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February 20, 2004

Mark B. McClellan, MD, PhD
Commissioner of Food and Drugs
U.S. Food and Drug Administration
5600 Fisher Lane
Rockville, Maryland 20857

Dear Dr. McClellan:

I am writing as a certified obstetrician/gynecologist, a member of the American College of Obstetricians and Gynecologists (ACOG), and a member of the Association of Reproductive Health Professionals (ARHP) to support over-the-counter (OTC) status for Plan B emergency contraceptive pills (ECPs). I have reviewed the scientific literature and believe the evidence clearly supports this change. I agree with the FDA advisory panel's finding that the data shows ECPs to be safe and effective for reducing unintended pregnancy and that it is appropriate for over-the-counter use. I urge you to support OTC access to ECPs.

Concerns that ECPs are not safe are unsubstantiated and contradict the scientific evidence presented to the FDA. Concerns that emergency contraception cause increased sexual activity among adolescents and teens are equally unfounded. Research shows that ECPs do not increase sexual activity and that they have a significant public health benefit by reducing unintended pregnancies among women of all ages, including teens.

The sooner emergency contraceptive pills are taken after unprotected intercourse, the more effective they can be. Evidence shows that some women still find it difficult or impossible to get emergency

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contraception from a provider or health care professional in time. In a recent news story about ECPs, several pregnant teenagers at our urban hospital, Grady Memorial in Atlanta, were interviewed. They all stated that they wished that ECPs had been available over-the-counter to them, with hopes that they may have been able to prevent their pregnancies.

The evidence is clear: ECPs should be available over the counter for the women who can benefit. All women deserve the opportunity to safely and effectively protect themselves from unintended pregnancy.

Sincerely,

A handwritten signature in black ink, appearing to read "Carrie Cwiak". The signature is fluid and cursive, with the first name "Carrie" written in a larger, more prominent script than the last name "Cwiak".

Carrie Cwiak, MD, MPH

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