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## **BPA: The threat is real; the defense is inexcusable.**

Bisphenol A, or BPA, is an estrogen-like chemical that has been linked to a range of health disorders including autism, prostate cancer, breast cancer, heart disease, diabetes, early puberty, intestinal problems, obesity and learning and behavioral problems. According to a wide range of independent studies, it can be especially dangerous to infants and toddlers.

Recently (on Jan. 14) the Pennsylvania legislature's Consumer Affairs Committee held a public hearing to take testimony regarding legislation Rep. Lawrence H. Curry (D-Montgomery/Phila.) introduced (H.B. 221) that would prohibit the manufacture or sale in Pennsylvania of baby bottles, training cups, formula cans or other child-care items or toys that contain BPA.

Coincidentally, the following day, on Friday, Jan. 15, the Food and Drug Administration took the extraordinary step of recanting its previously stated position that BPA is safe for human consumption, while expressing for the first time concerns about health risks associated with BPA, announcing it would fund further research into its effects, and providing tips for parents to minimize infants' exposure.

Faced with this setback, forces allied with BPA manufacturers and the chemical industry have redoubled their efforts to deflect criticism aimed at them, disparage academic experts and scientific studies that refute claims that BPA is safe, and distort the arguments posed by opponents of BPA that are based on a growing volume of clear, measurable evidence.

A lengthy editorial diatribe in the *Wall Street Journal* is the most recent example.

As evidenced by the WSJ editorial, the pattern of attack used by the "pro-BPA" forces is very consistent:

- The first ploy is to characterize the opposition as alarmist bumpkins or left-leaning fanatics associated with the environmental movement.
- The second is to claim that BPA has been used for 50 years and that its safety is therefore proven – the same basic argument once used by manufacturers of lead paint, asbestos and cigarettes (although at least a half-dozen major university-sponsored and independent studies in the past six months alone suggest otherwise).
- A third is to cite industry-funded studies dating mostly from before 2008 which allegedly reinforce the notion that BPA is safe (non-industry and independent laboratory studies by their very nature represent unproven or suspect science).

- A fourth ploy is to essentially claim that if BPA is outlawed, civilization as we know it will cease to function – the price of canned foods and baby products will soar and as the WSJ stated: “Without BPA, people would be exposed to more harmful metals and substances.”<sup>ii</sup>
- A fifth standard pillar to the argument used to be that the FDA considers Bisphenol A to be perfectly safe and believes it poses absolutely no danger to human health. That one doesn’t hold up so well anymore.

It is ironic that pro-BPA forces are trying to present their position as one which seeks to prevent politics from infringing on scientific turf.

The fact is, the FDA’s move to reopen the case on BPA is a direct response to the chemical industry’s long-term effort to undermine that agency’s scientific integrity. An in-depth investigation by the *Milwaukee Journal Sentinel* found that FDA officials repeatedly relied on lobbyists from the American Chemical Council to examine BPA’s risks, track legislation to ban it and even monitor press coverage. The Journal Sentinel reports: “In one instance, the U.S. Food and Drug Administration’s deputy director sought information from the BPA industry’s chief lobbyist to discredit a Japanese study that found it caused miscarriages in workers who were exposed to it. This was before government scientists even had a chance to review the study.”<sup>iii</sup>

This was nothing new, according to the Journal Sentinel, which obtained dozens of emails and more than 100 pages of attachments through the Freedom of Information Act. “(The materials) show that chemical trade association lobbyists routinely have met with FDA administrators over the past nine years to give their opinion on various studies on the effects of BPA.” During the course of its investigation, the paper also contacted a number of well-known independent scientists who are recognized as BPA experts – “all said they were not given such access to FDA safety assessors. Nor did the FDA seek their opinions or ask them to review studies.”

Not surprisingly, when the agency made its controversial assessment that BPA was perfectly safe, “the FDA relied on two studies – both paid for by chemical makers – to form the framework of its draft review declaring BPA to be safe,” the same article reported.

Six months before this article appeared, another *Milwaukee Journal Sentinel* article reported that “a retired medical supply manufacturer who considers Bisphenol-A to be ‘perfectly safe’ gave \$5 million to the research center of Martin Philbert, chairman of the Food and Drug Administration panel about to make a pivotal ruling on the chemical’s safety... Philbert did not disclose the donation, which is nearly 25 times larger than the \$210,000 annual budget of the University of Michigan Risk Science Center, where he is founder and co-director.”<sup>iii</sup>

Shortly after the donation came to light, the FDA’s scientific advisory board issued a report that said the exclusion of certain studies from its assessment and a less-than-full examination of how BPA can affect the prostate and neurobehavior amounted to “a major omission” on the part of the FDA. The panel also declared that certain topics were “not well explored” and concluded that the FDA’s assessment has “important limitations” because it did not use enough samples of infant formula to adequately examine babies’ exposure to BPA.<sup>iv</sup>

Despite chemical lobbyists’ furtive claims, that should hardly be considered a clean bill of health.

Furthermore, there is good reason to believe that industry-sponsored studies which allegedly attest to the safety of BPA were inherently flawed.

In a wide-ranging investigation last year, *Fast Company* magazine made the following point. “Consider this: Of the more than 100 independently funded experiments on BPA, about 90%

have found evidence of adverse health effects at levels similar to human exposure. On the other hand, every single industry-funded study ever conducted – 14 in all – has found no such effects.”<sup>v</sup>

While a total of 29 studies (including the 14 industry-sponsored studies) have found BPA to be safe, the article notes, there are significant questions regarding scientific protocol. “The largest and most influential industry studies have been conducted by Rochelle Tyl of the Research Triangle Institute, a private lab in North Carolina... The study used a rat strain called the CD Sprague-Dawley, which has been shown to be insensitive to synthetic estrogens like BPA. (A Japanese study found that the CD Sprague-Dawley rat can withstand a dose of synthetic estrogen more than 100 times greater than what a female human can tolerate.) As of early 2007, of the 29 studies that have shown no harm due to BPA, 13 have used the CD Sprague-Dawley rat. Nonetheless, when the FDA declared BPA ‘safe’ this fall, it relied almost exclusively on Tyl’s work – a shortcoming that the agency’s science board publicly criticized in October.”<sup>vi</sup>

It also should be noted that a Congressional investigation is currently underway concerning the relationship between chemical lobbyists and the FDA.<sup>vii</sup>

Another point that BPA lobbyists often emphasize is that their industry studies utilize a set of standards that euphemistically are referred to as “Good Laboratory Practices.” But this is a term that is widely misused and misunderstood.

Dr. Frederick vom Saal, a well-regarded scientist and recognized expert on BPA, sought to clarify the term in recent testimony before a committee of the Pennsylvania legislature.

“Good laboratory practices,” he explained, “were instituted not to ensure great science but to actually stop rampant fraud that was taking place in the commercial laboratory testing realm.” By requiring very demanding and very extensive record-keeping, these practices are intended to ensure that the study has actually taken place. They do not guarantee that the research is done properly or that the results are valid.

“Unlike studies by academic scientists that are subjected to replication and verification, GLP studies demand recordkeeping, because the assumption is they will never be repeated. They are very expensive, and they typically are not repeated and validated and shown to be reliable,” Dr. vom Saal said.

But when both the FDA and the European Food Safety Authority relied on just two studies – and rejected all studies done by university scientists – it was based on the pretext that the university scientists did not use GLP, vom Saal noted. This reliance on GLP in deference to the hundreds of published investigator-initiated studies was sharply criticized by scientific review panels associated with both the FDA and the EFSA, Dr. vom Saal noted.

“And incredibly, in one of the two studies used by the FDA and EFSA that was GLP, the lead author presented conflicting data from three separate reports regarding this study – and this has led to a call for a federal investigation because of misreporting of data from this study,” Dr. vom Saal testified.

The scientific review panels also took issue with the apparent disregard that agency officials (none of whom were experts on endocrine disruption) gave to how babies metabolize BPA, and thus the potential effects that even low levels of BPA can have, Dr. vom Saal testified.

“The chemical industry states that babies can metabolize BPA,” Dr. vom Saal said. “What they are not telling you is what everyone probably knows, and that is that babies have very limited capacity to metabolize chemicals or drugs. Babies are not little adults.”

Dr. vom Saal said the EFSA made the “astonishing” statement that babies essentially have the ability to completely metabolize BPA, a position that the German Environmental Protection Agency rejected last March after reviewing the EFSA report. In fact, the science review found that babies have between three and 11-fold higher levels of BPA relative to the adults.

This is fairly common knowledge, because the fact is that many babies are born that have jaundice – a condition of excess bile – and the same enzyme system that metabolizes BPA also metabolizes bile. Excess bile, due to low enzyme activity, is a very common event in babies and an indication of their insufficiency to metabolize not only bile, but BPA, Dr. vom Saal said.

But the potential harm for this most at-risk population does not end there. According to Dr. vom Saal, there have been literally hundreds of cell culture studies relating to adverse effects in animals caused by doses that meet the levels of BPA that are at or below levels in the umbilical cords or the blood of babies at the time of birth. *(Note: An Environmental Working Group survey released in November, 2009, reported that 90% of randomly selected samples of umbilical cord blood, all from minority newborns, tested positive for BPA).*

Dr. Vom Saal noted the reported outcomes from the studies he identified include obesity, elevated insulin levels and insulin resistance, all of which lead to Type 2 diabetes – and may be contributing to the current epidemic of diabetes in our children.

In addition, BPA causes numerous neural behavioral findings – one study published in the Fall of 2009 showed that sex differences in aggression in two-year olds were related to BPA levels in their mothers. The United States National Toxicology Program (the science advisory agency to the FDA and EPA) reports that this loss of gender differences and behaviors such as aggression due to developmental exposure to Bisphenol-A was one of the most consistent and repeatable outcomes from animal research. According to Dr. vom Saal, there is also extensive animal research which demonstrates that every aspect of both male and female reproductive systems is affected by developmental exposure to BPA.

But if BPA is such a threat, why can't we look around and see the impact? The answer lies in the nature of the threat. The signature event of developmental exposure to harmful chemicals such as BPA and Diethylstilbestrol (DES) is a very long latency outcome.

DES is a synthetic estrogen first synthesized in 1938. Originally prescribed to prevent miscarriages, DES was FDA-approved and widely used in estrogen-replacement therapy from the 1940s until the late 1980s. During that time an estimated five million women were treated with DES.

“One of the things we learned from the millions of people exposed over 25 years to DES was that the doctors never saw the damage externally, because it was the internal organs of the babies that were damaged,” Dr. vom Saal explained. “It wasn't until they were in their twenties and getting vaginal cancer and showing infertility with grossly deformed uteri -- and now they are being found to be at elevated risk for breast cancer decades later -- that we realized there was this harm (being done).”

In fact, during the 1970s, the negative publicity surrounding the discovery of DES's long-term effects resulted in a wave of lawsuits against DES manufacturers. These culminated in a landmark 1980 decision of the Supreme Court of California, *Sindell v. Abbott Laboratories*, in which the court imposed a rebuttable presumption of market share liability upon all DES manufacturers, proportional to their share of the market at the time the drug was consumed by the mother of a particular plaintiff.<sup>viii</sup>

Another signal of the growing significance that the medical community is attributing to this issue is the recent statement by the American Medical Association that one of its strongest recommendations was to place people who are knowledgeable about endocrinology onto risk assessment panels, because Bisphenol-A was first considered for use as a hormonal drug prior to being used in plastic.

“It is a hormone, an endocrine activatrion, and you need to be an endocrinologist to really understand how to study this,” Dr. vom Saal said, noting that “there is not one expert on endocrine-disrupting chemicals” currently working at the FDA.

The bottom line is that citizens should not rely on the word (or even the scientific “evidence”) presented by chemical industry lobbyists acting as BPA apologists. Neither can we rely on the traditional watchdogs in government agencies, including the FDA, because they frankly have been in bed with industry lobbyists for too long. There are signs that may be changing, but for the sake of our youngest and most at-risk citizens, we cannot afford to wait.

It's not that there aren't alternatives available, either. Already we are seeing a wellspring of “BPA-free” water bottles being produced. While these may be seen as “environmentally chic” they are also practical and contribute to good health. Japanese can manufacturers began voluntarily removing BPA from can linings beginning in the 1990s and thus were able to reduce exposure to BPA by 50 percent. There is no reason we cannot do the same here in the U.S., and starting in Pennsylvania.

Now, within the past few days, yet a new study has emerged from the University of Texas Medical Branch at Galveston. Researchers there have produced evidence that a mother's exposure to BPA may increase the odds that her children will develop asthma.

*How much more independent evidence do we need in order to understand that exposing infants (including those in the womb) and children to BPA is literally risking their lives?*

It is morally disturbing that chemical industry lobbyists, BPA apologists and so-called capitalist conservatives can so cavalierly dismiss the potentially lethal dangers that BPA represents to our most at-risk population.

I urge you to lend your support to this important piece of legislation and to let your views be known to all your elected representatives and other public officials.

*This report was prepared for Rep. Lawrence Curry by Thomas Derr, Legislative Policy and Communications Analyst for Representative Curry.*

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<sup>i</sup> *Wall Street Journal*, “Baby Bottle Red Alert: Fear and loathing over a very common chemical,” January 30, 2010.

<sup>ii</sup> *Milwaukee Journal Sentinel*, “FDA relied heavily on BPA lobby: Regulators actively reached out to industry, e-mails show,” May 16, 2009.

<sup>iii</sup> *Milwaukee Journal Sentinel*, “Donation raises questions for head of FDA's Bisphenol A panel,” October 12, 2008.

<sup>iv</sup> *ABC News*, “Panel Rebukes FDA on Plastic Bottle Safety: Scientific Advisers Say Agency's Assessment on Safety of BPA was Flawed.,” October 29, 2008.

<sup>v</sup> *Fast Company*, “The Real Story Behind Bisphenol A,” January 14, 2009.

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<sup>vi</sup> Ibid.

<sup>vii</sup> Dr. Frederick Vom Saal, "Testimony to the Pennsylvania Legislature's Consumer Affairs Committee," Thursday, January 14, 2010.

<sup>viii</sup> See: <http://en.wikipedia.org/wiki/Diethylstilbestrol>