UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE: BABY FOOD PRODUCTS LIABILITY LITIGATION	Case No. 24-MD-3101-JSC MDL 3101 Hon. Jacqueline Scott Corley
This document relates to: ALL ACTIONS	**JOINT STATEMENT PURSUANT TO PRETRIAL ORDER NO. 1** Date: May 16, 2024 Time: 11:00 a.m. PT Location: Courtroom 8 19th Floor 450 Golden Gate Ave. San Francisco, CA 94102

Pursuant to Pretrial Order No. 1 (ECF No. 2), the Parties submit this Joint Statement.

I. LITIGATION BACKGROUND AND STATUS OF CASES

As the Court has reviewed the parties' submissions to the JPML, the parties will only briefly address the background of the litigation and status of the current cases.

As explained by the JPML, "Plaintiffs in each action, who are minors, allege they were exposed to elevated quantities of toxic heavy metals (namely, arsenic, lead, cadmium, and mercury) from consuming Defendants' baby food products and, as a result, suffered brain injury that manifested in diagnoses of autism spectrum disorder (ASD) and/or attention deficit

hyperactivity disorder (ADHD)." *In re Baby Food Mktg., Sales Pracs. & Prod. Liab. Litig. (No. II)*, No. MDL 3101, 2024 WL 1597351, at *1 (J.P.M.L. Apr. 11, 2024). Plaintiffs allege that, due to the susceptibility of an infant's developing brain, certain ingredients and additives used in Defendants' baby food products, e.g., arsenic-containing rice or lead-containing sweet potatoes, caused babies to be exposed to unsafe levels of toxic heavy metals which, in turn, led to a brain injury that, ultimately, led to a diagnosis of ASD and/or ADHD.

Defendants Beech-Nut Nutrition Company ("Beech-Nut"), Gerber Products Company ("Gerber"), The Hain Celestial Group, Inc. ("Hain"), Nurture, LLC (formerly Nurture, Inc.) ("Nurture"), Plum, PBC ("Plum"), Sprout Foods, Inc. ("Sprout"), and Walmart Inc. ("Walmart")[1] manufacture or sell baby food products, including pureed food sold in jars and pouches, rice and yogurt-based snacks and cereals, and other baby, infant, and toddler food products. Defendants contend that trace levels of arsenic, lead, and mercury enter the fruits, vegetables, and grains that are used in their products and enter the food supply generally through the air, water, and soil in which those ingredients are grown. Defendants dispute that these trace levels of heavy metals are capable of causing ASD and/or ADHD, that ASD and/or ADHD are "brain injuries," or that Defendants' foods had any connection to Plaintiffs' conditions. Defendants maintain and the available scientific literature confirms that ASD and/or ADHD are fundamentally genetic in nature and are not caused by a child's consumption of fruits, vegetables and grains.

A. Cases Before This Court and Pending Motions

Twenty-three cases, identified in the table below, have been transferred to this Court as part of this MDL. At the time of transfer, fact discovery had commenced in three cases, and motions to dismiss the plaintiffs' complaints were pending in seven cases; no motions practice or

[1] Nestlé S.A., Danone S.A., and Campbell Soup Company are also named as defendants in a small number of cases, although they have not all been served in each of them. Each has moved to dismiss in those cases based on lack of personal jurisdiction or other grounds or expects to do so at the appropriate time. Further, Whole Foods Market Services, Inc. ("Whole Foods") and Amazon.com Services LLC ("Amazon") are named as retailer defendants in the *Watkins v. Nurture LLC et al.* case, which the JPML ordered to be transferred to this MDL on April 26, 2024.

discovery has occurred in the remaining thirteen cases.[2]

Case	***Case No.***	***Transferee District***	***Pending Motions[3]***
Watkins v. Nurture LLC et al.	2:22cv551	E.D. La.	• Defendants' Motion to Dismiss Plaintiff's Punitive Damages Claim for Failure to State a Claim • Defendants Whole Foods and Amazon's Motion to Dismiss for Failure to State a Claim • Defendants' Motion for Science Day • Plaintiff's Motion to Compel Supplemental Interrogatory Response by Nurture and Additional Time for Nurture 30(b)(6) Deposition • Defendants' Motion to Compel Plaintiff to Provide Records Authorizations
P.A. v. The Hain Celestial Group, Inc. et al.	1:24cv8	D. Haw.	• Defendants' Motion to Compel Further Responses to Interrogatories and Requests for Production
A.A. et al. v. The Hain Celestial Group, Inc. et al.	3:23cv6087	N.D. Cal.	• Defendants' Motion to Dismiss Plaintiffs' Complaint for Lack of Standing and Failure to State a Claim*
M.H. v. The Hain Celestial Group, Inc. et al.	8:23cv2203	C.D. Cal.	• Defendants' Motion to Dismiss Plaintiff's Complaint for Lack of Standing and Failure to State a Claim*
D.S. v. The Hain Celestial Group, Inc. et al.	2:23cv10193	C.D. Cal.	• Defendants' Motion to Dismiss Plaintiff's Complaint for Lack of Standing and Failure to State a Claim*
Clark v. The Hain Celestial Group, Inc. et al.	2:23cv2607	D. Ariz.	• Defendants' Motion to Dismiss Plaintiff's Complaint for Lack of Standing and Failure to State a Claim*
Mosley v. The Hain Celestial Group, Inc. et al.	3:23cv6176	W.D. Wash.	• Defendants Hain, Nurture, Plum, Beech-Nut, Gerber, and Walmart's Motion to Dismiss Plaintiff's Complaint for Lack of Standing and Failure to State a Claim* • Defendant Campbell Soup Co.'s Motion to Dismiss Plaintiff's Complaint for

[2] Prior to creation of this MDL, the parties anticipated that the extensive fact discovery that has occurred in the litigation as a whole (specifically in *N.C.* in California state court and by the plaintiff and manufacturing defendants in *Watkins* in the Eastern District of Louisiana) would be reused in other cases. The parties hope to negotiate an agreement to allow the use of prior discovery in this MDL, subject to specific conditions.

[3] Pending motions for *pro hac vice* admission in each case are not included.

			Lack of Standing and Failure to State a Claim* • Defendant Nestlé S.A.'s Motion to Dismiss Plaintiff's Complaint for Lack of Personal Jurisdiction*
V.Z. v. Gerber Prods. Co.	3:23cv6324	N.D. Cal.	• Defendants' Motion to Dismiss Plaintiff's Complaint for Lack of Standing and Failure to State a Claim*
A.T. v. Gerber Prods. Co. et al.	3:23cv6344	N.D. Cal.	• Defendants' Motion to Dismiss Plaintiff's Complaint for Lack of Standing and Failure to State a Claim*
D.M.P. et al. v. Beech-Nut Nutrition Co. et al.	2:23cv344	D. Nev.	• No pending motions
C.G. v. The Hain Celestial Group, Inc. et al.	8:24cv148	C.D. Cal.	• No pending motions
C.L. et al. v. The Hain Celestial Group, Inc. et al.	1:24cv177	D. Del.	• No pending motions
L.C.N. et al. v. The Hain Celestial Group, Inc. et al.	1:24cv317	D. Del.	• No pending motions
J.Z. v. Gerber Prods. Co. et al.	1:24cv2378	N.D. Ill.	• No pending motions
J.S. v. Gerber Prods. Co. et al.	2:24cv2398	C.D. Cal.	• No pending motions
B.B. v. Gerber Prods. Co. et al.	2:24cv2382	C.D. Cal.	• No pending motions
H.N. v. Gerber Prods. Co. et al.	4:23cv942	W.D. Mo.	• No pending motions
N.C. v. Gerber Prods. Co. et al.	5:24cv612	C.D. Cal.	• No pending motions
B.P. v. Beech-Nut Nutrition Co. et al.	2:24cv304	E.D. Cal.	• No pending motions
T.F. v. Gerber Prods. Co. et al.	4:24cv201	W.D. Mo.	• No pending motions
Maglinti et al. v. Beech-Nut Nutrition Co. et al.	2:23cv2121	D. Nev.	• No pending motions
Garcia v. Beech-Nut Nutrition Co. et al.	2:24cv580	D. Nev.	• No pending motions
Z.W. v. Gerber Prods. Co. et al.	1:24cv2379	N.D. Ill.	• No pending motions

*No response or reply has yet been filed.

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B. Pending Cases Not Before This Court

Thirteen baby food products liability cases, identified in the table below, are pending in other jurisdictions. One federal case is on appeal following directed verdict at trial for the defense; three cases are pending in federal district courts, with no motions practice or discovery to date, but have not yet been transferred or related to this Court. One case is pending in Florida state court with written fact discovery underway. One case in California Superior Court has been dismissed and has been subject to entry of judgment, awaiting only a final stipulation on costs. Seven additional cases are pending in California Superior Court, with fact discovery underway in one of them. *Landon R. v. The Hain Celestial Group et al.* (Case N. 23STCV24844) is currently set for trial on January 21, 2025. On May 9, 2024, in response to Plaintiffs' Petition for Coordination seeking a Judicial Council Coordinated Proceeding ("JCCP"), the court stated he would grant the Petition for Coordination of all of the cases pending in California state court as JCCP No. 5317 and recommend assignment to the Honorable Lawrence P. Riff in the California Superior Court for the County of Los Angeles.

Case	***Case No.***	***Court***	***Current Status***
Palmquist et al. v. The Hain Celestial Group, Inc.	23-40197	USCA Fifth Circuit	• Appeal decision pending, following oral argument on February 6, 2024
N.C. v. The Hain Celestial Group, Inc. et al.	21STCV22822	Cal. Super. Ct. (Los Angeles)	• *Sargon* motion to exclude plaintiff causation experts granted as to certain experts on August 24, 2024 • Summary judgment granted for Defendants on September 1, 2024 • Agreement on costs pending
Daye v. Beech-Nut Nutrition Co. et al.	2023-CA-000948-O	Fla. Cir. Ct. (9th Cir. Orange County)	• Written fact discovery in progress • Trial date not yet set
Landon R. v. The Hain Celestial Group et al.	23STCV24844	Cal. Super. Ct. (Los Angeles)	• Discovery in progress • Trial date set for January 21, 2025 • Plaintiff's Motion to Compel Heavy Metal Testing and Formulations from 2010 to Present and Additional Discovery is pending • Coordinated at part of JCCP No. 5317
Pourdanesh v. The	23STCV02484	Cal. Super.	• Coordinated at part of JCCP No.

Hain Celestial Group et al.		Ct. (Los Angeles)	5317 • No pending motions • Stayed until status conference on August 16, 2024
Paul L. v. The Hain Celestial Group et al.	23STCV24710	Cal. Super. Ct. (Los Angeles)	• Coordinated at part of JCCP No. 5317 • No pending motions • Stayed until status conference on August 16, 2024
Josue G. v. The Hain Celestial Group et al.	23STCV29046	Cal. Super. Ct. (Los Angeles)	• Coordinated at part of JCCP No. 5317 • Campbell Soup Company filed a demurrer to dismiss the complaint on April 5, 2024. Plaintiff has not yet responded. • Stayed until status conference on August 16, 2024
Princeton N.C. v. The Hain Celestial Group et al.	23STCV29035	Cal. Super. Ct. (Los Angeles)	• Coordinated at part of JCCP No. 5317 • No pending motions • Stayed until status conference on August 16, 2024
Kaleb R. v. The Hain Celestial Group et al.	235TCV30542	Cal. Super. Ct. (Los Angeles)	• Coordinated at part of JCCP No. 5317 • Campbell Soup Company filed a demurrer to dismiss the complaint on April 5, 2024. Plaintiff has not yet responded. • Stayed until status conference on August 16, 2024
Samuel R. v. The Hain Celestial Group et al.	23CV057126	Cal. Super. Ct. (Alameda)	• Coordinated at part of JCCP No. 5317
O.V. v. The Hain Celestial Group, Inc.	5:24cv1780	N.D. Cal.	• Filed on March 22, 2024 • Notice of Related Case to be filed • No motions practice or discovery to date
D.J. v. The Hain Celestial Group, Inc. et al.	3:24cv1836	N.D. Cal.	• Filed on March 22, 2024 • Notice of Related Case to be filed • No motions practice or discovery to date
A.L. v. Gerber Prods. Co. et al.	1:24cv3141	S.D.N.Y.	• Filed on April 24, 2024 • Notice of Tag-Along Action to be filed with JPML • No motions practice or discovery to date

Two lawsuits alleging claims like Plaintiffs' claims here have reached a merits resolution at the trial court. The Parties disagree about the disposition of those two cases and, thus, provide separate statements regarding each.

Palmquist et al. v. The Hain Celestial Group, Inc.

Plaintiffs: In 2021, a law firm that is not participating in this MDL and does not appear to have any other cases pending in state or federal court, filed *Palmquist et al. v. The Hain Celestial Grp., Inc.* (S.D. Tex., No. 3:21-CV-90), *appeal pending*, No. 23-40197 (5th Cir.). The plaintiff alleged that his exposure to the metals in Hain's baby food products caused "brain injury caused by heavy[-]metals poisoning." *Palmquist v. Hain Celestial Grp., Inc.*, No. 3:21-CV-90, 2022 WL 18143413, at *2 (S.D. Tex. Dec. 28, 2022). Importantly, "the Palmquists never refer to 'autism' in their complaint" and "do not claim that heavy-metal exposure either generally causes autism or specifically caused [plaintiff]'s autism symptoms." *Id.* at *1–2. Thus, when Hain moved to exclude the Palmquists' experts under *Daubert*, claiming that the experts failed to opine that the minor plaintiff's exposure to toxic heavy metals from Hain's baby food products caused his autism, the district court denied the motion "because they attack a claim the Palmquists have not alleged." *Id.* a *2. The Court reasoned that "Hain may not impose a causation burden on the Palmquists that *is wholly unrelated to the injury* for which they seek to hold Hain responsible[.]" *Id.* (emphasis added). Instead, the Court held that the experts provided reliable opinions about the injury alleged, that is, "that heavy-metal exposure causes heavy-metals toxicity, which causes brain injury/decline and—specifically—that [plaintiff]'s consumption of heavy metals in Hain's baby food caused his heavy-metal toxicity and resultant cognitive decline." *Id.* At trial, the Palmquists did not call all their disclosed general causation experts, electing to only present specific causation witnesses. Thus, the jury "heard no testimony from a qualified expert that the ingestion of heavy metals can cause the array of symptoms that [plaintiff] suffers from" and thus left the court "with no evidence of general causation." Trial Tr., *Palmquist et al. v. The Hain Celestial Group, Inc.* (S.D. Tex. Feb. 17, 2023), at 43:25–44:6. And, "[a] failure to offer evidence of general causation is fatal to all of the plaintiffs' claims." *Id.* at 44:15–16. Thus, the district court entered a directed verdict. The case is now on appeal.

Defendants: The *Palmquist* plaintiffs, represented by law firms not involved in this MDL, alleged claims against one baby food manufacturer defendant (Hain). Prior to trial, each party filed Rule 702 motions seeking to exclude certain of the other party's experts. The court denied those motions, allowing the plaintiffs to present to a jury expert witness testimony on causation. At trial, the jury heard from many of the minor plaintiff's treating physicians, who all affirmed his proper diagnoses was autism and no other condition, although the plaintiffs' counsel sought to avoid that label. Although the plaintiffs presented multiple expert witnesses, they did not present any expert evidence connecting the food that the minor plaintiff ingested (i.e., dose) was sufficient to cause the type of neurological condition alleged, whatever its label. After the plaintiff's case in chief concluded, the court directed a verdict for Hain because the plaintiffs did not present sufficient evidence that the food ingested by their minor son was capable of causing the neurological conditions alleged. *Palmquist et al. v. The Hain Celestial Group, Inc.*, No. 3:21-cv-90, ECF No. 190, at 1 (S.D. Tex. Mar. 3, 2023), *appeal pending*, No. 23-40197 (5th Cir.). The court stated: "I do not believe the failure to present any expert evidence on general causation was a failure of lawyering[;] rather, *such general causation is simply not supported by the science*." Trial Tr., *Palmquist et al. v. The Hain Celestial Group, Inc.* (S.D. Tex. Feb. 17, 2023), at 44:7–10 (Ex. 1 to Defendants' J.P.M.L. brief) (emphasis added).

N.C. v. The Hain Celestial Group, Inc. et al.

Plaintiffs: The first personal injury case related to ASD and ADHD was filed in California Superior Court of the County of Los Angeles, *N.C. v. Hain Celestial, et al*. (Case No. 21STCV22822). The matter was assigned to the Hon. Amy D. Hogue. At the first status conference, Defendants claimed that there was no scientific data supporting N.C.'s claim that toxic heavy metal exposure could cause ASD or ADHD. Defendants requested that this issue of general causation be litigated *before any discovery*. N.C. reluctantly agreed. The "general causation" question addressed by the court was "whether heavy metals can cause ASD and ADHD." *N.C. v. Hain Celestial Group, Inc.*, No. 21STCV22822, 2022 WL 21778549, at *2, n.3 (Cal. Super. Ct. May 24, 2022). The court made sure to distinguish this from "specific causation" which would entail examination of "the dosages of heavy metals to which Plaintiff was allegedly exposed, the

time frame when he was allegedly exposed, or whether heavy metals were a substantial factor in causing his disorders." *Id.* After a week-long hearing, replete with opening statements, direct and cross examinations of the plaintiff's and defendants' experts, and closing arguments, the court issued a 60-page detailed order discussing the general causation science at the heart of this lawsuit, and admitting the opinions of the plaintiff's general causation experts in full. *Id.* Judge Hogue, shortly thereafter, retired.

The Hon. Lawrence P. Riff took over the department and the case. He opened discovery and set trial for October 2023 on an expedited basis. Defendants limited discovery in N.C. to the specific products and timeframes applicable to N.C. In matter of months, over fifty depositions were taken of Defendants' employees and about two hundred thousand documents were produced. Before trial, the Defendants again challenged general causation as well as specific causation. The court specifically found, again, that Plaintiff's experts passed general causation, describing them as "stunningly qualified" and "impressive people of science[.]" Hearing Tr., *N.C. v. The Hain Celestial Group, Inc. et al* (Cal. Sup. Ct. Aug. 24, 2023) at 11:22–26, 22:1–24:6. The court however, excluded the plaintiff's specific causation experts for two straightforward reasons. First, in calculating the dose of N.C.'s toxic heavy metals from the Defendants' baby food products, the plaintiff's expert used an incorrect method to deal with testing values represented as "below" (<) values. The expert should have taken half of the detection limit, for example, if the result was <100 ppb, he should have used 50 ppb. However, the expert used the full amount, i.e., 100 ppb, and the court found that method unreliable. And, without that dose calculation, the plaintiff's other experts were not able to rely on that exposure in rendering specific causation opinions. Second, the court believed that the plaintiff's specific causation experts should have considered what, if any, protective effect may be provided by the food's other nutrients against toxic heavy metal exposure. The plaintiff's experts did not believe there was a scientific basis for such an effect—because other nutrients do not cancel out the neurotoxic effects of heavy metal—but the trial court believed the plaintiff's experts should have at least considered and rejected this issue in their reports. Judge Riff invited Plaintiff's counsel to make these corrections in future cases. Thus, the case was dismissed.

Defendants: The *N.C.* plaintiff alleged claims against seven baby food manufacturers and/or sellers who are Defendants in this MDL, and he was represented by the same counsel who represent many of the MDL Plaintiffs. *N.C.* was filed in Los Angeles County Superior Court and, after being deemed complex, assigned to Judge Amy Hogue until her retirement, at which time the case was assigned to Judge Lawrence Riff. Substantial fact and expert discovery took place in this case.

Per the defendants' suggestion to address threshold causation questions early for efficient litigation management, Judge Hogue initially considered the question of whether lead, arsenic, or mercury could theoretically be linked to autism and/or ADHD, irrespective of the dose, method of delivery, or timing of exposure to the trace levels of arsenic, lead, and mercury (i.e., without considering prenatal versus postnatal exposures or exposure within specific postnatal windows when children eat baby food versus at other times). Judge Hogue also did not consider whether the trace heavy metals ingested through consumption of baby food, which also contains nutrients that are both beneficial to infant development and help reduce the absorption of certain metals, could be causally connected to these disorders. After depositions of experts and motion practice, Judge Hogue issued a lengthy ruling finding sufficient under the *Sargon* standard the opinions of the plaintiff's experts that exposure to heavy metals generally — not specific to potential exposure through baby food or during the time period when baby food is eaten — can cause ASD and/or ADHD.

Judge Riff assumed oversight of the case at that point, and the parties proceeded to litigate the case fully. At the conclusion of discovery, the *N.C.* defendants filed *Sargon* motions asking the court to hold that the plaintiff's experts did not reliably opine that heavy metals *in baby food* caused the plaintiff's autism or ADHD. Defendants do not believe Plaintiffs fairly characterize Judge Riff's ruling. In granting the defendants' motions, Judge Riff excluded the opinions of the plaintiff's causation experts on two independent grounds: (1) no plaintiff expert performed "a general causation analysis" as to heavy metals in baby food specifically; and (2) the plaintiff's experts' method of estimating an individual's actual exposure to heavy metals based on a regulatory risk assessment was unreliable. *See* Hearing Tr., *N.C. v. The Hain Celestial Group,*

Inc., et al. (Cal. Super. Ct. Aug. 24, 2023), at 15:9–16:22, 26:4–28:2 (Ex. 3 to Defendants' J.P.M.L. brief). Judge Riff also granted summary judgment in favor of the defendants because he concluded that the plaintiff failed to provide evidence that any individual defendant's baby foods could have caused the plaintiff's alleged injuries. *See* No. 21STCV22822, 2023 WL 8261722, at *5 (Cal. Super. Ct. Sep. 01, 2023).

II. SUGGESTIONS ON CASE MANAGEMENT

A. Plaintiffs' Position

In one sense, this is a mature litigation. The work the parties did in *N.C.* was critical in identifying the core liability and scientific disputes that lie at the heart of this litigation. However, in another sense, there is still substantial work that needs to be done in discovery and case management so, in the context of an MDL, these cases can be expeditiously worked up through pretrial and trial. In this section, Plaintiffs present their suggestions for case management in four sections: (1) Anticipated Discovery, (2) MDL Scheduling, and (3) Early Pretrial Orders, and (4) Responding to Policy Arguments.

1. Anticipated Discovery

There are three tranches of discovery in this case: Defendant discovery, third-party discovery, and Plaintiff discovery.

Defendant Discovery

- **Limited Scope of Prior Discovery:** Despite sitting for fifty depositions, Defendants refused to allow broad discovery in prior cases—insisting that they will not produce documents or testimony outside narrow time frames and only as it relates to the specific products consumed by a specific plaintiff, i.e., *N.C.* and *Watkins*. Moreover, because the prior cases were worked up on an expedited basis, Plaintiff's counsel did not pursue certain requests, custodians, use advanced ESI collection methods, or conduct certain depositions. Indeed, in *N.C.*, Defendants opposed many depositions from proceeding beyond the tight discovery deadlines, forcing Plaintiff's counsel to forgo certain discovery to avoid delaying trial. Here, in the context of an MDL, with potentially many thousands of cases in the wings,

Plaintiffs intend to pursue broad discovery, covering every baby food product and ingredient for the entire duration those products have been sold in the United States. Doing comprehensive will avoid the confusing patchwork of discovery that has been conducted in prior cases, a Defendants' insistence and give Plaintiffs an opportunity to conduct, one-time, full discovery.

- **Use of Prior Discovery:** The Parties will need to agree on whether discovery conducted in prior cases can be used in this MDL. In the pending *Landon R.* case, Defendants have refused to allow use of prior discovery absent agreements to incorporate prior orders and to forgo future discovery. Plaintiffs will not agree to those terms, either in *Landon R.*, or here in this MDL; there are many new law firms involved in this MDL (which was one of the reasons it was formed) and considering the limits of the prior discovery, Plaintiffs cannot agree to forgo or limit discovery *a priori*, especially when Defendants refuse to unconditionally allow prior discovery's use. That said, Plaintiffs will endeavor to work with Defendants to avoid duplicating discovery to the extent possible. A substantial amount of discovery was conducted in the prior proceedings and to the extent Plaintiffs can avoid duplicating that discovery, Plaintiffs will endeavor to do that.
- **New Defendants:** There are several new Defendants included within this MDL, namely various parent company defendants and/or retailers, for which discovery will be required. Indeed, based on prior discovery, it appears that these parent companies possess considerable documentation related to the core scientific issues in this case. The new Defendants will likely seek dismissal from the case on various grounds, such as jurisdiction, which will need the Court's early adjudication.
- **Metal Discovery:** The most important area of discovery relates to toxic heavy metals. Specifically, Plaintiffs intend to obtain all heavy metal testing on every baby food product and ingredient. This is needed to examine how metals have changed over time and explore whether these Defendants were capable of using

ingredients with no detectable metal levels. It is also highly important for creating a standardized dosing calculation for each Plaintiff relative to each Defendant's baby food products. Plaintiffs will also seek discovery concerning these Defendants communications and actions related to heavy metal in their baby food products and ingredients without limitation on time. This is likely a topic that Defendants will oppose and will need the Court's intervention—indeed, as discussed below, Defendants oppose all discovery on them. Once all metal data is collected, Plaintiffs propose that the Parties work together to create a heavy metal database that each side can use for general causation and specific causation purposes—both sides agreeing on the scope of the testing data, even if each side uses that data differently. Such a database would avoid disputes about "missing results" or authenticity and allow the Parties to wage their "dose disputes" in specific causation on the same playing field.

- **Product Discovery:** Plaintiffs will seek discovery to identify each baby food product these Defendants sold, including when they were sold, where (geographically) those products were distributed, and the precise formulation used in those products during each period. Once that data is collected, Plaintiffs will build a product database that can be used to determine which specific foods were available for consumption for each Plaintiff. This avoids any ambiguity or confusion about product identification. This is likely a topic that Defendants will oppose and will need the Court's intervention. Indeed, a key "strategy" by these Defendants in state court is to insist on each Plaintiff identifying all possible products they consumed and then, when that estimation effort inevitably results in some mistake (because it is exceptionally difficult for a mother or father to recall every specific product and flavor by memory stretching back years), Defendants then argue that the parents are being dishonest. It is a "gotcha" game that not only runs counter to the basic tenets of discovery and transparency, but it serves no probative purpose. Thus, Plaintiffs will attempt to seek discovery and create a

product identification database that specifies which products were sold, when, and where. This database can then be use by all Plaintiffs to accurately respond to discovery concerning product identification.

- **Rule 30(b)(6) and Company Witness Depositions:** As all prior discovery was limited to facts, products, and timeframes of the Plaintiffs, i.e., *N.C.* and *Watkins*, there is still substantial discovery that will need to be done outside of those narrow slivers. And, as such, Plaintiffs will need to retake depositions of Defendants' company witnesses with a complete set of discovery. This will also include taking depositions pursuant to Rule 30(b)(6), as the vast majority of the corporate representative depositions were taken under California law, which Defendants have argued—as recently as this week—does not have the same binding effect as Rule 30(b)(6).
- **Privilege and Confidentiality:** In prior discovery, Defendants aggressively withheld documents and made redactions based on privilege. As the prior litigation was accelerated, challenges to those designations were not feasible. Plaintiffs intend to challenge many of the claimed "privileged" documents and redactions before this Court (or an appointed Magistrate / Discovery Referee / Special Master). Similarly, Defendants designated nearly every document "confidential" or "highly confidential, attorneys' eyes only" in previous cases. Here, Plaintiffs intend to challenge those designations (assuming they are reasserted in this MDL).

Third Party Discovery

- **Co-Manufacturers:** In prior litigation, it was discovered that Defendants do not, directly, manufacture or source many of their baby food products. Instead, Defendants rely on "co-manufacturers" that source, process, pack, and distribute the baby food products using the Defendants brand and product formulation. These Co-Manufacturers were, in some instances, supposedly expected to test for heavy metals in the finished products and/or ingredients. Almost no discovery has been conducted on Co-Manufacturers and Defendants maintain that they do not have

possession, custody, or control of that discovery. During discovery in prior cases, various Defendants claimed that they lacked possession, custody, and/or control over the Co-Manufacturers documents and testing data. In prior discovery, no discovery was effectuated on Co-Manufacturers. Although several subpoenas were served in some of the underlying federal cases before being transferred into this MDL, they were withdrawn or held in abeyance pending the formation and organization of the MDL. Plaintiffs estimate that there are a few dozen third-party Co-Manufacturers that will require substantial discovery. Plaintiffs intend to form a committee within leadership to spearhead the collection of that information and, as appropriate, take relevant depositions of those third parties. The goal would be to conduct discovery on these Co-Manufacturers one time, coordinated between the MDL and various state court cases, to ensure the data and information is available for all Plaintiffs in a centralized database and, where applicable, integrated into the heavy metal testing database.

- **Suppliers and Specific Farms:** Plaintiffs intended to conduct targeted discovery on ingredient suppliers as well. Discovery in earlier litigation indicates that, in certain circumstances, heavy metal testing was relegated to the suppliers directly. Additionally, it appears few suppliers tested the soil of farms where ingredients were grown, leading to the cultivation of certain ingredients with exceptionally high levels of toxic heavy metals. Like the Co-Manufacturers, Defendants have maintained that they do have possession, custody, or control over supplier testing and other documents. Thus, Plaintiffs intend to conduct substantial targeted discovery on suppliers. This data will be integrated into the databases, including the heavy metal testing database discussed above.
- **Other Third Parties:** Plaintiffs also intend to conduct discovery on other third parties that likely have relevant information. This includes stakeholders like Healthy Babies Bright Futures and the Environmental Defense Fund, industry groups like the Baby Food Council, and scientists studying the effects of heavy

metals on neurodevelopment. Plaintiff also may seek discovery from the U.S. Food and Drug Administration.

Plaintiff Discovery

- **Profile Forms:** As is typical in MDLs, Plaintiffs intend to create a form, in conjunction with Defendants, that will be used to collect Plaintiff-specific information, i.e., a Plaintiff Profile Form ("PPF"). The PPF should include essential discovery information, including medical history, injuries, baby food product identification, and consumption patterns. These forms can then be used to help identify bellwether cases for more exhaustive discovery.
- **Medical Records:** Plaintiffs selected as a bellwether trial will provide all medical records in their possession, custody, and control. Additionally, selected Plaintiffs will provide medical record authorizations to allow Defendants to collect additional medical records of the plaintiff they believe is pertinent.
- **Defense Medical Examinations ("DMEs"):** In previous cases, Defendants have insisted on conducting an in-person medical examination of the minor Plaintiff. Plaintiffs maintain that such invasive discovery steps be limited to those Plaintiffs selected as bellwether trial picks. All DMEs should also be subject to a negotiated protocol that will set out the specific limits of any DME.
- **Scope of Discovery:** One of the thornier issues arisen in the prior cases is the scope of Plaintiff discovery as it relates to third party family members. Specifically, Defendants have argued that they are entitled to all medical records of the Plaintiff's parents and siblings, including highly sensitive counseling and mental health notes. This is likely an issue that will need, when the time arises, the Court's input. At a fundamental level, it is unclear how a minor Plaintiff, in pursuing her personal injury claim, can waive or "put at issue" the highly sensitive medical and mental health records of his family members. Those third parties, although related by blood, are not parties to the lawsuit and they have their own important and valid privacy interests in preventing disclosure of the more private

and sensitive of information. Indeed, if one's sibling was able to put one's medical and mental health records at issue, without their consent, it would chill seeking important medical intervention—i.e., the precise interest the privileges are meant to protect. The issue becomes even more complicated in the context of a minor third party. That minor third-party will need to be fully represented by a separate guardian *ad litem* and potentially separate counsel to ensure the privacy interests of that child are protected. At this early stage of this MDL, this issue need not be litigated immediately—but, it should be addressed relatively early as it will guide discovery in bellwether trial picks.

2. MDL Scheduling

An important issue is how to initially schedule the MDL. For example, Plaintiffs believe that monthly in-person Case Management Conferences are key, as well as standardizing procedures for bringing issues to the Court.

Plaintiffs believe that the schedule of this MDL should proceed with the goal of the first bellwether cases proceeding to trial in mid-2025. Within eighteen months, Plaintiffs should be able to complete the Defendant, third-party, and Plaintiff discovery discussed above. Plaintiffs would like to submit a proposed MDL schedule that contemplates this goal, accompanied with a short memorandum in support. Defendants raise a few "sequencing" proposals in their section. They warrant a response.

Determining the Admissibility of Plaintiffs' General Causation Experts' Opinions

There is one "lighting rod" issue that will need to be addressed early, i.e., whether to separate out and litigate the admissibility of Plaintiffs' general causation experts under Fed. R. Evid. 702 and *Daubert* on an expedited basis. This has become the standard position for product liability defendants, and some MDL courts have entertained the approach. Indeed, this is exactly what happened in *N.C.*, where Defendants insisted that before *anything* happened, the admissibility of Plaintiffs' general causation experts be determined. And, after hundreds of hours of expert discovery, hearings, and argument, and hundreds of pages of briefing, Judge Hogue issued a thoughtful and detailed 60-page order. At that point, one would think the issue settled.

Not so. As the *N.C.* case approached trial, Defendants relitigated every aspect of general causation again, and claimed that Judge Hogue's 60-page order was not *really* probative of general causation. Indeed, they claim as much in this Joint Statement. In other words, after insisting that general causation be addressed first, and then losing, Defendants spent the greater part of the next year trying to change the question of general causation to get yet another bite at the apple. It might be a shrewd legal tactic to take after losing. But, it highlights, structurally, the risks of proceeding with a "general causation first" approach without clear guardrails. It also underscores the prejudice caused to a Plaintiff by delay, when all other discovery is stopped while the admissibility of Plaintiffs' general causation experts are resolved.

Plaintiffs do not think, in light of having already done this twice before (once with Judge Hogue and then, again, with Judge Riff) that addressing the admissibility of Plaintiffs' general causation experts needs to be separated out from the traditional timeline of a case proceeding to trial. Rather, it makes more sense to set a bellwether trial process and address both general and specific causation issues through those cases, after fulsome discovery of the Defendants is completed. In other words, this MDL should proceed like any other case would if it were not in an MDL, i.e., fairly.

That said, Plaintiffs are willing to agree to have the admissibility of Plaintiffs' general causation experts adjudicated separately and at an otherwise earlier stage, provided a few important guardrails are put in place:

- **Other Discovery:** Plaintiffs would request that the entire MDL not be put on hold while consideration of Defendants' preferred issue, i.e., the admissibly of Plaintiffs' general causation experts, is addressed. This is what happened in *N.C.*, and it led to considerable delay. There is no reason why, even if early general causation expert discovery is undergone, that all other discovery cannot also, in tandem, proceed. This has been the practice of modern MDLs when they chose to focus, early, on general causation.
- **The Question:** The line between what constitutes general and specific causation is often difficult to nail down—a problem that is acute when issues of dose arise. The

issue boils down to the simple fact the dose that makes a substance toxic for one person does not necessarily make it toxic for another. The famous scene from the Princess Bride ("Battle of Wits")[4], where a dose of poison kills the villain but has no effect on the hero, illustrates this core toxicological concept. Dose makes the poison *depending on the person*. This is why Judge Hogue excluded considerations of dose in addressing general causation — it was an inquiry that fell into the specific causation bucket. Another issue centers on whether "baby food" is part of the question. Plaintiffs do not allege that baby food, generally, causes ASD or ADHD. Baby food is food. Rather, the allegation is that the toxic heavy metals found in Defendants' baby food products—especially ones that have high levels of toxic heavy metal—when consumed, can cause damage to the developing brain of an infant. That damage *can* cause all sorts of issues, from lower IQ, behavioral issues, lower mental acuity, etc. However, in some circumstances, the injury to brain development manifests as ASD and ADHD. So, the question is not whether baby food causes ASD or ADHD. The question is whether the toxic heavy metals a specific Plaintiff consumed from baby food products substantially contributed to or caused brain damage that led to their ASD and/or ADHD diagnosis. And, in the context of general causation, the focus must be on whether toxic heavy metals, at any dose, can cause ASD and/or ADHD; like Judge Hogue explained two years ago: "This Order only addresses Plaintiff's experts on general causation, that is, the issue of whether heavy metals can cause ASD and ADHD." *N.C.*, 2022 WL 21778549, at *2, n.3. The Parties will never agree on this point; even though, conceptually, Plaintiffs should be allowed to proceed on their chosen theory of causation. That said, should the Court want to address the admissibility of Plaintiffs' general causation experts early, then it would likely warrant briefing about how that question is framed.

[4] https://youtu.be/rMz7JBRbmNo

- **Discovery Needed:** Depending on the general causation question, Plaintiffs may need additional discovery from Defendants and, possibly, third parties. Ascertaining what that discovery needs to be is difficult. That said, complete data on toxic heavy metal testing, product identification, and Defendants' internal communications regarding the risks and dangers of heavy metals on neurodevelopment will be required.
- **Binding Effect:** It is only fair, should the Court entertain the resource-intensive process of an early determination of the admissibly of Plaintiffs' general causation experts, that the ruling bind Defendants in each case on file (obviously, the ruling could not bind unfiled cases or unnamed defendants on Due Process grounds). These Defendants should not be allowed to re-challenge general causation again, as the first trial approaches, like they did in *N.C.* To hold otherwise would undermine any value of indulging Defendants' request for an early *Daubert* process.

Plaintiffs believe that the Parties, once leadership is established, should meet and confer and see if they can reach agreement about an MDL scheduling order that can be proposed to the Court. Should agreement not be reached, Plaintiffs propose that the Parties simultaneously submit competing schedules accompanied by a short brief in support. Then, each side should respond and reply to each sides' proposal, and the Court can hear argument at the next Case Management Conference or a specially set hearing date.

Early Pleading Challenges

Plaintiffs believe that ensuring the pleadings are "at issue" is essential. There are two related issues. First, Defendants believe that various complaints filed by Plaintiffs fail to properly plead causation. Indeed, several motions were filed in certain cases before the MDL was formed. Second, certain international Defendants—who have yet to be served—do not believe jurisdiction exists over them in the United States. Plaintiffs agree that these two issues should be addressed early on in this case.

Plaintiffs propose that, within the next thirty days, the Parties negotiate a proposed Pretrial Order that spells out the following, and if they cannot agree, submit competing proposed Pretrial

Orders:

- Allows service of each international Defendant, without waiver of jurisdictional challenges;
- Requires the filing of a "Primary Complaint" that will contain general factual and jurisdictional allegations, causes of action, and other generalized relief against each defendant;
- Requires Plaintiffs to file a Short Form Complaint adopting the Primary Complaint and identifying Plaintiff-specific allegations, including venue, named defendants, and causes of action.
- Provides a briefing schedule / procedure for Defendants to bring pleading and jurisdictional challenges to those complaints.

This approach will give Defendants an opportunity to challenge the pleadings and jurisdiction and ensure these complaints are fully at issue in a coordinate manner.

3. Early Pretrial Orders and Management

Within the next few months, Plaintiffs would like to have the following Pretrial Orders resolved, either by agreement, or by the Court:

- Protective Order
- Privilege Order
- ESI Protocol
- Direct Filing Order
- Primary Complaint and Short Form Complaint Order
- Plaintiff Profile Form Order
- Bellwether Selection and Trial Schedule
- Motions to Remand Protocol
- Docket Control Order
- Common Benefit Order

At the hearing, Plaintiffs will be prepared to address each of these orders and why they will be important to get put in place to help manage this MDL.

4. Responding to Policy Arguments

Below, Defendants attack this case in various ways, couched in a section devoted to "Suggestions on Case Management." Plaintiffs do not believe this is appropriate, or consistent with what the Court asked the Parties to do. That said, it warrants a response.

Defendants claim this litigation poses a danger to public health and compares it to the scare concerning vaccines and autism. *This is complete nonsense*.

Arsenic, lead, cadmium, and mercury are neurotoxins that provide no benefit to humans. They are poisons that specifically target and affect the brain's development. When exposed to the developing brain of an infant—who are uniquely susceptible to the neurotoxic effects of heavy metal—it increases the risk of causing brain damage that, for some, manifests in neurodevelopmental symptoms that doctors diagnose as ASD and ADHD.

Targeted discovery in state court over the past two years reveals a dark truth. Defendants manufactured and sold baby food knowing that certain common ingredients used in those foods contain high levels of toxic heavy metals – and they didn't care. They knew this because Defendants (sometimes) tested it. And, despite repeatedly finding dangerous levels of toxic heavy metal—even when internal and external scientists raised concerns about the effect of these metals on baby brain development—they kept selling it. They did this even though they knew there were alternative ingredients and foods—ingredients used in other foods sold by these Defendants—that did not have any detectable heavy metals in them. In other words, Defendants knowingly poisoned a generation of babies; a generation that has seen an unprecedented rise in ASD and ADHD. When Congress blew the whistle on the true scope of this issue, it noted:

> Baby food manufacturers hold a special position of public trust. Consumers believe that they would not sell products that are unsafe. Consumers also believe that the federal government would not knowingly permit the sale of unsafe baby food. As this staff report reveals, baby food manufacturers and the Trump administration's federal regulators have broken the faith.

Staff Report Subcommittee on Economic and Consumer Policy Committee on Oversight and Reform U.S. House of Representatives, *Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury* (February 4, 2021) at 6.

This is a consequence of a near complete absence of regulatory oversight. Until recently, there was almost no regulation regarding heavy metals in baby food by the U.S. Food and Drug Administration ("FDA"). Prior to this litigation, FDA only regulated lead in fruit juice, lead in candy, and arsenic in rice cereal; *all other baby food were unregulated*. And, in the absence of regulation, left to their own devices, internal documents reveal a near-complete disregard for the safety of the babies—a notion compounded by public-facing claims of their foods being organic and safe for baby development.

In 2021, in response to public outcry, FDA created the "Closer to Zero" program, designed reduce infant exposure to heavy metal contaminants to as close to zero has possible.[5] In January 2023, the FDA issued a draft guidance for lead in baby food.[6] In the draft guidance, the FDA discussed its interim reference level ("IRL") for lead, and explained that "[e]ven though no safe level of lead exposure has yet been identified for children's health, the IRL serves as a useful benchmark in evaluating the potential for adverse effects of dietary lead. In particular, FDA is focused on the potential for neurodevelopmental effects from lead exposure, as review of the scientific literature indicates that such adverse effects of lead consistently occur at a blood lead level associated with FDA's IRL for children."[7]

This litigation does not pose a risk to public heath—the Defendants "organic" and "safe" baby food products containing toxic heavy metals do. This is nothing like the vaccine-autism issued that arose a decade ago. There, the mercury compound contained in the thimerosal vaccine – ethylmercury – is completely different to the organic methylmercury found in food. While ethylmercury is quickly excreted from the body and is generally considered harmless, methylmercury is a known neurotoxin. And, while anti-vax groups used the connection to autism

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[5] https://www.fda.gov/food/environmental-contaminants-food/closer-zero-reducing-childhood-exposure-contaminants-foods

[6] https://www.fda.gov/media/164684/download

[7] The FDA intends to issue a final draft guidance in December 2024. FDA also anticipates issuing draft guidance for arsenic and cadmium in December 2024, with final guidance a year later, in December 2025.

to suggest that parents stop vaccinating their children, here, Plaintiffs are not advocating for babies to stop consuming food. Rather, the demand is very simple. If these Defendants sell food intended for baby consumption, they should make sure it is free of lead, arsenic, mercury, and cadmium, and if unavoidable, parents should be told the truth to make informed decisions about how they want to foster and nurture their child's development.

B. Defendants' Position

It is unfortunate that Plaintiffs' first communication with the Court is laden with invective as to what has transpired in this litigation to date and is at odds with what they have represented to many courts — including the JPML and the presiding judge in the California cases. The undersigned Defendants will not respond in kind or endeavor to itemize each instance of what they respectfully believe to be mischaracterizations, half-truths, or unfair accusations. Defendants will only remind the Court that the most important and overarching truth in this litigation is that there exists not a single scientific paper that purports to find baby food (or any of the healthy ingredients in baby food) are a cause of autism or ADHD. Defendants' submission thus will focus on how best to deliver on the goals of Rule 1. To achieve that goal, Defendants propose that the Court address three threshold issues in parallel at the start of the MDL proceedings: (1) phasing of the consideration of the central general causation question that led to the creation of this MDL; (2) whether Plaintiffs can adequately plead a viable cause of action that delineates the legal liability and responsibility of the individual Defendants; and (3) whether the current and former parent companies named in some of the complaints are proper defendants (including due to lack of personal jurisdiction).

1. Phasing The General Causation Question

Defendants seek a pretrial schedule that frontloads expert general causation discovery and an early briefing schedule and hearing on Defendants' anticipated Rule 702 motion to exclude Plaintiffs' general causation experts. Specifically, Defendants ask that the Court (1) require early designation of experts who will speak to the issue of general causation; (2) set a briefing schedule for a Rule 702 motion directed at exclusion of Plaintiffs' general causation experts; and (3) propose to Judge Riff a coordinated Federal-State joint proceeding to consider the threshold

scientific questions.

Baby food is of course not monolithic, and Defendants in this litigation make hundreds of different foods using scores of fruits, vegetables, and grains. As the Court knows from its review of the JPML pleadings, these fruits, vegetables, and grains take up trace levels of arsenic, lead, and mercury as an unavoidable part of the growing process. While these levels can vary somewhat — and vary by metal and product at issue — there is no evidence that any of these products contains levels of these heavy metals anywhere close to a level that could cause any harm, let alone the unique neurological harm principally alleged here, ASD, alone or co-occurring with ADHD. As such, the central question in this litigation will be whether one or more heavy metals at the levels present in various types of Defendants' baby food products can cause ASD and/or ADHD. This question is common to all cases, and failure to establish that arsenic, lead, and/or mercury present in the foods at issue cause ASD and/or ADHD would be dispositive of all of Plaintiffs' claims. As Plaintiffs themselves put it to the JPML, general causation is "an identical issue that is dispositive for all actions, involving the same underlying body of science." Reply in Support of Pls.' Motion to Transfer, *In re: Baby Food Marketing, Sales Practices, and Products Liability Litigation (No. II)*, ECF No. 35, at 20 (J.P.M.L. Feb. 20, 2024).

For this reason, the Court should adopt a schedule that allows the parties and the Court to address as a threshold motion under Rule 702 pertaining to the key general causation question in this litigation: whether the consumption by children of commercial baby food containing one or more heavy metals at the levels naturally found in commercial baby foods is capable of causing Plaintiffs' injuries, i.e., autism with or without concomitant ADHD. Addressing general causation first will be efficient, regardless of the outcome: if Plaintiffs are unable to establish that one or more of the baby food products made and sold by Defendants are capable of causing Plaintiffs' injuries, the cases will conclude and no further discovery will be necessary — and certainly not the level of drain-the-ocean discovery contemplated in Plaintiffs' submission; on the other hand, if Plaintiffs can establish the admissibility of expert testimony under Rule 702 that meets their burden to establish general causation as to one or more of the metals and products at issue, the case will still have advanced considerably at no cost to the Court or the parties, allowing the

parties to move on to other discovery and legal issues. While Defendants agree that some aspects of the elaborate apparatus Plaintiffs propose above might need to eventually be undertaken, much of the cost of doing so may well be avoided. Not only will phasing general causation discovery and motion practice be efficient for the MDL, but it would also allow the Court to coordinate on this common issue with Judge Riff overseeing JCCP No. 5317 and thus benefit broader litigation as well, as described below. Indeed, in connection with the Federal Rules Committee's consideration of proposed Rule 16.1 relating to MDLs, the judges of the Los Angeles Superior Court complex bench, of which Judge Riff is a part, submitted comments to the Rules Committee extolling the benefits of Federal-State coordination in these situations. *See* Comments on Federal Rule of Civil Procedure 16.1, Submitted by Judges of the Superior Court of the State of California for the County of Los Angeles Assigned to the Complex Civil Litigation Program, *available at* https://www.regulations.gov/comment/USC-RULES-CV-2023-0003-0032.

MDL courts — in this district and elsewhere — frequently order the phasing of the general causation question in these circumstances. *See, e.g.*, *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 3:05-md-01699, ECF No. 1098, at 1–4 (N.D. Cal. Mar. 16, 2007) (Breyer, J.) (order phasing general causation); *In re Incretin Mimetics Prods. Liab. Litig.*, No. 3:13-md-02452, ECF No. 325, at 1 (S.D. Cal. Feb. 18, 2014) (same); *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 2:01-md-01407, ECF No. 340, at 1 (W.D. Wash. Mar. 22, 2002) (same); *In re Viagra/Cialis Prod. Liab. Litig.*, No. 3:16-md-02691, 424 F. Supp. 3d 781, 799 (N.D. Cal. 2020) (Seeborg, C.J.) (granting Rule 702 motion excluding general causation experts after phasing); *In re Acetaminophen Prod. Liab. Litig.*, 1:22-md-3043, 2023 WL 8711617, at *1–2 (S.D.N.Y. Dec. 18, 2023) (same); *In re Nexium (Esomeprazole) Prods. Liab. Litig.*, No. 2:12-ml-2404, ECF No. 89, at 7 (C.D. Cal. Mar. 11, 2013) (phasing discovery to "determine certain potentially dispositive legal issues"); *Avila v. Willits Envl. Remediation Trust*, 633 F.3d 828, 833–34, 839 (9th Cir. 2011) (explaining district court's discretion to phase discovery to address causation and affirming exclusion of general causation expert); *In re Onglyza Prod. Liab. Litig.*, 2022 WL 3050665, at *14 (E.D. Ky. Aug. 2, 2022) (granting summary judgment for lack of general causation after phasing); *In re Mirena IUD Prod. Liab. Litig. (II)*, 982 F.3d 113, 122–24

(2d Cir. 2020) (affirming order excluding general cause experts after phasing).

The Manual for Complex Litigation expressly highlights this option in appropriate cases. Ann. Manual Complex Lit. ("MCL") § 22.634 (4th ed.) ("Issues to be taken up early in the litigation may include . . . whether the facts and expert evidence support a finding that the products or acts in question have the capacity to cause the type of injuries alleged."). Adjudicating the pivotal issue of general causation *before* the parties divert more resources to additional fact discovery unrelated to that gateway issue furthers one of the purposes of multi-district litigation: "promot[ing] the just and efficient conduct of [MDL] actions." 28 U.S.C. § 1407; *see, e.g.*, *Vallejo v. Amgen, Inc.*, No. 14-cv-0050, 2015 WL 13964310, at *1 (D. Neb. Aug. 26, 2015) ("Early resolution of the general causation issue promotes judicial efficiency and prevents the potential waste of the parties' and the Court's resources." (citing MCL § 11.422)); *Giglio v. Monsanto Co.*, No. 15-CV-2279, 2016 WL 4098285, at *1 (S.D. Cal. Aug. 2, 2016) ("Proceeding immediately on all issues would subject the parties to highly extensive discovery that may ultimately be unnecessary if defendant prevails on its *Daubert* motion. Limiting phase one to general causation, on the other hand, will enable the parties and the Court to arrive expeditiously at a potentially dispositive issue that the Court firmly believes can be separated from other liability and damages issues.").

In addition, this Court will be one of the first MDL Courts to apply the new version of Rule 702, which was amended effective December 2023 to clarify the standard that district courts must apply when evaluating the admissibility of expert testimony. As the Committee observed, "[t]he amendment clarifies that the preponderance standard applies to the three reliability-based requirements added [to Rule 702] in 2000 — requirements that many courts have incorrectly determined to be governed by the more permissive Rule 104(b) standard." Fed. R. Evid. 702, advisory committee's note to 2023 amendment. The Committee emphasized that "[j]udicial gatekeeping is essential because just as jurors may be unable, due to lack of specialized knowledge, to evaluate meaningfully the reliability of scientific and other methods underlying expert opinion, jurors may also lack the specialized knowledge to determine whether the conclusions of an expert go beyond what the expert's basis and methodology may reliably

support." *Id.* Given these recent changes to Rule 702 to firmly reestablish how judges must perform their gatekeeping role, this Court should tackle general causation first to ensure that Plaintiffs' experts can meet Rule 702's requirements.

The outcomes of the two baby food products liability cases that have reached a merits resolution underscore the importance of general causation. For example, in the first phase of the *N.C.* matter, Judge Hogue considered the question at the highest level of generality. While the defendants advocated that she consider the general causation question as it relates to baby food and whether food ingested during early childhood can cause autism or ADHD, Judge Hogue ultimately decided to look at the potential impact of any metals exposure at any time and via any method of exposure.[8] Framing the question in this manner (which, as Judge Riff later acknowledged, was over the defendants' objection), the plaintiff's experts were able to avoid any questioning and defer any analysis related to the alleged risk of *baby food* until at a later stage. While Judge Hogue allowed the case to proceed past this initial consideration, at the second stage that was supposed to focus on the alleged risk of baby food, the plaintiff's *general* causation experts never supplemented their opinions to address the key question reserved from their earlier opinions: whether any or all types of commercial baby food products were capable of causing ASD with or without ADHD. Reviewing the plaintiff's experts' causation opinions in *N.C.* at the second *Sargon* hearing, Judge Riff determined that none of the plaintiff's experts did "a general causation analysis of the correct material at issue here, namely, the defendants' baby food products." Hearing Tr., *N.C. v. The Hain Celestial Group, Inc., et al.* (Cal. Super. Ct. Aug. 24, 2023), at 26:4–28:2 (Ex. 3 to Defendants' J.P.M.L. brief). Without this analysis, the plaintiff's specific causation experts "could not properly rule in those products" as the cause of the plaintiff's

[8] *N.C. v. The Hain Celestial Group, Inc., et al.*, No. 21STCV22822, Order Denying Defs.' Mot. in Limine to Exclude Pl.'s Expert Testimony on General Causation, at 3 n.3 (Cal. Super. Ct. May 24, 2022) (Ex. 1 to Plaintiffs' J.P.M.L. opening brief) ("This Order only addresses Plaintiffs experts on general causation, that is, the issue of whether heavy metals can cause ASD and ADHD. As the term implies, general causation is mostly abstracted from specific causation and the specific allegations of this case. This Order does not consider, for example, the dosages of heavy metals to which Plaintiff was allegedly exposed, the time frame when he was allegedly exposed, or whether heavy metals were a substantial factor in causing his disorders.").

injuries, and thus the plaintiff was unable to establish that the defendants' products caused his ASD and ADHD. *Id.* at 27:27–28:2.

Plaintiffs are wrong to suggest (as they did before the JPML) that Judge Riff's *N.C.* ruling pertained only to specific causation. While Judge Riff did not go back and reconsider Judge Hogue's ruling as far as it went, he held that whether *baby food* can cause ASD or ADHD *is* "a general causation analysis" that *someone* in the plaintiff's expert roster must do and that no one did. *See id.* at 27:7–14. This makes sense — general causation is whether "*the product* is capable of causing the harm" alleged. *Monroe v. Zimmer U.S. Inc.*, 766 F. Supp. 2d 1012, 1028 (E.D. Cal. 2011) (emphasis added); *see also In re Hanford Nuclear Rsrv. Litig.*, 292 F.3d 1124, 1133 (9th Cir. 2002). And there is simply no scientific study anywhere that examines baby food as a putative cause of ASD or ADHD and finds the link that the plaintiffs in this case are trying to create.

In *Palmquist*, the trial court initially denied Hain's Rule 702 motion as to the plaintiffs' general causation experts. That decision relied on caselaw and decisional principles that have since been called into question through the new amendments to Rule 702. After actually hearing that evidence at trial, the court directed a verdict in favor of the baby food manufacturer for the failure to provide reliable evidence of general causation.

Moreover, given the extensive record that has already been compiled over the last three years of vigorous litigation, the Court can put in place a prompt schedule to resolve the general causation question. First, the Plaintiffs presumably already have their experts in place and developed. They named a full panoply of general causation experts in the *N.C.* case, and have pressed for a prompt trial in another case in state court (*Landon R.*), where they recently have indicated to Judge Riff that they plan to use essentially the same experts from *N.C.* in the new case. Moreover, Plaintiffs were weeks away from naming experts in the *Watkins* case in the Eastern District of Louisiana, which was transferred and is now pending before this Court.

Second, as Judge Battaglia observed when he first phased the incretin litigation, general causation is a pure science question and typically can be litigated without the need for substantial company-facing discovery. *See, e.g.*, *In re Incretin Mimetics Prods. Liab. Litig.*, No. 13-md-2452,

ECF No. 377, at 2–3 (S.D. Cal. Mar. 25, 2014) ("[G]eneral causation . . . is a matter of science, and therefore, scientific documents and/or scientific evidence frame the universe of contemplated discovery."). In this case, given the substantial discovery that occurred in the cases to date, there is already more than sufficient company-side discovery to inform any tangential relevance issue here, including testing data. As Plaintiffs' counsel stated when pressing for an expedited trial in state court, "98 percent" of the defendant discovery necessary for a future trial is complete. Hearing Tr., *Pourdanesh et al. v. Hain Celestial Group, Inc.*, No. 23stcv03484 (Cal. Super. Ct. Feb 6, 2024), at 14:21–22 (Ex. 11 to Defendants' J.P.M.L. brief). Plaintiffs collected thousands of documents from Defendants about Defendants' baby food products and results of heavy metals testing performed on those products and ingredients over years, and they also have access to extensive independent testing by independent groups like Healthy Babies, Bright Futures. Access to this extensive information has allowed Plaintiffs' counsel to observe on multiple occasions that the vast majority of baby foods are safe, including in argument before the JPML. *See, e.g.*, Hearing Tr., *N.C. v. The Hain Celestial Group, Inc., et al.* (Cal. Super. Ct. June 29, 2023), at 40:2–3 ("By the way, I'd say about 80 percent, 70 percent of their products they sell, perfectly safe."); Hearing Tr., *In re: Baby Food Mktg., Sales Pracs. & Prods. Liab. Litig. No. II* (J.P.M.L. Mar. 28, 2024), at 24:13–14 ("Most baby food is actually safe.").

Addressing general causation first will also allow coordination with related litigation in California state court. Just as in this MDL, general causation will be a critical issue in the JCCP and will be based on the same science and existing company discovery. If this Court takes up general causation at the outset, Defendants would urge that it do so in tandem with the JCCP court by setting up a coordinated expert discovery schedule and a joint Rule 702/*Sargon* motions hearing. The joint MDL-JCCP approach has recently been employed in both the *Onglyza* litigation (Judges Caldwell and Massullo) and the *Incretin* litigation (Judges Battaglia and Highberger).

Finally, the nature of the claims in this MDL warrant promptly addressing the basic, novel tenet of those claims — that commercial baby food consumed by countless babies and young children for decades can cause ASD and ADHD. If this claim is permitted to linger in litigation,

significant public health concerns would arise. Our society has already seen similar misguided efforts to tie autism to unproven theories regarding products such as vaccines and acetaminophen, theories which if allowed to take root can cause broader public health ills.[9] If parents stop feeding their children nutritious baby food out of an unwarranted fear that doing so could lead to autism, the nutritional status of the nation's children will meaningfully suffer (including, ironically, their healthy brain development). The sooner this Court addresses this issue, the better the outcome for children and families throughout the country. Accordingly, Defendants request that the Court adopt a pretrial schedule that frontloads expert general causation discovery and set an early briefing schedule and hearing on Defendants' anticipated Rule 702 motion to exclude Plaintiffs' general causation experts.

2. Evaluating Plaintiffs' Ability to Plead Sufficient Allegations Against Individual Defendants

In parallel with general causation phasing, the Court should address the purely legal question of whether Plaintiffs can adequately plead viable causes of action against individual Defendants. In most of the cases in the MDL and pending elsewhere, Plaintiffs have brought identical claims against *multiple* baby food manufacturers, grouping them together as a collective whole without pleading facts sufficient to show that any one Defendant caused the Plaintiff's injury. Moreover, in virtually all of the complaints that have been filed now before the Court, Plaintiffs have made no effort even to identify the relevant products, or to distinguish between the broad array of products using different ingredients, for different stages of development, and meant to play different roles within total diet, let alone how and which products from which Defendant

[9] *See generally*, Centers for Disease Control, Autism and Vaccines, https://www.cdc.gov/vaccinesafety/concerns/autism.html ("Some people have had concerns that ASD might be linked to the vaccines children receive, but studies have shown that there is no link between receiving vaccines and developing ASD."); *In re Acetaminophen – ASD-ADHD Prods. Liab. Litig.*, 1:22md3043, 2023 WL 8711617, at *16 (S.D.N.Y. Dec. 28, 2023). Plaintiffs' suggestion that the vaccine scare is inapt because it involved a different type of mercury misses the point. The problem is that a scientifically unfounded fear based on the same kind of illogic at issue here (mercury is a neurotoxin, children are exposed to mercury in vaccines and manifest ASD around the time of receiving those vaccines, ergo vaccines explain ASD) can drive dangerous public health outcomes.

led to a Plaintiff's alleged harm.

In several pending cases in the MDL, Defendants have filed motions to dismiss based on this pleading failure. As those motions explain, "[n]otwithstanding that [the] [p]laintiff[s] ha[ve] sued [multiple] distinct companies . . . that produce or sell a wide variety of baby food products using different ingredients, in different recipe combinations, sourced from different suppliers, [the] [p]laintiff[s] fail[] to identify even one product that [they] consumed from any Defendant," instead "group[ing] many different types of products manufactured and sold by those Defendants into one general category of 'Defendants' Baby Food products.'" *E.g.*, Defs.' Mot. to Dismiss, *Mosley v. The Hain Celestial Group, Inc. et al.*, No. 3:23-cv-06176, ECF No. 44, at 9–10 (Feb. 16, 2024); *see, e.g.*, *In re: E. I. Du Pont de Nemours & Co. C-8 Pers. Inj. Litig.*, 87 F.4th 315, 320 (6th Cir. 2023) ("[A] plaintiff cannot sue ten defendants — by lumping them all together in his allegations — when the more particular facts would allow him to proceed against only one. (Much less none.)").

In *N.C.*, lack of any specification as to the purported liability of any one defendant was a *case-dispositive* issue. Judge Riff granted the defendants' motion for summary judgment on that ground, holding that the "plaintiff has no evidence whatever from which a jury could find that *any particular defendant's products*" caused the plaintiff's conditions. *N.C. v. Hain Celestial Group, Inc.*, 2023 WL 8261722, at *5 (alterations and emphasis in original). By the time Judge Riff granted summary judgment, the parties had spent two years on extensive discovery and motions practice, none of which would have been necessary if the plaintiff had been required to reveal from the outset that he had no reliable scientific method for claiming that any individual defendant's baby food product(s) was its own substantial cause of harm — and that all of his opinions were dependent on a theory of aggregate harm, which the law does not allow. That result underscores the importance of tackling this issue up front to effectively manage the litigation.

This issue would, by definition, not be suitable to address through a challenge to a generic Master Complaint, the typical vehicle in an MDL to set forth the legal claims. A Master Complaint would contain allegations common to all Plaintiffs, *see, e.g.*, MCL § 40.52, and thus could not include detail on which of Defendants' products each Plaintiff allegedly consumed,

when, and in what amounts. Accordingly, Defendants propose the Court require Plaintiffs to submit short-form complaints that plead, among other things, sufficient facts to delineate the specific products allegedly consumed and the purported responsibility of the individual Defendants for Plaintiffs' injuries (as well as all other facts necessary to state a *prima facie* case). This Court has discretion to address this fundamental issue early on to avoid unnecessary expenditure of resources should Plaintiffs be unable to resolve it.

This issue is capable of resolution at this stage because the information required to resolve it is entirely within Plaintiffs' control. Plaintiffs are the only parties to the litigation who know which products they consumed, the quantities consumed, and the timing of consumption. Plaintiffs do not need any information from Defendants or third parties to provide more specificity as to which of Defendants' products they allege caused their injuries. If Plaintiffs cannot provide this crucial information — which product(s) from which Defendant(s) caused which injuries and when — then these cases cannot proceed.

3. Determining Whether Parent Company Defendants Are Subject to the Court's Jurisdiction

In addition to phasing general causation and adjudicating whether Plaintiffs can plausibly maintain viable legal claims against the individual Defendants, the Court should address whether certain corporate parent entities of the baby food manufacturer Defendants named in some of the complaints are subject to the Court's jurisdiction. In several cases in the MDL, Plaintiffs have sued certain of the baby food manufacturer Defendants' parent companies: Nestlé S.A., Danone S.A., and Campbell Soup Company. For instance, in the *Mosley* case, prior to centralization, Nestlé S.A. filed a motion to dismiss based on the lack of personal jurisdiction, as it is based in Switzerland with no presence in the United States and is not involved in the day-to-day activities of Gerber, one of hundreds of Nestlé's affiliates worldwide. Nestlé S.A.'s Mot. to Dismiss, *Mosley v. The Hain Celestial Group, Inc. et al.*, No. 3:23-cv-06176, ECF No. 63, at 6–7 (Mar. 28, 2024). Also in *Mosley*, Campbell Soup Company moved to dismiss for lack of standing and failure to state a claim, as the complaint fails to plausibly allege that the plaintiff's injuries are traceable to any Campbell Soup Company product and does not allege that Campbell Soup

Company manufactured or sold baby food products. Campbell Soup Co.'s Mot. to Dismiss, *Mosley v. The Hain Celestial Group, Inc. et al.*, No. 3:23-cv-06176, ECF No. 43, at 2–3 (Feb. 16, 2024). Danone S.A. is a French entity with no operations or presence in the United States, which likewise intends to move to dismiss in *Mosley* for lack of personal jurisdiction. Nestlé S.A.'s and Campbell Soup Company's motions to dismiss are still pending; Danone S.A.'s response deadline was pending at the time the MDL petition was granted. These companies are expected to file similar motions in cases in which they have been named, to the extent they are served.

Defendants ask the Court to establish a prompt briefing schedule for motions to dismiss to address whether the corporate parents of baby food manufacturers belong in this litigation, including threshold issues like personal jurisdiction and standing. Personal jurisdiction and standing should be determined before considering the merits of the case. *See Hilsenrath v. Equity Tr. (Jersey) Ltd.*, No. C 07-3312SW, 2008 WL 728902, at *6 (N.D. Cal. Mar. 17, 2008), *aff'd*, 402 F. App'x 300 (9th Cir. 2010) (personal jurisdiction); *Salsedo v. California Dep't of Transp.*, No. C 04-1715 WHA, 2004 WL 2095700, at *2 (N.D. Cal. Sept. 20, 2004) (standing). Addressing these issues up front will prevent potentially unnecessary use of judicial resources and expenditures by the parties pertaining to Defendants that should not be before this Court for jurisdictional reasons.

III. OTHER PROPOSED CASE MANAGEMENT CONFERENCE AGENDA ITEMS

The Parties propose the Court address the following additional topics at the Initial Case Management Conference:

1) Plaintiffs' leadership;
2) Process and timing of submission of pretrial orders (protective order, privilege order, ESI protocol, direct-filing, short-form / master complaint order);
3) Process and timing of submitting competing MDL scheduling orders;
4) Early disputes warranting Court's resolution:
    - Jurisdictional challenges
    - Pleading challenges
    - Scope and sequence of discovery
    - Coordination with state court litigation

- Additional plaintiff filings
- Information / Science day

Dated: May 10, 2024

Respectfully submitted,

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ATTESTATION OF CONCURRENCE IN FILING

In accordance with the Northern District of California Local Rule 5-1(i)(3), I attest that concurrence in the filing of this document has been obtained from each of the signatories who are listed on the signature page.

Dated: May 10, 2024

WISNER BAUM, LLP

By: *R. Brent Wisner*
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Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on May 10, 2024, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system which will send a notice of electronic filing to all counsel of record registered in the federal CM/ECF system.

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