Society for Women's Health Research

March 29, 2019

Submitted electronically to: *https://www.regulations.gov*

Vanila M. Singh, MD, MACM
Chief Medical Officer
Office of the Assistant Secretary for Health

Re: Docket No. HHS-OS-2018-0027 for "Request for Public Comments on the Pain Management Best Practices Inter-Agency Task Force Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations"

Dear Dr. Singh,

The Society for Women's Health Research (SWHR®) commends the significant, collaborative work of the Pain Management Best Practices Inter-Agency Task Force and its particular attention to the specific needs of women in relation to pain management.

SWHR is a nearly 30-year-old education and advocacy nonprofit dedicated to promoting research on biological differences in disease and improving women's health through science, policy, and education. SWHR strongly supports the task force's attention to the specific needs of women in this draft report as well as the emphasis on an individualized, patient-centered approach to addressing the public health pain crisis. We are pleased to provide comments on the following sections:

- 2.7.3 Unique Issues Related to Pain in Women
- 2.7.4 Special Populations: Pregnancy
- 3.1 Cross-Cutting Clinical and Policy Best Practices: Stigma
- 3.3.4 Access to Pain Care: Research

2.7.3 Unique Issues Related to Pain Management in Women
Women suffer from chronic pain and disability at increased rates in comparison to men.[i,ii] While the majority of those with chronic pain are women, pain studies have mostly used male subjects. Yet, research shows there are differences in how women and men process and respond to pain, and that women have lower pain reduction responses to opioids compared to men.[iii] Despite this evidence, biological sex differences are rarely considered in research, during treatment, or in the development of new pain therapies.[iv]

SWHR supports recommendation 1a, which highlights the need for increased research of sex differences in pain responses and mechanism-based therapies. As highlighted in a recent article in *Biology of Sex Differences*, consideration of sex and gender differences is essential to the development of a successful response to the opioid crisis.[v]

SWHR also commends the inclusion of recommendation 1b to raise awareness of the unique challenges that women face during pregnancy and in the postpartum period. This recommendation complements recommendations in 2.7.4 on pregnancy and 3.1 on stigma, discussed below. However, *SWHR encourages the task force to consider how chronic pain disproportionately affects women, not only during pregnancy and in the postpartum period, but overall across the lifespan (e.g., older women).*

2.7.4 Special Populations: Pregnancy
Each year, nearly 4 million women give birth and about 83% breastfeed.[vi,vii] Nearly 94% of pregnant women take at least one prescription or over-the-counter (OTC) medication during pregnancy, and over 50% of pregnant women take four or more prescriptions or OTC medications during pregnancy.[viii] Exclusion of pregnant women in research has led to significant knowledge gaps regarding the effects therapeutics could have on the fetus, the woman, the pregnancy, or the breast milk.

SWHR supports recommendation 1a to develop clinical best practices with regards to pain management specific to pregnant and postpartum women, in order to ensure the safety and well-being of both the mother and the fetus or newborn. However, *SWHR seeks clarification as to whether this recommendation includes breastfeeding women.* In addition to increased research on chronic pain management in pregnancy, *SWHR applauds recommendation 1b to counsel women of childbearing age on the risks of opioids and other medications in pregnancy.*

3.1 Cross-Cutting Clinical and Policy Best Practices: Stigma
Psychological and sociocultural influences play a large role in women's decision-making in relation to pain management. A 2011 study by the Institute of Medicine (IOM) of the National Academies of Sciences, Engineering, and Medicine found that not only did women appear to suffer from more pain than men, but women's reports of pain were more likely to be dismissed.[ix] For example, health care providers of women seeking diagnosis of endometriosis may trivialize pain symptoms or be quick to dismiss symptoms as "normal," leading to a provider-related delay in diagnosis.[x] As a consequence, women's pain continues to be improperly treated and managed.

SWHR commends the Task Force's focus on addressing stigma (gap 1) for chronic pain patients and supports recommendations 1a-d of the draft report:

1a: Increase patient, physician, other health care provider, and societal education on the underlying disease processes of acute and chronic pain to reduce stigma.
1b: Increase patient, physician, other health care provider, and societal education on the disease of addiction.
1c: Counter societal attitudes that equate pain with weakness through an awareness campaign that urges early treatment for pain that persists beyond the expected duration for that condition or injury.
1d: Encourage research aimed at discovering biomarkers for neurobiological mechanisms of chronic pain.

*However, stigma specific to women should be addressed in the draft report. SWHR recommends amending recommendation 1d to read: "Encourage research, **including sex differences research**, aimed at discovering biomarkers for neurobiological mechanisms of chronic pain."*

3.3.4. Access to Pain Care: Research
Despite national policies that require the inclusion of women in research, large gender gaps still exist, negatively affecting the breadth of understanding about many diseases and conditions — particularly those related to chronic pain — as well as the best treatment course and the development of therapies, specifically for women.[xi] *SWHR recommends including sex differences research for recommendations 1a (funding of), 2a, 3a, 3b, and 4a:*

1a: Increase federal (and state) funding through the NIH, DoD, and other agencies to support and accelerate basic science, translational, and clinical research of pain. Allocate funding to develop

innovative therapies and build research capabilities for better clinical outcomes tracking and evidence gathering.

2a: Improve understanding of the specific interplay of genetic and experiential contributions to pain, including identification of biomarkers, factors that play a role in persistent pain and eventually chronic pain, the role of comorbid conditions, and predictive risk factors.

3a: Further evaluate the lifelong risk factors for the development of SUD rather than the isolated evaluation of prescription opioid use (e.g., adolescent substance use, early life trauma).

3b: Conduct research to identify biomarkers, genetic predisposition, and other patient factors to assist in improved and accurate identification of those patients at risk for SUD and addiction disease.

4a: Increase the levels of research into novel strategies that target the underlying mechanisms of chronic pain, including pharmacologic and biologic research and development, medical devices, new and innovative technological advancements, medication delivery systems, neuromodulation, regenerative medicine, and complementary and integrative health approaches, as well as movement-based modalities.

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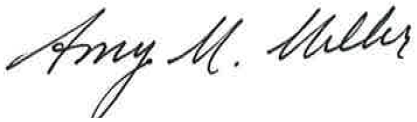
Thank you for providing SWHR this opportunity to comment on Docket No. HHS-OS-2018-0027 and for your consideration of the above comments. We look forward to serving as a resource on this important health issue, particularly as it affects women's health. If you have questions, please contact Sherie Lou Santos, Director of Science Policy, at 202.496.5006 or sherielou@swhr.org.

Sincerely,



Amy M. Miller, PhD
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