Congress of the United States
Washington, DC 20515

February 26, 2004

The Honorable Mark B. McClellan, M.D., Ph.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. McClellan:

Recently, the Food and Drug Administration announced a delay in its consideration of Barr Laboratories' application for over-the-counter (OTC) status for the emergency contraception drug Plan B.[1] Since the joint advisory committee that considered this application voted overwhelmingly to approve it, the delay does not appear to have a scientific basis. We understand that you will soon be leaving FDA and we hope that you act on this application before you leave.

The scientific standards for approval of an OTC application are straightforward. When a firm submits a supplemental New Drug Application for a previously-approved prescription drug to be switched to OTC status, it must demonstrate that consumers can use the drug safely and effectively without professional supervision.[2] Advisory Review Panels composed of experts on the relevant category of drug must consider evidence on safety, effectiveness, and labeling and make a recommendation to the Commissioner regarding the switch.[3]

In the case of Plan B, an overwhelming majority of the experts found that the standards for approval of OTC status had been met. The Nonprescription Drugs and Reproductive Health Drugs Advisory Committees met jointly on December 16, 2003, to discuss evidence on Plan B.[4] FDA instructed the panel to answer a set of questions relating to the safety and effectiveness of the drug; the questions and voting tallies were as follows:

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[1] '*Morning After' Pill Backers React To Delay by FDA*, Wall Street Journal (Feb. 17, 2004).

[2] FDA, Center for Drug Evaluation and Research, *Questions and Answers: Over-the-Counter Drug Products Public Hearing June 28 and 29, 2000* (online at http://www.fda.gov/cder/meeting/otcqa-600.htm).

[3] 21 C.F.R. §330(10).

[4] FDA, Center for Drug Evaluation and Research, Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs Meeting (Dec.16, 2003) (online at http://www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.DOC).

1. Does the actual use study demonstrate that consumers used the product as recommended in the proposed labeling? **27 Yes; 1 No**

2. Is the actual use study data generalizable to the overall population of potential non-Rx users of Plan B? **27 Yes; 1 No**

3. Based on the actual use study and literature review, is there evidence that non-Rx availability of Plan B leads to substitution of emergency contraceptive for the regular use of other methods of contraception? **0 Yes; 28 No**

4. Does the data demonstrate that Plan B is safe for use in the nonprescription setting? **28 Yes; 0 No**

5. Are the plans for introduction of Plan B into the non-Rx setting adequate with respect to consumer access and safe use? **22 Yes; 5 No; 1 Abstain**

6. Do you recommend Plan B be switched from Rx to non-Rx status? **23 Yes; 4 No**

Despite the strong vote in support of making the drug available without a prescription, FDA has delayed this decision. While FDA is certainly not bound by the decisions of its advisory committees, it is unusual for an advisory committee recommendation not to be adopted, especially in a case such as this where the vote was so strong and where there is so little evidence to support a decision not to adopt the panel's recommendation.

According to press accounts, this delay follows pressure from conservative Members of Congress who speculate that improved access to Plan B would increase "promiscuity" and sexually transmitted diseases among teenagers.[5] The press is also reporting that you have asked Barr Laboratories to provide you with data on this question.[6] During its deliberations, the advisory committee considered whether there was any evidence that the availability of Plan B would result in the substitution of Plan B for other means of contraception. The panel voted unanimously that there is no evidence that a substitution would occur. Furthermore, over-the-counter availability of Plan B has been endorsed by both the American Academy of Pediatrics and the Society for Adolescent Medicine. They assert in a joint letter that "[i]t is important to

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[5] *'Morning After' Pill Backers React To Delay by FDA*, *supra* note 1.

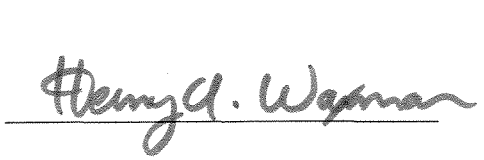
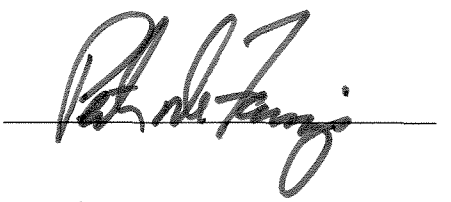
[6] *Id.*

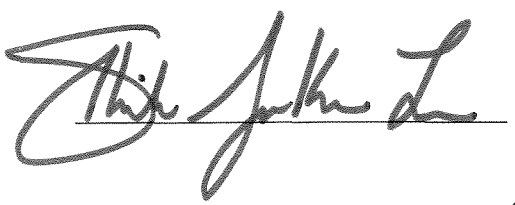
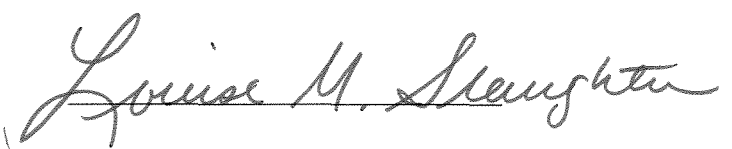
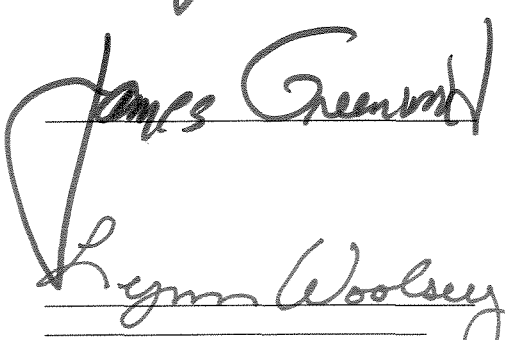
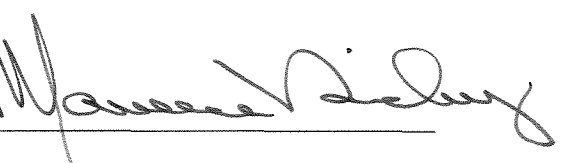
provide easily accessible and affordable emergency contraception for adolescents whose contraception fails or is not used during the most recent sexual encounter."[7]

There is increasing concern among the scientific community that the Bush Administration is letting politics and ideology interfere with scientific decision-making. In cases like this one, such interference could have a direct and irreversible effect on the health and well-being of thousands of women.

As you review the data on Plan B and decide whether to make this crucial drug available to more women, we urge you to ensure that FDA carries on its mission as a science-based agency even in the face of political pressure.

Sincerely,


[7] Letter from Carden Johnston, M.D., F.A.A.P., President, American Academy of Pediatrics, and Vaughn I. Rickert, Psy.D., President, Society for Adolescent Medicine, to Health and Human Services Secretary Tommy G. Thompson (Feb. 9, 2004).

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