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Grace Meng

Congress of the United States

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August 2, 2018

The Honorable Scott Gottlieb
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Gottlieb:

I write to alert you to a report released by the American Academy of Pediatrics (Academy) that appears in this month's issue of the journal *Pediatrics*. It is entitled "Food Additives and Child Health" and it highlights the emerging child health concerns related to the use of colorings, flavorings, and chemicals deliberately added to food during processing. It also proposes urgently needed reforms to the food additive regulatory process at the U.S. Food and Drug Administration (FDA).

Respectfully, I request your immediate review of the Academy's recommendations and a public response. In particular, I wish to know your response to the following proposals, which I strongly support:

- 1) The FDA should establish requirements for the labeling of additives with limited or no toxicity data and those not reviewed for safety by the FDA.
- 2) The FDA should update the scientific foundation for the FDA safety assessment process, including but not limited to the following: expand the scope of the recommended testing battery to cover endocrine-related and neurobehavioral effects, ensure adequate safety factors for pregnant and breastfeeding women and additional vulnerable populations, and develop strategies to integrate emerging testing techniques.
- 3) The FDA should establish requirements for prioritization and retesting of previously approved chemicals.
- 4) The FDA should consider cumulative and mixture effects from dietary sources, including other additives and contaminants that interact with relevant biological pathways.

- 5) The FDA should leverage expertise and technical evaluations from other agencies to gather missing data and identify knowledge gaps while the current generally recognized as safe designation process remains in place.

I am particularly troubled by the report's claim that "the FDA does not regularly consider cumulative effects of food additives in the context of other chemical exposures that may affect the same biological receptor or mechanism, despite its legal requirement to do so." Additionally, I have grave concerns that a recent evaluation of 451 "generally recognized as safe" determination evaluations of food additives voluntarily submitted to the FDA "revealed that 22.4% of evaluations were made by an employee of the manufacturer, 13.3% were made by an employee of a consulting firm selected by the manufacturer, and 64.3% were made by an expert panel selected by the consulting firm or manufacturer. None were made by a third party." Clearly, this determination system is flawed at best, but more likely broken.

I concur with the Academy when it states that the potential for endocrine system disruption posed by food additives is of great concern, especially in early life, when developmental programming of organ systems is susceptible to permanent and lifelong disruption. According to the Academy, "The international medical and scientific communities have called attention to these issues in several recent landmark reports, including a scientific statement from the Endocrine Society in 2009 which was updated in 2015 to reflect rapidly accumulating knowledge; a joint report from the World Health Organization and United Nations Environment Program in 2013; and a statement from the International Federation of Gynecology and Obstetrics in 2015." Specific chemicals and additives flagged for concern include the following:

- artificial food colors, nitrates, and nitrites;
- bisphenols, which are used in the lining of metal cans to prevent corrosion;
- phthalates, which are esters of diphtalic acid that are often used in adhesives, lubricants, and plasticizers during the manufacturing process;
- nonpersistent pesticides;
- perfluoroalkyl chemicals (PFCs), which are used in grease-proof paper and packaging; and
- perchlorate, an antistatic agent used for plastic packaging in contact with dry foods with surfaces that do not contain free fat or oil.

Again, I implore you to review this alarming report and to implement the Academy's recommendations. I stand ready to assist you in any way you may need. As the mother of two young children, I am committed to ensuring that every American child and family is protected from unknowingly consuming chemicals that may cause them harm. Thank you for your time.

Sincerely,



Grace Meng
Member of Congress