

Important Milestones in the History of FDA Approved Emergency Contraceptive Pills

- *February 25, 1997:* The U.S. Food and Drug Administration (FDA) concludes that certain combined oral contraceptives containing ethinyl estradiol and norgestrel or levonorgestrel are safe and effective for use as postcoital emergency contraception (EC). The FDA requests submission of new drug applications for this use.
- *September 1, 1998:* Preven[®], containing ethinyl estradiol (synthetic estrogen) and levonorgestrel (synthetic progesterone), becomes the first FDA approved EC product on the market.
- *July 28, 1999:* The FDA [approves](#) Plan B[®], a levonorgestrel-based EC pill, finding it safe and effective for women of all ages to use as a prescription product.
- *February 14, 2001:* The Reproductive Health Technologies Project (RHTP) and the Center for Reproductive Rights (CRR), on behalf of more than 70 medical and public health organizations, file a Citizen Petition with the FDA to make EC available over-the-counter (OTC).
- *April 21, 2003:* Barr Pharmaceuticals, the manufacturer of Plan B[®], files an application with the FDA to make it available OTC.
- *December 16, 2003:* An [FDA independent panel](#) of experts votes 23 to 4 to recommend Plan B[®] be made available OTC, without age restrictions. The panel also votes unanimously that Plan B[®] is safe for nonprescription use.
- *Late December 2003/January 2004:* A panel of FDA experts recommends approval of the Plan B[®] application, but Dr. Steven Galson, the head of the office responsible for making the final decision, informs his staff that the regular procedures wouldn't be followed this time, and that the office wouldn't make the final decision. Galson confesses to a co-worker that he had to reject the Plan B[®] application because he was afraid he would lose his job. Dr. Janet Woodcock, the second in command at the FDA, tells a colleague that the agency first had to reject the application, then approve the drug later with an age restriction in order to “appease the administration's constituents.”
- *May 2004:* Preven[®] is discontinued.
- *May 6, 2004:* Galson overrides FDA professional staff recommendations and issues a [“not approvable” letter](#) to Plan B[®]'s manufacturer, citing concerns about young teens using the drug.
- *July 22, 2004:* Barr submits a revised OTC proposal to the FDA, which would make it available OTC to women 16 and older, while requiring a prescription for women 15 and under.
- *January 21, 2005:* The FDA fails to issue a decision on the Plan B[®] application by the deadline imposed under the federal law governing performance standards for drug approvals. After four years of unexplained delays, CRR files suit against the Acting Commissioner of FDA for holding EC to a different standard than all other drugs.

- *March 17, 2005:* Members of the Senate Committee on Health, Education, Labor, and Pensions (HELP) question the FDA's Acting Commissioner Lester Crawford about the agency's inaction on the Plan B[®] OTC application during hearings on his nomination to permanently head the FDA. Unsatisfied with Crawford's answers, Senators Clinton, Murray, and Kennedy request a closed-door meeting with him.
- *April 6, 2005:* Following the closed-door meeting, Senators Clinton and Murray announce their intention to place a "hold" on Crawford's nomination, citing the FDA's failure to act on a host of public health issues – including the Plan B[®] OTC application – during Crawford's tenure as Acting Commissioner.
- *May 15, 2005:* News reports indicate that David Hager, a controversial member of the FDA's Reproductive Health Drugs Advisory Committee, was asked to author an unprecedented minority opinion opposing FDA approval of OTC access for Plan B[®] – after the advisory panel voted overwhelmingly to support the application.
- *July 15, 2005:* Senators Clinton and Murray lift the "hold" on Crawford's nomination to head the FDA after receiving assurances from Health and Human Services Secretary Mike Leavitt that the FDA will act on the Plan B[®] OTC application by September 1.
- *July 18, 2005:* Crawford is confirmed as FDA Commissioner.
- *August 26, 2005:* Commissioner Crawford cites "regulatory and policy concerns" about Barr's proposal to sell Plan B[®] OTC to OTC to women 16 and older, while requiring a prescription for women 15 and under. He announces his decision to submit the application to the administrative rulemaking process and open a 60-day public comment period on the application. This proposed rulemaking is a thinly veiled attempt to postpone the application indefinitely.
- *August 31, 2005:* Dr. Susan Wood, Assistant Commissioner for Women's Health and Director of the FDA Office of Women's Health, resigns from the FDA on principle in response to the decision to once again delay approval of Plan B[®], despite the recommendation of FDA scientific staff and advisory committees and the pledges received by Senators Clinton and Murray. "I can no longer serve as staff when scientific and clinical evidence, fully evaluated and recommended for approval by the professional staff here, has been overruled," she wrote in an e-mail to her staff and FDA colleagues.
- *September 13, 2005:* The FDA announces that Dr. Norris Alderson, a senior official at the Center for Veterinary Medicine, has been appointed Acting Director to the Office of Women's Health. However, three days later, the FDA announces Dr. Theresa Toigo, Director of the Office of Special Health Issues, as the Acting Director of the Office of Women's Health and denies Alderson's appointment.
- *September 23, 2005:* Citing age and personal reasons, Commissioner Crawford announces his sudden resignation as Commissioner of the FDA. President George W. Bush immediately appoints Dr. Andrew von Eschenbach, Director of the National Cancer Institute, as Acting Commissioner.

- *October 13, 2005:* The Government Accountability Office (GAO) releases a draft report of the investigation into the FDA’s denial of Barr’s original application. The report deems the process leading up to the denial highly unusual, with an atypical level of involvement by high-ranking FDA officials. Further, the report shows there were conflicting accounts on when the decision was made.
- *November 1, 2005:* The period of time for public comments on the FDA Proposed New Rulemaking closes. The FDA does not reveal any plans on when it will move forward with the rulemaking process and it is not statutorily required to do so.
- *November 14, 2005:* The GAO releases a [final report](#) documenting the FDA’s denial of Barr’s original application.
- *February 16, 2006:* Nearly a full 6 months after the FDA announced the Proposed New Rulemaking, Acting Commissioner von Eschenbach is called to testify before the House Agriculture Appropriations Subcommittee, where he faces intense questioning from Representatives Sam Farr and Rosa DeLauro regarding the FDA’s failure to act on the application or received comments. Von Eschenbach does not provide any details of the FDA’s schedule for Plan B[®].
- *March 9, 2006:* Representative Henry Waxman, after receiving documentation that revealed that the FDA had, in fact, internally examined at least one year before the very issues it claimed were so “novel” as to require rulemaking, writes a letter to von Eschenbach. The letter asks why the FDA did not act in a timely manner on the information that it possessed and why the FDA deleted the e-mails of its senior staff in violation of the Federal Records Act. A response is requested by March 27, 2006.
- *March 10, 2006:* Von Eschenbach is nominated by President Bush to become permanent Director of the FDA 169 days after he was appointed as Acting Commissioner.
- *Week of April 24, 2006:* CRR carries out depositions of high ranking FDA officials with regards to bad faith in decision making on the Plan B[®] application.
- *June 9, 2006:* The FDA denies CRR’s Citizen Petition on the grounds that it was not adequately supported by scientific evidence.
- *July 31, 2006:* The day before von Eschenbach’s confirmation hearing begins, the FDA announces plans to meet with Barr to “to resolve the remaining policy issues” related to making Plan B[®] available OTC for women “18 years and older.”
- *August 1, 2006:* During his confirmation hearing, von Eschenbach announces his support for Plan B[®] to be available OTC for women 18 years and older, but declines to offer any timetable.
- *August 18, 2006:* The FDA announces that Barr has resubmitted its application to sell Plan B[®] OTC.
- *August 21, 2006:* In a press conference, President Bush indicates his support for making Plan B[®] available for women 18 and older by saying, “I believe Plan B[®] ought to be a required prescription for minors,” and adding that he supports “Andy’s [von Eschenbach’s] decision.”

- *August 24, 2006:* The FDA [approves](#) the distribution of Plan B® without a prescription for women 18 and older, granting Barr three years of market exclusivity. However, those younger than 18 or without ID must produce a prescription. As a result, the product has a “dual label” and is kept behind the counter at pharmacies. EC becomes the only drug which is sold OTC to customers of a certain age, while requiring a prescription for those younger than the specified age.
- *November 6, 2006:* Barr begins sales of dual label Plan B®.
- *December 7, 2006:* Von Eschenbach is confirmed by the Senate as FDA Commissioner.
- *March 30, 2007:* CRR files for summary judgment in the case, arguing that the undisputed facts found in evidence gathered through discovery make it unnecessary for the Court to hold a trial, and that the Court should order the FDA to make Plan B® available without a prescription to women of all ages.
- *December 23, 2008:* Teva Pharmaceutical acquires Barr.
- *March 23, 2009:* The U.S. District Court for the Eastern District of New York [rules](#) that the FDA acted “arbitrarily and capriciously” in restricting OTC access to women 18 and over. The judge orders FDA to re-review the rationale for imposing any age restriction and simultaneously orders the FDA to make Plan B® available without a prescription to consumers 17 and older.
- *April 22, 2009:* Complying with a part of the District Court’s decision, the FDA indicates that it would be willing to lower the age restriction on OTC access to Plan B® from 18 to 17. The FDA sends a letter to Teva stating that upon submission and approval of an appropriate application, the company may market Plan B® without a prescription to women 17 and older.
- *July 10, 2009:* In compliance with the ruling, the FDA approves OTC availability of Plan B® to consumers 17 and older. At the same time, the FDA approves Plan B One-Step®, a single-pill EC, also to be available OTC for women 17 and older and prescription-only for women 16 and younger.
- *August 24, 2009:* Plan B®’s market exclusivity expires, opening the market up for new OTC EC.
- *August 28, 2009:* The FDA approves the first generic version of Plan B® called Next Choice® by Watson Pharmaceuticals. The product is made available OTC for those 17 and older and by prescription for those 16 and younger.
- *June 17, 2010:* The FDA Reproductive Health Drugs Advisory Committee unanimously recommends the approval of ulipristal acetate 30mg (ella®), a safe and effective EC product that delays ovulation and prevents pregnancy for five days after unprotected sex.
- *August 13, 2010:* The FDA approves ella®, finding it safe and effective for women of all ages to use as a prescription-only product.
- *November 16, 2010:* CRR files a motion for contempt of court against the FDA for failing to follow the District Court’s order that the FDA reconsider and re-review its decision to impose age restrictions on access to EC.

- *December 1, 2010:* Watson Pharmaceuticals launches ella[®] on the U.S. market, where it is available by prescription-only to women of all ages. KwikMed.com, an online pharmacy legally authorized to write and dispense certain prescriptions, begins sales of ella[®].
- *December 30, 2010:* FDA approves a second generic form of Plan B[®], called [Levonorgestrel tablets](#), manufactured by Perrigo Pharmaceuticals.
- *February 7, 2011:* Teva files an application with the FDA to re-label Plan B One-Step[®] as OTC without an age restriction in response to new data on actual use and [label comprehension](#) of adolescents.
- *December 7, 2011:* In an unprecedented move, Health and Human Services Secretary Kathleen Sebelius overrules FDA Commissioner Margaret Hamburg's [recommendation to approve](#) Plan B One-Step[®] for full OTC status, saying there was not enough data on young adolescents. The FDA issues a "complete response letter" to Teva.
- *December 8, 2011:* "As a father of two daughters," President Barack Obama publicly says he supports Sebelius' decision.
- *December 12, 2011:* Sebelius [says](#) the door is open for Teva to come back to the FDA with more data and resubmit its application to make Plan B One-Step[®] OTC for all ages, but does not provide a pathway for the company within the complete response letter.
- *December 12, 2011:* The night before the contempt hearing, the FDA [denies](#) the Citizen Petition for a second time based on a lack of teen-specific data for the two-pill formulation.
- *December 13, 2011:* U.S. District Court Judge Edward Korman hears oral arguments on CRR's motion for contempt against the FDA. He finds the contempt motion moot, but agrees to reopen the case and allow for the future addition of Sebelius as a defendant.
- *February 8, 2012:* CRR files a motion to reopen the case, adding Sebelius as a defendant. They also file a motion for a preliminary injunction and summary judgment seeking immediate relief that would allow OTC access for all levonorgestrel-based EC pills (both one and two pill versions) without any age or point of sale restrictions.
- *February 16, 2012:* The Court issues an order to show cause to the FDA, asking the agency to explain "why the FDA should not be directed to make Plan B[®] available to those persons whom the studies submitted to the FDA demonstrate are capable of understanding when the use of Plan B[®] is appropriate and the instructions for its use."
- *July 20, 2012:* The FDA files a cross-motion for partial summary judgment.
- *February 22, 2013:* GAVIS Pharmaceuticals introduces My Way[®], a generic version of Plan B One-Step[®].

- *April 4, 2013*: Judge Korman [orders](#) FDA to approve all levonorgestrel pills as OTC without age restrictions.
- *April 30, 2013*: The FDA approves Plan B One-Step[®] for sale without a prescription for women 15 years of age and older. The product will now be labeled “*not for sale to those under 15 years of age *proof of age required* not for sale where age cannot be verified.*”
- *May 1, 2013*: The Obama Administration [files](#) a notice of appeal and moves for a stay pending appeal regarding the April 4th order from Judge Korman.
- *May 7, 2013*: In a hearing about whether to grant an extension of time for the FDA to comply with the April ruling, Judge Korman calls out the administration’s attempts to create political cover for its decisions.
- *May 10, 2013*: Judge Korman [refuses](#) to grant an extension of time to the FDA to comply with the April 4th ruling. He instead grants a temporary extension (a stay) giving the FDA until noon May 13th to request an extension.
- *May 13, 2013*: The Obama Administration files an appeal asking the U.S. Court of Appeals for the Second Circuit to postpone Judge Korman’s ruling that eliminated age limits on all levonorgestrel EC pills while the government appeals that overall decision.
- *June 5, 2013*: The U.S. Court of Appeals for the Second Circuit [partially denies](#) the administration’s motion for a stay, mandating that the two-pill version of EC become available to anyone regardless of age.
- *June 10, 2013*: The Obama Administration [announces](#) in a letter to Judge Korman that it would no longer pursue an appeal but will comply with the court’s order by making the one-pill version of Plan B One-Step[®] available OTC. It does not agree to make one-pill generics or the two-pill version available without age restrictions.
- *June 12, 2013*: Judge Korman [accepts](#) the Obama Administration’s plan to make Plan B One-Step[®] available without age or point-of-sale restrictions.
- *June 20, 2013*: FDA [approves](#) Plan B One-Step[®] for use without a prescription for all women of all ages.
- *July 20, 2013*: Teva begins shipping Plan B One-Step[®] with the new OTC label to retailers.
- *July 22, 2013*: FDA grants Teva three years of market exclusivity, to run from April 30, 2013, during which no generic EC products may be sold OTC to women 16 and under, resulting in those products remaining behind-the-counter.
- *August 1, 2013*: For the first time, Plan B One-Step[®] appears on store shelves and may be purchased by any person of any age.

- *February 17, 2014:* Teva introduces Take Action[®], its authorized generic, meaning it has the same status as Plan B One-Step[®] (without a prescription for all women of all ages).
- *February 25, 2014:* [FDA approves](#) generic one-pill EC products for unrestricted OTC sale. Though proof of age is not required, non-Teva generic labels must state that their product is intended only for women 17 and older throughout Teva's exclusivity period.
- *March 11, 2015:* Afaxys Pharmaceuticals, the makers of ella[®], launches a generic levonorgestrel EC product, EContra EZ[™]. The product is not available in retail stores but is available at a discounted price at many clinics, community health centers, urgent care centers, and university health centers.
- *July 2014:* Syzygy Healthcare Solutions begins online sales of AfterPill[™], a generic version of Plan B One-Step[®].
- *July 22, 2014:* Lupin Pharmaceuticals introduces Fallback Solo[™], a generic version of Plan B One-Step[®].
- *October 28, 2014:* Teva introduces Aftera[™], its second generic version of Plan B One-Step[®], sold only at CVS Pharmacy.
- *April 30, 2016:* Teva's three-year market exclusivity for women 16 and younger expires, allowing non-Teva generic versions of Plan B One-Step[®] to remove any reference to an age indication from their labels.