April 17, 2012

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U.S. Food and Drug Administration
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Re: Comments on the American Chemistry Council's Petition to Remove Approval for Polycarbonate Resins in Infant Feeding Bottles and Certain Spill-Proof Cups Due to the Abandonment of these Uses (Docket No. FDA-2012-F-0031)

The American Chemistry's Council (ACC) September 19, 2011, *Petition Seeking Food Additive Regulation 21 C.F.R. § 177.1580* (ACC Petition) is a step in the right direction to limit the dangerous effects of Bisphenol A (BPA) in the U.S. food supply, but stops short of the needed action on the part of the FDA in addressing infants', children's, and adults' exposure to this dangerous and ubiquitous endocrine-disrupting chemical. Under 21 C.F.R. § 171.130(a), the U.S. Food and Drug Administration (FDA) has the authority to issue new regulations without limitation on scope and is not bound by the limits or request set forth in the ACC Petition. **We propose that FDA utilize its full authority and issue new regulations encompassing the ACC's Petition and Rep. Edward Markey's March 16, 2012 Petitions. We also propose that FDA ban a much broader range of BPA uses and mandate labeling of BPA in all food contact materials.**

Our proposals are based on convincing scientific evidence that BPA poses serious health risks not only to infants, toddlers, and children, but also to adults, particularly those of child-bearing age. The traditional risk assessment methods to determine safety do not adequately address the latest scientific evaluations of BPA, which demonstrate serious low-dose effects for a broad range of ages, including obesity, diabetes, reproductive effects, and even some forms of cancer. Consumers do not want to be test subjects while government scientific protocols play catch-up, and they have called on manufacturers to remove BPA from products. FDA must consider the underlying safety and health motives behind manufacturers' abandonment of BPA and use its full authority to amend existing BPA regulations and issue new ones.

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FDA's Authority and Responsibility

FDA has the authority, on its own initiative, to promulgate regulations beyond the scope of petitioners' requests. The regulation under which ACC submitted its petition, 21 C.F.R. § 171.130, states: "The Commissioner, *on his own initiative or on the petition of any interested person* … may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive or granting or repealing an exception for such additive."[1] Petitioners must select whether the request for a food additive amendment is based on new information, new uses, abandoned uses, new toxicity data, or experiences with the regulation.[2] Any one of those justifications on its own is sufficient, but there are no limitations on selecting multiple kinds of support for a petition.

More importantly, FDA's authority to amend or repeal a food additive regulation is not limited by 21 C.F.R. § 171.130. There is no requirement that FDA amend or repeal a food additive regulation pursuant only to the terms and reasons set forth in a petition. This unfettered authority allows FDA to grant the ACC Petition *and* issue new regulations prohibiting uses of BPA, as suggested in other recent petitions and as justified by the science. In the *Federal Register* notice requesting public comment on the ACC Petition, however, FDA has made an implicit decision not to use its full authority, opting instead to weigh the merits of a limited exclusion of BPA from certain products proposed by ACC. FDA's decision to use its authority in such a limited manner undercuts its overarching responsibility to protect the safety of all Americans.

Inadequacy of Definitions

ACC's Petition fails to adequately define the scope of abandoned uses and fails to mention other clear examples of abandonment of BPA. Demonstrating the inadequacy of the ACC's definitions and supporting information, Rep. Markey's Petitions identified three additional food contact materials and uses containing BPA where manufacturers had abandoned or are in the process of abandoning the use. According to Rep. Markey's Petitions, manufacturers of reuseable food and beverage containers and infant formula packaging and baby and toddler food packaging have all abandoned use of BPA. Additionally, manufacturers of food and beverage cans containing BPA resins are taking significant steps towards abandoning BPA.

To assess whether these additional uses had been abandoned, Rep. Markey and his staff determined market-manufacturing shares for these food contact materials, compiled company and manufacturer statements concerning these uses, and contacted representatives of the manufacturer or parent company to confirm the abandonment. These methods of polling and use assessment mirrored those of the ACC's information collection efforts. The ACC had blinders on in concluding that only "sippy cup" and "baby bottle" uses of BPA have been abandoned. The ACC's narrow petition should not dictate FDA's decision to amend or repeal regulations concerning BPA more broadly.

"Sippy Cup" and "Baby Bottle" definitions fail to identity the full-spectrum of beverage containers from which infants, toddlers, and children consume beverages. FDA explains in its notice that "[f]or the purposes of this petition, FDA considers 'sippy cups' to mean spill-resistant training cups, including their closures and lids, intended for use by babies or toddlers." The

[1] 21 C.F.R. § 171.130(a) (emphasis added).
[2] 21 C.F.R. § 171.130(b).

ACC Petition defines "baby bottles" as "infant feeding bottles" and FDA offers no additional description or clarification. The narrow definition ignores the fact that infants, toddlers, and children consume beverages from a variety of sources, including hard plastic drinking cups that are not "sippy cups." It also ignores the fact that manufacturers may not have considered certain uses that fell outside of the these narrow definitions when responding to the ACC's petition.

FDA should prohibit BPA's use in all food contact materials, regardless of the target consumers and users. As Rep. Markey's petitions demonstrate, most food contact uses of BPA have simply been abandoned by manufacturers themselves. Therefore, according to the ACC's own logic, there is no valid reason for continuing to permit these food contact uses of BPA. At a minimum, the FDA should prohibit the use of BPA in all food and beverage containers designed for children up to age 8. "Designed for" should be defined both functionally (e.g., containers that are spill-resistant) and aesthetically (i.e., anything with cartoon characters, etc.) The definitions should be broad enough to prevent loopholes that leave the public unprotected.

Introduction or Delivery of BPA Containing Materials into the U.S. Market

FDA's specific request for comment on whether baby bottles or sippy cups containing polycarbonate resins are currently being introduced or delivered for introduction into the U.S. market ignores an underlying problem of insufficient public access to knowledge concerning what products and materials contain BPA. Even if the general public took it upon themselves to conduct the extensive polling and research necessary to determine abandonment of use, there is virtually no way for the public to confirm the assertions of the manufacturers and companies responsible for BPA production and use in food contact materials. Because there is no mandatory BPA or polycarbonate resin labeling on products, the general public is defenseless to counter industry assertions about abandonment. Had FDA required BPA labeling 5 years ago, when safety concerns began to enter the public's awareness, the public would have better information on which to assess industry assertions. Whether or not FDA grants ACC's petition, **FDA should require labeling of all food contact materials that contain BPA**. Such labeling would allow citizens to make their own choices about exposure to BPA-containing products and would help to confirm whether uses of BPA have in fact been abandoned. It is simply intolerable that Americans are left in the dark about whether food and liquids that they consume are in contact with materials that contain a known endocrine-disrupting compound. Ideally, BPA labeling standards would take the form of a regulation that sets specific labeling and substitution requirements and applies to all BPA food-contact uses, manufacturers, and distributors.

New Information on Toxicity and the FDA's Responsibility

ACC's Petition ignores new information concerning BPA's toxicity and FDA's responsibility to the public. Recent studies of BPA exposure and risks cannot be ignored when considering the ultimate reason for manufacturers abandonment of BPA use—consumer demand for safe products. New scientific research concerning the low-dose effects of BPA, among other endocrine-disrupting chemicals, continues to mount. One study released just a month ago, involved a review of numerous endocrine-disrupting chemicals, including BPA, and "concluded after examining hundreds of studies that health effects 'are remarkably common' when people or

animals are exposed to low doses of endocrine-disrupting compounds."[3] **These low-dose effects are not properly accounted for in current risk assessments of BPA.**

Attempting to divorce safety issues from the discussion of the ACC's petition ignores FDA responsibility to act in the interest of the U.S. consumer's safety and its unfettered authority to issue regulations in support of that aim. Allowing industry to dictate the scope and definitions of such regulations flies in the face of FDA's mission.

Conclusion

We support the end result of both the ACC Petition and Rep. Markey's Petitions that would ban BPA's use in the identified food contact materials and containers. While we presume that the identified uses have been abandoned in the manner described by the ACC, we do not have any further information to support or counter factual assertions of abandonment as it is impossible for the general public to discern what materials contain BPA or are even made with polycarbonate resins. Based on this insufficiency and the belief that FDA can utilize its full powers to protect the public against the demonstrated dangers of BPA, we propose that in granting the petitions of the ACC and Rep. Markey, FDA expand the scope of proposed regulation and implement a broader ban of BPA uses and mandate labeling requirements.

Sincerely,

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[3] Marla Cone, *Low doses, big effects: Scientists seek 'fundamental changes' in testing, regulation of hormone-like chemicals*, March 15, 2012, Envt'l Health News, http://www.environmentalhealthnews.org/ehs/news/2012/low-doses-big-effects; *see also* Vandenberg, *et al*., *Hormones and Endocrine-Disrupting Chemicals: Low-Dose Effects and Nonmonotonic Dose Responses*, Endocrine Reviews, doi:10.1210/er.2011-1050, June 2012, http://edrv.endojournals.org/content/early/2012/03/14/er.2011-1050.full.pdf.