

September 18, 2007

James Swink
Center for Devices and Radiological Health (HFZ-450)
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

Dear Mr. Swink,

This letter is prepared in response to the meeting notice published in the Federal Register on September 12, regarding the Circulatory System Devices Panel of the Medical Devices Advisory Committee. The following members of the TACIT (Transatlantic Asymptomatic Carotid Intervention Trial) Executive Committee will be present at the October 11th meeting and respectfully request 10 minutes of time to present the summarized information below for consideration:

Barry T. Katzen, MD, FSIR, FACR, FACC
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Baptist Hospital
8900 North Kendall Drive
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John H. Rundback, MD, FAHA, FSVMB, FSIR
Columbia University College of Physicians and Surgeons
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Asymptomatic cervical carotid stenosis (CAS) represents approximately 3/4 of carotid disease patients, affecting 5-33% of individuals over the age of 60. Despite the magnitude of the clinical problem, the preferable therapeutic approach to patients with asymptomatic CAS is currently unknown due to variably reported rates of spontaneous neurological complications and an undefined risk of neurocognitive decline. Several studies have previously suggested the therapeutic value for medical therapy (Antiplatelet Trialist Group, CAPRIE, 4S, HOPE, ORIOM), stenting (SAPPHIRE, SHELTER, CABERNET, BEACH, others), and surgery (ACAS, ACST, NASCET). However, comparative data are not available and previous studies have not included a currently valid medical treatment arm.

The TACIT study (Transatlantic Asymptomatic Carotid Intervention Trial), is a pivotal 3-arm study comparing best medical therapy alone (BMT), BMT+ carotid stenting, and BMT + endarterectomy in asymptomatic patients with >60% CAS by duplex. The primary endpoint is a composite of 30 day mortality and five year all strokes and neurocognitive decline.

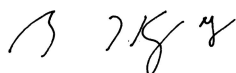
Key differences that will be addressed in this study not addressed in previous studies include: (a) the incorporation in the study design of contemporary data on antiplatelet, lipid-lowering, and antihypertensive medical therapies, not present at the time of other trial designs, have been used to construct a cohort of patients treated without revascularization; (b) the use of broader inclusion and exclusion criteria that reflect modern populations of patients considered for carotid disease management; (c) prospective randomized comparison of outcomes in patients undergoing revascularization strategies compared with an optimized targeted medical treatment group alone; (d) evaluation of numerous other critical intermediary and mechanistic outcomes never before studied, and which may have a substantial impact on therapeutic decisions -- plaque characterization, quality of life, and cost-effectiveness.

A finding that revascularization combined with medical therapy reduces events will lead to increased utilization of the best mode of revascularization and medical therapy in the prevention of stroke in asymptomatic patients with $\geq 60\%$ carotid artery stenosis. If the reverse is found to be true, these patients will increasingly be treated with medical therapy alone. Findings of risk factors and characteristics predisposing to clinical events or procedural outcomes will dramatically alter patterns of care.

The TACIT trial is distinctive and adds important data to existing studies comparing endarterectomy and stenting in asymptomatic patients and also holds the promise to provide stratified data on neurocognitive performance, plaque morphology, and economics and quality of life, which have never before been investigated.

Thank you for the opportunity to participate in this important meeting. Please feel free to contact Dr. John Rundback at (914) 907-6980 or rundback@mail.holyname.org should you have any questions or require any additional information.

Sincerely,



Barry T. Katzen, MD
U.S. Study Chair, TACIT



John H. Rundback, MD
U.S. Principal Investigator, TACIT