Waiver to Allow Participation in a Food and Drug Administration Advisory Committee

DATE: August 3, 2023

TO: Russell Fortney
Director, Advisory Committee Oversight and Management Staff
Office of the Chief Scientist

FROM: CDR Daniel Bailey, M.S., M.B.A., M.DIV, COR III
Assistant Director, Committee Management and Planning
Division of Management Services, Office of Management
Center for Devices and Radiological Health (CDRH)

Name of Advisory Committee Meeting Member: Stephen B. Wilcox, Ph.D., FIDSA

Committee: Patient Engagement Advisory Committee (PEAC)

Meeting date: September 6, 2023

Description of the Particular Matter to Which the Waiver Applies:

On September 6, 2023, the committee will discuss and make recommendations on the topic of "Advancing Health Equity in Medical Devices." The recommendations provided by the committee will address considerations for FDA and industry on these topics. The committee will consider ways to advance access to devices that allow for care outside a hospital or clinical care setting, for example, in the home setting. The committee will also discuss considerations for improving reach and comprehension of FDA's patient and caregiver communications, across diverse demographic groups. Additionally, the committee will discuss patient-focused considerations for when a device should be evaluated in diverse populations to support marketing authorization.

The meeting type is a particular matter of general applicability. The PEAC will discuss general topics, no specific marketing applications will be discussed, and the discussion will not focus on approval, ongoing approval, or conditions of approval of any specific products. The particular matter will affect any medical device firms/products that allow for care outside a hospital or clinical care setting, for example in the home.

Type, Nature, and Magnitude of the Financial Interest(s):

Dr. Wilcox, a temporary non-voting member to the PEAC, reported he is a Principal and the Founder of Design Science, and also services as Chairman of the Board. The organization provides various combinations of human factor support, usability studies, development of instructions for use, and labeling on consulting contracts/projects with numerous medical device firms that could be affected by the particular matter. Specifically, the following medical device manufacturers are clients of Design Science and have paid or will pay the specified amounts to Design Science for services in 2022 through 2024:

- (b)(4) : between $100,000 and $250,000
- (b)(4) : between $25,000 and $50,000
- (b)(4) between $250,000 and $500,000, (plus additional payment for a project whose value is yet to be determined)
- (b)(4) between $50,000 and $100,000
- (b)(4) between $100,000 and $250,000
- (b)(4) between $25,000 and $50,000
- (b)(4) between $25,000 and $50,000
- (b)(4) between $50,000 and $100,000
- (b)(4) between $10,000 and $25,000

Basis for Granting the Waiver:

Dr. Wilcox has unique qualifications and specialized expertise needed for this matter.

Stephen B. Wilcox, Ph.D., FIDSA is the Founder and Chairman of the Board of Design Science, a 40-person firm with offices in Philadelphia, Pennsylvania; Evanston, Illinois; and Munich, Germany. The firm specializes in research to support the usability of products, particularly those that are healthcare related. He is also an Adjunct Professor in the Integrated Product Design Program at the University of Pennsylvania. Dr. Wilcox has a Ph.D. in Experimental Psychology from Penn State, a B.S. in Psychology and Anthropology from Tulane, and a Certificate in Business Administration from the Wharton School of the University of Pennsylvania.

He is one of the pioneers of ethnographic field research/contextual inquiry. He has published over 70 articles in professional journals and was the recent Editor in Chief of the Human Factors journal Ergonomics in Design. He has chaired the Include conference at the Royal College of Art in London and the annual meeting of the Industrial Designers Society of America. He serves on a number of standards committees and has served on the board for the Design Departments of Carnegie Mellon and Jefferson Universities.

His book with Michael Wiklund, Designing Usability into Medical Products, was published in 2005. Dr. Wilcox's expertise in Human Factors, Medical Product Development and Safety Engineering will make him a valuable contributor to the deliberations at the advisory committee meeting.

There is limited expertise available, and it is difficult to locate similarly qualified individuals without a disqualifying financial interest.

The CDRH division responsible for the advisory committee has struggled to find qualified patient experts with expertise in medical devices who were similarly qualified, without disqualifying conflicts of interest and who could participate in the committee meeting. To date, multiple experts had to be excluded due to unavailability and conflicts. Human Factors cover several areas of research that includes technology, design, human performance and human-computer interaction. It's extremely difficult to find experts that do not have some involvement with device companies. Dr. Wilcox's conflict exists because he serves as the Chairman of the Board of Directors for Design Sciences, which has consulting relationship that are unrelated to the matter before the committee with numerous entities affected by the particular matter. His conflict is less critical because the committee topic is about general matters relating to medical device health equity, and not related to any specific medical device.

The matter is not sensitive.

There is no specific device being evaluated by the advisory committee for this meeting. This topic is not considered sensitive because Health Equity in Medical Devices has been a subject of concern for several years. The interest in this matter reinforces the need to have the appropriate experts on this committee to provide FDA with important insights and feedback. The committee discussion, deliberations, and recommendations will not focus on individual devices or manufacturers, but on the "Advancing Health Equity in Medical Devices" topic as a whole.

Dr. Wilcox's expertise in this matter is necessary in the interest of public health.

In the interest of public health, FDA CDRH is committed to working toward ensuring that all patients have access to high-quality, safe, and effective medical devices. This includes ensuring devices are designed to be safe and effective when used by various populations, are evaluated in the diverse populations for which they are intended, and that patients and consumers have the information they need to make decisions about their healthcare and quality of life. Technology, including digital health technology, may help bridge gaps in health equity by extending access and bringing healthcare to patients at home, at work, and in their communities. Dr. Wilcox's knowledge of Human Factors, Medical Product Development and Safety Engineering will provide the necessary expertise for this discussion.

Any potential for a conflict of interest is greatly outweighed by the strong need for Dr. Wilcox's expertise in this matter.

The committee is not evaluating any specific device. Dr. Wilcox's consultant role is primarily to provide research to support the usability of products, particularly those that are healthcare-related, to medical device firms, whose specific devices are not being evaluated during the

meeting. Dr. Wilcox's expertise includes ethnographic field research/contextual inquiry and he has published over 70 articles in professional journals, which makes his perspective highly valuable to the PEAC discussion topic. Therefore, it is essential that Dr. Wilcox be considered for participation as a temporary non-voting member at this committee meeting. We believe any potential conflict of interest created by this situation is greatly outweighed by the FDA's particularly strong need for the services of Dr. Wilcox in the matter before the committee. In addition, the matter under consideration by the committee is one of general applicability and will not focus on any specific company, medical device, or application. Therefore, his substantial work and experience in the topics identified above will greatly contribute to the success of this advisory meeting.

Accordingly, I recommend that you grant Dr. Wilcox, a temporary non-voting member of the Patient Engagement Advisory Committee, a waiver from the conflict-of-interest prohibitions of 18 U.S.C. § 208(a).

Certification:

____**X**___ The individual may participate, pursuant to 18 U.S.C. 208(b)(3) – The need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved.

Limitations on the Regular Government Employee's or Special Government Employee's Ability to Act:

____**X**___ Non-voting

_____ Other (specify):

_____

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_____ Denied – The individual may not participate.

_____**/S/**_____ __**August 21, 2023**____

Russell Fortney
Director, Advisory Committee Oversight and Management Staff
Office of the Chief Scientist

Date