061020752

SENATE JOINT RESOLUTION NO. 97

Offered January 11, 2006

Prefiled January 11, 2006

Encouraging the United States Food and Drug Administration to approve the use of Plan B emergency contraception as over-the-counter medication.

Patron—Lucas

Referred to Committee on Rules

WHEREAS, Plan B is emergency contraception designed as a back-up method of birth control and is currently available only by prescription; and

WHEREAS, experts estimate that wider access to emergency contraception could prevent up to two million pregnancies and 800,000 abortions each year; and

WHEREAS, in February 2001, more than 70 medical and public health organizations filed a citizen's petition with the Food and Drug Administration seeking to make emergency contraception available over-the-counter; and

WHEREAS, in April 2003, the Food and Drug Administration (FDA) received an application, accompanied by more than 15,000 pages of data from Barr Laboratories including research from 39 clinical studies involving 22,000 women, to switch Plan B from prescription to over-the-counter (OTC) status; and

WHEREAS, in December 2003, after review of scientific data including an actual use study and label comprehension study, the FDA Nonprescription Drugs Advisory Committee voted 23-4 in favor of recommending that Plan B be switched from prescription to nonprescription and 28-0 in their determination that Plan B was safe for over-the-counter access; and

WHEREAS, in May 2004, the Acting Director for the Center for Drug Evaluation and Research rejected the recommendations of the FDA's joint advisory committee and FDA review officials by signing the not-approvable letter for the Plan B switch application; and

WHEREAS, because the not-approvable decision for the Plan B OTC switch application was contrary to the recommendations of the FDA's joint advisory committee and FDA review staff, the General Accounting Office (GAO) was asked to examine (i) how the decision was made to not approve the switch, (ii) how the Plan B decision compares to the decisions for other proposed prescription-to-OTC switches from 1994 through 2004, and (iii) whether there are age-related marketing restrictions for prescription Plan B and other prescription and OTC contraceptives; and

WHEREAS, according to the GAO report, the following four aspects of the FDA's review process were unusual: (i) the directors of the offices that reviewed the application, 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; (ii) the FDA's high-level management was more involved in the review of Plan B than those of other OTC switch applications; (iii) there were conflicting accounts of whether the decision to not approve the application was made before the reviews were completed; and (iv) the rationale for the Acting Director's decision was novel and did not follow traditional practices; and

WHEREAS, the GAO found that the Plan B decision was not typical of the other 67 proposed prescription-to-OTC switch decisions made by the FDA from 1994 through 2004 because the Plan B OTC switch application was the only one during this period that was not approved after the advisory committees recommended approval; and

WHEREAS, on August 31, 2005, Susan F. Wood, the Food and Drug Administration's assistant commissioner for women's health and director of the Office of Women's Health, resigned her position because of the Administration's handling of the application for over-the-counter sales of Plan B; and

WHEREAS, on October 6, 2005, Dr. Frank Davidoff, a member of the Nonprescription Drugs Advisory Committee, resigned in protest of the Administration's handling of the Plan B application and its ignorance of science in favor of politics; now, therefore, be it

RESOLVED by the Senate, the House of Delegates concurring, That the United States Food and Drug Administration be encouraged to approve the use of Plan B emergency contraception as over-the-counter medication; and, be it

RESOLVED FURTHER, That the Clerk of the Senate transmit a copy of this resolution to the Commissioner of the United States Food and Drug Administration, requesting that the Commissioner further disseminate copies of this resolution to their respective constituents so that they may be apprised of the sense of the General Assembly of Virginia in this matter.