

September 16, 2004

Lynn Lang
United States Pharmacopoeia
12601 Twin brook Parkway
Rockville, MD 20852-179

Dear Ms Lang:

On behalf of the Society for Women's Health Research, we are responding to the United States Pharmacopoeia solicitation of comments on its proposed guidelines for the Medicare drug benefit program. We appreciate having this opportunity and hope that you will take our comments into consideration in your final recommendations.

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. Our primary concern is that the USP proposed guidelines governing the Medicare Part D drug program must not impede research and development of new drugs for conditions that affect women disproportionately, predominately, or differently than men.

It is with this focus in mind that the Society reviewed and would like to make the following comments on the USP proposed guidelines as directed by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA).

The USP proposed guidelines should include detailed plans for modifying or adding new therapeutic classes and categories of drugs; adding newly approved drugs; and adding new indications of approved drugs. This plan must be transparent science-based and open for public comment.

The Society is concerned that the proposed guidelines could have a disproportionate impact on women who generally live longer than men, and are more likely than men to suffer from more than one chronic disease. Women are therefore, more likely to be prescribed several medications at the same time. The Society feels strongly that USP's

guideline recommendations must allow for safe and effective treatment of coexisting medical conditions and multiple drug regimens.

We feel it is imperative that USP's recommendation on formulary drugs be based solely on clinical effectiveness and that such formulary selection recommendations take into consideration the unique needs of subpopulations – women, children, elderly.

Thank you for providing this opportunity to comment on the USP proposed model guidelines to the Medicare drug plan. We hope that you will take our comments into consideration in your final recommendations.

Sincerely,

Phyllis Greenberger
President

Martha Nolan
Vice President, Public Policy