



DEPARTMENT OF HEALTH & HUMAN SERVICES

MEMORANDUM

Food and Drug Administration  
Rockville MD 20857

**DATE:** June 30, 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 George Macones,  
M.D., M.S.C.E.

I am writing to request a waiver for George Macones, M.D., M.S.C.E., 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 18 U.S.C. §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. You are the appointing official for purposes of section 208; therefore, you have the authority to grant Dr. Macones a waiver under section 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. Macones 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. Macones has been asked to participate in all official matters regarding new drug application (NDA) 21-945, 17 alpha-hydroxyprogesterone caproate 250 mg/mL injection, sponsored by Adeza Biomedical Corporation for the proposed indication of the prevention of preterm delivery in women with a history of a prior preterm delivery. This matter is coming before the Reproductive Health Drugs Advisory Committee.

The function of the Reproductive Health Drugs Advisory committee is to review and evaluate data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of obstetrics, gynecology, and related specialties, and make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Macones has advised the Food and Drug Administration (FDA) that he has a financial interest that could potentially be affected by his participation in the matter described above. Dr. Macones is the Chairman of the Department of Obstetrics and Gynecology at the Washington University School of Medicine. There are over twenty-five full-time faculty members on staff in his department. One of these faculty members, Dr. \_\_\_\_\_, serves as the principal site investigator for a phase III study of \_\_\_\_\_ for the prevention of preterm delivery in women at increase risk for preterm delivery. The Washington University is one of twelve clinical sites for the study, which began in 2005 and is expected to end in 2007. The Washington University receives approximately \$\_\_\_\_\_ per patient enrolled from \_\_\_\_\_, with two patients enrolled. Dr. Macones has no direct involvement in the study. His only involvement is administrative. He does not receive any personal remuneration or salary support from the funds received. The \_\_\_\_\_ is a competing product to 17 alpha-hydroxyprogesterone caproate.

As a consultant advising the Reproductive Health Drugs Advisory Committee, Dr. Macones could potentially become involved in matters that could affect his financial interests. Under section 208, 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. George Macones 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. Macones that would allow him to participate fully in the matter described above.

**First, although Dr. Macones' employer currently has a financial interest in \_\_\_\_\_, he himself has no personal financial interest in the firm or its product.** Although the financial interest of an employer imputes to the individual under 18 U.S.C. §208, generally there is less likelihood that the judgment of the individual will be affected by an imputed interest of an employer than by a personal financial interest.

Second, it is important to note that Dr. Macones is not an investigator in this study. His only involvement is administrative, as Chairman of the Department of Obstetrics and Gynecology.

**Moreover, the amount of funding to be received in support of the \_\_\_\_\_ study is not so substantial as to preclude Dr. Macones' participation in this meeting. The Washington University receives minimal funding from \_\_\_\_\_ for the study.**

Further, it is difficult to predict what impact, if any, that Dr. Macones' participation in this matter will have upon the clinical trial currently underway within the Department of Obstetrics and Gynecology. It is unlikely that any action, short of a "clinical hold," would effect this study or cause the sponsor to prematurely terminate the study. Even if it were possible that the firm would be more or less likely to continue to provide financial support to the Washington University in the future as a result of the committee's deliberations, the financial impact would probably be relatively insignificant since this is not a significant financial interest. The Washington University receives funding from a variety of public, private, and governmental agencies in support of its research activities. It does not depend upon one or two sources for its funding.

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. Also, the committee's intended purpose would be significantly impaired if the Agency could not call upon experts who have become eminent in their fields, notwithstanding the financial interest and affiliations they may have acquired as a result of their demonstrated abilities. Dr. Macones is Professor of Medicine and Chairman of the Department of Obstetrics and Gynecology at the Washington University School of Medicine. He specializes in clinical epidemiology, obstetrics and gynecology, and maternal-fetal medicine. Dr. Macones is an elected member of the American Gynecologist and Obstetrical Society and the Perinatal Research Society. He also serves as a reviewer for numerous professional journals including the American Journal of Obstetrics and Gynecology, the Annals of Internal Medicine, Lancet, and the Journal of the American Medical Association. I believe that Dr. Macones' participation will contribute to the diversity of expertise and viewpoints represented and will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

