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IN THIS ISSUE

This article summarizes events from the last few years, showing how, in the author's opinion, a useful product can be denigrated by poor science and virtually marginalized out of existence.

BPA Update and Opinions: Legislation, Regulation, Science, and Litigation Concerning Bisphenol-A

ABOUT THE AUTHOR

Bruce J. Berger is a partner in the Washington, DC office of Hollingsworth LLP. He has expertise in pharmaceutical product liability defense, environmental litigation, and toxic tort defense. He can be reached at bberger@hollingsworthllp.com. The author thanks Erica Trachtman for her assistance on this project.

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Michael L. Fox
Vice-Chair of Newsletters
Sedgwick LLP
(415) 781-7900
michael.fox@sedgwicklaw.com

Bisphenol-A ("BPA"), one of the so-called endocrine disrupters,[1] has been the target of continued legislative and regulatory action, and the federal government has devoted tens of millions of dollars towards its study. This brief article summarizes events from the last few years, showing how, in my opinion, a useful product can be denigrated by poor science and virtually marginalized out of existence.

A. Legislative and Regulatory Activities

In October 2008, the Natural Resources Defense Council ["NRDC"] started the ball rolling by filing a citizen petition[2] requesting that the Commissioner of Food and Drugs issue a regulation prohibiting the use of bisphenol-A ["BPA"] in human food and packaging, and revoke all regulations permitting the use of any food additive that may result in BPA becoming a component of food. In January 2010, prior to issuing a direct decision, FDA released an interim update on BPA that expressed "some concern about the potential effects of BPA on the brain, behavior, and prostate gland in fetuses, infants, and young children."[3] That action did not satisfy NRDC, which filed suit against the agency in an effort to compel a definitive decision[4] and, on March 30, 2012 FDA formally denied the request, explaining that the studies presented by NRDC were too small to be conclusive and lacked sufficient research conducted on humans. Although FDA was not persuaded by the scientific data provided by the NRDC, the agency explained it would "continue in its broader and more comprehensive review of emerging data and information on BPA," and, "[d]epending on the results, any of these studies or data could influence FDA's assessment and future regulatory decisions about BPA."[5]

At the time of its March 2012 decision, FDA released another "Update on BPA for Use in Food Contact Applications,"[6] nearly identical to the January 2010 update. The update explained that while FDA's National Center for Toxicological Research ["NCTR"] is "carrying out in-depth studies to answer key questions and clarify uncertainties about the risks of BPA," FDA would be taking additional steps to reduce human exposure to BPA in the food supply, to support more

[1] Bruce J. Berger & Michael G. Elliot, *Pesticide Chemicals and Endocrine Disruptor Allegations: Update on the Environmental Protection Agency's Endocrine Disruptor Screening Program*; IADC TOXIC AND HAZARDOUS SUBSTANCES LITIGATION NEWSLETTER, Dec. 2009; Bruce J. Berger & Michael L. Junk, *Endocrine Disrupters – An Update*, IADC PRODUCT LIABILITY NEWSLETTER, Mar. 2008; Bruce J. Berger & Michael L. Junk, *Endocrine Disrupters: The Potential Cloud of Manufacturer Toxic Tort Liability*, DEF. COUNS. J., Apr. 2007; Bruce J. Berger, *Endocrine Disrupter Studies Can Be Challenged as Lacking Proper "Fit" With the Human Question*, IADC PRODUCT LIABILITY NEWS LETTER, July 2006.

[2] In its petition, the NRDC asserted that BPA can cause serious health problems and poses a particular risk to infants and young children. The organization pointed to scientific studies purportedly linking BPA exposure to altered development of the brain, various forms of cancer, diabetes, reproductive harm and cardiovascular disease.

[3] FDA, Update on Bisphenol A for Use in Food Contact Applications, January 2010, *available at:* http://www.fda.gov/downloads/NewsEvents/PublicHealthFocus/UCM197778.pdf.

[4] The U.S. Circuit Court of Appeals for the District of Columbia dismissed the suit for lack of jurisdiction, holding that the district courts have exclusive jurisdiction over this type of case. *In re Natural Res. Def. Council*, No. 10-1142, 2011 WL 2417124 (D.C. Cir. June 17, 2011).

[5] DEP'T OF HEALTH AND HUMAN SERV., Petition Denial to NRDC (2010), *available at*: http://www.regulations.gov/#!documentDetail;D=FDA-2008-P-0577-0007.

[6] FDA, Update on Bisphenol A for Use in Food Contact Applications, March 2012, *available at*: http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm064437.htm.

robust regulatory oversight of BPA and seek further public comment and input on the science surrounding BPA. One may well wonder why FDA announced it would seek to reduce exposures before it conducted its "in-depth studies to answer key questions." The March 2012 update explained that FDA has adopted the National Toxicology Program's ["NTP"] level of concern (*see infra*) over the potential effects of BPA, while detailing the many uncertainties inherent in NTP's research.[7]

In the March 2012 update, FDA discussed the food additives regulatory structure, under which BPA was approved more that 40 years ago. At present, the agency claimed, manufacturers of food and food packaging are not required to disclose to FDA the existence of BPA-containing substances. According to FDA, revocation of the approved uses of BPA would require FDA to undertake the lengthy process of rulemaking. Thus, the agency asserts, the current "regulatory structure limits the oversight and flexibility of FDA."[8] Notwithstanding these limitations, however, FDA's actions strike at the heart of BPA use, because its announced "concern" pushes users of BPA to seek alternatives and erodes the business of BPA manufacturers.

Such erosion can be seen by following the efforts of Representative Edward J. Markey (D-Mass.) to keep the chemical out of certain food containers. Rather than forcing FDA to accept the results of inconsistent studies and ban BPA for safety reasons, Markey sought to show under FDA regulations[9] that BPA use had been abandoned.[10] Markey's office polled major manufacturers to determine BPA's prevalence in packaging and then argued to FDA that the chemical is no longer in use. FDA preliminarily accepted his petition on infant formula as a result of the "market preferences" that prompted manufacturers to eliminate BPA use in formula products.[11] These "market preferences" of course were brought about in the first instance by NRDC's petition and unreasonable "concerns" that cannot be supported by sound and reliable science. Markey's petitions to ban the use of BPA in small, reusable food containers and in packaging for canned foods and beverages were rejected because responses from manufacturers of those products did not demonstrate that a significant percentage of the industry has abandoned BPA in their packaging. However, I predict that it is only a matter of time before those uses disappear as well.

Separate federal legislative efforts to ban BPA have been largely unsuccessful, with anti-BPA bills dying in committee. On December 16, 2009, Representative Timothy J. Ryan (D-OH) introduced the BPA Consumer Information Act of 2009,[12] which sought to amend the FDCA to require a

[7] *Id.* ("These uncertainties relate to issues such as the routes of exposure employed, the lack of consistency among some of the measured endpoints or results between studies, the relevance of some animal models to human health, differences in the metabolism (and detoxification) of an responses to BPA both at different ages and in different species, and limited or absent dose response information for some studies.").
[8] *Id.*

[9] 21 C.F.R. § 171.130.
[10] Dina ElBoghdady, *FDA considers banning BPA in infant formula containers in response to lawmaker's stratagem*, WASHINGTON POST, June 12, 2012, *available at*: http://www.washingtonpost.com/business/economy/fda-considers-ban-on-bpa-in-infant-formula-containers-in-response-to-lawmakers-stratagem/2012/06/12/gJQAFXJeYV_story.html.
[11] *See* Formula and Baby Food Company Response, Jan. 6, 2012, *available at*: http://markey.house.gov/sites/markey.house.gov/files/documents/All%20formula%20and%20baby%20food%20company%20responses.pdf.
[12] H.R. 4341, 111th Cong. (2009).

warning on the label of any food container that is composed, in whole or in part, of BPA or could release BPA into food. Ryan's bill was referred to the Subcommittee on Commerce, Trade and Consumer Protection, but failed to proceed further. The BPA-Free Kids Act[13] was reintroduced most recently by Representative Anthony Weiner (D-NY) on January 13, 2010 and also remains in committee. Representative Markey reintroduced the Ban Poisonous Additives Act ["BPAA"] again on January 25, 2011 with Senator Dianne Feinstein (D-CA) introducing an identical bill on that day in the Senate. Both were referred to committee and remain dormant.[14]

Notwithstanding the failure of federal legislation, BPA manufacturers and users cannot question that the product is on the way out. Many state legislatures have banned BPA from childcare products, including California, Connecticut, Delaware, the District of Columbia, Maryland, Minnesota, New York, Vermont, Washington, and Wisconsin.[15] Connecticut has gone even further, eliminating BPA from all reusable food and beverage containers[16] (not just those for children), and from "thermal receipt paper or cash register receipt paper."[17] Many other state legislatures have seen the introduction of bills banning BPA from child care products or all food and beverage products generally.[18]

[13] H.R. 4456, 111th Cong. (2010).

[14] H.R. 432, 112th Cong. (2011) (referred to the Subcommittee on Health); S. 136, 112th Cong. (2011) (read twice and referred to the Committee on Health, Education, Labor, and Pensions).

[15] CAL. HEALTH & SAFETY CODE § 108940 (West 2011); CONN. GEN. STAT. ANN. § 21a-12c (West 2012); DEL. CODE ANN. tit. 6, § 2509 (West 2011); D.C. CODE § 8-108.01 (2011); MD. CODE ANN., HEALTH-GEN. § 24-304 (West 2011); MINN. STAT. ANN. § 325F.173 (West 2011); N.Y. ENVTL. CONSERV. LAW § (McKinney 2011); VT. STAT. ANN. tit. 18, § 1512 (West 2011); WASH. REV. CODE ANN. § 70.280.020 (West 2011); WIS. STAT. ANN. § 100.335 (West 2011).

[16] CONN. GEN. STAT. ANN. § 21a-12b (West 2011).

[17] CONN. GEN. STAT. ANN. § 21a-12e (West 2011).

[18] *See* H.B. 362, 2011 Sess. (Ala. 2011) (referred to Committee on Health); H.B. 172, 27th Leg., 1st Sess. (Alaska 2011) (referred to Health & Social Services); H.B. 2620, 50th Leg., 2d Sess. (Ariz. 2012) (introduced January 19, 2012); S.B. 350, 88th Gen Assem. 2011 Sess. (Ark. 2011) (recommended for study in Senate Committee on Public Health, Welfare and Labor); H.B. 1174, 95th Gen. Assem. 2d Reg. Sess. (Colo. 2012) (introduced January 20, 2012); H.B. 431, 151st Gen. Assem., 2011-2012 Reg. Sess. (Ga. 2011) (ordered to second reading March 3, 2011); H.B. 1934, 26th Leg., 2012 Reg. Sess. (Haw. 2012) (introduced January 18, 2012); Toxin-Free Toddler Act, S.B. 2950, 97th Gen. Assem., 2d Reg. Sess. (Ill. 2012) (enrolled May 30, 2012); H.F. 2303, 84th Gen. Assem., 2012 Sess. (Iowa 2012) (introduced February 15, 2012); H.B. 236, 2012 Reg. Sess. (Ky. 2012) (introduced January 10, 2012); H.B. 2360, 187th Gen. Court (Mass. 2011) (referred to Joint Committee on Public Health); H.B. 1910, 96th Gen. Assem., 2d Reg. Sess. (Mo. 2012) (introduced March 7, 2012); H.B. 1182, 162d Sess. (N.H. 2012) (introduced January 4, 2012); Toxic-Free Beverage Containers Act, S.B. 1383, 215th Leg., 1st Ann. Sess. (N.J. 2012) (introduced February 6, 2012); NC Toxic-Free Kids Act, H.B. 1187, 2011 Gen. Assem., 2012 Reg. Sess. (N.C. 2012) (introduced May 30, 2012); H.B. 1332, 62d Leg. Assem. (N.D. 2011) (reported back from committee will not pass); H.B. 450, 129th Gen. Assem., 2011-2012 Sess. (Ohio 2013) (introduced March 13, 2012); H.B. 3258, 76th Leg. (Or. 2011) (referred to Energy, Environment and Water Committee); H.B. 1808, 195th Gen. Assem. (Pa. 2011) (referred to Consumer Affairs Committee); H.B. 192, 195th Gen. Assem. (Pa. 2011) (re-referred to Health Committee); H.B. 5499, 2011 Leg. Sess. (R.I. 2011) (held for further study); H.B. 1246, 87th Leg. Assem. (S.D. 2012) (engrossed February 9, 2012); H.B. 445, 107th Gen. Assem. 1st Reg. Sess. (Tenn. 2011) (withdrawn February 28, 2011); Bisphenol A-Free Children and Babies Act, S.B. 1449, 2011 Reg. Sess. (Va. 2010) (passed by Health Care Subcommittee February 3, 2011); BPA-Free Kids Act, H.B. 3261, 80th Leg., Reg. Sess. (W. Va. 2012) (introduced January 11, 2012).

B. Science

Legitimate science does not support any human health concern related to uses of BPA. In response to NTP's April 2008 draft brief on BPA, FDA released a document entitled *Draft Assessment of Bisphenol A for Use in Food Contact Applications* in August 2008.[19] A stated goal of the assessment "was to examine BPA data to determine if the safety standard for food additives was still met with regard to the continued use of BPA."[20] In the document, FDA addresses NTP's (as well as other foreign government organizations') potential concerns for developmental exposures on select endpoints, ultimately concluding that the data are insufficient to provide a basis to alter the no observed adverse effect level ["NOAEL"] used to calculate the margin of safety. Thus, "an adequate margin of safety exists for BPA at current levels of exposure from food contact uses, for infants and adults."[21]

NTP had released its completed 321-page review of BPA in September 2008.[22] NTP uses five different terms to rate its concern regarding the effects of chemicals: negligible concern, minimal concern, some concern, concern, and serious concern. In its 2008 review, NTP expressed "*some concern* for effects on the brain, behavior, and prostate gland in fetuses, infants, and children at current human exposures to bisphenol A," "*minimal concern* for effects on the mammary gland and an earlier age for puberty for females in fetuses, infants, and children at current human exposures to bisphenol A," and "*negligible concern*" for other outcomes.[23] Though NTP found no direct evidence that exposure to BPA adversely affects reproduction or development, studies with rodents suggest that exposure to high levels of BPA during pregnancy and/or lactation can reduce survival, birth weight, and growth early in life. However, the dose levels associated with these issues far exceeded the highest estimated daily intake of BPA in children, adults, or workers (*e.g.* 300 mg/kg bw/day (growth reductions) versus 0.0147 mg/kg bw/day (exposure in children)).[24]

Aside from survival and growth effects seen at high dose levels of BPA, a variety of effects related to neural and behavior alterations, potentially precancerous lesions in the prostate and mammary glands, altered prostate gland and urinary tract development, and early onset of puberty in females were reported in rodents exposed during development to much lower doses of BPA (0.0024 mg/kg bw/day).[25] NTP detailed the limitations of these "low" dose findings in lab animals, including concern for insufficient replication by independent investigators, questions on the suitability of various experimental approaches, relevance of the specific animal model used for evaluating potential human risks, and incomplete understanding or agreement on the potential adverse nature of reported effects.[26]

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[19] FDA, *Draft Assessment of Bisphenol A for Use In Food Contact Applications, available at:* http://www.fda.gov/ohrms/dockets/AC/08/briefing/2008-0038b1_01_02_FDA%20BPA%20Draft%20Assessment.pdf.

[20] *Id.*at 31.

[21] *Id.* at 36.

[22] NTP-CERHR *Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A*, NIH Publication No. 08-5994, September 2008, *available at* http://ntp.niehs.nih.gov/ntp/ohat/bisphenol/bisphenol.pdf.

[23] *Id.* at 38-39.

[24] *Id.* at 34.

[25] *Id.* at 36.

[26] *Id.* at 9.

NTP also noted that only a very small number of studies have examined the association between BPA exposure and reproductive or developmental effects in humans.[27] As NTP explains, "[d]rawing firm conclusions about potential reproductive or developmental effects of bisphenol A in humans from these studies is difficult because of factors such as small sample size, cross-sectional design, lack of large variations in exposure, or lack of adjustment for potential confounders."[28] Accordingly, a rational society would not have used NTP's report as a basis for banning BPA as a result of feared human health effects.

FDA's August 2008 *Draft Assessment* was reviewed by a Subcommittee of FDA's Science Board, which released its peer-review at the end of October 2008,[29] noting some concerns. Since then, the Center for Food Safety and Applied Nutrition ["CFSAN"] within FDA has reviewed studies of low-dose toxicity cited by NTP and the Science Board Subcommittee as well as other such studies that have become available. CFSAN then prepared a document entitled *Bisphenol A (CAS RN. 80-05): Review of Low Dose Studies*,[30] released August 31, 2009. The document dismissed several NTP studies for failing to meet certain adequacy criteria,[31] and subjected the remaining "adequate" studies to additional review. Ultimately, the Center agreed with FDA's *Draft Assessment* that the lowest NOAEL is 5 mg/kg bw/day. The review also made several determinations regarding specific developmental endpoints.[32]

Importantly, in October 2009, CFSAN determined that exposure to dietary BPA for an infant was less than previously estimated.[33] The initial FDA exposure estimate had been 2.42 micrograms/kg bw/day for infants. The later estimate of average dietary exposure, based on increased data collection, was 0.2-0.4 micrograms/kw-bw/day for infants. Thus, the original estimate overstated exposure by a factor of roughly 10, or one order of magnitude, further illustrating how over-reaction to initial data can grossly exaggerate potential health effects.

Other more recent studies[34] pursued by FDA's NCTR, and discussed in FDA's March 2012 update, have:

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[27] *Id.* at 15.
[28] *Id.*
[29] *Id.* at 12-13 ("The strengths of the draft safety assessment notwithstanding, the Subcommittee identified several significant concerns with the assessment in its current form. The exposure assessment lacks an adequate number of infant formula samples and relies on mean values rather than accounting for the variability in samples. The draft lacks a clear description of the criteria for eliminating an increasing number of non-GLP studies that indicate the possibility of toxic effects that are not mediated by interaction of BPA with the estrogen receptor, and the Subcommittee does not agree with the exclusion of the non-GLP studies in the safety assessment. Additional concern is expressed with the calculation of the NOAEL and specifically whether the exposure assessment to 'at risk' infants with minimal or impaired metabolic function and exposures from medical devices and procedures is as conservative as the assessment claims. In fact, it is the judgment of the Subcommittee that lack of consideration of the totality of exposures from other sources severely limits the usefulness of the safety assessment with respect to food contact applications.").

[30] CFSAN, *Bisphenol A: Review of Low Dose Studies, available at*: http://www.regulations.gov/#!documentDetail;D=FDA-2010-N-0100-0006.
[31] *See id.* at 4-13 (administration, same size and statistical analysis, end point measure, plausibility, dose response, sex, repeatability, and environmental contamination).
[32] *Id.* at 67-68.
[33] *See* Dept. of Health & Human Serv., *Exposure to Bisphenol A for infants, toddlers and adults*, Oct. 22, 2009, *available at*: http://www.regulations.gov/#!documentDetail;D=FDA-2010-N-0100-0009.
[34] Doerge D.R., Twaddle N.C., Woodling K.A., Fisher J.W., *Pharmacokinetics of bisphenol A in neonatal*

- Found evidence in rodent studies that the level of the active form of BPA passed from expectant mothers to their unborn offspring, following oral exposure, is so low it could not be measured. The study orally dosed pregnant rodents with 100-1000 times more BPA than people are exposed to through food, and could not detect the active form of BPA in the fetus 8 hours after the mother's exposure.

- Demonstrated that oral BPA administration results in rapid metabolism of BPA to an inactive form. This results in much lower internal exposure of aglycone BPA (i.e., the active form) than what occurs from other routes of exposure such as injection. Primates of all ages were also found to effectively metabolize BPA to its inactive form and excrete it much more rapidly and efficiently than rodents, thus reducing concerns about results from some rodent studies using oral and, particularly, non-oral exposures which result in higher actual internal exposures of rodents than of primates, including humans, exposed to the same dose.

- Developed a physiologically based pharmacokinetic model which can be used to predict the level of internal exposure to the active and inactive forms of BPA. This model allows comparisons of internal exposure across different ages and routes of exposure (e.g., oral and intravenous routes). Based on the effects of metabolism, internal exposures to aglycone BPA following oral administration are predicted to be below 1% or less of the total BPA level administered.

FDA is working toward completing another updated safety review on BPA this year to include all relevant studies and publications, and is working with the National Institute of Environmental Health Sciences, which has invested $30 million into BPA research.

and adult rhesus monkeys, Toxicology and Applied Pharmacology 2010; 248: 1–11; Doerge D.R., Twaddle N.C., Vanlandingham M., Fisher J.W. *Pharmacokinetics of Bisphenol A in neonatal and adult CD-1 mice: Inter-species comparisons with Sprague-Dawley rats and rhesus monkeys*, Toxicology Letters 2011; 207: 298– 305; Doerge D.R., Twaddle N.C., Vanlandingham M., Brown R.P., Fisher J.W. *Distribution of bisphenol A into tissues of adult, neonatal, and fetal Sprague–Dawley rats*, Toxicology and Applied Pharmacology 2011; 255: 261–270; Doerge D.R., Vanlandingham M., Twaddle N.C., Delclos K.B., Lactational *transfer of bisphenol A in Sprague–Dawley rats*, Toxicology Letters 2010; 199: 372–376; Twaddle N.C., Churchwell M.I., Vanlandingham M., Doerge D.R. *Quantification of deuterated bisphenol A in serum, tissues, and excreta from adult Sprague Dawley rats using liquid chromatography with tandem mass spectrometry*, Rapid Communications in Mass Spectrometry 2010; 24: 3011–3020; Doerge D.R., Twaddle N.C., Vanlandingham M., Fisher J.W., *Pharmacokinetics of bisphenol A in neonatal and adult Sprague-Dawley rats*, Toxicology and Applied Pharmacology 2010; 247: 158–165; Fisher J.W., Twaddle N.C., Vanlandingham M., Doerge D.R., *Pharmacokinetic Modeling: Prediction and Evaluation of Route Dependent Dosimetry of Bisphenol A in Monkeys with Extrapolation to Humans*, Toxicology and Applied Pharmacology 2011; 257; 122-136.

Given the lack of reliable data showing human health effects at this point, one may well question whether the expenditure of additional millions of dollars is money well spent.

C. Litigation

In August 2008, 14 putative class actions against manufacturers of plastic bottle products containing BPA were transferred to the Western District of Missouri for consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407.[35] By September 2009, the number of consolidated cases had expanded to almost 50,[36] and included BPA claims against manufacturers of baby bottles, sippy cups, and sports bottles as well as companies selling/or that sold infant formula packaged in cans with lining containing BPA.[37] The *In re Bisphenol-A* plaintiffs claim that the industry knew more about the potential dangers of BPA than it told consumers, but do not allege personal injuries. Their complaints assert on behalf of all consumers: (1) violations of state consumer protection laws, (2) breach of express warranty, (3) breach of the implied warranties of merchantability and fitness for a particular purpose, (4) intentional misrepresentation, (5) negligent representation, and (6) unjust enrichment.[38]

The defendants succeeded in getting many claims dismissed,[39] and the only remaining claims are those against the "bottle defendants"[40] for unjust enrichment, fraudulent and negligent omissions of material fact, and breach of implied warranty of merchantability for those plaintiffs who still possessed any of the goods at the time they learned about BPA's potential health effects.[41] Judge Ortrie Smith (of the Western District of Missouri) also granted the "formula defendants'" motion to dismiss on federal preemption grounds.[42]

In May 2011, plaintiffs settled with defendant Philips Electronics Corporation North America[43] for an award that included refunds

[35] *In re Bisphenol-A (BPA) Polycarbonate Plastic Prods. Liab. Litig.*, 571 F. Supp. 2d 1374, 1375 (J.P.M.L. 2008) ("These actions share factual questions arising out of allegations that various defendants manufactured, sold or distributed polycarbonate plastic bottle products containing Bisphenol-A without disclosing its possible harmful effects.").
[36] *In re Bisphenol-A (BPA) Polycarbonate Plastic Prods. Liab. Litig.*, 687 F. Supp. 2d 897, 901 (W.D. Mo. 2009) *clarified on denial of reconsideration*, MDL 1967, 2010 WL 286428 (W.D. Mos. Jan. 19, 2010).
[37] *Id.*
[38] *Id.*
[39] *See id.* at 903 (dismissing intentional misrepresentation, negligent misrepresentation, and express warranty claims because plaintiffs failed to identify defendants' statements that could form the basis for these claims).
[40] *See id.* at 901 ("The Defendants roughly fall into two categories: the Bottle Defendants and the Formula Defendants. The Bottle Defendants consist of Evenflo Company, Gerber Products Company, Handi–Craft Company, Nalge Nunc International Corporation ("NNIC"), Playtex Products, Inc., RC2 Corporation, and Philips Electronics North America Corporation. All but one of the Bottle Defendants make baby bottles, sippy cups and similar products for infants and toddlers; the exception, NNIC, makes sport bottles. The Formula Defendants consist of Abbott Laboratories, Mead Johnson & Company, and Nestle USA Inc.; these Defendants sell infant formula packaged in metal cans lined with a substance containing BPA.").
[41] *In re Bisphenol-A (BPA) Polycarbonate Plastic Products Liab. Litig.*, MDL No. 1967, 2009 WL 3762958 at *5 (W.D. Mo. Nov. 9, 2009).
[42] *In re Bisphenol-A (BPA) Polycarbonate Plastic Products Liab. Litig.*, MDL No. 1967, 2009 WL 3762965 at *5 (W.D. Mo. Nov. 9, 2009) (explaining that the formula defendants are exempt from disclosing the presence of BPA in their products because BPA-containing epoxy liners are considered an "incidental additive" by FDA.).
[43] Philips sold Advent brand plastic bottles and sippy cups that contained BPA.

and/or vouchers, injunctive relief, and attorney fees and expenses.[44]

Judge Smith later denied plaintiffs' motions for class certification, finding that the class failed to demonstrate the requisite commonality, predominance, and superiority.[45] At present, three plaintiffs' trials have been set for March 2013.[46]

Other putative class actions against aluminum water bottle manufacturers SIGG Switzerland (USA) Inc. ["SIGG"] and Gaiam, Inc., have followed;[47] in both cases plaintiffs alleged that the companies affirmatively misrepresented their reusable aluminum bottles as BPA-free. The action against SIGG was dropped in April 2012 when the company filed for bankruptcy. Defendant Gaiam settled claims by agreeing to establish a replacement water bottle exchange program.

Conclusion

BPA has been an extremely useful and safe product for decades. The attack against BPA is not founded upon reliable science. Yet, BPA continues to be banned in a growing number of states and ultimately will be phased out by users, regardless of the scientific truth. One can only guess as to whether the alternatives to use of BPA create a safer, or more dangerous, world.

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[44] *In re Bisphenol-A (BPA) Polycarbonate Plastic Products Liab. Litig.*, MDL No. 1967, 2011 WL 1790603 (W.D. Mo. May 10, 2011).

[45] *In re Bisphenol-A (BPA) Polycarbonate Plastic Products Liab. Litig.*, 276 F.R.D. 336, 340 (W.D. Mo. 2011).

[46] Order Setting Megan Thornberry Claims Against Handi-Craft Company for Jury Trial on 03/25/2013, MDL No. 1967 (W.D. Mo. April 6, 2012); Order Setting Maria Sullivan Claims Against Handi-Craft Company for Jury Trial on 03/18/2013, MDL No. 1967 (W.D. Mo. April 6, 2012); Order Setting Jennifer Moellering Claims Against Handi-Craft Company for Jury Trial on 03/11/2013, MDL No. 1967 (W.D. Mo. April 6, 2012).

[47] *In re Sigg Switzerland (USA), Inc., Aluminum Bottles Mktg. & Sales Practices Litig.*, MDL 2137, 2010 WL 424107 (J.P.M.L. Feb. 3, 2010); *In re Gaiam, Inc.Water Bottle Mktg., Sales Practices & Products Liab. Litig.*, MDL 2128, 2010 WL 431685 (J.P.M.L. Feb. 4, 2010).

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