



**U.S. Food and Drug Administration
Advisory Committee for Reproductive Health Drugs
General Meeting**

**Statement by Kirsten Moore
January 24, 2007**

We want to thank the scientists at the FDA for convening this meeting to take stock of a changing landscape of contraception and contraceptive use. My name is Kirsten Moore and I am President of the Reproductive Health Technologies Project, a national nonprofit advocacy organization. Our mission is to advance the ability of every woman to achieve full reproductive freedom with access to the safest, most effective, appropriate, and acceptable technologies for ensuring her health and controlling her fertility. RHTP does not receive any funding from pharmaceutical companies.

RHTP believes each contraceptive method – indeed any reproductive health technology – requires careful analysis of its safety, effectiveness, acceptability, appropriateness, and ethical aspects. These vary from person to person and from community. To better reflect this variability, we urge the FDA and sponsors to use a more dynamic model in clinical trial design and labeling.

While we recognize that clinical trials are by nature artificial environments, we are concerned that these environments contribute to poorly informed expectations among women and their health care providers about the safety and efficacy of any particular contraceptive method. And when expectations don't match up to reality, women are more likely to discontinue their contraceptive use, perhaps exposing themselves to an unintended pregnancy.

The Guttmacher Institute estimates that more than 16 million women are today using some method of hormonal contraception. It defies logic to think this number includes only women who are younger than 35, non-smoking or have a BMI < 35. For this reason, we urge entry criteria be expanded to reflect the general population. Similarly, we would urge the agency to consider asking for Phase III data from a range of service delivery settings – reminiscent of the clinical trials that were run here in the US for mifepristone/medical abortion – to see whether there is anything that could be learned about counseling or follow up care that might affect efficacy or more timely recognition and treatment of contraindications.

As noted in the briefing document, any woman using contraception weighs a range of factors in finding the best method for her contraceptive needs. A woman may consider a method that is less effective an acceptable risk if it causes her fewer side effects or in some other way matches with her

lifestyle (e.g., a method that can be used periodically). For this reason, we urge the FDA *not* to set a lower limit of efficacy for contraceptive methods.

In short, the more clinical trial designs can mimic real world use, the more confidence the public in general and women in particular can have in their contraceptive method. Whether the FDA and sponsors agree to criteria for new trial designs, we strongly urge that the limits of our information be more accurately reflected on current labels. If women have been excluded from a trial of a particular method, this should be stated explicitly in the product's label. If conclusions about safety or efficacy is drawn from other trials, that should also be stated explicitly.

We would also like to see labeling – or FDA approved patient information – better reflect the dynamic nature of contraceptive use and provide women with more and better information about what she might expect from this method if she is starting contraceptive use, if she is switching from another method, if she misses a pill or injection, if she has spotting, or when she stops using a particular method. Such information could help contribute to more realistic expectations of hormonal contraception and increase a woman's reproductive autonomy.

My last comment goes beyond the scope of work for this committee and indeed the FDA, but I feel compelled to offer it anyway. The high rates of unintended pregnancy and sexually transmitted infections in this country tell us that as public health advocates and experts we are not doing enough to meet the reproductive health needs of women and men. We need more social science and clinical research that will evaluate innovative service delivery, and counseling models that will help more women who want to plan their pregnancies do so. Unfortunately, government funding is going in the wrong direction to support such research. I urge all those in this room who are supportive of a broader contraceptive research agenda to begin speaking out about this need.