Breast Cancer Fund • Natural Resources Defense Council Cancer Prevention and Treatment Fund • National Research Center for Women and Families

October 11, 2012

Inez Marie Tenenbaum Chairman U.S. Consumer Product Safety Commission 4330 East West Highway Bethesda, MD 20814

Dear Chairman Tenenbaum,

We are writing about the on-going review of phthalates and phthalate alternatives by the CPSC's Chronic Hazard Advisory Panel (CHAP). Recently, the CPSC has been contacted by the American Chemistry Council (ACC) about conducting an external peer review of the draft CHAP report that follows criteria outlined in a 2004 OMB bulletin. We have serious concerns about delays in the timely completion of the report – which has already missed the statutory deadline set out in the Consumer Product Safety Improvement Act (CPSIA)² – and oppose requests for an unnecessary peer review of the draft report that will only further and unnecessarily delay its completion.

We agree that a transparent process in developing the CHAP report is critical to the integrity of the report. As such, we would like to commend the CPSC and CHAP for conducting their process in an exceptionally open and transparent way to date. The CHAP has undertaken all of their deliberations publicly and there has been ample opportunity to provide input both verbally and in written form to the panel. Given the tremendous strides the CPSC has taken to make this process accessible to the public, we were disappointed and surprised to hear industry representatives claim that they have not had sufficient opportunity to provide ample feedback.

In fact, industry representatives have had a *greater* opportunity to provide input than public health advocates. On July 26, 2010, the public was invited to provide in-person formal comment to the CHAP process, and approximately three-quarters of that time was used by industry representatives. Then, in November 2011, the Hamner Institute was given an extraordinary opportunity to present Exxon Mobil-funded research to the CHAP – despite the fact that the CHAP initially denied their request – and neither public health advocates nor independent scientists were notified or given an opportunity to present their own comments or respond to the extra presentation at the time.

¹ Letter [PDF] from Cal Dooley, CEO, American Chemistry Council, to CPSC Chairman Inez Tenenbaum. August 13, 2012. http://www.cpsc.gov/about/cpsia/docs/acc081312.pdf

² According to the timeline referenced in CPSIA (Sec. 108 (b)(2)(A)), within 18 months of their appointment, the CHAP was to have completed their review of science on phthalates and phthalate alternatives, and was to have submitted a report of their results and recommendations not later than 180 days after completion of their review. The CHAP was appointed on April 14, 2010, and therefore should have completed their examination by October 14, 2011 and submitted their final report to the CPSC in April, 2012.

We support a rigorous peer review process when it is warranted. In this instance, we do not think a peer review of the draft CHAP report is warranted. We understand that the members of the current CHAP have already requested a peer review of their draft report; however, such a review would be redundant and is not needed. The very purpose of the CHAP is to review the existing scientific literature (including literature that has already been peer-reviewed) on which they base their recommendations. To subject expert opinion to another, second layer of review is unnecessary and needlessly time-consuming for a report that is already significantly delayed.

If the CPSC decides that a peer review of the CHAP report is indeed necessary, the peer review process should be done as previously outlined by the CPSC. As explained to the CHAP members, CPSC intends to work with the National Academy of Sciences to review and nominate peer reviewers to ensure that all peer reviewers are balanced, have the proper expertise, and do not have conflicts of interest. Such a process to appoint peer reviewers will help assure the continued integrity and credibility of the report.

Conversely, the peer review process that ACC is requesting is not appropriate for a draft CHAP report and OMB guidelines are not applicable to the CHAP. The OMB bulletin referenced by the ACC "addresses peer review of scientific information disseminations that contain findings or conclusions that represent the official position of one or more agencies of the federal government." As you know, the CHAP report is not written by government scientists, and it does not represent an "official position" of the Commission. The report only represents the CHAP's opinion and recommendations; any official position taken by the CPSC is at the sole discretion of the Commissioners. As such, the CHAP's report is not required to be peer-reviewed according to the OMB's guidelines.

We are also concerned that the OMB peer review process that is being requested by the ACC would not be in compliance with the CPSIA. CPSIA Sections 108(b)(2)(B) and (C) make no mention of further review of the CHAP report. The statute plainly calls for the "panel" – not some alternative body or authority – to report to the CPSC, and it specifies what the "panel" should determine. Requiring further review of the CHAP report before the report can be finalized and sent to CPSC appears extra-statutory. Congress could have required peer review of the report, but it did not do so. Instead, it set a specific timeline for prompt action, that is now considerably behind schedule, and laid out exactly the steps that needed to be followed.

The ACC has asked for the public to be able to submit information directly to the peer review panel, something that would more properly be done through public comment to the Commission during the standard rule-making process. The ACC has also specifically asked that any peer review include an evaluation of previous CHAP assessments, despite the fact that the CHAP panel's review of the science is *de novo* and already takes into account findings of previous CHAP panels and previous studies conducted by the CPSC. ⁴ The ACC further requests that peer reviewers assess all background data, studies, and perspectives provided to the CHAP. We believe that this would be overly cumbersome, repetitive of the CHAP's work, and result in unnecessary delay. It is also inconsistent with previous CHAP

³ Office of Management and Budget, *Final Information Quality Bulletin for Peer Review*, December 16, 2004. http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf

⁴ Sec. 108(b)(2)B) states: "The panel's examinations pursuant to this paragraph shall be conducted *de novo*. The findings and conclusions of any previous Chronic Hazard Advisory Panel on this issue and other studies conducted by the Commission shall be reviewed by the panel but shall not be considered determinative."

reviews of phthalates, as the previous CHAP report to the CPSC concerning the phthalate DiNP was not peer-reviewed.

While it might benefit the chemical manufacturers represented by ACC to delay the CHAP report – and to have additional opportunities to try to change the outcome of a report it fears will not be to its liking – we believe that the Commission should act in the interest of public health first and encourage the CHAP to continue to conduct and complete its work transparently, scientifically, and as quickly as possible. Therefore, we respectfully request that CPSC move forward with the draft report without unnecessary additional review so that it can be finalized and acted upon by the CPSC as soon as possible.

Sincerely,

Breast Cancer Fund
Natural Resources Defense Council
Cancer Prevention and Treatment Fund
National Research Center for Women and Families

CC: Commissioners Adler, Nord, Northrup Michael Babich, PhD, CHAP Project Manager Mary T. Boyle, Acting General Counsel