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May 23, 2008

Dr. Barbara Shane

Executive Secretary for the NTP Board of Scientific Counselors
NTP Office of Liaison, Policy and Review
National Institute for Environmental Health Sciences
P.O. Box 12233, MD A3-01
Research Triangle Park, NC 27709

Dear Dr. Shane:

The American Academy of Pediatrics (AAP), a non-profit professional organization of 60,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists, appreciates this opportunity to comment on the National Toxicology Program (NTP) Draft Brief on Bisphenol A (BPA), as released on April 14, 2008.

The AAP commends the National Toxicology Program for producing a thorough, thoughtful review of the current scientific literature on the human health effects of BPA. Parents and physicians alike have questions about the potential health effects of BPA and what measures, if any, should be taken to reduce exposure. The NTP Brief provides pediatricians and health care officials with information that will assist them in counseling concerned families and communities.

The AAP is deeply concerned, however, that the current scientific evidence is largely insufficient to draw accurate conclusions about the safety of exposure to BPA, particularly with respect to vulnerable populations including pregnant women, infants and children. Absence of evidence is not equivalent to evidence of safety. Because this document is intended to provide the public with the NTP's "conclusions regarding the potential for the chemical to adversely affect human reproductive health or children's development," it is important that the report not provide potentially false reassurance that there is a "negligible concern" in these areas in the face of such large gaps in understanding.

The AAP agrees with the NTP report's statement that the available evidence indicates "some concern" regarding neural and behavioral effects of BPA in fetuses, infants and children at current exposures. The AAP also supports the NTP's statement that there is "some concern" about the impact of BPA in these populations based on observed effects in animal studies in the prostate gland, mammary gland, and an earlier age for puberty in females.

The AAP disagrees with the NTP's conclusion of a "negligible concern" with regard to (1) pregnant women's exposures with respect to fetal or neonatal mortality, birth defects, reduced birth weight and growth and (2) reproductive effects in non-occupationally exposed adults and minimal concern for workers exposed to high levels in occupational settings. The AAP considers the evidence in humans to be "insufficient to draw this conclusion."

The NTP's report acknowledges many questions regarding pregnant women's exposures to BPA, impacts on their offspring, and children's unique vulnerabilities. Based on the report of the NTP, as well as concerns expressed by other entities, pressing research priorities should include but not be limited to the following:

- Since infancy and childhood appear to be the most important periods of exposure, research should focus on improving our understanding of BPA exposure and health effects among children. Efforts should include the collection of biomonitoring data and examination of issues such as the rate and efficacy of BPA metabolism in infants and young children.
- Further animal studies, including those in higher mammals, must be conducted to assess exposures during critical windows of development.
- Further human studies must be performed to determine whether outcomes are observed similar to those in animal studies. In particular, data is critically needed on infants and children under the age of 6 and pregnant women.
- Research is needed to examine mixed exposures, such as combinations of BPA with other endocrine disruptors and other exposures that may also contribute to a common adverse outcome.
- The accuracy and utility of current biomarkers for BPA exposure must be reviewed, and the potential for improved biomarkers examined.
- Studies must be performed on cumulative exposures to BPA throughout the lifespan and the relative contribution of various sources of exposures over time.

Given these significant research gaps, the AAP recommends the establishment of a comprehensive interagency research program to address these issues. Efforts should be coordinated among the National Institutes of Health, Food and Drug Administration, and Environmental Protection Agency to design a research agenda that builds upon the current efforts of each agency while addressing the many current shortcomings in BPA data and analysis. The existing efforts at each agency, while laudable, are entirely inadequate to address these urgent issues. Only with a concerted research focus on BPA and other endocrine disruptors will the public and the health care community be able to obtain sufficient information to make reliable recommendations to families about the health effects of BPA.

In conclusion, the American Academy of Pediatrics commends the NTP for producing a useful Draft Brief on Bisphenol A and urges the inclusion of the changes and recommendations noted above. If the Academy may be of further assistance, please contact Cindy Pellegrini in our Washington, DC office at 202/347-8600.

Sincerely,

Renée R. Jenkins, MD, FAAP
President

RRJ:cp