Public Comments on the NTP Draft Brief on Bisphenol A

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BPA-Free Kids Act of 2008

Introduced on April 29th
by Senators Dianne Feinstein (D-Calif.)
and Charles Schumer (D-N.Y.)

- Prohibit the use of bisphenol A in children's products.
- Require the CDC to study the health effects of bisphenol A exposure in all age groups and in pregnant women.

"We cannot let the health of our children hang in the balance while we wait for more studies..."

- Senator Dianne Feinstein

PETA

Reliance on animal tests delays regulation

- Cigarette smoke:
  - Landmark epidemiological studies by the American Cancer Society in the 1950's linked smoking to cancer.
  - For decades, the tobacco industry cited tests showing that animals forced to inhale smoke did not develop cancer.

- Other examples include asbestos, arsenic and benzene.

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Bisphenol A: More of the same?

The NTP continues to rely on animal tests calling for new studies of bisphenol A's controversial low-dose effects in animals.

- These effects include changes in:
  - neural and behavioral endpoints,
  - mammary and prostate gland and urinary tract development,
  - onset of puberty.

The multi-generation reproductive and developmental studies called for would consume thousands of animals' lives but could only delay regulation that is needed now to protect public health.

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Animal tests are problematic

"[t]he endpoints of concern are endocrine-mediated and potentially impacted by factors that include phytoestrogen content of the animal feed, extent of bisphenol A exposure from caging or water bottles, and the alleged sensitivity of the animal model to estrogens."

NTP-CERHR Expert Panel Report on Bisphenol A

PETA

Low-dose effects are controversial

"While the panel did not necessarily expect a specific effect to display a monotonic dose response…, many members of the panel expected the high dose studies with bisphenol A to detect some manifestation of toxicity… in tissues reported to be affected at low doses even if the study could not replicate the reported low dose effect. There are several large, robust, well designed studies with multiple dose groups using several strains of rats and mice and none of these detected any adverse reproductive effects at low to moderate dosage levels of BPA administered via the relevant route of human exposures."

NTP-CERHR Expert Panel Report on Bisphenol A

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Low-dose effects are controversial

Rochelle W. Tyl, et al. Two-Generation Reproductive Toxicity Study of Dietary Bisphenol A (BPA) in CD-1 (Swiss) Mice. *Toxicol Sci.* May 6, 2008.

- Conducted in response to 2003 EU risk assessment with oversight by the EU Bisphenol A Steering Group.
- Dietary BPA was evaluated in a two-generation study at 0, 0.003, 0.03, 0.3, 5, 50, or 600 mg BPA/kg/day.
- Concurrent positive control using 17ß-estradiol confirmed the sensitivity of CD-1 mice to an endogenous estrogen.
- *"At lower doses [0.003 – 5 mg BPA/kg/day], there were no treatment-related effects and no evidence of non-monotonic dose response curves for any parameter.*

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Results in animals are not relevant to humans

Völkel, W et al. Metabolism and kinetics of bisphenol A in humans at low doses following oral administration. *Chem. Res. Toxicol.* 2002. 15: 1281-1287.

"The obtained data indicate major species differences in the disposition of bisphenol A. Enterohepatic circulation of bisphenol A glucuronide in rats results in a slow rate of excretion, whereas bisphenol A is rapidly conjugated and excreted by humans due to the absence of enterohepatic circulation. The efficient glucuronidation of bisphenol A and the rapid excretion of the formed glucuronide result in a low body burden of the estrogenic bisphenol A in humans following oral absorption of low doses."

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Summary and Recommendations

- There is already an extensive body of literature on the toxicity of bisphenol A in animals.

- Controversial low-dose effects are likely to remain controversial, as evidenced by recently published studies that have failed to reproduce these effects.

The time has come for the concerns expressed by the NTP and others over bisphenol A's development effects to be addressed by precautionary regulation.

Further unreliable and irrelevant animal tests are unnecessary and unlikely to provide more actionable information.

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