



Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

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

DATE: July 29, 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

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: Michael B. Mayor, M.D.

Committee: Orthopaedic and Rehabilitation Devices Panel

Meeting date: August 18, 2009

Description of the Facts on Which the Waiver is Based:

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

Dr. Michael B. Mayor serves on the Orthopaedic and Rehabilitation Devices Panel, which reviews and evaluates data concerning the safety and effectiveness of marketed and investigational orthopaedic and rehabilitation devices and makes appropriate recommendations to the Commissioner of Food and Drugs. Dr. Mayor has advised the Food and Drug Administration (FDA) that his employer has an interest with the sponsor, DePuy Orthopaedics, Inc., a unit of Johnson & Johnson. The interest involves a research support project within the Dartmouth Biomedical Engineering Laboratory for Orthopaedics, the purpose of which is to assess the consequences of materials used in implants. Retrieved surgeons from around the world submit their retrieved implants to the laboratory for assessment and analysis. The laboratory encourages

visits for scientific review among all the major U.S. orthopaedic manufacturers. In various stages of analysis are over 6,000 specimens of retrieved human joint components, making this retrieval collection the world's largest.

The research project does not involve any clinical research associated with the **CoMplete™ Acetabular Hip System** to be discussed at the Panel meeting; Dr. Mayor reported that his laboratory has not received any **CoMplete™ Acetabular Hip System** components for retrieval analysis. This project is supported by DePuy and the National Institute of Standards and Technology (NIST). The lab is run by Dr. Mayor and John Collier, Ph.D., who are co-principal investigators. DePuy/J&J contributed approximately [ redacted ] for fiscal year 2009, [ redacted ]. The research project's support from NIST is on a 3-year grant cycle providing approximately \$300,000 for the current fiscal year. Dr. Mayor does not receive any personal compensation from DePuy. This contract started in 1995 and is ongoing.

Description of the Particular Matter to Which the Waiver Applies:

Dr. Mayor has been asked to participate in the meeting to discuss and make recommendations on a premarket approval application (PMA) for the **CoMplete™ Acetabular Hip System**, sponsored by **DePuy Orthopaedics**. The device system is intended for use as a primary joint replacement prosthesis in total hip arthroplasty, and is indicated for skeletally mature patients suffering severe pain and disability due to structural damage in the hip joint from non-inflammatory degenerative joint disease and its composite diagnoses of osteoarthritis or post-traumatic arthritis.

Additional Facts: None

Basis for Granting the Waiver:

Dr. Mayor is a William and Bessie Allyn Professor of Surgery in Orthopaedics at Dartmouth Medical School and an Adjunct Professor of Engineering at the Thayer School of Engineering at Dartmouth in Lebanon, NH. Through both of these capacities, Dr. Mayor has pursued his research interests related to biomechanics, biomaterials, and orthopaedic implant retrieval analyses. His expertise in these research areas is directly relevant to the discussion at the August 18, 2009 meeting of the Orthopaedic and Rehabilitation Devices Panel, in which a new ceramic-on-metal articulating hip system will be discussed. Dr. Mayor's expertise will allow him to comment on the device function from a surgical perspective, as well as to analyze failure modes pertaining to this first-of-a-kind articulating couple. Dr. Mayor has over 30 years of experience in orthopaedic hip joint surgery. While there are four other orthopaedic joint surgeons participating in the upcoming Panel meeting, Dr. Mayor is the only orthopaedic joint surgeon who possesses expertise in retrieval and failure analysis of orthopaedic hip implants, which is considered essential for the Panel discussion. A search of NIH and CDRH databases did not reveal any individuals with comparable expertise to Dr. Mayor. I believe that participation by Dr. Mayor in the committee's deliberations will contribute to the diversity of opinions and expertise represented on the committee.

Accordingly, I recommend that you grant a limited waiver for Dr. Michael Mayor, a temporary member, of the Orthopaedic and Rehabilitation Devices Panel, from the conflict of interest prohibitions of 18 U.S.C. §208(b)(3) that will allow him to participate in the meeting but not vote.

Certification:

  X   The individual may participate – The need for the Special Government Employee's services outweighs the potential for a conflict of interest.

