

Testimony of Marlene McCarthy H.L.D.

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My name is Marlene McCarthy, Volunteer Chair of the Rhode Island Breast Cancer Coalition. My organization has been a part of the National Breast Cancer Coalition (NBCC) since its inception in 1992. I welcome the opportunity to present testimony on behalf of the National Breast Cancer Coalition (NBCC) and the Rhode Island Breast Cancer Coalition at this hearing on women's health research.

NBCC is a grassroots organization dedicated to ending breast cancer through action and advocacy. The Coalition's main goals are to increase federal funding for breast cancer research and collaborate with the scientific community to implement new models of research; improve access to high quality health care and breast cancer clinical trials for all women; and expand the influence of breast cancer advocates wherever breast cancer decisions are made. The NBCC has developed core values for breast cancer research that reflect its vision and are fundamental to all of its research-related work. **NBCC's Position Statement on Core Values for Breast Cancer Research** articulates and describes these values: integrity, impact, accountability, respect, beneficence, justice, shared decision-making, and flexibility. These values can and should be applied to all forms of women's health research.

I commend the Office of Research on Women's Health at NIH for embarking on this endeavor to collect information and solicit input from scientific and public policy experts, health care providers and advocacy organizations as it looks toward the next decade of women's health research. NBCC strongly believes that the enterprise of clinical and scientific research at NIH could be vastly improved with greater participation from educated health care consumers and trained advocates who can help to inform all aspects of decision making at the Office of Women's Health Research and across the Institutes.

NBCC also has deep concerns about the lack of transparency, external oversight and accountability in research priority-setting, decision-making and evaluation. What is important now is to determine the right process for and atmosphere within which women's health research will be prioritized and conducted. **We must make certain that the process maximizes our getting the right research done in the right way.**

Need for Greater Transparency, Oversight and Accountability

During this era of change, all federal agencies, but particularly at the NIH, must embrace and incorporate greater transparency and public accountability at every level and in everything they do. As our nation's foremost biomedical research institution, NIH's lack of diversity in stakeholder representation and dissenting viewpoints in evaluating programs and projects is alarming. For instance, when NCI decided to evaluate the cancer centers, the committee chosen had a significant number of cancer center directors as members. The NIH Reform Act created the Scientific Management Review Board to conduct periodic reviews and issue reports on organizational issues at NIH. The NIH Director submitted the list of members of this Board to Congress and its membership includes nine institute directors, several major institutions that receive significant funding from NIH and one industry representative. **There were no consumer advocates as part of this Review Board. The Review Board clearly lacks independence and the ability to conduct meaningful oversight.**

While there is a great deal of discussion about reform and innovation there does not appear to be an overarching framework or objectives and a strategy to analyze past funding and to govern funding going forward, at least not one that includes meaningful benchmarks and critical evaluations and is accessible by the public and policy makers.

Taxpayers deserve to know that the agency tasked with charting scientific and medical breakthroughs is being prudent stewards of the billions being appropriated to its mission each year.

Consumer Advocate Participation in Research Decision Making

Consumers – lay advocates who are trained and educated - can play an integral role in ensuring that the research that is funded is responsive to needs of both the scientific and patient communities. Their perspective is necessary to ensure that the grants funded are meaningful and will have impact. **Consumer advocates bring a vitally important perspective to scientific research. And they keep the scientists on task.** Together, they can look at the current state of knowledge, and then design appropriate and necessary mechanisms to allow scientists, in collaboration with advocates, to develop proposals to research the most important questions as well as advise on priorities for funding research. The Department of Defense Peer Review Breast Cancer research program has proven that this is an effective and valuable model of scientist-advocate collaboration.

The peer review process is the accepted method for identifying meritorious scientific trials and studies. However the peer review process has traditionally excluded those most affected by research—the patients themselves. The peer review process is only enhanced by the involvement of advocate “peers”—activists outside the scientific and medical communities who bring a unique and important perspective to the scientific discussion. Ideally educated advocates must be included on all research peer review panels, in both the public and private sector.

Clinical trials are another critical area for advocate involvement. Advocates can provide important insights into the design of clinical trials and invaluable assistance in increasing awareness and knowledge of clinical trials. They must be substantive collaborators in the research process. Moreover, it is important to have meaningful advocate involvement in scientific meetings in which the Office on Women’s Health is involved. Advocates must be part of program planning committees and participate as session chairs or co-chairs. There must be opportunities for interaction between scientists and advocates at discussion sessions and in mentoring programs. Finally, advocates must be provided opportunities to present their work and their perspective at poster and platform sessions.

Educated advocates can have a meaningful impact on how best to communicate information and research findings to providers, patients and the public. The NBCC framework for national health care reform calls for a national panel to be established to work with the public to review evidence and help design effective methods for communicating health care information to consumers, providers and plans.

An example of where educated advocates played a critical part in the development and evolution of a research project is the Women’s Health Initiative (WHI). As you are well aware, it is a large clinical trial, one part of which looked at a particular hormone replacement therapy – progestin plus estrogen vs. placebo – to determine the benefits and risks of that approach. The trial was supposed to end in 2005, but it was stopped in 2002, because the overall health risks of HRT exceeded the benefits. In fact, the trial showed an increased risk of breast cancer as well as heart disease, blood clots and stroke. Women had taken HRT for years before the trial was conducted to look at these issues. While the intervention aspect of the trial was stopped, that is, women were no longer given the drugs, HRT or placebo, as in any well-designed trial, the investigators continued to follow the women.

Several years of following these women after the trial stopped, it was determined that the cardiovascular risks were no longer greater in the group of women who had taken HRT than in the women who received placebo. However, it appears that the breast cancer risk may continue. While the higher risk remained throughout the intervention and the follow up period, looking at the follow up period alone, the results were not statistically significant. What does that mean? Since we are not certain what drugs the women took after the trial was stopped – or what else changed in their lives – and because the follow up was only three years, we cannot yet say with certainty that the breast cancer risk continues. We can say it is likely.

It is important to keep in mind that the Women's Health Initiative would not have happened without advocacy from the women's community. It is very important to remember that women took these drugs when there was no high level evidence they would benefit and not harm them. And it is extremely relevant to note that advocacy groups such as the National Breast Cancer Coalition questioned the lack of evidence behind these drugs for many years.

Conclusion

In summary, **the agenda for women's health research must be set and implemented in an atmosphere of transparency and through a process that is accountable and includes trained, educated advocates.**

We must make certain that the public can access and understand allocation of resources and the vast array of research projects being undertaken. NIH must enhance its ability to conduct meaningful science through these changes.

Again, I thank you for the opportunity to present these views and look forward to working with the Office of Women's Health Research and others at NIH **to transform the Institutes, conduct meaningful research and give the American public greater insight and involvement in women's health research and biomedical research in general.**

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