SOCIETY FOR
WOMEN'S HEALTH RESEARCH

December 14, 2005

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 are responding to the Food and Drug Administration's solicitation of comments on "Consumer-Directed Promotion of Regulated Medical Products" (Docket No. 2005N-0354). We appreciate having this opportunity and hope that you will take our comments into consideration.

We are responding to the first question, *"Does current DTC promotion present the benefits and risks of using medical products in an accurate, nonmisleading, balanced, and understandable way?"* The Society believes that, regarding sex differences, DTC advertising needs to do more to explain to patients the differing biological responses men and women may have to the same prescription drugs. We are well aware that currently, there is not a sufficient body of information concerning how drugs may work differently in women and men or in specific ethnic communities. However, the Society feels it is imperative that companies are encouraged to analyze for those differences in their clinical trials and that the FDA require those answers before they determine whether a drug should receive approval. Any information on differences between men and women known at the time of approval, whether it be differences in action, interactions, or adverse reactions, should be included in DTC advertising, and as more is learned about such differences, this information should always be included along with generally accepted risks.

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. The Society successfully fought for this to be recognized by the scientific community, which has resulted in research discoveries over the last decade proving that many conditions and drugs affect women differently, disproportionately, or uniquely. 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 represents 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 A 2001 Government Accountability Office (GAO) report found that, of the ten prescription drugs withdrawn from the United States market between January 1997 and December 2000, eight caused statistically greater health risks for women than men.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.

As sex differences in drug utilization are discovered, they need to be reflected in DTC advertising to explain to patients how a drug may differently impact women and men. Few, if any, DTC ads mention sex differences. We believe drug advertisements should state, where available and appropriate, that research has shown that some drugs affect women and men differently, and that patients should discuss this possibility with their doctor before beginning treatment.

The inclusion of such information in DTC ads would not only alert consumers to potential sex differences in drug responses but would be useful in beginning a dialogue between patients and doctors on this important topic. We believe that overall, when DTC advertisements adequately explain the risks associated with prescriptions, the result is greater communication between doctors and patients.

In the cases of drugs for which concrete sex differences have been established, more specific language about these differences should be included in DTC advertisements. For example, women may require a lower dosage of certain drugs than men because of different rates of absorption or chemical breakdown. Older women who likely have more chronic illnesses and diseases also have a greater challenge caused by multi-prescription drug regimens that increases issues of potential adverse drug interaction or reduction in efficacy or metabolism. This information needs to be provided to them or at least the questions to ask should be included in prescription drug labels and other patient educational and instructional materials, such as DTC ads.

The Society is also interested in the related issue of sex differences and drug labeling. We encourage the establishment of drug-labeling requirements to ensure that drug labels include language about potential differences experienced by women and men. Further, we would encourage additional research on the comparative effectiveness of drugs with specific emphasis on data analysis by sex.

Finally, the Society wants the FDA to ensure that drug companies increase their reporting of sex-based analysis data to the agency and in a useful manner to ensure that it can be utilized to its full potential, such as in further research, drug labels, ads, etc. Consumers have a right to know if risks for certain prescriptions are greater in women or in men.

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 be

included in prescription drug labels and other patient educational and instructional materials.

FDA Commissioner Mark McClellan, speaking at the Society's 2003 Corporate Advisory Council meeting, acknowledged this issue, saying, "[The FDA is] developing a new demographic information and data repository that will have the capacity to track and encourage the inclusion of women in clinical studies as well as to provide more gender specific analysis to support drug-labeling information." We are encouraged by the FDA's commitment to improve the health of all women and its recognition of the need for more specific drug labeling by sex, and look forward to continuing to work with the agency on this issue.

Thank you for providing this opportunity to comment on "Consumer-Directed Promotion of Regulated Medical Products." 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.