MINORITY STAFF
COMMITTEE ON GOVERNMENT REFORM
U.S. HOUSE OF REPRESENTATIVES
OCTOBER 2005

Fact Sheet

The Politicization of Emergency Contraception

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In April 2003, the makers of the emergency contraceptive "Plan B" applied to allow the drug to be sold over-the-counter. Public health experts have estimated that expanded access to emergency contraception will reduce the rate of unintended pregnancy by at least 50 percent and the number of abortions by 500,000 per year.[1] However, over the last two years, the Food and Drug Administration has twice rejected the over-the-counter sales of Plan B.

The Bush Administration has claimed that expanded access to Plan B raises safety concerns. In fact, such concerns have been rejected by FDA's expert advisory panel and FDA's own professional evaluators, as well as by professional societies including the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics and medical publications including the *New England Journal of Medicine*. The Administration's actions have been praised by social conservatives, who favor limiting the availability of emergency contraception and have argued that it is a form of abortion.

After the Administration refused for the second time to approve Plan B, Dr. Susan Wood, the FDA's Assistant Commissioner for Women's Health, resigned. She stated: "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."[2]

Chronology of Political Interference

October 22, 2002: The Administration nominates Dr. W. David Hager, a conservative religious activist, to chair the FDA's Reproductive Health Drugs Advisory Committee. The committee is charged with evaluating the safety and effectiveness of drugs for obstetrics, gynecology, and related specialties.[3] In the past, FDA has chosen for this important position highly respected members of the scientific community with strong credentials in the field of reproductive health.

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[1] American College of Obstetricians and Gynecologists, *Medical Groups Set the Record Straight on Emergency Contraception* (May 4, 2004).

[2] *FDA Official Quits Over Delay on Plan B; Women's Health Chief Says Commissioner's Decision on Contraceptive Was Political*, Washington Post (Sept. 1, 2005).

[3] FDA, *Committee Charter: Reproductive Health Drugs Advisory Committee* (in effect through Mar. 23, 2004) (online at http://www.fda.gov/cder/audiences/acspage/reproductivecharter1.htm).

According to the medical journal *The Lancet*, Dr. Hager's "track record" is "sparse."[4] Dr. Hager's major publications are medical books imbued with religious themes, such as the advice that women who suffer from premenstrual syndrome should pray and read the bible.[5] Although ultimately not appointed chair, Dr. Hager is named a member of the committee.[6] He later takes part in the committee's deliberations on emergency contraception.

April 22, 2003: The Women's Capital Corporation, maker of Plan B, submits an application to FDA to switch the drug from prescription to over-the-counter status.[7] The scientific standards for approval of over-the-counter sales are straightforward: a company must demonstrate that consumers can use the drug safely and effectively without professional supervision.[8]

December 16, 2003: Two FDA advisory committees, the Over-the-Counter and the Reproductive Health Drugs Advisory Committees, convene jointly to review data on safety, effectiveness, and labeling and make a recommendation on the proposed switch of Plan B to over-the-counter status.[9] All 28 members find that there is no evidence that nonprescription availability of Plan B causes women to stop using regular contraception, and all 28 members find that data demonstrate that Plan B is safe for a non-prescription setting. Twenty-three of 27 members vote to approve the switch, with dissenters including Dr. David Hager.[10]

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[4] *Keeping Scientific Advice Non-Partisan*, Lancet, 1525 (Nov. 16, 2002).

[5] David W. Hager and Linda Carruth Hager, *Stress and the Woman's Body* (1996) as cited in *Jesus and the FDA*, Time (Oct. 5, 2002).

[6] FDA, *Roster of the Advisory Committee for Reproductive Drugs* (online at http://www.fda.gov/cder/audiences/acspage/reproductiveRoster.htm).

[7] *Nonprescription Sale Sought for Contraceptive*, Washington Post (Apr. 21, 2003).

[8] FDA, Center for Drug Evaluation and Research, *Questions and Answers: Over-the-Counter Drug Products Public Hearing June 28 and 29, 2000* (online at http://www.fda.gov/cder/meeting/otcqa-600.htm).

[9] FDA, Center for Drug Evaluation and Research, Nonprescription Drugs Advisory Committee (NDAC) in Joint Session with the Advisory Committee for Reproductive Health Drugs (ACRHD) Meeting (Dec.16, 2003) (online at http://www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.DOC).

[10] The full set of advisory committee questions and votes were:

1. Does the actual use study demonstrate that consumers used the product as recommended in the proposed labeling? **27 Yes; 1 No**
2. Are the actual use study data generalizable to the overall population of potential non-Rx users of Plan B? **27 Yes; 1 No**
3. Based on the actual use study and literature review, is there evidence that non-Rx availability of Plan B leads to substitution of emergency contraceptive for the regular use of other methods of contraception? **0 Yes; 28 No**
4. Do the data demonstrate that Plan B is safe for use in the nonprescription setting? **28 Yes; 0 No**
5. Are the plans for introduction of Plan B into the non-Rx setting adequate with respect to consumer access and safe use? **22 Yes; 5 No; 1 Abstain**
6. Do you recommend Plan B be switched from Rx to non-Rx status? **23 Yes; 4 No**

February 2004: The pharmaceutical company Barr Laboratories acquires the right to manufacture and market Plan B from the Women's Capital Corporation.[11]

April 22, 2004: Professional FDA evaluators agree with the advisory committee's conclusion that Plan B should be approved for over-the-counter availability. Dr. John K. Jenkins, the director of the Office of New Drugs at FDA, writes in an internal memorandum that "both divisions and offices responsible for review of this application have recommended approval."[12] He adds that "the data from the studies submitted by the sponsor are sufficient and adequate on which to base a regulatory approval."[13]

May 7, 2004: In spite of the agreement of both the expert panel and its staff scientists, the FDA rejects the application for over-the-counter sales of Plan B.[14] In an unprecedented step, the acting director of the Center for Drug Evaluation and Research signs the agency's action because "his opinion … differed from that of the review staff."[15] In explaining this decision, the acting director states that there was not enough evidence to be sure that the product could be used safely by the youngest teenagers.[16]

According to FDA staff and scientific experts, this reasoning is not credible. The logic of the argument — that young teenagers might forgo contraception in order to use the morning-after pill — had been rejected by the advisory committee.[17] Moreover, over-the-counter availability of Plan B is endorsed by both the American Academy of Pediatrics and the Society for Adolescent Medicine. They conclude in a joint letter that "[i]t is important to provide easily accessible and affordable emergency contraception for adolescents whose contraception fails or is not used during the most recent sexual encounter."[18] Another study published in the *Journal of Obstetrics and Gynecology* further confirms that young adolescents "behaved no differently in response to increased access to emergency contraception (EC) from the other age groups."[19]

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[11] Barr Laboratories, *Barr Completes Acquisition of Women's Capital Corporation and Plan B Emergency Contraceptive* (Feb. 26, 2004).

[12] John K. Jenkins, Memorandum: Review of NDA for Rx to OTC Switch for Plan B (Apr. 22, 2004).

[13] *Id.*

[14] *U.S. Rules Morning-After Pill Can't Be Sold Over the Counter*, New York Times (May 7, 2004).

[15] FDA, *FDA's Decision Regarding Plan B: Questions and Answers* (May 7, 2004) (online at: http://www.fda.gov/cder/drug/infopage/planB/planBQandA.htm).

[16] *FDA: Plan B Sales Rejected Against Advice; Official Denies That Politics Blocked Contraceptive's Over-the-Counter Status*, Washington Post (May 7, 2004).

[17] The advisory committee, including Dr. Hager voted unanimously that the "data demonstrate[s] that Plan B is safe for use in the nonprescription setting." See note 15.

[18] Letter from Carden Johnston, MD, FAAP, President, American Academy of Pediatrics, and Vaughn I. Rickert, PsyD, President, Society for Adolescent Medicine to HHS Secretary Tommy Thompson (Feb. 9, 2004).

[19] Harper, CC, et al. *The Effect of Increased Access to Emergency Contraception Among Young Adults*, The Journal of Obstetrics and Gynecology (Sept. 2005).

The medical community concludes that FDA's actions were based on politics, not science. The *New England Journal of Medicine* editorializes, "In this case, there is no medical dispute."[20] Dr. David Grimes writes in the *American Journal of Obstetrics and Gynecology* that "the agency caved into political pressure."[21] The President of the American College of Obstetrics and Gynecology, Dr. Vivian M. Dickerson, says that the FDA's "action is a tragedy for American women, and a dark stain on the reputation of an evidence-based agency like the FDA."[22] In addition, it becomes public that Dr. Hager had sought to exert his influence beyond Advisory Committee channels in a memo sent to the FDA Commissioner urging the rejection the Plan B application.[23]

In rejecting Plan B's proposal, FDA presents Barr Laboratories with options on how it might alter its application to satisfy its concerns over the data on adolescent users.[24] FDA informs Barr Laboratories that it could provide additional data for adolescents, a proposal which would require extensive additional research.[25] Alternatively, the agency suggests that Barr could resubmit the application if it included a two-tier availability system in which women who are under 16 would be able to buy the drug only with a prescription, while other customers could purchase the drug over-the-counter.[26]

July 22, 2004: Barr Laboratories resubmits its application, which includes the two-tier system proposed by FDA.[27]

July 16, 2005: Plan B's new application sits for nearly a year at FDA. Then HHS Secretary Michael Leavitt assures the Senate Committee on Health, Education, Labor and Pensions that action will be taken by September 1, 2005.[28] Senators Hilary Rodham Clinton and Patty Murray, who had placed a hold on Lester Crawford's confirmation as FDA Commissioner pending a decision on Plan B, state that "[i]t is long past time that the American people had a decision on Plan B, and the FDA has finally agreed to give women across the country what we have fought for from the beginning — a yes or no decision."[29]

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[20] Jeffrey M. Drazen, Michael F. Greene, and Alastair J. J. Wood, *The FDA, Politics and Plan B,* New England Journal of Medicine, 1561-2 (Apr. 8, 2004).

[21] David Grimes, *Emergency Contraception: Politics Trumps Science at the U.S. Food and Drug Administration*, American Journal of Obstetrics and Gynecology, 220 (Aug. 2004).

[22] *FDA: Plan B Sales Rejected Against Advice,* Washington Post (May 8, 2004).

[23] *Memo May Have Swayed Plan B Ruling; FDA Received 'Minority Report' From Conservative Doctor on Panel,* Washington Post (May 12, 2005).

[24] Letter from Steven Galson, M.D., Acting Director, Center for Drug Evaluation and Research, Food and Drug Administration to Barr Research, Inc. (May 6, 2004).

[25] *Id.*

[26] *FDA: Doctor Must Still OK 'Morning-After' Pill; the Maker of Plan B is Given Options to Obtain Nonprescription Status,* Los Angeles Times (May 7, 2004).

[27] *Morning-After Pill Maker Asks for Approval,* Associated Press (July 23, 2004).

[28] *FDA Nominee to Get Vote; Agency to Act on Plan B Pill,* Washington Post (July 16, 2005).

[29] Senator Hilary Rodham Clinton, *Murray, Clinton Declare Victory in Fight Over Plan B: Decision On Over-The-Counter Sales Of Emergency Contraceptives Will Be Made By September 1* (July 15, 2005).

August 26, 2005: In spite of these assurances, the FDA announces that it will not reach a conclusion on the approval of emergency contraception.[30] The rationale presented for this decision is misleading. In his announcement, Commissioner Crawford claims that "the agency is unable at this time to reach a decision on the approvability of the application because of … unresolved regulatory and policy issues that relate to the application we were asked to evaluate."[31] Dr. Crawford states that the two-tier availability system that "was put forward by Barr labs, presented us with many difficult and novel policy and regulatory issues."[32] In fact, it was FDA that had proposed the regulatory change in its July 2004 letter to Barr Laboratories.[33]

Experts view this additional delay as further political interference. Lorraine Tulman, an associate member of the Reproductive Health Drugs Advisory Committee that had recommended Plan B for over-the-counter sales, said of the decision: "The bottom line is they couldn't deny [the application] based on scientific grounds. Therefore, one must retreat into the bureaucratic mode and deny it on some regulatory technicality."[34] The *New England Journal of Medicine* reacted in an editorial, stating that the "recent actions of the FDA leadership have made a mockery of the process of evaluating scientific evidence, disillusioned many of the participating scientists both inside and outside the agency, squandered the public trust, and tarnished the agency's image."[35]

August 31, 2005: Dr. Susan Wood resigns from her position as FDA's Assistant Commissioner for Women's Health as the result of FDA's action.[36] In resigning, Dr. Wood points to political interference in a decision that should be based solely on science. She states of her decision to leave: "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."[37]

October 6, 2005: Citing the "unacceptable" delay in approving Plan B, Dr. Frank Davidoff, the editor emeritus of the *Annals of Internal Medicine*, announces his resignation as consultant to FDA's Nonprescription Drugs Advisory Committee.[38] He earlier served as a member of this committee when it recommended the approval of Plan B for over-the-counter sales. In resigning, Dr. Davidoff states: "I can no longer associate myself with an organization that is capable of making such an important decision so flagrantly on the basis of political influence, rather than the scientific and clinical evidence."[39]

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[30] *FDA Delays Ruling on 'Morning After' Contraceptive*, Los Angeles Times (Aug. 27, 2005).

[31] FDA, *FDA Takes Action on Plan B: Statement by FDA Commissioner Lester M. Crawford* (Aug. 26, 2005).

[32] *Id.*

[33] Letter from Steven Galson, M.D., Acting Director, Center for Drug Evaluation and Research, Food and Drug Administration to Barr Research, Inc. (May 6, 2004).

[34] *FDA Delays Ruling on 'Morning After' Contraceptive*, Los Angeles Times (Aug. 27, 2004).

[35] Alastair J. J. Wood, Jeffrey M. Drazen, and Michael F. Greene, *A Sad Day for Science at the FDA*, New England Journal of Medicine, 1197-9 (Sept. 22, 2005).

[36] Washington Post, *supra* note 2.

[37] *Id.*

[38] *FDA Adviser Resigns Over Plan B Handling,* Associated Press (Oct. 6, 2005).

[39] *Plan B Casualties*, Hartford Courant (Oct. 2, 2005).