



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

DATE: March 29, 2009

TO: Joshua M. Sharfstein, M.D.
Acting Commissioner of Food and Drugs
Principal Deputy Commissioner

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

Randall Lutter, Ph.D. _____ //s//
Deputy Commissioner
Office of Policy, Planning, and Preparedness

Jesse Goodman, M.D. _____ //s//
Acting Chief Scientist
Food and Drug Administration

FROM: Karen Midthun M.D. _____ //s//
Acting Director
Center for Biologics Evaluation and Research

Name of Advisory Committee Temporary Member: Richard D. Coutts, M.D.

Committee: Cellular, Tissue and Gene Therapies Advisory Committee

Meeting Date: May 14-15, 2009

This waiver is necessary for Dr. Coutts to participate in the advisory committee meeting described above because Dr. Coutts has financial interests in an organization potentially affected by the particular matter scheduled to come before the advisory committee. These interests – stock holdings in Johnson & Johnson, an international company with a very diverse product portfolio that includes medical devices and diagnostics – exceed the exemption of \$25,000 for stock holdings laid out in regulations issued by the Office of Government Ethics (5 CFR 2640.202(b)). Moreover, the stock holdings have in recent weeks exceeded \$50,000, a level identified in FDA's guidance as one where the member would not ordinarily be considered for a waiver and would not participate, unless the Commissioner reviews the request for a waiver and makes a determination on the appropriateness of the waiver.

Description of the Facts on Which the Waiver is Based:

Type, Nature, and Magnitude of Financial Interest:

Dr. Coutts' only financial interest necessitating a waiver is stock holdings in a company – Johnson & Johnson – with interests in three smaller affected firms: DePuy, DePuy Mitek and Advanced Technologies and Regenerative Medicine. For example, total sales of the DePuy companies in 2008 were roughly ten percent of the sales of Johnson & Johnson.

Description of the Particular Matter to Which the Waiver Applies:

The particular matter before the committee is to make recommendations on clinical issues related to the FDA draft guidance “Preparation of IDEs and INDs for Products Intended to Repair or Replace Knee Cartilage.” CBER has determined this to be a particular matter of general applicability.

Basis for Granting the Waiver:

The need for Dr. Coutts' services outweighs the risk of a conflict of interest. Dr. Coutts' participation is necessary to provide the Committee with essential clinical/surgical expertise in experimental cellular models for joint reconstruction. Dr. Coutts is Board Certified by the American Board of Orthopaedic Surgery, has been honored with the William Harris Award from the Orthopaedic Research Society, and has been active in a number of professional societies, including as president of the Orthopaedic Research Society; president of the Hip Society; member of the Board of Directors of the American Academy of Orthopaedic Surgeons (AAOS); Chair of the AAOS Council of Musculoskeletal Specialty Societies; and Chair of the Board and Vice President of grants at the Orthopaedic Research and Education Foundation. He is currently the President of the Board of Directors for the Malcolm and Dorothy Coutts Institute for Joint Reconstruction and Research. His extensive expertise in the evaluation of cartilage products for joint repair is critical to the Committee discussion of issues related to clinical parameters for measuring improvement in knee function and long term follow-up to evaluate clinical benefit. Dr. Coutts has published 191 articles over the last 37 years, including 16 book chapters, has 37 years of clinical practice, and has been in the orthopaedic field since 1972. Four other Special Government Employees with comparable expertise, were contacted and considered for this meeting, but were unavailable to attend.

The risk of a conflict of interest is small because the focus of the meeting and questions for the Committee's discussion are not anticipated to have a distinguishable effect on any one manufacturer over another. It is also highly unlikely that the outcome of the meeting would have any meaningful effect on the value of Dr. Coutt's Johnson & Johnson stock. Three of the firms that are potentially affected by this meeting are subsidiaries of or affiliated with Johnson & Johnson, but collectively they represent a small fraction of Johnson & Johnson's entire business. The potential that the outcome of the meeting – related to the FDA draft guidance on cellular products to repair or replace knee cartilage – would affect the value of Dr. Coutts' stock is remote.

