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## FDA Sued for Nonresponse to Petition Against Bisphenol A

Barbara Boughton

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July 21, 2010 — The Natural Resources Defense Council (NRDC), a national nonprofit environmental health group with more than 525,000 members, is suing the US Food and Drug Administration (FDA) over its failure to respond to NRDC's citizen petition asking that the ubiquitous chemical bisphenol A (BPA) be banned from products such as plastic bottles and food can liners.

The lawsuit, filed in late June in the US Court of Appeals for the District of Columbia Circuit, asks for a "writ of mandamus," or a court order that will require the FDA to respond to the NRDC's petition with either a rule banning BPA or a statement of why the FDA is denying the environmental group's petition.

The FDA is required by law to respond to citizen petitions for new regulations within 90 days by granting or denying the petition but can extend the time it takes to consider the issue at stake — but only by an additional 90 days. The NRDC's petition to the FDA, filed on behalf of their members in October 2008, asked that the agency revoke all regulations permitting BPA in food packaging, citing health concerns that have been raised about the chemical in a variety of scientific studies. Although the issue is controversial, animal and human studies have linked the chemical to an increased risk for a number of conditions, including diabetes, obesity, cancer, and cardiovascular disease, especially when exposure to BPA occurs in infancy or childhood.

Although the FDA has clearly failed to act on the citizen petition about BPA in the time frame mandated by law, whether or not the NRDC's unusual request for a court order will be granted remains open to question, according to legal experts.

"We filed a petition in 2008 asking the FDA to revoke its approvals and ban the use of BPA in food packaging, and the FDA has still not responded. We're hoping to prod the FDA into action," said NRDC Senior Scientist Sarah Janssen, MD, PhD.

In an email to *Medscape Medical News*, the FDA refused a request for an interview and declined to comment on the NRDC's action, saying that it does not issue statements on pending lawsuits. However, according to NRDC documents filed in court, the FDA replied to the environmental group's initial petition after 6 months, but with a "boilerplate letter" that said the agency had failed to respond because of limited resources and "other agency priorities."

At the heart of the lawsuit are questions about whether the FDA's failure to act is "unreasonable," despite its claim of limited resources, and whether its lack of response may affect human health, said Sean Hecht, JD, executive director of the University of California–Los Angeles Environmental Law Center.

"Although it's pretty clear that according to law, the FDA should have made a decision, writs of mandamus are also considered extraordinary, so it's possible that the court may not compel the agency to take action," he said. The court will consider whether the NRDC had other means of compelling the FDA to act, as well as the amount of time the FDA delayed action, and whether its inaction will have significant consequences, Mr. Hecht said.

"The court is not being asked to make a decision about the science regarding BPA, or whether there should be a rule that eliminates BPA," he added. Yet to intervene, the court has to be convinced that harm to human health might result from the agency's failure to respond to the NRDC petition, and so will need to evaluate the evidence presented by the NRDC about the health risks of exposure to BPA, Mr. Hecht explained. Although granting a writ of mandamus is unusual, it is not unprecedented, he added.

BPA is found in polycarbonate plastic, including refillable water bottles, and in epoxy resins, which are used to line metal products, including canned foods. Most people are exposed to BPA primarily through the use of canned foods, although concerns have been raised about whether BPA leaches out of plastic containers, especially when heated. The chemical has come under intense scrutiny in recent years because it is considered an endocrine disruptor, and animal studies have suggested it can have detrimental health effects on the brain, prostate, and mammary glands and on behavior.

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In 2008, a report by the US National Toxicology Program expressed concerns about the chemical's health effects on fetuses, infants, and children, although it expressed "negligible concern" for most adults. Some states have moved to ban the chemical. Several baby bottle manufacturers and a manufacturer of plastic water bottles no longer use BPA in their products.

A number of large epidemiological studies published since 2008 have linked BPA to increased risk in humans for health conditions that include heart disease, liver disease, and diabetes. Earlier this year, the FDA said that it officially agreed there might be health concerns over exposure to BPA for fetuses and infants and announced the launch of a \$30 million BPA research program. At a press conference in January, the agency also revealed that it was seeking greater regulatory power to track and control industrial use of the chemical.

"There is evidence that the levels of BPA found in canned foods are dangerously close to the levels shown to cause harm in animal studies, and now from emerging epidemiological studies, to cause harm to humans as well," Dr. Janssen said. Many studies have shown evidence of detrimental health effects from BPA even at low doses, she added, and those that have not have been industry-sponsored, she added.

Yet, a spokesperson for the American Council on Science and Health, a nonprofit that receives industry funding as well as funding from other sources, called the NRDC lawsuit "bizarre." "Every scientific body that has evaluated BPA has ruled that it is safe in the amounts that most people are exposed to in our environment," said Gilbert Ross, MD, medical director of the American Council on Science and Health. "There's no scientific basis for this crusade against BPA, and the lawsuit against the FDA is simply a way to get attention for the NRDC," he said.

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