



**Association of  
American Medical Colleges**  
2450 N Street, N.W., Washington, D.C. 20037-1127  
**T** 202 828 0400 **F** 202 828 1125  
www.aamc.org

March 31, 2005

**BY ELECTRONIC MAIL: [ethics@hhs.gov](mailto:ethics@hhs.gov)**

Linda L. Conte  
Office of General Counsel  
Ethics Division  
Department of Health and Human Services  
Room 700-E  
Hubert Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

**Re: Comments on Interim Final HHS Supplemental Ethics Rule**

Dear Ms. Conte:

I am writing on behalf of the Association of American Medical Colleges (AAMC) in response to the request for comments on the Interim Final Rule: Supplemental Standards of Ethical Conduct and Financial Disclosure Requirements for Employees of the Department of Health and Human Services (HHS), 5 CFR parts 5501 and 5502, appearing in the Federal Register on February 3, 2005 (70 FR 5543).

The AAMC is a non-profit organization representing all 126 accredited U.S. medical schools, some 400 major teaching hospitals, and 94 academic and professional societies representing 109,000 faculty members. The new Supplemental Standards will significantly affect scientists at the National Institutes of Health (NIH), many of whom are members of the academic and professional societies that make up one of AAMC's three governing Councils, the Council of Academic Societies. Moreover, NIH scientists contribute importantly to the educational and patient care programs of the AAMC's member medical schools and teaching hospitals. Accordingly, our comments are focused especially on those portions of the Supplemental Standards that regulate the interactions of NIH scientists with academic and professional societies, medical schools, and teaching hospitals.

The AAMC strongly endorses the responsible regulation of NIH employees through the promulgation and effective enforcement of unambiguous ethical standards to assure the integrity and credibility of NIH employees and programs and to maintain public confidence in the agency. The special status of the NIH requires that any activities with the potential for creating real or apparent conflicts of interest be scrupulously avoided wherever possible and, where allowed, be carefully restricted through accountable disclosure and monitoring.



However, the AAMC believes that the NIH-specific provisions of the Supplemental Standards substantially over-regulate employees, both in terms of the content of the Standards and in their sweeping embrace of all NIH employees, irrespective of the nature of their official duties. By so doing, NIH has created sharp restrictions and absolute prohibitions that are not carefully aligned with risk of potential conflict and go significantly beyond those necessary to protect integrity. The provisions limit, without corresponding gain in protection from conflicts of interest, the ability of NIH scientists to engage in important and mutually valuable academic interactions with medical schools and teaching hospitals and in scholarly activities with professional and academic societies of the kinds treasured by all scientists.

Not only are NIH employees thus isolated from worthy professional interactions and activities that should not be proscribed, but they and their families are also prohibited from holding a wide (and yet to be defined) range of financial interests above \$15,000, again, without corresponding gain in protection from conflicts of interest. These restrictions extend throughout the rank and file of NIH employment and fail to focus, as they should, solely on those positions that have influence over NIH decisions, programs and activities.

Our comments are directed at those provisions that we believe are most problematic, and that deserve *timely* modification lest irreparable damage be done to the agency properly regarded as “the jewel in the crown” of the federal government.

The preamble to the Supplemental Standards states that they “are focused on those types of activities and external entities that may pose the most significant risk of potential conflicts.” However, this asserted linkage between risk and regulation of the risk-prone activity is not consistently reflected in the Standards. Necessary efforts to avoid conflicts of interest must not prevent NIH scientists from engaging in legitimate activities that are beneficial to the scientists, NIH, biomedical science, and the broader public, *when the activities are not realistically associated with risk of conflicts of interest*. AAMC believes that DHHS’ stated goal of protecting the integrity of NIH and assuring the accountability of its employees can be met credibly without imposing certain of the current stringent restrictions on important scholarly and professional activities and relationships, and by focusing the Standards more precisely on those in positions of authority and influence.

### **Applicability**

NIH employs a diverse community of highly talented and motivated scientists and others, making the agency one of the most successful and widely respected research organizations in the world. In particular, the agency attracts excellent postdoctoral and clinical trainees, accomplished visiting and guest researchers, and the laboratory and administrative support staffs necessary to sustain the research enterprise. Regulations restricting outside relations and financial interests should be tailored to the roles these different individuals and groups fill and to



the risk of conflict that their outside interests could pose for NIH activities. Research fellows, trainees and visitors with only temporary associations with NIH should be governed by different rules from those applicable to regular employees. AAMC is gratified that, according to published reports, research fellows have recently been exempted from divestiture requirements for certain financial interests. Burdening those with only temporary associations will surely make the NIH a less attractive place for men and women who will be the next generation of biomedical scientists.

The AAMC recommends that the interim final regulation be modified to accommodate better the diversity of employees that serve NIH, based on the nature of their responsibilities and the reasonable risk associated with their roles. In addition, the AAMC endorses the recommendation of the NIH Fellows Committee that explicit exemption be provided for trainees and fellows from the prohibited financial holdings provisions, and that alternative regulations be proposed for regulating their outside activities, consistent with their temporary status. The AAMC acknowledges the steps already taken by NIH to address this concern.

### **Prohibited outside activities**

AAMC is especially troubled about the breadth of the regulations directed at outside activities [Sec. 5501.109]. We believe that academic and professional societies should be excluded from the definition of “related trade, professional, or similar association”. We do not agree that these activities pose problems of conflict of interest that threaten public trust in biomedical research or the ability of NIH to provide independent public health advice.

Academic and professional societies are not-for-profit, primarily 501(c)(3) independent scientific, scholarly, and educational organizations whose members are individual researchers, clinicians, and educators. These societies serve the scientific community by fostering the professional career development and education of members, advancing their disciplines through publication of peer-reviewed scientific and educational journals, and organizing scientific meetings and programs that nurture the next generation of scientists. These missions are distinct from those of trade associations or consumer or advocacy organizations. Most if not all NIH scientists have scholarly relationships with such academic and professional societies, or have performed uncompensated services for them. NIH employees should be encouraged, not discouraged, from participating in these kinds of scientific and scholarly activities for the benefit of the entire community.

The Supplemental Standards unnecessarily restrict NIH scientists from engaging in legitimate activities. Existing rules already provide sufficient guidance for situations that may pose conflicts, such as those rules regulating the holding of positions with fiduciary responsibility, and existing laws (the Anti-Lobbying Act and the Anti-Representation Statute) governing lobbying and representation of outside interests. We do not object to the requirement that such outside activity be pre-approved in order to monitor time commitments, provided that “pre-approval” is



defined and administered so as not to discourage such activity. However, we do object to restrictions on modest compensation of off-duty time for this worthy service (for example, editing premier scientific journals) on behalf of organizations that serve the entire scientific and scholarly community. Therefore, the AAMC strongly recommends that academic and professional societies be excluded from the definition of “related trade, professional, or similar association” so that activities on behalf of such organizations can be undertaken by rank and file NIH employees as permitted outside activity (provided advance approval is obtained on an individual basis).

In addition, though the AAMC appreciates that six exceptions are provided to the broad prohibition on outside activities, two of the exceptions are so narrowly drawn as to restrict entirely activity that is appropriate and not associated with conflicts of interest. For example, teaching and interacting with students are valuable services to the community, fostering the development of the next generation of physicians and scientists. Yet teaching, in particular, is not part of the official duties of NIH scientists. The exception for teaching recognizes the importance of teaching to the NIH, to the scientist, and to the community but only by exempting those who give *multiple lectures as part of an established curriculum*. In point of fact, single presentations by guest lecturers are very common in medical education, and, whether part of an established curriculum or a single seminar, are also very important. The AAMC recommends that this category of teaching activity be given exempt status as well.

Similar arguments may be made about the restriction on clinical, medical, or health-related professional practice activity to “personal provision of care” to or in connection with “individual patients”. We believe that NIH clinician-scientists perform valuable service in the clinical teaching of medical students and supervision of residents in a format that may require the clinician-teacher to provide care indirectly to populations of patients. The AAMC urges that allowance be made for these constructive activities that do not present the risk of inappropriate outside influence that the Standards seek to address. Therefore, the AAMC recommends the deletion of the phrase “personal provision of” and the phrase “to or in connection with individual patients” from the exception for clinical, medical, or health-related professional practice. The remaining restrictions on these activities are appropriately risk-linked and guard against conflict of interest.

### **Submission of requests for approval of outside activities**

Successful implementation of the Supplemental Standards depends greatly on the process by which activities will be evaluated for approval. NIH should have the necessary information to make sound determinations while minimizing the administrative burden that may discourage its scientists and others from engaging in legitimate and beneficial activities. AAMC believes that the rules governing the content of the requests for prior approval as described [Sec. 5501.106(d)(3)] are unnecessarily burdensome and will discourage activities that are clearly permitted. The Standards themselves describe the process as “complicated.” Especially



problematic is the impact on writing and editing for peer-reviewed journals that is a frequent activity of NIH scientists. Such activity, permitted by one of the exceptions to Sec. 5501.106(d)(3), generally does not pose the risk of conflict of interest. Because we recognize the need to monitor outside time commitments of permitted activity, and to the extent that some of the information described in the relevant Section is deemed essential to evaluation of external time commitments, NIH should have sufficient electronic resources to streamline and automate the process. The AAMC recommends consideration of an alternative, less onerous format for requesting approval for activities covered by the exceptions, including teaching, clinical care, writing and editing for peer-reviewed journals, and other activities for professional and academic societies.

### **Prohibited financial interests**

Regulations governing financial holdings in substantially affected organizations by NIH employees (Sec. 5501.110) must be more carefully stratified, and “substantially affected organizations” far more clearly defined. Especially in light of the over-reach of the existing definition of “substantially affected organizations,” this rule will have significant negative impact on current NIH employees and their families and on recruitment of new employees, especially in cases where no real or apparent conflicts of interest may exist. Although some stratification is already provided based on the filing status of an employee, we believe that further distinctions must be drawn. We understand that NIH has announced that non-employee fellows are not subject to the new prohibited holdings provisions, and employee fellows who do not file financial disclosure reports and who do not stay at NIH more than four years are similarly exempted.

However, further exemptions must be crafted so as to relieve rank and file employees from the prohibited holdings provisions, although they would still be subject to the financial disclosure provisions. Similarly, when an NIH scientist authors a paper on a topic in which she/he has, or may be perceived to have, a financial conflict of interest, that conflict should be disclosed to the journal and all reviewers. Particularly in light of disclosure requirements, it appears quite inappropriate to us to use the blunt instrument of prohibition to “cure” potential conflicts of employees who in fact cannot influence NIH policy or decisions. The credibility of the entire conflict of interest regime would be undermined by indiscriminately imposing penalties entirely disproportionate to risk. Furthermore, clarification is needed of the definition of “significantly affected organization” and of possible alternatives to complete divestiture. The AAMC recommends (a) that the deadline for divesting prohibited holdings be explicitly extended until such time as NIH limits the applicability of this rule appropriately to those who are in positions with substantial authority and discretion, and (b) the Standards be modified to permit, with disclosure, financial holdings for rank and file NIH scientists and other employees who are not in policy-making or discretion-exercising positions, as well as for research and clinical fellows, postdoctoral fellows, and guest researchers.



### **Awards tendered to employees of NIH**

Outstanding scientists, including those at NIH, are often given awards by outside organizations. The peer recognition and public acclaim are highly valued, and some exceptionally prestigious awards carry substantial monetary prizes. AAMC recognizes that some awards, or awarding organizations, may be associated with real or perceived conflicts of interest. The implementation of the awards rule [Sec. 5501.111] should proceed according to standards of reasonableness and efficiency. We have been assured that NIH employees will be able to accept the honor of an award; however, problems appear to be surfacing in getting awards approved. The AAMC recommends that the specific criteria used to approve awards be published and that the list of those awards pre-approved for acceptance be prepared expeditiously by the Advisory Committee to the Director. Certain awards funded by unrestricted industry grants but wholly selected and awarded by scientific organizations, exclusive of any industry involvement, should be allowed under stated conditions.

### **Evaluation and assessment of the Supplemental Standards**

The excellence of the intramural program depends critically on the ability of NIH to attract and retain the best scientists. The effects of these regulations on recruitment and retention are impossible to predict, will be difficult to measure, and may not be readily apparent in the short term. Nevertheless, there is a danger that they will result in the inability to retain some of NIH's most prominent scientists and to recruit outstanding talent. Accordingly, in order to protect the public's interest in maintaining the quality of NIH science, the impact of the Standards must be carefully monitored and evaluated. As a part of this evaluation, NIH should publish an annual agency-wide statistical report on the number and types of outside activities approved for its employees, as recommended by the NIH Blue Ribbon Panel on Conflict of Interest Policies. We encourage NIH to move forward with a plan to evaluate effects on hiring, retention, quality of science, and technology transfer resulting from the Interim Standards. DHHS and NIH must take action promptly to interdict negative effects by appropriate modifications of the Interim Rules over both the short- and longer-terms. AAMC is pleased that NIH has already begun this process by their recently announced revisions of certain provisions.

### **Enforcement**

Finally, it is essential to note that no conflicts rules, no matter how carefully crafted and precisely calibrated, can be effective without a responsible, comprehensive, and consistent enforcement process. Such enforcement appears to have been inadequate in the past. Going forward, it is essential that even handed application of the rules and consistent and reliable enforcement measures accompany any new standards.



**Conclusion**

The AAMC appreciates the opportunity to comment on the Interim Final Rule. It is critical that the Final Rule provide the most targeted and effective management of conflicts of interest at NIH, while not isolating agency scientists from the scientific mainstream. We urge that the Final Rule be modified quickly to achieve that goal. Accordingly, the AAMC recommends that careful consideration of public comments and completion of the internal review of outside activities proceed apace and be followed by appropriate revision and diligent implementation of the Final Rule. It is especially important that NIH employees not be forced to terminate legitimate outside activities and divest themselves of non-problematic financial holdings.

Sincerely,

A handwritten signature in black ink, appearing to read "Jordan J. Cohen". The signature is fluid and cursive.

Jordan J. Cohen, M.D.  
President

cc: Elias Zerhouni, M.D.  
Raynard Kington, M.D., Ph.D.  
Holli Beckerman-Jaffe, J.D.  
Secretary Michael O. Leavitt