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## United States Senate

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October 2, 2024

The Honorable Robert M. Califf, M.D.  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue, NW  
Silver Spring, MD 20993

Dear Commissioner Califf,

The Food and Drug Administration (FDA) has a statutory responsibility to ensure that packaging and production materials that come into contact with food do not contain toxic chemicals that can harm consumers.<sup>1</sup> The FDA has approved nine types of phthalates for use in food contact materials (FCM)—chemicals that are often found in food manufacturing components and fast-food packaging, which make plastics more durable, flexible, and transparent. But there is mounting evidence that exposure to phthalates is extremely harmful to humans, especially brain development in infants and children. We urge the FDA to review this evidence and to use its existing authorities to ban phthalates from FCM. One way in which the FDA could achieve this goal is by granting the relief requested in the pending objections to FDA's denial of the 2016 food additive petition submitted by Earthjustice and other stakeholders and by reconsidering its denial of the related 2016 citizen petition, which together asked that the FDA revoke food-additive authorizations and prior-sanctioned uses of certain phthalates in FCM.

There are currently nine phthalates FDA approved for use in FCM.<sup>2</sup> The FDA holds the legal authority to revoke these regulatory authorizations, if the approved phthalates do not meet the safety standards established by the *Food, Drug, and Cosmetic Act* for the chemicals used in food or FCM.<sup>3</sup> The safety standards require the FDA to affirm that any chemicals used in FCM do not pose a public health risk, are not carcinogenic, and pose no health or safety concerns from potential dietary exposure.<sup>4</sup>

<sup>1</sup> 21 U.S.C. § 348.

<sup>2</sup> *Phthalates in Food Packaging and Food Contact Applications*, U.S. Food and Drug Administration (July 21, 2023), <https://www.fda.gov/food/food-additives-and-gras-ingredients-information-consumers/phthalates-food-packaging-and-food-contact-applications>; 21 C.F.R. §§ 175-178; 21 C.F.R. §§ 181.1, 181.27.

<sup>3</sup> 21 C.F.R. §§ 171.130, 181.1(b); 21 U.S.C. § 348(i).

<sup>4</sup> 21 U.S.C. § 348(c)(3)(A), (h)(1); 21 C.F.R. §§ 170.3(i), 170.39, 181.1(b)

The current evidence demonstrates that the phthalates in question do not satisfy these requirements. These “everywhere chemicals” are “are found in hundreds of auto, home, food and personal care items: food packaging; detergents; vinyl flooring, clothing, furniture and shower curtains; automotive plastics; lubricating oils and adhesives; rain and stain-resistant products; and scores of products including shampoo, soap, hair spray and nail polish, in which they make fragrances last longer.”<sup>5</sup> Alarming, studies have found that prenatal, infant, and toddler exposure to phthalates is linked to impaired child brain development and function, as well as pre-term labor.<sup>6</sup> One study “found children of mothers with the highest levels of phthalates in their urine during their second trimester had almost three times the odds of being diagnosed with ADHD as children with mothers who had much lower levels.”<sup>7</sup> Another concluded that “children who were exposed to higher levels of phthalates in utero had an IQ level that was seven points lower than children with less exposure.”<sup>8</sup> Consequently, the FDA should no longer permit the use of phthalates in FCM nor approve their use.<sup>9</sup>

Other federal agencies have already affirmed risks to human and environmental health related to phthalates. The Environmental Protection Agency (EPA) has already highlighted health concerns with phthalates, designating multiple phthalates as High-Priority Substances for risk evaluation under the Toxic Substances Control Act and toxic pollutants under Section 307 (a)(1) of the Clean Water Act.<sup>10</sup> Additionally, under the Consumer Product Safety Improvement Act of 2008, the Consumer Product Safety Commission (CPSC) has banned the use of multiple types of phthalates at concentrations greater than 0.1 percent in toys and children’s articles due to harmful levels of toxicity.<sup>11</sup> Further, the CPSC has found, and EPA has affirmed, that diet is the

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<sup>5</sup> Sandee LaMotte, *Chemicals in plastics damage babies’ brains and must be banned immediately, expert group says*, CNN (Feb. 20, 2021), <https://www.cnn.com/2021/02/20/health/baby-brain-damage-plastic-phthalates-wellness/index.html>.

<sup>6</sup> Yu Wang et al., *A review of biomonitoring of phthalate exposures*, 7 *Toxics* 21 (Apr. 5, 2019), <https://doi.org/10.3390/toxics7020021>; Jake E. Thistle et al., *Urinary metabolite concentrations of phthalate and plasticizers in infancy and childhood in the UNC Baby Connectome Project*, 259 *Environmental Research* 119467 (Oct. 15, 2024), <https://doi.org/10.1016/j.envres.2024.119467>; Stephanie M. Engel et al., *Neurotoxicity of Ortho-Phthalates: Recommendations for Critical Policy Reform to Protect Brain Development in Children*, 111 *American Journal of Public Health (AJPH)* 4 (Mar. 10, 2021), <https://doi.org/10.2105/AJPH.2020.306014>; Matthieu Rolland et al., *Effects of early exposure to phthalates on cognitive development and visual behavior at 24 months*, 219 *Environmental Research* 115068 (Feb. 15, 2024), <https://doi.org/10.1016/j.envres.2022.115068>.

<sup>7</sup> Sandee LaMotte, *Chemicals in plastics damage babies’ brains and must be banned immediately, expert group says*, CNN (Feb. 20, 2021), <https://www.cnn.com/2021/02/20/health/baby-brain-damage-plastic-phthalates-wellness/index.html> (citing Stephanie M. Engel et al., *Prenatal Phthalates, Maternal Thyroid Function, and Risk of Attention-Deficit Hyperactivity Disorder in the Norwegian Mother and Child Cohort*, *Environmental Health Perspectives*, Vol 126, Issue 5 (May 2018), <https://ehp.niehs.nih.gov/doi/epdf/10.1289/EHP2358>).

<sup>8</sup> *Id.* (citing Pam Factor-Litvak, *Persistent Associations between Maternal Prenatal Exposure to Phthalates on Child IQ at Age 7 Years*, *Plos One* (Dec. 10, 2014), <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0114003>).

<sup>9</sup> Yu Wang & Haifeng Qian, *Phthalates and Their Impacts on Human Health*, 9 *Healthcare (Basel)* 603 (May 18, 2021), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8157593/>.

<sup>10</sup> 84 Fed. Reg. 71924; 40 C.F.R. § 401.15.

<sup>11</sup> 16 C.F.R. § 1307.

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primary source of exposure to FDA-approved phthalates for women, infants, toddlers, and children.<sup>12</sup>

In the absence of proactive federal action, states are being forced to take unilateral steps to protect their residents from phthalates. To date, California, Maine, and Vermont have enacted their own regulations either banning, controlling, or limiting the use of phthalates in FCMs and other materials.<sup>13</sup> Additionally, last year, legislation to ban phthalates in FCMs was introduced in Michigan's legislature.<sup>14</sup> A robust federal response would help avoid a patchwork solution, where materials are allowed in some states but banned in others.

By continuing to permit the use of toxic phthalates in FCM, the FDA is out of step not only with other American federal agencies and state regulators regarding the safety of these chemicals, but with the European Union's food safety standards. The European Food Safety Authority (EFSA) severely restricted at least five commonly used phthalates in FCM, four of which are currently approved for use in the United States.<sup>15</sup>

The FDA can revoke its authorizations for the use of phthalates in FCM independently or in response to formal requests filed by citizens, so we urge the FDA to revoke the regulations allowing phthalates in FCMs—either of its own volition or by granting pending objections and reconsidering its denial of the 2016 phthalates food additive petition and citizen petition.<sup>16</sup> These dangerous chemicals have been linked to health harms, particularly for vulnerable populations, and as a result, should not be used in food packaging or any other FCM.

Thank you for your consideration of this important issue.

Sincerely,

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<sup>12</sup> See, e.g., EPA, *Draft Risk Evaluation for Diisononyl Phthalate (DINP)* 10 (2024) (discussing diisononyl phthalate), <https://www.epa.gov/system/files/documents/2024-08/01--dinp--draft-risk-evaluation--public-release--hero--august-2024.pdf>; Report to the U.S. Consumer Product Safety Comm'n by the Chronic Hazard Advisory Panel on Phthalates and Phthalate Alternatives (2014), <https://www.cpsc.gov/s3fs-public/CHAP-REPORT-With-Appendices.pdf>.

<sup>13</sup> Cal. Dep't of Toxic Substances Control, *Draft 2024-2026 Priority Product Work Plan* (2023); Pub. L. c. 277, An Act To Protect the Environment and Public Health by Further Reducing Toxic Chemicals in Packaging, LD 1433, 128th Leg. (Me. 2019); Vt. Stat. Ann. tit. 18, §§ 1671–1675 (2023).

<sup>14</sup> S.B. 327, 102nd Leg., Reg. Sess. (Mich. 2023).

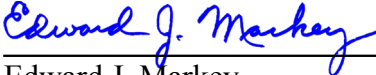
<sup>15</sup> Joel Schuezer, *16th amendment to EU Regulation 10/2011 on plastic FCMs now in force* | *Food Packaging Forum*, Food Packaging Forum (Aug. 10, 2023), <https://www.foodpackagingforum.org/news/16th-amendment-to-eu-regulation-10-2011-on-plastic-fcms-now-in-force>.

<sup>16</sup> Env't Def. Fund et al., *Objections and Request for Evidentiary Public Hearing Regarding FDA's Denial of Phthalates Food Additive Petition* (FAP 6B4815), Docket No. FDA-2016-F-1253 (June 21, 2022), <https://www.regulations.gov/document/FDA-2016-P-1171-0016>; Env't Def. Fund et al., *Petition for Reconsideration*, Docket No. FDA-2016-P-1171, <https://www.regulations.gov/document/FDA-2016-P-1171-0013>; 21 C.F.R. § 10.33 (authorizing FDA to reconsider petition at any time).

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Edward J. Markey

United States Senator



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Cory A. Booker

United States Senator