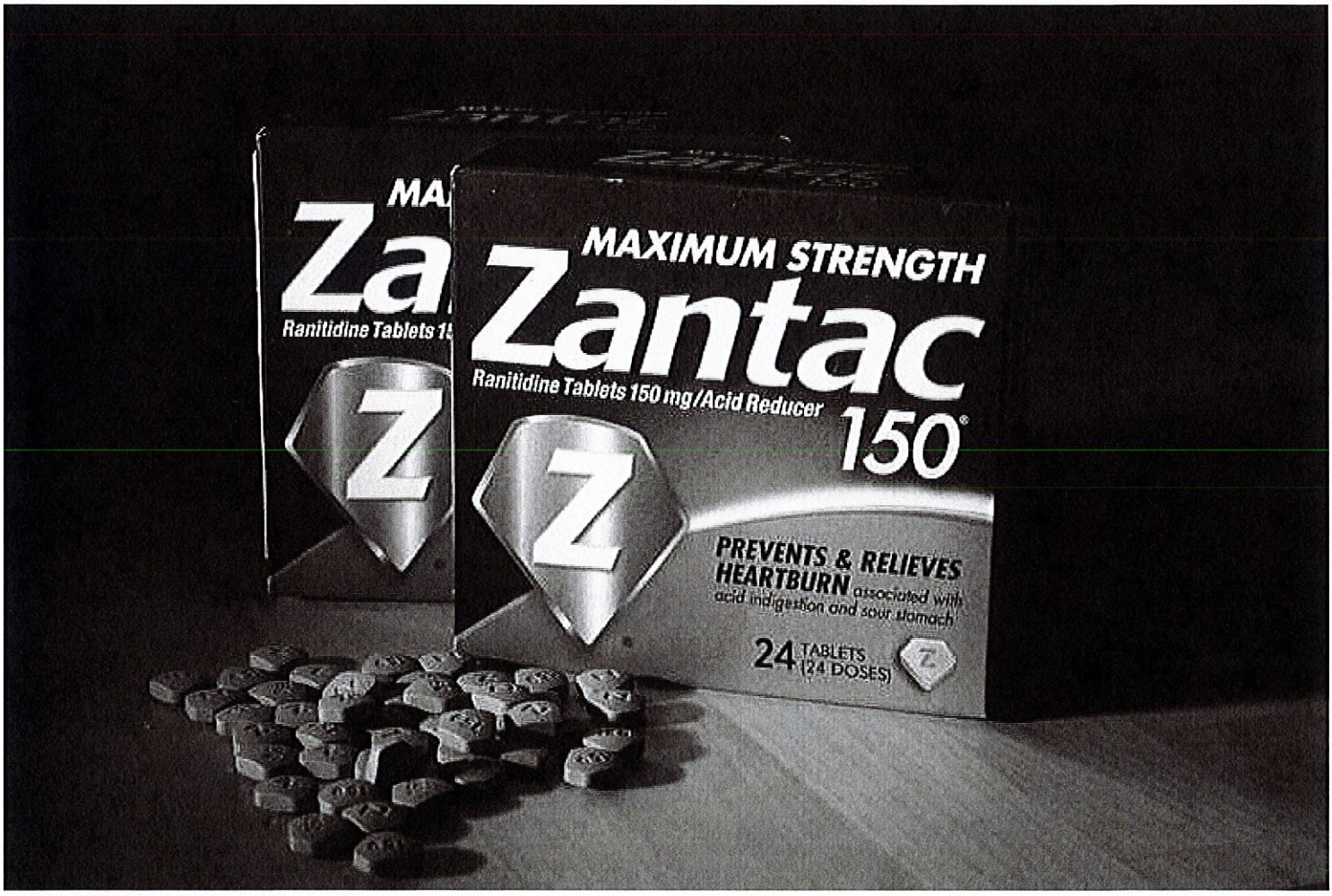
Markets

FDA Head Questioned on Zantac's Hidden Cancer Risk by Top Democrat DeLauro

- How will agency hold GSK accountable, DeLauro asks in letter
- Drugmaker's actions were reported in Bloomberg Businessweek



Photographer: Drew Angerer/Getty Images

By Anna Edney
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The Food and Drug Administration's chief is facing questions from a top lawmaker about the agency's response to a report that UK drugmaker GSK Plc hid and downplayed cancer risks from Zantac, its blockbuster heartburn drug, for four decades.

Representative Rosa DeLauro, the House Appropriations Committee's ranking Democrat, wrote FDA Commissioner Robert Califf Tuesday demanding to know whether the agency plans to investigate GSK's actions reported in *Bloomberg Businessweek* in February. DeLauro asked how the FDA plans to hold the company accountable, according to her letter that was reviewed by Bloomberg.

Zantac and its generics were removed from the market in April 2020 after it was determined that their active ingredient, ranitidine, could degrade to form a probable carcinogen called NDMA. GSK's research showed a year before its 1983 approval that Zantac could form the chemical under certain circumstances, but the UK company didn't share those findings with some its most senior US managers or the FDA, *Bloomberg Businessweek* reported last month.

"All the while the company continued to sell and profit from a drug that might harm people (including those who took it routinely for years), attempted to discredit evidence of the cancer risks, and failed to provide any warning," DeLauro wrote.

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Once a component in rocket fuel, NDMA is now only used to induce cancer in lab rats. Even when GSK learned of Zantac pills and injections becoming discolored, a sign of degradation, the drugmaker never checked for the presence of the chemical, also called N-Nitrosodimethylamine.

Similar Findings

The National Toxicology Program, the Environmental Protection Agency and the International Agency for Research on Cancer all "have found significant positive associations between NDMA intake and increased cancer risk." according to a legal filing by former National Institutes of Health toxicologist Ronald Melnick that DeLauro cited in her letter. Drawn from documents obtained during discovery in the lawsuits, its findings are similar to those of the *Bloomberg Businessweek* story. The filing was written for plaintiffs in federal lawsuits against GSK by people who developed cancer after taking Zantac or generic forms of the drug.

So far, the courts have shot those cases down. US District Judge Robin Rosenberg, in the Southern District of Florida, dismissed the suits last year, saying there wasn't a "widespread acceptance in the scientific community of an observable, statistically significant association between ranitidine and cancer." GSK has also said there's no consistent, reliable evidence that Zantac increases the risk of cancer.

It's hard to prove a single product is responsible for a disease, and epidemiological studies of the relationship between Zantac and cancer have yielded inconsistent findings. Plaintiffs are more likely to have their day in state court if GSK doesn't settle. The first such trial is set for July in California.

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DeLauro has long been a watchdog over the FDA, calling for greater oversight of products such as baby formula and e-cigarettes. Valisure, the independent laboratory that found NDMA in Zantac in 2019, is located in DeLauro's Connecticut district. While Valisure's testing methods have been criticized, the FDA also found NDMA in Zantac after being alerted by the lab.

DeLauro called on the FDA to remove Zantac and its generics from shelves in December 2019. Yet the agency didn't force the drugs off the market until April 2020, "which was months behind other countries in taking the products off the shelves," DeLauro said in the letter. The congresswoman plans to reintroduce legislation she has pushed that would give the FDA expanded authority to force drug recalls.

Other Products

Since 2021, Valisure has also uncovered harmful chemicals in hand sanitizers, sunscreens, antiperspirants and dry shampoos. All those products were contaminated with a potent carcinogen called benzene, a derivative of crude oil. Recalls of some also took more than a year after Valisure released its findings. The company has called for Congress to mandate the kind of independent testing of drugs and personal-care products that it does.

After Valisure discovered benzene in some aerosol sunscreens and antiperspirants, Procter & Gamble Co. tested all of its spray-on products. The company issued a large recall in December 2021 of several dry shampoos, including Pantene and Herbal Essences brands.

In contrast, Unilever Plc didn't take action until almost a year later in October 2022 when the company issued a massive recall that included Dove, Suave, Bed Head and Tresemme dry shampoo brands. Congress gave the FDA mandatory recall authority over cosmetics in December when it passed a large appropriations bill.

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Bloomberg filed a Freedom of Information Act request in December to learn what FDA testing had turned up about benzene levels in these dry shampoos but was told by the agency in January that it didn't have any records responsive to the request, meaning the FDA hadn't done any analysis. The agency didn't respond to requests for comment in January or again this week.

DeLauro didn't give the FDA a deadline for a response to her questions, including how the agency plans to prevent other companies from taking actions like GSK's, but did say she expects a prompt reply.