**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: August 28, 2006

TO: Randall Lutter, Ph.D.
Associate Commissioner for Policy and Planning
Food and Drug Administration

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

FROM: Igor Cerny, Pharm.D. /S/
Director, Advisors and Consultants Staff
Center for Drug Evaluation and Research

SUBJECT: Conflict of Interest Waiver for Robert Tuttle, M.D.

I am writing to request a waiver for Robert Tuttle, M.D., a consultant to the Center for Drug Evaluation and Research, from the conflict of interest prohibitions of 18 U.S.C. §208(a). The appointing official may grant waivers under section 208(b) (3) where "the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved" and where the individual has made a disclosure of the financial interests at issue. We have determined that you are the appointing official for purposes of section 208. Therefore, you have the authority to grant Dr. Tuttle a waiver under 18 U.S.C. §208(b) (3).

Section 208(a) prohibits Federal executive branch employees, including special Government employees, from participating personally and substantially in matters in which the employee, or any other person whose interests are imputed to the employee under 18 U.S.C. §208, has a financial interest. Since Dr. Tuttle is a special Government employee, he is under a statutory obligation to refrain from participating in an official capacity in any particular matter having a direct and predictable effect on a financial interest attributable to him, his spouse, minor child, or general partner; an organization or entity for which he serves as an officer, director, trustee,

general partner, or employee; and, a person with whom he is negotiating for, or has an arrangement concerning, prospective employment.

Dr. Tuttle has been asked to participate in the committees' discussions of FDA's efforts to assess the product quality of currently marketed levothyroxine sodium drug products. Earlier this year, FDA requested that manufacturers of currently marketed levothyroxine sodium products provide to it certain product release and stability information. The committees' will consider FDA's analyses and any clinical significance. This issue is coming before a joint meeting of the Endocrinologic and Metabolic Drugs Advisory Committee and the Advisory Committee for Pharmaceutical Science.

The committees' function statements as stated in their Charters are as follows: The Endocrinologic and Metabolic Drugs Advisory Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of endocrine and metabolic disorders. The Pharmaceutical Science Advisory Committee provides advice on scientific and technical issues concerning the safety, and effectiveness of human generic drug products for use in the treatment of a broad spectrum of human diseases, and as required, any other product for which the Food and Drug Administration has regulatory responsibility. The Committee may also review Agency sponsored intramural and extramural biomedical research programs in support of FDA's generic drug regulatory responsibilities. Both committees make their appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Tuttle has advised the Food and Drug Administration that he has a financial interest that could potentially be affected by his participation in the matter at issue. **Over the years, Dr. Tuttle has worked with [redacted] as a consultant/advisor and speaker on a number of educational projects concerning various thyroid diseases. Dr. Tuttle receives moderate compensation for these activities. [redacted] is one of the currently marketed levothyroxine products that could be affected by the committees' discussions.**

As a non-voting consultant advising the Endocrinologic and Metabolic Drugs Advisory Committee and the Advisory Committee for Pharmaceutical Science, Dr. Tuttle potentially could become involved in matters that could affect his financial interest. Under 18 U.S.C. §208(a), he is prohibited from participating in such matters. However, as noted above, you have the authority under 18 U.S.C. §208(b) (3) to grant a waiver permitting Dr. Tuttle to participate in such matters as you deem appropriate.

For the following reasons, I believe that it would be appropriate for you to grant a waiver to Dr. Tuttle, which would permit him to participate in the committees' discussions of FDA's efforts to assess the product quality of currently marketed levothyroxine sodium drug products.

First, this waiver is justified, in part, because of the nature of the matters to be discussed. The committees' discussions of FDA's efforts to assess the product quality of currently marketed levothyroxine sodium drug products will not have a unique and distinct impact on any particular product or manufacturer, but rather may affect classes of similarly situated products and manufacturers to the same extent. While this participation may be covered by section 208, it poses far less risk of a conflict than participation in matters that relate specifically to a particular firm in which Dr. Tuttle has an interest.

Second, **Dr. Tuttle's interest is not so substantial as to preclude his participation in this matter. He receives moderate compensation from** [redacted].

Third, **it is unclear whether** [redacted] **would be more or less likely to retain Dr. Tuttle's services, in the future, because of the committees' recommendations and the agency's action on the matters under discussion. Dr. Tuttle is a leading expert in clinical care of thyroid cancer patients and his services are sought by regulated industry and the government alike. Moreover, the fact that he has worked with** [redacted] **for a number of years makes it less likely that his participation in this matter will affect his relationship with** [redacted].

Finally, the Federal Advisory Committee Act requires that committee memberships be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee. In addition, the committees' intended purpose would be significantly impaired if the Agency could not call upon experts who have become eminent in their fields, notwithstanding the financial interests and affiliations they may have acquired because of their demonstrated abilities. Dr. Robert Tuttle is Associate Member, Memorial Sloan Kettering Cancer Center, Associate Attending Physician, Department of Medicine, Memorial Hospital for Cancer and Allied Diseases and Associate Professor of Medicine, Joan and Sanford I. Weill, Medical College of Cornell University. He is a member of several professional societies, such as, the Endocrine Society, the American Thyroid Association, and the Academy of Medicine. Dr Tuttle's primary research interests have been in thyroid cancer and specifically radiation induced thyroid cancer. His research efforts have taken him from Kwajalein Atoll in the Marshall Islands to the Hanford Nuclear power-plant in Washington State to regions of Russia exposed to fallout from the Chernobyl accident. His clinical research has focused on novel approaches to early detection and treatment of advanced thyroid cancer. I believe Dr. Tuttle's unique combination of expertise in the clinical care of thyroid cancer patients and his extensive experience in molecular biology will provide the committees' with much needed expertise and is essential for an appropriate discussion of the topic to be considered at this meeting.

Accordingly, I recommend that you grant Robert Tuttle, M.D., a non-voting consultant, a waiver that will permit him to participate in the committees' discussions of FDA's efforts to assess the product quality of currently marketed levothyroxine sodium drug products. I believe that this waiver is appropriate because in this case, the need for the services of Dr. Tuttle

outweighs the potential for a conflict of interest created by the financial interest attributable to him.

CONCURRENCE: /S/ 9/14/06

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

Date

DECISION:

✓ Waiver granted based on my determination, made in accordance with section 18 U.S.C. §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/ 9/14/06

Randall Lutter, Ph.D.
Associate Commissioner for Policy
and Planning
Food and Drug Administration

Date