



NARAL
Pro-Choice America Foundation

**THE FDA AND EMERGENCY CONTRACEPTION:
AFTER THREE YEARS OF WAITING, IT'S FINALLY AVAILABLE OVER
THE COUNTER.**

Emergency contraception (EC) – also known as the “morning-after” pill - is simply a concentrated dosage of ordinary birth-control pills which, if taken within days of unprotected sex, can significantly reduce a woman’s chance of becoming pregnant.¹ It is safe, effective, and simple to use. It is not associated with any serious or harmful side effects, and it is not dangerous for women with particular medical conditions. In addition, women can diagnose their own need for treatment.²

For these reasons, EC meets the FDA’s criteria for over-the-counter drug status.³ However, for more than three years, the FDA denied approval on the application to make EC an over-the-counter drug, thus blocking many women’s access to a safe and effective means of preventing pregnancy. Finally, in August 2006, the FDA approved non-prescription sales for EC but only for women ages 18 and older. Please read below for a timeline of the FDA’s review of EC for over-the-counter status.

- **July 1999:** The FDA approves the emergency contraceptive Plan B® for prescription use.⁴
- **February 2001:** NARAL Pro-Choice America and more than 70 organizations, including the American Nurses Association, the American Academy of Pediatrics, the American Public Health Association, and the Association of Reproductive Health Professionals, files a citizen’s petition to request that the FDA switch certain emergency contraceptive drug products from prescription to over-the-counter status.⁵
- **April 21, 2003:** Women’s Capital Corporation (WCC), former product manufacturer of Plan B®, submits an application to the FDA requesting to switch Plan B® from prescription-only to over-the-counter-status.⁶
- **October 2003:** New York-based generic drug maker Barr Laboratories announces its acquisition of Plan B® from WCC.
- **December 8, 2003:** Forty-four anti-choice members of Congress write a letter to the FDA, urging the agency to reject the application, claiming it will make emergency contraception “as accessible to our nation’s daughters as aspirin or hairspray.”⁷

- **December 16, 2003:** After hearing and reviewing both oral and written testimony from Barr officials, medical experts, and advocacy groups—including NARAL Pro-Choice America—the FDA Advisory Committees on Reproductive Health Drugs and Nonprescription Drugs overwhelmingly recommends (23-4) that Plan B® be made available over-the-counter.⁸ In addition, the committees unanimously agree that Plan B® is safe for OTC use and will not cause women to substitute EC for regular contraception.⁹
- **January 9, 2004:** Forty-nine anti-choice members of Congress write to President Bush, urging him and the FDA commissioner to reject the advisory panels' recommendation and deny the Plan B® application.¹⁰
- **February 2004:** The FDA postpones its decision on Plan B® for 90 days.¹¹

NARAL Pro-Choice America files a Freedom of Information Act (FOIA) request seeking documentation of the FDA's internal decision-making process in the Plan B® application. (The agency fails to comply with the request.)

- **March 2004:** FDA Commissioner Mark McClellan resigns to oversee the federal Medicaid and Medicare programs. Lester Crawford begins tenure as acting commissioner.
- **May 6, 2004:** The FDA bows to political pressure from the far right and denies the application to switch Plan B® to over-the-counter status.¹²
 - In its “non approvable” letter to the manufacturer of Plan B®, Barr Laboratories, the FDA outlines two possible options for Barr to obtain approval for over-the-counter sale of Plan B®: (1) submit additional data demonstrating that the drug can be used safely by women under the age of 16; or (2) supply information supporting a revised “dual label” indication, which would allow for the marketing of Plan B® as a prescription-only product for women under 16 years old and an over-the-counter product for women 16 and older.¹³ This kind of discriminatory labeling has never before been issued and runs counter to the recommendations of the vast majority of public-health experts. Even Steven Galson, acting director of the FDA's Center for Drug Evaluation and Research acknowledges at a subsequent press conference that his decision overrode FDA staff opinion as well as that of the expert advisory committees.¹⁴
- **June 2004:** Press reports reveal that top FDA staff believe that top agency officials applied a different standard to Plan B® than to other drugs. One FDA staff member calls the logic for rejecting the application “flawed and speculative.”¹⁵

Rep. James Greenwood (R-PA), chairman of a subcommittee with jurisdiction over the FDA, blasts the Plan B® decision as a “horrible one” and meets privately with Galson after a number of lawmakers call for a congressional hearing on the Plan B® decision. Rep. Greenwood reports that Galson suggested during the meeting that the FDA was leaning toward approving Plan B® with a “dual label” in six months.¹⁶

Sen. Hillary Rodham Clinton (D-NY) and 23 colleagues formally request the Committee on Health, Education, Labor and Pensions to conduct an oversight hearing about the FDA’s actions. They also request a Government Accountability Office investigation, noting reports that suggested “there may have been irregularities in the decision and the process by which it was reached.”¹⁷

- **July 2004:** As the FDA suggested, Barr Laboratories submits a response to the FDA proposing the marketing of Plan B® with the “dual label.”¹⁸
- **January 2005:** The FDA delays its decision on Plan B® again, indicating to Barr Laboratories that it will complete its review of the application in the near future.

The Center for Reproductive Rights files a lawsuit in a New York federal court on behalf of several plaintiffs. The suit challenges the FDA's ongoing denial of Barr Laboratories’ application and seeks an order requiring the FDA to approve Plan B® for over-the-counter status for women of all ages.

- **February 2005:** President Bush nominates Lester Crawford to be commissioner of the Food and Drug Administration.
- **March 17, 2005:** During his confirmation hearing, Lester Crawford fails to answer senators’ questions about the Plan B® application’s hold-up.
- **April 2005:** Crawford meets privately with selected HELP Committee Democrats but, according to press reports, is no more forthcoming on when the application might be acted on.¹⁹

Sens. Hillary Rodham Clinton (D-NY) and Patty Murray (D-WA) announce that they will place a hold on Crawford’s nomination until the FDA acts on the much-delayed Plan B® application.

In an unrelated development, the HELP Committee postpones a vote on Crawford’s nomination while awaiting an investigation by the Inspector General (IG) into personal allegations raised by an agency employee.

- **May 2005:** Press reports reveal that Bush appointee to the FDA’s Reproductive Health Drugs Advisory Committee W. David Hager claimed to have been asked to

write a memo to Crawford critical of Plan B® which he further claimed played a central role in the agency's decision to deny the application.

NARAL Pro-Choice America announces plans to file a second request under the Freedom of Information Act for all documents showing contact between the FDA and the White House on the Plan B® application. (The agency refuses to comply with the request.)

- **June 2005:** The IG report is released, clearing the way for committee action on Crawford's nomination.
- **June 15, 2005:** The HELP Committee passes Crawford's nomination by voice vote. As his nomination moves to the Senate floor, for various reasons Crawford's confirmation continues to draw holds on floor action from both sides of the aisle.
- **July 2005:** Sens. Clinton and Murray lift their hold on Crawford's nomination after receiving written assurances from Health and Human Services Secretary Michael Leavitt that the FDA will act on the Plan B® application by September 1, 2005.
- **August 2005:** The FDA once again delays its decision on whether to allow the emergency contraceptive pill Plan B® to be sold without a prescription, breaking a written promise by the Bush administration to make a decision on the application by September 1.²⁰ A few days later, Susan F. Wood, the FDA's commissioner for women's health and director of the Office of Women's Health, left the FDA over the Administration's refusal to issue a final decision on the Plan B® application. She said, "I can no longer serve as staff when scientific and clinic evidence, fully evaluated and recommended for approval by professional staff here, has been overruled."²¹
- **September 2005:** FDA Commissioner Lester Crawford resigns.²²
- **November 3, 2005:** Pro-choice lawmakers introduce the Plan B for Plan B Act (H.R.4229) to require the FDA to end its two-year delay and make a decision on the application.
- **November 2005:** The U.S. General Accountability Office makes public an extensive report to Congress that shows political interference played a role in the FDA's delay on the original Plan B® decision. The report, *Decision Process to Deny Initial Application for Over-the-Counter Marketing of the Emergency Contraceptive Drug Plan B Was Unusual*, finds: (1) directors of FDA offices that reviewed the Plan B® application – and normally would have been in charge of signing the Plan B® action letter – disagreed with the FDA's "not approvable" decision and did not sign the letter; (2) the FDA's high-level management was much more involved in the review

of the Plan B® application compared to other over-the-counter switch applications; (3) there were conflicting accounts on whether the decision on the Plan B® application had been made before reviews of the application were completed; and (4) the rationale for refusing to switch Plan B® to over-the-counter status was “novel” and did not follow traditional FDA practices.²³

- **March 10, 2006:** Rep. Henry Waxman (D-CA) announces that he has received copies of previously undisclosed documents and asks acting FDA Commissioner Andrew von Eschenbach to provide an explanation for the continuing delay on the Plan B® application. In his letter, Rep. Waxman raises additional questions about the FDA’s claim that the second “dual-label” application posed “novel and difficult” issues, pointing out that agency staff outlined potential solutions to such regulatory questions at least 15 months before the FDA announced in August 2005 that the issues required an indefinite delay.²⁴
- **March 15, 2006:** President Bush nominates von Eschenbach to be commissioner of the Food and Drug Administration.²⁵ Sens. Clinton and Murray announce they will place a hold on von Eschenbach’s nomination until the FDA issues a final decision on the Plan B® application.²⁶
- **July 31, 2006:** In a letter to Barr Laboratories, von Eschenbach indicates that the FDA may be willing to approve Plan B® for over-the-counter sales for women ages 18 and older. However, at his Senate confirmation hearing the very next day, von Eschenbach refuses to provide a deadline for when the FDA would make such a decision. He also admits that the decision to raise the age restriction to 18 is not based on scientific or medical data.²⁷
- **August 18, 2006:** The media reports that, after meeting with FDA officials, Barr Laboratories submits a revised application to sell Plan B® over the counter to women ages 18 and older.²⁸
- **August 24, 2006:** After stalling on the application for more than three years, the FDA finally approves Plan B® for over-the-counter sales for women ages 18 and older. Public-health experts agree that this age restriction is unnecessary, so unfortunately, the FDA decision will do little to stem the teen-pregnancy epidemic in America. Requiring those under 18 to get a prescription and find a pharmacist means some teens simply won't have access to the medication, and will face unintended pregnancy - and some, abortion - as a result.

August 24, 2006

Notes

¹ Press Release, Women's Capital Corporation, *A New Generation of Emergency Contraception Has Arrived* (July 28, 1999). While labels for FDA-approved ECPs indicate that they should be used within 72 hours after unprotected sex, recent research shows that ECPs can be effective up to 120 hours after sex. However, ECPs are more effective the sooner they are taken. Charlotte Ellertson et al., *Extending the Time Limit for Starting the Yuzpe Regimen of Emergency Contraception to 120 Hours*, 101 *OBSTETRICS & GYNECOLOGY* 1168, 1168-71 (2003); Helena von Hertzen et al., *Low Dose Mifepristone and Two Regimens of Levonorgestrel for Emergency Contraception: a WHO Multicentre Randomised Trial*, 360 *THE LANCET* 1803, 1803-10 (2002); Gilda Piaggio et al., *Timing of Emergency Contraception with Levonorgestrel or the Yuzpe Regimen*, 353 *THE LANCET* 721 (1999).

² Charlotte Ellertson et al., *Should Emergency Contraceptive Pills Be Available Without Prescription?*, 53 *JAMWA* 226, 227-28 (1998); David A. Grimes, *Switching Emergency Contraception to Over-the-Counter Status*, 347 *NEW ENGLAND JOURNAL OF MEDICINE* 846, 846-47 (2002).

³ 21 C.F.R. § 310.200(b); 21 U.S.C.A. § 353(b)(1)(A).

⁴ Press release, Women's Capital Corporation, *A New Generation of Emergency Contraception Has Arrived* (July, 28, 1999).

⁵ Center for Reproductive Law & Policy (CRLP), Citizen's Petition to the U.S. Food and Drug Administration on behalf of the American Nurses Association, the American Academy of Pediatrics, the American Public Health Association, the Association of Reproductive Health Professionals et al. (Feb. 14, 2001).

⁶ Reproductive Health Technologies Project (RHTP), *FDA Review of OTC Application for Plan B[®]: Milestones* (undated).

⁷ Letter from the Hon. Joseph Pitts, U.S. Representative, to Food and Drug Administration (Dec. 8, 2003).

⁸ Reproductive Health Technologies Project (RHTP), *FDA Review of OTC Application for Plan B[®]: Milestones* (undated); Gina Kolata, *A Contraceptive Clears a Hurdle to Wider Access*, *N.Y. TIMES*, Dec. 17, 2003.

⁹ RHTP, *Facts on Plan B Over-the-Counter Application*, (2004).

¹⁰ Letter from the Hon. David Weldon, U.S. Representative, to President George W. Bush (Jan. 9, 2004).

¹¹ Marc Kaufman, *FDA Delays Decision on 'Morning After' Pill*, *WASH. POST*, Feb. 14, 2004, at A15.

¹² Letter from Dr. Steven Galson, Acting Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, to Dr. Joseph A. Carrado, Senior Director, Regulatory Affairs, Barr Research, Inc. (May 6, 2004).

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- ¹³ Letter from Dr. Steven Galson, Acting Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, to Dr. Joseph A. Carrado, Senior Director, Regulatory Affairs, Barr Research, Inc. (May 6, 2004).
- ¹⁴ Rita Rubin, *Plan B Decision Called Political*, USA TODAY, May 9, 2004, at http://www.usatoday.com/news/health/2004-05-09-fda-morning-after_x.htm.
- ¹⁵ Marc Kaufman, *Staff Scientists Reject FDA's Plan B Reasoning*, WASH. POST, June 18, 2004, at A02.
- ¹⁶ Marc Kaufman, *Staff Scientists Reject FDA's Plan B Reasoning*, WASH. POST, June 18, 2004, at A02.
- ¹⁷ Letter from The Honorable Hillary Rodham Clinton, U.S. Senator, to The Honorable Judd Gregg, U.S. Senator, Chairman, Committee on Health, Education, Labor and Pensions (June 15, 2004).
- ¹⁸ Press Release, Barr Pharmaceuticals, Inc., *Barr Submits Response to FDA in Support of Over-the-Counter Status for Plan B Emergency Contraceptive: Company Proposes Dual Marketing Status* (July 22, 2004).
- ¹⁹ Marc Kaufman, *Contraception Debate Delays Nomination of FDA Chief*, WASH. POST, April 7, 2005, at A07; Sheryl Gay Stolberg, *Democrats Block Nomination Over Morning-After Pill*, N.Y. TIMES, April 7, 2005.
- ²⁰ Letter from Lester M. Crawford, Commissioner of Food and Drugs, Department of Health and Human Services, to Joseph A. Carrado, Duramed Research, Inc. (Aug. 2005); Letter from Michael O. Leavitt, Secretary, Department of Health and Human Services, to The Honorable Michael Enzi, Chairman, Committee on Health, Education, Labor and Pensions, United States Senate (July 13, 2005).
- ²¹ Marc Kaufman, *FDA Official Resigns in Protest of 'Morning-After Pill' Decision*, WASH. POST, Aug. 31, 2005.
- ²² Memorandum from Lester M. Crawford, Commissioner of Food and Drugs, to FDA All-Hands (Sept. 23, 2005).
- ²³ U.S. Government Accountability Office, *Decision Process to Deny Initial Application for Over-the-Counter Marketing of the Emergency Contraceptive Drug Plan B Was Unusual* (Nov. 2005).
- ²⁴ Letter from The Honorable Henry A. Waxman, Ranking Member, Committee on Government Reform, United States House of Representatives, to Andrew C. von Eschenbach, Acting Commissioner of Food and Drugs, Department of Health and Human Services (Mar. 9, 2006).
- ²⁵ Press Release, The White House, *Personnel Announcement*, (Mar. 15, 2006).

²⁶ Press Release, Sens. Hillary Rodham Clinton and Patty Murray, *Statement by Senators Hillary Rodham Clinton and Patty Murray on Expected Nomination of Andrew von Eschenbach as FDA Commissioner*, (Mar. 15, 2006).

²⁷ Rick Weiss, *Senators Prod FDA Nominee On Politicization of Agency*, WASH. POST, Aug. 2, 2006.

²⁸ *Barr Refiles Morning-After Pill Bid, US FDA Says*, REUTERS, Aug. 18, 2006.