

store Hobby Lobby need not provide employees contraception coverage—including emergency contraception—under the Affordable Care Act. (See Chapter 9 for more on the ACA.) The plaintiffs had argued for a partial exemption from the ACA's coverage requirements, based on their religious beliefs that contraceptives such as the IUD and Plan B constituted a form of abortion. Despite the growing scientific consensus that neither of these methods prevents the implantation of fertilized eggs, the ruling posed a setback for those who advocate broader access to emergency contraception.

Studies also suggest that, despite FDA regulations, as many as 20 percent of pharmacies still refuse to allow adolescents to

purchase emergency contraception over the counter and an equal number do not keep the drugs in stock. For these pharmacists, too, the refusal is frequently cast as a matter of religious conscience. If scientific evidence on levonorgestrel and related drugs continues to demonstrate that the drugs do not prevent the implantation of blastocysts, some of this reluctance may fade over time. There is also substantial evidence that as much as 70 percent of the American public does not see fertilization versus implantation as a serious moral issue. Nevertheless, opinions about emergency contraception, like opinions about abortion, are deeply rooted in beliefs about sex, procreation, and personhood. Therefore it is unlikely that the conflict over emergency contraception will disappear any time soon.

CASE PRESENTATION

The “Abortion Pill”: The Rise of Medication Abortion

Sandra Crane, as we'll call her, became concerned after looking at her calendar. She was thirty-one years old and ordinarily her menstrual cycle was as regular as clockwork. Because her period was now a week overdue, she worried she might be pregnant.

The feeling was familiar. She had two children already: six-year-old Jennifer and two-year-old Thomas. She and her husband Carl had decided not to have any more kids. Their finances were tight and they had recently started caring for Carl's elderly mother in their home. They had already agreed that if the condoms they used for birth control ever failed, they would take steps to end the pregnancy.

Sandra paid a visit to her gynecologist's office to take a pregnancy test, and the day after that a nurse practitioner called to inform her that the test was positive. She was likely to be about two weeks pregnant. Sandra explained that she wanted to end the pregnancy as soon as possible, and the nurse made an appointment for her to see a doctor at a local women's health clinic. There, Sandra discussed her decision with Dr. Tina Merida, who also performed an ultrasound to

confirm the date of Sandra's pregnancy. The next day, Sandra and Carl returned to the clinic, where Sandra was given one tablet to swallow—a 200-milligram dose of the hormone blocker mifepristone (formerly known as RU-486). She was also given a prescription for 400 micrograms of the prostaglandin misoprostol, to be administered at home the next day.

Just six hours after letting the misoprostol dissolve under her tongue, Sandra began to experience uterine cramping and bleeding. Eventually, the lining of her uterus was expelled, just as it would be in a miscarriage. Sandra felt some pain, but the experience differed little from a heavy menstrual period. After two days of rest, she felt almost her usual self again. Two weeks later, she returned to the clinic for an examination to confirm that the abortion was complete.

Sandra's experience appears to be representative of most medication abortions in the United States. Although they usually involve more discomfort than surgical abortions, serious complications are extremely rare. Like the vast majority of abortions in the United States, medication abortions take place very early in

pregnancy. But since abortion in general remains a highly divisive issue in the United States, the "abortion pill" has been the subject of intense political and moral debate.

Background

Mifepristone, originally called RU-486, was developed by the French endocrinologist Étienne-Émile Baulieu. The drug works by blocking the action of progesterone, the hormone that prepares the uterine wall for the implantation of a fertilized egg. The dose of misoprostol (a kind of prostaglandin) then induces uterine contractions that expel the sloughed-off lining, including the embryo or fetus.

When it approved the drug in 2000, the FDA concluded it should be taken no later than seven weeks into a pregnancy, although a number of studies and systematic reviews later found it could be effective up to ten weeks. Subsequent research by the World Health Organization (WHO) and other researchers also demonstrated that the drug combination was effective at substantially lower doses than originally thought and that the misoprostol dose could be safely administered at home—recommendations that over 80 percent of U.S. providers have now adopted.

If mifepristone is taken soon after sexual intercourse, it also blocks the action of progesterone, and as a result, a fertilized egg won't be able to implant itself in the uterine wall. Hence, the drug also has the possibility of serving as a "morning-after pill" for preventing pregnancy. But the drug's main use lies in its power to induce an abortion. When taken on its own, the drug is roughly 95 percent effective at inducing abortion, a rate that rises to as much as 99 percent when combined with misoprostol.

Conflict

From the beginning, mifepristone was a source of intense controversy, condemned by abortion opponents and hailed by reproductive rights proponents. The French pharmaceutical company that developed it, Roussel-Uclaf, pulled the drug after boycott threats, only to reinstate it after the French health ministry threatened to transfer the patent to another company. Roussel licensed the drug for use in China, Sweden, and Britain, but its plans to market the drug in the United States were

abandoned because of opposition from antiabortion groups. The general position was stated by a representative of the National Right to Life Committee, who characterized the use of the drug as "chemical warfare against an entire class of innocent humans."

The Population Council, a nonprofit research organization committed to making medical abortion available to U.S. women, was frustrated by Roussel's decision and persuaded the company to grant it a license to manufacture and distribute the drug in the United States. The council conducted another clinical trial, which, like the French studies, showed high efficacy and few complications. The data were presented to the FDA, and in September 2000 the agency approved RU-486 (as it was then known) as a safe and effective prescription drug.

Reactions to the approval were predictably mixed. Abortion opponents denounced the FDA decision, calling mifepristone a "baby poison" and vowing to lobby for legislation to prohibit its use. Pro-choice advocates hoped that the approval of the drug would effectively defuse the public abortion debate by allowing women to make abortion decisions privately. Given the concentration of abortion clinics in urban areas, they also hoped that women living in rural and other areas far from such clinics would now have a safe and legal alternative.

Restriction and Risk

Only some of the hopes that pro-choice advocates pinned on medication abortion have materialized. For one thing, it turned out that the FDA's approval of mifepristone came with a number of restrictions that do not apply to most other prescription drugs. Before physicians can prescribe the drug, they must present special information about their qualifications. Patients must also take mifepristone at the doctor's office rather than obtaining it at a pharmacy.

As a result, many physicians still prefer the speed and reliability of surgical abortions. Those procedures take only a few minutes, and then the patient is on the way to recovery. Mifepristone is limited to use during the first seven to ten weeks of pregnancy, and once a woman is given the drug, the protocol approved by the FDA requires that she return to the office two more times.

Many physicians who thought they were likely to prescribe mifepristone also soon came to realize that abortion is regulated by a bewildering and complicated

set of state laws. Many of these laws were lobbied for by abortion opponents who wanted to make it difficult for women to obtain abortions, and they apply to all abortion providers, including those prescribing mifepristone.

Some states require, for example, that a physician performing abortions have an ultrasound machine, life-support equipment, and an operating suite available. Other states have laws stipulating specific standards the facility must satisfy, including hall width, temperature of running water, and amount of ventilation. Others mandate that providers read patients long lists of scientifically controversial warnings about health risks. The laws of some states regulate abortion in general, but those in other states specifically mention drug-induced abortion. In 2015, for instance, Arizona enacted a law that physicians must tell patients that medication abortions are "reversible," a claim that the medical community has rejected as lacking scientific grounding. (See Social Context: State Abortion Laws.)

The political debate over abortion has also led to increased scrutiny of the safety of medication abortion. As with the highly charged debate over vaccine safety, this scrutiny has tended to focus on a small number of ambiguous cases whose causal relationship to the drugs in question is unclear. In 2008, after the drugs had been prescribed an estimated 915,000 times over the course of eight years, researchers identified seven deaths that might be attributable to them. One death was due to an undiagnosed ectopic pregnancy, while the other six involved rare bacterial infections of *Clostridium sordellii* and *Clostridium perfringens*. Some researchers suggested that misoprostol might have lowered women's immune response to these bacteria, while others suggested that the off-label administration of misoprostol as a vaginal suppository might be responsible. The possibility that a particular lot of the drugs had become contaminated was also suggested, since the deaths all occurred in 2005 and 2006 and no similar deaths were reported in other countries. A joint CDC-NIH-FDA investigation, however, later concluded that the evidence did not indicate that the drugs had caused the infections. Instead, they cited CDC studies and other research indicating that pregnancy itself, rather than the medication, was likely the critical risk factor. They pointed to another cluster of

ten fatal clostridial infections before 2001, eight of which occurred after childbirth.

Nevertheless, there is clearly some small risk of adverse reactions to medication abortion, particularly excess bleeding as well as other (nonfatal) infections. A study conducted by Princeton University and Planned Parenthood published in 2009 found that the very rare (0.93 in 1,000) risk of a serious infection after taking the drugs could be reduced to 0.06 in 1,000 if practitioners avoided the vaginal suppository approach and prescribed antibiotics with the drugs. Although subsequent studies have continued to find complication rates well below 1 percent for both the FDA protocol and the lower-dose approach adopted by most providers, some physicians still prefer surgical abortion. For one thing, a drug-induced abortion is five to ten times more likely to fail and then require a surgical procedure.

In addition, abortion opponents continue to cite safety when fighting efforts to make medication abortion more easily accessible—lobbying against videoconference consultations for patients in rural areas and administration of the drugs by nurses and physician's assistants. Abortion rights advocates argue that these expressions of concern for women's health are disingenuous efforts to fight abortion by fanning irrational fear. They also point to evidence that childbirth is fourteen times more likely to kill women than any form of abortion.

Despite this ongoing conflict, mifepristone has been used in 2.3 million procedures and now accounts for a third of all abortions that occur before ten weeks of gestation. Despite the fact that overall abortion rates in the United States continue to fall to their lowest levels since the mid-1970s, the proportion of abortions performed using medication is on the rise. The drug combination also appears to have accelerated the overall trend toward earlier abortions, 73 percent of which take place in the first nine weeks of pregnancy and 90 percent of which take place during the first trimester.

Still, fifteen years after the approval of mifepristone, it has not ended the abortion controversy in the United States, as some advocates had hoped it would. Nor has it provided a legal abortion route for women who live in rural areas and cannot afford to travel to the urban centers where most surgical and medication abortions are available. As a result of the dozens of new abortion restrictions that have been adopted on the state level, the number

of clinics providing abortion of any kind has continued to fall precipitously in many states. (In just three years, the number of clinics in Texas fell from forty-four to nineteen, and there is now just one abortion provider in the entire state of Mississippi.) This situation has given rise to new uses of mifepristone and misoprostol that occupy a gray area in the law.

Mail-Order Abortion?

In September 2014, Jennifer Whalen, a thirty-nine-year-old mother of three from a small town in rural Pennsylvania, started serving a nine-to-eighteen-month prison term. Her crime was ordering mifepristone and misoprostol online and providing them to her sixteen-year-old daughter.

In the winter of 2012, Whalen's daughter had come to her and told her she was pregnant. Whalen told her daughter she would "support any decision she made," but the girl ultimately decided, "I can't have a baby right now."

When Whalen and her daughter began to research abortion clinics, however, they encountered problems. The closest clinic was seventy-five miles away, and Pennsylvania's twenty-four-hour abortion waiting period meant they would have to spend the night in Harrisburg before the procedure, which itself would cost as much as \$600. Whalen was a personal care aide at a nursing home who shared one car with her husband, and she had no health insurance for her daughter. When she and her daughter found a reputable-looking European website that offered mifepristone and misoprostol for sale for \$45, the choice seemed obvious.

They ordered the pills, which arrived and worked as promised. But Whalen became alarmed after her daughter experienced abdominal pains and took her to the hospital as a precaution. Her daughter turned out to be fine, but the hospital reported Whalen to the police after learning what her daughter had taken. Whalen later said she had no idea she needed a prescription to order the pills and her defenders argue that her prison sentence is unusual for personal online drug purchases. (Whalen's felony conviction was for offering abortion consultation without a medical license; she was also convicted of assault and endangering the welfare of a child.)

Whatever one makes of Jennifer Whalen's choices, they exemplify the fact that abortion has become considerably harder to access for millions of women in certain regions of the country. In the Rio Grande Valley of Texas, where the last abortion clinic closed in early 2014, women now regularly cross the border to buy misoprostol in Mexico, where it is legally sold over the counter, and volunteer groups have been organized to get women access to the drugs and monitor their reactions to them.

The organized provision of medication abortion across international borders is relatively new in the United States, but it has been going on elsewhere in the world for over a decade. Nearly 40 percent of the world's population lives in countries where abortion is either officially or effectively banned, and dangerous "back alley" abortions are still the only route available for ending unwanted pregnancies. As a result, several nonprofit groups have sprung up to offer medication abortion to women who cannot access it in their home countries. Women on Web, founded by the Dutch physician and activist Rebecca Gomperts, offers online medical consultations followed by mail-order prescriptions for mifepristone and misoprostol. The service is provided for free or for a donation and comes with detailed instructions on how to use the pills.

Women on Web's physicians advise women who experience any complications to seek local medical care but not disclose that they have taken the pills, since any treatment they need will be identical to that provided for spontaneous miscarriage. (The group does not operate in the United States and other countries where abortion is still legal.)

Envoi

The dream of many women's health groups in the 1980s was that mifepristone and misoprostol would make abortion safe, private, and easily secured by all women who sought one. The failure to achieve this dream reflects how contentious the abortion issue remains in the United States and how much progress opponents of abortion have made, especially at the state level. The fact that medication abortion is now being sought out illegally or quasi-legally reflects a familiar pattern: as abortions become more difficult to obtain, the steps women will take to end unintended pregnancies become more desperate and extreme.