



## Science Suppressed: How America became obsessed with BPA

A STATS investigation

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## Science Suppressed: How America became obsessed with BPA

A handful of scientists and environmental activist groups claim that bisphenol A is the biological equivalent of global warming, and its presence in plastic bottles and can linings is endangering “millions of babies.” Their message – and their accusation that the Food and Drug Administration has been swayed by industry-sponsored studies and has ignored vital scientific evidence – has led Congress to ask the agency to re-examine the safety of the chemical. A decision is expected by the end of the summer.

Missing in this debate is that it’s not just “industry groups” that think BPA shouldn’t be banned – or just industry-sponsored studies that say it’s safe. Scientists, regulators, and politicians in Europe, Australia, and Japan have all rejected the evidence that the chemical is harmful as methodologically flawed, badly conducted or irrelevant – with some warning that banning it could actually endanger the public. Now that the National Institutes of Health has acknowledged it funded a lot of poorly-designed research on BPA – the very research that activists touted as evidence that the chemical is deadly – it’s time to ask whether America has been spun by clever marketing rather than clever science.



### Introduction

Why did the chemical bisphenol A (BPA) become the hottest environmental topic in 2008 after global warming? A building block of polycarbonate plastic and epoxy resins, BPA was neither new to the marketplace nor unstudied by scientists: By 2007, there were over 4,200 studies covering a dizzying range of possible ways it might be toxic – and there was a remarkable global consensus that it didn’t pose a threat to health. A half dozen risk assessments evaluating the weight of evidence had found no cause for alarm. Even the very notion of risk assessment seemed to overstate the case for quantifiable danger, as scientists weren’t actually discussing actuarial or measurable risks – the odds, in other words, of someone, somewhere getting sick – but hypothetical risks, scaled up from laboratory studies where animals had been dosed through the mouth with massive quantities of the chemical to produce an effect.

In fact, after a review of the available research in 2006, Europe decided that BPA was *safer* than had been previously thought. The European equivalent of America’s Food and Drug Administration – the European Food Safety Authority (EFSA) – said the amount considered safe to ingest on a daily basis for life should be raised by a factor of five. Separate risk assessments by individual member countries – Norway, Switzerland, Denmark and Germany – sometimes focusing on different areas of concern, reached the same conclusion. A Japanese risk assessment also concurred.

In recent months, Food Standards Australia and New Zealand – a bi-national Government agency charged with ensuring food safety – [said](#) that it had “assessed the risk to infants from exposure to BPA and concurred with the conclusions reached by the US FDA and the EFSA that the levels of exposure are very low and do not pose a significant health risk.” Canada followed a different path, saying that the chemical should be banned from baby bottles as a precautionary measure, even though it explicitly said there was no evidence that babies were at risk.

In March of this year, the French Minister for Health, Roselyne Bachelot, responding to a question as to why France wasn’t doing the same as Canada, told the French National Assembly that Canada’s decision was an emotional rather than a rational decision:

“The precautionary principle only applies when there are no reliable studies,” she said. “Here, there are reliable studies which conclude, with current scientific data, that baby bottles containing this chemical compound are innocuous,” said Bachelot. “These studies are confirmed by all major health agencies,” she added, notably the European Food Safety Authority (EFSA).

But in the United States, an entirely different theme emerged in public debate: unremitting panic. There was a run on glass bottles as terrified parents junked polycarbonate; environmental activist groups warned that “millions of babies” were at risk; the media raged at how BPA was proof that America’s regulatory system was broken and that the Food and Drug Administration was relying on industry-sponsored studies to justify inaction; journalists reported, it seemed, every new shred of data on BPA, which now appeared to link BPA to almost every disease imaginable from asthma to cancer to obesity.

In the wake of this reporting came the lawsuits: In April 2008, a woman filed suit against Nalge Nunc in the U.S. District Court in Sacramento for asserting BPA was safe; the woman and her two children had used polycarbonate bottles from the maker for several years. As Reuters [noted](#) “The lawsuit does not describe any physical ailment suffered by the plaintiffs and seeks unspecified damages.” A [similar](#) lawsuit was filed against another manufacturer in Connecticut. Sen. Diane Feinstein has proposed a bill in the Senate to ban the chemical – as states and cities enact their own bans. According to the National Conference of State Legislatures, there are currently 55 bills in 20 states that aim to curtail the use or sale of baby-food jars and cans of formula that contain BPA. Despite concluding that the evidence did not merit any restriction on the use of BPA, the Food and Drug Administration has agreed to review the evidence again, at the request of Democratic lawmakers on the House Energy and Commerce Committee. The review is expected to be completed by the end of the summer.

One newspaper, the *Milwaukee Journal Sentinel* even went so far as to commission its own, apparently scientific, study to show how the chemical could leach from microwaveable plastic containers to jeopardize health, and how the FDA was failing to consider vast amounts of evidence showing that the public was in danger. The journalists who wrote tens of thousands of words exposing this “Chemical Fallout” were lauded with prestigious journalism prizes, including the Polk Award, and the Oakes Award in Environmental Reporting from Columbia University’s Graduate School of Journalism. The juggernaut

***“The precautionary principle is a principle of reason, and under no circumstances a principle of emotion” – Roselyne Bachelot***

“Reliable studies have concluded that baby bottles containing bisphenol-A are innocuous,” said the Minister of Health Roselyne Bachelot at the National Assembly, answering a question from the MP for Seine-Saint-Denis Jean-Christophe Lagarde (*Nouveau Centre*).

“We think we must urgently apply the precautionary principle and ban the use of bisphenol-A, including in the manufacturing of baby bottles,” said Mr. Lagarde to the minister, reminding that Canada banned it last year.

“The precautionary principle only applies when there are no reliable studies. Here, there are reliable studies which conclude, with current scientific data, that baby bottles containing this chemical compound are innocuous,” replied Mrs. Bachelot.

The minister said that the results of studies conducted by the *Agence française de sécurité sanitaire des aliments* (AFSSA) have proven the harmlessness of bisphenol-A, even with a major thermal shock.

“These studies are confirmed by all major health agencies,” she added, notably the European Food Safety Authority (EFSA).

“Canadian authorities banned bisphenol A under public pressure and without any serious scientific study,” the minister added. “The precautionary principle is a principle of reason, and under no circumstances a principle of emotion,” she concluded...

- *Agence France Press, March 31, 2009*

of journalism and environmentalism and political concern all seemed to confirm the existence of a public health crisis.

But were the journalists, the environmentalists, and the politicians, looking at *all* the available evidence – and looking at it impartially and scientifically? Or were they listening only to the losing side in the intra-scientific debate because it just made for a better story? Scientific research has long been plagued by the problem that studies which failed to prove a thesis or confirm a hypothesis don't get the attention they deserve – even though the absence of a result is just as important as the presence of a result in figuring out a problem. But in journalism the problem is even more acute: as one reporter for a leading business magazine put it, “dying is sexy – and if you can watch your child suffer while they die, well that's even sexier.” Did the *Milwaukee Journal Sentinel*, which wrote over 30,000 words on BPA in 2008 get lost in the evidence, and end up being seduced by a storyline that made for great journalism but not very good science?

The newspaper's investigative team, much like most of the other reporters at other news organizations covering the story, sourced the dangers of BPA to a handful of mostly American scientists whose work seemed to prove the existence of a threat, and who were willing to go on the record with sound bites that were irresistibly alarming, and suggested the possibility of a horrible compact between industry and regulators that was putting the public at risk.

In the words of Frederick vom Saal, a scientist at the University of Missouri who has led the charge against BPA for over a decade, the chemical was, as he told *Discover Magazine* in May 2008, the biological equivalent of global warming. And if BPA was just like global warming, it meant that those who begged to differ were – the just *had to be* – chemical industry stooges. An article by a science writer, Linda Gross, in *PLoS Biology* got the ball rolling by [purporting to explain](#) how the chemical industry conspired to undermine vom Saal's evidence. It was hailed by *Salon's* Andrew Leonard as “[a superb exposé](#),” without any mention that the primary source and focus of the article was vom Saal and that it quotes him and his collaborators extensively and without any serious corresponding attention to the voluminous criticism of his and their experimental methods.

In fact, what has gone missing in the coverage of BPA across the media was that the body of research hailed by vom Saal as demonstrating that BPA was dangerous at low doses had been studied and rejected as scientifically invalid or irrelevant by the European Union's Food Safety Authority (EFSA), individual European countries, and Japan – along with various evaluations in the United States. As EFSA's current BPA panel told STATS, “many of the studies indicating low dose effects of BPA were contradictory and not well conducted.” These flaws were first pointed out by the National Toxicology Program in 2001, when it convened a panel of statisticians who then identified the statistical limitations in the way the experiments were conducted and, crucially, how they should be corrected. (These criteria and their significance are discussed below).

Every risk assessment that followed, whether in the U.S. or abroad used these criteria to determine which studies should carry weight and which shouldn't. And the net result was that NTP dismissed most of the evidence against BPA in a 2007 evaluation by an expert panel, with one caveat, namely, that there was “some concern” over neurodevelopmental risks, a statement which meant that the available data only provided limited evidence of risk, and that more research was needed. Parsed by the media, this was translated into an admission by the NTP that vom Saal was right all along and that the public was in danger. It didn't seem to register with journalists that the *reproductive* risks vom Saal and others had been touting for years were rejected.

Even though “some concern” is the lowest level of concern in the NTP's nomenclature of risk, the European Union in 2008 called into question whether the NTP was now under so much pressure to

respond to the campaign against BPA that it was being much too concerned. EFSA looked at the studies that the NTP relied on to determine “some concern” and said they all had “major shortcomings” and couldn’t be taken as evidence of risk. Denmark’s Environment Protection Agency also looked at these studies and agreed that they weren’t worth worrying about, and France’s Food Safety Agency declared them unreliable. This was particularly noteworthy, given that all these countries use the precautionary principle to regulate chemicals – and are, in theory, more risk averse than the U.S. These developments were largely ignored by the U.S. media.

This overall body of evidence claiming BPA was harmful was also dismissed by a risk assessment carried out by NSF International in 2008, a World Health Organization collaborative center, and one of the leading independent, scientific, consumer affairs organizations in the world. The research was carried out by a prominent American toxicologist, Calvin Willhite, who co-authored the chapter of development toxicity for one of the standard textbooks on toxicology. It received no attention from the mainstream media.

And in a recent and revealing development, the National Institutes of Health, which funded some of this BPA research (including vom Saal’s original work on BPA) under the auspices of the National Institute of Environmental Health Sciences, has tightened its guidelines for research on BPA because too many of the studies it funded in the past have been dismissed by the scientists charged with conducting risk assessments –

“due to a variety of experimental limitations including the use of a single dose, small numbers of animals per group, non-oral route of administration, lack of proper statistics and lack of data on specific phenotypic endpoints.”

The NIEHS will now only fund two-year studies on BPA, of sufficient sample size “to ensure power to detect a statistical difference between experimental groups,” and that the “route of exposure should be oral or justified to provide similar blood levels as oral route,” among with [other requirements](#). In effect, the government body that funded much of the so-called “independent” science supporting the idea that BPA is dangerous now demands the kind of study protocols used by the very industry-funded studies that vom Saal, environmental activists and the media have insisted can’t be trusted. This irony hasn’t received any attention in the media, even though it suggests that had these protocols been required over a decade ago, BPA would not have become the issue it is today.

**Journalists in the U.S. were so staggeringly resistant to the idea that BPA was safe that the NSF International research was virtually ignored by the American press – as were the risk assessments in Europe, along with any study that showed that BPA didn’t present a threat to health, even if those studies were independently funded and well conducted from an experimental and statistical perspective.**

It is difficult not to see the cumulative effect of these changes as a tacit admission by the NIH and NIEHS that it has funded a lot of useless studies on BPA – particularly as many of the requirements it now demands of research proposals were deemed essential as far back as 2001, when the National Toxicology Program commissioned a subpanel of statisticians to evaluate the quality of emerging research on BPA.

In other words, for almost a decade, the flaws in research claiming that BPA has been a threat to health have been in plain sight; they were discussed openly and sometimes heatedly by scientists, but always with the same conclusion: the research used to claim BPA was a risk was poorly done, or couldn’t be

replicated, or was just experimentally irrelevant. But the dogged failure by most reporters and news organizations to examine and understand why certain methodological choices produced irrelevant or flawed studies has kept the threat of BPA a constant source of news and editorial outrage while suppressing the very science which the public ought to be told about.

In fact, journalists in the U.S. were so staggeringly resistant to the idea that BPA was safe that the NSF International research was virtually ignored by the American press – as were the risk assessments in Europe, along with any study that showed that BPA didn't present a threat to health, even if those studies were independently funded and well conducted from an experimental and statistical perspective. Instead, newspapers like the *Journal Sentinel* turned to environmental activists and the scientists whose work had been dismissed to press the case that the public was in danger.

When, for instance, the *Milwaukee Journal Sentinel* reported (August 16, 2008) on the the National Toxicology Program's evaluation, it focused only on the "some concern" for neurodevelopment risks and ignored all the "negligible" risk conclusions. The context – what "some concern" meant - was not explained; the criticism of the research by other countries was never reported. Instead, the Food and Drug Administration was lambasted for ignoring the alarm raised by the NTP's evaluation. Environmental activist groups were quoted chiding the FDA for going down the path of the drug Vioxx, and relying on "industry-funded" studies.

This all provided the kind of narrative urgency that journalism thrives on – the sense of being on a mission to hold truth up to power, to make the newspaper a vital public watchdog . But according to the authors of the European Risk Assessment and the NSF International paper, the *Journal Sentinel's* mania to indict BPA (and the other news reports that have mirrored its approach) have made a mockery of science. In the following analysis, they explain in detail why this reporting is misleading and inaccurate, and why the low dose research was rejected as irrelevant or scientifically invalid by their assessments. They explain why the *Milwaukee Journal Sentinel* didn't just fail the public in basic toxicology, it failed to follow basic scientific principles in evaluating evidence – the principles that govern whether research is reliable and relevant or not.

The analysis also shows how the paper's sourcing was dramatically skewed towards environmental activists and a handful of scientists whose common bonds, collaborative interests, and, in one case, mutual financial interests were never disclosed to readers. At the same time, the paper doggedly ignored a vast array of longstanding and breaking evidence that BPA was safe.

The newspaper was also explicitly warned by the head of the National Toxicology Program expert panel that it was relying too much on one scientist whose work and perspective had been repeatedly rejected by international risk assessments. Despite this warning, the paper chose to conduct its own scientific study of BPA at that scientist's lab, and then gave the results to the same scientist and several of his collaborators to validate and interpret. But when STATS asked NSF's Willhite to analyze these results, he declared them "erroneous."

The analysis also looks at the Oakes Award jury convened by Columbia University's Graduate School of Journalism, and whether the decision to give the award to the paper was affected by a jury sensitized to only one side of the debate.

### **The route of the controversy: Eat or inject?**

On June 10, 2008, Calvin Willhite Ph.D, a developmental toxicologist and member of the NSF International Health Advisory Board [testified](#) to the House of Representative Energy and Commerce

Committee about the alarm BPA was triggering in public debate. Willhite was the lead author of an NSF study that calculated an oral reference dose for BPA (the amount of the chemical that could be safely ingested on a daily basis), a two-year journey that had led him to evaluate the quality and significance of the key research on BPA [NSF International is an independent organization that evaluates and certifies products and materials to specific criteria and standards, including those from the American National Standards Institute (ANSI)] He was one of a small group of people in the world who had looked at both the big picture and the detail. One of the key reasons BPA had become a “controversy,” said Willhite, was that the scientific evidence was divided into two conflicting camps:

“Many of the studies that show adverse effects in rodents given small doses of bisphenol A used subcutaneous injections. Most of the studies in rodents that did not show adverse effects even at high doses used the oral route. Keeping in mind that nearly all (99%) of a child’s bisphenol A exposure occurs via ingestion (Wilson et al., 2007), several agencies have published criteria and conclusions on this important point:

- “In routine tests, administration should be by the anticipated route(s) of human exposure. This is logical, since the amount and rate of a chemical that reaches the embryo varies according to the route of administration.” (WHO, 1984)
- “The route of exposure in these studies is usually oral, unless the chemical or physical characteristics of the test substance or pattern of human exposure suggests a more appropriate route of administration.” (US EPA, 1991)
- “The injection route of administration renders those studies of no utility for quantitative risk assessment as this is not a relevant route of exposure.” (CERHR in Boekelheide et al., 2004)
- “Section 6A. Route of Administration. If the population exposure to the chemical entity is by ingestion, then the compound will be administered orally.” (Health and Welfare Canada, 1975)

Since 99% of human bisphenol A exposure occurs via ingestion, only those laboratory studies that used the oral route are candidate key studies for human health risk assessment.”

That oral studies should be given primacy in assessing risk was the position taken by European Food Safety Authority, the Food and Drug Administration, the National Toxicology Program – and, in fact, in every risk assessment that systematically looked at BPA.

The reason why the distinction between oral and subcutaneous or intravenous exposure is so important is because different things happen to the chemical depending on the way it makes itself into and through the body.

When BPA is ingested, it is rapidly detoxified, first in the gastrointestinal tract (GI) and then in the liver by enzymes which add a sugar molecule to BPA, transforming it into a water soluble BPA-glucuronide. The sugar conjugate is easily and quickly excreted in urine. The half life of BPA-glucuronide is six hours. There is a minor metabolic pathway in which some BPA is converted to a sulfate, but this is also water soluble and quickly excreted from the body (Tsukioka et al., 2004; Völkel et al., 2002, 2005).

In both of these pathways, BPA is deactivated, meaning it loses its capacity to act like an estrogen (Matthews et al., 2001; Shimizu et al., 2002; Snyder et al., 2000). This is important to note as BPA is considered to have a weak estrogenic capacity (approximately 15,000 times weaker than the strongest

naturally-occurring estrogen in humans) – one of the reasons it has been dubbed an “endocrine disruptor” by environmental activists. The way orally ingested BPA is metabolized removes that capacity.

When a rat or mouse is injected with BPA as opposed to being fed BPA different things happen. The chemical retains its estrogenic capacity as it circulates in the blood and enters cells.

If oral exposure is the key to determining whether BPA is a risk, we need to know how much of it we’re actually exposed to. In the most comprehensive study of oral ingestion that used the latest biomonitoring techniques, two German researchers concluded that our daily exposure to BPA works out at less than one-tenth of a microgram per kilogram of body weight (Dekant, W. and W. Volkel 2008. Human exposure to bisphenol A by biomonitoring: Methods, results and assessment of environmental exposures, *Toxicology and Applied Pharmacology* Volume 228, pages 114-134):

“The average daily doses of bisphenol A in adults delineated by biomonitoring and supported by the exposure assessment based on concentrations of bisphenol A in the diet are more than 500-fold below the TDI set by EFSA and the US EPA reference dose (both 50 µg/kg bw/ day) suggesting that the exposure to bisphenol A does not result in a health risk to the general population. In addition, the bisphenol A exposures of the general population are also well below the daily doses of bisphenol A that sometimes have been reported to cause responses of unknown toxicological relevance in highly sensitive animal systems (20 µg/kg bw/day) (Timms et al., 2005) giving Margins-of-Exposure of 200 or more. For a comparison with human intake of other weakly estrogenic compounds, bisphenol A intake is at least 30 fold lower than that of phytoestrogens, which are more potent estrogens as compared to bisphenol A (Moors et al., 2007, Safe, 2004, Valentin-Blasini et al., 2005).”

This means that there is “a 500,000 fold difference between the lowest *oral* exposures in animals associated with any adverse effects and the *oral* human exposure,” says Willhite. By any measure, this does not constitute a health risk. We get vastly more estrogenic chemicals from eating nuts, cereals and bread.

**In two years of media reporting and editorializing, and activist lobbying of politicians and the public, the difference between the outcomes produced by different routes of exposure has been almost entirely ignored. Despite every regulatory agency in the world’s decision to accord greater relevance to studies based on the ingestion of BPA, the media has overwhelmingly focused on studies using injections of BPA. This, of course, has turned BPA from being innocuous – a non issue in Europe and the rest of the world – into a major public health scare in the U.S. and Canada.**

But what about babies? Environmental activists in the U.S. have focused largely on the risk to infants and not adults from exposure to BPA given that they do not have a fully developed adult metabolism and that even tiny, almost insignificant amounts of “free” BPA (unconjugated BPA) could be damaging – as if it was being injected into their blood. STATS put the question to Wolfgang Dekant., professor of toxicology at the University of Würzburg and one of the lead authors of the European Food Safety Authority risk assessment (as well as a co-author of the BPA biomonitoring study).

“The exposure of babies to BPA is well below the tolerable levels based on the most sensitive toxicity endpoint seen in reliable animal studies [with the] inclusion of an additional safety factor of 100. Moreover, babies are exposed to a variety of other compounds with weak estrogenicity such as isoflavones from diet (higher exposures and more potent hormones compared to BPA)

without effects. Actually, isoflavone exposures are orders of magnitude above those to BPA in babies given soy formula and this is considered ‘healthy.’ Should we not worry about soy ingredients and the transfer of such compounds to babies much more than about BPA?”

This question appears not to have occurred to journalists covering BPA. (Similarly, the very latest research by the EPA – A.M. Calafat et al. (2009) Exposure to bisphenol A and other phenols in neonatal intensive care unit premature infants. *Environmental Health Perspectives* Volume 117, pages 639-644 – which demonstrates that even premature babies are capable of metabolizing BPA in the same way as adults has generated no coverage).

In two years of media reporting and editorializing, and activist lobbying of politicians and the public, the difference between the outcomes produced by different routes of exposure has been almost entirely ignored. Despite every regulatory agency in the world’s decision to accord greater relevance to studies based on the ingestion of BPA, the media has overwhelmingly focused on studies using injections of BPA. This, of course, has turned BPA from being innocuous – a non issue in Europe and the rest of the world – into a major public health scare in the U.S. and Canada.



### Why was the route of exposure to BPA ignored?

One explanation for how this came about is that many journalists turned to a biologist at the University of Missouri, Frederick vom Saal, as *the* leading authority on BPA. For example, the *Milwaukee Journal Sentinel* claimed on April 16, 2008 that he is “one of the nation’s leading experts on BPA;” and the Orange County Register [described](#) him as “the nation’s leading BPA researcher” on August 9, 2008.

Vom Saal appears to have encouraged this view of his work: “What the hell is the FDA doing ignoring the world’s leading experts on the subject?” he said of the FDA’s failure to pay attention to his research, according to a [report](#) published on September 12, 2008, on NewsInferno.

But this designation is perplexing given that his expertise and his research on BPA has failed – and failed rather spectacularly – to influence the numerous risk assessments of BPA around the world. It is more apt to say he has led the charges that BPA is dangerous in this debate for over a decade, but that his contribution has been and remains highly controversial.

Vom Saal had argued, back in February 1998 on [PBS Frontline](#), that the entire field of toxicology needed to realize there was a paradigm change afoot in the way it assessed the risk from chemicals – a change necessitated by his research on BPA.

The stimulus for this paradigm change came from his research on the hormone estradiol. Mice exposed to extremely small amounts of estradiol– much smaller than previously thought – could have significant consequences for reproductive development. Vom Saal then told Frontline that the same thing was happening with BPA:

**Vom Saal:** We’ve been working with a chemical, bisphenol-A. It’s what polycarbonate plastic, hard plastics, are made out of: CD’s, the plastic in your glasses’ lens, milk containers, baby bottles. It’s the chemical that they use to line cans with, it’s the chemical they put on your teeth as a sealant and it is a very potent estrogen. It mimics the hormone that women produce in their

ovaries, and it mimics this hormone estradiol that is actually being produced in fetuses and during pregnancy that is a major coordinator [transcript is garbled]

Estradiol plays a critical role in development and then normal functioning of the body for the rest of an individual's life. The amount of estradiol you're exposed to throughout your life is also the best predictor of breast cancer. This chemical mimics that hormone. The body can't tell the difference between bisphenol-A and estradiol. In other words, it sees this chemical and it thinks it's getting exposed to its natural hormone.

**Frontline:** So you're saying that the hormone that has the clearest link to breast cancer, the hormone that is responsible for sexual development in any animal or human, is found in plastics?

**Vom Saal:** Absolutely. The plastic materials, if they are polycarbonates, are made with this chemical bisphenol-A. And you can think of polycarbonate as a house made of bricks. Essentially you take this brick, this building block, which is bisphenol-A, and you link it together with other bisphenol-A molecules. That's a polymerization reaction. The bisphenol-A is the monomer used to construct these plastic materials. When it's attached to another one, that forms a polymer. And unfortunately in the process of making these plastics not all of the bisphenol-A gets linked together. So you put your food or other material in the plastic and it absorbs the unreacted bisphenol-A into it. And now in your food is a sex hormone.

**Frontline:** And what are you finding to be the effect?

**Vom Saal:** Okay, the chemical bisphenol-A passes out of the plastic or out of the dental sealant that's put on your child's teeth or out of the lining of cans, into the food or liquid that's in contact with the plastic. Now the important point about detection by instrumentation of the bisphenol-A is that, based on our research, the ability of the current instruments used to monitor for bisphenol-A in food is a much lower level of detection than what our animals are able to detect. It's a huge difference as a matter of fact. So that you can put food that you have in contact with plastic into a chemical analysis and say there is no plastic material there. We extract from that same food, put it into animals and we get a big effect. The animals are more sensitive to the chemicals than the machinery. So detection limits, where people say our machine didn't detect this, doesn't mean it's not there and doesn't mean that it won't damage your baby. We have shown that in our experiments.

**Frontline:** So the plastics we use in daily life, the baby bottles, the food containers, leach chemicals into the food at levels that cause effects in lab animals?

**Vom Saal:** One of the things that we started doing a number of years ago is we started looking at the effects of the materials that plastics are made out of in cell culture. We used human cells to see how responsive these cells were to these chemicals, and at what doses the chemicals could influence human cells to start growing and doing things differently. So, in other words, we're getting biological responses out of the cells and we were astonished at the incredibly small amounts of these chemicals that were actually able to alter human cell function.

So what we did in mice was based on the studies using human cells. We know that mouse cells are essentially identical to human cells in the way that they respond to these hormones. That's been known actually for quite a long time. So we used our information from human cells to then start treating animals with these very, very low doses of estrogenic chemicals found in plastics. So we had mechanistic information that really directed us towards very low doses.

Now one of the surprising things is that when we started looking into the literature concerning the amounts of these chemicals that were being released into food from plastic containers, and we compared that to the doses active in our cell culture studies, they were the same doses. But they were also doses that the toxicological community was saying were absolutely safe.”

But in the decade that followed, vom Saal’s paradigm change didn’t quite happen. First, there were significant objections to his argument and his research reporting changes in the reproductive tract of mice fed BPA (Vom Saal 1998). John Ashby, a toxicologist with AstraZeneca Central Toxicology Laboratory in Britain, tried to replicate vom Saal’s original studies and those of another research group that had found similar results (Nagel et al 1997).

In a 1999 paper for the journal *Regulatory Toxicology and Pharmacology* Ashby increased the statistical power of the original studies with a greater number of randomly selected animals but he failed to confirm what vom Saal and others had found.

“The failure of the present experiment to confirm the reported increase in prostate weight caused by BPA (Nagel *et al.*, 1997) and DES (vom Saal *et al.*, 1997), or the decrease in sperm efficiency caused by BPA (vom Saal *et al.*, 1998), agrees with the results of similar repeat studies on BPA and DES reported by Cagen *et al.* (1999). In addition, we found no significant effects for either of the test agents on the sexual maturation (vaginal opening) or reproductive tissue weights in the female offspring of mice exposed to either BPA or DES.”

There were criticisms of the Ashby and Cagen studies, including that one or the other had failed to play music quietly in the background and the mice became stressed, and that his study was conducted in an industrial toxicology lab. Given that replication is a key factor in science when it comes to deciding whether to adopt new evidence that seems to overturn consensus, Ashby and Cagen’s research raised significant doubt about vom Saal’s claims within the field of toxicology, particularly as these attempts at replication had greater, albeit still limited, statistical power.

Ashby’s work has been denounced by environmental activists on the “Our Stolen Future” website as “incompetent” – citing an exchange of letters by vom Saal and others with Ashby over the study protocols and endorsing vom Saal’s perspective on the matter. Our Stolen Future charged that the use of an estrogen DES as a positive control which then failed rendered Ashby and Cagen’s critique of vom Saal invalid. Ashby has retired, and could not be found; Cagen did not respond to questions about his work; however, vom Saal told STATS that:

“Ashby and Cagen both sought my advise [sic] about their studies, but of course I had no control over what they did; in fact I made suggestions that were rejected. They obviously chose the DES dose based on our published data about BPA in our 1997 PNAS article, which has been replicated - in fact Ashby's DES data were identical to ours. Not one person on either of those publications had every published a paper on the reproductive system in male mice, and they asked me to train them how to do the research (this is acknowledged in their publications) - they thought that this was possible to accomplish in a few hours. That is an indictment of the level of training that people think is appropriate to conduct a GLP [Good Laboratory Practice – international protocols that have the force of Federal law in the U.S.] study.

But the National Toxicology Program’s subpanel on BPA in 2001 [concluded](#) that the DES control was insufficient to render the findings unusable. Instead, the subpanel found that the strength and statistical power of those studies finding no association between low dose exposure to BPA and adverse effects, a group of studies which included John Ashby’s work, was “noteworthy.”

“As a group these studies are very consistent, the conclusions are supported by appropriate statistical analyses, and the Statistics Subpanel confirmed the lack of BPA effects.”

The BPA subpanel also noted that the food fed to the mice by vom Saal had double the amount of dietary estrogens as the food fed to the studies which found no association, and that this could have had an impact

on the results. The NTP panel noted the possible effect of vom Saal using a closed colony of mice and that:

“the studies that reported a positive low dose effect did not specifically analyze their dosing solutions or starting material, and one has to recognize this is always a potential confounder. Thus, without analyses done at the time of the actual study, one cannot unequivocally rule out potential effects of contaminants or errors in the preparation of dosing solutions.”

Unfortunately – and somewhat controversially – vom Saal terminated the entire colony of mice he did his research on, which meant that other researchers were unable to exactly replicate this crucial element of his original research. The statistics subpanel also reanalyzed vom Saal’s data on a study that found a statistically significant reduction in sperm efficiency in mice given BPA and found that the computation was in error, and there was no statistically significant relationship. This raised the question about the statistical validity of other studies by vom Saal, but as he did not provide the raw data to the biostatistics subpanel for reanalysis, the panel simply noted that it couldn’t confirm the validity of vom Saal’s findings.

Reviews by the Japanese Government’s Office of Chemicals Safety, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labor and Welfare in 2001, The European Commission’s Scientific Committee on Toxicity, Ecotoxicity and the Environment’s (CSTEE) in 2002, Harvard’s Center for Risk Analysis in [2004](#) Gradient in 2006 ([Goodman et al](#)), the European Food Safety Authority in 2006, the Center for the Evaluation of Risks to Human Reproduction in 2007 and Gradient in 2009 ([Goodman et al](#)) all reaffirmed the unreliability of the studies claiming low dose effects of BPA as means for determining human risk exposures. And EFSA noted:

“The effects of BPA reported in some

### **BPA and statistics: why not all studies are created equal**

The NTP also created a statistics subpanel to provide “an independent assessment of the experimental design and data analysis used in each of the studies and, perhaps even more important, to identify and discuss key statistical issues relevant to all studies.” The statistics panel identified the following key points among others, which are reproduced here at length to illustrate the fact that in risk assessment, studies are not accepted or rejected for trivial reasons, which again is something press coverage fails to explain:

**A. Study sensitivity (power)** – One important experimental design consideration is a study’s power, which is defined as the probability of detecting a treatment effect if it is present in the data. Study sensitivity or power is influenced by a number of factors: (i) sample size; (ii) the underlying variability of the data; (iii) the magnitude of the treatment effect that is present; and (iv) the method of statistical analysis and the associated level of significance chosen. Obviously, a larger study will generally have more power for detecting chemical-related effects than a smaller study. Moreover, the interpretation that a study is “negative” should be given more weight when relatively large sample sizes are used. The number of animals per group ranged from 3 to 179 in the studies that were re-evaluated, and this is a factor that must be considered when comparing and interpreting study results.

Importantly, the effective sample size of a study is the number of independent sampling units. Thus, if littermates are used and litter effects are present in the data, the effective sample size becomes the number of litters, not the number of individual pups.

**B. Replication** - Reproducibility of experimental results is an important and necessary feature of any scientific finding before it can be generally accepted as valid. There are several types of replication, which are discussed below. First, there is replication within an individual experiment. If multiple replications are used within a study, then each experimental group should be represented in each replicate. In one experiment we evaluated, three replicates were used, but the mid and high dose groups (which had only three animals per group) were represented only once, and in different replicates. Additionally, there were significant differences among the control groups in the three replicates, although the study authors pooled these groups in their statistical analysis. ...  
(cont’d)

studies at low doses in sensitive animal systems were small changes in organ weight or changes in tissue architecture, increased or decreased receptor expression, changes in hormone concentrations in plasma or tissues, small changes in the time required to attain puberty landmarks, and behavioural effects. The Panel noted that the changes observed were often not sustained through adulthood. The biological consequences of many of the changes in the affected animals are unknown and some, such as small increases in prostate weight, are not considered as precursors of pathological change. While some of the changes may be indicative of biomarkers of effect in very sensitive species and strains, in the light of present knowledge, they cannot be readily interpreted as adverse effects.

The Panel also noted that in some studies reporting low-dose effects, only a single dose level was investigated, or there was absence of a dose-response relationship where several dose levels had been used. Many studies also used only small numbers of animals per dose group. There are also a number of other potential confounding factors in these types of study that may contribute to the lack of consistency in the database.”

EFSA reiterated the point to STATS: “the scientists considered that many of the studies indicating low dose effects of BPA were contradictory and not well conducted.”

What does that mean? Consider the following, the NTP statistics panel in 2001 warned that the litter and not the individual rodent pup should be used as the experimental unit for statistical analysis:

“For example, when significant litter effects are present, a study with dosed groups comprised of 20 pups will have more power if each of the 20 pups is from a separate litter rather than having

### Statistics (cont'd)

This is not an ideal experimental design or data analysis. In another study we investigated, control and three dosed groups were each evaluated in separate time frames, extending over a period of one year.

The Statistics Subpanel felt that the lack of concurrent controls was a serious deficiency of the experimental design that greatly limited the general inferences that could be drawn from this study.

Another type of replication is the reproducibility of results among separate experiments within a given laboratory. In one publication we evaluated, the investigator carried out eight similar experiments with the same chemical, although these technically were not replicates, because different dose levels of the test compound were used in some experiments. This investigator found statistically positive effects on uterus weight in four experiments and no effect in the other four experiments. The author concluded that his investigation had shown that even the same investigator may be unable to repeat experimental findings, and we agree with this conclusion.

...Perhaps the most important type of replication is reproducibility among different laboratories trying to confirm the findings of another laboratory. Among the data sets we evaluated, there were several studies that attempted to duplicate the studies of other investigators. Some confirmed the original results, but many did not. It is difficult to achieve exact reproducibility of all aspects of an experimental design, and when conflicting results are obtained by different investigators, one should try to identify study differences that could account for the contradictory results.

The NTP panel also warned of unblinding studies prior to measuring organ sizes and weights as a source of potential bias, and it found that a failure to control for a single outlier in groups of animals (possibly simply due to placing a decimal point in the wrong position giving the animal an organ weight ten times greater than the mean) radically skewed the final results in some studies. It is the kind of detail that determines how regulatory agencies set reference doses and determine risks – but it is science and statistics at a level of complexity that is simply not part of the media and public debate on chemical and pharmacological risk.

four pups from each of five litters. The false positive rates will be identical in both cases. Thus, the authors' emphasis on increasing the number of pups per litter rather than increasing the number of litters is misguided.”

Numerous studies have failed to follow this requirement, thus inviting disqualification when reviewed for risk assessment (Goodman et al 2006). Willhite (2008) also notes that the failure of various studies to account for inter-litter variability “increased the numbers of incorrect conclusions concerning the presence or absence of adverse effects.”

But more to the point, by 2006 large, multi-generational studies, conducted under rigorous protocols failed to show the low-dose effects that vom Saal continued to warn about in the media. One of the early and important contentions made by vom Saal was that BPA behaved just like the synthetic hormone estradiol at a cellular level. But Tyl et al (2006) controlled for animal strain, feed, and the use of positive controls in a two generation reproductivity toxicity study, and while the control, estradiol, produced effects, BPA didn't. (Tyl et al, Two-Generation Reproductive Toxicity Study of Dietary Bisphenol A in CD-1 (Swiss) Mice, *Toxicological Sciences* 2008 104(2):362-384).

In 2007, research by the EPA's Kembra Howdeshell, who had collaborated earlier in her career with vom Saal on several studies, found that lactational and gestational exposure to both estradiol and BPA over a broad range of orally-administered low dose endpoints in rats only produces effects for estradiol. (Howdeshell et al, Gestational and Lactational Exposure To Ethinyl estradiol, But Not Bisphenol A, Decreases Androgen-dependent Reproductive Organ Weights and Epididymal Sperm Abundance In The Male Long Evans Hooded Rat, *Toxicological Sciences*, [Toxicol. Sci. 2008 102: 371-382; doi:10.1093/toxsci/kfm306](https://doi.org/10.1093/toxsci/kfm306)) Neither of these studies received any mainstream media coverage.

The cumulative effect of all this research and statistical analysis is that vom Saal, though highly vocal about the risks of BPA and the media's go-to source for explaining the science, has found his research and his claims repeatedly rejected in regulatory assessments of the chemical's risk in the past decade. When the *Milwaukee Journal Sentinel* claims he is considered a “leading authority” on the chemical, it is by virtue of the consideration of journalists and not toxicologists. His contention that BPA is highly toxic to humans has not been accepted by any major risk assessment conducted in the last decade. Indeed, EFSA went in the opposite direction, raising the reference dose for BPA by a factor of five, meaning that it considered the allowable daily intake for the chemical over the course of a lifetime to be significantly safer than had once been thought.

**The cumulative effect of all this research and statistical analysis is that vom Saal, though highly vocal about the risks of BPA, and the media's go-to source for explaining the science, has found his research and his claims repeatedly rejected in regulatory assessments of the chemical's risk in the past decade.**

NSF International's survey of the research on BPA concurred, but concluded that the reference dose should be slightly lower, to account for hypothetical neurodevelopmental risks, but even still, the quantity of BPA that we can safely ingest is vastly greater than the quantity of BPA that we actually do ingest.

And yet, the European Food Safety Authority and NSF International's risk assessments have been largely ignored by the media; instead, reporters have continued to rely on vom Saal or scientists that he has worked with or who endorse his position, and environmental activist groups who have backed him,

### What if BPA were tea? An analogy

Imagine I'm a scientist who comes to you, a newspaper reporter, with the following story: "I did this experiment where I injected six mice with tiny amounts of tea and they all developed heart disease. You need to warn the world that drinking tea is putting millions of people at risk of heart attack." Do you as a reporter say, "stop the presses – we have a new story for page one," or do you think, well this sounds a little odd, but he has a Ph.D, he's been published in peer-reviewed journals, and has a job at a University, so let's check him out and see what other scientists make of this theory?

Imagine you then find out that very few other scientists think my research has any merit – in fact, some tried to replicate my experiment, but couldn't get the results I did. You come back to me and tell me all this. "Pshaw," I say, "these guys are Tea industry scientists and you can't trust anything they say; their work is a joke, a mockery of research." But you respond, "Actually, there are these two-year studies that used far more mice, many more doses of tea, controlled for a whole bunch of factors you didn't, and they *still* didn't find your results. They were funded by industry but supervised by international protocols. What's more, the US EPA did a wholly independent two-year study on rats, to see if they could find what you found – the lead researcher even once collaborated with you – and they found nothing either."

But I say, "Look, I'm challenging the entire worldview of toxicology – my research is ushering in a paradigm shift in the way we think about drinking tea and chemical risk. These protocols are a joke – they're keeping good research from saving lives – look, here are more studies that find tea is linked to obesity, breast cancer, genital defects, and neurodevelopment problems. Tea is incredibly dangerous substance and needs to be banned." You reply – "but the body that funded many of these studies won't fund this kind of research any more because it says these studies all have design flaws. The National Toxicology Program convened a bunch of statisticians, and they all said these studies were flawed. And Europe, Japan, Australia and New Zealand, along with the FDA, also said these studies are flawed – and they all keep saying that injecting tea directly into the blood of mice is not the way to assess the risk of drinking tea. We *drink* tea - so you should be feeding them tea. And I reply, "I am one of the world's leading tea researchers, all these people know nothing about tea. They are all beholden to the tea industry."

Would you, as a reporter, not only take me at my word, and write page-one stories warning about the risks of tea and an industry cover up, but also bury all the research saying tea is safe and that my research is irrelevant? Ignore scientists who warned you that my tea research was lousy? Construct a narrative dominated by people who only reflect my viewpoint or who I have collaborated with? This may be a cartoon analogy, but when you boil down the BPA story, this is, in essence, what much of the American media did and why BPA is a hot-button political issue.

USA Today, for instance, ran a large photograph of vom Saal with a mouse on his hand under the headline "[Can a plastic 'alter human cells'?](#)" The subhead claimed that "scientists say the chemical can alter cell behavior at very low levels – in the parts per trillion range – yet humans are consistently exposed to BPA at levels 10 to 100 times greater." Vom Saal is quoted saying "this is a phenomenally potent chemical." USA Today reporter Liz Szabo turns to environmental activists to explain that

"the FDA's standard is biased and outdated, leading the agency to discount a dozen key studies that the [National] toxicology program used to conclude that BPA may pose a threat.

Although the FDA's laboratory guidelines aim to prevent fraud by requiring detailed notes, they don't necessarily ensure good science, says Sonya Lunder of the Environmental Working Group, a private organization that says BPA is dangerous. Independent academic researchers are performing far more sophisticated tests than the ones upon which the FDA based its decision, she says."

USA Today did not tell readers that the National Toxicology Program dismissed most of the evidence against BPA and had negligible concern for the many of the risks vom Saal had been claiming for over a decade. Nor did it put “some concern” into the scientific perspective that this is very limited data. Instead, the reporter jumps immediately to say that because the FDA said BPA is safe, it was using “controversial” methods to assess the evidence. The Environmental Working Group, a highly visible activist group (weirdly described as “a private organization”) is allowed to explain why this is the case.

The explanation doesn’t actually deal with the “limited evidence” the NTP found for neurodevelopmental toxicity, it leaps to attack the general principles the FDA used to assess all the evidence for BPA, and the priority given to something that is called “Good Laboratory Practice (GLP).” While there are many valid criticisms of GLP (it is onerous and stifles creativity), as far as BPA goes, it means the EWG was claiming that studies with greater statistical power are inferior to studies with less statistical power, and studies that tested low dose exposures with just one low dose are superior to those which tested for low dose exposures with multiple low doses. As already noted, the National Institute of Environmental Health Sciences will no longer fund what the EWG claims are “far more sophisticated tests” on BPA, because they were actually not that sophisticated: It’s not simply about paperwork, these studies did not have sufficient statistical power (i.e., use sufficient sample sizes) or use multiple doses, or oral exposure routes.

In June 2008, Time magazine published a story “[The Truth About Plastic](#),” which is almost entirely sourced to vom Saal, “a prominent member of a group of researchers who have raised worrisome questions in recent years about the safety of some common types of plastics.” There is no mention at all of any of the criticism of vom Saal’s work, save one line that mention’s that the FDA and European Union say there’s no danger. The only other scientist quoted in the piece recommends avoiding plastics as its better to be safe than sorry.

**“Scientific debate isn't driving the baby bottle war; a hard-hitting push by activist groups, politicians and trial lawyers is...”** – Marc Gunther, *Fortune Magazine*

In “[The Dirty Truth About Plastics](#),” Discover magazine featured vom Saal declaring that BPA “is the global warming of biology and human health,” and two other researchers who claim BPA is dangerous. No critics of their work were quoted

Some astonishingly basic questions were not asked in newsrooms around the country: if multiple risk assessments around the world keep rejecting the same body of research on the same methodological grounds, and yet independent of each other, why are we exclusively promoting this rejected research and ignoring the methodological problem? If vom Saal’s arguments have been consistently ignored or rejected, shouldn’t we find out why? Shouldn’t this worldwide consensus that BPA is safe set off an alarm bell – or call into play some degree of skepticism the idea that BPA is, as the Environmental Working Group puts it, threatening the lives of “millions of babies” and is responsible for a host of major diseases? This skepticism simply didn’t occur in the American press with a few exceptions.

Fortune magazine’s Marc Gunther [warned](#) that the entire furore about BPA in 2008 had more to do with activism than science:

“scientific debate isn't driving the baby bottle war; a hard-hitting push by activist groups, politicians and trial lawyers is...”

The BPA battles were fought like a political campaign, with catchy soundbites, press releases, personal attacks, and warring Web sites. The anti-BPA general is Dr. Frederick vom Saal. He has testified before state legislatures and appeared on TV to denounce BPA in terms that gloss over the scientific uncertainty. Referring to the fact that BPA is a mild estrogen, he says things like "the idea that you're using sex hormones to make plastic is just totally insane.

ABC 7 in San Francisco ran a long, Emmy-nominated investigation which featured both Willhite and STATS and focused on the controversy over studies that injected BPA and those that fed BPA.

But these were in the minority – every media organization put together couldn't match the coverage given to BPA by one, small regional U.S. newspaper, the *Milwaukee Journal Sentinel*.



### **The *Milwaukee Journal Sentinel*'s "Chemical Fallout" Crusade**

The *Milwaukee Journal Sentinel* devoted 40 articles adding up to over 30,000 words to BPA in 2008 alone (excluding separate articles written for the McClatchy News Service), winning four major awards for its coverage, the George Polk Award from Long Island University, The John B. Oakes Award for Distinguished Environmental Journalism from Columbia University's Graduate School of Journalism, the Scripps Howard award, and a Sigma Delta Chi Award from the Society of Professional Journalists. As the *Journal Sentinel* noted:

"Journal Sentinel reporters Susanne Rust and Meg Kissinger have won a George Polk Award - one of journalism's highest honors - for doing work long neglected by federal regulators: They stepped in to alert the public of ill health effects caused by exposure to chemicals commonly found in American homes."

In bestowing the Oakes Award, associate dean and director of the prize Arlene Morgan of Columbia University said:

"We received almost 100 entries in the newspaper and magazine divisions for this prize and concluded that the *Journal Sentinel* once again led the nation in performing a watchdog role that has a far-reaching implication on health issues"

As Mark Katches assistant managing editor for projects and investigations at the *Journal Sentinel* noted on December 21,

"These stories have changed a lot of people's habits and how they shop when they walk into any grocery store. That's a powerful thing."

The paper's position at the end of this epic coverage is best summarized by David Haynes in a piece which appeared on December 17, 2008 criticizing the FDA's decision not to take action on BPA:

"If it wasn't clear before Monday's disappointing letter from the U.S. Food and Drug Administration, it should be clear now: The FDA is punting. The agency sees no reason to ban, or even restrict, the use of the chemical bisphenol A.

In the letter to its advisory board, the FDA said it would review more studies and do more research on BPA. Until then, the chemical should be considered safe for anyone to use, even babies.

Is this the FDA or the CYA?

The FDA has dithered for years, embracing studies that found the ubiquitous chemical to be harmless - nearly all of which were paid for by the chemical industry - while ignoring a much larger body of independent research that linked BPA to an array of health problems, including diabetes and cancer.

BPA has been studied to death. There is no need for further research to reach the conclusion that it shouldn't be in kids' products.

BPA is found in thousands of consumer products, including hardened plastics such as water bottles, dental sealants and the epoxy liners used to protect canned food from bacteria. The chemical, which mimics the hormone estrogen, poses a risk of disrupting the human endocrine system, a risk that increases in young children, who do not excrete the chemical as rapidly as adults.”

In light of this trenchant criticism, it is not surprising that the *Journal Sentinel*'s stories in 2008 consistently portrayed BPA as a serious threat to health and argued that industry-funded studies were being given precedence by regulatory bodies in the U.S., despite a large but undefined number of “independent” studies claiming otherwise.

But in making the claim that there is “a much larger body of independent research” linking BPA to health problems the paper failed to explain the grounds for this numerical claim. In 2007, the paper conducted a “[review](#)” of “258 research papers and found that a large majority showed bisphenol A was harmful to lab animals. Those that didn't find harm overwhelmingly were paid for by the chemical industry.” The selection appears of these studies was determined by an internet search of a medical database. The paper declared its report to be “groundbreaking” (David Haynes, Nov 9, 2008).

But it would appear that no scientific criteria were applied to determining whether the studies were reliable or not; instead, the key criteria for judging was a positive finding for harm and whether the study was independent or industry funded. If a study found an effect and was independently funded it was significant; if a study didn't find an effect and it was industry funded it was significant. In short, the “groundbreaking” study was unscientific even as it laid claim to determining what the science said about BPA. The scale of this error is revealed by the fact that the NIEHS has revised its criteria for funding academic research because many of the studies which it funded (and which the *Journal Sentinel* claims found harmful effects) were experimentally flawed.

Repeated requests to the *Journal Sentinel* reporters to explain why they didn't appear to apply any statistical or methodological criteria to distinguish relevant from irrelevant research (such as the criteria recommended by the NTP statistics subpanel in 2001) went unanswered – as did requests for actual study citations (the paper, maddeningly, never provides citations for any study it refers to or characterizes).

This means that the *Journal Sentinel* gave its readers began its investigation with a false premise, an estimation and evaluation of the research findings on BPA that completely bypassed the scientific principles by which research is judged to be rigorous or not. In terms of brute numbers, there were, according to Willhite's testimony to Congress in 2007:

“4,263 published scientific papers on developmental toxicity, acute and chronic toxicity, carcinogenesis, immunotoxicity, neurobehavioral toxicity, genotoxicity, biochemical toxicology, epidemiology studies, studies with workers exposed to bisphenol A and analyses of its concentrations in food, water and soil (summarized in Goodman et al., 2006; United Kingdom Health and Safety Executive, 2007, Willhite et al., 2008).”

Willhite, as lead author of NSF International’s paper, references 444 studies and papers in calculating a reference dose for BPA. But the critical question is not how many papers there are on a given position, but whether the design, route of exposure, dose-response relation, statistical power, and plausible mode of action give these studies the rigor and robustness to accept their conclusions and their utility in a human risk assessment. If the study’s findings are then replicated by other research, it becomes part of the evidence for a particular position. This is how the weight of evidence is adjudicated – not simply by counting up studies that found results pro or contra and accepting the higher number as the truth.

A well-designed study counts; a well-designed study that has been replicated counts even more: a poorly-designed study counts for little; a poorly-designed study that fails the test of replication counts for even less – or nothing at all.

**“They [vom Saal et al] just say that all studies by industry are biased, which frees them of any need to demonstrate that they are correct” – Wolfgang Dekant, Professor of Toxicology, University of Würzburg**

One of the key factors in a well-designed toxicology study is that the chemical is tested at more than one dose level. Many of the independent studies that the *Journal Sentinel* “found” were dismissed in the risk assessments because they used only one dose level. (The NIEHS now says “single dose experiments are not acceptable” in present and future funding requests for research on BPA). As Dekant explains:

“When you just have a response at one dose, you always wonder if this is something really associated to the administration of a chemical or to whatever else. Moreover, studies with only one dose are useless for any assessment of health risks, since you can not determine a starting point for assessment, such as a NOAEL [No Observable Adverse Effect Level] or a benchmark dose. In the context of BPA, it is specifically of interest since, early on, vom Saal and others claimed non-linear dose-responses but never did any experiments to confirm. Now, they just say that all studies by industry are biased, which frees them of any need to demonstrate that they are correct.”

Because the charge of industry bias resonates so powerfully with journalists, it often serves to obscure both the fiscal realities and methodological rigor of scientific research. In other words, it frees journalists from the need to demonstrate which studies are correct and which are not.

One of the problems in toxicology is that studies raising questions about public health are often small in scale, which means that they can lack statistical power and the associations may well be random. The studies which then set out to either confirm or refute the finding need to be large in scale in order to produce statistical measures that suggest causality (the association then needs to be explained by a plausible biochemical process). But the bigger the study, the more expensive it’s going to be, which means that regulatory bodies tell industry to fund them. For example, in 2003, when the European Chemicals Bureau concluded that more research was needed due to uncertainty over possible low-dose effects of BPA, “a steering group, made of up experts from several EU member states, was subsequently

set up to resolve this issue and proposed a 2-generation study on mice,” said an EFSA spokesman by email.

“This study (the second Tyl et al study, from 2006) was indeed funded by industry – as is general practice for chemicals which are to be marketed – but the steering group supervised the design of the study and the interpretation of its results, and was also able to comment during the conduct of the study. This study confirmed the NOAEL of 5mg/kg/bw per day, which is well above current exposure levels.”

To ensure rigor these studies are often conducted under a set of international standards called Good Laboratory Practice. “There is a quality assessment scale for toxicological studies regarding reliability,” said Dekant in an email.

“Studies performed under ‘good laboratory practice’ following study designs developed by [scientific panels](#) from the OECD (Organization for Economic Co-operation and Development) are usually considered of highest quality. Studies with explicit quality control such as those done in university labs but with good study design (several doses!) and adequate description are still reliable. Other studies with either limited reporting or flaws in the design (such as using only one dose or inadequate controls) are not considered reliable. This approach is widely used in assessment and is also a centerpiece in the EU REACH legislation. Due to the use of GLP, cover-ups are difficult, if not impossible.”

EFSA elaborated in a statement to STATS:

“Many non-GLP studies were considered for the EFSA opinion of 2006 but were not considered adequate for reasons explained in the opinion. Each of the non-GLP studies examined, many of which concern neurodevelopmental effects, suffers from limitations with regard to the study design or the reporting of the results, and taken together the results show no reproducible pattern. A study does not necessarily have to adhere to GLP in order to be taken into account in EFSA’s opinions, but does need to demonstrate adequate design and show reproducible results. No study linking exposure to BPA at levels lower than the existing NOAEL has yet to fulfill these criteria.”

The *Journal Sentinel* simply ignored these distinctions, and instead appeared to argue that GLP regulations – which are Federal regulations with the force of law – were being used to cover up the truth about BPA. As the paper reported on October 24, 2008,

“The guidelines, known as “Good Laboratory Practice,” give greater credibility to studies that use more animals. National Institutes of Health guidelines limit the number of animals that can be tested by government scientists and those who work for many publicly funded institutions.

“The FDA’s task force report on bisphenol A dismissed or gave lesser credence to hundreds of studies that showed the chemical caused harm. These studies were conducted by government and academic scientists, using state-of-the-art techniques and methods but did not have the stamp of Good Laboratory Practices.

Instead, the agency relied on a handful of industry-funded studies that had the stamp, even though they were flawed in other ways.”

The FDA’s approach and conclusions were based on the National Toxicology Program’s report on BPA, and follow those of the European Food Safety Authority. As noted, the studies that were rejected were not rejected without cause – and all the risk assessments explain why. In contrast, the *Journal Sentinel* never

separated oral studies from injection studies, single dose from dose-response studies, or presented a statistical argument explaining why the exclusion of oral studies is wrong or why an industry-funded dose response study is inferior to an independent study using a single dose. Instead, it uses an equivalent of the *ad hominem* argument: if it's not independent, it can't be trusted.

**“A study does not necessarily have to adhere to GLP in order to be taken into account in EFSA’s opinions, but does need to demonstrate adequate design and show reproducible results. No study linking exposure to BPA at levels lower than the existing NOAEL has yet to fulfill these criteria.” – European Food Safety Authority**

In fact, the paper went further. “Based on the weight of independent research,” wrote David Haynes on Nov 9, 2008, “the government should ban” metal containers containing infant formula, BPA in polycarbonate bottles and so on. But the phrase “the weight of independent research” is meaningless – an Alice in Wonderlandism – because the weight of evidence in science is only ever determined by scientific and statistical principles, not whether it's industry funded or not.

Is it, perhaps, not uncoincidental that the *Journal Sentinel*'s independent vs industry theme is mirrored by vom Saal, who has long denounced his scientific critics as industry funded. This kind of rhetoric has a distinct appeal for journalists, who instinctively see a conflict of interest in industry-funded *anything* – and who become even more suspicious when an industry funded study confirms that something is safe in the face of “independent” evidence that it is risky. Thus it is easy for journalism to fall into a formulaic response to a scientific controversy: independent research good; industry-funded research bad. If the Food and Drug Administration is relying on industry-funded studies to regulate BPA and rejecting the “independent” research, the key ingredients for a scandal are in place.

This is clearly the formula the *Milwaukee Journal Sentinel* fell into, and the consequence is that it fed its readers, activist groups, politicians, and the wider journalistic community a diet of confirmation bias, as it seized, without any scientific criteria to separate good research from bad, on any “independent” evidence that seemed to confirm the thesis that BPA was dangerous while ignoring or criticizing information that disproved it was dangerous (this included well-conducted, robust independent studies too). Robert Chapin, a toxicologist who chaired the panel convened by the NTP's Center for the Evaluation of Risks to Human Reproduction (CERHR) to weigh the evidence and come up with a level of scientific concern over BPA, told STATS:

“I talked with them for at least an hour, trying to make them understand the concept of ‘weight of the evidence,’ and to explain why we had more confidence in bigger and more rigorous studies, and why smaller studies gave less confidence. They seemed to understand what I was talking about. At least they did not challenge me outright. They were reasonably polite, not hostile. One of the reporters probed me for a while, trying to find out why I was getting agitated describing Fred vom Saal's highjacking of our science. So OK, I got agitated because I think Fred does (or reported) miserable studies which should not be given the weight they were receiving. Their attitude to me was reasonably polite and accepting.”

But the paper ignored everything he said, most importantly the “weight of evidence” – the scientific coherence of the full body of research on BPA. Said Chapin in an email to STATS:

“They jumped straight to the conclusion that vom Saal must be right and everything else must be wrong. There was no puzzling out how such a flagrant dichotomy could come to be, there was no

exploring of our position, no digging around to try to understand what was happening. And important research WAS ignored.”

Journalism is all about choosing what to report and who to talk to, and selective sourcing can create make the innocent seem guilty and the guilty innocent. The chemical industry and the Food and Drug Administration are never going to play a societal role that the public will spontaneously applaud, but babies – well, who doesn’t want to protect babies? If reporting is to be worth anything – if it is, simply, to be ethical – journalists need to be fair.

**“They [the *Milwaukee Journal Sentinel*] jumped straight to the conclusion that vom Saal must be right and everything else must be wrong. There was no puzzling out how such a flagrant dichotomy could come to be, there was no exploring of our position, no digging around to try to understand what was happening. And important research WAS ignored”** – Robert Chapin Ph.D, chair, NTP’s Center for the Evaluation of Risks to Human Reproduction (CERHR) BPA panel

In this respect, one doesn’t need to be a toxicologist to address in the problems raised by what the *Journal Sentinel* chose not to report or missed.

### **The European Union**

The European Food Safety Authority [EFSA] is the European agency is the European Union’s equivalent to the Food and Drug Administration, and is charged with the scientific assessment of food safety. In 2006, EFSA published its risk assessment of BPA – “Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to 2,2-BIS(4-HYDROXYPHENYL)PROPANE (Bisphenol A)” [ref] It was conducted by 21 scientists from across the EU.

EFSA took the exact opposite position to the *Journal Sentinel* reporters, junking much of the “independent” research that provide the grounds for the paper’s claims of regulatory mismanagement in the U.S. As EFSA told STATS, “the scientists considered that many of the studies indicating low dose effects of BPA were contradictory and not well conducted.”

The European parliament could have overturned the risk assessment’s conclusions (as it has with other risk assessments), but it didn’t. This – and other member states separate risk analyses – is the key reason that BPA is *not* a public health controversy in Europe.

And yet, the EFSA risk assessment only received a passing mention in the *Journal Sentinel*’s 30,000 plus words of reporting, being alluded to twice and cited just once. On October 30, the paper quoted from an FDA press release:

"Consumers should know that, based on all available evidence, the present consensus among regulatory agencies in the United States, Canada, Europe, and Japan is that current levels of exposure to BPA through food packaging do not pose an immediate health risk to the general population, including infants and babies,"

The same quote is repeated in an article on October 29. On August 18, the *Journal Sentinel* noted

“However, the European Union and the European Food Safety Authority, which both recently reviewed the research on bisphenol A, have deemed the chemical safe.”

It doesn't appear to have occurred to the journalists or editors at the paper to ask, why has the EU, which regulates chemicals according to the precautionary principle (meaning that substantial proof of actual risk doesn't have to be determined in order to ban a substance), concluded that BPA is safe, when we are telling readers that it is highly dangerous?

Indeed, as already noted, EFSA *found BPA to be safe enough to recommend raising the reference dose* (rfd – the amount of a substance that a person can safely ingest on a daily basis over a lifetime, known as “tolerable daily intake” in Europe) by a factor of five.

### **EFSA's 2008 update, Norway's Scientific Committee on Food Safety and neurotoxicity, Denmark's Environment Protection Agency**

Though the *Journal Sentinel* reported that BPA was linked to neurological disorders and neurotoxicity (April 30, May 19, October 23, 29, November 16, 18 of 2008), and that the National Toxicology Program “found some concern for the neurodevelopment of young children, infants and fetuses” (October 23, 24, 2008), the paper did not note that EFSA rejected this evidence in an update to its 2006 risk assessment in July 2008.

“EFSA also took into account the recent report published by one of the institutes of the European Commission's Joint Research Centre (EC, 2008) which concluded that due to the low confidence in the reliability of the developmental neurotoxicity studies and the lack of consistency in the results of behavioural testing, no conclusions can be drawn from these studies.”

EFSA also cited an evaluation ([ref](#)) of four studies on developmental neurotoxicity by the Norwegian Scientific Committee on Food Safety. The panel concluded that

“the four studies suffer from major shortcomings and do not provide sufficient evidence for setting a robust lower NOAEL for BPA than the current EFSA NOAEL of 5 mg/kg bw/day.”

(The panel recommended further study in light of the NTP decision to express “some concern” over neurotoxicity based on this research).

Denmark – no slouch on environmental protection – was also concerned about the gap between EFSA and the NTP on neurodevelopment and toxicity, and its Environment Protection Agency conducted a separate investigation with outside experts on the risk to infants. The conclusion was that the EFSA decision to reject these studies was correct.

In light of repeated criticism in the *Journal Sentinel* and elsewhere that the FDA wasn't doing enough to protect the public from BPA, it is noteworthy to find European environmental agencies – which operate under more risk-sensitive protocols – concluding that the *U.S. was being too risk averse*. This would probably surprise, if not shock, many American readers along with those politicians who fear the FDA is failing to protect the public. But such news never made the news; instead, the *Journal Sentinel* focused on what Canada thought of BPA.

### **Oh Canada!**

In a contrast to the European Union's risk assessment, Canada's risk assessment was cited at least 18 times and given, in addition, one entire article. Unlike the European Union, Canada appeared to decide that BPA was dangerous, and therefore supported the *Journal Sentinel's* reporting and editorial line; as the paper declared on May 19, 2008: “Canada gets it.”

“Earlier this year, Canada declared BPA to be toxic and is moving to ban it from use in baby bottles.” (Dec 16, 2008)

“Canada has declared BPA to be toxic and is moving to ban it in baby bottles, the lining of infant formula containers and all children’s tableware.” (Dec 4, 2008)

“In addition to Congress, 13 states have proposed bans on BPA. Wisconsin is not one of them. But State Sen. Julie Lassa (D-Stevens Point) said Monday that she is preparing legislation to ban BPA from children’s products in Wisconsin. Lassa, chairman of the state Senate’s Committee on Economic Development, said she became concerned about the chemical last spring after learning that Canada was banning the chemical in baby bottles and children’s products. ‘It’s scary stuff,’ said Lassa, who has children ages 4 and 17 months.” (Nov 18, 2008)

“Canada has declared BPA a toxin and is moving to ban it from baby bottles, infant formula and other children’s products.... In April, after Canada’s announcement of a ban, several corporations said they would stop producing and selling certain products made with BPA.” (Nov 16, 2008)

“Canadian health officials have been far quicker to address concerns about BPA than their American counterparts. Canada is set to ban the chemical in plastic baby bottles and reduce exposure in canned infant formula.” (Nov 9, 2008)

“Canada announced on Oct. 17 that it considers bisphenol A to be toxic and will move to ban it in baby bottles.” (Nov 1, 2008)

“Earlier this month, Canada declared bisphenol A to be toxic and moved to ban its use, import and advertising in baby bottles and other products for children. Lunder said Canada’s move raises serious questions about how well the FDA is protecting the American public. The FDA and Canada’s health regulatory agency considered the same body of evidence and came to vastly different conclusions, Lunder said.” (Oct 30, 2008)

“U.S. Rep. Edward J. Markey (D-Mass.), who serves on the committee that oversees the FDA, sent a letter to Commissioner Andrew von Eschenbach on Thursday citing the *Journal Sentinel* reports, and asking for the agency to follow Canada’s lead and declare the chemical to be toxic and ban it from use in children’s products. Canada on Saturday became the first country to declare the chemical a toxin.” (Oct 24, 2008)

“David Michaels, a professor of occupational and environmental health at George Washington University and who was not an author of the review, said the regulatory process clearly is flawed. ‘The discord between the National Toxicology Program, Health Canada and the FDA spotlights the limitation of the FDA’s approach,’” Michaels said. (Oct 24, 2008)

“Last week, the government of Canada declared that bisphenol A is a toxin and is banning its use in baby bottles and other products used by children.” (Oct 23, 2008)

“Oct. 18: Canada declares bisphenol A toxic and announces a move to ban the sale, import and advertising of baby bottles and other children’s products containing the chemical.” (Oct 23, 2008)

“Canadian health officials announced Saturday that bisphenol A is toxic and said they will ban baby bottles made with the chemical. The move, a first by any country, is giving fuel to those who want the chemical, found in plastic baby bottles and in the linings of cans, declared

dangerous in the United States and elsewhere. Canadian regulators will begin writing rules prohibiting the sale, import and advertising of the chemical in baby products. Those bans likely will begin in 2009, according to Health Canada, the federal health agency. Canada's action is directed only at products for young children. The health officials found no cause for concern in older children or adults.” (October 19, 2008 – entire article is about the ban.)

“For inspiration, it needs to look no further than Canada, which recently declared bisphenol A a dangerous substance and banned the sale, import and advertising of baby bottles made with it.” (June 16, 2008)

“Canada gets it. So do an increasing number of retailers in the United States, including the biggest, Wal-Mart. Now, the U.S. government must take action to ban bisphenol A from all children's products...” (May 19, 2008)

“Canada said in April it would classify bisphenol A as a toxin, which likely will lead to its ban there by June.” (May 19, 2008)

“In the last couple of weeks, the U.S. and Canada have called for concern regarding the plastic chemical. The U.S. National Toxicology Program said the chemical posed some concern for fetuses, infants and children, and the Canadian government is considering a ban on all baby products containing bisphenol A.” (May 1, 2008)

“Canada announced April 18 that it will classify bisphenol A as a toxin and, barring any unforeseen circumstances, will ban the use of the chemical by June.” (Apr 30, 2008)

“Canada on Friday became the first country to declare bisphenol A, a chemical used in hundreds of common household products, a toxin. It immediately declared a ban on the sale, import and advertising of baby bottles made with the chemical.” (Apr 19, 2008)

“John Baird, Canada's minister of the environment, called the decision the most important in decades on a single chemical. ‘This shows the world that we are serious about protecting human health,’ Baird said. Chemical makers maintain that bisphenol A is safe. Canada's announcement provides reassurance to parents concerned about the chemical, Steve Hentges, a spokesman for the American Chemistry Council, said in a news conference Friday.” (Apr. 19, 2008)

This sounds quite alarming, especially if one goes back to the October 30 comment by Sonya Lunder, paraphrased by the *Journal Sentinel* as “The FDA and Canada's health regulatory agency considered the same body of evidence and came to vastly different conclusions.”

But is this what really happened?

Lunder belongs to an Environmental Working Group, an activist organization with a long track record of exaggerating chemical risks (a separate [survey of members](#) of the Society of Toxicology by STATS and George Mason University's Center for Health and Risk Communication found that 79 percent of those toxicologists who were familiar with the Environmental Working Group said the organization overstated the risks from chemicals.). As we shall see later, the *Journal Sentinel* often relied on environmental activists to explain what the science meant at crucial narrative junctures. The problem here is that Health Canada **did not come to a vastly different conclusion** about the evidence – at least not according to its [official position](#):

“The current research tells us the general public need not be concerned. In general, most Canadians are exposed to very low levels of bisphenol A, therefore, it does not pose a health risk.

Our focus now is on the health of newborns and infants under 18 months. Science tells us that exposure levels are below those that could cause health effects.”

So far, Canada is in agreement with EFSA and the FDA and the breathless reporting by the *Journal Sentinel* seems obtuse. Health Canada continues

“However, due to the uncertainty raised in some studies relating to the potential effects of low levels of bisphenol A, the Government of Canada is taking action to enhance the protection of infants and young children.

Studies have shown the main sources of exposure for newborns and infants are from bisphenol A migrating from the lining of cans into liquid infant formula and migrating from the polycarbonate baby bottles into the liquid inside following the addition of boiling water.”

Canada, as Europe, regulates chemicals according to the precautionary principle, which obligates it to take action – as Health Canada notes,

“Even though scientific information may be inconclusive, decisions have to be made to meet society's expectations that risks be addressed and living standards maintained.”

As a consequence, the uncertainty over BPA requires that it be [labeled](#) “toxic” under Section 64 of the Canadian Environmental Protection Act when used in food containers. BPA has been a hot environmental topic in Canada for years, fueled in large part by environmental activist groups, and newspapers, such as the Toronto Globe and Mail following the same path as the *Journal Sentinel* and citing the same core group of scientists claiming a risk.

That Canada’s decision on BPA was scientifically controversial is highlighted not only by the EU’s rejection of the evidence upon which it determined precautionary action, but, as already noted by France’s Health Minister’s explicit criticism of the decision when asked whether France would follow Canada’s lead.

### **Germany’s Federal Institute for Risk Assessment and baby bottles; Norway and Switzerland’s analysis of BPA migration; France’s Food Safety Agency**

The *Journal Sentinel* also failed to report that Germany’s BfR Federal Institute for Risk Assessment had separately [reviewed](#) the safety of BPA and concluded that:

“Following careful checking of all the studies, in particular those studies in the low dose range of bisphenol A, the BfR carried out a scientific assessment of the results and came to the conclusion that the presence of bisphenol A in polycarbonate bottles poses no health risk to babies and infants during normal use. The BfR is not alone in this assessment of the situation: the European Food Safety Authority (EFSA) and the American Food and Drugs Administration (FDA) share this view. Japan, which has carried out its own investigations into problems associated with BPA, also saw no need for a ban.”

The BfR also [dismissed](#) the idea animating Canada’s decision to label BPA toxic, namely that BPA in polycarbonate baby bottles posed a risk to children:

“Official food monitoring could not detect any bisphenol A during spot checks on the contents of baby bottles that were heated under normal domestic conditions. The BfR does not recognize any health risk for babies that are fed from baby bottles made of polycarbonate. Stopping the use of polycarbonate bottles is an unnecessary step, in the opinion of the Institute.”

In contrast to official food monitoring and spot checks, the *Journal Sentinel* repeatedly warned readers about the dangers of BPA in polycarbonate bottles, for example on October 19, 2008:

“Studies have shown the main sources of exposure for newborns and infants are from bisphenol A migrating from the linings of cans into liquid infant formula and migrating from polycarbonate baby bottles into the liquid inside after the addition of boiling water.”

The paper called for a ban on BPA in plastics used by children (November 18, 2008):

“It should ban BPA from polycarbonate bottles and tableware intended for small children”

And it recommended not placing warm liquids in such products (November 16, 2008):

“If using hard polycarbonate plastics (water bottles, baby bottles or sippy cups), do not use for warm or hot liquids”

But the paper failed to report a joint [study](#) published in February 2008 in the journal *European Food Research and Technology* by Per Fjeldal of the Norwegian Food Safety Authority and Sandra Biedermann-Brem and Koni Grob of the Official Food Control Authority of the Canton of Zürich that examined the worst case scenarios for BPA leeching from baby bottles.

The maximum amounts of BPA these researchers managed to extract from bottles under normal washing conditions was between 1 and 7 micrograms per liter ( $\mu\text{g}/\text{l}$ ) of fluid. Given that the European Union’s Tolerable Daily Intake for BPA for infants is 250 micrograms per liter of fluid, the researchers concluded that:

“[T]he amount of BPA contained in the polycarbonate is so small that BPA migration in the proper sense is below 1  $\mu\text{g}/\text{l}$ ; also liquids with a strong extraction power do not extract much BPA.

BPA is formed and transferred into the beverage when alkali aqueous solutions are “baked” onto the polycarbonate during the drying process, as it occurs when the washing liquid is poured out, but rinsing with water fails. However, the BPA still amounted to less than 10  $\mu\text{g}/\text{l}$  when referred to a 100 ml filling

With this understanding of the mechanisms of BPA formation and transfer into beverages it seems possible to confirm that even under extreme conditions and scenarios the amount of BPA released from polycarbonate baby bottles is clearly below the TDI for babies. In particular it can be ruled out that the observed increase of BPA release with aging of the bottle may extend to levels which could be of health concern.”

A follow up [study](#) by Biedermann-Brem and Grob (published online in November 2008 in *European Food Research and Technology*) added significantly to our understanding of BPA exposure from polycarbonate bottles. Exposure was not an issue due to normal migration from the polymer, the levels in the food or liquid content were below one microgram per liter; the problem was degradation. If you boil

tap water, you increase its alkalinity, which makes the water more caustic, which in turn strips more BPA from the bottle.

“BPA concentrations may reach 50 [micrograms per liter] if a polycarbonate bottle is sterilized by boiling water in it (well feasible only by means of microwave heating) and this same water is used to prepare a beverage. Increased concentrations are also observed when boiling hot beverages with a high pH are filled into the bottle, such as boiled plain water or tea.”

The paper noted that higher amounts of BPA release through degradation required unrealistic test situations – such as boiling water in a bottle continuously for an hour or more. The researchers concluded that realistic daily exposures would be unlikely to reach 50 micrograms per liter, an amount considered safe for infants by EFSA. As the researchers note,

“Assuming a daily consumption of 800 ml from baby bottles and a body weight of 4 kg, the TDI [Tolerable Daily Intake] of 0.05 mg/kg bw would be reached with a BPA concentration of 250 micrograms per liter.”

If you wanted to reduce that low level of exposure a hundred fold (and satisfy Canadian concerns about uncertainty), the researchers noted that you should “not boil water to be used for preparing drinks in a polycarbonate bottle,” or fill a polycarbonate bottle with hot water or tea, and you should rinse such bottles after they are washed in a dishwasher.

In October 2008, the French Food Safety Agency – *Agence française de sécurité sanitaire des aliments* (AFSSA) – was asked by the French Department of Health to study Canada’s decision to ban BPA in baby bottles. AFFSA conducted an [evaluation](#) of the evidence and concluded that there was neither cause for concern nor a need to regulate BPA according to precautionary principles.

Again, the failure of the *Journal Sentinel* to cover any of this research creates a false numerical sense of risk when it reports on BPA in baby bottles.

### **Japan**

The *Journal Sentinel* does not mention that a 2005 Japanese [risk assessment](#) on BPA, produced by The Research Center for Chemical Risk Management, concluded that:

“[C]urrent BPA exposure levels were unlikely to pose unacceptable risks to human health.”

### **NSF International**

But perhaps the most perplexing omission of all, given the recurring theme in the *Journal Sentinel*’s reporting of “independent” research being ignored by regulatory agencies, was that in 2008 the paper ignored the most comprehensive independent evaluation of the research on BPA, conducted by [NSF International](#). An independent, not-for-profit organization devoted to consumer protection, NSF started in 1944 as the National Sanitation Foundation in the Public Health department of the University of Michigan, Ann Arbor, and has expanded over the years to 18 countries. It is a collaborating center with

**No matter what position one takes on BPA scientifically, the failure to address such a huge body of counter-evidence is stunning. The *Journal Sentinel* reporters managed to avoid anything that might have contradicted the thrust of their reporting. This kind of confirmation bias is one of the problems of investigative reporting in general: the need to justify spending scant resources covering a topic in immense depth can lead reporters to discount information that could wind up wrecking their whole project.**

the World Health Organization on food and drinking water safety, and it has expanded its monitoring operations in China following a series of public health controversies over lead in toys.

NSF International won a competition to run the EPA's direct and indirect drinking water additives regulatory program in the mid-1980s, and decided to develop a drinking water limit for BPA in the absence of federal limits or guideline values for BPA that might be detected in water through a plastic component in faucets or pipes.

NSF's review of the research on BPA calculate a reference dose (in European-speak, a Tolerable Daily Intake, TDI) or how much BPA can be safely ingested on a daily basis. The result was [published](#) in the peer-reviewed *Journal of Toxicology and Environmental Health* in February. The conclusion? BPA does not pose a health risk to adults or infants at present exposure levels.

No matter what position one takes on BPA scientifically, the failure to address such a huge body of counter-evidence is stunning. The *Journal Sentinel* reporters managed to avoid anything that might have contradicted the thrust of their reporting. This kind of confirmation bias is one of the problems of investigative reporting in general: the need to justify spending scant resources covering a topic in immense depth can lead reporters to discount information that could wind up wrecking their whole project.

### **How the *Milwaukee Journal Sentinel* sourced its reporting.**

The flip side of ignoring the evidence that BPA is safe is a crusade driven entirely by evidence that BPA is dangerous. Still, one would expect that the *Journal Sentinel* would have made a strong scientific argument for BPA being dangerous by extensively quoting from that science; and yet, in reviewing the *Journal Sentinel*'s 40 articles on BPA in 2008, one of the most striking aspects is how *few* scientists are quoted by the paper and how little actual scientific discussion occurs, despite the volume of coverage.

Indeed, one of the most troubling features of the way the *Journal Sentinel* sourced claims about the dangers of BPA was that it relied on environmental activists to interpret what the science meant, or why the FDA or other governmental bodies were remiss or negligent, for example:

Pete Myers, chief scientist of the nonprofit group Environmental Health Sciences, noted the draft's heavy reliance on two industry-funded studies that found the chemical poses no harm. "You think the FDA would have learned not to rely so heavily on industry-funded research after the Vioxx episode," he said, referring to an FDA gaffe over the prescription arthritis medicine in 2004. (August 16, 2008)

Richard Wiles, president of the Environmental Working Group, also called for an investigation. "Dr. Philbert has 5 million reasons to make sure FDA comes down in favor of the chemical industry and against protecting the health of millions of babies," (October 15, 2009)

"The bottom line is that each of the four major studies cited by the FDA were flawed," said J. Peterson Myers, lead author of the critical review and chief scientist of the nonprofit group Environmental Health Sciences. The standard used by the FDA "does not guarantee quality, reliability or validity in the scientific process," he said. (October 24, 2008)

"There is no justification for waiting when safer products are available now. It's indefensible," said Sonya Lunder, senior analyst for Environmental Working Group, a health advocacy group that has done extensive testing on baby bottles and infant formula, and has lobbied for the chemical to be removed from those products. (October 30, 2008)

"You cannot tell parents with a straight face that BPA is safe," said Sonya Lunder, a senior analyst with the advocacy group, Environmental Working Group. (December 9, 2008)

"BPA is a toxic chemical and should not be present in products that children and adults are exposed to on a daily basis - especially children," Jovana Ruzicic, spokeswoman with Environmental Working Group, a health advocacy group, told *Journal Sentinel* reporters. "There is enough evidence out there already to take immediate action." (December 16, 2008)

Mike Schade of the Center for Health, Environment and Justice said the matter is urgent. "While the FDA continues to delay action, infants and women of childbearing age are being exposed to potentially dangerous levels of this highly potent chemical," he said. "The U.S. should be a leader, not a laggard, when it comes to protecting infants and American families." (December 16, 2008)

**STATS asked Professor Dekant, one of the lead authors of the EFSA risk assessment, and co-author on the latest, most accurate assessments of human exposure to BPA whether he thought "millions of babies" were at risk. "I do not think so," he said via email, noting that babies exposure to BPA was well below the safe level derived from the most sensitive animal response to BPA with a built in safety factor of 100.**

The *Journal Sentinel* relied on several activist groups as expert sources even though none of them had conducted any peer-reviewed scientific research on BPA. Rather, these groups appeared to rely on vom Saal and the scientists represented by the Chapel Hill Consensus for their scientific data. And those are the scientists the *Journal Sentinel* then turns to elaborate on the science. In other words, what appears as extensive sourcing turns out to be more an echo chamber for the same claims.

Some of the controversies over vom Saal's research and his position on BPA have already been noted. But his activism against BPA has come in for sharp criticism from Dr. Bill Durodié, Senior Fellow at the S.Rajaratnam School of International Studies at Nanyang Technological University in Singapore. In 2005, Durodié was a Research Fellow in the International Policy Institute at King's College London and had been investigating risk issues and chemicals. He noted that vom Saal was scheduled to speak at an event in London hosted by a baby bottle manufacturer going by the name of B Free (standing for BPA free baby bottles).

Vom Saal told STATS by email that he "received no payment for my talk in London in 2005 - I paid my airfare to go there and hotel cost to stay there. Any suggestion that this is not true would be libel and would lead to legal action. This has been raised periodically by people associated with the chemical industry and is a pathetic and desperate attempt to discredit me because those pulling the strings and their

puppets are unable to provide credible scientific arguments regarding the hazards posed by BPA that I discussed in London and have discussed elsewhere.”

But Durodié says that it was the tenor of the talk that troubled him. “It was quite hard for anyone outside of the world of nursery magazines and the like to access the meeting,” he said by email, but once inside he challenged vom Saal’s presentation of the evidence, and was ejected from the lecture by the manufacturer. Explains Durodié,

“I felt vom Saal’s presentation in London had every hall-mark of old-fashioned quackery. That is just my opinion after all. My reading of the literature indicated he was viewed by others in the field with a degree of circumspection to say the least. Gail Charnley, the then President of the Society for Risk Analysis, whilst not describing him specifically, suggested in an editorial that the whole field of endocrine disruption was a conclusion in search of data. Finally, the very fact that the detractors have to, again and again, refer to the work of a single investigator, or a limited number of his past collaborators, the results of whom others are unable to replicate, should alert them to a problem. In science at least, data does have to be independently verified.”

This independent verification of data becomes one of the key issues in what is the *Journal Sentinel’s* most ambitious venture in its examination of BPA – the decision to conduct its own scientific tests.

### **The \$4,450 test**

On November 16, the *Journal Sentinel* reporters [explained](#) how they had:

“bought canned foods, storage containers, frozen foods and baby bottles at a Wal-Mart in *Milwaukee*. Some of the items were known to contain bisphenol A, or BPA, such as the Rubbermaid Premier container, which has a No. 7 recycling number on its bottom. Reporters also wanted to test items for which it was unclear if bisphenol A was present, such as the frozen-food containers.

Testing for bisphenol A is costly, so a limited number of items were purchased and sent to a laboratory - 10 items in all. For eight of the items, three of each were purchased so that the laboratory could repeat the tests. One can of Enfamil liquid infant formula was bought, as were four Gerber 2nd Foods Hawaiian Delight desserts, which came in packs of two.

Items were sent to XeroAnalytical LLC, based in Columbia, Mo. This laboratory is run by Frederick vom Saal, a BPA researcher at the University of Missouri.

Vom Saal's laboratory is one of the few that repeatedly have looked for bisphenol A levels leaching from food containers. The laboratory has performed testing for other media organizations, though this was the first time he had done media tests of items that had been placed in a microwave.

Julia Taylor, a researcher in vom Saal's laboratory, performed the [experiments](#).

The paper sought outside experts to vouchsafe the results.

### **Patricia Hunt**

The University of Washington’s Patricia Hunt one of three “independent” experts on BPA to evaluate the tests on BPA migration from the microwaved infant products. Hunt found cause for concern:

“This is stuff that shouldn't be in our babies' and infants' bodies,' said Patricia Hunt, a professor at Washington State University who pioneered studies linking BPA to cancer.” (November 16, 2008)

“...Hunt, the Washington State University scientist, called the levels found leaching from the plastic food-storage containers 'real doozies.'”

Hunt was cited by the paper for her earlier research on BPA:

“1998: Patricia Hunt, a geneticist at Washington State University, notices that control mice had many more defective eggs when stored in polycarbonate cages.”

This finding had caused a storm of interest as one of the implications of linking BPA to induction errors in mouse chromosomes was the possibility of a connection between BPA and aneuploidy – a condition where chromosomes are abnormal. Such chronic low-dose exposure to BPA in humans could have a similar effect, it was hypothesized, and thus have serious implications an impact on miscarriage. In 2008, *Scientific American* [quoted](#) vom Saal saying of Hunt “In the field one thing people say is, 'Pat does not get it wrong.'”

But a study paid for by the European Union and Food Safety Authority (Eichenlaub-Ritter et al, 2007), was unable to replicate Hunt's findings. Another EU-funded study (Pacchierotti et al, 2007) administered various oral doses – acute, sub-chronic, and low chronic – of BPA to mice on a daily basis and failed to find any significant effect on chromosome segregation. The researchers concluded that some other factors must have contributed to Hunt et al's findings rather than accidental BPA exposure. Neither of these studies was reported by the *Journal Sentinel* even though they failed to replicate Hunt's findings.

But this is not the only reason why Hunt is a problematic choice to review the vom Saal laboratory results. Hunt and vom Saal are both signatories of the Chapel Hill Consensus, and are the two most prominent scientific voices claiming that BPA is dangerous. They are also co-authors of a [commentary](#) in *Environmental Health Perspectives* (along with other Chapel Hill signatories) criticizing Good Laboratory Practice. Vom Saal has also been a highly public defender and promoter of Hunt's research.

Given the degree to which the paper pursues conflicts of interest among those claiming BPA is safe, it would seem incumbent on the paper to disclose Hunt and vom Saal's common bond. It degrades the pursuit of independent scientific verification to allow a comrade in arms against BPA to review another comrade's work. One might justifiably wonder whether Hunt's evaluation of vom Saal's laboratory is influenced by the view view that 'Fred does not get it wrong.'

### **Angel Nadal**

The second “independent” scientist called on to evaluate the results from Vom Saal's lab was Angel Nadal, a physiologist at the Spanish Biomedical Research Network in Diabetes and Associated Metabolic Disorders in Alicante, Spain. Angel is also a signatory on the Chapel Hill Consensus on BPA, and another co-author of the commentary in *Environmental Health Perspectives* criticizing Good Laboratory Practice. As with Hunt, Nadal found the results from vom Saal's lab “to be of concern for human health.”

### **Nira Ben-Jonathan**

A professor of cancer and cell biology at the University of Cincinnati, Nira Ben-Jonathan has conducted research on BPA exposure and its links to metabolic syndrome, but did not sign on to the Chapel Hill Consensus or the EHP commentary. Ben-Jonathan “was skeptical that such small amounts of BPA could be detected using the laboratory's method,” said the *Journal Sentinel*.

Ben Jonathan and Nadal were dropped from the next stage of the evaluation process, wherein the paper used the results to calculate how much BPA children of varying ages would consume if they ate the products. These figures – not actually enumerated in the feature – “were examined by three scientists: vom Saal, Hunt and Robert Moore, a senior scientist at the University of Wisconsin-Madison,” and found them correct.

Nevertheless, it is troubling, from both a journalistic and a scientific point of view, that vom Saal is partially evaluating the work of his own laboratory. Equally troubling is Moore’s comment to STATS by email on the evaluation:

“I remember speaking with a reporter from the *Milwaukee Journal-Sentinel*. I did check their calculations but that didn’t involved anything beyond what I learned in high school. The main thing I remember is being surprised that they didn’t actually measure BPA concentrations in foods. Instead, what was measured was the BPA concentration in extracts. The reporter said it was all done according to the standard FDA method, but I cautioned her to report the results as surrogate measurements, not as actual concentrations in foods.

The newspaper [story](#) that explained the findings (as opposed to the one cited above, which explained how the testing was done) did not observe this distinction. Instead it reported the findings in a way that suggested that the amounts released (after heating would actually be consumed):

“Products marketed for infants or billed as ‘microwave safe’ release toxic doses of the chemical bisphenol A when heated, an analysis by the *Journal Sentinel* has found... the *Journal Sentinel* identified several peer-reviewed studies that found harm to animals at levels similar to those detected in the newspaper’s tests - in some cases, as low as 25 parts per trillion. Scientists with an expertise in BPA say the findings are cause for concern, especially considering how vulnerable a baby’s development is and how even tiny amounts of BPA can trigger cell damage.”

STATS asked Calvin Willhite, lead author of the NSF International evaluation of the safety of BPA to examine the two articles published in the *Journal Sentinel* on November 16. [See sidebar for Willhite’s comments] he concluded:

“Much of the confusion evident in the *Journal Sentinel* article appears to stem from the fact that the authors failed to appreciate the differences in route of BPA exposure (ingestion vs. injection) and how the different routes of exposure influence the body’s metabolic detoxification and excretion of this substance. In the absence of understanding the role of biotransformation and elimination of BPA in relation to route of exposure, one can arrive at erroneous conclusions about risk to human health posed by trace levels of any material present in our environment.”

The claims the paper makes – including raising the specter of breast cancer – come from studies of BPA exposure in animals that administered BPA intravenously, said Willhite. The test, the comparison, the alarm is meaningless. Children aren’t injecting BPA into their veins, they are ingesting it in food, and as every regulatory body has noted, the effects produced by ingestion are different to injection; when exposure to a chemical is through ingestion, risk assessment should also be based on ingestion. The paper tries to get around this awkward fact by noting that

“Animals tested were fed BPA through pumps under the skin that regularly administered the chemical. Some critics say that method exaggerates the chemical’s effects. But others say it is an acceptable method because newborns are constantly feeding.”

How would readers understand this passage if they knew that “some critics” included the World Health Organization, the Environmental Protection Agency, and the European Food Safety Authority? What editor would allow such a characterization to make it to print if they were truly aware of the degree of opposition within toxicology and pharmacology to assessing the risks of oral ingestion through subcutaneous injection? It skews the entire story. As Willhite notes,

“The various results with BPA studies that used injection are best considered laboratory artifacts and have no relation to a human health risk assessment since a) all human exposure is via ingestion and b) how the body handles BPA by injection or oral routes of administration in the laboratory is so different. One simply cannot extrapolate injection study results in animals directly to humans who receive very small exposures via ingestion. A good example is the reported changes seen in the rodent mammary gland after injection whereas even massive oral doses for the full lifetime showed no changes whatsoever in that same organ.”

Robert Chapin, Chair of the panel convened by Center for the Evaluation of Risks to Human Reproduction (CERHR) to weigh the evidence and come up with a level of scientific concern over BPA agrees. The *Journal Sentinel*'s “fatal flaw is not understanding and accepting that intravenous exposure gives us erroneously high blood levels,” he said by email.

“When BPA is ingested by mouth, it is absorbed through the intestines and then passes through the liver. Enzymes in the gut and liver break it down into inactive metabolites. If you give the stuff under the skin or into veins, it bypasses the metabolism in gut and liver, and levels of the active compound are much higher in the blood. In fact, they never reach these levels after oral exposure. That's why any route other than the oral route is effectively irrelevant UNLESS you also measure blood levels so you know how much active parent is there.”

Durodié is also critical of the incestuous nature of the testing and evaluation:

“The *Sentinel* study is quite remarkable (assuming we can aggrandize it with the label study at all) in allowing Frederick vom Saal to act as judge, jury and executioner. Vom Saal ‘oversaw the newspaper’s testing,’ his laboratory conducted the tests and he then gets to be one of the main commentators about them.

In any other situation, a liberal paper such as this would (to coin a pun) ‘smell a rat’. The conflict of interest transparently evident in vom Saal receiving money for work he then comments on, about an issue he has a well-documented interest in, is quite remarkable.”

## Willhite's critique of the paper's Watchdog report on microwaveable plastic containers

A. The *Journal Sentinel* report states: "The amounts detected were at levels that scientists have found cause neurological and developmental damage in laboratory animals. The problems include genital defects, behavioral changes and abnormal development of mammary glands."

### Observations.

Unfortunately, no publications from the toxicological literature were cited in the newspaper report but it appears the authors neglected the conclusions of the U.S. National Institute of Health's review panel on bisphenol A (BPA). That panel report was convened by the Center for the Evaluation of Risks to Human Reproduction (CERHR) and it can be read in its entirety in *Birth Defects Research* (Part B) Volume 83, pages 157-395. This publication is readily available through the World Wide Web and in most university libraries. On the point about "developmental damage to laboratory animals", the CERHR (2008) concluded:

- "Bisphenol A does not cause malformations or birth defects in rats or mice at levels up to the highest doses evaluated: 640 mg/kg-day (rats) and 1250 mg/kg-day (mice).
- Bisphenol A does not alter male or female fertility after gestational exposure up to doses of 450 mg/kg-day in the rat and 600 mg/kg-day in the mouse (highest dose levels evaluated).
- Bisphenol A does not cause prostate cancer in rats or mice after adult exposure at up to 148 or 600 mg/kg-day, respectively.
- Bisphenol A does change the age of puberty in male or female rats at high doses (~ 475 mg/kg-day).

And

- Rodent studies suggest that bisphenol A causes neural and behavioral alterations related to disruptions in normal sex differences in rats and mice (0.01 – 0.2 mg/kg-day)."

Therefore, the *Journal Sentinel* conclusion that prenatal BPA exposure in rodents causes 'developmental damage' cannot be supported from the available literature. The CERHR (2008) conclusion that rodent studies suggest changes in behavior associated with BPA exposure is based on studies that examined only a single dose level or that studied only one or two offspring per litter. Ordinarily, these studies examine a series of doses and examine all of the members of a litter. Of those that examined more than a single dose level, there was no dose-response relationship – a prerequisite to establishment of cause-and-effect. The studies are highly variable; in some the males were more sensitive, in others the females were more sensitive and in others there were no differences at all. When one takes into account the very efficient intestinal and liver detoxification of BPA after ingestion, it is not clear that any of the extremely small quantities of BPA (sometimes microgram per kilogram of body weight given to the animals in those studies) could survive the trip through the gut and the liver to make it to the brain. Since many of the changes reported are within the range of normal behaviors of these animals, it is not clear there was any actual adverse effect of BPA exposure at all.

Unfortunately, the behavioral and neurological database for BPA suffers from the fact that a rigorous neurobehavioral evaluation of BPA ingestion that meets current US EPA test guidelines has not been conducted. In the absence of sound behavioral studies that evaluate developmental landmarks, motor activity, a functional observational battery with evaluations of learning, memory and startle response, brain morphometry and *in situ* perfusion with routine histopathology taken together with measurements of free BPA concentrations in the brain (if any), it is likely that speculation concerning BPA and its influence on behavior as in the *Journal Sentinel* article will continue.

B. The *Journal Sentinel* report states: "The changes to the mammary glands were identical to those observed in women at higher risk for breast cancer" and it concludes, "But the *Journal Sentinel* identified several peer-reviewed studies that found harm to animals at levels similar to those detected in the newspaper's [extraction] tests – in some cases as low as 25 parts per trillion."

### Observations

The *Journal Sentinel* report neglected to mention that all of the observations of changes in the female rodent mammary gland associated with BPA exposure were made after subcutaneous injections (e.g., *Biology of Reproduction*, Volume 65, pages 1215-1223, 2001; *Congenital Anomalies*, Volume 41, pages 187-193, 2002; *Endocrinology*, Volume 148, pages 116-127, 2007; *Reproductive Toxicology*, Volume 18, pages 803-811, 2004).

(Willhite cont'd)....

In contrast, the U.S. National Toxicology Program in 1982 [Carcinogenesis Bioassay of Bisphenol A (CAS No. 80-05-7) in F344 Rats and B6C3F1 Mice (Feed Study), Technical Report No. 215] concluded based on the results of lifetime BPA feeding studies that “there was no convincing evidence that bisphenol A was carcinogenic for F344 rats or B6C3F1 mice of either sex.” Given the irrefragable fact the animal evidence demonstrates a lack of any carcinogenic effect in both sexes (**including that in the female mammary gland**) based on well-designed and well-conducted lifetime oral exposure studies in at least two appropriate animal species and in the absence of other animal or human data suggesting a potential for carcinogenic effects, BPA can be considered not likely to be carcinogenic to human beings. Since there was no indication whatsoever of preneoplastic or neoplastic changes in the mammary gland of the rats and mice after lifetime ingestion of very high BPA doses (to as much as 148 milligrams/kilogram per day in rats and 1,900 milligrams/kilogram per day in mice), the suggestion that somehow BPA injection studies in rodents are directly relevant to human health is without empirical support.

### Conclusion

It is now well established that 99% of a child’s BPA exposure is due to ingestion (*Environmental Research*, Volume 103, pages 9-20, 2007). It is noteworthy that the *Journal Sentinel* made no mention of actual human oral BPA exposures be they associated with migration from plastics (be they new or used) or from epoxy resins or from other environmental sources (including dust and soil collected in home vacuum cleaner bags). Rather, the *Journal Sentinel* made reference to only selected studies where the animals were exposed by subcutaneous injections.

In their concise review, Kang and associates (*Toxicology* Volume 226, pages 79-89, 2006) compiled many of the BPA exposure studies and concluded that human BPA exposure is less than 1 microgram per kilogram of body weight per day. In a 2008 biomonitoring study of BPA in 257 adults and 30 children (ages 5-6 years) living in the European Union, Volkel and coworkers (*Toxicology Letters* Volume 179, pages 155-162) found that the average daily BPA intake (over the years 2005 to 2008) was 0.03 microgram per kilogram of body weight per day. The highest BPA exposure was 0.233 micrograms per kilogram body weight per day. It is also noteworthy that the data from Volkel et al. (2008) are reasonably consistent with those from 5 other similar studies conducted in Japan and the United States.

Volkel et al. (2008) then calculated what is known as the “margin of exposure;” that is, one compares the Tolerable Daily Intake (a term used in the European Union) or the Acceptable Daily Intake (a term used by US regulatory authorities), to the actual human exposure. The margin of exposure is a ratio of these two amounts, and the higher it is the farther we are away from being exposed to the amounts that could cause adverse effects.

For the 95<sup>th</sup> percentile, the margin of exposure was 5000 and in the worst case (maximum exposure), the margin of exposure was 800. Since most authorities consider a 10-fold exposure over the Tolerable Daily Intake (that is the human exposure is 10 or more times less than the Tolerable Daily Intake) to represent ‘minimal risk’, a BPA exposure between 800 and 5000 is normally interpreted as *de minimis* (trivial) risk.

Another way to compare the data is to contrast the daily doses consumed by the female rats and mice in the National Toxicology Program’s lifetime carcinogenesis bioassay with BPA to a daily human exposure of 1 microgram BPA per kilogram body weight per day, even though exposure is typically significantly lower (Kang et al., 2006). *Using that ratio, the human daily oral exposure is 0.00005% to 0.00067% of that of rats and mice fed BPA each day for their entire life that failed to induce cancer of the mammary gland or other organs.*

Much of the confusion evident in the *Journal Sentinel* article appears to stem from the fact that the authors failed to appreciate the differences in route of BPA exposure (ingestion vs. injection) and how the different routes of exposure influence the body’s metabolic detoxification and excretion of this substance. In the absence of understanding the role of biotransformation and elimination of BPA in relation to route of exposure, one can arrive at erroneous conclusions about risk to human health posed by trace levels of any material present in our environment.

### **“Their decision was absurd”**

One of the other major discussions of the science around BPA in the paper also deserves close analysis, as it again shows how the focus of the paper’s investigation was virtually dominated by vom Saal and his collaborators’ perspective on BPA. This is an extract from a story published in the Journal Sentinel on Jan 23, 2008:

“Another study, funded by the National Institutes of Health, showed that mice exposed in utero had a higher propensity to have prostate lesions than animals that were not exposed. Again, this study was considered of only limited value because the animals were not exposed orally.

In response, Frederick vom Saal, a biologist at the University of Missouri-Columbia and a vocal critic of the panel, decided to test the panel's assumption.

‘Their decision was absurd,’ he said.

‘First of all, fetuses don't eat,’ he said. ‘Anything in maternal blood will freely cross the placenta. And unless the chemical is immediately cleared out of the mother's system, which it isn't, that blood will go immediately to the baby.’

In addition, fetuses and newborns lack, or express at low levels, the liver enzyme that deactivates the chemical.

‘This is not news,’ said vom Saal. ‘Pediatricians will tell you, babies are not little adults. They do not process chemicals the same way adults do.’

To demonstrate this, vom Saal and fellow researchers Wade Welshons and Juliet Taylor exposed 3-day-old female mice to bisphenol A. They separated the mice into four groups.

Two groups were exposed to the chemical through the mouth - one group received a high dose, the other a low dose. Two other groups received injections - again, one high and one low.

Animals were killed at intervals over the next 24 hours, and concentrations of bisphenol A in the blood were measured.

The team found no difference between animals that had received the chemical orally or via injection.

‘It wasn't just that there was no difference,’ said vom Saal. ‘It was exactly the same.’

Vom Saal said that both people and rodents have this particular enzyme, and in both cases, fetuses and newborns do not express it at the same level as adults.

This new research has the potential to upset the panel's findings, said Gail Prins, a researcher at the University of Illinois at Chicago who has been critical of the panel's report.

The bottom line

She said that what really matters in these studies is the concentration of biologically active bisphenol A in the blood, irrespective of how it got there. Animals should have concentrations that are similar to what is found in people, because that is what is relevant in these studies.

However, Robert Chapin, the chairman of the panel, and an executive at Pfizer, said the new research ‘stands in contrast to a number of other studies that show the opposite.’ He said it was those other studies that ‘led us to the logical conclusion we reached.’

When asked to supply the citations for those studies, he said he could not remember them offhand. He also said that if other scientists could replicate vom Saal's work ‘and provide a rational explanation for the sudden shift,’ the panel would reconvene and reconsider its position.

Prins said her lab will take up that challenge immediately.

The *Journal Sentinel* reviewed the panel's report and found several studies that showed differences between oral and non-oral exposures in adult animals, but none that looked at newborns.

When asked to respond to the Missouri study, L. Earl Gray Jr., an Environmental Protection Agency toxicologist and a member of the panel, forwarded a study funded by the American Plastics Society. He said the study, which was reviewed by the panel, suggested that newborn mice have enough of the liver enzyme to deactivate bisphenol A at low doses.

However, the authors of the study, who were from Dow Chemical, reported that 4-day-old mice had a 10- to 18-fold higher concentration of biologically active bisphenol A in their blood than adults - a finding that vom Saal and Prins say supports their contention.

'They had this information right there,' said Prins. 'Yet, they ignored it.'

First, Chapin is not an executive at Pfizer; he is a researcher – the head of the Screening and Investigative Lab in the Developmental and Reproductive Group, where he leads a group of investigative developmental toxicologists and works on mechanisms of male and female reproductive toxicity and fetal developmental toxicology. Before that he was at the National Institute of Environmental Health Sciences, working on mechanisms of male reproductive toxicity. By labeling him an executive it makes it seem as if he is on the business side of Pfizer and not someone with real scientific expertise.

Second, in asking Gail Prins to comment on the validity of vom Saal's critique, the *Journal Sentinel* neglected to mention that vom Saal was co-investigator with Prins on a five year study funded by the National Institute of Health's NIEHS on "Developmental Toxicity of Environmental Chemicals", R01 ES11283. Prins was also a signatory on the Chapel Hill Consensus statement on BPA.

This again raises the issue of cherry-picking seemingly independent experts to comment on the validity of the science or arbitrate a point of dispute in the narrative, when those experts have specific links and perspectives to the science and scientist in question. In effect, Prins is validating her own position in being asked to validate vom Saal. That's fine, but the *Journal Sentinel* should have disclosed that they are co-researchers.

The first substantive issue with the passage is that studies showing the effects of BPA in mice need to be treated with caution. As the European Food Safety Authority cautioned, caution that extrapolating results from toxicity studies on mice was problematic because

"The much higher levels of oestradiol, oestrone and oestriol sustained by the human fetus as compared to the mouse fetus suggest a much lower sensitivity of humans as compared to rats or mice to possible additive effects of weak oestrogens such as BPA (Witorsch, 2002b)."

With respect to the idea put by vom Saal that "*Pediatricians will tell you, babies are not little adults. They do not process chemicals the same way adults do.*" Willhite noted the following via email:

"Adult rats and mice are not just little people - just like people are not just big rats or mice. While it is true that infants and children are not just 'little adults', it is also true that baby rats and baby mice are not baby people."

When we compare the BPA rodent data to the human, we must take into account not only the rates of conjugation but also the ability to eliminate the BPA-glucuronide product of metabolism in the urine; that is why we have integrated methods called "physiologically-based pharmacokinetic models" (like that published for BPA during 2007 in *Toxicology and Applied Pharmacology* Volume 224, pages 182-191). One cannot just "cherry-pick" the data and make interspecies (or even intraspecies) comparisons based on a single factor like a difference in

glucuronidation efficiency.”

Willhite pointed out that there are, therefore, two questions to consider. The difference between rodents and humans in how BPA is metabolized and the difference between people of different ages, genders and races. With the former there are always going to be conditions particular to each chemical, but, writes Willhite,

“[W]e do know that the activity of UDP-glucuronosyltransferase in humans is twice that of the rat. This contributes to the often more rapid (not slower) rate of detoxification of drugs and other chemicals that are processed by phase II conjugation reactions in people than in rats (see *Drug Metabolism and Disposition* Volume 33, pages 1513-1520, 2005).

As to the second question he continues

“Assessing the differences in conjugation capacity between infants, young children and adults must rely on studies with various therapeutic drugs that are metabolized by what are called phase II reactions (as described above and on pages 79-81 of the 2008 review by NSF International published in the *Journal of Toxicology and Environmental Health B* Volume 11). Since the BPA-glucuronide conjugate is eliminated in urine, one must also remember that the infant rate of glomerular filtration (a measure of kidney function) is less than that in the adult so this can prolong the rate of elimination of some drugs and other chemicals in babies compared to adults. This does not mean that a chemical is "more" or "less" toxic in infants than adults, only that the rate of elimination is different.

In humans and rodents, this conjugation (detoxification) is carried out by a set of enzymes called UDP-glucuronosyltransferase. In humans, there is a progressive increase in the activity of this enzyme system with increasing age. Among children less than 11 years of age, the activity of this enzyme system is less than that of adults, but when the rate of its activity is compared on a body surface area basis (a correlation called allometric scaling that can be used to compare differences in metabolic activity between species - say between an elephant and a hummingbird - or between members of the same species) there is actually no difference in enzyme conjugation activity between any of the pediatric age categories and that in the adult (see *Drug Metabolism and Disposition* Volume 34, pages 2097-2102, 2004).

In very young children, these metabolic pathways are not fully mature until ~3 months of age (see *Food Additives Contamination* Volume 15, pages 45-51, 1998). As the infant ages from premature to full term, studies with various drugs show the premature infant is about 4 times less efficient than the adult and the newborn full term infant is about 3 times less efficient than the adult; but for toddlers at 1 year the rates are equivalent to those in the adult (*Developmental Pharmacology and Therapeutics* Volume 16, pages 71-77, 1991). But this is only part of the difference.

If one then examines a broad range of chemicals [as was done by the Connecticut Department of Health and the U.S. EPA], it can be seen that the overall differences between adults and infants in their rates of conjugation and urinary elimination disappear by 2 to 6 months of age. Even more to the point for children ages greater than 6 months, the rates of elimination of some chemicals **can actually be faster** than in adults (see G. Ginsberg, D. Hattis, B. Sonawane, A. Russ, P. Banati, M. Kozlak, S. Smolenski and R. Goble. 2002. Evaluation of child/adult pharmacokinetic differences from a database derived from the therapeutic drug literature. *Toxicological Sciences* Volume 66, pages 185-200). These factors are specific to the particular chemical under consideration - so one cannot make helter-skelter generalizations about the differences in

conjugation and elimination rates between adults, infants and children. It depends on the particular substance - be it a therapeutic drug or an environmental chemical.

Often more important than whether you consider the age of a person, it is their individual genotype that dictates the efficiency of glucuronidation – but this again depends on the specific chemical. One of the best examples happens to be that for estradiol, the most potent physiologic form of the estrogens. Human interindividual differences in conjugation of estradiol vary up to 16-fold (see *British Journal of Clinical Pharmacology* Volume 64, pages 458-468, 2007) – a value greater than the difference between that of an infant and that of an adult. In the case of BPA, however, we know from studies in Korean adults (see *Environmental and Molecular Mutagenesis* Volume 47, pages 571-587, 2006) that there are no metabolic differences between males and females or that depend on lifestyle factors (e.g., tobacco use, ethanol consumption) or differences in expression of enzyme polymorphisms (differences in UDP-glucuronosyltransferase and sulfotransferase) that influence BPA elimination. Therefore, when deriving a reference dose for BPA the standard application of a 10-fold interspecies uncertainty factor encompasses nearly all people.

So at this point with BPA, we don't need to kill more mice. We need the urinary BPA data for infants, then we can compare the daily exposures for infants and other age groups to the oral reference dose calculated from the available and very robust database that already exists in animals to the human level of daily BPA exposure, and then determine the quantitative margin of exposure - as has been done by Dekant and Volkel (Dekant, W. and W. Volkel 2008. Human exposure to bisphenol A by biomonitoring: Methods, results and assessment of environmental exposures, *Toxicology and Applied Pharmacology*, Volume 228, pages 114-134.) for all groups - except for of course the missing infant exposure assessment.

That data has begun to materialize, and it appears to give even further credence to the arguments that the risk of BPA is best assessed from oral exposure rather than injection.



### **New research and a missing piece of the puzzle**

A study [published](#) in April 2009 (A.M. Calafat et al. (2009) Exposure to bisphenol A and other phensols in neonatal intensive care unit premature infants. *Environmental Health Perspectives* Volume 117, pages 639-644. ), provides important evidence that infants – even those born prematurely – are able to detoxify BPA in the same way as adults.

About a quarter of the infants in the study had elevations of free bisphenol A in their urine, which was collected from diapers. But for the majority of the infants, 90 percent of BPA present in their urine was conjugated. As Willhite notes, “the Calafat data do show a substantial capability of even premature infants to conjugate and excrete BPA as contrast to previous assertions that infants are unable to detoxify BPA. “

Of course, it is important to figure out what produced the elevated levels of BPA, and it seems that the authors of the paper suspect medical products and procedures that use polycarbonate plastics in the ICUs. And while they found no indication of any adverse health outcomes associated this non-oral exposure to BPA, they note that:

"Concerns related to BPA toxicity as well as high BPA exposure levels in this sensitive population of low-birth-weight premature infants may justify using [medical] products that do not contain BPA while not compromising the quality of medical care."

Despite this study, which was led by a researcher at the Centers for Disease Control, providing strong evidence that “millions of babies” are not at risk from oral exposure to BPA, and contradicting the assertions that babies cannot process the chemical in the same way as adults, the study received no coverage in the media.

### **Cherry picking and over-interpretation.**

There are a few other reporting issues in Chemical Fallout worth noting. On September 17, the *Journal Sentinel* reported on a new study published in the *Journal of the American Medical Association* (Lang et al) which claimed that adults with higher levels of BPA metabolites in their urine had “significantly increased risk of heart disease, diabetes and liver abnormalities.”

The piece was written by John Fauber, who was not a regular contributor to the Chemical Fallout series, and he entered a note of caution in interpreting the results to mean that BPA was the cause of these diseases, driven by a similar reservations among the researchers about the limits of a cross-sectional study: “However the methodology used in the research is not definitive and the study did not provide proof that bisphenol A was the cause of the increased disease risk.” Fauber had two scientists weigh in on the study pro and contra – the former an epidemiologist who has long warned about trace exposures to chemicals, the latter warning that people who eat a lot of fast food could be simply exposing themselves to more BPA via the food packaging. In all, it was one of the most balanced, least alarmist pieces in the paper’s coverage of the chemical. But when the journalists who normally wrote about BPA for the paper, Susanne Rust and Meg Kissinger, mentioned the study, its limitations disappeared:

“A second, published today, found that bisphenol A is correlated with an increased risk of heart disease and diabetes in adults.” (September 17, 2008)

“A study published last month in the *Journal of the American Medical Association* linked bisphenol A to heart disease.” (October 19, 2008)

“Bisphenol A, developed as an estrogen replacement, has been linked to heart disease and diabetes in humans,” (November 1, 2008)

“A study published in the *Journal of the American Medical Association* in September tied BPA to heart disease in humans.” (November 16, 2008)

“BPA, used to make baby bottles and the lining of metal food cans, including those containing infant formula, is tied to reproductive failures, breast cancer risk, diabetes and heart disease.” (November 18, 2008)

“BPA has been linked to heart disease and diabetes in humans.” (December 4, 2008)

“The chemical has been linked to heart disease and diabetes in humans.” (December 16, 2008)

There turned out to be good grounds for Fauber’s more cautious evaluation of the study. On October 19, the European Union’s Food Safety Authority published a statement on Lang et al, noting that the dataset it used was:

“...an estimation of the exposure to BPA within 24 hrs of sample collection. However, there is no information on exposure during the time needed for development of diseases such as diabetes and cardiovascular conditions or changes in plasma liver-enzyme activities.

Although the study authors attempted to rule out several commonly identified confounders of studies of this type, the observed association between urinary BPA elimination and the conditions mentioned above may have been a chance finding or may be due to non-identified confounders.”

EFSA concluded that the study did “not provide sufficient proof for a causal link between exposure to BPA and the health conditions mentioned above.” The paper did not report this reaction.

In February of this year, the National Institute for Statistical Sciences [published](#) a critique of the JAMA paper by Dr. Stanley Young, Assistant Director of Bioinformatics, and an expert on data mining, and Min Yu of the University of British Columbia.

“Young and Yu note that the CDC National Health and Nutrition Examination Survey [2003-2004] that was used in Lang et al’s study measured 275 environmental chemicals and a wide range of health outcomes. Although the Lang et al study focused on one chemical and 16 health outcomes, Young and Yu note that it is important to focus on how many questions were at issue. They point out that with 32 possible health outcomes, including combinations, potentially associated with any of the 275 chemicals, along with multiple confounders and statistical models, there could be as many as approximately 9 million statistical models available to analyze the data. Given the number of questions at issue and possible modeling variations in the CDC design, Young and Yu conclude that the findings reported by the authors could well be the result of chance rather than representing real health concerns.”

Young and Yu’s criticism was published as a letter in the February 18 issue of JAMA.

The *Journal Sentinel* did not report Young and Yu’s criticism of the study and their warning that mining the CDC survey could throw up all manner of false conclusions. This isn’t especially surprising, as one of the general features of the way the media report scientific research is a rush to publish novel or alarming findings and a corresponding reluctance to follow up when those findings turn out to be more limited than originally advertised.

But the way the JAMA study was absorbed into the *Journal Sentinel*’s narrative – as with all the other research claiming increased health risks – illustrates the power of journalism’s confirmation bias: anything showing a risk is confirmation not only that there is a risk but that evidence to the contrary is not really evidence at all.

### **The NTP Draft Report**

This tendency to cherry pick and over-interpret was also evidenced by how the *Journal Sentinel* reported the conclusions of a draft report on BPA by the National Toxicology Program on April 16, 2008:

For the first time, the federal government said Tuesday that a chemical found in commonly used products such as dental sealants, baby bottles and aluminum cans is potentially dangerous to human development and reproduction.

The new report by the National Toxicology Program heightens concern about bisphenol A, a chemical found in the bodies of 93% of Americans recently tested. It overrides conclusions reached by a panel in November that found minimal concern that bisphenol A could cause

prostate and breast problems or early puberty for young children or those who were exposed to the chemical in the womb.

"The possibility that bisphenol A may alter human development cannot be dismissed," the report says.

The report is a compilation of the work of two panels convened last year by the National Institutes of Health. One was made up of scientists with expertise in bisphenol A. The other was a panel of scientists with no direct expertise in the chemical."

The paper turned to a spokesperson from the Natural Resources Defense Council, and Frederick vom Saal, to comment on the draft's significance:

"Scientific experts on bisphenol A said the findings should force the FDA to reconsider an earlier ruling that the chemical is safe for all to use.

'This leaves the FDA with little wiggle room,' said Frederick vom Saal, a researcher at the University of Missouri and one of the nation's leading experts on bisphenol A. "Their position of no concern looks ridiculous in light of these new assessments."

The specific reporting on the NTP draft is somewhat misleading. As the NTP notes:

"The Draft NTP Brief on Bisphenol A is not a quantitative risk assessment, nor is it intended to supersede risk assessments conducted by regulatory agencies. The Draft NTP Brief on Bisphenol A is intended to serve as an environmental health resource for the public, as well as regulatory and health agencies."

In other words, its goal is to give a *qualitative* assessment, which makes it, perhaps, harder to determine what the risk is. The NTP uses five categories of "concern" in non-technical language and in order of worry: negligible concern, minimal concern, some concern, concern, and serious concern. The brief was based on the conclusions of an expert panel, public comments, and additional scientific papers not used by the panel of experts (either because they had been dismissed or because they were published after the panel convened).

The draft report concluded that there was

1. *some concern* for neural and behavioral effects in fetuses, infants, and children at current human exposures.
2. *some concern* for bisphenol A exposure in these populations based on effects in the prostate gland, mammary gland, and an earlier age for puberty in females.
3. *negligible concern* that exposure of pregnant women to bisphenol A will result in fetal or neonatal mortality, birth defects, or reduced birth weight and growth in their offspring.
4. *negligible concern* that exposure to bisphenol A causes reproductive effects in non-occupationally exposed adults and *minimal concern* for workers exposed to higher levels in occupational settings.

The "bottom line" according to the NIEHS website on whether BPA affect human development or reproduction?

"Possibly. Although there is no direct evidence that exposure of people to bisphenol A adversely affects reproduction or development, studies with laboratory rodents show that exposure to high

dose levels of bisphenol A during pregnancy and/or lactation can reduce survival, birth weight, and growth of offspring early in life, and delay the onset of puberty in males and females. Recognizing the lack of data on the effects of bisphenol A in humans and despite the limitations in the evidence for "low" dose effects in laboratory animals, the possibility that bisphenol A may impact human development cannot be dismissed. More research is needed.”

As Michael D. Shelby, PhD, director of the National Toxicology Program's Center for the Evaluation of Risk to Human Reproduction told WebMD, the evidence from rodent studies was “very limited,”

“But our conclusion was that we couldn't dismiss the possibility that similar effects might occur in humans. This is a very controversial area with obvious differences in the way different groups have interpreted the data. We have tried to do it in as scientifically sound and thorough means as we could. Even in the areas where we've expressed some concern, the literature is not consistent on the endpoints reported. Some people find these effects; others may not, and their relevance to effects on human health -- there's still some uncertainty about that. That's why we didn't have a lower or higher level of concern in our conclusions.”

As already noted, a couple of months later the European Food Safety Authority – along with several environmental and health agencies in European countries dismissed the research that the NTP used to justify “some concern” as being poorly done. And the Food and Drug Administration appeared to reach the same conclusion by the same route, much to the fury of the *Journal Sentinel* and the signatories of the Chapel Hill Consensus.

The paper spent a lot of time trying to show that the FDA relied on industry-funded studies to justify its position, but as the paper never cites the actual studies in any of its reporting and appears to use no scientific or statistical criteria to decide whether the conclusions are robust or not on any given scientific study – apart that is from adducing rigor to, and relying on interpretation from, the designated “experts” on BPA such as vom Saal – it will suffice to say that the FDA’s position simply mirrors that of Europe, NSF International’s risk assessment, Germany’s risk assessment, etc.

Again, one can think of many interesting questions a reporter could have asked, namely, why is there a difference between multiple *quantitative* risk assessments – independent and governmental, domestic and international, and even industry-funded (for the sake of convenience, this analysis has ignored the numerous industry-funded assessments, from Gradient and Harvard’s Center for Risk Analysis, which all concur with the no risk view of BPA ) compared to the one *qualitative* risk assessment.

It’s worth noting the paper’s suggestion that chemical regulation is in the hands of people who are not “experts” in the specific chemicals being regulated as if there weren’t general scientific and statistical principles underlying chemistry, toxicology, and risk evaluation. This appears to be a rather bald rhetorical attempt to invalidate any findings that do not include the work of the Chapel Hill Consensus – because only those signatories are “experts” on BPA. And this, in turn, results in a rhetorical situation where anyone who testifies to BPA’s safety is not an “expert,” even if they have actually done research on BPA, because the *real* “experts” have found it dangerous. In other words, the *Journal Sentinel* ends up protecting its sources and, therefore, its investigation by engaging in a PR offense.

One could have imagined the *Journal Sentinel* going beyond the magic circle of sourcing that went from vom Saal to other Chapel Hill signatories to the activist groups and then back to vom Saal. But the paper never took that journalistic leap. It was trapped by its thesis. It was no longer engaged in journalism, but had joined the magic circle as a true believer, a source of novel “scientific” research, an “independent” activist group that was only interested in the public good.

### The Oakes Award in Environmental Reporting

Given that the *Journal Sentinel's* reporting on BPA simply left out the scientific research that disagreed with its thesis, wrongly dismissed the relevance of key methodological approaches in statistics and toxicology, and never gave critics of vom Saal and the Chapel Hill Consensus a fair hearing, it is hardly surprising that prize juries composed of journalists failed to spot these faults; they would have to be familiar with the National Toxicology Program and EFSA reports at the very least – reading encompassing hundreds of pages of technical material and statistical arguments.

But there are other reasons why, for instance, Columbia's decision to give the John B. Oakes Award in Environmental Reporting to the *Journal Sentinel* raises concerns about its jury's ability to consider the other side of the story.

Jury member Douglas Barasch is editor in chief of *On Earth* magazine, the quarterly publication of the Natural Resources Defense Council (NRDC). The NRDC [petitioned](#) the Food and Drug Administration to ban BPA in October 2008 and previously campaigned against the chemical. The *Journal Sentinel* cites the NRDC on April 16:

“This is the first federal agency to raise significant concerns about bisphenol A, and it affirms our view that it is potentially harmful to fetuses and children,” said Sarah Janssen, science fellow with the Natural Resources Defense Council. “This goes beyond what the committee originally identified as problems.”

Additionally *On Earth* magazine ran a story in 2006 called “Bad Chemistry,” which exclusively sources scientific concerns about BPA to Frederick vom Saal's ‘paradigm changing’ research and that of Patricia Hunt – essentially, the same sources driving the *Journal Sentinel* investigation. *On Earth* makes no attempt to address the methodological and statistical reasons that both scientists' research has not played pivotal roles in risk assessment anywhere in the world, merely reiterating the industry-funded nature of the criticism.

Jury member Jonathan Z. Larsen is also an editorial board member of *On Earth* and a trustee of the NRDC.

Jury member Dorothy Brown is a special projects editor at the Philadelphia Inquirer, the paper ran several pieces on the risks from BPA, the most recent, a [feature](#) in paper's magazine in April 26 2008 – “Plastic peril?; An Ursinus College researcher is convinced that a compound in products from baby bottles to helmets is a hazard to health. And others agree.” The paper also reported on Patricia Hunt's research in 2003, citing vom Saal as to its significance. In both cases, the reader is left with the overwhelming impression that BPA is dangerous. Any dissent to this perspective within the stories is largely sourced to chemical industry representatives.

(Oakes price cont'd)

Jury member Steve Curwood is the executive producer and host of National Public Radio's *Living On Earth*. The show has had several pieces on BPA. "War of the Sciences" in 2008 [features](#) vom Saal saying BPA:

"causes breast cancer, prostate cancer, low sperm count in males. If you take every major human health trend, bisphenol A causes that in animals."

The segment largely consists of vom Saal challenging the FDA's decision not to ban BPA, a position which is explained by the agency's Laura Tarantino.

The program also devoted a [show](#) to BPA in 2007, with its primary source being Ana Soto, a researcher at Tufts University School of medicine who collaborated with vom Saal on a 1993 paper launching the endocrine disruptor hypothesis. Soto is a signatory on the Chapel Hill Consensus and is cited by the *Journal Sentinel* in support of the thesis that BPA is risky. The segment also had a quote from Robert Chapin, chair of the expert panel convened by the National Toxicology Program to review the evidence on BPA. Chapin said he found little reason for concern based on his panel's evaluation of the evidence thus far.

The show also [interviewed](#) Nira Ben Jonathan, one of the experts the *Journal Sentinel* used to evaluate its study on BPA migration. Curwood also hosted vom Saal as a guest on the show to [explain](#) his thesis on BPA in 1997.

A search of *Living On Earth* failed to turn up any interviews with researchers who have challenged the BPA is dangerous thesis. In contrast, most of its coverage appears to be driven by the perspective that the chemical is a threat to the public..



## Conclusions

The public good is best served by open scientific debate governed by analytical and statistical rigor. Let's assume that tomorrow legislators in the U.S. decide to ban BPA from everything because the "possibility" that it might cause harm has alarmed so many people in the U.S. that it is politically unfeasible not to take drastic action. But what if removing BPA on the thinnest scientific grounds actually results in greater harm to the public? What if the protective value it confers in can linings is diminished or its replacement turns out to be measurably more toxic. What if some of the parents who turned to glass bottles for fear of polycarbonate "leaching" BPA drop and break them, causing injury to their babies? How often has this happened and might happen? We know now that even premature babies can process most of their exposure to BPA as adults, but what protection is there from flying glass? These are the kinds of questions – the inadvertent consequences to over-reacting to the perception of risk – that are routinely missing from the media's coverage of BPA and other chemicals and threats to our health.

It speaks to a philosophical chasm between journalism and science. The real give away – the real unyielding signal of bias at the *Journal Sentinel* – is not in what the paper failed to report but in the way it reported. One can argue about the motives behind the omission of so much contrary evidence and one can and should question the competence of the reporters at the paper to understand basic toxicology, experimental design and statistical reliability. In all of these areas, the *Journal Sentinel* failed to show *interest*, let alone competence. This is an enormous disservice to the public because these are the principles upon which we decide what is good science.

But the harshest criticism draws from something much simpler: the paper never raises any serious questions about the science that supports its contention that BPA is a risk. The evidence for BPA being dangerous to humans is always reported in a way that renders it unimpeachable. It is always perfect – completely right – while the opposing evidence is always imperfect and corrupted by scientific flaws or conflicts of interest. The *Journal Sentinel*, in other words, doth protest too much. Criticism, for the paper’s reporters, goes only one way; they decided from the outset that the position held by Frederick vom Saal and the Chapel Hill Consensus was the right one, and sourced and reported their investigation in a way that subtly and not so subtly excluded anything that might cause readers to think twice about what they were being told.

**The paper never raises any serious questions about the science that supports its contention that BPA is a risk. The evidence for BPA being dangerous to humans is always reported in a way that renders it unimpeachable. It is always perfect – completely right – while the opposing evidence is always imperfect and corrupted by scientific flaws or conflicts of interest.**

Few scientific papers end without discussing in what ways their results need to be improved, or treated with caution; and yet the *Journal Sentinel* never seems interested in even pausing for a moment to test its own position – its cherry picked body of research – against the possibility that it may have limitations or flaws – or may not be consistent or complete. There is no experimental disinterest seeking to test their strongest evidence against the strongest possible arguments that it could be really weak or wrong. There is just the relentless underlying assertion of power: we know the truth.

That this investigation won the paper so many journalism awards has made it practically impossible to backtrack – and the same approach, the same sourcing is now driving the paper’s 2009 coverage of BPA. Why did journalists accord the *Journal Sentinel* so many laurels? The answer is simple: who among the judging panels read the various risk assessments? How many journalists understand the basics of toxicology, let alone the kind of statistical designs that make one BPA study better than another? How would they have voted if they had been aware of the way the *Journal Sentinel* skewed the story on BPA to exclude such a vast array of regulatory research finding the chemical safe?

Of course, research finding that a chemical is safe doesn’t make a news story, let alone an investigation that wins awards. Finding that regulators are doing an okay job is not a story. Finding a crisis, a derogation of duty, an industry-driven cover up, that is the stuff of journalism, a story that will win awards. And so the most basic skepticism was abandoned. The obvious journalistic question – if this scientist’s claims are being dismissed across the world, shouldn’t we check him out? – wasn’t asked.

The basic scientific questions that confront anyone looking at the evidence on BPA weren’t asked: If all the large scale rat and mouse multi-generation studies and the NTP lifetime carcinogenesis bioassays in rats and mice turned up nothing on BPA and they administered BPA orally, and 99 percent plus of our exposure to BPA is oral, why would we focus overwhelmingly on the results of injection studies? How is injecting BPA into the brain of a mouse a realistic measure of our exposure risk?

If reporters don’t ask these kinds of questions, they end up writing PR for one side or the other in a controversy. Again, the point is not even about determining the truth – it’s about framing the story in a way in which the truth can be found.

There is also the issue of a powerful double standard that journalists seem incapable of extricating themselves from in stories where charges are leveled against industry: if you are going to raise questions

about motives, those questions cannot just be directed at one side in a controversy. In other words, what sort of vested interest did the Chapel Hill Consensus have in keeping the threat of BPA in the news? How much government research money has been spent and is available to spend in investigating the dangers of BPA? Do the tightening of research protocols on BPA at the NIEHS raises questions about the way that organization has been spending government money? Just how much money was wasted on studies that detracted rather than added to our sum of reliable knowledge because of their experimental design? How much money is being wasted on academic studies of dubious value across government?

If a story emerges from BPA, it is that new perspectives are needed in news rooms when it comes to reporting risk and regulation.

The problem is, of course, that industry still labors under the over-arching narrative exposé of the past – Ralph Nader’s invaluable and shocking investigation into car safety, the burying of evidence of the harm from cigarettes, the methyl mercury cover-up at Japan’s Minamata Bay, and the manipulation of research for Monsanto at its contract lab. The suspicion of industry malfeasance is a journalistic reflex encapsulated in the phrase, “follow the money.” But when this suspicion becomes so engrained that journalists start ignoring evidence and statistical rigor and basic science in order to prosecute industry and government regulation, and when they forget to follow the numbers in the data and focus only on the numbers paying for the data, journalism has gone badly wrong.

In this context, the bravado of the *Journal Sentinel* calling for an end to scientific debate on BPA and a ban on the chemical is remarkable. In effect, a small regional newspaper in the U.S. has declared its powers of scientific discernment to be far superior to and more reliable than the regulatory work of the U.S., Europe, Japan, and Australia and New Zealand. What’s even more remarkable is that many people – including legislators – have chosen to believe the paper’s account of BPA over all these expert bodies.

It can only be hoped that the consequences of the *Journal Sentinel*’s crusade – and similar stories by other news organizations relying exclusively on the same partial sourcing – will not afflict us all in some unforeseen way that only a rigorous, disinterested presentation of the science could have prevented. As the Swiss Federal Office of Public Health FOPH (Bundesamt für Gesundheit BAG) dryly explained in rejecting a ban on BPA:

“A ban on BPA would inevitably cause manufactures of packaging and consumer products (food contact materials) to have to switch to other substances, the toxicity of which is less well known. This would mean a well characterized risk would be replaced with a conspicuously unpredictable risk.”

When journalism’s prosecutorial zeal ignores this kind of precautionary thinking, and legislators take their scientific cues from journalists and not scientists, we are all at risk.