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May 18, 2007

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Miami, FL 33128

**RE: REQUEST FOR ADVISORY OPINION 07-14**

Dear Ms. Christian:

The Commission on Ethics and Public Trust considered your request for an advisory opinion at its meeting on May 17, 2007 and rendered its opinion based on the facts stated in your letter.

You requested an opinion regarding whether the Public Health Trust may contract with a company if the company has provided honoraria to physicians who are involved in a clinical trial.

In your letter, you stated that two physicians from the University of Miami Medical School, Drs. Parodi and Eton, are participating in a clinical trial of the Gore Neuro Protection Device. The device will be used during balloon angioplasty procedures. During the procedure, a blocked blood vessel is opened by the insertion of a balloon. The device is used to prevent any particles from entering the brain and causing a stroke. The UM clinical trial is part of a nationwide study of the device.

Drs. Parodi and Eton received honoraria from W.L. Gore during the past two years for conducting presentations. Dr. Parodi is also receiving royalties from W.L. Gore for the development of the device. Dr. Parodi will

provide technical assistance regarding the use of the device and Dr. Eaton will select patients and supervise treatment during the trial.

All medical staff personnel, including physicians from the University of Miami School of Medicine, are governed by the Trust's conflict of interest policy. The conflict of interest policy generally provides that Trust employees are not permitted to make decisions when financial interests are involved such as any type of employment or consulting agreement with a Trust vendor or contractor, where the Trust employee's relative is employed by the vendor or where the vendor has provided funding for research conducted by the employee. The Trust's procurement policy requires each employee to complete a conflict of interest certification when the physician does not follow normal procurement policy but indicates a clinical preference for a particular product or service. The corporate sponsor, W.L. Gore and Drs. Parodi and Eton have executed the required conflict of interest forms.

The Ethics Commission found the Public Health Trust may contract with W.L. Gore to conduct a clinical trial of the Gore Neuro Protection Device. The payment of honoraria to the doctors does not create an impermissible conflict under the Conflict of Interest ordinance or the Conflict of Interest policy of the Public Health Trust.

Section 2-11.1(n) of the Conflict of Interest ordinance prohibits covered persons from taking actions where their financial interests are involved. Section 2-11.1(n) is inapplicable in this situation because the UM doctors are not county employees. In RQO 06-46, the Commission opined that University of Miami physicians are not employees of the Public Health Trust or Miami-Dade County. Therefore, Section 2-11.1(n) does not

prohibit the Trust from contracting with W.L. Gore for the clinical study.

Further, the UM doctors are not contractors or vendors for purpose of the Conflict of Interest and Code of Ethics ordinance. The contract for the clinical study will be between the Public Health Trust and W.L Gore. The doctors will not be parties to the contract. Therefore, the doctors are not contractors or vendors for the purpose of the Conflict of Interest ordinance.

Accordingly, the Conflict of Interest ordinance permits the Public Health Trust to contract with W.L. Gore for the clinical trial for the Neuro-Protection Device. The Conflict of Interest ordinance does not apply to UM doctors who supervise and participate in clinical studies as part of their research responsibilities.

This opinion construes the Miami-Dade Conflict of Interest and Code of Ethics ordinance only and is not applicable to any conflict under state law. Please contact the State of Florida Commission on Ethics if you have any questions regarding possible conflicts under state law.

If you have any questions regarding this opinion, please call the undersigned at (305) 579-2594 or Ardyth Walker, Staff General Counsel at (305) 350-0616.

Sincerely Yours,



ROBERT MEYERS  
Executive Director

cc: Cindy Augustyn, University of Miami