



Waiver to Allow Participation in a Food and Drug Administration  
Advisory Committee

DATE: March 20, 2009

TO: Randall W. Lutter, Ph.D.  
Deputy Commissioner for Policy  
Food and Drug Administration

THROUGH: Vince Tolino \_\_\_\_\_ /s/  
Director, Ethics and Integrity Staff  
Office of Management Programs  
Office of Management

Michael F. Ortwerth, Ph.D. \_\_\_\_\_ /s/  
Director, Advisory Committee Oversight and Management Staff  
Office of Policy, Planning, and Preparedness

FROM: Kathleen L. Walker \_\_\_\_\_ /s/  
Chief, Integrity, Committee and Conference Management Branch  
Division of Ethics and Management Operations, OMO  
Center for Devices and Radiological Health

Name of Advisory Committee Member: Thomas A. Vassiliades, Jr., M.D., MBA

Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee

Meeting date: April 23, 2009

Description of the Facts on Which the Waiver is Based:

Type, Nature, and Magnitude of the Financial Interest(s):

Thomas A. Vassiliades, Jr., M.D., MBA, currently serves on the Circulatory System Devices Panel, which reviews and evaluates data concerning the safety and effectiveness of marketed and investigational devices for use in the cardiovascular system and makes appropriate recommendations to the Commissioner of Food and Drugs. Dr. Vassiliades' institute, Emory University, is a clinical site for the premarket approval application (PMA) study coming before the panel for discussion. He had no involvement in the study nor received any compensation. Dr. Vassiliades works in the Department of Surgery, Division of Cardiothoracic Surgery; the two principal investigators work in a separate department and there is no managerial relationship between the three physicians. His employer will receive from the sponsor annual fees for patient follow-up between \$20,000-\$30,000.

Description of the Particular Matter to Which the Waiver Applies:

Dr. Vassiliades has been asked to participate in the meeting to discuss, make recommendations, and vote on a PMA, sponsored by Atritech, Inc. for the WATCHMAN® Left Atrial Appendage (LAA) Closure Technology. The WATCHMAN® device, a percutaneously placed permanent implant, is intended as an alternative to warfarin therapy for patients with non-valvular atrial fibrillation. The WATCHMAN® LAA Closure Technology is designed to prevent embolization of thrombi that may form in the left atrial appendage thereby preventing the occurrence of ischemic stroke and systemic thromboembolism.

Additional Facts: None

Basis for Granting the Waiver:

The WATCHMAN® device, a first-of-a-kind technology, will be used potentially by interventional cardiologists and cardiac electrophysiologists. This technology has potential use in the 1% of the U.S. population with atrial fibrillation, approximately 3 million people. Dr. Vassiliades is an experienced cardiothoracic surgeon who will provide a different perspective to the Panel discussion. He is Associate Professor, Department of Surgery, Division of Cardiothoracic Surgery at Emory University School of Medicine, has practiced in both private and academic settings, and serves on multiple national and international committees tasked with the evaluation of new cardiovascular technologies. Furthermore, Dr. Vassiliades has unique experience in evaluating devices used in the left side of the heart (as this device will be), based on his research and participation in studies of percutaneously delivered aortic valve replacements. The Center sought the participation of six other cardiac surgeons, however, only one other surgeon was free of schedule or investigational site conflicts. In order to provide a balanced and thought provoking discussion, the Center believes it is critical that the cardiac surgical viewpoint be represented by more than one expert. I believe that Dr. Vassiliades' expertise as a cardiothoracic surgeon and researcher greatly outweighs any of the perceived conflicts of interest and his presence will contribute to the opinions and expertise represented on the Panel.

