October 30, 2015

Division of Dockets Management (HFA-305)
U.S. 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®) is pleased to submit a response to the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) request for comments on updated medical device labeling guidance for industry. 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. Our response will address the following patient and consumer concerns regarding medical device labeling; including health literacy and the appropriateness of label content for specific audiences.

## *Comments on Current Medical Device Labeling Guidance*

Voluntary standards provide guidance for industry as they develop medical device labels for public use. These standards are designed to ensure that labels reach their intended population with pertinent information as well as instructions on use that are appropriate and easily understood by patients. In addition, voluntary standards should provide a uniform outline for labeling structure—helping patients who may be using multiple medical devices to identify needed information quickly.

SWHR applauds FDA for taking the lead in developing a two-day public workshop on this issue. FDA should continue to lead such workshops or meetings (including webcast opportunities) that bring together patient and advocacy groups, academic and professional organizations, industry, standards organizations, and government agencies to discuss and address medical device labeling needs throughout the entire FDA guidelines development process.



1025 Connecticut Avenue, NW | Suite 601| Washington, D.C. 20036 Phone 202-223-8224 | Fax 202-833-3472 |SWHR.org

We believe the labeling guidance process needs to be flexible to allow for input from all stakeholders prior to drafting and finalizing the guidance. Additionally, we believe that stakeholder engagement should not end with the final guidance. FDA should continue stakeholder meetings to discuss updates, newly perceived barriers, or changes that should be made as a result of implementation.

***Comments on Medical Device Labeling Needs Prioritization & Assessment***

FDA and industry should consider three questions when determining priority areas for medical device labeling development, review, and approval.

1) Is it demographically appropriate? Labels should reflect an understanding of the population targeted for use of the device. For example, is it more likely older or younger people may use it? Or men rather than women? For men and women, will height and weight differences affect their use of the device?

2) What is the context in which patients receive medical device labels? The labels and/or devices should include instructions for clinicians on when to give labeling to patients and how to help answer any initial questions on appropriate device use. FDA should also specify the appropriate types of devices that need to have patient labeling attached.

3) Can patients understand it? Continuing to ensure labeling is clear and written in an easy-to-understand format, is paramount to ensuring compliance to instructions and harm avoidance. A recent study by the Organization for Economic Cooperation and Development[i] found that U.S. adults were among the least likely to reach a literacy level 2 out of 5 in the 23 countries studied. Level 2 literacy reflects an adult's ability to integrate two or more pieces of information together, make low-level inferences, and navigate digital texts to access and identify information.

   Additionally, FDA should ensure that labels are culturally appropriate as well. Given the changing cultural dynamics in the United States, labels should be printed and available in both English and Spanish at a minimum. Additional languages could be made available on the manufacturer's website.

To conduct a successful needs assessment of medical device labeling, FDA should utilize its various stakeholder communities (patient and advocacy groups, academic and professional organizations, industry, and standards organizations) to develop the needs assessment questions. This could be a focus area for additional public workshops or stakeholder meetings.

FDA should continue the relationship it has built with these stakeholders by encouraging them to take the assessment as well as disseminate it to their constituencies. Developing an online survey targeting each stakeholder group would facilitate dissemination efforts and improve response by a wide variety of groups.



1025 Connecticut Avenue, NW | Suite 601| Washington, D.C. 20036 Phone 202-223-8224 | Fax 202-833-3472 |SWHR.org

***Comments on Advancing Development of Medical Device Patient Labels***

Alerting patients and clinicians to the importance of these labels will greatly assist in advancing the use of medical device patient labeling. Many patients may be using a medical device for the first time and will not realize they should be receiving a patient label. Public education will be needed to inform patients that they should be receiving a label/information sheet every time they are prescribed a device as well as what they should expect to see on them. A similar education campaign can be conducted in partnership with medical professional societies to alert clinicians to providing and reviewing labels with patients, ensuring any questions are answered prior to use.

As previously mentioned, FDA should seek comments from industry on developing appropriate medical device label guidance. Manufacturers should be involved in the guidance development process and support it prior to final release.

The end product of an easy-to-read and understand document should be the goal at all medical device labeling developmental stages. Often, patients or their caregivers will be the only people with prolonged exposure to this device so it is important to be able to communicate risks, instructions, and basic troubleshooting directly to them. FDA should continue to advocate for adequate patient testing (via focus groups, interviews, usability, etc.) throughout the guidance development process.

In addition to registries, patient advocacy groups, and other industry partners, FDA and industry should seek input and expertise from medical professional societies and customer warranty databases to advance the development of medical device patient labeling.

Medical professional societies will be able to provide labeling advice from a clinical perspective, such as whether a particular device would truly need a patient label. In addition, these societies could disseminate information encouraging their members to read and provide these labels to their patients.

Outside of patient registries, industry can reach out to customers who have provided contact information for device warranties. Outreach efforts may include updates on changes to or risks of the current device that may impact use. Industry could also seek customer participation in focus groups on medical device labeling for similar products under development.

Finally, SWHR recommends FDA encourage industry to conduct test marketing and usability trials among diverse subgroups and develop device use recommendations strongly weighing subgroup analysis of such tests. Different sexes, age groups, and cultural backgrounds will understand the information provided in a label differently. As a result, industry should collect data on the usability of the device



1025 Connecticut Avenue, NW | Suite 601| Washington, D.C. 20036 Phone 202-223-8224 | Fax 202-833-3472 |SWHR.org

label among a diverse population of patients that would need it (i.e. women, men, elderly, etc.).

For example, certain labels may need to list that those "under height X" should adjust the device for proper use, as particular subgroups may not find that intuitive. However, manufacturers may not know this unless label usability was tested in diverse populations. While it would be unlikely for a manufacturer to create a separate label for each group, ensuring recruitment of a diverse group of patients as well as analyzing their feedback by subgroup could identify nuances in language that need to be changed prior to its final release.

Thank you for the opportunity to provide comments. We look forward to reviewing the draft guidance when it becomes available.

Sincerely,

Andrea L. Lowe, MPH, CPH
Health Policy Analyst

Leslie Ritter, MA
Vice President, Public Policy

[i] OECD (2013), *OECD Skills Outlook 2013: First Results from the Survey of Adult Skills,* OECD Publishing. http://dx.doi.org/10.1787/9789264204256-en



1025 Connecticut Avenue, NW | Suite 601| Washington, D.C. 20036 Phone 202-223-8224 | Fax 202-833-3472 |SWHR.org