**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
Silver Spring MD 20993

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Researcher

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Dear Drs. Almashat, Wolfe, and Carome,

Thank you for your correspondence expressing concern about special government employees (SGEs) serving as representatives to industry sponsors. You raise important issues and I appreciate your sharing your thoughts on this matter.

As you know, FDA often requires external, scientific and technical expertise on complex issues to inform effective decision-making and draws upon SGEs to serve this vital role. FDA SGEs are often required to have a deep familiarity with highly technical and challenging scientific issues and expertise in the design, conduct, and analysis of clinical trials derived from years of experience working on drug discovery and development. This experience is often acquired by involvement in sponsor directed research. The ability to attract and retain such qualified individuals is critical to the successful performance of the advisory committee system.

The Agency works actively to meet both the need for expertise and impartiality and takes concerns about potential appearance of lack of impartiality or bias very seriously. Prior to appointment, we require potential SGEs to submit background information, including conflict of interest information, to FDA for review. Further, for many years FDA has screened, prior to each Advisory Committee meeting, all potential participants who are SGEs or regular government employees, to determine whether the potential for a financial conflict of interest or appearance of a lack of impartiality exists.

Additional policies are in place to prevent conflicts of interest involving SGEs seeking to represent sponsors before FDA. Among these, FDA's Center for Drug Evaluation and Research (CDER) observes the following policy (outlined in FDA's Manual of Policies and Procedures 6001.1, and available on the FDA website at:

http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/default.htm), which:

- Prohibits SGEs who have been involved in the same matter as part of their FDA duties from representing sponsors on these matters

- Limits sponsor representation to SGEs who have worked less than 60 days out of the previous 365 days for the government.

- Requires written Center concurrence to serve as a sponsor representative before CDER. SGEs are advised to submit a request for sponsor representational activity to FDA at least two weeks prior to an event. The written request must include a description of the SGEs' present and past relationship with the sponsor and the application under consideration.

- Establishes considerations for FDA determination on a case-by-case basis.

- Further restricts advisory committee members from representing sponsors in any capacity before their own advisory committee without written permission from the Center Director or Deputy Center Director.

CDER provides this MAPP to each prospective SGE at the time of his or her SGE appointment.

CDER followed the procedures outlined in MAPP 6001.1 in granting concurrence for Dr. Milton Packer's request to speak at the March 27, 2014, Cardiovascular and Renal Drugs Advisory Committee (CRDAC) meeting as a Novartis consultant during consideration of FDA's review of serelaxin injection. Dr. Packer, as noted in your correspondence, is an eminent cardiologist and specialist in heart failure, who was instrumental in the design of the clinical endpoint adapted for use in the serelaxin clinical trials.

While Dr. Packer's participation in this meeting was cited as the example of a practice that risks "compromising the integrity" of the advisory committee process, the results suggest otherwise. CRDAC recommended unanimously against serelaxin's approval despite Dr. Packer's presentation at the meeting.

You have raised several questions concerning Dr. Packer's speaking and consultant roles for industry:

Regarding Questions (1) and (2), your letter requested certain agency records regarding Dr. Packer's participation at advisory committee meetings. We forwarded your letter to the Division of Freedom of Information for logging as a Freedom of Information Act (FOIA) request. It has been assigned FOIA request number 2014-7981.

Regarding your recommendation for FDA to issue a guidance document, we will take your suggestions under consideration.

My colleagues and I share your commitment to base public health decisions on objective evaluations of scientific evidence and to minimize conflicts of interest. Once again, we appreciate your sharing your comments and concerns and hope that you will continue to do so on this and other important issues.

Sincerely,

Jill Hartzler Warner, J.D.
Associate Commissioner for Special
Medical Programs