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Pennsylvania's Erosion of the Fair Share Act in Products Liability Cases

BY JONATHAN T. WOY
Special to the Legal

Pennsylvania's Fair Share Act (FSA), 42 Pa. C.S. Section 7102, was enacted in 2011 with the twin aims of ensuring that defendants were only required to pay their fair share of any damages awarded in multi-defendant litigation and curtailing joint and several liability. In *Roverano v. John Crane,* 226 A.3d 526 (Pa. 2020), however, the Pennsylvania Supreme Court began eroding the protection afforded by the FSA, holding that liability must be apportioned among strict liability defendants on a per capita basis. Following *Roverano*, the Pennsylvania Superior Court threatened to gut the FSA's protections by suggesting in *Spencer v. Johnson*, 249 A.3d 529 (Pa. Super. Ct. 2021) that the FSA only applies if a plaintiff has been apportioned a degree of comparative fault. Taken together, these two decisions set the stage for a re-imposition of the per capita apportionment and joint and several liability schemes that the FSA was enacted to limit.

This article will explain how *Roverano's* reliance on *Azzarello*-era precedent to reinstate per capita apportionment among strict liability defendants opens the door to a *Tincher*-based challenge to Pennsylvania's method of apportionment. It will also examine whether the Pennsylvania Superior Court's analysis of the FSA in *Spencer* suggests that the FSA will be found inapplicable to strict liability defendants.

'ROVERANO': REVERSION TO PER CAPITA APPORTIONMENT

For nearly a decade after the FSA was enacted, there was broad agreement that it had eliminated per capita apportionment among strict liability defendants and replaced it with apportionment based on the degree to which each defendant caused the injury at issue. This understanding was consistent with the text of the FSA and the intent of the legislature. In fact, during debate on the FSA's predecessor in the Pennsylvania House of Representatives in 2002, representative Mike Turzai (the bill's floor manager in the House) explained how apportionment would work in strict liability cases and "made clear that liability apportionment between two strictly liable tortfeasors would not be per capita, but instead would be based on 'the degree that the jury or the judge found them causally responsible,' in a manner similar to allocation among negligent joint tortfeasors." *Roverano v. John Crane,* 177 A.3d 892, 908 (Pa. Super Ct. 2017) (quoting Rep. Turzai in 2002 Pa. Leg. J. (House) 1199 (June 4, 2002)). As the Pennsylvania Superior Court recognized, "at no time during the debates on the [FSA or its predecessor] was there ever any suggestion that Rep. Turzai's view of liability allocation under the [FSA] was incorrect or that there would be any allocation among strictly liable joint tortfeasors on a per capita basis."

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Despite the clearly stated intent of the legislature, the Pennsylvania Supreme Court in *Roverano* upended nearly a decade of consensus within Pennsylvania's legal community by holding that the FSA did not disturb the pre-FSA method of apportionment of liability among strict liability defendants. See *Roverano v. John Crane,* 226 A.3d 526 (Pa. 2020). Looking to pre-FSA common law, *Roverano* re-imposed the *per capita* method of apportionment that was the prevailing standard at the time the FSA was enacted in 2011. In doing so, however, the court overlooked the intervening paradigm shift in Pennsylvania products liability law brought about by *Tincher*.

Roverano's determination that Pennsylvania common law required per capita apportionment was based on the *Azzarello*-era decision *Walton v. Avco*, 610 A.2d 454 (Pa. 1992). In *Walton*, the Pennsylvania Supreme Court addressed for the first time whether apportionment among strictly liable defendants should be on a per capita basis or on a comparative fault basis as the Superior Court had held. The court chose per capita apportionment, basing its decision squarely on the *Azzarello*-era edict that all notions of negligence must be kept out of strict liability claims. Citing *Azzarello* as precedential support for its observation that "this court has continually fortified the theoretical dam between the notions of negligence and strict 'no fault' liability," the court reasoned that "it would serve only to muddy the waters to introduce comparative fault into an action based solely on strict liability." Accordingly, the court concluded that—in the *Azzarello* era—it was "improper to introduce concepts of fault in the damage-apportionment process," making per capita the preferred method of apportionment.

In 2014, *Tincher* rejected the *Azzarello*-era exclusion of negligence principles from strict liability claims, thereby dismantling the "theoretical dam" described in *Walton*. In so holding, the court observed that "strict liability as it evolved overlaps in effect with the theories of negligence and breach of warranty." The court went on to criticize *Azzarello*-era decisions that "elevated the notion that negligence concepts create confusion in strict liability cases to a doctrinal imperative, whose merits were not examined to determine whether such a bright-line rule was consistent with reason." *Tincher* underscored Pennsylvania's new approach by adopting the risk-utility and consumer expectations tests, both of which incorporate concepts of negligence that previously would have been off-limits. The risk-utility test, for example, considers whether a "'reasonable person would conclude that the probability and seriousness of the harm caused by the product outweigh the burden or costs of taking precautions." Similarly, the consumer expectations test "defines a 'defective condition' as a condition, upon normal use, dangerous beyond the reasonable consumer's contemplations."

> *"If Spencer's alternative analysis were applied in such a case, the FSA may be inapplicable, leaving the strictly liable defendants subject to joint and several liability. Although Spencer's commentary is dicta and is of no precedential value, trial courts may find it persuasive.*

Given the sea change brought about by *Tincher*, Pennsylvania courts have instructed that "the bench and bar must assess the *Tincher* opinion's implications for a large body of post-*Azzarello* and pre-*Tincher* case law." See *Renninger v. A&R Machine Shop*, 2017 Pa. Super. 98 (2017). Indeed, the court in *Tincher* recognized that its decision would impact many subsidiary issues of products liability law and instructed that "the common law regarding these related considerations should develop within the proper factual contexts against the backdrop of targeted advocacy."

Although *Roverano's* interpretation of the FSA itself is binding, the *per capita* apportionment of liability among strict liability defendants is ripe for challenge. Under *Tincher*, *Walton's* primary justification for *per capita* apportionment in strict liability cases—the exclusion of negligence concepts from strict liability matters—no longer exists. Given the intervening shift in Pennsylvania law brought about by *Tincher*, the *Azzarello*-era per capita standard must be reconsidered and replaced with a method that takes into account the degree to which the injury was caused by each defendant. Doing so will modernize Pennsylvania's method of apportioning liability and bring this crucial aspect of the common law into compliance with *Tincher*. It will also fulfill the legislature's explicit goals in enacting the FSA. As it stands now, however, *Roverano* represents a significant departure from the manner in which liability was apportioned among strict liability defendants over the past decade.

'SPENCER': ABANDONMENT OF THE FAIR SHARE ACT IN STRICT LIABILITY MATTERS

Shortly after *Roverano*, Pennsylvania's appellate courts raised the spectre of further erosion of the FSA in *Spencer v. Johnson*, 249 A.3d 529 (Pa. Super. Ct. 2021). The plaintiff in *Spencer* was a pedestrian who was struck by a company-owned vehicle that was being operated by the spouse of the employer/vehicle owner's employee. The jury apportioned liability as follows: 36% to the driver, 19% to the employee, and 45% to the employer/vehicle owner. *Spencer* held that the liability apportioned to the employee (19%) could be combined with the liability apportioned to the employer/vehicle owner (45%) because the employer/vehicle owner was vicariously liable for the actions of its employee relative to the vehicle. This resulted in the employer/vehicle owner being held jointly and severally liable under the FSA because its liability exceeded the requisite 60%.

Although there were no strict liability claims at issue in *Spencer*, the Superior Court inadvertently offered extraneous commentary that, if adopted by Pennsylvania's courts, could undercut strict liability defendants' ability to claim the benefits of the FSA. That is, the court examined the text of the FSA and hypothesized in dicta that the FSA only applies where a plaintiff has been assigned some degree of comparative fault. Because the plaintiff pedestrian in *Spencer* had not been assigned any comparative fault, the Superior Court suggested that the FSA would have been inapplicable even if the employer/vehicle owner had not been found vicariously liable.

Although parallel negligence-based claims are often pleaded at the outset of products liability matters, products liability plaintiffs typically abandon negligence theories at trial in an attempt to avoid comparative fault. Unless the trial court allows the jury to assess the plaintiff's conduct (which *Tincher* arguably permits), no jury could ever assign comparative fault to a strict liability plaintiff. If *Spencer's* alternative analysis were applied in such a case, the FSA may be inapplicable, leaving the strictly liable defendants subject to joint and several liability. Although *Spencer's* commentary is dicta and is of no precedential value, trial courts may find it persuasive. ●

Tainted by Tuberculosis: The Bad Bone Litigation

BY LARRY COHAN AND JOSHUA COHAN
Special to the Legal

In 2021 in America, over 100 patients went to their local hospitals for orthopedic surgery but got much more than they bargained for—a case of tuberculosis from a contaminated human tissue product used in their surgeries. The human tissue industry is a rapidly growing part of the medical landscape but recent issues have brought to light certain flaws in the industry.

Human tissue is taken from donor cadavers and turned into a wide variety of medical products, many of which are lifesaving. Last year, one donor lot of a human tissue product used primarily in spinal fusion surgeries, FiberCel Viable Bone Matrix (FiberCel), was sold to 37 medical facilities across the country even though it was contaminated with deadly tuberculosis (TB) bacteria. The 113 victims that received the contaminated bone graft are all believed to have developed active TB as a result. The litigation around this catastrophe has focused a microscope on this emerging industry and the safety and potential uses of human tissue and bone products harvested from donor cadavers for use in medical procedures.

PRIOR HUMAN TISSUE LITIGATION

You may remember the now infamous case of the "body snatchers," which involved the illegal "harvesting" of cadavers in funeral homes in Philadelphia, New Jersey and New York. In that case, from 2000 to 2005, a properly registered human tissue company by the name of Biomedical Tissue Services, Ltd., led by criminal mastermind Michael Mastromarino, illegally "harvested" over 1,000 cadavers supplied by funeral homes without proper consent or medical screening. As a result, more than 25,000 human tissue products were sold across the country for surgical implantation into unsuspecting, innocent victim patients. Many of those human tissue products contained communicable diseases that were not adequately screened for.

Thousands of patients, complaining of everything from fear to the development of specific diseases, filed suit against not only the harvesting company, but also the manufacturers and distributors of the potentially tainted human tissue products. On June 21, 2006, those cases were consolidated into a federal Multi-District Litigation (MDL), *In re Human Tissue Products Liability Litigation,* MDL 1763, assigned to the U.S. District Court for the District of New Jersey. The victims' claims were litigated for six years, and ultimately the civil claims were resolved in 2012. Mastromarino faced both civil claims and criminal charges and was ultimately sentenced to 56 years in federal prison in New York, where he expired just a few years later.

THE HUMAN TISSUE INDUSTRY

The "body snatchers" litigation informed an entire industry, and was a wakeup call for the legal, medical and scientific community. Over the past several decades, the use of human tissue products for surgeries of all types has grown exponentially. "Human tissue," per FDA regulations, includes bone, skin, corneas, cells, ligaments, tendons, as well as other types of tissue harvested from human donor cadavers. Cadaver skin can be used for burn patients, skin graphs and breast reconstruction. Human bone can be used both whole or ground into paste for any surgery requiring repair to damaged bone, particularly spinal fusion surgeries. Because of their broad range of uses and incredible benefits, patients today welcome and accept the use of human tissue products.

Human tissue intended for implantation or transfer into a human recipient is generally regulated by the FDA's Center for Biologics Evaluation and Research (CBER) under 21 CFR Parts 1270 and 1271. The regulations require manufacturers of human tissue products to create donor eligibility criteria and to establish procedures to prevent the spread of communicable diseases. The FDA regulates human tissue products under a completely different framework than its regulations for drugs and medical devices.

As of 2019, the human tissue market totaled nearly $10 billion and is continuing to grow. The lesson learned from the earlier fiasco is that harvested cadavers that are contaminated with communicable disease can lead to the spread of that disease to innocent recipients. The industry pledged to make certain that harvesting, processing and distribution procedures would be scrutinized and that contaminated human tissue would not find its way into surgical suites around the country. Unfortunately, the resulting changes to the FDA's regulations fell short of protecting patients from these risks.

THE FIBERCEL RECALL

On June 2, 2021, Aziyo Biologics Inc. (Aziyo) issued a voluntary recall of a single lot of FiberCel that was sold to 37 hospitals across 20 states. The product was recalled after a number of patients tested positive for TB after undergoing orthopedic surgery utilizing FiberCel. FiberCel is a human tissue product made from cryopreserved bone. It is primarily used in orthopedic and reconstructive bone grafting procedures and is intended to maintain characteristics of natural human tissue. FiberCel is manufactured by Aziyo and had been distributed by Medtronic, Inc., through its subsidiaries, Medtronic Sofamor Danek USA, Inc., and Spinalgraft Technologies, LLC.

One hundred and thirteen innocent patients who underwent complex spinal fusion surgery in early 2021 had FiberCel from the contaminated lot used in their surgeries. All of these patients are believed to have subsequently tested positive for TB or died prior to being tested for TB.

Early reports suggest that the harvesting company, New Mexico Donor Services, Inc., harvested a cadaver that was infected with TB and then sold that cadaver's infected human tissue to Aziyo. Aziyo then used the infected human tissue in the production of FiberCel and that infection was transferred to the surgical patients intraoperatively by the placement of the FiberCel product at the site of the spinal fusion. The plaintiffs allege that none of the parties involved in the harvesting, processing, manufacturing, sale, or distribution of the contaminated FiberCel product adequately tested the product or the human tissue used in the product to ensure that it was free from TB contamination.

TUBERCULOSIS

The horror faced by each of these patients should never have come to pass. Tuberculosis in the bone, and eventually spreading to plates, rods, screws, and then to other parts of the body, presents a rare and almost insurmountable challenge to the infectious disease doctors treating these victims. Most people who have TB are originally exposed to TB through aerosol transmission. TB bacterium are inhaled into the lungs and then spread to highly oxygenated parts of the body where there is good blood flow. Only about 5% of people exposed to TB actually develop active disease. For most, the TB stays latent and does not cause harm.

The situation these patients are in is extraordinarily unusual because their TB came from bone fiber material and the TB went directly into their bone. Because these patients received FiberCel as part of their spinal fusion surgeries, the risk of TB entering their spinal cord is greatly heightened. Once TB enters the spinal cord, it can result in significant neurological effects, the formation of abscesses up and down the spinal cord, as well as other severe complications. The TB can also spread to the hardware used in these patients' spinal fusion surgeries which makes the infection much more difficult to treat effectively, as antibiotics cannot reach the hardware through the bloodstream.

Many of the victims have been compelled to undergo painful revision surgeries, having rods, plates, and screws removed, in an attempt to better fight the TB infections, and some will likely have to undergo additional surgeries in the future. These victims must all take four to six different medications for upwards of a year or more in order to fight their TB infection. Numerous victims have been admitted to hospitals for prolonged hospitalizations, some of them by court order and against their will, to receive aggressive inpatient treatment to fight their TB. Local departments of health are involved in almost every case and are monitoring these TB-infected patients on a daily basis to ensure they are taking their TB medication. These innocent victims have lost their ability to work, remain homebound, and have daily unrelenting pain associated with virulent TB infections. Many are suffering from additional complications as a result of their TB, including loss of memory, lesions on the lungs, brain, and on other organs, spreading infections, large abscesses and other devastating complications.

FIBERCEL LITIGATION

The FiberCel litigation is still in its infancy. The first case in the country was filed in Delaware Superior Court in June 2021, *Williams v. Aziyo,* C.A. No. N21C-06-166 EMD, and additional cases have been filed in both federal and state courts in Delaware, Florida, Ohio, Indiana, Michigan, Kentucky, and Oregon. Since the contaminated product was used in 20 different states and impacted up to 113 individuals, additional filings in other jurisdictions are expected.

The lawsuits primarily allege that the defendants failed to adequately screen the donor cadaver's medical history, failed to adequately test the product, failed to manufacture the product in a way that ensured it was free from contamination, and failed to warn patients of the risk of contracting TB. Lawsuits have been filed against the

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LARRY COHAN

JOSHUA COHAN

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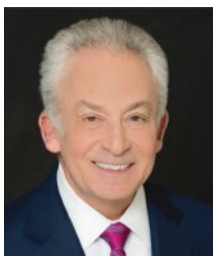
> *"This case should be the final lesson to make sure the industry is properly regulated, and that exhaustive testing is performed so doctors can feel safe when using human tissue products, and so patients can knowingly consent to their use without fear or uncertainty.*

The Hidden Dangers of Infant Sleep Products: Tips to Win Your Case and Save Lives

BY ALAN M. FELDMAN, DANIEL J. MANN, EDWARD S. GOLDIS AND BETHANY R. NIKITENKO
Special to the Legal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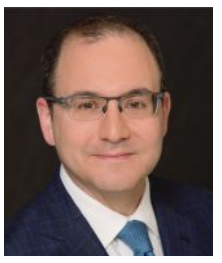
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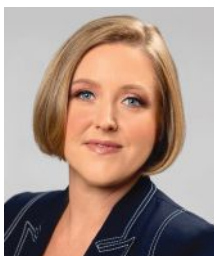
NIKITENKO

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While it may seem unthinkable that a trusted manufacturer of infant products would sell a baby sleeper with little, if any, regard for pediatric sleep safety, that scenario has repeatedly played out across multiple name brands and popular products that have been linked to infant deaths throughout the United States.

Indeed, consumers often operate under the false assumption that infant sleep products are safe and designed by professionals with relevant expertise. The reality, however, is that these products are created to maximize corporate profits and often disregard the guidelines issued by the American Academy of Pediatrics (AAP), which instruct that infants should be put to sleep on their backs, on a separate, flat and firm sleep surface without any bumpers, loose bedding or stuffed toys.

Our firm currently represents in excess of 10 families who lost infants when they asphyxiated while using inclined sleepers. In contravention of AAP guidelines, inclined sleepers (often referred to as rockers, nappers or loungers) place babies at angles of up to 30 degrees, which allow them to adopt unsafe sleep positions that cause asphyxia. In 2009, Fisher-Price brought to market the first inclined sleeper, the Rock 'n Play, without clinical research as to whether it was safe. When the Rock 'n Play was a hit, other companies entered the market with similarly designed products.

The tragic outcome was predictable. In October 2019, the Consumer Product Safety Commission (CPSC) warned consumers to stop using infant inclined sleep products, citing reports of 73 deaths and 1,108 incidents from January 2005 to June 2019. The warning was issued after an independent study commissioned by the CPSC of 14 inclined infant sleep products found that none of them were safe for infant sleep. Astoundingly, Fisher-Price executives admitted in June 2021 in testimony before the U.S. House of Representatives Committee on Oversight and Reform, which was investigating infant deaths in inclined sleepers, and specifically the Rock 'n Play, that the company had received 97 reports of infant deaths occurring in its product. More recently, three Boppy infant lounger products were recalled after eight reports of infant deaths came to light.

> *"When settling cases involving unsafe baby sleep products, be mindful that you can achieve a fair financial result for your clients, while also negotiating terms that promote recalls, public awareness and design practices that will help keep other infants safe.*

The problem is not limited to inclined sleep products. The CPSC is aware of 254 incidents, including 21 fatalities, related to infant sleep products (inclined and flat), occurring between January 2019 and December 2020, according to a June

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Re-Evaluating the Role of Technology in Consolidated and Complex Litigation

BY MATTHEW DOEBLER
Special to the Legal

Since the pandemic, we have formed new relationships with existing technology. We attend streaming worship services, help our children with school assignments on their iPads, and order our burritos by app before we arrive at the restaurant. These technologies all existed before the pandemic, but we have been forced to reevaluate them.

This rapid technological shift has affected the legal industry as much as any other. Regardless of practice area, lawyers and judges have been forced to adopt technologies that had been overlooked for years. The practicalities of providing legal services under pandemic conditions have required re-evaluation of tools and techniques that would have been inconceivable two years ago.

Multidistrict litigation (MDL) is an area of the law that is particularly ripe for this technological reevaluation. This field demands significant travel, it requires coordination of large groups of individuals who all have diverging interests, and the stakes are almost always sky-high. In short, the MDL process is the perfect target for a virus whose disruptive powers include upending our transportation capabilities, limiting face-to-face contact and preventing large gatherings.

With omicron again closing courtrooms, this is an ideal time to take a step back and look at existing technological tools that may be useful to keep these cases running smoothly. Lawyers and judges involved in consolidated and complex litigation may find new interest in tech-forward approaches that had been overlooked in the past.

WAYS TECHNOLOGY COULD ASSIST THE MDL PROCESS

• Webcasting can be used to improve communication between plaintiff's leadership teams and lawyers who represent member plaintiffs.

Steve Herman has a long history of serving on plaintiffs leadership teams for MDL cases. He was co-lead counsel in the BP Oil Spill litigation, he was settlement class counsel for the Chinese drywall litigation, and he has been on the plaintiffs' steering committee (PSC) for many cases. He said that from the court's point of view, information flow is one of the main jobs of plaintiffs' leadership teams. Christopher Robertson, a professor of law at the Boston University School of Law, agreed, pointing out that it is important ethically for plaintiffs to know what is going on. "It can be maddening for plaintiffs to file a case and have it go into a black hole for two to three years," Robertson said.

However, according to Herman, lawyers outside of the PSC frequently complain that they are not getting enough information. While court orders are frequently emailed to lawyers for member plaintiffs and are usually aggregated on a publicly available website, he acknowledged the potential for information overload. "I've been in MDLs before where I wasn't in leadership and I didn't need to read 50 orders and filings per week that don't have anything to do with me and my cases," he said.

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One solution that Herman proposed was to have litigation group meetings via Zoom where attorneys for member plaintiffs are updated about obligations, deadlines, and settlement negotiations. The idea would be to hold ongoing, short meetings where lawyers from across the country can both give and receive updates on the litigation without onerous travel requirements. By limiting the time commitment required to participate in these update meetings, Herman believes the black hole of information can be avoided. "You have to have a systematic way of communicating what's going on," he said.

• Courts could webcast MDL proceedings.

MDL cases are typically marked by regular status conferences with the court, science day proceedings, and *Daubert* hearings. Traditionally, these appearances have involved countless hours of travel and courtrooms packed with hundreds of attorneys.

But Herman believes that beyond the initial status conference, in-person attendance is frequently not necessary. Eric Chaffin feels the same way. He and his firm have been involved in plaintiffs leadership for numerous MDLs, including Paraquat, Zantac and the denture adhesive litigation. Since the pandemic, he said, the courts have been handling MDL case management conferences by Zoom. The benefit Chaffin sees in this approach is that it is no longer cost prohibitive to get real information about what is happening in MDL cases because travel is eliminated.

Chaffin sees a benefit to plaintiffs' leadership attorneys in this approach, too. It is easier for PSC members to work with attorneys for member plaintiffs about resolutions when they are seeing the court's rulings in real time, he said. When status conferences, science day proceedings, and *Daubert* hearings are webcast, he believes lawyers for member plaintiffs have a better tenor of what is happening. Once lawyers have actually listened to the process and the hearings, it is much more compelling to say "this resolution makes sense given the actual presentation of the evidence."

> *"Lawyers and judges involved in consolidated and complex litigation may find new interest in tech-forward approaches that had been overlooked in the past.*

• Depositions could be taken via Zoom to reduce the common benefit expense that must be paid by settling plaintiffs.

Part of the common benefit work involved in most MDLs involves scores of depositions that must be both taken and defended. Engineers, sales executives, and experts who need to be deposed may be scattered all over the country, if not the world. Traditionally, this discovery has required extensive travel, which was generally reimbursed by funds generated by taxing plaintiffs' settlements.

However, Chaffin believes that taking these depositions via Zoom will make it much more efficient for firms to capitalize, be involved in the cases, and send more money back to the clients. Furthermore, he sees similar savings by having experts testify at *Daubert* hearings and Science Day proceedings.

Herman takes this logic a step farther. He believes judges are wise to set up parameters for what is reimbursable up front and can envision a scenario where a judge says "If it's not a 30(b)(6) deposition and it's not going to take more than four hours, Zoom is acceptable and lawyers will not be reimbursed for travel to attend in person."

However, Chaffin does not view Zoom depositions negatively. To the contrary, he believes he is more effective taking a deposition remotely than he is in a room with the deponent. "If they're going to lie, they're going to lie," he said. He particularly prefers Zoom depositions where the alternative is an in-person deposition with the witness in a mask.

• When a settlement is reached, crowdsourcing can be used to help determine who gets what.

When a global settlement is reached in an MDL, it typically results in a pot of money being provided by the settling defendant. According to Robertson, the challenge is to figure out who gets what among the settling plaintiffs. There is a huge human discretionary choice, he said, in making the algorithm that determines how much goes to each plaintiff.

However, Robertson believes we can do a better job of making the algorithm less arbitrary so we construct the formula around actual data from valuations. The best way to decide who gets what, he said, is to recruit large groups of online jurors and "systematically manipulate case facts to figure out how they affect case valuation." Robertson believes that this crowd-sourced approach would allow us to create rigorous models of damages that apply to groups of plaintiffs. That data can then be aggregated to the whole to help reach a settlement value, he said.

• Lawyers for member plaintiffs could use an electronic rating system to grade the plaintiffs' leadership team.

Robertson asserted that there is a credibility determination that judges must conduct when they are appointing individuals to positions on plaintiffs' leadership teams. "Your entire reason for having the job as lead counsel is to represent the interest of the member plaintiffs," he said. To that end, he espoused a system where lawyers for member plaintiffs rate the plaintiffs' leadership team on issues such as communication, efficiency, and cost-effectiveness. He likened these reviews to online ratings for doctors or other service providers. "If these officers of the court are representing that they are the best person for plaintiffs' leadership jobs," he said, "maybe being accountable to their clients is appropriate."

According to Robertson, these ratings could serve several important purposes. First, data from these evaluations could be used by the MDL judge when evaluating fee awards. Second, when a future court is appointing plaintiffs' leadership for new consolidated cases, it would have the benefit of a data point concerning that lawyer's performance from past MDLs.

CONCLUSION

"In a year and a half," Chaffin said, "the entire legal industry has progressed three to four years worth of technology changes." MDL proceedings are poised to develop these technology tools especially quickly, given their unique characteristics and travel-heavy litigation models. Lawyers representing member plaintiffs, attorneys on plaintiffs' leadership teams, and—perhaps most importantly—MDL judges must make new decisions about these technologies. Some may see these choices as disruptive since the new technologies and approaches will definitely require lawyers to adopt new skills and approaches.

Chaffin, however, remains optimistic. "Once we do it and we know we can do it," he said, "the resistance to doing it actually goes away, because … why can't we do this?" ●

Effectively Obtaining and Using Other Similar Incident Evidence

BY LARRY BENDESKY AND ROBERT W. ZIMMERMAN
Special to the Legal

Imagine you're a juror in a products liability trial. The case involves a catastrophically injured plaintiff and a defendant that designed, manufactured and sold a product. The plaintiff suffered her injuries while using the product and claims a product defect caused her injuries. The defendant claims the product was designed and manufactured safely, and the plaintiff's unfortunate injuries were her own (or someone else's) fault.

As a juror, you will consider evidence including design drawings, product testing and analysis, marketing materials, and corporate designee and expert testimony. But imagine the impact it would have if the plaintiffs attorney tells you the following information in opening:

"My client isn't the only victim of this defective product. Twenty-two other people in the last five years alone suffered injuries from similar incidents while using the defendant's product."

Now instead imagine another case where the defense attorney says:

"This product has been sold thousands of times over 10 years. And the plaintiff is the only person who injured herself while using this product, despite the hundreds of thousands of hours these products have been in use."

These statements, and the underlying evidence admitted at trial to prove them, are enormously powerful information for a jury to consider. They can prove a defendant had (or lacked) notice of problems and injuries from its product, or to directly prove that the product was (or was not) defective.

For either party to use this evidence at trial, they must have a detailed discovery plan. Discovery on other similar incidents (OSIs) will require counsel to:

- Identify which of the defendant's products are similarly designed and should be included in the search of OSIs;
- Identify what constitutes "similarity" of incidents; and
- Determine an appropriate timeframe for production.

The amount of information produced in discovery and admissible at trial will depend on the following factors.

Obtaining OSI Evidence in Discovery

Evidence of OSIs is admissible to establish "a defect or dangerous condition existed or that the defendant had knowledge of the defect." See *Lockley v. CSX Transportation*, 5 A.3d 383, 395 (Pa. Super. 2010). See also *Hutchinson v. Penske Truck Leasing*, 876 A.2d 978, 983 (Pa. Super. 2005); *Blumer v. Ford Motor*, 20 A.3d 1222 (Pa. Super. 2011). "For other accident evidence to be admissible, the plaintiff must first establish there is a substantial similarity of conditions between the other accidents and the accident that injured the plaintiff." To determine whether the other accidents are sufficiently similar, courts look to whether they involved the same instrumentality and whether the accidents occurred under the same or similar conditions or circumstances. *See also Valentine v. Acme Markets*, 687 A.2d 1157, 1163 (Pa. Super. 1997). "If the evidence of other accidents is substantially similar ... then that evidence will assist the trier of fact by making the existence of a fact in dispute more or less probable, and the greater the degree of similarity the more relevant the evidence."

When serving OSI discovery, requests should include "accidents, incidents, near misses, reports, claims, complaints and inquiries" similar to the hazard and incident described in the complaint. Interrogatories, document requests, and requests for admission will reveal whether any of the defendant's employees discussed or corresponded regarding the hazard described in the complaint, or proposed or took efforts to identify or fix the problem. These requests likely require search terms and parameters for electronically stored information retrieval. The plaintiffs should request other lawsuits arising from similar incidents, including case captions, complaints/answers, discovery, depositions and expert reports. In many cases, other models of the defendant's product catalog substantially similar designs and should be included in the discovery requests and production.

Disputes often arise in the scope of OSI discovery. The plaintiffs must serve OSI discovery early, review the defendant's production immediately, and identify areas of dispute so the parties can attempt to resolve these issues and ultimately file appropriate motions with the court. Obtaining meaningful OSI evidence will take months and could require court intervention, so make sure your requests are carefully crafted and your scope is reasonable and based on the facts of your case and history of the product.

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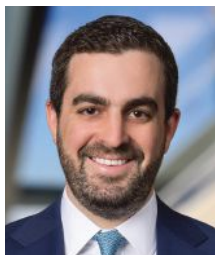

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> *"Discovering OSIs is vitally important to a plaintiff's lawyer. Similarly, defense attorneys must find out early in the case how comprehensive their client's accident reporting, investigation and retention policies are.*

Uncovering Defendant's Accident Tracking Policies (or Lack Thereof)

If there is no evidence of prior, similar incidents, Defendant will attempt to argue the lack of OSIs proves the product is safe. Pennsylvania only allows defendants to admit a *lack* of OSIs where the defendant's reporting mechanism for cataloging other accidents is a "comprehensive record of all reports of claims or problems which the [defendant] had received from any source." See *Spino v. John S. Tilley Ladder*, 671 A.2d 726, 737, aff'd, 548 Pa. 286, 696 A.2d 1169 (1997). In *Spino*, the Supreme Court recognized the onus is on the plaintiffs to challenge the reliability of the defendant's incident cataloging system. The *Spino* plaintiffs failed to raise any issues related to the reliability of the defendant's logs and had little ground to challenge its efficacy on appeal.

Well-crafted discovery requests and corporate designee areas of inquiry will allow plaintiffs counsel to learn the defendant's methods for receiving information; its procedures for investigating incidents; and its policies for tracking and recording incident information. Many companies simply do not have an adequate system to learn of and retain OSIs that permits them to argue no other similar incidents have occurred.

Discovery and corporate designee questioning should include:

- Defendant's policies for identifying and investigating incidents, and tracking, cataloging and retaining this information;
- Identifying written information on the product and accompanying literature directing users to contact the company in the event of an incident;
- Information provided to dealers regarding what they should do if an incident is reported to them;
- Who the corporation designates to receive information on accidents and what that person does with the information; and
- How often the defendant learns of accidents from lawsuits and how the defendant learned of the plaintiff's accident.

In many situations, the defendant learns of the plaintiff's accident through a lawsuit. If no lawsuit was brought, the defendant never would have learned of the accident. Even when a defendant claims to have an accident reporting and tracking system, it may not have an accident report for your client's accident, or for other accidents uncovered through diligent investigation. When a product manufacturer uses a dealer network, it may only require dealers to notify the manufacturer of lawsuits, and not when the dealer learns of accidents that do not result in litigation. The following exchanges occurred at a recent deposition:

Q: Do you have any information that your company would have known about this accident that resulted in quadriplegia to my client without him hiring an attorney?

A: Not that I know of today.

Q: Has the defendant done anything to determine if your dealers are providing accident reports for every single injury and accident they learn of?

A: No.

Q: Is there a section of your website where people who learn of an accident can let you know of an accident?

A: Not those specifics.

If the defendant's system does not adequately capture, investigate, record and retain incidents, and does not give information on how to report incidents, the defendant will not be permitted to introduce evidence that no other similar accidents exist.

Motions in Limine and Trial

In cases where the parties seek to introduce OSIs or lack thereof, it is vital to file motions in limine in advance. Even if these issues came before the court during discovery, there is a different standard for the information's relevance and admissibility at trial. The plaintiff's counsel will often file two motions: one to admit the OSI evidence, and another to preclude the defendant from arguing there are no other incidents. The plaintiff's counsel should argue that, if they have discovered OSIs despite the defendant's deficient incident reporting and tracking program, the defendant must be precluded from arguing the incidents found are the only incidents that ever occurred, and the plaintiff must be permitted to state there are at least X number of OSIs.

The court may permit only a portion of the other similar incidents the plaintiff

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The Merger Doctrine—Avoiding Piecemeal Appeals in Multidistrict Litigation

BY TERRY M. HENRY AND MELISSA F. MURPHY
Special to the Legal

Do individual plaintiffs in multidistrict litigation (MDL) involving thousands of individual claims against a multitude of different defendants have an automatic right to appeal when all their claims are dismissed with prejudice, but only as to a subset of defendants?

The issue appeared to be settled by the U.S. Supreme Court in its 2015 decision in *Gelboim v. Bank of Am. Corp.*, 574 U.S. 405 (2015), but a footnote in that opinion turns out to have created a giant exception: the merger doctrine. While individual pleadings retain their separate character for purposes of appeals from MDL proceedings as held in *Gelboim*, the footnote in the opinion suggests that parties and the district courts managing MDLs can change the default separate-character rule through the use of master pleadings.

The issue created by the *Gelboim* footnote was recently before the district court for the Southern District of Florida in an MDL involving the drug Zantac and its generic counterpart ranitidine, *In re Zantac (Ranitidine) Products Liability Litigation,* MDL 2924. The issue was further complicated, however, by the wording of the stipulated pre-trial orders that blurred the line between individual pleadings and master pleadings.

In July 2021, U.S. District Court Judge Robin L. Rosenberg, presiding over the *Zantac* MDL in the Southern District of Florida, dismissed claims brought against dozens of defendants by more than 1,400 plaintiffs around the country and tens of thousands of plaintiffs registered with the court's Census Registry. The essence of the plaintiffs' claims was that the defendants had misbranded their drugs in connection with the drug's alleged potential risk for causing cancer. Among its decisions on the motions to dismiss, the court agreed with the group of generic drug manufacturer defendants that federal law preempted all of the plaintiffs' claims regardless of how the plaintiffs styled their claims. The court granted the generic defendants' motion to dismiss and dismissed with prejudice all claims against generic manufacturers.

However, a vast majority of plaintiffs in the litigation had also named as defendants brand manufacturers, retailers, and distributors, in addition to the now-dismissed generic defendants. This meant that the court's order dismissing the generic manufacturers was not "final" for purposes of appeal as to those plaintiffs naming other defendants.

The court's order, the mix of parties in individual cases, and rules of appellate procedure created a conundrum for individual plaintiffs seeking to appeal the court's dismissal orders, as well as for generic defendants who wanted to secure the finality of their MDL-wide win. The parties and the court were faced with an important question:

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For those cases in which the court's order dismissing the generic defendants was not final as to all claims and all parties (mixed cases), were defendants able to avoid the crush of piecemeal appeals following remand in individual actions, potentially over the course of many years and in circuit courts around the country?

At first blush, the right of individual plaintiffs to separately appeal appeared straightforward under the Supreme Court's ruling in *Gelboim v. Bank of America*, 574 U.S. 405 (2015). There, the court held that individual actions consolidated in an MDL retain their separate identity for purposes of automatic appeal. Thus, the dismissal of an individual pleading asserting claims solely against defendants that were dismissed with prejudice (generic only cases) should qualify as an appealable final decision. But the circumstances of the *Zantac* MDL brought to the forefront a footnote in *Gelboim*. There, the court noted that the parties could change the default rule and "elect to file a 'master complaint' and a corresponding 'consolidated answer,' which supersede prior individual pleadings. In such a case, the transferee court may treat the master pleadings as merging the discrete actions for the duration of the MDL pretrial proceedings."

The *Zantac* plaintiffs had agreed to file master complaints, with individual plaintiffs filing short form complaints. The defendants were permitted to move to dismiss the master complaints only, and the court's decisions on those motions analyzed only the claims brought in the master complaints. Thus, the court's *Gelboim* footnote exception appeared to squarely apply. Under the merger approach, the district court's order dismissing only generic defendants was not final as to any plaintiff's case, even those short form complaints naming just generic

> *"This issue is one that future MDL district judges and all parties should be aware of as they fashion pretrial orders that seek to streamline the pleadings for purposes of pretrial dispositive motions in large MDLs.*

defendants, because all cases were merged for purposes of the pleadings and motions to dismiss. In this situation, the plaintiffs would need to seek a Rule 54(b) certification to perfect their right to appeal.

Under Federal Rule of Civil Procedure 54(b), the court may direct entry of a final judgment as to one or more, but fewer than all, claims or parties if the court expressly determines that there is no just reason for delay. Upon entry of a Rule 54(b) partial final judgment, *all* of the plaintiffs' claims against the dismissed generic defendants become immediately appealable, even for those plaintiffs whose actions against other defendants proceed in the MDL. The benefit of this approach was the obvious efficiency to the parties and the courts to have one Circuit Court of Appeals address, at the earliest practicable time and in a consolidated fashion, the identical claims of all plaintiffs consolidated in an MDL.

In determining how to enter judgment, the *Zantac* court closely analyzed *Gelboim* and two circuit court decisions on the merger approach: *In re Refrigerant Compressors Antitrust Litigation*, 731 F. 3d 586 (6th Cir. 2013), and *Bell v. Publix Super Markets,* 982 F. 3d 468 (7th Cir. 2020). The court noted that all deadlines in the case were set to the master pleadings; the court heard three rounds of motions to dismiss—a total of twenty motions—all directed to the master pleadings; and the parties and the court looked solely to the claims advanced in the master pleadings when arguing and ultimately deciding the motions to dismiss. The court also noted that the pretrial order setting forth the process for master pleadings stated that all claims in the master pleadings would supersede and replace all claims pleaded in any complaint previously filed or transferred to the MDL.

But the district court's pretrial order setting forth the master pleading procedure was arguably ambiguous as to whether the individual short form complaints retained some minor legal effect notwithstanding the filing of master complaints. The plaintiffs seized on the language in the court's pretrial order to argue that the *Gelboim* footnote did not preclude some plaintiffs from appealing immediately and leaving other plaintiffs to wait for their cases to eventually be remanded to their originating courts to appeal the same order later in a different court. While the court found unpersuasive the plaintiffs' contention that their short form complaints, standing alone, were operative pleadings, the court was concerned by plaintiffs' argument that their subjective intent was to preserve their individual appellate rights, which the plaintiffs attempted to unilaterally memorialize in their master pleadings.

The court acknowledged that the language in the master pleadings could not be squared with the court's pretrial order or how the parties and the court had conducted this litigation, and admonished the notion that the plaintiffs could simply run from the pretrial order—to which the plaintiffs consented—by unilaterally inserting language that the master pleadings were not intended to consolidate "for any purpose" the various claims of the individual plaintiffs.

Given the specific circumstances of the pretrial orders and pleadings in this case, however, the court ultimately found that the *Gelboim* footnote could not squarely control. But the court noted that "in perfect hindsight [the court] wishes that it had a better appreciation of the significance of the language in its pretrial order and the governing law as to the merger doctrine at the time the pretrial order was entered," clearly expressing a preference for resolving the appellate issues in one uniform, MDL-efficient manner. Ultimately, Rosenberg adopted a remedy with largely the same effect as a finding of merger. The district court entered a single Rule 54(b) partial judgment with respect to all but a handful of claims and entered that order on the main MDL docket, applicable to all mixed cases. The generic defendants were thus protected from the real risk of burdensome piecemeal appeals and inconsistent rulings, and the plaintiffs' appellate rights were fixed.

This issue is one that future MDL district judges and all parties should be aware of as they fashion pretrial orders that seek to streamline the pleadings for purposes of pretrial dispositive motions in large MDLs. The merger doctrine, endorsed by the Supreme Court, the U.S. Courts of Appeal for the Sixth and Seventh Circuits, and now the Southern District of Florida, "holds the court and the parties to their actions to prevent them from springing traps by treating a consolidated complaint as the real complaint in the district court but then denying its importance and effect once a party tries to appeal." As a takeaway from the *Zantac* MDL, all involved must be careful to fashion pretrial orders and pleadings clearly and unambiguously so as to avoid those traps. ●

Editor's note: Blank Rome attorneys represent a party that was a defendant in the generic drug manufacturing group mentioned in this article.

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harvesting company, the manufacturer and the distributor of FiberCel. Due to the number of victims and the long and uncertain road to recovery that many of them face, this litigation will likely be ongoing across the country for years to come. While these cases are being fought in court, it is imperative that the defendants involved do everything in their power to ensure that a tragedy like this never happens again.

NEXT STEPS

The questions raised by this tragic situation include: how could this possibly have occurred, what is the standard for selecting a donor cadaver, and what has been done to ensure that this industry, so critical to our modern and evolving medical world, has taken the necessary steps to assure the safety of its products. We have to encourage the FDA, the human tissue industry, and the medical community to have a high and demanding standard. Simply put, there should be no opportunity for diseased human tissue to reach operating rooms.

This case should be the final lesson to make sure the industry is properly regulated, and that exhaustive testing is performed so doctors can feel safe when using human tissue products, and so patients can knowingly consent to their use without fear or uncertainty. ●

Dangers

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2021 press release. In addition to inclined sleepers, other products tied to infant deaths include in-bed sleepers (meant for parents to co-sleep with their baby, which the AAP advises against), baby boxes (cardboard boxes with a fitted mattress), sleep hammocks, and travel and compact bassinets. The CPSC has also identified 113 fatal incidents from January 1990 to March 2019 and 113 nonfatal incidents from January 2008 to March 2019 associated with crib bumpers, which the AAP also recommends that parents not use.

How can so many unsafe infant sleep products enter, and remain in, the marketplace and people's homes? The short answer is a perfect storm of statutory and regulatory shortcomings.

First, the CPSC lacks sufficient authority to effectively regulate the baby product industry, or any industry for that matter. Under Section 6(b) of the Consumer Product Safety Act, when the CPSC wants to notify the public about a hazardous product, it usually must get the company's permission first. If the company objects, which is usually the case, the CPSC may be forced to litigate the issue. Section 6(b) also allows companies to negotiate the language the agency uses in the event of a safety alert or product recall. Moreover, the CPSC is powerless to force a recall and must engage in protracted litigation or administrative proceedings if a company does not voluntarily agree to withdraw its product. Likewise, reports of incidents and deaths involving infant products are not readily available to the public.

Notably, Fisher-Price and other manufacturers agreed to recall more than 5 million inclined sleepers in 2019 only after the CPSC accidentally disclosed, in violation of the laws protecting manufacturers, unredacted data to *Consumer Report*s about infant deaths associated with these products, and *Consumer Reports* indicated its intent to publish the information. By that time, the Rock 'n Play sleeper had been on the market for 10 years and had generated at least $200 million in revenue for Fisher-Price, according to the staff report from the Committee on Oversight and Reform's investigation, titled "Infant Deaths in Inclined Sleepers: Fisher-Price's Rock 'n Play Reveals Dangerous Flaws in U.S. Product Safety." The report concluded that the Rock 'n Play might still be on the market today if not for the data leak.

While infant sleep cases often pose difficult and unique challenges, multiple claims, verdicts and settlements, can, over time, provide strong incentives for manufacturers to adopt safer product designs and recall unsafe sleepers. Below are strategies for screening, preparing and successfully resolving these cases, which may resonate beyond your client and help to keep other infants safe.

INITIAL STEPS

When a family contacts you about a potential infant sleeper case, your first step is to gather some key information.

- Get all available information about the sleep product, including the model, instruction manual, where it was purchased and the receipt.
- Determine whether there are any warnings in the manual, on the sleeper itself or on the box in which it was sold, if still available.
- Take possession of the sleeper and any related products sold with the sleeper and store them in a secure facility, in the condition acquired.
- Conduct an in-depth interview with the parents or caregivers about the events leading up to the incident and how they learned of it.
- Check the CPSC website to ascertain whether the sleeper has been subject to a recall and obtain all available CPSC data, including prior incidents.
- Report the incident to the CPSC. If the CPSC desires an interview with your client, make certain that you are with your client (in person or virtually) when the interview is conducted to prevent any unfair or inappropriate questions.

LITIGATION TIPS

- Collect exemplars of the product. They will disappear from store shelves and websites if the product is recalled.
- Download all available information, including marketing claims and product manuals.
- Retain experts. Experts to consider include product design and human factors experts, a causation/airway specialist, and a forensic pathologist.
- Request key documents from the manufacturer. These may include a history of internal testing; warnings and instructions supplied with the product and other sleepers sold by the manufacturer; reports of all other incidents involving the sleeper which resulted in either injury or death; and memoranda arising from participation in relevant ASTM International committee meetings, where voluntary safety standards are developed.
- Depose the designers of the products, those responsible for marketing it, the executive responsible for recall decisions, and the company CEO if possible.
- Ascertain what hazard testing was done.

LEGAL CLAIMS

Possible legal claims include:

- Unsafe design, meaning that the sleep product is not safe for its intended or expected use. These claims can be asserted under negligence or product liability theories. In Pennsylvania, *Tincher v. Omega Flex*, 104 A.3d 328 (Pa. 2014), provides two tests to apply to product defects: risk utility and consumer expectations. Under a risk-utility test, a product is defective if a "reasonable person" would conclude that the probability and seriousness of harm caused by the product outweigh the burden or costs of taking precautions. A consumer expectations test defines a defective condition as one that, upon normal use, is dangerous beyond a reasonable consumer's contemplation. A negligence claim may be appropriate in circumstances where the manufacturer failed to perform hazard testing before releasing its product into the marketplace. Our firm has handled multiple cases in which infants died in products under circumstances where no hazard testing was performed.
- Failure to warn, which is based upon the absence of clear instructions and adequate warnings about the safe use of the product, pursuant to Section 402A of the Restatement (Second) of Torts.
- Whether a post-sale duty to warn exists in Pennsylvania for products like inclined sleepers is problematic under current law, but in our view warrants a fresh look, given the state of industry knowledge of significant risks and the law of other jurisdictions permitting these types of claims.

Punitive damages may be possible when there is evidence that a manufacturer recklessly failed to consult with medical specialists in designing the sleeper, or received notice or was otherwise aware of injuries or deaths occurring in its product, and did little or nothing to investigate such incidents.

SETTLEMENTS THAT SAVE LIVES

As trial lawyers we know that the impetus for product safety arises not only from regulations and standards, but also from creative and impactful lawyering. In our experience, most parents who lose a child to a dangerous product want to spare other families from similar tragedies and will consent to utilizing their case to accomplish this objective.

When settling cases involving unsafe baby sleep products, be mindful that you can achieve a fair financial result for your clients, while also negotiating terms that promote recalls, public awareness and design practices that will help keep other infants safe. ●

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uncovered, or perhaps none at all, if the substantial similarity has not been adequately identified. For this reason, it is necessary that the parties understand exactly which OSIs will be admitted at trial, and for what purpose. In product liability cases, the parties will often file dozens of motions in limine collectively. In cases where certain motions in limine, such as OSI evidence, would benefit the parties and the court if heard in advance, consider requesting an early trial assignment to prepare openings and witness examinations based upon the court's rulings. The parties should use OSI information in openings, and should provide notice to opposing counsel in advance and receive permission from the court to use the items that have been determined to be admissible during trial.

During trial, OSI evidence should be used during the defendant's corporate designee examination, as well as through each party's experts. The experts should identify in their reports the OSI information relevant to their opinions so they may discuss these topics at trial. The parties should not simply admit the OSI evidence through one witness and move on to other issues. They must allow all relevant witnesses to explain why the information is important in a way in which jurors can connect. Visual aids should be used, including timelines of incidents reported to the defendant, and photos or video from other substantially similarity accidents.

Discovering OSIs is vitally important to a plaintiff's lawyer. Similarly, defense attorneys must find out early in the case how comprehensive their client's accident reporting, investigation and retention policies are. ●

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