the Hypothalamic-Pituitary-Adrenal Axis, Glucocorticoids and Glucocorticoid Receptors in Toxic Sequelae of Exposure to Bacterial and Viral Products*, 181 J. ENDOCRINOLOGY 207, 207–17 (2004); Miech, *supra* note 56, at 1484; Marc Fischer et al., *Fatal Toxic Shock Syndrome Associated with* Clostridium Sordellii *after Medical Abortion*, 353 NEW ENG. J. MED. 2352, 2352–54, 2358 (2005) (reporting four deaths "after abortions that were medically induced with 200 mg of oral mifepristone and 800 ug of vaginal misoprostol"); House Subcommittee Staff Report, *supra* note 58, at 32–35.

[61] BAULIEU & SEGAL, *supra* note 55, at 91 fig.3.

[62] George Delgado & Mary Davenport, *Progesterone Use to Reverse the Effects of Mifepristone*, 46 ANNALS PHARMACOTHERAPY 1723, 1723 (2012) (case report); George Delgado et al., *A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone*, 33 ISSUES L. & MED. 21, 26, 27 tbl.1 (2018). *See also* Ruth Graham, A New Front in the War Over Reproductive Rights: 'Abortion-Pill Reversal,' N.Y. TIMES (July 18, 2017), https://www.nytimes.com/2017/07/18/magazine/a-new-front-in-the-war-over-reproductive-rights-abortion-pill-reversal.html ("'It makes biological sense,' says Dr. Harvey Kliman, director of the reproductive and placental research unit at the Yale School of Medicine. 'I think this is actually totally feasible.' Kliman, who has published research on progesterone and miscarriage, is in favor of abortion rights, and made clear he wasn't advocating widespread use of the treatment. But if one of his daughters came to him and said she had somehow accidentally taken mifepristone during pregnancy, he said, he would tell her to take 200 milligrams of progesterone three times a day for several days, just long enough for the mifepristone to leave her system. 'I bet you it would work.'").

receptors and its abortifacient properties.[63] That study separated pregnant rats into three groups. The first group received no drugs, the second group received mifepristone, and the third group received mifepristone followed by natural progesterone.[64] Every member of the no-drug group delivered live offspring.[65] Only 33.3% of the mifepristone-only group delivered live offspring.[66] One hundred percent of the third group, which received mifepristone and then progesterone, delivered live offspring.[67] This experiment effectively demonstrated that the mifepristone blockade can be overcome by the presence of sufficient natural progesterone to out-compete mifepristone at the progesterone receptor.[68]

Studies about the use of mifepristone to induce abortion in human beings show that the use of mifepristone alone at the current dosage used today (200 mg.) is associated with fetal survival rates from 10%–23%.[69] This fetal survival rate was considered unacceptable for an effective abortion-inducing drug.[70] Thus, early in the development of the current drug regimen scientists added a second drug, a prostaglandin, which is administered twenty-four to forty-eight hours after mifepristone. The prostaglandin induces powerful uterine contractions, which cause the expulsion of the fetus and placenta.[71] For pregnancies less than forty-nine days from the first day of the woman's last menstrual period (LMP), the combination of mifepristone and misoprostol causes the complete expulsion of both human embryo and placenta in about 95% of pregnancies.[72] However, this effectiveness declines significantly as the age of the pregnancy advances, such that by thirteen weeks, approximately one out of every three women who attempt abortion with mifepristone and misoprostol need emergency surgery for hemorrhage or retained tissue.[73]

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[63] Shingo Yamabe et al., *The Effect of RU486 and Progesterone on Luteal Function During Pregnancy*, PUBMED (May 20, 1989), https://pubmed.ncbi.nlm.nih.gov/2776921/. See the discussion of Yamabe in Davenport et al., *supra* note 4, at 5–6.

[64] *Id.*

[65] *Id.*

[66] *Id.*

[67] *Id.*

[68] *Id.* The progesterone infusion process is being challenged by the American Medical Association (AMA) in federal court litigation in North Dakota. Complaint at 1, 14–16, AMA v. Stenehjem, No. 1:19-cv-125 (D.N.D. June 25, 2019).

[69] Davenport et al., *supra* note 4, at 14–15 tbl.

[70] *Id.* at 4, 6.

[71] *Id.* at 4.

[72] Mentula et al., *supra* note 46, at 931 fig.2.

[73] *See id.*

2. FDA Approval of RU-486

The French pharmaceutical company Roussel Uclaf initially prohibited the commencement of any new studies in the United States and stated that "'under no circumstance[s]' would it permit a new drug application to be filed with [the] FDA."[74] However,

> [O]n January 22, 1993, President Clinton directed Department of Health and Human Services [] Secretary Donna Shalala to assess initiatives to promote the testing and licensing of mifepristone or other antiprogestins in the United States. . . . President Clinton reportedly "wrote to Hoechst asking the company to file a new drug application with the FDA (an unprecedented situation in the pharmaceutical industry!), which Hoechst intransigently refused to do."
>
> In early 1993, Secretary Shalala and FDA Commissioner David Kessler "communicated with senior Roussel Uclaf officials to begin efforts to pave the way for bringing RU-486 into the American marketplace." On May 16, 1994, the Population Council reached an agreement with Roussel Uclaf, pursuant to which the European drug maker transferred "without renumeration, its United States patent rights for mifepristone (RU-486) to the Population Council . . . ."[75]

On March 18, 1996, the Population Council/Planned Parenthood filed a new drug application (NDA) with the FDA.[76] However, to avoid legal liability, the Population Council transferred the rights to manufacture and distribute RU-486 to a shell company called Danco Laboratories, which was incorporated in the Cayman Islands.[77] Danco did not actually manufacture drugs, so Danco

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[74] Citizen Petition re: Request for Stay and Repeal of the Approval of Mifeprex (mifepristone) for the Medical Termination of Intrauterine Pregnancy Through 49 Days' Gestation at 8, FDA-2002-P-0364-0001 (Aug. 20, 2002) [hereinafter 2002 Citizen Petition], https://aaplog.org/wp-content/uploads/2021/01/2002-Aug-Citizen-Petition_Mifeprex-8.20.02.pdf.

[75] *Id.* at 8–9; *see also* Katharine Q. Seelye, *Accord Opens Way for Abortion Pill in U.S. in 2 Years*, N.Y. TIMES (May 17, 1994), https://www.nytimes.com/1994/05/17/us/accord-opens-way-for-abortion-pill-in-us-in-2-years.html (referring to the Clinton Administration's pressure on the manufacturer of RU-486 to apply for FDA approval).

[76] 2002 Citizen Petition, *supra* note 74, at 10.

[77] *See id.* at 9 & n.25; DELLAPENNA, *supra* note 1, at 831 ("Danco Laboratories, LLC, the company that undertook to market the drug, shrouded its activities and its very location in secrecy in an effort to insulate itself from anti-abortion protestors. Whether because of the

selected Hua Lian Pharmaceuticals, a Chinese drug manufacturer based in Shanghai, to manufacture the drug.[78] Shanghai Hua Lian Pharmaceuticals later faced scandal and factory closures due to tainted drugs.[79]

The FDA based mifepristone's approval on data from a single, non-blinded, uncontrolled study of the effectiveness of mifepristone in the United States conducted by the Population Council.[80] The FDA usually requires two blinded, randomized controlled trials as the basis of an NDA.[81] In an unusual move, the FDA not only allowed the one trial to serve as the sole study, but also admitted additional manufacturer's data, despite the fact that these data were impeached by falsified and incomplete records as discovered on an FDA review:

> The problems identified by the investigator suggested carelessness, fraud, evidence tampering and the systematic under-reporting of serious adverse events. The inspection "revealed a failure to maintain complete and accurate records." The violations that were discovered included: "laboratory reports that were missing" for 11 patients, "missing ultrasound documents" for 20 patients, "pages missing from the case record files and unreported aspirations [suction curettages]," inclusion of 4 ineligible patients, and "consent forms were dated after the start of study for some subjects, and the investigator had signed consent form[s] sometimes in advance, up to 4 days before the subjects had signed." . . . After elaborating on the deficiencies found, the FDA inspector

secrecy or because of fear for the profitability of the company, Danco had difficulty raising capital until it was rescued by a $10,000,000 loan, made on advantageous terms by the David and Lucille Packard Foundation.").

[78] 2002 Citizen Petition, *supra* note 74, at 9–10; Philip P. Pan, *Chinese to Make RU-486 for U.S.*, WASH. POST (Oct.12, 2000), https://www.washingtonpost.com/archive/politics/2000/10/12/chinese-to-make-ru-486-for-us/97e37b0f-a6fd-41f5-8ce3-d2af86adea63/.

[79] *SFDA Closes Down Shaghai Hualian Pharmaceutical*, PINK SHEET: INFORMA PHARMA INTEL. (Apr. 21, 2008), https://pink.pharmaintelligence.informa.com/SC068257/SFDA-Closes-Down-Shanghai-Hualian-Pharmaceutical; Jake Hooker & Walt Bogdanich, *Tainted Drugs Tied to Chinese Plant*, CHI. TRIB. (Jan. 31, 2008), https://www.chicagotribune.com/news/ct-xpm-2008-01-31-0801301033-story.html.

[80] Irving M. Spitz et al., *Early Pregnancy Termination With Mifepristone and Misoprostol in the United States*, 338 NEW ENG. J. MED. 1241, 1241–47 (1998); *see* House Subcommittee Staff Report, *supra* note 58, at 16–19.

[81] House Subcommittee Staff Report, *supra* note 58, at 15; *see* 21 U.S.C. § 355(d); 21 C.F.R. §§ 314.126(b)(2), (5); Jonathan J. Darrow, *Crowdsourcing Clinical Trials*, 98 MINN. L. REV. 805, 852 (2014) ("Under the current system, these trials generally (but not always) are randomized, controlled, and double-blinded.").

> concluded: "Notwithstanding these objectionable conditions, [redacted name of an FDA official] assured Dr. Aubeny that he would not recommend that the studies not be included in the evaluation of the NDA application."[82]

Irregularities in the approval process continued.

Although the Population Council filed an NDA with the FDA for approval of mifepristone as an abortifacient, it was clear that mifepristone must be used in conjunction with misoprostol, which was manufactured by Searle.[83] Searle opposed the use of its drug in conjunction with mifepristone as an abortifacient and did not file a Supplemental NDA for the use of misoprostol with mifepristone.[84] However, the FDA set an "extraordinary precedent" according to a former FDA general counsel[85] by requiring the unapproved use of misoprostol as part of the approval of RU-486,[86] a requirement which the FDA had uncertain authority to mandate.[87] Further, the FDA inexplicably waived the Pediatric Rule, which required testing of drugs intended for use in the pediatric population.[88]

In addition, the review process itself was truncated. The FDA initially began a standard review, but later decided to grant an accelerated approval process under Subpart H.[89] By 2000, the FDA announced that it had "considered this application under the restricted distribution regulations contained in 21 CFR 314.500 (Subpart H) and [had] concluded that restrictions as per [21] CFR

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[82] 2002 Citizen Petition, *supra* note 74, at 40–41.

[83] *Id.* at 10, 41–42.

[84] *Id.* at 42 & n.190 ("Searle wrote an open letter to all health care practitioners stating that 'Cytotec is not approved for the induction of labor or abortion.' The letter listed a number of potential '[s]erious adverse events reported following off-label use of Cytotec in pregnant women includ[ing] maternal or fetal death.'"); House Subcommittee Staff Report, *supra* note 58, at 24 n.113 (citing Searle letter).

[85] House Subcommittee Staff Report, *supra* note 58, at 23.

[86] *Id.* ("When FDA approved the Population Council's RU-486 application it also mandated the use of another drug, misoprostol, as part of a two-drug regimen. The use of misoprostol was not only an unapproved or off-label use – it was actually contraindicated at that time."); Rachel Zimmerman, *FDA-Pharmacia Clash May Curb The Widespread Use of RU-486*, WALL ST. J. (Oct. 18, 2000, 12:01 AM), https://www.wsj.com/articles/SB971827114427477389.

[87] House Subcommittee Staff Report, *supra* note 58, at 23–25 (addressing lack of FDA authority); 2002 Citizen Petition, *supra* note 74, at 43–45; Lars Noah, *A Miscarriage in the Drug Approval Process: Mifepristone Embroils the FDA in Abortion Politics*, 36 WAKE FOREST L. REV. 571, 590 (2001) ("Normally, the agency has no power to demand that manufacturers add expanded indications to their drug labeling.").

[88] 2002 Citizen Petition, *supra* note 74, at 76–77.

[89] 21 C.F.R. §§ 314.500–314.560 (Subpart H); DELLAPENNA, *supra* note 1, at 830; Noah, *supra* note 87, at 580–81, 581 n.43; 2002 Citizen Petition, *supra* note 74, at 10 n.30.

314.520 on the distribution and use of mifepristone are needed to assure safe use of this product."[90] The FDA further explained that approval under Subpart H "applies when [the] FDA concludes that a drug product shown to be effective can be safely used only if distribution or use is restricted, such as to certain physicians with certain skills or experience."[91] In fact, Subpart H was the only mechanism the FDA had at the time to impose post-marketing restrictions on the use of the drug,[92] and some of these restrictions were later codified as the Risk Evaluation and Mitigation Strategy (REMS) for mifepristone, with Elements to Assure Safe Use (ETASU).

The intent behind Subpart H was to accelerate the approval of drugs effective for treating "serious or life-threatening illnesses."[93] According to the FDA's self-reported data, by early 2002, the FDA had approved only thirty-eight NDAs under Subpart H.[94] "Of these approvals, 20 were for the treatment of HIV and HIV-related diseases, nine were for the treatment of various cancers and their symptoms, four were for severe bacterial infections, one was for [leprosy], one was for hypotension, and, finally, one was for" the deliberate destruction of prenatal human beings—mifepristone.[95] However, it is clear that pregnancy is not a disease, but rather a normal physiological process in which two human beings are in a symbiotic, biological relationship. Elective abortion does not "treat[] . . . serious or life-threatening disease."[96] From beginning to end, the FDA's approval of mifepristone represented a serious miscarriage in the drug approval process.[97]

3. Post-Marketing Restrictions

The irregularities continued after FDA approval. Despite the fact that the FDA established post-marketing restrictions on the use of RU-486, abortion

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[90] 2002 Citizen Petition, *supra* note 74, at 11.

[91] *Id.*

[92] 2002 Citizen Petition, *supra* note 74, at 23.

[93] *See* New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval, 57 Fed. Reg. 58942-01 (Dec. 11, 1992) (codified as amended at 21 C.F.R. § 314.500) ("treating serious or life-threatening illnesses"); *see also* Sheila R. Shulman & Jeffrey S. Brown, *The Food and Drug Administration's Early Access and Fast-Track Approval Initiatives: How Have They Worked?*, 50 FOOD & DRUG L.J. 503, 503–04, 503–04 n.5 (1995); House Subcommittee Staff Report, *supra* note 58, at 20.

[94] 2002 Citizen Petition, *supra* note 74, at 19, 19 n.74.

[95] *Id.* at 19.

[96] New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval, 57 Fed. Reg. 58942-01 (Dec. 11, 1992) (codified as amended at 21 C.F.R. § 314.500); House Subcommittee Staff Report, *supra* note 58, at 20.

[97] *See* Noah, *supra* note 87, at 571–73.

advocates exhibited no sign that they would comply with FDA restrictions.[98] Even the then-president of Danco Laboratories, Dr. Richard Hausknecht was advertising the home administration of misoprostol and vaginal administration of mifepristone on his website within weeks of the FDA approval.[99] Both of Dr. Hausknecht's recommendations were contravened by the FDA post-marketing restrictions.[100] The FDA was aware of this breach but took no action. Years later, the FDA codified some of the post-marketing restrictions as a REMS with ETASU. This allowed the FDA to theoretically impose financial sanctions for noncompliance. But to date, no financial sanctions have ever been imposed, despite the fact that non-compliance with the FDA REMS was the rule for the abortion industry.

In 2002, a Citizen Petition was filed with the FDA documenting the aberrant drug approval process and the predictable risks of hemorrhage and infection.[101] The FDA did not respond for fourteen years.[102] By 2005, five women had died in North America from an overwhelming septic infection caused by a common soil bacteria called *Clostridium sordellii* (abbreviated *C. sordellii*).[103] These unexpected, yet predictable deaths caught Danco and the Population Council in the midst of their non-compliance.[104] As noted earlier, studies have shown that both mifepristone[105] and misoprostol[106] suppress a woman's immune response to infection, which can allow simple infections to become overwhelming, leading to fatal sepsis. After the deaths of at least four otherwise healthy women from fatal sepsis within two weeks of the use of

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[98] 2002 Citizen Petition, *supra* note 74, at 71–72.

[99] *Id.* at 71 n.309.

[100] *Id.*

[101] *Id.* at 1, 3; DEP'T OF HEALTH & HUM. SERVS., FDA-2002-P-0364-0002, CITIZEN DENIAL RESPONSE FROM FDA CDER TO THE AMERICAN ASSOCIATION OF PRO LIFE OBSTETRICIANS AND GYNECOLOGISTS, ET AL. 1 (2016).

[102] DEP'T OF HEALTH & HUM. SERVS., *supra* note 101, at 1.

[103] Dep't of Health & Hum. Servs., Ctr. for Disease Control & Prevention, U.S. Food & Drug Admin., Nat'l. Inst. of Health, Emerging Clostridial Disease Workshop 4, 78–80 (May 11, 2006), https://aaplog.wildapricot.org/resources/2006%20CDC%20FDA%20Clostridial%20Disease%20Transcript.pdf; Public Notice of Emerging Clostridial Disease Workshop, 71 Fed. Reg. 7778–79 (Feb. 14, 2006).

[104] *See* 2002 Citizen Petition, *supra* note 74, at 65–66, 66 n.290.

[105] *See* Jeanette I. Webster & Ester M. Sternberg, *Role of the Hypothalamic-Pituitary-Adrenal Axis, Glucocorticoids and Glucocorticoid Receptors in Toxic Sequelae of Exposure to Bacterial and Viral Products*, 181 J. ENDOCRINOLOGY 207, 212, 217 (2004); *see also* Miech, *supra* note 56, at 1487.

[106] David M. Aronoff et al., *Misoprostol Impairs Female Reproductive Tract Innate Immunity Against* Clostridium Sordellii, 180 J. IMMUNOLOGY 8222, 8229 (2008).

mifepristone—all had used the off-label vaginal administration of misoprostol instead of the oral (buccal (pronounced "buckle")) administration required by the FDA—the FDA and the Centers for Disease Control and Prevention (CDC) convened a special meeting in May 2006 to investigate the use of mifepristone in relationship to the septic deaths.[107] In fact, the concern about serious infections led Planned Parenthood to abandon the off-label vaginal administration of misoprostol and substitute instead the off-label use of misoprostol in the cheek (buccal administration).[108] However, deaths from *Clostridium sordellii* continue with the current use of buccal administration.[109]

In October 2006, the U.S. House Subcommittee on Criminal Justice, Drug Policy, and Human Resources held a special hearing to investigate the FDA's handling of mifepristone's approval and lack of post-marketing surveillance.[110] The 40-page Staff Report concluded that the FDA had been deficient in handling both the approval of mifepristone and the surveillance of the drug's post-marketing complications.[111]

In 2016, the FDA relaxed the initial post-marketing restrictions imposed in 2000.[112] On the same day, the FDA also finally answered the Citizen Petition filed in 2002 that documented the irregularities of the approval and post-marketing use and requested the repeal of the approval.[113] Remarkably, the FDA did not contest the substantial findings of the Petition, but simply dismissed by fiat the documented concerns.[114] In relaxing the restrictions in 2016, the FDA no longer required prescribers to submit Adverse Event

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[107] Dep't of Health & Hum. Servs., Ctr. for Disease Control & Prevention, U.S. Food & Drug Admin., Nat'l. Inst. of Health, Emerging Clostridial Disease Workshop 4, 78–80 (May 11, 2006), https://aaplog.wildapricot.org/resources/2006%20CDC%20FDA%20Clostridial%20Disease%20Transcript.pdf; Public Notice of Emerging Clostridial Disease Workshop, 71 Fed. Reg. 7778–79 (Feb. 14, 2006).

[108] Mary Fjerstad et al., *Rates of Serious Infection After Changes in Regimens for Medical Abortion*, 361 NEW ENG. J. MED. 145, 145 (2009).

[109] U.S. FOOD & DRUG ADMIN., MIFEPRISTONE U.S. POST-MARKETING ADVERSE EVENTS SUMMARY THROUGH 12/31/2018 (2019), https://www.fda.gov/media/112118/download.

[110] House Subcommittee Staff Report, *supra* note 58, at 3. The May 17, 2006, hearing before the House Subcommittee is available at: https://www.govinfo.gov/content/pkg/CHRG-109hhrg31397/html/CHRG-109hhrg31397.htm (transcript).

[111] *Id.* at 38, 40.

[112] Aultman et al., *supra* note 12, at 23–24, 24 nn.47–48.

[113] DEP'T OF HEALTH & HUM. SERVS., *supra* note 101, at 1.

[114] *See id.*

Reports and only required the reporting of deaths.[115] As expected, the number of Adverse Event Reports dropped precipitously after prescribers were no longer required to report hospitalizations, hemorrhages, transfusions, surgeries, ongoing pregnancies, or any other complication except death.[116] This change conveniently obscured any ability to trace the impact of the other changes the FDA made to the use of mifepristone, such as the expansion of use from forty-nine to seventy days gestation and the allowance of abortion providers to not check to ensure the complete passage of tissue (a completed abortion).[117]

In 2017, Graham Chelius, an individual provider, sued the FDA demanding the removal of REMS from mifepristone as violative of the Administrative Procedures Act (APA) and the Fifth Amendment to the U.S. Constitution.[118] In 2020, the American College of Obstetricians & Gynecologists (ACOG)[119] also sued the FDA demanding the removal of the REMS entirely from mifepristone, this time under the guise of COVID-19. However, abortion advocates had been working for years prior to the COVID-19 pandemic to completely de-medicalize mifepristone, with the end goal being over-the-counter access to mifepristone.[120] This would eliminate the "obstacle" of conscientious objection by healthcare professionals and effectively nullify many laws regulating abortion throughout the United States.

Drugs with REMS cannot be sold over-the-counter. Elimination of the REMS would allow mifepristone and misoprostol to be sold over-the-counter.[121] In October 2020, the Supreme Court suspended an injunction by

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[115] Aultman et al., *supra* note 12, at 23–24.

[116] *Id.*

[117] *Id.* at 6–7.

[118] Complaint at 9, 62, Chelius v. Wright, No. 1:17-cv-00493 (D. Haw. Oct. 3, 2017).

[119] Complaint at 2–4, Am. Coll. of Obstetricians & Gynecologists v. FDA, No. 8:20-cv-01320 (D. Md. May 27, 2020).

[120] *See, e.g.*, Univ. Cal. S.F., *Over-the-Counter Medication Abortion*, ANSIRH, www.ansirh.org/research/ongoing/over-counter-medication-abortion (last visited Jan. 29, 2022); Renee B. Sherman & Daniel Grossman, *The FDA Didn't Liberate Abortion—But We Still Can*, NATION (Dec. 17, 2021), https://www.thenation.com/article/society/fda-abortion-pill/; Carrie N. Baker, *FDA Lifts Some Abortion Pill Restrictions, Leaves Others in Place*, MS. MAG. (Dec. 17, 2021), https://msmagazine.com/2021/12/17/fda-abortion-pill-medication-biden-mifepristone/; R. Alta Charo, *A Political History of RU-486*, *in* BIOMEDICAL POLITICS 48 (Kathi E. Hanna ed., 1991) ("The drug offers the prospect of performing abortions in any physician's office and even at home. The prospect of eliminating abortion clinics . . . has made feminists enthusiastic supporters of the drug.").

[121] *Frequently Asked Questions (FAQs) About REMS*, FDA, https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/frequently-

a federal district court and left in place the part of the REMS requiring in-person administration of mifepristone by a physician.[122] However, after the Biden Administration took office, the FDA suspended the requirement in December 2021.[123]

In summary, the FDA's approval of mifepristone was fraught with irregularities including: the accelerated approval under Subpart H which was intended solely for drugs that treat "serious or life-threatening conditions"; the inexplicable waiver of the Pediatric Rule which requires testing in the population of women under 18; the unprecedented requirement of Cytotec as part of the abortion regiment despite the objections of the manufacturer; and the unlawful waiver of the two blinded, controlled trials requirement. After approval, the FDA failed to enforce post-marketing restrictions despite the fact that abortion providers began violating those restrictions within weeks of approval and after the off-label vaginal use of the second drug, misoprostol, resulted in the deaths of women from a deadly infection. The FDA continued to relax restrictions on mifepristone use without any reliable mechanism of verifying either complications or deaths. In fact, by removing the adverse event reporting requirement for prescribers in 2016, the FDA guaranteed that data on adverse events would not be collected or reported.[124] Then, in 2021, the FDA made the unprecedented decision to no longer require that a woman be examined by a competent medical professional before being given mifepristone.[125] That in-person exam is the only opportunity to rule out an ectopic (outside the uterus) pregnancy.[126] An in-person exam is also necessary to accurately determine gestational age, administer Rhogam for women with Rh negative blood types, and to screen for coercion and abuse. The FDA has abandoned its responsibility to minimize the risks to women from chemical abortion.

III. THE LIMITS OF FEDERAL APPROVAL & OVERSIGHT OF CHEMICAL ABORTION

A. *Abortion in a Post-*Roe *World*

asked-questions-faqs-about-rems (Jan. 26, 2018) ("REMS do not apply to over-the-counter (OTC) medications.").

[122] FDA v. Am. Coll. of Obstetricians & Gynecologists, 141 S. Ct. 578, 578 (2021).

[123] Letter from Patrizia Cavazzoni to Graham Chelius, *supra* note 13.

[124] Aultman et al., *supra* note 12, at 6–7.

[125] *See id.*

[126] Mifepristone is contraindicated for ectopic pregnancy; it cannot treat an ectopic pregnancy and may mask the symptoms, leading to the risk of life-threatening complications. Aultman et al., *supra* note 12, at 21–22; *see also* House Subcommittee Staff Report, *supra* note 58, at 4–5.

The Supreme Court's decision in 2021 to hear the case of *Dobbs v. Jackson Women's Health Organization*,[127] a direct challenge to *Roe v. Wade*, will likely spur abortion advocates to accelerate their drive toward complete de-medicalization of mifepristone. There are more than seventy websites where a woman can order abortion pills without any physician involvement.[128] In 2021, the FDA replied to the Chelius and ACOG suits by announcing that the FDA would no longer enforce the in-person requirement, thereby allowing the distribution of abortion drugs by mail.[129]

The implications of the FDA deciding to relax its requirements are significant. The average American woman will now not know the risks of this drug. If she has a complication, it will not be tracked, analyzed, or anonymously reported to public health agencies. Complications will certainly occur, and increase, because women can now use the drug at advanced gestational ages. This also has serious implications for the risk of coerced abortion. Currently, there is no meaningful or effective way to prevent bad actors like disgruntled boyfriends, pimps, sex traffickers, or abusers from ordering mifepristone.[130] Women and girls forced into sex trafficking, and those who choose to work as prostitutes, may experience forced abortion. The risk for coerced abortion using online abortifacient drugs is significant.[131]

But the implications do not end there. If the complication rate increases from DIY abortions, it may be attributed to state limits on abortion, rather

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[127] Dobbs v. Jackson Women's Health Org., 141 S. Ct. 2619, 2619–20 (2021).

[128] *Fact Sheet: Online Sales of Mifeprex and Misoprostol for Self-Abortion*, CHARLOTTE LOZIER INST. (Apr. 23, 2018), https://lozierinstitute.org/fact-sheet-online-sales-of-mifeprex-and-misoprostol-for-self-abortion/.

[129] Letter from Janet Woodcock, M.D., Acting Comm'r Food & Drugs, U.S. Food & Drug Admin., to Maureen G. Phipps, M.D., CEO, Am. Coll. of Obstetricians & Gynecologists & William Grobman, M.D., President, Soc'y Maternal-Fetal Med. (Apr. 12, 2021), https://www.aclu.org/sites/default/files/field_document/fda_acting_commissioner_letter_to_acog_april_12_2021.pdf; *see also* Letter from Patrizia Cavazzoni to Graham Chelius, *supra* note 13; Kate Smith, *Biden Administration to Lift Abortion Pill Restriction Amid Pandemic*, CBS NEWS (April 13, 2021, 11:30 AM), https://www.cbsnews.com/news/abortion-pill-restrictions-lifted-pandemic-fda/ (quoting statement by ACOG CEO Maureen G. Phipps that "the in-person dispensing requirement for mifepristone is unnecessary and restrictive").

[130] AM. ASS'N OF PRO-LIFE OBSTETRICIANS & GYNECOLOGIST & AM. COLL. OF PEDIATRICIANS, JOINT COMMITTEE OPINION PORNOGRAPHY, SEX TRAFFICKING AND ABORTION 1, 8 (2019) [hereinafter JOINT COMMITTEE OPINION]; *see generally* Catherine T. Coyle et al., *The Relationship of Abortion and Violence Against Women: Violence Prevention Strategies and Research Needs*, 30 ISSUES L. & MED. 111, 114–15, 117 (2015).

[131] *See* JOINT COMMITTEE OPINION, *supra* note 130, at 8. *See generally* Coyle et al., *supra* note 130, at 114–15, 117. Some states prohibit coerced abortion. *See, e.g.*, IDAHO CODE § 18-615 (2022) (prohibiting coerced abortion); WIS. STAT. § 253.10(3)(b), (3)(c) (2021).

than the increase in DIY abortions.[132] The challenge to state legislators, law enforcement, and public health officials will be obvious.

B. *Lack of Adequate Abortion Data Collection Analysis & Reporting in the U.S.*

The FDA approved RU-486 for the U.S. medical market without any reliable national system of abortion data collection, reporting, and analysis. The Supreme Court issued *Roe* in 1973 without such a reliable system in the U.S., and none exists today. There is no federal law mandating the collection and reporting of abortion data from states or abortion providers. The Supreme Court invalidated state reporting laws in *Thornburgh v. American College of Obstetricians and Gynecologists*.[133] Only two organizations in the U.S. collect and report national abortion data, and the collection and reporting from both is terribly flawed and incomplete. The Guttmacher Institute is a private, abortion-advocacy organization, which collects data directly from abortion providers, but that reporting is voluntary. Only 40%–50% of clinics report data in any given year.[134] The U.S. Centers for Disease Control and Prevention (CDC) collects data from the states; that reporting is also voluntary, and not all states report their data.[135] California is the most significant state that has not reported its abortion data to the CDC in many years. Since "nearly a quarter" of all induced abortions in the U.S. are done in California, "much of the data regarding induced abortion is entirely immune to analysis."[136] The voluntary and inconsistent nature of abortion reporting from the states makes the CDC's annual report incomplete at best and skewed by selective reporting at worst. Consequently, the annual number of abortions reported by the CDC is merely an *estimate*. The annual number

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[132] *See, e.g.*, ROBIN MARTY, NEW HANDBOOK FOR A POST-*ROE* AMERICA 153 (2nd ed. 2021) ("What to Know About Self-Managed Abortion Care with Abortion Pills and/or Herbs"); Baker, *supra* note 120; Amelia Butterly et al., *100 Women: The Modern Face of the 'DIY Abortion'*, BBC (June 6, 2018), https://www.bbc.com/news/world-44089526.

[133] Thornburgh v. Am. Coll. of Obstetricians & Gynecologists, 476 U.S. 747, 765–68 (1986) (invalidating § 3214 and § 3211 of Pennsylvania's reporting requirements), *overruled by* Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833 (1992).

[134] Rachel K. Jones et al., *Abortion in the United States: Incidence and Access to Services, 2005*, 40 PERSP. ON SEXUAL & REPROD. HEALTH 6, 7, 15–16 (2008) (collecting data from responses to mailed questionnaires and recognizing limitations of failing to identify certain abortion providers and other abortion providers failing to respond or submitting incomplete responses).

[135] *See* Burk Schaible, *Improving the Accuracy of Maternal Mortality and Pregnancy Related Death*, 29 ISSUES L. & MED. 231, 232 (2014).

[136] Schaible, *supra* note 135, at 232.

of abortions reported by the CDC and the AGI differs by 15% or more.[137] Americans cannot reliably know the annual number of abortions, nor the number or rate of complications for surgical or chemical abortions.

In addition, accurate abortion collection and reporting is necessary to accurately compare maternal death from abortion with death from childbirth, but this "remains an impossible task given the current limitations within the CDC *Abortion Mortality Surveillance System and* [the World Health Organization's] *International Statistical Classification of Diseases and Related Health Problems (ICD).*"[138] Unfortunately, "[t]hese systems lack a systematic and comprehensive method of collecting complete records regarding abortion outcomes in each state," and "the ICD-10 classification does not identify the most proximal causes of death related to induced abortion."[139] The CDC admits that reporting abortion-related deaths is "not federally mandated."[140] Thus, no valid comparison can be made between deaths from abortion and deaths from childbirth, making the common claim that "abortion is safer than childbirth" scientifically unsupportable.[141]

Consequently, there is an inability to reliably track abortion complications in the United States. Because there is no reliable national number of abortions, but rather, simply estimates, there is no reliable national number or rate of complications. Thus, women cannot receive accurate data on complication rates, and it is doubtful that they are ever informed about the lack of reliable data. Without accurate data on the risks of an abortion procedure, patients cannot be fully informed or truly give informed consent.[142] Data also are

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[137] *See* Karen Pazol et al., *Abortion Surveillance—United States, 2008*, CTRS. FOR DISEASE CONTROL & PREVENTION MORBIDITY & MORTALITY WKLY. REP.: SURVEILLANCE SUMMARIES, Nov. 25, 2011, at 1, 10.

[138] *Id.*; *see also* WORLD HEALTH ORG., 2 ICD-10: INTERNATIONAL STATISTICAL CLASSIFICATION OF DISEASES AND RELATED HEALTH PROBLEMS 99 (10th rev. 2d ed. 2004), https://apps.who.int/iris/bitstream/handle/10665/42980/9241546530_eng.pdf?sequence=1&isAllowed=y.

[139] Schaible, *supra* note 135, at 238–39.

[140] Tara C. Jatlaoui et al., *Abortion Surveillance—United States, 2016*, CTRS. DISEASE CONTROL & PREVENTION MORBIDITY & MORTALITY WKLY. REP.: SURVEILLANCE SUMMARIES, Nov. 29, 2019, at 1, 37 tbl.17.

[141] *See* Schaible, *supra* note 135, at 232; Clarke D. Forsythe & Bradley N. Kehr, *A Road Map Through the Supreme Court's Back Alley*, 57 VILL. L. REV. 45, 60–62 (2012) (comparing the published abortion mortality rate and the childbirth mortality rate); Brief for the American Center for Law and Justice et al. as Amici Curiae Supporting Petitioner at *27, Gonzales v. Planned Parenthood Fed'n of Am., 547 U.S. 1205 (2006) (No. 05-1382), 2006 U.S. S. Ct. Briefs LEXIS 613.

[142] *See* Clarke D. Forsythe & Rachel N. Morrison, *Stare Decisis, Workability, and* Roe v. Wade*: An Introduction*, 18 AVE MARIA L. REV. 48, 77–85 (2020) (providing a more detailed analysis of this problem).

unavailable or incomplete because of the number of patients who fail to return for follow-up examinations.[143] The lack of completed patient follow-up visits impedes accurate reporting of latent complications and adverse events.

Finally, the FDA administers an FDA Adverse Event Reporting System (FAERS) that covers mifepristone abortions, though it too is seriously compromised in its efficacy and accuracy.[144] The FAERS system detects only a small proportion of adverse events that actually occur, as documented in a recent publication by Cirucci, Aultman, and Harrison:

> There is also concern that the FDA will continue to rely on the FAERS to make decisions about removing mifepristone REMS, despite the findings herein that FAERS does not include all the events even known to the abortion provider. To compound this problem, in 2016, the FDA eliminated the requirement to report adverse events resulting from mifepristone other than death. Nevertheless, in her April 12, 2021[,] letter to the American College of Obstetricians and Gynecologists, FDA Commissioner Janet Woodcock stated that, based on a review of post-marketing AEs from January 27, 2020, to January 12, 2021, the in-person dispensing requirements in the mifepristone REMS would not be enforced. It is alarming that policy decisions that affect women's safety are based on a lack of information in the FAERS. Whether the inaccuracy of FAERS extends to required reporting for other medications is unknown to us, but the findings in this paper have significant implications for drug safety evaluation in general.[145]

The FDA requires manufacturers and doctors to follow the REMS in their provision of mifepristone and misoprostol.[146] The FDA emphasized that "[i]n

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[143] Aultman et al., *supra* note 12, at 22–24.

[144] *See id.* at 8–10, 22–24; Christina A. Cirucci et al., *Mifepristone Adverse Events Identified by Planned Parenthood in 2009 and 2010 Compared to Those in the FDA Adverse Event Reporting System and Those Obtained Through the Freedom of Information Act*, 8 HEALTH SERVS. RSCH. & MANAGERIAL EPIDEMIOLOGY 1, 1 (2021).

[145] Cirucci et al., *supra* note 144, at 3 (footnotes omitted).

[146] U.S. FOOD & DRUG ADMIN., RISK EVALUATION AND MITIGATION STRATEGY (REMS) SINGLE SHARED SYSTEM FOR MIFEPRISTONE 200MG (Apr. 2019), https://www.accessdata.fda.gov/drugsatfda_docs/rems/mifepristone_2019_04_11_REMS_Document.pdf.

some cases[,] very heavy vaginal bleeding will need to be stopped by a surgical procedure, which can often be performed in a healthcare provider's office."[147]

Contrast the U.S. with other nations. For example, Scandinavian countries have a national registry that thoroughly records abortions and collects, analyzes, and reports data for public health purposes.[148] They have more reliable data because they pay for and track abortions. They have a registry that the U.S. lacks.[149] Those nations have better abortion data recording and stronger safety controls on distribution and administration of RU-486. In France, in 1992, the process of administering RU-486 involved four visits with a physician.[150] France also required a "one week [] reflection" period and carefully controlled distribution.[151]

For these reasons, international data may be more reliable than domestic data in assessing the risks of mifepristone and misoprostol. A 2009 study found that chemical abortion had higher complication rates than surgical abortion.[152] There are numerous international, peer-reviewed studies of women finding an increased risk of preterm birth after abortion,[153] an increased risk of mental trauma after abortion,[154] and an increased risk of breast cancer after abortion.[155] There is also evidence of an increased risk of preterm birth in the one out of five women who require a surgical completion after chemical abortion.[156]

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[147] *Questions and Answers on Mifeprex*, FDA, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex (Dec. 16, 2021).

[148] Schaible, *supra* note 135, at 232–33 (citing countries).

[149] *Id*.

[150] Baulieu, *supra* note 59, at 154.

[151] *Id.*

[152] Maarit Niinimäki et al., *Immediate Complications After Medical Compared with Surgical Termination of Pregnancy*, 114 OBSTETRICS & GYNECOLOGY 795, 795 (2009).

[153] *Practice Guideline 11: A Detailed Examination of the Data on Surgical Abortion and Preterm Birth*, AM. ASS'N PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS, Nov. 2021, at 1, 1, https://aaplog.org/wp-content/uploads/2021/11/PG-11-A-Detailed-Examination-of-the-Data-on-Surgical-Abortion-and-Preterm-Birth.pdf.

[154] *Practice Bulletin 7: Abortion and Mental Health*, AM. ASS'N PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS, Dec. 30, 2019, at 1, 1, https://aaplog.org/wp-content/uploads/2019/12/FINAL-Abortion-Mental-Health-PB7.pdf.

[155] Pro. Ethics Comm. AAPLOG, *Committee Opinion 8: Abortion and Breast Cancer*, AM. ASS'N PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS (Jan. 5, 2020), https://aaplog.org/wp-content/uploads/2020/01/FINAL-CO-8-Abortion-Breast-Cancer-1.9.20.pdf.

[156] Hua Liao et al., *Repeated Medical Abortions and the Risk of Preterm Birth in the Subsequent Pregnancy*, 284 ARCHIVES GYNECOLOGY & OBSTETRICS 579, 583–84 (2011) ("Overall, 20.3% of the patients in the medical cohort received a postabortion suction curettage. . . . Compared to women without postabortion curettage, women with a history of

Women who take mifepristone also need to know whether they are Rh negative. If a woman is Rh negative, the ACOG recommends an injection of Rh immunoglobulin (brand name, RhoGAM) at the time of the abortion.[157] This is an international medical standard: "After miscarriage or threatened abortion or induced abortion during the first 12 weeks of gestation, non-sensitized D-negative women should be given a minimum anti-D of 120 μg. After 12 weeks' gestation, they should be given 300 μg. (II-3B)."[158] If a physician does not administer RhoGAM, Rh negative women may experience Rh incompatibility in future pregnancies, which could create a significant risk of complications and miscarriages.[159] Therefore, a qualified doctor must determine blood type and provide RhoGAM if a woman is Rh negative.[160] RhoGAM cannot be adequately administered in a mail-order system for chemical abortion. Neither DIY, nor mail-order abortions will provide informed consent and follow-up care which doctors could provide.

IV. THE NEED FOR STATE REGULATION

A. *The Importance of State Regulation*

Because of the inherent risks of mifepristone and misoprostol, the weaknesses of the FAERS system, the FDA's decision to relax the REMS, and the lack of any reliable national system of abortion data, the U.S. has a national medical climate that does not adequately protect women's health when it comes to abortion. These inadequacies are compounded by the FDA's refusal to track medical complications of abortion.[161]

Some states may prohibit chemical abortion if *Dobbs v. Jackson Women's Health Organization* overturns *Roe v. Wade* and the abortion issue is returned to the states, because of the states' traditional protection of the life of prenatal human beings. Other states, such as California, Illinois, and New York, will

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MA earlier than 7 completed weeks and postabortion curettage were at an increased risk of PTB (OR 1.69, 95% CI 1.02–3.16); and the risk was even higher for very PTB (OR 3.61, 95% CI 1.43–4.93) (Table 4)").

[157] Robert M. Silver & Am. Coll. of Obstetricians and Gynecologists, *Practice Bulletin 181: Prevention of Rh D Alloimmunization*, 130 OBSTETRICS & GYNECOLOGY e57, e62–e63 (2017) [hereinafter Practice Bulletin No. 181].

[158] Karen Fung Kee Fung & Erica Eason, *Prevention of Rh Alloimmunization*, 25 J. OBSTETRICS & GYNAECOLOGY CAN. 765, 766 (2003).

[159] *See* Practice Bulletin No. 181, *supra* note 157, at e58, e65.

[160] *Id.* at e61.

[161] AM. ASS'N PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS, COMMITTEE OPINION 6: INDUCED ABORTION AND THE INCREASED RISK OF MATERNAL MORTALITY 5 (2019), https://aaplog.org/wp-content/uploads/2019/08/AAPLOG-CO-6-Induced-Abortion-and-the-Increased-Risk-of-Maternal-Mortality.pdf.

undoubtedly allow abortion for the foreseeable future. These states have a compelling interest in independently regulating chemical abortion to protect women's health and ensure fully informed consent.

The lack of state and federal regulation puts the burden on women to obtain fully informed consent. Women cannot be fully informed without an accurate understanding of the risks. States should act to ensure that women are fully informed by requiring medical oversight and accurate medical data.

During the FDA's evaluation of RU-486 and before its approval, more than a dozen states had introduced legislation to regulate RU-486.[162] To adequately protect women's health and guard against the documented risks, states should require (1) in-person screening for risk factors for adverse mental health outcomes including screening for sex trafficking and coercion; (2) intra-uterine pregnancy verification by ultrasound; (3) fully-informed consent by the patient; (4) identification of blood type to rule out Rh negativity; (5) in-person administration of mifepristone by a physician in order to ensure that the patient is the actual recipient of the drug and that the drug is not surreptitiously administered to another person; (6) administration only by a physician who is credentialed and has admitting privileges or has made written arrangements with another physician to manage expected complications; (7) a second follow-up visit with a doctor to confirm a completed abortion; (8) a third in-person visit to ensure complete expulsion and rule out retained tissue; (9) gestational limits on the use of mifepristone and misoprostol; (10) adequate documentation of the fulfillment of all requirements; and (11) that essential medical data is reported for public health analysis.

Since the FDA approved RU-486 in 2000, a number of states have acted to partially fill the vacuum and regulate chemical abortion consistent with the medical risks and in light of the minimal FDA regulations. Nearly half the states

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[162] Stephanie Simon, *Abortion Rights Group Challenges Mich. Law*, L.A. TIMES (Feb. 27, 2001, 12:00 AM), https://www.latimes.com/archives/la-xpm-2001-feb-27-mn-30745-story.html ("16 states have introduced legislation to restrict the use of RU-486.").

now regulate chemical abortion specifically.[163] More considered chemical abortion regulations in the 2022 state legislative sessions.[164]

At least twelve states that regulate chemical abortion require physicians to inform their patients about the established medical process of reversing

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[163] ALA. STAT. § 26-23E-7 (2021) (requiring a physician to prescribe abortion-inducing drugs); ARIZ. REV. STAT. § 36-2153 (2021); ARIZ. REV. STAT. § 36-2160 (2021) (requiring in-person distribution of abortion-inducing drugs prescribed by a physician); ARK. CODE ANN. § 20-16-1504 (2021) (detailing physician requirements before prescribing an abortion-inducing drug and requiring in-person distribution of abortion-inducing drugs); IDAHO CODE § 18-617 (2021) (regulating chemical abortions); IND. CODE ANN. § 16-34-2-1 (2021) (criminalizing abortion unless certain circumstances are present); 410 IND. ADMIN. CODE 26.5-1-1 (2022); IOWA CODE § 144.29A (2021) (reporting requirement); IOWA ADMIN. CODE r. 653-13.10 (2022) (outlining standards of practice for physicians who administer abortion-inducing drugs); KAN. STAT. ANN. § 65-4a10 (2021) (requiring the physician to be physically present when mifepristone is administered); KY. REV. STAT. ANN. § 311.728 (LexisNexis 2021) (requiring the physician to be physically present when an abortion is induced or performed); KY. REV. STAT. ANN. § 311.774 (LexisNexis 2021) (reporting requirements); LA. STAT. ANN. § 40:1061 (2021); MISS. CODE ANN. § 41-41-107 (2021) (requirements for physicians); MO. REV. STAT. § 188.021 (2021) (requirements for administering abortion-inducing drugs); MONT. CODE ANN. § 50-20-704 (2021) (requiring a physician to be physically present when abortion-inducing drugs are administered); MONT. CODE ANN. § 50-20-705 (2021) (requirements for distributing abortion-inducing drugs); NEB. REV. STAT. ANN. § 28-335 (2021) (requiring a licensed physician to be physically present when an abortion is induced or performed); N.D. CENT. CODE § 14-02.1-03.5 (2021) (requiring a physician to prescribe and administer an abortion-inducing drug); OHIO REV. CODE ANN. § 2919.123 (LexisNexis 2022); OHIO REV. CODE ANN. § 2919.124 (LexisNexis 2022) (requiring a physician to be physically present when an abortion-inducing drug is consumed); OKLA. STAT. tit. 63, §§ 1-756.1–1-756.11 (2021) ("Oklahoma Abortion-Inducing Drug Risk Protocol Act"); S.C. CODE ANN. § 44-41-460 (2021) (reporting requirements); S.D. CODIFIED LAWS § 34-23A-10.1 (2021) (requiring informed consent); S.D. Exec. Order 2021-12 (Sept. 7, 2021); TENN. CODE ANN. § 39-15-218 (2021) (requiring physician to provide information about reversal); TEX. HEALTH & SAFETY CODE ANN. §§ 171.061–171.065 (2021); UTAH CODE ANN. §§ 76-7-305–76-7-305.5 (LexisNexis 2021) (requiring informed consent including the consequences of medication-induced abortion and the option to consult doctor about mifepristone reversal); W. VA. CODE ANN. §§ 16-2I-2–16-2I-3 (2021); WIS. STAT. § 253.105 (2022) (requiring a physical exam and a physician's physical presence when abortion-inducing drug is administered).

[164] *See, e.g.*, Nicole Ki, *South Dakota Gov. Kristi Noem Announces Proposal to Ban Most Abortions in the State*, USA TODAY (Jan. 23, 2022, 3:34 PM), https://www.usatoday.com/story/news/nation/2022/01/23/south-dakota-kristi-noem-abortion-ban/6630393001/; Elizabeth Nash et al., *2022 State Legislative Sessions: Abortion Bans and Restrictions on Medication Abortion Dominate*, GUTTMACHER INST. (Mar. 16, 2022), https://www.guttmacher.org/article/2022/03/2022-state-legislative-sessions-abortion-bans-and-restrictions-medication-abortion?utm_source=Guttmacher+Email+Alerts&utm_campaign=b77de93c8b-abortionsbansandmedicationabortions&utm_medium=email&utm_term=0_9ac83dc920-b77de93c8b-260729057.

progesterone with administration of natural progesterone.[165] This reversal process is based both on understanding the basic pharmacology of mifepristone as well as animal studies and human retrospective studies. Mifepristone works by blocking a natural pregnancy hormone called progesterone.[166] Progesterone is produced by the mother's body to allow her womb to grow the placenta[167]—the organ needed to provide nourishment to the baby.[168] Mifepristone blocks progesterone's actions in a woman's uterus.[169] When mifepristone blocks progesterone, the placenta deteriorates and can no longer provide nourishment to the baby.[170] During the development of mifepristone, researchers clearly demonstrated that mifepristone is a reversible blocker of progesterone.[171] Thus, if a woman's progesterone is blocked with mifepristone, and then, within a limited time period, a physician administers more progesterone, the mifepristone blockade may be overcome, and the effects of mifepristone nullified.[172] By giving a woman progesterone, the mifepristone abortion can be stopped and the chances of the baby surviving increase from 25% (the survival rate without natural progesterone) to 68% (the best protocol survival rate after giving natural progesterone).[173] This is a significantly increased chance of the baby surviving the attempted chemical abortion after mifepristone. For a

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[165] ARK. CODE ANN. §§ 20-16-1703 to 20-16-1704 (2021); IND. CODE ANN. §§ 16-34-2-1, 16-34-2-1.1(2021); KY. REV. STAT. ANN. § 311.774 (LexisNexis 2021); LA. STAT. ANN. § 40:1061 (2021); MONT. CODE ANN. § 50-20-708 (2021); NEB. REV. STAT. ANN. § 28-327.01 (2021); N.D. CENT. CODE § 14-02.1-02.1 (2021); OKLA. STAT. ANN. tit. 63, § 1-756.7 (2021); S.D. CODIFIED LAWS § 34-23A-10.1 (2021); TENN. CODE ANN. § 39-15-218 (2021); UTAH CODE ANN. § 76-7-305.5 (LexisNexis 2021); W. VA. CODE ANN. § 16-2I-2 (2022). The laws of Oklahoma and North Dakota are not currently in effect. *See* Tulsa Women's Reproductive Clinic v. Hunter [D and E ban], REWIRE NEWS GRP., https://rewirenewsgroup.com/legislative-tracker/legal-case/tulsa-womens-reproductive-clinic-v-hunter-d-and-e-ban/ (last updated Nov. 4, 2019); Am. Med. Ass'n v. Stenhjem, 412 F. Supp. 3d 1134, 1138, 1152 (D.N.D. 2019) (granting preliminary injunction).

[166] *See supra* notes 58–63 and accompanying text.

[167] Gracy Rosario et al., *Role of Progesterone in Structural and Biomedical Remodeling of Endometrium*, 8 FRONTIERS BIOSCIENCE 924, 925–26 (2003).

[168] Graham J. Burton & Eric Jauniaux, *What is the Placenta?*, AM. J. OBSTETRICS & GYNECOLOGY, Oct. 2015, at S6, S6.

[169] Davenport et al., *supra* note 69, at 6.

[170] *Id.*

[171] *Id.* at 5–6.

[172] *Practice Bulletin 6: The Reversal of the Effects of Mifepristone by Progesterone*, AM. ASS'N PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS, Nov. 16, 2019, at 1, 2-3 [hereinafter *Practice Bulletin* 6], https://aaplog.org/wp-content/uploads/2020/01/FINAL-PB-6-Abortion-Pill-Reversal-1.pdf.

[173] *Id.* at 4.

woman who changes her mind after starting a chemical abortion, the administration of progesterone can give her real hope of saving her unborn child.

IVF practitioners have used progesterone for over forty years to help women carry pregnancies after embryo implantation into the womb.[174] There is a very long and solid history of safety with the use of natural progesterone in pregnancy.[175] Natural progesterone use in pregnancy for the last fifty years has not been associated with any increased risk of birth defects.[176] The use of mifepristone without the use of misoprostol has not demonstrated an increased risk of birth defects that would advise against the use of progesterone to reverse the effects of mifepristone before misoprostol is taken in the two-drug regimen.[177] Thus, to date, there does not appear to be any significant risk of birth defects in the unborn child from abortion pill reversal.[178] Moreover, abortion pill reversal offers another reproductive choice for women facing the abortion decision.

To adequately protect women's health in the context of chemical abortion, there are numerous facets that must be addressed. At least nineteen states require a physician's physical presence when abortion-inducing drugs are

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[174] Walter Ciampaglia & Graciela E. Cognigni, *Clinical Use of Progesterone in Infertility and Assisted Reproduction*, 94 ACTA OBSTETRICIA ET GYNECOLOGICA SCANDINAVICA 17, 19 (2015).

[175] The Prac. Comm. of the Am. Soc'y of Reprod. Med., *Progesterone Supplementation During the Luteal Phase and in Early Pregnancy in the Treatment of Infertility: An Educational Bulletin*, 89 FERTILITY & STERILITY 789, 789, 791 (2008). "The weight of available evidence indicates that the most common forms of P supplementation during early pregnancy pose no significant risk to mother and fetus" and "[c]ontrolled studies show no increase in congenital anomalies, including genital abnormalities in male and female infants, resulting from maternal exposure to P . . . during early pregnancy." *Id.* at 791.

[176] Delgado et al., *supra* note 62, at 26.

[177] *Practice Bulletin 6*, *supra* note 172, at 4.

[178] Delgado et al., *supra* note 62, at 26.

administered.[179] Approximately thirty-three states require that only physicians may administer abortions.[180]

States set standards for informed consent in numerous areas of health and medicine.[181] State requirements for the anonymous reporting of abortion data is critical for public health, for accurate understanding of complications, and for fully informed consent about the safety of medical procedures. This is necessary to prevent complications from being filtered out of the public health system. For

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[179] These include Alabama (ALA. CODE § 26-23E-7 (2021)), Arizona (ARIZ. REV. STAT. § 36-2160 (2021)), Arkansas (ARK. CODE ANN. § 20-16-1504 (2021)), Indiana (IND. CODE ANN. § 16-34-2-1 (LexisNexis 2021)), Iowa (IOWA ADMIN. CODE r. 653.13-10 (2022)) (requiring physician to perform a physical exam before mifepristone abortion, be physically present when providing abortion, and schedule follow-up appointment) (enjoined by court *See* Planned Parenthood v. Iowa Bd. of Med., 865 N.W.2d 252, 269 (Iowa 2015)), Kentucky (KY. REV. STAT. ANN. § 311.728 (LexisNexis 2021)), Louisiana (LA. STAT. ANN. § 40:1061.11 (2021)), Mississippi (MISS. CODE ANN. § 41-41-107 (2021)), Missouri (MO. REV. STAT. § 188.021 (2021)), Nebraska (NEB. REV. STAT. ANN. § 28-335 (2021)), North Carolina (N.C. GEN. STAT. § 90-21.82 (2021)), North Dakota (N.D. CENT. CODE § 14-02.1-03.5 (2021)), Oklahoma (OKLA. STAT. tit. 63, § 1-756.3 (2021)), South Carolina (*see* S.C. CODE ANN. § 44-41-20 (2022)), South Dakota (S.D. Exec. Order 2021-12 (Sept. 7, 2021)), Tennessee, Texas (TEX. HEALTH & SAFETY CODE ANN. § 171.063 (West 2021)), West Virginia, Wisconsin (WIS. STAT. § 253.105 (2022)).

[180] These include Alabama (ALA. CODE § 26-23E-7 (LexisNexis 2021)), Alaska (ALASKA STAT. § 18.16.010 (2021), Arizona (ARIZ. REV. STAT. § 36-2160 (2021)), Arkansas (ARK. CODE ANN. § 20-16-1504 (2021)), Delaware (DEL. CODE ANN. tit. 24, § 1790 (2022)), Florida (FLA. STAT. ANN. § 390.0111 (LexisNexis 2021)), Georgia (GA. CODE ANN. § 16-12-141 (2021)), Idaho (IDAHO CODE § 18-608A (2022)), Indiana (IND. CODE ANN. § 16-34-2-1 (2021)), Iowa, Kansas (KAN. STAT. ANN. § 65-4a10 (2021)), Kentucky (KY. REV. STAT. ANN. § 311.728 (LexisNexis 2021)), Louisiana (LA. STAT. ANN. § 40:1061.10 (2021)), Maryland (MD. CODE ANN. HEALTH-GENERAL § 20-208 (LexisNexis 2021)), Michigan, Minnesota (MINN. STAT. § 145.412 (2022)), Mississippi (MISS. CODE ANN. § 41-41-107 (2022)), Missouri (MO. REV. STAT. § 188.020 (2021)), Nebraska (NEB. REV. STAT. ANN. § 28-335 (2022)), Nevada (NEB. REV. STAT. ANN. § 442.250 (2021)), North Carolina (N.C. GEN. STAT. § 14-45.1 (2021)), North Dakota (N.D. CENT. CODE § 14-02.1-04 (2021)), Ohio (OHIO REV. CODE ANN. § 2929.123 (LexisNexis 2022)), Oklahoma (OKLA. STAT. ANN. tit. 63, § 1-756.3 (2021)), Pennsylvania, South Carolina (S.C. CODE ANN. § 44-41-20 (2022)), South Dakota (S.D. CODIFIED LAWS § 34-23A-3 (2022)), Tennessee (TENN. CODE. ANN. § 63-6-241 (2021)), Texas (TEX. HEALTH & SAFETY CODE ANN. § 170A.002 (West 2021)), Utah (UTAH CODE ANN. § 76-7-302 (LexisNexis 2021)), West Virginia, Wisconsin (WIS. STAT. § 940.15 (2022)), and Wyoming (WYO. STAT. ANN. § 35-6-11 (2021)).

[181] *See, e.g.*, Marc D. Ginsberg, *Informed Consent: No Longer Just What the Doctor Ordered? Revisited*, 52 AKRON L. REV. 49 (2018); Alicia Ouellette, *Body Modification and Adolescent Decision Making: Proceed with Caution*, 15 J. HEALTH CARE L. & POL'Y 129 (2012); A.D. Burnett III, Comment, *Suturing the Loophole: Informed Consent as a Requirement for Procedures Not Enumerated in Pennsylvania's Medical Informed Consent Statute*, 108 PENN. STATE L. REV. 1249 (2004); Maria Woltjen, *Regulation of Informed Consent to Human Experimentation*, 17 LOY. U. L.J. 507 (1986).

example, Arkansas enacted an abortion complications reporting law in 2019.[182] During 2020, the state found that of the forty-five complication reports filed in 2020, forty (88%) of them resulted from chemical abortion.[183]

States have expressed concern with the risks of hemorrhage, severe infection, and temporary or permanent loss of fertility from chemical abortion.[184] States have also been concerned with the need to rule out an ectopic (outside the uterus) pregnancy,[185] since RU-486 is contraindicated in the case of an ectopic pregnancy.[186] If a woman has an ectopic pregnancy there are risks that RU-486 will not effectively end the pregnancy, the ectopic pregnancy could rupture, or the woman could suffer a severe, life-threatening hemorrhage.[187] In addition, there is a need for states to step in to ensure providers are following the health and safety regulations that they previously ignored.[188]

However, states have not completely filled the vacuum left by the lack of federal regulations. No state requires the tracking of the sale and delivery of chemical abortion. Severe infection complications—like sepsis from ectopic pregnancy and emergency surgery—should all be tracked. Pharmaceutical protocols could also protect women's health. States also have the authority to restrict mail-order abortions. Texas and other states prohibit mail-order abortion.[189]

States have good reason to second-guess the courts on the safety of abortion. For example, in *Planned Parenthood v. Danforth*, the Supreme Court struck down a Missouri law prohibiting the use of saline abortion on the rationale

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[182] ARK. CODE ANN. § 20-16-605 (West 2021) (effective July 24, 2019).

[183] CTR. OF HEALTH STATISTICS, ARK. DEP'T OF HEALTH, INDUCED ABORTIONS COMPLICATIONS REPORT: REQUIRED BY ACT 620 OF 2019, https://www.healthy.arkansas.gov/images/uploads/pdf/complication_final_2020.pdf (last visited Mar. 3, 2022).

[184] *See* 2012 Ariz. Sess. Laws 250; 2017 Idaho Sess. Laws 242; OKLA. STAT. tit. 63, § 1729-a (2021).

[185] *See* 2012 Ariz. Sess. Laws 250; 2017 Idaho Sess. Laws 242; OKLA. STAT. tit. 63, § 1729-a (2021).

[186] Sabina Parveen et al., *Rupture Ectopic Pregnancy in Early Gestation Due to Mifepristone & Misoprostol Abuse*, 5 INT'L J. MED. RSCH. PROS. 218, 220 (2019).

[187] *Id.*

[188] Some abortion clinics prescribe mifepristone up to fourteen weeks, beyond the original forty-nine days and beyond the current FDA-approved deadline of ten weeks (seventy days). *Women's Center of Tampa: Medical & Surgical Abortion Clinic*, ORLANDO WOMEN'S CTR., https://www.womenscenter.com/womens_center_hyde_park.html (last visited Mar. 4, 2022). The same clinic advertises in-patient mifepristone abortion up to twenty-four weeks gestation. *Id.*

[189] Besides Texas (TEX. HEALTH & SAFETY CODE ANN. § 171.063 (West 2021)), these include Louisiana (LA. STAT. ANN. § 40:1061.11 (2021)), and Mississippi (MISS. CODE ANN. § 41-41-107 (2022)).

that that would take away a widely used method of abortion.[190] However, the prohibition of saline as an abortifacient could have induced providers to use an alternative that was less risky to women. As it turned out and was apparent to some at the time, saline was not a good method and was soon succeeded by alternatives.[191] The Supreme Court in *City of Akron v. Akron Center for Reproductive Health*, expressly affirmed that "[o]f course, the State retains an interest in ensuring the validity of *Roe*'s factual assumption that 'the first trimester abortion [is] as safe for the woman as normal childbirth at term.'"[192]

States have good reason to limit the gestational weeks in which mifepristone and misoprostol can be used and to require in-person administration by a physician, pregnancy verification, the use of ultrasound to rule out an ectopic pregnancy, and gestational verification by ultrasound. In addition, states are justified in adopting requirements to identify if Rh negativity is present, to require an in-person follow up visit; to verify fetal remains; to require fully informed consent with a sufficient reflection period; and to require that abortion data be recorded and reported for public health examination.

Although federal preemption of state regulations of mifepristone may be litigated, there is a presumption in favor of state police powers over public health and the practice of medicine.[193] As Justice Stevens wrote for the Supreme Court in *Wyeth v. Levine*, "we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."[194] Since colonial days, states

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[190] Planned Parenthood of Cent. Mo. v. Danforth, 428 U.S. 52, 75–79 (1976).

[191] Dellapenna, *supra* note 52, at 360 n.10 ("Despite such rapid technological changes, the Court seems to have accepted the role of Medical Review Board; this position became most clear with the review of the prohibition of saline amniocentesis (salting out) as a method of abortion by Missouri*; see* Planned Parenthood v. Danforth, 428 U.S. 52, 75–79, 95–99 (1976). This approach seems to freeze law in a pattern perhaps appropriate to a given point of technological development, but a point which has been passed by the time the case has reached the Supreme Court. The role of Supreme Medical Review Board is ill suited to a body which has no institutional competence for questions of health."); DELLAPENNA, *supra* note 1, at 668 ("Because of the risks of saline amniocentesis, by 1970 doctors were already turning to a different technique for second trimester abortions—prostaglandin induction.").

[192] City of Akron v. Akron Ctr. for Reprod. Health, 462 U.S. 416, 430 n.12 (1983).

[193] *See generally* Elizabeth Y. McCuskey, *Body of Preemption: Health Law Traditions and the Presumption against Preemption*, 89 TEMP. L. REV. 95 (2016).

[194] Wyeth v. Levine, 555 U.S. 555, 565 (2009) (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996); *see also* S. Bay United Pentecostal Church v. Newsom, 140 S. Ct. 1613, 1613 (2020) (Roberts, J., concurring) ("Our Constitution principally entrusts '[t]he safety and the health of the people' to the politically accountable officials of the States 'to guard and protect.'" (quoting Jacobson v. Massachusetts, 197 U.S. 11, 38 (1905))).

have restricted or prohibited abortion.[195] Recognizing the diversity of abortion mechanisms, states have traditionally identified and prohibited various mechanisms, including medicines, drugs, and other abortifacients.[196] There is no federal statute approving mifepristone, let alone one that *clearly preempts* state regulations. The Supreme Court recently affirmed in *National Federation of Independent Business v. Department of Labor*, that "[a]dministrative agencies are creatures of statute. They accordingly possess only the authority that Congress has provided."[197] The Court affirmed that "[w]e expect Congress to speak clearly when authorizing an agency to exercise powers of vast economic and political significance."[198] The FDA's expertise extends to determining whether a drug is safe and effective.[199] Whether the use of a drug is good public policy traditionally falls within the states' police powers.[200] Finally, there is good reason to believe that Congress has limited constitutional power over abortion.[201] For all these reasons, the traditional presumption favoring state regulation of medicine and medical practice is especially strong in the case

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[195] *See* DELLAPENNA, *supra* note 1, at 211–28.

[196] Noah, *supra* note 87, at 600 n.136 ("Many state laws restricting abortion include 'medicines' or 'drugs' in their definitions."). Noah further cited to the statutes current at the time of publication. *Id.* For the current statutes, see GA. CODE ANN. § 16-12-140 (2021); 750 ILL. COMP. STAT. ANN. 70/10 (LexisNexis 2021); KY. REV. STAT. ANN. § 311.732 (LexisNexis 2021); MINN. STAT. § 145.411 (2022); N.C. GEN. STAT. § 90-21.6 (2021); S.C. CODE ANN. § 44-41-10 (2022); TENN. CODE ANN. § 37-10-302 (2022); TEX. HEALTH & SAFETY CODE ANN. § 245.002 (West 2021). Eugene Quay, *Justifiable Abortion—Medical and Legal Foundations*, 49 GEO. L.J. 395, 447–520 (1961) (Appendix I, with abortion statutes of the 50 states).

[197] Nat'l Fed'n of Indep. Bus. v. Dep't of Lab., 142 S. Ct. 661, 665 (2022) (per curiam).

[198] *Id*. (quoting Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs., 141 S. Ct. 2485, 2489 (2021) (per curiam)).

[199] 21 U.S.C. § 393(b) (2021).

[200] *See* Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996); Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 226–27 (2000) (noting that courts generally read federal express preemption provisions narrowly when they cover subject matter that generally falls into the states' purview of health, safety, and welfare). *See generally* Cipollone v. Liggett Grp., 505 U.S. 504 (1992) (finding that federal regulation on cigarette advertising did not expressly preempt state common law claims for damages from cigarette manufacturers and therefore deferred to the state); Hillsborough Cnty. v. Automated Med. Lab., Inc., 471 U.S. 707 (1985) (finding that federal regulations on plasma collection were not pervasive enough to preempt state ordinances and noted the Supremacy Clause did not traditionally overcome state laws on matters of health and safety); Jacobson v. Massachusetts, 197 U.S. 11 (1905) (noting that state laws regarding health and welfare were granted great deference but yielded to the Constitution; however, state small pox vaccination mandate did not violate the Fourteenth Amendment).

[201] *See, e.g.*, Robert J. Pushaw, Jr., *Does Congress Have the Constitutional Power to Prohibit Partial-Birth Abortion?*, 42 HARV. J. ON LEGIS. 319 (2005).

of an elective abortion, which does not treat disease or any life-threatening condition.[202]

V. CONCLUSION

The inherent risks of mifepristone and misoprostol combined with the failure of adequate federal governmental oversight over the approval of chemical abortion in the U.S. over the past quarter-century means that state abortion policy may come full circle. Just as states in the nineteenth and twentieth centuries sought to prohibit dangerous abortion methods to protect the lives and health of women and children,[203] states need to now prevent DIY and mail-order abortions using mifepristone and misoprostol in order to prevent significant health risks to women and to protect the lives of prenatal human beings. Effective regulations will require that women receive full information about the risks of chemical abortion and give fully informed consent; that providers are qualified and able to adequately address any medical complications; that mifepristone-misoprostol is only administered with medical supervision; that emergency medical care is available; that public health data is comprehensively collected, analyzed, and reported in their state; and that these laws are effectively enforced.

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[202] *See* sources cited *supra* note 43.

[203] DELLAPENNA, *supra* note 1, at 297, 342, 371, 423–25, 453 ("a concern to protect mothers from what was still a highly dangerous set of procedures"), 1055 ("the protection of the mother's life and health . . . and . . . the protection of mothers from being pressured or coerced into abortions they did not want . . . .").