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January 26, 2009

The Honorable Tom Harkin
United States Senate
Washington, D.C. 20510

Dear Senator Harkin,

We are writing to you on behalf of the Society for Women's Health Research to express our concerns regarding the proposed comparative effectiveness research (CER) language in the House Economic Stimulus Package, and in particular, the House Committee Report Language. The Society appreciates and agrees with Congress' recognition that comparative effectiveness research is important. However, the current proposal fails to recognize three significant factors:

1. this research must study both men and women and fully analyze any sex-based difference in disease prevalence, treatment options, procedures, or responses to treatment;
2. clinical effectiveness - not cost - must be the focus of this type of research; and
3. patients must be provided a voice in the health care decision-making process and be included in the determinations.

The mission of the Society for Women's Health Research is to improve the health of all women through advocacy, research and education. The Society has brought to national attention the need for the inclusion of women in medical research studies and the need for analysis of the sex- and gender-based differences in disease and treatment

The Society has long advocated that a strong patient-centered comparative effectiveness research program can be of tremendous value to understanding biological and physiological sex differences that affect disease prevention, diagnosis and treatment. A complex combination of genetic, hormonal, physiological, and environmental factors influences health and disease in extraordinarily different ways in women and men. Biological sex differences in disease and the response to therapeutics, some of which are present at birth and others that develop later, are pervasive and compelling.

For example, diseases such as cancer, obesity, coronary heart disease, autoimmune disorders, and mental health disorders exhibit sex differences in susceptibility, prevalence, time of onset, and severity. In addition, we now know but it is not widely understood in medical practices that there are sex-based differences in both devices and common medications, including antibiotics, antihistamines, antidepressants, antipsychotics and some heart medications. In the latter case, these medicines, either alone or in combination, cause more women than men to develop potentially fatal irregular heart beats or arrhythmia. Women often have a longer QT

interval than men and taking certain drugs can further lengthen this interval, thereby increasing the risk of a fatal arrhythmia more in women than in men.

Select high blood pressure medications and antibiotics appear to be more effective in women. Thrombolytic therapy may cause more serious bleeding in women than in men and needs to be administered differently for women. Certain anesthetics work differently in women than in men. For reasons not yet fully understood, women tend to wake up faster than men and are three times more likely to complain of being awake during surgery. Particular antidepressants appear to be affected by a woman's monthly menstrual cycle.

Scientists are not yet sure why drugs affect men and women differently, and the answer may turn out to be different for every class of medicine. One reason being studied is the varying rates at which men and women metabolize drugs and differences in liver enzymes that may affect the levels of drugs in the body, drug effectiveness or the severity of side effects from the drugs. Further, women take more medications than men, including over the counter drugs, herbal remedies, dietary supplements and vitamins which place them in a higher category for adverse drug reactions/interactions.

Devices and the procedures in which they are used also show sex differences. For example, women have twice the risk of men for local complications after cardiac catheterizations. This could be due to blood vessel size or hormonal differences. The research community is just on the cusp of understanding that men and women are different in ways that go beyond their reproductive systems, hormones and bone structure to include disease prevalence and progression, presenting symptoms and response to treatment. To date, this knowledge has not been commonly adopted or understood by clinicians compromising the quality of health care received by women. The Society believes that sex differences must be at the heart of comparative effectiveness research. Further, we are concerned that a push for "comparative cost effectiveness" will eliminate future research into the many differences that truly impact effectiveness, will slow badly needed education of clinicians about known differences and will prohibit prescribing physicians from taking into account important patient differences.

The Society understands the need to know what is "effective" and what is not, and appreciates the importance of cost saving. However, we are concerned that the current House proposed CER language will have a detrimental affect on research and development of new drugs, biologics and devices that ultimately will be more effective while eliminating or reducing adverse reactions and risk factors.

The research proposed must be able to freely evaluate and compare the clinical effectiveness, risks, and benefits of two or more medical treatments, services, drugs, devices, biologics, care processes and care management while also taking into account differences based on a patient's sex, age, race and ethnicity. To be consistent with that

purpose it must avoid unintended access barriers, coverage denials, or arbitrary dollar thresholds that can arise through centralized cost-effectiveness determinations. Further, by focusing on gaps in clinical knowledge, the research findings can improve the quality and, ultimately, the value of health care.

Finally, the Society recommends that a patient representative be added to the Federal Coordinating Council for Comparative Effectiveness Research. Patients are stakeholders of the proposed research and are best positioned to understand risks and benefits. They provide a unique perspective on what they believe should be the initial and long term research priorities. More importantly they understand best how open and transparent the research process must be so that the final research findings are viewed as credible and relevant to the real world decision making facing patients and providers.

The main focus of comparative effectiveness research should be in ensuring the most effective treatment is available to each individual; only in this manner will there be true cost savings. Research that emphasizes cost over effectiveness in different communities could easily result in sub-par treatments with unacceptable levels of risk and greater costs due to the ineffectiveness of the initial treatment or avoidable adverse effects.

Sincerely,



Phyllis Greenberger
President and CEO



Martha Nolan
Vice President, Public Policy