Bush administration plays to religious right in delaying contraceptive approval

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A new report from the US Government Accountability Office into deviations in Food and Drug Administration (FDA) procedure reveals ideological meddling by high-ranking officials in the Bush administration. The administration has stonewalled the review process of the emergency contraceptive Plan B for the past two years to appease the administration's religious base, trampling on science and the agency's own procedure.

In April 2003, Plan B manufacturer Women's Capital Corporation submitted an application to the FDA to have the availability status of the emergency contraceptive pill switched from by-prescription-only to over-the-counter (OTC). Plan B had already been approved by the FDA in 1999 as a prescription contraceptive.

The pill, which contains in stronger dosage the chemicals present in widely-used birth control pills, is formulated to prevent unwanted pregnancy if taken within 72 hours of unprotected sex. Because it is most effective if taken as soon as possible after intercourse, the case for non-prescription availability is one of practicality, common sense, and reproductive choice.

In 2004, Plan B was refused OTC status because of lack of data on the effects accessible emergency contraception would have on the behavior of teenagers. The concern that teenagers may engage in more risky sexual behavior if they have access to birth control has also been raised by the conservative right with regard to sex education curriculum, and is groundless. This moral policing has nothing to do with testing the safety and efficacy of the drug.

Barr Laboratories submitted a revised application which restricted OTC access to the drug to women age 16 and older. This was neither rejected nor approved by the FDA, but was simply suppressed for a year. The OTC availability age limit was raised to 17 by FDA reviewers in an attempt to placate conservatives within the agency, but on August 26, the review process was indefinitely deferred on the pretext that a new clinical trial on children must first be conducted.

The FDA Office of Women's Health director Susan Wood resigned five days after the indefinite deferment in protest, stating, "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." The Government Accountability Office conducted an investigation into the complaint in October, focusing on the initial rejection of the application, which was signed by then-Acting Director Lester Crawford.

The report, made public November 14, documented numerous instances in which the FDA's treatment of the contraceptive application was atypical from 67 other decisions made by the agency from 1994 to 2004.

According to the GAO report, the application went to the Office of Drug Evaluation V, where over-the-counter drugs are reviewed, as well as to the Office of Drug Evaluation III, specializing in reproductive drugs. In December of 2003, a joint advisory committee meeting there—made up of the Nonprescription Drugs Advisory Committee and the Advisory Committee for Reproductive Health Drugs—recommended by a margin of 23 to 4 that Plan B be approved for over-the-counter status.

Nevertheless, the following May, Crawford signed off on a "not approved" letter with the claim that the pill's safety had not been adequately tested for sexually-active females under the age of 16.

Four aspects of the review and decision procedure in particular were "unusual," the GAO reported. "First, the Directors of the Offices of Drug Evaluation III and

V, who would normally have been responsible for signing the Plan B action letter, disagreed with the decision and did not sign the not-approvable letter for Plan B. The Director of the Office of New Drugs also disagreed and did not sign the letter."

Second, "FDA's high-level management was more involved in the review of Plan B than in those of other OTC switch applications." This statement was denied by Bush administration officials but corroborated by FDA review staff interviewed by the GAO, who said they "were told early in the review process that the decision would be made by high-level management."

Third, how early in the review process high-level appointed officials stepped in remains unclear since accounts between staff and management conflict. Related documents and e-mail correspondence between then-FDA commissioner Mark McClellan, now head of Medicare and Medicaid Services, and other higher-ups have since been deleted in possible violation of federal records laws. Incidental evidence suggests that the decision to deny approval was made by upper management before viewing any data, as far back as December of 2003.

Finally, the report noted that the rationale for Crawford's rejection of the application was "novel" and was a significant departure from standard procedure. "Specifically, the Acting Director was concerned about the potential impact that the OTC marketing of Plan B would have on the propensity for younger adolescents to engage in unsafe sexual behaviors because of their lack of cognitive maturity compared to older adolescents. He also stated that it was invalid to extrapolate data from older to younger adolescents in this case."

The FDA review staff pointed out to investigators that for other OTC switch applications, data for older adolescents was considered scientifically adequate representation of younger subjects, and the review process had never taken into account behavioral differences between the two groups.

In fact, the joint advisory committee considered 23 similar applications between 1994 and 2004, and the Plan B application alone was rejected after receiving approval. It was also the only one to receive a rejection notice signed by the FDA director rather than a lower-ranking employee who had actually reviewed the application. In the midst of the GAO investigation Crawford resigned from his new post as FDA commissioner, saying only that it was time he "step aside."

The Plan B delay is the latest of many attempts by the fundamentalist right to insert religious restrictions on the civil liberties of women in the past several years. In 2003, Bush signed into law—briefly—the first federal ban on second and third trimester abortions, declared unconstitutional and a "significant health hazard to women" by US District judge Richard Kopf in 2004.

Significant groundwork for the overturning of *Roe v. Wade* has been laid through appointments of religious conservatives to high and low courts, as well as through legislative maneuvering. The 'Unborn Victims of Violence Act,' signed into law by Bush in 2004, which defines a fetus or fertilized egg as a person, is full of reactionary philosophical and legal implications for pregnant women. The Bush administration has focused school sex education curriculum on abstinence-until-marriage and away from contraceptive use and disease prevention. Women's aid organizations receiving US funding in foreign countries are gagged by severe restrictions on contraceptive and abortion counseling.

But the FDA decision to delay any decision on the over-the-counter status of the Plan B pill—which oversteps expert opinion as well as FDA procedure—is more than a fundamentalist intervention into women's rights. Along with data manipulation on global warming and natural resources, the overriding of medicinal research is part of an organized attack on science. The Bush administration has either deliberately ignored or suppressed scientific evidence wherever it conflicts with the corporate and Christian agenda.