



June 10, 2010

National Institutes of Health
Eunice Kennedy Shriver
National Institute of Child Health & Human Development
31 Center Drive, MSC 2425
Building 31, Room 2A03
Bethesda, MD 20892

Re: NICHD Scientific Vision Workshop on Reproduction

To whom it may concern,

The National Women's Health Network (NWHN) and the Reproductive Health Technologies Project (RHTP) are nonprofit advocacy organizations that work to improve the health of all women. We bring the voices of women consumers, advocates and researchers to policy and regulatory decision-making bodies. We are supported by foundations and our members and do not take financial contributions from drug companies, medical device manufacturers, insurance companies, or any other entities with a financial stake in women's health decision-making.

Thank you for the opportunity to comment on the White Paper from the National Institute of Child Health and Human Development (NICHD) Scientific Vision Workshop on Reproduction. We commend the institute's collaborative work with stakeholders to identify the most promising scientific opportunities of the next decade and appreciate the focus given to reproductive health as one of the nine overarching themes. We support the assessment that reproductive and sexual health is essential to overall health and wellbeing. Our comments offer support for specific crosscutting themes and scientific priorities identified in the white paper, and identify research opportunities not addressed in the white paper.

We are pleased to note that several of the crosscutting themes which emerged during the workshop address the impact of behavioral and environmental factors on reproductive health. Specifically, we support the need for fundamental and applied contraceptive research on both newly developed and existing methods. This research is essential to understand the behavioral issues related to contraceptive use and non-use in various settings and populations. A deeper understanding of these issues will in turn inform efforts to reduce the number of unintended pregnancies. We also support the crosscutting theme calling for a better understanding of a variety of developmental processes, including the impact of the environment and altered nutrition/disease on reproductive function (e.g., anorexia nervosa or bulimia and obesity). In particular, we would like to encourage NICHD to continue its efforts to conduct research on the safety and effectiveness of oral contraceptive pills for women who are overweight and obese.

We would also like to highlight the importance of the crosscutting themes related to reproductive research more generally. We agree it is essential to reevaluate the design and conduct of clinical trials as they relate to reproductive research. For example, there is not nearly enough information on the impact of prescription medication use on pregnant and lactating women largely because women who become pregnant during a clinical trial are immediately discontinued. Instead, these women should be offered the opportunity to stay in the trial by re-consenting according to the new potential risks; this would facilitate a safer way to gather data on this population. We also agree that mutual benefits could be leveraged through increased community participation and engagement in research. This type of engagement could ensure that the reproductive research conducted is able to answer the questions real women have about their health.

The NWHN and RHTP have been long-time advocates for many of the scientific opportunities identified in the white paper. We are extremely pleased that NICHD has stated that in ten years it will have taken the lead in contraceptive research and development (R&D) and strongly support the priorities outlined in the contraception section. We agree with the assessment that new and innovative methods have not been forthcoming from the pharmaceutical industry and support NICHD's goal to change the research paradigm in this field.

We support the development of scientifically sound tools to improve understanding of the risk factors for unintended pregnancy, inconsistent contraceptive use, and contraceptive failure. By identifying the determinants of contraceptive use and non-use and determining what interventions can increase use and decrease contraceptive failure, NICHD can better direct present and future R&D. A better understanding of how and why current methods are used and their impact on specific populations can help ensure the most effective use of current methods and can also help guide development of innovative new methods. Women should have more contraceptive options that better meet their changing needs throughout their reproductive lives and directing R&D based on women's preferences is a step towards achieving that goal.

We commend the institute for prioritizing the development of new methods. Specifically, we strongly support the development of new dual purpose contraceptive methods that also offer protection against HIV and other sexually transmitted infections. In addition to contraceptive options for men, we also strongly support the development of innovative non-hormonal contraceptive methods for women, including barrier methods. Anecdotal evidence suggests environmental footprint or 'greenness' is increasingly one of the factors women consider when choosing a method¹, thus the development of additional non-hormonal methods will provide women for whom this is a factor with more options.

In the Developmental Antecedents section, we would like to highlight our support for NICHD's intention to evaluate the interaction of genetics, epigenetics, environment, behaviors and socioeconomic status, as well as their impact on human reproductive development. However, we also feel that there are gaps in NICHD's intended areas of study – notably the absence of sexuality as a factor. In a paper published recently by the Guttmacher Institute, Sneha Barot wrote that "...sexuality may be the most underdeveloped area of sexual and reproductive health research, including fundamental questions such as what constitutes "sexual health" and how to

¹ "Birth Control in the Water: Separating Myth from Fact," Moore et al Contraception Editorial. In Press

achieve it.²” We agree, and we strongly urge NICHD to include research on healthy sexuality and sexual identity as a scientific priority over the next decade.

Lastly, we support NICHD’s efforts to advance reproductive science, which will enable the Institute to achieve this ambitious ten year agenda. It is essential that NICHD establish fellowships and training grants targeted to contraceptive development. A renewed focus on this area of research is essential to the creation of novel contraceptive methods, compounds and delivery systems for both women and men. We also support the development of innovative and educational training programs between academia, government, foundations, industry, NGOs, and advocacy organizations. Collaboration across the various reproductive fields is vital to approaching this research in a new way. We appreciate the inclusion of advocacy organizations in this new paradigm of reproductive health research and look forward to the opportunity to ensure that the voices of women consumers are heard and their perspectives and priorities are fully considered throughout the Institute’s contraceptive R&D process.

Sincerely,

National Women’s Health Network
Reproductive Health Technologies Project

² Barot, Sneha. “The Need for a Revitalized National Research Agenda On Sexual and Reproductive Health.” *Guttmacher Policy Review*. Winter 2011. Volume 14. Number 1. Pgs. 16-22.