



DEPARTMENT OF HEALTH & HUMAN SERVICES  
Public Health Service  
Food and Drug Administration  
Center for Biologics Evaluation and Research

DATE : November 25, 2005

FROM : William Freas, Ph.D. Will Freas  
Director, Scientific Advisors & Consultants, CBER

SUBJECT: Waiver of General Applicability under 18 U.S.C.  
208(b)(3) for Richard O. Snyder, Ph.D.

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

THROUGH: Jenny Slaughter  
Director, Ethics and Integrity Staff  
Office of Management Programs, OM

Richard O. Snyder, Ph.D., has been appointed as a special Government employee to the Center for Biologics Evaluation and Research. He has been asked to participate in the Cellular, Tissue and Gene Therapies Advisory Committee meeting. This memorandum constitutes a determination in accordance with 18 U.S.C. §208(b)(3) that the need for Dr. Snyder's services on the Committee outweighs the potential for a conflict of interest created by any personal or imputed financial-interest that he may have in matters of general applicability in which he is expected to participate.

The Committee will discuss, in open session, the potency for cellular and gene transfer products. It is expected that the Committee will focus largely, if not exclusively, on matters of general applicability, as opposed to matters involving specific parties or matters that uniquely and distinctly affect any particular person or organization.

These matters may affect certain financial interests of Dr. Snyder's or of persons and organizations with which he may have certain relationships. This would include:

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Associate Commissioner for External Relations, FDA

Financial investments in medical product companies, food related companies, drug related companies, health care industry, and any other industry that might be affected by the recommendations of the Committee, for example, stocks [REDACTED], [REDACTED] and [REDACTED]. Also included are patents the [REDACTED] and [REDACTED] for adeno-associated virus vectors;

Employment with research institutions, state and local governments, medical product manufacturers, food related companies, drug related companies, health care industry or other organizations that may be affected by the Committee's recommendations, for example, the University of Florida College of Medicine where he is employed as the Director of the BioTherapeutic Programs and Assistant Professor, Department of Molecular Genetics and Microbiology and Department of Pediatrics;

Grants, contracts or other funding for research or other services received from the federal government that might be affected by the Committee's recommendations, for example, his grant support from the National Institutes of Health, including the National Eye Institute; the National Institute for Diabetes, and Digestive and Kidney Disease; the National Center for Research Resources; the National Heart, Lung and Blood Institute; and the National Institute for Neurological Diseases and Stroke;

Grants, contracts or other funding for research or other services received from non-federal sources, including industry and foundations, that might be affected by the Committee's recommendations, for example, his research support from the [REDACTED]; and [REDACTED];

Expert witness, litigation or advocacy services in matters that might be affected by the recommendations of the Committee (i.e., interests currently reported);

Any interest of a group or other organization in which Dr. Snyder is appointed as an officer, director, trustee, officer or general partner that might be affected by the Committee's recommendations, for example, [REDACTED] where Dr. Snyder is a minority founder.

Under 18 U.S.C. §208, Dr. Snyder may not participate in any particular matter affecting these interests, unless he receives a waiver. However, pursuant to my authority to grant waivers under 18 U.S.C. §208(b)(3), I have determined that the need for services of Richard O. Snyder, Ph.D., with respect to matters of general applicability, outweighs any concern that these types of interests might create a potential for a conflict of interest. Consequently, Dr. Snyder may participate in matters of general applicability affecting any current and future financial interests of the types described above. This determination is based on the following considerations:

The Food and Drug Administration has a particularly strong need for Dr. Snyder's services. In addition to Dr. Snyder's positions listed above at the University of Florida College of Medicine, Dr. Snyder's other official duties attest to his expertise in the field of gene therapy. He is Director, Center of Excellence for Regenerative Health Biotechnology and Director of the Human Applications Laboratory, Powell Gene Therapy Center. Dr. Snyder is also a member of the University of Florida Genetics Institute and a member of the McKnight Brain Institute. Dr. Snyder is a leading expert in the development of methods for producing new gene vectors, including scale-up of production for human trials, automation and development of new assays. His extensive manufacturing experience is critical to the Committee discussion of potency issues related to all gene transfer products.

Furthermore, the Committee Charter requires the appointment of individuals who are authorities knowledgeable in a variety of scientific and medical professions. Consequently, it is expected that persons qualified to serve on the Committee will have interests, financial and otherwise, in the work of the Committee. This includes not only employment interests, but also investment and pension interests, as experience has shown that persons employed in the biomedical area frequently acquire investment and pension interests in organizations related to their expertise. In short, financial interests simply are unavoidable in view of the work and membership requirements of this Committee.

Likewise, the very diversity of interests required by the Charter will ensure that no one member is in a position to determine policy in favor of anyone affected interest. In addition to the specific requirements of the Charter, the Federal Advisory Committee Act requires fair balance and openness, which serve as important checks against real or apparent threats to the objectivity of Committee action.

Finally, the Committee is expected to focus mainly on matters of general applicability rather than matters involving specific parties. It is well-recognized that such general matters pose less risk of a conflict of interest. Matters of general applicability include regulations, legislations, and policies governing classes of organizations, individuals, and products.

However, this does not include matters involving specific parties, such as specific grants (as opposed to general recommendations for increased funding in a given area), contracts, product approval applications, or enforcement matters involving known parties.

Please note that this is a waiver of general applicability. It will not allow Dr. Snyder to participate in any matters involving specific parties that may affect his financial interests, or any person or organization described above. If the work of the Committee turns from matters of general applicability to more specific matters (e.g., recommendations regarding a specific product), participants will seek additional advice.

CONCURRENCE:

/s/  
Jenny Slaughter  
Director, Ethics and Integrity Staff  
Office Management Programs, OM

11/10/06  
Date

DECISION:

/  
General matters waiver granted based on my determination, made in accordance with section 208(b)(3), that the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest attributable to the individual.

       Waiver denied.

/s/  
Sheila Dearybury Walcoff, Esq.  
Associate Commissioner for  
External Relations, FDA

1-17-06  
Date