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Baby Food Contamination Cases Face Class Action Hurdles

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Litigation involving allegations of adulterated baby food products has given rise to a number of putative class action claims around the country. The claims involve different products, different companies, different state laws and different allegations regarding which ingredients are adulterating which products and in what amounts.

This simple recitation of these factors alone should demonstrate some of the difficulties that plaintiffs may have in turning any individual suit into one that implicates a class of plaintiffs.

Most of these class actions allege no specific actual physical injury, but instead claim that these products pose a risk for children who may have been exposed to heavy metals that are allegedly found in certain baby food products.[1] Among other causes of action, the complaints allege violations of various state consumer fraud statutes, asserting that the companies made false and misleading statements about the safety of their products.

The defendants include icons of the baby food industry like Gerber Products Co., Beech-Nut Nutrition Co. and Hain Celestial Group Inc. Complaints have been filed in at least 11 different states, including class actions filed in the Northern and Eastern Districts of New York, the District of Nevada, the Western District of Missouri and the Northern District of Illinois.[2]

Over 70 different actions were pending before the Judicial Panel on Multidistrict Litigation as a number of plaintiffs law firms asked the panel to exercise its power to transfer the matters to a single transferee court. The defendants and certain plaintiffs opposed this consolidation, and the panel recently denied the motion to transfer.[3]

The class action complaints generally rely on a recent report by the Subcommitee on Economic and Consumer Policy of the U.S. House of Representatives' Committee on Oversight and Reform,[4] in which various studies were cited to support the claim that dangerous levels of heavy metals have been detected in the products of these baby food manufacturers, thereby raising a health risk to the consumers of these products.

The U.S. Food and Drug Administration has the power to regulate baby food products but, with the exception of arsenic in rice cereal, has remained silent on the question of what information, if any, about heavy metals should be included in any product labeling or advertising, as well as whether or not maximum limits should be imposed for some or all of the heavy metals.[5]

In fact, the FDA just issued its "Action Plan for Reducing Exposure to Toxic Elements from Foods for Babies, Young Children," in which it acknowledged that its own testing "shows that children are not at an immediate health risk from exposure to toxic elements at the levels found in foods."[6] And the FDA action plan goes further:

We recognize that Americans want zero toxic elements in the foods eaten by their babies and young children. In reality, because these elements occur in our air, water and soil, there are limits to how low these levels can be. The FDA's goal, therefore, is to reduce the levels of arsenic, lead, cadmium and mercury in these foods to the greatest extent possible. We are also sensitive to the fact that requiring levels that are not currently feasible could result in significant reductions in the availability of nutritious, affordable foods that many families rely on for their children.[7]

The FDA's action plan envisions a timeline that stretches out to 2024 and beyond. In the meantime, aside from the amount of arsenic permitted in rice cereals, it has not set any specific maximum levels of any of the heavy metal ingredients in baby foods beyond which harm may occur, nor has it established any labeling requirements regarding heavy metals in these products.

Weaknesses in Scientific Publications Cited by the Subcommittee Report

Among other hurdles that plaintiffs in these cases must clear, they will have to demonstrate the scientific basis for their claims. Even putting the FDA's position aside, this may not be so easy.

Although the findings contained in the subcommittee report are seemingly based on data from scientific journals, scratching below the surface of some of the studies reveals issues that plaintiffs will face if this is all the proof they are able to gather.

As discussed more fully below, New York's consumer protection statutes only forbid statements by baby food manufacturers that are materially misleading. This issue is found in virtually all of the causes of action. If the scientific evidence that plaintiffs bring to bear in these cases does not reliably demonstrate the lack of safety that the plaintiffs claim, then class certification may be doomed as well.

The subcommittee report relied on a number of studies that have significant weaknesses, or that are otherwise not the type of primary source of data that is typically relied upon by experts. Examples include:

- Study design limitations: Some of the literature referenced in the report failed to properly account for confounding and multiple testing potentially leading to false positives.[8]

- Exposure issues: It is important to rely on data that match the exposure period in question, i.e., postnatal exposure; more specifically, the time period when the child consumed baby food. Several of the cited studies found IQ impact from mercury exposure, but only prenatal exposure, which is not particularly relevant to the postnatal consumption of baby food products that are alleged in the various complaints.[9]

- Review articles versus primary literature: Review articles suffer from many limitations and potential biases, including the possibility of gaps or omissions of relevant scientific research, potential errors or misrepresentations of the primary data, and bias from the authors' personal opinions. The subcommittee report ignores the limitations of review articles generally, including the limitations identified by their own references.[10]

- Problems with cross-sectional analyses: The subcommittee report relied on a number of cross-sectional studies. In a cross-sectional design, the exposure and outcome are measured at the same time, and it is not possible to establish a temporal relationship between the exposure and outcome, whether the exposure occurred before or after the outcome. Because of this, causality cannot be inferred.[11]

- Inconsistency between the referenced articles and statements in the report: The referenced articles do not always support the accompanying statements in the subcommittee report — a foundational flaw.[12]

In short, the "scientific support" provided by the subcommittee report does not depict a comprehensive and thorough investigation of the relationship between heavy metal exposure and child neurodevelopment.

The Subcommittee Report and FDA Regulatory History and Action Plan

The FDA seems to agree that the subcommittee report does not currently warrant a dramatic modification in its regulatory position regarding baby foods. With access to the same published literature relied on by the subcommittee report, the FDA has made clear in its action plan that any risk presented by the presence of the heavy metals identified in the report is at best inconclusive at this point.

It takes no immediate steps to add label warnings or to pull products from the market. Instead, it establishes a timeline for gathering data and engaging in research, with the goal of establishing action levels for categories of food consumed by babies and young children.[13]

Absent presently available credible evidence that exposure to the levels of heavy metals identified in the various baby food products is harmful at any dose, it may be difficult for a court to conclude that the absence of statements about heavy metals in the baby food product is misleading.

Class Actions

Federal court class actions are generally governed by Rule 23 of the Federal Rules of Civil Procedure.[14] To qualify for class action treatment, a case must satisfy four requirements pursuant to Rule 23(a):

- The class is so numerous that joinder of all members is impracticable;

- There are questions of law or fact common to the class;

- The claims or defenses of the representative parties are typical of the claims or defenses of the class; and

- The representative parties will fairly and adequately protect the interests of the class.

As courts have noted, these four threshold requirements are referred to as numerosity, commonality, typicality and adequacy of representation.[15] In addition, Rule 23 class certification also requires, among other things, that:

- Prosecuting separate actions by or against individual class members would create a risk of:
    - Inconsistent or varying adjudications with respect to individual class members that would establish incompatible standards of conduct for the party opposing the class; or
    - Adjudications with respect to individual class members that, as a practical matter, would be dispositive of the interests of the other members not parties to the individual adjudications or would substantially impair or impede their ability to protect their interests;
- The party opposing the class has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole; or
- The court finds that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.[16]

Obstacles to Certification in Baby Food Putative Class Actions

Complaints against the baby food manufacturers provide some indications of the challenges plaintiffs will face.

The complaint filed in the U.S. District Court for the Eastern District of New York on behalf of putative class representatives including Lori-Anne Albano alleges causes of actions against four separate manufacturers: Hain Celestial Group, Beech-Nut, Gerber and Nurture Inc.[17]

Complications exhibited by this complaint demonstrate some of the reasons why class certification may not be appropriate, particularly as the complaint is presently pled:

- The Albano complaint seeks class certification for a nationwide class for all purchasers of products from any of the four defendants from 2017 to the present, as well as state-specific classes for consumers of the products in Pennsylvania, New York and Massachusetts.
- Not all the causes of action apply to all the putative class representatives or to all the defendants. Some are asserted only for the New York state class on the basis of New York statutory causes of action. Another is asserted on behalf of only the putative Pennsylvania classes on the basis of a Pennsylvania statute. Yet another cause of action is asserted on behalf of the New York and Massachusetts classes, but not the Pennsylvania classes.
- Some of the causes of action implicate the Gerber and Nurture defendants only; others implicate Hain and Beech-Nut defendants only; while only two causes of action, out of five, implicate all four defendants.

Currently, this complaint would require the application of myriad different state statutes as well as the common law of various states. Thus, the requirements of Rule 23(a)(2), that there are "questions of law or fact common to the class," and Rule 23(b)(3), that "questions of law or fact common to class members predominate over any questions affecting only individual members" — the so-called predominance prong — would present significant obstacles to certifying a nationwide class.

If the Albano complaint were narrowed to a single-state class, it would still suffer from the infirmity that all of the putative single-state classes in the Albano complaint involve multiple defendants, each of which has different products with different levels and different types of alleged various heavy metals.[18]

Moreover, while the Albano complaint alleges that common to all the defendants is the question "[w]hether Defendants knew their products contained harmful heavy metals that rendered their baby food products unsafe for babies," questions about what each defendant knew about its ingredients vary significantly.[19] Even the subcommittee report, relied upon by the plaintiffs, makes this clear when it delineates different information in what certain companies' internal documents show, and identifies other companies that did not cooperate with the subcommittee's inquiries.[20]

Even a class action complaint against a single manufacturing defendant in a single state may fail to qualify for class action treatment. For example, as an alternative to causes of action seeking nationwide class certification, the Albano complaint alleges a New York state class action against four separate individual defendants. Questions still persist as to whether the multitude of different products that each company produces — each with different heavy metals, and different levels of any such heavy metals — would defeat class action.

Although the Albano complaint alleges that the "nature of the relief, including damages and equitable relief,"[21] sought is common to all class members, the claimed injuries hardly seem common, or that they predominate. The damages available will depend on:

- What products particular class members purchased;
- When they purchased the products;
- How much of each product they purchased;
- How much of the product was consumed; and
- What they might have purchased instead of these products to feed their babies and toddlers.

Moreover, it is unclear that the claims for injunctive relief or monetary damages satisfy the requirements under Rule 23(b)(2). The U.S. Supreme Court has noted that claims for individualized monetary damages bar class certification under Rule 23(b)(2) unless they are merely incidental to requested declaratory relief.[22]

Here, the Albano complaint seeks monetary damages for the members of the class who seek reimbursement for products that they would not have otherwise purchased, or which they would have purchased only at a reduced price. These allegations seem to suggest that the damages they seek are hardly incidental to the requested declaratory and injunctive relief.[23]

Class Actions and New York's General Business Law Sections 349 and 350

Even if any of these proposed classes manage to survive Rule 23 challenges, they still face additional hurdles when the consumer protection statutes that such class actions allegedly apply are examined more carefully. New York state's consumer protection statutes are prime examples:

The Albano complaint sets forth, among other causes of action, two based on New York state's consumer protection statutes, General Business Law Sections 349 and 350.[24] Under these provisions, New York state requires that a plaintiff must allege that a defendant has engaged in (1) consumer-oriented conduct that is (2) materially misleading, and that (3) the plaintiff suffered injury as a result of the allegedly deceptive act or practice.[25]

While the first element is likely beyond challenge, the second and third present additional difficulties for plaintiffs.

What constitutes a materially misleading statement in the baby food class action context?

A material misrepresentation under Sections 349 and 350 is one that is "likely to mislead a reasonable consumer."[26] Here, the plaintiffs must establish that the allegedly deceptive labels and marketing materials were "likely to mislead a reasonable consumer acting reasonably under the circumstances."[27]

The Albano complaint alleges that the labeling of the product failed to notify purchasers of the dangerous and harmful levels of heavy metals contained in all of the products. However, there are several problems with this allegation. First, the labels have no information about heavy metals at all, and there is currently no obligation to include such data in the product labeling.

Second, these labels contain misrepresentations that are misleading only if the companies knew or should have known that the ingredients in their products were unreasonably dangerous — a contention by the plaintiffs that relies on the data in the subcommittee report. There is reason to be suspicious of the conclusions that the plaintiffs draw from the report, and from the underlying data.

What constitutes an injury in the baby food class actions?

The injury element provides another significant challenge to the plaintiffs. The Albano complaint asserts that the plaintiffs "would not have purchased ... or would have paid less" for the products they did purchase.[28]

The Albano complaint provides no indication as to what products they might have purchased in the alternative, what price they may have expected to pay for products that did not include the allegedly offending ingredients, nor the amount they overpaid for the allegedly adulterated baby food products.

If precertification discovery fails to provide additional evidence to support the allegations that the consumers would not have purchased the products, or would have paid less for them, these claims will also fail.[29]

Conclusions

Plaintiffs in the baby food litigation face significant hurdles that may prove to be impassable barriers to

aggregating claims using the class action device. Just a sampling of these issues, including questions about commonality and predominance, are discussed above.

Make no mistake, the baby food defendants certainly have other arguments to rebut class action efforts of the plaintiffs counsel.[30] Perhaps equally problematic, efforts to use consumer protection statutes, such as New York's General Business Law Sections 349 and 350, also present significant challenges, particularly in the wake of the FDA's recent pronouncements about these products.

Whether the courts will find that the plaintiffs' allegations of misconduct by the baby food industry satisfy the requirements of Rule 23, or those of state consumer protection statutes, remains to be seen.

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[1] A few complaints allege actual injury to minor plaintiffs, but do not seek class action treatment. See, e.g., Matter of AG (Gibson) v. Hain Celestial Group Inc., No. 4:21-cv-01600 (N.D. Cal. March 5, 2021); Matter of IM (Ibert) v. Plum, PBC, No. 4:21-cv-02066 (N.D. Cal. March 24, 2021); Palmquist v. The Hain Celestial Group Inc., No. 3:21-cv-00090 (S.D. Tex. April 26, 2021). At least one complaint does seek class treatment and also alleges an injury to a minor plaintiff: Walls v. Beech-Nut Nutrition Co., No. 1:21-cv-00870 (E.D.N.Y. Feb. 17, 2021).

[2] Other venues include the Central, Eastern and Northern Districts of California, the District of Colorado, the District of Kansas, the District of New Jersey, the Eastern District of Virginia, and the Middle District of Florida.

[3] Order Denying Transfer, In re Baby Food Mktg., Sales and Pracs. and Prods. Liab. Litig., MDL No. 2997 (June 7, 2021).

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

[5] Currently, the FDA has issued only nonbinding guidance with regard only to levels of arsenic in rice cereal. No other heavy metals or foods are the subject of any similar guidance from the FDA. See U.S. Dep't of Health & Human Servs., FDA, Ctr. for Food Safety & Applied Nutrition, Inorganic Arsenic in Rice Cereals for Infants: Action Level Guidance for Industry, FDA (Aug. 2020), https://www.fda.gov/media/97234/download.

[6] Janet Woodcock, M.D., Acting Comm'r of Food & Drugs and Susan T. Mayne, Ph.D., Dir. of Ctr. for Food Safety & Applied Nutrition, Statement, FDA Releases Action Plan for Reducing Exposure to Toxic Elements from Foods for Babies, Young Children, FDA (April 8, 2021), https://www.fda.gov/news-events/press-announcements/fda-releases-action-plan-reducing-exposure-toxic-elements-foods-babies-young-children.

[7] Id.

[8] See, for example, Lee 2018 (Subcommittee Report, n.24), which stated: "[W]e did not evaluate some potentially confounding variables, such as children's school types, school marks, particular learning disability, family's SES, parents' IQ, and other environmental exposure. With regard to SES, which have been considered as a potential confounder of the association between lead exposure and children's neurodevelopment in early studies. Failure to control for the aforementioned factors was a major limitation of the study." Min-Jing Lee et al., Heavy Metals' Effect on Susceptibility to Attention-Deficit/Hyperactivity Disorder: Implication of Lead, Cadmium, and Antimony, Int'l J. of Envtl. Res. & Pub. Health, 8 (June 10, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6025252/pdf/ijerph-15-01221.pdf. Mazumdar 2011 (Subcommittee Report, n.19) stated: "Our study has a number of important limitations, the most important of which is its small sample size. The small numbers of subjects limited our ability to perform multivariate analysis and evaluate the effect of important potential confounders or interactions." Maitreyi Mazumdar et al., Low-Level Environmental Lead Exposure in Childhood and Adult Intellectual Function: a Follow-Up Study, Envtl. Health, 6 (March 30, 2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3072933/pdf/1476-069X-10-24.pdf. Signes-Pastor 2019 (Subcommittee Report, n.13) stated:"[M]ultiple testing could have led to false positive results, and therefore our finding should be interpreted with caution and be explored if they persist in further follow-up assessments." Antonio J. Signes-Pastor et al., Inorganic Arsenic Exposure and Neuropsychological Development of Children of 4-5 Years of Age Living in Spain, Envtl. Res., 11 (July 2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6541502/pdf/nihms-1528797.pdf.

[9] See, for example, Karagas 2012 and Jacobson 2015, (Subcommittee Report, n.26 & 27, respectively). The report failed to reference the statements from these articles related to postnatal exposure which are inconsistent with the report's findings. Jacobson 2015 noted: "In contrast with the prenatal exposures, none of the postnatal exposures, measured in terms of the child's current body burden, were significantly associated with IQ." Joseph L. Jacobson et al., Relation of Prenatal Methylmercury Exposure from Environmental Sources to Childhood IQ, Envtl. Health Perspectives, 831 (Aug. 1, 2015), https://ehp.niehs.nih.gov/doi/pdf/10.1289/ehp.1408554. Karagas 2012 stated: "Even with adjustment for fish consumption or related nutritional measures, associations of postnatal mercury exposure with neurodevelopment have been inconsistent." Margaret R. Karagas et al., Evidence on the Human Health Effects of Low-Level Methylmercury Exposure, Envtl. Health Perspectives, 802 (June 1, 2012), https://ehp.niehs.nih.gov/doi/pdf/10.1289/ehp.1104494.

[10] See, for example, Donzelli 2019 (Subcommittee Report, n.20) stated: "The searches may have failed to retrieve all the relevant publications concerning the association between ADHD and lead owing to the fact that the field of analysis was restricted to studies published in English available through the Pub Med and EMBASE databases. This review, like any other review about observational data, may suffer biases related to the publicity of the studies since it is believed that studies with significant positive results are more widely distributed than those without significant results or with negative ones." Gabriele Donzelli et al., The Association Between Lead and Attention-Deficit/Hyperactivity Disorder: a Systematic Review, Int'l J. of Envtl. Res. & Pub. Health, 10 (Jan. 29, 2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6388268/.

[11] See, for example, Lee 2018 (Subcommittee Report, n.24), Signes-Pastor 2019 (Subcommittee Report, n.13), and Wasserman 2014 (Subcommittee Report, n.12). Signes-Pastor 2019 stated: "Our results should be interpreted cautiously given the cross-sectional design of the study that precludes us from determining temporality and thus limits any inferences about causality." Signes-Pastor et al., supra

note vii at 10. Lee 2018 discussed that the cross-sectional nature of the study was "not sufficient to establish a definite causal relationship." Lee et al., supra note vii at 8. The subcommittee report did not employ such caution in its analyses.

[12] See, for example, Subcommittee Report, n.6, incorrectly referenced Bellanger 2013, which evaluated the economic benefits of methylmercury exposure control in Europe, and does not provide support for the report's statement about the decreased lifetime earning capacity in U.S. dollars.

[13] Closer to Zero: Action Plan for Baby Foods, FDA, https://www.fda.gov/food/metals-and-your-food/closer-zero-action-plan-baby-foods (last updated April 8, 2021).

[14] Fed. R. Civ. P. 23(a).

[15] In re McCormick & Co. Inc. Pepper Prods. Mktg. & Sales Practices Litig., 422 F. Supp. 3d 194, 222-223 (D.D.C. 2019), lv denied, No. 19-8003, 2019 WL 7602224 (D.C. Cir. Sept. 20, 2019). See also In re Lorazepam & Clorazepate Antitrust Litig., 289 F.3d 98, 106 (D.C. Cir. 2002).

[16] Fed. R. Civ. P. 23(b).

[17] See Complaint, Albano v. Hain Celestial Group Inc., No. 21-CV- 01118 (E.D.N.Y. March 2, 2021) ("Albano Complaint").

[18] As an example, the Albano Complaint, at 2, para. 1 alleges that the products at issue include:

- Hain's Earth's Best Whole Grain Rice Cereal, Whole Grain Oatmeal Cereal and Sweet Potatoes Organic Baby Food;
- Beech-Nut's Rice Single Grain Baby Cereal, Classic Sweet Potatoes, Naturals Just Sweet Potatoes and Classic Mixed Vegetables;
- Gerber's Puffs, Lil'Crunchies and Yogurt Melts; and
- Nurture's Happy Family Organic's HappyBABY Puffs, HappyBABY Rice Cakes, HappyBABY Creamies, HappyBABY Teethers and HappyBABY Yogis.

For each company, the Albano Complaint alleges multiple different "harmful" ingredients, at different doses that are not even consistent within the same product. For example, regarding the Hain products, the Albano Complaint only indicates that some of the ingredients in some of the products contained some of the heavy metals identified in the subcommittee report as dangerous. It does not indicate which particular products contain which heavy metals, at what dose and which of the Hain products the class representatives actually purchased. Albano Complaint at paras. 61-69.

[19] As the panel noted in its order from June 7, 2021, "each defendant manufactures, markets, and distributes its own baby food products subject to different manufacturing processes, suppliers, and quality control procedures. The claims against each defendant thus are likely to rise or fall on facts specific to that defendant, such as the amount of heavy metals in its products, the results of its internal testing, if any, and its marketing strategies." See Order Denying Transfer at 2, In re Baby Food Mktg., Sales and Pracs. and Prods. Liab. Litig.

[20] Subcommittee Report, supra note iii, at 33-47.

[21] Albano Complaint at 35, para. 134(f).

[22] Wal-Mart Stores Inc. v. Dukes, 564 U.S. 338, 360-65 (2011).

[23] Id.

[24] Albano Complaint at 36-40, paras. 141-171.

[25] Koch v. Acker, Merrall & Condit Co., 18 N.Y.3d 940, 941 (2012).

[26] Orlander v. Staples Inc., 802 F.3d 289, 300 (2d Cir. 2015) (quoting Cohen v. JP Morgan Chase & Co., 498 F.3d 111, 126 (2d Cir. 2007)).

[27] Fink v. Time Warner Cable, 714 F.3d 739, 741 (2d Cir. 2013). See also Brumfield v. Trader Joe's Co., No. 17 Civ. 3239, slip op. at 4 (S.D.N.Y. Aug. 30, 2018).

[28] Albano Complaint at 5-7, paras 19-22.

[29] See, for example, Segovia v. Vitamin Shoppe Inc., No. 14 Civ. 7061,2017 WL 6398747, at *5 (S.D.N.Y. Dec. 12, 2017).

[30] For example, defendants may also argue that the class is not ascertainable. In re Petrobras Sec., 862 F.3d 250, 267 (2d Cir. 2017).