THOMPSONHINE

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Product Liability eNewsletter
in this issue

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

Our practice has been quite busy since the last edition of our newsletter. We secured significant wins for several major clients, including BASF, Ford Motor Co., ITW Food Equipment Group, Louisiana-Pacific, Noranda Aluminum, and PPG. We thank these clients for entrusting us with their matters and look forward to continuing to help them achieve their legal and business goals.

In addition to serving as trial and appellate counsel for clients throughout the United States, we have been counseling manufacturers on risk mitigation strategies, conducting product liability risk audits, drafting warnings and instructional materials, advising on strategies to win the "battle of the forms" in commercial contracting, and developing risk mitigation strategies customized to their unique business needs.

In December, **Tim Coughlin** and **Bill Hubbard** (both Cleveland) hosted our third annual Chemical Industry Seminar, with multidisciplinary presentations tailored to our chemical industry clients. **Jen Mountcastle** (Columbus) presented on cutting edge topics at the Network of Trial Law Firms, covering techniques for communicating with Gen Y jurors, and at the ACI Drug & Medical Device Litigation conference, speaking on the use of social media in litigation. **Barbara Lum** (Cleveland) took over as vice chair of the Diversity Subcommittee of DRI's Young Lawyers' Committee and **Kip Bollin** (Cleveland) served on the Steering Committee for DRI's class action seminar. Kip also served as co-chair of the Civil Rules Committee for the Northern District of Ohio Advisory Board; the committee put forth a revision for the local rule dealing with class actions (23.1), which has been adopted by the court and has gone into effect.

Inside this edition of our newsletter is an article by **Gary Glass** (Cincinnati) and **Conor McLaughlin** (Cleveland) addressing the OSHA Hazard Communication Standards that impose new obligations on manufacturers. **Seth Litman** (Atlanta) offers practical guidance on implementing effective strategies for managing multidistrict litigation (MDL). **Fern O'Brian** and **Neelam Gill** (both Washington, D.C.) offer an overview of good manufacturing practice regulations and a practical approach to implementing FDA manufacturing requirements. And Fern and Barbara provide guidance on the new ISO regulations. We are also happy to offer a guest article from business litigators **Tony Rospert** and **Hope Lu** (both Cleveland) on handling premerger disputes.

We hope you enjoy our newsletter and, as always, welcome your questions, feedback, and suggestions for future editions.

Regards,

Andrew H. Cox

OSHA Implements Revised Hazard Communication Standards

Overview

Last year, many of our clients began implementing programs to comply with final Occupational Safety and Health Administration (OSHA) rules on hazard communications. In 2012, OSHA released a final rule modifying its current Hazard Communication Standard (29 CFR § 1910.1200) (HCS) to comport with the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals. Modifications to the standard, which primarily affect manufacturers and importers of hazardous chemicals, include the following:

- Revised criteria for classification of chemical hazards
- Revised labeling provisions that include requirements for use of standardized signal words, pictograms, hazard statements, and precautionary statements
- A specified form for safety data sheets
- Revised definitions of terms used in the standard
- Requirements for employee training on the revised labels and safety data sheets

The final rule requires chemical manufacturers and importers to reevaluate chemicals according to new criteria to ensure that they are classified appropriately. For example, health hazards must be assigned to an appropriate hazard category and subcategory (hazard class). Under the new classification criteria, chemicals will be classified by the type, degree, and severity of the hazards they pose.

The new regulations also require manufacturers and importers of chemicals to prepare and distribute modified labels and safety data sheets. No longer will differently formatted and non-uniform material safety data sheets suffice. Safety data sheets now must be uniform in structure, labeling, and word usage.

Important Dates for U.S. Implementation

OSHA's final rule became effective on May 26, 2012 with the following key implementation dates:

- **December 1, 2013 –** deadline to train employees on the new label requirements and safety data sheet format
- **June 1, 2015 –** date by which chemical manufacturers, importers, distributors, and employers must comply with all provisions of the final rule, except:
  - **December 1, 2015 –** distributors ***may*** ship containers labeled by manufacturers under the old system before this date. After December 1, 2015 the labels on all shipped containers must conform with the new requirements and format
- **June 1, 2016 –** deadline for employers to update workplace labeling and hazard communication programs, if necessary, and to provide any additional employee training
- **Transition period –** during this time, chemical manufacturers, importers, distributors, and employers may comply with either the old rule, the new rule, or both

We can help develop workplace training programs and safety data sheets that comply with the new rules.

New HCS May Not Preempt State Law

The revised HCS also contains a preemption provision that applies only to "legislative and regulatory enactment[s] of a state," which supplants a standard that preempted all state "legal requirements," and thus does

not preempt state common law. In a case recently decided by the D.C. Circuit Court of Appeals (*American Tort Reform Association v. OSHA and the Department of Labor,* No. 12-1229, 738 F.3d 387), the American Tort Reform Association (ATRA) argued the new rule should preempt state tort law. ATRA contended it is improper for the federal government to dictate the precise content of warnings and labels that companies must provide under the HCS while leaving those companies vulnerable to lawsuits for failure-to-warn claims based on state tort law.

OSHA disagreed, stating that the new HCS provided minimum requirements that companies had to meet and did not preempt state tort law. Moreover, OSHA argued, the standard's preemption clause is merely OSHA's interpretation of the law, not a binding rule, and therefore not ripe for legal challenge. The court sided with OSHA on the procedural arguments, holding that because its interpretation does not have the force of law, ATRA had suffered no injury and has no standing to sue.

The opinion does not, therefore, settle the ultimate issue: whether the HCS preempts state tort law. While the court refused to strike OSHA's interpretation of the preemption provision, it also stated that OSHA lacks legal authority to render a dispositive decision on preemption, and that its interpretation is not binding on any court. For the time being, safety data sheets are not a substitute for product warnings and instructions that may be required under state law. Our practice has long experience helping clients draft and evaluate product warnings and instructions.

New Faces
Meet Neelam Gill

Office: Washington, D.C.

Law school: University of Akron School of Law (2010)

Undergrad: John Carroll University (B.S., Biology, 2003)

Prior employers: Ben Venue Laboratories - Boehringer Ingelheim

Hobbies and interests: Music/piano, hiking, exercise, yoga, interior design and architecture, learning new languages, and of course time with family and friends, especially my niece and nephew.

What differentiates you from other lawyers? I have an extensive technical and regulatory background in pharmaceuticals, and this experience helps me understand my clients' needs from both a business and regulatory perspective.

Describe your areas of practice and focus: My practice focuses on FDA regulatory matters and covers products such as drugs, devices, biologics, diagnostics, foods, and cosmetics. I am also licensed to practice before the U.S. Patent and Trademark Office, and I believe having this background better enables me to understand patent, licensing, and technology transfer considerations as they apply to the pharmaceutical industry.

Types of clients served (industry, geography, size, etc.): Pharmaceutical, device, biotechnology, and medical technology companies of all sizes, ranging from startups to global companies.

Interesting facts: I am fluent in three languages: English, Hindi, and Punjabi.

MDL Strategies

History & Overview

Multidistrict litigation (MDL), created in 1968 with passage of 28 U.S.C. §1407, is used by federal courts to consolidate cases to reduce discovery time and cost. It is typically used in high-stakes litigation involving multiple plaintiffs, where cases are pending in many different federal jurisdictions against a common defendant(s), and where the cases present at least one common question of fact.

An MDL can be created through a motion filed by any party or by the Judicial Panel on Multidistrict Litigation (JPML) acting *sua sponte.* Once the JPML creates an MDL, ongoing proceedings in several federal jurisdictions are consolidated in front of one judge, who handles all pretrial activities. Cases that meet the JPML's MDL definition are transferred to the MDL judge's jurisdiction. Traditionally, when pretrial activities are sufficiently concluded, the MDL judge transfers, or remands, the cases back to the jurisdictions where they were filed for trial. *Lexecon v. Milber Weiss Bershad Hynes & Lerach,* 523 U.S. 26 (1998).

The purpose of MDL is to consolidate pretrial activities to shorten the proceedings, reduce the cost, and provide uniformity and coordination of pretrial activities. An MDL does this, for example, by ruling on matters common to all of the cases, such as determining the scope of document production, which large company witnesses will be deposed, whether certain experts meet the standard set by *Daubert,* and dispositive motions. With one court deciding universal fact and legal issues, a uniform set of rules is created to be used in individual cases as they proceed to trial.

Strategic Considerations

When considering whether to actively seek an MDL, or whether to support or oppose a motion to create one, a company should consider the following:

- Despite the coordination, MDLs can be long and expensive. In this regard, a company should make a business decision in consultation with counsel as to whether the value of the cases that could form the basis of an MDL is worthy of a large expenditure of funds, or whether the cases can be effectively coordinated by counsel without an MDL.
- If a product liability matter, a company must consider the potential for future cases involving the subject matter product. Often the issue of whether to have an MDL arises when only a few cases have been filed. The company must ask itself whether those cases are isolated incidents or just the tip of the iceberg. If more cases are expected, it may be better to seek an MDL to seize control of the litigation and coordinate it rather than waiting for an onslaught.
- A company also must consider whether an MDL will increase the number of cases filed. Many plaintiffs' lawyers wait for MDLs to be formed and then advertise for cases. When they jump on the bandwagon, an explosion in the number of cases filed can occur. Plaintiffs' lawyers do this to take advantage of the coordinating lawyers' work preparing the cases for trial or, more typically, in hope that a global settlement will be achieved so that they will be paid for having done little work. Because there always are a significant number of new cases filed following the creation of an MDL, companies must weigh the risk of "me too" filings. A swift internal analysis of the product and the potential for new claims, based on the company's knowledge early in the litigation, can provide a good roadmap for this decision.

Achieving Resolution

An MDL can be an effective forum in which to work toward resolution of a mass action because it offers a unique situation where counsel from a variety of districts are brought together with company counsel to appear in front of a single judge on a regular basis. In and of themselves, these meetings provide regular opportunities to resolve matters through negotiation that are not typically part of the litigation process. The meetings also lend themselves to forced negotiations and consolidated mediations advocated by an MDL

judge. Stories are told of judges requiring the litigants to attend after-hours cocktail parties (paid for by the litigants, of course) where the judge would work the room to push parties toward resolution of cases.

In recent years, MDL judges have implemented a more formal method of encouraging resolution: the bellwether trial. A bellwether trial is the practice of taking certain claims to trial in the MDL. Although the MDL judge is typically in a very strong position to conduct a trial due to his or her knowledge of the case and litigants, under the MDL rules an MDL court *does not* automatically have the power to try a case because of basic procedural issues such as personal jurisdiction and venue (28 USCA §1407(a)). An MDL judge, however, is typically positioned to convince the parties to provide consent to make a bellwether trial possible.

There are several benefits to bellwether trials, the most obvious of which is that it can set a precedent or case value as a benchmark for settlement. But a bellwether trial also pushes the parties through the trial preparation process, allows the parties to determine the effectiveness of their experts, and gives them the opportunity to create trial materials that can be shared with other counsel to make future trials more efficient.

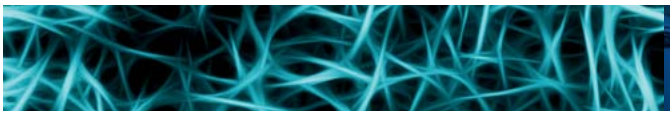
The process for selecting plaintiffs for bellwether trials is typically set by the MDL judge and starts with a having a good case management plan. Judge Fallon in the *Vioxx MDL* suggested a three-step process for case management to facilitate effective selection of bellwether plaintiffs:

- First, the parties and the court must group the cases into objective categories easily identifiable for each plaintiff so that the litigation can focus on the most common plaintiff characteristics.
- Second, the parties create discovery pools so that representative cases in each major category are properly prepared for trial.
- Finally, the parties choose bellwether plaintiffs from each major category to have their cases tried.

Courts have approached the selection of cases for bellwether trials in a number of ways. Cases can be chosen randomly by counsel in a process similar to jury selection that allows each side to participate, by the MDL judge, or some combination of these approaches. Of course, before any bellwether plaintiff can go to trial, appropriate waivers must be obtained.

If a defendant is asked to help select bellwether plaintiffs, the strategy for doing so will depend on rules set by the judge. Many commentators suggest that selecting a middle of the road "representative" plaintiff is the best way to go for a test case, because a representative plaintiff will provide a reliable measure of case value and a preview of how ensuing trials will proceed. Although this approach is noble, the decision about which plaintiffs to nominate for bellwether trials must be based on individual litigation factors and goals for the trial. Factors such as opposing counsel's aggressiveness, opposing counsel's trial ability, the judge's demeanor, the quality/perceived value of cases in the litigation pool, and the number of bellwether trials being held will vary widely from MDL to MDL. This means there are no hard and fast rules.

That said, defendants should be wary of tricks that plaintiffs' counsel might employ if a plaintiff chosen for a bellwether trial is not who they want. For example, if a case that counsel does not want tried is chosen, waivers can be revoked, cases can be dismissed, or plaintiffs can claim they are unavailable due to work or medical reasons. Although there are certainly legitimate instances in which these situations arise, the MDL court must be requested to exercise caution and demand significant proof before withdrawal is permitted. In addition to allowing one party to unfairly manipulate the proceedings, such tactics can put the bellwether process in jeopardy, as cases must be both representative of a category and ripe for trial. Once a chosen case is withdrawn, significant work and preparation goes by the wayside, and the parties may need to start all over again.




Conclusion

MDL has become an important tool for litigants and courts to coordinate multiple-plaintiff proceedings. However, a company must be mindful of potential pitfalls in seeking, acquiescing to, or opposing an MDL. Once involved in an MDL, much time must be taken to understand the litigation and the plaintiffs' claims to determine the best road to resolution, be it settlement, alternative dispute resolution, or participating in a bell-wether trial. Involving counsel in these decisions to tap prior experience is key in arriving at the best course of action.

New Faces

Meet Gregory P. Feldkamp

Office: Cleveland

Law school: The University of Michigan Law School (2000)

Undergrad: Marquette University (B.A., 1998)

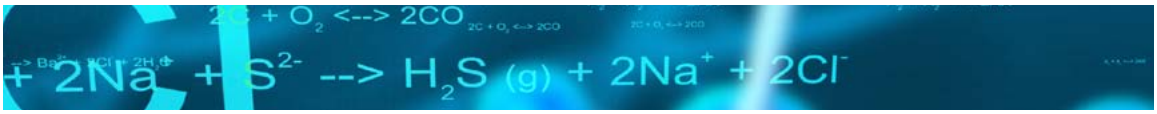
Years practicing as a lawyer: 12, including law clerk for Judge J.P. Stadtmueller, U.S. District Court for the Eastern District of Wisconsin

What differentiates you from other lawyers? I had the privilege of spending the first 6½ years of my legal career in a federal courtroom. I helped research and draft more than 1,000 orders across a spectrum of civil cases. My clerkship offered me an unparalleled opportunity to hone my research and writing skills and to adopt the best practices of the most skilled and prepared attorneys who filed written submissions or appeared before the court.

Now, as an attorney on the other side of the bench, it is my instinct to prepare cases and motions with an eye toward how the court will synthesize competing arguments. As national defense counsel for various pharmaceutical manufacturers, distributors, and sellers, I've obtained summary judgment, favorable settlement, and voluntary dismissals following motion practice and depositions. I attribute my effective advocacy, in large part, to the many years I served in the federal court system.

Describe your areas of practice and focus: Product liability and mass tort with a focus on the defense of claims involving pharmaceutical products and asbestos.

Types of clients served (industry, geography, size, etc.): I have defended manufacturers, distributors, and sellers in product liability and mass tort actions in federal and state courts throughout the country.



The Three Cs of cGMPs: Foundational Principles of FDA's Pharmaceutical & Medical Device Manufacturing Regulations

What Are cGMPs?

Current Good Manufacturing Practice regulations (cGMPs) are fundamental quality principles and the essential basis of a pharmaceutical or medical device company's regulatory license to operate and allow it to introduce products into interstate commerce.[1] cGMPs provide for systems that ensure proper design, monitoring, and control of manufacturing processes and facilities. In simple terms, they embody a practical, common-sense approach for implementing U.S. Food and Drug Administration (FDA) manufacturing requirements.

The regulations pertaining to cGMPs are enforced by FDA under the 1938 Food, Drug, and Cosmetic Act.[2] According to FDA, failure to comply with cGMP regulations for drug and device designing, purchasing, processing, manufacturing, packaging, labeling, storing, installing, and servicing shall render the drug or device to be adulterated, even if the finished product itself is free of any defects.[3] Thus, cGMP compliance is a mandatory aspect of pharmaceutical manufacturing that is necessary to avoid regulatory enforcement actions.

Despite an abundance of cGMPs governing various facets of pharmaceutical manufacturing operations such as organization/personnel, facilities, equipment, components, production, packaging/labeling, and laboratory controls, among others, cGMP compliance problems continue to lead to adverse findings for even the largest, most highly developed pharmaceutical firms with the most sophisticated quality systems.

Fundamental Quality Principles

A review of recent 2013 warning letters issued by FDA's Office of Manufacturing and Product Quality shows that industry continues to struggle with cGMP compliance. For example, in September 2013, a majority of the warning letters sent to drug and device companies cited cGMP observations.[4] This trend is not new for FDA enforcement actions, however. In 2011, nearly 70 percent of all drug shortages were related to manufacturing production problems, including quality-related issues and delays.[5] cGMP compliance struggles are further highlighted by systemic observations like this one:

> *Your firm failed to establish adequate written procedures for production and process control designed to assure that the drug products you manufacture have the identity, strength, quality, and purity they purport or are represented to possess, and your firm's quality control unit did not review and approve those procedures, including any changes.*[6]

Given these struggles, how can firms ensure their procedures and actions meet cGMP requirements?

cGMPs are by their very nature fundamental quality principles. The framework can be broken down into three basic concepts: control, consistency, and clarity (the three Cs). While FDA offers no recipe or rule book for following cGMPs, companies can interpret and apply the basic foundational principles to their own methods and procedures. In doing so, companies may arrive at scientifically justifiable conclusions that a product is safe, pure, and effective in a way that keeps up to date on current industry standards and technology – hence the *c* in *current* Good Manufacturing Practices.

Control

The first fundamental concept – control – encompasses regulation of production processes and quality systems. At its most basic level, the concept of control asks a simple question: Does a firm know what is going into the product and how it can impact the end product? It can include anything from control over the inputs (components, active pharmaceutical ingredients, excipients, environmental factors, and equipment, among others) to control over the various end product quality attributes such as purity, strength, and identity. Control also may be exercised in various forms: laboratory specifications, validated testing methods, written procedures, and proper documentation and assessment of changes to established procedures.

A common saying in the pharmaceutical industry is, "If it is not written down, it did not happen." This statement highlights the importance of proper documentation procedures and stresses that good documentation practices include recording not only results, but also deviations from results, along with the root causes of such deviations.

What does *not* define control, however, is testing quality into the product by relying solely on finished product test results that prove safety and efficacy. Rather, cGMPs place emphasis on controlled inputs that can scientifically lead to a precise and consistent output and a product that is safe, pure, and effective.

To meet these requirements, a business should have robust, scientifically challenged, and validated procedures in place to ensure the entire manufacturing process meets established criteria from beginning to end. If, for instance, an FDA inspector were to request a standard operating procedure for the requirements for active pharmaceutical ingredients testing, the company should be able to produce a well-written document that clearly defines its methods and criteria for testing.

Control also encompasses future control. One of the most frequently cited observations is the lack of a robust corrective and preventive action (CAPA) system. In warning letters, FDA often cites a company's failure to ensure that any deviations from standard operating procedures are investigated with thorough root-cause analysis and identification of appropriate corrective or preventive actions that minimize the risk of future reoccurrences. Rather than fixing a problem after the fact, these FDA observations now place increasing emphasis on prevention of future recurrences through robust CAPA programs.

Consistency

The second fundamental concept – consistency – considers conformity not only among units in a particular batch of product, but also consistency across quality systems and in the performance of a product across its life cycle. For example, are annual reporting requirements that depict product performance, from in-process testing through shelf life, met? Does the annual report also compare product performance to other lots of the same product?

Consistency may also refer to how a company's standard operating procedures are followed in day-to-day practice. It is crucial to stress the importance of proper training programs to ensure the intent of SOP requirements are met.

One way companies can assess the consistency of their processes and written procedures is by asking two employees performing the same task to describe the process and explain their role. This can be done during training or as part of an internal audit program. Answers may vary, inevitably due to training and experience, but the differences should not be significant enough to impact the final outcome or intent of the procedure.

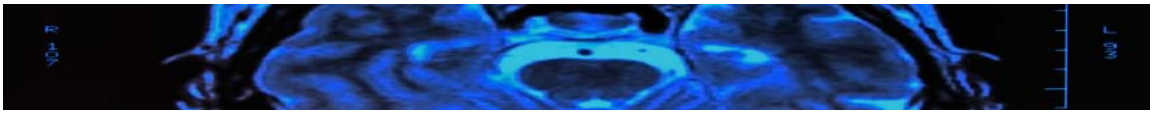
Thus, the concept of consistency encompasses a holistic overview of the pharmaceutical manufacturing process and product life cycle, rather than application to any particular facet of production or batch of product.

Clarity

The third foundational cGMP principle – clarity – requires clear, written procedures, well-defined organizational roles and responsibilities, and transparency and cooperation with regulating authorities.

Clarity necessitates availability of complete, unambiguously written instructions to ensure pharmaceutical employees follow procedures properly and produce consistent results.

Clarity also encompasses well-defined organizational roles and responsibilities. This is important for all roles in the organization equally. Although cGMP regulations specifically assign the quality unit the authority to create, monitor, and implement a quality system, FDA guidance states that "Such activities [of the quality



unit] do not substitute for, or preclude, the daily responsibility of manufacturing personnel to build quality into the product."[7]

Transparency, another aspect of clarity, reflects both a company's transparency of its operations to its employees as well as transparency and cooperation with regulating authorities. For instance, FDA recently issued a draft guidance[8] that further explains the FDA Safety and Innovation Act requirement that a drug is "deemed adulterated" if a factory, warehouse, or establishment delays, denies, or limits an entry or inspection.[9] While the draft guidance lists certain self-explanatory acts of denial or limitation of inspection, less obvious actions are also described, such as failing to provide all requested records, scheduling an unreasonably short period of time for direct observation of the manufacturing process, limiting sample collection, and not allowing photography by an FDA investigator.[10] Companies are well advised to bring such guidance to the attention of senior management and all employees (particularly those who participate in inspections) as part of a robust training plan, as well as during inspection preparation meetings.

Conclusion

cGMP compliance can be facilitated by all personnel involved in pharmaceutical manufacturing and operations who thoroughly comprehend the basic foundational principles. Robust training programs emphasizing these requirements can save companies considerable time, money, and resources for correcting deviations after the fact or forming remediation programs in response to FDA observations. When in doubt, simply recall the three Cs that support the concept of cGMP: control, consistency, and clarity.

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[1] FDA has revised the cGMP requirements for medical devices and incorporated them into the "Quality Systems Regulation." 21 C.F.R. 820. For the purposes of this article, drug and device requirements are described collectively as "cGMPs."

[2] Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. (1938).

[3] A product may be deemed "adulterated," even in the absence of any defects, if the manner in which the product was manufactured did not conform to cGMP requirements. 21 U.S.C. § 351.

[4] FDA's website shows that approximately 75 percent of the warning letters for drug and device manufacturers cited cGMP compliance issues in September 2013 (available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/).

[5] FDA Response Letter to House Oversight and Government Reform Committee Report: FDA's Contribution to the Drug Shortage Crisis from Jeanne Ireland (Assistant Commissioner for Legislation, FDA) to Representative Elijah E. Cummings (July 23, 2012).

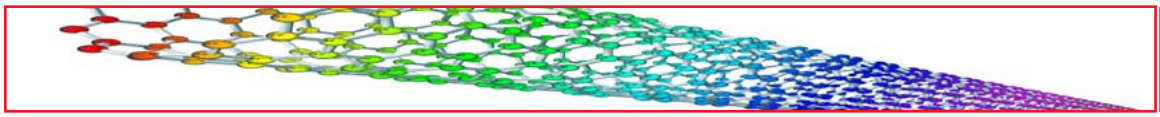
[6] P.A. Benjamin Manufacturing Co., Ltd. Warning Letter, Food & Drug Admin. (January 29, 2013) (available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm338048.htm).

[7] FDA, Guidance for Industry: Quality Systems Approach to Pharmaceutical CGMP Regulations (2006) (available at http://www.fda.gov/downloads/Drugs/.../Guidances/UCM070337.pdf).

[8] FDA, Guidance for Industry: Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection (2013) (available at http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm360484.pdf).

[9] Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, 126 Stat. 993 §707 (2012).

[10] *See id.*



ISO Issues Guidance for Manufacturers Concerning Labeling of Nano-Enabled Products

On December 19, 2013, the International Organization for Standardization (ISO) published guidance on labeling nanoproducts and products incorporating nanotechnology. ISO Technical Specification (TS) 13830:2013, *Nanotechnologies: Guidance on voluntary labelling for consumer products containing manufactured nano-objects,* was developed to better inform consumers about the presence of manufactured nano-objects in particular products. Although voluntary, the issuance of this TS continues the trend of pushing manufacturers to voluntarily disclose in-depth information concerning their nanoproducts and products incorporating nanotechnology as the consumer market for nanotechnologies expands.

Guidance for Labeling Content & Format

The TS provides specific guidance on labeling content and format. For instance, it recommends that a label on a consumer product containing manufactured nano-objects should reflect its nanoscale content by either using the term ***nano*** or ***nanoscale*** in the product's ingredient list or placing the phrase ***contains manufactured nano-objects on the label.***

The product's instructions for use should be provided either on the label or in instructions included with the product, attached to the product, or affixed to its packaging.

The TS recommends the information be "visible, legible and identifiable by consumers, on labels permanently attached to the product itself or (where that is impractical) on packaging in which the product is intended to be kept by the consumer." The labeling itself should be "visible, legible and durable" – for instance, "where the immediate container is enclosed in an outer container or wrapper through which the labelling cannot be read, the label should also be on such outer container or wrapper."

The TS applies broadly to any consumer product "intended to be acquired and used by an individual for personal rather than professional use, excluding its packaging." The TS is not applicable, however, to consumer products containing naturally occurring nano-objects that were not subjected to manufacturing processes, nor does it apply to consumer products containing nano-objects that are incidentally present.

ISO predicts there will be an increasing need for accurate and transparent labeling as the market for consumer products using nanotechnology expands. Because the TS is a "voluntary guidance . . . and is not intended to provide mandatory labelling requirements," product manufacturers and distributors are cautioned to additionally identify and implement applicable legal requirements and guidance issued by regulatory authorities.

Guest Article

Pre-Closing Merger Disputes: Preventing Broken Deals by Navigating MAC Clauses

By Tony Rospert & Hope Lu,
Cleveland Business Litigation Practice

This issue's guest article deals with how to navigate material adverse change clauses (MAC clauses) and prevent merger deals from breaking up. The article examines pre-closing disputes in merger transactions and the role that MAC clauses play in these disputes. Additionally, Tony and Hope review the current state of the law on MAC clauses and discuss how courts interpret materiality under these provisions. Finally, they outline drafting considerations for parties to help mitigate the risk of expensive and uncertain MAC related pre-closing litigation.

Read the full article **here**.

FEATURED WINS

Federal Court Issues Precedent-Setting Maritime Asbestos Order

Since 1986, Thompson Hine has represented hundreds of shipowner defendants in tens of thousands of maritime asbestos cases filed in federal court in Cleveland and other forums. After the courts declined to address personal jurisdiction defenses in 1989 and again in 1993, our team, led by **Hal Henderson**, recently obtained a favorable ruling on multiple personal jurisdiction motions from the court handling the federal asbestos MDL.

On August 26, 2013, Judge Eduardo Robreno of the U.S. District Court for the Eastern District of Pennsylvania issued a memorandum opinion and order granting 418 personal jurisdiction dismissals, primarily of 24 of our shipowner clients. The court found that the Northern District of Ohio (where the majority of the maritime cases were filed) did not have personal jurisdiction over shipowners that did not operate vessels in Ohio waters, even if the shipowners had contacts with Ohio unrelated to the maritime asbestos litigation. The court also rejected the plaintiffs' argument that the shipowners had waived their personal jurisdiction defenses. The court further held that the federal MDL court cannot transfer instead of dismissing cases in which personal jurisdiction is lacking as the plaintiffs had requested, but even if it could, transfer would not be appropriate.

In an opinion and order issued on March 11, 2014 the MDL court reviewed additional materials submitted by the plaintiffs on the waiver issue, again found no waivers of personal jurisdiction and granted another 5,974 personal jurisdiction motions to dismiss. A follow-up order issued April 11, 2014 granted an additional 4,400 personal jurisdiction motions to dismiss. Together, these orders grant nearly 10,800 personal jurisdiction dismissals to shipowner defendants in the federal MARDOC litigation, over 90 percent of which involved motions filed by the Thompson Hine team.

Louisiana-Pacific Affirmed on Appeal (Mostly)

On July 12, 2013, **Kip Bollin** and **Conor McLaughlin** obtained a favorable **ruling** for Louisiana-Pacific Corporation before the Sixth Circuit Court of Appeals.

From the beginning of the litigation, Louisiana-Pacific maintained the plaintiffs were attempting to contort a simple dispute about the evaluation of a claim under the express, written limited warranty relating to Louisiana-Pacific's TrimBoard product into something much bigger. In August 2012, District Judge Carr agreed and dismissed the entire putative class action.

On appeal, the plaintiffs conceded defeat on several of their claims but challenged the District Court's dismissal of five causes of action. After reviewing the briefs and hearing argument from Kip, the Sixth Circuit affirmed the bulk of the District Court's opinion, holding that the plaintiffs' claims under the Uniform Commercial Code, the Ohio Product Liability Act, and the Deceptive Trade Practices Act were properly dismissed. The Sixth Circuit allowed a single claim to proceed – a claim brought pursuant to Louisiana-Pacific's express, written limited warranty – the same claim that Louisiana-Pacific had acknowledged from the start of the litigation.

FEATURED WINS

Appeals Court Affirms Summary Judgment for BASF

In a unanimous **opinion**, the Ninth District Court of Appeals in Ohio affirmed summary judgment for BASF Corporation, a leading pesticide manufacturer represented by **Tim Coughlin** and **John Mitchell**. The panel agreed with the trial court that the plaintiffs could not establish proximate cause for any of their claims due to a lack of general causation expert opinion. The plaintiffs' "expert" attempted to opine that BASF's product, the termiticide Termidor SC, can cause hypothyroidism in humans, a claim he could not substantiate through the medical literature or a proper methodology, and Ohio's Ninth District affirmed his exclusion from offering a general causation opinion and the related no-evidence summary judgment ruling.

The expert was prepared to testify that exposure to fipronil, the active ingredient in Termidor SC, can cause hypothyroidism in humans. However, the trial court excluded his testimony and awarded BASF summary judgment on the ground that his inadmissible testimony was scientifically unreliable and was the plaintiffs' only required general causation opinion. Since the plaintiffs did not have any general causation opinion after the exclusion of their expert, summary judgment was proper because they were unable to meet their prima facie burden of proving general causation. The trial court subsequently awarded BASF a significant cost award.

Firm Wins Summary Judgment for Noranda Aluminum

Brian Troyer and **Bill Hubbard** notched an important win for Noranda Aluminum, Inc. in the first case filed against it by a plaintiff alleging that the company was liable for his developing chronic beryllium disease (CBD). CBD is a progressive, chronic hypersensitivity disease of the interstitial lung tissue caused by exposure to respirable beryllium. CBD results in tissue scarring and declining pulmonary function and can be fatal.

In April 2012, a former Noranda employee filed a federal negligence action against the company and four of its senior officers in the U.S. District Court for the Eastern District of Missouri, alleging that he contracted CBD during the course of his employment at the company's New Madrid, Missouri aluminum smelting plant. This case was the first filed against the company for alleged beryllium exposure and CBD, and the plaintiff was diagnosed at a leading CBD treatment center under Noranda's own voluntary testing program.

The principal legal challenge in the case was recent precedent in Missouri that stripped employers of the "exclusive remedy" defense for occupational disease claims under the Missouri Workers' Compensation Act. As in most states, under the exclusive remedy provision, a Missouri worker's sole recourse for an occupational injury historically had been through the Division of Workers' Compensation. In 2011, however, Missouri courts interpreted a 2005 statutory amendment to reactivate and expand common law remedies for workers, effectively nullifying the exclusive remedy provision and permitting workers to file negligence claims against employers for occupational diseases. In addition, the courts reinterpreted the statute to permit employees to sue co-employees, including officers of the company. These rulings predictably stirred controversy and led the plaintiffs' bar of Missouri to begin organizing to bring large numbers of previously barred occupational disease actions against employers. The business community was correspondingly alarmed.

For four years, the plaintiff received workers' compensation benefits in excess of $70,000, and his claim remained open. Seeking to take advantage of the new legal landscape, however, he filed his common law negligence action against Noranda. Because the new Missouri precedent appeared to permit filing of the action and made dismissal highly unlikely, our team decided to answer the complaint and file an immediate motion for summary judgment, relying upon the plaintiff's receipt of workers' compensation benefits as barring his claim. The court granted Noranda's motion for summary judgment and entered judgment in its favor, finding that the plaintiff's claims were barred by election of remedies, making it unnecessary to rule on the estoppel defense. The court found the plaintiff's receipt of benefits to be a key fact excluding him from pursuing a broader negligence remedy. The court's judgment that a plaintiff's prior receipt of workers' compensation benefits constitutes an election of remedies and bars the filing of a negligence action under the recently established precedent permitting employees to file such actions against their employers sets a critical precedent for all employers in Missouri.

Because this strategy led to the case's resolution before proceeding with extensive discovery, Noranda avoided the costs of extensive discovery.

Partial Summary Judgment for ITW Food Equipment Group

Andrew Cox and **Conor McLaughlin**, representing ITW Food Equipment Group LLC, successfully moved the U.S. District Court, District of Columbia, to exclude the plaintiff's expert's design opinions and for summary judgment against the plaintiff's claim that a meat chopper is defectively designed. The plaintiff was injured when, after removing the meat chopper's feed pan and cylinder guard assembly and using a metal bowl to defeat the meat chopper's interlock, his hand came in contact with the meat chopper's moving parts.

The court agreed that the expert's design opinions were speculative and unreliable because, among other things, he failed to appropriately analyze the risks, costs, and benefits of the meat chopper's design, and he failed to test any of his alleged alternative designs. Without his expert testimony, the plaintiff could not meet his burden of proof regarding the existence of a design defect, and summary judgment was appropriate on that claim.

Plaintiff Forced to Voluntarily Dismiss PPG

Our aggressive defense of PPG resulted in the plaintiff's voluntary dismissal of his conspiracy allegations against the company. The plaintiff contracted lung cancer, which he attributed to his employment at a facility in Bloomington, Illinois that chrome-plated vacuum cleaners. This was the most recent in a string of cases brought by the same plaintiff's counsel on behalf of other employees from the same manufacturing plant, rather successfully, based on theories of employer intentional tort, product liability, negligence, failure to warn, and conspiracy against manufacturers and suppliers of asbestos, nickel, and chromium. PPG was at risk of becoming another frequent target.

The plaintiff alleged that PPG participated in a conspiracy to hide or misrepresent the health effects of exposure to chromium. PPG's defense included compiling the relevant historic product literature, the successful preparation and defense of PPG's corporate witnesses, and aggressive requests for admission that forced the plaintiff to admit that he had no basis for his conspiracy claim. This provided the foundation for PPG's state of the art expert

who opined that the warnings contained in PPG's product literature properly identified the known health risks. The defense also included securing the testimony of both a radiologist and pathologist who testified that the plaintiff's lung cancer could not have been caused by exposure to chromium but was more likely caused by his five-pack-a-day, 50-year smoking habit. The case is continuing to trial, and PPG is the only defendant to have been voluntarily dismissed. The team was led by **Tim Coughlin** and **Bill Hubbard** with assistance from **Susan Belman**, **John Hofstetter**, and **Liz Zaucha**.

Firm Wins Voluntary Dismissal for Construction Company in Asbestos Case

In October 2013, an Ohio-based plaintiff filed an asbestos suit in Madison County, Illinois against an Ohio-based construction company and 73 other manufacturer and construction company defendants. The plaintiff alleged that he contracted lung cancer from his exposure to asbestos, in part during the course of his employment with the defendant's company. On behalf of the Ohio-based construction company, **John Mitchell** and **Barbara Lum** quickly moved to dismiss the claim for lack of personal jurisdiction, as neither the plaintiff nor the Ohio-based construction company had any contacts with the state of Illinois. Rather than fight the motion, the plaintiff voluntarily dismissed us from the case in early February 2014.

Sixth Circuit Affirms Victory for Ford in "Unintended Acceleration" Product Liability Action

Linda Buck and her husband filed a product liability action against Ford alleging that a Ford vehicle driven by a third party was defectively designed, causing it to accelerate uncontrollably into a bakery where Mrs. Buck was shopping. The vehicle struck Mrs. Buck and pinned her against a wall, resulting in serious injuries. The Bucks also asserted a claim for failure-to-warn. Our team successfully excluded the testimony of the Bucks' two engineering experts, setting the stage for summary judgment in Ford's favor. The Sixth Circuit affirmed the District Court's order granting summary judgment, agreeing that the Bucks could not prove causation under Ohio law; the Bucks had no technical expert to support their design defect claim. In an attempt to make up for this lack of expert testimony, the Bucks proffered evidence of other incidents. However, the other incidents were not "substantially similar," and were thus inadmissible. Finally, the Sixth Circuit held that Ford had no duty to warn Mrs. Buck of any dangerous condition in the vehicle.

Firm Wins Summary Judgment for Commercial Food Equipment Manufacturer

Another aggressive attack on a plaintiff's expert paid off, as **Elizabeth Wright**, **Andrea Daloia**, and **John Hofstetter** obtained summary judgment in a New York product liability action alleging that a commercial food mixer was defectively designed and the manufacturer failed to warn of the mixer's dangers.

The plaintiff's only liability expert was precluded from testifying. With no expert to offer testimony regarding the plaintiff's design defect claim, we moved for summary judgment on that claim. The court agreed that without expert testimony the plaintiff could not, as a matter of law, prove her design defect claim.

Summary judgment on the failure-to-warn claim was also in order. We argued, and the court agreed, that the manufacturer had no duty to warn of the dangers of the mixer because the plaintiff was a knowledgeable user of the mixer, and the danger complained of was open and obvious as a matter of law.

Firm Secures Partial Dismissal & Sanctions on Behalf of Stanley Black & Decker

In late 2012, 30 homeowners filed a lawsuit against Stanley Black & Decker, Inc. (Stanley) in Pennsylvania state court asserting claims for medical monitoring and costs of response under Pennsylvania's Hazardous Sites Cleanup Act (HSCA), as well as common law claims, relating to alleged groundwater contamination and exposure. Stanley filed a motion for judgment on the pleadings in the spring of 2013, which was granted, dismissing all of the plaintiffs' common law claims as time barred, and limiting their action solely to medical monitoring and costs of response under HSCA. In November 2013, following extensive efforts to obtain delinquent and nonresponsive discovery from the plaintiffs, including filing a motion to compel, Stanley filed a motion for sanctions requesting dismissal of the plaintiffs' claims for their failure to comply with the court's order granting Stanley's motion to compel. The court granted Stanley's motion for sanctions in part, dismissing the claims of 15 of the 30 plaintiffs who entirely failed to respond to discovery, and ordered the remaining 15 plaintiffs to pay Stanley's expenses to pursue the plaintiffs' responses. Stanley continues to defend this lawsuit as to the remaining 15 plaintiffs' claims for medical monitoring and costs of response. **Tim Coughlin**, **Bill Hubbard** and **Devin Barry** are defending Stanley in this action.

OUT & ABOUT

Bill Hubbard participated on a panel discussing endocrine disruptors and developments in causation, dose, and epidemiology at the American Conference Institute's Chemical Products Liability & Environmental Litigation Seminar in Chicago on April 28-29, 2014.

Kip Bollin and **Bill Hubbard** attended the DRI Product Liability Conference, April 9-11, 2014 in Phoenix, during which Bill chaired the Building Products Specialized Litigation Group Workshop.

Gary Glass attended GlobalChem, the Global Chemical Regulations Conference jointly hosted by SOCMA and ACC, in Baltimore, March 3-5, 2014.

Tim Coughlin served as committee vice chair at the DRI Toxic Torts & Environmental Law Seminar in New Orleans on February 20-21, 2014.

Gary Glass presented a webinar on February 14 for ChemAlliance.org as part of its 2014 EHS&S Regulatory Webinar Series for SOCMA members and other interested parties. Gary's topic was "OSHA's Increased Targeting of Chemical Facilities: Are You Prepared?"

Fern O'Brian was a panelist for the "Congress & the Executive Branch: Where's the Beef?" session at the Food and Drug Law Institute's Food Week 2014 conference on February 10. The session addressed legislation and policy changes affecting food stakeholders.

Jen Mountcastle presented "A Good Offense Is the Best Defense: Effective Use of Social Media in Products Liability Litigation" at the ACI Drug and Medical Device Conference in New York on December 11, 2013.

Jen Mountcastle also presented "The Millennial Juror" at the Network of Trial Law Firms Litigation Management: Defend and Protect conference in Laguna Beach, California on November 9, 2013.

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About the Group

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: Andrew H. Cox • Practice Group Leader, Product Liability Litigation, Andrew.Cox@ThompsonHine.com, 216.566.5747.

Established in 1911, Thompson Hine is a business law firm dedicated to providing superior client service. The firm has been ranked among the top four in the country for "Value for the Dollar" and "Commitment to Help" by in-house counsel, and among the top ten firms for client service excellence, according to *The BTI Client Service A-Team: Survey of Law Firm Client Service Performance.* With offices in Atlanta, Cincinnati, Cleveland, Columbus, Dayton, New York and Washington, D.C., Thompson Hine serves premier businesses worldwide.

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4. We will be available when you need us.
5. We will communicate often.
6. We will provide the highest-quality counsel.

What Our Clients Can Do To Help . . .

1. We ask you to share your goals.
2. We want to know your preferences for working with us.
3. We need your feedback.