



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

DATE: March 24, 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: William Freas, Ph.D. /s/
Director, Division of Scientific Advisors and Consultant
Center for Biologics Evaluation and Research

Name of Advisory Committee Member: Richard N. Pierson, III, M.D.

Committee: Cellular, Tissue and Gene Therapies Advisory Committee

Meeting date: May 14-15, 2009

Description of the Facts on Which the Waiver is Based:

Type, Nature, and Magnitude of Financial Interest (s) for Topic II (May 14, 2009)

Dr. Richard Pierson advised the FDA that he holds stock in an affected firm in the range of
----(b)(6)----.

Description of the Particular Matter to Which the Waiver Applies:

Discussion and recommendations on animal models for porcine xenotransplantation products intended to treat type 1 diabetes or acute liver failure. This is determined to be a particular matter of general applicability.

Basis for Granting the Waiver:

1) Dr. Pierson's financial interest is not so substantial so as to be deemed likely to affect the integrity of the services provided. Dr. Pierson has stock in an affected firm, valued in the range of \$-----(b)(6)----. Since the meeting is a particular meeting of general applicability, there is an exemption for stock interests up to \$25,000 (5 CFR 2640.202(b)). Although Dr. Pierson's stock holdings exceed the exemption and it is therefore not applicable, the value of his interests is only slightly above the amount of the exemption. The affected firm has a -----(b)(4)-----.

There is minimal risk that the outcome of the meeting, related to preclinical models intended to treat type 1 diabetes or acute liver failure, will affect the value of the stock in the affected firm. Dr. Pierson's financial interest in the affected firm, is low and unlikely to affect the integrity of services provided.

2) Dr. Pierson's participation provides the Committee with essential expertise in xenotransplant immunology. Richard Pierson III, M.D, is Professor of Surgery, University of Maryland, VA Maryland Health Care System. He is the current President of the International Xenotransplant Association. Dr. Pierson's research focuses on modulating immune response to induce long term acceptance of porcine xenografts.

The Committee will discuss issues related to the immunology of porcine xenotransplant therapies to treat type 1 diabetes and acute liver failure. Dr. Pierson will provide essential expertise to address questions related to immune response and tolerance in both indications.

A pool of 9 of individuals (special Government employees and non-special Government employees) with xenotransplantation expertise was considered by FDA. It was determined that other individuals considered did not have the exact expertise that Dr. Pierson will provide for discussions of long term tolerance of porcine xenografts.

Accordingly, I recommend that you grant a waiver for Dr. Richard Pierson, a temporary member of the Cellular, Tissue and Gene Therapies Advisory Committee, from the conflict of interest prohibitions of 18 U.S.C §208(b)(1) as well as the conflict of interest prohibitions of section 712(c)(2)(B) of the Federal Food, Drug and Cosmetic Act.

