

Congress of the United States

Washington, DC 20515

August 6, 2001

The Honorable Tommy G. Thompson
Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Thompson:

We are writing to express our concern about the findings of the attached General Accounting Office (GAO) study of the inclusion of women in drug testing regulated by the Food and Drug Administration (FDA). As you will see, this report finds a number of problems in current industry and FDA practices, and we ask that you conduct a review of these problems and seek corrective action.

As you know, the inclusion of women in clinical research has been a longstanding problem and is one which has the potential to seriously threaten the health of women in this nation. The attached GAO report confirms that while there has been some progress on the part of the FDA to ensure the inclusion of women in the trials, there is still much work to be done.

Most notably, the GAO concludes that neither the industry nor the FDA itself reliably abides by the FDA regulations for data on women. While the GAO concludes that, overall, a sufficient number of women were included in research, it identifies a number of shortcomings in data analysis and presentation, shortcomings that could result in overlooking serious problems. Specific shortcomings were found in new drug summary documents, presentation and analysis of data related to sex differences, and management of information about women in research.

We were encouraged by the acknowledgment of both the FDA and the GAO that the Office of Women's Health is working to develop a clinical trials demographic database. Improved enforcement of standing FDA regulations and improved management tools are clearly needed, and we believe the Office has an important role to play in this area. We acknowledge this database as a step in the right direction and are pleased with the Office's effort. However, development of a database is not enough; even this tool cannot work unless it is used and monitored. The collection and analysis of data is essential to ensuring that drugs are safe and effective for women.

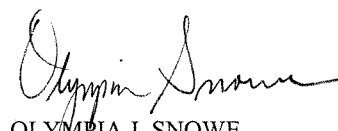
We hope that you will work with the agency to address these problems and underscore the need for policies that can expand public and private efforts to increase our understanding of how diseases manifest themselves in women and how diagnosis and treatment can be improved. We stand ready to assist you and your staff in doing so.

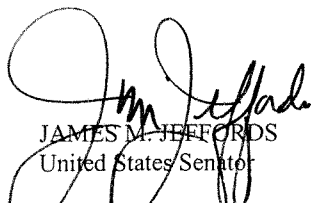
Sincerely,


HENRY A. WAXMAN
United States Representative


TOM HARKIN
United States Senator


BARBARA A. MIKULSKI
United States Senator


OLYMPIA J. SNOWE
United States Senator


JAMES M. JEFFORDS
United States Senator