



March 10, 2006

Nancy Beck, Ph.D.
Office of Information and
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Office of Management and Budget
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Jordan J. Cohen, M.D.
President

Re: OMB Proposed Risk Assessment Bulletin and Notice, 71 FR 2600

Dear Dr. Beck,

The Association of American Medical Colleges (AAMC) has noted with great interest the draft proposed risk assessment bulletin for federal agencies that was released by OMB on January 9, 2006, and notice published in the Federal Register on January 17. As you know, the AAMC represents the nation's 125 allopathic medical schools, nearly 400 teaching hospitals, and 96 academic medical societies. These organizations have a central interest in issues affecting public health policy.

As with the previous Information Quality Guidelines completed in 2003, the OMB and the Office of Information and Regulatory Affairs (OIRA) should be commended for providing extensive opportunity for public input on the proposed guidelines and for again seeking the advice of the National Academies on the merits of the proposed guidance. In advance of the Academies' expected thorough review of the draft guidelines, the AAMC will comment on only a single aspect of the proposal at this time: specifically, how the guidelines are envisioned to overlay established practices for risk assessment and *decision making* within the U.S. Public Health Service (PHS).

The Information Quality Guidelines recognized that the PHS has particular prerogatives for assessing the importance and timeliness for release of information related to public health, and that the PHS itself depends on processes and mechanisms—such as peer review—that best ensure the quality and reliability of information that is disseminated. Similarly, we believe strongly that a final federal-wide bulletin on risk assessment, which logically extends from the Information Quality Guidelines, should specifically defer to the PHS leadership's judgment of the timeliness or urgency of making decisions based on the adequacy of a risk assessment, in consideration with all other factors.

Our chief concern is that announcements or other actions important to public health not be subject to protracted delay, managerial impediments, or, frankly, "second-guessing" by other individuals or agencies. For example, if a Data Safety and Monitoring Board decides to interdict

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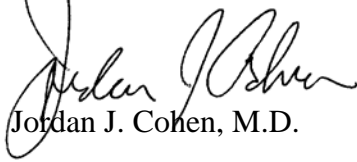
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a clinical trial based on judgment of clear evidence of asymmetric benefit or risk, that determination is fundamentally a risk assessment and should not be subject to other delay. The proposed bulletin limits OMB's and OIRA's own responsibilities, in consultation with the Office of Science and Technology Policy, to "overseeing agency implementation of this bulletin" and "foster[ing] learning about risk assessment practices across agencies." We are not clear about the implications of this for enforcement of the standards proposed in the bulletin, but we emphasize that the PHS has established practices for risk assessments and that the U.S. Surgeon General and the Secretary of Health and Human Services have final authority over the PHS.

The AAMC believes, therefore, that the final guidelines should explicitly recognize PHS prerogatives for information release or other action based upon findings of importance to public health without encumbrance or delay. We believe that such a statement should be consistent with the language in the Information Quality Guidelines.

If there are any questions about the AAMC position on this matter, please contact David Korn, M.D., AAMC's Senior Vice President for Biomedical and Health Sciences Research.

Sincerely,

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

Jordan J. Cohen, M.D.

cc: John Marburger, Ph.D. Director,
Office of Science and Technology Policy

David Korn, M.D., AAMC