

Obama Administration Yields to the Courts and the Evidence, Allows Emergency Contraception to Be Sold Without Restrictions

On June 10, after more than a decade of legal disputes regarding the over-the-counter status of emergency contraception (EC), the Obama administration announced that the U.S. Food and Drug Administration (FDA) would approve Plan B One-Step for sale without age or point-of-sale restrictions. That approval was granted on June 20. This policy change marks the end of two months of foot dragging by the administration to avoid cooperating with an April 5 ruling by U.S. District Court Judge Edward Korman (see chart).¹ The administration's compliance with the court's ruling means that this version of EC will be sold on shelves, as opposed to being stocked behind pharmacy counters where women need to provide government-issued photo identification as proof of age to purchase it without a prescription. Two-pill versions of levonorgestrel-based EC will continue to be subject to the age and point-of-sale restrictions, and the newest EC product, ella, which has a different active ingredient, will continue to be available by prescription only.

Age and point-of-sale restrictions have been in place since levonorgestrel-based EC was first approved for over-the-counter-sales in 2006, although the FDA lowered the prescription cutoff from age 18 to age 17 in 2009 after being sued. In December 2011, Secretary of Health and Human Services Kathleen Sebelius defended

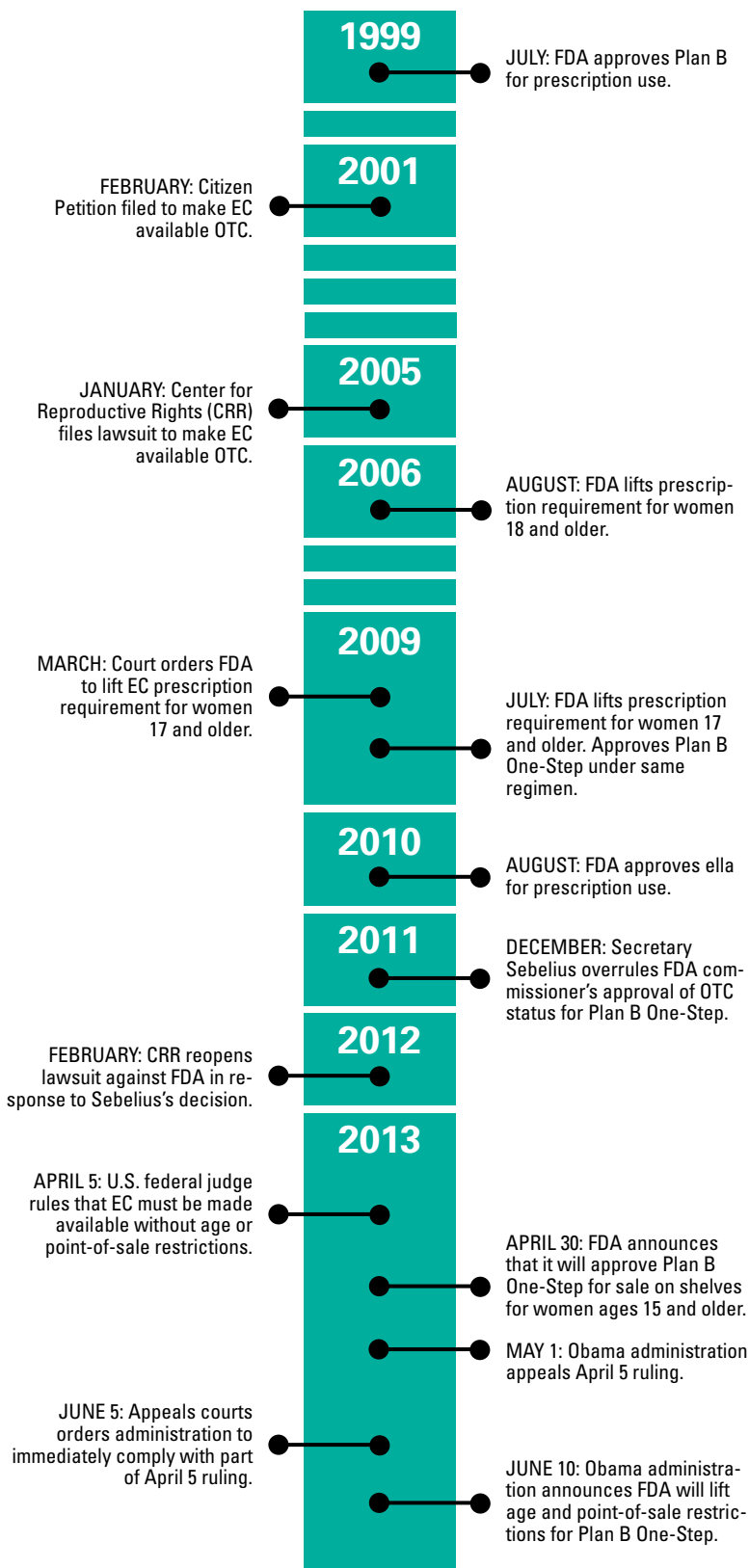
these limitations as she took the unprecedented step of overruling the FDA commissioner's decision that Plan B One-Step could be safely sold over-the-counter and without restrictions. In a memorandum to the FDA commissioner, Sebelius concluded that there was not adequate evidence to determine that EC could safely be made available to preteens. President Obama agreed with Sebelius's reasoning, stating that she was hesitant to permit "a 10-year-old or an 11-year-old...to buy a medication that potentially, if not used properly, could end up having an adverse effect."²

In his April 5 ruling, Judge Korman reprimanded Secretary Sebelius's "politically motivated, scientifically unjustified" decision to retain the age and point-of-sale restrictions for EC. In point of fact, very young adolescents have over-the-counter access to numerous medications that—unlike EC—can cause dangerous side effects if used improperly. For instance, acetaminophen, the active ingredient in Tylenol, can cause liver damage if the recommended dosage is exceeded. Numerous medical and scientific organizations, including the American Academy of Pediatrics, the Society for Adolescent Health and Medicine and the American College of Obstetricians and Gynecologists, agree that levonorgestrel-based EC is completely safe for use by women of reproductive age without a prescription.³ In any case, few very young

adolescents have reason to use EC. Guttmacher Institute research shows that only 0.6% of 11-year-olds girls and 1.3% of 12-year-olds girls have ever had sex.⁴ In attempting to protect the youngest adolescents from a drug they almost uniformly would never need or use, the age restrictions the administration had defended created barriers for others. For instance, in 2008, 8.6% of 14-year-old girls had had sex, leading to 10,200 pregnancies, the vast majority of them unintended.

Removing the age and point-of-sale restrictions means not only that adolescents in need of the drug will have easier access to it, but older women will too. Having to present government-issued photo identification as proof of age to obtain EC without a prescription may be particularly problematic for women of color and undocumented immigrants. Those groups are especially likely to lack valid identification and also to lack adequate access to health care and to experience unintended pregnancy. Moreover, now that women will no longer need to rely on pharmacists to dispense their EC, they will no longer be subject to the additional obstacle that some pharmacists erect as they refuse to dispense the medication on moral or religious grounds. As levonorgestrel-based EC must be taken within 72 hours of unprotected sex, removing all of these barriers will make a real difference in facilitating

EMERGENCY CONTRACEPTION TIMELINE



Source: reference 1.

timely access to this important back-up method of pregnancy prevention.

Yet, one last significant concern remains: cost. The administration indicated that it will consider granting marketing exclusivity to Teva, the manufacturer of Plan B One-Step. Marketing exclusivity would mean less expensive, generic versions of the product would not be exempt from age and point-of-sale restrictions, a move that would disadvantage low-income women. This could result in the drug becoming more available but less affordable, since public and private health insurance does not typically cover medications purchased over-the-counter. The administration's next moves, therefore, will be closely watched by reproductive health advocates.

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1. Center for Reproductive Rights, The fight for emergency contraception: every second counts, no date, <<http://reproductiverights.org/en/emergency-contraception-timeline>>, accessed June 19, 2013.

2. Keilar B, Obama endorses move to keep age restrictions on morning after pill, *CNN*, Dec. 8, 2011, <<http://whitehouse.blogs.cnn.com/2011/12/08/obama-endorses-move-to-keep-age-restrictions-on-morning-after-pill>>, accessed June 19, 2013.

3. American Academy of Pediatrics, American College of Obstetricians and Gynecologists, and Society for Adolescent Health and Medicine, Medical groups denounce administration's appeal of emergency contraception ruling, news release, May 2, 2013, <<http://www.aap.org/en-us/about-the-aap/aap-press-room/pages/ECRulingAppeal.aspx>>, accessed June 19, 2013.

4. Finer LB and Philbin JM, Sexual initiation, contraceptive use, and pregnancy among young adolescents, *Pediatrics*, 2013, 131(5):886–891, <<http://pediatrics.aappublications.org/content/early/2013/03/27/peds.2012-3495>>, accessed June 19, 2013.