American Dental Association
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Office of the Executive Director

February 1, 2007

Michael D. Shelby, Ph.D.
CERHR Director
NIEHS
P.O. Box 12233, MD EC-32
Research Triangle Park, NC 27709

Re: American Dental Association Response to the Draft Expert Panel Report for Bisphenol A (December 15, 2006)

Dear Doctor Shelby:

On behalf of the American Dental Association (ADA), I would like to take this opportunity to respond to the request published in the Federal Register (Vol. 71, No. 238/Tuesday, December 12, 2006/Notices) for public input on the draft "NTP-CERHR Report on the Reproductive and Developmental Toxicity of Bisphenol A."

The Association commends the comprehensive and objective review of the literature in the current document, particularly relating to the potential contribution of bisphenol A (BPA) from dental sealants and composites to the overall body burden of BPA in dental patients and the general population (section 1.2.3.3.). Additionally, the document also puts the role of estrogenic potential of BPA from dental products into proper perspective and provides the public with succinct summaries of the general toxicity and other potential adverse biological effects of BPA in Section 2.0 of the current document.

Since the publication by Olea, et al[1] in 1996, the alleged release of BPA from dental sealants and composites has remained a topic of debate. The thorough and systemic review of recent publications contained in this report will help to dispel the mistaken belief that dental sealants or composites are a significant source of human exposure to BPA and that its related estrogenic potential are a concern to dental patients and the general population. This belief is founded on the misconception that:

- BPA is a starting material in the formulation and manufacture of dental sealants and composites;
- BPA is a prevalent carry-over or unreacted chemical contaminant from the synthesis of the commonly used dental monomer, bispheneol A glycidyl methacrylate (bis-GMA); and
- BPA is one of the degradation products resulting from the breakdown of bis-GMA used in dental sealants and composites.

All these statements are untrue. BPA is not a known starting ingredient in any dental product.

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The current standard method of synthesis for bis-GMA[6-7] involves the reaction of diglycidyl ether of BPA (BADGE) with methacrylic acid, which excludes the use of BPA as a starting material. This method is used in all manufacturing of dental bis-GMA monomers today and is the reason why study after study has not identified significant quantities of BPA in dental sealants and composites. Great care is taken in the synthesis of dental monomers to assure that BPA is not present in the final product.

The trace amounts of BPA found in the saliva of dental patients after application of sealant has been documented to be derived not from bis-GMA, but from bisphenol A dimethacrylate (bis-DMA).[2-3,5] Bis-DMA was added to one particular dental sealant product to dilute the highly viscous bis-GMA monomer. This product is the material cited in the original Olea, et al, 1996 study and several subsequent studies. Bis-DMA has not been identified as a diluent in any composite resin formulation.

Chemically, the bis-DMA monomer contains an ester-linkage, which is susceptible to hydrolysis by nonspecific salivary esterases.[2,6] This hydrolysis results in the release of BPA in situ. Only one dental sealant documented in the literature, namely, Delton LC, uses bis-DMA as a diluent in its formulation. Other monomers used in dental composites, such as bis-GMA, contain only ethyl linkages that are not susceptible to hydrolysis by salivary esterases and, therefore, do not degrade to produce BPA.

The trace amounts of BPA detected in saliva immediately after placement of the Delton sealant may pose no demonstrable health risk, since many studies have demonstrated rapid absorption of BPA from the gastrointestional tract, conjugation with glucuronic acid in the liver and rapid elimination of the BPA glucuronide in urine (half-life in humans is estimated to be 4-5 hours).[4] Furthermore, the rapid and complete excretion of BPA glucuronide in the urine suggested that, in contrast to rodents where BPA glucuronide is primarily excreted in the bile and feces, enterohepatic circulation of BPA did not occur in humans. This indicates that prolonging the half-life by recirculation of BPA in humans is unlikely.

I hope the information provided above will be helpful in the expert panel's deliberations and in completing the current draft during your scheduled meeting on March 5-7, 2007.

Sincerely,

James B. Bramson, D.D.S.

James B. Bramson, D.D.S.
Executive Director

JB:cb
cc: Ms. Mary K. Logan, chief operating officer
Dr. Daniel M. Meyer, associate executive director, Division of Science

1. Olea N, Pulgar R, Perez P, et al. Estrogenicity of resin-based composites and sealants used in dentistry. Environ Health Perspect 1996; 104(37):298-305.

2. Fung EY, Ewoldsen NO, St Germain HA Jr., et al. Pharmacokinetics of bisphenol A released from a dental sealant. JADA 2000; 131(1):51-8.

3. Sasaki N, Okuda K, Kato T, et al. Salivary bisphenol A levels detected by ELISA after restoration with composite resin. J Mater. Med 205;16: 297-300.

4. Volket W, Colnot T, Csnady GA, et al. Metabolism and kinetics of bisphenol A in humans at low doses following oral administration. Chem Res Toxicol 2002; 15:1281-7.

5. Arenholt-Bindsleve D, Breinholt V, et al. Time-related bisphenol A content and estrogenic activity in saliva samples collected in relation to placement of fissure sealants. Clin Oral Investig 1999; 3(3): 120-5.

6. Soderholm KJ, Mariotte A. Bis-GMA resins in dentistry. Is it safe? JADA 1999; 130:201-9.

7. Bowen RL, inventor. Method of preparing a monomer having phenoxy and methacrylate groups linked hydroxyl glycerol groups. U.S. patent 3179623. April 1965.