ON DECEMBER 7, 2011, HEALTH AND HUMAN SERVICES Secretary Kathleen Sebelius overruled the US Food and Drug Administration's (FDA's) decision that levonorgestrel emergency contraception (sold under the brand name Plan B One-Step) was safe and effective for all women of childbearing potential, regardless of their age, and should be approved for sale as a nonprescription drug. Plan B One-Step is a single-dose 1.5-mg tablet of levonorgestrel that should be taken as soon as possible and within 72 hours after an episode of unprotected intercourse.

Emphasizing a concern about nonprescription use by the youngest girls of reproductive age, Sebelius wrote to Margaret Hamburg, MD, the FDA commissioner that the studies submitted to the agency “do not include data on all ages for which the drug would be approved and available over the counter” and “do not establish that prescription dispensing requirements should be eliminated for all ages.” Although the Health and Human Services (HHS) secretary has the legal authority under the Food, Drug, and Cosmetic Act to reverse an FDA decision, Sebelius was apparently the first to ever do so.

Plan B One-Step is manufactured by Teva Women’s Health and sells for about US $50. The FDA has approved the drug for use without a prescription in women aged 17 years or older and with a prescription for those who are younger. Most who use emergency contraception are 17 years or older. The pills are dispensed from behind the counter at pharmacies and clinics; they are more difficult to obtain than they would be if they were in the aisles of pharmacies, grocers, and other retailers, as are condoms and spermicides. A generic product that consists of two 0.75-mg pills of levonorgestrel (sold under the brand name Next Choice) is also approved under the same dual status.

Federal agencies know that decisions involving sexual matters are often controversial. But virtually no one foresaw the extraordinary reversal of an FDA decision about drug approval by a secretary in President Barack Obama’s cabinet, a decision the president said that he fully supported.

In his inaugural address in January 2009, Obama heralded a new era that would “return science to its rightful place” in government. In March 2009, he ended the ban on federal funding for embryonic stem cell research and directed the head of the White House Office of Science and Technology Policy “to develop a strategy for restoring scientific integrity to government decision making” and “to ensure that in this new administration, we base our public policies on the soundest science; that we appoint scientific advisors based on their credentials and experience, not their politics or ideology; and that we are open and honest with the American people about the science behind our decisions.” Soon thereafter, Obama appointed the FDA commissioner and principal deputy commissioner, and they vowed to establish the FDA “as a public health agency” that “the public must trust...to base its decisions on science” and to “define and protect integrity in its basic processes.”

Less than 3 years later, Obama’s HHS Secretary rejected Plan B One-Step for nonprescription use without an age restriction because of a lack of confidence that the youngest girls of reproductive age could use the medication properly. Sebelius’s decision renewed concerns about the relation between science and politics in the federal government, regardless of the party in office.

The facts are that adolescents who have had sexual intercourse typically have intercourse for the first time at about age 17 years. About 28% of never-married females aged 15 to 17 years and 60% of those aged 18 to 19 years have ever had intercourse. In contrast, only 3.1% of female high school students had intercourse for the first time before the age of 13. Of the 372 252 births to mothers 19 years or younger in 2010, 4500 (1.2%) were to those younger than age 15 years.

Plan B One-Step has adverse effects, such as nausea and menstrual disruption; it is not intended for routine use as a contraceptive and is not effective in terminating an existing pregnancy. Plan B, its predecessor, which consists of two 0.75-mg levonorgestrel tablets taken 12 hours apart but is no longer marketed in the United States, was approved for prescription use in 1999. In 2003, the drug’s manufacturer at the time applied for nonprescription status. In 2004, the
The actual-use trial has yet to be published, although the FDA, according to a statement from Hamburg "reviewed the totality of the data, and agreed that it met the regulatory standard for a nonprescription drug." The study involved more than 300 teenagers who sought emergency contraception at reproductive health clinics for adolescents over a 2-year period. Although those between the ages of 11 and 17 years were eligible, no 11- or 12-year-olds were enrolled because no one of these ages requested emergency contraception at the clinics; only a handful of 13-year-olds could be studied. According to Tina Raine-Bennett, MD, MPH, of the Women’s Health Research Institute at Kaiser Permanente Northern California, a principal investigator of the University of California-San Francisco study, “It is unreasonable and virtually impossible to study the use of emergency contraception in 11- and 12-year-olds, because only a small fraction of them will have had sex by that age” (written communication, December 13, 2011).6

Emergency contraception reduces a women’s risk of pregnancy following an episode of unprotected intercourse by at least 50%. There are no data, however, that increasing access reduces pregnancy or abortion rates on a population basis. The recent decline in the birth rate for teenagers in the United States aged 15 though 19 years (to a record low of 34.3 per 1000 women in 2010)2 primarily reflects improved use of contraceptives that are designed for regular use—not emergency contraception—and an older age at which girls start to have intercourse.7,8

As the presidential election of November 2012 approaches, it is perhaps not surprising that HHS Secretary Sebelius and President Obama are now part of the continuing saga of over-the-counter emergency contraception in the United States. Teva Women’s Health is determining its next steps in responding to Secretary Sebelius’s decision. The decision has set an unfortunate precedent. The controversies about Plan B One-Step and the intrusion of science into politics in the federal government will continue.


Financial Disclosure: The author has completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and reports being a member of the Medicare Evidence Development and Coverage Advisory Committee and serving as a consultant to the FDA’s Drug Safety and Risk Management Advisory Committee.

REFERENCES