TO: Steven Kozlowski
Chief Scientist, Office of the Chief Scientist (OCS)
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. William Jarvis under 18 U.S.C. § 208(b)(3) for Participation on the Medical Devices Advisory Committee, December 10, 2025

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. William Jarvis, as a member of the Medical Devices Advisory Committee (MDAC) for deliberation and recommendations on issues related to an emerging technology in the context of medical devices, germicidal ultraviolet (UV) light as a mode of disinfection.

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 MDAC, 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 Chief Scientist, this authority has been delegated to you. (SMG 1410.21).

The Medical Devices Advisory Committee (MDAC) consists of 18 panels. With the exception of the Medical Devices Dispute Resolution Panel, the panels advise the Commissioner about issues related to the safety and effectiveness of medical devices. The Medical Devices Dispute Resolution Panel provides advice to the Commissioner on complex or contested scientific issues between the FDA and medical device sponsors, applicants, or manufacturers. The General Hospital and Personal Use Devices Panel (GHPUDP) reviews and evaluates data concerning the safety and effectiveness of marketed and investigational general hospital, infection control and personal use devices and makes appropriate recommendations to the Commissioner of Food and Drugs.

On December 10, 2025, the Advisory Committee will deliberate and make recommendations on issues related to an emerging technology in the context of medical devices and germicidal ultraviolet (UV) light as a mode of disinfection. The FDA is seeking to obtain feedback to improve the total product life cycle (TPLC) evaluation of UV disinfection devices. In addition, the Committee will meet to discuss and provide advice to the FDA on devices used in pandemic preparedness and response to satisfy, in part, a requirement under the Food and Drug Omnibus Reform Act of 2022 (FDORA). The meeting is not intended to discuss and make recommendations related to specific FDA submissions, firms, or devices. The topic for the meeting is a particular matter of general applicability.

The matters on which MDAC will focus may affect certain financial interests of Dr. Jarvis or of persons and organizations with which he has certain relationships and whose interests are imputed to his, such as a spouse, minor children, general partners, organizations in which he serves as an officer, director, or trustee, or any organization in which he is employed or is seeking employment. Based upon a review of the financial disclosure report (FDA 3410) filed by Dr. Jarvis and discussions about his financial interests and those interests imputed to him, these may include:

Interest

Dr. Jarvis reported a financial interest that he originally received in June 2015 in the form of (b)(4) stock options as compensation for his participation in an advisory board meeting with (b)(4) a privately held company. Those options expired after (b)(4), and in (b)(4), Dr. Jarvis received a new grant with the same number of options and fair market value as the original grant. The current market value of Dr. Jarvis's stock options, including both vested and unvested options, in (b)(4) is between $1,000 to $5,000. This waiver is intended to cover all of the aforementioned disclosed options.

Under a regulatory exemption issued by the Office of Government Ethics, an employee may participate in any particular matter of general applicability in which the disqualifying financial interest arises from the ownership by the employee, his spouse or minor children of securities issued by one or more entities affected by the matter, if the aggregate market value of the holdings does not exceed $25,000 in any one such entity or $50,000 in all affected entities. See 5 C.F.R. 2640.202(c). Per Office of Government Ethics guidance, stock options pose the same conflict of interest concerns under 18 U.S.C. § 208 as actual shares of the underlying security. However, because options do not constitute ownership of the underlying stock and are not securities as defined at 5 C.F.R. § 2640.102(r), the exemptions at 5 C.F.R. § 2640.202 for interests in securities are not available.

Accordingly, absent a waiver, Dr. Jarvis's financial interest in (b)(4) would otherwise preclude him from participating in the December 10, 2025, MDAC meeting regarding issues related to an emerging technology in the context of medical devices, germicidal ultraviolet (UV) light as a mode of disinfection.

Factors for Consideration

In determining whether the need for Dr. Jarvis's services on MDAC 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) Dr. Jarvis is an infectious disease specialist with expertise in immunology, epidemiology, infection control, and hospital-acquired infections. He is an internationally recognized expert in healthcare-associated infection control and has published over 500 peer-reviewed publications, book chapters, and editorials on these topics. Dr. Jarvis has also served on numerous national committees and task forces to support infection control guideline and policy

development. The December 10 panel meeting will be discussing emerging infection control technology and pandemic preparedness which requires his expertise and leadership related to the impact of UV technologies on existing infection control practices, the performance of UV technologies expected for healthcare-associated infection prevention, how such technologies may impact antimicrobial resistance considerations, and the types of research that may support future pandemic preparedness. Dr. Jarvis has outstanding experience chairing the General Hospital and Personal Use Panel for over 18 years where he has demonstrated an ability to analyze complex technology and public health issues and provide expertise and recommendations to the Agency.

(2) The issues being evaluated by the Advisory Panel are not considered sensitive because CDRH has previously had other similar meetings for novel technologies and pandemic preparedness. CDRH did not consider past Advisory Panel meetings addressing pandemic preparedness to be of "high visibility," and this meeting is a continuation of a series of advisory meetings required by statute and held since 2022 without specific sensitivities.

(3) The Federal Advisory Committee Act (FACA) requires that membership be fairly balanced in terms of the points of view represented and the functions to be performed by MDAC. This diversity of interests will ensure that no one member is in a position to determine policy in favor of any one affected interest. This serves as an important restraint against real or apparent threats to the objectivity of any action by MDAC members.

(4) FACA committees are necessarily composed of persons who are physicians, veterinarians, epidemiologists, microbiologists, 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 work. 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. Jarvis's experience and perspective on MDAC would pose similar conflict of interest concerns.

(5) It remains difficult to find qualified experts in the critical area of infection control without disqualifying conflicts of interest and who

are able to participate in the panel meeting. It is critical that the panel include leading experts who are familiar with the current challenges associated with hospital infection control practices, antimicrobial-resistant bacterial infections, surveillance and outbreak investigations, and infections associated with medical devices or procedures. Dr. Jarvis has a unique background which combines public health work, epidemiology, and expertise in infectious diseases.

(6) Most of the matters presented to MDAC Panel are discussed or deliberated in open session and the results of all recommendations will be made available to the public. The likelihood that the matter of general applicability discussed at the December 10, 2025, MDAC meeting would have a special or distinct effect on any organization or interest group that has involvement in the development, testing, licensing, production, procurement, distribution, and/or use of UV light disinfectant product, while possible, is remote.

(7) The value of Dr. Jarvis's financial interest in (b)(4) is very small and would otherwise be considered de minimis but for the fact that it is in the form of stock options held in a private company.

If you find that the need for Dr. Jarvis's services outweighs the potential for a conflict of interest, you may determine to issue Dr. Jarvis a limited waiver under section 208(b)(3) that would allow him to participate in the December 10, 2025, MDAC Panel regarding issues related to an emerging technology in the context of medical devices, germicidal ultraviolet (UV) light as a mode of disinfection.

RECOMMENDATION

It is recommended that you grant Dr. William Jarvis a limited waiver under 18 U.S.C. § 208(b)(3) for his participation in the December 10, 2025 meeting of the Medical Devices Advisory Committee.

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 December 10, 2025 meeting of the Medical Devices Advisory Committee 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: **11/25/2025**

/S/

Steven Kozlowski
Chief Scientist
Office of Chief Scientist

The undersigned confirms, acknowledges, and agrees to the terms of the waiver.

/S/

Dr. William Jarvis