Society for Women's Health Research

November 3, 2015

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

To Whom It May Concern:

The Society for Women's Health Research (SWHR®) greatly appreciates the opportunity to respond to the Food and Drug Administration's (FDA) request for comments on "Acute Ischemic Stroke Medical Devices Trials." SWHR, a national non-profit organization based in Washington, D.C., is widely recognized as the thought leader in promoting research on sex differences and is dedicated to improving women's health through advocacy, education, and research. SWHR supports the development of technologies to prevent morbidity and mortality due to acute ischemic strokes and provides the following thoughts regarding premarket content submissions by sponsors of such products.

Medical devices assisting patients who have had or are likely to experience an acute ischemic stroke is of great importance to the women's health community. Women are more likely than men to experience strokes at an older age, likely due to the protective effects of estrogen[1]. In addition, women are also more likely to suffer more severe strokes than men followed by complications such as post-stroke depression, lower quality of life, or death[1-2].

While stroke treatments appear to work well for both genders, women are still inadequately represented in clinical trials focused on products mitigating cardiovascular disease[3]. Researchers believe this may be a result of study entry criteria focused solely on stroke symptoms that are seen more commonly in men, while overlooking other symptoms that may be prevalent in female stroke patients[3]. This oversight is deeply troubling as women have smaller arteries and hearts than men, resulting in the potential development and approval of medical devices that are "too large" for the female cardiovascular system[2].

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As a result, SWHR respectfully requests FDA to mandate sponsor reporting and analysis of medical device trial results by sex in premarket content submissions. In addition, FDA should work with sponsors throughout the development process to ensure adequate selection and inclusion of women and men in all phases of the clinical trials. Sponsors should ensure that their study population accurately reflects the patient population most likely to use their medical devices when they reach the market in order to truly measure the safety and efficacy of such treatments.

Thank you for the opportunity to comment, we look forward to reviewing and commenting on the associated guidance when it becomes available.

Sincerely,

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[1] Appelros P, Stegmayr B, Terent A. A review on sex differences in stroke treatment and outcome. *Acta Neurol Scand.* 2010 Jun;121(6):359-69.
[2] Haast RA, Gustafson DR, Kiliaan AJ. Sex differences in stroke. *J Cereb Blood Flow Metab.* 2012 Dec;32(12):2100-7.
[3]Committee on Women's Health Research. 2010. *Women's Health Research: Progress, Pitfalls, and Promise*. Washington, DC: The National Academies Press. Institute of Medicine.

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