

United States Senate

WASHINGTON, DC 20510

May 8, 2009

Joshua Sharfstein, M.D.
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20903

Dear Dr. Sharfstein:

We write with concern regarding the unprecedented actions taken by the Food and Drug Administration (FDA) to allow the morning-after pill Plan B (levonorgestrel) to be sold to minor children without first receiving care from a physician. As you know, the FDA's 2006 initial approval of over-the-counter (OTC) sales of Plan B also required that minor children under the age of 18 obtain a physician's prescription in order to obtain these high-dose hormones. An April 22, 2009 statement by the FDA indicates that Plan B may soon be sold OTC to minors as young as 17 years of age.

We note that Plan B contains much higher doses of hormones than birth control pills contain, but birth control pills continue to require a physician's prescription. A physician also provides medical care with the prescription, including examination for contraindications and monitoring throughout the time of use. The OTC status of Plan B, which will now be available to minor children, means that many women may take Plan B without the benefit of the standard of care received by women taking lower-dose birth control or the close physician counseling and monitoring that accompanies patients' decisions to use every other oral, systemic birth control product. In addition to sound science, we believe that FDA decisions must be guided by common sense.

We continue to have overarching policy concerns with the OTC availability of Plan B, including the potential for Plan B to be given to women and minors in order to cover up sexual abuse. In cases of abuse, it is often a victim's interaction with a physician or other medical professional that detects and then prevents further abuse. We are concerned that the removal of the safeguard of a physician's examination and prescription before Plan B can be obtained will result in serious unintended consequences. This is particularly troubling when FDA has moved to allow the OTC sale of Plan B to minors.

We hope to better understand the government's decision not to appeal the March 23, 2009 federal court decision, which ordered the FDA to reverse its restrictions on OTC sale of Plan B to 17-year olds. Please provide detailed answers to the following questions and requests for information:

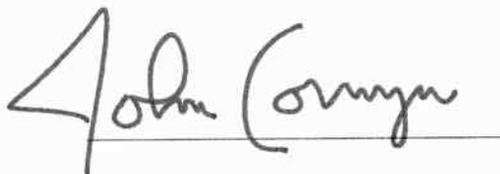
- In August of 2006, both the FDA Acting Commissioner and the Director of the Center for Drug Evaluation and Research (CDER) found that restricting OTC sales of Plan B to women age 18 and older was appropriate. The FDA Acting Commissioner wrote then that “18 (rather than 17) is the more appropriate cutoff point to best promote and protect the public health.” Other than the court’s findings, has the FDA received any new scientific evidence that granting 17-year old minors unfettered OTC access to high-dose hormones is now in the public’s best health interest?
- What studies have been completed on the various impacts of Plan B’s high doses of hormones on the various ages of women taking Plan B? Please provide a summary analysis of the studies on the biological spectrum of impact.
- Please provide a detailed analysis of the label comprehension studies submitted to the FDA in order to obtain initial OTC approval in 2006. Please include the population size of this study, specifically including the number of women under the age of 18 that were included in this study. Please provide a summary analysis of whether or not the results differed in women under the age of 18.
- Please provide a summary analysis of the impact of OTC Plan B approval on help-seeking behaviors. What process did the FDA use to consider the potential impact that OTC availability of Plan B might have on help-seeking behavior, including the potential for patients to lose the opportunity to receive counseling about safe sexual practices and the consequences this might have? What conclusions did the FDA reach, and more specifically, does the Agency believe that OTC availability of Plan B might have a different impact on the help-seeking behavior of adult women versus girls under the age of 18 or does FDA believe that the practices of both these age cohorts, and their propensity to seek counseling, are analogous? What data did FDA rely on to inform its views of the impact that OTC availability would have on help-seeking behavior for woman under the age of 18? Please provide details on the manner in which this data was collected, including the actual process used to provide this product to girls under the age of 18 and to collect information about how they used the product.
- Please provide a summary analysis of any adverse events reported from the use of Plan B since its initial Rx approval and since its limited OTC approval.
- In August of 2006, the Director of CDER concluded that “the CARE program [was] sufficiently rigorous to prevent young women from obtaining Plan B [OTC] without the supervision of a practitioner licensed by law to prescribe the drug.” The CDER Director noted that “Monitoring of the program’s effectiveness will allow FDA to assess whether further modifications will be necessary to prevent inappropriate use of Plan B.” Please provide the results and a summary analysis of the results of this monitoring. Has the FDA reviewed whether or not further modifications are necessary to prevent inappropriate use?

- In order to obtain FDA approval in August of 2006, Barr Pharmaceuticals agreed to the following activities: 1) monitor trends in the use of emergency contraception to evaluate the effectiveness of the CARE program, 2) use relevant survey data regularly collected by others to monitor for potential indicators that Plan B is being used in an inappropriate manner, 3) conduct a "Point-of-Purchase Monitoring Program" to track how Plan B is being sold at the time of purchase, and 4) report to FDA on the results of these activities on a six-month interval. Please provide a copy of each of these reports to date, as well as a summary analysis of these reports.
- Please provide a specific list of the names and positions of each FDA staff member involved in the government's decision not to appeal the March 23, 2009 federal court decision, which ordered the FDA to reverse its restrictions on OTC sale of Plan B to 17-year olds.
- Please provide a copy of any Executive Branch communications regarding the government's decision not to appeal the federal court decision. Specifically, please provide a copy of any communications regarding the decision not to appeal between officials of the Department of Justice, officials of the FDA, and/or officials at the White House.
- Please describe any interaction and provide copies of any communications regarding Plan B between Barr Pharmaceuticals, or its subsidiaries, and either the FDA or the Department of Justice since August of 2006.

We also note that the court ordered the FDA to review the appropriateness of making the emergency contraceptive available to all ages without first seeking the care of a physician. What are the next expected steps on the part of the FDA to fulfill this order? As the FDA undertakes this review, we look forward to learning of any new scientific evidence that would support a conclusion different from the conclusion reached in August 2005 by the Center for Drug Evaluation and Research (CDER). CDER found then that "Barr [Pharmaceuticals] had not established that Plan B could be used safely and effectively by young adolescents—girls 16 and younger—for emergency contraception without the professional supervision of a practitioner licensed by law to administer the drug."

Finally, we are concerned that the failure to appeal the March 23, 2009, federal court decision, which supersedes the FDA's decision-making authority, establishes a new legal precedent. While traditionally the courts have given great deference to the FDA on matters of its review process, we worry that this failure to appeal will lead to the courts second-guessing the FDA's findings in future cases. We are concerned about the effect this may have on ensuring that the FDA's review process is based on sound science.

Sincerely,




Jim DeWitt

Jim Bunnong

Sam Hatch

John Ewing

John Miller

Larry Miller

Joseph

Michael McConnell

Sam

Bill Martiney

John Kirsch

Sam Brown

John Barrett

Ray Tucker

Tom Roberts

Kay Bailey Hutchison

Jim Clarke

Sally Campbell

Sam Brumback

Mike Crapo