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June 2, 2010

Leslie Kux
Acting Assistant Commissioner for Policy
Food and Drug Administration
5630 Fishers Lane # 1061
Rockville, MD 20852
Division of Dockets Management (HFA-305)

Submitted electronically to <http://www.regulations.gov>

Re: **Food Additives; Bisphenol A; Notice and Request for Comment on Documents Prepared by FDA Center for Food Safety and Applied Nutrition.**
Docket No. FDA-2010-N-0100. 75 Fed. Reg. 17145 (April 5, 2010).

Dear Assistant Commissioner Kux:

The American Nurses Association (ANA) welcomes the opportunity to offer comments on the continuing assessment of Bisphenol A (BPA) by the Food and Drug Administration and its Center for Food Safety and Applied Nutrition (CFSAN).

The ANA is the only full-service professional organization representing the interests of the nation's 3.1 million registered nurses, the single largest group of health care professionals in the United States. We represent RNs in all roles and practice settings, through our state and constituent member nurses associations, and organizational affiliates. ANA is actively involved in forming public policy that affects human health and patient advocacy, and has long recognized that a clean, safe environment is a fundamental requirement for ensuring and maintaining the health of our patients, our families, and our community.

ANA applauds the FDA's efforts regarding BPA to educate the American public, reduce public exposure, and streamline the mechanism to remove harmful chemicals from general use. However, the available scientific evidence calls for even stronger measures. We urge the FDA to ban all BPA in food and beverage containers.

In September 2008, ANA advocated for a complete ban on the use of BPA in food, health care and children's products, in testimony before the FDA. We have also supported legislation requiring such a ban, as well as requests for major retailers and

manufacturers to do so voluntarily. In October 2009, ANA signed on to a letter urging the FDA to conduct an impartial evaluation of the science on BPA, including low-dose BPA exposure studies by government and academic scientists. Industry-funded scientific studies are inherently suspect and subject to bias.

Initially developed in the 1930's as a synthetic estrogen, BPA is used in polycarbonate plastics and epoxy resins. It is so prevalent that it is found in an extremely wide array of products – including drink containers, water bottles, liners of canned goods, baby bottles, and sippy cups. Today, global production exceeds 6 billion pounds. BPA can migrate out of food and drink containers, particularly when heated. Americans are likely to ingest some BPA virtually every day, by drinking or eating, or breathing particles in the air.

As a synthetic estrogen, BPA can disrupt normal hormone function, with devastating effects. Hormones are the body's "messengers," controlling important chemical functions such as growth, metabolism, digestion, sexual function, and the conversion of food into energy. More than 200 scientific studies suggest a link between BPA exposure, even in extremely small doses, and a multitude of health issues:

- Reproductive problems
- Birth defects
- Obesity
- Behavioral disorders
- Abnormal brain structure and chemistry
- Impaired immune function
- Breast and prostate cancers

This list is remarkable for containing so many of the major – and growing – public health problems of our nation. Children are very vulnerable to the harmful effects of BPA. Even miniscule amounts of Bisphenol A have been shown to cross the placenta. Baby bottles are frequently made of polycarbonates which contain Bisphenol A. BPA can leach out of the plastic, especially with age, and heat from sterilization and dishwashers.

The overwhelming majority of government-funded studies have shown an effect from BPA at environmentally relevant doses. The Centers for Disease Control and Prevention (CDC) has found that "[w]hen laboratory test animals are dosed during pregnancy, BPA has been shown to have hormone-like effects on the developing reproductive system and neurobehavioral changes in the offspring." The National Toxicology Program has expressed concerns about the effects of BPA exposure on the developing brain and prostate gland of fetuses, as well as behavioral effects in infants and children. When the CDC National Health and Nutrition Survey studied 2,517 people in 2003 to 2004, close to 93% had detectable amounts of BPA in their urine. A September 2008 study in the Journal of the American Medical Association has linked BPA to heart disease, diabetes, and liver abnormalities in adults. A University of Cincinnati study found that BPA can interfere with the efficacy of chemotherapy treatment for breast cancer.

BPA is the subject of partial or complete bans in Minnesota; Connecticut; Chicago; Suffolk County, New York; and Norway. Canada is proceeding with a proposed ban on advertising, selling, and importing baby bottles with BPA. Several leading manufacturers and retailers have voluntarily decided to stop producing or selling products with BPA.

If the FDA intends to continue to assess the health effects of BPA, this must be based on the full scope of evidence, and must be conducted free of inappropriate industry influence. Unfortunately, some FDA research, such as that conducted in 2008 by Dr. Mitchell Cheeseman, has been heavily influenced by the industry which produces and sells products with BPA. We understand that the FDA is undertaking a major effort to adopt more even-handed and valid research methods. We urge the agency, in future research and evaluations of BPA – and other harmful chemicals -- to keep the health interests of the public as the number one priority and consideration.

Conclusion

The American Nurses Association appreciates this opportunity to comment on this important issue. If we can be of further assistance, or if you have any questions or comments, please feel free to contact Holly Carpenter, BSN, RN, Senior Staff Specialist, Center for Occupational and Environmental Health, at holly.carpenter@ana.org, 301-628-5105.

Sincerely,

A handwritten signature in cursive script that reads "Mary Jean Schumann".

Mary Jean Schumann, MSN, MBA, RN, CPNP
Chief Programs Officer
American Nurses Association