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Digesting Danger

THE CONNECTION BETWEEN ENFAMIL/SIMILAC AND NEC.

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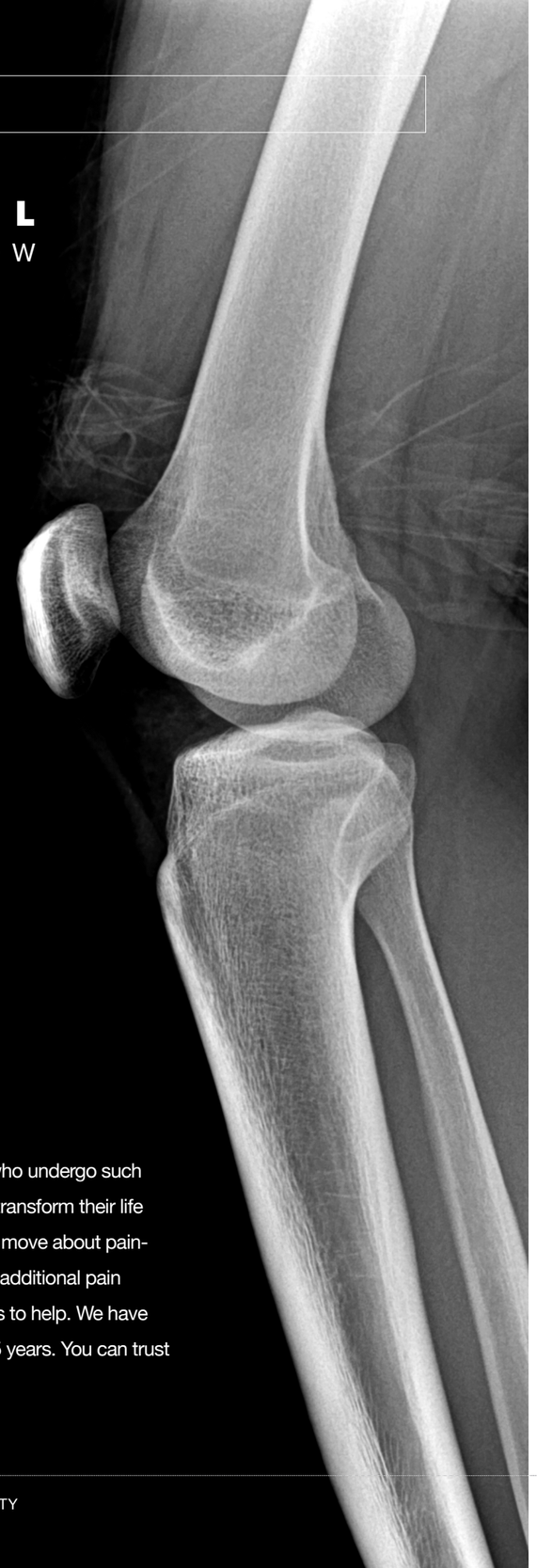
GOLDENBERGLAW
PRODUCTS LIABILITY & PERSONAL INJURY ATTORNEYS

BY THE NUMBERS

EXACTECH RECALL
WHAT YOU NEED TO KNOW



Many individuals have required knee and ankle revision surgeries due to the failure of Exactech's arthroplasty polyethylene inserts. The inserts are placed between the metal components in knee and ankle replacement devices to provide stability and are therefore critical for the devices themselves to perform as expected. Exactech initially recalled some inserts in August 2021, and the company expanded the recall to cover all of its knee and ankle inserts in February 2022 due to insufficient product packaging that exposed the inserts to high levels of oxygen. The resultant oxidation weakens the inserts prior to implantation, and that weakening leads to early wear, fracture, and ultimately high rates of revision surgery.

Exactech's recall letter to surgeons acknowledges its devices' alarmingly high failure rates, stating that the "Optetrak Knee system has shown statistically significant higher overall revision rates as compared to other TKA's in the Australian, United Kingdom and New Zealand registries."

Injuries Associated With Exactech Knee & Ankle Devices

- Revision Surgery
- Bone Loss
- Loosening
- Swelling
- Instability
- Pain

Knee and ankle replacements are no small matter, as most people who undergo such procedures have hopes that implantation of a joint replacement will transform their life from one of pain and limited mobility to one in which they are free to move about pain-free. So it is heartbreaking when these products fail and even cause additional pain and surgical intervention. That's not right, and GoldenbergLaw wants to help. We have represented victims of defective orthopedic device cases for over 35 years. You can trust our team to deliver the Gold Standard advocacy you deserve.

STUART GOLDENBERG
SENIOR PARTNER

"GoldenbergLaw has developed a specialty part of our practice that is devoted to justice for kids."

It's about the kids.

"Children are the world's most valuable resource and its best hope for the future."

JOHN F. KENNEDY

I am a proud father and grandfather. My grandkids, Robby, Goldie, Harrison, and Parker are all under the age of five. It is hard to describe the joy that young kids bring into the world. Watching them grow, learn, and experience life makes me appreciate what is really important. They are our future. However, in our law practice, it is especially hard to see children that are sexually abused, injured, or even killed through the actions of bad people or bad corporate behavior. We are so appalled at this conduct that GoldenbergLaw has developed a specialty part of our practice that is devoted to justice for kids.

Our firm is engaged in pro bono work to advocate for children and in fact, Marlene Goldenberg, one of our partners, has now become a temporary foster parent to two small children. I have advocated over the years against many defective products marketed to children including defective toys, baby equipment, and baby supplements. The result is that some of those products are now off the market or have been modified. I think we are proudest of some of our advocacy where the results have allowed severely injured children to have special trusts to purchase modified homes or fund lifetime care.

One of our newest litigations involves baby formulas such as **Enfamil** and **Similac** that have been linked to a horrible gastrointestinal disorder called NEC which affects premature infants, (see page 5). Partner Noah Lauricella has twins that were born prematurely and he and his wife Amy have lived through the challenges of having children born early, (see page 7). Noah has a special appreciation for parents dealing with these issues and will be heading up the NEC cases for our firm.

There is a saying "that you are only as happy as your unhappiest child." Parents or Grandparents dealing with injured or abused children need special help. These kids deserve justice to help protect them, get the treatment they need, and allow them to live their best lives. Because at the end of day, it's all about the kids.

For many years, doctors have recommended that babies born prematurely receive their nutrition from cow milk-based baby formula or fortifier. However, studies dating back to 1983 have found that preterm infants exclusively fed cow milk-based formulas are at a significantly higher risk of developing the devastating digestive disease necrotizing enterocolitis (NEC).

What is Necrotizing Enterocolitis (NEC)?

NEC is a serious gastrointestinal illness that mostly affects premature babies. The condition inflames intestinal tissue and can lead to tissue death. Severe NEC can cause a hole to form in a baby's large or small intestine. Bacteria can then leak through the hole into the abdomen or bloodstream and increase the risk of a life-threatening blood infection called sepsis.

Cow milk-based formula is considered a potential cause of NEC. Human milk is easier to digest than other alternatives. Human milk also contains substances that help fight infection and help intestinal cells mature. Studies have consistently found that premature infants who consume human milk in the first days of their life are less likely to get infections such as NEC. Fortunately, nearly half of neonatal intensive care units in the United States are now using human milk fortifiers for preterm nourishment.

How Common Is NEC?

Thousands of babies in the United States develop NEC every year, and hundreds of those babies die due to NEC's 30% mortality rate. NEC affects between 1 in 2000 and 1 in 4000 births and equates to between 1%-5% of neonatal intensive care unit (NICU) admissions. NEC occurs in nearly 10% of premature infants.

Nearly 90 percent of babies who get NEC are born prematurely. NEC usually affects babies born before the 37th week of pregnancy, babies who are fed through a tube in the stomach (enteral nutrition), and babies weighing less than 5.5 pounds at birth. The condition usually develops within 2-6 weeks after birth.

Cow Milk-Based Infant Formulas

Cow milk-based infant formulas Enfamil (manufactured by Mead Johnson Nutrition) and Similac (manufactured by Abbott Laboratories) are popular substitutes for human milk. Neither Enfamil nor Similac have warning labels on their products to alert parents of the increased risk to their premature infants of developing NEC if they are fed cow milk-based formulas.

If your premature infant developed NEC after receiving Enfamil or Similac, contact us today for a free consultation. We'll deliver the Gold Standard advocacy you and your child deserve. ■

Bad Formulas

OTHER RISKS ASSOCIATED WITH BABY FORMULA

Sadly, NEC-related formula issues are not the only dangers associated with baby formula.

2022 Abbott Formula Recalls

In February 2022, Abbott Nutrition recalled certain lots of its Similac, Alimentum, and EleCare baby formulas after several infants fell ill or died after consuming the formulas. The infants were infected with Cronobacter bacteria, which can cause fatal blood infections or meningitis.

The recalled products were manufactured at an Abbott facility in Michigan. An FDA investigation of the facility found Cronobacter on machinery that comes into contact with the formula, as well as other areas of the facility that are supposed to be sterile. The investigation also found that Abbott's own testing had detected Cronobacter at the facility 8 times between October 2019 and February 2022.

Symptoms of Cronobacter infection in infants include poor feeding, jaundice, fever, and diarrhea.

Neocate & Bone Fractures

Neocate is a prescribed formula for children and infants with food allergies and intolerances to regular formulas. In 2016, Neocate's manufacturer, Nutricia, warned that babies and children taking Neocate formula as a primary or sole source of nutrition "should be routinely monitored by clinicians." The company did not warn about the possibility of children suffering from bone fractures due to taking the formula.

A 2017 Yale study found that certain participants who relied solely on Neocate for nutrition showed signs of severe calcium and phosphate deficiencies in their blood. These deficiencies can lead to serious bone conditions such as rickets and fractures.

To date, Nutricia has failed to warn of this side effect.

GET TO KNOW NOAH

"This is a place where everyone has value and everyone sees value in helping our fellow humans."

NOAH LAURICELLA
PARTNER

For GoldenbergLaw Partner Noah Lauricella, working on necrotizing enterocolitis (NEC) cases is personal. As a father of twins born prematurely at 28 weeks, he knows the anguish of watching your child fight for their life in the NICU. Manufacturers of cow milk-based formulas have been failing preemie families for years, and Noah looks forward to holding them accountable.

What caused you to decide to become a lawyer?

Unlike many, I did not grow up dreaming of being a lawyer. In fact, I grew up in a parsonage and routinely envisioned growing up to be a pastor or a social worker. All I knew then was that I wanted to grow up to help people. Looking back on it now, I had yet to grasp the degree to which lawyers can help people. That all changed when I became a social worker after I graduated college. In running a transitional housing program for individuals struggling with substance abuse, I came to realize that recovery and progress for so many had been damaged by legal impediments they had no ability to overcome without the assistance of a caring attorney. Then and there, it became clear to me that law school provided an opportunity for me to become that caring attorney who could better the lives of their clients and utilize their skills for the betterment of others.

Why did you choose GoldenbergLaw?

GoldenbergLaw cares. I felt it from my first interactions with the attorneys and staff, and I have felt it every day for the past eight years. Everyone at this firm comes to work each and every day to make the lives of our clients better and to make the world in which we all live better. It's evident in the way in which we interact with our clients. It's evident in the amount of work we put into investigating and litigating each and every case. And it's evident in our tireless efforts to promote accountability and justice. This is a place where everyone has value and everyone sees value in helping our fellow humans.

What is the best part of your job?

The best part of my job is that I get to handle cases that I'm truly passionate about. My time and my energy are spent on causes I truly believe in, and that makes it a joy to put in the work necessary. It truly is a blessing to do what I do and represent the people I represent.

Why are you so invested in the firm's infant formula NEC cases?

The infant formula NEC cases perfectly exemplify how blessed I am to be in this position and to have the opportunity to fight for families of premature infants injured by these dangerous products. My wife and I are the proud parents of seven-year-old twins, Deacon and Tate. Our children had a very rough start to life, as they were born three months early at just 28 weeks gestational age. Deacon weighed only 2 pounds, 10 ounces at birth. Tate was less than half that size, at 1 pound, 3 ounces. Both were whisked away to the NICU immediately upon birth, leaving us with conflicting feelings of joy and terror. Rather than newborn snuggles, we wondered if we would ever even have the opportunity to hold our children. We anxiously awaited each update from their medical teams, as every word felt as if our entire world hung in the balance.

For my wife, this resulted in massive feelings of guilt and struggles with issues of self-worth. She has shared her pain over the fact that our children were put at risk being born so early and that she missed out on so many special pregnancy milestones. That pain was then compounded by the reality that her body was also not physically ready to support and nurture our children such that she then missed newborn milestones as well. She felt massive pressure to jumpstart her milk supply and struggled through sleepless nights waking up to pump while our babies lay miles away in the NICU. And once those babies came home, she was forced to supplement her limited milk supply with formula and therefore felt even more pressure to continue pumping while simultaneously bottle-feeding them. If it had turned out that the formula we selected had harmed our children after she was unable to feed them with her own body, it would have destroyed her.

For me, I struggled to put on a brave face and maintain any semblance of outward positivity as internally I wrestled with the terrible knowledge that our children may never leave the NICU. I wanted to dive so deeply into each moment of hope and progress that I can still vividly remember the joy of giving my children their first taste of formula with the end of a q-tip as they laid in their isolettes. But I also found myself being sucked just as forcefully into each moment of despair and fear, as I remember just as poignantly that joy being ripped away and replaced with immense fear that coursed through my body when I first heard that Tate might have NEC.

Needless to say, we faced much uncertainty as we began our journey as parents. We came to know well the sleepless nights of preemie parents. The short-term fears. The long-term concerns. The daily managing of emotions. The willingness to do anything and everything to give your child just the chance to grow and develop. And we came to resolve that we simply had to trust the treatment providers and find comfort in the fact that our children were receiving everything possible to help them grow and survive.

That's what breaks my heart about these cases and motivates me to fight for the families involved. Preemies and their families have to trust that they are receiving the safest nutrition possible. But for so many families, that trust was betrayed. Rather than safe nutrition that supported growth and development, they received products that ravaged their bodies and left them with a catastrophic and potentially fatal diagnosis. Those preemies and their families deserved better.

Deacon and Tate are thankfully now seven years old and are happy, healthy children enjoying first grade and all the wonders of learning and growing. But I can still see in my mind those preemies fighting every second for months on end just to survive. Those memories motivate me in handling these cases. I am a preemie dad, and I am a lawyer. That combination makes me exceedingly passionate, and I consider myself so very blessed to seek justice for families and preemies already injured while also endeavoring to make sure future families don't suffer the same horrors. ■

FDA: PHILIPS RESPIRONICS KNEW OF CPAP MACHINE DEFECT FOR YEARS

A recent Food and Drug Administration (FDA) investigation of Philips Respironics revealed that the manufacturer knew of its CPAP devices' dangerous defect for almost six years before it issued a nationwide recall.

The Recall

On June 14, 2021, Philips issued a voluntary recall of over 15 million ventilators, CPAP, and BiPAP machines used to treat sleep apnea due to a defect with the devices' polyester-based polyurethane (PE-PUR) noise-canceling foam.

The PE-PUR foam was found to degrade into particles that can enter the device's air pathway and may also emit dangerous gas chemicals. Inhalation of the particles or chemicals is linked to cancer and other serious illnesses.

In July 2021, the FDA classified the Philips recall as Class I – the most serious class of recall.

FDA Investigation

In August 2021, the FDA launched its own investigation of the Philips recall. After examining internal documents and communications between Philips employees, the investigation concluded that Philips likely knew of the degradation problems with the PE-PUR foam as early as 2016.

The FDA uncovered over 220,000 customer complaints, with at least 110 directly pertaining to foam degradation. It also brought to light several internal tests that confirmed the degradation issues with the PE-PUR foam. Despite awareness of the issues and significant dangers associated with the foam's degradation, Philips ultimately decided not to alter the design of the foam.

Specifically, the FDA noted that Philips failed to conduct an adequate risk analysis or take proper corrective action once it learned of the risks of degradation.

Philips' "Inadequate" Notification Efforts

On March 10, 2022, the FDA ordered Philips to notify patients with recalled machines and other affected parties of the June 2021 recall. The agency determined this extraordinary order was necessary after many patients, suppliers, and providers reported being unaware of the recall or received insufficient information from Philips about the recall process.

The FDA deemed the Philips' notification efforts to be "inadequate" and outlined a series of actions the company is required to take to ensure affected patients have sufficient information about the device replacement process.

CPAP Injuries

Injuries linked to inhalation of PE-PUR foam from Philips recalled CPAP devices include:

- Esophageal Cancer
- Liver Cancer
- Liver Failure
- Nasal or Paranasal Cancer
- Lung Cancer
- Kidney Cancer
- Kidney Failure
- Pulmonary Fibrosis
- Lymph Node Cancer
- Sinus Cancer
- Significant respiratory problems that have required hospitalization
- Sudden respiratory failure leading to heart attack
- Tonsil Cancer

Let Us Help

GoldenbergLaw is currently investigating cases where an individual was diagnosed with one of the injuries listed above after using a recalled CPAP machine. Contact Senior Partner **Stuart Goldenberg** today at **slgoldenberg@goldenberglaw.com** or **612-335-9960** to discuss your potential CPAP case.

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Cow Milk-Based Baby Formulas Linked to NEC

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