U.S. FOOD & DRUG ADMINISTRATION

TO: Steven Kozlowski
Chief Scientist
Food and Drug Administration (FDA)

FROM: Asim A. Akbari
Director, Office of Ethics and Integrity
Food and Drug Administration (FDA)

SUBJECT: Conflict of Interest Waiver for Dr. Hussein Tawbi under 18 U.S.C. § 208(b)(3) for Participation on the Cellular, Tissue, and Gene Therapies Advisory Committee (CTGTAC) Meetings on July 30, 2026

ISSUE

The purpose of this memorandum is to grant a limited waiver from the provision of the federal financial conflict of interest law, 18 U.S.C. § 208, for Dr. Hussein Tawbi, as a member of the Cellular, Tissue, and Gene Therapies Advisory Committee when it meets on July 30, 2026, for deliberation and recommendations on issues related to BLA 125827 from Replimune, Inc. for vusolimogene oderparepvec for the treatment, in combination with nivolumab, of adult patients with unresectable advanced cutaneous melanoma who experienced disease progression with a programmed death receptor-1 (PD-1)-blocking antibody-based regimen.

DISCUSSION

The criminal conflict of interest statute, 18 U.S.C. § 208(a) prohibits government employees, including special government employees (SGEs), from participating personally and substantially in particular matters that may have a direct and predictable effect on the employee's personal financial interests or the financial interest of certain organizations with which they are affiliated (including their employers) and other persons whose interests are imputed to them such as spouses, minor children, or general partners.

The term "particular matters" covers two categories of matters: (1) those that involve specific parties, and (2) those that do not involve specific parties but at least focus on the interests of a discrete and identifiable class of persons, such as a particular industry or profession. The first category "typically involves a specific proceeding affecting the legal rights of the parties, or an isolatable transaction or related set of transactions between identified parties." 5 C.F.R. § 2640.102(1). Examples of particular matters involving specific parties include contracts, grants, licenses,

product approval applications, investigations, and litigation. The U.S. Office of Government Ethics (OGE) regulations sometimes refer to the second category of particular matters as "particular matter of general applicability." 5 C.F.R. § 2640.102(m). This category can include legislation and policymaking, as long as it is narrowly focused on a discrete and identifiable class. Examples provided by OGE include a regulation applicable only to meat packing companies or a regulation prescribing safety standards for trucks on interstate highways. 5 C.F.R. § 2640.103(a)(l)(example 3); 5 C.F.R. § 2635.402(b)(3)(example 2).

Under 18 U.S.C. § 208(b)(3), an employee's appointing official may grant a waiver of this prohibition to an SGE serving on a federal advisory committee, such as the CTGTAC, when the individual has made full disclosure of the financial interests at issue and when the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved. As FDA's Chief Scientist, you have authority to serve as appointing official for members of the CTGTAC.

The Cellular, Tissue, and Gene Therapies Advisory Committee (CTGTAC) reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of human cells, human tissues, gene transfer therapies and xenotransplantation products which are intended for transplantation, implantation, infusion and transfer in the prevention and treatment of a broad spectrum of human diseases and in the reconstruction, repair or replacement of tissues for various conditions.

On July 30, 2026, the Advisory Committee will deliberate and make recommendations on issues related to BLA 125827 from Replimune, Inc. for vusolimogene oderparepvec for the treatment, in combination with nivolumab, of adult patients with unresectable advanced cutaneous melanoma who experienced disease progression with a programmed death receptor-1 (PD-1)-blocking antibody-based regimen. The topic for this meeting is a particular matter involving specific parties.

The matter on which CTGTAC will focus at its July 30 meeting may affect certain financial interests of Dr. Tawbi's employer, whose interests are imputed to him.

Interest

Based upon a review of Dr. Tawbi's most recent confidential financial disclosure report (OGE 450) and discussions about his financial interests and those interests imputed to him, Dr. Tawbi does not have any personal financial interest that would be affected by this particular matter. Since he is employed with University of Texas MD Anderson Cancer Center (MDACC), the conflict of interest law imputes the financial interest of MDACC to Dr. Tawbi.

The ethics regulations provide an exemption to allow an SGE serving on an advisory committee within the meaning of the Federal Advisory Committee Act (5 U.S.C. app.)

to participate in any particular matter of general applicability where the disqualifying financial interest arises from his non-Federal employment, provided that the matter will not have a special or distinct effect on the employee or employer other than as part of a class. See C.F.R. § 2640.203(g). Dr. Tawbi cannot avail himself of this exemption because the July 30 meeting is considered a particular matter involving specific parties, namely Replimune Inc.

MDACC is a world-renowned cancer center in Houston, Texas and part of the University of Texas System. It is extensively involved in cancer treatment and research including clinical trials. It is one of many institutions participating in the IGNYTE-3 clinical trial studying Replimune Inc.'s oncolytic immunotherapy vusolimogene oderparepvec in combination with nivolumab to treat advanced melanoma, which is the subject of Replimune's BLA being considered at the July 30, 2026, CTGTAC meeting.

The Office of Legal Counsel (OLC), in the Department of Justice opined that OGE's regulations interpret the words "financial interest" "in" "a particular matter" to require a link between a governmental matter and a *pecuniary gain or loss* to the employee or specified entity. A disqualifying financial interest is "the potential for gain or loss to the employee, or other person specified in section 208, as a result of governmental action on the particular matter." See FAA Opinion, 28 Op. O.L.C. at 239–40; OGE, *Letter to Designated Agency Ethics Official*, Informal Advisory Ltr. 85x10, 1985 WL 57309, at *2 (July 15).

Dr. Tawbi is merely a salaried employee of MDACC. Based on our discussions with Dr. Tawbi, the July 30 meeting would not affect his personal compensation in any way. In this case, it is especially challenging to determine how this meeting may have a pecuniary gain or loss to MDACC, because while MDACC generally has clinical trial agreements with companies that elaborate the details of each project including financial arrangements, , the details of MDACC's agreement, if any, with Replimune Inc. regarding the IGNYTE-3 trial has not been publicly disclosed. But, given that MDACC's clinical trial agreements typically include terms about financing, it is possible that CTGTAC's recommendations to the FDA may have a direct and predictable effect on MDACC's financial interest in the IGNYTE-3 clinical trial, which is investigating the product at the July 30, 2026, CTGTAC meeting.

This waiver is intended to cover any such financial interest of MDACC that may be affected by the meeting.

Factors for Consideration

In determining whether the need for Dr. Hussein Tawbi's services on CTGTAC outweighs the potential for a conflict of interest created by the disqualifying financial interests, you should consider the following factors as described in 5 C.F.R. § 2640.302(b):

(1) **The type of interest that is creating the disqualification.** The interest is MDACC's financial interest as a clinical trial site for Replimune's oncolytic immunotherapy vusolimogene oderparepvec in combination with nivolumab to treat advanced melanoma, which is the subject of Replimune's BLA being considered at the July 30, 2026, CTGTAC meeting. As previously mentioned, the existence and nature of any such financial interest have not been publicly disclosed, but MDACC typically has clinical trial agreements with product sponsors that include financial arrangements to pay for the cost of the research.

(2) **The identity of the person whose financial interest is involved, and if the interest is not the individual's, the relationship of that person to the individual.** The financial interests are those of MDACC, a comprehensive cancer center in Houston, Texas and part of the University of Texas System. As a professor and clinician, Dr. Hussein Tawbi is a salaried employee of MDACC. His personal financial interests are not impacted by the July 30, 2026, CTGTAC meeting. He is not a principal investigator for the IGNYTE-3 clinical trial, although as a physician at MDACC he has had patients he has treated enroll in the trial. He does not receive any salary support from his participation in the IGNYTE-3 trial.

(3) **The uniqueness of the individual's qualifications.** Dr. Hussein Tawbi is an oncologist with expertise in melanoma and translational science. He is an internationally recognized expert in melanoma and translational science who has studied in both areas for over two decades. He has authored and published over 120 articles spanning multiple topics, including his two areas of internationally recognized expertise. Dr. Tawbi also has expertise in drug development and early phase clinical trials. These 3 areas of expertise will be relevant to the specific issues under discussion during the July 30, 2026 CTGTAC meeting.

(4) **The difficulty of locating a similarly qualified individual without a disqualifying financial interest to serve on the committee.** FACA committees are necessarily composed of persons who are physicians, veterinarians, epidemiologists, microbiologist, or other health care professionals who have expertise, experience, and/or knowledge of the primary subject of the committee's work. Consequently, it is expected that persons qualified to serve on the committee will have interests, financial and otherwise, in its subject matter. This includes not only employment interests, but also investment interests, as experience has shown that experts in the human biomedical, public health, and health care professions acquire securities through their employment or as a result of their familiarity with the programs of health-related companies. Thus, it is likely that any possible replacement for Dr. Hussein Tawbi's experience and perspective on CTGTAC would pose similar or greater conflict of interest concerns.

(5) **The dollar value of the disqualifying financial interest, if it is known or can be estimated.** As previously stated, MDACC has not publicly disclosed the dollar value of its clinical trial agreement, if any, with Replimune Inc. regarding the IGNYTE-3 trial, which is studying the product at issue at the July 30, 2026,

CTGTAC meeting.

(6) **The value of the financial instrument or holding from which the disqualifying financial interest arises and its value in relationship to the individual's assets.** The potentially disqualifying financial interests are not part of Dr. Tawbi's personal assets, but are those of his employer, MDACC, which are imputed to him under the federal conflict of interest statute. As previously stated, the dollar value of the interest is unknown because it has not been publicly disclosed, but since MDACC is a world-renowned cancer center involved in numerous clinical trials for different types of cancer, it is that its financial interest in the IGNYTE-3 trial, if any, is small in comparison to its overall financial structure.

(7) **The extent to which the disqualifying financial interest will be affected individually or particularly by the actions of the advisory committee.** Since there is no specific information about MDACC's financial interest in the IGNYTE-3 trial, the extent that it may be affected by the CTGTAC's recommendation is not known. Furthermore, it is important to note that the agency, not the committee, makes the final determination on the approval of the products under consideration at these meetings.

If you find that the need for Dr. Tawbi's services outweighs the potential for a conflict of interest, you may determine to issue Dr. Hussein Tawbi a limited waiver under section 208(b)(3) that would allow him to participate in the July 30, 2026, meeting of CTGTAC regarding Replimune, Inc.'s BLA for vusolimogene oderparepvec for the treatment of melanoma, despite MDACC's participation in the IGNYTE-3 trial.

RECOMMENDATION

It is recommended that you grant Dr. Hussein Tawbi a limited waiver under 18 U.S.C. § 208(b)(3) for his participation in the July 30, 2026, meeting of CTGTAC.

DECISION

Based on my determination in accordance with the relevant factors set forth in 5 C.F.R.§ 2640.302, I certify that the need for your services on the July 30, 2026, meeting of CTGTAC outweighs the potential for a conflict of interest created by the financial interests involved, and the waiver as described above is hereby granted.

Approved__X__ Disapprove_____ Date: 7/27/2026

/s/

Steven Kozlowski
Chief Scientist