



## **Milestones on Road to Over-the-Counter Plan B:**

- July 1999: The U.S. Food and Drug Administration approves Plan B, a levonorgestrel-only emergency contraceptive (EC) pill, finding it safe and effective for women of all ages to use as a prescription product.
- February 2001: RHTP and the Center for Reproductive Rights, on behalf of more than 70 medical and public health organizations, file a Citizen's Petition with the U.S. Food and Drug Administration to make EC available over-the-counter (OTC).
- April 21, 2003: The manufacturer of Plan B files an application with the FDA to make it available over-the-counter.
- December 16, 2003: FDA independent panel of experts votes 23 to 4 to recommend Plan B be made available OTC, with no age restriction. The panel also voted unanimously that Plan B is safe for nonprescription use.
- May 6, 2004: Dr. Steven Galson, Acting Director of the Center for Drug Evaluation and Research 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: Plan B manufacturer submits a revised over-the-counter proposal to FDA, which would make it available to women 16 and older without a prescription while requiring one for women 15 and under.
- January 21, 2005: 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.
- March 17, 2005: Members of the Senate HELP Committee question FDA 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, Sens. Clinton (D-NY), Murray (D-WA) and Kennedy (D-MA) request a closed-door meeting with him.
- April 6, 2005: Following the closed-door meeting, Sens. Clinton (D-NY) and Murray (D-WA) announce their intention to place a "hold" on Crawford's nomination, citing the FDA's failure to act on a host of public health issue—including the Plan B OTC application—during Crawford's tenure as acting commissioner as the reason for the hold.
- 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.
- August 26, 2005: Citing "regulatory and policy concerns" about whether Barr's 'dual label' proposal is permissible under FDA regulation, then-Commissioner Crawford 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 resigns her position as Director of the Office of Women's Health and Assistant Commissioner for Women's Health at the FDA in protest over the FDA's handling of the Plan B application.
- 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. Three days later, the FDA announces Dr. Theresa Toigo, director of the Office of Special Health Issues, as the real acting director of the Office of Women's Health and denies Dr. Alderson's appointment.
- September 23, 2005: Citing age and personal issues, Crawford announces his sudden resignation as Commissioner of the FDA. President Bush immediately appoints Dr. Andrew von Eschenbach, director of the National Cancer Institute, as acting Commissioner.
- October 12, 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 are conflicting accounts on when the decision was made.
- November 1, 2005: The period of time during which 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.
- February 16, 2006: Nearly a full 6 months after the FDA announced the Proposed New Rulemaking, Acting Commissioner von Eschenbach was called to testify before the House Agriculture Appropriations Subcommittee, where he faced intense questioning from Representatives Farr and DeLauro regarding the FDA's failure to act on the application or received comments. Von Eschenbach did not provide any details of the FDA's schedule for Plan B.
- March 9, 2006: Representative 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 also 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: Andrew 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.
- July 31, 2006: The day before Dr. 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 announced his support for Plan B to be available over the counter for women 18 years and older, but declined to offer any timetable.
- August 8, 2006: Barr meets with the FDA.
- 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 Plan B 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."