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Illinois Official Reports

Appellate Court

Watson v. Mead Johnson & Co., 2026 IL App (5th) 240936

Appellate Court Caption	JASMINE WATSON, Individually and on Behalf of the Estate of Chance Dean, Plaintiff-Appellee, v. MEAD JOHNSON & COMPANY, LLC, and MEAD JOHNSON NUTRITION COMPANY, Defendants-Appellants.
District & No.	Fifth District No. 5-24-0936
Filed	June 12, 2026
Decision Under Review	Appeal from the Circuit Court of St. Clair County, No. 21-L-1032; the Hon. Patrick R. Foley, Judge, presiding.
Judgment	Reversed and remanded.
Counsel on Appeal	Joel D. Bertocchi, of Akerman LLP, and Anthony J. Anscombe and Darlene K. Alt, of Steptoe & Johnson, LLP, both of Chicago, and Paul W. Schmidt, Phyllis A. Jones, Emily S. Ullman, and Nicole M. Antoine, of Covington & Burling LLP, of Washington, D.C., for appellants.

Ashley Keller and Ben Whiting, of Keller Postman LLC, of Chicago, David Cates, of The Cates Law Firm, LLC, of Swansea, Amelia Frenkel and Zachary Clark, of Keller Postman LLC, of Washington, D.C., and Sean Grimsley, Kenzo Kawanabe, Abigail Hinchcliff, and Samara Hoose, of Olson Grimsley Kawanabe Hinchcliff & Murray LLC, of Denver, Colorado, for appellee.

Hugh C. Griffin, of Hall Prangle & Schoonveld, LLC, of Chicago, for *amici curiae* American Academy of Pediatrics *et al.*

Panel JUSTICE McHANEY delivered the judgment of the court, with opinion.
Justices Boie and Bollinger concurred in the judgment and opinion.[*]

OPINION

¶ 1 On October 28, 2021, Jasmine Watson (Mother) filed a lawsuit in the circuit court of St. Clair County against defendants, Mead Johnson & Company, LLC, Mead Johnson Nutrition Company (collectively, Mead Johnson), and Abbott Laboratories.[1] Mother brought the action as the independent administrator of the estate of Chance Dean, deceased.

¶ 2 On June 24, 2022, Mother filed a first amended complaint, which alleged that Chance Dean, the plaintiff infant born prematurely, was given the defendants' cow-milk-based infant formula product, which caused him to develop necrotizing enterocolitis (NEC), resulting in his death. Count I of Mother's first amended complaint alleged strict liability based on design defects, count II alleged strict liability for failure to warn, and count III alleged negligence.[2]

¶ 3 The jury returned a verdict in favor of Mother on strict liability for failure to warn and negligence and awarded Mother $60 million in damages. The trial court denied Mead Johnson's motion for a directed verdict at the close of Mother's case and again when Mead Johnson renewed its motion at the close of the evidence. The trial court also denied Mead Johnson's posttrial motions for judgment notwithstanding the verdict and for a new trial.

¶ 4 On appeal, Mead Johnson argues that the trial court erred when it failed to apply the learned intermediary doctrine, the trial court erred in instructing the jury, the trial court erred in key evidentiary rulings, and Mother failed to prove proximate cause or medical cause. For the

[*]Justice Moore was originally assigned to the panel. Justice Bollinger was later substituted on the panel and has listened to oral arguments and read the briefs.

[1]On November 2, 2023, Abbott Laboratories was voluntarily dismissed as a defendant.

[2]Plaintiff moved to voluntarily dismiss count IV (intentional misrepresentation) and count V (negligent representation).

reasons that follow, we reverse and remand for a new trial.

¶ 5 I. BACKGROUND

¶ 6 We limit our recitation of the facts to those relevant to this opinion. On March 3, 2020, Mother, who was expecting twins in May 2020, went to Memorial Hospital Shiloh Family Care Birthing Center (Memorial Hospital) located in Shiloh, Illinois. Because she had a high-risk pregnancy and was having twins, she was transferred to Barnes-Jewish Hospital in St. Louis, Missouri.

¶ 7 On March 3, 2020, Dr. Anna Lijowska, a neonatologist at Barnes-Jewish Hospital, met with Mother for a neonatology antenatal consultation while Mother was in labor. Mother was attentive during the conversation and asked appropriate questions. The doctor generally discussed the potential risks involved with prematurity and discussed the importance of breast milk, especially for premature infants. When Mother informed Dr. Lijowska that she intended to breastfeed her premature infants, Dr. Lijowska explained that nutrition initially would be provided to the twins intravenously (I.V.) before they were slowly transitioned to breast milk. Dr. Lijowska also briefly explained to Mother the possible complication of NEC. Dr. Lijowska created a care plan which indicated that Mother intended to breastfeed, but Mother also had consented to the infants receiving pasteurized human donor milk.

¶ 8 Mother gave birth to Chance and his twin brother, Chase. The twins were born more than 2 months premature, at 31 weeks and 2 days, which was considered preterm. Chase, the larger of the two babies, weighed 1,719 grams at birth (or 3 pounds, 15 ounces). His brother Chance weighed 1,660 grams (or 3 pounds, 10.6 ounces). The twins were immediately transferred to the neonatal intensive care unit (NICU) at St. Louis Children's Hospital (Children's Hospital), where they were each assigned a team of neonatologists, physicians, and dieticians.

¶ 9 Dr. Tasnim Najaf was the admitting neonatologist at Children's Hospital the day the twins were born and treated them until they were transferred to Memorial Hospital. After his birth, Chance began receiving I.V. nutrition. Dr. Najaf reviewed the care plan created by Dr. Lijowska, which indicated that Mother intended to breastfeed but also had consented for the infants to receive donor milk.

¶ 10 On March 4, 2020, Chance began receiving enteral feedings, also referred to as tube feedings. Premature infants such as Chance typically cannot take food by mouth because they have not yet developed the ability to swallow; thus, enteral feedings are given through a tube directly into the infant's stomach. This was true regardless of whether the infant was receiving its mother's breast milk, donor milk, or formula. Although Mother wanted to continue breastfeeding, she was unable to produce sufficient breast milk. With Mother's consent, Dr. Najaf ordered that Chance receive donor milk to supplement Mother's breast milk.

¶ 11 On March 8, 2020, Chance had decreased in weight to 1,358 grams, meaning he was now under 3 pounds. Dr. Najaf ordered that Similac Human Milk Fortifier be added to Chance's diet.[3] It typically took a few days to reach full feedings, as a preterm infant was started with the smallest amount and slowly increased depending on how the infant tolerates the feeding.

[3]Similac Human Milk Fortifier, which is manufactured by Abbott Laboratories, is a cow-milk-derived product that may be added to provide adequate nutrients to support a preterm infant's growth.

Chance reached full feedings on March 9, 2020. He was receiving Mother's expressed breast milk and donor milk. On March 13, 2020, Chance was still under his birth weight.

¶ 12 After Mother was discharged from the hospital, she visited the twins every day while they were in the Children's Hospital NICU. At some point, discussions were held about transferring the twins back to Memorial Hospital in Illinois to be closer to home. In March 2020, Memorial Hospital did not have donor milk as a feeding option. To prepare the twins for transfer to Memorial Hospital, on March 14, 2020, Dr. Najaf began transitioning them to "Enfamil Premature 24 Cal/fl oz" with iron (EPF24) every other feeding. EPF24 is a cow-milk-based infant formula for preterm infants that is manufactured by Mead Johnson. Chance continued to receive some donor milk as well. On March 15, 2020, Chance was transitioned to EPF24 in addition to Mother's expressed breast milk for each feeding.

¶ 13 On March 15, 2020, when the twins were less than two weeks old, they were transferred to Memorial Hospital across the river in Illinois to be closer to where Mother lived. At the time of his discharge from Children's Hospital, Chance weighed 1,396 grams (or 3 pounds, 1.2 ounces), meaning that Chance had lost weight from his original birth weight of 1,660 grams. Dr. Patrick Sloan was the admitting physician on March 15, 2020, when Chance arrived at Memorial Hospital. Dr. Sloan reviewed the discharge summary created by Dr. Najaf, which indicated that Chance had been transitioned to EPF24 plus Mother's expressed breast milk, 120 kcal per kilogram per day. Dr. Sloan determined this was an appropriate nutritional course and continued the feeding plan. On March 15, 2020, Dr. Sloan ordered that Chance begin taking caffeine citrate solution for apnea of prematurity.

¶ 14 Dr. Elena Minakova also treated the twins while they were at Memorial Hospital. Dr. Minakova was aware that Chance had been transitioned to EPF24 before being transferred. On March 21, 2020, Chance was growing and doing well. Progress notes indicated he had good bowel sounds and his belly was soft. There were no concerns revealed upon examination. As Mother did not have sufficient breast milk, Chance continued receiving EPF24. On March 23, 2020, Dr. Minakova discontinued Chances's caffeine treatment because he was not experiencing apneas, heart rate drops, or oxygen saturations. On the morning of March 24, 2020, Chance was doing well upon examination. Two hours later, NICU nurses noticed a clinical change in Chance and contacted Dr. Minakova. When she examined Chance this time, he was experiencing oxygen drops, was breathing quickly, and had a profoundly distended and enlarged belly. Dr. Minakova ordered an X-ray and bloodwork. She also ordered fluids and antibiotics. Dr. Minakova suspected Chance had developed NEC, and Chance was transferred back to Children's Hospital.

¶ 15 On March 25, 2020, follow-up testing confirmed Dr. Minakova's suspicion that Chance had developed NEC. Chance underwent the first of three surgeries. Three days later, Chance died. He was 25 days old. Chance's brother, Chase, survived.

¶ 16 A. Pretrial Issues

¶ 17 Prior to trial, Mead Johnson filed a motion for summary judgment, arguing, *inter alia*, that the trial court should grant summary judgment on Mother's failure-to-warn and design-defect claims. Mead Johnson maintained that Mother could not prove her failure-to-warn claim because, under the learned intermediary doctrine, a manufacturer has no duty to warn the ultimate patient or consumer because the manufacturer's duty, if any, is owed to the physician. Mead Johnson further maintained that there is no such duty when, as here, doctors generally

understand the risk. At the motion hearing, the trial court expressed concern that the doctors were not aware of the magnitude of the increased risk of NEC with use of EPF24 and denied Mead Johnson's summary judgment motion, finding there were genuine issues of material fact.

¶ 18 During pretrial proceedings and throughout the trial, a significant evidentiary dispute emerged regarding the scope of materials Mother sought to introduce. Mother proffered hundreds of internal Mead Johnson documents, including marketing presentations, competitive analyses concerning donor-milk suppliers, financial records, chief executive officer (CEO) compensation materials, and promotional content unrelated to EPF24. Many documents were created months or years after Chance's death; other documents referenced products Chance never received, including human-milk fortifiers manufactured by third parties. Mother also introduced materials discussing Mead Johnson's commercial strategy in other markets and for other product lines.

¶ 19 Mead Johnson objected to much of this evidence on grounds of relevance and unfair prejudice, arguing that the materials had no connection to EPF24, to the physicians' decision-making, or to the medical events that preceded Chance developing NEC. Mead Johnson further argued that none of the treating physicians had ever seen the marketing materials, that Mother herself had never seen any warnings or promotional materials, and that introducing such evidence risked portraying the company as profit-driven or ethically questionable without shedding light on whether EPF24 caused Chance's death.

¶ 20 The parties filed a number of motions *in limine* as well as motions to exclude evidence. Mother maintained that the trial court should exclude, among other things, evidence of her marijuana use, a Facebook post she made regarding drinking wine, and Chance's alleged liver laceration/abrasion. Mead Johnson argued, *inter alia*, that the trial court should exclude advertising, marketing, or other consumer or healthcare provider information that neither Mother nor Chance's treating physicians had received, which the trial court denied. Mead Johnson also moved to exclude Mother's marketing expert, Jennifer Pomeranz, who offered extensive deposition testimony that Mead Johnson argued went beyond her marketing qualifications. The trial court reserved ruling on this motion. Mead Johnson sought to have the trial court prohibit any reference to the financial resources, revenue, or profitability of Mead Johnson or its corporate parent, Reckitt Benckiser (Reckitt), as Mother was seeking only compensatory damages. The trial court reserved ruling on this motion.

¶ 21 B. Mother's Case-in-Chief

¶ 22 1. Dr. Lijowska's Testimony

¶ 23 Dr. Joanna Lijowska, a board-certified pediatrician and neonatologist, served on the faculty of Washington University in St. Louis with clinical privileges at Children's Hospital and also practiced as an attending neonatologist at Barnes-Jewish Hospital. She testified that NEC occurred in both exclusively breastfed infants and infants who received formula, though she noted a slight increase in the risk of NEC among formula-fed infants. While the precise cause of NEC remained unknown, she explained that several factors were recognized as increasing risk; however, she cautioned that, even when a medication or medical condition was associated with NEC, such an association did not establish causation. Dr. Lijowska further testified that in her regular practice as a neonatologist she routinely ordered formula for infants when clinically appropriate.

¶ 24 Dr. Lijowska lacked independent recollection of the specific counseling she provided to Mother beyond what appeared in the medical records. She testified that, when a mother had already chosen to breastfeed, she typically did not emphasize NEC-related risks because those discussions were generally unnecessary in that context. She explained, however, that it was the standard practice at Children's Hospital for clinicians to review the risks and benefits of all feeding options with parents of premature infants. In alignment with that practice, the hospital had developed a written handout advising parents that the use of donor milk reduces the risk of NEC compared to preterm formula. Dr. Lijowska testified that feeding guidelines at the hospital were established through a committee composed of neonatologists, NICU dietitians, and nurse practitioners. Although Children's Hospital maintained guidelines specifying when donor milk may be used, she stated that individualized feeding plans could be developed based on an infant's specific medical history.

¶ 25 2. Dr. Najaf's Testimony

¶ 26 Dr. Najaf worked as a neonatologist for Washington University in St. Louis, practicing at Children's Hospital and other affiliated institutions. She testified that, although she was aware of an association between formula use and a slightly increased risk of NEC, she did not know what caused NEC and did not believe that the medical community had a firm understanding of its causes. She explained that NEC could develop in infants who received breast milk, donor milk, or formula. Based on her training and review of medical literature, she understood that formula carried a slightly higher NEC risk than human milk, and this was the information she conveyed to parents. When asked whether she knew the degree of increased risk, she stated that no one knew the exact amount.

¶ 27 Dr. Najaf identified known NEC risk factors, including prematurity, low birth weight, lower gestational age, overall illness, antibiotics, and caffeine. Despite the recognized association between antibiotics and caffeine and an increased NEC risk, she testified that she nevertheless administered these treatments to Chance because, in her medical judgment, their benefits outweighed any incremental risk. She continued to order preterm formula in her practice and stated that she would not have ordered a preterm formula such as EPF24 if she believed it was dangerous or harmful to infants.

¶ 28 Dr. Najaf testified that she did not know why some infants developed NEC and others did not, noting that NEC could occur even in circumstances where twins received identical feedings but only one developed the condition. She treated both Chance, the smaller twin, and Chase, the larger twin. Chase received caffeine therapy, antibiotics, and the same pattern of enteral feeding as Chance, beginning on March 4, 2020. He received Similac Human Milk Fortifier, reached full feedings on March 9, and was transitioned to EPF24 every other feeding on March 14 and then to full EPF24 plus expressed breast milk on March 15. Unlike Chance, however, Chase did not develop NEC.

¶ 29 Dr. Najaf testified that Chance began enteral feedings on March 4, 2020, reaching full feedings on March 9. She described the nutritional options available to premature infants as term formulas, preterm formulas such as EPF24, breast milk, and donor milk. She explained that Children's Hospital required feeding plans for each infant. Although standardized guidelines existed, these could be individualized based on the infant's medical needs. Feeding plans were developed by a team of experts, including nurses, nurse practitioners, dietitians, and lactation consultants, and could be adjusted as an infant progressed in the NICU. The

guidelines themselves were periodically updated as new scientific information became available.

¶ 30 On March 14, 2020, Dr. Najaf began transitioning Chance to EPF24 every other feeding. She testified that feeding decisions were ordinarily made through discussions between the parents and the infant's care team and that, before Chance could have been given EPF24, Dr. Najaf would have been required to make or approve that decision. Although she had no specific recollection of the conversation, she testified that, as part of the transfer planning for Chance's move to Memorial Hospital, she—or another provider—would have discussed with Mother that Memorial Hospital did not have donor milk. She believed that no change to Chance's feeding plan would have occurred without both communication with Mother and her consent.

¶ 31 Dr. Najaf testified that she had never read an EPF24 label and had never visited Mead Johnson's website. Her knowledge of infant nutrition came from the published medical literature. She testified that all treatment decisions she made for Chance were based on her professional judgment, hospital guidelines, and established science and not on Mead Johnson's marketing or on information from any sales representative. She stated that she would have expected Mead Johnson to publicly disclose complaints involving NEC or deaths associated with EPF24 and would have considered such information important in determining whether to allow its use in the NICU.

¶ 32 On cross-examination, Dr. Najaf testified that she would not conclude that an event was associated with an injury based on a single report. She did not believe formula caused NEC and stated that she continued to order preterm formula for infants because the benefits outweighed any identified NEC risk. She stated that she believed she had provided Mother with enough information regarding the potential risk of NEC to permit her to make an informed decision to transfer Chance to Memorial Hospital, where donor milk would not be available.

¶ 33 3. Dr. Minakova's Testimony

¶ 34 Dr. Minakova was a board-certified neonatologist who treated Chance at Memorial Hospital. She was aware that, before his transfer, Chance had been receiving a combination of donor milk, Mother's milk, and fortifier at Children's Hospital and that he had been transitioned to EPF24 prior to the transfer. She testified that in March 2020 Memorial Hospital did not have donor milk available. It was typical practice for an infant transferred from Children's Hospital to Memorial Hospital to be transitioned to formula before transport if insufficient maternal milk was available. Dr. Minakova indicated that a neonatologist at Children's Hospital would have discussed the transition to EPF24 with Mother before Chance's transfer.

¶ 35 After examining Chance on March 24, Dr. Minakova observed significant abdominal distention and noted that he appeared very uncomfortable with palpation. Based on her examination, she suspected that Chance had developed NEC and ordered further testing, which confirmed her suspicion. She discussed with Mother the need to transfer Chance back to Children's Hospital, where he would have access to pediatric surgical care.

¶ 36 Dr. Minakova testified that she was aware of the higher risk of NEC associated with formula feeding regardless of labeling. Although she had not seen a study quantifying the extent of the increased risk, she stated that it was generally accepted within the medical community that formula feeding carried a higher NEC risk. She explained that a mother's breast milk was considered protective against NEC and that preterm formula might not provide

the same protection. She also testified that formula feeding was associated with a potentially higher incidence of NEC. Nonetheless, Dr. Minakova stated that she continued to order preterm formula in circumstances where neither breast milk nor donor milk was available, because there were no alternative means to feed a premature infant in those situations.

¶ 37 4. Mother's Testimony

¶ 38 Mother testified that she did not recall having a consultation with Dr. Lijowska before the twins were born, although she remembered asking about some of the medical equipment after their birth. She did not recall receiving a patient-education handout from Children's Hospital explaining that studies had shown breast milk decreased the risk of NEC in preterm infants, nor did she recall receiving any materials informing her that her premature infants might be at significantly higher risk of NEC if they received formula. During the twins' stay in the NICU, Mother regularly spoke with the doctors to stay informed about their condition. She stated that she wished to breastfeed and therefore pumped breast milk, but she did not produce enough for both infants. She understood that the twins were receiving donor milk in addition to her own but did not recall anyone telling her that donor milk would not be available once they were transferred to Memorial Hospital. She also did not recall Dr. Najaf informing her of the risk of NEC before Chance's transfer.

¶ 39 After the transfer, Mother first learned that Chance was receiving formula when she saw a bottle of EPF24 in the NICU at Memorial Hospital. She did not recall whether she read or handled the bottle. When asked if she had decided to feed Chance formula, she testified that she was surprised to discover that he was receiving it, as she believed he would continue to receive donor milk. She testified that she did not purchase the formula for him while he was at Memorial Hospital, and she did not remember seeing any advertising, marketing materials, or coupons from Mead Johnson before Chance received EPF24. Mother stated that during Chance's hospitalization she trusted the doctors, nurses, and other medical professionals to provide appropriate care and nutrition.

¶ 40 Mother further testified that, had she been aware of the risks, she would have sought an alternative or asked that the twins be transferred back to Children's Hospital where donor milk was available. When a doctor informed her that Chance had NEC, she searched online for information and learned that NEC could be associated with dairy or milk. After Chance was transferred back to Children's Hospital, she requested that he be taken off formula, and he was started on EleCare, a non-milk-based formula, on the day he died.

¶ 41 5. Dr. Sims's Testimony

¶ 42 Dr. Brian Sims testified as a retained expert for Mother. He was a board-certified neonatologist who had practiced for nearly 18 years at the University of Alabama in Birmingham (UAB), where he also served as a tenured professor of pediatrics. He testified that he had cared for thousands of infants and had taught hundreds of medical and graduate students in areas including neuroscience, cell biology, brain injury, and glial development. He further stated that he served on the editorial board of the journal *Pediatrics & Therapeutics* since 2012 and had authored or contributed to more than 50 manuscripts, abstracts, or book chapters.

¶ 43 Dr. Sims explained that the NICU at UAB, capable of caring for approximately 120 infants at a time, regularly treated premature infants at high risk for severe complications, including NEC. He described NEC as an inflammatory, potentially fatal intestinal disease most often

found in premature or medically fragile infants. He testified that NEC could progress rapidly, sometimes moving from subtle symptoms to life-threatening deterioration within minutes. He identified common signs of NEC as feeding intolerance, abdominal discoloration or distention, bloody stools, respiratory difficulty, and metabolic acidosis.

¶ 44 Dr. Sims testified that risk factors for NEC included prematurity, low birth weight, low oxygen levels, enteral feedings, antibiotic exposure, changes in the gut microbiome, and cow-milk-based formula. He explained that premature infants were more susceptible to NEC because their intestines were not fully prepared to process food and that, when born too soon, infants required nutritional support in order to survive. Dr. Sims described UAB's three-tier feeding hierarchy, supported by professional guidelines, stating that the preferred nutrition for premature infants was the mother's own breast milk, followed by pasteurized donor milk, with cow-milk-based formula as the final option. He testified that premature infant formulas such as EPF24 were "tougher on the intestines than human milk" and that fortifiers were introduced only after an infant demonstrated tolerance of enteral feeding.

¶ 45 Dr. Sims testified that full-term infants were born between 37 and 40 weeks of gestation, while preterm infants were born before 34 weeks. He stated that, the earlier an infant was born, the greater the risk of serious illness or death. Approximately 10% of low-birth-weight, premature infants, he stated, developed some form of NEC. He explained that NEC involved intestinal inflammation that could lead to tissue death and, while some infants survived, others did not. When NEC was suspected, medical staff stopped feedings and began treatment with I.V. antibiotics, and in some cases surgery became necessary to remove necrotic tissue.

¶ 46 Dr. Sims testified that, although the cause of NEC remained unclear, it was most commonly associated with prematurity and low birth weight and that prematurity alone increased the risk of NEC regardless of what the infant was fed. He stated that Chance was already at an increased baseline risk for NEC simply because he was premature.

¶ 47 Dr. Sims opined, to a reasonable degree of medical certainty, that EPF24 caused or contributed to Chance's development of NEC. He based his opinion on his clinical experience, his review of scientific studies, and his review of Chance's medical records. He acknowledged the existence of medical literature indicating increased NEC risk with formula feeding, as well as studies showing no higher risk of NEC with formula compared to donor milk.

¶ 48 On cross-examination, Dr. Sims testified that a premature infant could develop NEC even if fed only breast milk or donor milk and that NEC could develop in an infant receiving donor milk with fortifier, as Chance had. He agreed that none of the treating physicians had stated that EPF24 caused Chance's NEC. He also acknowledged that in his own scientific publications he had not written that cow-milk-based preterm formula causes NEC.

¶ 49 Dr. Sims testified that he did not advise physicians never to use cow-milk-based preterm formulas, and he acknowledged that such formulas were used in the NICU at UAB when medically necessary and when maternal milk was unavailable. He stated that he would not give an infant a product he believed could kill them. Dr. Sims explained that UAB maintained a written feeding protocol indicating that an infant weighing 1,500 grams at 32 to 36 weeks' gestation should be transitioned to cow-milk-based preterm formula if the mother's milk was not available, though professional judgment was always required to determine the best course for any infant. He testified that his medical decisions were not influenced by infant formula companies.

¶ 50 Dr. Sims stated that he did not review product labeling for any infant formula in preparing for trial and did not know whether Chance's treating physicians had reviewed the EPF24 label. He also did not review or rely on Mead Johnson marketing materials. He testified that it would be untrue to suggest that he had been misled or biased by the formula industry. He did not disagree with the decision of Chance's healthcare providers to use cow-milk-based formula. Dr. Sims was unable to identify any specific component in cow-milk-based formula that caused Chance to develop NEC.

¶ 51 6. Dr. Swanson's Testimony

¶ 52 Dr. Jonathan Swanson testified as a retained expert on behalf of Mother. Dr. Swanson was a neonatologist, professor of pediatrics at the University of Virginia (UVA), medical director of the UVA NICU, and chief quality officer for children's services. He described more than 15 years of clinical practice in a level IV NICU, which routinely cared for more than 50 infants a day and received transfers from across Virginia and surrounding states.

¶ 53 Dr. Swanson's primary research interests centered on NEC, the nutrition of premature infants, and neonatal quality-improvement efforts. He had authored or coauthored more than 75 publications, many related to NEC or human milk-based feeding strategies, and testified that he frequently speaks at conferences across the United States and internationally.

¶ 54 Dr. Swanson described UVA's decision, beginning in 2016, to implement an exclusive human milk diet for infants under 34 weeks' gestational age. He testified that, upon returning to UVA in 2011, he initially questioned whether donor milk offered benefits significant enough to justify its challenges. However, he stated that, as studies accumulated and as UVA collected internal outcome data, he came to believe that use of maternal and donor milk substantially reduced NEC risk. He further testified that UVA relies on maternal milk when available and donor milk in its absence, and it only rarely provides cow-milk-based formula to infants under 34 weeks. Above 34 weeks, however, UVA frequently transitions infants to cow-milk-based formula, and he acknowledged that infants between 33 and 34 weeks may also receive cow-milk-based fortifier or formula earlier if they demonstrate poor growth or inadequate nutritional response.

¶ 55 Dr. Swanson opined that, to a reasonable degree of medical certainty, cow-milk-based formula caused or contributed to cause NEC in certain premature infants, specifically those under 34 weeks. Much of Dr. Swanson's direct examination was devoted to discussing the literature he believed supported his views. He cited studies such as Lucas & Cole (1990), Sullivan (2010), Cristofalo (2013), Colaizy (2024), Meinzen-Derr (2009), Abrams (2014), Assad (2016), and Johnson (2020), asserting that the collective evidence showed that formula-fed infants are between two and five times more likely to develop NEC than those who receive human milk.[4] He also referenced the 2012 American Academy of Pediatrics (AAP) statement

[4]Dr. Swanson described these articles while they were presented, in part, on slides, and several were also admitted into evidence as plaintiff's or defendant's exhibits. See A. Lucas and T.J. Cole, *Breast Milk and Neonatal Necrotizing Enterocolitis*, 336 The Lancet 1519 (1990); Sandra Sullivan *et al.*, *An Exclusively Human Milk-Based Diet Is Associated With a Lower Rate of Necrotizing Enterocolitis Than a Diet of Human Milk and Bovine Milk-Based Products*, J. Pediatrics, Apr. 2010, at 562, https://www.jpeds.com/article/S0022-3476(09)01085-3/fulltext [https://perma.cc/TS2G-RKUP]; Elizabeth A. Cristofalo *et al.*, *Randomized Trial of Exclusive Human Milk Versus Preterm Formula*

recommending human milk for very low birth-weight infants and highlighting a reported 77% reduction in NEC among infants fed human milk compared to formula.

¶ 56 On cross-examination, Dr. Swanson acknowledged that many of the studies he relied upon, including Sullivan (2010) and Cristofalo (2013), were conducted in extremely low-birth-weight infants, often under 1,250 grams or even under 1,000 grams. He conceded that such studies did not enroll infants comparable in size to many premature infants and particularly not to all NICU populations. These studies also included significant maternal-milk exposure even within the "formula" arms, a methodological feature that cross-examination emphasized could diminish the ability to isolate the effect of cow-milk-based formula. Several of the studies he heavily endorsed were funded by Prolacta, the manufacturer of human-milk-based products and a major Mead Johnson competitor, and multiple authors of these studies were either employees or paid consultants of Prolacta.

¶ 57 In addition, Dr. Swanson conceded that NEC can and does occur even in infants who receive exclusive human-milk diets, including those fed only maternal or donor milk. He acknowledged that the exact protective mechanism of human milk remains unknown, as does any precise harmful mechanism in formula. Dr. Swanson admitted that he could not identify any specific cow-milk ingredient shown to cause NEC. Moreover, although he testified to a general two- to five-fold increased risk with formula, he acknowledged in prior sworn testimony, which he was confronted with at trial, that "the magnitude and the risk is different for every patient," and he agreed that risk estimates depend heavily on population characteristics such as gestational age, birth weight, comorbidities, feeding tolerance, maternal-milk availability, and other individualized factors. Dr. Swanson further admitted he could not give a universal numerical risk applicable to all preterm infants.

¶ 58 Although Dr. Swanson emphasized donor milk as the preferred alternative to formula for high-risk infants, he acknowledged that he was aware of national surveys showing that donor milk was not available in many NICUs, particularly level II units, and that the American Academy of Pediatrics (AAP) itself had stated donor-milk accessibility remained substantially limited by supply, cost, and distribution. Cross-examination also highlighted his prior deposition testimony in which he agreed that cow-milk-based formula remains "a necessary tool in the toolbox" for NICU professionals in the real world.

Diets in Extremely Premature Infants, J. Pediatrics, Dec. 2013, at 1592, https://www.jpeds.com/article/S0022-3476(13)00865-2/fulltext [https://perma.cc/66V5-3X2W]; Tarah T. Colaizy *et al.*, *Neurodevelopmental Outcomes of Extremely Preterm Infants Fed Donor Milk or Preterm Infant Formula: A Randomized Clinical Trial*, J. Am. Med. Ass'n (Jan. 30, 2024), https://jamanetwork.com/journals/jama/fullarticle/2814657 [https://perma.cc/HWL4-A8UN]; J. Meinzen-Derr *et al.*, *Role of Human Milk in Extremely Low Birth Weight Infants' Risk of Necrotizing Enterocolitis or Death*, 29 J. Perinatology 57 (2009); Steven A. Abrams *et al.*, *Greater Mortality and Morbidity in Extremely Preterm Infants Fed a Diet Containing Cow Milk Protein Products*, Breastfeeding Med. July 2014, at 281, https://pmc.ncbi.nlm.nih.gov/articles/PMC4074755/ [https://perma.cc/UBX2-582S]; M. Assad, M.J. Elliott, & J.H. Abraham, *Decreased Cost and Improved Feeding Tolerance in VLBW Infants Fed an Exclusive Human Milk Diet*, 36 J. Perinatology 216-20 (2016); Tricia J. Johnson *et al.*, *Cost Savings of Mother's Own Milk for Very Low Birth Weight Infants in the Neonatal Intensive Care Unit*, 6 PharmacoEconomics 451 (2022), https://link.springer.com/article/10.1007/s41669-022-00324-8 [https://perma.cc/HQ2A-RPER].

¶ 59 Dr. Swanson acknowledged being a paid speaker for Prolacta since 2019, receiving $3,000 per presentation plus travel reimbursement, and being bound by contractual provisions addressing conflicts and confidentiality. He conceded that Prolacta used his presentations in its marketing and that at least one of his publications listed Prolacta as a competing interest. Cross-examination further revealed that, although he acknowledged an ethical imperative to disclose potential conflicts in academic publications, he did not disclose his paid litigation work for Mother, approximately $40,000 at the time of trial, in his published writings, even when discussing the same subject matter at issue in this case.

¶ 60 The cross-examination also highlighted disparities between peer-reviewed and non-peer-reviewed data. One peer-reviewed publication he coauthored before entering a paid relationship with Prolacta reported no statistically significant difference in NEC or surgical NEC when comparing exclusive human-milk diets to mixed or formula-fed groups. In contrast, a later presentation, created after becoming a Prolacta speaker and not peer-reviewed for publication, reported significant reductions in surgical NEC.

¶ 61 Finally, although Dr. Swanson emphasized that many neonatologists underestimated the magnitude of NEC risk with formula, he conceded that he had not reviewed the depositions of the treating neonatologists in this case and that his belief was based largely on general impressions and surveys rather than any case-specific assessment. He acknowledged that he had reviewed only limited materials from the litigation and that he was not offering any opinion on the medical care of the infant involved in this case.

¶ 62 7. Financial Testimony

¶ 63 Mother also presented extensive evidence regarding Mead Johnson's financial information although she was not asserting a punitive damages claim. This evidence included budget, profit, and executive compensation information, including the executive compensation of the former CEO of Mead Johnson's nonparty, overseas parent company.

¶ 64 a. Robert Cleveland's Testimony

¶ 65 Robert Cleveland was the senior vice president for North America nutrition at Mead Johnson/Reckitt. Cleveland testified regarding Mead Johnson's marketing practices, competitive strategy, and the central role of the NICU in its business model. He also testified extensively about Mead Johnson's financial structure, revenue model, NICU-driven business strategy, and economic underpinnings of its infant-formula operations.

¶ 66 As the executive directly responsible for all sales, revenue, and profit outcomes in the United States, Cleveland was evaluated and compensated entirely on achieving financial metrics. His annual bonus, which in 2022 resulted in a total payout exceeding $620,000, depended solely on hitting revenue and profit targets rather than safety benchmarks or clinical outcomes. He confirmed that this compensation structure extended downward throughout the organization, with employees across departments receiving bonuses tied to revenue generation. Although Cleveland emphasized Mead Johnson's commitment to safety, transparency, and ethical conduct, his own financial incentives, and those of company leadership, were tied exclusively to profit generation rather than safety performance or risk-mitigation initiatives.

¶ 67 Against this financial backdrop, Cleveland described a marketing strategy built around the pivotal role of the hospital, particularly the NICU, as the gateway to long-term corporate

revenue. Nearly all of Mead Johnson's United States revenue came from retail sales to parents after their infants were discharged. Hospitals rarely paid for infant formula; instead, Mead Johnson provided formula free or at steep discounts in exchange for contracts obligating hospitals to use Mead Johnson products for 80-90% of feedings. Cleveland acknowledged that this practice was not rooted in altruism but in commercial necessity: the "conversion rate," *i.e.*, Mead Johnson's internal term for the percentage of parents who continue buying Mead Johnson formula after an infant received it in the hospital, stood at roughly 70%. Capturing infants in the NICU, thus, became the mechanism for capturing the family as long-term retail customers. Cleveland conceded that loss of NICU market share would be "financially disastrous" for Mead Johnson because it would sever this conversion pipeline.

¶ 68 Internal documents presented to Cleveland at trial quantified the financial value of NICU exposure. The evidence revealed Mead Johnson had calculated that each infant exposed to its formula in the hospital generated approximately $700 in postdischarge retail revenue. Though Cleveland insisted this figure did not mean Mead Johnson "puts a value on babies," the evidence showed that Mead Johnson used this calculation operationally in forecasting, in competitive analysis, and in internal modeling. Mead Johnson's own strategic plans recognized its premature portfolio as one of the "strongest drivers" of incremental net revenue, with internal slide decks estimating that NICU-driven rotation accounted for one-third of all United States revenue, roughly $233 million (or about $900 million in 2020 dollars). Cleveland agreed that maintaining NICU product placement was essential to the company's national financial health.

¶ 69 In a 2010 e-mail authored by Cleveland, he acknowledged that treating a single case of NEC cost more than $450,000 per infant and that NEC imposed a national burden of more than $5 billion annually. Yet despite this awareness, Mead Johnson had issued no NICU-specific warnings and provided no NEC-related disclosures to physicians or parents. The evidence revealed instead that Mead Johnson focused on countering the commercial threat posed by Abbott Laboratories' partnership with Prolacta, a manufacturer of human-milk-derived nutritional products known to reduce NEC risk. Cleveland acknowledged that human milk carried immunoprotective benefits cow-milk products could not match and conceded that legislation requiring broader insurance coverage for human-milk-derived products would be "dangerous" to Mead Johnson's business.

¶ 70 Cleveland denied that Mead Johnson ever sought to undermine research, yet internal marketing directives instructed employees to "disrupt the Schanler study," which had reported unfavorable findings about Mead Johnson's acidified liquid human-milk fortifier. Cleveland characterized "disrupt" as merely encouraging clinicians to view additional data. Meanwhile, although Cleveland stated that Mead Johnson would never target "vulnerable moms," internal corporate plans, which he reviewed in his role as senior leadership, used precisely that term, calling for strategies to "maximize value tier profitability among vulnerable moms" and "win in the vulnerable consumer segment." He attempted to distinguish economic vulnerability from emotional or social vulnerability.

¶ 71 When asked whether EPF24 was available for purchase at retail stores, Cleveland testified that it was not generally available at the retail level. He explained that, although it may be available online, this access existed to ensure continuity of care when physicians directed parents to continue feeding the same formula provided in the hospital following discharge. He stated that families often had difficulty obtaining the product at retail stores, particularly in

certain geographic areas, and hospitals did not supply all of the formula needed after discharge. As a result, the company maintained a direct-to-consumer online option so parents could obtain the product when necessary. Cleveland further testified that, in general, parents purchased EPF24 online at the direction of a healthcare professional and that the product was not stocked on the shelves of retailers such as Target, Walmart, or Walgreens, though it may occasionally be available by special order through a pharmacist.

¶ 72 b. Rakesh Kapoor's Testimony

¶ 73 Rakesh Kapoor was the former CEO of Reckitt. Kapoor testified regarding Reckitt's acquisition of Mead Johnson, the company's financial interests in the preterm-formula market, and Reckitt's awareness of the medical and financial implications of human-milk-based alternatives. Kapoor served as Reckitt's CEO from 2011 to 2019, overseeing its 2017 acquisition of Mead Johnson for nearly $17 billion. During his tenure and at the time he left the company, Kapoor acknowledged that he received substantial executive compensation, testifying that his total remuneration across several years, including 2017 through 2019, amounted to approximately $23 to $24 million. He further testified that he continued to hold shares in Reckitt after leaving the company and, therefore, retained an ongoing financial interest in its performance.

¶ 74 Kapoor was questioned extensively about the financial and strategic considerations underlying Reckitt's evaluation of a potential partnership with Medolac, a company developing donor human-milk products and a human-milk-based fortifier. He testified that, during this timeframe, Mead Johnson's revenue was hundreds of millions of dollars annually. He acknowledged receiving internal presentations and communications in 2017 and 2018 describing Medolac's technology as potentially significant to NICUs and noting that human-milk-based products were increasingly viewed as the standard of care due to their association with improved gut health and reduced risk of NEC. Kapoor further acknowledged that Mead Johnson leadership informed him that the NICU played a disproportionate role in hospital contracting decisions and that nutritional offerings in the NICU influenced a majority of hospital formula contracts.

¶ 75 Kapoor testified that Reckitt engaged the consulting firm Advancy to evaluate the commercial and strategic attractiveness of a potential Medolac partnership. According to that evaluation, he was informed that a partnership could generate incremental top-line revenue for Mead Johnson, with projections ranging from approximately $51 million in a base case to $99 million in a high case, driven largely by enhanced hospital contracting and revenue-sharing arrangements. Kapoor also acknowledged that the projected revenue attributable specifically to donor human-milk sales would be comparatively modest and described in the analysis as yielding marginal net revenue due to lower margins. He nevertheless confirmed that the proposed partnership was presented as having strategic value beyond immediate profitability, including competitive advantages in hospital contracting and portfolio expansion.

¶ 76 Throughout his testimony, Kapoor denied that profit considerations would have prevented Reckitt from pursuing safer or more beneficial infant nutrition products. He testified that safety was Mead Johnson's top priority and that he would have supported initiatives that improved product safety or advanced the company's stated purpose, even where immediate profitability was limited. At the same time, he acknowledged that no partnership with Medolac was ultimately consummated during his tenure and that Mead Johnson did not introduce a human-

milk-based preterm product while he served as CEO. He testified that he could not recall why the discussions did not result in a completed transaction and stated that the absence of a deal did not reflect a lack of intent, but rather an inability to reach a viable arrangement for reasons he could no longer specifically identify.

¶ 77 C. Mead Johnson's Case-in-Chief

¶ 78 1. Dr. Sloan's Testimony

¶ 79 Dr. Sloan was a neonatologist who treated Chance upon his arrival at Memorial Hospital. He did not have an independent recollection of treating Chance, but he reviewed the contemporaneous medical records. He testified that he had first learned of NEC during his pediatric residency. Although Dr. Sloan did not know what caused NEC, he understood its origins to be multifactorial. He further testified that preterm infant formula might increase the risk of NEC and that early introduction of breast milk could be protective. Dr. Sloan had treated infants with NEC in his practice but did not consider himself an expert on the condition. He stated that prematurity was the greatest risk factor for NEC, that NEC could occur in infants fed only breast milk, and that low birth weight also significantly increased the risk.

¶ 80 Dr. Sloan testified that he had not personally studied nutritional guidelines regarding NEC but he had received training on the subject. After reviewing Dr. Najaf's feeding plan for Chance, he concluded it was reasonable and continued it. He was aware that Chance had been receiving donor milk at Children's Hospital, but he stated that donor milk was not available at Memorial Hospital in March 2020. Accordingly, the only feeding option at Memorial Hospital was infant formula. He reviewed a patient order summary showing that he had requested a dietician consultation, explaining that all NICU infants were routinely monitored to ensure appropriate nutrition and growth. The medical records indicated that Chance would receive EPF24 along with unfortified breast milk by oral or tube feeding.

¶ 81 Dr. Sloan testified that as a neonatologist he made decisions for premature infants using evidence-based science and by considering all available information. He relied upon his medical training, his clinical experience, and the feeding guidelines of the hospitals where he practiced. When asked whether he would rely on information from a formula company if it conflicted with scientific literature, he stated that he would rely on his medical training and experience. He agreed that it was important to know whether a formula carried a higher NEC incidence relative to human milk, but he testified that the mere fact that an infant developed NEC after receiving formula did not establish causation.

¶ 82 Dr. Sloan stated that no infant in the preterm nursery at Memorial Hospital could receive formula without a physician's order, and he explained that Chance would not have received preterm formula without Mother's consent. He also testified, however, that without preterm formula available at Memorial Hospital, Chance would not have received sufficient nutrients to support his growth. He stated that he prescribed EPF24 based on his best medical judgment and that he weighed the associated risks and benefits. He testified that he understood that formula feeding was less protective against NEC than human breast milk.

¶ 83 Dr. Sloan testified that he kept current with advances in neonatal care, including research on the risks and benefits of foods and medications commonly used for preterm infants. He was familiar with the 2012 AAP policy statement, Breastfeeding and the Use of Human Milk, which summarized research indicating that human milk was associated with a significant reduction in NEC incidence. See Am. Acad. Pediatrics, *Policy Statement: Breastfeeding and*

the Use of Human Milk, J. Pediatrics, Mar. 2012, at 827, https://publications.aap.org/pediatrics/article/129/3/e827/31785/Breastfeeding-and-the-Use-of-Human-Milk [https://perma.cc/RB6U-R7RV]. He stated that he was aware of this information in 2020 and would have considered it when determining feedings for preterm infants. He further testified that cow-milk-based infant formula carried an increased NEC risk relative to breast milk, although he did not recall the specific percentages reported in the literature. Even with that knowledge, he continued to prescribe preterm formula for NICU infants when neither breast milk nor donor milk was available.

¶ 84 Dr. Sloan testified that he did not recall ever accessing Mead Johnson's website. Although he remembered reviewing formula labels during residency, he did not recall their specific contents and did not rely on labels when making feeding decisions. He did not recall whether he had ever spoken to a Mead Johnson sales representative, though he remembered attending a fellowship-era conference at which industry representatives were present, without recalling which company sponsored the event.

¶ 85 2. Dr. Minakova Recalled

¶ 86 Dr. Minakova was recalled as a witness by Mead Johnson. She testified that NEC was a widely recognized issue among neonatologists and a long-standing focus within the neonatal field. She first learned about NEC during medical school and continued throughout her career to stay current on the scientific literature, including the most recent studies and journals. She stated that in 2020 she was aware of the potential association between formula use and an increased incidence of NEC. When prescribing formula, Dr. Minakova weighed the risks and benefits of the feeding choice for the particular preterm infant, and although she knew of the NEC risk associated with formula, she continued to transition infants to preterm formula when she believed it was medically appropriate.

¶ 87 When asked about the cause of NEC, Dr. Minakova testified that multiple theories existed and that the exact cause remained unknown. She explained that, although several risk factors might predispose an infant to NEC, physicians still had not identified biomarkers that would predict which infants were likely to develop the condition. She stated that higher NEC risk was associated with the immaturity of a preterm infant's intestines, possibly due to overproliferation of gut bacteria, and that lower birth weight, anemia, and formula feeding had all been implicated as contributing factors. She explained that infants born under 32 weeks' gestation and weighing less than 1,500 grams tended to be at particularly high risk.

¶ 88 When asked whether something in formula caused NEC, Dr. Minakova testified that she did not know. She stated that NEC could occur in an infant who had received only its mother's breast milk and likewise in an infant who had received only donor milk. She reiterated that when ordering formula she evaluated the risks and benefits for each infant, taking into account gestational age, birth weight, and level of prematurity. She testified that she did not rely on marketing materials from formula manufacturers and that she generally did not have contact with sales representatives. She stated that she would not rely on a sales representative in deciding what product to prescribe for an infant.

¶ 89 Dr. Minakova testified that, when a preterm infant was transferred to Memorial Hospital, the neonatologist was responsible for ordering formula and scheduling feedings upon admission. She stated that she was not concerned that Chance had been transitioned to preterm formula before arriving at Memorial Hospital because that transition was consistent with

Children's Hospital guidelines for an infant of nearly 34 weeks' gestational age. When asked whether preterm formula had caused Chance to develop NEC, Dr. Minakova testified that it would be speculative to make such a conclusion. She stated that preterm formula was one of several risk factors that could potentially increase the likelihood of NEC, but she did not believe it was possible to determine specifically what had caused Chance to develop the disease.

¶ 90 3. Dr. Hay's Testimony

¶ 91 Dr. Susanne Hay testified for Mead Johnson as a neonatologist at Beth Israel Deaconess Medical Center in Boston and a faculty member at Harvard Medical School. Dr. Hay was board-certified in pediatrics and neonatology and had treated thousands of preterm infants across more than a decade in NICUs. Her clinical practice included daily decisions regarding neonatal nutrition, the use of mother's milk, donor milk, fortifiers, and preterm formula. Dr. Hay testified that attending neonatologists made the ultimate feeding decisions based on evidence-based guidelines rather than formula labels or manufacturer marketing.

¶ 92 Regarding Chance Dean, Dr. Hay testified that his feeding course progressed from mother's milk, to donor human milk, to donor milk plus cow-milk fortifier, and later to preterm formula. She indicated the feeding course was medically appropriate and consistent with both Children's Hospital policy and AAP guidelines. She explained that donor milk was generally prioritized for infants under 1,500 grams, and Chance, born at 1,660 grams, fell outside that priority category. On cross-examination, however, Mother's counsel pointed to Children's Hospital's written policy allowing donor milk to be continued for heavier infants at the attending physician's discretion, suggesting that continuation of donor milk remained permissible and that formula use was not unavoidable.

¶ 93 Dr. Hay testified that NEC was a multifactorial disease with an unknown cause and that human milk was protective, while donor milk offers attenuated protection due to pasteurization. She denied that formula causes NEC and emphasized that NEC occurs even in exclusively breast-fed infants. She identified several risk factors Chance had, including prematurity, anemia, enteral feeding, preeclampsia, and antibiotic exposure. Dr. Hay additionally testified that Chance's twin, Chase, who received nearly identical feedings, did not develop NEC, which she characterized as evidence that NEC is unpredictable. Counsel for Mother countered that unpredictability does not negate relative risk.

¶ 94 On redirect examination, Dr. Hay reiterated that formula does not cause NEC, that human milk's protective qualities explain relative-risk differences, that NEC is a complex and multifactorial disease, and that Chance's feeding progression complied with accepted medical guidelines. She maintained that the scientific evidence did not support concluding that formula caused Chance's NEC.

¶ 95 4. Dr. Underwood's Testimony

¶ 96 Dr. Mark Underwood testified on behalf of Mead Johnson. Dr. Underwood previously served as a professor, division chief, and NICU attending at the University of California, Davis, and, at the time of trial, practiced in Spokane, Washington. He had treated NEC since 1987, taught trainees about NEC, and had published extensively on neonatal nutrition and intestinal development, including federally funded research.

¶ 97 Dr. Underwood confirmed he was retained by Mead Johnson for this case. He acknowledged giving prior paid educational talks supported by Abbott Laboratories and participating in Prolacta-related research activities, but he denied any influence on his testimony. He explained that he was not retained to offer opinions on Chance specifically and did not review the infant's medical records. Dr. Underwood addressed general neonatal physiology, which he explained renders premature infants vulnerable to NEC due to immature intestinal structure, impaired motility, underdeveloped immune responses, and susceptibility to harmful bacterial colonization. He emphasized that NEC's precise cause is unknown and multifactorial.

¶ 98 Dr. Underwood described the nutritional needs of preterm infants and the role of mothers' milk, donor milk, and preterm formula. He testified that mothers' milk contained numerous protective components absent from formula and donor milk. While donor milk provided some protection, it lost many bioactive factors during pasteurization. Formula, he testified, remained necessary to meet the high caloric and nutrient demands of premature infants. He stated that available evidence did not show that cow-milk formula or maltodextrin causes NEC in humans.

¶ 99 On cross-examination, Dr. Underwood acknowledged that his own NICUs used donor milk until roughly 32-34 weeks' gestation to reduce NEC risk and admitted that he did not inform parents that formula may carry NEC risks not shared by donor or mothers' milk. Mother questioned Dr. Underwood regarding a 2013 article he authored noting scientific uncertainty as to whether NEC reductions associated with human milk were due to protective components of human milk or potentially harmful components of bovine milk. Dr. Underwood affirmed the article but testified that no subsequent research had demonstrated that formula causes NEC.

¶ 100 Dr. Underwood reiterated that NEC occurs in infants fed mothers' milk, donor milk, and formula; that NEC rates had decreased even as formula composition had evolved; and that he would continue using cow-milk-based preterm formula in clinical practice when indicated.

¶ 101 D. Jury Instruction Conference

¶ 102 During pretrial proceedings and throughout the trial, the parties disagreed about whether the learned intermediary doctrine governed the failure-to-warn claims. Mead Johnson maintained that, because EPF24 was used exclusively under the direction and supervision of physicians in the NICU and cannot be purchased or administered by laypersons in that setting, any duty to warn ran to the treating physicians, not to Mother. Mother argued that the doctrine should not apply because EPF24 was not formally a "prescription drug" and that a warning directed to her would have been meaningful.

¶ 103 A jury instruction conference was held outside the presence of the jury on March 12, 2024, and included extensive argument and clarification of the governing substantive law, the proper structure of the issues instructions for strict liability and negligence, the inclusion or exclusion of certain allegations, the formulation of proximate-cause language, the persons to whom Mead Johnson's duty to warn was owed, the separation of Survival Act (755 ILCS 5/27-6 (West 2024)) and Wrongful Death Act (740 ILCS 180/1 *et seq.* (West 2024)) claims, and the format of the verdict forms.

¶ 104 The trial court permitted Mead Johnson to make an offer of proof concerning two subjects that the trial court had excluded from the case: testimony from Dr. Susanne Hay regarding (1) an alleged liver laceration incurred during Chance's second surgery and (2) Mother's prenatal marijuana use. Mead Johnson argued that each topic was relevant either as an

alternative cause of death or to Mother's claimed failure-to-warn theory. Mother objected, incorporating her motions *in limine* and arguing that the evidence was irrelevant, unsupported, and prejudicial. Mother also asserted that the underlying surgical and medical records did not support Mead Johnson's factual premise regarding the liver injury. The trial court took the offer of proof but adhered to its prior exclusion.

¶ 105 The trial court addressed the issues instructions for strict liability. Mother's proposed instruction No. 10 (strict liability-design defect) and instruction No. 11 (strict liability-failure to warn) prompted extensive argument. Mead Johnson contended that Mother's issues instructions improperly (1) separated design-defect and failure-to-warn theories into two instructions rather than a single combined issues instruction, (2) included argumentative "line-item" allegations from the complaint, (3) listed allegations unsupported by evidence, including feasible alternative designs, and (4) omitted the "unreasonably dangerous" language required by the pattern instructions. Mother responded that the Illinois Pattern Jury Instructions, Civil, No. 400.01 (2000) (hereinafter IPI Civil (2000) No. 400.01) expressly required the issues instruction to recite the plaintiff's alleged conditions making the product unreasonably dangerous and that the allegations were supported by record evidence, including expert testimony and internal company documents.

¶ 106 The trial court examined IPI Civil (2000) No. 400.01 and its notes on use, which required that allegations be stated "in simple form without undue emphasis or repetition" (IPI Civil (2000) No. 400.01 & Notes on Use (rev. 2007)) and agreed with Mead Johnson that certain proposed allegations exceeded the pattern's limits. The trial court struck several subparagraphs, finding them either unsupported by evidence or duplicative. As to feasible alternative design, Mead Johnson argued that Mother had offered no expert testimony establishing feasibility. Mother countered with evidence regarding human-milk-based formulations. The trial court ruled that the question was for the jury and retained the subparagraph.

¶ 107 A major dispute then arose over the "duty to warn" instruction (plaintiff's instruction No. 12). Mead Johnson argued that the instruction should not identify Mother personally as the person to whom the duty to warn ran because, they argued, the record established that only treating physicians could authorize and administer the preterm formula; therefore, the duty, if any, ran to healthcare providers. They invoked the learned intermediary doctrine, asserting that, even if the trial court declined to give the formal learned intermediary instruction, the evidence required that warnings be directed to physicians, not Mother. Mother vigorously contested this, pointing to testimony that parents were decision-makers regarding feedings, that Mead Johnson knew how to warn parents, and that its own representatives acknowledged that parents could and should be warned. After extended argument, the trial court rejected Mead Johnson's position and refused to modify the instruction, expressly declining to apply the learned intermediary doctrine to infant formula, reasoning that EPF24 was a food product and not a prescription drug or device. Plaintiff's instruction No. 12 was then adopted with minor grammatical revisions.

¶ 108 The final dispute concerned Mead Johnson's proposed special interrogatory asking whether "Enfamil Premature 24 formula is unreasonably dangerous to feed preterm infants in the NICU." Mead Johnson argued that the interrogatory was necessary to detect an inconsistent general verdict. The trial court denied the request, reasoning that the interrogatory risked inconsistency with the jury's consideration of both design-defect and strict liability

failure-to-warn theories and that the modern statutory scheme granted trial courts broad discretion to refuse special interrogatories.

¶ 109 E. Verdict and Posttrial Motions

¶ 110 Following deliberations, the jury returned a verdict in favor of Mother and awarded her $60 million in damages. Mead Johnson filed a posttrial motion arguing that the trial court committed reversible error where the jury was erroneously instructed on Mead Johnson's duty to warn; where the trial court improperly admitted, and improperly excluded, evidence that affected the outcome of the trial; where Mother presented no evidence to support a finding of proximate cause as to failure to warn; where the trial court erred in failing to apply the learned intermediary doctrine; where Mead Johnson had no duty to warn of comparable effects; and where Mother failed to prove medical cause. Mead Johnson also argued the trial court should enter a remittitur of the excessive damages award. The trial court denied the motion. Mead Johnson filed a timely appeal.

¶ 111 We allowed the American Academy of Pediatrics (AAP) and the Illinois Chapter of the American Academy of Pediatrics (ICAAP) to file an *amici curiae* brief. See Ill. S. Ct. R. 345 (eff. Sept. 20, 2010). One in 10 infants, or more than 300,000 per year, are born prematurely, *i.e.*, before 37 weeks' gestational age.[5] One of the recognized risks for preterm infants, particularly those weighing less than 1,500 grams (3.3 pounds), is NEC in which the tissue lining of the infant's intestines becomes inflamed. NEC may be fatal, and approximately 356 infants die each year from NEC. NEC occurs in 3-9% of preterm infants and also occurs rarely in full-term infants.

¶ 112 II. ANALYSIS

¶ 113 A. General Verdict Rule

¶ 114 Prior to addressing Mead Johnson's arguments, we must address Mother's claim that Mead Johnson is foreclosed by the general verdict rule from challenging the jury's verdict. Specifically, Mother posits that Mead Johnson's learned intermediary doctrine argument applies only to her claim of strict liability failure to warn and not to her negligence claim.

¶ 115 The general verdict rule is implicated when the jury renders a general verdict on a case that involves multiple theories of liability or grounds of recovery. " 'When there is a general verdict and more than one theory is presented, the verdict will be upheld if there was sufficient evidence to sustain either theory, and the defendant, having failed to request special interrogatories, cannot complain.' " *Dillon v. Evanston Hospital*, 199 Ill. 2d 483, 492 (2002) (quoting *Witherell v. Weimer*, 118 Ill. 2d 321, 329 (1987)).

¶ 116 Mother contends that Mead Johnson failed to request that the jury be given a special interrogatory as to the specific theory or theories upon which the jury based its verdict. Although Mead Johnson did request a special interrogatory regarding the design-defect and strict liability failure-to-warn theories, Mother argues it did not request a special interrogatory regarding her four distinct theories of negligence.

[5]The information regarding frequency of occurrence and death is provided by AAP and ICAAP's *amici curiae* brief, citing the 2024 Report of the Working Group to the Secretary of Health & Human Services and the AAP 2023 Clinical Report.

¶ 117 "The learned intermediary doctrine, a rule of common law origin, is an exception to the general rule that a failure to warn of a product's dangerous propensities may serve as a basis for holding a manufacturer *strictly liable* in tort." (Emphasis added.) *Martin v. Ortho Pharmaceutical Corp.*, 169 Ill. 2d 234, 238 (1996). "[T]he failure-to-warn theory in strict liability has been upheld as a distinguishable doctrine from its counterpart in negligence, based on the fact that it is the inadequacy of the warning that is looked to, rather than the conduct of the particular manufacturer, to establish strict liability." *Woodill v. Parke Davis & Co.*, 79 Ill. 2d 26, 34 (1980).

¶ 118 As previously noted, Mother proceeded on three substantive theories at trial: (1) count I, strict liability defective product; (2) count II, strict liability failure to warn; and (3) count III, negligence. Mother argues that Mead Johnson's learned intermediary doctrine argument applies only to her claim of strict liability failure to warn and not to her negligence claim. We disagree. "To prevail in an action for negligence, the plaintiff must establish that the defendant owed a duty of care, that the defendant breached that duty, and that the plaintiff incurred injuries proximately caused by the breach." *Adams v. Northern Illinois Gas Co.*, 211 Ill. 2d 32, 43 (2004). "The existence of a duty is a question of law for the court to decide ***." *Id.* at 43. Accordingly, Mother's negligence claim requires the court to decide as a matter of law to whom the duty was owed.

¶ 119 Mother observes that the jury rejected her defective product claim but found Mead Johnson liable on two counts: strict liability failure to warn and negligence. However, she argues, the jury was instructed on four separate theories of negligence, contending that each constituted a distinct and actionable breach of duty:

> "a. Mead Johnson knew or reasonably should have known at the time of production that its cow's milk-based infant formula significantly increased the risk of NEC for premature infants like Chance Dean; and/or
>
> b. Putting a product on the market that Mead Johnson knew or should have known was likely to harm premature infants like Chance Dean; and/or
>
> c. Marketing a product for premature infants that Mead Johnson knew or should have known was likely to harm premature infants like Chance Dean; and/or
>
> d. Failing to disclose information that Mead Johnson knew or should have known about the risks posed by Mead Johnson's premature infant formula to parents and health care professionals."

¶ 120 Mother insists that the first three theories of negligence had nothing to do with failure to warn. She argues the theories were that Mead Johnson failed to take ordinary care in how it marketed and sold its product; Mead Johnson marketed EPF24 as safe and the company as science-led while knowing the epidemiology showed that EPF24 significantly increased the risk of NEC for preterm infants; and Mead Johnson sold a product it knew was dangerous while actively concealing those dangers, including by muddying the public science on the topic. Mother argues that the jury could have concluded that Mead Johnson's conduct in manufacturing, marketing, and selling EPF24 was unreasonable even if the jury believed that EPF24 was not defectively designed.

¶ 121 We disagree. Mother's asserted negligence theories materially overlap with, and in several instances merely restate, the same factual grounds underlying her strict liability design-defect and failure-to-warn claims.

¶ 122 Under count I, Mother alleged that EPF24 was unreasonably dangerous because feasible alternative designs existed, the likelihood and magnitude of the risk of NEC rendered EPF24 unsafe, and consumers reasonably expect that food for premature infants will not materially increase the risk of a deadly disease. These allegations rest squarely on traditional design-defect principles as recognized in Illinois, employing both the consumer-expectation and risk-utility formulations of product defect. See *Mikolajczyk v. Ford Motor Co.*, 231 Ill. 2d 516, 556 (2008). The allegations focus on the objective condition and characteristics of EPF24, not on Mead Johnson's conduct.

¶ 123 Under count II, Mother asserted that EPF24 was unreasonably dangerous due to Mead Johnson's failure to provide adequate warnings. The alleged deficiencies included the complete absence of warnings on product labeling, inadequate warnings to parents and healthcare providers, failure to disclose known NEC-related risks, and omissions by sales representatives when marketing the formula. These theories fall within the established bounds of strict liability failure to warn, where the central inquiry is whether the absence of adequate warnings rendered the product unsafe.

¶ 124 Count III set forth Mother's negligence theories, alleging that Mead Johnson (a) knew or should have known of the NEC risk, (b) placed a harmful product into the stream of commerce, (c) marketed the product for premature infants despite the risk, and (d) failed to disclose information about risks to parents and healthcare providers. Although pleaded as four separate acts of negligence, these assertions do not constitute independent theories of liability. Rather, they mirror and restate the factual assertions already advanced under counts I and II.

¶ 125 Negligence allegation (a), which asserted that Mead Johnson knew or should have known that EPF24 significantly increased the risk of NEC, corresponds directly to Mother's strict-liability failure-to-warn claims, each of which rest on Mead Johnson's alleged knowledge and failure to communicate that risk. Allegation (d), which concerned failure to disclose information to parents and providers, is effectively identical to count II(d), which alleged failure to disclose information known to Mead Johnson linking EPF24 to NEC.

¶ 126 Negligence allegation (b), which asserted that Mead Johnson placed a harmful product on the market, does not differ in substance from Mother's strict liability design-defect claims under count I. Both theories rest on the assertion that EPF24 was unreasonably dangerous based on its risks, foreseeable harms, and the availability of safer alternatives. This negligence allegation merely attempts to reframe the same product-condition assertions into a claim about Mead Johnson's conduct and, therefore, does not create a separate or legally distinct theory of liability.

¶ 127 Negligence allegation (c), which asserted negligent marketing of a product that was known or should have been known to be harmful, added no separate theory where Illinois does not recognize negligent marketing as a stand-alone cause of action.[6] Thus, where the complained-of marketing omission was the alleged failure to communicate risk, the theory was simply a restatement of Mother's failure-to-warn claim. Moreover, the allegation mirrors count II(e), which alleged that sales representatives did not discuss NEC risks when marketing EPF24.

[6]Mother fails to cite Illinois law recognizing negligent marketing as an independent cause of action or argue that negligent marketing should be recognized as an independent cause of action.

¶ 128 Taken as a whole, the negligence count did not set forth four distinct theories of negligence. Instead, each is derivative of, and duplicative of, the strict-liability claims asserted under counts I and II. The jury was therefore not presented with four legal theories but, rather, with repeated iterations of the same operative facts framed under multiple labels. A careful review of the record reveals that Mother's negligence theories overlapped substantively with her design-defect or failure-to-warn claims. Where the negligence claims simply repackaged the same conduct or omissions that formed the basis of the strict-liability claims, we will not treat it as a separate basis for recovery. Accordingly, we find that the general verdict rule does not foreclose appellate review of Mead Johnson's claims.

¶ 129 B. Learned Intermediary Doctrine

¶ 130 "A strict products liability claim may proceed under three different theories of liability: a manufacturing defect, a design defect, or a failure to warn." *Salerno v. Innovative Surveillance Technology, Inc.*, 402 Ill. App. 3d 490, 497 (2010). Mother did not raise a manufacturing defect claim, and as previously noted, the jury rejected Mother's claim of design defect but found in favor of her failure-to-warn claim. Under a strict liability failure-to-warn theory, "a plaintiff must demonstrate that the manufacturer did not disclose an unreasonably dangerous condition or instruct on the proper use of the product as to which the average consumer would not be aware." *Id.* at 499. "A manufacturer has a duty to warn where the product possesses dangerous propensities and there is unequal knowledge with respect to the risk of harm, and the manufacturer, possessed of such knowledge, knows or should know that harm may occur absent a warning." *Sollami v. Eaton*, 201 Ill. 2d 1, 7 (2002).

¶ 131 The crux of Mother's strict liability claim was that Mead Johnson failed to provide adequate warnings. Throughout the trial, the parties vigorously debated the duty to warn, or more specifically, to whom the duty was owed. Mead Johnson contends that, because EPF24 is a product designed for medical use in an intensive-care setting and is administered by medical professionals at the direction of doctors, the learned intermediary doctrine applies and, therefore, any duty to warn was owed to Chance's doctors, rather than to Mother. There is no dispute that EPF24 was ordered by Chance's neonatologists after consideration of the feeding options available, relying on hospital protocols, medical literature, and their professional judgment. Moreover, EPF24 was administered to Chance in the NICU by hospital staff.

¶ 132 Mother argues that the learned intermediary doctrine does not apply because EPF24 is not regulated as a prescription drug and EPF24 is an infant food that consumers can purchase online without a prescription. Although Mother correctly notes that the learned intermediary doctrine has not been applied to over-the-counter drugs or nonprescription medical devices, she cites no authority for the proposition that the doctrine is limited only to prescription drugs and medical devices. In other words, Mother asks us to consider the nature of EPF24, while Mead Johnson asks us to consider not only the nature of EPF24 but also the context in which the product was administered to determine whether the doctrine applies.

¶ 133 Mead Johnson contends that, under the learned intermediary doctrine, it had a duty to warn Chance's doctors and not Mother. The learned intermediary doctrine, which has been adopted in Illinois, provides that a prescription drug manufacturer has a duty to warn the prescribing doctor of a drug's known dangerous propensities and that the doctor, in turn, using her medical judgment, has a duty to convey any relevant warnings to her patient. *Kirk v. Michael Reese*

Hospital & Medical Center, 117 Ill. 2d 507, 517, 519 (1987). The rationale for the learned intermediary doctrine was set forth in *Kirk*:

> " ' "Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, [an] individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a 'learned intermediary' between manufacturer and consumer." ' " *Id.* at 518 (quoting *Stone v. Smith, Kline & French Laboratories*, 731 F.2d 1575, 1579-80 (11th Cir. 1984), quoting *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1276 (5th Cir. 1974)).

¶ 134 The learned intermediary doctrine later was extended to apply to medical device manufacturers. See *Hansen v. Baxter Healthcare Corp.*, 309 Ill. App. 3d 869, 881 (1999) (recognizing application of doctrine to medical device manufacturers). In *Hansen*, the Illinois Supreme Court applied the learned intermediary doctrine to nonlocking intravenous component sets that, like EPF24, were used exclusively within a hospital under physician oversight.

¶ 135 As there are no published Illinois cases directly on point, we look to a recent case considering whether the learned intermediary doctrine should be applied to a cow-milk-based infant formula, *Hunte v. Abbott Laboratories, Inc.*, 569 F. Supp. 3d 115 (D. Conn. 2021). We recognize that "federal district court cases have no precedential value in Illinois courts." *Board of Education of Springfield School District No. 186 v. Attorney General*, 2017 IL 120343, ¶ 54. Moreover, this decision is a certification order by the district court to the Connecticut Supreme Court. Nevertheless, we find the framing of the issue is insightful.

¶ 136 In *Hunte*, the plaintiff's infant was born three months premature and spent his entire three-month life in the NICU where he was fed defendant's cow-milk-based infant formula. *Hunte*, 569 F. Supp. 3d at 117. Following his death, the plaintiff filed a complaint, alleging that the defendant's formula caused her preterm infant to develop NEC. *Id.* The district court denied the defendant's motion to dismiss as to the plaintiff's failure to warn claim, finding that the claim depended on a threshold issue regarding whether the learned intermediary doctrine applied to cow-milk-based infant formula intended to feed premature infants. *Id.* at 117-18. The district court observed that, generally, courts had applied the learned intermediary doctrine in cases involving prescription products but had declined to apply the doctrine in cases involving products available for purchase over the counter. *Id.* at 122.

> "See, *e.g.*, *Brown v. Johnson & Johnson*, 64 F. Supp. 3d 717, 721 (E.D. Pa. 2014) ('Defendants had no duty to inform physicians *** because Children's Motrin is an over-the-counter drug.'); *Reyes v. Wyeth [Laboratories]*, 498 F.2d 1264, 1276 (5th Cir. 1974) ('Pharmaceutical companies *** must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter' but 'in selling prescription drugs are required to warn only the prescribing physician'); *Prager v. Allergan, Inc.*, [No. 89 C 6721,] 1990 WL 70875, at *4 (N.D. Ill. May 2, 1990) (refusing to extend LID to 'non-prescription contact lens cleaner'—even though plaintiff's 'physician recommended' the product—because it was 'sold with package inserts designed to inform the average

consumer,' 'could have [been] obtained and used without the recommendation,' and the plaintiff 'was free to use another lens cleaner'); *Mitchell v. VLI Corp.*, 786 F. Supp. 966, 970 (M.D. Fla. 1992) (declining to apply the LID because the plaintiff 'could have obtained the sponge over-the-counter,' and so 'it would be illogical to treat her differently based on the mere fortuity that she obtained a sample of the sponge from her physician'); *Torsiello v. Whitehall [Laboratories, Division of Home Products Corp.*, 398 A.2d 132 (N.J. Super. 1979)] (citing cases differentiating between prescription and non-prescription)." *Id.* at 122 n.9.

¶ 137 Noting that Connecticut courts had "not explicitly identified or analyzed [the] prescription/non-prescription distinction," the district court concluded that a strict distinction did not neatly apply to such infant formulas, which the district court described as "a hybrid between prescription and non-prescription products." *Id.* at 122-23. The question certified by the district court, which is relevant to the instant case, was whether the learned intermediary doctrine applied to a cow-milk-based formula intended for premature infants, given the medical context in which the product was used and how it was administered. *Id.* at 127.

¶ 138 The fact that EPF24 was not formally prescribed by a physician is not dispositive. The EPF24 provided to Chance was obtained directly by the hospital from Mead Johnson. The product was available to Chance only at the direction of his neonatologists and other healthcare providers, who evaluated the risks and benefits of the available feeding products. EPF24 was administered to Chance through a tube directly into his stomach in the highly supervised, round-the-clock setting of a hospital NICU. Its clinical use in the NICU required specialized medical oversight, and its use required physicians to weigh the risk of NEC and Chance's nutritional needs, gestational age, comorbidities, growth trajectory, and overall health status. In other words, the decision to order EPF24 involved individualized medical judgment of the type described in *Kirk*. Thus, under the *Kirk* rationale, these facts place EPF24 squarely within the class of products for which the learned intermediary doctrine applies.

¶ 139 Although EPF24 generally is not available at retail stores, there was testimony that it could be purchased online by parents without a prescription *after* the infant was discharged from the hospital. However, the retail availability of EPF24 following an infant's discharge is not relevant where Chance spent his entire life in the NICU. Mother did not purchase EPF24. Instead, she admitted that the decision to administer EPF24 to Chance was made by his doctors and that she first learned Chance was receiving it when she saw a bottle of EPF24 in the NICU at Memorial Hospital. Considering the nature of EPF24 and the context in which the product was administered, we hold that the learned intermediary doctrine applied as a matter of law to Mother's claim. Accordingly, Mead Johnson's duty was owed to the physicians, not Mother.

¶ 140 C. Jury Instructions

¶ 141 The trial court erred when it expressly declined to apply the learned intermediary doctrine and instructed the jury that Mead Johnson's duty to warn was owed both to Mother and Chance's physicians. Because the learned intermediary doctrine applied to EPF24, the jury was improperly guided on the applicable law, which prejudiced the jury and tainted the trial.

¶ 142 "In Illinois, the parties are entitled to have the jury instructed on the issues presented, the principles of law to be applied, and the necessary facts to be proved to support its verdict." *Dillon*, 199 Ill. 2d at 505. A trial court's decision to grant or deny a jury instruction is reviewed for an abuse of discretion. *Bailey v. Mercy Hospital & Medical Center*, 2021 IL 126748, ¶ 42.

Whether the instruction accurately conveyed the applicable law is a legal question this court reviews *de novo*. *Id.* "Ultimately, a reviewing court should grant a new trial only when the trial court's refusal to give a tendered jury instruction results in serious prejudice to the party's right to a fair trial." *Id.* "When evaluating the propriety of given jury instructions, the reviewing court must view the instructions as a whole." *Solich v. George & Anna Portes Cancer Prevention Center of Chicago, Inc.*, 273 Ill. App. 3d 977, 988 (1995).

¶ 143 Illinois courts have consistently held that jury instructions must "fairly, fully, and comprehensively" apprise jurors of the law governing the case and that reversal is required where an instruction "clearly misled the jury and resulted in prejudice." *Martin v. City of Chicago*, 2023 IL App (1st) 221116, ¶ 18. " 'When a case is tried under an incorrect theory of law the appropriate action is to reverse the judgment and remand for a new trial.' " *Reliable Fire Equipment Co. v. Arredondo*, 2011 IL 111871, ¶ 46 (quoting *Sparling v. Peabody Coal Co.*, 59 Ill. 2d 491, 496 (1974)).

¶ 144 Here, Mead Johnson tendered a jury instruction that accurately stated the learned intermediary doctrine. By rejecting the doctrine, the trial court fundamentally skewed the legal lens through which jurors evaluated the evidence because the jury instruction misstated to whom Mead Johnson's duty was owed. The trial court abused its discretion when it instructed the jury under the general duty to warn, which precluded the jury from applying the legally correct standard. This error tainted the entirety of the trial proceedings and prejudiced the jury. *Solich*, 273 Ill. App. 3d at 990 ("instructions did not accurately reflect the plaintiffs' theory of the case which served to taint the entire trial and prejudice the jury"). Illinois precedent makes clear that, when a case is tried under an erroneous theory of law, a new trial is required. Accordingly, we find the jury instructions were erroneous and prejudicial, mandating reversal and remand for a new trial.

¶ 145 D. Improper Financial Information

¶ 146 Having concluded that reversal and remand are warranted, we decline to address all but one of Mead Johnson's remaining claims of error. A reviewing court may address issues that are likely to recur on remand in order to provide guidance to the lower court and thereby expedite the ultimate termination of the litigation. *Pielet v. Pielet*, 2012 IL 112064, ¶ 56. Therefore, we will address a specific evidentiary issue likely to recur on remand in the interest of judicial economy. *Solis v. BASF Corp.*, 2012 IL App (1st) 110875, ¶ 74.

¶ 147 Prior to trial, Mead Johnson moved to exclude any evidence referencing its size, wealth, profitability, executive compensation, revenue, marketing expenditures, and similar financial details. The trial court denied the motion in significant part, allowing such evidence for purposes Mother characterized as demonstrating motive, knowledge, and corporate priorities. After the jury returned a verdict for Mother, Mead Johnson filed posttrial motions arguing, *inter alia*, that the damages award was excessive and that the admission of extensive financial information deprived it of a fair trial. The trial court denied these motions. On appeal, Mead Johnson maintains that the trial court erred in admitting irrelevant and prejudicial evidence regarding the company's financial status, particularly in the absence of a punitive damages claim. Mead Johnson contends the evidence had no relevance to causation, product defect, warnings, or the medical facts surrounding NEC but instead improperly portrayed the company as wealthy and profit-driven.

¶ 148 "To be admissible, evidence must meet the threshold requirement of relevance." *Snowstar Corp. v. A&A Air Conditioning & Refrigeration Service, Inc.*, 2024 IL App (4th) 230757, ¶ 111. "Relevant" evidence is defined as " 'evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.' " *Id.* (quoting Ill. R. Evid. 401 (eff. Jan. 1, 2011)). Nevertheless, relevant evidence may be excluded where "its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury." Ill. R. Evid. 403 (eff. Jan. 1, 2011). "Evidence is probative when to the normal mind it tends to prove or disprove a matter at issue." *Camco, Inc. v. Lowery*, 362 Ill. App. 3d 421, 433 (2005).

¶ 149 Under Illinois law, evidentiary rulings are reviewed for abuse of discretion. *Gunn v. Sobucki*, 216 Ill. 2d 602, 609 (2005). To justify a new trial based on the evidentiary rulings, the error must have caused substantial prejudice and affected the outcome of the trial. *Browning v. Advocate Health & Hospital Corp.*, 2023 IL App (1st) 221430, ¶ 49. The party seeking reversal has the burden to demonstrate prejudice. *Id.* "An abuse of discretion occurs when the court's ruling is arbitrary, fanciful or unreasonable or where no reasonable person would adopt the court's view." *McHale v. Kiswani Trucking, Inc.*, 2015 IL App (1st) 132625, ¶ 28. "When, as here, only compensatory damages are recoverable, the financial condition of the parties is irrelevant and often prejudicial as it appeals to the sympathy of the jury, which presumably will favor those least able to bear the loss." *Id.* ¶ 30. Thus, evidence of the financial condition of the parties is not allowed. *Id.* While not every reference that touches upon a party's financial status constitutes reversible error (*Lagoni v. Holiday Inn Midway*, 262 Ill. App. 3d 1020, 1033 (1994)), reversal is warranted where undue emphasis is placed on the irrelevant evidence or where the jury's verdict is affected by it (*Rush v. Hamdy*, 255 Ill. App. 3d 352, 362 (1993)).

¶ 150 A thorough review of the record leaves little doubt that the jury reached a verdict more punitive than compensatory. Before a single witness was presented, the jury was informed during Mother's opening statement that the infant formula business is a multibillion-dollar business in the United States and that Reckitt, the parent company of Mead Johnson, is a multibillion-dollar company. Twice during opening statements, the jury was informed that, in 2020 alone, Mead Johnson made $900 million in revenue in United States sales.

¶ 151 Here, the volume and breadth of the admitted financial evidence did more than merely touch upon corporate finances. The jury heard extensive testimony regarding Mead Johnson's revenues, executive compensation, profit margins, and marketing budgets, none of which bore on any element of liability or compensatory damages. Such evidence created a substantial risk that the jury would infer culpability from Mead Johnson's wealth rather than from evidence related to defect, causation, or adequacy of warnings.

¶ 152 Mother counters that the financial evidence was relevant to show motive, knowledge, and Mead Johnson's corporate decision-making. She maintains the evidence provided the jury with necessary context regarding corporate priorities, and that any risk of prejudice was mitigated by the trial court's limiting instructions. She contends that the jury's verdict rested on the medical and scientific evidence, not on wealth-based considerations.

¶ 153 Motive, however, was not a required element of Mother's burden of proof, and the financial evidence provided no meaningful assistance to the jury in evaluating whether EPF24 was defective or whether any provided warnings were adequate. Assuming, *arguendo*, that motive

had marginal relevance, Illinois Rule of Evidence 403 (eff. Jan. 1, 2011) required exclusion of the financial evidence where the danger of unfair prejudice substantially outweighed any probative value. The trial court failed to adequately perform the necessary balancing test, resulting in the admission of financial information with minimal legitimate purpose and substantial prejudicial effect.

¶ 154 Moreover, even if a limited reference to financial resources could be justified to show motive or internal priorities, the repeatedly emphasized and wide-ranging financial testimony admitted at trial far exceeded any permissible purpose. The financial evidence was not isolated or incidental. Instead, it was repeatedly highlighted during trial and in closing argument. Such use of financial evidence posed a substantial danger that the jury would return a verdict based not on scientific causation, product defect, or inadequate warnings but on the perceived ability of a large corporation to bear the cost of a verdict. This is precisely the type of prejudice that warrants reversal.

¶ 155 As the jury was presented not only with extensive financial evidence but with commentary during Mother's opening statement and closing argument that linked corporate wealth to culpability, the risk of undue influence was high. The cumulative impact of extensive references to Mead Johnson's wealth could not be cured by limiting instructions and undermined confidence in the fairness of the verdict. Under Rule 403, the extreme prejudicial effect of corporate-profit and executive-compensation testimony substantially outweighed its slight probative value. On retrial, such evidence is inadmissible unless directly relevant to an issue the jury must decide.

¶ 156 III. CONCLUSION

¶ 157 For the foregoing reasons, we reverse the judgment of the trial court, and we remand the cause for further proceedings consistent with this opinion.

¶ 158 Reversed and remanded.