



**Chemical Fallout:  
Milwaukee *Journal Sentinel* and the BPA story  
Epilogue**

The Milwaukee *Journal Sentinel* ran a two-part series entitled “Chemical Fallout.” The first article, which appeared on November 24, 2007, beneath the headline: “Are your products safe? You can’t tell,” provided an overview of endocrine disruptors, a history of the government’s response, and its failure to screen the chemicals for their effects on the endocrine system. The piece provided a range of opinions on the issue, included Frederick vom Saal’s “chemical audit” of Ellen Lang Roder’s home and a section on the work of consumer groups “trying to answer some of the questions that the government is not.”

The second article appeared on December 2, beneath the words: “WARNING: The chemical bisphenol A has been known to pose severe health risks to laboratory animals. AND THE CHEMICAL IS IN YOU.” The piece focused on bisphenol A, including its background, development, and suspected links to a range of illnesses. It then zeroed in on the *Journal Sentinel*’s own investigation into the 258 BPA-focused studies and work of the National Toxicology Program’s 12-person panel. The conclusions were damning. Government assurances regarding bisphenol A’s safety were, the *Journal Sentinel* stated, based on “outdated, incomplete government studies and research heavily funded by the chemical industry.”

Local reaction to the articles was swift. Milwaukee mothers stopped buying baby bottles containing BPA, prompting local stores to instead stock ones made of glass and BPA-free plastic. The paper said that it received no demands for retraction or requests for clarification from the chemical industry regarding the series. But that did not mean the controversy was over. In the months following the story, bisphenol A continued to spark debate and action, which the *Journal Sentinel* continued to cover extensively in articles and online blogs.

In April 2008, for example, Wal-Mart, Toys “R” Us, and Babies “R” Us announced that they would phase out baby bottles containing BPA. The same month, the Food and Drug

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Administration (FDA) convened a task force on the safety of the compound, and released a draft report on August 15 declaring it to be safe. On September 3, however, the National Toxicology Program issued its own final report on BPA safety, concluding that human exposure to the chemical was of “some concern” for brain and prostate gland development, and for behavioral effects in fetuses, infants and children.

Further developments followed in October 2008, when the attorneys general of Connecticut, New Jersey and Delaware appealed to 11 companies that made baby bottles and formula containers to stop using the chemical. Meanwhile charges of corruption emerged against some BPA oversight figures. On October 11, Rust and Kissinger wrote an article that questioned the impartiality of Dr. Martin Philbert, the chairman of the FDA panel charged with evaluating the safety of BPA. Their article prompted a congressional committee to launch an investigation into possible conflicts of interest. A week later, on October 18, Canada became the first country to declare the chemical a toxin and hazardous to human health, opening the door for regulatory action.

With pressure on them mounting, chemical companies and baby-formula makers in early November 2008 said that they would intensify efforts to develop new products without BPA and find a substitute for the compound. On December 15, the FDA stuck with its ruling that bisphenol A was safe, telling members of its advisory board in a letter that it would survey more studies and conduct more research, but would continue to rule BPA safe unless new research indicated otherwise.

Kissinger, Spivak and Rust received a number of accolades for their “Chemical Fallout” articles, including a 2007 Sigma Delta Chi Award for excellence in journalism and, in April 2008, a Society of American Business Editors and Writers award for best project at a large newspaper. The following month, “Chemical Fallout” was the subject of a Bill Moyers “Expose” PBS program. In September 2008, the Wisconsin Public Health Association recognized Rust for her “Chemical Fallout” reporting, and in October 2008, the story received honorable mention in the prestigious Barlett & Steele awards for business investigative reporting.

## Appendix 1

### **“Are Your Products Safe? You Can’t Tell; labels often fail to list compounds that can disrupt biological development”**

By Susanne Rust, Cary Spivak and Meg Kissinger of the *Journal Sentinel*

November 24, 2007

[See: <http://www2.jsonline.com/story/index.aspx?id=689731>]

Take a look at your shoes, your shampoo, your carpet.  
Your baby's bottles, even the dental sealants in your mouth.  
These products contain chemicals that disrupt the natural way hormones work inside of you.  
The chemicals known as endocrine disruptors are all over your house, your clothing, your car.  
The chemicals are even in you.  
They promise to make skin softer, clothes smell fresher and food keep longer.

The problem is, neither the companies that make these products nor federal regulators are telling you that some of these substances may be dangerous. Many have been found to cause life-threatening illnesses in laboratory animals.

Chemical makers maintain that their products are safe. They point to government assurances and the millions of dollars they have spent on their own research as proof.

But a growing number of scientists are convinced the chemicals interfere with the body's reproductive, developmental and behavioral systems.

Hundreds of studies have shown that these compounds cause a host of problems in lab animals. They include cancers of the breast, brain and testicles; lowered sperm counts, early puberty, miscarriages and other defects of the reproductive system; diabetes; attention deficit disorder, asthma and autism - all of which have spiked in people in recent decades since many of these chemicals saturated the marketplace.

A Journal Sentinel investigation found that the government has failed to regulate these chemicals, despite repeated promises to do so. The regulatory effort has been marked by wasted time, wasted money and influence from chemical manufacturers.

The newspaper reviewed more than 250 scientific studies written over the past 20 years; examined thousands of pages of regulatory documents and industry correspondence; and interviewed more than 100 scientists, physicians, and industry and government officials.

Among the findings:

- U.S. regulators promised a decade ago to screen more than 15,000 chemicals for their effects on the endocrine system. They've spent tens of millions of dollars on the testing program. As yet, not a single screen has been done.

- Dozens of chemicals the government wants to screen first have already been tested over and over, even while thousands of untested chemicals are waiting to be screened.

- By the time the government gets around to doing the testing, chances are the results will be outdated and inconclusive. The government's proposed tests lack new, more sensitive measures that would identify dangerous chemicals that older screens could miss.

- As the U.S. testing process remains grounded, hundreds of products have been banned in countries around the world. Children's products - including some baby toys and teething rings - outlawed as dangerous by the European Union, Japan and Canada, are available here without warning.

- Lacking any regulation in the U.S., it's impossible for consumers to know which products are made with the dangerous compounds. Many companies don't list chemicals known to disrupt the endocrine system on product labels.

The government's efforts have been "an abject failure, a disaster," said Philip Landrigan, a pediatrician and chairman of the department of community and preventive medicine at Mount Sinai School of Medicine in New York.

Landrigan was at the White House ceremony in 1996 when President Clinton signed laws requiring the U.S. Environmental Protection Agency to screen chemicals for their effects on the endocrine system.

Because the effects of endocrine disruptors may take years to reveal themselves, it is almost impossible to say that a particular chemical caused a certain disease. There also is a lot of uncertainty about how these chemicals work inside your body. So, scientists extrapolate. They can't test their theories on humans. Instead, they have to rely on animal studies and try to figure out the implications for people.

By mimicking or blocking the body's hormones, endocrine disruptors can trigger faulty messages that disrupt development. That makes them particularly dangerous to fetuses and young children, scientists say. These chemicals can be ingested, inhaled and absorbed through the skin.

Michael E. Mitchell, chief of pediatric urology at Children's Hospital of Wisconsin, has seen the consequences he attributes to these unregulated chemicals.

He has witnessed a dramatic spike in the number of genital birth defects in the last 30 years. And it breaks his heart, he said, to see the damage done to so many children who must undergo painful surgery to correct birth deformities.

Considering the number of chemicals that developing fetuses are exposed to, "it's amazing that anyone turns out OK," he said.

Anxiety is rising over the growing number of cancer cases and other diseases linked to these chemicals. But few answers are forthcoming.

"People should know what they're being exposed to and be given the option to choose alternatives," said Shanna Swan, director of the Center for Reproductive Epidemiology at the University of Rochester School of Medicine and Dentistry. "And that is not happening very fast."

EPA officials blame their lack of progress on the complexity of the undertaking.

"Clearly, we would have liked to have been a lot further along," said Elaine Francis, national program director of the EPA's endocrine disruptors research program. "But science tends to move at its own pace."

To find how pervasive these compounds are in everyday use, the Journal Sentinel asked Frederick vom Saal, an internationally known expert in endocrine disruption, to perform a chemical audit of the Greendale home of Dean and Ellen Lang Roder and their four children, ages 3 to 10.

As the University of Missouri biologist went through each room in the house, vom Saal found hundreds of reasons for the Roder family to worry - from the bathtub rubber duck to the plastic pipes that bring water into their home.

"Anything that goes in your child's mouth is a factor for you to be concerned about," vom Saal told Ellen Roder as he held one of her children's dolls. "Particularly, dolls made from a plastic called polyvinyl chloride that 10 years from now just won't exist. It will be looked at like cigarettes. It is that dangerous."

Industry scientists dispute that.

"Science supports our side," said Marty Durbin, federal affairs managing director for the American Chemistry Council, the trade group representing the plastics industry.

They say there is no reason to fear the toys, baby bottles and other products containing the chemicals because none of their studies has proved that the chemicals cause harm to people. Chemists for the industry say you would have to consume 1,300 pounds of canned and bottled foods each day to notice any effects from the chemicals those products contain.

"I'm very comfortable with my kids and grandkids using these products, and that's really my bottom line," said James Lamb, an industry consultant and former EPA regulator. "And it is because I believe the industry has done the studies that need to be done and that they're interpreting them properly."

### **Lack of screening**

There are roughly 100,000 chemicals on the market today. Yet, lacking a coordinated screening program, there is no way to know how many of these chemicals interfere with the human endocrine system.

The chemicals at issue are used as additives in plastics, fragrances, creams and as flame retardants. Some of the more controversial compounds include bisphenol A and certain phthalates. Six billion pounds of bisphenol A, the raw material of polycarbonate plastic and epoxy resins, are produced each year in the United States.

Phthalates (pronounced "THAL-ates") are the chemicals that make plastic flexible and allow creams and personal-care products to hold their smell. U.S. chemical companies produce more than 2 billion pounds of these compounds a year. They are commonly found in nail polishes and hair sprays, shower curtains and even Halloween costumes.

For more than a decade, government agencies have said that several of these chemicals are safe at levels that people are exposed to every day.

Chemical makers have relied on these assurances as proof that their products are safe. They bolster these conclusions with millions of dollars of research and testing.

But the newspaper's review of 258 studies of bisphenol A, a common ingredient in baby bottles, reusable water bottles, eyeglass lenses and DVDs, shows otherwise.

More than 80% of studies analyzed by the Journal Sentinel show that the chemical adversely affects animals, causing cancer and other diseases.

Developing embryos exposed to endocrine disruptors through their mothers are most at risk, said Theo Colborn, a scientist trained at the University of Wisconsin-Madison whose book on the explosion of dangerous chemicals in the environment, titled "Our Stolen Future," stirred passionate calls for reform and regulation when it was published in 1996.

"You need the right hormones in the right place at the right time sending out the right signals," Colborn said. "If that's fouled up prenatally, you're in trouble." Colborn, like many of her colleagues, has changed the way she deals with these compounds, refusing to store her food in plastic or use certain creams and lotions that contain chemicals suspected of causing harm.

### **Wildlife abnormalities**

Scientists first suspected that endocrine disruptors were wreaking havoc decades ago when they began observing freakish abnormalities in wild animals, particularly along the Great Lakes with its legacy of industrial pollution.

They were seeing female gulls nesting together, birds with twisted bills and frogs with severe deformities, including one with an eye growing inside its mouth. Elsewhere across the country, scientists reported finding male fish with sacks of eggs and alligators with withered penises.

In 1991, Colborn, then a zoologist working for the World Wildlife Fund, convened a conference of some of the country's leading wildlife biologists, toxicologists and endocrinologists at Wingspread Conference Center in Racine to discuss the emerging science.

It was there that the term "endocrine disruptor" was coined. The 21 scientists signed a consensus statement, expressing concern about the dangers that these new chemicals posed and calling for them to be tested immediately.

Five years later, Colborn and two colleagues chronicled the bizarre spectacles of nature and their theories about the causes. The authors wondered that if the toxins in the environment could cause these effects in animals, what were they doing to people? Just as with lead and tobacco decades before, these chemicals are all around us, ravaging nature's delicate design, the authors said.

Their book stirred controversy in the scientific community, and many dismissed the claims as "junk science" because there was no direct link between specific chemicals and illnesses in people.

Within days of the book's publication, the chemical industry's trade group issued an alert to its members, warning them to expect a swarm of calls about the book's claims. The memo predicted the fallout could be fierce.

It was.

Later that year, Congress unanimously passed two laws ordering the EPA to begin screening and testing chemicals and pesticides for endocrine disrupting effects by 1999. The EPA convened a committee of scientists from academia, the government and the chemical industry to lay the groundwork for testing these

chemicals. They came up with a way to identify and test chemicals for the risks and get the information to the public.

In the beginning, there was a groundswell of enthusiasm. Then-EPA administrator Carol Browner said in 1998 that her agency would begin fast-tracking efforts to screen these compounds by the end of that year.

"Some 15,000 chemicals used in thousands of common products, ranging from pesticides to plastics," would be screened, Browner said.

Officials identified the program as a top priority. Browner appointed the first panel of scientists to build a framework for how to screen the chemicals. She left the agency after the presidential election in 2000.

More than \$80 million later, the government program has yet to screen its first chemical. That has left Browner, and others, concerned about the lack of any results.

"It doesn't take nine years," she said with a sigh. "You adjust as you go. You don't have to build a Cadillac when a Model T will do."

### **Promise unfulfilled**

Frustrated at the lack of action, a consortium of environmental, patient advocacy and labor groups filed a federal lawsuit, prompting the EPA to promise that screening would begin by the end of 2003.

But the agency repeatedly has missed its self-imposed deadlines as well as those set by law. Agency administrators testified twice before Congress, first in August 2000 and again two years later, pledging that the screening would be in place soon. Three separate committees of academic and industry scientists, including the one Browner formed, have been appointed by the EPA to take up the issue.

"A lot of bureaucratic foot-stomping and dust-raising," was the observation of Peter DeFur, a researcher at the Center for Environmental Studies at Virginia Commonwealth University who served on all three of the committees.

"To delay is to win on the part of the industrial community," DeFur said.

Industry, he said, tried mightily to slow the effort. He was particularly critical of one test pushed by chemical makers that involved studying mature male rats to see the chemicals' effects on the development of the reproductive system.

"What does the old white rat have to do with development?" DeFur said. "By the time he gets to be mature, or even nearly mature, all the organs are developed."

Industry and other groups have flooded the EPA and the committees with research, said L. Earl Gray Jr., an EPA research biologist.

The industry's lobbying efforts are led by the American Chemistry Council. The group has a \$75 million budget and includes some of the biggest names in commerce - Dow Chemical Corp., Procter & Gamble Co. and DuPont.

Chemical makers have "in some sense learned that if you play on the uncertainty of danger, you're going to be able to stop regulatory action especially in an anti-regulatory era," said David Rosner, professor of history and public health at Columbia University. That's particularly true "in a time when so many of our regulatory agencies have been neutered politically and socially," he added.

Durbin, of the trade group, denied any stall tactics.

"If it was our interest to delay things around here, we'd just sit on our hands and see whether or not EPA gets any funding," said Durbin, noting that the trade group frequently lobbies for increases in the EPA's budget.

Annual federal funding for the endocrine disruptor screening program peaked at \$12.6 million in 2000 and has dropped by about one-third.

Critics have charged that the White House has cut back on efforts to regulate a wide array of industries. DeFur, among others, felt that frustration while serving on the endocrine disruptor committees.

Clifford Gabriel, director of the EPA's Office of Science Coordination and Policy, countered that budgetary constraints have not hurt the progress.

Stephen L. Johnson, Browner's successor as head of the EPA, declined requests to be interviewed. Whatever the reason, the committees met less frequently as time went by. By April 2006, 10 years after the congressional order to begin the screening, progress stalled altogether.

Gerald LeBlanc, chairman of the committee charged with developing the screens, got a call from an EPA administrator, assuming that the two would be setting the committee's next meeting. Instead, LeBlanc was told the committee was being terminated.

"They were not going to allow me to take this job to completion," said LeBlanc, toxicology professor at North Carolina State University.

Edward Orlando, a biology professor at Florida Atlantic University and a member of the last committee, said its abrupt dissolution came as a disappointment - not to mention a waste of public money.

"How long will this take? Another five years? Another 10?" Orlando said.

The EPA's Francis said that LeBlanc's committee had a set term, and the agency felt it was more efficient to turn the work over to an advisory panel, where it remains today. But committee members say the effort was doomed for the past several years.

"Frankly, there was not enough political oomph behind it," said Gina Solomon, a member of the first EPA committee and senior scientist for the National Resources Defense Council.

Those with ties to industry say they, too, wish the process moved faster.

"Everyone is disappointed that you can't make quicker progress, but it does take time," said Thomas Osimitz, an industry consultant who sat on two of the three EPA committees. "It's frustrating, but, on the other hand, I don't know what could be quicker."

### **Outdated testing**

By the time the government gets around to the tests, they likely will be of little value. Under the current model, government tests do not screen for the chemicals' effects at low doses. Instead, government researchers follow standard toxicology testing practices, feeding animals such as rats huge doses of the chemical.

Then they record the damage to the animal, most often cancer, behavioral or reproductive failures. The researchers then test the rats at lower and lower doses until they no longer find those problems.

But bisphenol A and phthalates don't work that way, many scientists say. They can elicit different effects in animals at extremely low doses.

Two groups of scientists, one from the National Academy of Science and the other from the National Toxicology Program, have called for a radical reform in the way that government screens these chemicals. But, so far, the government hasn't budged from its original formula.

"The EPA is lumbering along trying to clumsily incorporate the science of a couple of decades ago," Solomon said.

The list of chemicals scheduled to be screened is also being questioned. The EPA will first screen 73 chemicals - all pesticides, none of the chemicals found in household products. The tests aren't set to happen until sometime next year.

EPA officials declined to say exactly when the screening would occur, explaining that the agency must finish its study of the tests before shipping them to another panel for review. But most of the pesticides have already been tested, and many have been established as endocrine disruptors.

Francis, of the EPA, says her agency chose to screen that relatively small batch of chemicals as a way to test the reliability of the process. But even scientists hired by the chemical industry question the value of screening chemicals that have been studied thoroughly.

"Most of those on the list have already been tested, so why are we doing this?" asked Lamb, the toxicologist who works as a consultant to the chemistry council.

The EPA hopes to conclude the first round of tests by 2010, said Enesta Jones, an agency spokeswoman. Only then will the agency have an idea when the next group of chemicals will be screened.

### **Buyer beware**

For as slow as the process of screening chemicals has been in the U.S., concern about the safety of endocrine disruptors has caught on in Europe, Japan, South America, the Middle East, Mexico and even Fiji.

Reports of declining sperm counts, birth defects and fertility problems have sparked widespread concern there. The European Union has banned 1,100 chemicals from cosmetics that are thought to cause cancer or reproductive harm.

"When we go to Europe, I breathe a sigh of relief because of all of the things I'm not exposed to over there," said Rochester's Swan, an epidemiologist and biostatistician.

Earlier this year, the European Union passed a law that requires chemical companies to prove their products are safe before they are put on the market.

The U.S. has no such protocol, known as the precautionary principle, and the chemical industry has argued against it.

"The problem with the precautionary principle is that you have a moving target," said Tim Shestek, a chemistry council lobbyist. "You need to prove that something is safe - safe is never really defined by anybody."

Lacking testing or regulation by the U.S. government, it falls to consumers to watch out for themselves.

Buyers must know the names of specific chemicals - such as dibutyl phthalate and diethyl phthalate - if they want to find out if a bottle of nail polish or a jar of hand lotion contains endocrine disruptors.

Even then, if the chemical is not considered a key ingredient, the company is not required to include it on the label.

There is nothing listed on a bottle of Chanel Precision Energising Radiance Lotion, for example, to let you know that it contains at least six chemicals that have been linked in laboratory studies to cancer in animals. Nor can you know by looking at the label for Avon's Anew Ultimate Skin Transforming Cream that it contains chemicals linked to cancer and endocrine disruption, according to a review by the nonprofit Environmental Working Group.

A spokeswoman for Chanel declined comment, and officials from Avon Products Inc. referred questions to the Cosmetic, Toiletry and Fragrance Association, which dismissed the claims as unfounded.

### **Consumer groups**

Consumer interest groups are trying to answer some of the questions that the government is not. The Campaign for Safe Cosmetics, a coalition of groups concerned with women's health, labor, consumer rights and the environment, offers a Web site run by the Environmental Working Group that enables shoppers to check the safety of cosmetics and personal-care products. The site identifies more than 450 products that are banned as dangerous in other countries but are widely available here.

As consumers learn more about these chemicals, more firms are taking steps to remove them from product lines.

Cosmetics giant Revlon Inc., for example, stopped using phthalates 15 years ago. A company spokeswoman said its products, including those sold in the U.S., comply with the stricter rules of the European governments.

Other companies following similar policies include the L'Oreal Group, Hasbro Inc. and McDonald's Corp. In 1998, the fast-food giant stopped using phthalates in its Happy Meal toys designed for children age 3 and younger.

Retailers, including Target Corp. and Whole Foods Market Inc., have removed items and are looking at ways to eliminate products that contain some endocrine disruptors.

"We are committed to reducing PVC in our products and packaging," said Susan Kahn, a vice president at Target, referring to polyvinyl chloride, the plastic that contains phthalates and is found in shower curtains, children's toys and packaging materials.

Some companies, such as Born Free LLC, a Florida-based baby bottle-maker, are promoting goods that do not contain bisphenol A. Ron Vigdor, Born Free president, said his small company is experiencing rapid sales growth.

Most consumers remain unaware of the potential dangers they are bringing into their homes, said Jane Adams, a neurotoxicologist at the University of Massachusetts.



"Most of the population would not be well-informed and necessarily know what steps to take," Adams said.

Roder, the Greendale mother who volunteered to have her house checked for endocrine disruptors, is grateful for the information she got.

Since the audit, Roder filled a garbage bin full of items that she'll no longer use - waxed paper, plastic wrap, old plastic cups, toys and containers.

She says her husband teases her for whacking bugs with shoes now, refusing to use bug spray. Instead of giving in to anxiety, Roder says her newfound awareness has brought peace of mind.

"It made me feel safe," she said.

But few people have the luxury of knowing what in their house is safe because few products contain any labeling of these compounds. Even the government scientists charged with alerting the public to the chemicals' dangers say information is sorely lacking.

"The real problem is that we don't know where all the different phthalates are coming from in our environment," said Gray, the EPA biologist whose lab has examined effects of endocrine disruptors for two decades. "I can't tell them what products to specifically avoid. The information isn't there."

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## Appendix 2

**“Bisphenol A is in you; It's in baby bottles, soda cans and 93% of us. It causes breast cancer, testicular cancer, diabetes and hyperactivity in lab animals, according to most studies. But U.S. regulators side with the chemical-makers and say it's safe”**

By Susanne Rust, Cary Spivak and Meg Kissinger of the *Journal Sentinel*

December 2, 2007

[See: <http://www2.jsonline.com/story/index.aspx?id=692145>]

For more than a decade, the federal government and chemical-makers have assured the public that a hormone-mimicking compound found in baby bottles, aluminum cans and hundreds of other household products is safe.

But a Journal Sentinel investigation found that these promises are based on outdated, incomplete government studies and research heavily funded by the chemical industry.

In the first analysis of its kind by a newspaper, the Journal Sentinel reviewed 258 scientific studies of the chemical bisphenol A, a compound detected in the urine of 93% of Americans recently tested. An overwhelming majority of these studies show that the chemical is harmful - causing breast cancer, testicular cancer, diabetes, hyperactivity, obesity, low sperm counts, miscarriage and a host of other reproductive failures in laboratory animals.

Studies paid for by the chemical industry are much less likely to find damaging effects or disease.

U.S. regulators so far have sided with industry by minimizing concern about the compound's safety.

Last week, a panel commissioned by the National Toxicology Program released a report finding bisphenol A to be of some concern for fetuses and small children. It found that adults have almost nothing to worry about.

Its recommendations could be used by the U.S. Environmental Protection Agency and other regulators to assess federal policies on how much bisphenol A is safe and may have huge ramifications for the multibillion-dollar chemical industry.

The panel said it considered more than 700 studies by university scientists, government researchers and industry-funded chemists. It picked the work it felt was best and threw out the rest.

The Journal Sentinel found that panel members gave more weight to industry-funded studies and more leeway to industry-funded researchers.

- The panel rejected academic studies that found harm - citing inadequate methods. But the panel accepted industry-funded studies using the same methods that concluded the chemical does not pose risks.

- The panel missed dozens of studies publicly available that the Journal Sentinel found online using a medical research Internet search engine. The studies the panel considered were chosen, in part, by a consultant with links to firms that made bisphenol A.

- More and more university researchers and foreign governments are finding that bisphenol A can do serious damage in small doses. But the panel rejected studies mostly submitted by university and international government scientists that looked at the impact at these levels.

- The panel accepted a Korean study translated by the chemical industry's trade group that found bisphenol A to be safe. It also accepted two studies that were not subjected to any peer review - the gold standard of scientific credibility. Both studies were funded by General Electric Co., which made bisphenol A until it sold its plastics division earlier this year.

"This undermines the government's authority," said David Rosner, professor of history and public health at Columbia University. "It makes you think twice about accepting their conclusions."

Panel chairman Robert Chapin, a toxicologist who works for Pfizer Inc., the pharmaceutical giant, defended his group's work.

"We didn't flippin' care who does the study," said Chapin, who worked as a government scientist for 18 years before joining Pfizer.

If the studies followed good laboratory practices and were backed with strong data, they were accepted, Chapin said.

### **Created to act as hormone**

Bisphenol A was developed in 1891 as a synthetic estrogen. It came into widespread use in the 1950s when scientists realized it could be used to make polycarbonate plastic and some epoxy resins to line food and beverage cans.

With the advent of plastic products such as dental sealants and baby bottles, the use of bisphenol A has skyrocketed. The chemical is used to make reusable water bottles, CDs, DVDs and eyeglasses. More than 6 billion pounds are produced each year in the United States.

In recent decades, increases in the number of boys born with genital deformities, girls experiencing early puberty and adults with low sperm counts, uterine cysts and infertility prompted some researchers to wonder whether the prevalence of bisphenol A could be interfering with human development and reproduction.

Scientists began looking for a link between bisphenol A and spikes in cancer, obesity and hyperactivity. Others, such as Patricia Hunt, simply stumbled onto it.

Hunt, a scientist at Case Western Reserve University, was investigating the connection between maternal age and Down syndrome in 1998 when all of her laboratory mice, including those not treated in any way, began exhibiting chromosomal abnormalities.

Her investigation revealed that bisphenol A was leaching from the animals' polycarbonate cages, and it was the chemical that had caused the problems.

Ana Soto, a researcher at Tufts University, began noticing that her lab mice treated with bisphenol A were a lot fatter than her other mice.

More alarming still was the work scientists found in their breast and prostate cancer research. They injected cancer cells in test tubes of bisphenol A and watched as the cells grew rapidly, even at doses lower than what people are normally exposed to. Reports such as these sparked fear that bisphenol A could become the new lead or asbestos.

As scientists' suspicions grew, regulators repeatedly reassured the public that the chemical was safe. The Food and Drug Administration and the EPA routinely pointed to studies by government regulators in the 1980s that found no serious effects.

In 1998, the National Toxicology Program formed the Center for the Evaluation of Risks to Human Reproduction to look at why so many people were unable to conceive or carry their babies to term. Scientists were suspicious of the environmental impact from chemicals, including hormone-mimicking chemicals such as bisphenol A.

Last year, two groups of scientists were appointed by the federal government to gauge bisphenol A's risks.

One panel was purely academic, made up of 38 international experts in bisphenol A who work for universities or governments. In an August report, they found a strong cause for concern. Levels of bisphenol A in people were higher than the levels found to cause harm in lab animals, the panel said. The average level found was above what the EPA considered safe.

The other group, led by Chapin, included 12 scientists. The members were chosen because of their lack of detailed knowledge about bisphenol A. The idea was that the group would serve as an impartial jury, Chapin said.

It considered 742 studies conducted over the past 30 years.

The non-expert panel was less alarmed about bisphenol A's effects.

The non-expert panel's report was posted Monday on the center's Web site without a press release or fanfare. When the panel released an earlier draft, critics assailed it as arbitrary, biased and incomplete.

The sharpest response came from bisphenol A experts, many of whom had their work rejected by the non-expert panel. Even those whose work was accepted were critical of the findings.

"When panels that are sponsored by the government come out with reports and say that there is not convincing evidence yet, that gives me great concern, knowing what I do about some studies showing that

there are effects," said Gail Prins, professor of physiology at the University of Illinois at Chicago and an expert in bisphenol A.

The federal government will now weigh the reports of both the expert and non-expert panels before assessing safe levels of bisphenol A.

### **Studies found widespread effects**

Before reviewing the panel's reports, the Journal Sentinel analyzed 258 studies spanning two decades. All studies involved live animals with spines - those species scientists consider most relevant to people. The studies were found on PubMed, an online search engine used by researchers.

Four out of five studies found that bisphenol A caused problems in the lab animals tested, ranging from allergies to reproductive deformities. The vast majority of these studies were funded by government agencies and universities.

One federally funded study found that rats exposed to bisphenol A before birth were at increased risk of developing precancerous prostate lesions. Another study, funded by the U.S. and Argentine governments, found that the chemical increased the likelihood of rats developing mammary tumors.

Just 12% of the studies found that bisphenol A had no ill effects. Most of those studies were paid for or partially written by scientists hired by the chemical industry.

A study funded by the Society of the Plastic Industry found that bisphenol A did not pose harm to developing rats. Another study discounted any reproductive effects on exposed rats. The authors included scientists affiliated with Shell Chemicals, Dow Chemical Co. and General Electric - all then makers of bisphenol A.

Two studies actually determined that bisphenol A may be beneficial. One funded by drug-maker Eli Lilly & Co. said it could lower cholesterol in rats. The other study said the chemical might prevent or cure breast cancer in rats.

Industry scientists dispute any claims that bisphenol A is harmful to humans.

"Our view is consistent with what has been concluded by government and scientific bodies around the world, which is that bisphenol A is not a risk to human health based on the weight of scientific evidence," said Steven G. Hentges, executive director of the American Chemistry Council's Polycarbonate/BPA Global Group. Hentges called the newspaper's review superficial.

Norman Fost, founder and director of the medical ethics program at the University of Wisconsin-Madison, said industry and academic studies come to radically different conclusions all the time. Fost would not comment directly on the panel's work because he hadn't studied it. But he said the universe of scientific research is replete with studies conducted by organizations with a vested interest.

"It's up to us to be skeptical, cautious and critical when we consider how much of their work to believe," said Fost, who is chairman of an FDA committee looking at the ethics of pediatric studies.

### **Human safety levels**

Bisphenol A is just about everywhere. But trying to get a handle on how much of the chemical a person can tolerate is not easy.

The government established a safety level for bisphenol A about 20 years ago - well before most scientific studies on the chemical had been conducted. The government considers a safe daily level of bisphenol A to be 50 micrograms per kilogram of body weight. For a 200-pound person, that would be the equivalent of no more than one drop of the chemical every five days.

The American Chemistry Council says an average adult would have to ingest more than 500 pounds of canned food and beverages every day for an entire lifetime to be at risk. The chemical industry based those conclusions on its own research.

Others say there is no way to know how much bisphenol A one is exposed to when microwaving dinner in a plastic container, eating tuna from a can or drinking from a reusable plastic water bottle.

"Even if you go out of your way to avoid products, you don't know all of your exposures," said Soto, the bisphenol A expert from Tufts. "At the end of the day, you may have cut your exposure by 5 percent or by 95 percent. We just don't know."

Because bisphenol A is so ever-present in the environment, there are many ways to be exposed to it. But the biggest risk comes from those products that people put in their mouths or that come directly into contact with food, scientists say.

A number of studies looked at how bisphenol A affects lab animals at low doses. Bisphenol A experts say that the chemical works like a hormone and, therefore, needs to be tested at low doses where much damage can be done.

"This is basic endocrinology," said Frederick vom Saal, a biologist at the University of Missouri who has been studying bisphenol A for more than a decade. "You learn this in any introductory class. Hormones work on an extremely sensitive system."

For instance, it only takes 40 parts per billion of the hormone MIS to produce male sexual organs in the human embryo. That's about one drop in 15 bathtubs of water.

Two groups of scientists - from the National Academy of Sciences and the National Toxicology Program - have called for the U.S. government to radically overhaul the way it tests chemicals to include these low doses. But the government has yet to do so. Instead, it continues to cite the government studies from the early 1980s that focused only on high doses.

Of the 258 studies reviewed by the Journal Sentinel, 168 studies looked at low-dose effects of bisphenol A.

The vast majority - 132 studies- found health problems at low doses, including hyperactivity, diabetes and genital deformities. All but one of those studies were conducted by non-industry scientists. Nearly three-fourths of the studies that found the chemical had no harmful effects were funded by industry.

But Chapin's panel did not accept any studies that found an effect at low doses in its review of 742 studies.

Once the panel weeded out studies it believed had been done poorly, no studies remained that showed effects from low doses, Chapin said.

"There's a lot of bad science out there," he said.

Most of the low-dose studies the Journal Sentinel reviewed - including some the panel rejected - were published in reputable scientific journals.

Prins, the bisphenol A expert from the University of Illinois at Chicago, said she was a late convert to the idea that the chemical causes harm at low doses. She changed her mind after reading repeated studies.

Then she saw it in her lab.

"We gave very small doses to male rats and saw cancerous lesions form on their prostates," Prins said.

For the panel to dismiss low-dose effects is a fatal flaw, she said.

Chapin conceded that the panel did not give equal weight to studies that considered low-dose effects, the levels that most people are exposed to every day.

"I'll admit it. We may be off in like totally uncharted territory," Chapin said.

The chemical industry defended the panel's choice of studies, noting that their scientists have been unable to replicate the work of some university scientists.

"Replication is a hallmark of science, and studies that cannot be replicated cannot be accepted as valid," said Hentges of the chemistry council.

### **Panel's work studied**

The Journal Sentinel reviewed the work that the panel did, comparing each of its two drafts and the final report, together totaling more than 1,000 pages.

Two of the panel's four chapters considered the same kind of studies the newspaper reviewed - looking at the effects of bisphenol A on live animals. In one of those chapters, focusing on reproductive toxicology, 20 studies by either government or academia were tossed. No study that disclosed it had been funded by industry was rejected.

Chapin said they gave greater weight to studies that used more animals. Critics say only the chemical-makers can afford to conduct studies with more animals.

The panel failed to apply consistent standards, the newspaper's review found.

Not all studies recorded the kind of feed, caging, bedding or specific type of animal used. Those factors can influence the studies' results.

Chemical industry researchers used the same methodology in studies the panel accepted that caused other studies to be rejected. They included studies that used a single high dose and injected rats with bisphenol A rather than having the chemical administered orally. Chapin's panel rejected some studies, including those conducted by Soto, because they used an oil called DMSO to administer bisphenol A to rats.

"That just helps compounds waltz into cells," Chapin said.

But Chapin's panel accepted another study that used DMSO, never citing that oil as a limitation or concern.

The panel also accepted a study by Shell Chemical, Dow Chemical and General Electric that found no effects from bisphenol A. The same study also found no effects when rats were exposed to the powerful chemical diethylstilbestrol, or DES - a compound known to cause reproductive harm.

The rats' resistance to DES should have been an immediate red flag, critics said. But the panel accepted the research.

### **Consulting firm fired**

Chapin's group has been dogged by controversy from the beginning. Last year, conflict-of-interest concerns were raised regarding the panel's use of Sciences International. The Virginia-based consulting firm had been hired to choose and summarize research for panel members. However, it had not been revealed that Sciences International had clients that included bisphenol A producers.

The company was fired in April, and the National Institutes of Health audited the firm's report. It found no conflict, and the company is credited in the final report.

Chapin dismissed criticisms against the panel.

"I'm tired of having my credibility as a scientist questioned when the panel bent over backwards to apply standards of good scientific conduct . . . evenly across the board," Chapin said. "My accusers have a great deal more bias than I do.

"They are not unbiased," Chapin added, "even though they keep holding themselves up as the white hats, the pure, the only holders of the cup of scientific chastity."

The newspaper found dozens of studies of bisphenol A that were not brought to the panel's attention.

Among them was a 2005 study that determined the chemical disrupted brain development in rats at very low levels. The panel also missed a study last year by Yale University researchers that found the chemical altered reproductive tract development in female mice exposed in the womb. Again, the researchers found these effects at low levels - below what the EPA considers safe.

"I'm surprised because my understanding was after all the hoo-ha was raised about Sciences International, the NTP went out and did its own search," Chapin said. "That's weird."

In one study accepted by Chapin's panel, the work was translated into English by the American Plastics Council, a division of the American Chemistry Council. The Korean study found that the sperm density and the reproductive systems of male rats were not harmed by bisphenol A.

Rosner, the public health professor, said that practice "immediately raises eyebrows."

"You have to have a neutral party doing the translations," he said. "It's the only way to really trust the accuracy."

Michael Shelby, director of the government agency that selected the panel to evaluate bisphenol A, acknowledged that the translation could be called into question. However, he denied any conflict.

Chapin said panel members agreed that they wanted to see any data they could, regardless of how they got it.

"I hear what you're saying about the perception," Chapin said. "Too bad."

Two studies, both funded by industry, were not peer reviewed, the newspaper found. Peer review is considered the foundation of scientific credibility. Most scientific journals will not publish a study unless it is peer reviewed.

The studies found no effects from bisphenol A, and were funded by General Electric in 1976 and 1978. They were accepted despite concerns similar to those that led the panel to disqualify academic and government studies. They included a small sample size of animals, the use of high doses and questions about the statistical methodology.

The panel also accepted at least a dozen studies that had not been published in any scientific journal - another check and balance in the scientific community to maintain high standards.

Shelby said the panel considered studies that were not peer reviewed if they included sufficient details.

Even scientists on the panel who agreed with the findings say they are uneasy about broad claims that bisphenol A is safe.

Jane Adams, a professor at the University of Massachusetts, doesn't allow her teenage son to get dental sealants because of her worries about bisphenol A.

"I am concerned about this chemical," she said. "Much more research needs to be done." Simon Hayward, another panelist, agrees.

"Where there's smoke, there's fire," said Hayward, professor of prostate biology at Vanderbilt University Medical Center. "There is definitely enough smoke to be worried."

Rosner, the public health historian, says bisphenol A's potential for danger is too great to allow its widespread use without being certain of its safety. Consider what happened with lead and tobacco, he said.

"The government needs to work with caution," he said, noting that we have lived well for thousands of years without this chemical. "Until we know that it is safe, it is more prudent to avoid it."

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