

**Congress of the United States**  
**House of Representatives**

COMMITTEE ON OVERSIGHT AND REFORM

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WASHINGTON, DC 20515-6143

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<https://oversight.house.gov>

January 10, 2022

Dr. Janet Woodcock  
Acting Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Dear Acting Commissioner Woodcock:

I am writing to request information about the Food and Drug Administration's (FDA) regulation of phthalates—dangerous chemicals commonly found in food packaging and processing materials that can cause significant health problems in individuals who are exposed to higher levels than the general population.<sup>1</sup> This is a longstanding issue that demands urgent action by FDA.

Phthalates are known endocrine-disruptors that have been linked to fertility and reproductive problems. In children, phthalates increase the risk for learning, attention, and behavioral disorders.<sup>2</sup> Children who are exposed to phthalates in their mother's womb can suffer from negative health effects: prenatal exposure can affect cognitive development and cause other health problems.<sup>3</sup>

Some steps have been taken by Congress and federal agencies in recent years to address the use of phthalates in common household goods. Eight phthalates are now banned at concentrations of more than 0.1% in children's toys and child care articles as a result of 2008

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<sup>1</sup> *Some Fast-Food Items Contain Plastics Linked to Serious Health Problems, New Report Shows*, Washington Post (Oct. 27, 2021) (online at [www.washingtonpost.com/business/2021/10/27/fast-food-phthalates-plastics/](http://www.washingtonpost.com/business/2021/10/27/fast-food-phthalates-plastics/)); Engel et al., *Neurotoxicity of Ortho-Phthalates: Recommendations for Critical Policy Reforms to Protect Brain Development in Children*, American Journal of Public Health (Apr. 2021) (online at <https://ajph.aphapublications.org/doi/pdfplus/10.2105/AJPH.2020.306014>).

<sup>2</sup> *Some Fast-Food Items Contain Plastics Linked to Serious Health Problems, New Report Shows*, Washington Post (Oct. 27, 2021) (online at [www.washingtonpost.com/business/2021/10/27/fast-food-phthalates-plastics/](http://www.washingtonpost.com/business/2021/10/27/fast-food-phthalates-plastics/)).

<sup>3</sup> Stephanie M. Engel et al., *Neurotoxicity of Ortho-Phthalates: Recommendations for Critical Policy Reforms to Protect Brain Development in Children*, American Journal of Public Health (Apr. 2021) (online at <https://ajph.aphapublications.org/doi/pdfplus/10.2105/AJPH.2020.306014>).

legislation and a 2017 regulation promulgated by the Consumer Product Safety Commission.<sup>4</sup> The Environmental Protection Agency recently designated five phthalates as high-priority substances for risk evaluation under the Toxic Substances Control Act.<sup>5</sup> Despite this progress, and mounting evidence linking phthalate exposure to serious and irreversible negative health outcomes, FDA regulations still allow 28 different phthalates for use in food processing and packaging materials.<sup>6</sup> Health and environment advocates recently sued FDA over its failure to rule on Food Additive Petition No. 6B4815, a 2016 petition to ban phthalates in food packaging and processing materials.<sup>7</sup>

The harms from phthalate exposure disproportionately affect communities of color—groups that are more likely to experience higher levels of phthalate exposure.<sup>8</sup> According to a 2019 study that examined racial disparities in maternal phthalate exposure, pregnant Black women have greater phthalate exposures than pregnant white women, which is associated with poorer birth outcomes and creates health disparities that cascade from one generation to the next.<sup>9</sup>

FDA is tasked with ensuring the safety of our nation's food supply, but over multiple administrations the agency has fallen short in protecting vulnerable Americans from the pernicious effects of foods contaminated with phthalates. FDA must not allow these dangerous chemicals to continue to hurt American families. FDA must act without further delay, and should start by ruling on the outstanding petition to ban phthalates.

To assist the Subcommittee in its review of this matter, we request that you provide the following information by January 24, 2022:

1. Does FDA plan to issue a final decision on Food Additive Petition No. 6B4815, which could substantially reduce dietary exposure to phthalates and, if so, when?

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<sup>4</sup> U.S. Consumer Product Safety Commission, *Phthalates Business Guidance & Small Entity Compliance Guide* (online at [www.cpsc.gov/Business--Manufacturing/Business-Education/Business-Guidance/Phthalates-Information](http://www.cpsc.gov/Business--Manufacturing/Business-Education/Business-Guidance/Phthalates-Information)) (accessed Dec. 14, 2021); 15 U.S.C. § 2057c; 16 C.F.R. § 1307.3 (2021).

<sup>5</sup> Stephanie M. Engel et al., *Neurotoxicity of Ortho-Phthalates: Recommendations for Critical Policy Reforms to Protect Brain Development in Children*, *American Journal of Public Health* (Apr. 2021) (online at <https://ajph.aphapublications.org/doi/pdfplus/10.2105/AJPH.2020.306014>).

<sup>6</sup> *Id.*

<sup>7</sup> Earth Justice, *Press Release: Groups Sue to Force FDA Decision on Petitions to Ban Phthalates in Food* (Dec. 7, 2021) (online at <https://earthjustice.org/news/press/2021/groups-sue-to-force-fda-decision-on-petitions-to-ban-phthalates-in-food>); Petition for Writ of Mandamus (Dec. 7, 2021), *In re Environmental Defense Fund et al.*, D.C. Cir. (No. 21-1255) (online at [https://earthjustice.org/sites/default/files/files/2021.12.7\\_mandamus\\_pet.final\\_.pdf](https://earthjustice.org/sites/default/files/files/2021.12.7_mandamus_pet.final_.pdf)).

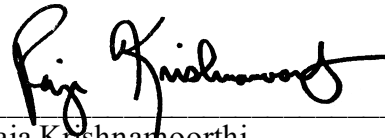
<sup>8</sup> Stephanie M. Engel et al., *Neurotoxicity of Ortho-Phthalates: Recommendations for Critical Policy Reforms to Protect Brain Development in Children*, *American Journal of Public Health* (Apr. 2021) (online at <https://ajph.aphapublications.org/doi/pdfplus/10.2105/AJPH.2020.306014>).

<sup>9</sup> Michael S. Bloom et al., *Racial Disparity in Maternal Phthalate Exposure; Association with Racial Disparity in Fetal Growth and Birth Outcomes*, *Environment International* (Apr. 2019) (online at [www.sciencedirect.com/science/article/pii/S0160412018329908](http://www.sciencedirect.com/science/article/pii/S0160412018329908)).

2. What steps, if any, is FDA taking to evaluate the effects that phthalates found in food packaging and processing materials have on human health?
3. What steps, if any, is FDA taking to work toward banning phthalates from use in food packaging and processing materials?
4. What test data or studies, if any, does FDA have showing that the 28 currently allowed phthalates are safe for use in products that touch food?

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate “any matter” at “any time” under House Rule X. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Sincerely,



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Raja Krishnamoorthi

Chairman

Subcommittee on Economic and Consumer Policy

cc: The Honorable Michael Cloud, Ranking Member  
Subcommittee on Economic and Consumer Policy