

United States Senate

WASHINGTON, DC 20510

February 8, 2019

The Honorable Scott Gottlieb, M.D.
Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Commissioner Gottlieb:

We write to you with serious concerns regarding recent findings of heavy metals at potentially harmful levels in fruit juices, including brands marketed for children. Children deserve nothing short of the highest standard of safety. As such, we write to strongly urge the U.S. Food and Drug Administration (FDA) to promptly establish mandatory standards to strictly limit heavy metals in children's food, including fruit juices, in order to protect public health.

A recent study¹ by Consumer Reports tested 45 popular fruit juices—across 24 national, store, and private-label brands—and found that every single product had detectable levels of cadmium, inorganic arsenic or lead. Twenty-one of the products had concerning levels of at least one heavy metal. Some of the products even registered high enough concentrations to pose a risk to adults.

Children eat and drink more per pound of body weight than adults do, so they are more likely to be harmfully exposed to heavy metals. In addition, they are also particularly vulnerable to heavy metals because their bodies and brains are still developing. These toxic elements have been linked to carcinogenic, cognitive, and reproductive harms, as well as behavioral problems and lower IQ.

It is unconscionable that the FDA has still not taken effective action to protect children from being exposed to dangerous levels of heavy metals. Specifically, it is past time for the agency to finalize 2013 draft guidance for industry on arsenic in apple juice limiting inorganic arsenic to 10ppb—the same as the federal arsenic drinking water standard.² However, this proposed action level only covers apple juice, which we now know is not the only kind of juice with concerning levels heavy metals. Accordingly, we strongly urge the FDA to use its explicit authority under 21 U.S.C. § 2201 to prioritize the health of our children and take the following additional important actions:

- Initiate rulemaking to strictly limit in children's food any heavy metals—including lead, inorganic arsenic, and cadmium—that do not have any safe levels.

¹ <https://www.consumerreports.org/food-safety/arsenic-and-lead-are-in-your-fruit-juice-what-you-need-to-know/>

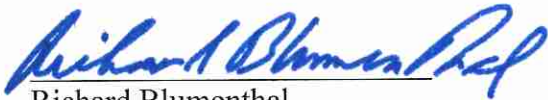
² "Draft Guidance for Industry: Arsenic in Apple Juice - Action Level." U. S. Food and Drug Administration. July 2013. <https://www.fda.gov/RegulatoryInformation/Guidances/ucm360020.htm>.

- Strongly consider Consumer Reports' recommendations that lead and cadmium in fruit juice be limited to 1ppb, and that inorganic arsenic be limited to 3ppb. Currently, guidance to manufactures merely suggests lead levels in juice remain below 50ppb. This is unacceptable, considering FDA requirements for lead in bottled water allow is no greater than 5ppb. Cadmium poses similar risks as lead and should be similarly limited in food products.
- Set interim goals and recall limits for heavy metals in all juice products and food types children commonly eat or drink.

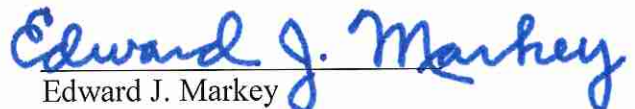
In your response to a letter we wrote to you last year regarding heavy metals in baby food,³ you also promised to continue to update our offices on the FDA's actions and activities related to reducing and preventing foodborne exposure to toxic elements by vulnerable populations. We urge you to keep this commitment.⁴

Thank you for your attention to this important matter. We respectfully request a response by February 22, 2019 detailing the steps the FDA will take to protect our children from unnecessary exposure to heavy metals that continue to persist in food products.

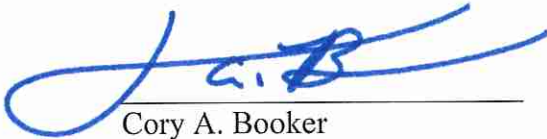
Sincerely,



Richard Blumenthal
United States Senate



Edward J. Markey
United States Senate



Cory A. Booker
United States Senate

³ Senators Blumenthal, Booker, and Markey sent Commissioner Scott Gottlieb a letter regarding heavy metals in baby and toddler food products on October 2, 2018.

⁴ John Martin, Principal Associate Commissioner for Legislative Affairs at the U.S. Food & Drug Administration, wrote a response letter to Senators Blumenthal, Booker, and Markey regarding heavy metals in baby and toddler food products.