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UNITED STATES
HOUSE OF REPRESENTATIVES
ROSA L. DeLAURO
3RD DISTRICT, CONNECTICUT

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COMMITTEE ON THE BUDGET

December 18, 2019

Dr. Stephen Hahn
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Alex M. Azar II
Secretary
Department of Health & Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Azar and Commissioner Hahn,

I write today with concern regarding the Food and Drug Administration's (FDA) decision to continue to allow the drug ranitidine, commonly sold under the brand Zantac, an antacid, to remain on the market. Ranitidine poses a significant risk to public health and safety, and it is imperative that swift action is taken.

Due to a historically very high perception of safety, ranitidine is heavily prescribed to adults and infants and sold over-the-counter. Yet, Valisure, an analytical pharmacy based in my District, has detected extremely high levels of N-Nitrososdimethylamine ("NDMA"), a probable human carcinogen, in every lot tested, across multiple manufacturers and dosage forms of the drug ranitidine. Valisure discovered the link between ranitidine and NDMA formation during its routine analysis of drug products in its pharmacy. It is my understanding that ranitidine's carcinogenicity has not been fully vetted by the FDA. Valisure's data, in combination with four decades of scientific research, strongly suggests that ranitidine is a fundamentally unstable molecule and all products containing this drug have a risk of cancer. It is incomprehensible that FDA is fully aware of this fact, yet, it continues to allow this drug to remain on the shelves. Yet, Bangladesh, Canada, Egypt, and South Korea have banned all sales, while, Denmark, Germany, Kenya, Pakistan, and Vietnam have recalled ranitidine products from shelves and distribution. In total, 41 countries have acted, ranging from issuing a warning to citizens of the dangers of ranitidine to complete ban on sales and facing fines for noncompliance with the recall.

FDA's failure to stop companies from selling ranitidine makes the United States government complicit in exposing infants and adults to the risk of cancer. I urge you to act and uphold the mission of the FDA, as well as the Department of Health and Human Services, by immediately removing ranitidine from shelves and banning all sales.

Thank you for your attention to this critical matter.

Sincerely,

Rosa L. DeLauro

ROSA L. DeLAURO
Member of Congress