DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of the Assistant Secretary for Health

Office for Human Research Protections
Rockville, Maryland 20852

JAN 2 3 2008

Michael A. Carome, M.D.
Deputy Director
Public Citizen's Health Research Group
1600 20th Street, N.W.
Washington, D.C. 20009

Dear Dr. Carome:

I thank you and Dr. Sidney Wolfe for your August 27 response to my letter regarding the concerns you raised with the Centers for Medicare and Medicaid Services' (CMS) decision memorandum for Transcatheter Aortic Valve Replacement (TAVR), which requires Medicare and Medicaid beneficiaries to participate in a research registry as a condition of coverage for TAVR. I have sent a similar letter to Dr. Wolfe.

I appreciate your perspective and understand that we may not view the issues in the same way. In the case of CMS's coverage determination for TAVR, we believe it is ethical and regulatorily compliant to require participation in a research registry as a condition of coverage for TAVR. In circumstances where there is insufficient evidence about the benefits of a treatment, we believe there is ethical justification for CMS to offer payment for such treatment only in the context of a research study for the purpose of evaluating the effectiveness of the treatment. Studies such as these enable beneficiaries to receive a form of treatment that they might not otherwise have access to, and enables CMS to collect additional data to inform the agency's future coverage determinations.

With regard to your question of whether consent from subjects will be sought or waived for including identifiable health information in the TAVR research registry, we suggest that you contact CMS directly.

Thank you for your interest in this issue and your ongoing concern about the protection of research subjects.

Sincerely,

Jerry Menikoff, M.D., J.D.
Director
Office for Human Research Protections

cc: Dr. Sidney M. Wolfe, Public Citizen's Health Research Group
Dr. Louis B. Jacques, CMS