

# Testimony: FDA Leaders Put Politics First on Plan B

*In a lawsuit, the Center for Reproductive Rights and other groups are seeking over-the-counter access for all.*

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The Food and Drug Administration is once again under fire for its evaluation of the proposed over-the-counter use of the emergency contraceptive Plan B, with advocates for approval accusing the agency of putting politics first.

Fueling the accusations are recently released depositions from a lawsuit filed against the FDA by the Center for Reproductive Rights along with the Association of Reproductive Health Professionals, the National Latina Institute for Reproductive Health, and individual members of the Morning-After Pill Conspiracy, an advocacy group.

The plaintiffs are asking a U.S. District Court in New York to order the FDA to make Plan B (levonorgestrel) available without a prescription to women of all ages.

In a deposition taken in April as part of the lawsuit and released in late May, Dr. Steven Galson, director of the Center for Drug Evaluation and Research, testified that he had been leaning toward approval of over-the-counter use of Plan B for older teens and women in early 2005 when Lester Crawford, Ph.D., who was then acting FDA commissioner, took over decision making on the application.

"Dr. Crawford ... told me that he was concerned about where we were heading because he knew that I was heading to-

wards [supporting an over-the-counter approval for Plan B], and he told me that he was going to make the decision on what to do with the application," Dr. Galson said in his deposition.

Dr. Galson added that this was the first time that the FDA commissioner had ever removed authority over a drug application from him and he did not know of it happening to anyone else in his position.

In May 2004, the FDA rejected an application from Barr Pharmaceuticals Inc. to make Plan B available without a prescription.

In August 2005, Dr. Crawford announced that the agency was issued an advance notice of proposed rule making to solicit comments about the regulatory issues involved in split approval of the drug—with over-the-counter availability for women aged 17 and older and prescription-only access for those under 17.

The agency has yet to issue a decision on this proposed dual marketing approach to Plan B.

In his deposition, Dr. Galson said that he supported the approval of Plan B for over-the-counter use among certain women based on public health considerations.

However, he testified that he was not pressured into issuing the May 2004 not-approvable letter for making Plan B available over the counter for women of all ages.

In his deposition, Dr. Galson also expressed concerns about the lack of data on

the effect of OTC access among younger girls.

The Center for Reproductive Rights also released a deposition taken in April from FDA Deputy Commissioner Dr. Janet Woodcock. She testified that Dr. Crawford had assumed the authority for the Plan B decision.

Dr. Crawford gave testimony in late May, but a transcript was not available at press time.

Dr. Mark McClellan, former FDA commissioner and current administrator of the Centers for Medicare and Medicaid Services, is expected to give a deposition in June. Officials with the Center for Reproductive Rights have requested that five other FDA officials give depositions as part of the lawsuit.

Officials at the FDA had no comment on the lawsuit or the recently released depositions.

Jodie Curtis, assistant director of government relations for the Planned Parenthood Federation of America, said that the information coming out of the depositions continues to raise concerns about the role politics played in FDA decision making on Plan B. She said she hopes that the lawsuit will "shine a light" on what is going on within the FDA and that Congress will also use its oversight authority to start asking questions.

But despite irregularities in the way

Plan B has been handled, in most instances the drug approval process works well, she said. "The system is broken in this case," Ms. Curtis said. "I don't know that the system is broken overall."

Susan F. Wood, Ph.D., a consultant with the Reproductive Health Technologies Project and the former head of the FDA's Office of Women's Health, said that from what she has read in media reports, the information from the depositions is "consistent" with her impressions that the FDA's professional staff was cut out of the decision making on Plan B.

Dr. Wood resigned from the FDA in 2005 in protest of the agency's delay in approving Plan B for OTC use. The handling of the Plan B application has damaged the FDA's credibility and in the long-term could make it difficult to recruit and retain talented scientists, Dr. Wood said. If the FDA had relied on its normal process for evaluating Plan B, it would already have been approved, she said.

But David Christensen, director of congressional affairs for the Family Research Council, said Dr. Crawford acted properly in taking time to consider the legal and regulatory issues that go along with this type of dual marketing approval. The implications go beyond Plan B and beyond just scientific considerations, he said. "This wasn't politics," he said. "This was just prudence." ■

**The hope is that the lawsuit will 'shine a light' on what is going on within the Food and Drug Administration and that Congress will also use its oversight authority to start asking questions.**

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