

United States Senate WASHINGTON, DC 20510-4704

COMMITTEES:
APPROPRIATIONS
BUDGET
HEALTH, EDUCATION, LABOR,
AND PENSIONS
VETERANS' AFFAIRS

July 26, 2024

The Honorable Robert M. Califf Commissioner of Food and Drugs U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

## Dear Commissioner Califf:

I write today to express my deep concern about a new study which found that tampons from several popular brands often contain toxic metals, such as lead, arsenic, and cadmium.<sup>1</sup> In light of this alarming reporting, I urge the U.S. Food and Drug Administration (FDA) to carefully examine these new findings and evaluate any necessary actions to ensure the safety of tampons and menstrual products. FDA plays an essential role in protecting the public's health and ensuring the safety of food, medication, and medical devices, and women in America deserve no less than to know their tampons and period products are safe.

The majority of Americans who menstruate use tampons, and research has found that women may use more than 7,400 tampons in their lifetime.<sup>2</sup> This means that on any given day, millions of women are being potentially exposed to heavy metals and toxins, simply by managing their periods by using tampons. The safety of tampons is a serious concern since the vagina has highly absorptive tissue, allowing chemicals or metals to enter directly into the bloodstream, without any detoxification. Exposure to heavy metals, especially through chronic absorption, has been linked to increased risk of Alzheimer's disease<sup>3</sup>, cancer<sup>4</sup>, infertility<sup>5</sup>, and other health issues. Given the extended use of tampons and systemic exposure over time, it is necessary to ensure women are not inadvertently exposed to heavy metals and contaminants and subject to increased health risks.

The June 2024 study, "Tampons as a source of exposure to metal(loid)s," was the first of its kind to examine the presence of metals in tampons. Researchers tested 30 individual tampons from across 14 brands and 18 product lines, including major name brands and store-brands, for the presence and concentrations of metals. The researchers found measurable concentrations of all 16 metals they tested for—and most concerningly, found lead in every single tampon tested—of which there is no safe exposure level.<sup>6</sup>

<sup>&</sup>lt;sup>1</sup> https://www.sciencedirect.com/science/article/pii/S0160412024004355

<sup>&</sup>lt;sup>2</sup> https://www.sciencedirect.com/science/article/pii/S0160412024004355

<sup>&</sup>lt;sup>3</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9465172/

<sup>&</sup>lt;sup>4</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4699750/

<sup>&</sup>lt;sup>5</sup> https://www.aaem.pl/Impact-of-heavy-metals-on-the-female-reproductive-system,72271,0,2.html

<sup>&</sup>lt;sup>6</sup> https://www.sciencedirect.com/science/article/pii/S0160412024004355

Given the FDA's role in regulating tampons and menstrual products, please provide written responses to the following questions on what steps the Administration is currently taking, or will take, to ensure the safety of tampons and period products by August 23, 2024:

- What steps does FDA take, both pre-market and post-market, to evaluate the safety of tampons and regulate them as a class II medical device?
- Does FDA require testing for metals, toxins, or contaminants in tampons, pads, and other menstrual products? If so, please detail this process, which toxins are tested for, and at which time intervals testing occurs (i.e. pre or post-market).
- In reviewing the June 2024 study (Shearston et al.), what steps are you taking or planning to take to improve the FDA's tampon and menstrual product safety efforts?
- Has the FDA previously reviewed any other studies, evidence, or findings related to metals, toxins, or contaminants in menstrual products? If so, what were the key findings and has FDA changed any practices as a result of those findings?
- Does FDA have the administrative authority to institute more stringent safeguards against heavy metals and contaminants in menstrual products, including requiring testing? If not, is additional statutory authority needed?
- Does FDA have the administrative authority to institute ingredient labeling requirements for menstrual products, including tampons? If not, is additional statutory authority needed?

In addition, I request that FDA brief my staff on the regulation and safety processes for tampons and menstrual products, no later than August 9, 2024. Thank you for your attention to this matter. Please direct any correspondence pertaining to this request to Shauna Rust (Shauna Rust@murray.senate.gov) on my staff.

Sincerely,

Patty Murray

United States Senator