
From: Zazenski, Rich (LNA) [Rich.Zazenski@america.luzenac.com]
Sent: Thursday, January 06, 2005 4:01 PM
To: Mann, Steven [CPCUS]
Subject: OMB Letter
Attachments: OMB letter to NIH.pdf

Steve - Here is the letter from the head of OMB's Office of Information and Regulatory Affairs to the Director of NIH. Note the stern tone of OMB's "concerns" about NTP. Keep in mind that the Director of NIH has an annual budget of \$28 BILLION. NIEHS which administers the NTP program has a budget of \$650 MILLION. You can bet that Zerhouni at NIH sent word to Olden at NIEHS to implement OMB's recommendations "pronto" - with an additional order to improve your process to prevent any more data quality challenges. With a \$28 billion budget to protect, NIH doesn't want any more heat from OMB.

This could be significant for us because we (CRE) have been warning NTP that they can expect more data quality challenges on the basis that the talc nomination categories are overly broad and do not specifically exclude talc containing asbestos. Perhaps they are now reconsidering the nominations.

<<OMB letter to NIH.pdf>>



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

ADMINISTRATOR
OFFICE OF
INFORMATION AND
REGULATORY AFFAIRS

November 16, 2004

Dr. Elias A. Zerhouni
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Zerhouni:

I greatly appreciated your recent visit with us to talk about the proposed NIH Public Access Policy. We strongly support your commitment to increase both the transparency of and access to NIH funded research.

With regard to transparency I would like to bring to your attention some concerns I have regarding the National Toxicology Program (NTP) that is administratively located at NIEHS/NIH.

Under the Information Quality Act, the National Toxicology Program (NTP) has already received six distinct information quality correction requests related to either the NTP Report on Carcinogens or to the NTP review process for individual substances. These correction requests have brought to my attention concerns about how NTP handles comments from the public and scientific advisors. While NTP already has a rigorous process of scientific deliberation, I would like to make three suggestions that, based on experience at other Federal agencies, are likely to further instill public confidence in the NTP process and the Report on Carcinogens.

First, when NTP receives comments from the public on substances being reviewed for listing or delisting in the Report on Carcinogens, NTP should prepare a response-to-comments document and make this document available to the public in a timely manner. The Report on Carcinogens already acknowledges that "opportunities for public comment and participation are an integral part of the review process." To fully realize the value of the comment process, NTP should prepare and disseminate a response-to-comments document before completion of a substance's review. This document would improve the transparency of the process and assure the public that their perspectives have not only been sought but also considered. Moreover, the discipline of preparing this document will ensure that the scientists responsible for the Report on Carcinogens have systematically considered and addressed all the significant scientific comments that NTP has received. It would also be desirable for this document to be made available before an NTP review committee evaluates a particular substance. With this structure, the members of these important committees will also have the benefit of both the insights of the public and the NTP's responses to these comments.

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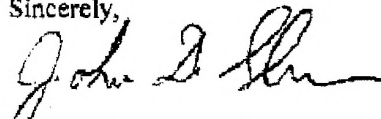
Second, when the NTP review committees (e.g., RG1, RG2 and Board of Scientific Counselors) provide technical comments to NTP staff aimed at improving an NTP background document, the NTP staff should prepare an updated version of the background document -- including responses to comments from these science advisors -- before final decisions on particular substances are made. Making these updated documents publicly available would reassure everyone that listing decisions are based on a supporting document that has addressed concerns raised by both the NTP's science advisors and the public.

Finally, I suggest that the substance profiles, which appear in the biennial Report on Carcinogens, be reviewed by external reviewers, perhaps the Board of Scientific Counselors, before being finalized. This layer of review would ensure that the writers of the profiles have incorporated the concerns and issues brought forth by the multiple review groups and have correctly captured and appropriately framed the information that needs to be in the final document of record.

I make these suggestions now because we are aware that NTP is already in the process of evaluating and modernizing the process used to prepare the Report on Carcinogens. Although implementing our three suggestions will require some additional staff work in the near term, we believe there may be resource savings in the long run. In any event, we believe the benefits in public transparency and agency accountability justify the additional staff effort.

I encourage you to consider these suggestions during your ongoing deliberations. My staff is eager to work with you on these suggestions.

Sincerely,



John D. Graham, Ph.D.
Administrator

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