November 3, 2011

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Re: Proposed National Toxicology Program (NTP) Review Process for the Report on Carcinogens: Request for Public Comment and Listening Session

Dear Dr. Birnbaum:

We are pleased that the National Toxicology Program (NTP) recognizes the need for improvements in the Report on Carcinogens (RoC), and appreciate NTP’s interest in obtaining stakeholder input on the “Proposed Report on Carcinogens Review Process” dated October 31, 2011. All stakeholders expect the RoC to be firmly based on up-to-date scientific knowledge, meet the highest of standards of scientific inquiry, and be evaluated in accordance with acceptable scientific approaches. Unfortunately, the current policies, practices and resulting assessments of the RoC do not consistently meet these standards, and improvements are clearly warranted.

ACC is concerned that timeframe and structure presented for NTP’s process for soliciting stakeholder perspectives on improvements to the RoC will not produce meaningful and substantive input. We are also concerned that the process outlined for public input is not adequate given the substantive scientific nature of the issues raised by the RoC. We are, therefore, writing to request that both the timeline and process be revised as specifically outlined later in this letter. In light of the truncated comment period, we would appreciate a response to our request for an extension of the comment period as soon as possible.

On October 31, 2011, NTP published its request for public comment on revisions to the RoC process, allowing only three weeks for the public to submit oral statements and/or slides for the public listening session by November 21, 2011. Moreover, registration to present oral remarks is unnecessarily limited to the first 15 registrants. Written comments are due on November 30, just

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1 Federal Register / Vol. 76, No. 210 / Monday, October 31, 2011, page 67200
days after the Thanksgiving holiday. In sum, NTP’s timelines are not adequate to obtain, review and respond to meaningful public input. In ACC’s view, this approach is not consistent with President Obama’s goals for transparency and scientific integrity.

The President pledged that the "science and scientific process must inform and guide decisions of my Administration." A Presidential Memorandum directs each agency to use well-established scientific processes to inform public policy decisions. As you are aware, many questions have arisen regarding the scientific evaluation and peer review processes used to develop the RoC. The striking differences between the National Research Council’s (NRC) peer review report of the draft Integrated Risk Information System assessment and the NTP findings regarding the causal relationship between formaldehyde exposure and leukemia is but one example of the need for NTP to substantively improve the RoC process. NTP must provide the public with a meaningful opportunity to comment on NTP’s proposed RoC process changes.

Therefore, ACC requests that NTP take the following actions:
1) Extend the written comment period to 90 days;
2) Replace the web-only format proposed by NTP for receiving oral public input with an in-person public meeting that is simultaneously webcast;
3) Reschedule the public meeting to two to three weeks after the submission deadline for written comments;
4) Structure the public meeting as a dialogue, in which NTP staff actively engage in discussions with stakeholders on the substantive issues, rather than as a one-way discourse; and
5) Following the public meeting, NTP should analyze and respond to public comments, providing a written record of NTP’s rationale for accepting or rejecting comments and for making specified policy choices, and publish a revised draft process clearly noting what changes have been made.

ACC also recommends that, after the actions above are completed, NTP submit the revised draft RoC process, including the improved scientific analysis procedures, for independent scientific peer review by the NRC. This will assure that before the next RoC is developed, the scientific procedures used in the RoC meet the highest standards of scientific inquiry.

Sincerely,

Cal Dooley
President and CEO

cc: HHS Secretary Kathleen Sebelius