Subject: Comment on NTP-CERHR Expert Panel Report on the Reproductive and Developmental Toxicity of Bisphenol A
Date: Friday, January 25, 2008 6:26 AM
From: Chris Talsness <chris.talsness@charite.de>
To: "Shelby, Michael (NIH/NIEHS) [E]" <shelby@niehs.nih.gov>
Conversation: Comment on NTP-CERHR Expert Panel Report on the Reproductive and Developmental Toxicity of Bisphenol A

Dear Dr. Shelby,

I believe that the stated aim of the panel to have a review which relies heavily on studies that reduce the risks for false negative findings (page 122) is in conflict with its standpoint that positive controls are not necessary. Regarding developmental toxicity data, the Panel states (page 123) that they "did not feel that positive controls were required for studies". I am in disagreement with the Panel's position and believe that incorporation of positive controls is fundamental to the design of an experiment. Positive controls are necessary to evaluate whether the animal model is appropriate and that the conditions of the experiment were suitable to address the question under investigation. It is unclear to me how this can be evaluated in a study with negative results and without a positive control.

Moreover, there appears to be inconsistencies regarding the purpose and usefulness of positive controls in judging the individual studies for their utility.

Following are a few examples:
1-One study with negative results and which did not employ a positive control were evaluated as useful. This is an example supporting the Panel's standpoint positive controls are not necessary, but one which does not further its aims.

2-At the same time, a study with negative findings and a positive control which did not function was not considered to be of utility. This is an example of the Panel attributing great value to the role of positive controls and which furthers its aims.

3-Moreover, a negative study using a positive control which did not function as expected, i.e., showing only weak or partial effects, was, nevertheless, regarded as having utility.

I believe the aims of the review would best be served by consistent application of the precept that positive controls are indispensable when interpreting negative findings.

Thank you for the opportunity to comment on this report.

Yours sincerely,
Chris Talsness

Dr. Chris Talsness DVM
Charité Universitätsmedizin Berlin
Benjamin Franklin Medical Center
Institute of Clinical Pharmacology and Toxicology
Department of Toxicology
Garystraße 5
D-14195 Berlin
Germany

Tel: +49-30 8445-1754
Fax: +49-30 8445-1761