Toxic Torts and Environmental Law Committee

THE SOPHISTICATED USER DEFENSE: IT’S NOT JUST FOR DRUG COMPANIES ANYMORE

By: Andrew M. Thompson and Stephen E. O’Day

The sophisticated user defense, also known as the learned intermediary doctrine, has been widely used by drug manufacturers in defending against failure to warn claims in products liability lawsuits. Although less well known, the sophisticated user defense has also been applied outside the pharmaceutical drug context and just recently, in Parker v. Schmiede Machine & Tool Corp., the U.S. Court of Appeals for the Eleventh Circuit relied on the sophisticated user defense in affirming a district court’s grant of summary judgment to the defendants in a case in which employees at Lockheed Martin’s Marietta, Georgia facility alleged that they developed illnesses as a result of exposure to beryllium.

The Use of the Sophisticated User Defense in Toxic Tort Cases

A plaintiff asserting a failure to warn claim must show that the defendant had a duty to warn, that the defendant breached that duty, and that the breach proximately caused the plaintiff’s injury. The “sophisticated user” or “learned intermediary” defense relieves a product supplier of the duty to warn an ultimate consumer or

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LETTER FROM THE CHAIR

I’m so pleased with the committee’s endeavors this year. We started 2012 with a productive strategic planning session during the ABA Midyear meeting in New Orleans, Louisiana. Our committee was also integral in some top-notch CLE programming that aired during the Midyear meeting. Specifically, we put on a CLE program entitled, “When the Levees Broke: Judicial and Governmental Response Following Hurricane Katrina.” The program was very well received and is now available for download on West LegalEd Center’s website. At the end of March, we had another fantastic spring CLE program at the Arizona Biltmore in Phoenix. Many thanks to program chair, Brian Gross, who did an excellent job of coordinating the CLE programs and social events. And the year’s not over yet. We will be putting on a CLE program during the ABA Annual Meeting in Chicago, Illinois. Our program, Hot Topics in Environmental Law, will be held Sunday, August 5 at 8:30 a.m. Come join us to hear Vice Chair Randi Mueller moderate a panel of preeminent speakers who will discuss hot topics, including recently promulgated EPA rules for utilities, the suite of greenhouse gas regulations, developing Clean Water Act regulations and the potential economic effect of these regulations. I would like to thank all of our Vice Chairs and members who have worked so hard and so creatively this year in support of all of our projects. It’s really been a fantastic year. See you in Chicago!

Jennifer Kilpatrick, Chair TTEL
It is our pleasure to present the TIPS TTEL Summer Newsletter, which features five intriguing articles ranging from the potential expansion of the sophisticated user doctrine for non-pharmaceutical product liability cases to a possible increase in personal injury actions pertaining to exposure to polychlorinated biphenyl (PCB) in consumer goods and products. We hope that you enjoy these articles, and we encourage committee members and nonmembers to submit article proposals for upcoming newsletters. We would like to thank the authors that have contributed to this edition, as well as the section members for their efforts in supporting this publication. A special thanks to committee chair, Jennifer Kilpatrick, for her help with this Newsletter.

Sincerely yours,

Eliot Harris & Leland Kellner

In Westport, Massachusetts, voters approved borrowing $3.2 million to pay for a clean-up at the local middle school. Evidencing the severity of the situation, the School District Superintendent stated, in an open letter, that if the loan was not approved, the district would begin cutting school programs and staffing to create funding for the clean-up. Meanwhile, in Bridgeport, Connecticut, the City paid to dismantle and inspect the ventilators at a school to ensure that the building was free from contamination.

However, it was not asbestos or lead paint that purportedly contaminated these classrooms; it was PCBs that leached from building products, installed in the 1960s and 1970s, such as caulk, ceiling tiles, lighting fixtures and floor tile mastic. While historic concern regarding potential toxins in public buildings has focused on schools, the installation of PCB construction materials during the 1960s and 1970s was not limited to school buildings and was more widespread than previously thought.

Though litigation concerning PCB pollution is not new, the interest in PCBs in buildings suggests that new personal injury claimants may come forward in the future. Unlike property damage claims, where the mere presence of PCBs can create a compensable event, recovery for personal injury depends upon proof of causation, which appears to be the new battleground for toxic tort litigation concerning PCB products.

PCBs stand for Polychlorinated Biphenyls, a class of human-made chemicals that were widely used in electrical equipment and fixtures, heating and cooling systems as well as in building materials such as plasticizers, insulators and flame retardants. PCBs exist in a form that ranges from a waxy solid to an oily liquid, and are durable, stable, non-flammable, non-conductive chemicals with a high-boiling point. While this endurance made PCB a valuable component in construction material, it created a downside. Testing reveals that PCBs can leach into surrounding surfaces and vaporize into an odorless gas that contaminates heating and cooling systems. Once introduced to the indoor environment, PCBs can be inhaled, ingested and absorbed transdermally. Growing concern over potential

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TIPS Annual Meeting CLE Programs

- Understanding and Preparing for Disasters Caused by Terrorist Acts
- Claims, Consequences and Conditions Subsequent
- An Insider’s View of Preparing for and Responding to Disasters Caused by Acts of Terrorism
- Cyber Risks Affecting Businesses
- So You Want to Become a Mediator? Transitioning Into Mediations Practice
- Disabilities and the Legal Profession: Law and Disabilities - The Often Overlooked
- Hot Topics in Environmental Law
- Sheltering Liability Legal Issues Surrounding Directors, Officers, Staff and Animals

We have a fantastic meeting planned that includes several valuable CLE programs to help you in your practice, various opportunities to network and socialize with your TIPS friends, colleagues and clients at events including our Welcome and Diversity Reception at the Sheraton and the James K. Carroll Leadership and Awards Dinner at the beautiful and historic Chicago Symphony Orchestra, along with the chance to give back through our public service projects.

www.americanbar.org/tips
EMERGENCE OF UN-VALIDATED BIOMARKERS IN TOXIC TORT

By: Angela J Harris, PhD, DABT1 and Anthony Hopp2

Toxicogenomics is defined as the study of the response of a genome to hazardous substances using “Omics” technologies such as genomic-scale mRNA expression (transcriptomics), cell and tissue-wide protein expression (proteomics), and metabolite profiling (metabolomics) in combination with bioinformatic methods and conventional toxicology. One of the many goals for use of this technology is to develop new biomarkers of exposure to, or toxicity from, chemicals in the environment.

Biomarkers of exposure and effect obtained from toxicogenomics studies are beginning to be used to show or negate causal relationships in toxic tort and workman’s compensation litigation. In many cases, the biomarkers in question have not been sufficiently validated to demonstrate that reported changes in gene expression patterns or circulating cytokines/proteins levels are indeed causally related to overexposure to a specific chemical or class of chemicals. Proper validation of a defensible biomarker developed from toxicogenomics data includes reproducibility by one or more independent scientific investigators; demonstration of dose-response and specificity; development of a blind test set as confirmation of the methodology; data transparency; and the absence of non-specific or confounding responses.

For as little at $99, any individual can order a kit online to determine their “personal” genome. While personal genomics data are increasingly used by physicians in individualized medicine, it is unclear how these data will be interpreted and used by members of the general population. Media attention to the Human Genome Project and the role this information may play in identifying individuals with increased susceptibilities to certain cancers and drugs led to widespread interest in genomic data. It is therefore unsurprising that attempts to use genomics data in litigation for causal purposes have started to emerge. Two examples are presented in this article; The Cytokine Institute (transcriptomics) and Dr. Ritchie Shoemaker (proteomics).

The Cytokine Institute

The Cytokine Institute (TCI) was founded in 2006 by Bruce S. Gillis, MD, MPH. It offers genomics based services for evaluation of occupational exposure, workman’s compensation claims, and toxic tort litigation. According to TCI’s website, their msds™ technology can be used to “determine with 99.9+% accuracy if an injurious exposure occurred based on chemical-specific signatures.” Although both the U.S. EPA and FDA accept submission of genomics data for evaluation of ecological and/or human health toxicity, neither agency considers submission of only genomic data sufficient for making health-based regulatory decisions. There is a lack of peer-reviewed published literature demonstrating that a chemical specific gene expression signature is predictive of past or present exposure to only that chemical or class of chemicals in every individual of the population.

Testing for msds™ consists of collecting peripheral blood mononuclear cells (PBMC) from the individual being testing, then determining the gene expression patterns using RNA isolated from the collected cells. The gene expression patterns from the individual being tested (isolated from a living organism or in vivo) are then compared with gene expression patterns in PBMC isolated from other individuals. The PBMC collected from other individuals are plated on cell culture dishes then treated with different doses of the chemical or chemical metabolite for about 18 hours. This type of testing is termed in vitro from the Latin for “within the glass.” The gene expression patterns from the tested individual (in vivo) are then compared to the gene expression patterns from chemically treated cells in vitro.

There are several limitations in the msds™ methodology. Data from in vitro testing are not always predictive of a response in vivo. There is no peer reviewed published literature from TCI demonstrating a correlation between gene expression patterns obtain cultured PBMC treated in vitro and PBMC exposed in

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THE DEBATE CONTINUES: MORE COURTS WEIGH IN ON COMPONENT PARTS LIABILITY

By: Lawrence G. Cetrulo, Esq.; Toni L. Frain, Esq.; Robert J. L. Moore, Esq.\(^1\)

Courts around the country continue to grapple with the scope of liability for manufacturers of “component parts” or “replacement parts” - parts integrated or incorporated into their products by other parties after manufacture and/or installation. In jurisdictions that recognize “component parts liability,” manufacturers of products can be liable for injuries caused by parts they neither supplied nor installed if they knew or should have known that others would incorporate “component parts” into their products. Jurisdictions that recognize “component parts liability” may recognize, in addition, product manufacturers’ liability for “replacement parts” - parts other parties install to replace components installed by the original manufacturer of the product. Related to “component parts liability” is the “component parts defense,” also known as the “raw material defense” or “bulk supplier defense,” which has been adopted by a majority of jurisdictions. The “component parts defense” shields product manufacturers from liability for harm caused by component parts installed into their products by other parties, after the products are sold by the original manufacturer, unless (1) the original product itself is defective, or (2) the manufacturer of the original product substantially participates in the integration of the component part into the product design, and the integration causes the final product to be defective.

California

In January 2012, the California Supreme Court rejected the notion that it should impose on “component parts liability” against equipment manufacturers for dangers associated with third party manufacturers’ products.\(^2\) In O’Neil, the plaintiff claimed exposure to asbestos aboard the USS Oriskany from June 1965 to August 1966 where he replaced asbestos-containing packing, gaskets, and insulation, manufactured and sold by third parties, on valves and pumps manufactured by, inter alia, one of the defendants, Crane Co, which moved for nonsuit on the ground that there was no evidence that plaintiff had been exposed to any asbestos from a Crane Co. product. The trial court granted the motion. The California Court of Appeals reversed, and held that a manufacturer is strictly liable for the dangerous components of its products and for dangerous products with which its product will necessarily be used. The Court of Appeals made no distinction between liability for original and replacement asbestos-containing gaskets and packing.

The California Supreme Court reversed, and held that a manufacturer may not be found strictly liable or negligent for harm caused by another manufacturer’s product unless the defendant’s own product contributed substantially to the harm, or the defendant participated “substantially” in creating a harmful “combined use” of the products. The Court determined that mere foreseeability of harm was not sufficient to impose strict liability for injuries arising from the use of another manufacturer’s product. The Court further found that the expansion of the duty of care urged by the plaintiffs would generate liability for manufacturers whose products caused no harm, which conflicts with decades of precedent in products liability law.

In O’Neil, Crane Co. did not manufacture, sell, or specify the use of the alleged asbestos-containing products. Apart from the Navy’s specifications, there was no evidence that Crane Co. designed the products at issue for use with asbestos-containing gaskets or packing. The Court noted that the Navy could have chosen non-asbestos-containing replacement parts, and the fact that Crane Co.’s products were compatible with asbestos-containing components did not render these products defective.

Following O’Neil, the Supreme Court of California declined to review a case involving a component supplier’s attempt to invoke the component parts

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Disasters Caused by Acts of Terrorism

Sponsored by the ABA Tort Trial & Insurance Practice Section and Exponent
Co-Sponsored by Thomson Reuters and the ABA Standing Committee
on Disaster Response and Preparedness

ABA Annual Meeting
Friday, August 3, 2012
The Hyatt Regency
Chicago, IL

Welcome and Introductory Remarks: Randy Aliment, Williams Kastner, Chair, ABA/TIPS

Understanding and Preparing for Disasters Caused By Terrorist Acts
8:30am-10:00am

Moderator:
Larry P. Schiffer, Patton Boggs LLP, New York, NY

Speakers:
Shari F. Natovitz, Vice President and Risk Manager, Silverstein Properties, Inc./World Trade Center Properties
Robert P. Hartwig, Ph.D., CPCU, President, Insurance Information Institute
Jonathan Granoff, President, Global Security Institute

This program addresses the private sector approach to preparing for and preventing disasters caused by terrorist acts, including the impact of a terrorist act like September 11th on the insurance protection and programs that were in place prior to September 11th, and how September 11th contributed to the existing insurance protection and programs for the World Trade Center, the insurance economics of both terrorism risks and losses and the availability of insurance coverage, and worldwide risks and exposures from an international expert’s perspective.

An Insider’s View of Preparing for and Responding to Disasters Caused by Acts of Terrorism
2:00pm-3:30pm

Moderator:
Kenneth M. Roberts, Schiff Hardin LLP, Chicago, IL

Speakers:
The Honorable Rahm Emanuel, Mayor of Chicago and former White House Chief of Staff for President Obama, Chicago, IL (Invited)
TBD, Department of Homeland Security (Invited)

We live in a world where terrorism is a reality and its prevention is our number one priority. The Department of Homeland Security was created in the aftermath of the September 11, 2001 terrorist attacks. Certain cities continue to be targets of terrorist threats. We must remain vigilant and prepared. This panel will discuss our current efforts, on both the national and local front, to be prepared for and to combat terrorism.
CANADIAN APPELLATE COURT OVERTURNS $36 MILLION AWARD FOR STIGMA DAMAGES IN ENVIRONMENTAL CLASS ACTION

By: Douglas F. Harrison and Vanessa Voakes, Stikeman Elliott LLP, Toronto

Compared to the United States, class actions for environmental damage have been slow to emerge in Canada as a mechanism to address widespread contamination. However, a judge of the Ontario Superior Court recently awarded $36 million in damages in one of the first environmental class actions to reach trial in Canada. In 2010, Vale (formerly Inco Limited) was ordered to compensate a group of approximately 7,000 homeowners whose properties are close to the Vale refinery in the town of Port Colborne, Ontario, on the north shore of Lake Erie, for the stigma of negative publicity about the long-term contamination of their properties.

The trial judge ruled that: (a) the class had suffered a diminution in the value of their residential properties due to publicity about elevated levels of nickel in the soil; (b) the discharge of nickel was a private nuisance; and (c) the company was strictly liable to the class for the discharge as a result of its failure to prevent the escape of a dangerous substance, pursuant to the common law doctrine in Rylands v. Fletcher. Notably, the action did not include claims for personal injury or adverse effects on health.

Vale appealed the trial judge’s finding that it was liable, as well as the trial judge’s assumption that the diminution of property value was caused by the negative publicity about the discharge of nickel particles onto the land. In October 2011, the Court of Appeal for Ontario granted the appeal. It set aside the entirety of the damages award and ordered the plaintiff to pay $100,000 to Vale for costs of its appeal.

In analyzing the trial decision, the Court of Appeal noted that it was important to emphasize the exact nature of the claim advanced at trial. It was not about contamination in the sense that it was alleged that the nickel emissions (which began in 1918 and continued until 1984 when nickel ceased being refined at the facility) posed a threat to human health or otherwise adversely affected the claimants’ use of their properties. Rather, it was that the claimants’ property values had not increased at the same rate as comparable property values in other small cities located nearby and that this was caused by widespread public health concerns over the nickel deposits in the soil.

In overturning the trial judge’s finding that Vale was liable in private nuisance, the Court of Appeal focused on the claimants’ argument that the nickel particles caused “physical injury” to their property by becoming part of the soil and the “subsequent adverse effect” of a decrease in the value of property. The Court held that it was an error for the trial judge to find that the nickel particles in the soil caused actual, substantial, physical damage to the claimants’ lands because the claimants could not, nor did they attempt to, show that the nickel particles had any impact on their ability to use their properties for any purpose. The Court stated,

In our view, a mere chemical alteration in the content of the soil, without more, does not amount to physical harm or damage to the property. … To constitute physical harm or damage, a change in the chemical composition must be shown to have had some detrimental effect on the land itself or rights associated with the use of the land.

The claims advanced were not predicated on any actual risk to health or wellbeing and could not, as framed, succeed. The Court said that it was not enough to show evidence that the existence of the nickel particles in the soil generated concerns about potential health risks because that did not amount to evidence that the presence of the particles caused actual, substantial harm

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2 Canadian dollars; approximately $35 million U.S. at the time.
3 Smith v. Inco, 2010 ONSC 3790; The action was formerly titled Pearson v. Inco, until the representative plaintiff was changed; Inco Limited was acquired by Vale in 2007.
4 Claims of public nuisance and trespass were dismissed on the basis that there was no allegation that the company’s conduct had affected public health, public morals, or public conduct or the use of a public place or, that the intrusion of the nickel particles onto the class members’ properties was indirect.
or damage to the property. Had the plaintiffs shown that the nickel levels in the properties posed a health risk, they would have established that those particles caused actual, substantial, and physical damage to their properties.

The Court of Appeal went on to examine the trial judge’s ruling that the claim under the *Rylands v. Fletcher* doctrine had been made out because nickel refining was a non-natural use of the land and the escape of the nickel particles from Vale’s land had the potential to cause damage to neighbouring properties. The Court of Appeal held that it did not accept that strict liability based exclusively on the “extra hazardous” nature of the defendant’s conduct is, or should be, part of the common law in Ontario and that, even if it were, the refinery was not shown to be an extra or “ultra-hazardous” activity. The Court stated,

If the characterization of a use as a non-natural one was ever tied solely to whether the substance was found naturally on the property, it has long since ceased to depend on the answer to that single question. It may be that something found naturally on the property cannot attract liability under *Rylands v. Fletcher*. It is not, however, the law that anything that is not found naturally on the property can be subject to strict liability under *Rylands v. Fletcher* if it escapes and causes damage.7

The plaintiffs had not discharged their onus to show that the operation of the refinery was a non-natural use of the property or that operation of the refinery for over 60 years presented “an exceptionally dangerous or mischievous thing” or that the circumstances were “extraordinary or unusual.” This failure was sufficient to find in Vale’s favour on this ground of appeal.

The Court of Appeal also determined that the trial judge made errors in principle in his analysis of the damages claim and that the property valuation information on which the damages award was based at trial was inaccurate. The Court found that when the property data from Port Colborne was considered fully and fairly, and compared with neighbouring municipalities, there was no basis to assume a lower rate of appreciation of property values in Port Colborne and the plaintiffs had therefore suffered no loss.

In April 2012, the Supreme Court of Canada dismissed the plaintiffs’ application for leave to appeal.8

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6 Ibid. at para 55.
7 Ibid. at para 96.
8 Ellen Smith v. Inco Limited, 2012 CanLII 22100 (SCC). The Supreme Court of Canada did not provide any reasons for its dismissal, in accordance with that court’s usual practice.
user of a known hazard where there is an intermediary with knowledge of the hazard.4

In Stuckey v. Northern Propane Gas Co., the Eleventh Circuit issued its first decision addressing the scope of the sophisticated user/learned intermediary defense outside the pharmaceutical drug context.5 In Stuckey, a plaintiff filed suit against a propane gas supplier after the plaintiff was burned in an explosion. The plaintiff alleged that the supplier failed to warn him about the tendency of the odorant added to propane gas to fade over time. However, the defendant supplier distributed propane to another company which then sold and delivered the propane at the location of the explosion. Although the Eleventh Circuit affirmed the trial court’s denial of the supplier’s directed verdict motion because the propane supplier was unable to establish that the seller of the propane had actual knowledge of odor fade, the court in Stuckey explained the scope of the learned intermediary defense. Relying on comment n to the Restatement (Second) of Torts § 388, the Eleventh Circuit held that “a supplier’s duty to warn a consumer does not turn on whether a warning was actually given to the intermediary, but on whether the intermediary’s knowledge was sufficient to protect the ultimate consumer.”6

As explained by subsequent courts, where a learned intermediary “has actual knowledge of the substance of the alleged warning and would have taken the same course of action even with the information the plaintiff contends should have been provided, courts typically conclude that the learned intermediary doctrine applies or that the causal link has been broken and the plaintiff cannot recover.”7

The Lengthy Saga of the Parker Beryllium Case

In 2004, a number of current and former employees of Lockheed Martin’s Marietta, Georgia facility filed a putative class action alleging that the plaintiffs and members of the putative class had developed beryllium sensitization and/or “sub-clinical, cellular, and sub-cellular damage” from exposure to beryllium-containing products utilized at the Lockheed facility.8 Early in the case, the federal district court dismissed the plaintiffs’ claims for alleged sub-clinical, cellular, and sub-cellular damage, and dismissed plaintiffs’ claims for emotional distress and for medical monitoring costs. The Court also concluded that the plaintiffs’ claims for beryllium sensitization did not constitute an actionable injury under Georgia law.9 On appeal, the Eleventh Circuit affirmed the district court’s dismissal of the plaintiffs’ claims for “sub-clinical, cellular, and sub-cellular damage” and for emotional distress and medical monitoring costs. However, the Court reversed the district court’s grant of summary judgment on the claims of the plaintiffs who alleged beryllium sensitization.10

Following remand of the case, and after extensive additional discovery, the district court granted summary judgment to the defendants after finding that the plaintiffs’ employer, Lockheed Martin, was a sophisticated user of beryllium, and thus, the plaintiffs’ failure to warn claims were barred.11

On October 21, 2011, the Eleventh Circuit affirmed the dismissal based on “the ‘sophisticated user’ or ‘learned intermediary’ doctrine, and found that Lockheed Martin was an intermediary with knowledge of the hazard.”12 In concluding that “the Defendants have established that Lockheed is a sophisticated user of beryllium and a learned intermediary between its employees and the manufacturers of beryllium products,” the court explained that, among other things, the Lockheed facility had produced aircraft containing beryllium parts for almost sixty years and employed a team of industrial hygienists and toxicologists who had studied beryllium health effects and developed Lockheed’s own internal warnings regarding the hazards of beryllium.13

In addition, the Eleventh Circuit expressly declined the plaintiffs’ invitation to rely on the decision in

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5 874 F.2d 1563 (11th Cir. 1989).
6 Id. at 1568.
7 Wheat, 46 F. Supp. 2d at 1363.
8 Beryllium is a light metal with extreme hardness and a high melting point that makes it very desirable for use in a number of industries, particularly the aerospace industry and in the production of nuclear energy and weapons. In certain individuals, exposure to beryllium can result in beryllium sensitization, which is similar to an allergy and can be a precursor to the development of chronic beryllium disease—a respiratory illness.
13 Id. at *3.
Genereux v. American Beryllia Corp., in which the First Circuit relied on Massachusetts law in concluding that a court considering a sophisticated user defense “must analyze ‘the particular dangers to be guarded against’” and engage in a detailed fact-specific analysis of whether the intermediary had sufficient knowledge of each and every particular danger of the allegedly hazardous substance. In contrast, Georgia law regarding the sophisticated user defense only requires that an intermediary possess general knowledge of the dangers associated with a product’s use. In addition, the decision in Genereux was readily distinguishable from the facts of Parker because the record evidence in Genereux established that the lead defendant had greater sophistication regarding beryllium than the plaintiffs’ employer and that the employer adjusted its industrial hygiene practices based upon input from that defendant.

In another important aspect of its decision in Parker, the Eleventh Circuit concluded that a plaintiff cannot avoid the application of the sophisticated user defense simply by showing that the intermediary failed to take measures to adequately protect against a certain hazard—rather, plaintiffs must show that the intermediary lacked actual knowledge of the hazard. Thus, the relevant inquiry is focused on the intermediary’s knowledge; not on the adequacy of the intermediary’s implementation of its knowledge or the intermediary’s failure to act on its knowledge.

The Future of the Sophisticated User Defense in Toxic Tort Cases

The decisions in Parker demonstrate the continuing viability of the sophisticated user defense in toxic tort cases in which plaintiffs allege that the supplier or manufacturer of a product failed to sufficiently warn the end user of the hazards of the product. Although the applicability of the defense tends to be fact-specific, numerous courts have made it clear that this issue can be resolved at the summary judgment stage.

Although not expressly addressed by the courts in the Parker decisions, the case also demonstrates how the timing of when an intermediary obtained its knowledge can impact the application of the sophisticated user defense in a case involving a lengthy alleged exposure period. In Parker, the plaintiffs alleged that they were exposed to beryllium for over a forty-year period and the knowledge of beryllium health risks had evolved over that time, but the record evidence was clear that Lockheed was always at the forefront of knowledge regarding beryllium health risks. However, it is not difficult to imagine a scenario where a plaintiff could attempt to create a fact issue by arguing that a particular intermediary was not a sophisticated user of a hazardous product during the early portion of the plaintiff’s alleged period of exposure to the product, and thus, the intermediary’s subsequent sophistication should not bar the plaintiff’s failure to warn claim against suppliers. In such a scenario, it will be important for courts to compare the respective knowledge of the industry and the intermediary at comparable time periods and not fall into an “apples to oranges” comparison of the current state of the art regarding a product’s hazards to what was known about the product during earlier time periods.

Conclusion

In light of the fact that employees allegedly exposed to toxic substances or hazardous products in the workplace are typically barred by workers’ compensation laws from recovering damages from their employers, it is commonplace for such employees to name manufacturers, suppliers, and distributors of allegedly hazardous products as defendants in toxic tort and product liability lawsuits. However, summary judgment may be available to manufacturers and suppliers based upon the sophisticated user defense when the plaintiffs’ employer possessed sufficient knowledge of the hazards associated with the substance or product at issue. It is reasonable to expect that the use of the sophisticated user defense will increase as society becomes more regulated, which imputes knowledge to the regulated community and creates more “learned intermediaries,” and information regarding hazardous substances and products becomes more readily available leading to more sophisticated users of hazardous products.

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14 577 F.3d 350 (1st Cir. 2009).
15 Id. at 366.
17 Genereux, 577 F.3d at 373.
18 Parker, 2011 WL 5025135 at *5 n.8 (“Even if the Plaintiffs could prove that Lockheed did not employ the proper [beryllium] control devices, that proof would not be enough to rebut the evidence that Lockheed had actual knowledge of the need for such controls”).
PCBS IN INDOOR AIR… Continued from page 4

adverse effects led to a ban of the manufacturer and use of PCBs in the late 1970s.5

As a result of widespread PCB pollution that occurred prior to its ban, virtually everyone has been exposed to some level of PCBs through consumption of certain food such as fish, meat and dairy products. PCB has also been found in water, air and soil. The health effects of PCBs have been studied for years, mostly in animals, and the results show that there is no causative link between exposure to PCBs and cancer or serious illness in humans. Nevertheless, the EPA classifies PCBs as “probable human carcinogens,” and regulators, as well as concerned citizens groups, are now focusing on PCBs as a source of indoor air contamination.

In 2011, New York Lawyers for the Public Interest filed a lawsuit claiming that the presence of PCBs in fluorescent light ballasts in New York City public schools endangers students, teachers and maintenance workers in violation of federal law.6 The suit recites that this issue was uncovered as the result of a survey that found PCB-laden caulk around windows in schools and alleges that PCBs “spontaneously volatize” out of caulk, paint and other construction materials in which they were once used. The pending action against the City of New York is the most recent of several property damage actions.7

Not surprisingly, PCBs have been found in other commercial buildings that were built or renovated from the 1950s through 1970s, including office buildings, hospitals, dormitories, museums and houses of worship. In a recent survey of 24 buildings in Boston where workers recalled installing caulking and sealants in the 1970s, 13 of the buildings tested positive for PCB-containing caulk.8 Notably, samples from 8 of these buildings exceeded 50 parts per million, the threshold at which the EPA requires a material to be regulated.

History has a way of repeating itself and premise owners and product manufacturers should not be surprised if PCB litigation follows the pattern of previous toxic exposure litigations such as asbestosis, where actions for alleged personal injuries followed on the heels of property damage claims. However, unlike the more straightforward property damage claim, personal injury plaintiffs must first confront the reality that virtually everyone has some level of PCB exposure, whether from food, water or soil. PCBs are fat soluble and do not break down readily, such that they remain in the body and levels build up over time. This compelled one court to hold that no cause of action for medical monitoring could proceed without proof that the plaintiff had sustained an exposure to PCBs that was greater than background levels.9

Even if plaintiffs can establish that a discrete building exposure occurred, they must next overcome the hurdle of proving causation. Because PCBs are complex compounds, expert testimony will be required to prove the plaintiff’s case. Accordingly, challenging the plaintiff’s expert’s testimony purporting to link PCBs with some illness is an important step in successfully defending alleged PCB-related damages. Given the lack of significant personal injury litigation, so far, related to PCBs, an aggressive strategy at the outset is necessary to establish a record of instances in which experts are precluded due to the lack of ability to establish exposure and causation.

In the case of injury or death related to an alleged toxic exposure, a plaintiff must prove two elements to establish proximate cause: general and specific causation.10 General causation is about the toxin’s capabilities, which entails establishing that the substance at issue is capable of causing the type of injury alleged by the plaintiff. Not all jurisdictions require epidemiology to prove general causation in every instance, but certain minimum standards must always be met and the evidence must exceed the jurisdiction’s threshold for admissibility of opinion testimony—Daubert or Frye.

In the case of PCBs, the scientific literature is in such a state of contention that it is difficult for a plaintiff to establish general causation. The absence of epidemiological studies conclusively linking PCBs to illnesses in humans is a substantial impediment to any plaintiff’s case because the plaintiff’s expert will be unable to cite to a peer-reviewed study when

7 As an example, see, Yorktown Central School District v. Monsanto Company, et. al., 07-CIV-8648 (S.D.N.Y. 2008).
9 Brown v. SEPTA, 113 F.3d 444, 450 (3d Cir. 1997).
seeking acceptance of his/her opinion on this topic. Additionally, previous studies of the human effects of PCBs are based on small samples or lack controls. These studies are also rife with confounding factors so that alternative causes of the particular illness cannot be excluded.

Animal studies concerning PCBs offer little, if any, assistance because they are insufficient indicators of the effect of a substance on humans, and can be excluded in many jurisdictions. Though not all jurisdictions require epidemiological support of expert opinion on causation, the lack of such support raises serious questions about the reliability of such an opinion.

If plaintiff clears the hurdle of general causation, the next step is specific causation—proof that the plaintiff ingested, inhaled, or absorbed a sufficient dose of the subject toxin for it to be the cause of the asserted illness. Here, the contestable issues are whether the dose is measurable and whether the threshold necessary to cause disease is knowable. In theory, specific causation requires a plaintiff to prove the precise dose of toxin to which he or she was exposed, and that this dose met or exceeded the dose known to cause the subject disease.

As a practical matter, most courts recognize that precise measurements of dose are impossible. Therefore, it becomes critical for defense counsel to insist that plaintiff come forward with a scientifically acceptable proxy measure of the plaintiff’s dose so that plaintiff is not excused from carrying the burden of proof on specific causation. In many jurisdictions, the plaintiff’s dosage can be proven with circumstantial and statistical evidence demonstrating exposure.

Specific causation is an issue for the plaintiff, given that the tests currently in use to detect the presence of PCBs in the human body generally cannot measure the precise level of PCBs in the body or their source. While the inability to prove a plaintiff’s specific dose may not be fatal to the plaintiff’s case, it means that the plaintiff will be forced to rely upon circumstantial evidence of specific causation. However, under the guidelines established by the Federal Reference Manual on Scientific Evidence, inferences of specific causation must be closely scrutinized where general causation is not established. Consequently, defense counsel should challenge any plaintiff that relies on circumstantial evidence to prove specific causation where the plaintiff cannot proffer reputable epidemiological evidence on general causation.

Certain jurisdictions have allowed challenges to evidence of causation to be made at the outset of a case in order to avoid incurring the costs of discovery. The “Lone Pine Order,” which gets its name from a New Jersey trial court case, permits the court to evaluate the plaintiff’s evidence regarding the substance to which the plaintiff was allegedly exposed, the illness from which the plaintiff allegedly suffers and the medical and scientific evidence regarding causation. Defendants additionally benefit from addressing causation as a gatekeeper issue, as this prevents proof of pain and suffering from influencing the court in favor of finding causation.

Where a plaintiff’s expert opinion on causation is inadmissible or insufficient to sustain a jury verdict, the defendants can obtain summary judgment or dismissal. Seeking a “Lone Pine Order” is thus an expedient means of putting these issues before the court, as well as signaling to the plaintiff that the defendants intend to contest causation through the litigation. Indeed, Courts should be pragmatic about taking the issue of causation out of turn when it could potentially resolve large numbers of cases that will ultimately fail based on the underlying scientific theories regarding causation.

The recent focus on PCB contamination in buildings suggests that personal injury claims may soon follow. The state of the applicable science, however, where there is little proof that PCBs cause disease in humans, should allow defendants to hold the line against these injury claims.
Emergence of Un-Validated ...

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vivo. The published gene expression data by TCI are from in vitro studies (Gavin et al., 2007; Gillis et al., 2007). PBMC from only eight individuals were used in the in vitro studies and no data were provided on the variability of gene expression among these different individuals or on the reproducibility of the in vitro data in vivo. TCI has only published gene expression data from PBMC treated in vitro with benzene, benzene metabolites and chromium; the doses used in the testing were limited and there was no discussion of the relevance of the doses to human exposure scenarios. In addition, cultured PBMC were treated for 18 hours and the treated cells were used to determine the gene expression signature for the chemical tested. There is a question of the temporal relevance of a gene expression signature in cultured PBMC immediately after chemical treatment to the gene expression signature in PBMC isolated from an individual who may have been exposed to that chemical months or years before testing.

There is substantial heterogeneity of gene expression responses in and among individuals, making comparison of gene expression levels to assess overexposure to chemicals a challenge. For instance, Dr. Gillis reported that expression of the gene CYP1B1 was increased 1.98 fold in cultured PBMC treated with 1,2,4 benzenetriol, a benzene metabolite, compared to untreated PBMC. However other investigators have reported that gene expression of CYP1B1 among the human population varies by 30 fold or higher (Tuominen et al., 2003). Further CYP1B1 expression in a single individual varies 3 – 21 fold over time (Finnstrom et al., 2001; Tuominen et al., 2003). It is difficult to understand or explain how one could differentiate a 1.98 fold change in CYP1B1 gene expression reportedly due to benzene exposure over background variability among individuals much less within any individual.

Ritchie Shoemaker, MD

Ritchie Shoemaker, MD has developed a panel of proteomic biomarkers to diagnose “biotoxin illness” attributable to exposure to toxins from mold and other microorganisms. Further Dr. Shoemaker claims the same panel of biomarkers can be used to evaluate efficacy of treatment. The basic premise of Dr. Shoemaker’s diagnosis and treatment is that exposure to biotoxins alters biomarker levels in the circulating blood of the individual. Diagnosis is based, in part, on the presence of non-specific symptoms such as fatigue, headache, problems in focus and concentration, morning stiffness, and diarrhea. Many of the biomarkers used by Dr. Shoemaker to diagnose “biotoxin illness” are known indicators of inflammatory processes and/or obesity, and are not specific indicators of exposure to biotoxins. Further there is no apparent consideration of the temporal relationships among exposure to biotoxins, the relatively quick elimination of most biotoxins from the body, and when measurement of biomarkers is performed. Take for example mycotoxins which are typically eliminated from the body days after exposure. Therefore no causal relationship can be established between biomarker concentrations evaluated in an individual weeks, months or years after a reported exposure.

Under Dr. Shoemaker’s process patients are treated with cholesteryramine, an ion exchange resin used to lower cholesterol, which Dr. Shoemaker opines facilitates removal of biotoxins from the body. The biomarker panel is used to evaluate the efficacy of treatment. Since many of the biomarkers used by Dr. Shoemaker are in fact biomarkers of inflammation and obesity, treatment with cholesteryramine likely affects biomarker levels in blood through its effects on metabolism of cholesterol, not on removal of biotoxins. There are no published peer reviewed data from Dr. Shoemaker demonstrating that measurable biotoxins are associated with cholesteryramine elimination after such treatment.

Dr. Shoemaker Decisions

Dr. Shoemaker has been asked to testify on the subject of biotoxin-related illness in state and federal courts. On some occasions, he has testified as a treating physician, and has simply reported on his diagnosis and course of treatment. When Dr. Shoemaker has been asked to provide medical opinions regarding the cause of alleged illnesses, some courts have rejected Dr. Shoemaker’s opinions as unreliable and inadmissible. In Herzner v. Fischer Attached Homes, Ltd., 2008 WL 2004473 (OH App. 2008), Dr. Shoemaker opined that the negligent construction of a condominium caused chronic biotoxin-related illness, which he called “mold illness.” The trial court ruled that Dr. Shoemaker’s opinions were not admissible for several reasons. First, Dr. Shoemaker based his opinion on an exposure study conducted three months after the unit was vacated. The unit was never tested for the presence of mycotoxins. Next, Dr. Shoemaker’s theory on the existence of “mold illness” had not been subjected to peer review outside of Dr. Shoemaker’s own medical group. Finally, Dr. Shoemaker relied on laboratory tests in a manner that is
not generally accepted in the medical community, and his differential diagnosis merely reflected his own opinions and unverified interpretation of laboratory results. No scientific evidence was provided to support the manner in which Dr. Shoemaker reached his diagnosis.

In *Montgomery Mutual Insurance Company v. Chesson*, 923 A.2d 939 (Md. App. 2007), the court held that Dr. Shoemaker’s theories regarding the cause of and treatment for “sick building syndrome” were too novel to be admitted without proof demonstrating his theories to be generally accepted in the scientific community for the purpose of diagnosing sick building syndrome. Further Dr. Shoemaker’s use of cholestyramine, although approved for treatment of some conditions, is not generally accepted for the purpose of treating the condition Dr. Shoemaker had diagnosed. The *Montgomery* court held that a full hearing was necessary to determine if Dr. Shoemaker’s theories were reliable and generally accepted in the medical community.

**Conclusion**

In summary, although the use of genomics data as biomarkers of exposure and/or effect in toxic tort litigation has been used with varying degrees of success, in many cases, the biomarkers have not been sufficiently validated for use in establishing chemical exposure or injury. As new biomarkers emerge using toxicogenomics technology to evaluate causal relationships in toxic tort, it is critical to evaluate the methodology used in development of such biomarkers and ensure that proper scientific validation has been performed and documented.

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**THE DEBATE CONTINUES:...**

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defense. In *Stewart v. Union Carbide Corp.*, 117 Cal. Rptr. 3d 791 (Cal. Ct. App. 2010), review denied 2011 Cal. LEXIS 2314 (Cal. Mar. 2, 2011), a retired plumber’s apprentice alleged that he contracted mesothelioma as a result of exposure to asbestos from, *inter alia*, joint compound used at construction sites. A jury found defendant Union Carbide Corp. (“Union Carbide”), a supplier of joint compound, 85% liable for the plaintiffs’ injuries and awarded $417,625 in economic damages, $850,000 in noneconomic damages, and $6 million in punitive damages. Union Carbide appealed, arguing that the component parts defense precluded recovery against it, and that the manufacturer of the drywall – not Union Carbide – had the duty to warn end users of the hazards of asbestos. The Court of Appeals disagreed and held that the component parts defense is unavailable to the supplier of a defective component, and that incorporation of asbestos into a component renders it defective under California law.

**Delaware**

To date, the Superior Court of Delaware has rejected “component parts liability” in a number of cases, applying the law of different states in some cases, and the law of Delaware in other cases. One example of Delaware Court applying foreign law was presented in the *Olson* case where the plaintiff alleged exposure to asbestos from component parts incorporated into CBS Corp.-manufactured generators, and Crane Co.-manufactured metal valves. The plaintiffs offered no evidence that the asbestos-containing components were manufactured by either CBS Corp. or Crane Co. The Delaware Superior Court applied Idaho law, which was silent on the issue of component parts liability, but had adopted Restatement (Second) of Torts. Based on the Restatement (Second) §§ 388 and 402A, and case law in other jurisdictions, the Court concluded that Idaho would reject “component parts liability”, and granted the defendants’ motions for summary judgment.

One day later, the same Delaware Court applied Connecticut law and granted Crane Co.’s motion for summary judgment, after finding that Connecticut courts would also not impose liability on Crane Co. for a product that it did not manufacture, distribute, or sell. There, the plaintiff alleged exposure to asbestos from Crane Co. while employed at a hospital in Connecticut. Three witnesses identified Crane Co. pumps and valves as a source of her exposure, but none of these witnesses had knowledge of the maintenance histories of the Crane Co. products at issue or could identify Crane Co. as the manufacturer of the component insulation, paste, or replacement gaskets and packing that would have been potential sources of the plaintiff’s asbestos exposure. Based on this lack of evidence of exposure, the Court held that there was no evidence that the plaintiff inhaled asbestos dust from a Crane Co. product.

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In another Delaware case, the Delaware Superior granted Crane Co.’s Motion for Summary Judgment under maritime law and cited cases from the U.S. Court of Appeals for the Sixth Circuit, **Lindstrom v. A-C Prod. Liability Trust**, 424 F.3d 488, 492 (6th Cir. 2005), and the United States District Court for the Western District of Pennsylvania, **Kummer v. Allied Signal, Inc.**, 2008 WL 4890175 (W.D. Pa. Oct. 31, 2008). In **Davis**, the plaintiff claimed that he worked with hundreds of defendant Crane Co.’s valves on the Navy ship **USS Holder**, but identified Garlock, not Crane Co., as the manufacturer of the alleged asbestos-containing packing and gaskets used in connection with the valves. The Court stated that the plaintiff provided no evidence that Crane Co. specified, required, or recommended the use of asbestos-containing packing or gaskets with its valves.

Finally, Delaware Courts also refused to apply “component parts liability” under Delaware law. In that case, the plaintiff claimed that he worked with Crane Co.’s valves, but identified asbestos-containing gaskets, packing and insulation from other manufacturers. The Court found that, under Delaware law, Crane Co. did not have a “duty to warn of the dangers of asbestos contained in products it did not manufacture, supply, or specify.”

**Massachusetts**

The Massachusetts Appeals Court expressly declined to rule on whether a product manufacturer owes a duty to warn of potential danger created by a third-party through foreseeable use of its product. In **Morin**, plaintiff brought a wrongful death action against multiple automobile parts manufacturer and retailers based on alleged exposure by the decedent to the defendants’ asbestos-containing products. The plaintiff appealed from summary judgment dismissal of defendant Great Dane Trailers, Inc. (“Great Dane”).

Plaintiff argued that Great Dane was liable under two independent theories: (1) direct liability for exposure to asbestos contained in brakes manufactured by Great Dane, and (2) component parts liability for failure to warn of the dangers associated with installing replacement asbestos-containing brakes manufactured by a third party. The Appeals Court declined to reach the second issue and held that the plaintiff’s allegations of speculative and *de minimis* exposure were enough to affirm summary judgment. In a positive sign for manufacturing defendants in asbestos cases, the Court in *dictum* suggested facts that weighed against the imposition of component parts liability for replacement automotive parts.

**New York**

Federal and state courts in New York have recognized the theory of “component parts liability” as a basis for liability.

In a significant decision, the U.S. District Court for the Southern District of New York found that a product manufacturer could be liable for injuries caused by third-party component parts installed after the product was placed into the stream of commerce. In *Curry* the District Court rejected Crane Co.’s argument that the asbestos-containing component parts on its valves were attached post-sale, and that it could not be held legally responsible for any injuries caused by said component parts. The Court noted that Crane Co. admitted that the valves were originally shipped with asbestos-containing components and that it knew that said components would need to be replaced.

Citing *Curry*, a subsequent New York Court also denied a motion for summary judgment by an equipment manufacturer when the plaintiffs alleged exposure to asbestos while working with asbestos-containing gaskets used in conjunction with boilers. Though there was no evidence that the plaintiff worked with an asbestos gasket manufactured, sold, or supplied by the boiler manufacturer, the Kersten Court noted that the boiler manufacturer’s catalogue provided for the use of asbestos-containing gaskets with its boilers. As a result, the Kersten Court found issues of material fact regarding foreseeability that precluded summary judgment.

Two subsequent New York Supreme Court cases have also cited *Curry* positively: **Sawyer v. A.C. & S., Inc.,** No. 111152/99, 2011 WL 3764074 (N.Y. Sup. Ct. June 24, 2011) and **Defazio v. Chesterton, No. 127988/02, 2011 WL 3667717** (N.Y. Sup. Ct. August 12, 2011). In both cases, Crane Co. moved for summary judgment, stating that it was not liable for any gaskets, packing or insulation applied to its valves by third parties. The
Supreme Court denied Crane Co.’s motion for summary judgment in both cases, again based on foreseeability.

The United States District Court for the Southern District of New York however reached a different result in *Surre v. Foster Wheeler, LLC*, 07-CIV-9431 2011 NL 6382545 (S.D.N.Y. December 20, 2011). In that case, plaintiff claimed exposure to asbestos when he applied insulation block and cement to the exterior of Pacific boilers sold by Crane Co. Crane Co.’s moved for summary judgment, arguing that there was no proof that it supplied the insulation block and cement. In response, Plaintiff argued that Crane Co. still had a duty to warn because it had reason to foresee that asbestos-containing insulation would be installed on Pacific boilers, citing Crane Co. literature and brochures that promoted the use of asbestos, among other materials, to insulate its products. The Court granted Crane Co.’s summary judgment motion and held Crane Co. did not manufacture or place into the stream of commerce the asbestos-containing materials to which plaintiff was exposed. Additionally, there was no evidence that Pacific boilers required asbestos-containing insulation, as opposed to another insulation material, to function or that asbestos-containing insulation was specified to be used on any particular Pacific boiler. Under the circumstances, the Court ruled that Crane Co. had no duty to warn plaintiff of the dangers posed by the asbestos-containing insulation he used on Pacific boilers, and that foreseeability that asbestos-containing insulation would be used on Pacific boilers, alone, did not give rise to a duty to warn on the part of Crane Co. To establish that Crane Co. owed such a duty, the Court noted, the plaintiff was required to provide evidence that Crane Co. played a role in selecting the type of insulation applied to the boiler. Because asbestos was just one of several types of material that could have been used to insulate Pacific boilers, the plaintiff had not met its burden.

In reaching this conclusion, the Court specifically distinguished *Curry, DeFazio* and *Sawyer*, noting that there was more specific evidence in those cases that defendants intended asbestos-containing materials to be used with their products.

**Washington**

Courts in Washington have also refused to impose “component parts liability.” In *Macias*, a retired tool worker sued various respirator manufacturers for failure to warn him of exposure to asbestos from cleaning respirators. After the trial court’s denied the respirator manufacturer’s motion for summary judgment, the the Court of Appeals of Washington reversed and found that foreseeability is irrelevant under Washington law for determining whether a duty to warn exists. Rather, the relevant inquiry is whether the manufacturer “is in the chain of distribution of the hazardous product.” The Washington Supreme Court heard argument on an appeal of this opinion on October 20, 2011, but no opinion has been issued as of the submission date of this article.

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## 2012 TIPS CALENDAR

### August 2012
- **2-7**  
  **ABA Annual Meeting**  
  Sheraton Chicago Hotel & Towers  
  Chicago, IL  
  Contact: Felisha A. Stewart – 312/988-5672  
  Speaker Contact: Donald Quarles – 312/988-5708  

### October 2012
- **11-15**  
  **TIPS Fall Leadership Meeting**  
  La Quinta Resort and Club  
  La Quinta, CA  
  Contact: Felisha A. Stewart – 312/988-5672  
  
- **18-19**  
  **Aviation Litigation National Program**  
  The Ritz-Carlton  
  Washington, DC  
  Contact: Donald Quarles – 312/988-5708  

### November 2012
- **7-9**  
  **Fidelity & Surety Committee Fall Meeting**  
  Marriott Hartford Downtown  
  Hartford, CT  
  Contact: Donald Quarles – 312/988-5708  

### January 2013
- **23-25**  
  **Fidelity & Surety Committee Midwinter Meeting**  
  Waldorf-Astoria Hotel  
  New York, NY  
  
### February 2013
- **6-12**  
  **ABA Midyear Meeting**  
  Hilton Anatole Dallas, TX  
  Contact: Felisha A. Stewart – 312/988-5672  
  Speaker Contact: Donald Quarles – 312/988-5708  

- **14-16**  
  **Insurance Coverage Litigation Spring CLE Meeting**  
  Arizona Biltmore Resort & Spa Phoenix, AZ  
  Contact: Ninah Moore – 312/988-5498  

### April 2013
- **23-28**  
  **TIPS Section Spring Leadership Meeting**  
  JW Marriott  
  Washington, DC  

### August 2013
- **8-13**  
  **ABA Annual Meeting**  
  San Francisco Marriott  
  San Francisco, CA  
  Contact: Felisha A. Stewart – 312/988-5672