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SOCIETY FOR  
WOMEN'S HEALTH RESEARCH

*Changing the Face of Medicine*

August 23, 2004

Division of Dockets Management  
Docket Number 2004S-0233  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20857

To Whom It May Concern:

On behalf of the Society for Women's Health Research, we are responding to the Department of Health and Human Services (HHS) solicitation of comments on stimulating innovation in medical technologies. We are pleased that HHS is taking the steps to move medical-technology innovation to the forefront of the biomedical research and development agenda.

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.

The Society believes it is important for HHS and its agencies to facilitate innovation and development of new medical technologies to meet the nation's health care needs. Critical to achieving this goal is consideration of the biological differences between men and women. Such differences must be explored at every phase of clinical development. By incorporating sex differences research into the development of medical technology, both HHS and the research sponsors could ensure that approved technologies are appropriately used in all patients, male or female.

Since 1990, the Society has advanced the conclusion that to ensure a full understanding of human biology for the prevention, diagnosis, and treatment of disease women need to be included in all phases of clinical trials. As a result of the Society's efforts, the National Institutes of Health (NIH) requires the inclusion of women in Phase III of clinical trials unless there is a scientifically valid reason for their exclusion. However, no such requirement is in place for Phase I and II trials.

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We are convinced that, were NIH to require the inclusion of women in all phases of clinical trials research, progress in the development of prevention approaches, diagnostics, and treatments, including medical technologies, would increase. In addition, such inclusion would lead to the discovery of differences between male and female response to disease and treatments at earlier stages of the research process, allowing for more accurate and useful research at Phase III.

The significance of sex differences is reflected in the Institute of Medicine's (IOM) landmark publication, *Exploring the Biological Contributions to Human Health: Does Sex Matter?*. In this report, the IOM Committee on Understanding the Biology of Sex and Gender Differences stated that, by better understanding sex differences at all levels of the human body from the single cell to the whole organism, medical researchers will be able to effectively design health care interventions for both men and women. The Society looks forward to the time when analysis of clinical trial data by sex has become the norm rather than the exception, and researchers take advantage of all opportunities to discover important differences between men and women.

There have been well-documented cases where medical devices and diagnostic tools, developed for and tested on men, have not served women well due to incomplete research. For example, earlier models of implanted defibrillators and artificial hearts were too large for most women patients; and cardiovascular stress tests were eventually found to be less accurate in women than men. For some conditions that affect women exclusively or disproportionately, such as ovarian and breast cancer, diagnostic tools are either not available or too frequently yield false-positive or false-negative results.

Researchers who attempt to recruit and retain women for their studies often find that there are significant barriers to doing so successfully. One such barrier is financial burden. If the costs of routine medical care associated with participation in a study are not covered by the study sponsor or by third-party payers, many women will be discouraged from participation due to financial strain on her and her family. We believe HHS and the Centers for Medicare and Medicaid Services (CMS) can work together more efficiently to facilitate the coverage of routine care costs of participation in clinical trials of breakthrough medical technologies. We applaud the attention this issue received in the Medicare Prescription Drug Improvement and Modernization Act. We expect CMS will implement this policy as rapidly and efficiently as possible to eliminate barriers impeding the participation of women in research and thus crucial development of information for new medical products.

The Society strives to make sure that knowledge gained from research is translated into better care and better health information for all patients, especially women. Innovative research is a key part of that process and so is access to the latest medical technology. Access spurs innovation. It is imperative that all patients are able to utilize breakthrough medical technologies by having them covered under government sponsored health insurance or private health insurance. It is important to remember that the determination of clinical effectiveness of many medical treatments can take time as experience and use grows and therapies evolve in real world practice settings.

When making decisions on the coverage for new technologies, CMS should recognize that the higher initial cost of a new diagnostic tool or treatment device may not reflect the true cost-effectiveness of the product. Decisions on coverage must take into account the subsequent effect on patient and provider access to innovative technology. We urge CMS to develop consistent criteria for approval of reimbursements for medical technologies and at the same time provide for flexibility in decision making in order to be able to adapt to the evolving nature of medical care and patient needs.

We would like to highlight three programs sponsored by the NIH that have been successful in fostering innovation. Two of these programs sponsored by and funded through the Office of Research on Women's Health at the NIH — the Specialized Centers of Research on Sex and Gender Factors Affecting Women's Health (SCOR) and the Building Interdisciplinary Research Careers in Women's Health (BIRCWH) awards. Both of these programs are central in promoting and developing interdisciplinary research as well as the performance of research and transfer of findings that are relevant to women's health.

Further, the General Clinical Research Centers sponsored by the National Center for Research Resources at NIH provide the infrastructure and resources for academic centers to support career opportunities and create optimal settings for clinical research. It would greatly benefit innovation if these programs were expanded upon, perhaps with a focus on medical technologies to reach additional research institutions and faculty.

The Society believes we cannot afford to lose momentum in medical innovation. We applaud your efforts to this area through the NIH Roadmap Initiative and the Food and Drug Administration Critical Path Initiative. Exciting discoveries are vital to all patients and will only be strengthened by the inclusion of women in biomedical research and analysis of resulting data by sex. We appreciate the opportunity to share our comments.

Sincerely,



Phyllis Greenberger  
President & CEO



Martha Nolan  
Vice President, Public Policy