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

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. Victor van Berkel under 18 U.S.C. § 208(b)(3) for Participation on the Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee (MDAC) Meeting on September 23, 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. Victor van Berkel, as a member of the Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee when it meets on September 23, 2026, to discuss, make recommendations, and vote on information regarding the premarket approval application (PMA) for the Galleri® test sponsored by GRAIL, Inc.

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 FDA's Chief Scientist, you have authority to serve as appointing official for members of the MDAC.

The Medical Devices Advisory Committee (MDAC) consists of 18 panels. The Molecular and Clinical Genetics Panel (MCGP) reviews and evaluates data concerning the safety and effectiveness of marketed and investigational in vitro devices for use in clinical laboratory medicine including clinical and molecular genetics and makes appropriate recommendations to the Commissioner of Food and Drugs.

On September 23, 2026, the MCGP will meet in an open session to discuss, make recommendations, and vote on information regarding the premarket approval application (PMA) for the Galleri® test sponsored by GRAIL, Inc. The topic for this meeting is a particular matter involving specific parties.

The matter on which MCGP will focus at its September 23 meeting may affect certain financial interests of Dr. Victor van Berkel 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 (OGE 450) filed by Dr. Van Berkel and discussions about his financial interests and those interests imputed to him, these may include:

<u>Interest</u>

Dr. Victor van Berkel reported owning (b)(4) [redacted], or (b)(4) [redacted], of Breath Diagnostics, Inc., a private company seeking to develop non-invasive tests for lung cancer. Dr. van Berkel is also the chief medical officer, founder, and on the board of directors for Breath Diagnostics. Additionally, as a professor at University of Louisville, Dr. van Berkel is the principal investigator for a clinical trial involving a pilot study of OneBreath technology from Breath Diagnostics for identification of lung cancer in an at-risk population. As an employee of the university, the conflict of interest law imputes the financial interest of University of Louisville to Dr. van Berkel. Finally, Dr. van Berkel has a royalty agreement through the University of Louisville to receive approximately two percent of revenue for the following patents: US 8,663,581 - "Pre-concentrator and method of using the same"; US 9,638,695 - "Noninvasive detection of lung cancer using exhaled breath"; and US application 15/223,756- "Noninvasive detection of cancer originating in tissue outside the lung using exhaled breath." Dr. van Berkel has stated that, to date, he has received no royalties from the patents.

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. van Berkel cannot avail himself of this exemption because the September 23, 2026, MCGP meeting is considered a particular matter involving specific parties, namely GRAIL Inc.

Breath Diagnostics is engaged in research to develop a diagnostic test specifically for lung cancer. GRAIL Inc.'s Galleri® test, by contrast, is intended for screening for the early detection of multiple types of cancer. Thus, there are meaningful differences between the test being developed by Breath Diagnostics and GRAIL's test, including the target populations, intended uses, and technologies. Still, although the uses of these products are different, they are both cancer diagnostics, and there is some potential for the market value of Breath Diagnostics' test, if successfully developed, to be affected by the availability of GRAIL's test. As such, Breath Diagnostics would be considered a nonparty affected by GRAIL's PMA, which is the particular matter at issue in the September 23, 2026, MCGP meeting, see § 2635.402(b)(1)(ii). Because the patents are for technology used for the detection of lung cancer, any payments Dr. van Berkel receives under the patent royalty agreement may be similarly affected.

Accordingly, absent a waiver, Dr. van Berkel's financial interests in Breath Diagnostics and the patent royalty agreement would otherwise preclude him from participating in the meeting. This waiver is intended to cover all such financial interests of Dr. Victor van Berkel and University of Louisville, his employer, that may be affected by the meeting.

<u>Factors for Consideration</u>

In determining whether the need for Dr. Victor van Berkel's services on the MCGP 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 interests include Dr. van Berkel's ownership of (b)(4) and his positions as chief medical officer and a member of the board of directors, of Breath Diagnostics, Inc.; royalty agreements with the University of Louisville under which he has the right to receive approximately two percent of revenue for U.S. patents 8,663,581, 9,638,695, and application 15/223,756 relating to cancer detection technology;

and the University of Louisville's financial interest in a clinical trial involving a pilot study of Breath Diagnostics' OneBreath technology for identification of lung cancer in an at-risk population. The financial interests in the clinical trial is imputed to Dr. van Berkel under the federal conflict of interest law as an employee of the university. He is the principal investigator for the clinical trial, but did not receive any additional compensation for it beyond his university salary.

(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 Dr. Victor van Berkel, founder of Breath Diagnostics and an officer and major shareholder, and University of Louisville, which is conducting a clinical trial using Breath Diagnostics' technology, as described above. As a professor, Dr. van Berkel is a salaried employee of University of Louisville.

(3) **The uniqueness of the individual's qualifications.** Dr. Victor van Berkel, M.D., Ph.D., is currently a tenured Professor in the Department of Cardiovascular and Thoracic Surgery and is the Division Chief of Thoracic Surgery for the department at the University of Louisville. He received his Bachelor of Science in Chemistry and his Bachelor of Science in Biology from the Massachusetts Institute of Technology. He graduated with his Doctor of Medicine and Ph.D. in the Medical Scientist Training Program from the Washington University School of Medicine in St. Louis. He completed his residency in General Surgery at Massachusetts General Hospital and a fellowship in Cardiothoracic Surgery at Barnes-Jewish Hospital. Since his training, he has served in clinical and academic leadership roles in the areas of cardiovascular and thoracic surgery and oncology. As a clinical physician concentrating on surgical treatment of benign and malignant thoracic disease, Dr. van Berkel provides care for the patient populations who may be directly impacted by the particular matter coming before the committee. He has been recognized by the American Lung Association as a recipient of the esteemed Honorary Chair Award for his exceptional career in the care for patients with lung diseases. Dr. van Berkel will provide an essential, unique viewpoint regarding the clinical significance of a multi-cancer detection test on the care of patients, particularly for those who are ultimately diagnosed with lung cancer.

Dr. van Berkel's high level of expertise is also reflected by his service on the editorial boards of several journals, including the Annals of Surgical Oncology, and his membership in numerous professional societies, including the American Association of Thoracic Surgery. He has authored over 50 peer-reviewed publications and over 25 reviews and book chapters, many of which are directly related to non-invasive approaches to the diagnosis of various lung diseases, including lung cancer. He has published on the benefits and limitations of current lung cancer screening modalities, demonstrating his unique ability to critically evaluate complementary cancer screening approaches and is precisely the type of analysis needed for deliberation on the particular matter before the Committee. Dr. van Berkel has also served as a member of other MDACs, giving him direct familiarity with panel processes and experience regarding the regulation of medical devices.

In summary, Dr. van Berkel's combination of basic science training, clinical thoracic oncology expertise, extensive research portfolio in the area of lung cancer screening, and direct experience with FDA advisory panels makes him exceptionally and uniquely qualified to contribute to the Committee's discussion of a multi-cancer detection test. There is limited expertise available among clinicians who simultaneously possess first-hand surgical and oncological experience with the relevant patient population and a deep understanding of the field of lung cancer screening. His expertise is essential to ensure that the Committee's deliberations are informed by the most current scientific understanding of non-invasive cancer screening technologies and their implications for patients and health care providers.

(4) **The difficulty of locating a similarly qualified individual without a disqualifying financial interest to serve on the committee.** The MCGP for this particular matter is necessarily composed of persons who are scientists, physicians, or other health care professionals who have expertise, experience, and/or knowledge of the particular matter before the committee. 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. FDA was unable to find any other individual with Dr. Victor van Berkel's unique level of expertise in thoracic oncology. He is the only panel member with such essential background who is available to participate.

(5) **The dollar value of the disqualifying financial interest, if it is known or can be estimated.** Although his shareholdings are significant, the dollar value of Dr. van Berkel's shares in Breath Diagnostics is highly uncertain. The company is private and its shares are not publicly traded, so there is no current market price for the shares. The company currently has no revenues and is years away from having a marketable product, according to Dr. van Berkel. So, the dollar value of the company's shares is very speculative at this point. Although the company did recently have a Regulation CF offering of shares priced at three dollars per share, it seems doubtful an existing shareholder could liquidate shares at that price. Generally speaking, shares in private companies are less liquid than publicly traded shares, and it is not clear how much, if any, monetary value Dr. van Berkel's shares currently have, although the shares have the potential to grow in value over time if the company successfully develops its products. Similarly, although he has a right under the patent royalty agreement to receive approximately two percent of revenues for the patents, Dr. van Berkel has stated that he has received no such revenue to date, and the dollar value of any future royalty payments he may receive is uncertain and highly speculative. Dr. van Berkel reports that the University of Louisville has a contract under which it receives (b)(4) for conducting the clinical trial; this financial interest is imputed to Dr. van Berkel as an employee of the university. He did not receive any additional compensation for being the principal investigator for the trial beyond his university salary.

(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.** As

explained above, the monetary value, if any, of Dr. van Berkel's shares in Breath Diagnostics is uncertain and highly speculative, although the shares have the potential to grow in value over time if the company successfully develops its products. Dr. van Berkel also reported significant personal assets other than his shares in Breath Diagnostics, so his stake in the company, whatever its value, is just one part of his whole investment portfolio. Similarly, he has received no payments to date from the patent royalty agreement, so its current value is negligible in relation to his whole portfolio, although he could potentially receive payments in the future if the technology is successfully marketed. Dr. van Berkel reports that the University of Louisville has a contract under which it receives (b)(4) for conducting the clinical trial; since University of Louisville is a large public university with a 2026 budget of $1.96 billion, the value of this contract is small in relation to the university's overall finances. Also, although the financial interest in this contract is imputed to him under the federal conflict of interest statute as an employee of University of Louisville, it would not affect the value of Dr. van Berkel's personal assets.

(7) **The extent to which the disqualifying financial interest will be affected individually or particularly by the actions of the advisory committee.** The value of Dr. van Berkel's financial interests in Breath Diagnostics' stock and the patent royalty agreement is tied to a diagnostic test, still in development, specifically for lung cancer. The subject of the advisory committee meeting is GRAIL Inc.'s PMA for its Galleri® test, which is intended for screening for the early detection of multiple types of cancer. Because both of these products are cancer diagnostics, there is some potential for the market value of Breath Diagnostics' test, if successfully developed, to be affected by the availability of GRAIL's test. However, this effect is likely to be limited by the fact that the tests have meaningful differences, including the target populations, intended uses, and technologies. Furthermore, given the long timespan between the present meeting and any potential market entry by Breath Diagnostics, it is unclear how any particular committee action would actually affect Breath Diagnostics. For example, if the Galleri test is approved, it is not clear whether Breath Diagnostics' interests would be positively or negatively affected: it is equally reasonable to assume either (1) that Breath Diagnostics would be harmed by the competitive pressure of an alternative test or (2) that Breath Diagnostics would be aided by the more mature and reimbursable market for such tests. Given this high causal uncertainty, it is unlikely that the meeting would affect Breath Diagnostics' present value to any meaningful extent. University of Louisville's financial interest in the clinical trial, imputed to Dr. van Berkel as an employee of the university, consists of a fixed monetary payment under contract for research services, which is unlikely to be affected by FDA's action on GRAIL's PMA, which concerns a different product. 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. Victor van Berkel's services outweighs the potential for a conflict of interest, you may determine to issue Dr. van Berkel a limited waiver under section 208(b)(3) that would allow him to participate in the September 23, 2026, meeting of the Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee to discuss, make recommendations, and vote on information regarding the premarket approval application (PMA) for the Galleri® test sponsored by GRAIL, Inc.

RECOMMENDATION

It is recommended that you grant Dr. Victor van Berkel a limited waiver under 18 U.S.C. § 208(b)(3) for his participation in the September 23, 2026, advisory committee meeting.

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 September 23, 2026, meeting of the Molecular and Clinical Genetics Panel 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: 9/8/2026

/S/
Steven Kozlowski
Chief Scientist

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

/S/
Dr. Victor van Berkel