



FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

MEMORANDUM

DATE: March 7, 2007

FROM: William Freas, Ph.D. W.F.
Director, Division of Scientific Advisors and Consultant

SUBJECT: 208(b)(3) Waiver for Adrian M. Di Bisceglie, M.D.

TO: Randall Lutter, Ph.D.
Associate Commissioner for Policy and Planning

Through: Vince Tolino
Director, Ethics and Integrity Staff
Office of Management Programs, OM

I am writing to request a waiver for Adrian M. Di Bisceglie, M.D., a member of the Blood Products Advisory Committee at the April 26-27, 2007 meeting, from conflict of interest prohibitions of 18 U.S.C. 208(a). On April 26, 2007, Topic 1, the Committee will discuss current considerations for implementation of Chagas Testing. This is a particular matter involving specific parties (not a product recommendation discussion). On April 27, 2007 Topic 3, the Committee will discuss current considerations for implementation of West Nile Virus testing. This is a particular matter involving specific parties (not a product recommendation discussion). Waivers under Section 208(b)(3) may be granted by the appointing official where "the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved" and where the individual has made a disclosure of the financial interests at issue. Because you are the appointing official, you have the authority to grant Dr. Di Bisceglie a waiver under Section 208(b)(3). Section 208(a) prohibits Federal executive branch employees, including special Government employees, from participating personally and substantially in matters in which, to his knowledge, the employee, his spouse, minor children, or general partner; an organization in which he is serving as officer, director, trustee, general partner, or employee, or a person or organization with which he is negotiating for or has arrangement concerning prospective employment has a financial interest. Dr. Di Bisceglie is a special Government employee and is under a statutory obligation to refrain from participating in any deliberations that involve a particular matter having a direct and predictable effect on a financial interest attributable to him or to his employer.

The function of the Committee, as stated in its Charter, is to advise the Commissioner of the Food and Drug Administration in discharging responsibilities as they relate to assuring safe and effective use of blood and products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human disease.

The Committee is scheduled to meet on April 26-27, 2007. On April 26, 2007 Topic 1, the Committee will discuss current considerations for implementation of Chagas Testing. This is a particular matter involving specific parties (not a product recommendation discussion). On April 27, 2007 Topic 3, the Committee will discuss current considerations for implementation of West Nile Virus testing. This is a particular matter involving specific parties (not a product recommendation discussion).

Dr. Di Bisceglie has advised the FDA that he consults with firms that could potentially be affected by his participation in the matter at issue. Dr. Di Bisceglie is a member of an advisory board for [REDACTED] on viral hepatitis (Hepatitis C and Hepatitis B). He receives [REDACTED] per year for his services. Dr. Di Bisceglie's consulting is ongoing since 2005. In addition, Dr. Di Bisceglie is a member of an advisory board for [REDACTED] which advises on the treatment of chronic Hepatitis B and the development of [REDACTED]. He receives [REDACTED] per year for his services. This consulting is also ongoing since 2005. Both consulting services are unrelated to the issues being discussed by the Committee. Dr. Di Bisceglie also reported that his institution has an unrelated research contract with [REDACTED] to study Hepatitis C virology as part of a multi-center clinical trial of [REDACTED]. Dr. Di Bisceglie is the Principal Investigator, but he receives no personal remuneration from this research contract. This research contract does not entail a direct and predictable affect on the interests.

Under 18 U.S.C. 208, Dr. Di Bisceglie is prohibited from participating in any matter affecting these interests, unless he receives a waiver. However, as noted above, you have the authority under 18 U.S.C. 208(b)(3) to grant a waiver.

For the following reasons, I believe that it would be appropriate for you to grant a waiver to Dr. Di Bisceglie that would allow him to participate in the discussions before the Committee.

First, Dr. Di Bisceglie is a standing member of the Blood Products Advisory Committee (BPAC), whose membership began in February 2006. He has attended two previous BPAC meetings. His presence at this meeting will provide continuity and will add historical relevance for future BPAC meetings on similar topics.

Second, the waiver is also justified because the Committee has a special need for Dr. Di Bisceglie's service because of his unique expertise, experience, and viewpoints with respect to the issue before the Committee. Dr. Di Bisceglie is Professor of Medicine and Chief of Hepatology at the St. Louis University School of Medicine. He is an established investigator and specialist in hepatology and infectious diseases. His expertise in liver tissue will be important in the discussion of Chagas disease and its parasitic effect on macrophages from spleen, liver and bone marrow. Additionally, Dr. Di Bisceglie has participated in numerous

DECISION:

X

Waiver granted based on my determination, made in accordance with section 208(b)(3), that the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest attributable to the individual.

Waiver denied.

/s/

Randall Lutter, Ph.D.

Associate Commissioner for Policy and Planning

3/20/07
Date