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By E-Mail & U.S. Mail

Dorothy Burk, Ph.D., Committee Chairperson, and Committee Members
Developmental and Reproductive Toxicant Identification Committee
California Environmental Protection Agency
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Re: Reasons Why ACC's Petition To Rescind The Designation Of NTP-CERHR As An Authoritative Body Should Be Granted

Dear Dr. Burk and Committee Members:

As you know, the petition to rescind the current designation of the National Toxicology Program-Center for Evaluation of Risks to Human Reproduction ("NTP-CERHR") as an "authoritative body" for purposes of Proposition 65 ("Petition"), filed by our client the Polycarbonate/BPA Global Group of the American Chemistry Council ("ACC"), is on the agenda for the upcoming July 12-13, 2011 meeting of the DART IC. In this letter, we summarize briefly a few points pertinent to the Petition that explain why the Committee should address it, and why the Petition should be granted.

- ***The Petition should be addressed separately from the new Proposal to identify NTP as an Authoritative Body.***

As a preliminary matter, we note that ACC's Petition is on the agenda under the heading "Consideration Of The Designation Of The National Toxicology Program (NTP) As An Authoritative Body," and appears to be commingled with a proposal to consider the "identification" of NTP as an authoritative body ("Proposal"). To our knowledge, no one outside of OEHHA knows what this Proposal is or what is intended by its submission.

Because NTP-CERHR no longer exists, having recently been subsumed by a new NTP Office of Health Assessment and Translation (OHAT), ***the Petition is retrospective only***. The Petition only raises the issue whether NTP-CERHR Monographs published before NTP-CERHR was eliminated as a distinct entity provide a suitable basis for listing chemicals under the Authoritative Bodies listing mechanism. On the other hand, ***the Proposal is***

prospective only, affecting the potential for using documents published in the future by NTP (or, perhaps, specific components of NTP) for future Authoritative Bodies listings.

Thus, the effect of the Proposal (to designate NTP as an authoritative body) is separate from that of the Petition (to rescind the designation of NTP-CERHR). Discussing the two together can only confuse the issues regarding each. We request that the two issues be untangled and the two matters be discussed separately, so that each can be considered on its own merits.

- ***THE NTP-CERHR MONOGRAPHS ARE FOCUSED ON EVALUATING RISK IN A WAY THAT IS INCONSISTENT WITH HAZARD-BASED REQUIREMENTS FOR LISTING UNDER PROPOSITION 65.***

Proposition 65 requires the identification of chemicals that are "known" to cause cancer or reproductive toxicity. It is well established that Proposition 65 is purely a hazard-based system that does not take exposure or risk into account in listing decisions. From its beginning, though, NTP-CERHR's purpose was to reach risk-based conclusions that are expressed qualitatively in the form of levels of concern. These are very different approaches.

The distinction between NTP-CERHR's risk-based approach and the hazard-based approach under Proposition 65 was expressed clearly by NTP's leaders in a recent announcement of the formation of OHAT:

> *"To our knowledge, CERHR was the only resource of its kind, producing evaluations that considered toxicity findings in the context of current human exposures to derive "level-of-concern" conclusions. This qualitative integration step is what distinguished CERHR documents from more traditional hazard evaluations prepared by other agencies."*[1]

Consistent with NTP-CERHR's purpose, scientific peer-review of draft reports focused on the level-of-concern conclusions. For example, the NTP Board of Scientific Counselors (NTP-BSC), acting as a peer-review panel, was presented with seven draft level-of-concern conclusions on bisphenol A at their June 2008 meeting.[2] The NTP-BSC formally voted on each of these risk-based ***conclusions***. Although the complete draft report was available to NTP-BSC, their review focused only on whether the report supported the conclusions (*i.e.*, the levels of concern); they did not formally vote on any other aspect of the report.

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[1] http://ehp03.niehs.nih.gov/article/fetchArticle.action?articleURI=info%3Adoi%2F10.1289%2Fehp.1103645

[2] See the meeting materials, presentations and meeting minutes for the June 2008 meeting at http://ntp.niehs.nih.gov/INDEX8D14_2.HTM?objectid=720164F2-BDB7-CEBA-F5C6A2E21851F0C4,

- ***THE STANDARD FOR EVALUATING HAZARD INFORMATION IN NTP-CERHR MONOGRAPHS IS NOT CONSISTENT WITH PROPOSITION 65.***

To evaluate risk, NTP-CERHR Monographs necessarily must consider both exposure and hazard information. However, a review of NTP-CERHR Monographs shows clearly that they did not consider fully (or sometimes, at all) all of the factors that must be taken into consideration for purposes of Proposition 65. Conversely, the Monographs sometimes put great weight on other factors, such as the extent of actual or potential human exposure, that are irrelevant to listing decisions under Proposition 65.

One of the most important differences between NTP-CERHR Monographs and Proposition 65 is the manner in which they treat studies that involve pre-natal and post-natal exposure (or both). As the Committee members know, developmental toxicity under Proposition 65 is confined to effects that are due solely to pre-natal exposures. The NTP-CERHR Monographs recognize no similar limitation in their assessment of developmental toxicity. All studies with relevant information on reproductive and developmental toxicity are included equally, regardless of the timing of exposure. This approach, which is very appropriate from a public health perspective, is also very inconsistent with Proposition 65.

A similar problem arises from the differences between the manner in which NTP-CERHR Monographs and Proposition 65 treat maternal toxicity. Under Proposition 65, any reproductive or developmental effect must be considered in light of maternal toxicity. However, NTP-CERHR Monographs are not required to consider maternal toxicity at all. The extent and manner in which maternal toxicity is considered is determined individually by each NTP-CERHR expert panel, and varies from panel to panel. In some circumstances an expert panel may choose to mention maternal toxicity, and in other circumstances a panel may not, or may mention it only in passing.

Thus, to the extent that NTP-CERHR Monographs include statements commenting on the potential for a chemical to cause developmental toxicity, it is not possible to determine from those statements alone whether they are relevant to Proposition 65; rather the reader must evaluate the studies cited in considerable detail. This is inconsistent with the Authoritative Bodies listing mechanism, however, because the OEHHA staff (in contrast to your Committee) is not permitted to evaluate or interpret the data underlying Authoritative Body reports, or to substitute their opinions for those of the Authoritative Body.

For example, the NTP-CERHR Monograph on bisphenol A cites eight studies that provide evidence for developmental effects at high doses. Only three of these studies involve pre-natal exposure only, while one study involves post-natal exposure only. The latter study is clearly not relevant to Proposition 65. The other four studies involved both pre-natal and post-natal exposure. Whether these studies are relevant for purposes of Proposition 65, and whether they would support listing, can be determined only after each study has been evaluated in detail. In addition, significant maternal toxicity was generally

observed in conjunction with developmental effects, but the significance of maternal toxicity was not assessed by NTP-CERHR as it must be under Proposition 65.

The NTP-CERHR Monographs simply do not make the clear hazard identification findings required to list a chemical under Proposition 65, which requires a finding that a chemical is known to cause developmental or reproductive toxicity. In contrast, the DART IC follows a rigorous process in making hazard identification decisions. In the case of bisphenol A, the Committee carefully evaluated studies to determine whether exposure was pre-natal and post-natal, assessed the relevance of maternal toxicity, and rightly decided not to list bisphenol A. The fact that OEHHA is even ***considering*** listing BPA on the basis of the NTP Monograph is clear evidence that the continued designation of NTP-CERHR as an authoritative body has a high potential to result in improper listings.

- ***GRANTING THE PETITION WOULD NOT PREVENT THE COMMITTEE FROM REVIEWING AND RELYING UPON NTP-CERHR MONOGRAPHS FOR ITS EVALUATIONS.***

At the October 21, 2010 meeting, Dr. Hobel raised the concern that the Committee should have the right to review NTP-CERHR Monographs (among other documents) in reaching a decision whether a chemical substance should be identified "as causing reproductive toxicity."[3] We fully agree with Dr. Hobel. The NTP-CERHR Monographs are an excellent resource for the Committee to review when evaluating chemicals under the State's Qualified Experts mechanism (and they will remain valuable for this purpose even though NTP-CERHR no longer exists). In fact, because the NTP-CERHR reports are so comprehensive, we suggested to OEHHA that the NTP-CERHR report on bisphenol A be used directly as the basis for the Committee's evaluation in 2009, to save the duplicative effort of preparing Hazard Identification Materials. The point of the Petition, explained above, is that the Monographs are not well-suited for use under the Authoritative Bodies listing mechanism. This process is separate and different from the State's Qualified Experts listing mechanism, in which the DART IC participates.

- ***BECAUSE NTP-CERHR NO LONGER EXISTS, THE COMMITTEE WILL NOT INCREASE ITS FUTURE WORKLOAD OR OTHERWISE LOSE A VALUABLE RESOURCE BY RESCINDING THE DESIGNATION OF NTP-CERHR AS AN AUTHORITATIVE BODY.***

As the Committee is aware, NTP has eliminated the former Center for Evaluation of Risks to Human Reproduction. As noted above, it was never the intent of the Petition to disparage the quality of NTP's scientists, or to suggest that the Committee could not or

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[3] Meeting of the Developmental and Reproductive Toxicant Identification Committee, October 21, 2010, Transcript at pp. 114-15.

should not review the Monographs and consider the views of the expert scientists who served on its Expert Panels, in the process of making the Committee's own listing decisions as the "State's Qualified Experts." If the Committee has or had any concern that its own workload would increase as a result of rescinding the designation of NTP-CERHR, however, that concern no longer exists. Nor would the Committee have to expend time and resources evaluating bisphenol A, because that has already been done.

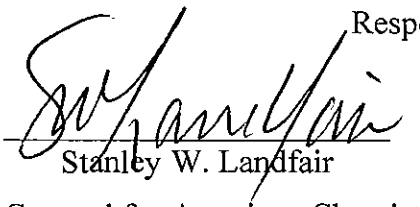
In fact, the Committee need not be concerned that granting the Petition will have far-reaching impacts on the implementation of Proposition 65 or cause chemicals that are the subject of NTP-CERHR Monographs to be overlooked. There are only three chemicals with potential to be affected by the Petition, to our knowledge. The Committee has already ruled on one of them (BPA), and may be asked to evaluate the other two under the State's Qualified Experts mechanism, if the Petition is granted.

- ***THE COMMITTEE SHOULD NOT MAKE A HASTY DECISION TO DESIGNATE NTP AS A "SUCCESSOR" IN NTP-CERHR'S PLACE.***

As noted above, we have not seen the Proposal to designate NTP as an authoritative body, and thus have no position on it at this time. From the agenda item, however, it appears at least possible that your Committee will be asked to make a decision to designate NTP (or perhaps NTP-OHAT) as an authoritative body as a successor to NTP-CERHR at the July 12-13 meeting. The reasons such a hasty decision would be unwise are obvious and numerous. As a matter of process, a decision to designate an agency as an authoritative body should be done in a deliberative manner, after allowing ample opportunity for public comment as well as consideration by the Committee. That has not happened in the present case. Moreover, on the merits of such a potential designation it is simply not possible to know, based on the "record" that will exist on July 12-13, whether NTP-OHAT's mission, priorities, focus on risks versus hazard identification, and the language and format of its reports will be suitable for purposes of Proposition 65. The Committee needs substantial information on all those issues in order to make an informed decision, and the potentially affected public deserves an opportunity to review that information and submit comments for the Committee's consideration.

We look forward to discussing the Petition with you at the meeting next week.

Respectfully submitted,



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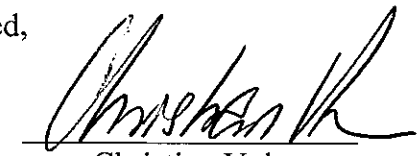

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