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SOCIETY FOR
WOMEN'S HEALTH RESEARCH

July 29, 2005

Dockets Management Branch (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for Women's Health Research, we are responding to the Food and Drug Administration's solicitation of comments on the Draft Guidance on the FDA's "Drug Watch" for Emerging Safety Information. We appreciate having this opportunity and hope that you will take our comments into consideration.

Scientists have long known of the anatomical differences between the sexes, but only within the past decade have they begun to uncover significant biological and physiological differences. Sex differences have been found everywhere from the composition of bone matter and the experience of pain to the metabolism of certain drugs and the rate of neurotransmitter synthesis in the brain.

Adverse reactions to prescription drugs represent an area illustrating clear sex differences between women and men. A 2001 Government Accountability Office (GAO) report found that, of the ten prescription drugs withdrawn from the United States market between January 1997 and December 2000, eight caused statistically greater health risks for women than men. Therefore, we know that sex differences exist in drug metabolism and drugs' effects on people. Additionally, since women are disproportionately represented among the chronically ill and elderly, they are particularly impacted by potential dangers of prescription drugs.

The Society appreciates the FDA's attempts to increase transparency and improve communication with patients about the safety of their prescriptions, and our comments are made in regard to that overall goal and not to the Drug Watch program itself. We have two comments. First of all, we believe that it is critical to report any sex-based or gender-specific data about drug safety, or to clearly indicate that this type of sex-based analysis was either not conducted or was unavailable. As many new discoveries are made with respect to women's health, the FDA is well situated to provide this information.

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Secondly, the Society urges the FDA to ensure the agency's Office of Women's Health (OWH) is represented in any public communication effort. The representation of OWH is important to ensuring that considerations of sex-based differences and women's health are factored into the agency's communications.

Thank you for providing this opportunity to comment on the draft guidance on FDA's "Drug Watch" for Emerging Safety Information. We hope that you will take our comments into consideration. If you have any questions, please feel free to contact Martha Nolan at 202-496-5007.

Sincerely,



Phyllis Greenberger
President



Martha Nolan
Vice President of Public Policy

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. We advocate for increased funding for research on women's health; encourage the study of sex differences that may affect the prevention, diagnosis and treatment of disease; promote the inclusion of women in medical research studies; and inform women, providers, policy makers and media about contemporary women's health issues.