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Dr. Susan T. Mayne
Director, Center for Food Safety and Applied Nutrition
Food and Drug Administration
Department of Health and Human Services
Silver Spring, Maryland 20993

Dear Dr. Mayne:

We are writing to draw FDA's attention to our new publication in the journal *Annals of Allergy, Asthma, & Immunology* titled "Adverse Events and Labeling Issues Related to Suspected Sesame Allergy Reported in an Online Survey."[1] This study adds to the body of literature documenting under-reporting of adverse events related to foods to FDA. We request a meeting with the Center for Food Safety and Applied Nutrition (CFSAN) to discuss our findings and, more generally, our recommendations for an improved adverse event reporting system.

In our study, we designed a questionnaire to collect information on sesame allergic reactions. Our survey tool was based on the MedWatch Online Voluntary Reporting Form 3500B for consumers/patients, but was tailored to include additional items relevant to food allergy reactions (*e.g.,* time between consumption and reaction, other foods consumed, and use of epinephrine) and to food labeling (*e.g.*, "Was the product sold in a package with a label that contained an ingredients list?"). We also excluded items that were not relevant to food exposures (*e.g.*, Product Type: Over-the-Counter, Compounded by a Pharmacy or Outsourcing Facility, Generic, and Biosimilar, Strength, and "Why was the person using the product?").

We distributed the survey via a Facebook group for people dealing with sesame allergy and via email between October-December 2018 and received reports of 379 adverse events related to sesame encompassing 327 individual subjects with 360 distinct adverse clinical reactions. Of these 360 reactions, 248 (69%) met the National Institute of Allergy and Infectious Disease/Food Allergy and Anaphylaxis Network criteria for anaphylaxis. Among 256 adverse reactions involving products sold in labeled packages, 144 (56%) did not include "sesame" on the label.

By contrast, FDA has received few reports of sesame allergic reactions through the CFSAN Adverse Event Reporting System (CAERS). A search for "sesame" in the publicly available spreadsheet of CAERS reports from 2018 reveals only one report listing "anaphylactic reaction" as a symptom.

Other recent research has also demonstrated the vast underreporting of adverse events related to foods to FDA. A study we published earlier this year found that only 18 adverse events involving poppy seeds were reported to CAERS between 2004 and 2018, whereas 604 exposures involving poppy were reported in the National Poison Data System (NPDS) between 2000-2018.[2] A 2019 study by FDA scientists found that between 2008 and 2015, 510 adverse events related to caffeinated energy drinks were reported to CAERS (357 single-product exposures, 153 exposures involving multiple products) while 13,753 adverse events (12,822 single-product, 931 multiple-product) were reported in NPDS.[3] In each of these studies, CAERS had 27 to 34 times fewer reports than NPDS.

An improved system for reporting adverse events related to foods could enhance the FDA's ability to assess the prevalence and severity of food allergies and other risks from food, including inadequate labeling and microbial contamination. We would appreciate an opportunity to present our findings and recommendations to CFSAN, and look forward to learning more about the progress CFSAN has made in developing an improved system for reporting adverse events related to foods.

Sincerely,

Peter Lurie, MD, MPH
Executive Director & President

Eva Greenthal, MS, MPH
Senior Science Policy Associate

Sarah Sorscher, JD, MPH
Deputy Director of Regulatory Affairs

References

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2 Greenthal E, Lurie P, Doyon S. Opioid exposure associated with poppy consumption reported to poison control centers and the U.S. Food and Drug Administration. *Clin Toxicol.* 2021;59(8):746-755.

3 Markon AO, Jones OE, Punzalan CM, Lurie P, Wolpert B. Caffeinated energy drinks: adverse event reports to the US Food and Drug Administration and the National Poison Data System, 2008 to 2015. *Public Health Nutr.* 2019;22(14):2531-2542.