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FDA used chemical industry lobbyists to assess bisphenol A, e-mails show

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As federal regulators hold fast to their claim that a chemical in baby bottles is safe, e-mails obtained by the Milwaukee Journal Sentinel show that they relied on chemical industry lobbyists to examine bisphenol A's risks, track legislation to ban it and monitor news coverage.

In one instance, the U.S. Food and Drug Administration's deputy director sought information from the BPA industry's chief lobbyist to discredit a Japanese study that found it caused miscarriages in workers who were exposed to it. This was before government scientists even had a chance to review the study.

"I'd like to get information together that our chemists could look at to determine if there are problems with that data in advance of possibly reviewing the study," Mitchell Cheeseman, deputy director of the FDA's center for food safety and applied nutrition, said in an e-mail seeking advice from Steven Hentges, executive director of the trade association's BPA group.

The FDA relied on two studies — both paid for by chemical makers — to form the framework of its draft review declaring BPA to be safe.

The Journal Sentinel reported last year that the trade group wrote entire sections of that draft. But the revelations contained in these e-mails show a pattern of preferential treatment over the past nine years that was not afforded to independent scientists.

Hentges did not respond to requests for comment. However, Kathryn St. John, spokeswoman for the American Chemistry Council, said, "We take very seriously our responsibility to fully communicate and cooperate with government regulatory authorities in a transparent manner, in compliance with legal and regulatory requirements." She said she could not comment on specifics.

BPA, used to make hard, clear plastic common in many food product containers, is found in the urine of 93% of Americans. It has been linked to neurological defects, diabetes, heart disease and breast and prostate cancer.

The Journal Sentinel contacted several independent scientists who are BPA experts, and all said they were not given such access to FDA safety assessors. Nor did the FDA seek their opinions or ask them to review studies, they said.

On the contrary, some said they were discouraged at not being able to get their views across to government regulators, and resented what they saw as uneven treatment.

Representatives for the Natural Resources Defense Council, an environmental activist organization that is working to ban BPA, said they have tried unsuccessfully for years to meet with FDA regulators. Sarah Janssen, a scientist at the NRDC, said the government agency has not responded to a petition it filed in October to ban BPA from food products.

The e-mails show how government regulators relied on the trade association to do much of their work for them.

In one e-mail, the FDA asked Hentges to give the trade association's opinion of a study by the U.S. Centers for Disease Control and Prevention on the prevalence of BPA. It is not clear why the FDA wouldn't do its own analysis or have the CDC provide that information.

FDA administrators wouldn't comment on the specifics of the e-mails. But Jesse Goodman, newly appointed as the FDA's acting chief medical officer, said the agency will take a "fresh look" at BPA that will include a wider network of opinions than previously had been considered.

"We have heard the criticism" about the FDA being too cozy with chemical makers, Goodman said. "We are following through to make sure that we look at all the science."

In October, the FDA's own advisory committee said that its examination was not thorough enough and that FDA scientists improperly discounted dozens of studies that showed the chemical caused harm. The committee recommended that the FDA reopen its review of the chemical, but so far the agency has not changed its opinion. And, six months later, the FDA has yet to hold a public meeting on BPA safety.

A spate of local and state bans on BPA has passed recently — including those in Chicago and Minnesota — and more are being considered. The bans prohibit the sale of products made with BPA for children under the age of 3.

In March, Suffolk County on New York's Long Island banned BPA in children's products. Similar bans have been proposed in Michigan, Maine, Massachusetts, New York state and Connecticut. Bills have been introduced in the House and the Senate to ban BPA in all food packaging.

Dozens of e-mails and more than 100 pages of attachments were obtained through the Freedom of Information Act. They show that chemical trade association lobbyists routinely have met with FDA administrators over the past nine years to give their opinion on various independent studies on the effects of BPA. At times, the lobbyists' comments appeared to dismiss work as incomplete or amateurish.

In flagging the FDA to a study from the University of Cincinnati that showed that BPA leaches from bottles when it is heated, Hentges seemed to belittle the effort as "a summer project for a couple of undergraduates."

Scott Belcher, who oversaw the research, defended the study. He bristled at the relationship between the government agency and the trade group.

"Science aside, as a consumer it is pretty unsettling to hear that someone who is paid to represent a powerful special interest group would even have access to influence FDA officials by raising points like those," he said.

The FDA has invited the trade association to come to its headquarters several times since 2000 to make presentations on BPA. At these meetings, lobbyists for the chemical makers provided the FDA with the current status of regulatory legislation in states, cities and other countries. And they provided the FDA with their assessments of current science.

The lobbyists met with government regulators to brief them on the developments regarding BPA even as independent scientists' requests for discussions were being rebuffed.

On July 24, 2007, for example, the lobbyists gave a 26-slide PowerPoint presentation to FDA regulators, updating them on developments concerning BPA.

Among their objectives was to gain understanding of the views of the FDA. The lobbyists used the time with government regulators to give details of their agenda, to go over recent regulatory and legislative activities, and to discuss their research developments.

The overview included advice from the lobbyists for how the government should consider news developments.

“New science, government activities and non-governmental organizations are news triggers,” the trade group wrote in its PowerPoint.

In other e-mails, trade lobbyists notified FDA officials about upcoming news reports on BPA and advised them how to respond.

“Laura and Mitch,” Hentges wrote in an e-mail to FDA administrators. “I send this note to give you a head’s up on something we understand is coming next week.”

The item was a report from the Environmental Working Group, an activist organization working to ban BPA.

“At this time we have no information on what information they will report or how it will be publicized,” Hentges wrote. “However, we can anticipate that it will be widely publicized as a serious food safety issue. If correct, it might be appropriate for FDA to consider issuing a statement to reassure consumers about the safety of the food supply.”

Some scientists, such as Fred vom Saal, a University of Missouri scientist who is working to ban the chemical, say they are outraged at not being afforded the same access.

“This is appalling,” vom Saal said. “These people are really now and have obviously been for a long time in industry’s pocket.”