Judge orders FDA to let 17-year-olds use Plan B (Update)

March 23 2009, By LARRY NEUMEISTER , Associated Press Writer

(AP) -- The Food and Drug Administration let politics cloud its judgment when it denied teenage girls over-the-counter access to the Plan B morning-after pill, a federal judge said Monday as he ordered the FDA to let 17-year-olds obtain the medication.

In a thorough denunciation of the Bush administration, U.S. District Judge Edward Korman blasted the FDA's handling of the issue, saying it had "repeatedly and unreasonably" delayed issuing a decision on the medication.

The morning-after pill is a source of tension for social conservatives who held great sway in the Bush administration and who believe the pill is tantamount to abortion.

The ruling said the FDA in several instances had delayed issuing a ruling for suspect reasons and on two occasions only took action to facilitate the confirmation of acting FDA commissioners whose confirmations had been held up by the repeated delays.

"These political considerations, delays, and implausible justifications for decision-making are not the only evidence of a lack of good faith and reasoned decision-making," Korman said. "Indeed, the record is clear that the FDA's course of conduct regarding Plan B departed in significant ways from the agency's normal procedures regarding similar applications to switch a drug product from prescription to non-prescription use."

The drug is marketed by Montvale, N.J.-based Barr Pharmaceuticals Inc. as Plan B. Korman ordered the FDA to permit Barr Pharmaceuticals to make Plan B available to 17-year-olds without a prescription under the same conditions as Plan B is now available to women over the age of 18. He said his order must be complied with within 30 days.

The FDA said it is reviewing the judge's decision. Women's groups said it's unlikely that the Obama administration would appeal. Social conservatives decried the ruling.

Susan Wood resigned as the top FDA official for women's health in 2005 to protest agency delays in issuing a decision on the morning-after pill. Now a professor at George Washington University's school of public health, Wood said the ruling represents a vote of confidence in the FDA's scientific staff.

"What happened with Plan B demonstrated that the agency was off track, and was not being allowed to do its job properly," Wood said. "This is telling the FDA to move forward with a focus on good science."

The conservative Family Research Council said the judge's decision bowed to ideological pressure from the left.

"Judge Korman has accepted lock, stock, and barrel all of the claims of a political ideology promoting sexual license for teens," said Chris Gacek, a regulation expert with the group.

"There is a real danger that Plan B may be given to women, especially sexually abused women and minors, under coercion or without their consent," Gacek added in a statement.

In February 2001, the Association of Reproductive Health Professionals and 65 other organizations petitioned the FDA to make Plan B available

over the counter to all, regardless of age. The FDA did not respond for five years, announcing in 2006 that the petition was denied.

As part of his order, Korman vacated the petition's denial and required the FDA to reconsider its decisions regarding the Plan B switch to over-the-counter use.

The lawsuit was filed in 2005 by the Center for Reproductive Rights and others.

In his ruling, Korman noted that FDA officials as far back as June 2002 discussed the "political sensitivity" of making Plan B available over the counter.

And he said depositions by several FDA senior staff members revealed that political and ideological factors played an important role in the nomination and selection process of members of FDA committees that would recommend how the FDA should act on Plan B requests.

One doctor testified that the FDA commissioner's office appointed members to its advisory committee not for their expertise but to achieve a "balance of opinion," meaning they were very active in the anti-abortion movement, Korman said.

Still, the FDA's Advisory Committee voted 23 to 4 in 2003 to approve Plan B for over-the-counter status without age restrictions. However, out of nearly two dozen applications to move a prescription drug to over-the-counter status, the Plan B request was the only one not approved after the committee recommended it.

The judge said top FDA officials at a meeting in late 2003 or early 2004 told their subordinates that over-the-counter status for Plan B would not be approved at that time and that it was a decision that would be made at

a higher level in the FDA than those decisions are usually made.

"Moreover, they were told that the White House had been involved in the decision on Plan B," he said.

"Today's ruling is a tremendous victory for all Americans who expect the government to safeguard public health," said Nancy Northup, president of the center.

Assistant U.S. Attorney F. Franklin Amanat, who argued the case for the government, said: "We're studying the decision and evaluating options."

"We need to discuss it with the agency and figure out what our next steps will be," he said.

The government in court papers has said politics played no role in the agency's decisions.

Plan B is a contraceptive that reduces the chance of pregnancy if taken within three days after sex. It contains a high dose of of birth control drugs. The drug works by preventing ovulation or by interfering with implantation of a fertilized egg. Opponents argue that is the equivalent of abortion.

In 2006, the FDA allowed Plan B to be sold without a prescription to adults, but only by pharmacies that checked photo ID before selling the pills. Girls 17 and younger were required to obtain a prescription.

Barr is now owned by Teva Pharmaceutical Industries, a global company headquartered in Israel.

Associated Press Writer Ricardo Alonso-Zaldivar in Washington contributed to this story.