



Reproductive Health Technologies Project

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May 3, 2004

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

Re: Docket No. 2000D-1350 in the *Federal Register* 5 March 2004 (Volume 69)

To Whom It May Concern:

I am writing on behalf of the Reproductive Health Technologies Project in reference to the "Draft Guidance for Industry: Labeling for Combined Oral Contraceptives." RHTP is a nonprofit advocacy organization that works to improve the political and commercial environment in the US so women and men have access to safe and effective technologies to protect and promote their reproductive health. RHTP does not accept any funding from the pharmaceutical industry.

With just under 3 million unintended pregnancies taking place each year, almost half to women using a method of contraception, it is clear we are not meeting the reproductive health needs of women. Clear, comprehensive, and accurate product labels may contribute to higher rates of correct and consistent use of combined oral contraceptives (COCs) and we applaud the Agency's demonstrated commitment to providing clear guidance to product manufacturers, and by extension, women and their health care providers.

We wish to draw attention to sections of the draft guidance where this goal could be reinforced:

- **Inclusion of Clinical Trial Data** (lines 82-84): Because clinical trials of oral contraceptives are not comparable, we recommend this section be omitted. If however, the Agency decides to include such data, we **strongly recommend that this information not be allowed in promotion materials used by manufacturers**. Our concerns here are multifold. To date, clinical trials vary widely in terms of numbers of women included in the study, amount of time in the study, comparable rigor of clinical trial design and, as important, failure rates. Furthermore, we believe the more general comment about the expected failure rate for COC users and the caveats provided in the Trussell efficacy table is a better representation of real world use issues, than explanations of clinical trial data which can be misconstrued and misunderstood across OC labels. We therefore recommend the Agency omit this section.
- While we appreciate the efforts to simplify the efficacy table currently in use, the efficacy table in the draft guidance has two significant flaws:

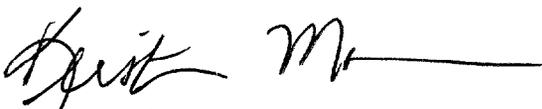
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- **Omission of Perfect vs. Typical Use:** The draft guidance seems to use both perfect and typical use data points and does not distinguish between them; if this is not clarified, this may be misleading to providers and consumers. We believe perfect and typical use data is helpful to consumers and providers when assessing efficacy rates and choosing an appropriate contraceptive method.
- **Exclusion of Certain Methods:** The new table fails to include the efficacy rates of the cervical cap, sponge, and female condom. These products are effective barrier methods available to women, and information on these products should be provided. Similarly, the new table fails to address the role of emergency contraception in preventing pregnancy after unprotected intercourse.
- **The Need for an Annual Exam:** Line 288 of the current draft guidance suggests women who use COCs must have an annual history and physical examination. This marks a reversal from previous guidance which in our opinion is unwarranted by the literature or by clinical practice. Evidence-based practice is moving away from this, as the requirement of an exam is not medically necessary and, for some women, poses an undue burden in accessing contraceptive services or compliance with COC regimens.^{1,2} Therefore, we suggest the adoption of language similar to the 2000 guidance, which advises subsequent visits to a health care provider be based on the patient's medical history and need for medical monitoring.
- **The Lack of Alternative Start Dates:** Line 525-527 of the current draft guidance provides women with only one start date option, taking the first pill on the first day of her menstrual cycle. Previous guidance and medical literature support alternative start dates such as any day after the start of one's cycle.³ Additionally, information on starting COCs after an abortion, miscarriage, or delivery, as well as information on how to appropriately switch contraceptive methods, has been omitted. We recommend language similar to the 2000 draft guidance be used.
- **Omission of Various Health Benefits:** When considering a contraceptive method consumers must weigh not only the risks associated with the use of a method but also the potential benefits. Line 431- 438 of the current draft omits additional health benefits published in previous guidance and supported by current medical literature such as: decreased incidence of ovarian cysts, ectopic pregnancy, endometrial cancer, ovarian cancer, and benign breast tumors.² Research has shown that educating patients on the benefits of OCs, increases compliance rates which in turn increases greater continuation of the product.⁴

We thank the FDA for the opportunity to share our concerns and would be happy to respond to any questions.

Sincerely,


Kirsten Moore
President

¹ American College of Obstetricians and Gynecologists Committee on Practice Bulletins-Gynecology. Cervical cytology screening. ACOG Practice Bulletin, No. 45, August 2003

² Stewart FH, Harper CC, Ellertson CE, Grimes DA, Sawaya GF, Trussell J. Clinical breast and pelvic examination requirements for hormonal contraception: Current practice vs. evidence. JAMA. 2001 May 2;285(17):2232-9

³ Hatcher RA, Guillebaud. The pill: combined oral contraceptives. In: Hatcher RA, Trussell J, Stewart F, Cates W, Stewart G, Guest F, Kowal D, eds. Contraceptive Technology, 17th revised edition. Ardent Media: New York, NY; 1998. p. 405-66.

⁴ Kaunitz, AM. Oral contraceptive health benefits; Perception versus reality. Contraception. 1999 January (59): 29S-33S)