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Chemical Abortion: A Review

Melanie Israel

KEY TAKEAWAYS

In addition to ending the life of an unborn child, chemical abortion poses serious health risks to women.

The use of chemical abortion in the United States has increased 120 percent in the past decade.

Policymakers should strengthen—not weaken—the regulation of dangerous abortion pills.

In September 2003, 18-year-old Holly Patterson, who was seven weeks pregnant, walked into a Planned Parenthood clinic in California and began the chemical abortion pill regimen. One week later, she died in a local hospital after going into septic shock from a bacterial infection, *Clostridium sordelli*. Her father, Monty Patterson, has spent the years since her death highlighting the dangers of the abortion pill. "I'm not pro-life or pro-choice," he said in one interview, "I'm pro-Holly." He described the look of fear in her eyes at the hospital shortly before she died. "I don't want anyone else to go through that."[1]

Testifying before Congress, Monty Patterson stated:

> There are no quick fixes or magical pills to make an unplanned pregnancy go away. My family, friends, and

> community were deeply saddened and are forever marred by Holly's preventable and tragic death. It is my vibrant memory of Holly and her premature death that have inspired me to make the public aware of the serious and lethal effects of the [abortion pill] regimen.... It is a natural instinct to protect our loved ones and speak for those who cannot speak for themselves."[2]

While Holly was the first person in the United States known to have died in this manner, she would not be the last.

The Chemical Abortion Process

In the chemical abortion process a woman typically takes two pills: mifepristone and misoprostol. Mifepristone blocks the uterus from receiving a critical hormone, progesterone, which is required to sustain a pregnancy. As a result of the progesterone inhibitor, the lining of the uterus deteriorates and cannot transfer adequate nutrients to the developing unborn child, causing its death. Twenty-four to 48 hours after taking mifepristone, a woman takes the second part of the abortion pill regimen, misoprostol, which causes uterine contractions to complete the abortion process and empty the uterus. Misoprostol's use in the abortion pill regimen is "off label," that is, it was not created to be used in the abortion process.

Surgical abortion, in contrast, is a procedure that—in the first or second trimester—involves a health care provider using instruments such as clamps, cutterete blades, or suction catheters to extract an unborn child from the womb. For a very late-term abortion, a lethal injection kills the child in utero, and the child is delivered stillborn.[3]

According to current Food and Drug Administration (FDA) guidelines, mifepristone may be taken up to 70 days (10 weeks) into pregnancy, although practitioners often fail to abide by the gestational limitation.[4] Common side effects of mifepristone include fever, nausea, vomiting, chills, and dizziness, along with cramping and bleeding more pronounced than a heavy menstrual period. Mifepristone is associated with other, more serious, adverse effects, including hemorrhaging, immune system inhibition, and septic shock.

Between 2000 and 2006, the FDA was aware of six deaths associated with mifepristone, as well as "nine life-threatening incidents, 232 hospitalizations, 116 blood transfusions, and 88 cases of infection."[5] As of 2018, the FDA is aware of 24 deaths associated with mifepristone and more than 4,000 adverse events.[6] Unfortunately, these reports likely do not represent the full scope of unfavorable outcomes as a result of weaknesses in the FDA's

Adverse Events Reporting System (FAERS), which are discussed later in this *Backgrounder*. As of December 2018, an estimated 3.7 million women had used mifepristone in the United States.[7]

In the past decade, the chemical abortion rate has increased an astounding 120 percent according to the Centers for Disease Control and Prevention (CDC). According to its 2018 abortion surveillance report, 40 percent of abortions reported were chemical in nature (38.6 percent occurred prior to nine weeks, and 1.4 percent occurred after nine weeks).[8] The Guttmacher Institute, an abortion-focused research organization, reports that chemical abortions comprised 6 percent of U.S. abortions after mifepristone's approval in 2000 and comprised 31 percent of abortions in 2014.[9]

Unfortunately, any discussion of U.S. abortion data requires a caveat. Reporting by the states to the CDC is not mandatory; not all states submit data, and the process is not streamlined. The Guttmacher Institute directly surveys abortion providers and is able to glean information from providers in states that are not represented in the CDC's report, but, again, reporting is not mandatory. Ultimately, U.S. abortion reporting standards are not timely and streamlined, which is detrimental to public policy discussions about the issue.[10]

Nonetheless, the data that are available conclusively demonstrate that chemical abortions make up a rapidly increasing share of abortions in the U.S.

History

Roughly four decades ago, chemical abortion did not exist. Today, it is pervasive. The road from nonexistence to ubiquitous usage is a winding tale and begins in a lab in France.

International Development. The compound that would lead to the advent of the abortion pill was discovered under the leadership of French scientist Dr. Etienne Baulieu in 1980 at Roussel-Uclaf, a French pharmaceutical group for which Baulieu was a consultant. The compound became known as RU-486, a shortened version of its registration.[11] After undergoing clinical tests in several countries in the early 1980s, the abortion pill became available in France in 1988.

Opposition to the drug—both in France and across the globe—was swift. Hoechst AG, a German pharmaceutical company and majority shareholder in Roussel-Uclaf, was concerned about the threat of boycotts due to its market share of drugs in the United States and ordered Roussel-Uclaf to stop producing the drug.[12]

Shortly after Roussel-Uclaf announced it would pull the drug from the market, the government of France (through a combination of French law and its status as a minority shareholder of Roussel-Uclaf) forced the company to continue distribution. Many observers believed that Roussel-Uclaf and the French Ministry of Health collaborated to keep the drug on the market and circumvent the Hoechst AG directive in order to direct public ire at the French government rather than the pharmaceutical companies.[13]

Roadblocks in the United States. With distribution in France underway, in 1989, the United States FDA issued an import alert on RU-486 out of concern for women's health and safety, drawing criticism from pro-abortion groups and policymakers.[14] In the years that followed, researchers and groups that promote abortion in the United States hoped that a pharmaceutical company would be willing to begin working to obtain FDA approval for legal distribution of the drug in the U.S. However, such an endeavor would be expensive and controversial. Unwilling to assume the high cost, as well as face social pressure from grassroots and political forces, no company stepped in to bring the drug to the U.S. market. Roussel-Uclaf was likewise unwilling to license the drug in the U.S. or attempt to obtain FDA approval due to the hostile political and social climate.

However, that changed in 1994 when Roussel-Uclaf agreed to license RU-486 at no cost to the U.S.-based Population Council, a nonprofit organization founded by John D. Rockefeller III, which focuses on reproductive health research and policy. The Population Council announced its intentions to find a U.S.-based manufacturer, sponsor an FDA approval application, and sponsor a clinical trial.[15]

But newspaper headlines about Roussel-Uclaf's decision to hand the drug's patent over to the Population Council do not tell the full story. The decision was not altruistic. Rather, it was the result of concerted closed-door lobbying from the highest levels of the Clinton Administration.

The Clinton Administration's Efforts to Bring Chemical Abortion to the U.S. When President Bill Clinton took office in 1993, among his very first acts as President was to direct officials at the Food and Drug Administration and Health and Human Services to work to bring the abortion pill to the U.S. market and reconsider the FDA's import alert.[16] The agencies swiftly initiated talks with Roussel-Uclaf. In an explosive 2006 report, documents uncovered by government accountability group Judicial Watch demonstrated the behind-the-scenes lengths the Clinton Administration went to broker a deal between the Population Council and Roussel-Uclaf, as well as shepherd the drug through the FDA approval process.

The report shines a light on the Clinton Administration's highly unusual role in the abortion pill's eventual presence in the United States. In summary, the Judicial Watch report details how—at the behest of the President—officials at the highest levels of the U.S. government exerted political and diplomatic pressure on Roussel-Uclaf and Hoechst AG to relent and end their policy of avoiding the U.S. market.

The Clinton Administration designated the Population Council as the conduit to bring the drug to the United States. Though Roussel-Uclaf was willing to give the patent for the drug to the United States government, the Clinton Administration believed that Population Council was the ideal candidate for a variety of political and administrative reasons. To wit:

- Its nonprofit status shielded it from political and economic consequences that would otherwise deter the government or a pharmaceutical company.

- The Population Council had a history of working with Roussel-Uclaf/RU-486 during research trials at the University of Southern California in the 1980s.

- The approval process would take less time if the U.S. government did not have to go through extra steps to accept the patent from Roussel-Uclaf and then transfer it to the Population Council.

- The Clinton Administration was concerned that pro-life Members of Congress would use legislation and/or appropriation riders to block U.S. government involvement in the process.

Roussel-Uclaf insisted that the U.S. government take the highly unusual step of shielding the company from any liability for damages that might occur should the drug be brought to the U.S., going so far as to request federal legislation to that end. Such an indemnity policy was not feasible, but the Clinton Administration continued its efforts to have the Population Council serve as a surrogate.

As a condition of releasing the patent for the drug to the Population Council, Roussel-Uclaf demanded a "request" letter from President Clinton. He complied and sent a letter in May 1994, requesting that Roussel-Uclaf and the Population Council bring their plans to market RU-486 in the United States to fruition. He thanked Roussel-Uclaf on behalf of both the U.S. government and the women of America.[17]

The Approval Process

The abortion pill Mifeprex went through a complicated and controversial approval process.

First Steps. Below is a timeline of events that led to the eventual approval of Mifeprex in the United States.

- April 1993: Roussel-Uclaf and the Population Council announced that the company would license RU-486 to the Population Council, and the Population Council would undertake a clinical trial as well as secure a manufacturer. However, activity stalled because the two parties could not come to a conclusive settlement.[18]

- May 1994: The Clinton Administration announced that a final agreement had been reached between the Population Council and Roussel-Uclaf. In addition to donating patent rights, Roussel-Uclaf would forgo any profits from the sale of the drug.[19]

- October 1994–September 1995: The Population Council conducted a clinical trial with more than 2,000 participants.[20]

- March 1996: The Population Council submitted a New Drug Application (NDA) to the FDA seeking approval for the abortion pill regimen of RU-486 used in conjunction with misoprostol. The NDA relied on data from two historic trials conducted in France, as well as preliminary results from the U.S. trial.[21]

- July 1996: The Reproductive Health Drugs Advisory Committee at the FDA decided favorably that the abortion pill is safe and effective and that the benefits of the drug outweighed the risks. While not binding, the FDA typically follows the advice of such committees.[22]

- September 1996: The FDA issued an "approvable letter" to the Population Council for RU-486 used in conjunction with misoprostol. Approvable letters suggest that while safety and efficacy have been established, further review is needed before receiving final approval. Among other things, the FDA required full data from the U.S. trial, as well as information about distribution plans, labeling, and a commitment to post-marketing studies.[23]

- 1997: Danco Laboratories, created as part of a complicated network of entities connected to the Population Council, is designated as the entity responsible for manufacturing and distributing the abortion pill in the U.S. Though information about its corporate structure and funding streams is limited, public information indicates that in addition to the Population Council, it has close ties to Planned Parenthood, as well as the Buffett and Packard foundations and George Soros' Open Society Institute.[24]

- 1997: Hoechst AG, the European manufacturer of RU-486, announced it would stop manufacturing the drug in light of boycott threats of a new and profitable allergy drug it produced, Allegra. Roussel-Uclaf, owned by Hoechst AG, transferred rights to the drug to a new company called Exelgyn, which was led by a former executive of Roussel-Uclaf. Exelgyn struggled for several years to secure a manufacturer and did not successfully introduce the abortion pill to additional European markets until 1999.[25]

- August 1999–February 2000: The FDA conducted a second review cycle of the Mifeprex application. The Population Council submitted additional information requested by the FDA, but was still in the process of finalizing manufacturing and distribution plans.[26] Throughout the FDA process, the Population Council/Danco faced a number of roadblocks, including a failed partnership with a Hungarian manufacturer, litigation involving a multi-million-dollar financial dispute with the company's lawyer, and reluctance on the part of U.S. manufacturers to involve themselves with an abortion drug or subject themselves to potential liability disputes.

- March 2000–September 2000: The FDA conducted a third and final review cycle and made its deliberations, and the drug sponsor secured an undisclosed manufacturer. According to a 2008 Government Accountability Office report, among the details the FDA deliberated was whether or not to approve Mifeprex under Subpart H regulations. Subpart H of the FDA drug approval process provides for accelerated approval and restricted distribution of certain drugs.[27] *The New York Times* reported[28] that during negotiations, the FDA was considering a number of stipulations, including requirements that only physicians prescribe the drug, that they be trained to provide ultrasounds, have admitting privileges at a nearby hospital, and that they register with

the drug distributor. Abortion advocates balked at the proposed restrictions and quickly convened to strategize ways to stop the FDA from imposing the restrictions.[29]

Final Approval. On September 28, 2000, the FDA approved Mifeprex through 49 days gestation. The proposed restrictions that pro-abortion groups had protested months earlier were largely absent from the final terms.

Danco was unable to secure a manufacturer in the U.S. or Europe. When the FDA approved the drug, it made the unprecedented step of refusing to identify "the names of the experts who reviewed RU-486 for the agency."[30] The FDA also would not specify where the drug would be made, citing safety and security concerns. However, officials in China confirmed that the drug would be manufactured by the Hua Lian Pharmaceutical Company, a state-owned company and subsidiary of the Shanghai Pharmaceutical Group.[31]

Pro-life critics were quick to voice their objections. The FDA's claim that it was concerned for employee safety and security at the Chinese plant was dubious considering the fact that demonstrations and protests are not allowed in the communist country. Furthermore, policymakers and the general public balked at the fact that a country with a brutal and draconian "one child policy" (now a two-child policy), carried out through forced abortions and sterilizations, was sourcing the drug to the U.S.[32]

Regulation

Upon approval through the Subpart H process in 2000, the FDA imposed certain restrictions on the drug in order to ensure safe use. Restrictions included requirements that qualified prescribing physicians had to be able to accurately date the pregnancy (including providing or referring for an ultrasound), diagnose an ectopic pregnancy, provide surgical intervention or make alternative plans for the woman's care if the chemical abortion was unsuccessful and complications ensued, and notify Danco of serious adverse events or a failed abortion.[33] A woman would take the initial dose of Mifeprex on day one, then take misoprostol after a doctor's appointment two days later. Two weeks after the chemical abortion, she would have a follow-up visit to confirm the abortion was completed.

In 2007, the Food and Drug Administration's Amendments Act established a risk evaluation and mitigation strategy (REMS) for certain drugs and determined that REMS would *automatically* apply to drugs previously approved under Subpart H with elements to assure safe use (ETASU). As of March 2021, 60 drugs are subject to REMS, and 88 percent of them include ETASU.[34]

In 2011, new REMS for Mifeprex included a requirement for a medication guide and three types of ETASU. These ETASU include requirements on the part of certified prescriber; a requirement that the drug only be dispensed in certain health care settings (not retail pharmacies); and patient informed-consent provisions, as well as a restricted shipping process.[35]

In 2016 under the Obama Administration, the FDA revised the mifepristone label and loosened the REMS regulating the drug in response to proposals from Danco.[36] The new labeling changed the dosage requirements from three 200mg pills to a single 200mg pill and eliminated the requirement that a patient receive an in-person evaluation two weeks later to ensure a completed abortion. Additionally, women no longer ingest mifepristone at a health care provider's office (though the requirement that mifepristone only be dispensed in certain health care settings, not retail pharmacies, remains in place). The FDA loosened the prescriber requirement by changing the term "licensed physician" to "healthcare provider who prescribes." The labeling expanded the use of mifepristone from 49 days gestation to 70 days gestation.[37]

The FDA determined that a REMS—including the ETASU—was still necessary, but made a number of modifications, one of which was a change to adverse events reporting. Prior to 2016, prescribing physicians had to agree to report serious adverse events and failed abortions to Danco. But under the new REMS, only *deaths* remain part of the reporting requirements.[38] GenBioPro's generic version of the drug, which was approved in April 2019, is subject to identical restrictions, and the REMS were combined into one shared system.[39]

The Guttmacher Institute notes that as early as 2001 approximately 83 percent[40] of abortion providers were not using the FDA's pre-2016 regimen; the abortion industry almost immediately used a lower mifepristone dosage, increased the gestational limit from seven weeks to nine weeks, lowered the number of visits required at a clinic, and allowed for the second half of the regimen—misoprostol—to be taken at home. The 2016 FDA label change largely mirrored these "evidence-based" practices.

Remaining Questions About the Approval Process

In the two decades since mifepristone became available in the U.S., concerns about the approval process have not been assuaged—and lingering questions remain.

Subpart H. The FDA approved mifepristone under the Subpart H regulatory scheme, which provides for an accelerated process. In order to

receive Subpart H approval, a drug must address a "serious or life-threatening illness," of which pregnancy is neither. As the sponsor, the Population Council reportedly objected to the drug's approval under Subpart H on identical grounds.[41]

For Subpart H approval, a drug must also show a therapeutic benefit over existing treatment options. The FDA justified its decision because a chemical abortion can allow a person to avoid a surgical procedure, but relied on historically controlled clinical trials rather than trials that would have compared women taking the abortion pill to women undergoing surgical abortion—and, therefore, did not establish a direct comparison of the safety and efficacy of those two specific options.

Off-Label Use of Misoprostol. Furthermore, the second half of the abortion pill, misoprostol, is designed to address conditions like ulcers for people who take non-steroidal anti-inflammatory drugs. In approving mifepristone and the abortion pill regimen, the FDA mandated the off-label, unapproved use of misoprostol for abortion. This promotion is a departure from the FDA's typical role in ensuring that a drug is used for its intended purposes.

G.D. Searle, which manufactures Cytotec (the brand name for misoprostol) issued an "Important Drug Warning" letter less than one year after the abortion pill received approval. The letter warned that Cytotec's intended use is for gastric ulcers, that "administration by any other route is contraindicated in women who are pregnant because it can cause abortion," and listed potential side effects such at uterine rupture.[42] To this day, the Cytotec/misoprostol label maintains a "black box" warning to pregnant women.

Cytotec/misoprostol is among the drugs often used during the labor induction process because it can spur cervical ripening and uterine contractions. This use in the labor and delivery setting is also not approved, and complications such as excessive contractions (uterine tachysytole) can lead to serious adverse effects such as amniotic fluid embolism and uterine rupture, with the risk of uterine rupture increasing with gestational age or if a woman has had prior uterine surgeries such as a C-section.[43]

The Cytotec/misoprostol label specifically warns that, when used outside its approved indication, a woman's "[u]terine activity and fetal status should be monitored by trained obstetrical personnel in a hospital setting."[44] It is striking that in the labor and delivery setting, Cytotec/misoprostol is used under close supervision of health care practitioners, whereas during the chemical abortion process (or, in some cases, miscarriage management) the drug is self-administered outside a health care setting.

Health and Safety Risks

The health risks associated with the abortion pill regimen are extensive, and the FDA's FAERS does not adequately capture the full extent of complications women have experienced.

Serious—in some cases, fatal—adverse events associated with mifepristone include sepsis and ruptured ectopic pregnancy. Other side effects, such as fever, pelvic inflammatory disease, cramping, and nausea, are not uncommon. The possibility that a woman will experience complications increases the further along she is in her pregnancy.[45]

Blood Type Incompatibility. If a woman obtains an abortion and her provider fails to determine her blood type and provide appropriate care, the health of her baby in subsequent pregnancies can be at risk. Determining Rh factor—the presence or absence of a protein found on red blood cells—is an important part of prenatal care, with a blood test typically occurring at the beginning of a pregnancy.

According to the American College of Obstetricians and Gynecologists (ACOG), complications can ensue if a woman is Rh-negative and the baby is Rh-positive because when the two different blood types mix, a woman's body will make antibodies to try to destroy the Rh-positive blood. "These antibodies can cross the placenta and attack the fetus's blood cells. This can lead to serious health problems, even death, for a fetus or a newborn."[46]

This problem typically does not occur during a first pregnancy because there is not enough time for many antibodies to develop. However, without receiving treatment during the first pregnancy, if "the woman later gets pregnant again with an Rh-positive fetus, she can make more antibodies. More antibodies put a future fetus at risk."[47] The ACOG notes that this issue can also arise even if a pregnancy is not carried to term, be it due to miscarriage, ectopic pregnancy, or abortion.

A RhoGAM shot—both during pregnancy and immediately after delivery—prevents the woman's body from initiating the antibody response, but is specific to the individual pregnancy and would be necessary for any other subsequent pregnancies with an Rh-positive baby.

ACOG recommends this treatment after an abortion at any gestation and regardless of method, surgical or chemical.[48] The National Abortion Federation, in contrast, does not recommend this treatment for abortions occurring before eight weeks.[49] So, providers who fail to determine a woman's blood type and, if indicated, initiate applicable treatment may be putting women in a situation where she makes antibodies that—in the words of ACOG—"put a future fetus at risk."

Adverse Events. As a condition of becoming a certified prescriber, the prescriber agreement originally required prescribers to report serious adverse events and complications to Danco, who, in turn, submits regular reports to the FDA. These adverse events—as well as voluntary reports to the MedWatch program (to which both health care professionals and consumers can contribute) are compiled in the FDA's FAERS. But when a woman experiences an abortion complication, she will likely report to an emergency room or other outpatient facility rather than the practitioner who prescribed the abortion pill regimen. Not all abortion providers have hospital admitting privileges, which inhibits continuity of care. There is no way to know how often emergency rooms and other facilities fail to report complications to Danco or the FDA, as they may not know the woman is undergoing an elective chemical abortion as opposed to a miscarriage.

In 2016, the FDA weakened the reporting requirements so that only deaths were required to be reported to the FDA. To date, mifepristone has been tied to 24 deaths and more than 4,000 adverse events.[50] Because reporting adverse events other than death is voluntary, it is impossible to capture a truly accurate representation of complications associated with chemical abortion.

Chemical abortion proponents tout chemical abortion as safe and effective, but many studies require caveats and additional context that call some of these claims into question.[51] Simply put, U.S. abortion data often leaves much to be desired, because there is no single federal standard or centralized tracking.[52] Studies in Finland, whose single-payer health system and robust record-keeping protocols differ from the systems and protocols in the U.S., paint a less rosy picture. One such study found that one in five women experienced an adverse event following a chemical abortion, and rates of complication were *four times higher* in chemical abortions compared to surgical abortions.[53]

Illegal Actors

Illegal actors, both foreign and domestic, ship chemical abortion pills directly to consumers through the mail service—some flagrantly, and some surreptitiously. Online websites such as PlanCPills.org instruct buyers on how to circumvent telemedicine restrictions and purchase abortion pills through unregulated online pharmacies. According to the FDA, only "three percent of online pharmacies are in compliance with U.S. pharmacy laws and practice standards."[54] These individuals and organizations are not only operating illegally or directing consumers toward illegal activity: They are endangering women.

Among the most well-known of these bad actors is a Netherlands-based doctor, Rebecca Gomperts, who is not licensed to practice medicine in the United States. Gomperts operates AidAccess, an Internet-based service that prescribes misbranded and unapproved abortion pills to women in the United States.[55]

These drugs, which, according to Gomperts, come from India,[56] are not approved for use in the U.S. The FDA webpage for Mifeprex/mifepristone contains a prominent warning that consumers should not purchase the drug over the Internet because its use in the United States is only allowed under the heightened REMS restrictions, and "drugs purchased from foreign Internet sources are not the FDA-approved versions of the drugs, and they are not subject to FDA-regulated manufacturing controls or FDA inspection of manufacturing facilities."[57]

In 2019 the FDA sent a warning letter[58] to AidAccess stating that the organization introduced misbranded and unapproved drugs into interstate commerce in violation of the Federal Food, Drug, and Cosmetic Act,[59] and demanding that the website immediately cease such activity. AidAccess fired back, defiantly alleging that the FDA was violating Gomperts' patients' constitutional rights by restricting their access to abortion.[60] AidAccess then filed a complaint in the District of Idaho asking the court to prevent the FDA from taking action against them—and made sweeping declarations that a host of U.S. laws violated Gomperts' patients' constitutional rights.[61] The FDA requested that the complaint be dismissed on a number of administrative and standing grounds, noting that interfering with Gomperts' patients' ability to obtain unapproved versions of abortion pills is not the same thing as interfering with her patients' right to obtain an abortion.[62] In July 2020, the court sided with the FDA and dismissed the Gomperts complaint. But AidAccess continues to operate in flagrant violation of U.S. law, and the FDA has not, to date, publicly followed up with any additional action since the 2019 warning letter.

Individual bad actors threaten women's health and safety as well. In July 2020, Ursula Wing of New York was fined and sentenced to two years of probation for illegally purchasing abortion pills from abroad and then selling them to people in the United States. She operated a website that purported to sell jewelry, and repackaged wholesale abortion pills sourced in India into individual quantities to send to purchasers in the United States. She shipped jewelry items in shipping envelopes with a hidden panel containing the abortion pills.[63]

By selling misbranded medication to individuals without a prescription or license to do so, Wing put an untold number of women in danger. She could not verify the gestation of an alleged pregnancy, rule out ectopic

pregnancy, or conduct any of the other verifications that an evaluation by a qualified medical provider should assess. Furthermore, she did not verify to whom she was shipping pills. In fact, one of Wing's customers was a Wisconsin man who purchased the abortion pills from Wing and secretly crushed them up in his girlfriend's drink in an attempt to abort their 21-week-old unborn child. He faces charges of attempted homicide of an unborn child and illegal prescription drug delivery.[64]

A study published in *Contraception*, a journal with close ties to the abortion industry, documented the experience of purchasing abortion pills from 18 online pharmacy sites, then tested the composition of pills they received. None of these websites required proof of prescription, nor did they ask for information such as gestational age of pregnancy or information that would ascertain contraindications. Some pills contained very little of the advertised amount of misoprostol. Some packages arrived damaged, and many did not match the picture of the online advertisement. Perhaps most troubling for a drug with a track record that includes maternal death, none of the packages contained instructions. Though pills were purchased from a number of different websites, many were run by the same vendors, and some of the websites were no longer live by the time the study was published.

Despite these appalling findings, the study authors characterize the online abortion pill ordering process mildly as "suboptimal," but nevertheless, still concluded that some people "may consider self-sourcing pills from the internet to be a rational option."[65] Two of the study's authors work for Gynuity, a pro-abortion research organization heavily involved with efforts to expand telemedicine abortion in the U.S.

Impact on the Abortion Landscape

The Guttmacher Institute's most recent Abortion Provider Census survey found that the number of facilities that provide abortions, including hospitals, clinics, and physician offices, declined 5 percent between 2014 and 2017.[66] Furthermore, the vast majority of private practice obstetricians and gynecologists do not perform abortions. Among those who do not perform abortions, only half are willing to refer patients elsewhere to obtain an abortion.[67] But a Kaiser Family Foundation survey released prior to the abortion pill's FDA approval found that many health care practitioners who were opposed to or ineligible to provide surgical abortions would be interested in providing chemical abortions.[68]

For the abortion industry, moving the procedure from the surgical realm to one in which a provider can simply prescribe a pill creates a perceived

separation from the procedure itself, and can make the prospect of providing chemical abortion more acceptable than providing surgical abortions. Furthermore, where surgical abortions require specific resources such as training, facilities, and equipment, chemical abortion does not require the same level of investment on the part of providers.

Chemical Abortion Reversal. Conversely, the advent of chemical abortion has also led to some providers offering abortion pill reversal (APR).[69] APR is a protocol that uses periodic doses of progesterone to counteract the effect of mifepristone, which is a progesterone inhibitor.[70] According to testimony of Dr. George Delgado, who published the first peer-reviewed article on the subject in 2012, hundreds of women have successfully given birth after pursuing APR to counteract the effect of mifepristone.[71]

From Surgical to Chemical. The abortion pill has been a relative panacea for the abortion industry. Though the overall abortion rate has consistently declined in recent decades, chemical abortion has provided the industry with the ability to expand abortion by opening the door to involving more providers outside a traditional abortion business (like Planned Parenthood) and go beyond the limitations of a brick-and-mortar clinic through telemedicine services and the option for women to take the abortion pills in a home setting.

If the abortion lobby achieves its goal of weakening or eliminating the mifepristone REMS, the abortion landscape in America would look drastically different. Weakening the regulations could lead to an increase in the number of providers willing to prescribe the drug because specific certification requirements and dispensing restrictions would not be required by the prescribing practitioner. There is also the potential for an explosion of telemedicine abortion.

Under current REMS, some chemical abortion providers are offering a "hybrid" telemedicine process in which a woman goes to a practice that is able to stock mifepristone, then communicates with the prescribing provider off-site so that the practice can dispense the medication for her.[72] The FDA is currently allowing an abortion pill telemedicine study to be conducted in a number of states that follow a more traditional telemedicine model and allow the abortion drugs to be sent to women directly via mail.[73]

Conscience Rights. Should the FDA open the door to expand chemical abortion to additional channels—retail pharmacies, for example—conscience rights can be implicated. Current federal law provides for various conscience protections regarding abortion in the context of health care. For example, entities receiving certain federal funds, such as hospitals, cannot discriminate against a provider who refuses to perform or participate in

an abortion procedure.[74] At the state level, varying degrees of conscience protection statutes in the health care space exist as well; according to the Guttmacher Institute, an abortion-rights research organization, 46 states provide for some sort of conscience protection for abortion services.

If regulations for chemical abortion drugs, specifically prescribing and dispensing them, were to be loosened or eliminated, individuals and entities could find themselves vulnerable, particularly pharmacists. Current conscience protections regarding abortion procedures were written with health care practitioners and institutions in mind—not necessarily pharmacists. Some states affirmatively require pharmacists to fill all prescriptions with no exceptions.[75] If chemical abortion drugs were ever expanded to additional retail settings, current conscience protection statutes might not provide adequate protection to objecting individuals and/or entities.

Recommendations

To protect women's health and safety, the federal government and state and federal policymakers should, at a minimum, ensure that policies are in place to robustly regulate chemical abortion drugs and provide for enforcement actions against bad actors.

At the federal level, steps should include, but are not limited to:

- **Strengthening the current REMS,** including restrictions on what practitioners may be qualified prescribers and returning to the pre-2016 gestational cutoff of 49 days gestation.

- **Strengthening the FDA Adverse Events Reporting System process** by requiring that all adverse events—not just deaths—be reported and requiring all qualified prescribers to report directly to the FDA rather than the abortion pill manufacturer.

- **Taking decisive action at relevant agencies** to prevent international actors from shipping chemical abortion drugs to women in the United States for distribution and prosecuting those who fail to comply with the law.

- **Requiring transparency** about where Danco and GenBioPro's U.S.-bound abortion pills are manufactured, and ensure that manufacturing facilities are regularly inspected.

- **Ending the dangerous abortion pill telemedicine trial** that is currently being conducted in a number of states. According to the trial's lead investigator, they are interested in exploring ways to circumvent state laws prohibiting telemedicine abortion.[76]

Pro-abortion actors have aggressively called for the FDA weaken or remove the REMS and allow for telemedicine abortion and retail pharmacy dispensing. In the future, a presidential administration hostile to life could do the bidding of the abortion lobby.

In order to ensure that important protections remain in place even under a hostile presidential administration, state policymakers should enact policies to protect women and unborn children within their jurisdictions, including:

- **Ensuring that women receive adequate informed consent prior to obtaining a chemical abortion**. From outlining health risks to sharing information about the availability of the abortion pill reversal protocol, states can provide women with the information they need to make a fully informed decision.

- **Regulating chemical abortion**, including bans on telemedicine abortion, heightened prescriber requirements, robust record-keeping and data collection, and other health and safety measures necessary to protect women in the absence of (or in addition to) federal requirements.

- **Enacting policies aimed at preventing women from being coerced into an abortion** by an unsupportive partner or abuser. From signs in clinic waiting rooms, exam rooms, and bathrooms to laws criminalizing coercion, states can do more to protect women from obtaining an abortion under duress, which can be facilitated through chemical abortion.

Conclusion

Chemical abortions subject women to serious health and safety risks. Despite its characterization by the abortion industry as an easy process, it "takes much longer, involves far more bleeding and pain, and complications occur four times more frequently from medical as compared to surgical abortions."[77] Yet pro-abortion actors like Planned Parenthood

and the American Civil Liberties Union are agitating in court, as well as the public policy sphere, to remove important FDA-imposed safety restrictions.

A presidential administration interested in expanding chemical abortion may make these FDA restrictions a thing of the past—endangering women and their unborn children in the process. Policymakers, particularly at the state level, must prepare for the increasing likelihood that the burden of protecting women from the dangerous chemical abortion pills falls on them.

Melanie Israel is Research Associate in the Richard and Helen DeVos Center for Religion and Civil Society, of the Institute for Family, Community, and Opportunity, at The Heritage Foundation.

Endnotes

1. Julian Guthrie, "Monty Patterson Learns About RU-486 the Hard Way," SFGate, December 5, 2011, https://www.sfgate.com/entertainment/article/Monty-Patterson-learns-about-RU-486-the-hard-way-2345757.php (accessed March 3, 2021).
2. "RU-486: Demonstrating a Low Standard for Women's Health?" hearing before the Subcommittee on Criminal Justice, Drug Policy, and Human Resources, Committee on Government Reform, U.S. House of Representatives, May 17, 2006, https://www.congress.gov/109/chrg/CHRG-109hhrg31397/CHRG-109hhrg31397.pdf (accessed March 3, 2021).
3. "Abortion Procedures: What You Need to Know," AbortionProcedures, https://www.abortionprocedures.com/ (accessed March 16, 2021).
4. See, e.g., *Planned Parenthood Cincinnati Region v. Taft*, 459 F. Supp. 2d 626 (S.D. Oh. 2006), and Planned Parenthood, "The Abortion Pill," https://www.plannedparenthood.org/learn/abortion/the-abortion-pill (accessed March 12, 2021). Planned Parenthood freely advertises chemical abortion up to 77 days from the first day of the last menstrual period.
5. U.S. House of Representatives, *The FDA and RU-486: Lowering the Standard for Women's Health*, Government Reform Committee, October 2006, p. 25, https://aaplog.wildapricot.org/resources/Souder%20Comm.%20Rprt_RU-486_October%202006_converted%5b1%5d%20(1).pdf (accessed March 3, 2021).
6. Mifepristone, U.S. Post-Marketing Adverse Events Summary through 12/31/2018, United States Food and Drug Administration, https://www.fda.gov/media/112118/download (accessed March 19, 2021).
7. Ibid.
8. Katherine Kortsmit et al., "Abortion Surveillance: United States, 2018," *Morbidity and Mortality Weekly Report*: *Surveillance Summaries*, Vol. 69, No. 7 (November 27, 2020), https://www.cdc.gov/mmwr/volumes/69/ss/ss6907a1.htm (accessed March 3, 2021).
9. Megan K. Donovan, "Self-Managed Medication Abortion: Expanding the Available Options for U.S. Abortion Care," *Guttmacher Policy Review*, Vol. 21 (October 17, 2018), https://www.guttmacher.org/gpr/2018/10/self-managed-medication-abortion-expanding-available-options-us-abortion-care (accessed March 3, 2021).
10. Chuck Donovan and Rebecca Gonzales, "Abortion Reporting: Toward a Better National Standard," The Charlotte Lozier Institute America *Reports Series*, Issue 12 (August 2016), https://s27589.pcdn.co/wp-content/uploads/2016/08/Abortion-Reporting-Toward-a-Better-National-Standard-FINAL.pdf (accessed March 3, 2021).
11. Steven Greenhouse, "A New Pill, A Fierce Battle," *New York Times Magazine*, February 12, 1989, https://www.nytimes.com/1989/02/12/magazine/a-new-pill-a-fierce-battle.html (accessed March 3, 2021).
12. Alexander Dorozynski, "Boycott Threat Forces French Company to Abandon RU486," *British Medical Journal*, Vol. 314 (April 19, 1997), p. 1150, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2126515/pdf/9146386.pdf (accessed March 3, 2021).
13. R. Alta Charo, "A Political History of RU-486," in Kathi E. Hanna, ed., *Biomedical Politics* (Washington, DC: National Academies Press, 1991), https://www.ncbi.nlm.nih.gov/books/NBK234199/ (accessed March 3, 2021).
14. U.S. House of Representatives, *The FDA and RU-486: Lowering the Standard for Women's Health*.
15. Warren E. Leary, "Maker of Abortion Pill Reaches Licensing Pact with U.S. Group," *New York Times*, April 21, 1993, https://www.nytimes.com/1993/04/21/us/maker-of-abortion-pill-reaches-licensing-pact-with-us-group.html (accessed March 3, 2021).
16. Judicial Watch, "A Judicial Watch Special Report: The Clinton RU-486 Files," April 26, 2006, Tab A, https://www.judicialwatch.org/archive/2006/jw-ru486-report.pdf (accessed March 3, 2021).
17. Ibid., Tab E.
18. Judith A. Johnson, "Abortion: Termination of Early Pregnancy with RU-486 (Mifepristone)," Congressional Research Service *Report for Congress*, February 23, 2001, https://www.everycrsreport.com/files/20010223_RL30866_c6c423f682c56ed7c586755595c02d5202ddf6bd.pdf (accessed March 3, 2021).
19. Katharine Q. Seelye, "Accord Opens Way for Abortion Pill in U.S. in Two Years," *New York Times*, May 17, 1994, https://www.nytimes.com/1994/05/17/us/accord-opens-way-for-abortion-pill-in-us-in-2-years.html (accessed March 3, 2021).
20. Johnson, "Abortion: Termination of Early Pregnancy with RU-486 (Mifepristone)."
21. Government Accountability Office, *Approval and Oversight of the Drug Mifeprex*, GAO–08–751, August 2008, p. 18, https://www.gao.gov/assets/gao-08-751.pdf (accessed March 16, 2021)
22. "FDA Panel Finds Mifepristone Safe and Effective," *Reproductive Freedom News*, Vol. 5, No. 13 (1996), pp. 7–8, https://pubmed.ncbi.nlm.nih.gov/12347288/ (accessed March 3, 2021).
23. Government Accountability Office, *Approval and Oversight of the Drug Mifeprex*, p. 18.
24. Melody Petersen, "Abortion Pill Distributor Energized by New Mission," *New York Times*, September 30, 2000, https://www.nytimes.com/2000/09/30/us/abortion-pill-distributor-energized-by-new-mission.html (accessed March 3, 2021).

25. Johnson, "Abortion: Termination of Early Pregnancy with RU-486 (Mifepristone)."
26. Government Accountability Office, *Approval and Oversight of the Drug Mifeprex*.
27. 21 Code of Federal Regulations § 314.500–560 (2020). Subpart H "applies to certain new drug products that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments (e.g., ability to treat patients unresponsive to, or intolerant of, available therapy, or improved patient response over available therapy)."
28. Sheryl Gay Stolber, "F.D.A. Adds Hurdles in Approval of Abortion Pill," *New York Times*, June 8, 2000, https://www.nytimes.com/2000/06/08/us/fda-adds-hurdles-in-approval-of-abortion-pill.html (accessed March 3, 2021).
29. Rachel Zimmerman and Sarah Lueck, "Abortion-Rights Leaders Will Meet to Fight FDA Limits on RU-486," *Wall Street Journal*, June 13, 2020, https://www.wsj.com/articles/SB960849036532137478 (accessed March 3, 2021).
30. Robert O'Harrow, Jr., "Drug's U.S. Marketer Remains Elusive," *Washington Post*, October 12, 2000, https://www.washingtonpost.com/archive/politics/2000/10/12/drugs-us-marketer-remains-elusive/8b7b732b-0f23-4c96-9051-714cd3d9f6f8/ (accessed March 3, 2021).
31. Philip P. Pan, "Chinese to Make RU-486 for U.S.," *Washington Post*, October 12, 2000, https://www.washingtonpost.com/archive/politics/2000/10/12/chinese-to-make-ru-486-for-us/97e37b0f-a6fd-41f5-8ce3-d2af86adea63/ (accessed March 3, 2021).
32. Rachel Zimmerman, "Chinese Firm Will Make Abortion Pill for U.S. Market as Partner with Danco," *Wall Street Journal*, https://www.wsj.com/articles/SB971392939523276337 (accessed March 3, 2021).
33. U.S. Food and Drug Administration, Mifeprex approval letter, Center for Drug Evaluation and Research, NDA 20687, September 28, 2000, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.htm (accessed March 3, 2021).
34. U.S. Food and Drug Administration, "Approved Risk Evaluation and Mitigation Strategies (REMS)," https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsData.page (accessed March 3, 2021).
35. U.S. Food and Drug Administration, "Risk Evaluation and Mitigation Strategy: Mifiprex" Center for Drug Evaluation and Research, June 8, 2011, https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2011-06-08_REMS%20DOCUMENT.pdf (accessed March 3, 2021).
36. Center for Drug and Evaluation Research, "Summary Review," March 29, 2016, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020SumR.pdf (accessed March 3, 2021).
37. Ibid.
38. U.S. Food and Drug Administration, "Mifeprex Prescriber Agreement Form," March 29, 2016, https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2016-03-29_Prescriber_Agreement_Form.pdf (accessed March 3, 2021).
39. U.S. Food and Drug Administration, ANDA approval letter, April 11, 2019, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/091178Orig1s000ltr.pdf (accessed March 3, 2021).
40. Heather D. Boonstra, "Medication Abortion Restrictions Burden Women and Providers—and Threaten U.S. Trend Toward Very Early Abortion," *Guttmacher Policy Review*, Vol. 16, No. 1 (March 19, 2013), https://www.guttmacher.org/gpr/2013/03/medication-abortion-restrictions-burden-women-and-providers-and-threaten-us-trend-toward (accessed March 3, 2021).
41. Government Accountability Office, *Approval and Oversight of the Drug Mifeprex*.
42. Rhonda Rowland and Michele Dula Baum, "Doctors Accuse Drug Maker of Limiting Abortion Pill," CNN, January 3, 2001, http://edition.cnn.com/2001/HEALTH/women/01/03/abortion.pill/ (accessed March 3, 2021).
43. U.S. Food and Drug Administration, "Cytotec Misoprostol Tablets," February 28, 2018, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/019268s051lbl.pdf (accessed March 3, 2021).
44. Ibid.
45. American Association of Pro-life Obstetricians and Gynecologists, "Practice Bulletin 8: Medical Management of Elective Induced Abortion," February 25, 2020, https://aaplog.org/wp-content/uploads/2020/03/FINAL-PB-8-Medical-Management-of-Elective-Induced-Abortion.pdf (accessed March 3, 2021).
46. American College of Obstetricians and Gynecologists, "The Rh Factor: How It Can Affect Your Pregnancy," https://www.acog.org/womens-health/faqs/the-rh-factor-how-it-can-affect-your-pregnancy (accessed March 3, 2021).
47. Ibid.
48. American College of Obstetricians and Gynecologists, "Practice Bulletin No. 181: Prevention of Rh D Alloimmunization," *Obstetrics & Gynecology*, Vol. 130, No. 2 (August 2017), https://journals.lww.com/greenjournal/Fulltext/2017/08000/Practice_Bulletin_No__181__Prevention_of_Rh_D.54.aspx (accessed March 3, 2021).
49. Mark A Foster et al., "Foregoing Rh Testing and Anti-D Immunoglobulin for Women Presenting for Early Abortion: A Recommendation from the National Abortion Federation's Clinical Policies Committee," *Contraception* (March 10, 2019), https://www.contraceptionjournal.org/article/S0010-7824(19)30053-8/fulltext (accessed March 3, 2021).
50. U.S. Food and Drug Administration, "Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2018," https://www.fda.gov/media/112118/download (accessed March 3, 2021).

51. American Association of Pro-life Obstetricians and Gynecologists, "Practice Medical Management of Elective Induced Abortion."
52. Although the Centers for Disease Control and Prevention collects annual state abortion data, reporting is not mandatory, and the different states often supply different information, making consistent comparisons and categorizations difficult.
53. American Association of Pro-life Obstetricians and Gynecologists, "Practice Bulletin 8: Medical Management of Elective Induced Abortion."
54. U.S. Food and Drug Administration, "BeSafeRX: For the Media," updated February 13, 2018, https://www.fda.gov/drugs/besaferx-your-source-online-pharmacy-information/media (accessed March 3, 2021).
55. AidAccess.com, "About Us," https://aidaccess.org/en/page/698649/about-aid-access (accessed March 17, 2021).
56. Sarah McCammon, "European Doctor Who Prescribes Abortion Pills to U.S. Women Online Sues FDA, NPR," September 9, 2019, https://www.npr.org/2019/09/09/758871490/european-doctor-who-prescribes-abortion-pills-to-u-s-women-online-sues-fda (accessed March 17, 2021).
57. U.S. Food and Drug Administration, "Mifeprex (Mifepristone) Information," updated February 5, 2018, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information (accessed March 3, 2021).
58. U.S. Food and Drug Administration, letter to Aidaccess.org, March 8, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/aidaccessorg-575658-03082019 (accessed March 3, 2021).
59. 21 U.S. Code §§ 331(a), 331(d), and 355(a).
60. Letter of Richard Hearn to Thomas Christl, May 16, 2019, https://aidaccess.org/en/media/inline/2019/5/16/19_05_16_gomperts_letter_and_exhibit_a.pdf (accessed March 3, 2021)
61. Rebecca Gomperts and Aid Access v. Alex Azar, 1:19-cv-00345-DCN (D. Idaho 2019), https://aidaccess.org/en/media/inline/2019/9/9/19_09_09_verified_complaint_with_exhibits-420116928.pdf (accessed March 3, 2021).
62. Ibid.
63. News release, "New York Woman Sentenced for Selling Abortion-Inducing Pills Illegally Smuggled into U.S.," U.S. Attorney's Office, July 10, 2020, https://www.justice.gov/usao-wdwi/pr/new-york-woman-sentenced-selling-abortion-inducing-pills-illegally-smuggled-us (accessed March 3, 2021).
64. Kevin Murphy, "Abortion-Drug Dealer Pleads Guilty, Linked to Grand Rapids Man Accused of Poisoning Pregnant Woman's Drink," *Wisconsin Rapids Tribune*, March 5, 2020, https://www.wisconsinrapidstribune.com/story/news/2020/03/05/abortion-pill-dealer-ursula-wing-guilty-case-tied-grand-rapids-man/4966488002/ (accessed March 3, 2021).
65. Chloe Murtagh et al., "Exploring the Feasibility of Obtaining Mifepristone and Misoprostol From the Internet," *Contraception*, Vol. 97, No. 4 (October 10, 2017), https://www.contraceptionjournal.org/article/S0010-7824(17)30475-4/fulltext# (accessed March 3, 2021).
66. Rachel K. Jones, Elizabeth Witwer, and Jenna Jerman, "Abortion Incidence and Service Availability in the United States, 2017," Guttmacher Institute, September 2019, https://www.guttmacher.org/report/abortion-incidence-service-availability-us-2017 (accessed March 19, 2021).
67. Sheila Desai, Rachel K. Jones, and Kate Castle, "Estimating Abortion Provision and Abortion Referrals Among United States Obstetrician-Gynecologists in Private Practice," *Contraception*, Vol. 97, No. 4 (November 21, 2017), pp. 297–302, https://pubmed.ncbi.nlm.nih.gov/29174883/ (accessed March 3, 2021).
68. Nancy Gibbs, "The Pill Arrives," CNN, October 2, 2000, https://www.cnn.com/ALLPOLITICS/time/2000/10/09/pill.html (accessed March 3, 2021).
69. Abortion Pill Rescue, "Reversal FAQ," https://abortionpillreversal.com/abortion-pill-reversal/faq (accessed March 17, 2021).
70. American Association of Pro-life Obstetricians and Gynecologists, "2019 AAPLOG Position Statement on Abortion Pill Reversal," February 2019, https://aaplog.org/wp-content/uploads/2019/02/2019-AAPLOG-Statement-on-Abortion-Pill-Reversal.pdf (accessed March 3, 2021).
71. George Delgado, "Written Testimony of George Delgado, M.D., F.A.A.F.P., in Support of Colorado Abortion Pill Reversal Bill," February 16, 2017, https://lozierinstitute.org/written-testimony-of-george-delgado-m-d-f-a-a-f-p-in-support-of-colorado-abortion-pill-reversal-bill/ (accessed March 17, 2021).
72. Donovan, "Self-Managed Medication Abortion: Expanding the Available Options for U.S. Abortion."
73. Carole Novielli, "Abortion Pill Clinical Trial Expands in Likely Attempt to Thwart FDA Safety Regulations," Live Action, April 3, 2020, https://www.liveaction.org/news/abortion-pill-trial-expands-thwart-fda-safety (accessed March 3, 2021).
74. Melanie Israel, "What Congress and the Administration Can Do to Protect Conscience Rights," Heritage Foundation *Issue Brief* No. 4795, December 7, 2017, https://www.heritage.org/civil-society/report/what-congress-and-the-administration-can-do-protect-conscience-rights.
75. Rachel La Corte, "High Court Won't Hear Challenge to Rules That Washington Pharmacies Dispense Emergency Contraceptives," *Seattle Times*, June 28, 2016, https://www.seattletimes.com/seattle-news/high-court-wont-hear-challenge-to-rule-that-washington-pharmacies-dispense-emergency-contraceptives/ (accessed March 3, 2021).
76. Novielli, "Abortion Pill Clinical Trial Expands in Likely Attempt to Thwart FDA Safety Regulations."
77. American Association of Pro-life Obstetricians and Gynecologists, "Practice Bulletin 8: Medical Management of Elective Induced Abortion."