DATE: December 20, 2024

TO: John S. Kirkpatrick, M.D.
Temporary Voting Member, Anesthetic and Analgesic Drug Products Advisory Committee
Center for Drug Evaluation and Research
Food and Drug Administration

FROM: Robert M. Califf, M.D.
Commissioner of Food and Drugs
Food and Drug Administration

SUBJECT: Waiver to Allow Participation in a Food and Drug Administration Advisory Committee Meeting, under Title 18, Section 208(b)(l) of the United States Code

LEGAL AUTHORITY

The criminal conflict of interest statute, 18 U.S.C. § 208(a), prohibits a federal executive branch employee from participating personally and substantially in any particular matter that will have a direct and predictable effect on the employee's financial interests or on the financial interests of certain other persons whose financial interests are imputed to the employee. Under 18 U.S.C. § 208(b)(l), however, the employee's appointing authority, or his or her delegate, may permit an employee to participate in a matter in which he or she has an otherwise disqualifying financial interest, if a waiver is issued based on a determination that the financial interest is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from the employee. As discussed below, I have decided to issue a conflict of interest waiver to permit you to participate in a certain particular matter.[1]

NATURE OF THE PARTICULAR MATTER

You, John Kirkpatrick, M.D., are a temporary voting member of the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) and have been invited to serve at the meeting of the AADPAC being held on January 10, 2025, to discuss biologics license application (BLA) 761393, condoliase injection submitted by Seikagaku Corporation, for the proposed indication of the treatment of radicular leg pain associated with lumbar disc herniation in adults. The topic of this advisory committee meeting is a particular matter involving specific parties.

[1] You are a federal government employee with the Department of Veteran Affairs. Therefore, waiver authority at 18 U.S.C. § 208(b)(3) related to the work of an SGE on a federal advisory committee does not apply to this waiver, which is being issued pursuant to 18 U.S.C. § 208(b)(l).

EMPLOYEE'S POSITION, DUTIES AND ROLE

You are a federal government employee with the Department of Veteran Affairs. You serve as an Orthopaedic Surgeon at the Orlando Veterans Affairs (VA) Medical Center. You are also employed by the University of Central Florida, where you serve as a Professor of Orthopaedic Surgery at the College of Medicine.

RELEVANT FACTORS CONSIDERED UNDER 18 U.S.C. § 208(b)(1)

In determining whether a waiver may be issued to allow your official participation in the particular matter described herein, I have considered each of the factors described in 5 C.F.R. § 2640.301(b), including the nature of the disqualifying financial interest as described below. I have also carefully considered the following additional factors:

1. *Value of the Financial Instrument or Holding from which the Disqualifying Interest Arises and Relationship to Your Assets, and Dollar Value of the Potential Gain or Loss Due to Resolution of the Matter.*

You reported a financial interest in the ownership of publicly traded common stocks in (b) (6) have been identified by the Center for Drug Evaluation and Research (CDER) as firms having interests that may be affected by the particular matter at issue, specifically due to their interests in potentially competing products. At the writing of this waiver, the aggregate market value of your financial interests in the common stocks of both (b) (6) and (b) (6), is between $25,000 and $50,000.

Under regulatory exemption 5 CFR § 2640.202(b) issued by the Office of Government Ethics, an employee may participate in any particular matter involving specific parties 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 that are competing/affected by the matter if the aggregate market value of the holdings of the employee, his spouse and minor children in the securities of all competing/affected entities does not exceed $25,000. Because your financial interests in the securities of all affected entities exceed that amount, you have a disqualifying financial interest.

Both of the companies listed above are large multinational firms with a number of products in the market and multi-billion-dollar market capitalizations. Therefore, CDER does not anticipate that any government action undertaken at this meeting will have a substantial effect on stock prices and does not anticipate the two companies' business health will be significantly impacted by any competitive pressure arising from the meeting.

Furthermore, your overall financial holdings significantly outweigh any interests addressed by this waiver. The two investments that are the subject of this waiver have a cumulative value well below 5% of your overall non-real estate investment interests.

2. *The Nature and Importance of Your Participation, and the Need for Your Services on the Matter.*

You have unique qualifications and specialized expertise needed for this particular matter. The upcoming Anesthetic and Analgesic Drug Products Advisory Committee meeting is focused on biologics license application (BLA) 761393, condoliase injection submitted by Seikagaku Corporation, for the proposed indication of the treatment of radicular leg pain associated with lumbar disc herniation in adults.

Your professional background indicates that you have the relevant qualifications and specialized expertise needed for this particular matter. You are an orthopedic surgeon at the Orlando Veterans Affairs Medical Center and a Professor of Orthopaedic Surgery at the College of Medicine, University of Central Florida. Orthopedic surgery relating to the spine is a specialty of yours, with your research output including authorship of an academic paper on vein access for anesthesia purposed in patients with spinal morbidities (e.g., ankylosing spondylitis, kyphosis, and chin-on-chest deformity), as well as numerous published articles regarding orthopedic spinal procedures (such as spinal fusions), treatment of spinal injuries, and alternatives to spinal surgery. You are also a published author of a piece regarding the costs and benefits of spinal interventions to resolve pain associated with lumbar spine issues.

You received your master's degree in Bioengineering at the University of California, San Diego and your medical degree from the Bowman Gray School of Medicine. After completing several surgical residencies at Duke University, you also completed an orthopedic fellowship at Case Western Reserve University. You are also certified by the American Board of Orthopaedic Surgery.

In addition to having over 30 years of experience in the medical field, you have also held numerous affiliations and academic appointments throughout your career. Most recently, you were Section Chief of Orthopedic Surgery with the Orlando VA Medical Center. While serving as Professor in the Department of Orthopedics and Rehabilitation with the University of Florida College of Medicine in Jacksonville, you served as chairman from 2006-2013 and program director from 2006-2014. You also served on the Orthopaedic and Rehabilitation Devices Panel for the FDA's Center for Devices and Radiological Health.

Furthermore, you are currently a member of the American Orthopaedic Association, where you served on the Fellowship Committee, Council of Orthopaedic Residency Directors, Sub-Committee on Knowledge and Skill, and Nominating Committee. You were also a Board of Specialty Societies Representative for the Cervical Spine Research Society and an Oral Examiner for the American Board of Orthopaedic Surgery. You were also an editorial reviewer for The Journal of Bone and Joint Surgery, Journal of the Southern Orthopaedic Association, and The Spine Journal.

Your expertise is critical to this advisory committee meeting given the limited expertise available. You will serve as one of two surgeons on the panel, with specialization in spine surgery that will contribute scientifically and clinically to the discussion on efficacy and safety of condoliase for the management of radicular leg pain. For fair balance on the panel, it is

imperative that the panel has an orthopedic surgeon and a neurosurgeon.

3. Sensitivity of the matter.

This topic is considered to be sensitive, as the FDA Division with responsibility for the review of this product states that the meeting is directly related to a significant Administration and HHS initiative. Condoliase is a novel, non-opioid product under review for an analgesic indication. Given the Agency's efforts toward combating the opioid epidemic, this is consistent with the Agency's initiative.

4. Your Expertise in this Particular Matter is Necessary in the Interest of Public Health.

Radicular leg pain refers to shooting pain down the leg, often caused by a compressed nerve root in the lower back. A lumbar disc herniation is a condition where the gel-like center of an intervertebral disc in the lower back pushes out and irritates nearby nerves, making it the most common cause of radicular leg pain. Radicular symptoms have a high prevalence among the general population and are a common reason for presentation for medical care. Studies vary, but it is estimated that between 13% and 40% of people will experience an episode of lumbar radicular pain during their lifetime. The cost burden of radicular leg pain caused by a lumbar disc herniation is significant, primarily due to the associated healthcare utilization, lost productivity from work absences, and the need for ongoing pain management, with studies indicating that the total cost of low back pain, often linked to disc herniation, can exceed $100 billion annually in the United States.

Most people with lumbar radicular pain caused by disc herniation will have their symptoms resolve without intervention, with the majority seeing improvement within 4–6 weeks with conservative management. Pain management could start with moderate nonsteroidal anti-inflammatory medication; if unresponsive, therapies used off-label and as labeled for neuropathic pain are used along with physical therapy. Treatment-resistant patients may escalate to a short or longer course of opioids. However, the risks and side effects of opioids should be taken into consideration. If symptoms persist beyond six weeks, epidural steroid injections may be considered for short term (2 to 4 weeks) pain relief in some patients with lumbar disc herniation and radiculopathy. Surgical intervention is the suggestion for patients with persistent disabling symptoms who do not respond to conservative and medical management. Condoliase is a non-opioid new molecular entity under review as an analgesic and is intended to treat lumbar disc herniation via a single, intradiscal injection. Condoliase does not require general anesthesia and is less invasive than surgical treatment.

In the interest of public health, it is important that the Agency has available the expertise that you will provide for the discussion of the particular matter before the committee.

DETERMINATION

Based on an evaluation of the factors in 5 C.F.R. 2640.301(b), FDA has determined that your financial interests are not so substantial as to be deemed likely to affect the integrity of the services that the federal Government may expect from you. For the specific reasons detailed above, FDA grants you, Dr. John S. Kirkpatrick, a waiver under 18 U.S.C. 208(b)(1) to permit

you to participate in the advisory committee meeting described herein. This waiver is based on your full disclosure of your financial interests and consideration of the nature of the particular matter that you will be involved in as an FDA employee. This waiver only applies to the conflicts of interest described herein and for the meeting of the AADPAC on January 10, 2025.

FDA Ethics Counsel and the HHS Alternate Designated Agency Ethics Official have reviewed this document, as required by the Delegation of Authority by the Secretary to the Heads of Operating and Staff Divisions to Grant Conflict of Interest Waivers under 18 U.S.C. §§ 203(d), 205(e), and 208(b), dated January 16, 2009, and has concluded that this waiver adequately addresses the requirements for such waivers as set forth in OGE regulations at 5 C.F.R. § 2640.301.

Accordingly, I issue this waiver from the conflict of interest prohibitions of 18 U.S.C. § 208(a) based on the factors found at 5 C.F.R. § 2640.301(b).

Certification

____X___ The individual may participate, pursuant to 18 U.S.C. 208(b)(1) – The financial interest is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from the employee.

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

_____ Non-voting

_____ Other (specify):

_____ Denied – The individual may not participate.

Robert M. Califf, M.D.
Commissioner of Food and Drug Administration

December 20, 2024
Date

JOHN KIRKPATRICK

Digitally signed by JOHN KIRKPATRICK
Date: 2024.12.20 15:38:46 -05'00'

John S. Kirkpatrick, M.D.

Date

PRIVACY ACT STATEMENT

Individuals seeking a conflict of interest waiver pursuant to 18 U.S.C. § 208 must provide relevant information in order for their request for a waiver to be considered. The information is reviewed by government officials to determine whether the issuance of such a waiver is justified under the particular circumstance. The information is also used to permit transparency with regard to waivers issued.

Failure to provide requested information may result in the denial of the waiver or the revocation of a previously granted waiver. Pursuant to 18 U.S.C. § 208(d)(1), waivers may be released to the public upon a proper request to the issuing agency (which is the agency at which the waiver recipient is employed). The waiver recipient's first and last name, government position, the type of waiver issued, and name of the employing agency may be publicly posted to the Office of Government Ethics website or the employing agency's website, in accordance with OGE/GOVT-1, Executive Branch Personnel Public Financial Disclosure Reports and Other Name-Retrieved Ethics Program Records (routine uses "b" and "c"). Please see OGE/GOVT-1 for more information about the maintenance and disclosure of this information.