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May 12, 2010

VIA E-MAIL

Dr. Joan Denton, Director
Office of Environmental Health Hazard Assessment
P.O. Box 4010, MS-19B
Sacramento, California 95812-4010

Re: Comments of the California Dental Association and the CDA Foundation on the Proposed Listing of Bisphenol-A Under Proposition 65

Dear Dr. Denton:

This response to OEHHA's March 23, 2010, request for comments on the proposed listing of Bisphenol-A (BPA) is submitted on behalf of the California Dental Association and the CDA Foundation (collectively, "CDA"). CDA appreciates this opportunity to comment on the proposal.

CDA supports dental health professionals in their practices and service to the public through innovation in education, advocacy and related programs. CDA is the recognized leader for excellence in member services and advocacy promoting oral health and the profession of dentistry.

As a champion of oral health, CDA supports the use of sealants and other products to prevent and treat dental caries. Dental sealants are no longer made with BPA, and do not cause exposures that would require a warning. It is rare for dental sealants to cause any exposure to BPA. In the few brands that elevate BPA saliva levels, the exposures last for less than an hour.

Nevertheless, the listing of BPA is likely to lead dentists and other oral health professionals to use warnings to avoid baseless litigation. Such warnings would discourage Californians, and especially pregnant women, from obtaining proper dental care. Moreover, the proliferation of warnings would undermine the legislative purposes of Proposition 65.

The National Toxicology Program document upon which the proposed listing is based does not formally identify BPA as causing reproductive toxicity within the meaning of Proposition 65 or of Title 27, California Code of Regulations, § 25306. NTP did not

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determine that there was sufficient evidence of reproductive toxicity in experimental animals to conclude that BPA is a reproductive toxicant.. As the DART-IC recently determined, BPA is not known to cause reproductive toxicity. BPA should not be listed under Proposition 65.

Moreover, as the Court of Appeal for the Second District made clear in *Nicolle-Wagner v. Deukmejian* (1991) 230 Cal.App.3d 652, 661, OEHHA is authorized to take regulatory action that promotes the purposes of Proposition 65 by protecting businesses and the public from proliferating and unnecessary warnings that “dilute to the point of meaninglessness” those required by Proposition 65. Since the DART-IC recently determined that BPA is not clearly shown to cause reproductive toxicity within the meaning of Proposition 65, the proposed listing would not promote accurate information or consumer safety. The public health is better served if OEHHA exercises discretion by refraining from listing.

Sealants and Composites Have Important Public Health Benefits.

According to the U.S. Centers for Disease Control and Prevention, dental caries remains the most common chronic disease of children aged 5 to 17 years and is 5 times more common than asthma.¹ Untreated cavities can cause pain, dysfunction, absence from school, and poor appearance—problems that can greatly affect a child’s quality of life. The 2006 California Smile Survey² showed that dental disease disproportionately affects the poor, ethnic minorities and the uninsured. This is consistent with data from the National Health and Nutrition Examination Survey (NHANES), which demonstrated that caries in permanent teeth was not distributed evenly among children and adolescents; among five to 17 year olds, 80% of caries occurred in just 25% of the population.³

Dental sealants play an essential role in prevention of caries, especially in high-risk groups. Sealants have been extensively studied and are recognized as one of the most effective methods for preventing tooth decay thereby decreasing the need for restorations. Reduction of caries incidence after placement of resin-based sealants ranges from 86% at one year to 79% at two years and 60% at four years. There is consistent evidence from private dental insurance and Medicaid databases that sealants on first and second

¹ Centers for Disease Control and Prevention and the American Dental Association (2006). Fluoridation: nature’s way to prevent tooth decay. Available at www.cdc.gov/Fluoridation/pdf/natures_way.pdf

² Dental Health Foundation, California Department of Health Services Office of Oral Health et al. (2006). Mommy, it hurts to chew: the California smile survey, an oral health assessment of California’s kindergarten and 3rd grade children. Available at www.healthysmilesoc.org/Documents/CaliforniaSmileSurvey.pdf

³ Vargas, C.M. et al (1998). Sociodemographic distribution of pediatric dental caries: NHANES III, 1988–1994. *Journal of the American Dental Association* 129:1229-1238. See also Kaste, L.S et al. (1996) Coronal caries in the primary and permanent dentition of children and adolescents 1-17 years of age: United States, 1988–1991. *Journal of Dental Research* 75:631-641.

permanent molars in children and adolescents is associated with reductions in the subsequent provision of restorative services.

Sealants and Composites Cause No Proposition 65 Exposure.

Contrary to the statement in OEHHA's notice, BPA is not an ingredient in dental sealants. The use in dental sealants of bis-DMA, which may degrade to release BPA after placement, is now rare. The estimated short-term exposure to a child from application of dental sealants that did release BPA was approximately one-ten-thousandth of the NOEL of 50 mg/kg. There is no detectable trace of BPA in saliva, blood or urine after 24 hours of sealant placement, and in most cases, none after 1 hour.

Listing BPA Would Undermine the Public Health.

Since there is no Proposition 65 exposure, no Proposition 65 warning is required. However, safe-harbor levels and exposures are the defendant's burden of proof, and meeting that burden requires expensive litigation through trial. This makes the settlement value of cases high, drawing actions against defendants who are not legally required to warn. To avoid costly civil litigation, many dentists will choose to provide warnings.

Warnings will promote misinformation about sealants, and may reduce sealant use. Reductions in sealant use would undermine state and federal goals for improving oral health.

In 2009, the Developmental and Reproductive Toxicant Identification Committee carefully reviewed the evidence on BPA and determined that it is *not* clearly shown to cause reproductive toxicity. Therefore, the addition of BPA to the Proposition 65 list cannot promote accurate information or any other public good.

BPA Is Not a Known Reproductive Toxicant.

Under Section 25306, the National Toxicology Program is an authoritative body "solely as to final reports of the National Toxicology Program's Center for Evaluation of Risks to Human Reproduction." Listing would be permitted under that section only if the NTP-CERHR report "concludes that the chemical causes ... reproductive toxicity."

But the NTP-CERHR does not so conclude. Rather, the NTP reported "some concern" that BPA "possibly" may "affect human development or reproduction," (see Abstract at vii). Therefore, the addition of BPA to the Proposition 65 list is not legally required. Thus there is no justification for causing the public health problems that would result from the proposed listing.

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For all these reasons, CDA believes the public good is best served by and urges OEHHA to determine that BPA is not known to cause reproductive toxicity within the meaning of Proposition 65, and to exercise its discretion to promote the purposes of Proposition 65 by refraining from the proposed listing.

Yours truly,

A handwritten signature in black ink, appearing to read "Lisa L. Halko". The signature is fluid and cursive, with a long horizontal stroke at the end.

Lisa L. Halko