DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of the Assistant Secretary for Health

Office for Human Research Protections
Rockville, Maryland 20852

JUL 18 2012

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:

My thanks to you and Dr. Sidney Wolfe for your February 28 letter regarding concerns with the Centers for Medicare and Medicaid Services' (CMS) proposed decision memorandum for Transcatheter Aortic Valve Replacement (TAVR), which would require 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.

As you may be aware, CMS's final coverage determination was issued on May 1, 2012, and can be accessed at http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?&NcaName=Transcatheter%20Aortic%20Valve%20Replacement%20(TAVR)&bc=AiAAAAAAIAAA&NCAId=257&. CMS's response to your comment is addressed in their decision memo.

As indicated in CMS's response, the Office for Human Research Protections (OHRP) believes that requiring participation in a research registry as a condition of coverage for a procedure that CMS would not ordinarily be required to cover does not constitute a violation of the informed consent requirements in the Department of Health and Human Services regulations for the protection of human subjects (45 CFR 46.116). The provision of certain types of care is often conditioned on participation in a research study. We believe this type of study design is ethical since it offers individuals access to care that they might not otherwise receive. With regard to your claim that this arrangement is coercive, we note that expanding a person's opportunities – as compared to threatening to violate someone's rights unless they do what you want – is not coercive. Those who choose not to participate in the research study are not penalized, but simply do not receive the additional benefits that CMS was not legally required to provide outside of the research. Moreover, we also find that this study does not create undue influence for individuals to participate.

I appreciate your concern about the protection of research subjects and thank you for bringing this issue to OHRP's and CMS's attention.

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, M.D., CMS