



NARAL *Foundation*
Reproductive Freedom & Choice

6347 '00 SEP -8 P1:15

September 5, 2000

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

Re: Docket No. 00D-1350

To Whom It May Concern:

Thank you for the opportunity to comment on the draft guidance, "Combined Oral Contraceptives – Labeling for Healthcare Providers and Patients." We are writing on behalf of NARAL, a 200,000-member grassroots advocacy organization committed to ensuring that women have access to the full range of reproductive options, including preventing unintended pregnancy, bearing healthy children, and choosing legal abortion.

Oral contraceptive labeling should include complete, accurate, and up-to-date information on the risks and benefits of the pill and should enable women to use the pill as effectively as possible to avoid unintended pregnancy. The FDA has deemed several brands of combined oral contraceptives safe and effective for use as emergency contraception. Widespread use of emergency contraception could reduce the number of unintended pregnancies and abortions in the U.S. by half annually.¹

The FDA has the opportunity, through labeling of oral contraceptives for emergency use, to make a tremendous contribution to women's health by informing women and doctors of this safe, effective, last-chance method to avoid unintended pregnancy.

The draft label could improve women's ability to avoid unintended pregnancy by emphasizing that oral contraceptives can be used as emergency contraception. We urge the FDA to make several specific changes.

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Labeling for Healthcare Providers section

- In the “**INDICATIONS**” section of the label, include information on emergency contraception similar to the information in Table 1 of the label (“Emergency Contraceptive Pills: Treatment initiated within 72 hours after unprotected intercourse reduces the risk of pregnancy by at least 75%”).
- Also in the “**INDICATIONS**” section, make clear that emergency contraceptive pills (ECPs) are more effective the sooner they are taken. A 1999 study indicates that ECPs are most effective in the first 12 hours after intercourse – taking ECPs more than 12 hours after unprotected intercourse increases a woman’s chance of becoming pregnant by 50 percent.²
- In the “**CONTRAINDICATIONS**” section, indicate that the listed contraindications are to ongoing use of oral contraceptives, *not* to their use as emergency contraception. In all instances, pregnancy itself is more dangerous than one-time use of emergency contraceptives.
- Include a complete list of brands of combined oral contraceptives that can be used as emergency contraception. In addition to those already listed in the draft label, the FDA has stated that **Levora**, **Ogestrel**, **Low-Ogestrel**, and **Levlite** are safe and effective as emergency contraception.³

Patient Labeling (Instructions for Use) section

Too few women know about emergency contraception – one survey found that nearly nine out of ten women aged 18-44 have not heard of or do not know the key facts critical to use of emergency contraception.⁴ Because emergency contraception is extremely safe – there are no contraindications to emergency contraception except pregnancy – it is appropriate to inform women about this important backup option for preventing unintended pregnancy.

Specifically, we urge the FDA to make the following changes:

- In the “**MOST IMPORTANT TO REMEMBER**” section, after the suggestion to use condoms or another backup method if two or more pills are missed, include information on how to use emergency contraception. This section should include information on timing and dosage (e.g. “Take [number] [color] pills within 72 hours of unprotected intercourse, and take a second dose 12 hours after the first dose”).
- This section should also explain that emergency contraception is most effective when treatment is started within 12 hours of unprotected intercourse.
- Include similar information about emergency contraception in the “**MISSED PILLS**” section.

Increasing access to emergency contraception is the single most promising avenue for reducing unintended pregnancy and the need for abortion, but lack of awareness of this option remains a substantial barrier to its wider use. By requiring manufacturers to label their products with information about emergency contraception, the FDA can increase access to a safe and effective pregnancy prevention method and improve women's health.

Sincerely,



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NARAL Legal Director
Vice President, The NARAL Foundation



Elizabeth Arndorfer, Esq.

Director of the Proactive Reproductive
Health Policy Institute

Notes

¹ Based on data from the 1980s, it is estimated that increased use of emergency contraceptive pills could reduce the number of unintended pregnancies by 1.7 million annually and the number of abortions by 800,000. James Trussell et al., *Emergency Contraceptive Pills: A Simple Proposal to Reduce Unintended Pregnancies*, 24 FAMILY PLANNING PERSPECTIVES 269-70 (1992).

² G. Piaggio, et al., *Timing of Emergency Contraception with Levonorgestrel or the Yuzpe Regimen*, 353 THE LANCET 721 (1999).

³ 62 Fed. Reg. 8610-8612 (1997).

⁴ KAISER FAMILY FOUNDATION, EMERGENCY CONTRACEPTION: IS THE SECRET GETTING OUT? 7-8 (1997) (summary of findings).

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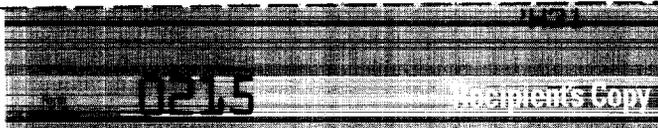
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