



May 12, 2010

Ms. Cynthia Oshita
California Office of Environmental Health and Hazard Assessment
Sacramento, CA 95812

Dear Ms. Oshita:

I want to provide comments from the Advanced Medical Technology Association, AdvaMed, on OEHHA's Request for Relevant Information on the listing of Bisphenol-A by the Authoritative Bodies Mechanism.

AdvaMed member companies produce the medical devices, diagnostic products, and health information systems transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our members produce nearly 90 percent of the healthcare technology purchased annually in the United States and more than 50 percent purchased around the world.

Medical device firms are committed to providing the safest, most effective devices to meet patients' health care needs. In many applications, BPA-derived polycarbonate plastic and epoxy resins have shown to be the optimal choice for meeting critical device performance characteristics, including shatter-resistance, optical clarity, heat resistance, dimensional stability, and electrical resistance.

Scientific debate continues to exist regarding the potential long-term health risks from exposures to BPA at low levels.¹ Further toxicological study is needed to more clearly evaluate the potential concern in order to target the appropriate procedures and patient populations of concern. In January, the Food and Drug Administration indicated concern with BPA, called for reasonable steps to reduce infants' exposure, and is studying the chemical further, but has not called for restrictions on the it's use.

We would urge against actions that could limit BPA's availability for life-saving or life-enhancing medical devices or would undermine the public's confidence in the safety of medical devices. Consideration of the length and amount of exposure to affected populations is critical in light of the need to preserve patient access to needed therapies, particularly when there is a notable absence of demonstrably safer alternatives for medical applications.

Thank you for consideration of our concerns.

Sincerely,

Thomas E. Tremble
Vice President, State Government Relations

¹ U.S. Department of Health and Human Services, National Toxicology Program, Center for the Evaluation of Risks to Human Reproduction, "NTP-CERHR Monograph on the Potential Human Reproductive and Development Effects of Bisphenol-A," NIH publication No. 08-5994 (September 2008)