

**Board of Directors**

November 30, 2017

**Amy M. Miller, PhD**  
President and CEO  
Society for Women's Health  
Research

**Submitted electronically to:** publiccomments@icer-review.org

**John J. Seng**  
Board Chair  
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Communications

Steven D. Pearson, MD, MSc, President  
Institute for Clinical and Economic Review  
Two Liberty Square, Ninth Floor  
Boston, MA 02109

**Florence P. Haseltine, PhD,  
MD**  
Haseltine Systems  
Secretary-Treasurer / Founder

Re: Open Input on ICER 2017-2018 Review of Migraine

Dear Dr. Pearson:

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**Anne B. Cropp, PharmD**  
Early Access Care, LLC

The Society for Women's Health Research (SWHR®) appreciates the opportunity to provide initial input to the Institute for Clinical and Economic Review (ICER) as it prepares to analyze and evaluate the evidence on the effectiveness and value of drugs for migraine.

**Shontelle Dodson, PharmD**  
Astellas Pharma, Inc.

SWHR is a nonprofit organization based in Washington, DC that is widely recognized as a thought leader in promoting research on biological differences in disease. We are dedicated to eliminating imbalances in care for women through science, advocacy, and education. Because of SWHR's advocacy efforts, women are now routinely included in most major medical research studies, and scientists are required to consider sex and gender as variables in their research. Biological sex is defined as the classification of living things as female or male based on the complement of sex chromosomes and the presence of reproductive organs.<sup>1</sup> Gender refers to a complex psychosocial construct that takes into account not only biology but also the influences of society and the environment.<sup>2</sup>

**Roberta Gartside, MD**  
New Image Plastic Surgery  
Associates, PLC

**Nieca Goldberg, MD**  
Joan H. Tisch NYU Langone  
Center for Women's Health

**Dawn Halkuff, MBA**  
TherapeuticsMD

**Carol Kelly, MA, MPA**  
Kelly Advocacy Outcomes, LLC

**David C. Page, MD**  
Whitehead Institute

**Gretta Stone**  
PhRMA

**Judith K. Wolf, MD, MS**  
Provista Diagnostics, Inc.

Migraine is a debilitating neurological condition affecting more than 47 million Americans – 14% of the United States population – and affects women differently than men.<sup>3</sup> Because women are disproportionately affected by migraine, ICER should take sex and gender differences into consideration in its assessment of migraine.

<sup>1</sup> Institute of Medicine. 2001. *Exploring the Biological Contributions to Human Health: Does Sex Matter?*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/10028>.

<sup>2</sup> Ibid.

<sup>3</sup> GBD 2016 Disease and Injury Incidence and Prevalence Collaborators. *Lancet*. 2017 Sep 16;390(10100):1211-1259. doi: 10.1016/S0140-6736(17)32154-2.

Migraine is two to three times more common in women than men. The highest prevalence occurs between the ages of 18 and 49,<sup>4</sup> during a time when many women are in the middle of their careers. Women are more likely than men to experience longer and more intense migraines, report more migraine-associated symptoms such as nausea and visual aura, and have higher levels of headache-related disability.<sup>5,6</sup> Women with migraine also have more comorbid conditions than men with migraine, with an average of 11 and 5 comorbid conditions, respectively.<sup>7</sup>

Migraine is a serious public health issue with social and economic consequences. Women account for 80 percent of direct and indirect costs associated with migraine in the United States, which are upwards of \$36 billion each year.<sup>8,9</sup> And yet, migraine remains a poorly understood disease that is often undiagnosed and undertreated. Seeking and receiving care for migraine also varies by gender. Women are more likely than men to receive a migraine diagnosis, but less likely than men to receive appropriate treatment.<sup>10,11</sup>

Managing migraine with appropriate treatments has the potential to improve health quality significantly and thus reduce the social and economic burdens associated with this disease. SWHR urges ICER to incorporate the extended impact and burden migraine has on individuals, families, the workplace, and the economy in its evidence analysis and evaluation. Not doing so could lead to an undervaluation, thereby depriving patient access to innovative needed treatments.

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SWHR appreciates the opportunity to provide the above initial input as ICER commences its value assessment of therapies for migraine, and we look forward to serving as a resource on this important topic.

If you have questions or if we can provide further information to inform ICER's analysis, please contact Sarah Wells Kocsis, Vice President of Public Policy, at 202.496.5003 or [swellskocsis@swhr.org](mailto:swellskocsis@swhr.org).

Sincerely,



Amy M. Miller, PhD  
President and Chief Executive Officer  
Society for Women's Health Research

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<sup>4</sup> Buse et al. *Headache*. 2013 Sep 28;53(8):1278-99. doi: 10.1111/head.12150. Epub 2013 Jun 28.

<sup>5</sup> Ibid.

<sup>6</sup> Bolay et al. *Cephalalgia*. 2015 Aug;35(9):792-800. doi: 10.1177/0333102414559735. Epub 2014 Nov 25.

<sup>7</sup> Le et al. *Cephalalgia*. 2011 Jan 2;31(1):43-64. doi: 10.1177/0333102410373159. Epub 2010 Jun 2.

<sup>8</sup> Migraine Research Foundation, available at: <http://migraineresearchfoundation.org/about-migraine/migraine-facts/>

<sup>9</sup> Hu et al. *Arch Intern Med*. 1999 Apr 26;159(8):813-8. doi: 10.1001/archinte.159.8.813.

<sup>10</sup> Lipton et al. *Headache*. 2013 Jan;53(1):81-92. doi: 10.1111/j.1526-4610.2012.02265.x. Epub 2012 Oct 18.

<sup>11</sup> Buse et al. *Headache*. 2013 Sep 28;53(8):1278-99. doi: 10.1111/head.12150. Epub 2013 Jun 28.