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WOMEN'S HEALTH RESEARCH

Changing the Face of Medicine

July 28, 2004

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

To Whom It May Concern:

On behalf of the Society for Women's Health Research, we would like to submit the following comments on the Food and Drug Administration's (FDA) new Critical Path Initiative.

The Society is the nation's only not-for-profit organization whose mission is to improve the health of all women through research, education and advocacy. Founded in 1990, the Society brought to national attention the need for the appropriate inclusion of women in major medical research studies and the need for more information about conditions affecting women disproportionately, predominately, or differently than men.

We believe that the Critical Path Initiative offers an important opportunity to improve the process of developing medical products that can save and improve the lives of millions of Americans. However, the Society believes it is crucial for the FDA to take biological differences between the sexes into account in this initiative in a variety of ways.

First, it is important to realize it has been shown that women may metabolize drugs differently from men and that the same drug may require different dosages in women than in men. These potential differences must be considered during the drug development and approval process. Women need to be included all stages of clinical trials, not only in Phase III trials as is generally the case today, in order for these issues of drug dosing to be addressed.

Second, it is necessary, but not sufficient, that women be included in all phases of clinical trials. Studies must include sufficient representation of women subjects to allow for analysis by sex, ethnicity and other demographics. The proper analysis of resulting data could lead to the detection of significant sex differences. For example, a 2001 GAO report found that eight of ten prescription drugs that had been withdrawn from the United States market since January 1997 caused serious adverse reactions more often in women than in men. This example demonstrates

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that the inclusion of more women in clinical trials is insufficient without appropriate analysis of data by sex.

Third, the Society supports the establishment of drug-labeling requirements to ensure that drug labels include language about differences experienced by women and men. Further, it advocates for research on the comparative effectiveness of drugs with specific emphasis on data analysis by sex, and for the reporting and sex-based analysis of adverse events resulting from prescription drug use. Our country's drug development process has succeeded in developing new and better medicines for the health of both women and men. However, there is no requirement that the research data about a new drug's safety and effectiveness be analyzed for sex differences or that information about the ways drugs may differ in various populations (e.g., women requiring a lower dosage because of different rates of absorption or chemical breakdown) be included in prescription drug labels and other patient educational and instructional materials.

Additionally, proper drug labeling is not always the complete solution. If the drug is not a new type of product or if the sex-specific information is detected only in post-marketing studies, the drug label will not be the primary source of information for the prescribing physician, and it may be difficult to get new information incorporated into physicians' prescribing habits. The Society is encouraged by the FDA's recognition of the need for more specific drug labeling by sex, and hopes to continue working with the agency and pharmaceutical companies to ensure proper sex-based analyses be conducted to gain a greater understanding of gender differences in response to drugs.

We hope that the FDA will take all of these issues into consideration as you seek to improve the medical development process under the Critical Path Initiative.

Sincerely,



Phyllis Greenberger, MSW  
President and CEO



Martha Nolan  
Vice President of Public Policy