# No. 23-220

**UNITED STATES COURT OF APPEALS**
**FOR THE SECOND CIRCUIT**

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JORDAN WHITE, ROBERT PARTELLO, ERIN ABDOO, BRIDGET SALOPEK, OLIVIA BOYER, REBECCA GEORGE, CORINTHEA PANGELINAN, ELIZABETH AUSTIN, STEPHANIE NORGAARD, AMANDA SCHRAM, LATOYA MCHENRY, ERICA DOUGLAS, TABITHA LATTEYER, MORGAN ENGEBRETSEN, MCGLINCHKALI, AMANDA ROGERS, MAURICE PETERSON, SHEILA CURRY, KATHERINE MCGIBNEY, NATALIE FRANCOIS, HEATHER MALAGA, TAMAYA STEVENSON,

*(Caption continued on inside cover and inside pages)*

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On Appeal from the United States District Court
for the Northern District of New York, No. 21-cv-133

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**BRIEF OF CONSUMER BRANDS ASSOCIATION, CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, AND FOOD MARKETING INSTITUTE AS *AMICI CURIAE* IN SUPPORT OF DEFENDANT-APPELLEE AND AFFIRMANCE OF THE DISTRICT COURT'S DECISION**

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*Consul Plaintiffs*,

v.

BEECH-NUT NUTRITION COMPANY,

*Defendant-Appellee*.

## CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, *amici curiae*, by and through its undersigned attorney, hereby certifies that none of them has a parent corporation and no publicly held corporation owns 10% or more in any *amici*.

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## INTERESTS OF AMICI CURIAE

*Amici curiae* are national associations whose members are involved in the manufacture, distribution, and retail sale of food and food products. *Amici* have extensive experience with the U.S. Food & Drug Administration ("FDA"), state consumer protection laws, and the impacts of regulations on food producers, distributors, and retailers.[1]

The Consumer Brands Association represents the world's leading consumer-packaged goods companies, as well as local and neighborhood businesses. The consumer-packaged goods industry is the largest U.S. manufacturing employment sector, delivering products vital to the wellbeing of people's lives every day, and contributes $2 trillion to U.S. gross domestic product and supports more than 20 million American jobs.

The Food Industry Association proudly advocates on behalf of a wide range of members across the value chain—from retailers who sell to consumers, to producers who supply the food, as well as the wide variety of companies providing critical services—to amplify the collective work of the food industry. Our collective membership represents a $1 trillion industry with nearly 6 million

[1] No counsel for any party authored this brief in whole or in part, and no person or entity, other than *amici*, their members, and their counsel, has contributed money intended to fund the preparation or submission of this brief. *See* Fed. R. App. P. 29(a)(4)(E).

employees and includes approximately 1,000 food retail and wholesale companies encompassing 33,000 retail store locations in all 50 states. These members serve more than 100 million American households with the foods and other items they need every single day. Our retailer membership also includes nearly 12,000 supermarket pharmacy locations that provide critical health care products and services for communities across the nation. The Food Industry Association also represents 21 product suppliers that generate $160 billion in annual sales and employ thousands of American workers in communities across the country.

The Chamber of Commerce of the United States of America is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than 3 million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files amicus curiae briefs in cases, like this one, that raise issues of concern to the nation's business community. The Chamber and its members—including those subject to food safety and labeling laws—have a vital interest in promoting the proper application of the primary jurisdiction doctrine. An adverse holding on this issue would subject businesses to

piecemeal standards, inconsistent rulings, and unnecessary costs that will prevent greater investment and reduce the quality of goods and services.

The *amici* file this brief pursuant to Rule 29(a) of the Federal Rules of Appellate Procedure upon the accompanying Motion for Leave to File Brief of Amici Curiae.

## INTRODUCTION

This case arises in the context of ongoing regulatory activity concerning the inherent presence of trace amounts of heavy metals in baby food products. The same 2021 congressional subcommittee staff report[2] that prompted this action, *see* Compl., at 37, also prompted the FDA to launch an intensive effort to establish and revise its standards for heavy metals in baby food. In light of that backstory, this is no run-of-the-mill false advertising case. The FDA is actively working to balance the multifarious policy considerations at issue in ensuring that babies and young children in the United States have access to safe, nutritious, well-balanced, and affordable foods. That complex mix of scientific and policy considerations requires application of the primary jurisdiction doctrine. The District Court

[2] *See* U.S. House of Representatives, Subcomm. on Econ. & Consumer Policy, Staff Report, *Baby Foods are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury* (Feb. 4, 2021), https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/2021-02-04%20ECP%20Baby%20Food%20Staff%20Report.pdf.

correctly declined to leapfrog the FDA and establish its own food safety standards, and its decision should be affirmed.

The basic contention of this case, and similar actions filed by private plaintiffs' lawyers across the country, is that the trace presence of certain heavy metals in the food supply, including in baby foods, mandates some affirmative change to their labels, including potential "warnings" about these substances. But there is no scientific, regulatory, or health-based justification for this relief. Heavy metals occur in the Earth's air, water, and soil both naturally and as a result of industrial activity. Trace heavy metals are therefore ubiquitous in foods made from nutritious fruits, vegetables, and grains grown in the soil—a fact that has been well-known for decades by regulators, public health officials, food manufacturers, and reasonable consumers.

Private plaintiffs' lawyers nevertheless are demanding *ad hoc* labeling changes due to supposed "safety" concerns about baby foods. But assenting to demands for "warnings" on foods that federal agencies deem safe could reduce the accessibility and affordability of nutritious, convenient, and healthy foods. Whether, when, and how to label foods to reflect the presence of trace heavy metals is a complex scientific and policy decision best left to the FDA.

Should a court determine that food products, including the baby food products at issue, cannot be sold if they contain *any* level of trace heavy metals,

parents will be left to substitute such foods with less nutritious ones—avoiding crops like spinach, carrots, and kale based on unfounded assertions that the health benefits of these foods are somehow negated by the mere presence of trace heavy metals. Warnings may therefore prompt consumers to make unwarranted changes to the diets of their children, which—when multiplied across millions of American families—could have profound effects on the nutrition and public health of the United States.

Put differently, without the FDA's application of its scientific, technical, and public policy expertise—developed over decades by thousands of employees deploying the resources of a large federal agency—individual judges across the country should not be required to determine what levels of trace heavy metals in foods are sufficient to justify supposed "warnings" or any other relief that Plaintiffs seek. Indeed, the FDA has *already* concluded that the presence of trace heavy metals in baby foods, and which are omnipresent in the food supply, "does not mean the food is unsafe to eat."[3] Court-ordered regulation of this issue, outside of the FDA's careful *Closer to Zero* plan, could have severe unintended consequences. Indeed, switching to homemade baby foods "may actually result in

[3] FDA, *FDA Announces Action Levels for Lead in Categories of Processed Baby Foods* (Jan. 24, 2023), https://www.fda.gov/news-events/press-announcements/fda-announces-action-levels-lead-categories-processed-baby-foods.

higher concentrations of toxic elements" in children's and babies' diets and "[e]liminating entire food groups from [a] child[]'s diet may result in nutrient deficiencies and potential poor health outcomes."[4]

The FDA's expertise in food safety and its ability to regulate on a nationwide scale and balance different policy concerns make it a more suitable decisionmaker on this important issue. The District Court, in line with other courts, correctly applied the primary jurisdiction doctrine and declined to usurp the agency's role.[5] This Court should affirm.

## ARGUMENT

The primary jurisdiction doctrine "applies where a claim is originally cognizable in the courts, but enforcement of the claim requires, or is materially aided by, the resolution of threshold issues, usually of a factual nature, which are placed within the special competence of the administrative body." *Golden Hill Paugussett Tribe of Indians v. Weicker*, 39 F.3d 51, 58–59 (2d Cir. 1994). "The

[4] FDA, *FDA Shares Action Plan for Reducing Exposure to Toxic Elements from Foods for Babies and Young Children* (Apr. 8, 2021), https://www.fda.gov/food/cfsan-constituent-updates/fda-shares-action-plan-reducing-exposure-toxic-elements-foods-babies-and-young-children.

[5] *See, e.g.*, *In re Gerber Prods. Co. Heavy Metals Baby Food Litig.*, No. 1:21-cv-269 (MSN/JFA), 2022 WL 10197651 (E.D. Va. Oct. 17, 2022); *Kimca v. Sprout Foods, Inc.*, No. BER-L-2538-22, 2022 WL 3586095 (N.J. Super. Ct. Law Div. Aug. 17, 2022); *District of Columbia v. Beech-Nut Nutrition Co.*, No. 2021 CA 001292 B, 2023 WL 3880389 (D.C. Super. Ct. June 5, 2023).

doctrine's central aim is to allocate initial decisionmaking responsibility between courts and agencies and to ensure that they do not work at cross-purposes." *Ellis v. Trib. Television Co.*, 443 F.3d 71, 81 (2d Cir. 2006) (citation omitted). Primary jurisdiction "is a prudential doctrine under which courts may, under appropriate circumstances, determine that the initial decisionmaking responsibility should be performed by the relevant agency rather than the courts." *Syntek Semiconductor Co., Ltd. v. Microchip Tech. Inc.*, 307 F.3d 775, 780 (9th Cir. 2002). "Whether there should be judicial forbearance hinges therefore on the authority Congress delegated to the agency in the legislative scheme." *Golden Hill Paugussett Tribe of Indians*, 39 F.3d at 59.

While there is "[n]o fixed formula . . . for applying the doctrine of primary jurisdiction," *United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 64 (1956), two principal rationales underlie it: promoting uniformity in a regulated field and employing the specialized knowledge of agencies. *Id.* at 3. Despite Plaintiffs' contention that these rationales are absent, *see* Appellants' Br. at 9, 24, both are satisfied and support the District Court's application of primary jurisdiction.

## I. THE FDA'S FOOD SAFETY EXPERTISE WARRANTS APPLICATION OF THE PRIMARY JURISDICTION DOCTRINE.

The primary jurisdiction doctrine counsels courts to permit federal agencies with special knowledge and discretion over an issue to decide it in the first instance. *See Far E. Conf. v. United States*, 342 U.S. 570, 574 (1952). The

Supreme Court has recognized that turning to an agency may be appropriate even if the claim is judicially cognizable, and the agency's action may not completely resolve the matter. *Id.* at 574, 576–77. The question is not whether a court *could* make a decision on the issue, but whether an agency decision is "likely to make a meaningful contribution" to resolving the question. *Ricci v. Chi. Mercantile Exch.*, 409 U.S. 289, 306 (1973). To make this determination, this Court has assessed whether a given issue is "legal in nature," *Goya Foods, Inc. v. Tropicana Prods., Inc.*, 846 F.2d 848, 851–52 (2d Cir. 1988), or instead is "of a factual nature," *Golden Hill Paugussett Tribe of Indians*, 39 F.3d at 58–59. *See also Palmer v. Amazon.com, Inc.*, 51 F.4th 491, 508 (2d Cir. 2022). In doing so, courts recognize that "'the expert and specialized knowledge of the agencies' should be ascertained before judicial consideration of the legal claim." *Goya Foods*, 846 F.2d at 851 (quoting *W. Pac. R.R.*, 352 U.S. at 64); *see Great N. Ry. Co. v. Merchs.' Elevator Co.*, 259 U.S. 285, 291 (1922) (invoking primary jurisdiction because "the inquiry is essentially one of fact and of discretion in technical matters").

Here, the extent consumers should be "warned" about the presence of trace heavy metals in baby foods because of some purported safety concern is an issue that falls within the FDA's authority and expertise. This quintessentially factual question, which requires technical and scientific expertise and touches on public policy issues such as feasibility and accessibility, is an issue that the FDA itself

admits is "complicated and multifaceted" and ripe for "unintended consequences."[6] It therefore cannot plausibly be said to fall within "the daily fare of federal judges." *Palmer*, 51 F.4th at 507 (citation and quotations omitted). Congress instead has entrusted the FDA with the regulation of food safety.[7] The FDA has over the years developed unique expertise on food safety and public health, and is currently taking action on this issue. Application of the primary jurisdiction therefore both materially aids the courts and best ensures the protection of public health.

### A. Congress Has Entrusted the FDA with Regulating Food Safety.

The FDA is the oldest comprehensive federal consumer protection agency in the United States and boasts a budget of $8.4 billion[8] and a staff of 18,500 "food technicians, chemists, nutritionists, and numerous other specialists in order to address public health and safety issues relating to foods and medicines." *Coyle v. Hornell Brewing Co.*, No. CIV. 08-02797 (JBS), 2010 WL 2539386, at *4 (D.N.J. June 15, 2010).

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[6] FDA, *Closer to Zero: Reducing Childhood Exposure to Contaminants from Foods* (Aug. 10, 2023), https://www.fda.gov/food/environmental-contaminants-food/closer-zero-reducing-childhood-exposure-contaminants-foods.

[7] 21 U.S.C. §§ 301 *et seq.*; FDA, *What We Do* (Mar. 28, 2018), https://www.fda.gov/about-fda/what-we-do.

[8] U.S. Dep't of Health & Human Servs., *FDA Fiscal Year 2023 Justifications of Estimates for Appropriations Committee* (March 8, 2023), https://www.fda.gov/media/157192/download?attachment.

The FDA's modern era began in 1906 when Congress added regulatory functions to the agency's scientific mission by requiring that foods bear truthful labeling statements and meet certain standards for purity and strength.[9] The agency's regulatory power expanded in 1938 with the landmark Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, by which Congress authorized the FDA to oversee and regulate the production, sale, and distribution of foods. *See* 21 U.S.C. §§ 371, 393. This role included protecting the public from adulterated or misbranded food products, *see* 21 U.S.C. §§ 331, 342–343, and ensuring that "foods are safe, wholesome, sanitary, and properly labeled." 21 U.S.C. § 393.

Congress thus granted the FDA broad authority to "promote the public health by promptly and effectively reviewing clinical research and taking appropriate action . . . in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products." 21 U.S.C. § 393(b). Whereas "[t]he average consumer cannot be expected to analyze and weigh each conflicting study," the FDA "possesses the requisite know-how to conduct such

[9] FDA, *FDA History* (June 29, 2018), https://www.fda.gov/about-fda/fda-history; FDA, *80 Years of the Federal Food, Drug, and Cosmetic Act* (July 11, 2018), https://www.fda.gov/about-fda/fda-history-exhibits/80-years-federal-food-drug-and-cosmetic-act.

analyses, by sifting through the scientific evidence to determine the most accurate and up-to-date information." *Henley v. Food & Drug Admin.*, 77 F.3d 616, 621 (2d Cir. 1996). Under Congress's directive, should FDA "find[] that the level of a contaminant causes [a] food to be unsafe, [it] [should] take action, which may include working with the manufacturer to resolve the issue and taking steps to prevent the product from entering, or remaining in, the U.S. market."[10]

In addition to analyzing all available technical, scientific, and public policy data, FDA's regulations are subject to notice-and-comment so that "all interested persons" are given the "opportunity to present their views." *See* 21 U.S.C. § 371(e)(1). The FDA recognizes that its regulations "have considerable impact on the nation's health, industries, and economy," and therefore "encourages public comment" by all interested parties because that "input provides critical insight into the effects of the regulation on the public."[11] Through this process, as opposed to the judicial process where the input of interested stakeholders is more limited, the FDA is able to consider and weigh a wide range of potential benefits or drawbacks of a proposed action.

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[10] FDA, *Chemical Contaminants & Pesticides* (Mar. 8, 2023), https://www.fda.gov/food/chemical-contaminants-pesticides.

[11] FDA, *The Importance of Public Comment to the FDA* (Sept. 14, 2018), https://www.fda.gov/drugs/information-consumers-and-patients-drugs/importance-public-comment-fda.

Perhaps most importantly, members of Congress expressly sought FDA's action on *this precise issue*.[12] The congressional subcommittee staff report that spurred this case, as well as others across the country, actively called on the FDA (not the courts) to decide the issue: "The time is now *for FDA* to determine whether there is any safe exposure level for babies to inorganic arsenic, lead, cadmium, and mercury, to require manufacturers to meet those levels, and to inform consumers through labels."[13] The FDA has actively taking up that task, and this Court should permit the agency to which Congress has delegated the necessary authority to determine this issue of national importance.

### B. The FDA Is Diligently Investigating Acceptable Levels of Heavy Metals in Baby Food Products.

The FDA helps safeguard the U.S. food supply and public health by actively monitoring heavy metals in foods, which includes a "prioritiz[ation]" for monitoring arsenic, lead, mercury, and cadmium.[14] For more than 30 years, the FDA has been "working to reduce exposure to lead, and other environmental

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[12] Plaintiffs insinuate that the FDA is not sufficiently or expeditiously investigating this issue, *see, e.g.*, Appellants' Br. at 21–23. But Congress is closely watching the issue and can take separate action if needed. *See* Baby Food Safety Act of 2021, H.R. 2229, 117th Cong. (2021), https://www.congress.gov/bill/117th-congress/house-bill/2229. Furthermore, the District Court's dismissal is without prejudice to the Plaintiffs potentially re-filing the suit.

[13] U.S. House of Representatives, *supra* note 2, at 59.

[14] FDA, *supra* note 10.

contaminants, from foods" in a way that "will result in long-term, meaningful and substantiable reductions."[15] Through the FDA's work to reduce dietary lead exposure for young children, beginning in the 1970s, lead levels have decreased by more than 97%.[16]

The FDA has acknowledged the reality that trace heavy metals are unavoidably present in certain foods, because these "elements occur naturally and as environmental pollutants in air, water, and soil, and they enter the food supply when plants take them up as they grow."[17] In response, the FDA has crafted a plan—*Closer to Zero*—to address any health risks these elements may present.[18] This program "is a science-based, iterative approach to decreasing toxic elements, including lead, in foods over time, including by setting action levels,"[19] with an understanding that a total ban on heavy metals in foods would result in adverse

[15] FDA, *supra* note 3.

[16] FDA, *Closer to Zero: Trends in Exposure to Toxic Elements from Foods for Babies & Young Children* (Jan. 24, 2023), https://www.fda.gov/media/147324/download.

[17] FDA, *What FDA is Doing to Protect Consumers from Toxic Metals in Foods* (Apr. 20, 2018), https://www.fda.gov/food/conversations-experts-food-topics/what-fda-doing-protect-consumers-toxic-metals-foods.

[18] FDA, *supra* note 6.

[19] FDA, *Action Levels for Lead Intended for Babies and Young Children: Draft Guidance for Industry*, at 3 (Jan. 2023), https://www.fda.gov/media/164684/download?attachment.

consequences. Through this plan, the FDA intends to determine the "levels of the different contaminants in foods and other products, the amount of the products consumed, and the population groups that consume them, to identify areas where we can have the greatest impact[,] . . . [and] to consider the feasibility of any potential solution," considering input from all stakeholders to help "make the best recommendations possible."[20] As part of this ongoing regulatory effort, the FDA is taking four steps to ensure that, at the end of the day, "all Americans have access to nutritious and safe food."[21]

The FDA's four-step plan includes: (1) evaluating the scientific basis for action levels, including analyzing existing data, researching risk and exposure assessments and other scientific information, and engaging with advisory committees, public workshops, scientific experts, federal agency partners,[22] and other stakeholders; (2) proposing action levels, and submitting draft guidance for review by federal agencies; (3) consulting stakeholders on the proposed action

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[20] FDA, *supra* note 17.

[21] U.S. Dep't of Agric., *Closer to Zero: Partnership to Protect Our Food* (Jan. 21, 2022), https://www.usda.gov/media/blog/2022/01/21/closer-zero-partnership-protect-our-food.

[22] The FDA is collaborating with the USDA and its components, including the Agriculture Research Service, the National Institute for Food and Agriculture, the Food Safety and Inspection Service, and the Food and Nutrition Service. *See id.*

levels, including to assess whether the levels are achievable and feasible; and (4) finalizing the action levels, using the information gathered from stakeholders, updated scientific data, and routine monitoring of data to make any needed adjustments in a "cycle of continuing improvement."[23] This systematic effort will enable FDA to "reduce dietary exposure to contaminants to as low as possible, *while maintaining access to nutritious foods*."[24] The FDA observes that this process is both "complicated and multifaceted," and steps must to be taken to ensure the measures adopted "do not have unintended consequences."[25]

The FDA has shown its commitment to this goal through its recent publication of draft guidance on action levels for lead in certain foods intended for babies and young children, which has included significant stakeholder engagement. Indeed, despite Plaintiffs' contention that "appl[ication] of the primary jurisdiction would indefinitely delay the resolution of this case," *see* Appellants' Br., at 47, the FDA is already in the *final* phase of this process (finalizing action levels) as to lead in juices and certain foods intended for babies and young children.[26] Plaintiffs argue in response that the FDA's action levels will "not offer the guidance

[23] FDA, *supra* note 6.

[24] *Id.* (emphasis added).

[25] *Id.*

[26] *Id.*

necessary or useful to resolve this case," citing to an FDA statement that "'[t]he action levels in [the] draft guidance are not intended to direct consumers in making food choices.'" Appellants' Br., at 33 (quoting FDA, *supra* note 3). But these action levels are not intended to direct *consumers'* decisions on food. As the FDA has explained, "it is not possible to remove these elements entirely from the food supply" because the fruits, vegetables, and grains that are the primary ingredients in an infant's diet readily absorb vital nutrients as well as trace levels of heavy metals, but the "presence of a contaminant, however, does not mean the food is unsafe to eat."[27] The FDA accordingly recommends children have a varied and nutrient-dense diet across and within these food groups of fruits, vegetables, and grains (whether store-bought or homemade) because such a diet can help children "get important nutrients" while "reduc[ing] potential harmful effects from exposure to contaminants."[28] The FDA action levels are intended to guide *manufacturers* (and thereby suppliers) on the acceptable levels of heavy metals in baby foods. That is why the same FDA statement details that "these action levels will cause *manufacturers* to implement . . . measures to lower lead levels in their

[27] FDA, *supra* note 3.

[28] *See id.* This concept is well understood by public health authorities. "Undernourished children are more susceptible to lead because their bodies absorb more lead if other nutrients, such as calcium or iron, are lacking." *Lead poisoning*, World Health Org. (Aug. 11, 2023), https://www.who.int/news-room/fact-sheets/detail/lead-poisoning-and-health.

food products. . . thus reducing the potential harmful effects associated with dietary lead exposure."[29]

The FDA's work is not limited to lead. Within the last few weeks, the FDA has also published a study on the oral toxicological reference value (TRV) for cadmium in foods.[30] The FDA found that, "based on the current available evidence, there is high confidence that the range of the proposed TRV . . . will be protective of human health."[31] Therefore, despite Plaintiffs' repeated assertion that the FDA delayed or abandoned its plans for establishing action levels, *see, e.g.*, Appellant's Br., at 18–23, the FDA has consistently shown its commitment to determining the proper action levels for heavy metals in baby foods.

In a similar vein, Plaintiffs complain that the action levels to be set by the FDA are non-binding. *See, e.g.*, Appellants' Br., at 4, 6, 20, 44. Plaintiffs miss the point. The action levels that the FDA establishes "are levels at which FDA may

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[29] FDA, *supra* note 3 (emphasis added).

[30] Heather R. Schaefer, et al., FDA, *Reassessment of the cadmium toxicological reference value for use in human health assessments of foods*, 144 REGUL. TOXICOLOGY & PHARMACOLOGY 105487 (Aug. 25, 2023), https://doi.org/10.1016/j.yrtph.2023.105487.

[31] *Id.*

regard a food as adulterated" within the meaning of 21 U.S.C 342(a)(1),[32] as Plaintiffs concede. *See* Appellants' Br. at 18–19. "The introduction or delivery for introduction into interstate commerce of any food . . . that is adulterated" is expressly prohibited. 21 U.S.C. §331(a). Moreover, the FDA clearly states that it "intend[s] to consider these action levels . . . when considering whether to bring enforcement action in a particular case."[33] And "[i]f the FDA finds that a product violates the law," taking action levels into account, "the agency takes steps to stop the product from being imported, takes court action to stop its sale or recalls it if it is in the domestic market."[34]

The bottom line is the FDA is actively investigating what levels of heavy metals in baby foods are safe and establishing corresponding standards. Through these action levels, the FDA will convey to consumers, manufacturers, suppliers, and the courts what the appropriate levels are, with the authority to enforce these action levels should any manufacturer fail to adhere to them. These standards will

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[32] "A food shall be deemed to be adulterated . . . [i]f it bears or contains any poisonous or deleterious substance that may render it injurious to health." FDA, *supra* note 19, at 3–4.

[33] *See id.*

[34] FDA, *FDA Response to Questions About Levels of Toxic Elements in Baby Food, Following Congressional Report* (Feb. 16, 2021), https://www.fda.gov/food/cfsan-constituent-updates/fda-response-questions-about-levels-toxic-elements-baby-food-following-congressional-report.

have a direct bearing on Plaintiffs' claims and the relief they seek. The District Court therefore appropriately applied the primary jurisdiction doctrine as those standards are being set by the FDA.

### C. The FDA Is Best Suited to Determine the Appropriate and Safe Amount of Heavy Metals in Baby Food Products.

The FDA "as distinguished from a court, possesses superior expertise, usually of a complex scientific nature." *Premo Pharm. Lab'ys, Inc. v. United States*, 629 F.2d 795, 803 (2d Cir. 1980). For this reason, when the FDA is actively investigating a scientific or technical question at issue, courts in this Circuit commonly apply the primary jurisdiction doctrine.[35] Indeed, this Court has noted that, "[c]ourts should be especially solicitous in deferring to agencies that are simultaneously contemplating the same issues. Because an agency 'is currently conducting an investigation into the lawfulness of the [practice] under attack,' 'to permit the court below initially to determine [the issue] would invite the very disruption . . . that the doctrine is meant to discourage.'" *Ellis*, 443 F.3d at 88 (citations omitted).

[35] *See, e.g.*, *Forsher v. J.M. Smucker Co.*, No. CV-2015-7180-RJD-MDG, 2016 WL 5678567, at *2 (E.D.N.Y. Sept. 30, 2016); *In re KIND LLC "Healthy & All Natural" Litig.*, 209 F. Supp. 3d 689, 693–97 (S.D.N.Y. 2016); *Scholder v. Riviana Foods Inc.*, No. 16-CV-6002(ADS)(AKT), 2017 WL 2773586, at *4 (E.D.N.Y. June 23, 2017) (citing cases).

The FDA's expertise makes it best suited to gather and weigh considerations from all stakeholders and make an initial determination on action levels for trace elements in baby food. For instance, when designing food safety regulations, "[t]he agency considers the health effects of the '*whole food*,' which includes the potential harmful health effects of specific contaminants that may be present, as well as the food's nutrients that are vital to growth and development for babies and small children and help promote health and prevent disease throughout our lifespan."[36] Similarly, in crafting *Closer to Zero* action levels, the FDA's goal is to reduce heavy metals levels "while *maintaining access* to nutritious foods."[37]

The FDA's deliberate and holistic approach follows the fundamental scientific principle that the "dose makes the poison": any chemical can be toxic if too much of it is consumed or absorbed.[38] A primary purpose in public health is to identify the permissible dosage of elements by balancing various factors. It is

[36] FDA, *Lead in Food, Foodwares, and Dietary Supplements* (Mar. 1, 2023), https://www.fda.gov/food/environmental-contaminants-food/lead-food-foodwares-and-dietary-supplements (emphasis added).

[37] FDA, *supra* note 6 (emphasis added).

[38] This principle is attributed to Paracelsus in 1538: "All things are poison, and nothing is without poison; the dosage alone makes it so a thing is not a poison." Paracelsus, Die dritte Defension wegen des Schreibens der neuen Rezepte, *Septem Defensiones* 510 (1538) Werke Bd. 2, Darmstadt 1965.

therefore crucial to balance all potential benefits and drawbacks of any decision, which is exactly what the FDA is doing:

> Reducing levels of contaminants in foods is complicated and multifaceted, . . . [and] [i]t is [therefore] crucial to ensure that measures taken to limit arsenic, lead, cadmium, and mercury in foods do not have unintended consequences—like eliminating from the marketplace foods that have significant nutritional benefits or reducing the presence of one element while increasing another.[39]

For instance, entirely cutting out certain vegetables, which unavoidably contain trace levels of heavy metals but which also contain vital vitamins, could cause harmful long-term effects. And even if manufacturers could hypothetically locate suppliers for which the raw materials did not include *any* levels of trace metals, the finite nature of such supplies (if they exist) would drastically decrease the overall availability of nutritious foods for children, particularly those from families of lesser means. For this reason, the FDA has emphasized parents should *not* throw away store-bought baby foods, despite the potential presence of trace heavy metals, and has indicated that homemade baby foods—which include raw materials that likely contain the same or higher levels of heavy metals—might indeed have greater risks.[40]

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[39] FDA, *supra* note 6.

[40] FDA, *supra* note 4.

The recent study conducted by Healthy Babies Bright Future—the same organization whose study on heavy metals in store-bought baby foods was a basis for the congressional subcommittee staff report—confirms as much. The purpose of this study was to determine whether the "DIY work-around" of replacing store-bought baby foods with homemade versions "actually works."[41] The study found that there is "*no* evidence to suggest that homemade baby food has *lower* heavy metal levels than store-bought brands . . . [as] [h]eavy metal levels varied widely by food type, not by who made the food."[42] Specifically, "94% of *all* food samples . . . tested contained detectable amounts of toxic heavy metals: 94% of store-bought baby food and 94% of homemade purees and family brand foods."[43] This finding readily contradicts Plaintiffs' allegation that "no consumer would knowingly purchase baby foods from a retailer that allowed its baby foods to contain (or risk containing) heavy metals." Appellants' Br. at 16. Parents making homemade baby foods are on the same footing as manufacturers.

Plainly, the Court should not give credence to Plaintiffs' attempt to recharacterize the issue as one merely of food labeling, which supposedly is

[41] Jane Houlihan, Healthy Babies Bright Futures, *Is Homemade Baby Food Better?* (Aug. 2022), https://hbbf.org/sites/default/files/2023-03/BabyFoodReport2022_R11_Web.pdf.

[42] *Id.* (emphasis added).

[43] *Id.*

"within the conventional experience of judges," and not of food safety, which can "requir[e] the exercise of administrative discretion." *See Far E. Conf.*, 342 U.S. at 574; Appellants' Br., at 31–43. Plaintiffs allege that Beech-Nut "knew that consumers purchased the Baby Foods based on the reasonable expectation that [Beech-Nut] manufactured the Baby Foods to the highest standards to be safe and healthy for consumption by babies." Compl., ¶36. But if the FDA determines that Beech-Nut's products are *safe* and *healthy* for consumption through the action levels it sets, then there is *no* deception and *no* injury to consumers.[44]

Plaintiffs' additional argument that the FDA's *Closer to Zero* plan "will not govern labeling, [and] will not materially aid any court in determining whether, under the facts alleged, any legal standard was violated" is beside the point. Appellants' Br., at 23. In a typical labeling matter, a court determines whether a phrase on a product's labeling has the capacity to deceive the reasonable consumer, and the injunctive relief sought is generally to remove or revise the statement.

[44] Courts across the country have rejected this false distinction between labeling and safety concerns. *See, e.g.*, *Kimca*, 2022 WL 3586095, at *3 ("[G]uidance from the FDA on what constitutes a safe level of heavy metals in baby food is integral to determining whether any of Sprout's label statements were misleading."); *Gerber*, 2022 WL 10197651, at *13 ("The Court is thus unable to conclude whether Defendant's labeling was misleading without guidance from the FDA on the Heavy Metals' toxicity."); *Beech-Nut*, 2023 WL 3880389, at *3 (rejecting plaintiff's recharacterization of its allegations because the labeling claims turned on "a preliminary determination of whether the levels of toxic heavy metals in Defendants' products are 'high' or 'dangerous'").

Here, however, this issue poses a predicate question uniquely within the FDA's bailiwick: whether a product needs a warning label or some other court-mandated relief affecting the product's composition or availability—despite the FDA's assertion that trace heavy metals do not render products unsafe to consume. Therefore, the FDA's action levels for heavy metals in baby foods are central.

Indeed, the FDA's decision to set action levels instead of mandating warning labels on baby foods is logical. Adding warning labels, particularly on only baby foods, would scare parents away from feeding such products to their children, and the FDA is charged with ensuring that children have access to the necessary nutrition. Moreover, warnings on foods have other drawbacks: (1) warnings tend to undermine consumer confidence in the food supply; (2) consumers often do not heed warnings, particularly when alternative courses of action are unclear or practically unavailable; (3) warnings imply that some products are safer than others, which (as the Healthy Babies' study shows) may not be accurate; and (4) ubiquitous warnings are more likely to be ignored, undermining other warnings. *See, e.g.*, Restatement (Third) of Torts: Prods. Liab. § 2 cmt. j (Am. L. Inst. 1998) (noting that excessive, multitudinous warnings "may be ignored by users and consumers and may diminish the significance of warnings about [other] risks" and

"could reduce the efficacy of warnings generally").[45] Due to these drawbacks, it makes no sense for the FDA to require warning labels on foods it deems "safe." And if a product is truly "unsafe" then the FDA would simply remove it from the marketplace.

The District Court understood that the possibility of conflict with the FDA as the key policymaker was far from hypothetical. Because the FDA is actively investigating this issue and is issuing action levels for baby foods, this Court should uphold the District Court's ruling and permit the FDA to complete the mission with which Congress has charged it.

## II. THE NEED FOR UNIFORMITY AND CONSISTENCY WARRANTS APPLYING THE PRIMARY JURISDICTION DOCTRINE HERE.

Uniform and consistent regulation is vital to the effective operation of all businesses, which need to know what to expect and be able to plan accordingly. The primary jurisdiction doctrine promotes this important principle by ensuring that the agency entrusted with regulating the relevant industry—and not private

[45] This policy is acknowledged even by the California agency that implements Proposition 65, a state law that requires manufacturers to provide warnings to consumers. Cal. Health & Safety Code § 25249.5 *et seq.* In adopting an exemption for warnings from naturally occurring substances, such as heavy metals in foods, the agency noted that "unnecessary warnings . . . could distract the public from other important warnings." *Nicolle-Wagner v. Deukmejian*, 230 Cal. App. 3d 652, 661 (1991). And the court upholding the regulation emphasized that "such warnings would be diluted to the point of meaninglessness if they were to be found on most or all food products." *Id.*

plaintiffs proceeding through individual lawsuits—establishes one, nationwide set of applicable standards. *See Far E. Conf.*, 342 U.S. at 574–75 ("Uniformity and consistency in the regulation of business entrusted to a particular agency are secured . . . by preliminary resort . . . to agencies that are better equipped than courts by specialization, by insight gained through experience, and by more flexible procedure."); *see also Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 673 (2003) (Breyer, J., concurring) (explaining that the primary jurisdiction doctrine "allow[s] courts to take advantage of an agency's . . . central position within a regulatory regime" to "produce better informed and uniform legal rulings").

The need for a uniform and predictable regulatory scheme is particularly important in the food industry. Congress has entrusted the FDA with the task of creating and enforcing nationally applicable regulations. If individual courts intervene to set individual food safety rules and policy, there is great risk of undercutting the FDA's judgment and authority. This risk of inconsistent safety standards is even greater when, as here, the agency is currently crafting standards bearing on the very same issue. Indeed, even though this action only involves *one* manufacturer, it cannot be said that its repercussions (and subsequent regulatory confusion) will not impact *all* manufacturers—thereby also impacting all suppliers, distributors, and consumers. For instance, if a court were to decide that Beech-

Nut's Organics Carrots product (whose sole ingredient is carrots) cannot be sold in New York without a warning, regardless of the trace lead level, then this would: *first*, conflict with the FDA's draft action level of 20 ppb for single ingredient root vegetables products,[46] and *second*, create industry-wide confusion as to whether other manufacturers of root vegetable products (whether for babies, children, or adults) must follow that court's guidance or the FDA's. On top of that, if one baby food manufacturer were required by a court to add a warning to its products, but other companies were not, it would (i) scare consumers from purchasing that manufacturer's products for their children, (ii) make consumers believe that related products do not contain similar amounts of heavy metals in their products (even though the amounts of heavy metals are likely similar), and (iii) restrict the baby food supply chain, which could initiate widespread public health problems. Courts should try to avoid making independent and potentially conflicting determinations on issues that may directly undermine the FDA's mission to "ensur[e] the safety of our nation's food supply."[47] This issue has nationwide impact; it should be regulated on a nationwide level.

[46] FDA, *supra* note 19.

[47] FDA, *supra* note 7.

This concern about the tenuous baby food supply chain is not hypothetical. Take, for instance, the infant formula crisis of 2022. Due to pandemic-related supply chain issues and one manufacturer's voluntary recall and pause in infant formula production, out-of-stock rates for infant formula were 74% nationally and 90% in some states.[48] This widespread shortage persisted despite other manufacturers' attempts to accelerate and increase their productions, with manufacturers predicting that the effects of the shortage would be felt into spring 2023.[49] In fact, this acute shortage was found to have adversely impacted over half of the infants in the United States, as formula is commonly used to provide or supplement essential vitamins and nutrients for a baby's growth and development.[50] Without proper nutrients, children can face long- and short-term

[48] Maria Kalaitzandonakes, et al., *Coping with the 2022 infant formula shortage*, 32 PREVENTIVE MED. REPS. 102123 (Apr. 2023), https://doi.org/10.1016/j.pmedr.2023.102123; Elizabeth Williams & Samantha Artiga, *Key Characteristics of Infants and Implications of the Recent Formula Shortage*, KFF (June 9, 2022), https://www.kff.org/medicaid/issue-brief/key-characteristics-of-infants-and-implications-of-the-recent-formula-shortage/.

[49] Richa Naidu, *Exclusive: Reckitt expects U.S. infant formula shortage until spring*, REUTERS (Dec. 2, 2022), https://www.reuters.com/business/healthcare-pharmaceuticals/enfamil-maker-reckitt-sees-formula-shortage-continuing-until-spring-2022-12-01/.

[50] Kalaitzandonakes, et al., *supra* note 48; Williams & Artiga, *supra* note 48.

health complications,[51] and a shortage of infant formula can exacerbate health disparities based on race, income, and geography.[52] Even apart from the physical effects of the shortage, the crisis also caused emotional trauma for caregivers who had to worry for months whether they would be able to properly feed their children.[53] This crisis highlights the delicate balance needed to ensure children's nutritional needs are properly met, as well as the major consequences that can occur if that balance is disrupted.

A patchwork of judicial determinations regarding the allowable amounts of heavy metals in baby foods and the specifications or necessity of warning labels would also make uniform food labeling, even for one manufacturer, impossible. *See Coyle*, 2010 WL 2539386, at *4 ("The prospect that different labels would be permissible in different jurisdictions would impose a burden on [the food] industry that may be alleviated if the FDA chooses to speak directly to the question."). For this reason, dismissing this action "until the FDA offers guidance at the federal level would almost certainly help harmonize court rulings . . . [which is] an

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[51] Williams & Artiga, *supra* note 48.

[52] Kalaitzandonakes, et al., *supra* note 48.

[53] Deidre McPhillips, *A year later, formula stock has recovered from the shortage, but parents haven't*, CNN (Feb. 17, 2023), https://www.cnn.com/2023/02/17/health/formula-shortage-one-year-later/index.html.

important consideration in view of the fact that 'Congress [did] not want to allow states to impose disclosure requirements of their own on packaged food products, most of which are sold nationwide' in order to avoid the need for '[m]anufacturers . . . to print 50 different labels.'" *In re KIND* , 209 F. Supp. 3d at 696 (citing *Turek v. Gen. Mills, Inc.*, 662 F.3d 423, 426 (7th Cir. 2011)). Besides the inconsistencies that would result from individual decisions on the dozens of lawsuits on this issue already, courts cannot (and should not) be open to private plaintiffs' attempts to determine the United States' food policy as this is both inefficient and potentially dangerous to public health.

Furthermore, for the sake of uniformity, "application of the [primary jurisdiction] doctrine," as here, "is appropriate when policy considerations are at issue,' such as when resolution of the issue could have an impact on future viability of regulated businesses or how they conduct their business." *Sprint Commc'ns Co., L.P. v. Butler-Bremer Mut. Tel. Co.*, No. C 14-3028-MWB, 2014 WL 4980539, at *3 (N.D. Iowa Oct. 6, 2014) (citations omitted). Courts have applied the doctrine in cases affecting diverse regulated industries. In the telecommunications industry, referral to the applicable agency was warranted where a court ruling would "impact the [] industry far beyond the interests of the parties before this Court," *IPCO Safety Corp. v. WorldCom, Inc.*, 944 F. Supp. 352, 357 (D.N.J. 1996), or "could affect the competitive dynamics . . . and

unintentionally initiate changes throughout the telecommunications industry." *Phone-Tel Commc'ns, Inc. v. AT & T Corp.*, 100 F. Supp. 2d 313, 320 (E.D. Pa. 2000). In the railroad industry, referral was appropriate when the dispute required "not only legal analysis, but also 'an informed evaluation of the economics or technology of the regulated industry.'" *DeBruce Grain, Inc. v. Union Pac. R.R. Co.*, 149 F.3d 787, 789 (8th Cir. 1998). The baby food industry is no different. Affirmance of the District Court's primary jurisdiction ruling will promote the clarity, predictability, and uniformity that this regulated industry needs to supply food to children across the country.

"[W]hen the FDA acts, its actions affect an entire industry." *Haggag v. Welch Foods, Inc.*, No. CV 13-00341-JGB (OPX), 2014 WL 1246299, at *6 (C.D. Cal. Mar. 24, 2014). The FDA should be given the opportunity, which Congress intended, and which the District Court's decision enables, to make a uniform and nationally applicable determination as to the safe and appropriate levels of heavy metals in baby foods, weighing all concerns from all stakeholders.

## CONCLUSION

For the foregoing reasons, and those in Beech-Nut's brief, the District Court's judgment should be affirmed.

Dated: September 8, 2023

San Francisco, California

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Second Circuit Rule 29.1(c) and Federal Rules of Appellate Procedure 29(a)(5) because this brief contains 6,985 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 365 in 14 point Times New Roman font.

Dated: September 8, 2023

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## CERTIFICATE OF SERVICE

I hereby certify that, on September 8, 2023, an electronic copy of the foregoing Brief of Consumer Brands Association, Chamber of Commerce of the United States of America, and Food Marketing Institute as Amici Curiae in Support of Defendant-Appellee and Affirmance of the District Court's Decision was filed with the Clerk of Court using the ECF system and thereby served upon all counsel appearing in this case.

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