

May 3, 2004

Division of Documents Management (HFA – 305)  
United States Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Docket No. 2000D-1350

To Whom It May Concern:

Thank you for the opportunity to comment on the Food and Drug Administration's (FDA) March 2004 draft guidance for industry on labeling for combined oral contraceptives. Through its work as an independent, not-for-profit organization focusing on reproductive health research, policy analysis and public education in the United States and internationally, The Alan Guttmacher Institute (AGI) has developed and analyzed a great deal of information on the effectiveness of various methods of birth control and implications of their use for women's health (e.g., AGI's publication, *Preventing Pregnancy, Protecting Health: A New Look at Birth Control Choices in the United States*).

Choosing a contraceptive method is a complex process. American women (and the medical professionals they consult) depend on the FDA to develop labeling guidance that is based on the best available science in order to help them make informed decisions with respect to the different options available to them. Women must take a number of factors into consideration in choosing a contraceptive method; central among these, of course, are how effective a given method will be in helping them prevent pregnancy and what impact that method may have on their health, both in the short-term and the long-term.

Our comment is limited to these two aspects of the wide-ranging draft guidance:

**Line 90: Table of method effectiveness rates**

The table of method effectiveness rates is an important tool for women, and no doubt many health professionals as well, in comparing various methods. In that light, it is disappointing that the March 2004 guidance for industry on labeling

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includes a table that is significantly reduced from that which appears in the current labeling, as well as in the draft guidance published in the *Federal Register* on July 10, 2000. Information that is both pertinent and useful has been removed. We strongly recommend that the full scope of information contained in both the current table of method effectiveness and the 2000 draft guidance be retained in the final document.

Of particular concern is the fact that the truncated March 2004 table presents a conflation of “perfect use” and “typical use” effectiveness rates for different methods. For the pill, patch and vaginal ring, the table presents “perfect-use” rates of about 1%, while for the condom, diaphragm and spermicides, it presents “typical-use” rates of 15–25%. This is a significant distortion of the effectiveness of the latter methods, all of which have “perfect-use” failure rates of 5–6% according to Hatcher et al.’s *Contraceptive Technology*. We believe that both the perfect-use and typical-use effectiveness rates should be presented for every method. Women need to be informed about what can be achieved with perfect use so that they can determine for themselves how “typical” or “atypical” they consider themselves to be in terms of their ability to comply with a particular contraceptive regimen.

#### **Line 431: Possible health benefits**

Many women and health professionals are not aware of the beneficial effects of pill use. Behind the media headlines that most often address the possible negative implications of pill use, reports in scientific journals of benefits are accruing, but these reports tend to be read by a limited pool of scientists and medical specialists. Labeling instructions are a key source of trusted information for women and medical professionals generally about what women can confidently expect from using combined oral contraceptives.

The March 2004 draft guidance for industry on labeling, without any explanation, radically downplays the health benefits for women of using combined oral contraceptives. The March 2004 draft guidance includes a section on “possible health benefits” that is considerably narrower than that which is included in the current labeling, as well as the 2000 draft guidance. The March 2004 draft guidance addresses the beneficial effects of pill use on menses, but does not include any discussion of other benefits—namely, that pill use prevents ectopic pregnancy and decreases women’s risk of endometrial cancer, ovarian cancer and benign breast tumors.

To our knowledge, the scientific and medical literature has not changed so as to warrant such a revision to the label. There is, in fact, considerable evidence that some of the above-mentioned benefits affect women soon after starting pill use, become stronger with greater duration of use and persist long after use is discontinued. We strongly urge the FDA to resist any attempt to suppress or in any way downplay scientific findings about the benefits of combined oral contraceptives for women's health. Indeed, we recommend that the text of the 2000 draft guidance be reinstated in the current document.

We thank the FDA for the opportunity to provide these comments and would be happy to respond to any questions it may have.

Sincerely,

A handwritten signature in cursive script that reads "Scamp/s".

Sharon L. Camp, Ph.D.  
President and CEO

CC: The Center for Drug Evaluation and Research