



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

DATE: March 26, 2021

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

FROM: Byron Marshall  
Director, Division of Advisory Committee and Consultant Management  
Office of Executive Programs  
Center for Drug Evaluation and Research

Name of Advisory Committee Temporary Voting Member: **Christopher John Sperati, MD, MHS,  
FNKF**

Committee: Arthritis Advisory Committee

Meeting date: May 6, 2021

Description of the Particular Matter to Which the Waiver Applies:

Christopher John Sperati, MD, MHS, FNKF, is a temporary voting member of the Arthritis Advisory Committee (AAC). The committee's function is to review and evaluate data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of arthritis, rheumatism, and related diseases, and make appropriate recommendations to the Commissioner of Food and Drugs.

The committee will discuss New Drug Application (NDA) 214487, for avacopan oral capsules, submitted by ChemoCentryx, Inc., for the treatment of anti-neutrophil cytoplasmic antibody-(ANCA) - associated vasculitis (AAV). Under a prior development and commercialization agreement with Glaxo Group Limited, or GSK, which ended in 2013, ChemoCentryx is subject to reverse royalties to GSK on annual worldwide net sales of avacopan. The topic of this meeting is a particular matter involving specific parties.

Type, Nature, and Magnitude of the Financial Interest:

Dr. Sperati reported a financial interest in (b) (6), a healthcare sector mutual fund. The value of his holdings in this fund is between \$100,001 – \$300,000. At the writing of this waiver, based on publicly available fund information, the (b) (6) sector fund contains assets in the potentially competing firms (b) (6).

(b) (6),  
 representing (b) (6) %, respectively,  
 of the underlying holdings of the fund.

Under a regulatory exemption issued by the Office of Government Ethics, an employee may participate in any particular matter affecting one or more holdings in a sector mutual fund where the disqualifying financial interest in the matter arises because of ownership of an interest in the fund and the aggregate market value of interests in all funds in which there is a disqualifying financial interest and which concentrate in the same sector does not exceed \$50,000. Because Dr. Sperati's financial interest in the (b) (6) exceeds that amount, he has a disqualifying financial interest based on the fund's holdings of the above-listed companies.

Basis for Granting the Waiver:

*Dr. Christopher John Sperati has unique qualifications and specialized expertise needed for this particular matter.*

Dr. Sperati is an Associate Professor of Medicine at the Johns Hopkins University School of Medicine in the Department of Medicine, Division of Nephrology. Dr. Sperati is also Director of the Nephrology Fellowship Training Program and serves as the Firm Faculty Leader of the Barker Firm. In addition, he co-directs the Johns Hopkins Osler Learning Initiative which brings the principles of medical residency training to executive education worldwide.

He obtained his medical degree from the Pennsylvania State University College of Medicine and a Master in Health Science from the Johns Hopkins Bloomberg School of Public Health. He completed an internship and residency in Internal Medicine at the Johns Hopkins Hospital, followed by a year as an Assistant Chief of Service (chief resident). He subsequently pursued subspecialty training in nephrology at the Johns Hopkins Hospital and joined the faculty in the Division of Nephrology. He is board certified in Internal Medicine and Nephrology.

Dr. Sperati's clinical interests are in thrombotic microangiopathy including atypical hemolytic uremic syndrome (aHUS), complement mediated kidney diseases including C3 glomerulopathy, secondary and resistant hypertension (fibromuscular dysplasia, atherosclerotic renal arterial disease, hyperaldosteronism, and genetic hypertensive syndromes), glomerulonephritis (e.g., IgA nephropathy, MPGN), and nephrotic syndromes (e.g., FSGS, membranous, minimal change, amyloidosis, and others). In this context, he is one of the most clinically active faculties in his Division and he is heavily involved in the teaching of these topics to staff and fellows. Dr. Sperati is recognized as a national expert in the evaluation and management of these disorders. Dr. Sperati is the institutional lead for multicenter studies of thrombotic microangiopathies and glomerular disease. He also serves on editorial boards and is a member of the National Kidney Foundation Education Committee as well as the Nephrology Knowledge Check-in Task Force of the American Board of Internal Medicine. His clinical expertise has been recognized by induction into the Miller Coulson Academy of Clinical Excellence.

The committee will discuss the efficacy, safety, and overall risk benefit considerations for avacopan, a new molecular entity, for the treatment of AAV. In light of the prevalence of renal

manifestations in AAV and the renal assessments in the avacopan application, a productive discussion of the issues would depend upon having strong expertise in this area and hearing many perspectives, including an adequate number of nephrologists and rheumatologists with experience managing patients with AAV. Because of Dr. Sperati's knowledge and his breadth of experiences as a nephrologist, educator and clinical researcher, his participation in the committee's discussion will ensure an expansive level of expertise and objectivity required to provide expert advice and recommendations to the Agency.

*The particular matter is considered sensitive.*

The matter coming before the committee will garner public interest as there are limited approved therapies for the treatment of AAV, and there is significant interest in limiting glucocorticoid exposure in patients with rheumatologic diseases. Results from the pivotal study have been presented at academic meetings and recently published in literature. Therefore, it is anticipated that this meeting is likely to receive significant public interest and interest from the rheumatology and nephrology communities.

*Dr. Christopher John Sperati's expertise in this particular matter is necessary in the interest of public health.*

AAV is a group of disorders characterized by inflammation and destruction of small- and medium-sized blood vessels and the presence of circulating ANCA. AAV is divided into 3 clinical diseases (granulomatosis with polyangiitis [GPA], microscopic polyangiitis [MPA], and eosinophilic GPA [EGPA]). AAV has a predilection for the kidney, with >75% of patients having renal involvement characterized by rapidly progressive glomerulonephritis. The cause and pathogenesis of AAV are multifactorial and influenced by genetics, environmental factors, and responses of the innate and adaptive immune system.

AAV is an uncommon disease with an incidence of about 20 per million population per year in Europe and North America. There is a slight male preponderance. Incidence increases with age, with a peak in the 60- to 70-year age range. AAV is more common in white and Asian populations and less common in African American populations. There is notable geographic variation, with GPA being more common in Northern Europe and Australia/New Zealand, whereas MPA is more common in Southern Europe and Asia.

Randomized controlled trials in the past two decades have refined the therapy of AAV and transformed AAV from a fatal disease to a chronic illness with relapsing course and associated morbidity. In the interest of public health, it is important that the Agency has available the unique expertise that Dr. Sperati will provide for the discussion of the particular matter before the committee.

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

The perspectives of multiple nephrologists are required for an informative discussion of the efficacy results in the avacopan application, including the results on renal outcomes, which are

part of the benefit risk considerations. To conduct this meeting without multiple nephrology experts would render the advice from the meeting difficult to interpret; the clearance of multiple nephrology experts is imperative for this committee's discussion. Being able to draw upon a diverse set of competencies and knowledge is essential if the committee is to successfully address the issues being discussed. Because of Dr. Sperati's knowledge and his breadth of experiences as a nephrologist, educator and clinical researcher he is uniquely qualified to provide insight and feedback on the New Drug Application, 214487, for avacopan.

Accordingly, I recommend that you grant Dr. Christopher John Sperati, a temporary voting member of the Arthritis Advisory Committee, a waiver from the conflict of interest prohibitions of 18 U.S.C. § 208(a).

Certification:

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:

Non-voting

Other (specify):

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Denied – The individual may not participate.

**Russell Fortney -S**  
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Date: 2021.04.12 07:49:52 -04'00'

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

April 12, 2021  
Date