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2157 RAYBURN HOUSE OFFICE BUILDING

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MAJORITY (202) 225-5051
FACSIMILE (202) 225-4784
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August 29, 2007

Dr. John Bucher
Associate Director
National Toxicology Program
P.O. Box 12233
Research Triangle Park, NC 27709-2233

Dear Dr. Bucher:

I am writing regarding the recent report prepared by a working group of the Board of Scientific Counselors of the National Toxicology Program (NTP) "to evaluate and assess existing NTP contracts for conflicts of interest."¹ Although the report's recommendations for preventing and mitigating future conflicts of interest are promising, the report's analysis of potential conflicts of interest under current NTP contracts appears to have serious weaknesses.

The establishment of the working group was one of the measures undertaken by the National Institute of Environmental Health Sciences (NIEHS) in the wake of revelations of apparent conflicts of interest involving Sciences International, Inc., a contractor involved with an assessment of the reproductive and developmental risks of the chemical bisphenol-A. In April, NIEHS terminated the Sciences International contract. In addition, NIEHS committed to conducting an audit of the bisphenol-A evaluation, developing contract language on conflicts of interest for insertion into NTP contracts, and establishing a working group of scientists and contract experts to evaluate all 42 NTP contracts for potential or actual conflicts of interest.²

The working group's evaluation of contractor conflicts of interest was finalized on June 22, 2007. The group attempted to assess both conflicts of interest of individual investigators and organizational conflicts stemming from a firm serving multiple clients whose

¹ National Toxicology Program, *Report of the Board of Scientific Counselors Working Group for the Review of the National Toxicology Program Contracts for Conflicts of Interest* (June 22, 2007).

² Briefing by National Institute for Environmental Health Sciences and National Institutes of Health for majority staff, Committee on Oversight and Government Reform (Apr. 23, 2007).

interests may be at odds. The working group “determined no actual or apparent COI exists in any of the cross-section of contracts reviewed.”³

This conclusion, however, appears to be based primarily on self-certification by the contractors themselves, not an independent assessment of organizational conflicts by the working group.

According to the report, “The [working group] relied on the contractor’s self-certifications regarding conflicts with current clients.”⁴ To assess organizational conflicts of interest, instead of requesting the client lists of NTP contractors, the working group asked contractors generic questions about their non-NTP clients, such as: “Does the contractor do business with organizations that might appear to be in conflict with the mission of NIH/NIEHS or have a relationship (financial, organization, contractual or otherwise) with such organizations or firms that could impair its objectivity or independence?”⁵ Not surprisingly, “[n]one of the contractors reported an actual or potential COI.”⁶

The working group’s reliance on contractor reports is a questionable way to assess conflicts of interest. Many of the contractors do not appear to have adequate systems for tracking such conflicts. According to the report, although “most” of the ten contractors that completed questionnaires had a designated official to solicit and review financial disclosure statements from their investigators, “[f]ewer” contractors collected disclosure statements listing significant financial interests from their investigators.⁷ “Even fewer” contractors updated these disclosure statements during the life of their NTP contracts.⁸ And “very few” contractors kept the disclosure statements for the mandatory three-year period following the completion of their NTP contracts.⁹ In other words, many of the contractors that provided self-certifications to the working group did not collect or retain the information necessary to determine whether individual conflicts of interest existed under their NTP contracts.

My concern is that simply asking contractors whether they or their employees have conflicts of interest that would impair their objectivity is not likely to provide any assurance that

³ *Report of the Board of Scientific Counselors* at 12.

⁴ *Report of the Board of Scientific Counselors* at 8.

⁵ *Report of the Board of Scientific Counselors* at Attachment 9.

⁶ *Report of the Board of Scientific Counselors* at 7.

⁷ *Report of the Board of Scientific Counselors* at 7.

⁸ *Report of the Board of Scientific Counselors* at 7.

⁹ *Report of the Board of Scientific Counselors* at 7.

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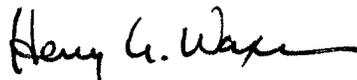
such conflicts do not exist. This is especially true when the contractors themselves may not know whether their employees have conflicts of interest.

The case of Sciences International demonstrates the flawed nature of this approach. In a letter to NIEHS regarding its contract, Sciences International vehemently denied that it had conflicts of interest.¹⁰ Sciences International made this assertion despite the fact that its principal investigator for NIEHS co-authored a paper with an employee of Dow Chemical, a manufacturer of bisphenol-A, and testified on behalf of a chemical manufacturer in civil litigation. The company also declined to address statements in its promotional materials that "its role as a Federal Government Contractor would be advantageous to regulated industries."¹¹

I request that you provide the Committee with a plan for conducting an assessment of actual or potential conflicts under existing NTP contracts that does not rely on the self-certifications of contractors. I also request that you provide the Committee with copies of the working group questionnaires completed by NTP contractors. I would appreciate receiving the requested information and documents by September 12, 2007.

If you have any questions concerning this request, please ask your staff to contact Jeff Baran or Naomi Seiler of the Committee staff at (202) 225-4407.

Sincerely,



Henry A. Waxman
Chairman

Enclosure

cc: Tom Davis
Ranking Minority Member

¹⁰ Letter from Herman J. Gibb, President, Sciences International, Inc., to Dr. Allen Dearry and Donald Gula, National Institute of Environmental Health Sciences (Mar. 19, 2007) (stating, "We...certify that no conflicts existed that impaired judgments or objectivity in any of the tasks performed for the Center...No conflict of interest ever existed regarding Sciences' preparation of this document.").

¹¹ Letter from David A. Schwartz, Director, National Institute of Environmental Health Sciences, to Rep. Henry A. Waxman (Mar. 26, 2007).