

ABORTION PILL EXPOSED




LIVE ACTION

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INTRODUCTION



Since *Roe v. Wade* became law in 1973, the abortion industry has conducted its business of dismembering children at brick-and-mortar abortion facilities. Roe was supposed to eliminate “back-alley” abortions, making the practice safer for women—albeit no less dangerous for the aborted children. Despite decades of calling for “safe, legal, and rare” abortions, the industry consistently opposes health and safety regulations on abortion.

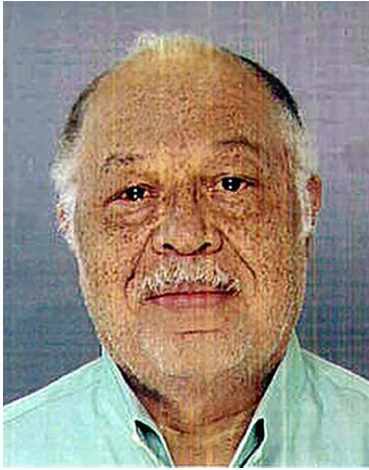
In *Whole Women’s Health v. Hellerstedt*, the Supreme Court held in 2016 that requiring abortionists to obtain admitting privileges at a hospital within 30 miles of the abortion facility constitutes an “undue burden” to Roe’s constitutional right to abortion. Such laws require abortion facilities to observe the same standards as ambulatory surgical centers, which require hospital admitting privileges. Ambulatory surgical centers are required to have admitting privileges or transfer agreements with the hospital. Surgical abortions involve the risks of infection, excessive bleeding, and uterine perforation.

Hospital admitting privilege laws went into effect in the 1980s in states like Missouri and Massachusetts. However, according to the pro-abortion Guttmacher Institute, “**it was not until 2011** that several other states” started passing similar laws. (emphasis added).

Kermit Gosnell

In 2010, abortionist Kermit Gosnell gained national attention when his facilities were raided by the Philadelphia Police Department and federal agents from the Drug Enforcement Agency (DEA) and the Federal Bureau of Investigation (FBI).

**Gosnell “routinely
killed viable babies
and irreparably
damaged women.”**



Kermit Gosnell

The agents obtained a search warrant to look for evidence of illegal prescriptions for opioids and other highly addictive drugs they suspected Gosnell was distributing. Upon entering Women’s Medical Society, the agents encountered the appalling conditions women were subjected to by Gosnell and his staff.

According to the 2011 grand jury report, Gosnell “routinely killed viable babies and **irreparably damaged women.**” (emphasis added). The report described Gosnell’s facility as a “wretched, filthy space,” where “[d]irty facilities; unsanitary instruments; an absence of functioning monitoring and resuscitation equipment; the use of cheap, but dangerous, drugs; illegal procedures; and inadequate emergency access for when things inevitably went wrong, all put patients at grave risk—every day.”¹

The report went on in chilling detail: “There was blood on the floor. A stench of urine filled the air. A flea-infested cat was wandering through the facility, and there were cat feces on the stairs. Semi-conscious women scheduled for abortions were moaning in the waiting room or the recovery room, where they sat on dirty recliners covered with blood-stained blankets. All the women had been sedated by unlicensed staff – long before Gosnell arrived at the clinic – and staff members could not accurately state what medications or dosages they had administered to the waiting patients. Many of the medications in inventory were past their expiration dates.”

Gosnell’s license was revoked, and he was later arrested and charged on eight counts of murder—of seven babies and of 41-year old Karnamaya Mongar. Gosnell’s employees described cutting the spines of *hundreds* of live infants as “standard procedure.” For the seven babies charges were brought for, employees testified they had seen the children

¹ Report of the Grand Jury XXIII MISC. NO.0009901-2008 in the First Judicial District of Pennsylvania (Commonwealth of Pennsylvania v. Kermit Gosnell).

move and cry before Gosnell murdered them. Gosnell also killed Karnamaya Mongar by giving her a lethal amount of painkillers. In 2013, Gosnell was convicted on three counts of murder and involuntary manslaughter of Mongar.

The Purpose of Health and Safety Regulations

The Gosnell case led to nine more states passing laws between 2011 and 2014 requiring abortionists to obtain hospital admitting privileges. As a result, dozens of abortions clinics began closing before several of these laws were stopped by court order. The closures were testament to the fact that abortionists, who operate in substandard conditions, tend to have difficulty obtaining privileges at nearby hospitals.

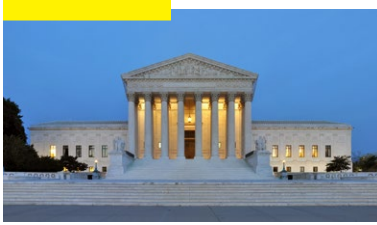


Dr. Kathi Aultman, former abortionist and associate scholar at the Charlotte Lozier Institute

Defending these requirements as necessary for women's safety, Dr. Kathi Aultman, a former abortionist and associate scholar at the Charlotte Lozier Institute, wrote in *USA Today*: "As a gynecologist on call in the emergency room, I personally treated women experiencing severe complications, including life-threatening hemorrhage and infection from abortions, because no one at the abortion clinic had admitting privileges. No abortion clinic personnel ever called to give me information on a patient they were sending to the ER. This is not a safe way to practice medicine."²

Aultman also tells of an abortion facility manager who said she was told to use "dish washing liquid to clean their instruments when their sanitizer broke down," and of a patient experiencing complications from a late-term abortion who "was kept in a cold room overnight without a blanket during an induction abortion," and "forced to give birth in a toilet the next morning, only to watch her still living baby drown."

² Kathi Aultman, "I was an abortionist. The abortion industry isn't willing to prioritize patient safety," *USA TODAY*, January 22, 2020, <https://www.usatoday.com/story/opinion/2020/01/22/abortion-doctor-complications-pro-life-roe-wade-column/4530180002/>.



U.S. Supreme Court Building

Despite the abortion industry's documented history of running substandard and unsanitary facilities, *Hellerstedt* struck down the Texas hospital admitting privileges law. In 2020, *June Medical Services, LLC v. Russo* placed the issue before the Supreme Court again, this time over Louisiana's similar admitting privileges requirement. While health and safety regulations are almost always upheld as constitutional by the Supreme Court, so long as there is a "rational basis" for enacting the law, the Supreme Court once again decided that abortion facilities get to operate under a different set of rules than every other industry. Chief Justice John Roberts, who dissented in *Hellerstedt*, even came to the shocking conclusion in his *June Medical* concurrence that *Hellerstedt* is now fundamental judicial precedent.³

And nevermind, as Justice Alito pointed out in his scathing dissent, that letting the abortion industry evade health and safety regulations by asserting the constitutional rights of women (i.e., their paying clients) poses an extraordinary conflict of interest. "[T]he idea that a regulated party," Alito said, "can invoke the right of a third party for the purpose of attacking legislation enacted to protect the third party is stunning." Indeed, why not allow automobile manufacturers to overturn safety regulations on behalf of drivers? Or let Big Tobacco enjoin Food and Drug Administration (FDA) warning standards, on behalf of smokers?

Pro-lifers realize that the purpose of these laws is not to protect preborn children in the womb. Not directly. In fact, these laws acknowledge the disturbing reality that Roe enshrined the killing of preborn children into the US Constitution. Nevertheless, the pro-life movement supports laws and regulations protecting the health and safety of women seeking abortions—many of whom are victims of

³ Guttmacher Institute, "Admitting Privileges are Back at the U.S. Supreme Court with Serious Implications for Abortion Access," *Policy Analysis*, <https://www.guttmacher.org/article/2019/10/admitting-privileges-are-back-us-supreme-court-serious-implications-abortion-access#>.

abortion industry lies. At a minimum, health and safety regulations on the abortion industry can **mitigate the damage** in the effort to end legalized abortion—namely, **irreparable damage to women**—even though they fail to protect the lives of the more than 800,000 preborn victims killed in the US each year by the industry.

Health and safety regulations place obstacles in the path of the abortion industry, which is bent on maximizing its profits at the expense of women's safety. In the same way, health and safety regulations on tobacco products and e-cigarettes make it difficult for Big Tobacco to push dangerous products on impressionable children. The FDA requires tobacco companies to disclose the health and safety risks associated with smoking, and the Federal Trade Commission (FTC), along with state regulatory agencies, prohibits deceptive advertising and tobacco advertising aimed at minors. All of these regulations increase the cost of doing business and impose legal compliance standards on companies specifically to protect consumers.

When the Clinton administration approved the abortion pill in 2000, a new frontier opened for the abortion industry. It offered abortion businesses the possibility to forgo the brick-and-mortar overhead costs of rent, employees, and medical equipment, to sell lethal drugs to women for at-home consumption. The abortion industry champions the pill's ability to *expand access* to abortion.

For its part, the FDA has imposed only one set of conditions: the abortion pill can only be prescribed during the first ten weeks of pregnancy and dispensed according to a "risk evaluation and mitigation strategy," (REMS).

Under REMS, the abortion pill must be prescribed and dispensed in clinics, medical offices, or hospitals. REMS requires the supervision of a clinician who is certified to

For its part, the FDA has imposed only one set of conditions: the abortion pill can only be prescribed during the first ten weeks of pregnancy, and dispensed subject to a "risk evaluation and mitigation strategy," or REMS. Under REMS, the abortion pill must be prescribed and dispensed in clinics, medical offices, or hospitals.



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prescribe the pill, and women must sign an FDA-approved “Patient Agreement” establishing informed consent to the pill’s risks. Those risks include excruciating abdominal pain, weeks of heavy bleeding, nausea, vomiting, diarrhea, headache, infection, sepsis, and in some cases, death.

Some states have put additional safety restrictions on the abortion pill, such as requiring the medical professionals who prescribe the pill to be licensed physicians or requiring that the clinician (or physician) be present in the clinic with the woman. Proponents of the abortion pill complain that this limits availability for women in rural areas who do not live near a healthcare facility that prescribes the abortion pill.

States like Arkansas, Arizona, Ohio, Oklahoma, North Dakota, and Texas passed laws prohibiting off-label use of the abortion pill. Some of these laws were blocked by court order until the Obama administration mooted the issue, loosening the existing FDA requirements to be in line with so-called “scientific evidence and best practices.” In 2016, under the Obama administration, the FDA extended the period women could take the abortion pill from the first seven weeks of pregnancy to the first ten weeks, reduced the required dosage of mifepristone from 600 milligrams to 200 milligrams, and reduced the number of required doctor visits from three to two.

But the 2016 changes were never intended to be the last word. Dr. Daniel Grossman, an obstetrician and researcher at the University of California San Francisco (UCSF) has been a leading voice calling for the complete removal of REMS. Now with Coronavirus (COVID-19) Pandemic and consequent lockdown orders extending into the foreseeable future, the abortion industry has ramped up demands for the abortion pills to be dispensed online, by mail, and entirely through telemedicine. In July, 2020, they even convinced a federal judge to suspend the In Person Requirements of REMS

for the duration of the COVID-19 Pandemic—meaning the abortion pill can now be dispensed through telemedicine.

In effect, the abortion industry seeks to “demedicalize” abortion, removing any requirement that licensed physicians be involved in the process. Physicians are legally liable for negligence. The facilities they operate in can be subject to additional health and safety regulations (such as sanitation standards or hospital admitting requirements). Before taking mifepristone, women are currently given laboratory tests to determine blood type, confirm pregnancy, and whether she is anemic, and an ultrasound can be administered to confirm gestational age and rule out ectopic pregnancy. The healthcare provider can also assess whether the patient has any of several contraindications to the drugs and provide antibiotics to prevent infection.




Dr. Rebecca Gomperts

Fully demedicalizing abortion would mean a woman can purchase the abortion pill at a pharmacy without a prescription or order it online, without a doctor’s oversight, without going into a clinic, without any blood test or ultrasound, and without giving informed consent or being advised of severe risks. There will be no one to confirm that the abortion is complete or to treat complications.

The abortion industry wants to expand access to areas where clinics and abortionists are not available within the US and into global regions where abortion is still illegal. Dr. Rebecca Gomperts, an abortion activist licensed in the Netherlands, used to sail around the world with her Women on Waves organization, bringing the abortion pill to women in countries where abortion is illegal. In 2005, she shifted her approach with Women on Web to advocate abortion pill distribution using telemedicine.

In March of 2019, Gomperts’ mail-order abortion pill organization, Aid Access, which ships abortion pills around



This report argues the abortion industry, including its allies in academia, news media, the medical community, the pharmaceutical industry, billionaire-philanthropic circles, and politics, simply want abortion to be legal and ubiquitous, while health and safety requirements must not interfere with “access” (and profits).

the globe from a manufacturer in India, finally received a warning letter from the FDA to cease distributing unapproved and misbranded abortion pills into the US in violation of FDA protocols. The FDA warning letter threatened to take “regulatory action” against Gomperts, including “seizure or injunction.” In an open letter that same year, more than 100 pro-life Congressmen applauded the FDA’s swift action and urged the agency to keep up its consistent enforcement of REMS.⁴

In May of 2020, several leading pro-life organizations, including Live Action, Susan B. Anthony (SBA) List, the American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG), Americans United for Life (AUL), National Right to Life (NRLC), Heartbeat International, Family Research Council (FRC), Thomas More Society, Operation Rescue, and March for Life, signed onto a letter urging the FDA to seize the website domains of organizations like Aid Access, Rablon, and Plan C, which publicly advertise their defiance of REMS.

According to Gomperts, shipments have been seized, transactions with US clients have been blocked, and wire service companies are refusing to do business with her. Gomperts sued the FDA in federal court, claiming the FDA warning letter and the REMS protocols constitute an undue burden on a woman’s right to choose under the US Constitution, as well as a violation of her due process rights under the Fifth Amendment. Gomperts’ complaint points to the recent indictment of Ursula Wing as evidence of the government’s attempt to threaten her with fines or imprisonment. Wing was charged under the same statute the FDA threatened Gomperts with, 21 USC § 331(a), for illegal importation of misbranded abortion pills into US commerce.

⁴ Food and Drug Administration (FDA), “Aidaccess.org - 575658 - March 08, 2019,” *Warning Letters*. <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/aidaccessorg-575658-03082019>.

Wing, a resident of New York City, imported abortion pills from India and sold them to a man named Jeffrey Smith in Grand Rapids, Michigan. Smith bought the pills from Wing's blog, the *Macrobiotic Stoner*, and slipped them into his girlfriend's water bottle. Smith's girlfriend noticed the residue and turned Smith into the police. Smith was charged with attempted homicide of a preborn child, and Wing, who claimed she was glad to undermine FDA requirements, pleaded guilty to conspiracy and faces up to five years in prison. Against her attorney's advice, Wing said she wanted to see cypcats and that there are "not enough people" ordering abortion pills online.

The eagerness of abortion industry allies to sweep aside the **minimal health and safety regulations imposed by REMS** puts the farce of "safe, legal, and rare" in focus. This report argues the abortion industry, including its allies in academia, news media, the medical community, the pharmaceutical industry, billionaire-philanthropic circles, and politics, simply want abortion to be **legal and ubiquitous**, while health and safety requirements must not interfere with "access" (and profits). Nothing will accomplish this goal better than a lethal pill ordered online and with minimal supervision, taken in the anonymity of a woman's bathroom, where she will expel the remains of her preborn child, keeled over in pain, over a toilet.



WHAT IS A CHEMICAL ABORTION?



The Preborn Child's Early Development

(The age listed is the embryonic or post fertilization age which is two weeks less than the gestational age)

A woman taking the abortion pill will most likely force the child out while sitting on the toilet and flush the child's remains. The woman may even see body parts as she expels her preborn child.

The abortion industry lies to women about the preborn

child's early development. At week 7, the child's head, face, nostrils, and retinas are forming. By week 8, the child's nose is developing, and the neck begins to straighten. Between weeks 9 and 10, arms, eyelids, toes, and fingers are forming, and the elbows start to bend.

Medical research continues to reveal the extent to which preborn children experience pain. According to the Charlotte Lozier Institute, the "basic anatomical organization of the human nervous system is established by 6 weeks." Additionally, "[n]erve synapses for spinal reflex are in place by 10 weeks," and "[s]ensory receptors for pain" develop at 7 weeks. Within the first 8 weeks, a preborn child "exhibits reflex movement during invasive procedures." When preborn children undergo surgeries in the womb, both mother and child receive anesthesia.⁵

In the 2nd week, the child's brain appears. In the 3rd week, her heart begins to beat. By week 6, she begins to move, and her teeth are forming. By the 7th week, brainwave activity

⁵ Charlotte Lozier Institute, "Fact Sheet: Science of Fetal Pain," February 19, 2020, <https://lozierinstitute.org/fact-sheet-science-of-fetal-pain/#:~:text=The%20basic%20anatomical%20organization%20of%20the%20human%20nervous,reflex%20are%20in%20place%20by%2010%20week.%20%5B4%5D>

Mifepristone chemically starves a preborn child of progesterone, a naturally occurring hormone that stabilizes the uterine lining and promotes the proper development of the child. Mifepristone cuts off blood to the child and breaks down the uterine lining. Unless the process is reversed quickly, mifepristone kills the child.



has begun and her face withdraws from light touch. By week 8, her head rotates and her legs move. Her hands can reach one another, and her fingers can overlap. By the 9th week, she exhibits complex responses to touch, and her eardrums are developing.⁶

Mifepristone

Chemical abortions are caused by a regimen consisting of two FDA-approved drugs: mifepristone (previously known as RU-486) and misoprostol.

Mifepristone chemically starves a preborn child of progesterone, a naturally occurring hormone that stabilizes the uterine lining and the placenta, the pre-born child's sole source of nutrition. By blocking progesterone, it causes the placenta to degenerate so that it can no longer provide oxygen and nutrients to the baby. Unless the process is reversed quickly, mifepristone will likely kill the child. To complete the abortion pill regimen, the woman then takes misoprostol within 24 to 48 hours, inducing uterine contractions to expel the dead child from her womb.

Mifepristone, sold in the US as *Mifeprex*, is the actual abortion pill, while misoprostol is a separate FDA-approved anti-ulcer pill. Misoprostol carries the brand name *Cytotec*. The FDA does not approve misoprostol as a stand-alone abortifacient and warns that using it this way can lead to uterine rupture, hemorrhage, retained tissue which can cause infection, and death of the woman and child. Yet, pro-abortion groups like International Women's Health Coalition, Women on Web, and even the World Health Organization (WHO) openly recommend dangerous misoprostol-only abortions. According to WHO: "For pregnancies beyond

⁶ "Fetal development: The 1st trimester," Mayo Clinic, <https://www.mayoclinic.org/healthy-lifestyle/pregnancy-week-by-week/in-depth/prenatal-care/art-200453>.

24 weeks, the dose of misoprostol should be reduced, due to the greater sensitivity of the uterus to prostaglandins, **but the lack of clinical studies precludes specific dosing recommendations.**” (emphasis added).

Mifepristone causes severe cramping, contractions, and heavy bleeding. The intense bleeding and pain can last anywhere from a few hours to several days. According to the FDA, women can expect the bleeding to last 9 to 16 days on average, while 8% experience bleeding for more than 30 days, and 1% of women require hospitalization. According to recent studies from Finland—a nation with single-payer healthcare and meticulous medical reporting—6% of women using chemical abortion needed emergency surgery and 16% experienced hemorrhaging. In the same studies, women needing surgery after attempting chemical abortion in the second skyrocketed to 40%.⁷

The Big Lie: The Abortion Pill is Safer than Surgical Abortion

Dr. Donna Harrison, a physician who is board-certified in obstetrics and gynecology and currently serving as Executive Director of AAPLOG, claims the abortion pill is riskier to a woman’s health than surgical abortions, causing up to four-times the immediate complication rate as compared to first-trimester surgical abortions.

With a surgical abortion, a woman is often under anesthesia and bleeds for about a day after the abortion. Bleeding from the abortion pill can last for weeks or months. Unlike a surgical abortion, the mother must pass her preborn child as if she is miscarrying—again, without anesthesia.

⁷ Upadhyay, Ushma, PhD, MPH, Sheila Desai, MPH, Vera Zlidar, MHS, Tracy Weitz, PhD, MPA, Daniel Grossman, MD, Patricia Anderson, MPH, Diana Taylor, PhD, RNP, “Incidence of Emergency Department Visits and Complications After Abortion,” *Obstetrics & Gynecology* 125, issue 1 (2015), https://journals.lww.com/greenjournal/Fulltext/2015/01000/Incidence_of_Emergency_Department_Visits_and.29.aspx.

If the abortion pill fails to kill the child, the woman will be instructed to have a surgical abortion. The failure rate increases dramatically with the gestational age of the baby—meaning, the further along in the pregnancy a woman takes the abortion pill, the less likely it is to result in a complete abortion; thus, the more likely she is to seek a follow-up surgical abortion. Even in the many cases where the baby is killed, surgical or emergency intervention may be needed to clear any remaining tissue to prevent deadly infections.

The FDA, Planned Parenthood, and abortion pill manufacturer Danco Laboratories, Inc. (Danco) all admit that the failure rate increases from as low as 2% if mifepristone is taken in the eighth week of pregnancy to as high as 9% when taken in the tenth week. According to the pro-abortion Guttmacher Institute, about 339,640 American women used the abortion pill in 2017 alone. Based on these numbers, the number of failed abortions using the pill is in the thousands or tens of thousands in any given year. These failed abortions typically include “incomplete” abortions, meaning the child is dead but the woman’s body has not completely expelled the child’s remains.

Since 2000, **24 deaths** have been reported under the FDA’s Adverse Event Reporting System (FAERS). There have been over **1,000 hospitalizations** and **4195 total adverse events reported**. Many of the deaths occurred from infection or undiagnosed ectopic pregnancies (when an embryo implants outside the uterus, often in the fallopian tube). Notably, as a precondition of being certified to prescribe the abortion pill, REMS requires a healthcare provider to be qualified to diagnose ectopic pregnancy.⁸

Still, the Guttmacher Institute claims, “[t]he complication rate for medication abortion is exceedingly low (less than 0.5%), whether it is provided in-person or by telemedicine.”

⁸ FDA, “Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018,” <https://www.fda.gov/media/112118/download>.



The FDA admits not all adverse events are reported . . . A recent study by the Institute for Safe Medication Practices found that FAERS data, which largely relies on voluntary reporting, may only reflect about 1% of all adverse events associated with FDA-approved drugs, devices, and products.

Guttmacher bases its claims of safety on studies by Dr. Grossman, who is also a Planned Parenthood consultant and former board member of the National Abortion and Reproductive Rights Action League (NARAL). A 2017 Grossman study found, “0.18% of telemedicine patients with any adverse event [95% CI 0.11-0.29%] and 0.32% of in-person patients.”

However, **it is difficult to know the actual number of adverse events or deaths resulting from the abortion pill.**

As Dr. Harrison stated in a 2006 Congressional hearing: “Adverse events are typically under-reported, since they are offered voluntarily by consumers and health care professionals, so it is most likely that there are many more cases that we don’t even know about.” The FDA admits not all adverse events are reported, and Harrison suggests fewer than 10% of adverse events are reported for any given FDA-approved drug. A recent study by the Institute for Safe Medication Practices found that FAERS data, which largely relies on voluntary reporting, may only reflect about **1% of all adverse events** associated with FDA-approved drugs, devices, and products.

Under REMS, Danco, the abortion pill manufacturer, is required to report all adverse events to the FDA. Until 2016, abortion facilities like Planned Parenthood had to submit adverse event reports—hospitalizations, transfusions, and deaths—to Danco, which in turn reported the adverse events to the FDA. As of 2016, REMS only requires Danco to report fatalities to the FDA.


Moreover, many women with undiagnosed ectopic pregnancies or who experience adverse events like hemorrhaging or sepsis, will not return to the abortion facility for treatment. Many will go to an emergency room. Grossman’s study surveyed emergency departments, noting, “[s]ome women with adverse events may present to

emergency departments, and this care may not be reported to Planned Parenthood or Danco as a result of lack of awareness of the reporting requirements.” Of the 119 emergency departments surveyed, only 42 answered Grossman’s survey (a 35% report rate, to a voluntary survey).

actual numbers are likely much higher. Especially given that women—including minors and victims of rape or sex trafficking—may not even disclose their use of the abortion pill when coming to an emergency room. They may be under duress by an abuser trying to conceal their crimes. They may be minors who are scared to admit their pregnancy to a parent. They even may have been advised by abortion advocates or abortion facility workers to tell emergency room doctors they are experiencing a miscarriage.

The abortion industry and its allies would suggest that 24 dead American women over 20 years is a relatively small number. The death rate, they will argue, is lower than the rate of mothers who die in childbirth. Assuming that is even the correct number of fatalities from the abortion pill, this reasoning provides little solace to victims' families, some of whom have sued Planned Parenthood, Danco, and the Population Council. A New York-based nonprofit founded in 1952 by billionaire John D. Rockefeller III, the Population Council sponsored clinical trials for RU-486 in the US and established Danco as its "commercial arm" to distribute the abortion pill.

A HISTORY OF THE ABORTION PILL



The classical Hippocratic Oath read in part: "I will neither give a deadly drug to anybody who asked for it, nor will I make a suggestion to this effect. Similarly I will not give to a woman an abortive remedy."

The Hippocratic Oath

One could begin a history of "chemical" or "medication" abortion in the Greco-Roman period when the now-extinct plant silphium was used to induce abortion. The Hippocratic Oath—the earliest set of ethical guidelines for healthcare professionals, which dates to about 400 BC—proscribed doctors in ancient Greece from giving lethal drugs to induce abortion. The classical Hippocratic Oath read in part: "I will neither give a deadly drug to anybody who asked for it, nor will I make a suggestion to this effect. Similarly I will not give to a woman an abortive remedy."

Until relatively recently, the medical community opposed abortion as unethical. The Geneva Declaration, an updated form of the Hippocratic Oath adopted after World War II

by the World Medical Association (WMA), included the following oath for physicians: “I WILL MAINTAIN the utmost respect for human life from the time of conception.” By 1983, the revised oath said: “I WILL MAINTAIN the utmost respect for human life from its beginning.” By 2005, the Geneva Declaration failed to mention “conception” or the “beginning” of life.

The Nuremberg Trials

The Geneva Declaration was part of a broader humanitarian response to the war crimes committed under Nazi Germany. After WWII, the Allies established military tribunals in occupied German territory to put Nazi officials on trial for crimes against humanity. Between 1946 and 1949, the US military held 12 trials at Nuremberg.

The first trial, *United States of America v. Karl Brandt, et al.* (1947), put 23 Nazi doctors on trial for their participation in tortuous medical experiments and a “Euthanasia Program” targeting people with disabilities. In the death camps, German doctors experimented with forced sterilization on Jewish women, and forced abortions were routine.

The sixth trial, *United States of America vs. Carl Krauch, et al.* (1948), also known as the “**IG Farben Trial**,” put 24 executives and scientists from the German chemical conglomerate IG Farben on trial. Known as the “devil’s chemist,” IG Farben used slave labor from Auschwitz (some 35,000 people), built a concentration camp, and manufactured a poison called “Zyklon B” for the gas chambers.

After the evils of the Holocaust were exposed and put on trial, the civilized world declared “Never Again.” IG Farben was forcibly dissolved, and its assets and factories were divided into three subsidiaries, now independent companies: Bayer, BASF, and **Hoechst**.

Roussel Uclaf Develops RU-486

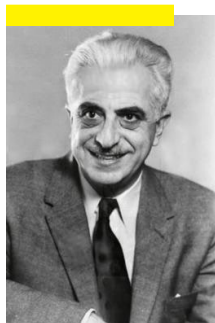


Former headquarters of Roussel Uclaf, Paris, France

In 1968, Hoechst bought a stake in the French pharmaceutical company **Roussel Uclaf**—the company that, 12 years later, would synthesize mifepristone under the research of chemist **Georges Teutsch**. Mifepristone became Roussel Uclaf’s 38,486th compound, taking the shorthand “RU-486” from the company’s initials and the last digits of the compound’s serial number.⁹

Teutsch claimed the compound, discovered to be a progesterone receptor antagonist, was not researched as an abortifacient. But **Dr. Etienne-Emile Baulieu**, a Roussel consultant and endocrinologist, was looking for an abortifacient. According to Baulieu, Teutsch “followed the course of research” Baulieu charted.

Baulieu began researching fertility in 1961 at Columbia University under the mentorship of **Gregory G. Pincus**, the American developer of the birth control pill. In 1966, Baulieu was even appointed by French President Charles de Gaulle to serve on the committee that helped legalize birth control in France.



Gregory G. Pincus, American biologist and developer of the birth control pill

At the University of Paris in 1970, Baulieu identified receptors that received messages from progesterone and learned there could be a way to interrupt the progesterone and terminate a pregnancy. Baulieu explored progesterone “impostors” to disrupt these messages. “The receptors,” he said, “are like a keyhole, and we were trying to produce a false key.” Baulieu gave the idea to Roussel, and Teutsch succeeded in less than a decade.

In 1966, Baulieu recommended endocrinologist **Edouard Sakiz** as director of biological research at Roussel. By the

⁹ Encyclopedia Britannica. “RU-486.” Accessed June 15, 2020. <https://www.britannica.com/science/RU-486>.

time RU-486 was discovered, Sakiz was chairman of Roussel. Sakiz later admitted his regret that Roussel stayed out of the birth control controversy of the 1960s to avoid offending the Catholic Church. Sakiz did not want to make the same mistake with RU-486.

In 1982, Roussel began clinical trials of RU-486 in Switzerland, which showed an 85% success rate in completed abortions. A 1984 study in Sweden that combined RU-486 with prostaglandin to induce uterine contractions reached 100% success rates. Studies conducted by WHO in Britain, China, France, and Sweden had a 95% success rate combined with a prostaglandin analog.

Baulieu advocated RU-486 to be “contragestive,” and a **once-a-month pill to replace birth control**. Baulieu said women in the “Third World” would be the “main target.” But eventually, “it could be used protectively in developed nations, like a monthly contraceptive pill.”¹⁰



Jean-Claude Roussel, CEO of Roussel-Uclaf from 1961–1972

In September 1988, the French government approved RU-486 to be marketed in France as an abortifacient. But church leaders and pro-life groups in France and the US rallied to stop RU-486. US organizations like NRLC threatened to boycott Roussel and Hoechst, which by 1988 held a controlling 54.5% stake in Roussel.

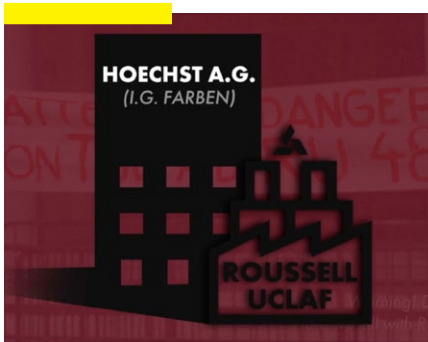
Pro-life groups also lobbied the US Congress to block the FDA from approving RU-486 clinical trials in the US. Some trials were already underway at the University of Southern California (USC) and sponsored by the Population Council.

In addition to threats of boycotts, Roussel feared the potential for product liability claims against RU-486, with its approximate 95% success rate (5% failure rate). In previous decades, political pressure from a “coalition of longtime

¹⁰ Institute of Medicine, “A Political History of RU-486,” *The National Academies Press*, <https://www.nap.edu/read/1793/chapter/4>.

adversaries” that included pro-life advocates, feminists, trial attorneys, manufacturers, religious groups, and the Catholic Church led all four manufacturers of intrauterine devices (IUDs) to pull their products off the US market (after some IUDs were found to cause severe and fatal infections). RU-486’s 5% failure rate would mean tremendous liability to the multibillion dollar pharmaceutical company.

In June 1988, Sakiz faced hundreds of pro-life protestors on his way to Roussel’s annual meeting. French bishops, including Archbishop of Paris Jean-Marie Cardinal Lustiger, condemned RU-486, and the Vatican blasted the pill as “a way of killing with no risk for the assassin.” Pope John Paul II denounced RU-486 as the “pill of Cain – the monster that cynically kills its brothers.” French pro-life groups like the Committee to Save Unborn Children demanded the “destruction of all stocks of the chemical weapon RU-486.” Even some French physicians wrote to Roussel, refusing to prescribe any Roussel products to their patients.



Hoechst was also feeling the pressure and received multiple threats of boycott against its American subsidiary. One-quarter of Hoescht’s \$23 billion business came from the US. The company finally determined that RU-486 was not worth the risk of bad press, political opposition, boycotts, and product liability claims. It was also not lost on Hoechst executives that the company’s historical connection to IG Farben and Zyklon B would be widely cited by opponents, who were now condemning RU-486 as a lethal tool for genocide against the preborn. Three of Hoescht’s five executives opposed RU-486. Finally Sakiz gave in, and Roussel withdrew RU-486 from the market.

On October 26, 1988, Roussel said an “outcry of public opinion” caused their decision to pull RU-486. Their announcement came only one month after the French Minister of Health Claude Évin had approved Roussel’s

application for RU-486. Angered by Roussel's decision and anxious that the renewed vigor of the French pro-life movement could lead to a repeal of France's 1975 law that legalized abortion or its 1984 decision to subsidize abortions with national health funds, Évin stepped in to force Roussel's hand. The French government was 36% owner of Roussel, and French law allowed him to transfer the patent for RU-486 to another company in the name of the "public good." Évin declared RU-486 "medical progress" and hailed it as the "moral property of women." On October 28, 1988, Roussel put RU-486 back on the market.

Roussel and Hoescht both denied any cooperation with the French government, but Sakiz made no secret of his relief that the government shifted political responsibility for RU-486. "The Government's order," he said, "helped us." Sheldon Seagal, director of population policy at the pro-abortion Rockefeller Foundation, later said of Sakiz and the French government order, "I personally believe that this was a joint decision."

Within a few years, RU-486 would be approved and marketed in France, Sweden, Britain, and China. But the US continued to resist this lethal drug's entry into its markets.

The Bush Administration: 1989 to 1993

Under the Bush administration, the US banned the importation of RU-486. Pro-life groups like NRLC, AUL, International Right to Life Federation, and Operation Rescue, and Congressional leaders like Robert Dornan (R-Calif), kept up the pressure keep RU-486 off the US market. Dornan unsuccessfully attempted to block all federal funding used to research RU-486. Some feared the Bush administration would cut off WHO for promoting RU-486 after the administration cut funds to International Planned Parenthood and the United Nations (UN) Fund for Population Activities, which

financed abortion facilities and “family planning services” in China. At the time, WHO was already sponsoring clinical trials of RU-486 for safety and effectiveness.

At the same time, groups like NARAL, the American Civil Liberties Union (ACLU), Planned Parenthood, and the National Organization for Women (NOW) organized to bring RU-486 into the US market. In 1990, the American Medical Association (AMA) came out in support of RU-486 testing. Pro-abortion activist groups urged supporters to engage in counterprotests and counterboycotts to pressure Congress and the FDA. But Roussel and Hoescht refused to market the drug outside of France or any market unless a foreign government made a direct appeal for RU-486.

RU-486 advocates considered the best ways to get it into the US market. One idea was to form a single-purpose company, preferably a nonprofit, that only produced the abortion pill. The company could purchase the patent from Roussel, and by manufacturing just one product, the company would isolate its risk of potential product liability claims and would not fear public boycotts against other more profitable product lines. Some considered WHO as a contender for the job, but WHO did not have the infrastructure to manufacture pharmaceuticals.

RU-486 advocates also viewed China, a nonsignatory to the International Convention on Patents that could manufacture the drug without Roussel’s patent, as an ideal location to manufacture and distribute the pill.

Eventually, Roussel opened discussions with the Population Council. The Population Council was already sponsoring clinical trials of RU-486 at USC in the late 1980s before the FDA imposed the import ban. Soon, the Population Council and RU-486 advocates would find an ally in the White House.

The Clinton Administration: 1993 to 2001

In 2006, Judicial Watch, a nonprofit activist group that “promotes transparency, accountability and integrity in government,” produced a special report detailing the Clinton administration’s push to bring RU-486 into the US. The report included documents from the National Archives at the Clinton Presidential Library, such as strategy memoranda from Health and Human Services (HHS) and the FDA, and a letter from President Clinton to Roussel Chairman Edouard Sakiz.¹¹

One of the most revealing documents from the special report is a letter attached to a handwritten note by Clinton’s Chief of Staff, Betsey Wright. Wright’s note appears to instruct the Director of White House Domestic Policy Council, Carol Rasco, to deliver the attached letter to HHS Secretary **Donna Shalala**. The letter Wright wanted Shalala to read is from attorney **Ron Weddington** to “President-To-Be Clinton.” Weddington, who served as co-counsel in *Roe*, is also the ex-husband of Sarah Weddington. Sarah Weddington served as counsel for Norma McCorvey (“Jane Roe”) and helped convince McCorvey to sue Dallas district attorney Henry Wade over the Texas abortion law.

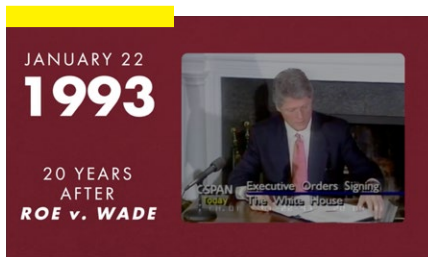


Donna Shalala, HHS Secretary, with President Bill Clinton in 1993

Mr. Weddington reveals that he and “Sarah” had been discussing setting up a nonprofit to license and distribute RU-486, concluding that “26 million food stamp recipients is more than the economy can stand.” Weddington then jokes about sending “dart guns [of birth control] to the ghetto.” He suggests the government will need to “provide vasectomies, tubal ligations and abortions...RU 486 and conventional abortions.” He insists: “We don’t need more poor babies.” Finally, Weddington acknowledges that he had personally “sired zero children and one fetus,” indicating that his ex-wife aborted.

¹¹ Judicial Watch. “A Judicial Watch Special Report: The Clinton RU-486 Files.” Accessed June 15, 2020. <http://www.judicialwatch.org/archive/2006/jw-ru486-report.pdf>.

Ron Weddington believed President Clinton was just the man to bring RU-486 into the US.



On January 22, 1993, the 20th anniversary of *Roe*, Clinton issued a series executive orders to emphasize his administration's top domestic agenda: expanding access to abortion. In addition to overturning the Reagan era “Mexico City Policy” that cut off federal funding of foreign organizations that performed or promoted abortions overseas, lifting the ban on fetal tissue research, and permitting abortions at military hospitals, Clinton lifted the FDA ban on importation of RU-486. Clinton then personally directed Shalala and FDA Commissioner Dr. **David Kessler** to get RU-486 approved and into the US.

By April of 1993, Kessler was convincing RU-486 manufacturers to file a new drug application with the FDA. The Clinton administration used the Population Council, which was already conducting clinical trials of RU-486, as a surrogate to broker a deal with Roussel. But Roussel still feared product liability claims.

In a memo to the White House, Shalala relays Sakiz's fears of product liability damages, “if a woman had an incomplete abortion and delivered a deformed fetus.” Shalala writes: “Dr. Sakiz's view was that if the United States Government wanted RU-486 to be marketed in the United States, it should compensate Roussel Uclaf for any damages that the company might suffer from complying with the United States Government's request.”

Sakiz and Roussel wanted blanket indemnification from the US government. Roussel was also openly offering a royalty-free license to any US pharmaceutical willing to take RU-486. Yet, none was willing to take the license. Roussel offered the patent “free of charge” to the US government as an “unconditional gift” to the American people. Roussel did not

want to profit from RU-486 in the US and was willing to give the patent away for free, provided they received an assurance of indemnification from products liability claims.


In a memo from Kessler to Shalala, Kessler notes the apparent conflict of interest for the FDA to be in a position of investigating a drug's safety and effectiveness, while at the same time considering a blanket indemnification in the event the drug causes death or injury. In the end, Roussel asked for and ultimately received a letter from President Clinton requesting the company make RU-486 available in the US on behalf of women.

In Clinton's letter, the president acknowledged his administration's role in directing Roussel's negotiations with the Population Council and urged Sakiz to bring these negotiations to fruition. "I understand," Clinton said, "that your company will assign without remuneration your United States patent rights on mifepristone to The Population Council." He concluded by thanking Sakiz and Roussel on behalf of the US government and the women of America.

Eventually, the Population Council and Roussel agreed that the Population Council would conduct clinical trials, submit the new drug application to the FDA, and Roussel would transfer its patent and technology to the Population Council. The Population Council then licensed these rights to Danco.

In 1983, the FDA had already given the Population Council a testing permit for RU-486 clinical trials at USC. But in 1994, the new clinical trials at UCSF would involve over 2,100 women, recruited to kill their preborn children as a medical experiment. The trials and the FDA review process remained largely confidential until 1996 when an FDA advisory committee convened to recommend the FDA approve RU-486. As the *New York Times* wrote at the time, the committee met "in a windowless building" to recommend the lethal drug's approval.

FDA APPROVAL & REMS



On September 28, 2000, under the Clinton administration, the FDA approved RU-486. The drug would be marketed in the US by Danco as Mifeprex. Danco has never publicly revealed the identity or location of its manufacturer. In 2006, Shanghai-based Hualian Pharmaceutical Co. (Hualian), a pharmaceutical company owned by the Chinese Communist Party, was identified as at least one of Danco's manufacturers. In 2008, Hualian was caught giving contaminated leukemia drugs that paralyzed at least 200 Chinese cancer patients.

AAPLOG, Judicial Watch, and the Family Research Council have each documented the politicized atmosphere of the Clinton era FDA. The FDA's Reproductive Health Drugs Advisory Committee, tasked with reviewing RU-486 for approval, was stacked with pro-abortion advocates. Eight of the eleven committee members were either directly affiliated with abortion groups like National Women's Health Network, Center for Reproductive Health Research and Policy, and Reproductive Health Technologies or had publicly made openly pro-abortion comments. Committee Chair Ezra Davidson served on Planned Parenthood's advisory board.

The FDA set aside standard protocol and opted for a speedy approval process. As Dr. Harrison wrote in 2004, the FDA's "five standard procedural and scientific requirements to prove safety and effectiveness were circumvented to get RU-486 onto the market quickly." The FDA based its approval on uncontrolled clinical trials, as opposed to the standard requirement of a double-blind, randomized, and controlled test. The FDA used "accelerated approval" protocols typically reserved for high-risk drugs that address life-threatening illnesses like AIDS. But "pregnancy," as Dr. Harrison noted, "isn't an illness, serious or life-threatening."

The FDA also approved RU-486 for women of any age, with no clinical data on women under 18. Finally, the FDA allowed an unapproved use of the anti-ulcer drug misoprostol, first approved in 1985 as Cytotec. Cytotec manufacturer Searle objected and opposed the off-label use of the drug, paired with Mifeprex to induce abortions. Cytotec's warning label reads: "CYTOTEC SHOULD NOT BE TAKEN BY PREGNANT WOMEN" and warns it can cause "ABORTION, PREMATURE BIRTH, OR BIRTH DEFECTS" and that "UTERINE RUPTURE HAS BEEN REPORTED WHEN CYTOTEC WAS ADMINISTERED IN PREGNANT WOMEN TO INDUCE LABOR OR TO INDUCE ABORTION BEYOND THE EIGHTH WEEK OF PREGNANCY."

The FDA approved RU-486 in 2000 under a special provision for fast-tracked drugs, called "SubPart H," which was the only to apply post-approval restrictions on a drug the FDA considered too dangerous for unrestricted consumer use. These restrictions were later formalized in 2007 as REMS. In 2011, the FDA approved its existing REMS along with Elements to Assure Safe Use (ETASU), which can be imposed on a drug "associated with a serious adverse drug experience."¹² The FDA reviewed REMS again in 2013, and then in 2016 conducted an additional review.

Originally, Mifeprex was to be provided "under the supervision of a physician" capable of assessing the duration of pregnancy, diagnosing ectopic pregnancy, and able to provide or ensure surgical intervention in cases of incomplete abortion or severe bleeding. Physicians were also required to report "any hospitalization, transfusion or other serious events" to Danco. Mifeprex was only approved for use during the first seven weeks of pregnancy (extended to 10 weeks in 2016 by the Obama FDA). Yet, for many years, the FDA did little to stop abortionists from prescribing the drug after seven weeks. Many even advertised their noncompliance on their websites with impunity.

¹² 21 U.S. Code § 355-1.

Current REMS Requirements

Today, the FDA implements REMS for 74 medications with serious safety concerns to mitigate potential adverse risks to the consumer and to ensure the safest use of these medications. REMS is designed to go beyond mere safety and usage information contained on a standard FDA approved warning label. Under the current REMS, Mifeprex may still only be prescribed and dispensed in a healthcare setting—a clinic, medical office, or hospital—by a certified healthcare provider (some states permit healthcare providers other than licensed physicians).

Prescribers still must confirm the gestational age of the preborn child, rule out ectopic pregnancy, and verify informed consent with a “Patient Agreement” signed by the woman. The “Patient Agreement” includes a list of statements the woman must assent to, such as:

“I will contact the clinic/office right away if in the days after treatment I have:

- a **fever of 100.4°F or higher** that lasts for more than four hours
- **severe stomach area (abdominal) pain**
- **heavy bleeding (soaking through two thick full-size sanitary pads per hour for two hours in a row)**
- stomach pain or discomfort, or I am ‘feeling sick’, including **weakness, nausea, vomiting, or diarrhea, more than 24 hours after taking misoprostol**

“My healthcare provider has told me that **these symptoms could require emergency care**. If I cannot

reach the clinic or office right away **my healthcare provider has told me who to call and what to do.**”

“I know that, **in some cases, the treatment will not work. This happens in about 2 to 7 out of 100 women** who use this treatment. If my pregnancy continues after treatment with Mifeprex and misoprostol, I will talk with my provider about a surgical procedure to end my pregnancy.”

“If I need a surgical procedure because the medicines did not end my pregnancy or to stop heavy bleeding, my healthcare provider has told me whether they will do the procedure or refer me to another healthcare provider who will.”

“I have the MEDICATION GUIDE for Mifeprex. **I will take it with me if I visit an emergency room or a healthcare provider who did not give me Mifeprex so that they will understand that I am having a medical abortion with Mifeprex.**”

“My healthcare provider has answered **all my questions.**”

(emphases added).

Prescribers must also provide patients a copy of the “Medication Guide,” informing the woman of potential risks of RU-486.

Prescribers must sign a “Prescriber Agreement” with the sponsor, Danco, or **GenBioPro, Inc.** (GenBioPro), which was approved by the FDA in 2019 to distribute a generic version

of Mifeprex. This agreement requires that the prescriber guarantees to the sponsor that the patient has signed the “Patient Agreement” and received the “Medication Guide,” and that the patient has been fully informed of the risks of RU-486. The prescriber guarantees to the sponsor that they are qualified to assess the duration of pregnancy and able to diagnose ectopic pregnancies. Prescribers also guarantee they will provide surgical intervention to women experiencing incomplete abortions or severe bleeding, or that they will make arrangements for the woman to receive care at a facility “equipped to provide blood transfusions and resuscitation, if necessary.”

Prescribers must record the serial number of each package of Mifeprex in the patient’s records. Under the current “Prescriber Agreement,” prescribers must only report patient deaths to the sponsor (Danco and GenBioPro).


Mifeprex requires a prescription and cannot be purchased over the counter at a retail pharmacy, by mail, or the Internet. The FDA warns that a woman—even if she is within the first ten weeks of pregnancy—should not use Mifeprex if she:

- has an ectopic pregnancy,
- has problems with the adrenal glands,
- is currently being treated with long-term corticosteroid therapy (medications),
- has had an allergic reaction to mifepristone, misoprostol or similar drugs,
- has bleeding problems or is taking anticoagulants,
- has inherited porphyria, or
- has an IUD in place.

In 2016, the FDA issued updated REMS and Mifeprex labeling. Before 2016, women were required to take both pills at the abortion facility or doctor’s office. After 2016, the woman may take the misoprostol at home. The 2016

changes reduced the dosage of mifepristone from 600 milligrams (three tablets) to 200 milligrams (one tablet), and misoprostol was increased from 400 micrograms (two tablets) to 800 micrograms (four tablets). Before 2016, the woman was also informed to return for an in-person examination within 14 days of taking mifepristone. After the 2016 changes, the post-treatment examination may be conducted remotely, over the phone.

TELEMEDICINE & SELF-MANAGED ABORTIONS



Telemedicine is the distribution of healthcare services using telecommunication technologies, allowing patients to receive remote healthcare services (e.g., diagnoses, monitoring, preventive care, consultations, and non-clinical services). Telemedicine expands access to healthcare for people who live in remote areas, those who otherwise lack mobility, transportation, or those who may be restricted from in-person access to a healthcare provider.

The threat of COVID-19 and lockdown orders restricting nonessential business has made telemedicine a standard means of healthcare. With millions of Americans under indefinite quarantines, lock-downs, and shelter-in-place orders, state and local governments are restricting in-person access to nonessential and elective medical services. Thus, many healthcare screenings and consultations are now done by videoconferencing and other technologies.

Telemedicine is a great advancement for medicine. And the abortion industry has identified telemedicine as its vehicle

to eliminate REMS and finally “demedicalize” abortion. For the abortion industry, RU-486 presents a method by which a woman performs her own abortion, at home, without ever setting foot in an abortion facility. If the FDA loosens REMS any further, we could see the abortion pill sold online, in pharmacies, and delivered by mail.

Groups like SASS, Plan C, and Gomperts’ Aid Access already promote the unlawful and dangerous online distribution of abortion pills and self-managed “do-it-yourself” abortions, as abortion advocates cheer.

Dr. Grossman has made it his mission to see the abortion pill sold over the counter and is involved in numerous studies and clinical trials to bring this about. Grossman, who serves as director of USCF’s Advancing New Standards in Reproductive Health (ANSIRH), favors the elimination of REMS and the distribution of the abortion pill at pharmacies.

The abortion industry is using COVID-19 to create a sense of urgency behind the elimination of REMS. But the goal to deregulate the abortion pill was in the works long before COVID-19. Since 2016, Gynuity Health Projects (Gynuity)—a nonprofit funded by the David and Lucile Packard Foundation (Packard Foundation), the Population Council, Ibis Reproductive Health, the Bill and Melinda Gates Foundation (Gates Foundation), the John D. and Catherine T. MacArthur Foundation, Planned Parenthood Global, Planned Parenthood Federation of America, the Society for Family Planning, the Rockefeller Foundation, National Institute of Allergy and Infectious Diseases (NIAID), and the William and Flora Hewlett Foundation—has sponsored a US clinical trial to determine the safety of distributing abortion pills using telemedicine.

Gynuity’s “TelAbortion” clinical trials are running in 13 states (Hawaii, Washington, Oregon, New Mexico, Colorado, Georgia,

New York, Maine, Iowa, Minnesota, Illinois, Maryland, and Montana). According to Gynuity's summary, the trials began in March of 2016, aim to enroll up to 1,000 participants, and are open to children as young as **ten years old**.

Gynuity has expanded its experiments to include about 100 African women and girls in Burkina Faso in their **second trimester**.¹³ Not only is the child more developed in the second trimester (growing hair by about the 19th week), the mother is even more likely to suffer severe side-effects like cervical laceration, infection, and uterine rupture. This is especially dangerous in a place like Burkina Faso, a landlocked and incredibly poor country in West Africa, where blood products are in short supply for women needing medical attention.¹⁴


The Dangers of At-Home and Do-It-Yourself Abortion

In response to the COVID 19 pandemic, the United Kingdom relaxed its requirement that RU-486 only be dispensed in hospitals and clinics, permitting women to take the pill at home. England, like the US, also restricts the abortion pill to the first ten weeks of pregnancy.

By May of 2020, police were investigating the death of a preborn child after its mother took the abortion pill at home, in her **28th week of pregnancy**. The British Pregnancy Advisory Services (BPAS) that runs a "pills by post" service is investigating at least eight other cases of women taking the pill beyond their tenth week. Only one month before this woman took the abortion pill at 28 weeks pregnant, a BPAS

¹³ Packard Foundation, "Gynuity Health Projects, LLC," <https://web.archive.org/web/20190517205834/>, <https://www.packard.org/grants-and-investments/grants-database/gynuity-health-projects-llc/>.

¹⁴ Mark Hemingway, "An American Later-Term Abortion Trial on Women in Impoverished Africa," *Real Clear Investigations*, December 26, 2019, https://www.realclearinvestigations.com/articles/2019/12/22/us_abortion_trial_in_impoverished_burkina_faso_121725.html.



Without REMS, the bare minimum supervision of these lethal pills vanishes, and each woman must fill the roles of doctor, prescriber, and patient.

spokesman said “[t]elemedicine is a safe, effective method of delivering early abortion care and will prevent thousands of unnecessary journeys.”

Without REMS, the bare minimum supervision of these lethal pills vanishes, and each woman must fill the roles of doctor, prescriber, and patient. Already, each woman is handed a “Patient Agreement” and a “Medication Guide” that she is instructed to bring along to the emergency room if she experiences adverse reactions like hemorrhaging. The prescriber, at a minimum, must be capable of diagnosing ectopic pregnancy.

Since Gynuity’s clinical trials extend to girls as young as ten years old, the abortion industry is aware of the likelihood minors will access the abortion pill without parental consent for at-home use.

A black market for abortion pills already exists. While a typical abortion facility charges up to \$500 for the abortion pill, websites like Aid Access request a \$90 donation. Anyone can order these pills by filling out a form online, without providing proof of pregnancy, without being examined for ectopic pregnancy, without verifying age or gender. An abusive boyfriend or sexual abuser can obtain these pills as easily as a pregnant woman. He can even drop the pill into his victim’s drink. Just ask Jeffrey Smith, the Grand Rapids, Michigan man charged with attempted murder after slipping abortion pills he purchased online into his girlfriend’s water bottle. The seller, Ursula Wing, a blogger who sells jewelry online and holds no medical license, hopes to see “copy cats.”

The FDA’s system for reporting adverse reactions, whereby Danco and GenBioPro must only report deaths provided Planned Parenthood reports deaths to them, cannot require black market sellers to report. The abortion industry’s vision for online sales without medical supervision will

be impossible to monitor, and the scarce information we currently have of the true number of fatalities and adverse reactions would be reduced to no data at all.

The abortion industry promotes the myth that mail-order abortion pills are just as safe as abortion pills prescribed under REMS, by a prescriber capable of diagnosing ectopic pregnancy and after the woman has signed written disclosures of the risks (which she is told to bring to the emergency room in case she experiences adverse reactions).

The reason REMS requires prescribers to be qualified to diagnose ectopic pregnancy is that it is a leading cause of maternal death and must be treated in a timely fashion. A woman with an undiagnosed ectopic pregnancy who takes the abortion pill may suffer an ongoing ectopic pregnancy, because mifepristone does not effectively abort these pregnancies. And since the symptoms of ectopic pregnancy are the same as a chemical abortion (admoninal pain and vaginal bleeding) she is likely to mistake her symptoms as a normal side-effect of the abortion pill. This leaves her in serious risk of harm or death if the ectopic pregnancy ruptures.

DONORS, FOUNDATIONS & UNIVERSITIES: WHO IS PUSHING TO DEREGULATE RU-486?



Who is driving the abortion pill's expansion and deregulation?

Several names have been mentioned already, including the Population Council, whose original mission was the same as the eugenics movement: to control population growth.



Bernard Berelson became President of the Population Council in 1962

In 1957, after founder John D. Rockefeller III's tenure ended, Frederic Osborn—founding member of the American Eugenics Society—became President of the Population Council. Osborn once said, “[b]irth control and abortion are turning out to be the great eugenic advances of our time.” Osborn's successor, Frank W. Notstein, was also a member of the American Eugenics Society. His successor, Bernard Berelson, once suggested that if voluntary birth control methods were unsuccessful, the government should place a “fertility control agent” in the water supply of “urban” neighborhoods. Alan Guttmacher—founder of the Guttmacher Institute, longtime President of Planned Parenthood, and vice-president of the American Eugenics Society—sat on the Population Council's first Medical Advisory Board.

Danco has been described as the “commercial arm” of the Population Council. Danco's sole purpose is to license RU-486 from the Population Council and market it in the US. In 1996, the Packard Foundation gave Danco a \$14 million loan. Other early Danco investors included the Open Society Foundation (founded by George Soros), the Buffett Foundation (founded by Warren Buffett), and the Kaiser Family Foundation.

The Packard Foundation—a private foundation, started by Hewlett Packard founder David Packard, and which now boasts a \$7.1 billion endowment—continues to fund the Population Council, the Kaiser Family Foundation, Danco, Ibis Reproductive Health, and Gynuity. Packard is also pouring millions into GenBioPro, which, as stated previously, was approved by the FDA in 2019 to produce a generic version of Mifeprex.

Warren Buffet—longtime Planned Parenthood supporter, chairman, and CEO of Berkshire Hathaway, and currently worth over \$88 billion, making him the fourth richest man

in the world—has given at least \$2 million to the Population Council for abortion pill clinical trials. Buffet funds the “Ryan Fellowship” which gives funding to universities and institutions that train abortionists. He has also given tens of millions to UCSF where Dr. Grossman is overseeing clinical trials for over the counter abortion pills.

UCSF trains abortion providers through its Bixby Center for Global Reproductive Health, which claims to be “one of the few research institutions to unflinchingly address abortion, investigating multidimensional aspects of abortion care in the United States and globally.” UCSF considers itself an “abortion pioneer,” contributing extensively to research and studies that led to the approval of RU-486. UCSF continues to conduct studies that push for the removal of REMS to expand abortion pill access, including the dispensation of the abortion pill at pharmacies.

Microsoft mogul Bill Gates, currently the second richest man in the world with over \$102 billion, is a longtime donor and financier of several abortion organizations. Gates revealed in 2003 that his father, Bill Gates Sr., served on the board of Planned Parenthood. Bill Gates Sr. is also a co-chair of the Gates Foundation, which has given over \$80 million to Planned Parenthood. Between 2018 and 2020, the foundation gave over \$11 million to the Population Council. The Gates Foundation has also given tens of millions of dollars to international “family planning” organization DKT International (DKT). DKT’s other funders include the Packard Foundation and the UN Population Fund. DKT boasts of over 4 million abortion pill “combipacks” sold, and over 10 million “unsafe abortions averted.” Aid Access, admits to filling its prescriptions through a manufacturer in India, Synokem Pharmaceuticals Ltd, whose product label states the abortion pills are marketed by “DKT India.”

DKT’s President and founder, Christopher Purdy, also serves

as President of abortion provider Carafem. DKT's CEO, Phil D. Harvey, serves on Carafem's board. Carafem is an abortion provider whose donors include the Packard Foundation. Carafem is partnering with Gynuity in conducting its clinical trials. Carafem is the "public face" of FemHealth USA, Inc. (FemHealth), a nonprofit "social enterprise to deliver early, safe abortion services and family planning products in the USA." FemHealth is listed as a "related organization" on DKT's 2018 IRS Form 990.

Finally, Planned Parenthood's major donors include the Packard Foundation, Buffet, and the Gates Foundation, each of which has given millions to the abortion giant over the decades. Planned Parenthood has partnered with Gynuity to expand its "TelAbortion" clinical trials. The abortion corporation makes hundreds of millions of dollars off the killing of children through surgical abortion, and no doubt the abortion pill proves to be quite lucrative as well. Planned Parenthood has a vested financial interest in the abortion pill's expansion, in the loosening of REMS, and the ability to sell abortion pills online or by direct to mail.

ABORTION PILL REVERSAL



How it Works

Research has shown that women can reverse the effects of mifepristone by starting a progesterone treatment after taking mifepristone. Abortion pill reversal (APR) must be done before misoprostol is taken. APR should be attempted as soon as possible and preferably within 24 hours of taking mifepristone. Researchers have observed successful cases of

APR, even where the progesterone treatment commenced within 72 hours of taking mifepristone.

A study conducted by Dr. George Delgado and Dr. Mary Davenport analyzed the outcomes of 547 women who attempted APR. Reversal success overall occurred in roughly 48% of cases. However, the reversal success rate reached 68% success among the women who were given high-dose oral progesterone treatment. If no progesterone treatment is offered, and the woman declines to take misoprostol, the survival rate for preborn children is 25% or less after mifepristone is taken. Delgado, board member of AAPLOG and Medical Director of Culture of Life Family Services, and Davenport found no increased risk of birth defects or preterm births.

Women interested in reversing the effects of the abortion pill should immediately contact **Abortion Pill Rescue**, a program founded and sponsored by **Heartbeat International**. The woman can call a 24/7 hotline that provides referrals from a network of medical professionals that offer APR.



Heartbeat International is the first network of pro-life pregnancy resource centers founded in the U.S., in 1971.

Predictably, the abortion industry discourages women from APR, calling it junk science and claiming progesterone treatment is ineffective and possibly dangerous. The American College of Obstetricians and Gynecologists (ACOG) claims a “survival” rate of between 30% and 50% for preborn children when a woman takes mifepristone, but declines misoprostol. Dr. Grossman has cited an 8-46% survival rate. Some abortion advocates also point out that APR is an off-label use of progesterone, not approved by the FDA. According to ACOG: “Progesterone, while generally well tolerated, can cause significant cardiovascular, nervous system and endocrine adverse reactions as well as other side effects.”

AAPLOG not only disputes the 30-50% survival rate claim but points to the hypocrisy of abortion pill advocates warning

against off-label use of progesterone. First, the 30%-50% rate is based on rates of incomplete abortions, which includes cases where the child has died but woman has not yet expelled the tissue and remains from her uterus. This number therefore does not indicate a true “survival rate” of failed chemical abortions where a child survives. Second, progesterone is routinely used by OB/GYNs and infertility specialists to support early (first trimester) pregnancies in women who have suffered recurrent miscarriages.

And while it is true that the FDA does not approve progesterone for APR, off-label uses of drugs are common. Off-label use of mifepristone has been prevalent for two decades. Before 2016, abortionists routinely prescribed mifepristone beyond seven weeks gestation, before REMS changed the protocol to allow for prescriptions up to 10 weeks and at dosages that were not approved by the FDA.

AAPLOG has also called it “scientific common sense” to increase progesterone, the naturally occurring hormone blocked by mifepristone, to improve the survival rate of the preborn child.

ACOG has disputed the APR studies by Delgado and Davenport, including the research methods that failed to assign placebos to women undergoing APR randomly. But as Delgado has said, a study using randomized placebo-controlled methods, “in women who regret their abortion and want to save the pregnancy would be unethical.” In 2019, the University of California Davis (UC Davis) sponsored a clinical trial on APR, which had to end early due to safety concerns. The study, led by Dr. Mitchell Creinin, a consultant of the abortion pill distributor Danco, seemed to indicate it was the progesterone treatment that caused the safety issues, rather than the mifepristone.

Yet, Creinin’s study actually proved what pro-life doctors already knew: mifepristone is a highly dangerous drug. The

patients who only received mifepristone and not progesterone experienced higher rates of complications, specifically hemorrhage. As Dr. Delgado observed, “[t]his study does make it clear that taking mifepristone and doing nothing else does pose a risk to the pregnant woman.”

But abortion pill advocates, like Dr. Grossman and Dr. Creinin, claim that APR is dangerous and puts women at risk of life-threatening bleeding. “It’s not that medical abortion is dangerous,” Creinin says. “It’s not completing the regimen, and encouraging women, leading them to believe that not finishing the regimen is safe. That’s really dangerous.”

When a woman experiences severe medical complications and requires emergency room care after attempting APR, the mifepristone is more likely the proximate cause than the progesterone she takes for APR. Again, progesterone is a hormone that occurs naturally in a pregnant woman’s body. Side-effects include fatigue, drowsiness, upset stomach, headache, and dizziness. According to the FDA, cramping and vaginal bleeding are “expected effects” of mifepristone, and other common side effects are, “nausea, weakness, fever/chills, vomiting, headache, diarrhea, and dizziness.” The FDA has placed mifepristone under REMS because of its inherently dangerous risks. Progesterone is not one of the 74 medications subject to REMS.

Of the 12 women Creinin’s study observed, the one who required a surgical abortion did not even receive progesterone treatment. One of the two who were transferred by ambulance to an emergency room had taken the progesterone treatment. The only patients who required suction aspiration (removal of the child from the uterus) to complete their abortions were in the placebo group and did not receive progesterone therapy. Two women voluntarily withdrew from the study. Ultimately, **four of the five women who received progesterone treatment in the study**

successfully gave birth to their babies. That means a study attempting to debunk the so-called “junk science” of APR, led by a Danco consultant, still showed an 80% success rate among women using progesterone treatment to reverse the abortion pill.¹⁵

Abortion Pill Regret

A recent UCSF study found that few women regret their abortions, with as many 95% reporting it was the right decision. Yet, Michael J. New, a professor at the Catholic University of America and an associate scholar at the Charlotte Lozier Institute, notes that fewer than 38% of women asked to participate agreed to answer the survey. And among participants, only 58.4% responded to the study five years after the study began. “Over time,” New writes, “a significant percentage of the women who originally agreed to participate either could no longer be contacted or refused to answer follow-up surveys.” New suggests, “it is likely that women who disappeared from the survey were experiencing more psychological suffering than women who responded.”

Live Action conducted a series of interviews of women who have tried APR. Rebekah was 18 years old, already a mom to a ten-month old baby Eli, when she decided to take the abortion pill. She was just shy of eight weeks pregnant when a Planned Parenthood employee gave her mifepristone, saying it would feel “really natural,” like a “monthly menstrual cycle,” and not “too painful.” But by the time Rebekah got to her car she was “paralyzed” with feelings of regret. “Oh my gosh,” she thought, “what did I just do? I have a baby at home that I love very much. I’m getting more and more attached to this baby that’s growing inside of me.” Rebekah wondered if her preborn child was already dead. “Did it feel any pain?” she thought.

¹⁵ “Blocking Mifepristone Action With Progesterone,” *US National Library Of Medicine*, <https://clinicaltrials.gov/ct2/show/NCT03774745?term=creinin>.

Rebekah got out her phone and started searching terms like “I started the medication abortion and I’ve changed my mind.” Rebekah found a website that talked about APR and was able to start progesterone treatment quickly. Planned Parenthood discovered she tried APR after Rebekah failed to return for her follow-up appointment to see if the abortion pill worked. Planned Parenthood was discouraging and told her over the phone, “If you carry to term, which is not likely, your baby will probably have severe abnormalities.”

Rebekah’s baby, Zachariah, was born in October 2013, “perfectly healthy” and with no physical disabilities. Grateful she discovered APR, Rebekah now understands, “what it’s like to start an abortion and feel instant guilt and regret and grief,” and “what it’s like to be given a second chance at choice, a second chance choosing life after making a decision that I initially regretted.”



Emily began to regret her abortion immediately. “I think about it a lot,” she said, “I would do anything to have them in my family today... I miss that person I didn’t keep.”

Emily was 17 years old when she took the abortion pill for the first time. “It was scary and it was traumatizing,” she said. “It’s so dangerous... the amount of blood that there is... I bled a lot.”

Emily began to regret her abortion immediately. “I think about it a lot,” she said, “I would do anything to have them in my family today... I miss that person I didn’t keep.”

But at 19, Emily was pregnant again. She went back to Planned Parenthood to take the abortion pill a second time. Emily held the pills in her hand and told the employee administering the mifepristone, “I don’t know if I want to do this.” The employee said nothing about Emily’s options or choices, and simply replied: “Well you already paid for them.”

Emily took the mifepristone and “cried the whole way home.” But that evening, she found the Abortion Pill Rescue Network online and spoke to Elizabeth Delgado. Elizabeth gave Emily hope and found an APR clinic within 30 minutes

of Emily's home. "They were so different than the people from Planned Parenthood," Emily said of the clinic. "They were welcoming and loving," and showed her models of a baby at eight weeks. "This is what's inside of you," they said.

Emily worried about how to tell her parents she was pregnant. According to Emily, the clinic told her: "Don't worry about your parents, we'll tell them with you. We'll be with you every step of the way. We'll get you a crib, well whatever you need." Emily says they kept their word and provided her "a lot of stuff, free pregnancy prenatal classes, a crib, bassinet, clothes, diaper bag." They even helped Emily break the news to her mother. "To this day," Emily says, "we're all friends."

Emily named her baby Ezekiel, and he is now a healthy six year old.

Grief and regret are strong emotions that may not manifest in a person for many years after a decision or a traumatic event. The abortion industry's business model rests on the notion that many of their customers regret their pregnancies but never their abortions. Common sense suggests women like Rebekah and Emily, who experienced regret by the time they reach their car in the parking lot, are not rare cases.

Fortunately, Rebekah and Emily found APR websites just in time. But medical ethics demand women be adequately informed of APR before taking mifepristone.

ADDITIONAL LAWS PROTECTING WOMEN'S HEALTH & LEGAL CHALLENGES



Abortion Pill Reversal Laws

States like Arkansas, Idaho, Kentucky, North Dakota, Nebraska, Oklahoma, South Dakota, and Utah have passed laws requiring that women be informed of APR when receiving a prescription for mifepristone.

In 2019, the AMA and Center for Reproductive Rights challenged a North Dakota law requiring abortionists to disclose APR to women being prescribed the abortion pill, claiming the law violates the First Amendment rights of doctors. “North Dakota’s laws undermine the patient-physician relationship, because it requires physicians to mislead and misinform their patients with messages that contradict reality and science,” said AMA President Dr. Patrice Harris.

The AMA cites a recent US Supreme Court case, *NIFLA v. Becerra*, which held that the government could not force people to speak against their personal beliefs. Alliance Defending Freedom (ADF) filed a motion to intervene on behalf of Heartbeat International, which operates the Abortion Pill Rescue Network. ADF argues that *NIFLA v. Becerra* does not overturn “longstanding canons of medical ethics,” requiring doctors to inform patients about the “risks, alternatives, and consequences” of medical procedures. In other words, a patient’s right to informed consent is not a violation of a doctor’s First Amendment rights.

Finally, in May 2020, the pro-abortion Campaign for Accountability (CfA) sent a letter to the FDA asking the

agency to seize the website domains or issue warning letters to “Abortion Pill Rescue, American Pregnancy Association, Obria Medical Clinics, and any other entities improperly marketing progesterone treatments to women who have taken mifepristone.” CfA’s alleged concern for websites that advertise the off-label use of progesterone appears to mirror the demand by pro-life groups that the FDA seize the websites of Aid Access and other organizations selling illegal and unapproved abortion pills. CfA’s letter cites Creinin’s UC Davis study that ended early after three of the 12 patients were hospitalized, but fails to mention that it was the mifepristone that caused these women to be hospitalized and not progesterone. CfA also fails to mention that four of the five women given progesterone successfully delivered their babies. Most importantly, CfA’s letter insists the off-label use of progesterone is dangerous, even though the abortion pill regimen requires the off-label use Cytotec, and even though the off-label use of Mifeprex was common practice among abortionists until 2016 (when the Obama administration relaxed REMS).

State Laws on Telemedicine & Legal Challenges to REMS

Several states have enacted health and safety laws that go beyond the protections of REMS.

Thirty-three states require the clinician prescribing the abortion pill to be a licensed physician. The distinction is important since the term “clinician” encompasses a broad range of healthcare workers, including medical assistants working in an abortion facility. However, a licensed physician means a medical doctor licensed by the state to perform the practice of medicine. Licensed physicians are held to a legal “standard of care” and owe their patients a duty to provide learned and reasonable medical advice. Physicians can be

sued for malpractice in the negligent performance of their medical practice.

Eighteen states require that the clinician or physician be physically present with the patient receiving the abortion pill prescription. This requirement makes telemedicine an impossibility in these states.

This report has already mentioned the case of *Gomperts v. Azar*, in which the Dutch-based abortionist Rebecca Gomperts has claimed a violation of her alleged due process right to peddle lethal abortion drugs onto US consumers with impunity. The case, filed in Idaho federal district court, claims REMS imposes an undue burden on a woman's Constitutional right to abortion under *Roe*. In 2017, the ACLU made the same argument in *Chelius v. Azar* on behalf of Hawaii abortionists, and they challenged REMS as a violation of women's right to privacy and equal protection. The ACLU has claimed REMS places an undue burden on abortion access without medical justification.

Abortion Advocates Use COVID-19 to Push for Do-It-Yourself Abortions

State governors in Texas, Louisiana, Tennessee, and several other states required the closure of abortion facilities as nonessential businesses under COVID-19 lockdown and social distancing orders. Planned Parenthood and other abortion industry allies like the ACLU challenged these executive orders, which deemed abortion not medically necessary. These state orders further sought to preserve personal protective equipment (PPE) for the healthcare industry during the COVID-19 pandemic. Abortion advocates argued that medication abortions do not require PPE. In April 2020, the Fifth Circuit Court of Appeals agreed and let medication abortions continue in Texas.

Yet, the abortion pill can lead to the use of PPE if the woman returns to the emergency room because she is hemorrhaging. The “Patient Agreement” each woman signs to set forth her informed consent explicitly advises of the possibility for an emergency room visit to address incomplete abortion or other severe complications.

Advocates are also pressuring the FDA to lift REMS, just as pro-life groups are demanding the FDA continue to enforce REMS against online sellers like Aid Access. In an April 2020 letter issued by the National Women’s Health Network (NWHN), signed by over 80 pro-abortion advocacy groups like NOW and NARAL, these advocates said REMS is endangering lives during COVID-19. REMS, they claim, will “force pregnant people to pursue alternatives” like turning to “overseas pharmacies,” or “nonmedical methods of self-managed abortion,” while other women are exposed to COVID-19 by being forced to travel long distances to clinics for the abortion pill. “And, of course,” they said, “many people will be forced to carry an unwanted pregnancy to term during a pandemic.”¹⁶

On May 27, 2020, ACOG and the ACLU filed a lawsuit to enjoin the FDA and HHS from enforcing REMS. These groups argue that REMS puts women in danger by requiring them to travel to clinics to receive the abortion pill, “facing needless” exposure to COVID-19. They point out that the FDA and HHS have each “emphatically promoted the widespread use of telemedicine during the pandemic,” and that the FDA has relaxed REMS for laboratory testing and imaging studies (such as MRIs) during the pandemic, thus “embracing health care delivery models that meet patients’ urgent needs while reducing unnecessary travel and in-person examinations.” According to the ACLU

¹⁶ Congress of the United States. “April 14, 2020 Letter to Honorable Stephen Hahn, MD, Commissioner, Food and Drug Administration.” Accessed June 15, 2020. <https://www.hydesmith.senate.gov/sites/default/files/2020-04/041420%20-%20MOC%20Letter%20to%20FCA%20on%20Chemical%20Abortion%20During%20Coronavirus%20-%20final.pdf>.

and ACOG, refusing to lift REMS for the abortion pill is discriminatory and without medical basis.

These groups argue that refusing to lift REMS violates “patients’ right to privacy and liberty as guaranteed by the due process clause of the Fifth Amendment” by requiring women to risk “life-threatening viral exposure” in order to abort their children. Finally, they argue that treating abortion pill prescribers and patients different from other “similarly situated clinicians and patients” violates “patients’ right to equal protection of the laws under the Fifth Amendment.”

In the meantime, women who may die from undiagnosed ectopic pregnancies, who will show up at emergency rooms hemorrhaging only to find critical blood shortages, who will never hear about APR, and who will suffer excruciating physical and emotional pain from the abortion pill, will not have the ACLU, ACOG, or the AMA fighting for their fundamental rights.

CONCLUSION

We Do Not Know the True Number of Adverse Events

Since 2000, nearly 4 million American women have used the abortion pill. According to the Guttmacher Institute, the abortion pill now accounts for 40% of all US abortions. According to the reported data, there have been 4,200 adverse events reports for RU-486 and 24 fatalities. But these numbers are highly deceiving.

A woman taking the abortion pill is at risk of excruciating



Since 2000, nearly 4 million American women have used the abortion pill. According to the Guttmacher Institute, the abortion pill now accounts for 40% of all US abortions.

abdominal pain, hemorrhaging, sepsis, infection, and death. If a woman's chemical abortion fails and she undergoes surgical abortion to complete the procedure, she is also at increased risk of preterm delivery for future pregnancies. Planned Parenthood and Danco agree mifepristone's failure rate is anywhere from 2% to 9%. Yet, Danco and GenBioPro are only required to report deaths to the FDA—provided the abortionist prescribing RU-486 reports these deaths to Danco and GenBioPro.

A woman experiencing severe complications is not likely to return to Planned Parenthood or the abortion facility where she first received the abortion pill. Instead, she will more likely seek care at an emergency room. In fact, abortion facilities routinely instruct women taking the abortion pill to seek care at emergency rooms, rather than returning to the abortion facility.

If a woman goes to an emergency room to seek care, she may, on the advice of several prominent abortion pill advocates or perhaps on the advice of an abuser, claim she is experiencing a miscarriage. Even if she tells the ER doctor, she took the abortion pill, the doctor is under no legal obligation to report an adverse event to the FDA.

There is also no adverse event reporting process for abortion pills brought into the US illegally on a black market and unapproved by the FDA. Rebecca Gomperts admits to personally prescribing the abortion pill to over 7,000 American women between March 2018 and August 2019 alone.

Health & Safety Regulations Matter, But They are Not Enough

The FDA was established in the early twentieth century to protect consumer safety. Under 21 CFR § 2.5 the FDA

Commissioner may halt sales of a drug that poses an “imminent hazard to the public health.”

In 1977, the FDA used this emergency power to halt sales of a diabetic drug, phenformin. Consumer groups pressured the FDA to ban the drug after hundreds of reports that it caused fatal lactic acidosis. At the time, phenformin was being prescribed to over 385,000 patients per year.

In 1997, the FDA pulled the anti-obesity drug combination Fen-Phen off the US market less than two years after its approval, after dozens of reports of heart valve disease linked to the drug. At the height of its popularity, between 40 million and 60 million people used the drugs worldwide, and 4 million in the US.

In 2019, the FDA acted decisively to regulate e-cigarettes and confront the growing teen vaping epidemic. Centers for Disease Control and Prevention (CDC) has reported at least 150 cases of minors sickened by lung illnesses related to vaping, and 26 total vaping-related deaths. Nearly 3.5 million minors were vaping by the end of 2018.

Yet, ever since the FDA forced RU-486 through the approval process, this agency has barely taken notice of the abortion industry’s noncompliance with even the most modest safety protocols. In fact, as a reward for the industry’s open and persistent defiance of FDA label requirements, the Obama administration relaxed REMS in 2016.

Pregnancy is not an illness, and the abortion pill is not intended to prevent or cure a disease. Yet, the Clinton FDA used “accelerated approval” protocols typically reserved for high-risk drugs that cure life-threatening illnesses. The FDA disregarded standard procedures and best practices for clinical trials based on political marching orders from the White House to bring RU-486 to the market. No US

pharmaceutical company wanted anything to do with this lethal drug, which is why the only organization willing to take Roussel Uclaf's "gift" was the Population Council—a nonprofit with deep ties to the eugenics movement.

By approving RU-486, the FDA disregarded its mandate to protect consumer safety, and pro-life leaders should not let the FDA continue to escape its responsibility when it comes to women and preborn children. At the same time, we must also put REMS and APR into perspective. REMS is a set of safety guidelines to protect the health and safety of women intentionally using a lethal drug that chemically destroys the lives of their preborn children. When these women experience a change of heart, APR offers them a way to reverse their deadly decision. REMS and APR each serve to mitigate the damage to women's health caused by RU-486.

However, we cannot be satisfied with a status quo that preserves REMS, or merely with the return of pre-2016 REMS. We cannot be satisfied by requiring abortionists to disclose APR to women taking the abortion pill. We cannot be satisfied with the FDA cracking down on foreign websites and organizations counseling women to defy REMS and trafficking illegal abortion pills into US commerce.

We must keep in mind that none of these health and safety regulations will spare the lives of the more than 800,000 preborn children killed by abortion annually in the US. At best, REMS and APR are merely short-term remedies. The end goal remains the complete US ban on importing, distributing, and selling mifepristone. This lethal drug is dangerous for women, and nothing less than a way for the abortion industry to reduce its liabilities, overhead costs, and public scrutiny in order to increase its profits from the deaths of children.

The abortion industry envisions a day when vulnerable women can be convinced in their most desperate hour with

We must keep in mind that none of these health and safety regulations will spare the lives of the more than 800,000 preborn children killed by abortion annually in the US.



the easy fix of a quick pill. They do not want her wasting too much time in making her decision, or driving to the abortion facility, or walking past sidewalk counselors who might offer her a prayer, a kind word, or access to resources she may desperately need. They do not want the red-tape of regulations or licensing requirements that might impose minimal standards of accountability on abortionists and their facilities. They do not want to make disclosures about medical risks, or women to give informed consent, or the liability that comes with operating brick-and-mortar facilities with licensed physicians.

The abortion industry tells us that abortion is a form of healthcare, often medically necessary. Yet abortion advocates want the abortion pill “demedicalized,” dispensed over the counter, without the slightest amount of supervision from licensed physicians or healthcare workers.

Abortion advocates once claimed they wanted abortions to be “safe” and “rare.” Even before the FDA and the FTC cracked down on the tobacco industry’s deceptive advertising of unsafe products, which targeted children, tobacco companies never claimed they wanted smoking to be “rare.” Possibly because nobody would sincerely believe any for-profit business wants fewer consumers using its products and services.

The abortion industry was never concerned with safety either. Abortion advocates insist on “access,” not safety. And a lethal drug that chemically starves preborn children in the womb, while causing excruciating abdominal pain and days of severe bleeding to women, in successful cases is anything but “safe.”

What Can Be Done

Live Action demands the removal of all legal protections for abortionists and any clinician that prescribes the abortion

pill. Until that day comes, the FDA must not approve new abortion drugs, and it must resist efforts by the abortion industry to lift REMS and allow dangerous, unsupervised do-it-yourself abortions. Women also deserve to learn about APR before they are given a prescription for the abortion pill.

Additionally, the FDA is charged with protecting the safety of human subjects used in clinical trials. The commissioner should take immediate steps to shut down the trials conducted by Gynuity for its dangerous and unethical practices, including soliciting girls as young as ten years old and high-risk foreign trials involving women in their second trimesters.

Finally, the FDA should pull mifepristone from the market today under its power to declare the drug an imminent hazard to public health. We urge the FDA commissioner to take immediate steps to ban this lethal drug due to the imminent danger it poses to women and preborn children.

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