# FDA Accused of Playing Politics With Plan B

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

In May 2004, the FDA rejected an application submitted by 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 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. He 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 Dr. Janet Woodcock, FDA Deputy Commissioner. 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 on the recently released depositions.

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**DR. WOOD**

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 begin to use its oversight authority to ask 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." ■

## POLICY & PRACTICE

### Feds Seek Electronic Credential

The ability to verify the identity and credentials of physicians after a disaster may be achieved via a chip or other technology, Anthony M. Cieri of the Department of Homeland Security said at a briefing sponsored by the Information Technology Association of America. Experts at the meeting pointed to the success of the Veterans Administration in maintaining credentialing information during the response to Hurricane Katrina. Kathryn Enchelmayer, VA director of credentialing, said she was able to "go down in [her] basement at 10:00 p.m." and verify physician credentials, and quickly send 151 displaced physicians from the area off to other jobs.

### Survey: FDA Influenced by Politics

A majority of Americans—82%—believe the Food and Drug Administration is greatly influenced by politics when making decisions about the safety and efficacy of new prescription drugs, according to a Wall Street Journal online Harris Interactive poll. The finding was similar across parties, with 87% of Democrats, 77% of Republicans, and 88% of Independents saying they thought that politics outweighed science greatly or to some extent in decision making. The survey of more than 2,300 adults was conducted in mid-May. In addition, almost 60% said the agency is doing a fair or poor job in ensuring the safety and efficacy of new drugs. Only 36% said the FDA was doing an excellent or good job. That is a reversal from 2 years ago, when 56% had a positive view, and 37% a negative view, of the FDA. Opinions have not changed much on the agency's performance in bringing innovative drugs to market quickly. In 2004, 62% said the FDA was not doing well on that front, compared with 70% in the latest poll. Most of those polled said FDA advisory panel members should not be allowed to have consulting agreements with, or stock in, drug companies.

### Too Many Screening Tests?

Physicians are needlessly ordering certain diagnostic tests during routine preventive health exams, which is inflating the cost of medical care, according to a study from Johns Hopkins University, Baltimore. The U.S. Preventive Services Task Force has rated such diagnostics according to level of evidence; the Hopkins researchers looked at five tests. Two tests (complete blood count and hematocrit) had "C" ratings from USPSTF, meaning there was no recommendation for or against their use; three (urinalysis, x-ray, and electrocardiogram) had "D" ratings with a recommendation against routine use. The study, which used National Ambulatory Medical Care Survey data for 1997-2002 for outpatient visits for nonpregnant adults aged 21 years or over, was in the May/June issue of the American Journal of Preventive Medicine, and was led by Dr. Dan Merenstein, who is now at Georgetown University, Washington. Cost data were obtained from the Medicare fee schedule. Thirty-seven million visits were identified as preventive by physicians and 190 million as such by patients. Most visits were to family physicians, ob.gyns., or internists. Urinalysis was performed most frequently, about 25%-33% of the time, but urine cultures were ordered only 3%-6% of the time. Annual direct costs for hematocrit and urinalysis run about $13-$61 million, depending on if it was a physician- or patient-identified visit, the authors estimated. For the D-rated tests, costs were $47-$194 million.

### J-1 Visas for Underserved Areas

J-1 visas remain the primary tool for recruiting physicians to work in underserved areas, according to a report by the Government Accountability Office. The GAO surveyed 50 states, the District of Columbia, Guam, Puerto Rico, and the U.S. Virgin Islands regarding their waiver requests for fiscal years 2003-2005. States and federal agencies reported requesting more than 1,000 waivers in each of the 3 years, although the number requested varied by state: About one-fourth of states requested the maximum number of 30 visas, while slightly more than a quarter requested 10 or fewer. About 80% of states said the 30-waiver limit was adequate for their needs, the report noted. Nearly half of the states' waiver requests were for physicians to practice primary care exclusively.

### ICD-10 Fraud Concerns

The Blue Cross and Blue Shield Association and the Medical Group Management Association are among those objecting to the planned implementation of ICD-10, the newest version of the comprehensive list of diagnostic billing codes used by health care providers. A bill currently being considered in the House would require payers to switch from the current ICD-9 codes to ICD-10 by Oct. 1, 2009. Blue Cross/Blue Shield argues in a statement that the deadline should be pushed back to 2012 "because much has to be done before a switch to ICD-10 can be started … and providers need time to automate their offices and be trained." The Blues are particularly concerned because the switch comes at the same time that Medicare is shrinking the number of its claims processors—many of which are Blues plans—from 50 to 15. At a press briefing, the association released a report by D. McCarty Thornton, former chief counsel to the Department of Housing and Human Services Inspector General, which found that forcing the switch to occur in 2009 "will not give the contractors who administer the Medicare fee-for-service claims process and payments systems sufficient time to upgrade their antifraud tools."

**—Nancy Nickell**