Congress of the United States

Washington, DC 20515

July 25, 2005

Commissioner Lester Crawford
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Commissioner Crawford,

We want to congratulate you on your recent confirmation as the Commissioner of the Food and Drug Administration (FDA). We look forward to working with you to advance the health of our nation.

To that end, we write to you concerned about the pending decision on the over-the-counter status of the morning-after pill, commonly called "Plan B." As you know, On May 6, 2004, Barr Laboratories, maker of Plan B, was issued a non-approvable letter for its initial application to make the morning-after pill available over the counter based on the insufficient data regarding its effect on children under the age of 16. However on July 22, 2004, Barr submitted a new application for the morning-after pill. The new proposal would allow girls and women age 16 and older to buy the drug over the counter, but girls 15 and younger would still need a prescription. This unprecedented, bifurcated approach for a prescription drug is highly alarming and puts many of our nation's women, especially young women and girls, at risk. We urge you to reject the petition currently before you to make the morning-after pill as accessible to our nation's teenage daughters as candy bars and hairspray.

We ask you to weigh the serious implications of allowing teenaged girls access to a powerful drug without the knowledge of their parents or family physician, the very people who are most familiar with the minor's health needs and history. Even under this bifurcated approach, there would be no assurance that the parents of a girl as young as 16 would have any knowledge of the powerful drug she is taking or the risky behaviors she is engaged in. Because of the important safety concerns and lasting heath effects on a girl's body, we believe it is essential parents are involved in these decisions.

This concern is highlighted by the fact the FDA never tested the effect of Plan B on young women when initially approving the drug for prescription sales. Under the pediatric rule, the FDA is required to gather information on each age group that will be affected by a drug that is pending approval. This information must include safety and effectiveness data for the age group and dosage recommendations for product. According to the FDA, a waiver to this rule may be granted only in cases where it can be proven that the effects on a younger population would be similar to the effects of the drug on an adult. Plan B will certainly have a different effect on girls who are at a younger developmental age. Plan B can contain as much as eight times the daily hormone dose of the average birth control pill. The effects of these hormones on the development of a young woman would be very different than the effects on an adult woman.

However Plan B was granted a waiver from the pediatric rule, under the Clinton Administration's Secretary of Health and Human Services, Donna Shalala. This should never

have happened. The fact that the FDA does not know the effect of this drug on younger women, combined with the possibility of eliminating the parents from this important health decision, is reason for significant alarm.

We are also very concerned about the impact the over-the-counter status for the morning after pill would have on sexually transmitted disease (STD) rates. There is very little data available to suggest what impact over-the-counter status would have on the sexual behavior of adolescents or what the subsequent impact would be on adolescent sexual health. According to Food and Drug Administration documents, when initially approving Plan B for prescription use, only the drug's safety and its effect on pregnancy were considered. The FDA did not consider the significant impact over-the-counter availability this product may have on the sexual health of adolescents and young people.

Part of the population that would be able to buy Plan B over the counter, adolescents and young adults (16-24), are the very same age group most at risk for contracting STD's. Approximately two-thirds of all people who acquire STD's are under the age of 25 and each year 15 million new cases are diagnosed. The Centers for Disease Control states that adolescents and young adults are at greater risk of acquiring a sexually transmitted infection because of their immature physiology and immune systems, the increased probability of adolescents having multiple sexual partners, and the greater likelihood of adolescents engaging in high-risk sexual activity.

In addition to these safety issues, we are also concerned about Plan B's package insert. As approved by the FDA, the insert may not clearly explain how the drug regimen works, possibly preventing women from exercising complete informed consent. It is crucial that drug literature is not misleading or ambiguous especially when it comes to the effects of a drug on a woman or on a human embryo inside of her.

According to FDA documents, the morning-after pill: "act[s] by delaying or inhibiting ovulation, and/or altering tubal transport of sperm and/or ova (thereby inhibiting fertilization), and/or altering the endometrium (thereby inhibiting implantation)."[1] Similarly, the Plan B manufacturer had admitted on its website, "In addition, it may inhibit implantation by altering the endometrium."

Though both the FDA and the manufacturers say the morning-after pill may "inhibit implantation," it is not clear that women are fully informed that this phrase means a human embryo inside them may be adversely affected by this drug. In order to ensure that women have completely informed consent, it is crucial that the FDA revisit and review current packaging inserts and other literature.

As you know, in order to qualify for over-the-counter status, a drug must be proven safe and effective for use without a doctor's supervision and must have an easily understood label. We believe that the concerns show that Plan B has not been proven safe and effective and we have further reservations that the labeling may not be accurate.

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[1] Federal Register, Vol. 62, No. 37; 8611; FDA. "Prescription Drug Products; Certain Combined Oral Contraceptives for Use as Postcoital Emergency Contraception", February 20, 1997

Lastly, we want to draw your attention to language that was included in the FY2005 Agriculture and Rural Development Appropriations Bill and was made a part of H.R. 4818, the FY2005 Consolidated Appropriations Act.

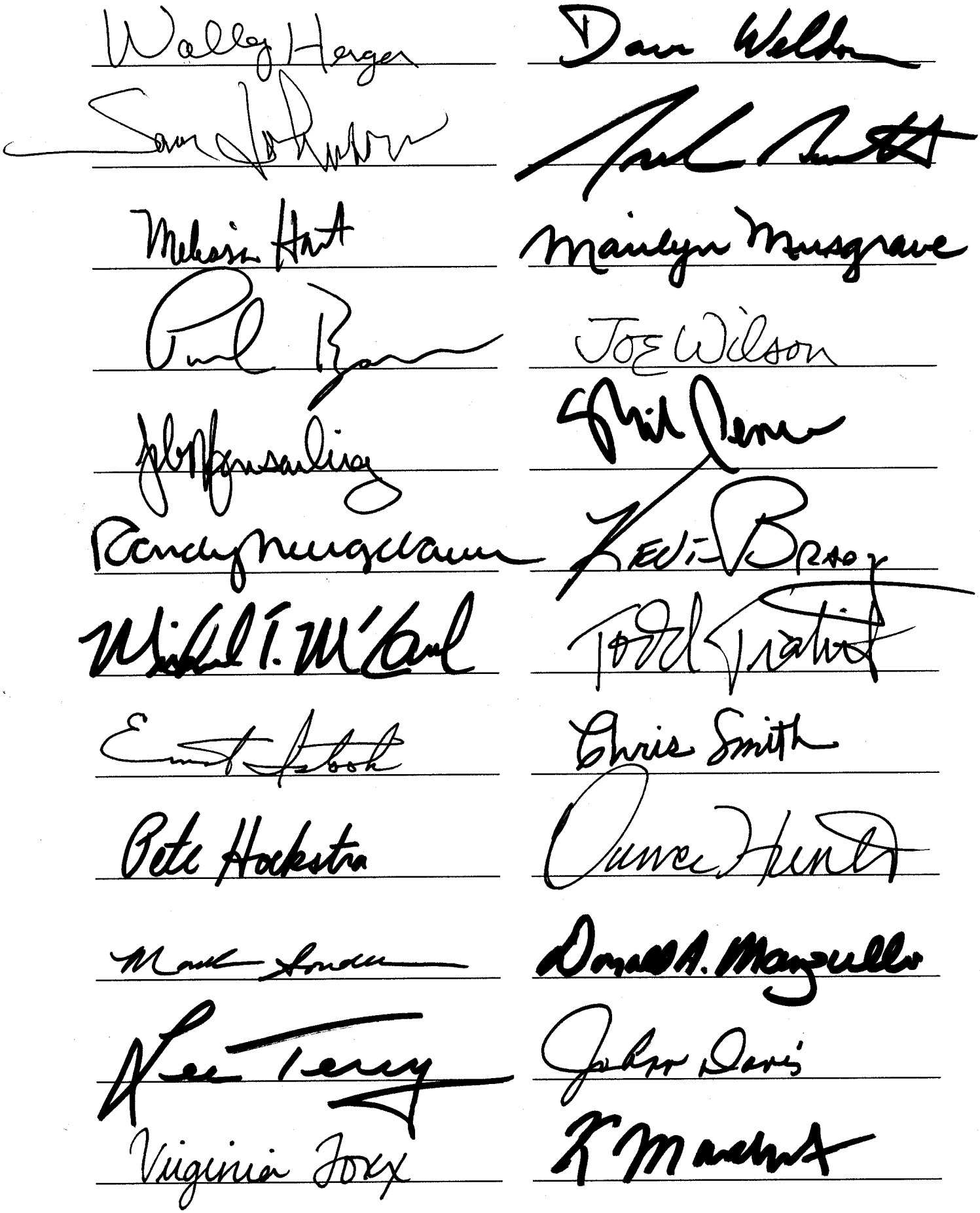
Section 744 states, "None of the funds made available in this Act may be used to restrict to prescription use a contraceptive that is determined to be safe and effective for use without the supervision of a practitioner licensed by law to administer prescription drugs under section 503(b) of the Federal Food, Drug, and Cosmetic Act."

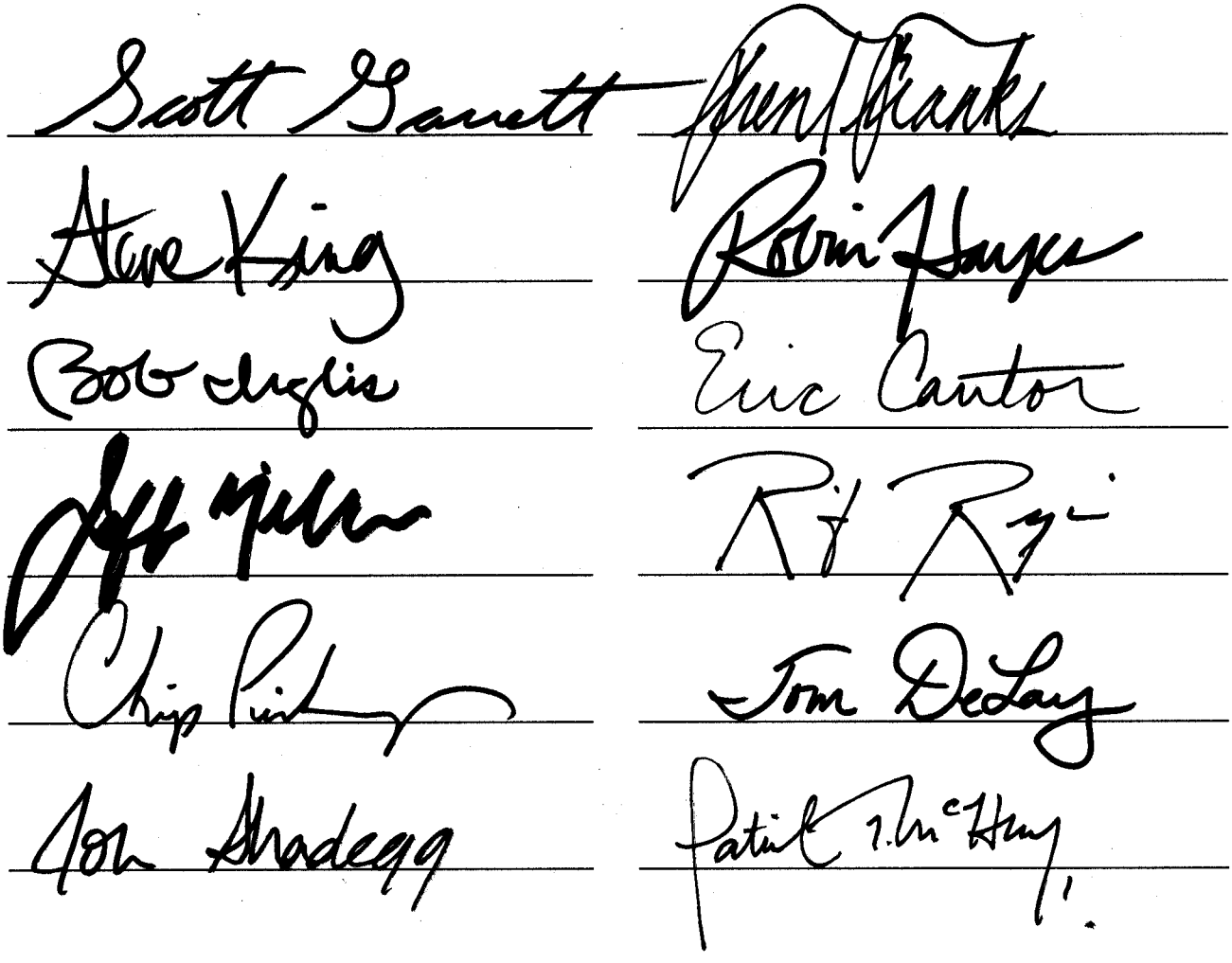
We contend that an accurate reading of this language would conclude that the contraceptive must be found safe to be made available without a prescription. If a drug is deemed safe for some groups but not for all, this language does not provide room for that drug to be made available over the counter for these select populations. Section 744 simply states that the drug must be effective without the supervision of a practitioner, arguably precluding the FDA from considering the bifurcated application submitted by Barr Labs.

The morning-after pill is a powerful drug that should not be on pharmacy shelves next to chewing gum and cough drops. Barr Labs has not submitted new information regarding the safety or effectiveness of Plan B. If the drug was not safe before, it is not safe now, and the FDA should reject its application.

Thank you for considering these views and for the work you do to ensure the safety of all Americans.

Sincerely,





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