

Studies on Chemical In Plastics Questioned

Congress Examines Role Of Industry in Regulation

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Despite more than 100 published studies by government scientists and university laboratories that have raised health concerns about a chemical compound that is central to the multibillion-dollar plastics industry, the Food and Drug Administration has deemed it safe largely because of two studies, both funded by an industry trade group.

The agency says it has relied on research backed by the American Plastics Council because it had input on its design, monitored its progress and reviewed the raw data.

The compound, bisphenol A (BPA), has been linked to breast and prostate cancer, behavioral disorders and reproductive health problems in laboratory animals.

As evidence mounts about the risks of using BPA in baby bottles and other products, some experts and industry critics contend that chemical manufacturers have exerted influence over federal regulators to keep a possibly unsafe product on the market.

Congressional Democrats have begun investigating any industry influence in regulating BPA.

"Tobacco figured this out, and essentially it's the same model," said David Michaels, who was a federal regulator in the Clinton administration. "If you fight the science, you're able to postpone regulation and victim compensation, as well. As in this case, eventually the science becomes overwhelming. But if you can get five or 10 years of avoiding pollution control or production of chemicals, you've greatly increased your product."

Mitchell Cheeseman, deputy director of the FDA's office of food additive safety, said the agency is not biased toward industry.

"The fact is, it's industry's responsibility to demonstrate the safety of their products," he said. "The fact that industry generated data to support the safety I don't think is an unusual thing."

The FDA's position on the compound was called into question earlier this month when a National Institutes of Health panel issued a draft report linking BPA to health concerns. Since then, Canadian regulators have banned BPA in baby products, and [Sen. Charles E. Schumer](#) (D-N.Y.) has introduced a bill to prohibit some uses of the compound. Ten states, including California and Maryland, are weighing their own restrictions.

U.S. manufacturers produce 7 billion pounds of BPA annually, and business worldwide has been growing about 4 percent a year, driven by rising demand in Asia. A U.S. government ban on BPA would affect thousands of businesses and perhaps billions of dollars in profit for its largest manufacturers.

As part of his investigation, [Rep. John D. Dingell](#) (D-Mich.), chairman of the House Energy and Commerce Committee, wants to examine the role played by the Weinberg Group, a Washington firm that employs scientists, lawyers and public relations specialists to defend products from legal and regulatory action. The firm has worked on Agent Orange, tobacco and Teflon, among other products linked to health hazards, and congressional investigators say it was hired by Sunoco, a BPA manufacturer.

Dingell has asked the Weinberg Group for all records related to its work in connection with BPA, including studies it has funded and payments made to experts. He cited a letter written by a company vice president in 2003 as Weinberg managed opposition in a long-running regulatory battle over a compound in Teflon. The strategy would be to discourage "governmental agencies, the plaintiffs' bar and misguided environmental groups from pursuing this matter any further," the letter said.

In a statement, Dingell said, "The tactics apparently employed by the Weinberg Group raise serious questions about whether science is for sale at these consulting groups, and the effect this faulty science might have on the public health."

Matthew Weinberg, the firm's chief executive, declined to be interviewed. But in a brief written statement, he said the company will cooperate with Dingell's investigation.

"The analyses we conduct are rigorous and adhere to established principles of scientific integrity," the statement said. "We believe it is in the public interest for all scientific research to be subject to scrutiny and the views of all affected parties to be heard."

Scientists first flagged possible health risks of BPA more than a decade ago. From 1997 to 2005, 116 studies of the compound were published, many of them focused on its effects in low doses. Of those funded by government, 90 percent showed a health effect linked to BPA. None of the industry-funded studies found an effect; all of them said BPA is safe.

There is a clear bias in studies funded by industry, said Michaels, who now runs the Project on Scientific Knowledge and Public Policy at George Washington University and wrote the book "Doubt is Their Product," which details how various industries have used science to stave off regulation.

"This is a great example of the funding effect," he said. "It's not so much because scientists are shaving the truth, but they ask questions in a way to give them the answers they want."

Sharon Kneiss, vice president of products divisions for the American Chemistry Council, said in a conference call with reporters two weeks ago that industry research is unassailable. "We make it a policy to supply government agencies with data, and we have done it in the case of BPA," she said. "We supplied studies following the highest levels of quality in terms of their study. We stand behind the quality of the studies."

The FDA and the Environmental Protection Agency both regulate BPA. Because the compound is most readily absorbed through food and drink, the FDA plays a critical regulatory role because it approves the compound's use in plastic food containers, bottles, tableware and the plastic linings of canned foods.

For much of the regulatory history of BPA, traditional toxicology was used to assess risk to people -- researchers tried to find the threshold amount above which BPA would cause cancer, malformation or death.

Sarah Vogel, who holds a master's degree in public health and is writing a doctoral dissertation at Columbia University on the politics and scientific history of BPA, said that because practical use of the compound was at levels much lower than the amount deemed toxic, scientists assumed it was safe. "The idea was: Look, this stuff is at such low levels, it really couldn't effect any harm," she said.

A decade ago, Frederick vom Saal, a reproductive scientist at University of Missouri at Columbia, came up with a different research strategy. He theorized that because BPA can mimic estrogen, a female sex hormone, minuscule amounts introduced to fetuses or infants could change cell structure and cause significant health problems later in life. He found that doses 25,000 times below what the government has labeled as safe harmed developing cells in mice.

In 1997, after he submitted his first study for publication in a peer-reviewed scientific journal, vom Saal said he was visited by a group of scientists including John M. Waechter of Dow Chemical, a manufacturer of BPA. According to vom Saal, Waechter began the meeting by expressing a hope for "some mutually beneficial outcome" if vom Saal held off on publication until a replicate study could be performed. Vom Saal refused, and, six weeks later, sent a pointed letter documenting the exchange to plastics industry representatives, including Waechter, and an FDA official.

Dow declined to make Waechter available for an interview. Spokesman Mark Walton said vom Saal misunderstood Waechter. "We categorically reject any suggestion that what we did was in any way unethical," he said.

Thomas A. Clare, a lawyer with Kirkland & Ellis, representing Dow and Waechter, said in a letter to The Washington Post that the "mutually beneficial outcome" to which Waechter referred was a "meaningful exchange of scientific ideas" with vom Saal, and that Waechter had never asked vom Saal to delay or withdraw his research. Clare also said that Waechter met with vom Saal as a representative of a Society of Plastics Industries task force studying BPA and not on Dow's behalf. Clare said that the SPI task force had already submitted vom Saal's research to the EPA before the two men met to discuss the study.

As the country's preeminent BPA researcher, vom Saal finds that his work is regularly attacked by the chemical industry. "We were not prepared at all for walking into a political minefield," said vom Saal, whose research is funded by foundations and the National Institutes of Health.

The chemical industry, meanwhile, has funded scientists who have served on expert review panels that advise the government about the safety of chemical compounds.

Last year, NIH convened two panels to help it analyze BPA risks. One panel, led by vom Saal, consisted of 38 international experts on BPA who work for universities or governments. Last August, it found a strong cause for health concerns, including cancer and early puberty.

The second panel included 12 scientists, none of whom had worked on BPA. In November, it found "some concern" about neurological effects of the compound in children but minimal concern that it would cause cancer or early puberty. The second group relied on Sciences International, an Alexandria-based consulting firm, to choose and summarize research for panel members.

The government later learned that Sciences International had done work for Dow and BASF, two BPA manufacturers. After inquiries by [Rep. Henry A. Waxman](#) (D-Calif.) and [Sen. Barbara Boxer](#) (D-Calif.), the government canceled its contract with the firm and audited its work. The panel reported "minimal" concern about the compound's impact on reproduction and development while saying it had "some concern" about effects on neurological development.

On April 15, the National Toxicology Program, part of NIH, issued a draft report acknowledging "some concern" about the risk of cancer, diabetes and other serious health problems in adults. The new report considered dozens of studies that the earlier panel had rejected and reviewed more than 400 studies published between April 2007 and February.

"That was the big change -- a decision was made to consider different sorts of studies in the evaluation," said Michaels, the former federal regulator.

In response to recent findings and media reports, Cheeseman said that FDA Commissioner Andrew C. von Eschenbach has created an agency task force to examine BPA but that the agency maintains it is "absolutely safe" for use in food and medical products.

Vom Saal said a flood of recent BPA studies have validated his work. "The scientific community basically said, 'This argument is over,' " he said. "It ended a long time ago. There's only an illusion of a controversy created by a well-financed public relations outfit. The idea that the FDA tells people this is safe is offensive."