

March 10, 2021

Joint Arthritis Advisory Committee  
Drug Safety and Risk Management Advisory Committee  
Food and Drug Administration  
HHS

RE: Docket FDA-2021-N-0134

Dear Advisory Committee Members:

- HealthyWomen is the nation's leading nonprofit health information organization for women, representing more than 18 million women. We provide consumers and healthcare providers accurate, evidence-based information about diseases and conditions, innovations in research and science, and changes in policy that affect women's access to treatment and care.
- We thank you for the opportunity to provide input and comments in support of nonaddictive treatment for chronic pain.
- Osteoarthritis (OA) is a chronic pain condition. According to the CDC, chronic pain affects one in three women and an estimated 11.3 million women live with high-impact chronic pain.
- African American and Chinese women are at a higher risk for developing knee OA compared to Caucasian women. African American women also have greater pain and functional limitations than Caucasian women.
- Similarly, [racial and ethnic minority women](#) are less likely than Caucasian women to receive any or adequate pain treatment.
- [Chronic overlapping pain conditions](#), which are two to three times more prevalent in women than men, make treatment of chronic pain more difficult. This can have a significant impact on quality of life for women.
- Many [challenges exist in treating and managing chronic pain in women](#). For example, currently available drug therapies for chronic pain conditions have limited efficacy and safety but also do not work similarly in women and men. This requires recognizing existing biological differences in pain but also analyzing clinical trial data and reporting of data by sex in outcomes and side effects. This can then help to educate both providers and patients as they make informed healthcare decisions together.
- Besides sex and gender, other factors such as age, race, ethnicity, genetics and diet can also affect chronic pain. Providing healthcare practitioners with options for their diverse patient populations is critically important. Therefore, new treatments and approaches are needed to treat and manage chronic pain to allow for a [personalized approach to chronic pain](#) management in the future.

- Further, providing [novel treatment options for OA](#) allows those living with the disease to remain active, especially women who are often juggling work, family and caregiving while living with debilitating chronic pain. This in turn will also make chronic pain management affordable and accessible for all women.
- Last year, HealthyWomen led a group effort ([sign-on-letter](#)) of 33 organizations to the FDA and NIH encouraging them to ensure that new nonaddictive pain treatments are available for patients. We also urged the FDA to expeditiously and effectively move forward with the various provisions of the SUPPORT ACT. A similar sentiment was recently echoed in a letter to the FDA commissioner by the [National Association of Attorneys General](#) urging the FDA to make available nonopioid, nonaddictive alternatives for treatment of pain.
- In addition, we want to note the important pain report by the [National Governors Association](#) on expanding access to nonopioid management of chronic pain.
- In conclusion, we present this information in an effort to ensure that the FDA understands the biological differences of the pain experience and the influence of other factors on these differences. Additionally, we hope the FDA understands the urgent need for novel nonaddictive pain treatment for women, as this disease affects millions of Americans and disproportionately impacts women, and particularly women of color.
- We look forward to continuing to work with the FDA and thank all of you again for the work you're doing to ensure that safe and effective treatments are available for chronic pain.

Sincerely,

Monica Mallampalli, PhD  
Senior Advisor, Scientific and Strategic Initiatives  
HealthyWomen