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

DATE: June 14, 2022

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: Omer Liran, M.D.

Committee: Patient Engagement Advisory Committee (PEAC)

Meeting date: July 12-13, 2022

Description of the Particular Matter to Which the Waiver Applies:

On July 12-13, 2022, the committee will discuss and make recommendations on the topic of "Augmented Reality (AR) and Virtual Reality (VR) Medical Devices." AR/VR devices are increasingly applied to healthcare settings across the patients' care continuum. From diagnostics to clinical decision making, to surgical support, and to directly treating patients, AR/VR devices are used across multiple medical specialties. These devices have novel attributes and considerations for the end users that impact FDA's evaluation of the device's safety and effectiveness. The novel attributes of digital health visualization, tracking techniques, and embedded software among other factors present unique challenges for pre and postmarket evaluation. The recommendations provided by the committee will address factors FDA and industry should consider when evaluating the benefits, risks, and the extent of uncertainty in the benefit-risk information for AR/VR medical devices.

The committee will also consider specific challenges related to specific populations (e.g., pediatric or cognitively impaired) who may use this technology. Additionally, the committee will discuss ways patient perspectives could be incorporated in FDA and industry benefit-risk decision making, as well as the healthcare provider decision-making process related to using or prescribing the technology.

The topic of this meeting 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 product. The particular matter will affect entities that make or are seeking to make AR/VR medical devices.

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

Omer Liran, M.D., serves as a temporary non-voting member for the Patient Engagement Advisory Committee, which provides advice to the Commissioner of Food and Drugs on complex scientific issues related to medical devices, the regulation of devices, and their use by patients.

Dr. Liran is identified as a co-inventor and developer of a VR software application to run on various headsets (VR cognitive behavioral therapy (CBT) intervention for irritable bowel syndrome (IBS)) for his employer, Cedars-Sinai Medical Center. His employer funded and owns the software's IP. This VR software application is only being used for research at this time. There is no current software agreement, but the Cedars-Sinai Medical Center's Tech Transfer office may choose to license it to a third-party vendor in the future. Dr. Liran, his employer and the other co-inventor are entitled to revenue if the software is commercialized in the future.

Basis for Granting the Waiver:

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

Dr. Liran is an Assistant Professor in the Department of Psychiatry & Behavioral Neurosciences at Cedars-Sinai Medical Center in Los Angeles, California (CA) where he co-directs Virtual Medicine and cares for patients on the psychiatry consult and liaison service. Dr. Liran received his B.Sc. in Neuroscience from the University of California, Los Angeles, CA and received his M.D. at the Sackler School of Medicine. Academically, Dr. Liran is studying how to leverage the unique properties of AR/VR technologies to improve outcomes in patient care. He has also been using AR/VR together with EEG to study neural mechanisms that underly human behaviors and psychiatric pathologies. Dr. Liran has an extensive programming background which enables him to code and quickly iterate AR/VR experiences based on patient feedback. He is well published and highly respected in the AR/VR field. Dr. Liran's expertise in psychiatry and studying AR/VR devices in different patient populations will be vital to the discussion and deliberations for this advisory committee meeting.

Dr. Liran has the critically-needed training and experience that the advisory committee requires to make informed recommendations to FDA about the benefits and risks for AR/VR medical devices. His expertise and experiences as a psychiatrist will make him a valuable contributor to the deliberations at the advisory committee meeting. The panel staff and CDRH division responsible for review of this product have reviewed the qualifications of clinicians who work with AR/VR devices, all with financial or scheduling conflicts. The committee requires AR/VR devices experts to conduct productive deliberations during this important 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 expert psychiatrists with expertise in AR/VR devices without disqualifying conflicts of interest and who could participate in the committee meeting. To date, multiple experts had to be recused due to unavailability and conflicts. Dr. Liran will be one of the few experts in his specialty area that can participate in the meeting. Because a significant number of clinicians who work with AR/VR devices are employed by industry, and have limited expertise in this area, it is difficult to find experts, sites and investigators that do not have direct involvement with potential device sponsors. Dr. Liran's conflict is that he has a co-inventor/developer role on a VR CBT for IBS device and future licensing potential of the VR device.

The particular 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 this is a particular matter of general applicability meeting. This emerging technology has been a subject of research and investigation for several years.

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

The July 12-13, 2022, Patient Engagement Advisory Committee meeting will discuss the benefits and risks of AR/VR medical devices intended to treat and diagnose patients in several clinical areas. Further, in the interest of public health, it is critical for the agency to review new products that can potentially provide device advancement in the area of digital health technologies and include advisory committee members with comprehensive knowledge of psychiatry consistent with the current standard of care, and situations in which AR/VR devices are a viable treatment or diagnostic option patients including for underserved and vulnerable patient populations. Dr. Liran's knowledge of psychiatry and VR devices will provide the necessary expertise for this important discussion.

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

Dr. Liran is one of the very few clinicians who does not work directly for industry in the AR/VR space. FDA was unable to find any other individual with Dr. Liran's level of expertise who was available to participate and who did not have a more significant conflict of interest. Therefore, it is essential that Dr. Liran 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. Liran in the matter before the committee. In addition, the matters under consideration by the committee are ones of general applicability and will not focus on any specific company, medical device, or application. Therefore, Dr. Liran should be allowed to attend this upcoming advisory committee meeting because his substantial work and experience in psychiatry and AR/VR devices are imperative to the success of this meeting.

Accordingly, I recommend that you grant Omer Liran, M.D., 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/ **June 22, 2022**

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

Date