



## **Society for Menstrual Cycle Research Priorities for Women's Health Research**

*Prepared Testimony to Office of Research on Women's Health at NIH, Chicago – October 4, 2009*

### **I. Preface: The Society for Menstrual Cycle Research**

Founded in 1979, the Society for Menstrual Cycle Research (SMCR) is a nonprofit, interdisciplinary research organization whose members have made significant contributions to menstruation research. We strive to be the source of guidance, expertise, and ethical considerations for researchers, practitioners, policy makers, and funding resources interested in the menstrual cycle. Our membership spans discipline, professional responsibilities, and geography to provide woman-centered perspectives on menstrual experiences. The purposes of the Society are to identify research priorities, to recommend research strategies, and to promote interdisciplinary woman-centered research on the menstrual cycle; to provide a formal communication network to facilitate interdisciplinary dialogue about menstrual cycle research in the context of women's health over the life span; to examine the practical, ethical, and policy issues surrounding menstrual cycle research; to generate and exchange information and to promote public discussion of issues related to the menstrual cycle; and to influence public policy for the enhancement of women's health.

We endorse the four overarching themes identified by NIH in 2009 for addressing research on women's health: Lifespan, Sex/Gender Determinants, Health Disparities/Differences and Diversity, and Interdisciplinary Research. In SMCR, we are particularly aware of the stigma and silence surrounding menstruation and reproductive health issues. We believe that context, wellness, and prevention must be highlighted when priorities for women's health are discussed and established in order to develop effective and realistic health strategies.

### **II. SMCR Recommendations for Research Priorities**

Medical research on sex hormones must be seen in terms of women's *health*, rather than disease. Menopause is not a disease of estrogen deficiency but a normal phase of an adult woman's life, nor is menstruation a disease requiring medication or other treatment.

#### **A. Menopause and Estrogen Therapy<sup>1</sup>**

The Women's Health Initiative (WHI) research provided strong evidence that hormone therapies are not safe and effective for prevention of chronic illness, and that menopause is not an estrogen deficiency disease. Prior to WHI, many in the medical community had advocated use of hormones for disease prevention notwithstanding a lack of experimental data pertaining to this, based on weaker kinds of evidence and their professional judgment. WHI provided strong clinical trial evidence, using the hormones that were most commonly prescribed in the US at the time of the study, that neither estrogen alone nor in combination with a progestin prevents heart disease, and, in

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<sup>1</sup> Adapted from *October, 2007: Women's Health Initiative & Estrogen Therapy*, online at <http://menstruationresearch.org/position-statements/position-statement/womens-health-initiative-ht-updated-2007/>, accessed September 18, 2009.

addition, when several outcomes were considered together, overall harm outweighed overall benefit. The conviction that hormones prevent disease relied on the idea that menopause is a disease state, in which estrogen deficiency creates vulnerability to a wide range of illnesses, including heart, bone, and brain disease. The WHI results therefore also supported SMCR's position that menopause is a normal phase of a woman's life and not an estrogen deficiency disease that requires so-called hormone *replacement* to prevent serious chronic illnesses.

A criticism of WHI that has been given great credence is the "timing hypothesis", which asserts that significant disease prevention was not observed in this study because the participants were too old. In this view, hormone therapy must be begun soon after menopause (or even in perimenopause) in order to be effective for disease prevention; if women begin hormone therapy many years after menopause, it is believed to be already too late to be helpful and, because of incipient development of disease, can be actually harmful. This idea is being generalized to a variety of chronic illnesses of old age, including heart and brain disease.

SMCR regards the credence given this emerging estrogen "timing hypothesis" with alarm. Some professional groups have already incorporated this possibility into their recommendations (for example, the North American Menopause Society) and many professional articles reference it. Yet the research supporting the hypothesis is not strong data, and often is not even acceptable as reliable data, when considered by the normal standards used by researchers. For example, conclusions are drawn from data that are not statistically significant or from research that is underpowered. Conclusions are drawn from markers of disease rather than from disease outcomes. Research data inconsistent with the hypothesis are not considered, for example, studies suggesting that younger women also have negative health effects from hormones. Data are inaccurately over-interpreted; for example, assuming that an observation in younger women will continue to be found as they age. Conclusions are drawn based on possible positive coronary artery outcomes while not simultaneously taking into account negative cardiovascular effects such as stroke and serious blood clots. Data on possible other negative outcomes like breast cancer are not given great credence. Further, the WHI study participants in fact reflected the demographic of hormone users when the study was started.

Ironically, WHI showed that a set of hypotheses based on weak data, no matter how firmly believed, can turn out to be inaccurate when clinical trial data are collected. We believe that this lesson of WHI should be remembered. The continued belief in the underlying idea that menopause is an estrogen-deficiency disease, rather than strong evidence, that has led to the hypothesis that hormone therapy immediately after menopause will prevent a broad variety of diseases.

This shows that more work on the natural history of menstruation, ovulation, and changes throughout the menopause transition is needed; such research must be conducted in a population-based contexts. Understanding the natural history of menopausal symptoms requires long-term data on numerous women from diverse backgrounds. In addition, research on medications that could be prescribed to large numbers of otherwise healthy women must use randomized, placebo-controlled trials.

SMCR advocates that avoiding harm should be a primary consideration in preventive health care and in research on preventive health. Even if it were true that hormone therapy could prevent heart and other chronic diseases, a prevention tool that requires medicating large numbers of women for long periods of time relative to the number of women who will benefit, is not effective prevention. This is especially true if the medication in question carries risks of serious outcomes like strokes and blood clots. While risks are not large enough to preclude treating symptomatic women, these medications are inappropriate in a prevention tool. Further, research on EPT and ET for menopausal women has repeatedly caused harm to study participants, in WHI and in previous studies.

A 2005 NIH State-of-the-Science conference recommended that menopause be de-medicalized. The conference statement read,

Menopause is “medicalized” in contemporary U.S. society. There is great need to develop and disseminate information that emphasizes menopause as a normal, healthy phase of women’s lives and promotes its demedicalization. Medical care and future clinical trials are best focused on women with the most severe and prolonged symptoms.<sup>2</sup>

The statement also asserted that much more research is needed to clearly define the natural history of menopause, associated symptoms, and effectiveness and safety of treatments for bothersome symptoms. Natural histories are important for both science and policy. Knowing how many women transit menopause with few or no symptoms, and how many manage menopause largely on their own, can lead to public health information that empowers women and increases their self-reliance.

We endorse these recommendations and believe they are crucial in studying the relationship of hormones and health. We also believe that menopause and aging need to be divorced in order to develop effective strategies for disease prevention and treatment, with continued research on lifestyle and other interventions.

### **B. Cycle-stopping Contraceptives<sup>3</sup>**

It is the position of the Society that menstruation is not a disease, and that further research on the potential health risks and long-term safety of cycle-stopping contraception is needed. While some research exists on endometrial safety and on patterns of unexpected and expected bleeding, long-term studies that address potential risks beyond the uterus, such as breast, bone, and cardiovascular health are still needed. Furthermore, there is an urgent need for studies that address impacts on adolescent development and bone density over time, since young women and girls are a target market for cycle-stopping contraceptives.

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<sup>2</sup> NIH State-of-the-Science Conference Statement on Management of Menopause-Related Symptoms, 2005, online at <http://consensus.nih.gov/2005/2005MenopausalSymptomsSOS025html.htm>, accessed September 26, 2009.

<sup>3</sup> Adapted from *June, 2007 (SMCR Meeting, Vancouver): Menstrual Suppression*, online at <http://menstruationresearch.org/position-statements/position-statement/menstrual-supression-2007/>, accessed September 18, 2009.

It is important to note that cycle-stopping contraceptives do not only reduce or eliminate menstrual bleeding, but also suppress the complex hormonal interplay of the menstrual cycle. The impacts of this cycle on women's health are not completely understood.

It is also critical to address the social, psychological, and cultural implications of menstrual suppression, as well as the biomedical effects. We remain concerned that campaigns used to market cycle-stopping contraception depict the menstrual cycle as abnormal, undesirable, unnecessary and even unhealthy. Messages that women's natural functions are defective or need to be medically controlled can lead to negative body image, especially in young women.

Arguments for cycle-stopping contraception often describe debilitating menstrual cramps and heavy flow as indications, but promote routine use by all women who would prefer not to menstruate for matters of convenience. Cycle-stopping contraception may be useful for some medical conditions (such as severe endometriosis), but we caution against its use as “a lifestyle choice” until safety is firmly established. Although women in the US have been using oral contraceptives for nearly 50 years with no large-scale disasters, there is no precedent for *continuous* use of such large doses of hormones from the teen years to menopause. Women currently use oral contraceptives from their teens until their late twenties or early thirties, when they typically complete their families, and then they choose a more permanent method of contraception (either tubal ligation or vasectomy for their male partners).

Hormonal contraception is a valid and appropriate choice for many women. But historically, nasty surprises with hormonal therapies for women (e.g., heart disease and hormone therapy for menopausal women, the link between oral contraceptives and blood clots, DES and multiple health problems) have taken many years to surface. We note that Lybrel, Seasonale, and other contraceptives marketed for their cycle-stopping properties underwent clinical testing for only one year. Additionally, when any medication is evaluated for healthy women, the potential risks should be weighed more heavily than in situations when medication is considered to treat a disease. Menstruation is not a disease.

Some have claimed that women should be “free” to choose cycle stopping contraception. However, informed choices are only possible when reliable, accurate, and comprehensive information is widely available.

### **III. Conclusions**

We appreciate the opportunity to present our positions on women's health research to the ORWH at NIH. As indicated above, we endorse the four overarching themes identified by NIH in 2009 for addressing research on women's health: Lifespan, Sex/Gender Determinants, Health Disparities/Differences and Diversity, and Interdisciplinary Research. Medical research on sex hormones must be seen in terms of women's *health*, rather than disease. Future NIH research on women's health must include increased attention to prevention and wellness, and be appropriately situated in the diverse social and cultural contexts of women's lives and women's bodies. We in SMCR are keenly aware of the stigma and silence surrounding menstruation and related health issues, and

concerned about the implications of such taboo for women's access to accurate medical knowledge and health care.

Ultimately the evaluation of and recommendations for women's health must be made on rigorous scientific standards, incorporate prevention and wellness along with diagnosis and treatment, and reject underlying or explicit assumptions that menstruation and menopause are diseases or deficiencies.

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