"safe, legal, and rare," to quote President Bill Clinton's famous phrase. But of course, agreement to such a general proposition does not translate into agreement about what restrictions are appropriate. Although abstract positions may have blurred for most people, debates over particular policies remain as divisive and acrimonious as ever.

SOCIAL CONTEXT

Plan B and Emergency Contraception

Every year, Americans have 3.4 million unintended pregnancies, which represents more than half the total. About 40 percent of unintended pregnancies will end with an abortion. Although the teen pregnancy rate has reached its lowest point in more than thirty years, the vast majority (77 percent) of pregnancies to women under twenty are unintended. More than 25,000 women a year become pregnant as a result of sexual assault and about 19,500 will have abortions to end pregnancies that occur as a result of rape or incest.

One way to further decrease the number of abortions performed each year would be to decrease the number of unwanted pregnancies. One way to accomplish this is through *emergency contraception* drugs that prevent pregnancy *after* intercourse. They are sometimes called "morning after" pills, but this name is somewhat misleading. It generally takes one to two days (and sometimes up to five days) after intercourse for a sperm to fertilize an egg. During this period of time, emergency contraceptives delay ovulation and thicken cervical mucus to prevent fertilization. (Some abortion opponents charge that the drugs can also prevent implantation of fertilized ova, a topic we will address below.)

Plan B

The synthetic hormone levonorgestrel, commonly known by its original brand name, "Plan B," is the most well-known emergency contraceptive. Plan B One-Step® (Teva) consists of one 1.5-milligram dose of levonorgestrel, which is the same synthetic version of progesterone used in many birth control pills. If taken within seventy-two hours of unprotected intercourse, it is estimated to be about 89 percent effective at preventing pregnancy, and 95 percent effective if taken within twenty-four hours. (Some studies have indicated a higher failure rate for the drug, however.)

Since 2013, Plan B has been available over the counter without age restrictions. The most common side effects of the drug are headaches and nausea. About 20 percent of women taking Plan B experience headaches and around 10 percent nausea and vomiting, and an over-the-counter antinausea medication is often recommended to prevent such side effects.

Research has shown that Plan B (and similar drugs such as ella) prevent pregnancy by delaying or preventing ovulation and inhibiting the passage of sperm by thickening cervical mucus. What research has *not* demonstrated so far is that these drugs prevent pregnancy by impeding the implantation of fertilized eggs. Instead, multiple studies have shown that when Plan B is taken after ovulation occurs, women are just as likely to become pregnant as those who have not taken the drug. Women who take the drug before ovulating, however, successfully prevent pregnancy.

This might seem to be a relatively minor issue, since the standard medical and

legal definition of the start of pregnancy is the implantation of a fertilized egg in the uterus. But for abortion opponents who argue that a fertilized ovum has the full moral standing of personhood, the days between fertilization and implantation are a crucial and perilous time for human life. Without any intervention, 50 to 80 percent of fertilized eggs naturally fail to implant in the uterine lining, a loss that is already a profound tragedy in the view of some abortion opponents. Taking steps that might prevent implantation would compound that natural tragedy with an active moral wrong, tantamount to abortion.

It is not surprising that some abortion opponents have focused on Plan B as potentially preventing implantation, since the original FDA label, drafted at the time of the drug's approval in 1999 and still in use as of early 2015, says that the drug "may also prevent fertilization or attachment of a fertilized egg to the uterus." But researchers at the NIH, along with the rest of the mainstream medical establishment, subsequently concluded that this language was inaccurate and out-of-date, modeled on labels for birth control pills from the 1960s, when scientists had little understanding of how the drugs worked. (The FDA approval process did not involve any studies about the drug's mechanism.) By 2012, both the NIH and the Mayo Clinic, as well as European regulators for the drug, had removed language on their websites about implantation disruption, and the International Federation of Gynecology and Obstetrics had issued a statement explicitly stating that levonorgestrel does not stop implantation.

Nevertheless, abortion opponents argue that further proof is needed and point out that if the current studies get further confirmation, Plan B's label should be changed to say that it is ineffective after ovulation. (This is a point on which both sides agree.) For now, Plan B, its generic equivalents, and the longer-acting drug, ella, continue to generate controversy. Indeed, they have done so for over a decade.

Conflict

In 1999, the FDA approved Plan B as a safe and effective prescription drug regimen. It originally involved two tablets to be taken within seventy-two hours of unprotected intercourse. Given the demonstrated safety of the drug and the practical difficulty of obtaining a prescription within the seventy-two-hour window, however, many physicians began to argue that Plan B should be made available over the counter (OTC). In October 2003, Barr Laboratories' application to sell the drug OTC was reviewed by an independent FDA advisory panel of scientists and physicians, which voted 23–4 for approval.

The FDA has generally taken the advice of its advisory panels, but this time the panel's recommendation was overruled by upper-level FDA officials. Plan B was controversial, and abortion opponents were lobbying Bush administration officials to deny Barr's application. Although the FDA's own scientific panel had already concluded that Plan B was a contraceptive agent, not an abortion drug, this finding was rejected by many social conservatives and the U.S. Conference of Catholic Bishops. They also objected to making the drug available OTC because, in their view, it might encourage sexual activity among unmarried women and teens who might otherwise avoid it due to the fear of pregnancy.

On the other side of the reproductive divide, the American Medical Association, American College of Gynecologists and Obstetricians, American Academy of Family Physicians, and American Academy of Pediatricians endorsed OTC sales of Plan B as serving the best medical interest of women.

As it turned out, Plan B was the only one of twenty-three applications to change a drug from prescription-required status to OTC to be turned down in the period 1994–2004. Some FDA staff claimed that Steven Galson, the head of the FDA's drug-review center, had told staff members that it did not matter what the independent advisory panel's recommendation was, because the decision would be made by top officials at the agency.

After the Plan B application was turned down, several members of Congress asked the Government Accountability Office (GAO) to conduct a review of what had taken place at the FDA. The GAO investigation discovered that the decision to reject the application had been made before the FDA's own scientific review of the application was finished.

Reapplication and Restriction

In his rejection of Barr's application, Steven Galson had argued that the original study on Plan B had not included enough teens fourteen to sixteen. So in July 2004, Barr resubmitted its application limiting OTC sales to females *older* than 16. But the FDA delayed action on the application for over a year, then announced in February 2005 that it was delaying its decision indefinitely for further study. In September of that year, Susan Wood, director of the FDA's Office of Women's Health, resigned to protest the agency's decision. "I feel very strongly that this shouldn't be about abortion politics," she said. She told a reporter that she could no longer serve at the FDA "when scientific and clinical evidence, fully evaluated and recommended by approval by the professional staff here, has been overruled."

In 2006, in response to congressional pressure and lawsuits, the FDA agreed that Plan B could be sold without a prescription to women ages eighteen and older. In August 2009, however, Judge Edward R. Korman of the New York Federal District Court ruled that this decision again appeared to be determined by politics, not science. He gave the agency thirty days to lower the limit to age seventeen and recommended they consider dropping the age requirement altogether. The FDA complied with the order, inviting the manufacturer to submit a plan to market Plan B "without a prescription to women seventeen years of age or older."

In 2011, Barr Laboratories—now owned by Teva Pharmaceuticals—submitted an application to move Plan B from "dual label" use to full OTC status without age limits. The FDA's Center for Drug Evaluation and Research (CDER) studied the application and determined that Plan B was effective and safe for "all females of child-bearing potential." They also concluded that adolescents were capable of understanding and using the drugs without a physician's aid. But later that year, the Director of Health and Human Services, Kathleen Sebelius, overruled the decision, again citing insufficient evidence on use by younger patients.

Finally, in April 2013, Judge Korman overruled Sebelius's decision, concluding it had involved "bad faith and improper political influence" and confirming the CDER's findings. Later that month, the FDA complied with Korman's order and approved the use of Plan B as a nonprescription product without age or point-of-sale restrictions.

Coverage and Conscience

The FDA's approval of Plan B for OTC use was praised by organizations promoting the reproductive autonomy of women and condemned by conservative groups on the grounds that easier access to emergency contraception would encourage more sex outside of marriage and procreation. It has also led to further legal action.

In June 2014, the Supreme Court ruled in *Burwell v. Hobby Lobby* that family-run Christian corporations such as the craft

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