ORAL ARGUMENT NOT YET SCHEDULED

No. 24-1382

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ALASKA COMMUNITY ACTION ON TOXICS, BREAST CANCER PREVENTION PARTNERS, CENTER FOR ENVIRONMENTAL HEALTH, CENTER FOR FOOD SAFETY, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, DEFEND OUR HEALTH, ENVIRONMENTAL DEFENSE FUND, and LEARNING DISABILITIES ASSOCIATION OF ILLINOIS,

Petitioners,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION and DR. MARTIN MAKARY, in his official capacity as Commissioner of the United States Food and Drug Administration,

Respondents.

On Petition for Review of a Final Order of the Food and Drug Administration, 89 Fed. Reg. 86,290 (Oct. 30, 2024)

PROOF BRIEF OF PETITIONERS

Dated: March 28, 2025

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), Petitioners Alaska Community Action on Toxics, Breast Cancer Prevention Partners, Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, Defend Our Health, Environmental Defense Fund, and Learning Disabilities Association of Illinois (collectively, "Petitioners") submit the following Certificate as to Parties, Rulings, and Related Cases.

A. Parties and Amici

Petitioners in this proceeding are Alaska Community Action on Toxics, Breast Cancer Prevention Partners, Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, Defend Our Health, Environmental Defense Fund, and Learning Disabilities Association of Illinois.

Respondents in this proceeding are the United States Food and Drug Administration ("FDA") and its Commissioner, Dr. Martin Makary.[1]

B. Ruling Under Review

Petitioners petition for review of, and request that the Court set aside, FDA's October 30, 2024, decision denying Petitioners' administrative objections and

[1] Per Federal Rule of Appellate Procedure 43(c), Commissioner Makary is automatically substituted for his predecessor.

hearing requests concerning FDA's denial of Food Additive Petition 6B4815, which requested revocation of FDA regulations authorizing the use of chemicals known as phthalates as additives in food-contact materials. *See* Env't Def. Fund, et al.; Response to Objections and Requests for a Public Hearing, 89 Fed. Reg. 86,290 (Oct. 30, 2024).

C. Related Cases

This case has not previously been before this Court or any other court. Petitioners are not aware of any other cases challenging the FDA decision at issue in this proceeding.

Dated: March 28, 2025

Respectfully submitted,

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RULE 26.1 DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and D.C. Circuit Rule 26.1, Petitioners state that they are non-profit organizations. They each have no parent corporations and no publicly held corporation owns a 10 percent or greater ownership interest in any of the organizations.

/s/Katherine K. O'Brien
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GLOSSARY

APA	Administrative Procedure Act
ATSDR	Agency for Toxic Substances and Disease Registry
CDC	Centers for Disease Control and Prevention
CPSC	Consumer Product Safety Commission
DAP	Diallyl phthalate
DCHP	Dicyclohexyl phthalate
DEHP	Di-(2-ethylhexyl) phthalate
DIDP	Diisodecyl phthalate
DINP	Diisononyl phthalate
DIOP	Diisooctyl phthalate
EPA	United States Environmental Protection Agency
Food Additive Petition	Food additive petition 6B4815 dated March 18, 2016
FDA	United States Food and Drug Administration
NHANES	National Health and Nutrition Examination Survey
Phthalate Additives	DAP, DCHP, DEHP, DIDP, DINP
Order	Env't Def. Fund, et al.; Response to Objections and Requests for a Public Hearing, 89 Fed. Reg. 86,290 (Oct. 30, 2024).

INTRODUCTION

This case challenges FDA's 2024 decision to maintain its authorizations allowing companies to use toxic chemicals called phthalates in food packaging and food-production materials. The use of phthalates in these food-contact materials contaminates the food supply and causes population-wide exposure to phthalates.

FDA's authorizations rely on safety assessments conducted at least 40 years ago. In the intervening decades, the evidence of phthalates' serious health risks—including their capacity to harm children's brain development and cause life-altering changes in cognition and behavior—has expanded substantially. Despite this evidence, and evidence that food is the primary source of Americans' phthalate exposure, FDA denied Petitioners' petition and related objections seeking revocation of FDA's authorizations for food-contact use of phthalates. FDA did so without updating its decades-old safety assessments and without affirming that the phthalates' continued use "will be safe," as the Federal Food, Drug, and Cosmetic Act ("Food Act") requires. 21 U.S.C. § 348(c)(3)(A).

FDA committed to update its safety assessments for food-additive uses of phthalates 17 years ago, and it presided over an 8-year administrative process to evaluate Petitioners' arguments that modern science does not support FDA's outdated safety findings. Yet FDA still has not done what the law requires: rationally affirm the chemicals' safety or revoke their authorizations.

As explained by Dr. Ami Zota, a leading expert in phthalate exposure and hazards, with every year that phthalates remain in food-contact materials, "more people continue to be exposed to levels of phthalates in their food that are damaging to their health." [FDA-010871]. This includes children, whose ongoing exposure to phthalates in their food is acutely concerning because "[t]he effects of these early-life exposures on health and development can alter a person's entire life trajectory." *Id.*

To address FDA's abdication of its statutory duty to ensure the safety of chemicals in food-contact materials and the resulting harm to people's health, Petitioners seek an order from this Court vacating FDA's denial of Petitioners' objections and directing FDA to take action within 60 days to revoke the disputed authorizations or notice a hearing on Petitioners' objections as the Food Act mandates.

STATEMENT OF JURISDICTION

FDA had jurisdiction over Petitioners' objections and related petition pursuant to 21 U.S.C. § 348(b)-(c), (f), (i). FDA issued a final decision denying Petitioners' objections and hearing requests on October 30, 2024. [FDA-000001-FDA-000002].

On December 19, 2024, Petitioners timely petitioned for review of FDA's decision under 21 U.S.C. § 348(g), which confers jurisdiction on this Court. Petition for Review, Doc. 2091192.

STATEMENT OF ISSUES

1. Whether FDA unlawfully imposed on Petitioners the burden of proving that the phthalate additives are harmful.

2. Whether FDA arbitrarily rejected evidence of the phthalate additives' toxicity that supports significant questions about their safety.

3. Whether FDA arbitrarily rejected evidence concerning the magnitude of exposure to the phthalate additives that supports significant safety questions.

4. Whether FDA unlawfully disregarded the cumulative effect of exposure to multiple phthalates that contribute to the same health harms.

5. Whether FDA unlawfully denied Petitioners' requests for a hearing on their objections.

STATUTES AND REGULATIONS

Pertinent statutes and regulations appear in the accompanying addendum.

STATEMENT OF THE CASE

I. PHTHALATES

Phthalates are a class of synthetic chemicals used primarily as "plasticizers," which make rigid plastics flexible. [FDA-021101]. Phthalates are used in numerous

products including toys, flooring, personal care products, pharmaceuticals, and food-contact materials. *Id.*[2]

"Because phthalates are not chemically bound to the materials to which they are added," phthalates leach out of these products—either into the surrounding environment or, when used in food-contact materials, into food and beverages. [FDA-010705-FDA-010706] (Declaration of Dr. Russ Hauser). Multiple authoritative assessments have concluded that diet is the primary source of phthalate exposure in the United States. [FDA-013535]; [FDA-010706].

Large-scale biomonitoring studies by the Centers for Disease Control and Prevention ("CDC"), which measure chemical metabolites in human blood and urine, indicate that almost everyone in the United States has multiple phthalates in their body. [FDA-010720]. Further, "[p]hthalates are readily transferred from mother to fetus during pregnancy." [FDA-011907] (Engel et al. 2021).

Leading scientists have declared that this near-ubiquitous exposure presents "an urgent public health issue" given phthalates' serious health risks. [FDA-010722] (Hauser Declaration); *see also* [FDA-010870] (Declaration of Dr. Ami Zota). It is well established that phthalates interfere with fetal testosterone

[2] The phthalates at issue here are "ortho-phthalates," the most commonly used category of phthalates. [FDA-011906-FDA-011907]. For simplicity we refer to them as "phthalates."

production, leading to penile malformations and other birth defects. [FDA-010717]. Phthalates are also associated with infertility, miscarriage, preterm birth, cancer, and harm to brain development manifesting in behavioral disorders and reduced IQ in children. [FDA-010708-FDA-010714]; [FDA-013535-FDA-013537]; [FDA-012874]; [FDA-010259]; [FDA-000383]. Children and developing fetuses are especially vulnerable to phthalates' effects, and leading scientists have concluded that fetal and early childhood exposure to phthalates puts children at risk of irreversible health harm. [FDA-010714-FDA-010718]; [FDA-011906-FDA-011912].

II. FDA'S AUTHORIZATIONS FOR FOOD-CONTACT USE OF PHTHALATES BASED ON HALF-CENTURY-OLD SCIENCE

Beginning roughly 60 years ago, FDA approved the use of 28 phthalates as "food additives" in food-contact materials. The chemicals are regulated as food additives because they are known or expected to migrate from food-contact materials into food. 21 U.S.C. § 321(s); 21 C.F.R. § 170.3(e)(1).

The FDA safety assessments supporting these authorizations are based on data provided between 1961-1985, meaning that the evidence justifying FDA's ongoing approval of phthalate use in food-contact materials is, depending on the specific phthalate, *at least 40 years old and, for some phthalates, more than 60 years old.* [FDA-021102]. As discussed *infra*, the evidence of phthalates' health risks has expanded substantially in the intervening decades. This includes new

studies identifying health harms from phthalates that were unknown or poorly understood when FDA approved their use and updated exposure data.

Based on the mounting evidence of phthalates' dangers to human health—particularly children's health—more than 15 years ago Congress banned use of three phthalates in toys and childcare articles[3] and directed the Consumer Product Safety Commission ("CPSC") to convene an expert panel to study phthalates' effects on children's health and recommend additional restrictions. 15 U.S.C. § 2057c(a)-(b). In 2014, that expert panel recommended interim or permanent bans on six additional phthalates. [FDA-001381-FDA-001382]. Though the panel's charge was limited to recommending regulations to address phthalate exposure from toys and childcare articles, the experts determined through a comprehensive exposure assessment that "food, beverages, and drugs via direct ingestion, and *not children's toys and their personal care products*, constituted the highest [source of] phthalate exposures" and urged FDA to act. [FDA-001427].

FDA promised to do so 17 years ago. In 2008, FDA established a Phthalate Task Group to "address the potential risks raised in the contemporary [scientific] literature and to ensure that the authorized uses continue to meet the 'reasonable

[3] These include products "intended … to facilitate sleep or the feeding of children age 3 and younger, or to help such children with sucking or teething." 15 U.S.C. § 2057c(g)(1)(C).

certainty of no harm' safety standard for food additives." [FDA-013184]. In 2014, FDA assured Congress that it was "conducting the necessary risk assessments," [FDA-013189], and would "take appropriate regulatory action to remove these materials from the marketplace" if the "data no longer support the[ir] continued safe use." [FDA-013185]. More than a decade later, those assessments remain unfinished, and the public continues consuming phthalates in our food based on data and analyses that are roughly a half-century old.

III. FDA'S DUTY TO ENSURE FOOD ADDITIVES ARE SAFE

A. The Safety Standard for Food Additives

FDA's intransigence is at odds with its duty under the Food Act to "protect the public health by ensuring that … foods are safe." 21 U.S.C. § 393(b)(2)(A); *see POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 108 (2014) (explaining that the Food Act's primary purpose is "to protect the health and safety of the public at large"). FDA has a statutory duty to ensure the safety of food additives, 21 U.S.C. § 348(a), (c)(3)(A), which include substances added directly to food (such as flavorings and preservatives) as well as indirect food additives, which are used in food packaging and processing materials and are known or "reasonably … expected" to migrate into food, *id.* § 321(s); *see also id.* § 348(a)(3); 21 C.F.R. § 170.3(e)(1), (3).

Congress established an exacting standard for food-additive authorizations to effectuate the Food Act's purpose of ensuring the safety of the food supply. The Act dictates that all additives are presumed unsafe and prohibited unless the evidence before FDA proves "that the proposed use of [a] food additive … will be safe." 21 U.S.C. § 348(c)(3)(A). Under FDA's regulations, an additive is "safe" if the evidence supports a "reasonable certainty in the minds of competent scientists that the substance is not harmful under the conditions of its intended use." 21 C.F.R. § 170.3(i); *see also* S. Rep. No. 85-2422, at 5305 (1958) (explaining that the Act "requires proof of reasonable certainty that *no harm will result* from the proposed use of an additive" (emphasis added) (quotation omitted)); *id.* at 5309-10 (explaining Congress's intent to ensure "that nothing shall be added to the foods [people] eat which can reasonably be expected to produce any type of illness," "disease or disability" in "humans or animals").

To determine whether additives satisfy this stringent safety standard, FDA must consider, "among other relevant factors," (1) "the probable consumption of the additive and of any substance formed in or on food because of the use of the additive"; (2) "the cumulative effect" of consuming the additive in combination with "any chemically or pharmacologically related … substances in [the] diet"; and (3) scientifically accepted "safety factors" to provide an appropriate margin of

safety for human health when FDA is extrapolating from toxicology studies on animals. 21 U.S.C. § 348(c)(5).

B. Petitions for Adoption or Revocation of Food-Additive Authorizations

Any person may file a "food additive petition" asking FDA to issue, amend, or repeal a food-additive authorization. *Id.* § 348(b)(1), (i); 21 C.F.R. §§ 171.1, 171.130. When companies petition FDA to approve additives, "the petitioner bears the burden of showing that the additive … 'will be safe for its intended use.'" *In re Nat. Res. Def. Council*, 645 F.3d 400, 402-03 (D.C. Cir. 2011) (quoting 21 C.F.R. § 171.1(c)).

Petitioners seeking revocation of food-additive authorizations do not bear a comparable burden of proof. Instead, such petitioners must provide

> an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the existing regulation … may justify its amendment or repeal.

21 C.F.R. § 171.130(b). As FDA explained in granting such a petition, it must revoke food-additive authorizations if the evidence raises "significant questions as to the safety of the authorized uses" and there is "a lack of data … to address these questions." [FDA-009083]; *see also* [FDA-002005] (FDA affirming in this proceeding that it must revoke food-additive authorizations when petitioners present "sufficient data to establish the existence of safety questions significant

enough to support a finding that there is no longer a reasonable certainty of no harm from the currently approved uses").

The Food Act requires FDA to issue an order granting or denying food additive petitions within 180 days. 21 U.S.C. § 348(c)(2). Any person adversely affected by FDA's decision may submit "objections" to FDA, which are a prerequisite to judicial review. *Id.* § 348(f)(1), (g)(1). The objections may introduce new evidence. Indeed, the Act mandates that FDA "shall" hold a hearing "for the purpose of receiving evidence relevant and material to the issues raised by [the] objections" "as promptly as possible" and, "[a]s soon as practicable after completion of the hearing, … shall by order act upon such objections and make such order public." *Id.* § 348(f)(1). FDA's order on the objections (but not its initial decision on the petition) is final agency action reviewable in this Court. *Id.* § 348(g)(1).

IV. FDA'S DECISION TO MAINTAIN ITS DECADES-OLD AUTHORIZATIONS FOR PHTHALATE ADDITIVES WITHOUT AFFIRMING THEIR SAFETY

A. The 2016 Food Additive Petition

In March 2016, most of the Petitioners and allied organizations filed the petition that initiated this proceeding, asking FDA to revoke its regulations authorizing food-contact use of phthalates and prospectively ban food-contact use

of the phthalates identified as unsafe by CPSC's expert panel.[4] [FDA-012416-012484] ("Food Additive Petition" or "Petition"). Petitioners' revocation requests targeted two categories of regulations: (1) FDA's regulations authorizing use of 28 phthalates as indirect food additives in food-contact materials,[5] and (2) FDA's regulation authorizing certain food-contact uses of five of those phthalates pursuant to "prior sanctions," which are authorizations FDA issued allowing direct or indirect addition of chemicals to food before Congress's 1958 amendments to the Food Act. 21 C.F.R. §§ 181.1, 181.5, 181.27.

FDA accepted the portion of the Petition asking FDA to revoke its regulations authorizing use of 28 phthalates as food additives. [FDA-018562]. But FDA notified Petitioners that they must submit a separate "citizen petition," which is governed by different procedures, to address their requests to revoke FDA's prior sanctions for five phthalates and adopt regulations prospectively prohibiting food-contact use of the phthalates determined to be unsafe for children's products by CPSC's expert panel. *Id*. Petitioners resubmitted those requests in a citizen petition

[4] For simplicity, we refer to both the organizations who submitted the 2016 petition and Petitioners before this Court as "Petitioners," as the differences in the specific organizations involved at various stages are immaterial to the issues presented.

[5] The Petition originally addressed 30 chemicals, but Petitioners subsequently narrowed its scope to 28 phthalates. [FDA-018690].

in April 2016. [FDA-018569-FDA-018574]. The citizen petition is not at issue in this proceeding.

The Food Additive Petition presented substantial scientific evidence published in the decades since FDA issued its food-additive authorizations for phthalates documenting the chemicals' health harms and identifying data gaps that add to safety concerns. [FDA-012422-FDA-012423, FDA-012432, FDA-012451-FDA-012468]. Further, going beyond the requirements of the Food Act and FDA's regulations, Petitioners presented an argument that dietary exposure among women and children to the 28 phthalates approved as additives at that time exceeds the level at which health harm may occur. [FDA-012416-FDA-012430, FDA-012432, FDA-012439-FDA-012444, FDA-012451-FDA-012468, FDA-012472]. This argument relied in part on the assertion that the 28 then-approved phthalates are sufficiently similar to treat them as a class for safety assessment, meaning FDA could rely on evidence of health harms associated with the more-studied phthalates to assess the safety of the class and that FDA must consider the cumulative effects of all phthalates in the class. [FDA-012416-FDA-012430, FDA-012432]. In response to FDA's request, Petitioners submitted additional toxicity and exposure data in 2017. [FDA-018690-FDA-018760].

B. FDA's 2022 Decisions on Phthalates in Food-Contact Materials

Contrary to FDA's statutory mandate to grant or deny the Food Additive Petition within six months, 21 U.S.C. § 348(c)(2), it failed to act for more than six years, forcing Petitioners to petition this Court for a writ of mandamus to compel FDA's overdue decision. Petition for Writ of Mandamus, *In re Env't Def. Fund et al.*, No. 21-1255 (D.C. Cir. Dec. 7, 2021), Doc. 1926652.

On May 20, 2022, FDA finally acted on the Petition and took three other actions concerning phthalates in food-contact materials:

First, FDA granted a 2018 petition from a plastics industry trade group to revoke FDA's food-additive authorizations for 23 of the 28 phthalates addressed in Petitioners' Food Additive Petition on the basis that industry has "abandoned" use of those phthalates such that FDA's authorizations are no longer needed. [FDA-021091-FDA-021100]. That decision substantially altered the regulatory landscape, leaving five phthalates—instead of 28—approved as food additives: dicyclohexyl phthalate ("DCHP"), di-(2-ethylhexyl) phthalate ("DEHP"), diisononyl phthalate ("DINP"), diisodecyl phthalate ("DIDP"), and diallyl phthalate ("DAP") (collectively, the "Phthalate Additives" or the "Additives"). [FDA-000007]. This does not signify a reduction in phthalate use or exposure; a 2023 study detected one or more phthalates in 100% of sampled foods, with DEHP detected in 100% of

foods tested, DINP in nearly 25%, and DCHP in roughly 10%. Carey Perez de Alejo Decl. ¶ 11.

Second, FDA denied Petitioners' Food Additive Petition. [FDA-002004-FDA-002017]. Puzzlingly, that decision rested on FDA's assertion that Petitioners failed to prove that the 28 phthalates previously approved as additives harm human health based on their evaluation as a class, ignoring that FDA had mooted Petitioners' arguments concerning class-based assessment of that group of 28, and the safety of 23 of those additives, by granting the industry abandonment petition. [FDA-002013].

Third, FDA denied Petitioners' citizen petition, leaving in place FDA's prior sanctions authorizing food-contact use of five phthalates: butylphthalyl butyl glycolate, diethyl phthalate, ethylphthalyl ethyl glycoate, DEHP, and diisooctyl phthalate ("DIOP"). [FDA-021077-FDA-021090].

Fourth, FDA published a "request for information" concerning phthalates in food-contact materials. [FDA-021101]. There, FDA affirmed that its still-active authorizations for food-contact uses of phthalates are "based on exposure and toxicological information and data provided during the period of 1961 through 1985." [FDA-021102]. FDA stated that it "*may* use [the] information [requested] to update the dietary exposure estimates and safety assessments" for phthalates in the future. *Id.* (emphasis added). FDA did not explain its decision to defer that

potential safety reassessment to an indeterminate future date, instead of conducting it in response to Petitioners' petitions that FDA had been considering for more than six years, or through the assessments initiated by FDA's Phthalate Task Group 17 years ago.

C. Petitioners' Objections to the 2022 Petition Denial

In June 2022 Petitioners submitted timely objections to FDA's decision denying their Food Additive Petition and requested a hearing. [FDA-009531-FDA-009585]. The objections focused on the safety of the five Phthalate Additives that remain approved, since, as noted, FDA's decision granting the industry abandonment petition mooted Petitioners' arguments about the safety of the 23 phthalates whose authorizations FDA had revoked. [FDA-009533-FDA-009535]. Consistent with the Food Act's provisions governing petition proceedings, which contemplate expanding the record at the objections stage, 21 U.S.C. § 348(f), Petitioners' objections included dozens of scientific studies and analyses concerning the Phthalate Additives' safety that were published since Petitioners last supplemented the Petition record in 2017. *See generally* [FDA-009547-FDA-009585].

Petitioners filed eight objections:

Objections 1 and 2 argued that FDA applied an erroneous legal standard to the Petition, unlawfully placing on Petitioners the burden of proving that the

Phthalate Additives cause harm under their approved conditions of use. [FDA-009538-FDA-009546]. As a result, FDA unlawfully denied the Petition and failed to reassess the Additives' safety, instead deciding to maintain its authorizations for the Additives without updating its decades-old safety assessments. *Id*.

Objection 3 argued that FDA failed to rationally address the substantial body of recent toxicity information Petitioners presented that links the Additives to numerous health harms—including health harms that were not documented in the scientific literature when FDA approved the Additives. [FDA-009547-FDA-009551]. Petitioners requested a hearing on this objection. [FDA-009551-FDA-009552].

Objections 4-6 argued that FDA applied an erroneous interpretation of "chemically or pharmacologically related" substances and, as a result, failed to consider that multiple Phthalate Additives, and additional phthalates found in food, pose cumulative health risks. [FDA-009552-FDA-009570]. Petitioners requested a hearing on whether multiple phthalates approved for food-contact use or otherwise present in food are "chemically or pharmacologically related" such that FDA must consider their cumulative effects in assessing safety. [FDA-009560-FDA-009561, FDA-009564-FDA-009565, FDA-009567-FDA-009570].

Objections 7 and 8 argued that FDA unlawfully required Petitioners to provide evidence that dietary exposure to the Phthalate Additives exceeds safe

levels and irrationally concluded that the exposure evidence Petitioners provided fails to establish significant safety questions. [FDA-009570-FDA-009579]. Petitioners requested a hearing on whether the exposure evidence they presented, in conjunction with other evidence, raises significant safety questions. [FDA-009579].

D. FDA's 2024 Order Denying Petitioners' Objections

More than two years later, FDA published the order under review, which summarily denied Petitioners' objections without a hearing. [FDA-000001-FDA-000016] (the "Order"). FDA's Order, like its prior petition denial, rests principally on the assertion that Petitioners "failed to provide sufficient support for [their] request to revoke the authorization for the 28 []phthalates that were the subject of the [2016] petition." [FDA-000004]. FDA did not update its safety assessments for the five Phthalate Additives that remain approved nor determine, based on the record before FDA, that their continued use "will be safe." 21 U.S.C. § 348(c)(3)(A).

SUMMARY OF ARGUMENT

FDA's Order is arbitrary, capricious, and contrary to the Food Act and FDA's regulations.

First, FDA unlawfully imposed on Petitioners the burden of proving that the Phthalate Additives are harmful. That approach contravenes the Food Act, FDA's

regulations, and past FDA practice, which establish that petitioners seeking revocation of food-additive authorizations need only introduce new evidence of the additives' toxicity that raises significant questions about their safety that FDA cannot rationally dispel. *Infra* Point II.

Second, FDA arbitrarily rejected record evidence demonstrating numerous toxic effects of the Phthalate Additives—including effects FDA never considered in approving them—and demonstrating that food is the predominant exposure source. Further, FDA unlawfully failed to consider the cumulative effects of exposure to multiple phthalates that cause the same health harm as part of an assessment of the Additives' safety. Contrary to FDA's conclusions, this evidence supports significant safety questions that FDA failed to rationally address. *Infra* Point III.

Finally, assuming for the sake of argument that FDA was not required to revoke the Phthalate Additives' approvals based on the existing record, FDA unlawfully denied Petitioners a hearing on disputed issues of material fact raised in their objections. *Infra* Point IV.

To remedy FDA's persistent and unlawful refusal to revoke the Additives' approval or rationally affirm their safety, the Court should vacate the Order and direct FDA to, within 60 days, initiate revocation proceedings or notice a hearing. *Infra* Point V.

STANDING

Petitioners are non-profit organizations dedicated to protecting people from toxic chemicals in food, consumer products, and the environment. They have standing to sue on behalf of their members and supporters, and their children, who suffer harm from FDA's food-additive authorizations for toxic phthalates that would be redressed by a favorable decision from this Court.

Where, as here, an organization sues on its members' behalf, it must show that: (1) "its members would otherwise have standing to sue in their own right"; (2) "the interests it seeks to protect are germane to the organization's purpose"; and (3) "neither the claim asserted nor the relief requested requires the participation of individual members." *Nat. Res. Def. Council v. Wheeler*, 955 F.3d 68, 76-77 (D.C. Cir. 2020) (quotation omitted); *see Flyers Rights Educ. Fund v. U.S. Dep't of Transp.*, 957 F.3d 1359, 1361-62 (D.C. Cir. 2020) (holding that this standard applies to organizations with functional equivalent of members).

Petitioners' members and supporters would have standing to sue in their own right because they suffer "injury in fact" that is traceable to FDA's decision and likely to be redressed by a favorable judicial decision. *Nat. Res. Def. Council*, 955 F.3d at 76 (quotation omitted). Because of FDA's decision to reject Petitioners' objections and maintain its authorizations for the Phthalate Additives, Petitioners' members and supporters are exposed to the Additives in food, putting them and

their children at risk of serious health harms. They eat numerous foods in which the Additives have been detected, including dairy products, meat, cooking oils, spices, and various processed foods. Tarrant Decl. ¶¶ 10-11; Cole Decl. ¶ 10; Doughty Decl. ¶ 13; Ames Decl. ¶ 6; Bissell Decl. ¶¶ 9-11; Durrant Decl. ¶ 6; Drew Decl. ¶¶ 7-8; Larson Decl. ¶ 11. Some of Petitioners' members and supporters have limited food options, leading them to rely on processed foods or cafeteria meals that often contain higher phthalate levels. [FDA-010862]; Tarrant Decl. ¶¶ 9, 11-13; Miller Decl. ¶¶ 10-11; Drew Decl. ¶ 6. Some are parents of young children, who are more susceptible to harm from phthalates. Durrant Decl. ¶ 2; Doughty Decl. ¶ 3; Johns Decl. ¶ 12. They invest time and money trying to reduce exposure to phthalates in their food, Tarrant Decl. ¶ 12; Cole Decl. ¶ 13; Doughty ¶¶ 11-12; Ames Decl. ¶ 9; Bissell Decl. ¶ 8; Drew Decl. ¶ 10, and they suffer stress and anxiety knowing they cannot effectively avoid phthalates in food so long as FDA continues authorizing their use, Cole Decl. ¶¶ 11, 15; Doughty ¶ 14; Bissell ¶¶ 8-10, 12; Durrant Decl. ¶ 8; Larson Decl. ¶ 15. These harms satisfy the injury-in-fact requirement. *See Sierra Club v. EPA*, 755 F.3d 968, 974 (D.C. Cir. 2014) (injury-in-fact demonstrated by "particularized fears of serious health and environmental consequences" and "individual behavioral changes prompted by the toxic exposure" that agency action "will cause").

A favorable decision would make it "likely, as opposed to merely speculative" that these injuries would be redressed. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992) (quotation omitted); *see also Teton Historic Aviation Found. v. Dep't of Def.*, 785 F.3d 719, 726 (D.C. Cir. 2015) ("[A] party seeking judicial relief need not show to a certainty that a favorable decision will redress its injury." (quotation and alteration omitted)). A decision from this Court setting aside FDA's Order would likely compel FDA to take action on remand to revoke approval for some or all of the Phthalate Additives, thereby reducing exposure to those chemicals among Petitioners' members and supporters and their children. *See Erwin v. FAA*, 23 F.4th 999, 1005-06 (D.C. Cir. 2022) (explaining that remand would likely redress injuries even if outcome was uncertain); *Competitive Enter. Inst. v. NHTSA*, 901 F.2d 107, 118 (D.C. Cir. 1990) (finding redressability met where "[a] remand that would leave the agency free to exercise its discretion in a proper manner … could lead to agency action that would redress petitioners' injury").

Second, this case advances Petitioners' purpose of protecting the health of their members, supporters, and the public from toxic chemicals such as phthalates. Miller Decl. ¶ 4; Van Vliet Decl. ¶¶ 2, 10; Azimi-Gaylon Decl. ¶¶ 2, 5; Hanson Decl. ¶¶ 3-4; Lurie Decl. ¶¶ 2, 9-10; Carey Perez de Alejo Decl. ¶ 1; Doa Decl. ¶ 3; Johns Decl. ¶ 10.

Third, this lawsuit does not require individual members' participation as it "turns entirely on whether [FDA] complied with its statutory obligations, and the relief it seeks is invalidation of agency action." *Ctr. for Sustainable Econ. v. Jewell*, 779 F.3d 588, 597 (D.C. Cir. 2015).

ARGUMENT

I. STANDARD OF REVIEW

Since the Food Act does not establish a standard for judicial review of FDA's Order, the Court should apply the standard set forth in the Administrative Procedure Act ("APA"). *Dickson v. Sec'y of Def.*, 68 F.3d 1396, 1404 n. 12 (D.C. Cir. 1995). The APA requires the Court to "hold unlawful and set aside" FDA action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2).

Agency action is arbitrary and capricious when "the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983). The agency must "examine the relevant data and articulate a … rational connection between the facts found and the choice made." *Id.* (quotation omitted).

The Court applies traditional tools of statutory interpretation to "determine the best reading of the statute"—"the reading the court would have reached if no agency were involved." *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 400 (2024) (quotation omitted).

II. FDA UNLAWFULLY PLACED ON PETITIONERS THE BURDEN OF PROVING THAT THE PHTHALATE ADDITIVES ARE HARMFUL

The Court should vacate FDA's Order because FDA applied an erroneous legal standard to Petitioners' requests to revoke approval for the Phthalate Additives, improperly imposing on Petitioners the burden of proving that the Additives cause harm under their approved conditions of use. *E.g.*, [FDA-000005-FDA-000006].

This error alone requires vacatur. "Under settled principles of administrative law, when a court reviewing agency action determines that an agency made an error of law, the court's inquiry is at an end: the case must be remanded to the agency for further action consistent with the corrected legal standards." *PPG Indus. v. United States*, 52 F.3d 363, 365 (D.C. Cir. 1995).

Moreover, because of this error, FDA failed to determine based on the evidence before it whether there remains a reasonable certainty of no harm from the Phthalate Additives' use, as the Food Act requires. 21 U.S.C. § 348(a)(2), (c)(3)(A); 21 C.F.R. § 170.3(i). Instead, FDA maintained the Additives'

authorizations based on decades-old safety assessments. This too violates the Food Act.

A. FDA's Approach Contravenes the Food Act

In its Order, FDA unlawfully imposed on Petitioners the burden of proving that the Phthalate Additives are harmful. FDA asserted that, like a company seeking approval for an additive, Petitioners had the burden of proof on the ultimate question of the Additives' safety. *See* [FDA-000005] (Order stating that the Food Act "make[s] clear that the evidentiary burden to support authorization of a food additive's use lies with the petitioner seeking such authorization" and that petitioners seeking revocation of food-additive authorizations "likewise must provide a well-supported petition adequately justifying such action"). And FDA rejected Petitioners' objections because they purportedly did not prove "that dietary exposure levels from [the Phthalate Additives] exceed a safe level." [FDA-000006]; *see also, e.g.*, [FDA-000009] (rejecting Petitioners' toxicity evidence because it supposedly is "insufficient to justify resolution of the factual question of safety" in Petitioners' favor).[6]

[6] Even assuming for the sake of argument that FDA applied the correct standard by requiring Petitioners to establish only significant questions regarding the Additives' safety, FDA irrationally concluded that Petitioners failed to meet that standard. *See infra* Point III.

FDA's approach is irreconcilable with the Food Act's central premise for food-additive regulation, which is a presumption that additives are unsafe and prohibited unless the company advocating for their use proves that their use "will be safe," 21 U.S.C. § 348(c)(3)(A)—meaning there is a reasonable certainty that they will cause no health harm under their intended conditions of use, 21 C.F.R. §§ 12.87(d), 170.3(i); *see also* [FDA-002005] (FDA acknowledging that the Act "makes clear that food additives introduced into commerce must be shown to be safe"). FDA's approach also contravenes the Act's broader food safety standard, which is precautionary and rigorous given Congress's "inten[t] to protect the public health from *possible* injury" threatened by substances "which *might* render [food] injurious to the health of consumers." *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399, 409 (1914) (emphases added). The Act prohibits substances in food that "may possibly injure the health of any" consumer, including those who are particularly susceptible to harm because of their age, underlying health conditions, or other factors. *Id.* at 411. Proof of harm "is not required." *Id.*[7]

[7] Under the Food Act, food containing any additive that is not proven safe is "adulterated" and its sale or distribution prohibited. 21 U.S.C. §§ 331, 342(a)(1). *Lexington Mill* discusses the adulteration standard, which, like the contemporary safety standard for additives, turns on whether any added substance in food may make it "injurious to health." 232 U.S. at 411.

To effectuate these standards, the burden of proof in a petition proceeding concerning an additive's safety is necessarily asymmetrical: Companies advocating to obtain or maintain approval for an additive bear a "heavy" burden of proving that its use will be harmless. *Fmali Herb, Inc. v. Heckler*, 715 F.2d 1385, 1391 (9th Cir. 1983). But when FDA or members of the public initiate the procedure to revoke an additive's approval based on safety concerns, they are not required to prove that the additive causes harm. Instead, as FDA has explained in prior proceedings, such petitioners must provide evidence that raises "significant questions as to the safety of the authorized uses." [FDA-009083]. If "there is a lack of data … to address these questions" and support a reasoned determination that the additives' continued use will be safe, revocation is warranted. *Id.*

Although FDA referenced the correct standard for revocation petitions in its 2022 decision denying the Food Additive Petition, [FDA-002005], and claimed in a portion of the Order that it applied that standard, [FDA-000006], the Order as a whole demonstrates that FDA imposed on Petitioners the burden of proving that the Additives cause harm under their approved conditions of use. FDA's rationale in the Order is not a model of clarity, but appears to rest on FDA's misguided view that, because the Food Act directs FDA to promulgate regulations establishing "procedure[s]" for revocation petitions that "conform" to the Act's procedures for approving additives, 21 U.S.C. § 348(i), the evidentiary burden on petitioners

seeking revocation of food-additive authorizations must be the same as the burden on petitioners seeking approval. [FDA-000004-FDA-000005].

That is not the "best reading" of the statute. *Loper Bright*, 603 U.S. at 400. The statutory directive to make the *procedures* for revocation petitions consistent with the procedures for approving additives does not alter the Food Act's substantive mandate prohibiting additives for which there are any significant safety concerns. *See* 21 U.S.C. § 348(c)(3)(A) (requiring proof that additive "will be safe"); 21 C.F.R. § 170.3(i) ("Safe … means … reasonable certainty … that the substance is not harmful under the conditions of its intended use."). To effectuate that mandate, FDA may not deny a revocation petition because, in its view, the petitioner has failed to prove that the additives' use is in fact harmful.

B. FDA's Approach Contravenes Its Regulations

Imposing the burden of proof on Petitioners also violates FDA's regulations. Those regulations are explicit that the party in petition proceedings "who is contending that the [additive] is safe … and who is … contesting withdrawal of approval has the burden of proof in establishing safety." 21 C.F.R. § 12.87(d); *see also Nat. Res. Def. Council v. FDA*, 884 F. Supp. 2d 127, 139 (S.D.N.Y. 2012) (holding that, in FDA-initiated proceeding to revoke animal drug approval, also governed by 21 C.F.R. § 12.87, "FDA has the initial burden of producing evidence that the drug has not been shown to be safe" but "the drug sponsor has the burden

of persuasion on the ultimate question of whether the drug is shown to be safe" (quotation and alteration omitted)); [FDA-021154] (FDA explaining that "to institute a proceeding to limit or revoke the approval of [an additive], FDA would not be required to show that [the additive] is unsafe.… [The company which petitioned for its approval] would have the burden to establish the safety of the additive.").

Accordingly, FDA's regulation governing revocation petitions does not require petitioners to provide evidence proving that exposure to the additive exceeds safe levels, as FDA required here. Instead, it requires revocation petitions to include only "an assertion of facts, supported by data, showing that new information exists with respect to the food additive …, that new data are available as to toxicity of the chemical, or that experience with the existing regulation … may justify its amendment or repeal." 21 C.F.R. § 171.130(b).

Interpreting substantially similar Food Act regulations governing petitions to repeal pesticide tolerances, which establish allowable levels of pesticide residue in food, the Ninth Circuit rejected the agency's argument (there, the Environmental Protection Agency ("EPA")) that petitioners seeking revocation of tolerances bear "a burden of persuasion" to "affirmatively demonstrate that the tolerances are unsafe." *League of United Latin Am. Citizens v. Regan*, 996 F.3d 673, 695 (9th Cir. 2021) ("*LULAC*"). Instead, the court held that the regulations—which, like those at

issue here, require petitioners to provide "an assertion of facts" with supporting data "showing … that new data are available as to toxicity of the chemical, or that experience with the application of the [existing regulation] … may justify its modification or revocation"—impose only "a burden of production" on petitioners, not the burden of proof on the tolerance's safety. *Id.* at 694-95 (quoting 40 C.F.R. § 180.32(b)). The court emphasized that imposing that burden of proof on petitioners would contravene the regulatory language and the Food Act's health-protective purpose—a conclusion that applies with equal force here. *Id.*[8]

C. FDA's Approach Is Inconsistent with Past Practice

FDA's Order cannot be reconciled with past agency practice, notably FDA's 2016 decision granting a petition to revoke food-additive authorizations for three long-chain perfluorinated chemicals (the "PFAS Additives"). [FDA-009081-FDA-009084]. There, FDA affirmed that its regulations require petitioners seeking revocation of food-additive authorizations to "demonstrate that new data are

[8] FDA's Order dismissed *LULAC* on the basis that the Food Act's provisions governing pesticide tolerances provide that EPA "may establish *or leave in effect* a tolerance … only if [EPA] determines that the [tolerance] is safe," which the Ninth Circuit read to "impose[] a continuous duty" to ensure the safety of tolerances. [FDA-000005] (quoting *LULAC*, 996 F.3d at 692). But this textual distinction does not salvage FDA's position. As FDA acknowledges, it, like EPA respecting pesticide tolerances, has a "continuing obligation to oversee the safety of the food supply," including by assessing "whether there continues to be a basis for a reasonable certainty that the use of [an approved food additive] is not harmful," [FDA-021153], and to revoke approval for additives when the current evidence no longer supports that safety finding, [FDA-009082-FDA-009083].

available as to the toxicity of the food additive that may justify amendment of the food additive regulation." [FDA-009082] (discussing 21 C.F.R. §§ 171.1, 171.100, 171.130). FDA noted that those petitioners provided information post-dating FDA's approval of the PFAS Additives showing that similar chemicals are associated with reproductive and developmental harm. [FDA-009083]. FDA determined that the evidence linking similar chemicals to these health harms and showing that the chemicals can build up in the body "raise[d] significant questions as to the safety of the authorized uses" of the PFAS Additives. *Id.* Because FDA lacked "data specific to the three [PFAS Additives] to address these questions," it concluded "that there is no longer a reasonable certainty of no harm from the[ir] food contact use" and revoked their authorizations. *Id.* FDA did not require the petitioners to prove that the PFAS Additives are harmful; indeed, it acknowledged a lack of studies establishing the toxic effects of the specific PFAS Additives or evidence that would permit FDA to quantify consumer exposures to those additives. *Id.*

FDA's approach here cannot be reconciled with its decision granting the PFAS Additives petition. FDA's "failure to come to grips with conflicting precedent constitutes an inexcusable departure from the essential requirement of reasoned decision making." *Ramaprakash v. FAA*, 346 F.3d 1121, 1125 (D.C. Cir. 2003) (quotation omitted).

In sum, contrary to the Food Act, FDA's regulations, and past practice, FDA required Petitioners to prove that use of the Phthalate Additives causes harm because their "dietary exposure levels … exceed a safe level." [FDA-000006]. For this reason alone, FDA's Order must be set aside. *PPG Indus.*, 52 F.3d at 365.

D. FDA Failed to Determine Whether the Phthalate Additives Are Safe

Moreover, due to this error, FDA failed to reassess the Phthalate Additives' safety in light of the evidence presented and either determine that there remains a reasonable certainty of no harm from the Additives' use or, if FDA could not rationally do so, revoke their approvals. *Cf.* [FDA-009083] (FDA explaining that it revoked the PFAS Additives' approvals because data for similar chemicals "raise[d] significant questions as to the safety of the [PFAS Additives]" and "there [was] a lack of data specific to the [PFAS Additives] to address these questions"). Thus, strikingly absent from FDA's Order is any determination that, based on the evidence before FDA at the time of its decision, ongoing use of the Phthalate Additives "will be safe." 21 U.S.C. § 348(c)(3)(A).

To the contrary, the information request FDA issued the same day it denied the Petition affirms that FDA is still relying on safety assessments it conducted on the Phthalate Additives approximately 40-60 years ago to justify their ongoing use, and that it "may" choose to update these assessments at some unidentified future time. [FDA-021102]. Consistent with those statements, FDA's Order makes no

claim that FDA assessed the Additives' safety in response to Petitioners' objections. *See* [FDA-000007] (FDA declining to dispute Petitioners' assertion that "FDA did not conduct a new safety analysis of … the five [Phthalate Additives]" and stating that FDA conducted that analysis only "[w]hen we originally authorized the use of these five additives" 40-plus years ago). Indeed, FDA did not even consider the basis for its safety determinations when evaluating whether the new evidence Petitioners presented undermines those determinations; FDA's safety assessments for the Additives are not in record. *See* Administrative Record Index, Doc. 2104809.

FDA's continued reliance on decades-old safety assessments for the Phthalate Additives, which it refused to update during its eight-year review of Petitioners' Petition and objections, violates the Food Act. As FDA acknowledges, the Act imposes on FDA a "continuing obligation to oversee the safety of the food supply" by determining "whether there *continues to be* a basis for a reasonable certainty that the use of [an additive] is not harmful." [FDA-021153] (emphasis added); *see also* 21 U.S.C. § 348(a), (c)(3) (providing that all additives are presumptively unsafe and unlawful unless "a fair evaluation of the data before [FDA]" proves their use "will be safe"). Here too, FDA's decision cannot be reconciled with its decision granting the PFAS Additives petition, where FDA reviewed the new safety information the petitioners provided and "also conducted

its own updated critical review of the literature database … in order to assess whether the overall weight of the evidence" supported the requisite safety finding. [FDA-003329]. This unexplained inconsistency is the hallmark of arbitrary decision-making. *Ramaprakash*, 346 F.3d at 1125.

Further, if accepted, FDA's approach would permit the agency to continue playing "administrative keep-away" with the question of the Phthalate Additives' safety, *In re Am. Rivers & Idaho Rivers United*, 372 F.3d 413, 420 (D.C. Cir. 2004), which leading experts have characterized as an urgent public health issue requiring immediate resolution, [FDA-010722] (Hauser Declaration); [FDA-010871] (Zota Declaration). FDA launched a formal investigation into the safety of using phthalates in food-contact materials *17 years ago*, [FDA-013184], and presided over an eight-year petition proceeding centered on the same question. Yet the public continues to consume the Phthalate Additives based on decades-old safety assessments, which FDA will not commit to updating. This recalcitrance makes a mockery of FDA's duty to "ensur[e] that … foods are safe," 21 U.S.C. § 393(b)(2)(A), and violates its obligation to determine "whether there continues to be reasonable certainty of no harm from the use of" the Phthalate Additives, [FDA-021153]; *see* 21 U.S.C. § 348(a), (c)(3). For this reason too, FDA's Order should be vacated.

III. FDA ARBITRARILY REJECTED EVIDENCE THAT RAISES SIGNIFICANT QUESTIONS ABOUT THE PHTHALATE ADDITIVES' SAFETY

In denying Petitioners' objections, FDA arbitrarily dismissed decades of evidence that raises significant questions about the Phthalate Additives' safety. First, FDA irrationally dismissed extensive toxicity evidence post-dating its authorizations that links the Additives to numerous health harms and identifies the exposure levels at which harm may occur. This includes toxicological studies on animals and epidemiological studies, which record observed associations between chemical exposures and health harms in people. Second, FDA irrationally disregarded evidence that dietary exposures to the Additives pose health risks. Third, FDA unlawfully disregarded the cumulative effects of people's exposure to multiple phthalates in their diet that contribute to the same health harms and therefore increase their risks of harm.

A. FDA Irrationally Disregarded Decades of New Toxicity Evidence

Petitioners provided FDA with decades of toxicity evidence post-dating FDA's approval of the Phthalate Additives, which satisfied Petitioners' burden of providing new toxicity data that creates significant safety questions. 21 C.F.R. § 171.130(b); [FDA-009083]; [FDA-002005]. FDA's Order irrationally dismisses this evidence and provides no reasoned basis for concluding that the evidence fails to establish significant safety questions.

1. Petitioners submitted extensive evidence post-dating FDA's approvals linking the Phthalate Additives to serious health harms

As FDA acknowledges, "the body of available toxicological information on phthalates has expanded" since FDA assessed the Phthalate Additives' safety "during the period of 1961 through 1985." [FDA-021102]. Indeed, in support of their Petition and objections, Petitioners presented more than two hundred new studies addressing phthalates' toxic effects, the doses at which those effects may occur, and the mechanisms through which the chemicals cause harmful changes in the body, as well as assessments of that evidence by other federal authorities. *See* [FDA-012446-FDA-012471]; [FDA-018696-FDA-018721]; [FDA-010658-FDA-010660, FDA-010692-FDA-010696]. Petitioners also submitted declarations from leading experts in phthalates' health effects synthesizing the evidence and concluding that FDA's authorization of phthalate use in food-contact materials is harming human health. [FDA-010697-FDA-010848]; [FDA-010849-FDA-010940].

The toxicity evidence presented includes peer-reviewed studies linking the Phthalate Additives to adverse effects on brain development and preterm birth, [FDA-009547-FDA-009549]; [FDA-018699-FDA-018700]—health harms that were not documented in the scientific literature when FDA approved the Additives decades ago and which, therefore, FDA never considered in determining the

Additives are safe. *Compare* [FDA-011906] (Engel et al. 2021) (explaining that "robust data from longitudinal birth cohort studies conducted over the last decade … have shown associations between prenatal exposures to ortho-phthalates and attention-deficit hyperactivity disorder (ADHD), other behavioral problems, adverse cognitive development including lower IQ, poorer psychomotor development, and impaired social communication"), *with* [FDA-002018-FDA-002024] (FDA scientists' 1973 paper summarizing toxicology literature on approved phthalates, identifying no studies on neurodevelopmental effects). *See also* [FDA-000610-FDA-000627] (reviewing studies on neurodevelopmental effects of DEHP, all of which post-date 1985); [FDA-000380, FDA-000574-FDA-000583] (reviewing pre-term birth studies, which likewise post-date 1985).

In addition, Petitioners submitted research showing that adverse effects may occur at substantially lower doses than studies indicated at the time of FDA's approvals. *Compare* [FDA-001125] (identifying 4.8 milligrams per kilogram of bodyweight per day as "no adverse effect" level for DEHP), *with* [FDA-002021] (1973 paper by FDA scientists identifying no-effect level for DEHP of 60 milligrams per kilogram of bodyweight per day or higher).

Petitioners also submitted evidence of many other health harms linked to the Phthalate Additives, including recent studies linking DCHP to elevated cholesterol and reproductive harm; DINP to liver toxicity and insulin resistance; and DEHP to

developmental toxicity, reproductive toxicity, liver toxicity, immune system harm, diabetes, hormonal effects, and breast cancer recurrence. [FDA-009547-FDA-009549, FDA-009581-009585]. And Petitioners provided FDA's 2012 guidance for drug manufacturers, which reviewed recent research linking DEHP to multiple adverse health effects and concluded that DEHP should not be used in regulated drugs because of the risks of developmental and reproductive toxicity. [FDA-013334-FDA-013337].

These submissions more than satisfied Petitioners' burden of "assert[ing] … facts, supported by data, showing that … new data are available as to toxicity of the [Phthalate Additives]" that raise significant questions about their safety, 21 C.F.R. § 171.130(b); [FDA-009083]; [FDA-002005], and belie FDA's conclusory assertion that Petitioners did not adequately explain "why these materials support a finding that there are significant [safety] questions." [FDA-000008].

2. FDA irrationally discounted Petitioners' toxicity evidence

To the extent FDA addressed the substance of this evidence, it failed to rationally conclude that the evidence raises no significant safety questions.

FDA's Order asserted that the evidence is inadequate because the toxicity studies purportedly fail to "place[]" the identified health hazards "in the context of exposure." *Id*. As FDA explained, "when evaluating the safety of a substance, scientists will often determine the 'dose-response' relationship of substance

exposure and toxic effect" and use that data to calculate an acceptable daily intake level for a chemical that can be compared to real-world exposures to assess risk. [FDA-000008-FDA-000009]. Contrary to FDA's claim, Petitioners provided dose-response studies. For example, they provided multiple studies showing reproductive and developmental effects from different doses of DEHP. *See, e.g.*, [FDA-012983-FDA-012994]; [FDA-015301-FDA-015312]; [FDA-011794-FDA-011803]; [FDA-009728-FDA-009747]; [FDA-009970-FDA-009979]. These studies contain precisely the sort of data on which FDA "typically base[s]" its calculation of acceptable intake levels. [FDA-000009] (Order). Petitioners also provided assessments by other governmental authorities synthesizing dose-response data for the Phthalate Additives and identifying exposure levels associated with harm. *See, e.g.*, [FDA-000386, FDA-000392-FDA-000470] (Agency for Toxic Substances and Disease Registry ("ATSDR") report reviewing dose-response studies on DEHP and calculating exposure levels below which non-cancer health harms are not expected).

FDA's Order does not dispute these studies' findings, asserting instead that the objections supposedly did not explain "how these studies would be adequate to assess the safety" of the Phthalate Additives. [FDA-000009]. This is inadequate to sustain FDA's decision. To the extent this statement reflects FDA's position that Petitioners had to prove that exposure to the Additives exceeds safe levels, [FDA-

000006], that approach is unlawful. *See supra* Point II. Further, "[w]hen an agency … is confronted with evidence that its current regulations are inadequate or the factual premises underlying its prior judgment have eroded, it must offer more to justify its decision to retain its regulations than mere conclusory statements." *Env't Health Tr. v. FCC*, 9 F.4th 893, 903 (D.C. Cir. 2021).

An FDA staff memorandum not referenced in FDA's Order but included in the record asserts that some studies Petitioners provided "exhibited multiple limitations" that make them unsuitable for assessing the Additives' risks. [FDA-009519-FDA-009520]. To the extent FDA relied on this memorandum, it only underscores the arbitrariness of FDA's approach. For example, the memorandum contends that "several" studies Petitioners provided assessed shorter-duration exposures to the Phthalate Additives and are "therefore insufficient to assess chronic toxicity which is essential for the assessment of food additive safety." [FDA-009519-20]. Assuming for the sake of argument that chronic toxicity studies are "essential," [FDA-009520], that only concedes the deficiency of FDA's own safety assessments. According to FDA scientists, FDA had no chronic studies to support its authorizations for numerous phthalates it approved for food-contact use, including DIDP. *See* [FDA-002021] (summarizing available toxicity studies for FDA-approved phthalates as of 1973). It is quintessentially arbitrary for FDA to hold Petitioners to an evidentiary standard that FDA's own safety assessments do

not meet. Indeed, as noted *supra* p. 32, in deciding to reject Petitioners' objections and retain its authorizations for the Phthalate Additives, FDA did not even consider whether its own assessments are supported by the evidence its Order and internal memoranda assert is essential to determine whether the Additives are safe.

Further, FDA's memorandum criticizes certain unidentified studies while ignoring others that do not exhibit the asserted "limitations." For example, the memorandum does not address the data from chronic exposure studies that Petitioners did provide. *See, e.g.*, [FDA-000449-FDA-000457] (summarizing chronic studies on DEHP); [FDA-001469] (summarizing chronic studies on DINP). Nor does the memorandum address the shorter-duration studies Petitioners provided documenting harm from phthalate exposure at specific life stages, *see, e.g.*, [FDA-009970-009979] (assessing effects of DEHP exposure during puberty); [FDA-009757-009769] (same), which FDA's memorandum acknowledges "may be sufficient" for assessing safety. [FDA-009520].

FDA's Order also irrationally dismissed the epidemiological studies Petitioners presented on the theory that epidemiological studies "are generally not useful for risk assessment." [FDA-000009]. This contravenes, without reasoned explanation, the approach of other federal authorities. *See* [FDA-001443] (CPSC expert panel explaining that it "employed a risk assessment approach that first analyzed the epidemiological evidence of associations between phthalate

exposures and risk to human health" in conjunction with animal studies); [FDA-000379-FDA-000382, FDA-000388-FDA-000391, FDA-000472-FDA-000670] (ATSDR evaluating epidemiological and animal studies to characterize DEHP's risks). FDA's position also inexplicably contravenes FDA's own reliance on epidemiological studies to support its conclusion that "DEHP from pharmaceuticals presents a potential risk of developmental and reproductive toxicity" and should not be used in certain drug products. [FDA-013336]. "Agency action is … arbitrary and capricious if it offered insufficient reasons for treating similar situations differently." *Cal. Cmtys. Against Toxics v. EPA*, 928 F.3d 1041, 1057 (D.C. Cir. 2019) (quotation omitted).

FDA also dismissed certain epidemiological studies because they are supposedly "insufficient to establish a relationship between the reported health effect outcomes and the purported cause being phthalate exposure." [FDA-009521]. But as CPSC explained, "[e]stablishing cause and effect in epidemiological studies is not required by federal and international agencies to conclude that a substance [with toxic effects in animal studies] is likely to cause similar effects in humans." Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates, 82 Fed. Reg. 49,938, 49,952 (Oct. 27, 2017).

FDA also considered the evidence piecemeal, asking whether subsets of studies by themselves establish sufficient questions about the Phthalate Additives'

safety. *See, e.g.*, [FDA-000009] (Order asserting that "data from [the] hazard identification studies are … not adequate to … justify resolution of the factual question of safety" in Petitioners' favor); *id.* (dismissing governmental assessments on identical grounds); *id.* (asserting that epidemiological studies are "not suitable to provide primary or sufficient basis for performing a risk assessment"). As FDA acknowledges, it must integrate all available data on "the projected human dietary exposure to the food additive, the additive's toxicological data, and other available relevant information." [FDA-000008-FDA-000009]. Further, it is irrational for FDA to discount discrete categories of evidence because they do not *alone* resolve the ultimate safety question. FDA's obligation is "to weigh the entire record," and "the corollary to [that] obligation … is that no single piece of evidence is dispositive." *Mississippi v. EPA*, 744 F.3d 1334, 1349 (D.C. Cir. 2013) (quotation omitted).

FDA was required to rationally consider the totality of the evidence to determine whether Petitioners raised significant questions about the Phthalate Additives' safety. Instead, FDA dismissed the wealth of evidence showing that the Additives pose serious health risks—*including risks FDA never considered in judging them safe decades ago*—based on reasoning at odds with other authoritative bodies, inconsistent with FDA's own approach in approving the Additives, and untethered from the requirements of the Food Act and FDA's

regulations. FDA thus did not rationally "examine the relevant data," and its decision is arbitrary. *Cigar Ass'n of Am. v. FDA*, 126 F.4th 699, 705 (D.C. Cir. 2025) (quotation omitted), *amended by* No. 23-5220, 2025 WL 913477 (D.C. Cir. Mar. 26, 2025); *see also id.* at 705 n.2 (concluding that FDA action was arbitrary when FDA described studies but "failed to *respond* to those studies' implications," since "[g]rappling with relevant data requires more than a mere recitation of unfavorable evidence without further explanation").

B. FDA Irrationally Disregarded Evidence of Unsafe Exposures

FDA also arbitrarily rejected Petitioners' objections on the basis that the information Petitioners provided about exposure to the Phthalate Additives was "lacking." [FDA-000013-FDA-000014]. Nothing in the Food Act or FDA's regulations requires petitioners seeking revocation of food-additive authorizations to provide data establishing levels of dietary exposure to the additives, let alone prove "that dietary exposure levels from [the] approved [additives] exceed a safe level," as FDA required here. [FDA-000006]. Even assuming that Petitioners were required to provide exposure information, they did, and that information more than suffices, in combination with the toxicity information, to raise "significant questions" about the Additives' safety. [FDA-009083].

1. FDA's position has no basis in the statute or regulations

Petitioners agree with FDA that it must consider the level of human exposure to an additive in assessing safety. *See* 21 U.S.C. § 348(c)(5)(A); 21 C.F.R. § 170.3(i)(1). However, nothing in the Food Act or FDA's regulations requires petitioners requesting revocation of food-additive authorizations to provide data that quantifies exposure to the additives. Instead, as noted, FDA's regulation requires such petitioners to provide factual assertions, supported by data, "showing that new information exists with respect to the food additive …, that new data are available *as to toxicity of the chemical*, or that experience with the existing regulation … may justify its amendment or repeal." 21 C.F.R. § 171.130(b) (emphasis added); *see also* [FDA-009082-FDA-009083] (FDA affirming, in granting PFAS Additives petition, that it may grant revocation petitions "based upon new data concerning *the toxicity* of the food additive" where "such data" support the petitioner's request (emphasis added)). The regulation's direction that this data "be furnished in *the form* specified" in 21 C.F.R. § 171.1, 21 C.F.R. § 171.130(b) (emphasis added), does not impose additional substantive requirements and, even if it did, section 171.1 does not require submission of exposure data. *See id.* § 171.1.

Nevertheless, FDA justified its denial of the objections in part by asserting that Petitioners' exposure information was "lacking." [FDA-000013-FDA-000014].

FDA did not identify any statutory or regulatory authority requiring Petitioners to submit exposure information or providing any standard against which FDA could reasonably find the information submitted inadequate; FDA merely stated that Petitioners "must provide support for the requested changes." [FDA-000013].

2. FDA's dismissal of the exposure evidence is irrational

The record demonstrates that—despite the lack of any statutory or regulatory requirement to do so—Petitioners provided substantial evidence that current levels of exposure to the Phthalate Additives threaten public health. FDA's justifications for dismissing that evidence do not reflect a reasoned evaluation of the evidence and are inadequate to sustain FDA's decision.

First, Petitioners provided multiple authoritative analyses concluding that diet is the primary source of exposure to, at a minimum, DINP, DIDP, and DEHP. These include ATSDR's 2022 toxicological profile of DEHP, which concluded that "[t]he principal route of human exposure to DEHP is oral" and "ingestion of food (including food from containers that leach DEHP) accounts for approximately 95% of total oral exposure." [FDA-000374].

Petitioners also presented the 2014 report from CPSC's expert panel, which conducted a comprehensive analysis of phthalate exposures and concluded that "food, beverages and drugs via direct ingestion … constituted the highest [source of] phthalate exposures to all subpopulations." [FDA-001377, FDA-001427]; *see*

82 Fed. Reg. at 49,946 (describing panel's methodology for estimating exposures). The panel specifically determined that diet is the primary source of exposure to DINP, DIDP, and DEHP for the populations at greatest risk of reproductive and developmental harm. *See* [FDA-001433].

Petitioners also provided a declaration from Dr. Russ Hauser, a member of CPSC's expert panel and an internationally recognized expert on phthalates' health effects, who explained that

> The [CPSC's] conclusions about the dangers associated with phthalates found in toys and other children's products apply with equal force to the dangers of exposure to phthalates in foods and beverages. The need to remove these chemicals from the food supply is critical given how widespread and substantial dietary phthalate exposures are among the U.S. population, including at developmentally critical periods in early life.

[FDA-010719-FDA-010720].

In addition, Petitioners provided their own analysis demonstrating that DEHP exposure in the U.S. exceeds safe levels, and that exposure to additional phthalates in food that contribute to the same health harms as DEHP exacerbates the health risks. [FDA-009577-FDA-009579]; [FDA-012365-FDA-012369]. This analysis utilized biomonitoring data from the CDC's National Health and Nutrition Examination Survey ("NHANES") and ATSDR's determination of the exposure level at which DEHP can cause harm. [FDA-009577-FDA-009578].

FDA's response to this evidence falls short of the reasoned decision-making the APA requires. FDA dismissed the CPSC expert panel's report because, on its

own, "it did not answer the question of whether specific food additive uses of [the Phthalate Additives] are safe." [FDA-000014]. But "the corollary to [the agency's] obligation to weigh the entire record … is that no single piece of evidence is dispositive." *Mississippi*, 744 F.3d at 1349 (quotation omitted). FDA cannot reasonably dismiss the report's findings because it alone "does not answer *all* of the technically complex questions" presented. *Pub. Citizen Health Rsch. Grp. v. Chao*, 314 F.3d 143, 156 (3d Cir. 2002) (quotation omitted).

CPSC's expert panel determined that exposure to multiple Phthalate Additives among high-risk populations presents unacceptable health risks and that this exposure comes primarily from food. [FDA-001426, FDA-001433, FDA-001465, FDA-001473]. Based on the panel's findings, CPSC determined that it was necessary to ban use of the Phthalate Additives DINP and DCHP in children's products (Congress had already banned DEHP)—to "ensure a reasonable certainty of no harm" to children and pregnant women. 82 Fed. Reg. at 49,966 (quotation omitted); *see also id.* at 49,970. It strains credulity for FDA to assert that the panel's findings are not relevant to determining whether there continues to be a reasonable certainty of no harm from using these same chemicals in food-contact materials.

FDA also irrationally dismissed ATSDR's findings concerning DEHP because, like the CPSC panel's report, ATSDR's toxicological profile for DEHP

does not alone "justify resolution of the factual question about unsafe exposure in the objectors' favor." [FDA-000014]. That is why Petitioners presented substantial additional evidence characterizing exposures to the Phthalate Additives that, in conjunction with the ATSDR profile, raises significant safety questions. FDA also suggested that ATSDR did not identify exposure levels of concern because it found that "the general population is exposed to DEHP at levels that are 3-4 orders of magnitude lower than those observed to cause adverse health effects *in animal studies*." *Id.* (emphasis added). But ATSDR calculated the exposure level at which DEHP may cause harm *to humans* and found that exposures in the U.S. exceed that level, providing the relevant point of comparison. [FDA-000386, FDA-000756, FDA-000870-FDA-000877]. FDA offered no explanation for why that finding is irrelevant or fails to support significant safety questions in conjunction with the other evidence presented.

FDA also failed to articulate a reasoned basis for dismissing Petitioners' independent analysis demonstrating that DEHP exposure exceeds safe levels, and that the resulting health risks are exacerbated by co-exposure to additional phthalates. FDA claimed it is inappropriate to "rely[] on biomonitoring data," such as that from NHANES, "alone" to estimate exposures because such data do not "differentiate the amount of exposure that results from the diet compared to other sources." [FDA-000015]. But Petitioners did not rely on biomonitoring-based

exposure estimates "alone" to establish significant questions about the Phthalate Additives' safety. In addition to the independent exposure analysis they provided utilizing NHANES data, they also relied, for example, on the findings of CPSC's expert panel, which conducted a "scenario-based exposure assessment" that was based on exposure modeling and supported the panel's conclusion that diet is the primary exposure source for multiple Phthalate Additives. 82 Fed. Reg. at 49,946. Further, given the undisputed findings by CPSC's expert panel and ATSDR that diet is the primary exposure source for multiple Phthalate Additives, biomonitoring data provide valuable information that FDA could use to, at a minimum, "qualitatively assess[]" the safety of exposure to the Phthalate Additives as FDA did for the PFAS Additives. [FDA-009083]. Indeed, CPSC relied on NHANES data to support its bans on phthalates in children's products. *See* 82 Fed. Reg. at 49,960 (CPSC describing NHANES as "a high quality study" that "provide[s] exposure data that are representative of the U.S. population" and appropriate for assessing phthalates' safety). And FDA itself invoked NHANES data to support its conclusion that DEHP's use in drugs presents unacceptable health risks. [FDA-013336]. In short, the fact that the NHANES biomonitoring data do not capture dietary exposures alone does not rationally justify dismissing exposure estimates based on that data.

Moreover, as the objections explained, total exposure to the Phthalate Additives from all sources is relevant to assessing whether their use in food-contact materials is safe, because exposure from food will more readily cause people to reach unsafe exposure levels if they are simultaneously exposed from other sources. [FDA-009576-FDA-009577]. FDA did not dispute that, consistent with the recommendations of the National Academy of Sciences, other federal agencies regularly consider chemical exposures from all sources even if some are outside the agency's regulatory authority. *Compare id.* (objections), *with* [FDA-000016] (Order). Instead, FDA claimed it can ignore non-food exposures to the Phthalate Additives because the Food Act does not explicitly mandate their consideration. [FDA-000016]. This argument ignores that the Act requires FDA to consider dietary exposure to additives and "other relevant factors" in evaluating an additive's safety. 21 U.S.C. § 348(c)(5). Petitioners explained why exposures to the Phthalate Additives from other sources are relevant to assessing whether additional exposures from food will be safe, [FDA-009576-FDA-009577], and FDA provided no substantive response, asserting only that it has "discretion" to consider safety-related factors beyond those enumerated in the statute. [FDA-000016]. But this bare appeal to discretion does nothing to answer Petitioners' argument that total exposure is a "relevant factor[]," which FDA is statutorily required to consider. 21 U.S.C. § 348(c)(5) (directing that FDA "shall consider … other relevant factors" in

assessing an additive's safety, beyond the three factors enumerated in the statute). FDA's "fail[ure] to consider [this] important aspect of the problem" renders its decision arbitrary and capricious. *State Farm*, 463 U.S. at 43.

C. FDA Irrationally Disregarded the Cumulative Effect of Multiple Phthalates That Cause the Same Health Harms

1. FDA must consider the cumulative effect of related phthalates in food

In evaluating a food additive's safety, FDA must consider "the cumulative effect of such additive in the diet …, taking into account any chemically or pharmacologically related substance or substances in [the] diet." 21 U.S.C. § 348(c)(5)(B); *see also* 21 C.F.R. §§ 170.18(a), 170.3(i)(2).

This is critical for evaluating the Phthalate Additives' safety. As noted, "almost all people in the United States have metabolites"—or breakdown products—"of multiple phthalates in their body, indicating exposure to many phthalates" simultaneously. [FDA-010720] (Hauser Declaration). Further, the scientific literature demonstrates that "exposure to multiple phthalates will, at a minimum, have additive health effects, if not synergistic health effects, that can magnify the health harms associated with individual phthalates." [FDA-010721] (Hauser Declaration).[9]

[9] "Synergistic" effects are effects from multiple chemicals working in combination that are greater than their additive effect.

2. FDA unlawfully disregarded the cumulative effect of dietary exposure to the related phthalates DEHP, DINP, DCHP, and DIOP

Contrary to the Food Act's mandate to consider the cumulative effect of related chemicals in the diet, FDA failed to address the undisputed evidence that three of the Phthalate Additives—DEHP, DINP, and DCHP—as well as DIOP, another phthalate approved for food-contact use under a prior sanction, are chemically and pharmacologically related and pose cumulative health risks. As Petitioners' objections explained, these four chemicals are structurally similar and all cause permanent malformations of the male reproductive system through a common mechanism of "antiandrogenic" action, which refers to the suppression of testosterone production, during fetal development. [FDA-009565-FDA-009567]; *see also* [FDA-002008] (FDA acknowledging that Petitioners provided data indicating that DEHP, DINP, and DCHP exhibit antiandrogenic effects).[10]

Petitioners thus demonstrated that DEHP, DINP, DCHP, and DIOP are "chemically or pharmacologically related," 21 U.S.C. § 348(c)(5)(B), because they have (1) "well-defined similarities in chemical structure," (2) a common "toxicological endpoint[]," or adverse health effect, and (3) "a common mechanism

[10] In the objections, Petitioners proposed alternative ways of grouping phthalates for cumulative effects analysis, [FDA-009558-FDA-009565], but focus here on FDA's unlawful failure to consider the cumulative effects of the known antiandrogenic phthalates that remain approved for food-contact use, which alone warrants vacatur of FDA's Order.

of action" for inducing that effect. [FDA-002009] (FDA identifying these factors as supporting other regulatory and scientific authorities' grouping of phthalates for cumulative effects analysis).[11] Petitioners also presented research explaining that, because "[a]nti-androgenic phthalates may have additive adverse effects on … reproductive organ development," assessing their risks cumulatively is more "relevant for human health and development than chemical-by-chemical approaches." [FDA-010913-FDA010914] (Varshavsky et al. 2018).

In declining to consider the cumulative effects of the four antiandrogenic phthalates still approved for food-contact use, FDA did not contest that they are "related" within the meaning of the Food Act. Instead, FDA asserted that even if Petitioners are correct that DEHP, DCHP, DINP, and DIOP are related, triggering the statutory requirement for FDA to consider their cumulative effects, "the outcome of FDA's denial order would not be altered" because the Food Additive

[11] There is no requirement that chemicals satisfy all three of these criteria to trigger the Food Act's requirement for a cumulative effects analysis. *See* 21 U.S.C. § 348(c)(5)(B) (requiring FDA to consider cumulative effects of any "chemically *or* pharmacologically related substance[s]," indicating that similarity in structure or effect suffices (emphasis added)); 21 C.F.R. § 170.18(a) (directing that "[f]ood additives that cause similar or related pharmacological effects will be regarded as a class, and in the absence of evidence to the contrary, as having additive toxic effects and will be considered as related food additives"). Regardless, DEHP, DINP, DCHP, and DIOP satisfy all three criteria.

Petition advanced a broader argument regarding the relatedness of the 28 phthalates approved as additives in 2016. [FDA-000012].

This is not a reasoned basis for FDA's refusal to consider the cumulative effects of the known antiandrogenic phthalates that remain approved for food-contact use. First, the Food Additive Petition argued that all 28 phthalates approved as additives in 2016 are related but never asserted that it would be improper to group a narrower subset for cumulative effects analysis. Further, as discussed above, it would have been irrational for Petitioners to continue pursuing arguments about the relatedness and safety of the 28 phthalates approved as additives in 2016 after FDA revoked approval for 23 of those chemicals in response to the industry abandonment petition. Moreover, FDA does not dispute that, at the objections stage of petition proceedings, parties may present new evidence and arguments, for example to respond to changed regulatory circumstances or provide new scientific findings or analysis. *See* 21 U.S.C. § 348(f), (g)(2); 21 C.F.R. §§ 12.22, 12.100. FDA acknowledged as much by evaluating the "new exposure analysis" Petitioners provided with their objections. *See* [FDA-000015]; *see supra* p. 48-51.

Indeed, FDA also implicitly recognized its duty to consider whether the currently authorized Phthalate Additives—not the group of 28 approved in 2016—present cumulative health risks. In a staff memorandum supporting its denial of the Food Additive Petition, FDA evaluated whether the five Phthalate Additives that

remain approved following FDA's grant of the abandonment petition—DINP, DEHP, DCHP, DIDP, and DAP—are "related" such that FDA must consider their cumulative effects. [FDA-000017-FDA-000026]. But Petitioners never argued that this group of five phthalates are related; as noted, Petitioners argued instead that three of the Phthalate Additives (DINP, DEHP, and DCHP), plus an additional phthalate approved under a prior sanction (DIOP) are related. [FDA-009565-FDA-009567]. Accordingly, FDA's memorandum provides no answer to the argument that the antiandrogenic phthalates DINP, DEHP, DCHP, and DIOP are chemically and pharmacologically related such that FDA must consider their cumulative effects as part of a determination of whether food-additive use of DINP, DEHP, or DCHP is safe. Nowhere in the record did FDA consider the cumulative effects of these related phthalates nor rationally refute Petitioners' argument that these chemicals are "related" within the meaning of the Food Act.

The Food Act requires FDA to consider the cumulative effect of related chemicals as part of a determination of whether their use as food additives continues to be safe. 21 U.S.C. § 348(c)(5)(B). By retaining its authorizations for DINP, DEHP, and DCHP without considering the cumulative effect of these antiandrogenic Phthalate Additives, and the antiandrogenic phthalate DIOP, in the diet, FDA acted arbitrarily and contrary to the Food Act. *Id*. For this reason too, FDA's Order must be set aside. *See State Farm*, 463 U.S. at 43 (agency action is

"arbitrary and capricious if the agency … entirely failed to consider an important aspect of the problem …."); *Cigar Ass'n*, 126 F.4th at 705 (concluding FDA decision was arbitrary and capricious where FDA "did not examine the relevant data" that was "at the heart of its inquiry" (quotation omitted)).

IV. FDA UNLAWFULLY DENIED PETITIONERS' HEARING REQUEST

A. The Food Act Mandates Hearings to Resolve Material Factual Disputes Raised by Objections

The Food Act permits "any person adversely affected by" FDA's order denying a food additive petition to "request[] a public hearing upon [their] objections." 21 U.S.C. § 348(f)(1). Upon receiving a hearing request, FDA "*shall* … as promptly as possible hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections." *Id.* (emphasis added).

On its face, this provision "obligates [FDA] to hold a hearing and issue an order based on the record made at the hearing." *Nader v. EPA*, 859 F.2d 747, 753 (9th Cir. 1988); *see also Sierra Club v. Jackson*, 648 F.3d 848, 856 (D.C. Cir. 2011) (affirming that "'shall' is usually interpreted as the language of command" (quotation omitted)). Nonetheless, this Court has held that a hearing is "appropriate only where material objections to the FDA's actions exist." *Cmty. Nutrition Inst. v. Young*, 773 F.2d 1356, 1361 (D.C. Cir. 1985); *accord Pharm. Mfg. Rsch. Servs. v. FDA*, 957 F.3d 254, 266 (D.C. Cir. 2020). FDA's regulations further state that it

must convene a hearing if the objectors show: (1) "[t]here is a genuine and substantial issue of fact for resolution at a hearing"; (2) "[t]he factual issue can be resolved by available and specifically identified reliable evidence"; (3) "[t]he data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the person"; and (4) "[r]esolution of the factual issue in the way sought by the person is adequate to justify the action requested." 21 C.F.R. § 12.24(b).

While the Court's "review of an agency's decision to grant or deny a hearing is necessarily deferential," *Pharm. Mfg.*, 957 F.3d at 266 (quotation omitted), "[n]either due process nor the Administrative [Procedure] Act permits an arbitrary denial [of a hearing request] in any case where it can be fairly said there are genuine and substantial issues of fact in dispute," *Hynson, Westcott & Dunning, Inc. v. Richardson*, 461 F.2d 215, 220 (4th Cir. 1972) (quotation omitted), *aff'd, sub. nom. Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973).

B. The Objections Raise Material Factual Issues Justifying a Hearing

Petitioners requested a hearing on their objections concerning whether the evidence presented on the Phthalate Additives' (1) toxicity, (2) exposures, and (3) cumulative effects creates significant questions about the Additives' safety. [FDA-009551-009552]; [FDA-009567-FDA-009568]; [FDA-009579]. These factual issues are material—indeed, central—to FDA's decision. Further, if FDA maintains

that the existing record does not justify revoking the Additives' approval under the correct legal standard, at a minimum that record reflects significant disputes regarding the conclusions supported by specific evidence and whether the totality of the evidence raises significant safety questions. *See, e.g.*, [FDA-000008-FDA-000009] (Order asserting that epidemiological studies are inappropriate for assessing Additives' safety and that Petitioners' presentation of toxicity studies "is not adequate to justify resolution in the objectors' favor of the factual question about safety of the still-authorized food additive uses"); [FDA-000014-FDA-000015] (Order asserting that exposure data is inadequate to "justify the factual determination about unsafe exposure" because of supposed deficiencies in analyses presented). In these circumstances, FDA lacked discretion to deny a hearing. 21 U.S.C. § 348(f)(1); *cf. Pharm. Mfg.*, 957 F.3d at 266 (holding that FDA may deny hearing request where the "proffered evidence create[s] no relevant factual dispute").

Further, FDA's justifications for denying a hearing are irrational. FDA asserted that a hearing is not justified because Petitioners' objections address the safety of the five Phthalate Additives that remain approved—not the 23 whose approval FDA revoked in 2022 in response to the industry abandonment petition—and therefore the objections do not justify the relief requested in the 2016 Food Additive Petition regarding the 28 phthalates approved at that time. [FDA-000009-

FDA-000010, FDA-000013-FDA-000014]. This is nonsensical. As explained above, Petitioners appropriately narrowed their arguments at the objections stage to focus on the five Phthalate Additives that remain approved. A hearing on the safety of the 23 phthalates that are no longer authorized for food-contact use would serve no purpose. Moreover, if FDA determined after a hearing that there is no longer a reasonable certainty of no harm from use of one or more of the five Phthalate Additives that remain approved, that would require FDA to alter its Order. Accordingly, a hearing was required. 21 U.S.C. § 348(f); 21 C.F.R. § 12.24(b).

Regarding Objection 8, which concerns whether the exposure evidence supports significant safety questions, FDA additionally asserted that a hearing was not justified because Petitioners purportedly failed to establish that dietary exposure to the Phthalate Additives exceeds safe levels. [FDA-000014] (citing 21 C.F.R. § 12.24(b)(3)). This rationale fails because, as explained *supra* Point II, Petitioners have no burden to prove that exposure exceeds safe levels and the Additives' use is therefore causing harm; instead, Petitioners properly sought to establish significant questions regarding the safety of exposure to the Additives. Moreover, FDA may not require Petitioners to establish the ultimate issue in the proceeding "as a predicate for securing [their] right to a hearing. If that were [their] burden, a hearing would never be necessary or appropriate." *Hynson*, 461 F.2d at 220.

V. REMEDY

FDA's decision to maintain its food-additive authorizations for the Phthalate Additives despite overwhelming evidence of their hazards and ubiquitous exposures driven by contaminated food is arbitrary and capricious and violates the Food Act and FDA's regulations. Further, FDA's decision to maintain those authorizations based on decades-old safety assessments that FDA has refused to update perpetuates an unconscionable delay in addressing a "serious public health problem of great magnitude." [FDA-010871] (Zota Declaration). Seventeen years after committing to update its safety assessments, FDA is still at the starting line, requesting more information that it "may" use to update its assessments in the future while arbitrarily dismissing the robust evidence presented in the eight-year petition proceeding that gave rise to this litigation.

"There comes a point when relegating issues to proceedings that go on without conclusion in any kind of reasonable time frame is tantamount to refusing to address the issues at all and the result is a denial of justice." *MCI Telecomms. Corp. v. FCC*, 627 F.2d 322, 344 (D.C. Cir. 1980) (quotation omitted). Given FDA's intransigence and the life-altering harm it is causing to children's health, the Court should "let [the] agency know, in no uncertain terms, that enough is enough." *Pub. Citizen Health Rsch. Grp. v. Brock*, 823 F.2d 626, 627 (D.C. Cir. 1987). Specifically, the Court should order FDA, within 60 days, to initiate

proceedings to revoke approval for the Phthalate Additives or notice a hearing on Petitioners' objections.

CONCLUSION

For the foregoing reasons, Petitioners respectfully request that this Court vacate FDA's Order and direct FDA to, within 60 days, initiate proceedings to revoke approval for the Phthalate Additives or notice a hearing on Petitioners' objections.

DATED: March 28, 2025

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that this document complies with the type-volume limitations of Fed. R. App. P. 32(a)(7)(B) because it contains 13,000 words, excluding those parts exempted by Fed. R. App. P. 32(f) and D.C. Cir. R. 32(e)(1).

I also certify that this document complies with the typeface requirements of Fed. R. App. 32(a)(5) and type style requirements of Fed. R. App. 32(a)(6) because it has been prepared in a proportionally spaced font using Microsoft Word Times New Roman 14-point font.

/s/Katherine K. O'Brien
KATHERINE K. O'BRIEN

CERTIFICATE OF SERVICE

I certify that on March 28, 2025, I electronically filed the foregoing document and its addendum with the Court's CM/ECF system, which will serve each party's counsel of record.

/s/Katherine K. O'Brien
KATHERINE K. O'BRIEN

ORAL ARGUMENT NOT YET SCHEDULED

No. 24-1382

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ALASKA COMMUNITY ACTION ON TOXICS, BREAST CANCER PREVENTION PARTNERS, CENTER FOR ENVIRONMENTAL HEALTH, CENTER FOR FOOD SAFETY, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, DEFEND OUR HEALTH, ENVIRONMENTAL DEFENSE FUND, and LEARNING DISABILITIES ASSOCIATION OF ILLINOIS,
Petitioners,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION and DR. MARTIN MAKARY, in his official capacity as Commissioner of the United States Food and Drug Administration,
Respondents.

On Petition for Review of a Final Order of the Food and Drug Administration, 89 Fed. Reg. 86,290 (Oct. 30, 2024)

PETITIONERS' ADDENDUM OF DECLARATIONS

Dated: March 28, 2025

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UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ALASKA COMMUNITY ACTION ON TOXICS, BREAST CANCER PREVENTION PARTNERS, CENTER FOR ENVIRONMENTAL HEALTH, CENTER FOR FOOD SAFETY, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, DEFEND OUR HEALTH, ENVIRONMENTAL DEFENSE FUND, and LEARNING DISABILITIES ASSOCIATION OF ILLINOIS, *Petitioners*, v. UNITED STATES FOOD AND DRUG ADMINISTRATION and DR. MARTIN MAKARY, in his official capacity as Commissioner of the United States Food and Drug Administration, *Respondents*.	No. 24-1382

DECLARATION OF PAMELA K. MILLER

I, Pamela K. Miller, declare and state as follows:

1. I am the Founder and Executive Director of Alaska Community Action on Toxics ("ACAT"). I founded ACAT in 1997 and have served as Executive Director since its founding. The information in this declaration is based on my personal knowledge and experience.

2. I hold a master's degree in environmental science with a specialty in aquatic biology from Miami University (1981) and a bachelor's degree in biology from Wittenberg University (1978). I have over thirty years of experience in research, policy, and advocacy related to environmental health and justice, and marine ecology on the local, state, and federal levels. I also have extensive experience in leading programs focused on these issues.

3. Since 1998, ACAT has been a participating organization of the International Pollutants Elimination Network ("IPEN"), a global network of more than 600 environmental health and justice organizations working in more than 124 countries for a toxics-free future, which has conducted considerable research on toxic phthalates in consumer products in multiple countries. I was elected to serve on the Steering Committee of IPEN in 2012 and as Co-Chair of IPEN in 2016.

4. My role as Executive Director makes me familiar with all aspects of ACAT's mission, purpose, and activities. ACAT is a 501(c)(3) non-profit public interest environmental health research and advocacy organization incorporated and

headquartered in Anchorage, Alaska. ACAT believes that everyone has the right to clean air, clean water, and toxic-free food. We work with individuals and communities in Alaska to tackle toxics, protect health, and achieve justice. Upon request, we assist individuals, tribes, and communities to implement effective strategies to prevent or reduce their exposures to toxic substances, protect the ecosystems that sustain them, and hold accountable those responsible for the contamination of their communities. Because existing remedies are so often inadequate to address Alaskans' concerns, we also work to achieve systemic policy change at the marketplace, local, state, national, and international levels.

5. Much of our work is done in collaboration with Alaska Natives, who make up twenty percent of our state's population and are disproportionately exposed to toxic chemicals because of contamination of their traditional food sources and a heavy reliance on packaged and processed foods. As a result, these communities face unique and serious environmental challenges. We support community-based environmental health research and train village leaders to conduct their own environmental sampling though our Community-Based Environmental Health Research Institute. We also work with coalitions to advocate for state policies that will protect Alaska's people, wildlife, and the environment. Our role is to listen to the voice and priorities of communities and be available to support initiatives to improve community health and provide helpful resources.

6. We currently have eight board members. Six of our eight board members are Alaska Native women representing the diverse communities that we serve (including Yupik, Inupiaq, Gwich'in Athabascan, Kaagwaantaan Tlingit, and Sugpiaq). One other board member is an Alaska resident, and the eighth and final member lived in Alaska for many years and now resides in Colorado. ACAT's board of directors is responsible for the governance of the organization, including approval of the organizational budget, organizational priorities, financial policies, and personnel policies; supervising the executive director; and fundraising. All board members make personal financial contributions and work with our development director on fundraising from individuals.

7. ACAT is supported financially by its 300 contributing members and 2,000 supporters, including individuals and foundations. Our members include both Alaska Natives and Non-Indigenous Alaskans as well as people from the lower forty-eight states.

8. The community members I work with share their frustrations and concerns about environmental contamination with me, and their priorities inform ACAT's work. Activists in Native villages identify issues for ACAT staff to engage on. ACAT has become a partner to community activists in working to address this issue. For example, we have collaborated with the communities of Gustavus, Fairbanks, Anchorage, Savoonga, Gambell, Dillingham and others to

collect samples for analysis of PFAS (per- and polyfluoroalkyl substances) found in drinking water caused by contamination from PFAS-based industrial firefighting foams used on airports and military bases. This work helped inform our successful policy work to achieve a statewide ban on PFAS-based firefighting foams in 2024 in favor of safer alternatives. We have also been engaged in the testing of household products for harmful substances and advocacy for safer products.

9. Currently, we are working with state policy makers to achieve a ban on polystyrene food packaging used in restaurants and other food establishments. We educate and advocate for the reduction of manufacturing and use of toxic plastics that contain phthalates such as polyvinyl chloride. We are also working on policies to eliminate phthalates and other toxic chemicals through our work on the new international treaty on plastics.

10. Communities in Alaska experience a disproportionate burden from chemicals like phthalates in our food because of a scarcity of food choices. Alaska is very rural. We rely on Alaska Commercial Company grocery stores, which have the most affordable food. Most of the Alaska Native population lives in small villages, where they rely on subsistence foods and rural grocery stores. Produce in Alaska is incredibly expensive, so there is a disproportionate reliance on packaged and processed food, and grocery stores disproportionately sell processed and packaged food. Native communities in particular face food deserts and are reliant

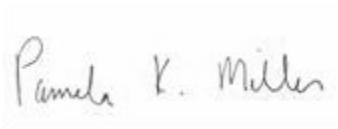
on grocery stores. There is a big resurgence in Alaska of traditional knowledge and subsistence living as a way to counter a scarcity of food options and to be more thoughtful about what we are putting into our bodies and our children's bodies. However, the reality today is that there are very limited food options available to Alaska Native communities.

11. Because our members disproportionately rely on packaged and processed foods, they experience an increased exposure to packaging and food contaminated with toxic phthalates.

12. FDA's denial harms ACAT's staff, members, and supporters by continuing to permit exposure to phthalates in their diet. If the court sets aside FDA's denial, it would force FDA to take action to remove unsafe phthalate additives from the market and thereby eliminate or reduce their exposures to these toxic phthalates.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed on the 12th day of March 2025, in Anchorage, Alaska.



Pamela Miller

ORAL ARGUMENT NOT YET SCHEDULED

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ALASKA COMMUNITY ACTION ON TOXICS, BREAST CANCER PREVENTION PARTNERS, CENTER FOR ENVIRONMENTAL HEALTH, CENTER FOR FOOD SAFETY, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, DEFEND OUR HEALTH, ENVIRONMENTAL DEFENSE FUND, and LEARNING DISABILITIES ASSOCIATION OF ILLINOIS, *Petitioners*, v. UNITED STATES FOOD AND DRUG ADMINISTRATION and DR. MARTIN MAKARY in his official capacity as Commissioner of the United States Food and Drug Administration, *Respondents*.	No. 24-1382

DECLARATION OF MARGARET MARY TARRANT

I, Margaret Mary Tarrant, declare and state as follows:

1. I am Mandan and Hidatsa and am originally from North Dakota. I now live in Anchorage, Alaska. I am the mother of three Inupiaq children, aged fifteen, sixteen, and eighteen years old. The information in this declaration is based on my personal knowledge and experience.

2. I have been involved with Alaska Community Action on Toxics ("ACAT") since 2018, when I began working with the organization as a canvasser, going door-to-door encouraging people to vote. I eventually became the coordinator of ACAT's canvassing program. I do not work full time currently with ACAT, but I am still contracted to coordinate their canvassing program.

3. I got involved in advocacy to protect people from toxic chemicals by providing samples from products my children used, like their crib and car seat, to be tested for toxic flame retardant chemicals. I then participated in an ACAT campaign in Anchorage to pass a law protecting children and firefighters from flame retardant chemicals. I also worked to get an ordinance passed in Anchorage to restrict flame retardants in children's products.

4. I was an Environmental Justice Organizer at ACAT from August 2018 until June 2023. In this role, I coordinated virtual gatherings of Indigenous women and created an Indigenous environmental network in Alaska, which was very important for reaching communities during the pandemic and for long-term

engagement with communities in Alaska that are very rural and off the road network. I provided trainings to women who wanted to begin advocating on environmental issues. I shared my experiences and educated them about how they can communicate with their legislators to make policy change. I focused on building relationships, especially with other Indigenous women, because we have been so impacted by issues such as toxic chemicals in food and our environment. I created spaces for Indigenous women to share information about toxic chemicals and highlight people who are doing work on these issues in their communities. In addition to my core organizing responsibilities, I also supported ACAT's programs by identifying funding sources and doing data management.

5. I also led a food security canvass project in Anchorage. I went into the lowest income community in Anchorage and got people excited about growing their own food and increasing food security for them and their community. I have advocated to Alaska legislators about getting lead, mercury, and other heavy metals and toxic chemicals out of baby food. I advocated for legislation to address per- and polyfluoroalkyl substances. This summer, I will be in Copper River working on documenting the history of Salmon as food and the cultural significance of Salmon in the Ahtna Region of Alaska.

6. I know that phthalates are put in food packaging to make the packaging softer and more malleable. When the packaging is heated, higher levels

of these chemicals can leach into the food. I am aware of the evidence showing that phthalates cause health problems, and I'm concerned about the endocrine-disrupting effects of toxic chemicals like phthalates. I was diagnosed with attention deficit hyperactivity disorder (ADHD), and many of my friends of my generation also have this diagnosis. I'm concerned that this may be a result of exposure to phthalates or other chemicals. I'm also concerned about the effects on future generations from the reproductive effects of phthalates.

7. I am concerned about FDA's approval of phthalates in food packaging and processing. Phthalates haven't been confirmed as safe for human beings in the long-term through testing, so we are exposing ourselves to these chemicals without knowing what long-term exposure in any amount may do, and what harm it may do to our health and the health of future generations. I know that plastic degrades over time. How do I know how long it's safe to have food in plastic packaging? I'm concerned that there is no testing to confirm whether it's safe. Looking around my house, I see plastic packaging everywhere, including food packaging, and I don't even know whether there are phthalates in it because this information is not on the labels.

8. I am concerned that my children and I are exposed to phthalates in the food we eat. My children and I eat out at restaurants or get takeout about once a week, including fast food meals from McDonald's.

9. Every school day, my children either eat cafeteria meals or go out to get fast food at lunchtime.

10. My family eats meat every day, and my kids drink a lot of milk. They like to drink chocolate milk and have milk with their cereal every day.

11. My family eats microwaveable meals. We also eat Voila! frozen packaged meals that I prepare on the stove about once a week. I prefer to cook my kids' meals, though I use a lot of frozen vegetables that come in plastic bags.

12. It would not realistically be possible for me to avoid all these foods. If fresh food didn't cost so much in Alaska, I could afford to make different choices, but it is prohibitively expensive here. I want to make better choices and buy organic produce, but it's not realistic with my income. So even if I want to eat better, I don't have the choices that most people have. I don't have the money to buy natural foods to give to my kids. I do try to avoid plastic water bottles and takeout food wrappers. And I spend extra time cooking meals and extra money buying organic fruits and vegetables and avoiding plastic packaging whenever possible. Even with this extra time and money, I still can't avoid foods that are likely to contain phthalates.

13. I've been poor and homeless. And I was a low-income, single mom. I had to rely on food banks. When I had to rely on food banks to sustain myself and

my family, I had no control at all over what I was given, and it was often packaged and processed food.

14. I supported the petition submitted by ACAT's partners asking FDA to ban phthalates in food packaging and materials for processing food. It is FDA's job to protect us. People living in rural, Native villages in Alaska, especially those who have lower incomes, have few fresh food options available and by necessity must rely on more packaged and processed foods. We face a disproportionate burden from not just phthalate exposure but also exposure to other toxic chemicals. If FDA followed the science and revoked its approvals for phthalates in materials that contact food, that would help me to avoid these phthalates for myself and my kids and keep them out of our community. It would also help to prevent environmental contamination with phthalates when the packaging is disposed of.

15. It is overwhelming to know that we have been exposed for years, and FDA has allowed the use of phthalates for so long in ways that can harm us. The way I was raised, as an Indigenous woman, I always think about how actions affect my grandkids. I'm concerned not just about how ingesting phthalates might affect me, but also how it affects people across generations. I'm not speaking just for myself; I'm speaking for the next seven generations.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed this 24th day of March, 2025 in Anchorage, Alaska.

Margaret Mary Tarrant

ORAL ARGUMENT NOT YET SCHEDULED

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ALASKA COMMUNITY ACTION ON TOXICS, BREAST CANCER PREVENTION PARTNERS, CENTER FOR ENVIRONMENTAL HEALTH, CENTER FOR FOOD SAFETY, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, DEFEND OUR HEALTH, ENVIRONMENTAL DEFENSE FUND, and LEARNING DISABILITIES ASSOCIATION OF ILLINOIS, *Petitioners*, v. UNITED STATES FOOD AND DRUG ADMINISTRATION and DR. MARTIN MAKARY, in his official capacity as Commissioner of the United States Food and Drug Administration, *Respondents*.	No. 24-1382

DECLARATION OF DEBRA COLE

I, Debra Cole, declare and state as follows:

1. I am a retired systems analyst, living in West Greenwich, Rhode Island. I am a 20-year breast cancer survivor, and I have two adult daughters.

2. I am a supporter of Breast Cancer Prevention Partners ("BCPP"). Since my diagnosis in 2005, I have been involved in breast cancer advocacy. I first learned about BCPP in 2008 when I saw an advertisement for Climb Against the Odds, one of the organization's signature fundraising events. I participated in 2009, proudly completing the climb of Mount Shasta in Northern California at the age of 53. I started my fundraising for BCPP with this event. I have found my niche with BCPP, and I want to focus my energies on breast cancer prevention.

3. After returning from Climb Against the Odds, I wanted to recreate the feeling of that event, and in 2013, I founded New England Peaks for Prevention ("New England Peaks"), an annual fundraising climb to the summit of Mount Washington benefitting BCPP. I am the Executive Director of New England Peaks, and to date, this event has raised over $900,000 for BCPP.

4. I also support BCPP by sharing BCPP information and resources at my personal fundraising events and New England Peaks' events. I have participated in other BCPP fundraising and educational events, such as LUNAFEST (an annual short film festival with films by and for women), a BCPP fundraising gala and celebration for the organization's retiring executive director,

and educational tabling with BCPP staff members at the University of Vermont in Burlington.

5. Over my many years of affiliation with BCPP, I have made very good friendships with a number of the staff, including its scientific advisor. I am in conversation with staff on a regular basis and I am aware that they share the concerns and priorities I raise in our discussions at staff meetings to help inform BCPP's work.

6. I support BCPP because I completely believe in the work that they do. It is important to me to be knowledgeable and educated about what chemicals I am exposed to in the environment on a daily basis, particularly because of my breast cancer history and concern about recurrence. I want to protect myself and my health. I am also very concerned about the health of my two daughters, who already face a heightened risk of breast cancer because of our family history.

7. I absolutely rely on BCPP to advocate for my interests in breast cancer prevention, including food toxics issues. I'm not a scientist, and I could never delve into all of the science and understand it. BCPP puts the information in terms that I can understand and in ways that are relevant to my life so I know how to evaluate products and make informed choices to protect my health. They are leaders in the area of breast cancer advocacy, and I know they are the organization that is advocating for me.

8. If it were not for BCPP, I wouldn't know anything about phthalates. I have been familiar with phthalates since I got involved with a company in my home state of Rhode Island that sells nontoxic products. This company also relied on science and information from BCPP. Through my work with this company and our mutual association with BCPP, I helped to promote nontoxic products and share information about exposure to phthalates in products and the importance of avoiding this exposure. I know that phthalates are linked to cancer, are endocrine disruptors, and can cause other health problems.

9. I am absolutely concerned about phthalates getting into my food and drinks. I am concerned about my health and the possibility of breast cancer recurrence due to exposure to endocrine-disrupting chemicals such as phthalates. I am concerned about both of my daughters' exposure to phthalates because they have an elevated risk of breast cancer, due to my own history.

10. I am aware that the food I eat could contain phthalates. I eat chicken a few times a week. I also eat cheese and use baking mixes once or twice a month. When I cook at home, I use cooking oils and spices.

11. I have avoided particular foods because I was concerned about exposure to harmful chemicals such as phthalates. I avoid fast food restaurants because I know that the packaging is known to have toxic chemicals. In the past, I had tried to avoid certain seafood because of my concerns with contaminants. I try

to use a lot of fresh vegetables from local farms because I am afraid of what is available in supermarkets and the potential for harmful chemicals to be in food by leaching out of the packaging.

12. It would probably be impossible for me to avoid all foods that contain phthalates because there would not be anything left for me to eat. I try to do the best that I can.

13. I spend more money purchasing food to try to minimize my exposure to chemicals such as phthalates in my food. I lean towards organic food, and that is more expensive. However, I am concerned even about the packaging of organic food.

14. I absolutely supported BCPP's petition asking FDA to ban food-additive uses of phthalates in food packaging and food-production materials. I don't understand why FDA, knowing that certain phthalates have been banned in children's toys because of their dangers, cannot do the same to address exposure through food. I feel complete outrage about the fact that no one in the government is protecting us.

15. If FDA's decision to deny BCPP's objections was set aside, FDA would likely revoke its approvals for food additive uses of phthalates in materials that contact food, and that would have a direct impact on me. I would not have to worry about food being a source of exposure to those phthalates and the risk of

breast cancer recurrence and other health problems. Revoking approval would reduce my chances of breast cancer recurrence and the chances of my daughters being diagnosed with breast cancer. I would finally feel protected.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct. Executed on this 28th day of February, 2025, in West Greenwich, RI.

Debra Cole

ORAL ARGUMENT NOT YET SCHEDULED

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ALASKA COMMUNITY ACTION ON TOXICS, BREAST CANCER PREVENTION PARTNERS, CENTER FOR ENVIRONMENTAL HEALTH, CENTER FOR FOOD SAFETY, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, DEFEND OUR HEALTH, ENVIRONMENTAL DEFENSE FUND, and LEARNING DISABILITIES ASSOCIATION OF ILLINOIS, *Petitioners*, v. UNITED STATES FOOD AND DRUG ADMINISTRATION and DR. MARTIN MAKARY, in his official capacity as Commissioner of the United States Food and Drug Administration, *Respondents*.	No. 24-1382

DECLARATION OF LISETTE VAN VLIET

I, Lisette van Vliet, declare and state as follows:

1. I am the Senior Policy Manager at Breast Cancer Prevention Partners ("BCPP"). I hold a Ph.D. from the Australian National University in International Environmental Politics. Prior to joining BCPP in 2017, I worked for twelve years as the Senior Policy Advisor for Chemicals at the Health and Environment Alliance ("HEAL") in Brussels, Belgium. At HEAL, I worked on the European Union-wide chemical safety regulation called Registration, Evaluation, Authorization, and Restriction of Chemicals ("REACH"), and several other laws and policies governing the use of hazardous chemicals. I was in touch with BCPP over the years through my work at HEAL, and I was drawn to BCPP's work because the risk of breast cancer can be reduced by eliminating toxic chemicals. Also, this illness has affected me personally through my friends. Eventually, I felt compelled to join BCPP's efforts to prevent this disease. The information in this declaration is based on my personal knowledge and experience.

2. Through my role as Senior Policy Manager at BCPP and my seven and a half years at the organization, I am familiar with the structure and mission of BCPP. BCPP is a non-profit organization based in San Francisco, California. For more than thirty years, BCPP has engaged in science-based policy and advocacy work with the goal of preventing breast cancer by eliminating exposure to toxic

chemicals and radiation. Our focus is on the intersection of breast cancer prevention and environmental health.

3. As BCPP's Senior Policy Manager, I analyze federal and state policy pertaining to chemicals and meet with legislators, legislative staff, and administrative agency staff to educate them about the science linking certain chemicals to cancer and advocate for policies that would reduce exposure to those chemicals. I also analyze legislation and comment on proposed regulations regarding chemicals linked to cancer. In addition, I spend quite a bit of time coordinating with other non-profit and community-based organizations, working on health-related issues of concern to us all. With these allies, I draft factsheets, offer supplemental science and policy resources, and coordinate responses to federal and state legislative proposals.

4. My main focus has predominantly been and continues to be toxic chemicals arising from food contact materials, both from end packaging and upstream food processing. Phthalates are one of several groups of high-profile chemicals that we work on at BCPP, given the strong scientific evidence of their role in breast cancer through their hormone disrupting properties.

5. BCPP's work fits within three key pillars. First, we work to educate the public about chemicals that have been linked to cancer—many of which are found in food and everyday consumer products—and the steps that people can take

to reduce their risk of exposure. Second, we carry out market campaigns to encourage companies to remove cancer-causing chemicals from their products. And third, we engage in policy work to encourage the federal government and state governments to take legislative and administrative action to protect the public from exposure to chemicals linked to cancer.

6. BCPP's work is driven, in part, by the organization's nineteen independent board members and 20,000 additional supporters nationwide, most of whom either have been diagnosed with cancer themselves or are closely connected to someone who has been touched by cancer. Our board members are responsible for adopting the mission and strategy of the organization, overseeing the organization's fiscal health, hiring and overseeing BCPP's President and CEO, electing new board members, and approving certain activities, such as litigation. All of our supporters care about working to prevent cancer—for themselves, their families and friends, and for the next generation. In general, our supporters—including our board members—provide about forty percent of our annual budget. Often, our supporters shape and influence our work by bringing their concern with a particular chemical or product to our attention.

7. BCPP provides our supporters with information. We do this by identifying the best science on chemicals linked to cancer and presenting that information in a way that makes it accessible to our supporters and the public. For

example, we maintain a Glossary of Breast Cancer Exposures on our website, which collects and summarizes current scientific evidence regarding the links between breast cancer and other adverse health effects and exposure to specific chemicals and classes of chemicals—including phthalates. We also work to make science actionable in people's lives. For example, by providing people with information about cancer-causing chemicals in consumer products, we empower them to make different product choices that could help to protect their health. Sometimes, our supporters will get in touch with us to ask about particular products or alternatives. For example, a supporter might ask, "What are the safest cosmetics?" or "Where can I find safer cleaning products?"

8. BCPP has many supporters, like Debra Cole, who are at risk of health harm from consuming food that is packaged with and/or produced in contact with materials that contain toxic phthalates. Enabling our supporters to take personal action is an important piece of our work, but our ultimate goal is changing federal and state policies so that everyone is protected, not just the people who have the time and resources to research and purchase food and other products without cancer-causing chemicals. So, in addition to providing our supporters with information, we provide them with the service of advocating on their behalf to convince governments to adopt protective policies and companies to make safer products.

9. Since at least 2011, BCPP has fought to prevent chemicals linked to cancer from being used in food and food packaging. For example, BCPP played a major role in educating policymakers and the public about the dangers of bisphenol A ("BPA"), a toxic chemical used in baby bottles, sippy cups, infant formula packaging, and the linings of food cans. After years of public education, market campaigns, and legislative and regulatory advocacy, we're proud to say that BCPP helped to convince many manufacturers to move away from using BPA. But our work isn't done. We've always seen BPA as a "poster child" for the larger problem of unsafe direct and indirect additives in food and food packaging. The continuing use of phthalates is, in our analysis, contributing to breast cancer incidence, and can and should be replaced with safer alternatives.

10. More than eight years ago, BCPP began to work with an informal coalition of organizations seeking to prohibit the use of a range of unsafe food additives, including phthalates. As part of this effort, we joined in petitioning FDA in 2016 to ban food-contact uses of phthalates, which relates directly to our fundamental mission of reducing exposure to chemicals linked to breast cancer among our supporters and the broader public. Every day that FDA does not revoke its authorizations permitting the use of toxic phthalates as additives in food-contact materials, more people—including BCPP's supporters—are unnecessarily exposed to phthalates in their food without their knowledge or consent. Further, FDA's

authorization of these phthalates frustrates BCPP's ability to protect our supporters from these exposures through the regulatory reforms we have been seeking since 2016.

11. If FDA were to revise its regulations to prohibit food-additive uses of phthalates, that would be a major victory for BCPP, our supporters, and the public, because it would eliminate a major source of exposure to these dangerous chemicals.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct. Executed on this 27th day of February 2025, in Davis, California.

Lisette van Vliet

Lisette van Vliet

ORAL ARGUMENT NOT YET SCHEDULED

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ALASKA COMMUNITY ACTION ON TOXICS, BREAST CANCER PREVENTION PARTNERS, CENTER FOR ENVIRONMENTAL HEALTH, CENTER FOR FOOD SAFETY, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, DEFEND OUR HEALTH, ENVIRONMENTAL DEFENSE FUND, and LEARNING DISABILITIES ASSOCIATION OF ILLINOIS, *Petitioners*, v. UNITED STATES FOOD AND DRUG ADMINISTRATION and DR. MARTIN MAKARY, in his official capacity as Commissioner of the United States Food and Drug Administration, *Respondents*.	No. 24-1382

DECLARATION OF SHAKOORA AZIMI-GAYLON

I, SHAKOORA AZIMI-GAYLON, declare and state as follows:

1. I am the Senior Director of the Toxic Exposures Reduction and Pollution Prevention ("TEPP") Program at the Center for Environmental Health ("CEH"). The information in this declaration is based on my personal knowledge and experience.

2. CEH is a national non-profit, public interest organization based in Oakland, California. For more than twenty-eight years, CEH has helped to lead the growing, nationwide effort to protect people from toxic chemicals that cause cancer, adverse reproductive effects, learning disabilities, and many other health problems. We use a range of strategies to achieve this goal—from public education to legal action. For instance, we work with state and federal policymakers to develop laws and regulations that support safer chemicals and consumer products. We also fight to ensure that governments allocate sufficient resources to implement those laws and regulations in a way that actually protects people from toxic chemicals. We advise companies in the development of business practices that don't harm people or the environment. And we protect people from immediate toxic threats by enforcing existing laws.

3. I hold a Master of Science in Environmental Science from California State University, Sacramento. I have dedicated over twenty years of my career to reducing environmental exposures to toxic chemicals and protecting public health,

which has involved developing policies and regulations to reduce environmental exposures and initiating and leading interventions to improve health and reduce disparities.

4. In my role as director of the TEPP Program, I use sound science and health policies to protect public health and reduce environmental exposures. My current focus at CEH is preventing the introduction of toxic chemicals into products, encouraging manufacturers to transition to safer alternatives, educating consumers about the presence of toxic chemicals in products, and building a list of preferable products to help purchasers transition to safer products.

5. Through my role as Senior Director of the TEPP program at CEH, I am familiar with the structure and mission of CEH. CEH's mission is to protect people from toxic chemicals by working with communities, consumers, workers, government, and the private sector to demand and support business practices that are safe for public health and the environment. In particular, CEH works to protect children from toxic chemicals, as their behaviors and physical needs make them more vulnerable to toxic chemicals than adults. CEH advances environmental health and justice for the greater good by encouraging business and government decisionmakers to heed the early warnings of science.

6. CEH pursues its mission using six strategies: science and research-based product and air testing, corporate and institutional engagement, litigation,

communications, policy advocacy, and community engagement. Our product testing work identifies products that expose consumers and sensitive populations to high levels of toxic chemicals so we can educate businesses, consumers, and the public about the risk of the products. CEH also identifies industrial polluters by reviewing publicly available discharge monitoring and sampling reports so we can educate fenceline communities about the risks the industrial activities pose and potentially take enforcement action against the polluters. Our product testing work in the past has included testing for flame retardants in furniture and children's products, such as nap mats, and per- and polyfluoroalkyl substances ("PFAS") in food packaging and foodware. Our corporate engagement work involves collaborating with responsible businesses to eliminate the threat to human health posed by toxic chemicals and has included work to encourage businesses not to purchase products with toxic chemicals, such as PFAS, toxic chemical flame retardants, and pesticides. We create legal change by pursuing litigation under federal and state laws to make sure dangerous consumer and food products are not permitted on the market, dangerous chemicals are not released into our environment, and to foster compliance with federal and state laws to protect public health and the environment. Our policy advocacy focuses on pursuing bans, limits, and disclosure requirements on toxic chemicals. For example, we advocate for requirements that manufacturers label furniture and children's products containing

flame retardants, bans on PFAS chemicals in food packaging, and requirements that chemicals of concern are labeled on products like cookware. Finally, we often partner with community groups affected by releases of toxic chemicals, such as our legal work to reduce toxic air releases by California industrial facilities and combat releases of PFAS in the Cape Fear River Basin in North Carolina.

7. CEH has approximately 50,000 supporters across the United States who have signed up to receive regular emails about our work. Our supporters help to drive our work by sharing their feedback and concerns. CEH's supporters can influence CEH's activities through participation in CEH's Virtual Town Halls, where supporters and other participants are able to submit questions to CEH and the guests/participants in the town halls. CEH posts on its website links to recordings of these events along with written answers to the frequently asked questions received from the participants. CEH also maintains a presence on social media, primarily through X (formerly known as Twitter), Instagram, Facebook, LinkedIn, Threads, and Bluesky, where CEH's supporters can provide feedback and amplify CEH's messaging. Through our website and social media channels, we answer questions, offer resources, and provide ways to take action through petitions and campaigns. We also engage supporters as partners in our advocacy campaigns. For example, we have partnered with CEH supporters to advocate for safer foodware in public schools across the country. We also encourage our

supporters to contact their elected representatives and companies regarding issues of concern to CEH and our supporters and provide educational resources to support their engagement.

8. CEH is governed by a board of directors, which currently consists of eleven members. CEH's Board Members are influential environmental health and justice experts and advocates who are also supporters of CEH. The CEH Board has a robust internal board candidate nominations process that ensures we have a diverse, dynamic board of environmental justice, environmental health, social justice, and corporate experts and advocates. Our board members help to determine our priorities by approving our annual budget and major projects, electing new board members, contributing financially, and helping to raise funds. In the event of a vacancy, the board would also help to select a new Executive Director. CEH Board Members actively participate in shaping the direction of CEH's work.

9. CEH is funded through a combination of grants from philanthropic organizations, legal enforcement revenue, institutional and corporate consulting, and supporter contributions. CEH relies significantly on contributions from its supporters, both big and small.

10. CEH is allied and actively partners with a diverse array of environmental health, public health, conservation, and environmental justice groups. We participate in coalition-led projects and provide technical and research

assistance to many partners who are our supporters and inform and influence our goals and activities. CEH's Community Engagement Manager works actively to fulfill and develop resources for these requests, which include the development and provision of educational materials about toxic exposure issues; training on right-to-know laws, regulations, tools, and labels; and advocacy and testimony support on local, state, and federal policy efforts.

11. Most of our board members and other supporters are people who are knowledgeable about toxic chemicals in food and other consumer products, who want to protect their health and the health of their families—but who don't necessarily have the knowledge, experience, or time to investigate safer alternatives to conventional products or successfully advocate for meaningful change as individuals. They support CEH because we fight for safer chemicals and consumer products on their behalf and because we provide them with the information they need to make safer choices.

12. Many of our supporters are particularly concerned about toxic chemicals in food and drinking water. Food and drinking water are often the most significant sources of exposure to toxic chemicals, and the threat of these exposures really resonates with people because they are so immediate; When you put something toxic into your mouth, the chemicals go directly into your body.

13. Over the past five years, CEH has spent about 15 percent of its time working to remove toxic chemicals from food and food packaging. For instance, we have negotiated hundreds of legal agreements, under which companies have committed to reducing the concentration of lead in their products to trace or background levels. Some of these agreements involved foods, like chili pepper candies, licorice, ginger snaps, and Indian sauces. We are currently working to remove fluorinated chemicals from disposable plates, microwave popcorn bags, and other materials that come in contact with food. Companies use fluorinated chemicals for their heat-, water-, and grease-resistant properties, but these chemicals can travel from plates and packaging into the food itself—and they are linked to cancer, hormone disruption, reproductive problems, and other negative health effects.

14. We also engage in advocacy around phthalates specifically. We have submitted multiple administrative comments on EPA's reviews of toxic phthalates under the Toxic Substances Control Act. We have also advocated for legislative policies that ban the use of phthalates in food packaging and food service products (Break Free From Plastic Pollution Act, S.3127), as well as intravenous bags and tubing (The Toxic Free Medical Devices Act, AB2300).

15. CEH petitioned FDA to ban uses of phthalates in food packaging and processing materials in 2016 because this effort aligned directly with our mission

and sought regulatory actions that are critical to protecting the health of our supporters, board members, and staff. We work to protect people from toxic chemicals, and there is no need for companies to put people at risk by adding phthalates that are linked to serious and irreversible health problems to food-contact materials from which the chemicals can leach into food and drinks.

16. FDA's decision to deny our objections harms CEH's staff, board members, and supporters by continuing their exposure to toxic phthalates in their diet. If the Court sets aside FDA's denial of our objections, it would likely force FDA to reduce or eliminate our constituents' exposure to toxic phthalates in their food.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed on the 12th of March 2025, in Oakland, CA.

Shakoora Azimi-Gaylon

ORAL ARGUMENT NOT YET SCHEDULED

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ALASKA COMMUNITY ACTION ON TOXICS, BREAST CANCER PREVENTION PARTNERS, CENTER FOR ENVIRONMENTAL HEALTH, CENTER FOR FOOD SAFETY, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, DEFEND OUR HEALTH, ENVIRONMENTAL DEFENSE FUND, and LEARNING DISABILITIES ASSOCIATION OF ILLINOIS, *Petitioners*, v. UNITED STATES FOOD AND DRUG ADMINISTRATION and DR. MARTIN MAKARY, in his official capacity as Commissioner of the United States Food and Drug Administration, *Respondents*.	No. 24-1382

DECLARATION OF RACHEL DOUGHTY

I, Rachel Doughty, state and declare as follows:

1. I am an attorney practicing public interest environmental and land use law in Berkeley, California. I have a J.D. from the University of Virginia, a M.S. in Natural Resources from Cornell University, and a B.S. in Biochemistry from the University of Tennessee.

2. Before graduate school, I conducted breast cancer research at Vanderbilt University and worked as a fellow at the U.S. Environmental Protection Agency. As an attorney, I have litigated cases concerning toxic chemicals in the environment as well as toxic exposure to people from consumer products. This work has addressed reproductive toxicants, including phthalates, as well as carcinogens.

3. I am the mother of two children, aged eight and eleven years old.

4. Because of the knowledge I've gained through my work and education, I am very concerned about my family's exposure to endocrine-disrupting chemicals, flame retardants, and other synthetic chemicals with known adverse health effects as well as unknown health effects.

5. As a parent volunteer, I worked for multiple years to get plastic foodware out of the school meals program in the Berkeley Unified School District, in which my kids are enrolled, a fight that continues with some success to date—an expanding District-wide pilot program and all reusables for PTA events.

6. I have been partnering with the Center for Environmental Health ("CEH") in this advocacy and have been a supporter of CEH for several years. I have signed up to receive communications from CEH, I've responded to CEH action alerts, and I've spoken directly with CEH staff members on many occasions about how they can support parents' efforts to eliminate toxic foodware from the school meals program in our community.

7. At my children's school, approximately one-third of the students qualify for free or reduced lunch, and most of these students also rely on the school meals program for breakfast and after-school snacks. I am very concerned about the exposure to phthalates, per- and polyfluoroalkyl substances ("PFAS"), and other chemicals of concern that these students in particular, and all students who eat cafeteria meals at the school, experience when they eat school meals.

8. I began advocating to address these issues as a parent volunteer and subsequently reached out to CEH for support. CEH conducted testing of the school's foodware for specific contaminants and became a key partner to the parent committee on which I serve in advocating for healthier changes. CEH did extensive research to help us identify a good, safe source of new foodware. They also have been instrumental in getting a pilot program up and running through which the school is trying out reusable steel foodware. CEH staff attended every meeting the parent committee had on this issue, which, at its height was about once

per month. The latest email I received from CEH was on February 4, 2025, inviting me to attend the inauguration of disposable-free lunch at Thousand Oaks Elementary in Berkeley. I look forward to the program expanding to my children's school. CEH has been an excellent partner in this work and helped concerned parents get the school district's attention on this issue. A couple of years ago, I wrote a letter of support for a grant application CEH submitted to support this work.

9. I am aware that phthalates are endocrine-disrupting chemicals and that exposure to phthalates—particularly among children—is linked to harmful effects on brain development and reproductive development. I know that phthalates are used widely as plasticizers in food packaging, food production materials, and other products, and that phthalates are also used in paperboard food packaging.

10. Because I am aware of the serious risks that phthalates and other endocrine-disrupting chemicals pose to health—particularly to the health of children—I try very hard to avoid food and other products that contain phthalates for myself and my children. I do not buy canned food and I try to avoid food that's packaged in plastic. My children are aware of these risks and generally refuse food in their school cafeteria or other settings where food is packaged in plastic. We very rarely eat take-out food served in disposable containers unless we are traveling.

11. I invest significant time preparing food from scratch because of my desire to avoid plastic packaging. For example, I make all of the yogurt that my family eats from scratch instead of buying it from the grocery store in a plastic container. We spend extra to buy milk packaged in glass. I avoid frozen foods and other packaged foods that would save me time if I felt comfortable and safe buying them. I spend extra time doing this because I am concerned about the waste generated by plastic food packaging and about contamination of my food and my kids' food with phthalates and other endocrine-disrupting chemicals.

12. I also discourage my kids from eating lunch in their school cafeteria on a regular basis because of my concerns about the use of plastic packaging and other materials that generate waste and contain phthalates, PFAS, and other harmful chemicals. Still, my kids choose to eat cafeteria meals from time to time. It would be wonderful if they could eat the cafeteria lunch every day, as the meals are free and it would save me the time and expense of making lunch for them at home, but I am concerned about the waste and health risks associated with cafeteria meals.

13. Despite my substantial efforts, I know that my kids and I are still exposed to phthalates in our food and drinks. We dine regularly at local restaurants; we like Indian food and sushi; and we regularly eat burritos and hamburgers. My kids do eat in the school cafeteria from time to time. We eat meat

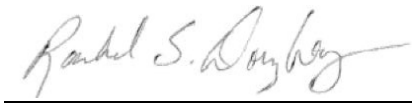
several times per week and we consume milk in our yogurt, in oatmeal, and in other meals we cook at home. My kids regularly eat ice cream, cheese, and deli meats. Many of these products are surely contaminated despite my efforts to minimize exposure because of how they are processed pre-packaging.

14. I feel stress and anger knowing that I cannot safeguard my kids or myself from exposure to phthalates in our food so long as these chemicals are approved for use in so many food-contact materials, despite the considerable effort I make to reduce our exposure.

15. I strongly supported the petitions submitted by CEH and its allies asking FDA to prohibit uses of phthalates in food packaging and food-production materials as FDA's authorization of the use of toxic phthalates in food packaging and materials harms me and my family. I know that I cannot effectively address this issue on my own, for my own family or for others, and I think it is essential for CEH to represent my interests and the interests of its other supporters in administrative advocacy to FDA. I want to see changes in FDA's authorizations for phthalate use in food contact materials that would protect my health and my kids' health and alleviate the burden on me as a parent of having to address this concern on my own, which I know I cannot do effectively.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed this 28th day of February, 2025, in Berkeley, California.



Rachel Doughty

ORAL ARGUMENT NOT YET SCHEDULED

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ALASKA COMMUNITY ACTION ON TOXICS, BREAST CANCER PREVENTION PARTNERS, CENTER FOR ENVIRONMENTAL HEALTH, CENTER FOR FOOD SAFETY, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, DEFEND OUR HEALTH, ENVIRONMENTAL DEFENSE FUND, and LEARNING DISABILITIES ASSOCIATION OF ILLINOIS, *Petitioners*, v. UNITED STATES FOOD AND DRUG ADMINISTRATION and DR. MARTIN MAKARY, in his official capacity as Commissioner of the United States Food and Drug Administration, *Respondents*.	No. 24-1382

DECLARATION OF SALLY J. DREW

I, Sally J. Drew, declare and state as follows:

1. I am a resident of Madison, Wisconsin. I have been retired for thirteen years following a career in library science. The information in this declaration is based on my personal knowledge and experience.

2. I am a member of the Center for Food Safety (CFS) and have followed the organization's activities for more than a decade. As a child in Ames, Iowa, I watched people spraying chemicals on farm fields, including chemicals that are now banned. I am now a member of several advocacy groups, including CFS, out of a sense of frustration; it has been fifty years since I watched that chemical spraying in Iowa, but still nothing is happening to stop toxic chemicals from getting into our food. I joined CFS, in particular, because it is taking an active role in identifying problematic chemicals and getting them out of our food system and environment.

3. I donate to CFS. I am signed up to receive emails from CFS, and I read their updates all the time. I review CFS's petitions and requests to submit comments or testimony to agencies such as the FDA, and I take part in those actions when I feel I have something to contribute. I would estimate that I respond to more than half of CFS's requests for engagement.

4. I understand that phthalates are in plastics and can end up in food in a variety of ways. I've looked up information about phthalates and their health

effects. I'm very familiar with the problem of dangerous chemicals like phthalates in plastics, and I want them gone in all forms due to the food safety and environmental problems they cause. I am concerned about any chemicals that might affect me if I ingest them or if they're in our environment.

5. I currently live in a continuous care retirement community (CCRC). For fifteen years, I cared for my husband after he had a stroke, and for eight months he lived with me in the nursing facility in the CCRC. I also provided care for my mother, who lived in the same community and lived with my husband and me during the height of the pandemic.

6. During much of this period, I could no longer take my husband or my mother in the community's dining facility because of their physical and/or cognitive limitations, so most of my meals and all of their meals were delivered to us from the kitchen in the facility where we live. These meals were prepared in a regulated kitchen setting and were generally delivered to our door packaged in massive amounts of carry-out plastic and a plastic film bag. I asked the facility if they could provide meals on our own dinnerware or dinnerware that is not disposable, but they said they are not able to do that because of regulations, so I ate out of plastic containers. I ate this way for about five years. I'm concerned that chemicals like phthalates were getting into my food that was prepared in the facility kitchen and from the packaging. Since both my husband and mother are

now gone, I do my best to eat a healthy diet and avoid plastic packaging but cannot fully avoid plastic packaging and know that if my health declines I would need to eat like I did previously.

7. I eat packaged crackers, which I try to buy organic, but I know that there may still be contaminated with chemicals like phthalates. I use olive, avocado, and canola oils, which I try to buy organic. I use organic canned tomatoes, corn, and beans in the winter.

8. I eat cheese and some local fish and sometimes eat sour cream and yogurt.

9. When I was growing up, my family was always focused on eating safely and well. We had an enormous garden; we all worked in it and ate from it. When I was in a position to prepare most of my meals from scratch and had alternatives available, I would make a great effort to avoid storing food in plastic containers and buying packaged foods. For example, for more than thirty years, I subscribed to an organic community supported agriculture (CSA) program in Wisconsin, but I no longer have access to a CSA although I do make an effort purchase fresh, local food all year.

10. I still make an effort to avoid eating foods that contain toxic chemicals like phthalates. For most of my life, I've tried avoiding plastic. I eat an organic, plant-based diet. I don't eat meat, and I don't drink much milk. I look for

foods that are safe, nutritious, and good for me. I try to cook for myself and buy from the farmer's market as much as I can. I still try to avoid letting plastic bags contact my food. I am motivated to do all of this to preserve my good health. However, it's very difficult because nobody, including the FDA, is really trying very hard to keep phthalates and other harmful chemicals out of food. It's amazing how much time it takes to figure out what is safe, or safer, to buy. I'm sure that I spend more money buying organic food and more time trying to find foods that are safe and nutritious. I try to be so careful all the time, but there's not much I can do about phthalates getting into my food.

11. If FDA took action to make it more difficult for phthalates to get into food, as CFS requested in its petition, then I would have faith that all my efforts are doing some good, and I would be able to identify safe foods I could eat. I believe that many of the illnesses we see are related to chemicals in our food. Living in a CCRC and talking to people, I have many opportunities to see the results of lack of knowledge or the choices people made reflected in their health.

12. I know chemicals like phthalates in our food are bad for everybody. I know that I must be getting exposed to phthalates in my food, and that they are bad for me, but I don't have any way to assure that I'm safe from ingesting phthalates in my food. That's why I want FDA's decision to be set aside, as it would likely

lead to FDA banning at least some phthalates in food packaging and materials for processing food and reduce my exposure.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct. Executed this 15th day of March, 2025, in Madison, Wisconsin.

Sally J. Drew

Sally J. Drew

ORAL ARGUMENT NOT YET SCHEDULED

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ALASKA COMMUNITY ACTION ON TOXICS, BREAST CANCER PREVENTION PARTNERS, CENTER FOR ENVIRONMENTAL HEALTH, CENTER FOR FOOD SAFETY, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, DEFEND OUR HEALTH, ENVIRONMENTAL DEFENSE FUND, and LEARNING DISABILITIES ASSOCIATION OF ILLINOIS, *Petitioners*, v. UNITED STATES FOOD AND DRUG ADMINISTRATION and DR. MARTIN MAKARY, in his official capacity as Acting Commissioner of the United States Food and Drug Administration, *Respondents*.	No. 24-1382

DECLARATION OF JAYDEE HANSON

I, Jaydee Hanson, declare and state as follows:

1. I am the Policy Director of the Center for Food Safety ("CFS"). The information in this declaration is based on my personal knowledge and experience.

2. Through my role as Policy Director for CFS, I am familiar with its structure and mission. CFS is a tax-exempt, 501(c)(3) nonprofit membership organization with offices in the District of Columbia; San Francisco, California; and Portland, Oregon, as well as other staff located remotely around the country. CFS has over a million members, who reside in each of the fifty states and the District of Columbia.

3. CFS was founded in 1997 to protect and promote its staff and members' right to safe food and the environment. Since its inception, CFS's mission has been to protect human health and the environment from the harmful impacts of industrial food production. CFS works to achieve its mission by curbing the use of harmful food production technologies, including unsafe food additives, and promoting organic, ecological, and sustainable alternatives. CFS uses multiple tools to achieve its mission, including science-based policy advocacy, public education, grassroots outreach, and groundbreaking legal action.

4. CFS provides oversight of government activities surrounding the safety of our food. CFS develops and disseminates a wide variety of educational and informational materials regarding the potential health effects of food

production technologies and agricultural products to members and other diverse audiences, including government agencies, lawmakers, nonprofits, and the general public. These materials include in-depth science and policy reports, news articles, white papers, legal briefs, press releases, newsletters, product guides, member communications, and fact sheets. Through these materials, CFS educates consumers, advocates, and policymakers about potentially unsafe food products on the market and encourages full public participation in food safety regulatory issues.

5. CFS works to protect the health and safety of its members, consumers, and the general public by petitioning the U.S. Food and Drug Administration ("FDA") to improve food additive regulations. In addition to the 2016 food additive petition underlying this litigation, CFS has also submitted the following petitions to FDA:

- 2014 petition seeking food additive regulation prohibiting the use of perchlorate as a food additive (Dkt. No. FDA-2015-F-0537);
- 2014 petition seeking to amend food additive regulations by removing FDA's approval of the use of long-chain perfluorocarboxylate compounds in food contact substances (Dkt. No. FDA-2015-F-0714-0002), which successfully led FDA to ban these unsafe compounds based on evidence demonstrating biopersistence and reproductive and developmental toxicity, *see* 81 Fed. Reg. 5 (Jan. 4, 2016);
- 2015 petition seeking food additive regulations prohibiting synthetic flavoring food additives (Dkt. No. FDA-2015-F-4317), which led FDA to ban six synthetic flavor additives based on evidence demonstrating carcinogenicity, *see* 83 Fed. Reg. 50,490 (Oct. 9, 2018);

- 2020 petition seeking regulations prohibiting the use of thirteen phthalates in food contact materials (Dkt. No FDA-2016-P-1171); and

- 2022 petition seeking regulations prohibiting FD&C Red No. 3 colorant (Dkt. No. FDA-2023-N-0437) which led FDA to ban the colorant's use in foods and ingested drugs, *see* 90 Fed. Reg. 4628 (Jan. 16, 2025).

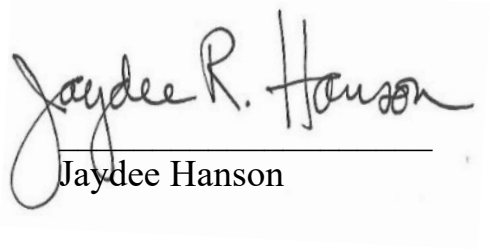
6. When necessary, CFS engages in public interest litigation to compel FDA to perform its statutory duties to protect the public and CFS members from the negative impacts of unsafe foods. Recently, CFS was a co-petitioner for a petition for a writ of mandamus in the Ninth Circuit over FDA's failure to respond to the aforementioned food additive petition to revoke FDA's approval of percholorate. *See* Petition for Writ of Mandamus, *In re Breast Cancer Fund v. FDA*, No. 16-70878 (9th Cir. Mar. 31, 2016), ECF No. 1-2. Before that, CFS filed suit against FDA for its failure to finalize its proposed rule governing the use of food additives that are "generally recognized as safe" ("GRAS") under the Federal, Food, Drug, and Cosmetic Act ("FDCA"), which resulted in a consent decree requiring FDA to issue a final rule governing GRAS food additives by August 31, 2016. *See* Consent Decree, *CFS v. Burwell*, No. 1:14-cv-267-RC (D.D.C. Oct. 20, 2014), ECF No. 15. In 2017, CFS sued FDA on the grounds that FDA's final GRAS rule, 81 Fed. Reg. 54,960 (Aug. 17, 2016), unlawfully subdelegates FDA's duty to ensure food safety in violation of the U.S. Constitution, the Administrative Procedure Act ("APA"), and the FDCA; exceeds FDA's statutory authority and

constitutes arbitrary and capricious agency action in violation of the FDCA and APA; and conflicts with the FDCA. *See* Complaint, *CFS v. FDA*, Case 1:17-cv-03833 (S.D.N.Y. May, 22, 2017), ECF No. 1. CFS also successfully sued FDA in 2012 for failing to timely promulgate regulations under the Food Safety Modernization Act, which resulted in a consent decree requiring FDA to issue final regulations by dates certain. *See CFS v. Hamburg*, 954 F. Supp. 2d 965 (N.D. Cal. 2013).

7. The underlying petition at issue in the instant litigation asks FDA to take action that will make our food system safer. FDA's denial of our objections has injured, and will continue to injure, CFS members by continuing to allow them to be exposed to phthalates currently approved for use in food-contact materials that are associated with serious and irreversible damage to human health, and by diminishing their sense of security and confidence in our nation's food supply and the agencies tasked with regulating the food supply. CFS members have an interest in protecting their right to consume safe foods that do not put them at increased risk of negative health effects, without having to take extreme precautionary measures; FDA's denial harms these interests. Setting aside FDA's denial could help protect CFS members and millions of Americans from the risk of harm due to exposure to these chemicals.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed on March 19, 2025, in Washington, DC.



Jaydee Hanson

ORAL ARGUMENT NOT YET SCHEDULED

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ALASKA COMMUNITY ACTION ON TOXICS, BREAST CANCER PREVENTION PARTNERS, CENTER FOR ENVIRONMENTAL HEALTH, CENTER FOR FOOD SAFETY, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, DEFEND OUR HEALTH, ENVIRONMENTAL DEFENSE FUND, and LEARNING DISABILITIES ASSOCIATION OF ILLINOIS, *Petitioners*, v. UNITED STATES FOOD AND DRUG ADMINISTRATION and DR. MARTIN MAKARY, in his official capacity as Commissioner of the United States Food and Drug Administration, *Respondents*.	No. 24-1382

DECLARATION OF JEAN BISSELL

I, Jean Bissell, declare and state as follows:

1. I am a long-time supporter of the Center for Science in the Public Interest (CSPI). My mother originally gifted to me and continually renewed a subscription to CSPI's health and nutrition newsletter, *Nutrition Action*. I later became a subscriber myself, and I have in turn gifted and continue to renew subscriptions to *Nutrition Action* to several of my adult children. Since 2013, I have donated to CSPI nearly every year.

2. I have written several letters to elected officials and agency leaders about food safety issues in response to CSPI Action Alerts, and I provided two prior declarations in support of CSPI's lawsuits seeking FDA action to eliminate harmful food additives. I have responded to at least one CSPI survey by mail to inform the organization of my top priorities for advocacy work on food safety and other health issues.

3. I absolutely rely on CSPI to advocate for my interests in eliminating toxic chemicals from food. CSPI is a very credible, trustworthy source of information about the food that we eat. Without CSPI, I wouldn't be nearly as knowledgeable as I am about these issues that affect my health, and I would have no voice in trying to change the policies that govern food safety.

4. I have had longstanding concerns about toxic chemicals in my food. My mother was raised on a farm and was horrified at the increase in packaged food

and non-real "food" on the market since I was a child. As I've gotten older and learned more about what is in food, my concerns for myself, my family, and close friends have intensified.

5. I am aware that phthalates (and other toxic chemicals) are used in food packaging and other materials that contact food and that these chemicals can leach into food and cause health problems. I see phthalates as scary in themselves and as part of a larger problem of widespread exposure to toxic chemicals in our food in the United States because there is inadequate regulation to protect consumers.

6. I read food labels assiduously and do my best to make healthy choices. But phthalates are not listed on food labels, so I am not able to avoid this exposure through my own choices. It is very upsetting to know that these chemicals are in foods I eat and to know they are harmful—but not be able to assess the risk or take action to avoid this exposure.

7. I am in my mid 60s, and I assume that I have been exposed to phthalates in my food for decades. I am very worried and angry that I may be at risk of serious health harms as a result and that I am unable to take meaningful action even now to stop exposing myself to phthalates through the things I eat.

8. I eat a lot of home-cooked meals because I enjoy cooking, and I also see this as a way to make healthier choices and reduce exposure to chemicals in my

food. I spend a lot of time preparing foods from scratch instead of using packaged foods because I am concerned about toxic chemicals such as phthalates being present at higher levels in packaged or processed food. I also spend a lot more money on groceries trying to find higher-end products that I *think*—I wish I *knew*—will have fewer chemicals. I wish that I did not have to do this and that I could walk into a grocery store and be able to rely on the foods being free of chemicals that are unsafe. At a minimum, I'd like to be able to tell if these chemicals are present in the foods I'm thinking about buying.

9. While I do cook frequently, I also enjoy going out to eat or ordering take-out, which I do two to four times per week. Generally, I order meals from locally owned restaurants. I'm concerned that I am exposed to phthalates when I eat meals prepared outside my home and that I have no knowledge of or control over this. Even restaurants I patronize that work hard to prepare healthy foods from locally grown and sourced ingredients may unknowingly include phthalates in their dishes. It tempers my enjoyment of taking a night off from cooking to have this constant worry.

10. I'm also concerned that even when I prepare my own meals at home, I am still exposed to phthalates. I understand that simple ingredients I regularly use *and cannot avoid using*, including cooking oils and spices, can be contaminated with phthalates.

11. I eat other foods that I'm concerned are contaminated with phthalates that leach out of the packaging or materials used to process the foods, including fish, chicken, packaged cereals, and take-out meals from restaurants. I consume about a gallon of milk per week. I am concerned and angry that even though I make a concerted effort to avoid highly processed foods, these items in my diet are exposing me to phthalates regardless.

12. It is not possible for me to avoid all of these foods, and even if I could, I worry I would unknowingly replace them with other foods containing phthalates. I feel defeated because, even with the knowledge that phthalates are in my food and the desire to reduce my exposure, *I can't escape these chemicals*. Knowing that I am consuming chemicals in my food without being able to figure out which ones or how much makes me feel helpless, like a lab specimen.

13. I strongly supported CSPI's petitions asking FDA to prohibit phthalates in food packaging and materials. I want FDA to ban these chemicals to help protect my health, the health of my adult children and their fiancées, the health of my future grandchildren, and the health of other consumers. I know that the companies producing food are motivated by profit and they have no reason to stop using chemicals that FDA is allowing them to use without transparency. Without a public agency stepping in and mandating change—or at least

transparency for consumers to make an informed choice— nothing is going to change, and I am not able to protect myself from this exposure on my own.

14. If FDA banned these chemicals as CSPI requested, it would eliminate or reduce my exposure to them. I could finally eat the foods I enjoy and not worry about running the risks of cancer or other serious health problems from phthalates. I want to enjoy my older years as a healthy and active period of my life, not a time that is ruined by illness from inadvertent, lifelong chemical exposure.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed on this 21 day of March, 2025, in Cincinnati, Ohio.

Jean Bissell

ORAL ARGUMENT NOT YET SCHEDULED

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ALASKA COMMUNITY ACTION ON TOXICS, BREAST CANCER PREVENTION PARTNERS, CENTER FOR ENVIRONMENTAL HEALTH, CENTER FOR FOOD SAFETY, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, DEFEND OUR HEALTH, ENVIRONMENTAL DEFENSE FUND, and LEARNING DISABILITIES ASSOCIATION OF ILLINOIS, *Petitioners*, v. UNITED STATES FOOD AND DRUG ADMINISTRATION and DR. MARTIN MAKARY, in his official capacity as Commissioner of the United States Food and Drug Administration, *Respondents*.	No. 24-1382

DECLARATION OF PETER LURIE

I, Peter Lurie, declare and state as follows:

1. I am the President and Executive Director of the Center for Science in the Public Interest ("CSPI"). I received a Doctor of Medicine degree from the Albert Einstein College of Medicine and a Master of Public Health degree from the University of California, Berkeley. Previously, I was the Associate Commissioner for Public Health Strategy and Analysis at the Food and Drug Administration ("FDA"), where I worked on a variety of issues, including arsenic in rice, mercury in fish, and antimicrobial resistance. Prior to that, I was the Deputy Director of Public Citizen's Health Research Group, where, in addition to addressing drug and device issues, I led efforts to reduce worker exposure to hexavalent chromium and beryllium. The information in this declaration is based on my personal knowledge and experience.

2. Through my role as the President and Executive Director of CSPI, I am familiar with CSPI's policies, practices, membership, and programs. CSPI is a non-profit consumer education and advocacy organization headquartered in Washington, D.C., that has worked since 1971 to improve the public's health through better nutrition and safer food. CSPI provides nutrition and food safety information directly to consumers and has long advocated for legislation, regulation, and judicial rulings to ensure that foods are safe and clearly labeled.

3. CSPI does not accept corporate grants. Instead, CSPI is supported by foundations and its approximately 200,000 members, including individuals who receive our health and nutrition newsletter, *Nutrition Action*, which is sometimes received as a CSPI membership benefit.

4. CSPI is a membership organization. CSPI's bylaws state that it is a membership organization, and CSPI's individual donors receive membership cards and are asked annually to renew their membership.

5. CSPI educates its members and engages with businesses and government decision-makers on their behalf to advocate for the implementation of policies and practices that promote more transparent labels, healthy diets, and safer food.

6. CSPI's members also contribute to its work. In response to CSPI's frequent action alerts, our members regularly sign petitions, provide comments to federal agencies, and call and write to elected representatives to support policies that promote the public health.

7. CSPI's members also frequently call and write to CSPI asking the organization to work on various issue areas. Those e-mails and calls are directed to relevant litigation, regulatory, and policy staff, are given thorough consideration, and have guided the organization's activities.

8. Collectively, CSPI's members contribute approximately 50 percent of its annual budget.

9. Food safety is a significant component of CSPI's advocacy and education work. CSPI has staff members who dedicate a substantial portion of their time to issues related to food safety and, specifically, the safety of food additives and other substances that are added to food either directly or indirectly.

10. CSPI's scientists evaluate the safety of substances that are directly or indirectly added to food and publish an authoritative online resource on food chemical safety, *Chemical Cuisine*. Moreover, the organization works to convince companies and government decision-makers to remove dangerous chemicals from our nation's food supply, primarily by communicating with food manufacturers and submitting petitions to the FDA. In addition, CSPI advocates for a more robust safety review process of substances that are directly or indirectly added to food, including, in particular, closing loopholes in the food additive approval process. As part of CSPI's efforts to protect its members and the public from unsafe chemicals in food, CSPI joined the March 2016 Food Additive Petition and the April 2016 Citizen Petition urging FDA to prohibit the use of phthalates in food packaging and food production materials.

11. Many of CSPI's members are concerned about toxic chemicals in their food, including phthalates. Through statements on CSPI's website and in

articles in *Nutrition Action*, CSPI has educated its members about the harms that can be caused by phthalates and provided guidance on how to reduce their exposure to phthalates. However, because phthalates are common in many foods and not labeled on products, CSPI's members are not able to fully avoid exposure to phthalates.

12. FDA's denial of our objections injures our members. If the Court sets aside FDA's decision, it would likely force FDA to take action to reduce our members' exposure to these harmful chemicals. To protect CSPI's members and all consumers, FDA's denial of our objections should be set aside.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed on this 8th day of March 2025, in Washington, D.C.

Peter Lurie, M.D., M.P.H.

ORAL ARGUMENT NOT YET SCHEDULED

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ALASKA COMMUNITY ACTION ON TOXICS, BREAST CANCER PREVENTION PARTNERS, CENTER FOR ENVIRONMENTAL HEALTH, CENTER FOR FOOD SAFETY, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, DEFEND OUR HEALTH, ENVIRONMENTAL DEFENSE FUND, and LEARNING DISABILITIES ASSOCIATION OF ILLINOIS, *Petitioners*, v. UNITED STATES FOOD AND DRUG ADMINISTRATION and DR. MARTIN MAKARY, in his official capacity as Commissioner of the United States Food and Drug Administration, *Respondents*.	No. 24-1382

DECLARATION OF EMILY CAREY PEREZ DE ALEJO

I, Emily Carey Perez de Alejo, declare and state as follows:

1. I am the President and Chief Executive Officer of Defend Our Health (formerly the Environmental Health Strategy Center), a non-profit organization based in Portland, Maine, that works to create a world where all people have equal access to safe food and drinking water, healthy homes, and products that are toxic-free and climate-friendly. Ensuring environmental justice is a key value for our organization and our supporters and is central to our mission. By seeking equal access to safe food, water, and products, we also mean eliminating racial disparities in exposure to toxic chemicals that result when people of color are disproportionately exposed compared to their white counterparts. In service of this mission, Defend Our Health engages in policy advocacy at the state and federal levels and pursues market-based strategies to encourage companies to identify toxic chemicals such as ortho-phthalates ("phthalates") in their supply chains and switch to safer alternatives.

2. I hold a Bachelor of Science in Environmental Policy, Institutions, and Behavior & Political Science from Rutgers University. Prior to my work at Defend Our Health, I worked for over fifteen years spearheading complex policy, strategy, and process improvement projects in healthcare, academia, non-profit, and governmental settings, most recently as program director for partnerships and strategic development at the Rutgers Cancer Institute. This declaration is based on

my personal knowledge of Defend Our Health's research and other activities and my professional expertise.

3. Defend Our Health engages with more than 13,000 supporters who have signed up to receive our educational materials, action alerts, and other communications. These individuals support our organization with their time and/or financial contributions expressly because we advance their interest in avoiding exposure to phthalates and other toxic chemicals. We have supporters across the nation, and around 4,000 supporters who live in the State of Maine, where we have worked for twenty-three years to improve environmental public health by successfully advocating for a series of first-in-the-nation public policies to phase out phthalates and other toxic chemicals in favor of safer alternatives. We regularly engage our supporters in our lobbying efforts and consumer campaigns by, for example: collaborating with them on op-eds, blog posts, and other communications that allow them to share their concerns and stories with public officials and the public at large; inviting them to provide testimony on bills addressing exposure to phthalates and other harmful chemicals; inviting them to sign petitions asking companies to eliminate toxic chemicals such as phthalates from their products; and recruiting them to participate in grassroots advocacy events such as rallies, petition deliveries to corporate headquarters, and news conferences. Our supporters also

influence our priorities by raising issues at Defend Our Health community meetings.

4. As elaborated below, Defend Our Health conducts and commissions research to identify sources of toxic chemical exposure in food and other products to guide and advance our advocacy and educate our supporters and the broader public. We engage various technical experts to inform our research and analysis on chemicals of concern, such as phthalates, in food, food-contact materials, and other products. For example, Trisha Vaidyanathan is our Senior Director of Research and leads the scientific strategy behind our organization's research and analysis work, ensuring scientific integrity. She has a Bachelor of Arts in Cognitive Neuroscience from the University of California, Berkeley and her Ph.D. in Neuroscience from the University of California, San Francisco. Ryan Bouldin, a science advisor to Defend Our Health, is a Ph.D. chemical engineer and Dean of the School of Applied Natural Sciences and a Professor of Sustainable Chemistry at Bentley University who focuses on a transition away from the use of toxic chemicals such as phthalates to more sustainable, green chemistries.

5. Defend Our Health also collaborated with New York University Langone Health Center for the Investigation of Environmental Health Hazards researchers like Leo Trasande, M.D., M.P.H., a pediatrician, professor, and leading environmental health researcher, on the effects of endocrine-disrupting chemicals

such as phthalates on children's health. In 2024, Dr. Trasande and our founder and former President and Executive Director Mike Belliveau published a paper on cost and health impacts of toxic exposures from plastics. These are just a few of the scientists and physicians who provide technical expertise and support for Defend Our Health's work.

6. Defend Our Health launched its Toxic-Free Food campaign in 2016. For the past nine years, we have conducted extensive research, public education, regulatory advocacy, and direct advocacy to companies regarding the urgent need to eliminate uses of phthalates in food-processing equipment, food packaging, and food service ware based on extensive evidence that these chemicals migrate into the food and beverages they contact and can cause serious harm to human health.

7. Our investigation into food-contact uses of phthalates began in 2016 with a comprehensive review of the peer-reviewed scientific literature and technical reports published by government and industry entities addressing the uses of phthalates in food-contact materials and the risks to human health from consuming food and beverages that are contaminated by phthalates that leach out of these materials. This review was conducted jointly by Mr. Belliveau; Dr. Gillian Miller, Senior Scientist with Ecology Center, who holds a Ph.D. in Chemical Engineering from Stanford University; and Nancy Uding, who holds a Master of Science Engineering in Environmental Engineering from the University of

Washington and formerly worked with Toxic-Free Future. We have used the results of this literature review to develop fact sheets and other public education resources and to inform our strategy for further research and advocacy to address dietary exposure to phthalates.

8. Our review of the peer-reviewed literature addressing dietary sources of phthalate exposure pointed to milk and other dairy products as a major concern, while also documenting phthalate contamination in numerous other food products—including meats, cooking oils, pasta and grains, bread, seafood, spices, preserved fruits and vegetables, and fresh produce.[1]

9. In an effort to update and expand upon this research, in 2016, Defend Our Health and a consortium of non-profit organizations engaged VITO, the Flemish Institute for Technological Research in Belgium, to conduct laboratory testing of fifty dairy products purchased at retail stores in the United States for thirteen distinct phthalate chemicals.[2] This analysis included a variety of cheese products, from natural hard block cheese to powdered cheese sold with boxed

[1] *See*, *e.g.*, Samantha E. Serrano et al., *Phthalates and Diet: A Review of the Food Monitoring and Epidemiology Data*, 13 Env't Health Art. No. 43 (2014), http://www.ehjournal.net/content/13/1/43.

[2] *See* Stefan Voorspoels et al., *Final Report, Analysis of Selected phthalates in Food Samples*, VITO (June 2017), https://www.toxicfreefood.org/wp-content/uploads/2018/10/PhthalatesLabReport.pdf; Coal. for Safer Food Processing & Packaging, *Testing Finds Industrial Chemical Phthalates in Cheese* (June 2017), https://www.toxicfreefood.org/wp-content/uploads/2018/10/data-summary.pdf.

macaroni and cheese meals, and included products that were certified organic. Phthalates were detected in twenty-nine of the thirty cheese products tested, with some food items containing as many as six different phthalates. Di(2-ethylhexyl) phthalate ("DEHP"), which is the most widely restricted phthalate due to the well-developed body of evidence demonstrating its toxic effects, was the most commonly detected phthalate, and it was detected at a much higher average concentration in the sampled food products than any other phthalate. Average phthalate levels in the powdered cheeses from macaroni and cheese meals were more than four times higher than in the other cheeses. The results of this study were reported widely in the media.[3]

10. Since 2016, we have also commissioned extensive laboratory testing to detect the presence of phthalates in a variety of food-contact materials, including

[3] *See*, *e.g.*, Roni Caryn Rabin, *The Chemicals in Your Mac and Cheese*, N.Y. Times (July 12, 2017), https://www.nytimes.com/2017/07/12/well/eat/the-chemicals-in-your-mac-and-cheese.html?searchResultPosition=1; Nadia Young, *What Chemicals Are in Your Mac and Cheese?*, CNN (July 17, 2017), https://www.cnn.com/2017/07/15/health/macaroni-and-cheese-phthalates-analysis-study/index.html.

dairy equipment,[4] food-handling gloves,[5] and cap gaskets (the plastic liners that seal glass jars or bottles to a metal cap).[6] These studies utilized validated test methods and screening technologies implemented under the direction of Dr. Gillian Miller to measure the total presence of phthalates, as well as their levels, in tested materials. Each of these investigations has revealed the continued use of phthalates in some varieties and brands of mechanical milking equipment, food service gloves, and glass bottled beverage packaging for products purchased in the United States.

11. In 2023, Defend Our Health's former director of research, Roopa Krithivasan, and former executive director, Mike Belliveau, and colleagues published a paper in the Journal of Exposure Science and Environmental

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[4] *See* Pure Strategies, *Sources of Phthalates in Dairy Farm Equipment* (Mar. 2018), https://www.ecocenter.org/sites/default/files/2022-07/Phthalates-Farm-Equipment.pdf.

[5] *See* Coal. for Safer Food Processing & Packaging, *Time to Take Off the Toxic Gloves: How Harmful Chemicals Used in Some Food Service Gloves Threaten Consumers' Health—And What Restaurants Can Do About It* (2019), https://www.toxicfreefood.org/wp-content/uploads/2019/08/Glove-Summary-FINAL.pdf.pdf; Lauren Olson et al., *Taking Off the Toxic Gloves: An Investigation of Phthalates and Other Chemicals of Concern in Food-Handling Gloves*, Ecology Ctr. (July 25, 2019), https://drive.google.com/file/d/1NbWOETSCoSd-PXT_4eTHgi7sTx8aOQgY/view.

[6] Defend Our Health, *Toxic Food Packaging Sold In Violation of Maine Law By Two Corporations* (2022), Toxic Food Packaging Sold in Violation of Maine Law by Two Corporations - Defend Our Health; Defend Our Health & Ecology Ctr, *Capped With Toxics: Toxic Chemicals Found in the Plastic Liners of Bottle Caps from Glass-bottled Beverages* (2021), https://toxicfreedrink.org/wp-content/uploads/2021/07/Capped-with-Toxics-Report2021.pdf.

Epidemiology documenting phthalate levels in vegetable oils, milk, infant formula, and cheese powders from macaroni and cheese kits.[7] The results of this study, which utilized food products purchased in 2021, demonstrate that phthalate contamination of common foods in the United States remains widespread despite industry's assertion that, as of 2018, it had abandoned the use of most phthalates approved by FDA as additives in food-contact materials. Indeed, 100 percent of foods tested contained one or more phthalates. DEHP, which is FDA-approved for use as a food additive, was detected in 100 percent of foods tested. The additive DINP was detected in nearly one quarter of foods tested, and the additive DCHP was detected in approximately ten percent of foods tested.

12. In addition, we have engaged in dialogues with dozens of food and beverage companies about their use of phthalates and other plasticizers in production and packaging materials and conducted research on safer alternatives. This work has enabled us to negotiate agreements with several food and beverage companies to provide for the phaseout of phthalates from food-contact materials

[7] Roopa Krithivasan et al., *Analysis of Ortho-Phthalates and Other Plasticizers in Select Organic and Conventional Foods in the United States*, 33 J. Exposure Sci. & Env't Epidemiology 778 (2023), https://www.nature.com/articles/s41370-023-00596-0.

the companies use or produce and has added to our direct knowledge of the uses of phthalates in food-contact materials and viable alternatives.[8]

13. Additionally, we have engaged in policymaking and played a part in Maine's passage and enactment of a ban on phthalates in food packaging.

14. Taken together, the product testing research conducted by Defend Our Health and our partners, our review of the published literature, as well as our direct engagement with food and beverage companies have all led me to conclude that phthalates can be found in nearly every category of food and beverage products, including foods that are certified organic or marketed as natural. As a result, I have concluded that it is not feasible for individuals to shop their way out of this problem and avoid dietary exposure to phthalates through their personal choices. Some choices, such as decreasing intake of processed foods, may help reduce exposure to some degree among people with the resources to make that choice. But reducing or even eliminating all consumption of processed foods will not eliminate

[8] *See* Michael Corkery, *Annie's Pledges to Purge a Class of Chemicals From Its Mac and Cheese*, N. Y. Times (Feb. 19, 2021), https://www.nytimes.com/2021/02/19/business/annies-mac-cheese-plastic-phthalates.html; Edward D. Murphy, *Portland Group Key to Convincing General Mills to Drop Chemical From Mac-and-Cheese Processing*, Portland Press Herald (Feb. 24, 2021), https://www.pressherald.com/2021/02/24/portland-group-key-to-convincing-general-mills-to-drop-chemical-from-mac-and-cheese-brand-packaging/; Erin Malsbury, *Martinelli's Among Brands Searching for Safer Bottle Cap Options*, Pajaronian (July 27, 2021), https://pajaronian.com/martinellis-among-brands-searching-for-safer-bottle-cap-options/.

a person's dietary exposure to phthalates, and doing so is not an option for many people who depend on packaged and processed foods—which frequently cost less than unprocessed alternatives—cafeteria meals, and restaurant or take-out food.

15. Further, based on our review of more than ten years of data on exposure to phthalates by a representative sample of the entire American population, we have concluded that widespread racial disparities exist in phthalate exposure.[9] For nine of ten phthalates for which data were reported by the National Biomonitoring Program, higher phthalate exposures were experienced by Black, Hispanic, and Asian people than white people in the United States.[10] This means that reducing and eliminating exposure to phthalates from food-contact materials is not only a public imperative; it's a matter of environmental justice.

16. Given these conclusions and the growing body of peer-reviewed research linking phthalate exposure to serious and irreversible health harms, Defend Our Health strongly supports the 2016 petition underlying this lawsuit, which asked FDA to prohibit the use of phthalates in food-contact materials from which the chemicals can migrate into food and beverages. From our review of the

[9] *See* Env't Health Strategy Ctr., *Racial, Age, and Gender Disparities in Exposure to Ortho-Phthalates in the U.S.* (2020), https://www.toxicfreefood.org/wp-content/uploads/Disparities-in-Phthalate-Exposure.pdf.

[10] *See* Ctrs. for Disease Control & Prevention, *Fourth National Report on Human Exposure to Environmental Chemicals*, Updated Tables, Volume 1 (Jan. 2019), https://www.cdc.gov/exposurereport/pdf/FourthReportUpdated TablesVolume1 Jan2019-508.pdf.

scientific literature and our own research and direct dialogue with food and beverage companies, Defend Our Health has concluded that for most people, dietary exposure is the primary exposure pathway for most phthalates, and that the use of phthalates in food-contact materials, especially for food processing, is the major source of food-borne phthalates. Therefore, only by revoking FDA permission to use phthalates in food-contact materials may public health be adequately protected. Defend Our Health also knows that safer alternatives to phthalates are widely available, including drop-in substitute chemicals as well as non-vinyl plastics that do not require added chemical plasticizers such as phthalates. FDA can readily solve this problem.

17. Unless and until FDA takes action to prohibit all uses of phthalates in food-contact materials used for food processing, food packaging, and food service, Defend Our Health's staff, board members, supporters and their children will continue to experience dietary exposures to phthalates that endanger their health and that they cannot avoid through their individual food choices. If the court were to set aside FDA's decision, it would force FDA to take action to remove unsafe phthalate additives from the market and thereby reduce or eliminate our supporters' exposure.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed on the 12th day of March 2025, in South Bound Brook, New Jersey.

Emily Carey Perez de Alejo

ARTICLE

Check for updates

Analysis of ortho-phthalates and other plasticizers in select organic and conventional foods in the United States

Roopa Krithivasan[1]✉, Gillian Zaharias Miller[2], Michael Belliveau[1], Jeff Gearhart[2], Vimalkumar Krishnamoorthi[3], Sunmi Lee[3] and Kurunthachalam Kannan[4]

BACKGROUND: ortho-phthalates and other plasticizers impart flexibility to plastics in food production, processing, and packaging; food consumption is a dominant plasticizer exposure pathway. Lower molecular weight ortho-phthalates are being replaced in plastic products due to toxicity concerns, but toxic hazards of and exposures to replacement ortho-phthalates and other plasticizers are poorly understood.
OBJECTIVE: We measured 12 ortho-phthalates and 9 other plasticizers in conventional and organic U.S. food products to assess magnitude and profiles of contamination.
METHODS: We measured plasticizers in 34 vegetable oils, 10 milks, 18 infant formulas, and 9 cheese powders from macaroni kits using gas chromatography coupled with mass spectrometry (GC-MS). We analyzed plastic packaging composition using FTIR spectroscopy.
RESULTS: We detected eight ortho-phthalates and three alternatives ((1,2-cyclohexane dicarboxylic acid diisononyl ester (DINCH), diethylhexyl terephthalate (DEHT), and diisobutyl adipate (DIBA). Diethylhexyl phthalate (DEHP) was measured in all 71 products. DEHT had the highest concentration of any plasticizer (>10,000 ng/g in three oils). Oils had the highest total plasticizer (median = 770 ng/g, max = 14,900 ng/g) and milk the lowest (median = 88 ng/g, max = 120 ng/g). Organic milk and refined oils had higher median plasticizer levels than conventional. Refined oils had significantly lower concentrations than unrefined oils. Maximum contributors for every category were non-ortho-phthalates: DEHT (powdered infant formula and oils) and DIBA (cheese powder, milk and liquid formula). Plasticizers were not detected in packaging except epoxidized soybean oil in liquid formula lids.

IMPACT STATEMENT: Human exposure to plasticizers is a significant public health concern. Nevertheless, sources of such exposures are poorly characterized. This study adds valuable information for estimating legacy and alternative plasticizer exposures from foods. The method developed for measuring DINCH, DINP and DIDP broadens the range of plasticizers other researchers may analyze in future work. The profiles of plasticizer contamination varied depending on the food type. We also document that food processing may be a source of plasticizer contamination in foods.

Keywords: Ortho-phthalates; Plasticizers in food; Food contact materials; Alternative plasticizers; DINCH; DINP

Journal of Exposure Science & Environmental Epidemiology; https://doi.org/10.1038/s41370-023-00596-0

INTRODUCTION

Ortho-Phthalate diesters (also referred to as phthalates and phthalic acid esters) are high production volume additives used in plastics to increase flexibility; they are also present in some food packaging, inks, adhesives, and lubricants. Since 2017, the U.S. Consumer Product Safety Commission has restricted eight ortho-phthalates including diisononyl phthalate (DINP), di(2-ethylhexyl) phthalate (DEHP) and di-n-butyl phthalate (DBP) in commercial products intended for use by infants and children [1]. A growing body of evidence links ortho-phthalates to endocrine disruption [2], reproductive and developmental toxicity including effects on male genital development [3], and neurodevelopmental risks including impacts on children's learning and behavior [4]. Human exposure to ortho-phthalates is ubiquitous with 98% of the US population showing the presence of biomarkers for ortho-phthalates in urine [5], with the majority exposed to more than one ortho-phthalate [4].

While replacement, non-ortho-phthalate plasticizers including Bis(2-ethylhexyl) terephthalate (DEHT), diethylhexyl adipate (DEHA), 1,2-cyclohexane dicarboxylic acid diisononyl ester (DINCH), and diisobutyl adipate (DIBA) have entered the market, few studies document their presence in commercial products including food contact materials [6, 7], and their health effects remain poorly studied [6, 8]. A study from Canada analyzed 30 cheese samples packaged in DEHA-plasticized cling films and detected concentrations ranging from 710 to 879,000 ng/g, with

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an average of 203,000 ng/g; DEHA was detected in the beef, pork, chicken, and fish samples packaged in DEHA-plasticized cling films at average concentrations of 6300, 9100, 2500, and 5900 ng/g, respectively [9]. Similarly, DEHT, a structural isomer of DEHP, has been reported to occur in hamburgers, chicken nuggets, and chicken burritos ($n = 19$; median = 2510 ng/g; max = 12,400 ng/g) and gloves ($n = 3$; range: 28–37% by weight) used in fast food restaurants [6]. Dietary exposure to DEHA in children was reported to be 1 µg/kg-day in a German study [10].

A significant pathway of human exposure to ortho-phthalates and other plasticizers is through diet [11], but the extent of plasticizer contamination in food products remains understudied. One of the major challenges associated with the measurements of plasticizers in food products is extensive contamination of laboratory supplies and products that contribute to background levels of contamination [12]. Currently available data do not fully capture the extent of plasticizers in common food products, particularly those that are marketed as healthy choices for families with infants and young children. While recent studies suggest ortho-phthalates and other plasticizers are ubiquitous in widely consumed foods including milk and other dairy products [13, 14], oils [15, 16], and infant formula [9, 16]), few studies capture data on a broad suite of plasticizers [17]. Such assessments are necessary to track if, how, and to what extent ortho-phthalates are being replaced by other plasticizers. Such assessments are particularly important for food and beverages targeting vulnerable populations: previous ortho-phthalate exposure studies suggest that infants, children, and people of color may be disproportionately exposed [4, 11].

The objective of this study is to quantify concentrations of 12 ortho-phthalate and nine non-ortho-phthalate plasticizers in 71 common foods purchased at U.S. retail stores in 2021. Selected food categories are representative of products widely consumed by infants, children, and families. We evaluate concentrations of each plasticizer by food type, and also by their organic certification status. We also discuss how plasticizer concentrations relate to processing and preparation methods unique to certain food categories (especially oils and infant formulas). Finally, we evaluate the composition of plastic packaging, which is sometimes assumed to be a significant source of plasticizer contamination in food [9]. We discuss potential pathways of plasticizer contamination in different food categories.

MATERIALS AND METHODS

Sample selection

Four food categories were chosen including items commonly used in home kitchens in the United States: cooking oil, milk, infant formula, and powdered cheese from macaroni and cheese kits. Within each category, brands and varieties were selected based on popularity among consumers and on market share. This information was collected from public sources including statista.com, marketwatch.com and amazon.com. Organic-certified and conventional (not certified organic) products were included within each category. Products were purchased in 2021 from retail stores in Michigan and California as well as ordered online from Costco and other retailers and were shipped to the analysis lab unopened. Perishable milk items were shipped on ice and refrigerated upon arrival.

Instrumental methods

The analytical method for plasticizer measurement in the foodstuffs was similar to the gas chromatography with mass spectrometry (GC-MS) method for ortho-phthalate quantification described in earlier publications [12, 18, 19] with some modifications as detailed below. Table 2 lists all plasticizers analyzed in this study.

ortho-Phthalate diester standards (purity ≥ 99%)), namely diethyl phthalate (DEP), dibutyl phthalate (DBP), diiso-butyl phthalate (DIBP), benzyl butyl phthalate (BzBP), dicyclohexyl phthalate (DcHP), di-n-hexyl phthalate (DnHP), di(2-ethylhexyl) phthalate (DEHP), di-n-octyl phthalate (DnOP), di(propyl heptyl) phthalate (DPHP), dipropyl phthalate (DPP) and dioctyl terephthalate (DOTP) were purchased from AccuStandard Inc (New Haven, CT, USA) and/or from C/D/N Isotopes (Pointe-Claire, Quebec, Canada). Di(isononyl)cyclohexane-1,2-dicarboxylate (DINCH), diisononyl phthalate (DINP) and diisodecyl phthalate (DIDP) were purchased from Matrix Scientific (Columbia, SC, USA), Toronto Research Chemicals (Toronto, ON, Canada) and Sigma Aldrich (St. Louis, MO, USA), respectively. Four adipate ester standards (≥98%), namely diethyl adipate (DEA), dibutyl adipate (DBA), di-isobutyl adipate (DIBA), and di(2-ethylhexyl)adipate (DEHA), as well as tributyl phosphate (TBP), acetyl butyl citrate (ATBC) and dibutyl sebacate (DBS) were purchased from Sigma Aldrich (St. Louis, MO, USA). Eleven deuterated standards, d4-DMP, d4-DEP, d4-DBP, d4-DIBP, d4-BzBP, d4-DcHP, d4-DnHP, d4-DEHP, d4-DnOP, d4-DPHP, and d4-DPP were purchased from Sigma Aldrich (St. Louis, MO, USA) and were used as internal standards. 13C4-DINCH, d4-DINP and d4-DIDP were purchased from Cambridge Isotope Laboratories, Inc (Tewksbury, MA, USA) and Toronto Research Chemicals (Toronto, ON, Canada) and were used as internal standards for the analysis of these three chemicals. The internal standards for DINCH, DINP and DIDP were purified isomers and therefore contained only one peak whereas native standards of them had a mixture of several isomers. Hexane, acetonitrile and acetone were of HPLC grade and purchased from J.T. Baker (Center Valley, PA, USA). All glassware used in this study were rinsed thoroughly with tap water followed by HPLC-grade water and acetone. Glassware were then wrapped in aluminum foil and kept in a hot air oven at 450 °C for 4–6 h prior to use.

Extraction of milk

Approximately 0.1 g of milk sample was transferred into a 15 mL glass tube. Two milliliters of acetone and hexane mixture (1:1 v/v) were added to the glass tube, followed by the addition of internal standards (20 ng each). The samples were ultrasonicated at 40 kHz for 30 min (Branson 3510 R-DTH, Branson Ultrasonics Corporation, Danbury, CT, USA) and then shaken in an orbital shaker at 250 S per minute for 40 min (Eberbach Corp., Ann Arbor, MI, USA). Samples were then centrifuged at 5000 rpm for 15 min (Eppendorf 5804, Hamburg, Germany). The solvent layer was carefully transferred into another glass tube and the sample was extracted again with 2 mL of acetone/hexane mixture. The extracts were combined and dried under gentle nitrogen stream (without heat). Sodium sulfate (anhydrous) was added to remove moisture, solvent layer was transferred and reconstituted with 1 mL of hexane, into a gas chromatographic (GC) glass vial for instrumental analysis.

Extraction of infant formula and powdered cheese

Approximately 0.1 g of infant formula and cheese (powder) samples were transferred into 15 mL glass tubes and 2 mL of hexane were added, followed by the addition of internal standards (20 ng each). The samples were ultrasonicated and centrifuged as described for milk. The extraction was repeated with 2 mL of hexane and the combined extracts were concentrated under a gentle stream of nitrogen to 1 mL, and the extract was transferred into a GC vial for instrumental analysis.

Extraction of vegetable oil

Approximately 0.1 g of oil was transferred into a 15 mL glass tube and 2.5 mL of acetonitrile and internal standards (20 ng each) were added. The samples were ultrasonicated and centrifuged as described above. The extraction was repeated and the extracts were dried under gentle nitrogen stream, and reconstituted with 1 mL of acetonitrile. The extract was kept at −20 °C for 10 h and the organic layer was carefully transferred into a GC glass vial for instrumental analysis.

GC-MS analysis

The concentrations of ortho-phthalate and other plasticizers were measured using an Agilent gas chromatograph (GC-7890A) interfaced with a mass spectrometer (MSD 5975 C). The analyte separation was accomplished using a fused-silica capillary HP-5 MS (UI) column (30 m, 0.25 mm i.d., 0.25-µm film thickness, Agilent Technologies) with the following temperature program for all target analytes, except DINCH, DINP and DIDP. The oven temperature was held at 80 °C for 1 min, increased to 180 °C (12 °C/min held for a min), then to 230 °C (6 °C/min), 270 °C (8 °C/min held for 2 min), 300 °C (30 °C/min held for 12 min) and finally, to 320 °C (8 °C/min and held for 5 min).

For DINCH, DINP and DIDP analysis, a separate MS method was developed to distinguish these analytes from one another and other ortho-phthalates. For these analytes, the oven temperature program was as follows: 180 °C for 0.5 min, increased to 280 °C at 20 °C per min and held for 7 min. Sample

injection (2 µl) was performed using an autosampler in splitless mode. Helium (99.999% purity) was used as the carrier gas at a flow rate of 1 ml/min. The injector port, interface, and ion source temperatures were kept at 260 °C, 310 °C, and 230 °C, respectively. The MS was operated in electron ionization (EI) at 70 eV and at an emission current of 34.6 µA. The MS was operated in selected ion monitoring (SIM) mode.

Quality assurance and quality control (QA/QC)

For each sample type, five procedural blanks and two matrix spikes were analyzed, as shown in Table S3. A seven-point calibration curve at concentrations ranging from 1 to 500 ng/mL (for ortho-phthalates and non-phthalate plasticizers) with a correlation coefficient of >0.99 for each compound, was used in the quantification. The mean recoveries of target compounds spiked into milk, infant formula, cheese powder and oil samples at 10 ng/g ($n = 5$) except for DINCH, DINP and DIDP which were spiked at 200 ng/g ($n = 5$), are shown in Table S3. Reported concentrations were corrected for the recoveries of internal standards. For the calculation of the recoveries of non-ortho-phthalate plasticizers, internal standards of analogs ortho-phthalates were used. Limits of quantification (LOQs) for all plasticizers were in the range of 1–10 ng/g on a wet-weight basis. LOQ were calculated from the lowest concentration of the calibration curve and a nominal sample weight of 1.0 g. Further details of recoveries, limit of detection (LOD), LOQ, and relative standard deviation (RSD) of replicate analysis of samples are provided in Table S4. Trace concentrations of DEP (0.5–3.6 ng/mL), DIBP (0.7–4 ng/mL), DBP (0.5–8 ng/mL), and DEHP (1.2–10 ng/mL) were quantified in procedural blanks. The median concentrations found in procedural blanks were subtracted from reported concentrations of analytes in samples. We did not analyze duplicate samples. Quantification was based on an external calibration standard, and recoveries were corrected using responses of internal standards spiked into each sample. For DINCH, DINP and DIDP, all the isomers were collectively integrated spanning the retention time. Concentrations of these three compounds were the sum of all the isomers. The positive detection of these compounds in samples was further confirmed by injecting sample extracts twice, once without fortifying native standards to the final sample extract and the other after fortifying native standards to the final sample extract. Selected chromatograms of DINCH, DINP and DIDP standards, sample extract and spiked sample extract for these three compounds are shown in Fig. S1. In addition, for each analyte, m/z ions were monitored for 2–3 transitions (target ion and qualifier ion) for quantitation and confirmation.

Fourier Transform Infrared (FTIR) analysis of packaging polymers

The surface of each packaging component directly contacting food was tested to determine polymer type and any additives present above approximately 1% by mass [20]. Packaging samples were cleaned of food residue using isopropyl alcohol and placed on the stage of a Nicolet iS5 FTIR spectrometer (Thermo Scientific) with a single-bounce diamond ATR accessory. Absorbance spectra were collected from 4000–500 cm^{-1} with 4 cm^{-1} resolution averaging 12 scans using Omnic software. No smoothing or processing was applied. We used a combination of visual inspection of the spectral data and match searching within FTIR libraries (Thermo Fisher Scientific). To determine a positive match we required visually apparent alignment of key peaks in the experimental spectrum with a known spectrum.

Statistical analysis

We calculated descriptive statistics (including median, 95th percentile, and maximum) by food type, certification (organic or conventional), packaging, and processing type (for oils), for all tested plasticizers. Where necessary, we substituted concentrations below the LOD with a value of zero. Unless otherwise noted, we used non-parametric tests (Wilcoxon Rank Sum for pairwise comparisons and Kruskall Wallis for independent observations) to evaluate differences in chemical concentrations by categories of interest. All statistical analyses were conducted in R (Version 4.2.2) and R studio (version 1.4.1106).

RESULTS

Product categories

As shown in Table 1, plasticizers were detected in 100% of the samples with total concentrations ranging from 9.0 to 14,900 ng/g (sum of all plasticizers measured). At least one ortho-phthalate was detected in 100% of samples, while at least one non–ortho-phthalate plasticizer was detected in 62%. DEHP was detected in all products. The highest concentration of a single plasticizer in a product was DEHT at 12,000 ng/g in a refined organic avocado oil sample, which also contained the highest concentration of DINP in any tested product at 2190 ng/g.

Plasticizer concentrations varied by food type and were on average higher in cooking oil and cheese powder than in infant formula or milk. Table 1 summarizes ortho-phthalate, other plasticizer, and total plasticizer concentrations by product type. For oil, milk, ready-to-feed infant formula, infant formula powder, and cheese powder respectively, median ortho-phthalate concentrations were 462, 23, 18.9, 30.5, and 31.4 ng/g, and median non-ortho-phthalate plasticizer concentrations were 187, 72.5, <LOQ, 144, and 332 ng/g. Despite the ubiquitous presence of DEHP, maximum contributors to total plasticizer concentrations for all product types were non-ortho-phthalate alternatives: DEHT for formula and oils; DINCH for cheese powder, and DIBA for milk.

Table 2 shows that of the 12 ortho-phthalate plasticizers measured, eight (DEP, DIBP, DBP, BzBP, DCHP, DEHP, DPHP, and DINP) were detected in at least one product. The five most common ortho-phthalates include two high-molecular weight (DEHP and DINP) and three low molecular weight (DBP, DIBP, DEP) ortho-phthalates. The ortho-phthalate DEHP was the only plasticizer detected in 100% of samples; the second most frequent ortho-phthalate was DBP (42% of samples). Of the nine other plasticizers measured, three (DINCH, DEHT, and DIBA) were detected in at least one product. The most frequently detected alternative plasticizers were DEHT (38%) and DIBA (34%).

Differences in the concentrations and profiles of plasticizers measured among food categories are apparent (Table 2, and Table S5). DINP, DCHP, and DINCH were present only in cooking oils (50%, 21%, and 6% of oils, respectively) and not in milk, formula, or cheese. DCHP and DINCH were detected only in olive oils (Table S1). BzBP was detected in 22% of cheese powders and not in the other food types. One cheese sauce (not shown in tables above as only a single sample was tested) had the highest total plasticizer concentrations in the macaroni and cheese sample category (1,000 ng/g) due to a high concentration of DINCH (962 ng/g).

Organic certification

Fig. 1 shows total plasticizer concentrations (on a log scale) for individual products, stratified by food category, as certified organic ($n = 18$) or conventionally produced ($n = 53$). Median concentration of total plasticizers, total ortho-phthalates, and total non–ortho-phthalates were significantly higher in organic samples than in conventional samples ($p = 0.004$, $p = 0.007$, and $p = 0.005$ respectively, after normalizing plasticizer concentrations of each product by category means). Within food types, median total plasticizer concentrations varied between organic and conventional milk ($p = 0.02$) and refined oil ($p = 0.014$), but were comparable for other food types.

Packaging and fat content

Packaging material composition did not appear to explain the occurrence or concentrations of plasticizers in the food products. Packaging polymers contacting the solid or liquid food in each product were characterized by FTIR spectroscopy and the results are presented in Table S1. Polyethylene terephthalate, polyethylene, and polypropylene were commonly detected in packaging materials analyzed. Infant formula packaging had the widest variety of different types of polymers used, including polyvinyl chloride (PVC) lid gaskets in two of the ready-to-feed liquid formula containers. These gaskets contained detectable concentrations of epoxidized soybean oil (ESBO), a non-ortho-phthalate plasticize, frequently used in PVC [21] that was not tested in food products in the present study. However, none of the packaging components tested had detectable (approx. >1% by mass) concentrations of any of the plasticizers listed in Table 2.

Table 1. Overview of ortho-phthalate and other (non-ortho-phthalate) plasticizer measurements in all products.

		Total phthalates[a]				Total non-phthalate plasticizers[b]				Total plasticizers[c]				Highest single plasticizer	
Product Type	**N**	**% >MDL[d]**	**Median (ng/g)**	**95th per. (ng/g)**	**Max (ng/g)**	**% >MDL**	**Median (ng/g)**	**95th per. (ng/g)**	**Max (ng/g)**	**% >MDL**	**Median (ng/g)**	**95th per. (ng/g)**	**Max (ng/g)**	**Max plast.**	**max val. (ng/g)**
ALL PRODUCTS															
Oil	34	100	462	2950	3150	50	187	10800	12000	100	770	12600	14900	DEHT	11980
Milk	10	100	12.0	32.0	44.3	100	72.5	104	106	100	88.3	118	120	DIBA	101
Infant Formula RTF[e]	3	100	18.9	20.3	20.4	33	<LOQ	436	484	100	20.4	455	503	DIBA	484
Infant Formula Powder	15	100	30.5	116	150	60	144	593	1200	100	202	628	1240	DEHT	1020
Cheese Powder	9	100	31.4	175	201	78	332	488	504	100	351	621	705	DIBA	504
ORGANIC ONLY															
Oil	8	100	1140	2630	2910	87.5	1250	11600	12000	100	2450	13900	14900	DEHT	11980
Milk	6	100	13.4	37.4	44.3	100	78.1	105	106	100	101	118.9	1120	DIBA	101
Infant Formula RTF	0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Infant Formula Powder	3	100	37.5	43.8	44.5	66.7	164	173	174	100	202	217	219	DIBA	174
Cheese Powder	1	100	201	201	201	100	504	503	504	100	705	705	705	DIBA	504
CONVENTIONAL ONLY															
Oil	26	100	98	2990	3150	38.5	<LOQ	3300	10700	100	98.0	532	13900	DEHT	10700
Milk	4	100	11.7	12.1	12.2	100	58.5	70.3	72.1	100	70.4	82.0	83.8	DIBA	72.1
Infant Formula RTF	3	100	18.9	20.3	20.4	33.3	<LOQ	436	484	100	20.4	455	503	DIBA	484
Infant Formula Powder	12	100	30.3	123	149	58.3	134	724	1200	100	199	759	1240	DEHT	1020
Cheese Powder	8	100	26.8	133	135	75.0	177	458	463	100	254	486	494	DIBA	353

[a]Sum of all phthalates in study: DEHP, DBP, DINP, DIBP, DEP, DCHP, DPHP, BzBP, DPP, DnHP, DnOP, and DIDP.
[b]Sum of all non-phthalate plasticizers in study: DEHT, DIBA, DINCH, DEA, TBP, DBA, DBS, ATBC, and DEHA.
[c]Sum of total phthalates and total non-phthalate plasticizers.
[d]*MDL* Maximum detection limit.
[e]*RTF* ready to feed.

Table 2. Detection frequency of ortho-phthalate and other (non-ortho-phthalate) plasticizers.

Plasticizer	Chemical Name	CAS	Mol.wt. (g/mol)	Median (ng/g)	95th per. (ng/g)	Max. (ng/g)	Detected in products by type (%)					
							ALL	Oil	Milk	Formula RTF	Formula Powder	Cheese Powder
							n = 71	*n* = 34	*n* = 10	*n* = 3	*n* = 15	*n* = 9
ortho-Phthalate Plasticizers												
DEHP	Di(2-ethylhexyl) phthalate	117-81-7	390.6	23.1	604	1160	100	100	100	100	100	100
DBP	Dibutyl phthalate	84-74-2	278.3	<LOQ	156	401	42.3	38.2	100	0.0	33.3	22.2
DINP	Diisononyl phthalate	28553-12-0	418.6	<LOQ	1950	2190	23.9	50.0	0.0	0.0	0.0	0.0
DIBP	Diisobutyl phthalate	84-69-5	278.3	<LOQ	22.2	166	15.5	23.5	0.0	0.0	6.7	22.2
DEP	Diethyl phthalate	84-66-2	222.2	<LOQ	4.0	26.0	9.9	8.8	0.0	66.7	13.3	0.0
DCHP	Dicyclohexyl phthalate	84-61-7	330.4	<LOQ	95.4	154	9.9	20.6	0.0	0.0	0.0	0.0
DPHP	di(2-propylheptyl) phthalate	53306-54-0	446.7	<LOQ	16.9	615	8.5	8.8	10.0	0.0	0.0	22.2
BzBP	Benzylbutyl phthalate	85-68-7	312.4	<LOQ	<LOQ	86.6	2.8	0.0	0.0	0.0	0.0	22.2
DPP	Dipropyl phthalate	131-16-8	250.3	<LOQ	<LOQ	<LOQ	0.0	0.0	0.0	0.0	0.0	0.0
DnHP	Di-n-hexyl phthalate	84-75-3	334.4	<LOQ	<LOQ	<LOQ	0.0	0.0	0.0	0.0	0.0	0.0
DnOP	Di-n-octyl phthalate	117-84-0	390.6	<LOQ	<LOQ	<LOQ	0.0	0.0	0.0	0.0	0.0	0.0
DIDP	Diisodecyl phthalate	26761-40-0	446.7	<LOQ	<LOQ	<LOQ	0.0	0.0	0.0	0.0	0.0	0.0
Other Plasticizers												
DEHT	Bis(2-ethylhexyl) terephthalate	6422-86-2	390.6	<LOQ	2090	11980	38.0	44.1	30.0	0.0	40.0	33.3
DIBA	Diisobutyl adipate	141-04-8	258.4	<LOQ	321	1220	33.8	2.9	100	33.3	33.3	77.8
DINCH	Diisononyl hexahydrophthalate	474919-59-0	424.7	<LOQ	<LOQ	2040	2.8	5.9	0.0	0.0	0.0	0.0
DEA	Diethyl adipate	141-28-6	202.3	<LOQ	<LOQ	<LOQ	0.0	0.0	0.0	0.0	0.0	0.0
TBP	Tributyl phosphate	126-73-8	266.3	<LOQ	<LOQ	<LOQ	0.0	0.0	0.0	0.0	0.0	0.0
DBA	Dibutyl adipate	105-99-7	258.4	<LOQ	<LOQ	<LOQ	0.0	0.0	0.0	0.0	0.0	0.0
DBS	Dibutyl sebacate	109-43-3	314.5	<LOQ	<LOQ	<LOQ	0.0	0.0	0.0	0.0	0.0	0.0
ATBC	Acetyltributyl citrate	77-90-7	402.5	<LOQ	<LOQ	<LOQ	0.0	0.0	0.0	0.0	0.0	0.0
DEHA	Di(2-ethylhexyl) adipate	103-23-1	370.6	<LOQ	<LOQ	<LOQ	0.0	0.0	0.0	0.0	0.0	0.0

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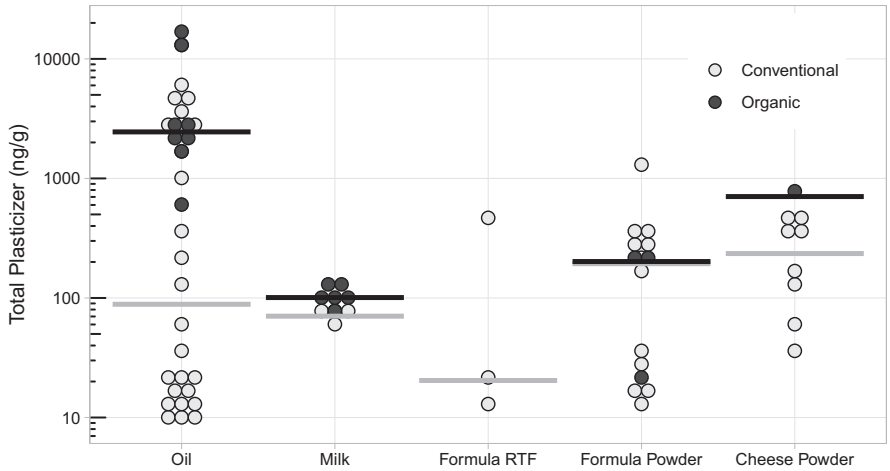

Fig. 1 Total Plasticizer values (on log scale) by category and certification. Circles depict organic samples (dark grey) and conventional samples (light grey). Horizontal lines represent median concentrations of total plasticizer (in ng/g) by category for organic samples (dark grey) and conventional samples (light grey).

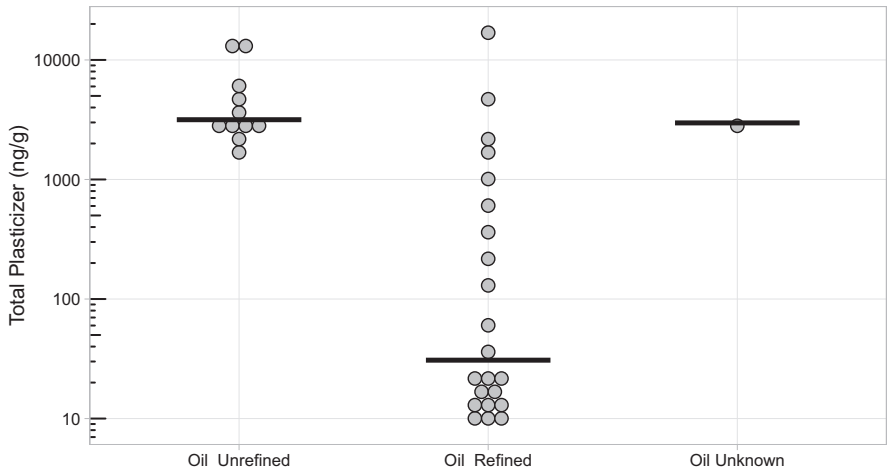

Fig. 2 Concentrations of plasticizers (on log scale) in unrefined vs refined oils. Circles represent oil samples by processing category. Horizontal lines represent median concentrations of total plasticizer (in ng/g) for each category. Processing type for one sample could not be established.

Since ortho-phthalates and other plasticizers are lipophilic and may partition into fats and oils, we noted the fat percentage, where obtainable, of each product tested (Table S1). For those products for which fat content could be obtained, correlation was found between fat content and total plasticizer concentration ($r(60) = 0.37$, $p = 0.003$).

Oil processing

Fig. 2 shows phthalate and non-phthalate plasticizer concentrations in oils labeled refined versus extra virgin and/or cold pressed. One sample (a conventional sesame oil) had neither of these labels on the packaging. "Refined" indicates several chemical and thermal processing steps designed to remove undesirable properties/constituents, including free fatty acids, colors and odors from an extracted oil [22]. "Extra virgin" indicates mechanical pressing of the seeds or fruits (most commonly olives), while "cold pressed" indicates extraction of fruits and seed oils below 49 °C. All eight tested olive oils were labeled extra virgin and of those, six were also labeled cold pressed. Non-olive oils labeled cold pressed comprised one each of avocado, sesame, sunflower, and safflower. Cooking oils labeled as "refined" had significantly lower concentrations of total plasticizers and ortho-phthalates than those labeled "cold pressed" or "extra virgin" ($p = 2.03$ e-05 and $p = 6.66$ e-05, respectively). However, alternative plasticizer concentrations alone were comparable between these two groups ($p = 0.07$).

Powdered and ready-to-feed infant formulas

To compare measured concentration in formula products, plasticizer concentrations were converted using the dilution factor obtained from preparation instructions on packaging (Table S1). After adjusting for dilution following preparation and assuming water used for dilution did not have detectable plasticizer concentrations, median total plasticizer and total non-ortho-phthalate plasticizer concentrations for prepared powdered formulas and ready-to-feed formulas were not significantly different ($p = 0.55$, and $p = 0.90$, respectively). However, total ortho-phthalate concentrations were significantly higher in ready-to-feed products compared to dry powder ($p = 0.02$).

DISCUSSION

In this study, we analyzed four food product categories – infant formula, milk, cheese in boxed macaroni and cheese products, and oils – for the presence of plasticizers. These categories are representative of products widely consumed by infants, children, and families. At least 54.2% of infants consume some formula in

the first 6 months of life [23], with higher percentages of low-income families and families of color relying on formula [24]. Milk continues to be promoted as a healthy choice for children [25], and the growing market of easy-to-prepare, "kid-friendly" meals like macaroni and cheese make these dairy products a potentially sizable contributor to children's ortho-phthalate exposure. Further, organic, less-processed products (such as organic unrefined oils) are assumed to be healthier choices [26], but to our knowledge few studies assess plasticizer concentrations based on organic certification and processing methods.

In our evaluation of plasticizers in common food products, we find that plasticizers are present at detectable concentrations in all products. The ortho-phthalate DEHP is present in every product tested. Our results are comparable in terms of orders of magnitude of DEHP reported in previous reviews summarizing DEHP test results for milk and formula products [9], oils and cheese [11]. Both of these reviews also report that DEHP is present in most (though not all) previously tested dairy and fat products. Additionally, in our study, the replacement plasticizer DEHT was the most frequently detected alternative plasticizer and occurred in all food categories. For comparison, one of the few studies evaluating food products for DEHT found that it occurred in some, but not all, tested fast-food categories, and when detected had median values of 2200 ng/g [6]. Eight of 12 ortho-phthalates and three out of nine alternative plasticizers were measured in at least one product (Table 2). The plasticizers that were not detected (DPP, DnHP, DnOP, DIDP, DEA, TBP, DBA, DBS, ATBC, and DEHA) are likely not currently used in food-processing materials, at least within the tested food categories. The low molecular weight phthalates detected (DBP, DIBP, BzBP) could be from solvents in inks or cleaning products present in food processing facilities, while the higher molecular weight phthalates (DEHP, DPHP, DINP) are more likely from contact with plasticized food-contact surfaces [9]. As for the alternative plasticizers, DEHT and DINCH are replacements for DEHP and DINP in PVC items such as food contact materials, while adipates like DIBA may be blended with other plasticizers to improve low-temperature properties [27].

Our findings contribute to the growing body of literature that highlights the ubiquity of plasticizers in foods, and adds important insights into the presence of previously underreported non-ortho-phthalate plasticizers including DEHT, DINCH, and DIBA. DEHT, DINCH, and DIBA are marketed as safer alternatives to ortho-phthalate plasticizers for PVC and other polymers. Data gaps remain with respect to endocrine disruption and reproductive impacts, however, and studies showing interaction of DEHT, DINCH, and DIBA with hormone receptors [27, 28] indicate caution may be needed, considering that exposure to these ortho-phthalate alternatives is now widespread [29].

Possible sources of plasticizers in food

Our findings suggest a need for closer examination of contamination sources besides packaging materials, which have historically been the focus of studies evaluating plasticizers in food [9]. Food contact surfaces in processing facilities throughout the supply chain (including plasticized tubing and holding tanks) are likely significant sources of plasticizer contamination [6, 9]. On the other hand, heat and chemical changes involved in the processing of some products, including refined oils and products containing refined oils, may remove some ortho-phthalates and other plasticizers. Potential sources of plasticizer entry and removal across relevant food supply chains are summarized in Table S6.

Oil processing

In this study, the products with the overall highest plasticizer concentrations (14,900 ng/g in a refined avocado oil with 12,000 ng/g from DEHT) and lowest plasticizer concentrations (a refined canola oil, 9 ng/g plasticizer entirely from DEHP) were both oils. As a category, refined oils had statistically significantly lower plasticizer concentrations compared to unrefined oils. Median ortho-phthalate concentrations were 1,800 ng/g (unrefined) and 32 ng/g (refined). Median non-ortho-phthalate plasticizers were 1500 ng/g in unrefined oil and were not detected in refined oil. This trend remained when comparing oils for which we tested both a refined and unrefined oil from the same plant source. For example, total plasticizer concentration in a refined safflower oil sample was 235 ng/g (primarily comprised of DINP at 219 ng/g), whereas that in an unrefined safflower oil was 14,900 ng/g (primarily DEHT, 11,000 ng/g).

FTIR analysis of oil packaging did not reveal a relationship between polymer type and the plasticizers measured in oil (see Table S1). On average, oils in glass bottles with polyethylene (PE) dispensers had significantly higher ortho-phthalate and alternative plasticizer concentration than oils packaged in fully plastic bottles (polyethylene terephthalate, or PET) with PE cap gaskets. This is probably due to a greater portion of unrefined oils bottled in glass, which typically had PE dispensers. No PVC was detected in oil packaging. Styrene-butadiene polymers, which may be plasticized, were detected in three gaskets of oil products, but those oils had very low plasticizer concentrations. Furthermore, while packaging as a source cannot be entirely ruled out, the concentrations we measured in many vegetable oils may be too high to be explained by plasticizers in packaging below 1% (10,000,000 ng/g, the approximate FTIR LOD). Ezerskis et al., for example, measured 2500–8700 ng/g DEHP in oily foods contained in glass jars with DEHP-plasticized lid gaskets [30]. They measured 15–42% ortho-phthalate in the gaskets, consistent with other measurements of PVC lid gaskets [20], making the ratio of ortho-phthalate in food vs. gasket range approximately from 6×10^{-6} to 6×10^{-5}. If we assume such ratios hold, gaskets with 1% plasticizer would lead to oily foods with 6 to 600 ng/g. Yet the present work quantified plasticizer concentrations in unrefined oils ranging from 1835 to 13,850 ng/g. Taken together, these findings suggest that processing methods may result in different plasticizer concentrations in refined and unrefined oils.

The fact that most oils labeled "refined" had significantly lower plasticizer levels than oils labeled "cold pressed" or "extra virgin" suggests loss of plasticizers during refining. Indeed, the processing of so-called RBD (refined, bleached, deodorized) cooking oils is known to remove many contaminants, including polyaromatic hydrocarbons and ortho-phthalates [31]. The RBD process involves mechanical and chemical extraction, filtration, acid or base wash at elevated temperature (around 80 °C), mixing with bleaching clay (around 100 °C), and deodorizing by steam distillation at low pressure and high temperature (220–260 °C) [22]. Steam distillation in particular removes ortho-phthalates from the oil which can then be detected in the distillate [31]. Since greater volatility leads to more rapid removal by steam distillation, a higher percentage of lower molecular weight ortho-phthalates such as DBP may be removed than high molecular weight ortho-phthalates such as DINP [32].

The two avocado oils we tested were exceptions to the trend. Their labels indicated "refined," yet they had high plasticizer concentrations: 2,900 ng/g ortho-phthalate and 12,000 ng/g other plasticizers in one; 3,000 ng/g ortho-phthalate and 1800 ng/g other plasticizers in the other. As with the unrefined oils, these avocado oils were dominated by DEHT, DINP, and DEHP. We speculate that avocado oil refining may differ in some way from the typical RBD process for oils like canola, corn, and soybean.

Milk and dairy operations and processing

The measured ortho-phthalate concentrations in dairy (milk and cheese) were within a range previously reported in the literature [9, 13]. Plasticizers have multiple potential points of entry into the dairy supply chain. Animal feed in the form of both pasture and silage may be contaminated with plasticizers, potentially through plastic wrap or uptake by plants used in feed [13]. Tubing (particularly PVC), and teat liners (also called dairy inflations) used to milk cows and convey milk are frequently plasticized and can be a source of ortho-phthalates in dairy [9, 33].

Packaging is another potential source of plasticizers. While FTIR did not detect plasticizers above approximately 1% in the milk packaging, lower concentrations could be present. All but one of the milk products were packaged in polyethylene containers (Table S1). Polyethylene polymers are not typically major sources of plasticizers, but can contain low levels [34]. As plasticizer concentrations overall were lowest of all categories in milk, and it is possible that less than 10,000,000 ng/g plasticizer in dairy packaging could be present, we cannot fully rule out packaging as a significant contributor of plasticizers to milk. We note, however, that Page and LaCroix in 1986 did not detect ortho-phthalates in milk packaging samples (paperboard cartons or polyethylene bottles) with a detection limit orders of magnitude lower than FTIR, while the milks themselves contained DEHP. They suggested PVC tubing used during milking was responsible [35].

In our sample, organic milk products ($n = 6$) had significantly higher concentrations of total plasticizer compared to conventional milk ($n = 4$; $p = 0.02$). Identifying the source of this difference is outside the scope of this study. To the best of the authors' knowledge, there are no known differences in how organic milk is processed compared to conventional milk processing that would contribute to the observed difference. Further research is needed to explore the source of this difference, ideally drawing on a larger milk sample. Additionally, drawing from previous studies that have traced the source of ortho-phthalates through the milk supply chain [36], future studies could identify potential sources of plasticizer contamination by quantifying plasticizers in milk at different stages of processing, packaging, and consumption in organic and conventional dairy operations.

Infant formula and cheese powder processing

Formula ingredients typically include sugars, plant or dairy based proteins, vegetable oils, and added minerals, vitamins, emulsifiers, and stabilizers. Specific formulations vary widely. As a result, plasticizer types and concentrations in formulas may be due to contamination and processing of dairy- and oil-based ingredients, as well as additional processing steps specific to their manufacturer [13, 37]. Similarly, sources of ortho-phthalates in cheese powder include all sources listed for milk, but may be compounded by further processing such as spraying and drying [38] that may involve plasticized surfaces. Notably, BzBP is detected in two cheese powders but is not present in any other products including any of the milk samples, suggesting possible introduction later in the supply chain. All of the cheese powders and many of the formulas were packaged in polyethylene and did not have detectable (at 1%) plasticizer concentrations in packaging, with the exception of ESBO in two ready-to-eat formula gaskets.

In 2021, a major macaroni and cheese brand committed to eliminating ortho-phthalates from their products [39] following an ortho-phthalate testing report published in 2017 [40] identifying ortho-phthalates in ten major mac and cheese brand powders. In both study years DEHP was detected at the highest concentrations among the ortho-phthalates tested. DEHP in the 2017 cheese powders ranged from 17 to 157 ng/g and in 2021 from 15 to 201 ng/g. The median DEHP concentrations were 70 and 22 ng/g in 2017 and 2022, respectively. In both study years BzBP, DIBP, and DBP were detected in at least some of the cheese powders. DEP was detected in all of the 2017 samples at relatively low levels (5–15 ng/g) but in none of the 2021 samples. DINP was detected in four of the 2017 samples but in none of the 2021 samples. The similarity in DEHP concentrations between two study periods could be e partially explained by lack of enforcement of corporate commitments to reduce ortho-phthalate exposure. The apparent decrease in detection of DEP and DINP requires further research.

Study limitations

An important limitation of this study is that our statistical analyses are limited by small sample sizes. In particular, comparisons between organic and conventional products, between refined and unrefined oils, and between different vegetable oils, are limited in their generalizability due to the small number of samples in each category. Furthermore, as mentioned above, analysis of ortho-phthalates in fatty foods is time consuming and requires careful monitoring of background levels of contamination including solvents used in the extraction of samples [18]. Finally, we are limited in our ability to specifically identify sources of plasticizer entry into the supply chains of different products; future studies should prioritize obtaining larger samples of products at different points in the supply chain to better elucidate relationships between total plasticizer concentrations and processing.

CONCLUSIONS

Our results contribute to growing understanding that ortho-phthalates and other plasticizers continue to occur in food products. Our analyses suggest that, despite policies intended to reduce the impacts of ortho-phthalate exposure, they and other plasticizers continue to be prevalent in food staples. The impacts are particularly pronounced for infants and children: most infants in the US consume some formula, and 16.8% of infants in the USA are exclusively formula-fed, with higher rates among of Black infants [23]. Mean milk consumption overall and per body weight is also highest among children [41]. These results suggest the need for stricter regulatory strategies aimed at reducing exposure, especially for the most historically marginalized and vulnerable populations.

DATA AVAILABILITY

All data generated and analyzed for this study can be found in the supplementary spreadsheets S1, S3, S4, S5.

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AUTHOR CONTRIBUTIONS

RK carried out statistical analyses, literature research, and outlined and helped write the manuscript. GZM carried out FTIR data analyses, product label analyses, literature research, and helped write the manuscript. MB helped conceive of the study design and sample selection and provided feedback on the manuscript. JG helped conceive of the study design and sample selection and provided feedback on the manuscript. VK carried out sample preparation, GC/MS analysis, and data collection. SL carried out sample preparation, GC/MS analysis, and data collection. KK helped design the study, supervised the GC/MS analysis, advised on the data interpretation, and provided feedback on the manuscript.

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COMPETING INTERESTS

The authors declare no competing interests.

ETHICAL APPROVAL

Ethical approval was not required as there were no human subjects involved in this study.

ADDITIONAL INFORMATION

Supplementary information The online version contains supplementary material available at https://doi.org/10.1038/s41370-023-00596-0.

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ORAL ARGUMENT NOT YET SCHEDULED

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ALASKA COMMUNITY ACTION ON TOXICS, BREAST CANCER PREVENTION PARTNERS, CENTER FOR ENVIRONMENTAL HEALTH, CENTER FOR FOOD SAFETY, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, DEFEND OUR HEALTH, ENVIRONMENTAL DEFENSE FUND, and LEARNING DISABILITIES ASSOCIATION OF ILLINOIS, *Petitioners*, v. UNITED STATES FOOD AND DRUG ADMINISTRATION and DR. MARTIN MAKARY, in his official capacity as Commissioner of the United States Food and Drug Administration, *Respondents*.	No. 24-1382

DECLARATION OF STEPHANIE DURRANT

I, Stephanie Durrant, declare and state as follows:

1. I am a former environmental chemistry lab technician and high school science teacher and hold a master's degree in teaching from the University of Washington and a Bachelor of Science in biology from Western Washington University. The information in this declaration is based on my personal knowledge and experience.

2. I have three children, aged twelve, ten, and nine. I live with my children and husband in Cumberland, Maine.

3. I am a supporter and staff member of Defend Our Health ("Defend"). I have worked at Defend for two years. I was originally hired as an office manager and currently work as Defend's Research and Operations Manager. I was also a supporter of Defend prior to my employment, and followed the organization on Instagram so I could learn about different non-toxic products and toxic chemicals.

4. Through my role on Defend's research team I have learned a great deal about toxic chemicals. I conduct research on a wide range of topics to support Defend's advocacy and campaigns. My research involves reading peer-reviewed literature on topics related to our campaigns, and I have conducted research on phthalates, per- and polyfluoroalkyl substances, and many other toxic chemicals.

5. I am aware that phthalates (and other toxic chemicals) are used in food packaging and other materials that contact food and that these chemicals can

leach into food and cause health problems. I first learned about the toxicity of phthalates when I was pregnant with my first child, fourteen years ago. I wanted to learn about non-toxic options I could purchase to best protect myself and my newborn daughter from toxic chemicals. Through my research I have learned that phthalates are endocrine disruptors and chronic exposure to phthalates can cause negative health impacts.

6. My family and I eat many foods that I am concerned are contaminated with phthalates. I do all the grocery shopping for my family, and we prepare almost all of our meals at home. Because there are no other options available, almost all the food I buy is packaged in plastic. We often eat basic dry staples that are packaged in plastic such as cereal, rice, and noodles. We consume a lot of dairy each week including: approximately five gallons of milk a week (two gallons of which come in large plastic jugs) and yogurt in both large plastic containers and smaller plastic cups. Many of our vegetables are packaged in plastic film or bags, including our spinach, carrots, celery, cucumbers, and peppers. I buy snacks for my children including granola bars, fruit leather, beef sticks, nuts, and dried fruits—all of which we purchase in plastic packaging. Our meat also comes in trays that are covered in plastic film or in plastic pouches.

7. I am also aware that these food products come in contact with manufacturing equipment and processing aids during the production process, and I

am concerned that this too causes them to become contaminated with phthalates and other harmful chemicals.

8. It is frustrating that the government is not doing a better job of protecting consumers from phthalates. Phthalates are ubiquitous in the production, packaging, and transportation of food, so even though I try to avoid them when I can, there is only so much I can do. I am concerned about my children being exposed to phthalates from the packaging our food comes in and the materials used to produce it, and I worry this exposure will contribute to the early onset of puberty, harm their reproductive health, or have other negative outcomes. I'm concerned that my family's chronic exposure to phthalates will harm our health in the future.

9. It is not possible for me to avoid food packaged in and produced with plastic, and as a result it's not currently possible for me to avoid phthalates in my food. If FDA banned phthalates in food-contact materials, it would eliminate or reduce my and my children's exposure to phthalates in our food, and I would feel safer eating the foods I purchase multiple times per week for my family.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed on this 21 day of March, 2025, in Cumberland, Maine.

Stephanie Durrant

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UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ALASKA COMMUNITY ACTION ON TOXICS, BREAST CANCER PREVENTION PARTNERS, CENTER FOR ENVIRONMENTAL HEALTH, CENTER FOR FOOD SAFETY, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, DEFEND OUR HEALTH, ENVIRONMENTAL DEFENSE FUND, and LEARNING DISABILITIES ASSOCIATION OF ILLINOIS, *Petitioners*, v. UNITED STATES FOOD AND DRUG ADMINISTRATION and DR. MARTIN MAKARY, in his official capacity as Commissioner of the United States Food and Drug Administration, *Respondents*.	No. 24-1382

DECLARATION OF PAUL AMES

I, Paul Ames, declare and state as follows:

1. I am currently retired following a career as a chemist and computer systems analyst for a public health department and laboratory in New York. I live with my wife in Bellport, New York.

2. I have been a member of the Environmental Defense Fund ("EDF") since the 1980s. I joined EDF because of my concern about damage to the environment and the need for environmental protection, both through legislation and educating people on why action is necessary and how they can participate.

3. I donate to EDF regularly. I renew my membership every year. I have been receiving EDF's newsletter for years, originally in paper form and now through email. I also receive EDF's magazine. I rely on EDF's emails to keep up to date on the organization's activities, especially those of particular interest to me. I rely on EDF to represent my interests in protecting the environment and human health.

4. I am aware that phthalates are used as plasticizers in a lot of plastic products, especially in food packaging, such as for frozen foods. Plasticizers are designed to stabilize the plastics, but they tend to volatilize or otherwise migrate out of plastics and into the actual food. If you heat the food, that will accelerate the process and lead to more migration of plasticizers like phthalates into the food.

Phthalates are endocrine disruptors, possible carcinogens, and linked to birth defects. It is not safe to consume phthalates in food.

5. I have been concerned about phthalates in the food I eat for a long time. The way food is packaged plays a big part in the safety of the product. The environmental impact of food packaging certainly needs to be taken into account as well.

6. I am concerned that I am exposed to phthalates in the food I eat, even though I buy locally when I can and generally avoid plastic packaging. My wife and I eat at a restaurant or get takeout food about once a week. We like to patronize local restaurants, including seafood and Chinese restaurants and our local deli. We eat seafood once or twice a week, usually local, fresh seafood. We also eat some cheese. We do augment our diet of primarily fresh food with some packaged foods, including pasta, which comes in plastic coated boxes, and canned beans and tomatoes, which have plastic linings.

7. It would be difficult for me to avoid all of these foods because when I go to the market, I have to buy grocery items as they're presented. I certainly lean towards buying fresh products, but their availability varies, such as during winter. My food purchasing choices are limited because I can only buy what the market offers. Even though I try to buy organic, even some organic foods, like frozen foods, are wrapped in plastic and sealed until you use them.

8. I have avoided certain foods because I was concerned about phthalates or other harmful chemicals being present in them. I am very concerned about the quality of the foods I eat and potential contaminants in them. This concern informs my opinion about whether I want to continue eating those foods. My primary criteria when choosing what items to buy are how the food is produced, what contaminants may be in it, where the contaminants come from, and why they are in food in the first place. I lean toward eating local foods and try not to purchase foods that are overly processed. Even so, I cannot completely avoid phthalates in the foods I purchase and consume.

9. I certainly spend extra money to minimize my exposure to chemicals such as phthalates in my food. I buy organic or freshly produced local foods, but it comes at a higher cost. For many years, my wife and I have belonged to a local, organic community-supported agriculture farm. We pay in advance and get a share of the produce in the spring. We pay a premium, an added cost up front. If the farm doesn't do well that season, we don't get as much food back.

10. I supported EDF's petition asking FDA to ban phthalates as additives in food packaging and materials for processing food. Phthalates are being used in plastic products but are ending up in the food. People are consuming phthalates, and even low concentrations of endocrine disruptors can have a major impact on your body.

11. I would benefit if FDA bans some or all phthalates in food packaging and materials for processing food because I would feel safer buying and consuming food packaged in plastic materials knowing that toxic plasticizers are not getting into the food and my body when I consume them. My exposure to these chemicals would be eliminated or reduced if they were no longer approved for producing and packaging the food I eat.

12. FDA's denial of EDF's objections to the denial of its petition harms me by maintaining FDA's approval of phthalates as additives in food packaging and production materials, which perpetuates my exposure to those chemicals. Even though I don't eat a lot of packaged foods, some foods in the freezer have to be wrapped or sealed to preserve the food. I buy what's in the market. I'm limited to what's available—I don't have an individual choice. I rely on government agencies like the FDA to regulate products that are unsafe and protect consumers like me.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct. Executed on this 28th day of FEBRUARY, 2025, in Bellport, New York.

Paul Ames

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UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ALASKA COMMUNITY ACTION ON TOXICS, BREAST CANCER PREVENTION PARTNERS, CENTER FOR ENVIRONMENTAL HEALTH, CENTER FOR FOOD SAFETY, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, DEFEND OUR HEALTH, ENVIRONMENTAL DEFENSE FUND, and LEARNING DISABILITIES ASSOCIATION OF ILLINOIS, *Petitioners*, v. UNITED STATES FOOD AND DRUG ADMINISTRATION and DR. MARTIN MAKARY, in his official capacity as Commissioner of the United States Food and Drug Administration, *Respondents*.	No. 24-1382

DECLARATION OF MARIA DOA

I, Maria Doa, declare and state as follows:

1. I serve as the Senior Director for Chemical Policy for the Environmental Defense Fund ("EDF") in Washington, D.C. I have held this position since 2021. Before joining EDF, I worked at the U.S. Environmental Protection Agency ("EPA"), where for twenty-two years I held various leadership positions focused on the science and regulation of toxic chemicals and the management of the application of scientific research and data to regulatory decisions. The information in this declaration is based on my personal knowledge and experience.

2. I am an organic chemist and hold a doctorate in organic chemistry from the University of Pittsburgh and a Bachelor of Science in chemistry from the University of Michigan.

3. My role as Senior Director of Chemical Policy makes me familiar with the structure and mission of EDF. EDF is one of the world's largest environmental organizations. We have more than 295,000 members in the United States and a staff of more than 1,000 scientists, economists, policy experts, and other professionals around the world. Guided by science and economics, EDF tackles urgent threats with practical solutions. We recognize that toxic chemicals are present in everyday items, including our food, drinking water, and household products. EDF's Healthy Communities Program works to protect public health,

including the health of EDF's members and their families, by reducing exposures to these chemicals.

4. As EDF's Senior Director for Chemical Policy, I am responsible for directing and managing strategic initiatives to drive significant reductions in the use of and exposure to toxic chemicals—especially among high-risk populations and communities—by securing lasting solutions that target long-standing inequities in exposures and associated health impacts. These EDF initiatives aim to strengthen federal oversight of toxic chemicals and to spur innovations that reduce the use of and exposure to toxic chemicals across the supply chain, including the point of production. A major part of my work is ensuring food is safe from harmful chemicals and contaminants such as heavy metals, chlorinated solvents, per- and polyfluorinated alkyl substances, and phthalates.

5. The food additive and citizen petition processes established in the Food, Drug, and Cosmetic Act (the "Food Act") and implementing regulations are critical tools in our efforts to protect our members and the broader public from chemicals in their food that threaten their health. Through food additive petitions, we can use the mechanism established by Congress in the Food Act to force the Food and Drug Administration ("FDA") to consider current scientific evidence and reassess the safety of food additives approved by the agency decades ago based on much less robust information about the additives' health effects. Because FDA has

interpreted narrowly the issues the public may raise in food additive petitions, we also use the citizen petition process as an important tool to advocate for prohibitions on unsafe chemicals in food and food-contact materials. EDF invests significant organizational resources and marshals scientific and legal expertise to advocate effectively for our members through the petition process in a manner most individual members could not accomplish on their own. We have successfully petitioned FDA to remove several carcinogenic flavors from the market as well as a class of harmful PFAS used in food-contact materials that get into food and accumulate in the body to cause harm.

6. Because many food additives, such as phthalates, are widely used in multiple food-contact applications, cause cumulative effects, and are not disclosed on food packaging, it is not feasible for EDF members, and members of the broader public, to prevent exposure to these chemicals through their food choices alone. Given that, we recognize the need for direct advocacy to FDA through the petitions process to eliminate from the market food additives that do not meet the applicable safety standard under the Food Act based on current scientific evidence.

7. EDF took a lead role in developing and drafting the 2016 food additive petition that led to this lawsuit and has been actively involved in every stage of the administrative process, including the preparation of objections to FDA's 2022 decision denying the food additive petition.

8. FDA's order denying our objections and maintaining approvals for the use of five phthalates as food additives has frustrated EDF's efforts to eliminate food-additive uses of phthalates and endangers the health of the EDF members on whose behalf we are pursuing this advocacy. If the Court were to set aside FDA's denial and force the agency to reconsider its decisions on the harmful cumulative effects of phthalates in our food based on the appropriate standards and evidence, I believe FDA would be compelled to take action to protect our members and the public at large from dietary exposure to phthalates.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed on this 12th day of March, 2025, in Washington, D.C.

Maria J. Doa

ORAL ARGUMENT NOT YET SCHEDULED

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ALASKA COMMUNITY ACTION ON TOXICS, BREAST CANCER PREVENTION PARTNERS, CENTER FOR ENVIRONMENTAL HEALTH, CENTER FOR FOOD SAFETY, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, DEFEND OUR HEALTH, ENVIRONMENTAL DEFENSE FUND, and LEARNING DISABILITIES ASSOCIATION OF ILLINOIS, *Petitioners*, v. UNITED STATES FOOD AND DRUG ADMINISTRATION and DR. MARTIN MAKARY, in his official capacity as Commissioner of the United States Food and Drug Administration, *Respondents*.	No. 24-1382

DECLARATION OF BEVERLEY HOLDEN JOHNS

I, Beverley Holden Johns, declare and state as follows:

1. I am the President of Learning Disabilities Association of Illinois ("LDA of IL"). I have been the President of LDA of IL for ten years, but I have been involved with the organization for approximately forty years. I have previously served as the LDA of IL's representative to the national board of Learning Disabilities Association of America ("LDAA"), of which LDA of IL is an affiliate and have served on multiple LDA of IL committees. I am also involved with the Learning Disabilities Association of America's Healthy Children Project and have been for over twenty years. The information in this declaration is based on my personal knowledge and experience.

2. I hold a Master of Science in Special Education from Southern Illinois University and a bachelor's degree from Catherine Spalding College in Louisville, Kentucky. I have forty years of experience working with students with learning disabilities and behavioral disorders within public schools. I have authored or co-authored thirty books on special education and have chaired the Illinois Special Education Coalition for thirty-eight years. My experience has provided me with a wealth of knowledge about the impact of toxic chemicals on childhood development.

3. Through my role as President of LDA of IL, I have become familiar with LDA of IL's policies, practices, membership, and programs. LDA of IL is a

recognized affiliate of LDAA, a national non-profit organization that works to create opportunities for success for all individuals affected by learning disabilities through support, education, and advocacy. We are the largest affiliate of LDAA, and our headquarters are located in Palos Hills, Illinois.

4. As an affiliate, we have our own bylaws, which are congruent with the bylaws of LDAA.

5. We have four local chapters: West Central; Chicago South Area; Kane-Kendall; and Orland Area.

6. We have approximately 350 members. Our members pay dues annually, which are allocated to their local chapter, LDA of IL, and LDAA.

7. Our members participate in elections. We have an annual election in May where our members elect members to our Board of Directors, as well as vote on leadership roles such as President and Regional Directors.

8. We maintain an e-mail list that is sent to approximately 700 individuals. This e-mail list includes members and non-members who may be interested in information regarding LDA of IL and the work we do, and includes people with learning disabilities and their parents and other family members; educators, including teachers, professors, and school administrators; medical professionals and healthcare workers, including psychiatrists, psychologists,

physicians, and nurses; therapists and other service providers; as well as lawyers and other education, human rights, and disability policy and law specialists.

9. We also create and circulate a quarterly state newsletter, *Scope*, that includes articles with information about toxic chemicals and the harm they cause. Some articles we have printed in the past have discussed toxic chemicals in back-to-school supplies, food, or holiday gifts.

10. LDA of IL's mission is to promote research into the causes of learning disabilities and other neurological disorders and advocate for policies that will reduce the number of individuals affected by learning disabilities. We monitor and advise our members on special education legislation at the federal and state levels. We also provide information and workshops for educators and parents about ways to advocate for children's healthy development. An important part of our mission is prevention of learning disabilities. LDA of IL works to prevent children's exposure to chemicals such as phthalates that can result in learning and developmental disabilities.

11. LDA of IL is also involved with LDAA's Healthy Children Project, which works to raise awareness of toxic chemicals that can harm brain development and contribute to learning and attention disabilities and behavior disorders and promotes policies that will prevent toxic exposures, especially among pregnant women and young children. The project also provides guidance to

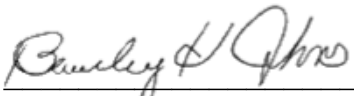
individuals and communities to help prevent exposure and builds a national network of LDA members working to protect children's health and reduce toxic exposures that may lead to learning disabilities in current and future generations. Some projects LDA of IL has been involved with through the Healthy Children Project include testing for toxic chemicals in products sold at Dollar Tree and Dollar General and launching a social media campaign to push these companies to reduce toxic chemicals in their products. We have also conducted testing for toxic chemicals in food packaging at fast casual restaurant Panera Bread.

12. FDA's denial of the objections filed by LDAA and our other partners harms our staff and members by rejecting their request for regulatory changes that would protect them from exposure to phthalates through food packaging and food-contact materials. In addition, many of our members are pregnant or have young children. Exposure to phthalates in food packaging and food-contact materials puts their children at risk of neurological harm.

13. If the court were to set aside FDA's decision, it would force FDA to take action to reduce our members' exposure to phthalates. This would advance our organization's mission and advocacy work to reduce toxic chemical exposure and the incidence of learning disabilities in children.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed on this 11th day of March, 2025, in Jacksonville, Illinois.



Beverley Holden Johns

ORAL ARGUMENT NOT YET SCHEDULED

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ALASKA COMMUNITY ACTION ON TOXICS, BREAST CANCER PREVENTION PARTNERS, CENTER FOR ENVIRONMENTAL HEALTH, CENTER FOR FOOD SAFETY, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, DEFEND OUR HEALTH, ENVIRONMENTAL DEFENSE FUND, and LEARNING DISABILITIES ASSOCIATION OF ILLINOIS, *Petitioners*, v. UNITED STATES FOOD AND DRUG ADMINISTRATION and DR. MARTIN MAKARY, in his official capacity as Commissioner of the United States Food and Drug Administration, *Respondents*.	No. 24-1382

DECLARATION OF JUDITH G. LARSON

I, Judith G. Larson, declare and state as follows:

1. I am a retired school secretary living in Orland Hills, Illinois.

2. I joined the Orland Area local chapter of Learning Disabilities Association of Illinois ("LDA of IL") in 1984. I am currently the Treasurer of the chapter and have been for approximately ten years. Prior to this position, I served as Director of the chapter for approximately ten years.

3. I pay annual dues to the local chapter, part of which are allocated to the state and national levels of the organization. I also donate outside of annual dues at least twice a year, for special occasions.

4. As a member of LDA of IL, I receive regular emails, which provide me with updates about the organization's projects and priority issues.

5. I have two daughters with learning disabilities—both of whom are adults now. I also have six grandchildren—two of whom also have learning disabilities. I currently live alone, but my daughters' families often come visit me on the weekends and during the summers.

6. I joined LDA of IL because I wanted to learn more about my daughters' learning disabilities and how it would impact their education and welfare. One of my daughters had a delay in language development and was receiving special education services until the seventh grade. My second daughter had a communication disorder and was in self-contained classes (*i.e.*, classes for

educating only students with learning disabilities) all the way through high school. When my daughters were in school, that was around the time that the education system began transitioning from self-contained classes to inclusive classes (*i.e.*, classes that educate students with and without learning disabilities together). I wanted to be more informed about the general picture of special education and through that process, I became very involved with LDA of IL first on the local level and then on the state level.

7. Soon after joining my local chapter, I produced and mailed the chapter newsletter and participated in chapter presentations and fundraisers. Six general meetings were open to parents and professionals to offer speakers with information on learning disabilities advocacy, legislation, and parents' rights. An annual flower sale generated the funds to provide the presentations and scholarships. Our local school district generously shared their facilities for our endeavors.

8. At the state level, I also served as Newsletter Director, prepared conference publications, and helped computerize the membership and conference registration processes.

9. Over the years, I have also been involved in some of the LDA of IL advocacy campaigns regarding toxic chemicals in our food and products. I have volunteered with the Healthy Children Project, a national initiative to raise awareness of toxic chemicals that can result in learning disabilities and to push for

policies to prevent exposures. As part of the Healthy Children Project, LDA and its state affiliates launched a campaign testing for chemicals in baby food. I went out and bought sample baby food to send in for testing. In partnership with Healthy Babies Bright Futures, LDA published a report of the results of that testing in 2019. In December of 2024, I worked on the Campaign for Healthier Solutions, which advocated for dollar stores to eliminate toxic chemicals in their products. I participated by going out to speak to my local dollar store managers, asking for them to raise our request of removing toxic chemicals in their products with their corporate office. I also took part in LDA's campaign calling on REI, an outdoor recreation retail company, to remove per- and polyfluoroalkyl substances from their weather proofing products. I am often the "legs on the ground" in my local area and visit retailers in person to advocate for the removal of toxic chemicals from products.

10. I am aware that I am exposed to phthalates through the food that I consume, and I am also aware that phthalates are endocrine-disrupting chemicals and could have other harmful health effects such as elevated risks of cancer and learning disabilities. I learn a lot of information about toxic chemicals in our food from other environmental nonprofits such as the Environmental Working Group.

11. I grocery shop usually once a week at Aldi. I often buy food that comes in plastic packaging, such as bread, cheese slices, deli meats, frozen

vegetables, fresh produce on trays or in plastic bags, butter in plastic tubs, and milk in plastic jugs. On occasion, I also consume fast food, which comes in plastic packaging.

12. I also sometimes re-use plastic bottles in my household to reduce waste. For example, I use plastic Gatorade bottles to freeze liquids in smaller volumes.

13. Additionally, when one of my daughters and her family come to visit, they often bring their own food, and they consume a lot of chips and salty snacks that come in plastic packaging, so I know that someone I love is regularly exposed to food in plastic packaging.

14. I know that the foods I eat and that my family eats also come into contact with plastic during the production process.

15. I am very mistrustful of any packaged foods, and I personally do not like to buy prepared foods because of this concern, but many of my foods still come in plastic packaging. I cannot really decipher what ingredients are safe by reading the ingredient labels, but I try to go for food with the fewest ingredients. However, even by doing this, I know I am unable to completely avoid toxic chemicals because they could leach out of the plastic packaging my food comes in or other materials used to process the food. Those chemicals are not on ingredient labels. Every time I buy something, I am concerned and question what I am being

exposed to. As a parent of children with learning disabilities, a grandmother with grandchildren with learning disabilities, as well as a woman with a family history of cancer, I am really concerned about phthalate exposure and how it impacts our health and our environment.

16. I absolutely want FDA to do more to keep toxic chemicals out of food by banning the use of phthalates in food packaging and food-production materials. If the court sets aside FDA's decision to continue allowing phthalates in food packaging and food production materials, the agency would have to reconsider that decision based on what the law and the science dictate. I believe that would lead to FDA revoking approval for these phthalates, and I would feel safer knowing that my exposure as well as my children and grandchildren's exposures are being reduced or eliminated.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed on this 20th day of March 2025, in Orland Hills, Illinois.

Judith G. Larson

Judith G. Larson