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BLOG

A Recipe for Exclusion: Why the Baby Food MDL Experts Failed Under *Daubert*

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In a high-stakes decision on expert exclusion authored late last month, the District Court for the Northern District of California granted defendants' motion to exclude plaintiffs' general causation expert witnesses in *In re Baby Food Products Liability Litigation*—a consolidated mass tort of over 100 pending cases regarding the alleged presence of toxic heavy metals in baby food.[1] Plaintiffs alleged that children consuming baby food allegedly contaminated with heavy metals causally led to an increase in two neurological disorders: autism spectrum disorder (ASD) and attention-deficit/hyperactivity disorder (ADHD).[2]

Defendants moved to exclude plaintiffs' general causation experts under Federal Rule of Evidence (FRE) 702. Under FRE 702, a court considers "whether the expert testimony's proponent has established, by a preponderance of the evidence, the testimony is admissible based on several factors, including 'whether the theory or technique employed by the expert is generally accepted in the scientific community; whether it's been subjected to peer review and publication; whether it can be and has been tested; and whether the known or potential rate of error is acceptable.'"[3] As to general causation, "the relevant inquiry is whether exposure to a substance for which a defendant is responsible, . . . at the level of exposure alleged by plaintiffs, is capable of causing a particular injury or condition in the general population."[4] And so, the court required plaintiffs to establish a causal relationship between their "injuries and the alleged toxic heavy metals in baby food, at levels people realistically may have experienced."[5]

As the court explained in a 43-page decision, plaintiffs failed to do so. The court took issue with plaintiffs' experts' (I) reliance on an attorney-driven exposure methodology; (II) usage of epidemiological studies that did not solely examine the product at issue; and (III) reliance on epidemiological studies with exposure and endpoints different from plaintiffs' allegations.

I. RELIANCE ON ATTORNEY-DRIVEN EXPOSURE METHODOLOGY CREATED A HOUSE OF CARDS

At the heart of the court's decision was a fundamental reliability problem: The exposure methodology that undergirded plaintiffs' entire general causation case was driven not by the experts but by attorneys.[6]

Plaintiffs named two exposure experts to establish general causation: The first, a dietitian, relied on hypothetical menus estimating baby food consumption patterns for children ages 0 to 3 to establish the amount of lead and arsenic consumption that an infant would incur in its daily diet.[7] The court found these menus unreliable because

plaintiffs' expert had not constructed any of them herself; rather, she was given the hypothetical menus by plaintiffs' counsel and then performed her consumption analysis.[8] Because her report did not address the basis for the assumptions baked into those consumption patterns or offer any explanation of how plaintiffs' counsel selected the products for the hypothetical menus, there was no way for the court to "assess the validity of that data, the method used to prepare it, or potential sources of bias in developing the consumption patterns."[9] Nor did plaintiffs' expert ever opine that the hypothetical menus were in any way representative of plaintiffs in the MDL.[10] For these reasons, the court characterized the menus as a "black box," concluding it was "just as likely, if not more likely, counsel cherry-picked the products for their higher lead or arsenic content as it is counsel [who] selected them based on any child's actual diet."[11] The court thus found that the expert's report "functions as an ex-post analysis to justify its plausibility," rendering her proffered opinions "unduly results-driven."[12]

The court also found the expert's report, which assumed that a consumption pattern is plausible so long as it applies to at least one child in the United States, a "poor fit" with the general causation standard requiring evidence of causation from exposure at a "level people realistically may have experienced."[13] For example, one of her hypothetical menus had a single product in one food group, which was a product manufactured by defendants, so, as the court noted, a child would be expected to consume this one product every day for a number of years.[14] Such a menu, although possible, was not realistic, and thus not able to establish a typical consumption pattern for young children.[15]

The same flaw doomed the opinions of plaintiffs' other exposure expert because she used the same hypothetical menus, along with defendants' heavy metal-testing results, to calculate daily intake of arsenic and lead for children.[16] While the court acknowledged that plaintiffs' second exposure expert had employed a reliable exposure assessment method endorsed by the EPA (even though she issued two amended reports to fix errors in her exposure calculation), her exposure analysis was rendered unreliable by relying on the hypothetical menu and consumption patterns set forth in the first expert's report.[17] The court held that an expert cannot "blindly accept data without assessing its reliability prior to incorporating it into her analysis."[18]

The exclusion of the exposure experts' opinions had cascading consequences for plaintiffs' remaining general causation case. Plaintiffs' five epidemiology and two toxicology experts each relied on the second exposure expert's lead and arsenic exposure calculations to form their general causation opinions.

II. EPIDEMIOLOGICAL STUDIES DID NOT EXAMINE THE PRODUCT AT ISSUE

Each of plaintiffs' five epidemiology and toxicology experts relied on plaintiffs' exposure experts' lead and arsenic exposure calculations and blood-lead estimates to form their causation opinions.[19] The court noted that this exposure data provided an "unreliable foundation" for the experts' general causation opinions about defendants' baby food products.[20] To overcome this failure, plaintiffs argued that "an exposure estimate is ultimately unnecessary" and contended that other court decisions established that definition of the precise "human-relevant dose" was not required to prove general causation.[21]

The court rejected plaintiffs' position and noted that plaintiffs' legal authority involved a substance that was "not a naturally occurring substance," and so epidemiological studies on the effect of that substance "were *necessarily* studies of the defendant's product at a 'human-relevant dose.'"[22] Conversely, lead and arsenic, the agents at issue in the baby food litigation, "are ubiquitous in the environment," and as a result, the court reasoned that epidemiological studies simply measuring lead's or arsenic's association with the development of ASD and ADHD "are not necessarily studies of defendants' products."[23] Indeed, none of the epidemiological studies specifically assessed whether consumption of baby food was associated with the development of ASD or ADHD.[24] Because general lead or arsenic exposure from the environment is not analogous to the specific levels of exposure from defendants' baby food, the court reasoned that these epidemiological studies could not establish a realistic estimated dose. And without a realistic general dose, the court found that these epidemiology studies did not properly fit the allegations in the litigation.[25]

III. EPIDEMIOLOGY STUDIES FAILED TO STUDY THE PROPER EXPOSURE PERIOD AND ENDPOINTS

The court further took issue with the analysis conducted by plaintiffs' epidemiology and toxicology experts, identifying an insurmountable "*Joiner* problem." Specifically, the court found that there was "simply too great an analytical gap" between the exposure and injuries in the epidemiological studies plaintiffs' experts cited and the alleged exposure and injuries in the present litigation.[26] The court specifically identified two fundamental defects in plaintiffs' epidemiological studies: First, they studied prenatal exposure instead of postnatal food consumption, and second, they studied autistic behaviors as an endpoint rather than plaintiffs' alleged injury of diagnosed ASD or ADHD.

Regarding the route of exposure issue, plaintiffs' experts relied on epidemiological studies analyzing prenatal exposures to heavy metals rather than the postnatal exposure alleged in the litigation.[27] Plaintiffs' experts also did not explain how studies assessing prenatal exposures were relevant to the question of whether postnatal exposures could cause the alleged injuries. The court noted that plaintiffs' experts failed to address the differences between the in utero environment and postnatal ingestion of lead through baby food. The court also observed that they failed to " articulate the overlap between neurodevelopment *in utero* and postnatally to justify a conclusion that the effect of lead on a fetus is the same as its effect on a child between the ages of 4 months and 3 years old."[28]

Regarding the endpoint issue, plaintiffs' experts relied on studies measuring an increase in autistic behaviors rather than diagnosed ASD.[29] The court noted that "[w]hile assessing gradations in behaviors can be useful clinically, this is a court of law, not a doctor's office or research lab," and to meet the general causation burden, plaintiffs must "present[] reliable expert evidence to show defendants' products can cause ASD, not merely autistic behaviors."[30] The court similarly shut down the studies plaintiffs' experts cited as "critical support" because the study authors had not found a statistically significant association between the alleged agent and injury. Relying on these mismatched findings was "too far a leap to satisfy Rule 702" as the "finding did not apply to the relevant outcome in this MDL—a diagnosis of ASD."[31]

Plaintiffs' epidemiology experts also applied a Bradford Hill analysis to assess causation that proved fatally flawed. The court observed that with respect to the Bradford Hill criteria, "there is no formula or algorithm that can be used to assess whether a causal inference is appropriate," but the temporality criterion "must exist to establish causation."[32] Addressing each of plaintiffs' "key studies" in turn, the court found that none established a statistically significant association between heavy metal exposure during the relevant postnatal period and an actual diagnosis of ASD or ADHD. Because the underlying studies failed to properly align with the plaintiffs' allegations, the experts could not satisfy this mandatory temporality requirement, rendering their Bradford Hill analysis unreliable.[33]

KEY TAKEAWAYS

Expert methodology must be driven by experts, not attorneys. The court's decision underscores that while attorneys may supply case-specific data to experts, the expert must independently apply a reliable scientific method. When a core analytical framework is created by counsel and handed to the expert wholesale, the methodology becomes an impermissible "black box." Experts who blindly adopt these frameworks render their opinions "unduly results-driven" and highly vulnerable to exclusion.

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[1] The court denied defendants' motion to exclude plaintiffs' biological plausibility expert, who did not offer a general causation opinion.

[2] *In re Baby Food Prods. Liab. Litig.*, 2025 WL 986959, at 1 (N.D. Cal. Apr. 2, 2025).

[3] *In re Baby Food Prods. Liab. Litig.*, 2026 WL 559857, at 2 (N.D. Cal. Feb. 27, 2026) (citing *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995)).

[4] *Id.*

[5] *Id.* (citation omitted).

[6] *Id.* at 16–21.

[7] *Id.* at 13–14.

[8] *Id.* at 16.

[9] *Id.* at 17.

[10] *Id.* at 20.

[11] *Id.*

[12] *Id.* at 21.

[13] *Id.* at 17.

[14] *Id.* at 18.

[15] *Id.* at 17–18.

[16] *Id.* at 21–22.

[17] *Id.* at 23–24.

[18] *Id.* at 23.

[19] *Id.* at 16.

[20] *Id.* at 17.

[21] *Id.*

[22] *Id.*

[23] *Id.*

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

[25] *Id.* at 18.

[26] *Id.* at 19.

[27] *Id.*

[28] *Id.* at 20.

[29] *Id.*

[30] *Id.* at 21.

[31] *Id.*

[32] *Id*. at 19.

[33] *Id*. at 21.

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Authors

Rand Brothers

John Drosick

Savannah L. Murin

Courtney Block

Mason Alexander Davenport

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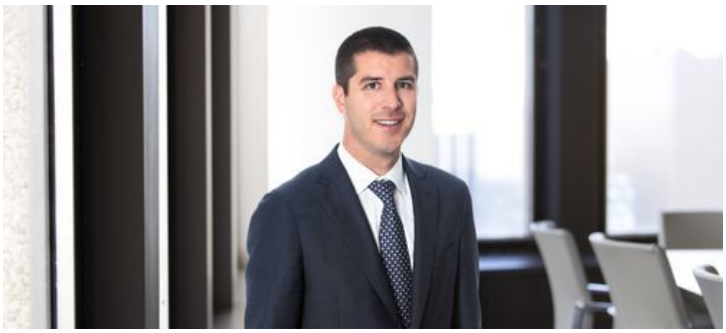

John Drosick

Savannah L. Murin

Courtney Block

Mason Alexander Davenport

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