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nanotechnology      admiralty & maritime  
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aviation litigation      green products litigation  
pharmaceutical & medical device litigation      mass & toxic tort litigation  
consumer product safety      risk management      phthalate litigation



## A Word From Our Product Liability Litigation Practice Group Leader . . .

On behalf of our Product Liability Litigation practice group, I am pleased to bring you this third edition of our e-newsletter. As with every edition, it is our goal to bring you timely, informative articles, as well as keep you apprised of our group's active product liability litigation practice.

Our group members have had a busy year so far. We sponsored DRI's Class Action Seminar. Cleveland partner **Andrew Cox** co-moderated a panel of in-house counsel and insurers at ACI's 3rd Annual Forum on Defending and Managing Aviation Litigation in Boston. **Fern O'Brian**, a partner in our Washington, D.C. office, gave an FDA regulatory update at the 2nd Annual Cancer Immunotherapy: A Long-Awaited Reality conference and also participated in the Product Liability Program on Recalls webinar sponsored by Strafford Publications. Fern, along with Cleveland partner **John Mitchell** and our colleague in the Intellectual Property practice group, **Troy Prince**, also recently spoke on "Regulating Tiny Technology" at the Nanomanufacturing Conference in Boston. **Brian Troyer**, a partner in our Cleveland office, participated in the Statistics in Class Action Litigation: Admissibility and Impact of Wal-Mart webinar sponsored by Strafford Publications. **Bill Hubbard** of the Cleveland office was a featured speaker at the Green Building Alliance's Green Building Products Summit in Pittsburgh. Our Atlanta office partner **Ileana Martinez** spoke at Medmarc's 24th Annual Medical Device Defense Seminar in California, and another partner in the Atlanta office, **Seth Litman** co-authored an article on limiting exposure for drugs made in China, which was published in the June edition of *ACC Docket*. **Kip Bollin**, a partner in the Cleveland office, spoke on "Developments in Class Action Management" at the Sixth Biennial Federal Bench Bar Conference in Columbus. And Cleveland associate **Barbara Lum** was instrumental in reactivating the Asian American Bar Association of Ohio and serves on its board of trustees.

We continue to handle interesting matters on behalf of a wide variety of clients and involving diverse products. Thompson Hine is defending a chemical industry client in a class action lawsuit arising out of alleged soil contamination from hexavalent chrome. Also in the chemical industry, we are defending toxic exposure claims relating to pesticides. In the drug and medical device arena, we serve as national counsel for a pharmaceutical client in hormone replacement therapy litigation, and also currently are defending claims involving, among other products, hip implants, knee implants, spinal fixation devices, an insulin pump and infusion set, and a surgical navigation system. In the transportation area, we are defending aviation product liability matters involving de-icing equipment and engine exhaust systems, and numerous automotive product liability and maritime matters. We regularly counsel clients on the ever-evolving product liability and regulatory issues pertaining to nanotechnology and other emerging technologies. In addition, we continue to assist clients in evaluating the need for and implementing recalls.

This edition has information on emerging trends in ISO consumer safety standards, the USDA's move away from the food pyramid in favor of MyPlate, as well as an update on the impact of the recently created CPSC database on businesses. We also include articles on proposed legislation relating to sealed protective orders and settlements, and the impact of recent U.S. Supreme Court decisions on personal jurisdiction, generic drug preemption, and class actions. Finally, we include an interview with group partner **Andrew Cox**, who shares some of our group's best practices for effective project management of large-scale product liability litigation.

As always, please share with us your thoughts on our e-newsletter, and let us know what topics you would like to read about in future editions.

*Missy Wright*

# FOCUS ON U.S. SUPREME COURT DECISIONS



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The 2010-2011 United States Supreme Court term resulted in many decisions affecting companies that face product liability claims. What follows is an overview of some of the more notable decisions.

## Personal Jurisdiction Over Foreign Manufacturers

Recently, in two separate rulings, the Court reined in states' jurisdiction over foreign product manufacturers and reinforced the due process requirements that must be satisfied to exercise personal jurisdiction: there must be a clear connection between the manufacturer and the subject forum.

**No Personal Jurisdiction in *McIntyre*.** A divided Court rejected New Jersey's jurisdiction over a foreign manufacturer of a metal-cutting machine in *J. McIntyre Machinery Ltd. v. Nicastro*, No. 09-1343, slip. op., 564 U.S. \_\_\_\_ (U.S. June 27, 2011). The plaintiff, who lost four fingers while using the machine at his job in New Jersey, filed a product liability action in New Jersey state court against McIntyre, the machine's U.K.-based manufacturer. The New Jersey Supreme Court affirmed the trial court's exercise of specific jurisdiction, holding that New Jersey's courts can exercise jurisdiction over a foreign manufacturer of a product so long as the manufacturer "knows or reasonably should know that its products are distributed through a nationwide distribution system that might lead to those products being sold

in any of the fifty states." *Nicastro v. McIntyre Machinery America, Ltd.*, 201 N.J. 48, 76, 77, 987 A.2d 575, 591, 592 (2010).

Disagreeing with the New Jersey Supreme Court, six justices held that New Jersey did not have personal jurisdiction because there was insufficient evidence that the manufacturer purposefully availed itself of conducting business in New Jersey. The machine was sold through McIntyre's independent U.S. distributor. At no time did McIntyre advertise in, send goods to, or target New Jersey in selling its machine. Therefore, despite the fact that the "stream of commerce" carried the machine to New Jersey, jurisdiction was not proper because McIntyre did not "purposefully avail" itself of the laws of New Jersey simply by manufacturing a product abroad that was then distributed in New Jersey by another company.

The *McIntyre* decision is also important in that it noted, but declined to resolve, the issue of whether certain Internet-based activity could form the basis for jurisdiction. In their concurring opinion, Justices Breyer and Alito cautioned that the broad rule of law announced by the plurality did not take modern-day sales practices into account, e.g., sales through a company's own website or an intermediary such as Amazon.com, or marketing through the use of pop-up advertisements that it knows will be viewed in a forum. None of those commercial issues were implicated in *McIntyre*, and therefore, Justices Breyer and

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Alito noted that the case “is an unsuitable vehicle for making broad pronouncements that refashion basic jurisdictional rules.” This suggests that at least some on the Court would welcome the opportunity to address these modern-day concerns.

**No General Jurisdiction in *Goodyear*.** Referencing “stream of commerce” again, a unanimous Court criticized the North Carolina courts’ application of the doctrine in *Goodyear Dunlop Tires Operations SA v. Brown*, No. 10-76, slip. op., 564 U.S. \_\_\_\_ (U.S. June 27, 2011), decided on the same day as *McIntyre*. Two 13-year-old boys from North Carolina were killed in a bus accident outside of Paris, and their parents commenced an action in North Carolina against Goodyear USA, an Ohio corporation, and three of its foreign subsidiaries (operating in Luxembourg, Turkey, and France) claiming the accident was the result of a defective tire manufactured in Turkey at the plant of one of the subsidiaries.

The Court held that North Carolina did not have jurisdiction over the three foreign subsidiaries and noted that the North Carolina Supreme Court confused and blended specific and general jurisdiction. Specific jurisdiction did not exist because the foreign entities did not conduct activity in the state that gave rise to the lawsuit – the accident occurred in Paris and the allegedly defective tire was produced and sold abroad.

As to general jurisdiction, the Court relied on the existing jurisprudence it first set forth in *International Shoe*, which requires that defendants’ affiliations with the state be “so ‘continuous and systematic’ as to render them essentially at home in the forum State.” The Court compared the only two general jurisdiction cases it has decided since *International Shoe*, and found that in light of those decisions against jurisdiction, it was improper to consider North Carolina a jurisdictional “home” on the basis of the foreign subsidiaries’ sporadic sales of their tires in North Carolina through intermediaries. The Court’s decision effectively reaffirmed the longstanding principles of specific and

general jurisdiction, and it emphasized the need for a strong connection between the defendant and the forum state to establish general jurisdiction. One arguably new aspect of general jurisdiction from *Goodyear* is the Court’s use of the phrase “at home,” which stresses the importance of that strong connection.

*McIntyre* and *Goodyear* reaffirm the need for product manufacturers to be conscious of their decisions to market, advertise, sell, or otherwise avail themselves of markets in individual states.

**Generic Drug Preemption.** *McIntyre* and *Goodyear* are only the latest in a series of the Court’s decisions having important implications for companies that defend product liability cases. On June 23, 2011, the Court held that U.S. Food and Drug Administration (FDA) regulations applicable to generic drug manufacturers preempt failure-to-warn claims under state law based on alleged failures to include warnings that would conflict with FDA labeling requirements under federal law. *PLIVA, Inc., et al. v. Mensing*, 564 U.S. \_\_\_\_ (2011). In *PLIVA*, the Court drew a clear distinction between generic drugs and the brand-name drugs subject to the Court’s decision in *Wyeth v. Levine*, 555 U.S. 555 (2009). While the decision was a major win for manufacturers of generic drugs, manufacturers of brand-name drugs already are beginning to experience negative consequences. Plaintiffs have begun to amend complaints they previously filed against manufacturers of the generic drugs they ingested to add the manufacturers of the brand-name drugs they did not use as additional defendants under the theory of brand-name drug manufacturer liability espoused in *Conte v. Wyeth, Inc., et al.*, 85 Cal.Rptr.3d 299 (Cal. Ct. App. 2008), review denied, Case No. S169116, Sup. Ct. Cal. (Jan. 21, 2009).

To read more about the *PLIVA* decision, [click here](#).

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**Class Actions.** In a trio of opinions released over the course of two months, the Court also clarified the law governing class actions in federal courts.

On April 27, 2011, the Court held that the Federal Arbitration Act (FAA) prevents courts from refusing to enforce arbitration agreements merely because they preclude plaintiffs from proceeding as a class. *AT&T Mobility LLC v. Concepcion*, 563 U.S. \_\_\_\_ (2011). More specifically, the Court held that the FAA preempts California common law holding that arbitration agreements are unconscionable and unenforceable unless they provide for classwide arbitration. Writing for a five-justice majority, Justice Scalia first noted that, where state law outright prohibits arbitration, the FAA displaces that state law. The Court next considered whether the doctrine of unconscionability, normally thought to be generally applicable and thus excepted from the FAA's broad preemption, was being applied in a manner that disfavored arbitration. The Court concluded that the California rule fundamentally undermined arbitration and recognized that "class arbitration greatly increases the risks to defendants" and results in the "in terrorem" settling of questionable claims. Because the California rule "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," the Court held that it was preempted by the FAA. *Concepcion*, slip op. at 18 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

To read more about the *Concepcion* decision, [click here](#).

Almost two months later, in a 9-0 decision, the Court reversed the Eighth Circuit's affirmation of an order enjoining a state court class action against Bayer Corporation after a similar class certification had been denied in federal court. *Smith v. Bayer Corp.*, 564 U.S. \_\_\_\_, No. 09-1205 (June 16, 2011). Two putative class actions were filed against the defendant Bayer within weeks of each other. Both then proceeded separately for six years – one in federal court and the other in state court – with both courts applying West

Virginia substantive law. After the federal court judge denied the plaintiffs' motion for class certification, Bayer sought to enjoin the state court action from proceeding (pursuant to an exception to the Anti-Injunction Act). Instead, the Court ruled that the state court action must be allowed to proceed. Because the state court's version of Rule 23 (the legal standard for class certification) was different from, and interpreted differently than, the federal version, and because the named class representatives were different in the putative state and federal class actions, the federal courts had no power to enjoin the second, state court action. Although "cold comfort" to the defendant in the *Smith* case, the Court did suggest that future defendants could avoid this result by removing repetitive state class actions to federal court where the doctrines of *stare decisis* and comity will allow them to avoid relitigation of the same issues.

To read more about the *Smith* decision, [click here](#).

Finally, on June 20, 2011 the Court reversed certification of a class consisting of approximately 1.5 million female Wal-Mart employees alleged to have suffered discrimination in relation to their pay and promotion, in violation of Title VII of the Civil Rights Act of 1964. *Wal-Mart Stores, Inc. v. Dukes*, No. 10-277 (S. Ct. June 20, 2011). The Court, by a 5-4 vote, clarified the scope of Federal Rule of Civil Procedure 23(a)(2), which addresses commonality, and by a unanimous 9-0 vote held that Rule 23(b)(2) does not authorize certification of classes whose members would be entitled to different (if any) injunctive or declaratory relief or to individualized monetary awards, whether or not such monetary claims "predominate" over claims for injunctive relief. *Dukes* clearly establishes that plaintiffs may not use (b)(2) to avoid the predominance, superiority, notice, and opt-out requirements in (b)(3) when pursuing monetary relief.

To read more about the *Dukes* decision, [click here](#).

# EMERGING TRENDS



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## International Safety Standards Related to Consumer Products on the Horizon

An international standard aimed at enhancing consumer product safety is on the verge of being finalized. On May 12, 2011, the Secretariat for the International Organization for Standardization (ISO) Project Committee 243 released the Committee Draft of ISO 10377, *Consumer Product Safety: Practical Guidance for Suppliers*. The ISO, which is a worldwide federation of national standards-setting bodies charged with developing international product standards, intends ISO 10377 to provide companies with practical guidance on how to identify, assess, eliminate, and/or reduce the risks to consumers associated with the products they manufacture, import, or sell. The draft standard, which is expected to be finalized by 2012, was created based on input from representatives of 19 countries (including the United States, Canada, China, and Japan). Although the international standards would apply to companies of all sizes, ISO 10377 is intended for small and medium-sized companies that might not have a detailed product safety plan in place.

In its proposed form, ISO 10377 is organized into three principal sections, representing the three primary phases of products in the supply chain:

### Safety in Product Design

- The proposed standards provide guidance to suppliers regarding measures to help

identify potential hazards associated with the design of their products, to reduce or eliminate those hazards, and to inform consumers about any hazards that cannot be eliminated.

- The standards focus on the importance of evaluating and eliminating risks associated with predictable uses (and misuses) of the product, identifying likely hazards associated with use of the product, and conducting a risk evaluation (*i.e.*, evaluation of the likelihood of consumer exposure to risks and the severity of any harm associated with those risks).

### Safety in Production

- Once a product passes the product design phase, the proposed standards set forth safety principles applicable to the production process, including design validation, production readiness, supply chain management, and tooling.
- Under the proposed standards, companies would be expected to perform quality monitoring, audits, and risk-based testing to assist in the identification of manufacturing safety issues before a product is provided to a consumer.
- Production facilities would be required to consider whether their process for distributing goods to consumers is safe.

### Safety in the Marketplace

- The proposed standards require suppliers to collect data to allow them to assess

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trends in product safety related to alleged defects, repairs, incidents, complaints, warranty returns, and lawsuits.

- The proposed standards require product tracing through use of serial or batch numbers on products. By capturing post-sale data, companies would have the information to evaluate and reduce risks through future design or production changes, if necessary.

ISO 10377 is intended to foster greater uniformity in the manufacture, supply, and sale of products by identifying and resolving (or limiting) product hazards at the design phase, evaluating potential safety concerns that are present in the manufacturing process, and collecting data related to post-production issues that may arise. Companies should be cognizant of the risk that plaintiffs pursuing litigation against them could attempt to rely on a failure to comply with the standard's design criteria as evidence to support a design defect claim. Ultimately, companies should evaluate their standards in light of ISO 10377 and objectively consider whether changes to their design and production protocol are needed to increase their products' safety, as well as to minimize the risk of product liability litigation.

## **New Emphasis on Nutrition and Marketing to Children Will Impact Food Industry**

In the past few months, the Obama administration has ramped up its efforts to confront obesity and promote nutritional health by propagating new nutritional and food marketing guidelines. The proposed guidelines, though voluntary, may prove challenging

for companies in the food industry to meet, and could give rise to consumer claims and litigation.

In April 2011, an interagency working group consisting of representatives from the FDA, the Federal Trade Commission, the Centers for Disease Control and Prevention, and the Department of Agriculture, suggested that by 2016, all food products within the 10 categories of food most heavily marketed directly to children be formulated to "make a meaningful contribution to a healthful diet" and minimize the content of nutrients that could have a negative impact on health and weight. The 10 categories of food covered by the guidelines are breakfast cereals, snack foods, candy, dairy products, baked goods, carbonated beverages, fruit juice and non-carbonated beverages, prepared foods and meals, frozen and chilled desserts, and restaurant foods. The proposed guidelines would reach any advertising for these products, including traditional media such as television, print, radio, and pop-up ads on Internet sites, as well as social media, toys in fast-food meals, ads shown in movie theaters, sponsorship of athletic teams and philanthropic activities, and product placement in movies and video games.

Additionally, in June 2011, the administration replaced the food pyramid with the "My Plate" symbol to help guide consumer food choices. The symbol, based on a new set of dietary guidelines released in January, is a general guideline that eliminates any references to sugars, fats, or oils, and replaces the "meat and beans" category with a simple "proteins" label. Over the next few years, the USDA

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hopes to spur changes in consumer behavior through media and how-to campaigns based on the My Plate symbol, and also encourage stronger and more meaningful self-regulation by the food industry.

Such self-regulation already has begun. In July 2011, McDonald's USA LLC, Coca-Cola Co., and 15 other food and beverage producers agreed to comply with an industry plan to reduce the calories, sodium, sugar, and fat contained in products advertised to children by 2013.

While the new guidelines are not law, companies could face an increase in unfair or deceptive marketing claims for advertising their products as "healthy" even though they did not meet the federal government's voluntary nutritional guidelines. Potential plaintiffs may argue that there is a presumption that the guidelines are based on scientific evidence and meaningful research. This trend already may have begun. For instance, a class action has been filed against a food manufacturer for "passing off genetically modified oils as '100% natural.'" Similarly, plaintiffs in a proposed class action against ice cream makers claimed that their chocolate ice cream improperly was advertised as "all natural" when it contained alkalized cocoa processed with potassium carbonate, a man-made ingredient. The plaintiffs seek a

refund after paying a premium for what they believed were all-natural products. Companies also are under fire simply for marketing to children. A class action was initiated accusing a fast-food chain of violating California state consumer protection laws by using toys to market allegedly nutritionally poor children's meals directly to children.

To reduce the risk of food-related litigation, companies should be mindful of the new guidelines and take a fresh look at their marketing and advertising practices.

# UPDATES IN THE LAW



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## Changes to the CPSIA and the Status of the CPSC Public Database

The Consumer Product Safety Commission's (CPSC) authority to regulate manufacturers, distributors, and retailers of consumer products continues to evolve as the Consumer Product Safety Improvement Act of 2008 (CPSIA) is amended and the CPSC's database goes live.

### Consumer Product Safety Improvement Act Amended

After years of failed bills attempting to address problems with the CPSIA, Congress voted on August 1, 2011 to amend the CPSIA and President Obama signed the amendment into law on August 12. The timing of the bill was crucial in that it prevented many manufacturers, distributors, and retailers of children's products from having to destroy inventory on August 14 pursuant to the CPSIA's limits on lead in children's products.

While the August 14 lead limit deadline drove the swift passage of the amendment, the deadline was not its only target. The amendment provides specific exclusions for certain products and businesses while giving the CPSC greater authority to grant other regulatory relief. It also relieves companies from costly third-party testing requirements and allows the CPSC to create alternatives and exemptions for "small-batch manufacturers," which previously had been treated the same as large multinational corporations. Specific changes include:

- Goods already on retail shelves need not meet the 100 ppm lead limit that went into effect on August 14. The CPSIA's lead limits previously applied retroactively; now, they apply only to goods manufactured after August 14, 2011, so long as those goods contain less than 300 ppm of lead.
- Children's products and components that cannot meet the standard that are not likely to be ingested or will have no measurable adverse effect on public health or safety are exempt from the 100 ppm lead standard.
- The lead limit now has a "functional purpose" exception so the CPSC, on its own or in response to a petition, may exempt certain products or product categories from the stricter lead limits under certain conditions.
- The CPSC now also has the authority to enact regulations that reduce testing and certification burdens on small businesses that already produce safe products.
- Children's products are now eligible for alternative testing methods that can help companies avoid the burdensome expense of third-party testing requirements previously imposed for lead and other standards.
- Certain used children's products are now exempted from the CPSIA, but the exemption does not apply to children's metal jewelry, any children's product the seller actually knows violates established lead limits, or any other children's product the CPSC exempts after a hearing.
- Ordinary books and reading material printed on paper are exempted from third-party testing requirements.
- Children's Off-Highway Vehicles (OHVs), including dirt bikes, all-terrain vehicles, go carts, and snowmobiles, are now exempt from the lead limits of the CPSIA. Although the CPSIA focused on toys and children's products, children's dirt bikes and ATVs previously were subject to its requirements because there can be trace amounts of lead in batteries and brake calipers.
- The current stay of enforcement related to bicycles and bicycle components (June 30, 2009) remains in effect. As of January 1, 2012, lead limits in these products shall not exceed 300 ppm.

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- The CPSC is tasked with developing an alternative testing framework that is not economically overwhelming for small-batch manufacturers or those with less than \$1 million in annual sales. Only products produced in quantities of fewer than 7,500 per year qualify for alternative testing methods. If the CPSC cannot identify an effective alternative test method, it has the discretion to exempt small-batch manufacturers from third-party testing requirements.
- The CPSC now has the flexibility to certify products that meet certain foreign safety standards, including some in the European Union.

CPSC Chairman Inez Tenenbaum praised the amendment as a compromise that protects consumers from harmful materials, yet implements a framework to protect businesses from the more oppressive and expensive requirements of the CPSIA. Now begins the rule-making process by which the CPSC implements and sets out the details of the new law.

## The CPSC Public Database

Section 212 of the CPSIA required the CPSC to create a publicly accessible and searchable incident database with the goal of providing a website where consumers, government agencies, health care professionals, child service providers, and public safety entities can report and search for information regarding product safety incidents. SaferProducts.gov, that long-awaited and hotly debated product safety database, went live on March 11, 2011. The database has been applauded by watchdog groups while being criticized by affected industry groups, some politicians, and even some CPSC commissioners. Specifically, concerns were expressed regarding database implementation, citing the potential for inaccurate reports and resulting harm to the reputations of products and manufacturers. Concerns also were expressed over the CPSC's and states' plans to use the database in connection with pursuing investigations and product recalls. In addition, the plaintiffs' bar easily can mine the database for potential personal injury or class action claims and for evidence to support punitive damages.

Now that the database is live, some of the anticipated problems have begun to surface. Many reports posted at SaferProducts.gov do not assert product harm or threat of harm, or they fail to accurately identify the product or manufacturer. Other reports relate to products that are subject to the jurisdiction of another agency or confuse compliance with requirements such as Proposition 65 as a safety issue. In addition, businesses report that the CPSC's process of determining whether a report is materially inaccurate (and, therefore, should not be published) is too cumbersome.

The amendment to the CPSIA includes some changes to the CPSC's operation of the database. It requires the CPSC to stay publication for five additional days (originally only 10) when it receives notice of materially inaccurate information and requires the CPSC to attempt to obtain model and serial numbers or a photo of a product in question. These changes, however, do not address all of the potential issues, and industry experience reinforces the importance of being prepared if a product is the subject of a report of harm. Recommended precautions include:

- Registering with the CPSC to receive incident reports as quickly as possible
- Developing internal procedures for properly investigating reports
  - Reviewing quality records, test reports, and incident information

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- o Determining if reports contain confidential business information (CBI) or material inaccuracy
- Developing guidelines for responding to reports
  - o Responding timely to a report of harm is essential to prevent publication of CBI and/or materially inaccurate information
  - o CPSC must post the report of harm 10 business days after transmitting it to the manufacturer
- Appointing a team leader and skilled staff to handle the reports
- Training appropriate personnel on using the database and responding to reports
- Determining whether additional action must be taken
  - o A Section 15(b) report may need to be submitted to the CPSC
  - o Reporting in other countries (e.g., Canada) may be required
  - o A recall may be necessary
- Tracking reports to determine whether they trigger a reporting obligation to the CPSC or a product recall
- Ensuring that an effective company-wide product liability risk management program is in place

Following these best practices will help to mitigate some of the risks associated with the database.

## Bill to Probe Sealed Product Liability Deals Advances

On May 5, 2011, the U.S. Senate Judiciary Committee approved the Sunshine in Litigation Act of 2011 (S. 623) (“Act”) through a bipartisan vote of 12-6. The Act would require judges to consider public health and safety concerns before sealing legal agreements and settlements in product liability suits. Under the Act, judges overseeing product liability suits would be directed to use a balancing test to strike the appropriate compromise between protecting the public and shielding legitimate confidential information, using their discretion to seal documents or enter protective orders. The Act does, however, contain specific protections for personal and national security and would not apply retroactively if passed. Commentators have described the purpose of the Act as preventing the nondisclosure of information regarding defective products – citing as examples silicone breast implants, IUDs, side-saddle gas tanks, defective heart valves, tires, and prescription painkillers – in order to save lives. Critics of the Act claim that it impermissibly circumvents established procedures for Congress to amend the Federal Rules of Civil Procedure, and that protective orders and confidentiality provisions in settlement agreements are not frequently abused.

Should the Act pass, the risks to manufacturers in product liability suits would be significant. Manufacturers entering into settlement agreements or protective orders in product liability suits may be compelled to reveal the terms of settlements or information disclosed in discovery despite the parties’ agreement otherwise. Plaintiffs’ lawyers would almost certainly use previous settlement amounts as benchmarks for future cases involving similar products. In addition, disclosing settlement agreements and information produced in discovery would likely increase the number of potential plaintiffs seeking to recover for their purported injuries resulting from a particular product. Further, if protective orders are eviscerated, information used by plaintiffs’ lawyers in one lawsuit would likely lead to the same information being used in another lawsuit involving the same product, creating a library of information for plaintiffs’ lawyers to use in future lawsuits.

# SHARING OUR PERSPECTIVE



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A discussion with partner **Andrew Cox** about the group's best practices for managing data and evidence throughout the life of large-scale product liability litigation.

**What are the group's best practices for managing evidence gathered and developed in large-scale product liability litigation?** At the core of our best practices is a process for collecting, culling, producing, developing, and presenting evidence. Although many look at the data collection and e-discovery aspects of litigation as an unavoidably time-consuming, expensive, and unpredictable process that cannot be controlled, properly viewed, this process is like any other business-related process. It can be organized, controlled, and carefully managed to maximize efficiency and minimize costs.

**What is the structure of your approach?** Our process has seven stages from preservation and harvesting data through the presentation of evidence at trial. The fact that our process continues past the production phase is important because there is a lot of focus in the industry on e-discovery and collecting and producing large data sets, as if the ultimate goal was to produce a massive amount of data and then stop. Of course, the litigation continues. Thus, our process continues, through review, litigation, and trial.

**When does the process begin?** Our best practices concepts can be applied to litigation readiness projects; however, generally the process starts when litigation is threatened or filed. The early process of identifying custodians and data sources, and documenting which of those sources are duplicative or "not readily accessible" is a key opportunity to avoid future expenses due to motion practice over whether certain sources have been or should be searched. The data identification phase should be treated as an action within an action. That is, you want to treat this process as though you are preparing to defend your search methodology, because in reality, you will most likely need to.

**Have you developed any tools to assist in the data identification phase?** One tool we use is an ESI questionnaire, which we tailor to each litigation. This ensures that each custodian is asked the same questions about their data sources and their personal habits for storing information. It is very powerful to be able to explain to the court that you have engaged in a formal process for identifying, preserving, and searching data sources, particularly when faced with an adversary who simply rants about e-discovery obligations.

**What are some other keys to increasing efficiency?** When we looked at the overall process, we found that transcript review was an area that could be improved. When you consider how many times attorneys review the same deposition transcript for different reasons, such as writing a motion or preparing a cross-examination, you have to wonder whether there might be a more efficient way. A more value-focused approach is to have one attorney review the transcript electronically in a transcript management software system, link the testimony to key facts gained from the testimony, and create an issue-coded database of the key facts. The facts, with links back to the actual deposition testimony, serve as a summary of the deposition and double as the beginning of the future motion or cross-examination. Again, the overall goal is to build upon the litigation team's collective work product and avoid duplication of efforts as we progress steadily toward the client's goal for resolution, whether that goal is an economic resolution or a win at trial.

**Andrew Cox** is a partner in our Cleveland office. He focuses his practice on the specialty plastics and aviation industries. Andrew is also part of the Thompson Hine team serving as national counsel for a manufacturer of commercial food processing equipment. Andrew has presented CLE programs nationally on the topic of effective electronic case management focused on techniques to streamline the process of managing data throughout litigation.

# WINS



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Our group is pleased that it has achieved successes for a number of our clients during the last several months:

**Missy Wright**, with significant assistance from **Stacey Greenwell**, obtained a defense verdict on behalf of the manufacturer of a cordless framing nailer in the United States District Court for the Western District of Oklahoma on claims that the nailer was defectively designed and manufactured, resulting in severe eye injury to the operator.

**Missy Wright** and **Stacey Greenwell** obtained summary judgment in favor of a commercial food equipment manufacturer in the United States District Court for the Eastern District of Pennsylvania on claims that a commercial mixer manufactured in 1982 was defective in design and manufacture, and for failure to warn.

**Missy Wright**, with significant assistance from **Conor McLaughlin**, obtained a defense verdict on behalf of an automotive manufacturer on claims that a police vehicle was defectively designed and manufactured, resulting in a fuel-fed fire in which a police officer sustained extensive burns.

**Missy Wright** and **Eric Daniel** obtained summary judgment on the basis of federal preemption on behalf of a medical device manufacturer on a claim alleging a product defect in a hip implant.

**Missy Wright**, **Jennifer Mountcastle**, and **Eric Daniel** obtained favorable decisions excluding the plaintiffs' experts and affirming the admissibility of the testimony of our client's expert on behalf of an automotive manufacturer in a case alleging that a vehicle suddenly accelerated.

**Ileana Martinez** and **Leslie Suson** obtained summary judgment on the basis of federal preemption in favor of our client, the manufacturer of a nerve stimulation device, in the United States District Court for the Northern District of Georgia.

# WHAT'S HAPPENING



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**Brian Troyer** will moderate a panel on international litigation issues at a [conference](#) sponsored by the Pharma and Medical Device subcommittees of the Products Liability Committee of the ABA's Litigation Section in Philadelphia on November 17, 2011.

**Brian Troyer** will participate in a panel on "Applying Favorable Recent Judicial Decisions and Policy Trends to Strengthen Your Class Actions Defense Strategies" at the [American Conference Institute's 16th Annual Drug and Medical Device Litigation Conference](#) in New York on December 5-7, 2011, of which Thompson Hine is a sponsor.

**Andrew Cox, Tim Coughlin, Kip Bollin, Bill Hubbard, and Fern O'Brian** will present at Thompson Hine's Chemical Industry Initiative CLE Seminar to be held on December 9, 2011 in the Cleveland office. Topics include warranty and terms and conditions best practices, the EPA's IRIS process, class actions, green marketing, and emerging regulatory policy for nanotechnology-enabled products.

**Brian Troyer** and **Jennifer Mountcastle** will participate in the [Best Practices for Managing Multi-Forum Litigation audio conference](#) hosted by Lorman Educational Services on December 12, 2011, from 1:00 - 2:30 p.m. EST.

**Tim Coughlin** will speak at [NBI's Civil Court Procedure and Strategy Boot Camp](#) in Cleveland on December 15 and 16, 2011.

**Tim Coughlin** and **John Mitchell** will present at Are You Covered? Emerging Threats and Insurance Coverage, a joint CLE presentation offered by Thompson Hine and Risk International at Thompson Hine's Cleveland office on December 20, 2011.

Our Product Liability lawyers have handled tens of thousands of cases throughout the United States and abroad involving all facets of product liability law. We have litigated product liability and major tort matters in a wide range of industries, including admiralty and maritime, aerospace, automotive, chemicals, commercial and consumer products, electrical, food equipment, mechanical, medical devices, nanotechnology, pharmaceuticals, and plastics.

Our trial lawyers actively are involved in national product liability organizations and have lectured and written extensively on product liability matters. We act as national and regional product liability counsel for Fortune 500 companies, protecting their interests throughout the United States and abroad. Our practice covers all aspects of product liability matters, from preventive counseling and alternative dispute resolution through trial and appeals.

For more information about our practice group and its services, contact: **Elizabeth B. Wright • Practice Group Leader, Product Liability Litigation**, [Elizabeth.Wright@ThompsonHine.com](mailto:Elizabeth.Wright@ThompsonHine.com), 216.566.5716

Established in 1911, Thompson Hine is a business law firm dedicated to providing superior client service. The firm has been named one of the top two law firms in the country for client service and the only firm ranked in the top tier for “Provides Value for the Dollar,” according to the *2011 BTI Client Service A-Team: Survey of Law Firm Client Service Performance*. The firm has offices in **Atlanta, Cincinnati, Columbus, Cleveland, Dayton, New York and Washington, D.C.** With approximately 400 lawyers, Thompson Hine serves premier businesses worldwide, including:

AKZONOBEL INC.	THE DAVEY TREE EXPERT COMPANY	KEYCORP/KEYBANK	PARKER HANNIFIN CORPORATION
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## OUR CLIENT SERVICE PLEDGE

### What Our Clients Can Expect From Us . . .

1. We will know your business. We make it our business to understand your business. We will invest our time and resources to develop and maintain knowledge of the dynamics that impact both your industry and your organization. Understanding your business will help us provide better counsel to you.
2. We will plan our engagements with you. We know that clients differ in their goals, risk tolerance and a variety of other factors that must be taken into consideration before work can begin on any matter. At the beginning of every significant matter, we will work with you to develop a plan to meet your strategic goals. By agreeing on a plan at the beginning – and adjusting it as needed – we will stay focused on what is most important to you.
3. We will manage your work as if we were the client. We will work with you to manage your costs. We will staff every matter with the right resources, and we will manage the work as if we were the client – delivering the highest quality of service on time and in the most cost-effective manner.

4. We will be available when you need us. We recognize that you often need to make swift decisions and act quickly. We will be ready to act for you when you need us, and we will make ourselves available wherever and whenever necessary.
5. We will communicate often. Our goal is that you will never be surprised about developments in anything we are handling. We will provide regular updates on the progress of your matters, including all significant developments and changes to scope, timeline or budget.
6. We will provide the highest-quality counsel. Above all else, we stand for the highest quality. Our lawyers, paralegals and staff take pride in the work they do. From the boardroom to the courtroom, you can count on Thompson Hine for the highest-quality service.

### What Our Clients Can Do To Help . . .

1. We ask you to share your goals. The more we know about your goals, the better we can manage our services to help you attain them. If your goals change as a matter progresses, we ask that you tell us, so we can adjust our approach to meet your expectations.
2. We want to know your preferences for working with us. We ask you to tell us your preferred methods of communication, invoice and billing procedures, and anything else that is important to you, so that we can deliver our service the way you want it.
3. We need your feedback. We want your feedback on our performance so that we can continue to meet and exceed your expectations.

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