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March 16, 2005

Ms. Linda L. Conte
Office of the General Counsel
Ethics Division
Department of Health and Human Services
Hubert H. Humphrey Building, Room 700-E
200 Independence Avenue, S.W.
Washington, D.C. 20201

by e-mail to ethics@hhs.gov

Re: Comments on Interim Final HHS Supplemental Ethics Rule

Dear Ms. Conte:

The American Association of Immunologists (AAI), a professional association representing more than 6,500 research scientists and physicians who are the world's leading experts on the immune system, urges the Department of Health and Human Services (DHHS) to withdraw immediately the interim final rule on conflicts of interest promulgated by DHHS/National Institutes of Health (NIH) on February 3, 2005. (*Supplemental Standards of Ethical Conduct and Financial Disclosure Requirements for Employees of the Department of Health and Human Services*, 5 CFR (Parts 5501 and 5502), Federal Register Vol. 70, No. 22, February 3, 2005, pages 5543 et seq.)

AAI shares DHHS/NIH's determination to avoid any conflicts of interest which could undermine the legitimacy, value, or credibility of NIH as an institution - or of its individual scientists or the research they conduct. Nevertheless, we believe that the rule as promulgated, which was adopted without public comment and which goes beyond the recommendations of the NIH Blue Ribbon Commission on Conflict of Interest Policies, is overly strict (e.g., preventing scientists from meaningful participation with not-for-profit professional scientific societies) and too broad (e.g., applying to all NIH employees, including those with no authority over funding, policy, etc.). Indeed, NIH's own internal investigation - clearing a large majority of scientists who had been suspected of such conflicts (see *The Washington Post*, February 23, 2005, pages A1 and A4, reporting that "more than half" and "as much as 80% of the seeming improprieties were actually the result of errors by government investigators") compels the conclusion that new conflict of interest rules, *if any*, should be crafted with the much more limited scope of the existing problem in mind.

AAI is deeply concerned about the negative effect that the interim final rule has already had on the morale of NIH's dedicated intramural community, the vast majority of whom have had no conflicts of interest or engaged in even the appearance of impropriety. AAI is also concerned about the effect of the rule - and the climate of mistrust that it reflects - on NIH's efforts to recruit and retain the very best scientists and employees. While AAI agrees that real conflicts of interest cannot be tolerated and that even the appearance of conflicts of interest should be avoided, we believe that the interim final rule unfairly presumes NIH employees guilty and incorrectly assumes the existence of massive numbers of real or perceived conflicts.

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Among our many other concerns, some of which we will address in subsequent comments, is that the new rule will undoubtedly decrease scientific communication between NIH scientists and industry, a clearly undesirable consequence if NIH's goal is to advance research "from the bench to the bedside".

AAI would be pleased to work with DHHS/NIH to ensure the ultimate adoption of reasonable, fair, and proportionate rules that are crafted in a climate of considered thought and reflection. In the meantime, we urge DHHS/NIH to withdraw the interim final rule and reissue any new draft rule only after careful consideration (and incorporation) of comments received during this public comment period.

Please feel free to call upon us if we may be of assistance as you move forward.

Sincerely,

Hugh Auchincloss, M.D.
Chair, AAI Committee on Public Affairs

Susan Swain, Ph.D.
President

cc. The Honorable Michael Leavitt, Secretary of Health and Human Services
Elias Zerhouni, M.D., Director, National Institutes of Health