DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Section 120 of Food and Drug Administration Modernization Act of 1997
21 U.S.C. 355 (n)(4)
Amendment of Section 505 of FD&C Act

This document is the 505(n)(4) waiver for Thomas G. Pickering, M.D.
Columbia University College of Physicians and Surgeons
New York, NY
Member of the Cardiovascular and Renal Drugs Advisory Committee

Summary of 505(n)(4) Requirements

A. The requirement refers only to those Advisory Committees that provide expert scientific advice and recommendations to the agency regarding a clinical investigation of a drug or the approval for marketing of a drug under section 505 of the Food, Drug, and Cosmetic Act or Section 351 of the Public Health Service Act.
B. The requirement applies only to the review of particular matters relating to clinical investigations and approvals of drugs and biologics (e.g. NDA, PLA/BLA, efficacy and labeling supplements). It focuses uniquely and distinctly on a given product/manufacturer with a predictable rather than a speculative effect on a financial interest.
C. The requirement applies only when the member or the member's immediate family has a financial interest in the matter at hand. Immediate family is defined as spouse and minor children. Absent a waiver no member of a panel may vote on any matter where the member or the immediate family of such member could gain financially from the advice given to the Secretary (e.g., a member owns stock in the sponsor or a competing firm or the member receives salary support from a research grant/contract for research on the same or competing product).
D. The requirement applies only to voting. A member may be granted a waiver if the member affords the Committee "essential" expertise.
E. The requirement, however, unequivocally excludes the vote of any member who has personally conducted research in the product before the Committee.

The following applications of this Act for Thomas Pickering, M.D., are checked as follows.

X A. The Committee is a CBER or CDER committee.

X B. The issue before the Committee is a particular matter.

X C. The member or the member's immediate family has financial interests in the product or competing product. The interests are as follows:

Dr. Pickering owns [redacted] shares of Novartis stock, worth approximately [redacted] This stock represents less than [redacted] of Dr. Pickering's net worth. Novartis is the sponsor of Certican (everolimus), the product at issue, and is the distributor of Myfortic (mycophenolic acid), one of the competing products to Certican.

X D. The individual's expertise has been considered and deemed essential by the Center for Drug Evaluation and Research, the Agency's Ethics and Integrity Staff, and the Associate Commissioner of External Relations. See below or refer to 18 U.S.C. §208 waiver, if appropriate.

Dr. Pickering is Medical Director, Columbia Behavioral Cardiovascular Health and Hypertension Program, Columbia University of Medical Center and Assistant Professor of Medicine, Columbia University. He is known for his work in behavioral influences on the recognition of white coat hypertension as a clinically important entity of behavioral origin, the role of job strain in the development of hypertension, and the use of ambulatory and home blood pressure monitoring for evaluating the cause and consequences of hypertension. He has authored more than 450 scientific articles and chapters with respect to hypertension, environmental influences on blood pressure, and advances in the treatment of hypertension. Dr. Pickering is a member of a number of prestigious professional societies, which include the American Society of Hypertension, the Society of Behavioral Medicine, the American Psychosomatic Society, and the Academy of Behavioral Medicine Research. I believe that Dr. Pickering's participation will bring an enormous amount of experience, knowledge, and expertise that is essential to the committee's discussions concerning Certican and will help to provide a foundation for developing advice and recommendations that are fair and comprehensive.

X E. The member's own scientific work is not under consideration by the Committee.

DECISION:

Accordingly, Section 505(n)(4) waiver

✓ is granted, contingent upon public disclosure of the financial interest as required by Section 505(n)(4) of FDAMA.

____ is denied.

Sheila Dearybury Walcoff, Esq.
Associate Commissioner for External Relations
Food and Drug Administration

11/8/05
Date

Acknowledgement and Consent for Disclosure of Waivers Under 18 U.S.C. §208(b)(2) and 21 U.S.C. §355 (n)(4) of the Food and Drug Administration Modernization Act of 1997

Thomas G. Pickering, M.D.

Committee: Cardiovascular and Renal Drugs Advisory Committee

Meeting Date: November 16, 2005

I acknowledge that contingent upon public disclosure of the financial interest listed below, related to New Drug Application (NDA) 21-628, proposed trade name Certican (everolimus) Tablets (0.25 mg, 0.5mg, 0.75mg and 1.0mg) sponsored by Novartis Pharmaceuticals Corporation, the U.S. affiliate of Novartis AG, for the proposed indication of prophylaxis of rejection in heart transplantation, I am eligible to receive an 18 U.S.C. 208§ (b)(2) regulatory waiver and a waiver under 21 U.S.C. § 355(n)(4) of the Food and Drug Administration Modernization Act of 1997.

Type of Interest	Nature	Magnitude
Stock	Sponsor and distributor of a competing product.	Valued from $5,001 to $25,000

I hereby request that FDA make this information publicly available on my behalf at the start of the advisory committee meeting for which it is issued. The public disclosure will be accomplished by reading a statement into the record and by FDA making a written copy publicly available at the time of the meeting. I understand that without public disclosure of this interest the waivers are not valid.

Thomas Pickering
Signature of SGE

11/03/05
Date