

# MUSC

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September 15, 1999

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Carol M. Browner  
Administrator  
Environmental Protection Agency  
401 M Street SW  
Washington, DC 20460

Dear Administrator Browner:

The Children's Health Protection Advisory Committee met on September 15-16, 1999 to continue its consideration of EPA's proposed revisions to its Guidelines for Cancer Risk Assessment (the Cancer Guidelines) among other topics.

In preparing these comments, the Committee's Science Work Group reviewed the Committee's May 12, 1999 comment letter, EPA's July 6, 1999 reply, and the discussion materials made available to the July 27-28, 1999 SAB Advisory meeting, which focused on pediatric aspects of the proposed revisions. The Science Work Group also received with appreciation a very useful briefing by Dr. Jeanette A. Wiltse, of the Office of Water's Health and Ecological Criteria Division.

The purpose of this letter is to offer some preliminary comments on the overall process for integrating new and improved science into EPA's cancer guidelines, which the Committee hopes will be incorporated into the next draft of the guidelines. The Committee will be considering further, more specific comments on the proposed revisions themselves at its December meeting. The Committee looks forward to continued dialogue with EPA on these issues and urges the agency to address this Committee's comments, and to incorporate both the information presented to and the recommendations from the July SAB Advisory meeting prior to finalization of the guidelines.

Clearly, EPA must continue to make decisions and improvements in its decision-making processes to reflect new and improved science. By necessity this means capturing what is known up to that point in time and, thus, often not having answers to every question that needs to be asked. However, it is essential to capture those questions and institutionalize them into a regular process that stimulates, encourages and even requires the application of ongoing learning. Thus, the Children's Health Protection Advisory Committee strongly urges EPA to identify unresolved issues and unanswered questions and to include them in an appendix to the Cancer Guidelines.



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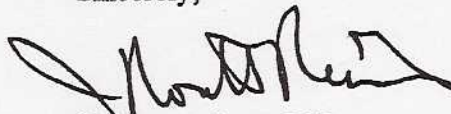
Further, the Committee recommends that EPA: 1) incorporate into the preamble of the guidelines a commitment to a regular peer review process, with a timetable for addressing the unresolved issues and questions, and 2) outline a research plan with adequate resources to address gaps in new information on cancer risks resulting from preconception, *in utero* and childhood exposures as well as on improved scientific methods that will enhance the ability of the scientific community and EPA to continue to incorporate new learning and policy applications into these guidelines.

Although the Committee recognizes the considerable investment that EPA has made in the two SAB meetings this year, the Committee is concerned that the January meeting did not address pediatric issues in any depth and that the July meeting addressed pediatric issues in a manner somewhat isolated from the context of the overall guidelines. The possibility that specific additional guidance for the characterization of risks to children might be separated from the guidance itself reinforces this concern. Because EPA, to its credit, has made considerable changes in the document since it was published for public comment in 1996 and since the January 1999 SAB meeting, the Committee recommends that as part of the commitment to regular peer review recommended above, EPA hold another Science Advisory Board meeting to take a comprehensive, integrated look at the full document as soon as possible after integrating changes based on the recommendations from the July SAB meeting. The Committee believes this will be useful regardless of whether EPA decides to publish a revised Cancer Guidelines before or after such a meeting.

Finally, the Children's Health Protection Advisory Committee requests EPA to identify those decisions in which EPA has used or is in the process of using both linear and non-linear models and asks for an opportunity to hear a presentation at its next Science Work Group meeting about how a mode of action approach actually has been applied, what judgements are required, what challenges that has presented, and what EPA is learning from this experience.

The Committee very much appreciates the opportunity to participate in a dialogue with EPA about these critical issues affecting children's health.

Sincerely,



J. R. Reigart, MD  
Chair, Children's Health Protection  
Advisory Committee