



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 Cassandra  
Henderson, M.D.

I am writing to request a waiver for Cassandra Henderson, 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 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. Henderson 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 her employer has a financial interest. Since Dr. Henderson is a special Government employee, she 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 her, her spouse, minor child, or general partner; an organization or entity for which she serves as an officer, director, trustee, general partner, or employee; and, a person with whom she is negotiating for, or has an arrangement concerning, prospective employment.

Dr. Henderson 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. Henderson has advised the Food and Drug Administration that she has a financial interest that could potentially be affected by her participation in the matter at issue. Dr. Henderson is a member of \_\_\_\_\_ 's Speaker's Bureau. She lectures on general maternal-fetal medicine topics that are unrelated to the product or to the competing products coming before the committee. \_\_\_\_\_ is the sponsor of \_\_\_\_\_.**

As a consultant advising the Reproductive Health Drugs Advisory Committee, Dr. Henderson could potentially become involved in matters that could affect her financial interests. Under section 208, she 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. Cassandra Henderson 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 Cassandra Henderson, M.D., that would permit her to participate in the matter previously described.

**First, and foremost, it is important to note that Dr. Henderson's interests in \_\_\_\_\_ is unrelated to the particular matter in which she is being asked to participate, or to the competing products. Arguably, her interests do not constitute financial interests in the particular matter within the meaning of 18**

U.S.C. § 208(a). Nevertheless, I recommend that this waiver be granted.

**Second, Dr. Henderson's personal financial interest in \_\_\_\_\_ is not so substantial as to preclude her participation in this matter. Dr. Henderson receives modest compensation for her speaking.**

Further, 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 various advisory committee members. 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 interests and affiliations they may have acquired as a result of their demonstrated abilities. Dr. Cassandra Henderson is Associate Professor of Obstetrics and Gynecology at the Albert Einstein College of Medicine. She is board certified in obstetrics and gynecology with a subspecialty in maternal fetal medicine. Dr. Henderson is also the author of several textbook chapters on maternal-fetal medicine and a member of several prestigious professional organizations, including the American College of Obstetrics & Gynecology, the American Medical Association, and the American Academy of Family Physicians. I believe that Dr. Henderson's 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.

