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Association of Reproductive Health Professionals
Association pour le Développement des Conceptions d'Urgence
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Center for Reproductive Health Research and Policy
Center for Reproductive Law and Policy
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American Society for Emergency Contraception

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September 11, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

To whom it may concern:

I am writing on behalf of the American Society for Emergency Contraception in reference to the "Draft Guidance for Industry: Combined Oral Contraceptives – Labeling for Healthcare Providers and Patients." While we are very pleased to see that the use of oral contraceptives for emergency contraception has been included in these guidelines, we would like to offer comments in hopes to increase both awareness and efficacy of emergency contraception.

Our first concern is that the only mention of emergency contraception is in the efficacy table. In order for women to truly benefit from this method of contraception, we are urging the FDA to include these instructions in the "Indications" section of the label, where providers and their patients will be much more likely to read it and to use the pills in this manner if needed.

Second, we ask that the FDA also include in the "Indications" section the crucial information that emergency contraceptive pills are more effective the sooner they are taken. The risk of pregnancy is eight times as high when treatment is started close to the 72-hour mark, as compared to when it is started in the first 12 hours after unprotected intercourse. Including the message of "the sooner the better" directly on the label will encourage women to take the pills as soon as possible following unprotected intercourse, increasing the efficacy of the method and thus reducing greatly the chance of an unwanted pregnancy.

Finally, we would like the FDA to include all possible pill types on the label. In 1997, the FDA declared six brands of oral contraceptive pills to be safe and effective for use for emergency contraception. One additional brand was added to the list shortly thereafter. Since then, several new brands of pills that contain equivalent hormone contents have entered the market: Ogestrel, Levlite, Levora, Low-Ogestrel, and Trivora. We request that the FDA expand their current list to include all brands of oral contraceptives available in the United States that are appropriate for this use.

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We urge the FDA to expand the information on emergency contraception that is currently available on oral contraceptive labeling. Emergency contraception has the potential to greatly reduce the number of unwanted pregnancies and subsequently the number of abortions, but this will happen only when providers and patients are fully aware of this method.

Sincerely,

A handwritten signature in black ink that reads "Tara Shochet". The signature is written in a cursive style with a large initial 'T' and 'S'.

Tara Shochet
Deputy Director

American Society for Emergency Contraception
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