

# Should informed consent be required prior to feeding bovine-derived human milk fortifier? Court Says Yes.

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## Introduction:

On December 12, 2025, a Court in Connecticut (1) found in favor of the parents of a deceased infant who developed necrotizing enterocolitis after being fed a bovine “human milk fortifier” added to the mother’s own milk without the consent of the parents against Yale New Haven Hospital and Yale University for failing to obtain informed consent. The Court awarded \$1,962,884.42 in economic damages and \$31,962,884.42 in non-economic damages against each of the defendants. The plaintiffs withdrew their allegation of medical malpractice against the treating neonatologist and loss of consortium.

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The Court considered testimony and evidence that included the medical record, and found that the plaintiffs had proven “by a preponderance of the evidence” that the defendants failed to obtain any consent and failed to obtain informed consent regarding the use of cow-based fortifier and cow-based formula, and that the estate of the deceased infant suffered damages as a result of failure to obtain consent and informed consent.

## Case Study:

The infant was born at 27 weeks 4 days of gestation and weighed 620 grams. The mother was not taking any medications that would affect the infant’s health. Upon birth, the infant was transferred to the NICU at Yale-New Haven Medical Center due to the infant’s prematurity and need for ventilatory and nutritional support. Over the following days, volumes and calories were increased, but the mother’s own milk accounted for less than 50% of the total volume of gavage feedings. On day 26, the infant experienced

increased respiratory distress, had a distended abdomen, vomiting, and lethargy. He was placed NPO, and an abdominal radiograph was concerning for NEC. The parents opted not to pursue surgical treatment, and TPN was restarted, and feedings were discontinued. The infant died on day 78.

The Court found that the parents desired to have the mother’s own milk and that she had an adequate amount of milk for her infant and had received a lactation consultation early in the infant’s NICU stay. The infant initially was NPO and received total parenteral nutrition. The parents indicated to the lactation consultant that they only wanted the mother’s own milk and that they were never advised that bovine-based products would be fed to their infant. On day 8, he was bolus gavage fed mother’s milk (MOM). Because of intermittent feeding intolerance manifested by vomiting and abdominal distension, he was at times placed NPO and then switched to continuous nasogastric feeds. He has several radiographs, some of which were concerning, but none showed definite NEC or obstruction.

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Because of insufficient weight gain by day 23, clinicians decided to fortify MOM with a bovine product but did not discuss it with the parents. The parents testified that they assumed this addition was to thicken MOM, and they were never told about the risks and benefits of using bovine-based products and wanted only MOM- or human milk-derived fortifier. During the following days, volumes and calories were increased, but MOM was less than 50% of the total feeding volume. After the infant’s death from NEC on day 78, his parents learned from reading the records that their infant had been fed a bovine-based fortifier. Furthermore, the parents

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The Court stated that the care team did not advise the parents of the use of bovine fortifier and that a human-derived human milk fortifier could have been made available, or the infant could have been transferred to a hospital that carried a human product such as Prolacta. The treating neonatologist and medical center representatives testified that the fortifier made from human milk was not available during the year the baby was born. The Court disagreed and believed the presented evidence that it had been available since 2006 and, in fact, was heavily marketed and readily available in 2018.

The plaintiff experts indicated that the defendants were legally required and had a duty to discuss the use of a bovine product with the parents prior to its use, since it significantly increased the risk of NEC. The mother had signed a consent form to use pasteurized donor milk if needed, but the increased risk of NEC when using bovine-derived formula or a fortifier was never explained to her. The treating neonatologist testified that the hospital used bovine-human milk fortifier because “it was protocol.” The parents learned that their infant had been fed a bovine-based fortifier only after reading the medical records. The parents also believed they were deceived, as the fortifier labelled “Human Milk Fortifier” is not

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made from human breast milk. An expert witness stated that by 2018, the development of NEC was known, and the material risk of the use of bovine-based products in feeding premature babies. The expert witness indicated that the defendants were legally required and had a duty to discuss with the infant’s parents prior to the use of a bovine product and that they “significantly increased the risk of developing NEC.” The infant died on day 78, and the Court noted that this infant died from respiratory failure “caused by NEC.”

#### **Commentary:**

The Court noted a 2012 American Academy of Pediatrics statement supporting breastfeeding and does not specifically mention the use of bovine-based fortifiers. It does state that “feeding preterm infant’s human milk is associated with a significant reduction (58%) in NEC and that a study by Quigley et. al. reported a 77% reduction in NEC and that one case of NEC could be prevented for every 10 infants fed an exclusively human milk diet (2). It also gives guidance to pediatricians to support breast feeding. The Court commented on the fact that the infant’s mother had to sign a consent for the use of donor human milk and that the form indicated that pasteurized donor human milk was a feeding option; however, her milk was in ample supply for her infant, and she was donating extra milk to a breast milk donor bank. She understood that all feeding other than her own milk required similar consent, and that the defendants did provide informed consent of the use of preterm infant formula when her own milk was being used to feed her infant. The Court noted that there is disagreement among medical experts regarding the cause of NEC. However, the defense Neonatologist opined that the use of a human-based fortifier is protective against the development of NEC but disagreed that the use of a bovine-based fortifier

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***“The Court concluded that bovine-based formula and fortifiers did increase the risk of NEC in this infant and questioned the expert’s testimony that use of a bovine-based fortifier was a ‘standard option’ for neonatologists, nor did this expert believe that an exclusive human milk diet was an appropriate choice for this infant. Further, the Court ‘did not find credible’ that there is no need to obtain consent or informed consent from the parents when using bovine-based products nor his assertion that bovine-based products do not increase the risk for NEC or that a doctor need not explain to a parent that a fortifier or formula is a bovine-based product associated with a higher incidence of NEC.”***

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contributed to the development of NEC in this infant and cited the report by Quigley et al. One defense expert witness indicated that “reasonable expert minds can disagree” about whether bovine-based products increased the risk of NEC and ultimately the death of the infant. The Court concluded that bovine-based formula and fortifiers did increase the risk of NEC in this infant and questioned the expert’s testimony that use of a bovine-based fortifier was a “standard option” for neonatologists, nor did this expert believe that an exclusive human milk diet was an appropriate choice for this infant. Further, the Court “did not find credible” that there is no need to obtain consent or informed consent from the parents when using bovine-based products nor his assertion that bovine-based products do not increase the risk for NEC or that a doctor need not explain to a parent that a fortifier or formula is a bovine-based product associated with a higher incidence of NEC. This expert witness agreed there was nothing in the medical record that contradicted the parents’ testimony, and he admitted that a human milk fortifier of human milk origin was available at the time of this infant’s treatment. Expert witnesses disagreed on whether it was appropriate for the Neonatologists to fortify the mother’s own milk with a bovine-based fortifier. The Court found the plaintiff’s experts’ testimony more credible than the defendants’. The Court also indicated that it was not logical to ask parents for consent for donor human milk and not likewise obtain consent for a bovine-fortifier. The Court received testimony regarding the infant’s lost earning capacity and discredited the defendants’ estimate of economic losses.

The Court determined that a civil assault occurred, consistent with Connecticut civil tort law, and that actual physical contact was not necessary to prove civil assault. The Court concluded that the defendants acted with the intention of causing harmful or offensive contact by feeding the infant bovine-derived products without any consent or informed consent of the parents and that thus the feeding resulted in NEC.

#### **Consent:**

This case addresses many issues related to consent and the duty of informed consent, alerting medical centers, NICU administrators, and neonatologists to these issues. Further, do not delegate this role to nonmedical staff or lay volunteers.

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The policy decision of the AAP’s Committee on Bioethics stresses that informed consent incorporates these duties; disclosure of information to parents or their surrogates for medical decision making, thus indicating that obtaining informed consent prior to ordering “special care formulas” or “human milk fortifiers” in place of mother’s own or donor human milk would probably avoid allegations of malpractice (4).

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#### **National Institute of Child Health and Human Development (NICHD):**

The NICHD convened an NEC working group in August 2024 that made multiple recommendations for the [then] Secretary of Health and Human Services regarding research goals to reduce the incidence of NEC. These recommendations were approved by the working group on September 5, 2024 include an emphasis on education regarding the benefits of maternal breast feeding, enhanced availability of donor human milk, especially in rural areas and among minority populations, and increased research to determine “ideal” feeding practices for VLBW infants in NICUs, reducing antibiotic use and duration and the prevention of premature births (5).

#### **Does this Court Decision in Connecticut have any effect in other states?**

A tort ruling from one state can be used in another state primarily through the “full faith and credit clause” of the U.S. Constitution requiring states to respect other states judgments, for full enforcement often involves domesticating the judgment in the second state to access local assets, while the actual choice of law (which state’s tort rules apply) depends on contracts, circumstances and state-specific conflicts-of-law rules, meaning that different states might govern different aspects of the case.

Domesticating the judgment usually applies to the collection of debts from a debtor in another state (6). Determining which state's tort laws (e.g. for negligence, demand caps) apply is complex and depends on where the injury occurred, where the parties live, and the specific "contacts" each state has with the case, with some states applying one state's law for certain issues and another's for different parts and should be determined by attorneys and the Courts in another state.

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Comity refers to courts of one state or jurisdiction respecting the laws and judicial decisions of other jurisdictions, whether state, federal, or international, not as a matter of obligation but out of deference and mutual respect. It is too early to determine whether similar tort claims will be brought in other states, and thus, the impact of the Connecticut decision in this case remains uncertain.

**What is in the name "Human Milk Fortifier"? Or is it Product Liability?**

The plaintiffs testified that they were confused and felt misled by being told that their infant was receiving a milk fortifier derived from human milk. Both Mead-Johnson and Abbott Laboratories label their fortifiers as "Human Milk Fortifier." This demonstrates how companies can shape the production, promotion, and integration of fortifiers into neonatal care and broader infant-feeding systems. Through strategies that construct marketing, leverage professional networks, and embed products within various NICUs, influencing clinical practices and consumer behaviors in ways that prioritize profit over equity. On the other hand, human milk-derived human milk fortifiers (Prolacta), which have been available and promoted since 2006, are more expensive and are

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not stocked or endorsed by hospital purchasers as superior to bovine-derived human milk fortifiers. Bovine and human-derived HMF are commercially available and vary in macronutrient content and the degree to which proteins are hydrolyzed (7, 8).

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Although clinicians may understand that neither "Human milk fortifiers" from two prominent formula companies is of human origin, greater transparency in discussions with parents is needed to avoid misleading parents into believing their infant is receiving a human product. Changing brand names and packaging should reveal the source of the fortifier to avoid deceiving parents or mislead administrators or purchasers of healthcare products.

**Conclusions:**

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***"Nutritional and Feeding Care of the VLBW Infant, as stated in the most recent clinical report 'Promoting Human Milk and Breastfeeding for Very Low Birth Weight Infant: Clinical report' (2025), stresses that 'local pasteurized donor human milk policies are needed to achieve consistency among staff regarding infant eligibility, duration of use, and consenting or assenting procedures.' As a part of the consenting or assenting procedures, families must be informed that 1) mother's own milk provides superior overall health benefits compared to pasteurized donor human milk (PDHM); 2) PDHM is associated with a reduced risk of NEC; and 3) PDHM can serve as a nutritional bridge until MOM becomes available."***

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Breastfeeding for Very Low Birth Weight Infant: Clinical report” (2025), stresses that “local pasteurized donor human milk policies are needed to achieve consistency among staff regarding infant eligibility, duration of use, and consenting or assenting procedures.’ As a part of the consenting or assenting procedures, families must be informed that 1) mother’s own milk provides superior overall health benefits compared to pasteurized donor human milk (PDHM); 2) PDHM is associated with a reduced risk of NEC; and 3) PDHM can serve as a nutritional bridge until MOM becomes available.

Families need to be informed about how pasteurization ensures safety and the planned duration of PDMH use. These discussions need to be documented in the medical record (9). It is logical that if parents are required to consent or give assent to PHMF, a reasonable person would expect the same regarding milk fortification.

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#### **Update:**

Yale University and the New Haven Hospital asked the Court to reconsider the award from \$32 million down to \$2 million because it was reasonable that the doctor was not legally obligated to discuss a risk that he believed did not exist (the association of cow’s milk or fortifier), and NEC did not exist. Lawyers for Yale and New Haven Hospital asserted that “if the infant’s family believes that the doctor’s medical knowledge was deficient, they should pursue a medical malpractice claim instead” (10). The hospital’s motion said that the judge misapplied the legal definition of battery, which they stated generally refers to the intentional infliction of physical harm without consent. They further asserted that many other factors “besides just a cow-based fortifier could have contributed to the infant’s development of NEC (10). These attorneys failed to consider or reference the most recent meta-analysis documenting that an exclusive human milk diet, including mother’s own or donor milk, and a human milk-derived fortifier, significantly reduced NEC, including surgical NEC, among infants ≤1250 grams at birth in 25 studies, including 5 randomized clinical trials and 15 observational trials of 4754 very low birth weight infants (11). As of February 9, 2026, no decision has been made by the judge regarding these motions.

#### **References:**

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*Disclosures: Neither author has any financial relationship with producers of bovine or human-sourced human milk fortifiers.*

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