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DATE OF CORRESPONDENCE: 01/08/04

DATE INTO FDA: 01/14/04

TO: MARK MCCLELLAN, FDA - COMMISSIONER

FROM: GEORGE C BENJAMIN, APHA, AMERICAN PUBLIC HEALTH ASSOCIATION

SYNOPSIS: URGES THE AGENCY TO MOVE FORWARD WITH THE RECOMMENDATIONS OF THE TWO FDA FEDERAL ADVISORY COMMITTEES WHICH VOTED TO RECOMMEND OVER THE COUNTER SALES OF EMERGENCY CONTRACEPTION.

LEAD OFFICE: HFD-1

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COORDINATION:

SIGNATURE REQUIRED:

REFERRALS FROM HF-40

ASSIGNED TO	ACTION	DUE DATE
----- HFD-1	----- PREPARE DIRECT REPLY	----- 01/26/04
REMARKS: PLEASE FORWARD COPY OF RESPONSE TO CAPRI MCCLENDON AT HF-40. THANK YOU.		

OIP-0075

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American Public Health Association

Working for a Healthier World

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January 8, 2004

The Honorable Mark B. McClellan
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Commissioner McClellan:

On behalf of the American Public Health Association (APHA), the largest and oldest organization of public health professionals in the nation, representing more than 50,000 members from over 50 public health occupations, I write to urge you to move forward with the recommendations of the two FDA federal advisory committees which voted overwhelmingly to recommend over-the-counter sales of emergency contraception (EC). We believe that EC is an integral part of reproductive health care and believe that limits to its access can lead to more unintended pregnancies and preventable abortions.

In 2003, APHA's Governing Council approved APHA policy 200315, "Support of Public Education about Emergency Contraception and Reduction or Elimination of Barriers to Access." The policy urges that women have both information about and access to EC. In order to eliminate barriers to EC, APHA supports the FDA advisory committee recommendations to switch the status of EC from prescription-only to over-the-counter. I am attaching a copy of the entire policy for your review. We hope you will take our position into consideration as you move forward with your final decision on the two committees' recommendations.

Thank you for your attention to our comments. Please do not hesitate to call me at 202-777-2430 if you would like additional information regarding APHA's position on this important public health matter.

Sincerely,


Georges C. Benjamin, MD, FACP
Executive Director

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Support of Public Education about Emergency Contraception and Reduction or Elimination of Barriers to Access

The AMERICAN PUBLIC HEALTH ASSOCIATION (APHA) has been at the forefront of numerous efforts to prevent disease and promote health, and specifically improve access to health care. Understanding that contraception is an integral part of reproductive health care and that barriers to access can lead to unintended pregnancies and preventable abortions, APHA supports measures to improve women's awareness of and access to a full range of contraceptive options.

In the United States, almost 50 percent of all pregnancies are unintended, and almost half of unintended pregnancies end in abortion.¹ Notably, more than half of unintended pregnancies occur among women who are using contraception.² However, researchers estimate that half of the unintended pregnancies could be avoided if women had information and timely access to emergency contraception (EC).³ The copper-T intrauterine device can also be used as EC. However, for the purposes of this policy statement, hereto forward, EC will refer to hormonal emergency contraceptive pills. In fact, EC use is estimated to have prevented more than 50,000 abortions in the U.S. in 2000 alone.⁴

In 1997, the United States Food and Drug Administration (FDA) ruled that certain combined oral contraceptives are safe and effective for use as postcoital contraception.⁵ When taken correctly within days of unprotected intercourse, contraceptive failure, or sexual assault, EC can reduce a woman's chance of becoming pregnant by up to 89 percent.⁶ While FDA-approved dedicated products indicate that EC should be administered within 72 hours, recent data shows EC is still effective within up to 120 hours of intercourse.⁷⁻⁹ The most common form of EC is emergency contraceptive pills, which contain high dosages of progestin or combined estrogen and progestin—the same hormones found in daily birth control pills.* Like other hormonal methods of contraception, EC works by delaying ovulation, by preventing fertilization, or by preventing implantation.¹⁰⁻¹⁷

Low awareness and barriers to access have led to lack of use. The vast majority of women have not heard of EC even though they have been available for many years, and only one in 10 OB/GYNs discuss EC with their patients as part of routine contraceptive counseling.¹⁸ However, according to a 2002 public opinion poll, 72 percent of the American public—a majority of Democrats, Republicans and Independents—support legislation to expand public health information about EC and its availability.¹⁹

Many women who seek to obtain EC have difficulty accessing care in a timely fashion. For example, a 2000 study showed that approximately one in four calls to the EC Hotline (1-888-NOT-2-LATE) do not result in an appointment with a health care professional or telephone prescription for EC within 72 hours.²⁰ Almost half of U.S. college health centers do not provide EC.²¹ Only 20 percent of female sexual assault survivors treated at hospital emergency departments, or less than half of those who are at risk of unintended pregnancy, are provided EC.²²

Women are more likely to use EC as a back-up method if they have it readily available either through advance prescription or provision, or pharmacies—practices that are well supported by professional medical and public health associations. Studies examining advance provision of EC report no serious side effects or concerns regarding repeat use.^{23,24} The American College of Obstetricians and Gynecologists (ACOG) encourages its physician members to prescribe EC in advance of need and more than 60 medical, public health, and women's health ad-

vocacy organizations, including APHA, submitted a Citizen's Petition to the Food and Drug Administration to change the status of EC from prescription to over-the-counter.²⁵ In addition, over 40 medical and women's organizations, including ACOG, the American Society for Reproductive Medicine, and the Association of Reproductive Health Professionals are co-sponsors of the national "Back Up Your Birth Control" campaign to promote awareness of EC and reduce barriers to access.

To ensure that women have the information and access to EC, the American Public Health Association asserts the following:

1. In order to promote awareness of EC among the public and providers:
 - Federal and state legislative bodies are urged to authorize and fund initiatives to develop and disseminate medically accurate information about the use, safety, efficacy, and availability of EC as a back-up method of contraception, such as the EC Education Act;
 - Relevant professional organizations are urged to update their standards of care for EC and to support the development and dissemination of education curricula about EC; and
 - State and local departments of health are urged to support development of medically accurate, age-appropriate educational initiatives about EC.
2. In order to reduce or eliminate barriers to access of EC:
 - APHA supports efforts to switch the status of EC from prescription-only to over-the-counter.

As interim measures:

- Health systems are urged to establish protocols that ensure timely access to treatment with EC, including permitting prescription of EC without unnecessary physical examination; allowing telephone prescription of EC; and ensuring the provision of information about EC and the dispensing of EC on site in hospital emergency departments to patients who are at risk of unintended pregnancy and desire the medication;
- Health systems are urged to establish protocols to ensure that a patient is not denied timely access to EC based on moral or religious objections of a health care provider;
- State legislatures and relevant regulatory bodies are urged to authorize measures to permit collaborative practice to permit trained pharmacists to dispense EC; and
- Health systems are urged to authorize standing orders for EC prescribing authority for mid-level providers.

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