UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: ABBOTT LABORATORIES, ET AL., PRETERM INFANT NUTRITION PRODUCTS LIABILITY LITIGATION	**MDL NO. 3026** **Master Docket No. 22 C 00071**
This Document Relates to: **All Cases**	**Hon. Rebecca R. Pallmeyer**

MEMORANDUM ORDER

Defendants Abbott Laboratories ("Abbott") and Mead Johnson Nutritional Company ("Mead Johnson") face hundreds of claims filed in courts across the country alleging that their cow's-milk-based infant formula ("CMBF")[1] caused pre-term infants to develop necrotizing enterocolitis ("NEC"), a serious and life-threatening disease for babies who are born too early. On April 8, 2022, the United States Judicial Panel on Multidistrict Litigation issued a transfer order [119] consolidating all actions against Abbott and Mead Johnson (relating to defects in their infant formulas) in this court as MDL No. 3026. The parties have selected four cases to proceed to trial as bellwethers; the first trial (*Mar v. Abbott Lab'y*s, No. 22-cv-00232) is scheduled to begin on May 12, 2025. (*See* Stip. [561].) As part of the consolidated proceedings, Plaintiffs have presented the testimony of two general causation experts—Dr. Jennifer Sucre and Dr. Logan Spector—which purports to establish a causal link between CMBF and an increased risk of NEC in pre-term infants, applicable to all claims in the MDL. As the first bellwether trial approaches,

[1] Throughout the reports and scientific literature at issue in these motions, Defendants' cow's-milk-based products are referred to by different terms and acronyms (including "cow's milk-based formula products (CMBPs)" and "bovine-based nutrition products (BBNP)"). The main distinction between the term CMBF and the terms CMBP and BBNP is that the latter terms include fortifier products *in addition* to ready-to-feed formula products (*see infra* n. 30.) Given the facts of the chosen bellwether cases, however, Plaintiffs are only using Dr. Spector and Dr. Sucre for their conclusions relating to *formula* products. (*See* Pls.' Summ. J. Opp'n [619] at 8.) Thus, for consistency, the court refers to the class of formula products at issue in the pending *Daubert* motions as CMBF.

Defendants jointly move to exclude Dr. Sucre [592] and Dr. Spector's [605] testimony under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). As exclusion of these experts would be fatal to Plaintiffs' claims, Defendants concurrently move for summary judgment [610] for all claims against them in the MDL. For the reasons below, the court denies Defendants' motions to exclude the experts and the related motion for summary judgment.

BACKGROUND

The claims underlying this MDL share a basic factual pattern: an infant is born prematurely, is fed with one of Defendants' CMBFs, and develops NEC shortly after. Plaintiffs claim that this is no coincidence; they proffer two experts providing distinct pathways to concluding that Defendants' CMBF products cause NEC. First, Dr. Spector makes the "epidemiological" case: looking at the *statistical* relationship between CMBF ingestion and NEC in experimental studies to draw a causal connection between them. (*See generally* Spector Rep. [616-23].) Dr. Sucre makes the "mechanistic" case: reviewing studies on the ingredients in CMBF to explain the biological mechanism (i.e. the "how") behind CMBF causing NEC. (*See generally* Sucre Rep. [616-35].)

I. Dr. Spector

A. Qualifications

Dr. Logan Spector is a Professor and Director of the Division of Epidemiology and Clinical Research in the Department of Pediatrics at the University of Minnesota Medical School. (Spector Rep. at 3.) He earned his Ph.D. in Epidemiology from Emory University in 2002 and then joined the University of Minnesota's faculty as a postdoctoral fellow. (*Id.*) He has published some 200 articles in peer-reviewed journals, with his research focused on the causes and outcomes of childhood cancers. (*Id.*) While Dr. Spector has not conducted research on NEC prior to this litigation, he is a generalist in pediatric epidemiology with experience in epidemiological study design and analysis. (*Id.* at 4.)

B. Methodology

In preparation for his report in this case, Dr. Spector performed a "systematic literature review" ("SLR"). (*Id*. at 5.) An SLR is a "well-accepted method" in epidemiology which "calls for the researcher to search for studies relevant to the defined research question using a pre-specified, comprehensive research strategy with pre-specified inclusion and exclusion criteria that are uniformly applied." (*Id*.) Once this defined search is complete, the researcher then conducts "a strong and objective critical appraisal of each identified study" and provides "a quantitative or qualitative summary of the evidence." (*Id*.) As explained in his report, Plaintiffs hired Dr. Spector to conduct an SLR reviewing the relationship, if any, between CMBF[2] and NEC among preterm infants. (*Id*. at 6.)

1. Initial Search

Dr. Spector began his SLR by designating eligible study designs, determining the time-period for the search, and choosing search terms likely to elicit relevant studies. (*Id*. at 6.) First, Dr. Spector limited his search to studies reporting original research on a human population using one of three study designs: randomized clinical trials ("RCT"), cohort studies, and case-control studies. (*Id*.)[3] Next, he limited the period of his search to studies published between 1970 and

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[2] As noted *supra* n. 1, the court uses CMBF to describe the products at issue in this litigation, but it is worth noting that Dr. Spector's report does not make a distinction between formula and fortifier products—his analysis includes studies that compare fortifier products as well as those that compare formula products. But given his testimony that any observed relationship between cow's-milk-products and NEC would be *stronger* for formula products than for fortifier products (*see* Spector Dep. Tr. [616-3] at 147:16–148:24), any conclusion as to the association between cow's-milk-based product (generally) and NEC applies, *a fortiori*, to CMBF.

[3] Dr. Spector describes these three study designs as the "three basic study designs . . . which form a hierarchy of evidence for causality," but does not describe the differences between the different kinds of epidemiological study. (*See id*. at 5.) Such a description can be found in the Reference Manual of Scientific Evidence published by the Federal Judicial Center. *See* Fed. Jud. Ctr., *Reference Manual on Scientific Evidence* 555 (3d. ed. 2011) (hereinafter "RMSE"). In an RCT, study participants are randomly assigned into two groups; one group is exposed to the agent (in this case, that would be CMBF), the other is not. *See* RMSE at

September 2023 (when he initially conducted his search), later supplemented by a search for the period between September 2023 and March 2024. (*Id*.) Finally, Dr. Spector selected a broad range of search terms to provide "a comprehensive universe of eligible literature" and include studies in which NEC may not have been the primary focus. (*Id*.) His selected search terms fell into three categories: population terms ("premature/prematurity," "low birth weight (LBW)," "small for gestational age (SGA)," and "Neonatal Intensive Care Unit (NICU)"); exposure terms ("feed," "feeding," "formula," "fortifier," "cow's milk," "bovine milk," "breast milk," "mother's milk," "total parenteral nutrition or (TPN)," and "Similac or Enfamil"); and outcome terms ("Adverse event(s)," "necrotizing enterocolitis" or "NEC," "neonatal morbidities," or "event-free survival"). (*Id*. at 6–7.)

With these limitations and search terms, Dr. Spector used two software programs ("Endnote" and "Covidence") to query two comprehensive databases of epidemiological research: Ovid MEDLINE and Web of Science. (*Id*. at 7.) The programs searched for every combination of population, exposure, and outcome terms, and detected and deleted any references that were duplicated across multiple searches. (*Id*.) After duplicates were deleted, the search resulted in 5,681 references (i.e. studies) that met the initial search criteria. (*Id*. at 8.)

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555. The study observes the difference in outcomes between the two groups of participants, and any RCT must end (for ethical reasons) the moment researchers have reason to suspect that exposure to the agent is harmful. *Id*. Because an RCT can be closely controlled by the researcher, it is considered the "gold standard" for determining the effect of exposure to an agent and a particular health outcome. *Id*. But because RCTs are not always possible (for instance, where a researcher suspects that exposure may have a negative effect), cohort studies and case-control studies are alternative "observational study designs" that do not actively administer the agent to study participants but observe health outcomes of individuals that have already been exposed. *Id*. at 557–59. In cohort studies, researchers define a study population without regard to the disease status of the individuals (they may or may not have the specific health outcome of interest), researchers then classify the participants into those who have been exposed to the agent, and those who have not, and observe the difference in health outcomes between those subgroups. *Id*. at 557–58. In case-control studies, researchers start with a group of individuals who have a certain health outcome (the "case" group) and then select a group of similarly situated individuals without that health outcome (the "control" group). *Id*. at 559. The researchers then observe incidence of past exposure within the case and control groups to determine whether there is a statistically significant difference. *Id*. at 559–60.

2. Relevance and Full-Text Review

Dr. Spector's next step was to review the titles and abstracts of the manuscripts found by the database searches and exclude any studies that were not relevant to the SLR. (*Id*. at 8.) A manuscript was excluded as irrelevant if, based on the title or abstract, (1) it did not appear to inform the purpose of the review, (2) it was a retrospective review (i.e., did not include original data)[4], or (3) it was an animal or in vitro study. (*Id*.) Dr. Spector was joined in this step by another epidemiologist, Dr. Meaghan Ransom, who separately performed a relevance review using the same relevance criteria. (*Id*.)

Following their independent reviews, Dr. Spector and Dr. Ransom largely agreed on a small resulting number of relevant manuscripts: they initially agreed that 62 manuscripts were relevant, disagreed on the relevance of 84 manuscripts, and agreed that 5,535 manuscripts were not relevant. (*Id*.) The two then met and discussed the 84 manuscripts on which they disagreed and came to a joint decision on whether to include the manuscripts, erring on the side of inclusion. (*Id*.) The result was inclusion of 45 additional manuscripts, bringing the total to 107 that were deemed relevant. Dr. Spector proceeded to a full-text review of those 107 manuscripts. (*Id*. at 9.)

[4] In a supplemental report, Dr. Spector corrects this, stating that he did in fact include retrospective cohort studies (Peng 2022, Sisk 2017, Xiong 2023, and Xu 2020) as well as prospective cohort studies in his analysis. (Supp. Spector Rep. [616-39] at 5 n. 6.)

In the full-text review, Dr. Spector read the content of each manuscript[5] and applied another set of exclusion criteria,[6] removing any manuscripts from the SLR that either (1) did not include relevant data that could be extracted, (2) did not report original data or was presented a re-analysis of previously-published data, (3) did not inform the SLR's intent,[7] (4) was not written in English, or (5) reported unadjusted[8] estimates of association between exposure and the NEC. (*Id.*) Out of the 107 manuscripts reviewed in this step, 47 were excluded for failing to meet these criteria, leaving 60 manuscripts eligible for the next step of Dr. Spector's SLR: data abstraction. (*Id.*)

3. Data Abstraction and Meta-Analysis

From the remaining 60 manuscripts, Dr. Spector abstracted any data or meta-data reflecting the estimate of association[9] between feeding methods and NEC observed in the study.

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[5] In his deposition, Dr. Spector testified that he only read 26 studies (the studies that ultimately met all his inclusion criteria) "in their entirety" prior to writing his report. (*See* Spector Dep. Tr. at 261:2–19.) The court does not read this as a necessary contradiction to the statement in his report that 60 studies were subject to a "full-text" review, as the exclusion criteria in the full-text review would be discernible without reading the manuscript in its entirety (*e.g.* manuscript excluded if written in another language). Rather, this testimony clarifies that Dr. Spector's full-text review did not include reading the full text of each manuscript in its entirety—rather, it involved looking to the text of the manuscript as opposed to the title and abstract for a deeper set of exclusion criteria.

[6] Because Dr. Spector's report does not compare his full-text review to a full-text review performed by Dr. Ransom, the court assumes that Dr. Ransom did not conduct a separate full-text review at this stage.

[7] Dr. Spector does not explain what this exclusion criteria means; the court assumes that it essentially reapplies the exclusion criteria from the relevance review, excluding studies that, based on his full-text review, he concludes do not bear on the relationship between formula and NEC.

[8] In this context, adjustment refers to the modification of the statistical relationship between exposure and disease to account for potential "confounding factors"; that is, possible alternative causes for the disease not accounted for in the study design. *See* RMSE at 596–97.

[9] As Dr. Spector explains, epidemiological studies may report an estimate of association through different mathematic representations: "risk ratio," "risk difference," "hazard ratio," or "odds ratio." (*See* Spector Rep. at 4, 9.) Each of these measures are calculated differently, but represent the same concept: they are a representation of the relative occurrence,

(*Id*. at 10.) In doing so, he observed that many of the remaining manuscripts did not, in fact, report *adjusted* estimates of association between feeding methods and NEC; he excluded these studies. (*Id*. at 11.) Furthermore, because many of the studies involved "mixed feedings" (different cohorts fed with different percentages of formula/fortifier rather than full formula or human-milk diets), Dr. Spector also excluded at this stage any studies for which he could not determine the percentage of the cohorts' diets that were formula. (*Id*. at 10.) This left him with 12 RCT manuscripts and 14 observational study manuscripts (i.e. cohort or case-control studies) that met his eligibility criteria and reported estimates of association between feeding diet and NEC,[10] adjusted for potential confounding factors. (*Id*. at 9.)

Dr. Spector provided the data abstracted from these 26 studies to Dr. Rebecca Betensky,[11] who performed four separate meta-analyses using the data provided: one synthesizing results from all 12 eligible RCT studies, one synthesizing results from 5 of the 12 eligible RCTs that specifically compared CMBF-diets to exclusively human-milk diets supplemented with human-milk-derived products (Prolacta),[12] one synthesizing results from the

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or "relative risk," of the health outcome in the exposed population compared to the unexposed population. (*Id*. at 4–5.)

[10] Importantly, because different studies compared different mixtures of human-milk and CMBF (i.e. one study may have compared a 100% human-diet to a mixture of human-milk and CMBF, while a different study compared a 75%/25% human-milk/CMBF mixture to a 25%/75% human-milk/CMBF mixture) Dr. Spector designated, for each study, the predominantly human-milk cohort and a predominantly cow's-milk cohort. (Spector Rep. at 10.)

[11] Dr. Betensky is a Professor and Chair of the Biostatistics Division of the New York University School of Global Public Health. (Betensky Rep. [616-38] at 51.) She prepared a report explaining her detailed background in biostatistics and her methods in preparing the meta-analysis incorporated into Dr. Spector's report. (*See generally id*.) Defendants have not moved to exclude her report.

[12] Despite its importance to this litigation, the parties' submissions for these motions contain little information about Prolacta and its production/availability. As the studies cited in Dr. Spector's report explain, Prolacta refers to human-milk derived feeding products produced by Prolacta Biosciences. (*See* Defs.' Ex. 13, Embleton 2023 [592-13] at 3.) Prolacta Biosciences produces both a human-milk derived *formula* (that is, "ready-to-feed" replacement for mother's milk) and human-milk derived *fortifier* (product adding nutrients to existing mother's milk supply).

10 eligible cohort studies, and one synthesizing results from the 4 eligible case-control studies. (*See id*. at 14–21.) Dr. Betensky's calculations produced composite relative risk values from each study-design category. From the RCT studies, she computed a relative risk of 1.67 with a 95% confidence interval of 1.22–2.28; in other words, infants exposed to a predominantly cow's-milk formula diet were 67% more likely to develop NEC than infants fed a predominantly human-milk diet.[13] (*Id*. at 15–16.) Because two of the eligible RCT studies (Lucas 1996 and Nogueira-Pileggi 2022) did not specify the NEC observed in the study as Bells Stage 2 or higher (advanced stages of NEC), Dr. Betensky also computed a relative risk value excluding those studies, arriving at a relative risk of 1.60 (increased risk of 60%) with a confidence interval between 1.15–2.21. (*Id*. at 17.) In her meta-analysis of the 5 RCTs that compared predominantly-CMBF diets to human-milk diets containing Prolacta, Dr. Betensky computed a relative risk of 1.89 and a confidence interval between 1.12–3.21. (*Id*.) From 10 eligible cohort studies, Dr. Betensky computed a relative risk of 3.26 with a 95% confidence interval of 2.47–4.31; infants fed predominantly-CMBF diets were 226% more likely to develop NEC. (*Id*. at 19; Spector Redline at 18.) Finally, Dr. Betensky computed an odds ratio[14] of 2.35 from the 4 eligible case-control studies with a 95% confidence

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(*See id*.) As the parties explain elsewhere, Prolacta formula was only made available in September 2014. (*See* Abbott Summ. J. Mem. [49] in No. 22 C 232, at 7 (citing September 2014 Prolacta Press Release, https://www.prolacta.com/en/news/prolact-rtf-100-human-milk-based-premature-infant-formula-for-nicus/ (last accessed April 25, 2025).) Its fortifier appears to have been on the market for "nearly two decades." (Pl.'s Opp'n to Summ. J. [51] in No. 22 C 232 at 11.)

[13] The 95% confidence interval means that this increased risk could be as low as 22% or as high as 128%. (*See* Spector Rep. at 16.) Note that, as discussed *infra*, Dr. Spector admits having accidentally misstated some of the confidence intervals in his original report—writing for example, that a 1.22–2.28 indicates a maximum possible risk of 228% rather than 128%. (*See* Spector Redline [605-8] at 15.) These errors are easy to identify in his report, as he correctly records the confidence interval (e.g. 1.22–2.28) even when misstating the percentages. (*See id*.) Where relevant, the court has supplied the correct percentage value, as noted in Dr. Spector's amended report.

[14] Neither Dr. Spector nor Dr. Betensky explain why only this meta-analysis produces a value in terms of "odds ratio" instead of "relative risk." But as Dr. Betensky explains, when

interval between 1.42–3.87—an increased odds of developing NEC of 135% among the exposed population. (*Id*. at 20; Spector Redline at 19.) Excluding one case-control study that did not specify the level of NEC, the odds ratio increased to 2.74 with a confidence interval of 1.48–5.09. (*Id*. at 21.)

4. Bradford Hill Analysis

In determining whether an observed association between exposure and disease is causal, epidemiologists rely on the nine factors articulated by English epidemiologist Sir Austin Bradford Hill, known as the "Hill criteria" or "Hill factors." (*Id*. at 22); *see also* RMSE at 597–600. These factors include (1) the strength of the association, (2) consistency of the exposure-disease relationship across different studies, (3) specificity of the association (whether the exposure is associated with only one disease or multiple outcomes), (4) the temporal relationship between exposure and disease, (5) "biological gradient," also known as dose-response (the amount of exposure resulting in the incidence of disease), (6) extent to which association has been established by experiment (as opposed to observation), (7) biological plausibility, (8) coherence with knowledge available to the researcher, and (9) analogy to similar causal mechanisms. (*Id*.)[15] The factors are not meant to be mandatory or exhaustive; causation may be found on the basis of several (but not all) factors, and there may be reasons outside the Hill criteria that counsel for or against a causal relationship. (*Id*.); *see* RMSE at 600.

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measuring the risk of low-frequency events like NEC, the calculation of the odds ratio becomes "similar" to the calculation of relative risk. (Betensky Rep. at 39–40.)

[15] The RMSE articulates the nine Hill factors slightly differently: (1) the temporal relationship between exposure and disease, (2) the strength of the observed association, (3) the dose-response relationship (how much exposure is associated with incidence of the disease), (4) replicability of the findings, (5) biological plausibility of causation or coherence with existing knowledge, (6) consideration of alternative explanations, (7) cessation of exposure (whether cessation reduces incidence of disease), (8) specificity of the association, and (9) consistency with other knowledge. RMSE at 600–06. The court does not observe a meaningful difference between the two articulations of the Bradford Hill analysis.

In assessing the associations observed in the collected studies and Dr. Betensky's meta-analysis, Dr. Spector focused on four of the Hill factors: strength, consistency, temporality, and establishment by experiment. Concerning strength, Dr. Spector concluded that the estimated relationship between predominantly CMBF diets and NEC across the RCTs (+60%), cohort studies (+226%), and case control studies (+174%) were strong associations supporting the inference of causation according to "generally accepted epidemiological standards." (*Id.*) As for consistency, Dr. Spector noted that a strong association between CMBF diets and NEC was observed across three different study designs, and further cited Dr. Betensky's quantitative measurement of consistency, known as the I^2 value,[16] which supported a finding of high consistency among the various studies. (*Id.* at 23; *see also* Betensky Rep. at 55–60 (showing I^2 calculations for each meta-analysis).) Next, Dr. Spector noted that the temporality factor of the Bradford Hill analysis was satisfied in each of the studies, as all recorded ingestion of the CMBF before the incidence of NEC. (*Id.*) Finally, Dr. Spector explains that the existence of RCTs—which are designed to minimize bias—establishing an association between CMBF and NEC further supports a finding of causation under the experiment factor of the Bradford Hill analysis. (*Id.* at 25.)

Dr. Spector's report also explains why he did not rely on specificity or dose-response in his analysis. While admitting that a finding of specificity (that is, a one-to-one link between exposure and disease) can be a strong factor in favor of causation, Dr. Spector noted that specificity is not a necessary feature for determining a causal relationship; his literature did not intend to determine an *exclusive* casual association between CMBF and pre-term NEC. (*Id.* at

[16] Neither Dr. Spector nor Dr. Betensky explain this term or how it is calculated, but as the raw data in Dr. Betensky's meta-analyses suggests, the I^2 term is a numerical representation of the "heterogeneity" of the sample (*see* Betensky Rep. at 55)—that is, how different the results of the studies in the meta-analyses are from each other. (*See* RMSE at 243 (explaining heterogeneity as a measurer of variance in a data set).) Low I^2 values mean low heterogeneity in the data sat, or low variance, which Dr. Spector explains is the same as high consistency. (*See* Spector Rep. at 23.)

23.) As for biological gradient, or dose-response, Dr. Spector noted that the studies either did not address dose-response, or did so qualitatively rather than quantitatively (that is, observing greater effects in full-formula diets compared to mixed-feeding diets, but not providing a precise dose of formula at which an association can be observed). (*Id*. at 24.)

Finally, grouping together the plausibility, coherence, and analogy Hill factors, Dr. Spector relied on and incorporated Dr. Sucre's report (described below), which includes a lengthy discussion of the possible biological mechanism of causation between CMBF and NEC. (*See id*. at 25–26.) He accepted Dr. Sucre's conclusions as consistent with his own generalist background in pediatric health. (*Id*.)

5. Conclusion

Based on the results of his SLR, the meta-analysis performed by Dr. Betensky, and his application of the Bradford Hill factors for causation, Dr. Spector "conclude[s] to a reasonable degree of scientific certainty that feeding preterm infants [CMBF] caused NEC compared to feeding [human milk]." (*Id*. at 26–27.)

C. Dr. Spector's Deposition and Amended Report

Dr. Spector's original report was submitted on September 27, 2024, and he was deposed on December 23, 2024. (*See* Supp. Spector Rep. [616-39] at 3; Spector Dep. Tr. [616-3].) During his deposition, Defendants' counsel brought his attention to a number of RCT studies that were not included in the full-text review of his SLR, but appeared to be eligible under his inclusion criteria. (*See* Supp. Spector Rep. at 7–8 (listing 13 studies identified by Defendants and Defendants' experts as missing from his analysis).) After his deposition, Dr. Spector prepared and submitted a supplemental report, offering various explanations for the absence from his SLR of the studies identified by Defendants: he notes the possibility that the Endnote and Covidence programs he used to delete duplicate references had erroneously deleted the 13 additional studies, and that the search terms he selected (while broad) may not have captured the specific terminology in the studies. (*Id*. at 4.) Moreover, he explains that for a vast majority of the allegedly

"missing" studies, they would not have satisfied his inclusion criteria even if he had reviewed them. For six of the identified studies (Gross 1983, Hagelberg 1990, Marseglia 2015, Martins 2009, Mukhopadhyay 2007, Tyson 1983), Dr. Spector determined that none of his outcome terms were contained in the titles or abstracts of the studies, meaning that they would have been excluded in his relevance review. (*See Id*. at 7–8.) Another four of the "missing" studies (Bhat 2003, Gupta 2020, Lucas 1990, Nandakumar 2020) would have been excluded because they had insufficient or unreliable RCT data for abstraction. (*Id*.)

Dr. Spector did identify three RCT studies (Costa 2019, Faerk 2000, Schanler 2005), however, that he did not review in his SLR but would have "likely included," had he reviewed them in his search. (*Id*.) In supplementing his original report, Dr. Spector provided a new series of meta-analyses, again performed by Dr. Betensky, incorporating the studies identified by Defendants and their experts. First, Dr. Spector re-analyzed the RCT studies with the results of the Schanler 2005 study added to the data set: this resulted in a relative risk value of 1.63 (increased from 1.60) with a confidence interval of 1.20–2.20. (*Id*. at 8.)[17] Next, Dr. Spector requested a meta-analysis of *all* 13 allegedly "missing" studies, resulting in a relative risk of 1.81 with a confidence interval of 1.05–3.12. (*Id*. at 10.) Then, Dr. Spector requested a meta-analysis of only the "missing" studies in which the subjects suffered from Bells Stage 2 NEC or higher (Schanler 2005, Gupta 2020, Lucas 1990, Nandakumar 2020, Tyson 1983), which together resulted in a relative risk of 2.29 with confidence interval of 1.10–4.75. (*Id*. at 11.) Dr. Spector then added all the missing studies into a meta-analysis with his existing 12 RCTs, creating two composite relative risk values: one value using only the RCT studies reporting NEC Bells Stage 2 or higher (1.70 with confidence interval of 1.36–2.28), and one combining all studies regardless of the level of NEC reported (1.70 with confidence interval of 1.30–2.23).

[17] Curiously, Dr. Spector did not request a meta-analysis adding only Costa 2019, Faerk 2000, and Schanler 2005 to his existing group of RCT studies. He does not explain why.

Finally, Dr. Spector addressed questions about an RCT, Adhisivam 2019. Dr. Spector had included that study in his RCT meta-analysis but not in the meta-analysis for studies comparing CMBF and Prolacta, as Defendants suggested he should have. (*See id*. at 12–13.) As Dr. Spector explains in the supplemental report, though he initially conceded in his deposition that Adhisivam 2019 should have been included in the Prolacta meta-analysis, a closer review of the study after the deposition (in preparation for the supplemental report) revealed that it did not in fact compare CMBF to diets containing Prolacta[18] and was properly excluded from the Prolacta meta-analysis. (*Id*.) Nonetheless, he requested that Dr. Betensky re-analyze the Prolacta RCTs with Adhisivam 2019 added to the set, finding that the addition resulted in a relative risk of 1.67 with a confidence interval of 1.01–2.77. (*Id*. at 16.)

In sum, incorporating the studies identified by the Defendants in his deposition and in the Defendants' experts' reports did not meaningfully alter the association between CMBF and NEC that Dr. Spector identified in his original report, and his "conclusions remain[ed] unchanged" in his supplemental report. (*Id*. at 17.)

II. Dr. Sucre

A. Qualifications

Dr. Jennifer Sucre is an Associate Professor in both the Mildred Stahlman Division of Neonatology in the Department of Pediatrics at the Vanderbilt University School of Medicine and of Cell and Developmental Biology at Vanderbilt University. (Sucre Rep. [616-35] at 4–5.) She received a B.S. with honors in genetics from the University of Georgia in 2003, her M.D. from Harvard Medical School in 2009, and completed an internship and residency in pediatrics at St. Louis Children's Hospital/Washington University School of Medicine in 2013. (*Id*.) She then completed a fellowship in Neonatal-Perinatal Medicine at UCLA from 2013–16, during which she

[18] As Dr. Spector points out in describing the study in his original report, Adhisivam 2019 compared pasteurized donor human milk fortified with CMBF to unfortified pasteurized donor human milk (not containing Prolacta)—it thus would not inform a comparison between CMBF and Prolacta. (Supp. Spector Rep. at 14.)

also completed a research postdoctoral fellowship at the Eli and Edythe Broad Stem Cell Research Center conducting research in cell and developmental biology. (*Id.*) She is a board-certified pediatrician with a subspecialty board certification in Neonatal-Perinatal Medicine. (*Id.*)

Beyond her professorships, Dr. Sucre is the founding director of Biodevelopmental Origins of Lung Disease (BOLD) Center at Vanderbilt. (*Id.*) Her research focuses on lung development and developmental lung disease in neonatal and perinatal infants. (*Id.* at 5–6.) Dr. Sucre has not conducted research or published a paper relating to NEC. (*See* Sucre Dep. Tr. [614-9] at 19:3–20:22.) She does maintain a clinical neonatology practice, however, and in that practice, Sucre routinely diagnoses and cares for infants diagnosed with or suspected to have NEC. (*Id.* at 5.)

B. Methodology

Dr. Sucre was retained by Plaintiffs to opine as to whether the weight of scientific evidence establishes that CMBF can cause or substantially contribute to the development of NEC in preterm infants. (*Id.* at 3.) In reaching her conclusion, she performed a "Qualitative Assessment" also known as "Weight of the Evidence Analysis." (*Id.* at 6.) In such an analysis, the scientist considers multiple possible hypotheses, and weighs the evidence that supports or refutes each hypothesis before arriving at a conclusion. (*Id.* at 7.) As Dr. Sucre describes it, the generally accepted approach to a qualitative assessment breaks the process down into five steps: (1) framing the question, (2) identifying the relevant publications; (3) assessing the quality of the studies; (4) summarizing the evidence; and (5) interpreting the findings. (*Id.* at 8.)

1. Framing the Question

Dr. Sucre framed the question for her analysis as "does exposure to CMBF cause and/or substantially contribute to the development of NEC?" (*Id.* at 8.)

2. Identifying Relevant Publications

In finding relevant articles for her review, Dr. Sucre queried the National Library of Medicine National Center for Biotechnology Information PubMed Resource ("PubMed"), a database of scientific and medical literature, for peer-reviewed articles studying the causes and

development of NEC. (*Id*. at 7–8.) She conducted a search of PubMed using two search terms, "Necrotizing enterocolitis" and "Formula," generating approximately 1,000 articles for review. (*Id*. at 8.) To simplify her review and isolate the most current research, Dr. Sucre restricted the search to articles published between 2014 and 2024—545 articles in total. (*Id*.) Consistent with accepted practice, Dr. Sucre reviewed additional manuscripts cited as references in those 545 articles, regardless of whether the cited manuscript was published between 2014 and 2024. (*Id*. 8–9.)

3. Assessing the Quality of the Studies

Having collected 545 articles that mention "Necrotizing enterocolitis" and "Formula" and were published between 2014 and 2024, Dr. Sucre proceeded to read the abstract of each article and gave each one a "rating" from 0 to 3. (*Id*. at 9.) She assigned a rating of "0" to papers where the topic was clearly irrelevant (not concerning pre-term infants or CMBF) or the paper was not written in English; "1" was assigned to papers that appeared to be of poor quality due to inadequate controls in the underlying study, inadequate statistical methods, or conclusions not supported by the data provided; "2" was assigned to articles that were relevant but merely reviewed other original research; and "3" was assigned to original research manuscripts whose conclusions appeared to be supported by data and rigorous research techniques. (*Id*.) This rating system informed how thoroughly Dr. Sucre would then examine each article. Articles rated "0" were not subject to further review. For articles rated between "1" and "3," Dr. Sucre did a further review for relevance to her research question. (*Id*.) She performed a more thorough read of all articles rated "2" or "3," reviewing the articles themselves and any references cited for important context or support. (*Id*.) In this section of her assessment, no article out of the 545 was excluded from her review; if an article proved to be irrelevant, it was assigned a "0." (*Id*.) Dr. Sucre's grade for every article she reviewed can be found on a "Grading Table" attached as an exhibit to Plaintiff's response. (*See* Sucre's Grading Table [614-7].)

4. Summarizing and Interpreting the Evidence[19]

The final step in Dr. Sucre's qualitative assessment is her proposed explanation for the way that ingesting CMBF causes NEC in pre-term infants. That explanation relies on articles studying the development of NEC, animal studies testing CMBF *in vivo* on animal subjects, and epidemiological analysis performed by Dr. Spector and Dr. Betensky. (*See generally* Sucre Rep. at 15–39.) Dr. Sucre's detailed report identifies the different stages of NEC (*id*. at 10–12), describes how NEC can result in life-threatening complications and require high-risk surgery (*id*. at 12–14), notes widely accepted clinical associations between NEC and different risk factors like birth weight and feeding (*id*. at 14–15), outlines the benefits and drawbacks of different modes of animal studies (*id.* at 17–23), and explains how malabsorption of macronutrients occurs in the gut (*id*. at 23–24). The report points to crucial differences in the macronutrient makeup between CMBF and human milk (*id*. at 24–29), as well as developmental differences between pre-term and term intestines resulting in lower absorption capacities in pre-term digestive tracts (*id*. at 30–33), and describes a mechanism through which activation of the TLR4, a protein that triggers an inflammatory response when activated, leads to development of NEC (*id*. at 33–36). Without reproducing Dr. Sucre's full report, her account of how CMBF causes NEC follows a straightforward set of principles:

1) CMBF contains complex macronutrients (carbohydrates, proteins, and fats) that differ from the nutrients found in human milk. (*Id*. at 24–29, 37.)
2) Because the preterm infant gut is undeveloped and lacks key enzymes, it is unable to digest these nutrients, resulting in malabsorption of these nutrients in the gut. (*Id*. at 37.)
3) Undigested CMBF nutrients can then remain malabsorbed in the gut, acting as an energy source for bacteria. (*Id*.)

[19] Dr. Sucre's report combines step 4 and 5 of her qualitative assessment into one section. (*See* Sucre Rep. at 10.)

4) Pathogenic bacteria (like *E. coli*) can feed on the malabsorbed nutrients, causing rapid overgrowth of bacteria in the preterm infant's gut. (*Id*.)

5) This process can result in NEC in three different ways: rapid growth of bacteria feeding on the malabsorbed nutrients can itself result in overdistension of the intestines, cell necrosis, or death of the surrounding tissue, leading to NEC; pathogenic bacteria like *E. coli* can proliferate and independently trigger the TLR4 receptor, leading to NEC; and the undigested CMBF nutrients and their byproducts can themselves activate TLR4, leading to NEC. (*Id*. at 38.)

5. Conclusion

Taking together the scientific evidence, epidemiological research, and her own clinical experience, Dr. Sucre concludes that "the weight of the scientific evidence supports my opinion that to a reasonable degree of medical and scientific certainty, CMBF is causally associated with and/or substantially contributes to the development of NEC." (*Id*. at 40.)

LEGAL STANDARDS

Federal Rule of Evidence 702 governs the admissibility of expert testimony. It states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

FED. R. EVID. 702. In *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), the Supreme Court recognized that Rule 702 creates a "gatekeeping role for the judge" by "assign[ing] to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." 509 U.S. at 597. Key to this gatekeeping role is determining

whether an expert has arrived at her conclusion using reliable methods; *Daubert* directs courts evaluating reliability to look to factors including "(1) whether the scientific theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether a particular technique has a known potential rate of error; and (4) whether the theory or technique is generally accepted in the relevant scientific community." *Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426, 431 (7th Cir. 2013) (citing *Daubert*, 509 U.S. at 593–94). "Importantly, this list is neither exhaustive nor mandatory." *C.W. ex rel. Wood v. Textron, Inc.*, 807 F.3d 827, 835 (7th Cir. 2015). "The key to the gate is not the ultimate correctness of the expert's conclusions," but "the soundness and care with which the expert arrived at her opinion." *Schultz*, 721 F.3d at 431.

DISCUSSION

I. Motion to Exclude Dr. Spector

Defendants raise several arguments challenging Dr. Spector's qualifications and the reliability of his methodology in arriving at his conclusions in this case. Regarding his qualifications, they assert that his lack of experience in nutrition, caring for preterm infants, or NEC renders him unqualified to render a causation opinion in this case. (*See* Defs.' Spector Mem. [605] at 24.) They further argue that Dr. Spector's conclusions should be excluded on the basis of "fit" because he could not opine about the "threshold" dose at which CMBF becomes dangerous, nor did he consider studies comparing a 100% human-milk diet to a 90% human-milk diet (fortified with 10% CMBF). (*Id.* at 20–24.) The bulk of Defendants' arguments, however, challenge the reliability of Dr. Spector's systematic literature review method and his application of the method in this case; they argue that he used a lower level of rigor in his SLR than he would in an academic setting, that he did not reliably apply the Bradford Hill criteria to the facts before him, that he failed to rule out alternative explanations for the epidemiological data, and that his opinions bore "recognized indicia of unreliability" like a high error rate and lack of peer review. (*See generally id.* at 5–20.) The court addresses these concerns in turn.

A. Dr. Spector's Qualifications

First, Defendants assert that because Dr. Spector is not a medical doctor, has not previously researched the potential relationship between feeding and NEC, and has not cared for preterm infants with NEC, he is not qualified to provide epidemiological opinions rendered in his report. (*Id*. at 25.) This misstates the standard. Rule 702(a) does not require that an expert have a specific expertise; it requires only that he "has the adequate education, skill, and training to reach" the conclusions rendered in the case. *Gayton v. McCoy*, 593 F.3d 610, 617 (7th Cir. 2010) (ultimately rejecting "the district court's assumption that Dr. Weinstein needed to have specific cardiac training to testify as an expert in a case involving a heart-related death"). Significantly, Dr. Spector's report does not express a clinical opinion about the treatment of NEC, but instead offers a review of epidemiological literature and biostatistical analysis. While he may lack specific subject matter expertise on NEC, his extensive background in pediatric epidemiology and study design make him qualified to render his opinion in this case.

This court's opinion in *In re Zimmer Nexgen Knee Implant Prods. Liab. Litig*., No. 11 C 5468, 2015 WL 5050214 (N.D. Ill. Aug. 25, 2015) is instructive. There, a bellwether case for an MDL involving allegedly defective knee implant devices, the plaintiff objected to the qualifications of an expert whose experience was in pediatric spine surgery—not knees or knee replacement surgery. 2015 WL 5050214, at 5. The court rejected this basis for excluding the expert, concluding that the expert surgeon's opinion was not "based on specialized knowledge of knee mechanics, surgical procedures, or the engineering design of [the knee implant] products," but "focuses on his review of clinical research—a discipline in which he has significant interest, knowledge, and expertise." *Id*. The court allowed the expert to testify to conclusions "based on his epidemiological and general clinical research expertise." *Id*. The same rule applies here; Dr. Spector's experience in epidemiological research qualifies him to review and interpret the findings of epidemiological research in this case.

B. "Fit" of Dr. Spector's Conclusions to the Facts

"[T]he *Daubert* inquiry requires that the district court determine whether the testimony would assist the trier of fact in understanding the evidence." *Deimer v. Cincinnati Sub-Zero Prods., Inc.*, 58 F.3d 341, 345 (7th Cir. 1995). The *Daubert* Court itself referred to this as a question of "relevance" and "fit," holding that an expert's testimony must have a "valid scientific connection to the pertinent inquiry as a precondition to admissibility." *Daubert*, 509 U.S. at 591–92.

Defendants argue that Dr. Spector's conclusions are unhelpful to the jury because he could not opine as to the threshold dose at which CMBF increases the risk of NEC and his conclusions "are wholly inapplicable to the facts of the cases here." (Defs.' Mem. at 20.) They point to Dr. Spector's deposition testimony, in which he declined to opine as to the percentage of formula at which CMBF is "sufficient to cause NEC," stating only that "[w]hen you get to 100 percent, I'll say it's sufficient." (*See* Spector Dep. at 286:23–287:9.) Because the vast majority of cases in the MDL involve some amount of mixed feeding or transition from mother's milk to formula (i.e. less than 100% CMBF diet), Defendants argue that Dr. Spector's conclusions do not fit the facts of these cases. (Defs.' Spector Mem. at 21.)

As a preliminary matter, Defendants take Dr. Spector's (admittedly inartful) answers in his deposition out of context. The court does not interpret Dr. Spector's answer that "[w]hen you get to 100 percent, I'll say it's sufficient" as an admission that his causation opinion is "limited" to 100% CMBF diets. Rather, the more natural reading of Dr. Spector's answers, in the context of the deposition and of his report, is that while he observed an association between higher percentage CMBF diets and higher rates of NEC, he was not able to reach a conclusion as to a specific triggering threshold dose in his literature review. (*See* Spector Rep. at 24 (explaining absence of threshold dose/dose-response data).) That does not make his causation opinion "wholly inapplicable" to cases involving mixed feedings of CMBF and human-milk. On the

contrary, Dr. Spector's broad analysis of studies exploring a range of different feeding mixtures (*see supra* n. 8) applies across the diverse feeding methods in the MDL cases.

As Defendants see things, in order to be qualified as a causation expert, Dr. Spector *must* opine on the threshold dose of CMBF. (*See* Defs.' Spector Mem. at 20.) They cite two cases, *Krik v. Exxon Mobil Corp.*, 870 F.3d 669 (7th Cir. 2017) and *In re Deepwater Horizon BELO Cases*, 119 F.4th 937 (11th Cir. 2024), for the suggestion that there is a "legal requirement" that a causation expert be able to opine about the level exposure required for an adverse effect. (*Id.*) But neither case creates the kind of strict rule Defendants suggest. In *Krik*, plaintiff, who suffered from lung cancer, sued his employer alleging that on-the-job exposure to asbestos was the cause of his disease. 870 F.3d at 672. On appeal from a verdict for the employer, the Seventh Circuit affirmed the trial court's exclusion of a toxicology expert who proposed to testify that "any exposure" to asbestos could cause lung cancer, thus effectively shifting the burden to the defendant to disprove alternative causes. *Id.* at 677. The court noted that plaintiff offered no "evidence about how much asbestos exposure Krik experienced and whether that dosage could have been a substantial contributing factor to lung cancer." *Id.* at 674–75, 677. But this holding—that a causation expert cannot shift the burden of proof to the defendant by suggesting that "any exposure" can cause a disease—does not establish an affirmative requirement that a causation expert must identify a *precise* threshold dose in order for the testimony to be admissible. In this case, Dr. Spector has not opined that "any exposure" to CMBF causes NEC. He has instead explained that although a precise triggering exposure may not be ascertainable, the epidemiological literature does establish that a dose-response relationship likely exists between CMBF and NEC (more formula increases likelihood of NEC). (Spector Rep. at 24.)

In re Deepwater also does not require that Dr. Spector opine about a precise threshold dose. In that case, a group of workers alleged that the chronic sinusitis they suffered from was caused by their exposure to chemicals during their work in cleanup of the Gulf coast oil spill. 119 F.4th at 940. The district court excluded the plaintiffs' general causation experts and granted

summary judgment for defendants. *Id*. Affirming that result, the Eleventh Circuit rejected plaintiff's suggestion that "proof of some threshold level of exposure is only relevant to *specific* causation." *Id*. at 946 (quotation marks omitted). Applying Eleventh Circuit precedent for admitting toxicology expert testimony,[20] the court held that the trial court did not abuse its discretion by requiring plaintiffs' causation expert to identify a specific threshold at which the purported toxin becomes hazardous. *Id*. at 945–46. Defendants take this to mean that a general causation expert must *always* testify to the threshold dose, but the Eleventh Circuit itself recognizes that a general causation expert can appropriately offer evidence on the issue of "whether an agent increases the incidence of disease in a group." *Id*. at 946 (quoting *McClain v. Metabolife Int'l, Inc*., 401 F.3d 1233, 1239 (11th Cir. 2005)). That is exactly what Dr. Spector's report establishes in this case—in the absence of clear threshold dose evidence, he opines about a dose-responsive relationship between CMBF feeding and NEC risk.

Judge Kennelly's opinion in *In re Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proc*., No. 14 C 1748, 2018 WL 4030585 (N.D. Ill. Aug. 23, 2018), while not binding on this court, presents a persuasive argument that the absence of a threshold dose is not a basis for excluding a causation expert. There, the defendant sought to exclude plaintiffs' general causation expert because he could not establish a dose-response relationship between defendant's product (AndroGel) and plaintiffs' alleged cardiovascular injuries. 2018 WL 4030585, at *5. But noting an absence of cases holding that a threshold dose opinion is required, and the fact that the expert "does discuss how certain studies suggest that higher doses of AndroGel pose greater [cardiovascular] risks," Judge Kennelly rejected the argument. *Id*. The same logic applies here. No case requires that Dr. Spector reach beyond the available scientific literature and assert

[20] The expert in *In re Deepwater* was an epidemiology expert, not a toxicologist. *See* 119 F.4th at 946. In opposing the application of a "threshold dose" requirement, the plaintiffs argued that the requirement should only apply to toxicological testimony, not epidemiological opinions. *Id*. The Eleventh Circuit did not resolve this question, noting that the district had a "myriad" of other reasons to exclude the expert. *Id*.

a threshold dose; it is sufficient that he discusses dose-response as it appears in the available studies.[21] (*See* Spector Rep. at 24.)

Regarding "fit," Defendants alternatively argue that Dr. Spector's opinions do not fit the facts of the MDL because "he limited his opinions to only infants with a birthweight of less than 1,500 grams" and "could not give a causation opinion applicable to infants born weighing above 1,500 grams" despite at least one of the bellwether infants weighing over 1,500 grams at the time of developing NEC. (Defs.' Spector Mem. at 23.) It is unclear how Defendants conclude that Dr. Spector's opinion is limited to infants weighing less than 1,500 grams—Dr. Spector's report does not state such a limitation and, as Plaintiffs point out, the studies that made up his analysis were not limited to infants below 1,500 grams. (*See* Pls.' Spector Mem. [617] at 21 (listing studies).) Defendants appear to rely on a handful of Dr. Spector's deposition answers where he was unable to provide a discrete opinion regarding *only* infants weighing above 1,500 grams (*see* Spector Dep. Tr. at 283:25–284:3; 338:23–339:8), but the fact that Dr. Spector could not provide an opinion limited to infants weighing more than 1,500 grams does not mean his opinion is "limited" to cases where the infant weighs less than that amount. This basis for exclusion is groundless.

[21] Defendants supplement their motion to exclude Dr. Spector by bringing the court's attention to Judge Tharp's recent decision in *Zurbriggen v. Twin Hill Acquisition Co., Inc., et al*., No. 1:17-CV-5648 (N.D. Ill. Apr. 11, 2025). (*See* Defs.' Supp. Authority [642-1].) In that case, airline employees brought claims against the manufacturer of their uniforms, claiming that the uniforms contained skin-irritant chemicals. (*Id*. at 2–3.) Relevant to Defendants' argument, Judge Tharp found that the plaintiffs' toxicology expert (Dr. Carson) was not reliable because he could not identify "the minimum dosage at which detected sensitizers and irritants become harmful." (*Id*. at 23.) But, importantly, the expert in *Zurbriggen* sought to opine to the same "any exposure" theory of dose that the Seventh Circuit ruled is inadmissible in *Krik*, and that this court noted does not describe Dr. Spector's testimony. (*See id*. at 24.) This was particularly egregious given that "[defendant] found many of the same supposedly hazardous chemicals on legacy uniforms Dr. Carson deems safe." (*Id*.) Here, Dr. Spector has not similarly conceded that certain diets are safe at a certain percentage of CMBF, and the court does not read Judge Tharp's opinion as holding that expert epidemiological testimony as to dose-response is not reliable where threshold dose is not established in the literature.

C. The Rigor of Dr. Spector's Analysis

Defendants challenge Dr. Spector's SLR methodology, asserting that he did not apply the same rigor to preparing his report as he would have in an academic setting. (Defs.' Spector Mem. at 6.) Defendants are correct that a key aspect of the court's gatekeeping function under *Daubert* is ensuring that the expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). Evidence that Dr. Spector used a different level of rigor in performing his SLR for this case than he would in an academic setting would indeed be grounds to doubt the reliability of his methods. *See In re Paraquat Prods. Liab. Litig.*, 730 F. Supp. 3d 793, 818 (S.D. Ill. 2024) (excluding expert that "failed to apply the same level of intellectual rigor to his work in the four trial selection cases that would be required of him and his peers in a non-litigation setting").

But in arguing that Dr. Spector's work lacked his usual academic rigor, Defendants offer nothing more than deposition answers taken out of context and misstatements about his SLR method. First, they note Dr. Spector's statement that he did not read study discussions "in depth" (Spector Dep. Tr. at 132:22–25), and calculate that Dr. Spector spent no more than thirty seconds with each of the 5,500 studies that turned up in his initial search (Defs.' Spector Mem. at 6 (citing *id*. at 260:14—21)). That practice, Defendants urge, is inconsistent with Dr. Spector's stated academic practice of "hours and hours of deliberation" and "agoniz[ing] over every word" (Spector Dep. Tr. at 201:10–14). But a closer read of the cited portions of the deposition undermines the notion that Dr. Spector was admitting a lack of rigor. Regarding his statement that he did not read the study discussions in depth, Dr. Spector explains in that same paragraph that he did not focus on the discussion sections of the studies because "it's methods and results that matter the most"—a reasonable judgment given that he was identifying the studies mainly for data abstraction. (*Id*. at 132:22–25.) As for Defendants' calculation that Dr. Spector spent an average of thirty seconds

with each paper that turned up in his search, they fail to mention that this calculation refers to the time spent per study during Dr. Spector's relevance review—in which he only reviewed the titles and abstracts. Given that abstracts are short, and the irrelevance of certain studies may be obvious on their face, an average of thirty seconds across 5,500 studies during a title and abstract review does not strike the court as unreasonable.[22]

Defendants next suggest that various "misstatements" and "errors" pointed out during his deposition confirm the lack of rigor in Dr. Spector's analysis. The various edits can be seen clearly in Dr. Spector's redlined amended report, showing changes made after the deposition. (*See* Spector Redline [605-8].) Some of these edits appear to be merely semantic edits, as Dr. Spector puts it, to make the report "read better." (*See* Spector Sec. Dep. Tr. [605-20] at 18:3–6.) The most substantive of these errors appear to be misstatements of the confidence intervals of several of the Dr. Spector's reported meta-analysis. (*See* Spector Redline at 18–19.) The reported errors were not biased in one direction or another—some of the errors mistakenly increased the minimum and maximum relative risk, others lowered them. As Dr. Spector explains, these were typographical, not mathematical errors, and did not ultimately impact his analysis; he focused on the *point* estimate when reaching his conclusion, not the confidence intervals. (*See* Spector Sec. Dep. Tr. at 14:9–13.) Dr. Spector's errors may reflect sloppy drafting on his part, but it does not, by itself, justify excluding his testimony. *See Gaston v. Hazeltine,* No. 3:21-CV-896-CCB, 2024 WL 4224356, at *6 (N.D. Ind. Sept. 18, 2024) (allowing expert despite 97 misquotes in 10-page report because "the unattributed quotes and typographical errors may be evidence of sloppy report drafting but do not, on their own, establish a lack of reliability").

Defendants also argue that Dr. Spector's report fails his own academic standards because he diverged from the "PRISMA" methodology he claimed to follow. (Defs.' Spector Mem. at 8.)

[22] As Plaintiffs point out, doing a similar calculation for Defendants' expert Dr. Makuch (dividing total studies reviewed by total hours spent on review *and* preparing his report) results in 50 seconds spent per article on average. (Pls.' Spector Mem. at 8.)

As Dr. Spector explains in his report, PRISMA[23] is a set of guidelines for reporting the results of an SLR, presented as a checklist. (Spector Rep. at 6; *see also id*. at 46–49 (Dr. Spector's completed PRISMA checklist).) PRISMA does not create any substantive or methodological requirements that a researcher must follow in reviewing the scientific literature but provides a standardized format for reporting the results of that review. (*See id*.) Nonetheless, Defendants argues that Dr. Spector's opinion must be excluded because he failed to discuss "implications of the results [of the work] for practice, policy, and future research," as he would have done in an academic article. (Defs.' Spector Mem. at 8.) But Defendants cite no authority for the position that the PRISMA guidelines are anything more than a formatting guide, much less a basis for excluding an expert opinion. Moreover, Dr. Spector's decision not to discuss the impact of his findings on "practice, policy, and future research" was reasonable—those impacts could be useful in an academic setting but would not be relevant to this case. *Daubert* requires that experts put the same rigor into preparing their reports for litigation as they would in academic practice, but it does not require that they produce a piece of academic writing divorced from the demands of the litigation.

Finally, Defendants fault Dr. Spector for "admit[ting]" that he would have phrased his conclusions differently in an academic setting. (Defs.' Spector Mem. at 10.) They cite again to deposition testimony where Dr. Spector stated that "I would perhaps have some sort of hedging language" if he had prepared his SLR for an academic setting because that "is what academics and scientists like to use because nobody likes to make a definitive statement that later will be proven wrong." (Spector Dep. Tr. at 198:19–199:2.) Again, Defendants confuse the methodology of an SLR with the writing of a report—that Dr. Spector would have *phrased* his conclusions differently in an academic context does not mean that the conclusions would in fact be different.

[23] The parties do not explain this, but PRISMA is an acronym for "Preferred Reporting Items for Systematic Reviews and Meta-Analyses," and is a publicly available resource providing guidance for the drafting and reporting of systematic reviews. *See* PRISMA Statement, https://www.prisma-statement.org/ (last accessed May 1, 2025).

This quote, like others, do not demonstrate that Dr. Spector used any less rigor in reviewing studies or interpreting meta-analysis for this case.

D. Application of Bradford Hill Criteria

As described earlier, Dr. Spector reviewed the Hill criteria in reaching his ultimate causation opinion. *See supra* pp. 8–10. Defendants nevertheless that Dr. Spector "made no real effort to consider, let alone weigh, the nine Bradford Hill factors." (Defs.' Spector Mem. at 11.) The court disagrees. Dr. Spector considered and discussed each of the nine factors, at least minimally, and arrived at his conclusion by focusing on four factors in particular: temporality, strength, consistency, and experiment. He also incorporated the report and analysis of Dr. Sucre, whose work discussed the biological plausibility, coherence, and analogy factors, finding that they were better answered in her analysis than in his meta-analysis. True, he did not conclude that the dose-response and specificity factors weighed in favor of causation, but the law does not require a causation expert to find *all* criteria weigh in favor of causation. *See In re Testosterone Replacement Therapy*, 2017 WL 1833173, at *11.

Defendants raise few arguments as to the methodology of Dr. Spector's appraisal of the Bradford Hill factors that weighed in favor of causation. As to his finding on temporality, they assert that Dr. Spector "only assumed" it existed, drawing from his deposition testimony that it "stands to reason that the [bovine-based nutrition product] was recorded with the correct temporality." (Defs.' Spector Mem. at 12–13.) But Defendants' argument misunderstands Dr. Spector's testimony; he did not "assume" the temporality factor—he reasoned that the peer-reviewed studies were accurately reporting their results in line with their study designs,[24] and drew

[24] In Dr. Spector's deposition, Defendants drew his attention to one of the studies included in his meta-analyses (Sullivan 2010) that appeared to erroneously record an infant as having ingested CMBF and developed NEC when, in fact, the NEC had been observed *before* the infant had ingested CMBF. (*See* Spector Dep. Tr. at 178:8–179:12.) Dr. Spector admits that this error was "sort of egregiously wrong and very surprising," and he was not aware of it prior to his deposition. (*Id*. at 317:17–23.) This is a flaw in his analysis, and it would be a serious one had Dr. Spector relied only on this data point in Sullivan 2010 for his temporality finding. But the

conclusions as to temporality based on that reasoning. (*See* Spector Rep. at 23.) Defendants contend that his application of the strength criterion factor was unreliable because he could not cite anything in "the NEC context" to support his claim that association between CMBF and NEC observed in his meta-analysis was a strong one by generally accepted standards. (Defs.' Spector Rep. at 14.) But Dr. Spector's established experience in epidemiology qualifies him to opine as to generally accepted standards for strong statistical associations. To the extent that Defendants believe this conclusion lacks support in relevant literature, that is grounds for cross examination. Defendants cite testimony in Dr. Spector's deposition that he "eyeballed" the studies to determine consistency (Defs.' Spector Mem. at 14)—a misleading characterization of his testimony, given that the full-answer referenced by their brief states that "I eyeballed [consistency], *supplemented with I-squared* . . . fortified with [I-squared]." (*See* Spector Dep. Tr. at 235:7–11.) Defendants make no claim that the I^2 value produced by Dr. Betensky was an unreliable or inaccurate measure of the heterogeneity of the study results, nor that it was unreasonable for Dr. Spector to rely on the low-I^2 value for a finding of high consistency.

In short, Defendants' issues with Dr. Spector's Bradford Hill analysis are not directed at his reasoning (i.e., his method). They instead challenge his conclusions, his reliance on Dr. Betensky's analysis, and his failure to account for Defendants' own proffered alternative explanation of the data. (*See* Defs.' Spector Mem. at 13–15.) None of these reasons form a basis for exclusion under 702. That Defendants believe that Dr. Spector should have come out the other way in his conclusions is a basis for cross-examination, not for rejecting his methods. Dr. Spector has demonstrated enough rigor in applying the Hill criteria in his report to satisfy *Daubert*.

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court is careful not to make too much of this one reporting error; the error (not committed by Dr. Spector himself) amounts to only one data point among the 26 studies Dr. Spector evaluated, and as Plaintiffs point out, even Defendants' *own* epidemiology expert included and relied on Sullivan 2010. (*See* Makuch Rep. [616-43] at 10.)

E. Indicia of Unreliability

Defendants' final salvo in its challenge to Dr. Spector is a general reference to the "checklist" of reliability factors articulated in *Daubert*, and an assertion that Dr. Spector's report fails each factor. (*Id*. at 17.) Factors mentioned in *Daubert* (subject to testing, peer-review, error rate, acceptance in scientific community) are important, though not dispositive, requirements, and each expert must be evaluated on a case-by-case basis. *See C.W. ex rel. Wood*., 807 F.3d at 835. Even so, many of Defendants' assertions that Dr. Spector's analysis fails to meet this standard are simply incorrect.

First, Defendants argue that Dr. Spector's report bears "indicia of unreliability" because his report has not been subject to testing or peer-review. But this misunderstands the nature of Dr. Spector's work in this case; he did not perform any of his own experiments, nor did he design studies. He instead reviewed the results of existing epidemiological research and subjected it to rigorous meta-analysis. While his literature review was not "tested" (whatever that would mean in this context) or peer-reviewed, the studies that he analyzed were experiments that were subject to peer review, and his easily replicable review meets the *Daubert* standard. *See Nelson v. Pace Suburban*, No. 17 C 7697, 2022 WL 1401529, at *2 (N.D. Ill. Mar. 21, 2022) (finding expert's literature review reliable under *Daubert* because she used "a clear, replicable method" in considering peer-reviewed articles). Furthermore, Dr. Spector's relevance review—where he narrowed down the relevant studies from over 5,500 down to 107—*was* subject to some form of peer review; Dr. Ransom performed an independent application of his exclusion criteria and the two arrived at similar results.

Defendants also argue that Dr. Spector's report is unreliable because his conclusion that CMBF causes or contributes to NEC is not "generally accepted in the scientific community." (Defs.' Spector Mem. at 18.) But the *Daubert* inquiry is chiefly concerned with the reliability of an expert's method, not the accuracy of the conclusions. *Schultz*, 721 F.3d at 431. Defendants do

not contest that a systematic literature review aided by a robust biostatistical meta-analysis is a reliable and widely accepted methodology (not unlike the methods used by their own causation experts). *See* RMSE at 723 ("When ordered from strongest to weakest, systematic review of randomized trials (meta-analysis) is at the top" of possible epidemiological evidence).

Defendants' allusion to a high "error rate," however, requires more attention. As Defendants emphasize, Dr. Spector did miss relevant studies in his original report and submitted a supplemental report addressing them. Defendants suggest that every one of the 13 RCT studies mentioned in Dr. Spector's deposition was a "missed" study, and since his original report included only 12 RCT studies, they calculate an error rate of 50%. (*See* Defs. Spector Reply [31] at 4.) The court will assume that a 50% error rate in a report would be grounds for excluding an expert, but it does not adopt Defendants' math. For one, their assertion assumes that every one of the studies cited in the Dr. Spector's deposition and included in his supplemental report was a "missed study," when in fact Dr. Spector's supplemental report only mentions three studies that would have been "likely included" in his original report. Moreover, Defendants' method of dividing the number of new RCTs by the total number of RCTs to calculate an "error rate" is not a useful way to measure the error in Dr. Spector's analysis. Not all RCTs are created equal; some include more subjects than others, some have wider confidence intervals, some have better methods than others—indeed, each study in Dr. Spector's meta-analysis is given a different "weighting." (*See* Spector Rep. at 41–45.) Insofar as "error rate" is a useful term in the context of an SLR, a better measure of the impact of the missed studies is to compare Dr. Spector's original RCT estimate of relative risk with the relative risk calculated in his supplemental report incorporating the missing studies. Dr. Spector does not perform a supplemental analysis including only the three studies that would have been "likely included" in his original meta-analysis. But granting, as Dr. Spector does, that all the studies referenced by Defendants were "missed," the relative risk calculation shifts from 1.60 to 1.70, a change (or "error rate") of 5% *in favor* of a stronger

association between CMBF and NEC. *See supra* pp 11–12. This is an acceptable error rate and does not justify exclusion.

II. Motion to Exclude Dr. Sucre

Some of Defendants' arguments for excluding Dr. Sucre have been resolved in the court's prior discussion of Dr. Spector's report. Defendants argue that Dr. Sucre must be excluded if the court excludes Dr. Spector due to her reliance on his report (*see* Defs.' Sucre Mem. [592] at 5)—a moot argument as the court has not excluded Dr. Spector's report. They also raise the same "threshold dose" argument discussed above, suggesting that Dr. Sucre must be excluded because she does not opine as to the threshold at which CMBF causes NEC. (*Id*. at 12-14.) But for the reasons described previously, the court does not conclude that Plaintiffs' causation experts are required to opine on a threshold, and Dr. Spector's evaluation of dose response (incorporated by reference into Dr. Sucre's report) is sufficient. (*See* Sucre Rep. at 3 n. b.)

That leaves three arguments that Defendants lodge towards Dr. Sucre: that her conclusions are not generally accepted in the scientific community, that she cherry-picked studies in her qualitative assessment, and that her testimony is unhelpful because she cannot explain the biological pathway of CMBF causing NEC in any particular infant.

A. General Acceptance of Conclusions

Defendants do not dispute that Dr. Sucre's chosen method—the qualitative assessment—is a widely accepted method of causation analysis. Rather, they assert that the result of her assessment (her explanation of the biological pathway by which CMBF increases the risk of NEC) is out of step with the scientific consensus. They specifically cite a "Consensus Statement" published jointly by the FDA, CDC, and NIH concluding that "[t]here is no conclusive evidence that preterm infant formula causes NEC"[25] and "[a]vailable evidence supports the hypothesis that

[25] Notably, this first conclusion by the agencies, that "there is no conclusive evidence that preterm formula causes NEC," does not directly contradict Dr. Sucre's and Dr. Spector's conclusions that CMBF substantially contributes to or causes NEC *to a reasonable degree of*

it is the absence of human milk—rather than the exposure to formula—that is associated with an increase in the risk of NEC." (Defs.' Sucre Mem. at 8 (citing Consensus Statement [592-1] at 1).) In response, Plaintiffs largely attempt to discredit the Consensus Statement—pointing to the lack of time and research that went into the Consensus Statement. (Pls.' Sucre Resp. [614] at 5–6.)

The court need not determine at this stage whether Dr. Sucre or the Consensus Statement are correct; the debate captured in the parties' respective briefs is exactly the kind of dispute a jury can and should resolve. The question under *Daubert* is whether Dr. Sucre came to her conclusions using reliable methods. General acceptance of a theory is one factor the court can look at to determine the reliability of Dr. Sucre's testimony; but it is only one of four non-dispositive factors mentioned in *Daubert*. *See C.W. ex rel. Wood*., 807 F.3d at 835.

Here, Dr. Sucre's report sets a clear methodology, identifying search terms likely to turn up relevant peer-reviewed studies, describing a grading system based on objective criteria, and walking through every step of her theory of the biological pathway of NEC replete with references to scientific literature. *See generally supra* pp. 13–16. Dr. Sucre's qualifications as an expert in neonatology are unassailable, and her report satisfies the *Daubert* inquiry's requirement that an expert demonstrates a reliable and replicable methodology. *See Nelson*, 2022 WL 1401529, at *2.

This methodological rigor sets Dr. Sucre's report apart from cases Defendants cite as examples of courts excluding experts for presenting opinions allegedly outside the scientific consensus. In *In re Paraquat Prods. Liab. Litig*., 730 F. Supp. 3d 793 (S.D. Ill. 2024), the court held that the lack of peer-reviewed support for an expert's conclusions "tend[ed] to undermine

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scientific certainty; there is no requirement under 702 that Dr. Sucre or Dr. Spector testify to "conclusive evidence" or "absolute certainty." *See Stutzman v. CRST, Inc*., 997 F.2d 291, 296 (7th Cir.1993) ("[A]n expert's lack of absolute certainty goes to the weight of his testimony, not the admissibility.") That said, the consensus statement goes on to interpret the available evidence to support a finding that it is the absence of human milk that increases the risk of NEC, which does create a conflict with Dr. Spector and Dr. Sucre's conclusions and will be fertile ground for cross-examination of these witnesses.

reliability, rather than support it." 730 F. Supp. at 850. But the court noted many other inadequacies in the expert's methodology, including the absence of any discernible weighting criteria, failure "to identify evidence in his two reports that supports his conclusions," and "extensive selection bias." *Id*. at 841–43. Similarly, in *In re Zantac (Ranitidine) Prods. Liab. Litig*., 644 F. Supp. 3d 1075 (S.D. Fla. 2022), the court observed that "no independent scientist or governmental body has made the analytical leap from the existing data as Dr. McTiernan does, and the Court deems this fact to be evidence of an unreliable methodology." 644 F. Supp. 3d at 1234. But the court equally faulted the expert's "failure to adequately explain to the Court how her opinion is formulated" and failure to "inform the Court, in either her deposition or her expert report, how she weighs the various studies." *Id*. at 1234-35. Here, Defendants cannot claim that Dr. Sucre failed to provide the reasons behind her weighting of different studies, or that she failed to cite studies when making factual or scientific claims in her report. In short, though "general acceptance" is not a factor affirmatively in favor of Dr. Sucre's conclusions, her report demonstrates other indicia of rigor and reliability that satisfies the *Daubert* inquiry.

B. Cherry-Picking

"Experts who engage in cherry-picking of the evidence fail to satisfy the scientific method and *Daubert*." *Van v. Ford Motor Co*., 332 F.R.D. 249, 269 (N.D. Ill. 2019) (citing *Barber v. United Airlines, Inc*., 17 F. App'x 433, 437 (7th Cir. 2001)). Defendants' primary charge against Dr. Sucre's *methods*, as opposed to her conclusions, is that Dr. Sucre selectively chose to consider literature that supported her causation conclusions and ignored evidence that would have refuted them. (Defs.' Sucre Mem. at 9.) Specifically, they cite five studies (Schanler 1995, Griffin 1999, Ng 2019, Hellström 2021, and Embleton 2023) that Dr. Sucre failed to review in her report, despite their relevance and apparent conflict with her theory of biological plausibility. (*Id*. at 10-11.)

Plaintiffs do not dispute that Dr. Sucre did not cite or refer to the five studies mentioned by Defendants in her report, but they urge that the omissions do not amount to "cherry-picking." First, they point out that two of the studies (Shulman 1995 and Griffin 1999) did not meet the

search criteria that Dr. Sucre used to frame her search for relevant articles: both were published before 2014,[26] and Shulman 1995 does not mention "necrotizing enterocolitis" at all. (Pls.' Sucre Mem. at 15.) Plaintiffs further point out that two of the studies (Ng 2019 and Embleton 2023) *were* included in Dr. Sucre's analysis; they can both be found on Dr. Sucre's Grading Table (though she did not explicitly mention them in her report). (*See* Grading Table at 5, 16.) It thus appears that Dr. Sucre did not selectively decide to exclude these articles from her qualitative analysis.

The question then becomes whether Dr. Sucre's decision to not explicitly discuss the articles amounts to "cherry-picking" only favorable studies. Failure to mention or discuss "highly relevant" studies that directly refute an expert's opinion can be a basis for exclusion under *Daubert*. *See In re Acetaminophen - ASD-ADHD Prods. Liab. Litig.*, 707 F. Supp. 3d 309, 336 (S.D.N.Y. 2023). Thus, the propriety of Dr. Sucre's omission of these studies from her written analysis turns on how directly they appear to contradict her conclusions. The parties hotly debate this issue. Defendants maintain that each of the studies directly contradict different portions of Dr. Sucre's opinion (*see* Defs.' Sucre Mem. at 10–11); Plaintiffs respond that the studies are either irrelevant or in fact supportive of Dr. Sucre's opinions (Pls.' Sucre Mem. at 15–16).

In reviewing the studies mentioned by Defendants and the parties' respective arguments, the court does not find that Dr. Sucre's failure to specifically address them rises to the level of "cherry-picking." Shulman 1995 was a study conducted on infants born at or around 33 weeks gestational age,[27] testing the differences in absorption rates between lactose (the primary carbohydrate in human milk), glucose polymers (the complex carbohydrates found in CMBF), and

[26] On this point, Defendants point out that both Shulman 1995 and Griffin 1999 were cited in other studies that made it into Dr. Sucre's report and, thus, should have been reviewed as "references" in relevant documents. (Defs.' Sucre Mem. at 10.) But as Dr. Sucre makes clear in her report, she reviewed references outside of the 2014–2024 timeframe only to "verify a claim by the authors or to provide additional background information." (Sucre Rep. at 9.)

[27] As Dr. Sucre noted when asked about Shulman 1995 in her deposition, the study population was made up of 21 infants with gestational ages between 28 and 42 weeks—that means that some, but not all, of the infants looked at in the study were pre-term births. (*See* Sucre Dep. Tr. [592-3] at 553:23–556:9; Shulman 1995 at 628.)

mixes of lactose and glucose polymers. (*See* Defs.' Ex. 7, Shulman 1995 [592-7] at 626.) As Defendants note, the study found that the infants in the study digested and absorbed the glucose polymers *better* than lactose—thus seeming to refute Dr. Sucre's conclusion that pre-term infants cannot absorb CMBF as well as human milk. (*See id*.) But Shulman 1995 has an important caveat to this conclusion; it noted that while rates of infant lactose absorption did not vary based on maturation, digestion and absorption of glucose polymers *did* depend on post-natal age and diet—suggesting that absorption rates of glucose polymers may be lower in a more pre-term set of study participants. (*Id*.) Given this modest equivocation, Shulman 1995 appears to be a strong topic for cross-examining Dr. Sucre and her conclusions regarding absorption of glucose polymers, but it is not so clearly inconsistent with her conclusions as to reduce her analysis to mere "cherry picking."

Griffin 1999 was a random-control study that compared rates of NEC and suspected NEC between pre-term infants fed lactose-containing formula (the carbohydrate common to human and cow's milk) and others fed a prepared "low-lactose" formula replacing lactose with maltose (one of the complex carbohydrates found in certain CMBFs that Dr. Sucre claims is malabsorbed by preterm infants). (*See* Defs.' Ex. 10, Griffin 1999 [592-10] at 587.) Defendants note language from the study's abstract where the researchers concluded that "there was no evidence that [low-lactose formula] altered the incidence of NEC," but omit the next clause "but the incidence of NEC in this study was too low to draw conclusions." (*Id*.) Given the researchers' admission that the data was insufficient to provide a conclusion, Dr. Sucre cannot be faulted for failing to discuss this study.

Ng 2019 was a review of RCTs comparing incidence of NEC in preterm infants fed standard CMBF with that of infants fed formula containing protein hydrolysate (that is, proteins that are already partially digested or "hydrolyzed"). (*See* Defs.' Ex. 11, Ng 2019 [592-11] at 1–2.) Defendants urge that the article's finding of statistically identical rates of NEC in these two groups undermines Dr. Sucre's conclusions that proteins in CMBF are causes of malabsorption and NEC.

(*See* Defs.' Sucre Mem. at 10–11 (citing Ng 2019 at 2).) The argument goes that if Dr. Sucre's position were correct, and the proteins in CMBF are malabsorbed and lead to NEC, then hydrolyzing the proteins should result in lower rates of NEC. But the fact that a result of a study does not prove a theory does not mean that the study affirmatively contradicts it. Dr. Sucre argues that it is the proteins, carbohydrates, *and* fats in CMBF that lead to NEC—that the proteins are hydrolyzed in a particular experiment does nothing to alter the carbohydrates and fats in the formula. Had Dr. Sucre not even reviewed Ng 2019 (which fits under her search criteria) at all, the court would be skeptical. But her Grading Table shows that she reviewed and graded it. (Grading Table at 5.) That she did not directly cite an article that neither affirmatively proves nor denies her theories is not a basis for exclusion.

Hellström 2021 is the one study mentioned by Defendants that appears to have met Dr. Sucre's search criteria (published 2014–24 and mentioning "necrotizing enterocolitis") but was not included in her Grading Table. (*See* Defs.' Ex. 12, Hellström 2021 [592-12] at 359.) It is also the only study not primarily interested in NEC. The study was a randomized clinical trial testing whether supplementing pre-term infant diets with fatty acids reduced incidence of eye disease. (*Id*.) The study also recorded any incidence of NEC (along with other health outcomes) in the infants given fatty acids and the control group but noted "[t]here were no significant differences in [necrotizing enterocolitis]" between the two groups. (*Id*. at 362.) Defendants argue that because Dr. Sucre concludes that the fats in CMBF contribute to NEC, she wrongfully ignored the study. (Defs.' Sucre Mem. at 11.) But Plaintiffs correctly note that the study makes no mention of the diets that the infants in the study were fed, and it is not obvious to the court that the "fatty acids" supplemented in the study are the same as the fats in CMBF discussed in Dr. Sucre's report (she was not asked about this study in her deposition). Defendants may be able to draw out a contradiction through cross-examination, but there is insufficient evidence at this point that Dr. Sucre erred by ignoring this study.

Finally, Embleton 2023 was an RCT testing the effect of an exclusively human milk diet on gut microbial diversity in preterm infants. (Defs.' Ex. 13, Embleton 2023 [592-13] at 1.) Dr. Sucre cited this study in her Grading Table, but did not cite it in her report. Defendants point out that the study found no differences in the gut microbiome between infants given exclusively human milk versus infants fed with formula. (*See id.*) Defendants interpret this finding as undermining Dr. Sucre's conclusions that "maldigestion of formula causes bacteria to proliferate." (Defs.' Sucre Mem. at 11.) But the relationship between malabsorption of CMBF nutrients (the basis of Dr. Sucre's conclusions) and gut microbiome diversity (the subject of Emberton 2023) is not obvious in the record; Emberton 2023 does not discuss the implications of its findings on malabsorption of nutrients, and Dr. Sucre was not questioned about the findings of the study in her deposition. Indeed, Dr. Sucre's discussion of the gut microbiome in her report was limited to noting that "[a]lthough the microbiome can play a role in NEC and may be altered by undigested carbohydrates, protein, and fats, none of [the] literature linking changes in the microbiome and NEC has demonstrated causation," ultimately concluding that "the microbiome has not been shown to be a dominant mechanism in the increased risk of NEC associated with exposure to CMBF." (Sucre Rep. at 40.) Given these conclusions, Emberton 2023 does not appear to be highly relevant to Dr. Sucre's conclusions.

The court recognizes that its own understanding of these studies is not infallible, and that Defendants may well defeat Dr. Sucre's conclusions in cross-examination or with the testimony of their own experts. The court concludes only that un-addressed studies are not so obviously relevant as to cast doubt on the reliability of Dr. Sucre's method.

C. Helpfulness

Defendants argue that Dr. Sucre's testimony should be excluded as unhelpful to the jury because she is not able to testify as to whether CMBF caused NEC in any specific infant. (Defs.'

Sucre Mem. at 14.)[28] They cite to statements in Dr. Sucre's deposition where she admitted that it is impossible "after the fact . . . [to] isolate which part of the formula caused the NEC" in a specific case. (*Id.* (quoting Sucre Dep. Tr. at 133:4–17).) This argument appears to look past the difference between general and specific causation experts. "General causation addresses whether a particular agent *can* cause a particular illness," while "[s]pecific causation addresses whether that agent *in fact* caused the particular plaintiff's illness." *Aurand v. Norfolk S. Ry. Co.*, 802 F. Supp. 2d 950, 953 (N.D. Ind. 2011) (citing *Milward v. Acuity Specialty Prods. Group, Inc.*, 639 F.3d 11, 13 (1st Cir. 2011)). As a general causation expert, Dr. Sucre need not opine that CMBF caused NEC in any particular infant.

Defendants further urge, however, that Dr. Sucre's testimony is unhelpful because neither "she nor the jury nor anyone else can link her general causation testimony to these specific cases." (Defs. Sucre Mem. at 15 (quoting *In re Mentor Corp. Obtape Transobturator Sling Prods. Liab. Litig.*, 2015 WL 7863032, at *1 (M.D. Ga.)).)[29] That remains to be seen; the court has yet to exclude any of Plaintiffs' specific causation experts. For now, Dr. Sucre's opinion putting forth an explanation of the biological plausibility of CMBF causing NEC is necessary and helpful for the jury.

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[28] In their reply brief, Defendants suggest that Plaintiffs "concede" this issue because Plaintiffs' opposition brief not directly address whether Dr. Sucre can tie her testimony to a specific infant. (Defs.' Sucre Reply [623] at 3.) This is not the case. Plaintiffs devote significant space in their opposition brief explaining how Dr. Sucre's testimony is helpful as a general causation expert. (Pls.' Sucre Opp'n at 11–14.)

[29] Defendants cite to *In re Mentor Corp.*, where the defendant moved to exclude a general causation expert on a similar basis: that it suspected the plaintiffs would be unable to introduce evidence connecting the expert's testimony to any specific case. 2015 WL 7863032, at *1. But the court *deferred* ruling on the matter, reasoning that "[i]f Plaintiffs produce a specific causation expert to tie [the expert's] general causation testimony to their specific cases, then his testimony will be admitted." *Id.* The case thus contradicts Defendants' apparent view that Dr. Sucre *herself* must connect her general causation testimony to the specific plaintiffs.

III. Motion for Summary Judgment

The court's conclusions concerning Dr. Spector and Dr. Sucre effectively resolve Defendants' motion for summary judgment. That motion rests on a determination that the court has not made—that Plaintiff's experts do not meet *Daubert*'s standard for inclusion under Federal Rule of Evidence 702. Specifically, as Defendants' memorandum makes clear, they seek summary judgment at this stage on the basis that (1) Plaintiffs require expert testimony on causation to prove their claims and (2) Plaintiffs lack such testimony if Dr. Spector and Dr. Sucre are excluded. (Defs.' Summ. J. Mem. [610-1] at 4–8.) Because the court does not exclude Dr. Spector or Dr. Sucre, this argument is moot.

Defendants, in the alternative, seek summary judgment as it relates to claims that their cow's-milk-based *fortifier*, not formula, caused NEC. (*Id*. at 8.)[30] Indeed, Dr. Sucre limited her opinion to formula, not fortifier products. (*See* Sucre Dep. Tr. at 283:6–8). Dr. Spector did not discriminate between formula and fortifier in his meta-analysis; he recognizes that formula presents a greater risk for than does fortifier but does not offer an opinion specific to fortifier. (*See* Spector Dep. Tr. at 147:16–149:13.) As Plaintiffs point out, however, it is premature to dismiss all fortifier claims in the MDL at this stage; none of the cases chosen as bellwethers involve infants fed exclusively fortifier. A "fortifier alone" expert opinion may be forthcoming as those cases develop. (*See* Pls. Summ. J. Opp'n at 8.) The court therefore withholds judgment on the "fortifier alone" cases for a later date.

[30] The difference between formula and fortifier is best explained in the report of Defendants' expert Dr. Camilia Martin. (*See* Martin Rep. [616-25] at 9–10.) As Dr. Martin explains, fortifier products "add energy, protein, and nutrients" to human milk "to meet the massive nutritional demands of premature infants who would otherwise be receiving nutrition from the placenta." (*Id*.) But "[w]hen human milk is unavailable, specialty preterm infant formula is the best option for nourishing premature infants." (*Id*. at 10.) In other words, fortifier provides key nutritional benefits to *supplement* an available supply of human milk, while formula *substitutes* for human milk where there is an absence of supply.

CONCLUSION

Daubert rulings, like all *in limine* determinations, are provisional and are subject to review at trial. At this stage, Defendants' motions to exclude Dr. Spector [605] and Dr. Sucre [592] under Federal Rule of Evidence 702 are denied without prejudice, as is their motion for summary judgment [610].

ENTER:

Dated: May 2, 2025

REBECCA R. PALLMEYER
United States District Judge