



The Era of the Global Product Recall Overview of Issues

Product Response Team



One Firm WorldwideSM

Table of Contents

THE ERA OF THE GLOBAL PRODUCT RECALL
OVERVIEW OF ISSUES

PRODUCT RESPONSE TEAM

Presented by:

Jones Day Product Liability Practice

Paul M. Pohl, Practice Chair
Tel: 1.412.391.3939

- Tab 1 Introduction
- Tab 2 U.S. Consumer Product Safety Commission—Overview
- Tab 3 Regulations, Voluntary Industry Standards, and Testing Requirements
- Tab 4 Toxicology Issues
- Tab 5 Class Actions, Aggregative Litigation, and Individual Actions
- Tab 6 Media and Governmental Relations
- Tab 7 Words of Caution About Potential Evidentiary Pitfalls
- Tab 8 SEC Issues and Disclosure Requirements
- Tab 9 Insurance Coverage Issues
- Tab 10 Necessary Provisions, Warranties, and Other “Boilerplate” Language for Contracts With Suppliers of Goods Manufactured Abroad
- Tab 11 Document Retention and E-Discovery Issues
- Tab 12 About Jones Day



Introduction

In the United States, liability for product-related injuries traditionally has been based on concepts of strict liability and negligence, applied carefully by judges on a case-by-case basis while being mindful of the limited role of the courts. Today, however, a new era has dawned. Class-action litigation, plaintiff-skewed jurisdictions, “big dollar” contingent-fee counsel, activist attorneys general, and legal actions based on public nuisance and recalls are now commonplace. And aggressive and novel lawsuits, nationwide class actions, and well-publicized settlements have only encouraged the plaintiffs’ bar to prime for their next assaults. The only certainty that product manufacturers have in this climate is that the era of large-scale litigation is not over.

Legal standards for product safety and product recalls cut across many areas of the law and, now, across national boundaries. Such problems can present a dizzying array of issues for in-house counsel to address. The idea that consumer product manufacturers, toy companies, tire manufacturers, paint companies, and product distributors should be viewed as insurers of their products, for indefinite periods of time and regardless of how their products have been used, has been embraced by many Americans—and courts—as a new generational mindset. Viewed against the backdrop of global trade, electronically stored information, government regulations, and media hype, what used to be a basic consumer product issue now has the potential to engulf a company in a multifaceted legal crisis. Companies need to be well armed and well prepared to defend against this trend, given the consequences to the company’s bottom line, the risks of shareholder suits, federal or state inquiries, and the potential for large compensatory and punitive damages verdicts.

Few firms in the United States, or in the world, are better positioned or more experienced than Jones Day to counsel and defend major companies having to face claims of product defect or demands for a recall. We know from experience that busy in-house lawyers often field a host of inquiries daily and have to manage fluid situations quickly. To help, we have designed the materials in this booklet as a practical and useful issue-identification tool.

This booklet is not meant to be an “A to Z” manual that provides complete or definitive answers for every product response and recall problem. It is also not a substitute for calling competent outside counsel if a product crisis arises. Rather, it is a primer to educate and alert companies and in-house counsel to the issues.



We also have identified attorneys who are on the cutting edge of these issues and who face them in their day-to-day practices. We hope that these materials will give you and your team the blueprint you need to be prepared for any unwelcome event.

If your company has the misfortune to come under attack, give us a chance to be your lawyers. Jones Day has proven experience and vast legal capabilities to deal with the many issues relating to product response and recall issues. With more than 2,300 lawyers resident in 30 offices worldwide, we have seen these issues relating to products in the marketplace. We know how to guide you through product recalls, government investigations, relationships with suppliers and customers, the dissemination of post-sale literature and, of course, the defense of litigation arising in single or multiple jurisdictions. Jones Day is distinctly positioned worldwide to provide such counseling.

Paul “Mickey” Pohl
Chair, Jones Day Product Liability Practice



U.S. Consumer Product Safety Commission—Overview

Overview/Agency Background

The U.S. Consumer Product Safety Commission (“CPSC”), created by an Act of Congress in 1972, is the lead U.S. agency charged with oversight of consumer safety as it relates to approximately 15,000 consumer products used in and around the home, in schools, and in recreation.

With some exceptions, “consumer product” is broadly defined to include any product sold to a consumer for personal use in or around a residence.

- A list of products over which the CPSC asserts jurisdiction may be accessed at <http://www.cpsc.gov/businfo/reg1.html>.
- A list of products for which mandatory standards have been issued can be found at <http://www.cpsc.gov/cgi-bin/regs.aspx>.
- The CPSC does *not* have jurisdiction over foods, drugs, cosmetics, medical devices, firearms and ammunition, boats, motor vehicles, aircraft, or tobacco. A list of products over which the CPSC does not have jurisdiction may be accessed at <http://www.cpsc.gov/businfo/notcpsc.html>.

The CPSC is fundamentally charged with protecting the public from “unreasonable risks of injury and death” associated with the consumer products within its jurisdiction. Companies involved in the manufacture, importation, distribution, or sale of these products may be subject to CPSC jurisdiction and oversight.

Entities subject to the CPSC’s jurisdiction must notify the agency when they obtain information “which reasonably supports the conclusion” that a consumer product:

- Fails to meet a consumer product safety standard or banning regulation;
- Contains a defect that could create a substantial product hazard to consumers;
- Creates an unreasonable risk of serious injury or death; or
- Fails to comply with a voluntary standard upon which the CPSC has relied under the Consumer Product Safety Act (*e.g.*, voluntary standards). *See* discussion of voluntary standards at Tab 3.

CPSC duties extend beyond the mere oversight of consumer product recalls. The agency also maintains an injury information clearinghouse, establishes safety standards for certain products, and assists outside organizations in developing safety standards.

CPSC Recalls—Important Questions and Planning Issues

Generally—Where to Begin:

- Does your company have a system in place for maintaining and reviewing information about your products that might suggest a product defect resulting in an “unreasonable risk of serious injury or death,” such as consumer complaints, warranty returns, insurance claims or payments, or reports of production problems?
 - How do you judge whether a product has a defect that “presents an unreasonable risk of injury”?
- Should your company’s “early warning” system include sufficient product testing?
- Does your company have a reasonable “Corrective Action Plan” in place in the event of a need to implement a recall?
- Does your company have a system in place for maintaining and reviewing information about its product distribution in case there is a need to notify consumers of a defect?
 - Is your company in a position to implement that notification as efficiently and economically as possible?
- What are the typical components of a program used to notify consumers of a defect and/or to recall a defective product?
- Do your contracts with other entities in the supply chain address recall issues, including indemnification for recall-related or CPSC-related costs? *See* discussion at Tab 10.

Interacting With the CPSC

Before you interact with the CPSC, make sure you have answers to the following questions, as they may have significant consequences as a product situation escalates or a crisis progresses.

- When must you contact the CPSC?
- How does the CPSC determine whether a product has a defect and whether the risk of injury or death attributable to the defect is significant?
 - What is the significance of the defect categories (Class A, Class B, Class C)?
- If you are conducting an internal investigation, must you report the results of that investigation?
 - What specific information must be reported?
 - Is the information supplied to the CPSC treated as confidential? *See* discussion at Tab 7.
- What is the extent of the CPSC’s authority to determine whether remedial action is necessary or to direct the scope of any subsequent remedial actions?
- What is the Fast Track Product Recall Program?
 - What are the ramifications of opting to participate in this program?

Penalties Associated With Consumer Product Safety Act (“CPSA”) Violations

Penalties and Fines for CPSA Reporting Violations

There are defined penalties associated with violations of the CPSA, which makes it unlawful for any person to manufacture for sale, offer for sale, distribute in commerce, or import into the United States:

- Any consumer product that does not conform with a consumer product safety standard, or
- A hazardous product banned by the CPSA.

The term “consumer product” in § 2064(b) means each individual unit of a product, rather than the product line as a whole. *United States v. Mirama Enters., Inc.*, 387 F.3d 983, 987–89 (9th Cir. 2004).

The CPSC need not actually prove the product at issue is defective before penalties for reporting violations can be assessed. A fine of \$5,000 (each violation) may be imposed for “knowingly” violating the rule.

A company generally commits a separate offense for every potentially dangerous unit it fails to report. The CPSC will deem it a separate offense for each product involved, unless:

- The person is not a manufacturer, private labeler, or distributor of the product involved (retailer liability), and
- The person did not have actual knowledge that distribution or sale was a violation, or of a notice from the CPSC that distribution/sale was a violation.
 - Note: A single internal CPSC memorandum regarding potential hazards associated with a product is insufficient to constitute actual knowledge that the CPSC is adequately informed as a matter of law. *United States v. Advance Mach. Co.*, 547 F. Supp. 1085, 1089–92 (D. Minn. 1982).

Upon a company’s failure to make a timely report to the CPSC, the violation accrues and continues. The statute of limitations will not begin to run “until a report is filed or the [company] acquires actual knowledge that the Commission is adequately informed.”

- Illustration: A distributor of electric kitchen appliances received 23 complaints that a particular juicer model was dangerous and defective. The distributor estimated that 30,000 to 40,000 of these juicers had been distributed throughout the U.S. but did not report this fact or the number of consumer complaints to the CPSC. After being specifically asked for a report by the CPSC, the distributor reported only the 23 complaints. Several months later, at the recall stage, the distributor was sued by the U.S. for violation of the reporting requirements. The distributor’s failure to report *each* potentially dangerous product sold or distributed for sale to consumers was a separate offense, bringing the total number of offenses to somewhere between 30,000 and 40,000.
- Compliance with the CPSA or its rules does not provide relief from civil liability.

Federal Causes of Action Other Than CPSA Violations

At least one case charged a corporation with committing mail and wire fraud during its recall program under the Racketeer Influenced and Corrupt Organizations Act (“RICO”), 18 U.S.C. §§ 1961–68. The complaint alleged that the company misled the CPSC and consumers about its dishwashers’ defects and fraudulently induced consumers to buy its new products. The complaint further alleged that the company used income derived from racketeering to operate the recall program.

- Result: The manufacturer and the California class-action plaintiffs reached a settlement agreement, which the trial court preliminarily approved. Class-action plaintiffs from suits in other states sought to intervene and objected to the settlement. One of the intervenors’ arguments was that the trial court lacked subject matter jurisdiction over the case. The court of appeals held that the trial court had federal question jurisdiction based on the RICO claims. While the court of appeals did not express an opinion as to the likelihood of success on the RICO claims, it did find that such claims were sufficiently nonfrivolous to warrant federal question jurisdiction. *Churchill Vill., L.L.C. v. Gen. Elec.*, 361 F.3d 566, 573–75 (9th Cir. 2004).

Punitive Damages Alert

While the CPSA itself does not provide for punitive damages, whether punitive damages will be allowed for CPSA claims is a matter of state law. *Wahba v. H&N Prescription Ctr., Inc.*, 539 F. Supp. 352, 355–58 (E.D.N.Y. 1982); compare *Baas v. Hoyer*, 766 F.2d 1190, 1195–96 (8th Cir. 1985) (not only did the CPSA fail to provide for punitive damages, but it specifically precluded them).

Injunction Issues

Companies also may be subject to an injunction prohibiting them from importing, distributing, or selling toys that were banned as hazardous substances under the Federal Hazardous Substances Act (“FHSA”) and the CPSA.

- Compare: One injunction was denied where the court found that the toy company was working hard to avoid future violations, had stopped selling all toys that qualified as banned hazardous substances under the FHSA and CPSA, and had “successfully executed every product recall requested by the CPSC.” In addition, the seller repeatedly sought guidance from the CPSC in improving quality control, but the CPSC refused to provide assistance. The deciding factor in the court’s decision not to grant the injunction, however, was that the seller had hired an outside lab “to design and implement a comprehensive testing and inspection program.” *United States v. Toys “R” Us, Inc.*, 754 F. Supp. 1050, 1058–61 (D.N.J. 1991).

Criminal Penalties

- Criminal penalties may also be imposed.

For more information on this topic, please contact
Peter Biersteker (Washington) at 1.202.879.3939 or
Harold Gordon (New York) at 1.212.326.3939.



Regulations, Voluntary Industry Standards, and Testing Requirements

Product manufacturers subject to safety standards under the Consumer Product Safety Act are required to certify that a product conforms to applicable consumer product safety standards. The CPSA requires that the certification specify all applicable standards, be furnished to any distributor or retailer to whom the product is delivered, and be based on a test of each product or “upon a reasonable testing program.” The CPSC also may “by rule prescribe reasonable testing programs for consumer products which are subject to consumer product safety standards under [the] Act.” (15 U.S.C. § 2063(a)(1–2)). Compliance with the CPSA and its associated standards is critical to ensuring product safety.

The CPSC works in conjunction with the private sector to develop product standards. The CPSC may also adopt industry-issued voluntary standards (rather than issue its own) when they are shown to adequately reduce the risk of injury to the consumer. There are hundreds of separate tests, technical requirements, and design specifications either mandated by federal regulation, recommended by the American Society for Testing and Materials (“ASTM”), or promoted by other voluntary standard-setting organizations. These tests and specifications run the gamut and may include very stringent tests for certain enumerated product types, including products used by children, such as use-and-abuse tests, tests for sharp points and edges, and flammability tests.

Regulatory and Mandatory Standards Generally

Consumer Product Safety Standards (15 U.S.C. § 2056)

Consumer product safety standards include performance requirements and requirements that a product be marked with warnings or instructions. These requirements must be “reasonably necessary to prevent or reduce an unreasonable risk of injury” associated with a product.

Banned Products (15 U.S.C. § 2057)

There are two requirements for banning a product: (1) the product presents an “unreasonable risk of injury”; and (2) there is no feasible CPSC standard that would protect the public from the unreasonable risk of injury.

Notification and Repair or Replacement Parts

There is also a duty to inform placed on the manufacturer, distributor, and retailer if they have information that a product: (1) does not comply with a consumer product safety rule or voluntary standard; (2) contains a defect that could create a substantial risk of injury to the public; or (3) creates an unreasonable risk of serious injury or death. A manufacturer, distributor, or retailer need not inform the CPSC of a hazard of which it knows the CPSC is already aware.

Consumer Products Used by Children

The CPSC has established an extensive testing regimen for many consumer products. However, no products are as closely regulated as those manufactured for use by children. More than 100 separate tests and design specifications are mandated by federal regulation or articulated (through voluntary procedures) by the American Society for Testing and Materials.

- **General Testing Requirements**—The general testing requirements promulgated by the CPSC are broad and govern many consumer products intended for use by children:

- **Use-and-abuse tests** (16 C.F.R. §§ 1500.50, 1500.51, 1500.52, 1500.53, & 1500.54.):

The objective of these tests is to describe specific test methods for simulating normal “use and abuse” of toys and other articles intended for children. Such tests include:

- Impact tests (*i.e.*, dropping the article 10 times from a height of 4.5 feet onto a particular impact medium);
- Bite tests (*i.e.*, running the article through an engineered viselike device to simulate a child’s bite);
- Torque tests (*i.e.*, testing toys with projections, parts, or assemblies that a child can grasp with his thumb and forefinger or teeth); and
- Tension tests (*i.e.*, testing the article with different tension loads).

Testing requirements vary according to intended use by age (*e.g.*, over 18 months but not over 36 months of age, or over 36 but not over 96 months of age).

- **Tests for toxic substances and primary irritant substances** (16 C.F.R. §§ 1500.40 & 1500.41).

- **Technical requirements for determining sharp points in toys and other articles intended for use by children under the age of eight:**

- The sharp-point test is used by the CPSC in making a preliminary determination whether points on toys and other articles intended for use by children under eight years of age present a potential risk of injury by puncture or laceration under § 2(e) of the Federal Hazardous Substances Act.
- Exemptions to this test include bicycles and full-size and non-full-size baby cribs (all subject to other regulations discussed herein).

- **Technical requirements for determining sharp metal or glass edges in toys and other articles intended for use by children under the age of eight:**

- The sharp-edge test is used by the CPSC in making a preliminary determination whether metal or glass edges on toys and other articles intended for use by children under eight years of age present a potential risk of injury by laceration or avulsion under § 2(s) of the Federal Hazardous Substances Act.
- Similar exemptions apply.

- **Tests for identifying toys and other articles intended for use by children under three years of age that present choking, aspiration, or ingestion hazards because of small parts.**



- **Methods for testing sound pressure levels produced by toy caps.**
- *Product-Specific Testing Requirements*—The CPSC has even more stringent requirements for specifically identified products used by children, including full-size and non-full-size baby cribs (on which component-spacing tests are performed, which check the distance between slats, spindles, crib rods, and corner posts), rattles, pacifiers, bicycles, bicycle helmets, bunk beds, and children’s sleepwear (which is tested for flammability).
- *Testing Facilities*
 - According to the Toy Industry Association (“TIA”), larger manufacturers typically have their own in-house testing laboratories to ensure that products meet safety standards.
 - Those manufacturers without testing facilities may use independent testing laboratories. Several such facilities are recommended by the CPSC and the TIA.

Voluntary Testing Standards

In addition to these government-issued mandatory standards, there are hundreds of standard-setting organizations that provide standards and recommendations to manufacturers. These standards, by themselves, do not have the force and effect of law, nor do the standard-setting organizations have authority to levy penalties or fines for noncompliance. In some cases, however, the federal government will adopt the voluntary standards, thus giving them legal effect. In addition, evidence of compliance or noncompliance can have a powerful impact in personal injury litigation regarding issues of state of the art, negligence, recklessness, and punitive damages. A manufacturer should ascertain whether any voluntary standard for its products has become legally binding because of its adoption by a government agency.

American Society for Testing and Materials (“ASTM”) (<http://www.astm.org>)

This organization comprises 30,000 voluntary members, which have developed more than 12,000 standards related to consumer products. The ASTM sets forth its own toy specifications, which provide recommendations for, among other things, age-labeling, toy packaging, material quality, flammability, and ventilation. The ASTM also has more specific product standards for toy chests (ASTM F734-84) and for home playground equipment (ASTM F1148-97a).

- ASTM toy safety standards:
 - ASTM F963 was developed in 1986 in collaboration with the toy industry’s trade association, the Toy Industry Association, and is enforced by the CPSC.
 - F963 addresses “possible hazards that may not be readily recognized by the public and that may be encountered in the normal use for which a toy is intended or after reasonably foreseeable abuse.” See <http://www.astm.org>.
 - F963 includes test criteria for paint and surface coatings, pacifiers and rattles, toy-cap noise levels, electrical-thermal toys, chemistry sets, sharp edges and points, small parts that could be swallowed or inhaled, use-and-abuse testing, hazardous substances, and flammability.
 - F963 provides direction for age-labeling, packaging, and shipping. It also covers testing methods for toy safety (not product performance or quality) for toys intended for use by children under the age of 14.

- Exemplar requirements:
 - Material quality: Material shall be assessed visually by an unaided eye and should be visually clean and free from infestation.
 - Wires and rods: If protective components are removed after tension tests, parts shall be free of sharp points and edges.
 - Cords and elastics in toys: If cords/elastics can tangle or form a loop in connection with any part of the toy, the loop shall not permit the passage of the head probe.
 - Ventilation: A minimum of two openings each with total area of at least one square inch placed at least six inches apart.
 - Battery-operated toys: Tests for stalled motors.
 - Exemptions include bicycles and tricycles; slingshots; crate items; sporting and camping goods; athletic equipment; musical instruments; and powered models of aircraft, rockets, boats, and land vehicles.
- Revisions published in 2003 include new requirements for pompoms, battery marking, labeling and flammability, battery-operated toys, battery-operated ride-ons, and acoustics and hemispheric toys.

Toy Industry Association ("TIA") (<http://www.toy-tia.org>)

This trade association historically functioned under the guidance of the National Bureau of Standards and developed a voluntary safety standard for all toys in 1976, which was updated under the ASTM standards in 1986. The TIA follows the current safety standard set forth in ASTM F963-07, Standard Consumer Safety Specification on Toy Safety, published in 2003.

The TIA also has a Safety Standards Committee, which was formed in the early 1930s and today is composed of a Quality Assurance or Safety Executive from each member company. This committee maintains an active role in standard-setting processes.

The American National Standards Institute ("ANSI") (<http://www.ansi.org>)

ANSI accredits individual standard-developing organizations like the Consumer Specialty Products Association, the National Electrical Manufacturers Association, the Rubber Manufacturers Association, and Underwriters Laboratories. ANSI does not develop any standards itself but instead sanctions private organizations that adhere to its standard-setting process. ANSI is also the U.S. representative to the International Organization for Standardization ("ISO").

Underwriters Laboratories ("UL") (<http://www.ul.com>)

The UL is an independent, nonprofit product safety certification organization. Examples of products that the UL tests are marine products and lifesaving devices; fire-suppression/containment equipment; industrial, mechanical, and automotive equipment; and heating, air conditioning, and refrigeration products. The UL will certify a product submitted by a manufacturer during its development process that is favorably tested by UL engineers.



National Institute of Standards and Technology (“NIST”) (<http://www.nist.gov>)

NIST (f.k.a. the National Bureau of Standards) coordinates federal activities in voluntary standards to ensure U.S. representation in international standards organizations. NIST makes sure that government agencies are aware of voluntary standards being developed and coordinates those standards with the appropriate agency where practicable. NIST also serves as a reference point for determining applicable standards and responds to public inquiries regarding standards.

International Testing and Reporting Standards

Canada: Health Canada

Health Canada, a federal department, is responsible for helping Canadians maintain and improve their health and carries out testing and research in investigating chemical, flammability, and mechanical hazards of consumer products. Most tests are designed to verify that products conform to existing safety regulations and standards.

International Organization for Standardization (“ISO”) (<http://www.iso.org>)

This organization is composed of the national standards institutes of 157 countries. The ISO develops its standards by relying on 193 distinct technical committees consisting of experts in the relevant disciplines. The ISO has developed more than 16,500 international standards and is recognized as the prominent worldwide standard-developing organization. The U.S. representative organization is ANSI.

The ISO conducts no safety testing itself, leaving the responsibility to the member organizations or manufacturers. The ISO’s standards are developed by a technical committee composed of experts in the field. The experts serve as national delegates, chosen by the ISO national member institute for the pertinent country. The technical committee meets to debate and discuss standards until it reaches a consensus. It has a review process for members and the public before finalization.

International Council of Toy Industries (“ICTI”) (<http://www.toy-icti.org>)

This organization is made up of toy trade associations from around the world and lists international safety standards on its web site.

European Union (“EU”) and RoHS (<http://www.rohs.gov.uk>)

The EU also has toy safety standards (EN-71) and RoHS, an EU directive restricting the use of certain hazardous substances in electrical and electronic equipment. RoHS also governs consumer products. Specifically, RoHS limits the amount of lead, cadmium, mercury, and other metals in electrical and electronic equipment.

Proposed Safety Testing Standards

According to media reports, some toy makers are calling for mandatory safety testing for all toys sold in the U.S. The proposal calls for “uniform standards for frequency of testing, to determine at what point during production the tests would be conducted, and what specific hazards, whether lead paint or small parts, must be checked for.” The proposal also outlines global requirements for laboratories that conduct safety testing.



The media also noted that the CPSC (which would presumably help enforce these standards, if enacted) had at one time only one full-time toy tester at its national laboratory. The CPSC publishes an Engineering Test Manual for its staff members who test toys and children's articles for compliance with CPSC regulations. These test manuals, however, provide guidance only and do not supersede or limit CPSC regulations.

Other Duties to Test

In the United States, there is no common-law "duty to test" consumer products, regardless of where they are manufactured. However, such a duty may be subsumed or encompassed by other common-law duties, such as the duty to refrain from selling defective products or the duty to design, manufacture, or warn about products in a nonnegligent manner. Even absent an express duty to test, the existence (or absence) of a history of testing may be powerful evidence bearing on liability for compensatory and punitive damages. The reasonableness of a decision to test or refrain from testing may depend on, among other factors, where in the distribution chain the defendant lies, the degree of involvement in the design or manufacture of the product, and the particular defendant's knowledge about the dangers of the product.

Liability for negligence or strict liability extends throughout the product distribution chain from manufacturer to retailer, and different jurisdictions have developed, by statute or court precedent, exceptions to the general rule.

For more information on this topic, please contact
Jim Johnson (Atlanta) at 1.404.521.3939 or
Tom Fennell (Dallas) at 1.214.220.3939.



Toxicology Issues

Lawyers who understand scientific issues can help guide a company through the testing and requirements thicket. This is especially true when questions of toxicity and health risks are raised.

Even companies with exacting standards and strict quality controls may on occasion produce a product that contains impermissible levels of a chemical, contaminant, or other regulated compound. A thorough understanding of the actual health risks presented by a nonconforming product is essential for developing a sound strategy for handling recalls, personal injury claims, and other actions that may arise from the introduction of a product into the marketplace. It is important to know the potential ramifications of producing a nonconforming product. It is equally important to know—and communicate—that just because a product may not comply precisely with each and every standard doesn't mean that the product poses a health risk.

The unique facts and circumstances surrounding each nonconforming product will determine the level of risk analysis required. In many instances, a nonconforming product is identified and quarantined before reaching the consumer. In such cases, the risk analysis would be straightforward—no exposure, no risk. But in those situations where a nonconforming product reaches the consumer, a more in-depth analysis is warranted.

An objective assessment of the analytical methods used to identify the impermissible levels of a chemical or contaminant provides one basis for interpreting the potential risk posed by the product. In some cases, additional product testing is warranted to determine whether the results can be replicated. Additional testing may also be conducted to determine the variability of the test results. Analyses that characterize the concentration of the chemical or contaminant in a product provide one aspect of understanding the potential health risk. But even potentially hazardous compounds present a health risk only to the extent that they can get into the body in a bioavailable form at a sufficient dose and for a sufficient duration.

To address these issues, it may be prudent for a company to conduct its own risk assessment. Risk assessments vary in scope and complexity and depend on the product at issue. For example, sometimes it is necessary to generate empirical data regarding the amount of the compound that could be getting into the body in a bioavailable form from a product. In other cases, a materials characterization analysis may suffice to determine the phase of the compound, the matrix, and other characteristics that may make the compound more or less bioavailable.

Similarly, an exposure-pathway analysis might be prudent to help a company define and understand the likely routes by which the compound could get into the body, *e.g.*, dermal absorption or ingestion, under foreseeable-use scenarios. Empirical tests designed to simulate those likely exposure pathways can then be conducted to determine the likely dose and the implications of that dose on biologically relevant indices assuming acute and chronic exposure scenarios. These types of results provide an objective assessment of the potential health risk posed by a so-called nonconforming product.

The unique facts and circumstances surrounding each nonconforming product will determine the level of risk analysis required and help the company to determine the appropriate action. Through the combined efforts of in-house scientists and relevant outside experts and testing labs, the proper balances can be

struck. When companies are armed with favorable results from a well-designed, biologically based risk assessment, allegations of health-related injuries can be defended from a position of strength and science.

For more information on this topic, please contact
Cynthia Driscoll, Ph.D. (Pittsburgh), 1.412.391.3939.

Class Actions, Aggregative Litigation, and Individual Actions

Litigation frequently follows closely in the wake of product recalls and other widespread product problems. The nature and extent of litigation often will be a function of the perceived risks of injury or other health or accident concerns associated with the product. But today's plaintiffs' bar also continues to pursue "no injury" class-action claims in many situations.

Any company (and its management and board) should recognize that significant product recalls and other well-publicized product problems are likely to generate a surge of claims and lawsuits, including any and all of the following types of litigation:

- Individual personal injury cases
- Consumer class actions
- State attorney general/regulatory investigations and cases
- Securities and/or shareholder derivative actions
- Consumer class actions in Canada
- Inquiries and investigations by foreign regulators

Typically, the number of cases and type of litigation claims will track factors such as the extent to which health issues or injuries have been (or can be) associated with the product, the publicity profile of the product problem, the size of the recall, the significance of the product in the company's overall business, pre-recall performance failures and related claims, and the perceived value of the recall remedy and relative difficulty in obtaining it. In addition, no matter what the claim history or litigation relating to the product may be before the recall, there is likely to be a surge of cases in the weeks following any recall announcement, including the possibility of multiple, overlapping consumer class actions and shareholder suits.

There is no "one size fits all" approach to defending product-related lawsuits. There are, however, some key concepts that can serve the company well in addressing the litigation.

- There must be total coordination across the various types of litigation and across the geographic reach of the cases.
- The company will be best served by having one lawyer, or firm, directing the litigation response and a team structure with very focused responsibilities for all counsel who are involved in the defense effort.
- The company should establish a protocol of priorities or steps in connection with the litigation.
- Sometimes it is best to wait for the litigation to "stabilize." Understanding the full scope of the litigation and having an informed appreciation of the real risks presented by the various cases are essential to establishing priorities, structuring the right total defense, and deciding on the best procedural steps.

- It is important to decide as soon as realistically possible on the endgame for the litigation and to develop a proactive plan designed to maximize the possibility of achieving it.

Proactive management of anticipated litigation is essential for an efficient and effective defense. While it obviously is not possible to control everything that adversaries or courts may do, in many situations, it is possible to move the litigation along a path designed to maximize the defense effort. For example, you can use effective case management and, where appropriate, available procedural tools, such as Class Action Fairness Act removals, federal and state MDL coordination, bifurcated discovery plans, and focused motion practice.

You might engage the court and attempt to tightly manage discovery. If possible, get the court involved to narrow the extent and scope of document collection and production requirements.

You may structure defenses and motions to narrow the issues and eliminate peripheral claims. Select motions to achieve early wins and litigate only issues that can have a meaningful effect on costs and/or the ultimate outcome. Where possible, defer the creation of document systems or databases until the issues have been focused and the court has ruled on the scope of discovery.

You should also establish a program to investigate and understand the facts fully. The importance of this cannot be overstated. You should recognize that a real understanding of the facts is critical to the defense and to the company's ability to develop a strategy for resolving the matters and to advocate positions on motions and in discovery. This is not necessarily a "no stone unturned" effort; rather, it should be structured to ensure that the litigation team has a complete factual understanding of the essential events, decisions, and product issues. Put in place protocols to ensure that factual matters are reviewed once and relevant factual materials are organized and preserved in usable formats for ongoing reference and use.

Finally, decide as early as possible whether some—or all—claims need to be resolved through settlement. Some settlements generate more claims; some matters cannot be quickly resolved, while others should be quickly resolved. This issue needs to be the focus of careful and rigorous deliberation from the start. If settlement is desirable, develop the priorities for settlement and the preferred mechanisms to maximize the benefits of the settlement initiative. Establish a proactive plan and, if possible, pursue settlements in order of priority. Even if settlement is the preferred outcome, recognize the need to develop the evidence for trial and, when necessary, to be credible about the company's willingness (and readiness) to try appropriate cases. At a minimum, this may require developing the essential trial themes and presentation outlines, engaging key experts and developing their analysis, working to develop admissible evidence to present the facts, and focusing on the right company personnel to provide necessary testimony. In appropriate cases, it may also mean relatively early retention of jury consultants and graphics experts. And all of these tasks must, for the good of the company, be done in a cost-effective manner.

For more information on this topic, please contact
Hugh R. Whiting (Cleveland) at 1.216.586.3939.



Media and Governmental Relations

There is a recognized and real-time correlation between media coverage of a product recall and subsequent lawsuits. Often, the more critical the media, the more lawsuits are filed. Communicating with the media and governmental officials, including law enforcement, concerning the product at issue is necessary and essential in most situations. Thus, a program to effectively manage communications related to a product glitch is crucial.

It is critical to identify, balance, and address a wide range of public and governmental interests in designing an effective communications program. This is no easy task, as there can be multiple competing public and governmental interests. For example, a company might face federal congressional inquiries and hearings about the product subject to a recall. At the same time, all 50 states have variations on attorney general investigations, state consumer protection laws, and Hazardous Substance Act violations. State departments of health and environment have regulations that are likely to be applicable, and state legislatures may initiate their own inquiries and hearings.

In the early stages of a crisis, there will be understandable pressures to be responsive to inquiries, to speak, and to “make things right.” Special care must be used because it is likely that the factual information at this stage will be incomplete. Unless properly managed, miscommunications can not only negatively affect governmental inquiries but also impact subsequent private litigation. Anything and everything said in response to these various constituencies will be scrutinized later in litigation. What is said to appease a noisy regulator, congressman, or investor group can become the headline admission in the plaintiff’s class-action brief or opening statement at trial. Given this, a disciplined approach to internal and external communications is essential. The company must have a working group that includes communications professionals, management representatives, and inside and outside counsel. Coordination between near-term required regulatory filings, advertisements, public statements, and the protocol for addressing consumer inquiries is crucial.

In developing a communications plan, keep in mind that the issues that typically surface will include at least the following:

- Responding to congressional investigations and related hearings;
- Responding to state attorney general investigations and multistate coordinated efforts;
- Coordinating corporate communications and protection of the attorney-client privilege;
- Utilizing corporate public affairs, government relations, and outside consultants;
- Handling media investigations and reporters; and
- Using company spokespersons and those with expertise with the media and government officials.

**For more information on this topic, please contact
Tony Dias (Pittsburgh) at 1.412.391.3939 or
Mary Ellen Powers (Washington) at 1.202.879.3939.**



Words of Caution About Potential Evidentiary Pitfalls

Media communications, governmental inquiries, and interaction with the CPSC can have immediate impact and long-term effects on business and on litigation. There are some important points to keep in mind as a company navigates these delicate matters.

Correspondence Between CPSC and Manufacturer May Be Discoverable

Confidentiality provisions in the CPSA do not necessarily prohibit discovery of correspondence between the CPSC and a defendant because these provisions limit disclosure *only by the CPSC*, not by a private party in a civil action. *Winstanley v. Royal Consumer Info. Prods., Inc.*, No. CV-06-281-PHX-DGC, 2006 U.S. Dist. LEXIS 44702, at *2–3 (D. Ariz. June 27, 2006).

Documents produced to the CPSC may be discoverable, as the language of the statute “suggests that the disclosure prohibitions do not apply in a civil discovery situation.” *Id.* A policy argument—that interpreting the statute to allow such discovery would have a chilling effect on companies’ willingness to report to the CPSC—was unconvincing to at least one court because companies are required by law to report and will therefore continue to report so as to avoid violating the law, regardless of whether the information may be discoverable in a private civil action. *Roberts v. Carrier Corp.*, 107 F.R.D. 678, 682–83 (N.D. Ind. 1985).

Be Careful of Well-Intentioned Statements, Which May Be Deemed Party Admissions at Trial

Some press releases regarding voluntary recalls may be admissible at trial as a party admission under Fed. R. Evid. 801(d)(2)(A)–(C). In at least one reported decision, a court found portions of a press release indicating that certain electrical components in toys could “overheat and cause fires” relevant under Fed. R. Evid. 401 because they made it more probable than not that the toy caused the plaintiff’s house fire. *Zeigler v. Fisher-Price, Inc.*, 302 F. Supp. 2d 999, 1021 (N.D. Iowa 2004).

The Very Action of a Recall May Be Used by a Plaintiff to Suggest a Defect at Trial

Even evidence of similar hazards in similar (not necessarily the same) products can preclude summary judgment. *Riley v. De’Longhi Corp.*, No. 99-2305, 2000 WL 1690183, at *4 (4th Cir. Oct. 30, 2000) (*per curiam*).

In one case, documents and information about similar accidents involving a different model shredder were relevant and therefore discoverable if the plaintiff could show “threshold relevance” by explaining the similarities in the two product models. The defendant’s conclusory statement that two product models were “completely different designs” was not enough to overcome this. *Winstanley v. Royal Consumer Info. Prods., Inc.*, No. CV-06-281-PHX-DGC, 2006 U.S. Dist. LEXIS 44702, at *4–5 (D. Ariz. June 27, 2006).

Self-Critical Analysis Privilege May Not Protect Certain Documents From Trial

At least one court has held that there is no uniform federal self-critical analysis privilege. Thus, while the CPSA may prevent a plaintiff from discovering information held by the CPSC, any similar information held by the defendant will likely be discoverable because the CPSA does not preclude such discovery. *See*



Lawson v. Fisher-Price, Inc., 191 F.R.D. 381, 383–85 (D. Vt. 1999). (Whether or not this privilege is available is generally a state-law issue.)

To the extent that some courts recognize this privilege, they will apply it only under the following standards: (1) privileged materials “must have been prepared for mandatory government reports”; (2) “[a]ny privilege extends only to subjective, evaluative materials”; (3) “[i]t does not extend to objective data in the same reports”; and (4) discovery is denied “only where the policy favoring exclusion has clearly outweighed plaintiff’s need.”

- The first standard has been interpreted to mean that only documents generated specifically for required reporting to the CPSC would be privileged. Thus, documents created for other internal reasons and merely provided to the CPSC would not be privileged.
- Additionally, even documents created specifically for the CPSC may not be entirely privileged because, based on the third standard, any objective data in the documents would not be privileged. Therefore, the available privilege is very narrow. *Roberts v. Carrier Corp.*, 107 F.R.D. 678, 684–85 (N.D. Ind. 1985).

For more information on this topic, please contact
Sharyl Reisman (New York) at 1.212.326.3939 or
Dennis Murphy (Cleveland) at 1.216.586.3939.



SEC Issues and Disclosure Requirements

In addition to litigation, regulatory, and common-law duties associated with a product recall, publicly traded companies are likely to have to consider a number of disclosure and other securities issues when faced with a potential recall or product-defect situation. Issues will arise quickly, and real-time judgments must be made that, if handled correctly, could limit a company's exposure to potentially significant liabilities. This process can be facilitated to a significant degree by early involvement of outside securities and disclosure counsel, who can bring to bear prior experience and harness the resources of the firm's lawyers.

Current Public Disclosures

Public disclosures such as earnings guidance need to be reviewed and monitored to determine whether updates or other revisions are required. It is critical to balance the need to update the market against the company's ability to provide meaningful disclosure, since markets do not like uncertainty.

Additional Disclosure Obligations

If the company is otherwise planning to address the market (*e.g.*, at a securities analyst conference), management should consider whether otherwise undisclosed information relating to the recall needs to be disclosed concurrently or, alternatively, the planned disclosure should be postponed. Statements made in such circumstances by management will be scrutinized in any resulting litigation.

Companies should take great care to ensure that communications to the public and consumers are consistent with those made to the investment community. Companies need to review the Securities and Exchange Commission ("SEC") current disclosure requirements mandated by Form 8-K (required to be provided within relatively short time periods, generally within 48 hours to four business days of the occurrence of the event to be reported), since a number of the 8-K items could be implicated by a product recall, including:

- Entry into, or termination of, a material definitive agreement (which could be required, depending on the significance of the relationship, and course of action pursued, with the supplier of an affected product);
- Triggering events that accelerate or increase a direct financial obligation (which could be required if the effect of the recall on a company's results of operations or financial condition leads to a covenant compliance issue under a senior credit facility or indenture);
- Material charges for impairment to assets; and
- Changes in management.

As events relating to a recall mature, the longer-term impact of the recall on the company's disclosure (*e.g.*, in the MD&A section of an issuer's quarterly and annual reports) should be considered. Risk factor disclosure in a company's SEC registration statements and/or periodic reports should be reviewed to determine whether such disclosure adequately and accurately describes the risks associated with the company's products, specifically insofar as the product subject to the recall and the circumstances surrounding it are concerned.

Companies that are in the midst of a securities offering or have a currently effective SEC registration statement (*e.g.*, a selling stockholder resale shelf) need to consider the impact of the recall on the offering and, in the case of an already effective registration statement, whether sales should be suspended. If a recall arises when a company's trading window is open, companies should consider whether the ability of the company's employees to trade in its securities should be suspended pending disclosure of material information.

Effective internal communications are the real key to addressing the myriad disclosure issues that are likely to arise in the product-recall context. A number of constituencies will be involved, with a major role likely played by a company's public relations and investor relations functions. A company will be better positioned to effectively manage the process associated with a recall by implementing an integrated communications strategy that involves in-house and outside securities and disclosure lawyers at an early stage and at each step of the process to address these critical issues.

For more information on this topic, please contact
Chris Kelly (Cleveland) at 1.216.586.3939 or
Ward Winslow (Chicago) at 1.312.782.3939.



Insurance Coverage Issues

Any business with a product that has been recalled, or threatened with recall, should address a number of issues regarding its insurance. First, it should identify all insurance policies that may provide coverage for all or part of its expenses, potential liability, and costs of defense. Second, it should analyze those policies to determine their scope of coverage. Third, it should provide notice to its insurers. Finally, it should take care not to prejudice or compromise its insurance rights in its dealings with other entities also involved in the recall. Experienced counsel can assist clients in assessing their insurance situation and providing appropriate guidance with respect to coverage decisions.

Identify Insurance Policies Potentially Providing Coverage

Several different kinds of insurance policies may provide coverage for all or a portion of the expenses and liabilities associated with a recall. It is essential that the policyholder conduct a careful canvass of its current and past policies to identify the policies that may provide such coverage.

Types of Insurance

Some businesses have *Product Recall* insurance that expressly covers the cost of recalling their products from the market. In addition, virtually all businesses have a *Commercial General Liability*, or “CGL,” policy. Among other things, such policies may cover liability incurred because of bodily injury resulting from a product defect. Lawsuits instituted in the wake of a recall may allege liability for bodily injury resulting from exposure to a subsequently recalled product. In addition, these policies may be interpreted to provide coverage of liability for long-term medical monitoring of those who allege that they may have been injured by exposure to a product. Alternatively, some businesses have purchased separate *Products Liability* insurance policies potentially covering these sorts of liabilities.

Occasionally a business that has not manufactured a recalled product is nonetheless made a party to lawsuits seeking damages resulting from exposure to that product. For example, a food broker might be involved in a suit alleging that a contaminated food product injured a class of plaintiffs. Intermediaries of other sorts could find themselves involved in similar situations. These businesses may be covered by *Errors & Omissions* (“E&O”) liability insurance policies.

Finally, officers and directors of a business whose product has been recalled may be subjected to suits by security holders alleging that the officers or directors have breached their duty of care to the corporation or have made misrepresentations relating to the product that have affected the value of securities issued by the corporation. *Directors & Officers* (“D&O”) liability insurance may provide coverage against these alleged liabilities.

In identifying policies that may provide coverage, it is important to distinguish between *occurrence-based* and *claims-made* policies. Occurrence policies provide coverage against liability for harm that occurs during the policy period, regardless of the year when a suit alleging liability for that harm is instituted. An occurrence policy issued for a prior policy period may therefore provide coverage of liability alleged in a lawsuit brought in the current year. In contrast, claims-made policies provide coverage of liability for claims made during the policy period, as long as the harm alleged in the suit occurred subsequent to a

specified date in the past. Which type of policy potentially covers recall expenses, defense costs, or liability will depend on the nature of the allegations in question.

Make a Coverage Assessment

After identifying all potentially applicable insurance policies, the policyholder should make an assessment of the coverage provided by these policies, in light of the claims that have been or may be made against the policyholder. Here, the critical questions will turn on the nature of the allegations made against the policyholder, the particular terms of the policies that may provide coverage, and prior interpretations of similar policies' coverage terms by the courts of the state whose law will govern the policyholders' claims.

One particular coverage issue is worthy of special emphasis. Product recalls are often followed by class actions alleging that members of the class who have been exposed to or used a dangerous product are entitled to long-term medical monitoring to protect their health. Whether the allegations in such suits fall within standard liability insurance policies' coverage of liability incurred "because of bodily injury" is likely to be a central issue in any claim for coverage of defense costs or liability for medical monitoring costs. Because state law governing the right to coverage for medical monitoring liability varies, selection of the appropriate state in which to bring a coverage suit may prove to be outcome-determinative.

Provide Notice to the Insurers

All insurance policies require, in substance, that the insurer be provided notice of a claim or suit made against the policyholder as soon as is practicable. Some policies require, or at least permit the policyholder to provide notice of, a "circumstance" that may lead to a claim or suit, and thus to preserve application of the policy in question even if a claim or suit is not brought for some time thereafter. Policyholders are sometimes reluctant to provide their insurers with notice of a claim, or notice of a "circumstance," out of fear that their next year's premiums will be increased as a result. This is a legitimate concern, but failing to provide notice may cost a policyholder its insurance coverage—a good deal more than the amount of an increased premium. The decision whether and when to provide notice to the insurer should therefore be made carefully and with an eye on the policyholder's long-term interests. Prior to giving notice, it is important for the policyholder to know if there is a particular advantage to the policyholder under the law of any state whose law may apply to a coverage dispute. This circumstance could affect the strategy of giving notice.

Each policy is likely to specify the appropriate method of providing notice. Some policies provide that notice is to be given to the insurance broker through which coverage was placed. Even when notice is to be given directly to the insurer, some policyholders rely on their brokers to assist them in providing notice. Although this is an appropriate practice, caution is in order.

Communications between a policyholder and its insurance broker may not be privileged. Anything a policyholder tells its broker may be subject to discovery by an insurer in a lawsuit between the policyholder and its insurer or insurers. Consequently, policyholders should exercise care in communications with their brokers. Ideally, counsel who will be involved in the policyholder's claim for coverage should approve the content of those communications, in order to avoid giving the appearance of making admissions to the broker that may ultimately find their way into the hands of the policyholder's insurers.



Do Not Inadvertently Waive Your Insurance Rights

Businesses subject to product recall, or to tort liability involving recalled products, frequently have rights of contribution or indemnity against third parties. A manufacturer may have such rights against the supplier of a component part, for example, or a wholesaler may have such rights against the manufacturer. There is a natural inclination for such parties to agree to share the costs of defending against such actions or to agree on their respective shares of liability in the event that they are held liable.

This inclination should be resisted, despite the fact that there may be otherwise good business reasons for settling with these parties. By the terms of virtually all insurance policies, an insurer is “subrogated” to the insured’s rights against third parties. Because a policyholder’s compromise of its rights against third parties interferes with its insurer’s subrogation rights, most courts hold that such a compromise voids the policyholder’s insurance coverage. Consequently, it is essential that policyholders be aware that their dealings with third parties associated with a product recall or with subsequent suits arising out of the recall may affect their right to insurance coverage. Do not inadvertently waive your insurance rights in dealing with third parties.

Where there is doubt or uncertainty, consult with counsel sooner rather than later. An insured should not depend primarily on the insurance broker for definitive advice about what is or is not covered or how to proceed in a crisis.

For more information on this topic, please contact
Tom Sear (New York) at 1.212.326.3939 or
J.W. “Jack” Montgomery or Mike Ginsberg (Pittsburgh) at 1.412.391.3939.



Necessary Provisions, Warranties, and Other “Boilerplate” Language for Contracts With Suppliers of Goods Manufactured Abroad

There are ways to protect yourself from some of the pitfalls described in this booklet during the contracting process. Indeed, many important considerations come into play when contracting with suppliers of products and goods, particularly those manufactured abroad. Careful planning and appropriate contractual language can assist companies in managing and reducing the risks involved in such arrangements. Regular monitoring of supplier compliance with contractual provisions is another important ingredient in managing the risks presented by foreign supplier contracts. Reassessment and analysis of current supplier contracts can also help identify potential areas of concern as well as areas for future negotiation and modification.

Set forth below are some of the issues typically presented when contracting with suppliers of foreign-manufactured goods. At Jones Day, we work closely with our clients to develop effective strategies and procedures to address these issues and to manage and reduce the risk of disputes and potential future liability.

Defining the Relevant Quality Specifications and Requirements

It is essential that the relevant product quality specifications be spelled out in an appropriate fashion in any supply contract. Obviously, these specifications will vary in each individual circumstance, depending on the products or goods involved. Contract provisions typically require that: (1) the products conform to certain predefined quality specifications or measurements; (2) the goods are free of any defects; and (3) the goods are of merchantable quality and fit for their intended use. It is also important for supply contracts to require compliance with all applicable laws, standards, and regulations relating to quality and safety (*e.g.*, CPSC, FDA, NHTSA, RoHS). In light of the recent publicity surrounding product recalls, increased governmental regulatory activity can be expected with respect to the importation and sale of many foreign-produced goods.

Formalizing and Documenting Quality Control Programs

Incorporating the appropriate quality standards into the supply contract is just the first step. Purchasers also can help ensure that the relevant quality and safety standards are met by requiring foreign suppliers to implement formal documented quality control programs. Depending on the specific products involved, these programs typically include certification of subcontractors or subsuppliers as well as testing of product components and raw materials.

Audits, Inspections, and Product Testing

Expressly providing for periodic audits and inspections is another method typically used to help verify compliance with quality and safety standards. Contractual provisions typically: (1) address the manner and method of such inspections; (2) require access to facilities, documentation, and supplier cooperation; and (3) provide for corrective action where necessary. When product quality and safety are of particular



concern, it is often necessary to establish a specific sampling and testing regime for products at different stages of the manufacturing process.

Federal Foreign Corrupt Practices Act ("FCPA") Compliance

Under certain circumstances, it may be appropriate to incorporate into foreign supplier contracts provisions requiring the supplier to comply with the FCPA. The FCPA generally prohibits certain improper payments to foreign officials intended to induce or obtain business.

Indemnification

Appropriate indemnification provisions can be incorporated into supplier contracts indemnifying the purchaser from certain liabilities that arise from the supply of products that: (1) do not meet contract specifications; (2) are substandard in quality or otherwise defective; and/or (3) are subject to a recall. Indemnification provisions typically spell out the circumstances under which indemnification will arise, the remedies available to the purchaser (*e.g.*, return or replacement of goods and setoff), and the procedures to be followed (*e.g.*, notice and defense and settlement of claims) in the event that a claim for indemnification is to be made.

Liability Insurance

Contracts with foreign suppliers should contain provisions that require suppliers to be adequately financed to meet any monetary obligations they may incur under the supply contracts. Foreign supplier contracts can also contain provisions requiring suppliers to maintain insurance policies to insure against specific contingencies and containing specified minimum coverage limits.

Dispute Resolution

When problems arise with foreign suppliers, it is particularly important to have specific mechanisms in place to resolve disputes effectively. Certain obstacles are presented by these situations, as foreign suppliers: (1) may not have assets in the U.S.; (2) may not be subject to the jurisdiction of the U.S. courts; and/or (3) may be located in countries that would not enforce a U.S. court judgment. Accordingly, supplier contracts should spell out the procedures to be followed when a dispute arises. In certain cases, these procedures may involve mediation and arbitration before appropriate international bodies (*e.g.*, the Hong Kong International Arbitration Centre, the International Court of Arbitration) whose rulings will be enforceable in the countries where the foreign suppliers reside.

The issues that arise in foreign supplier contracts are many and varied, and they are constantly evolving in today's environment. Jones Day has experienced, qualified professionals who will assist clients in addressing these issues to effectively manage risk and reduce the potential for future liability.

For more information on this topic, please contact
Dana Baiocco (Pittsburgh) at 1.412.391.3939 or
John Edwards (Silicon Valley) at 1.650.739.3939.



Document Retention and E-Discovery Issues

There are some very important issues that are easy to lose track of in a crisis but should be addressed early, rather than later, to protect a company's interests. These issues include, among others, document retention, litigation holds, and e-discovery.

Document Retention Issues

Litigation "Holds"

Generally, litigation holds should issue promptly upon the occurrence of an event that results in: (1) the reasonable anticipation of litigation; (2) a government agency investigation or subpoena; or (3) an official request for information. Events that "trigger" the duty to preserve documents and data are not based on consistently applied objective or subjective legal standards. Clearly, the service of a complaint or subpoena, or receipt of a governmental agency demand letter, are triggering events. Events that precede formal notice of a legal action are more ambiguous and may or may not be retrospectively viewed as a trigger. Given the absence of clear and consistently applied legal standards, corporations and their legal counsel should consider the nature of the matter and their experience with similar matters and act in a reasonable manner under the circumstances.

Who should issue the litigation hold notice?

It is frequently advisable to have the communications effectuation come from company executives or managers of sufficient rank to emphasize the importance of the hold. Corporations should be mindful that some courts find litigation hold notices to be privileged, while other courts do not. In some circumstances, a corporation may want the notice to be "not privileged" so that it can be used as evidence of good-faith preservation efforts.

Who should receive litigation hold notices?

Litigation hold notices are generally sent to all relevant departments, employees, and records custodians; to records management administration; and to the information technology department. "Relevant" means document custodians and departments that are reasonably likely to have information pertinent to the subject matter, claims, and defenses of the litigation. In certain circumstances, the notice may be sent to third parties, *e.g.*, suppliers, service providers, or agents, that may have potentially relevant information not duplicated within the company.

What information should be provided in the litigation hold notice?

Generally, litigation hold notices should contain: (a) a description of the litigation, investigation, or subpoena; (b) a description of the subject matters at issue; (c) an identification of the categories of documents, electronically stored information ("ESI"), nonstandard media (*e.g.*, video and audio tapes and disks), and things (*e.g.*, returned recalled products); (d) the means or method(s) to preserve certain categories of ESI (*e.g.*, emails) subject to preservation; and (e) the person(s) to contact if recipients have questions. The litigation hold may also identify the time period covered by the hold and the importance of

compliance and might also include a certification sheet. The notice should identify a point of contact who keeps records of inquiries and makes judgment calls on a consistent basis.

Other Litigation Hold Considerations

Follow-up meetings or contacts with key document custodians might be considered to: (a) ensure that information is being preserved in compliance with the litigation hold notice; (b) answer any open questions regarding scope and method of preserving potentially relevant ESI; (c) identify where potentially relevant ESI is (or might be) located; (d) inquire as to other possible sources of potentially relevant information; or (e) provide information regarding when and how potentially responsive information will be collected.

Meetings with key custodians may be particularly important where preservation of ESI requires specific technical actions by the custodian.

Additional litigation hold reminders may be appropriate if the hold is ongoing (*i.e.*, encompasses ESI created after the issuance of the hold) or if the scope of the hold is modified as the litigation or investigation evolves. Monitoring and internal audits of litigation hold compliance may also be appropriate in circumstances where compliance might prove cumbersome or require actions on the part of custodians beyond ordinary business procedures, *e.g.*, identifying and preserving potentially responsive sent and received emails.

ESI and the Litigation Hold

ESI storage devices and media must be considered when making preservation decisions. Considerations include whether to preserve: (a) mainframe and server hard drives (including shared drives); (b) personal computer hard drives; (c) PDAs (including cell phones and multipurpose devices); (d) backup tapes; (e) personal computer peripheral storage (thumb or key chain drives, computer disks, peripheral hard and zip drives, zip tapes, and disks); and (f) home computers.

The categories of ESI subject to preservation consideration, as an initial matter, include:

- Stored word processor (*e.g.*, MS Word), spreadsheet, and presentation (*e.g.*, MS PowerPoint) files;
- Emails and attachments;
- Voice mail;
- Instant messages;
- Team sites and SharePoint;
- Intranet postings;
- Databases and related applications; and
- Company web sites.

In some instances, communications with suppliers are through internet connections or dedicated, secure web sites that also may be subject to preservation. In addition, the company's IT personnel must be involved so that you know what is kept, what is available, and what is in danger of being lost.



E-Discovery Considerations

The volume of potentially relevant ESI in a complex product recall or liability litigation has dramatically increased in recent years, reflecting the growth of the creation, communication, and storage of digital information. The volume and distinctive characteristics of ESI can lead to substantial discovery burdens, costs, and risks of onerous discovery orders and potential discovery sanctions. More important, the discovery process is the source of rebuttal and affirmative evidence.

Strategies to Mitigate the Costs and Risks of ESI Discovery

- Corporations can mitigate burdens and risks by being proactive in the retention, litigation preservation, disclosure, and production of ESI. A proactive approach requires careful planning, preparation, and the development of internal expertise and witnesses to coordinate electronic discovery issues.
- Approaching Rule 26(f)¹ and Rule 16(b) conferences with a prepared, reasonable plan positions the corporation to state what it has done and to have greater influence on how the discovery of ESI will proceed as opposed to taking a defensive position that may advantage an aggressive opposing party and frustrate the court's likely desire to avoid discovery disputes and discovery-related delays.

Categories of ESI That Are Not Normally Saved Beyond Immediate Business Use

Some categories of ESI, *e.g.*, some types of data not backed up, are ephemeral and not intended to be stored after user access or the conclusion of an exchange of information. Whether such information should or must be preserved has not been resolved. To the extent that preserving such information is not possible, is technologically impracticable, or would require extraordinary efforts, *e.g.*, significant modification of existing software or substantial impact on ongoing business activities, the company might decide not to preserve. When decisions to not retain ephemeral data are made, the bases of the decision should be documented to demonstrate the reasonableness of the decision and mitigate the risk of a spoliation claim.

Dealing With Computer Application Protocols That Automatically Delete or Overwrite Data

Some applications are designed, or have user options, to delete or overwrite data, including potentially relevant ESI, after a specified time period or a specified action, *e.g.*, email system operating protocols that delete emails after a set number of days and databases that overwrite historic data when new data is entered in a field. Consideration of the practicality of suspending such protocols until alternative preservation procedures have been adopted may be advisable.

Backup Tapes

Extant backup tapes may also be considered for preservation to the extent that the tapes are reasonably likely to contain potentially relevant information *not duplicated in another location*. For example, the most recent set of backup tapes of email platforms may be the source of potentially relevant emails that may have been deleted from active email accounts (mailboxes) before a litigation hold was issued. In other circumstances, backup tapes may be the only available means to preserve certain types of ESI, at least until other means can be considered.

¹ Unless otherwise specified, references to rules are to the Federal Rules of Civil Procedure.

Inaccessible ESI

Rule 26(b)(2)(B) provides that a party need not produce ESI that the party identifies as not reasonably accessible due to cost and burden. The rule does obligate the party to identify not reasonably accessible ESI that will not be searched and produced. “Not reasonably accessible ESI” might include legacy computer systems or older backup tapes created for disaster recovery and not used in the ordinary course of business or used for litigation preservation. The rule applies to the production of ESI, *not* preservation. Accordingly, not reasonably accessible ESI that *is* reasonably likely to contain potentially responsive information should be preserved, identified if called for at Rule 26(f) conferences or in response to Rule 34 requests for production, and objection lodged to production.

Corporations, however, are under no obligation to search every nook and cranny to locate not reasonably accessible ESI. Conducting searches in locations where potentially relevant ESI is reasonably likely to be found should be acceptable so long as the company accurately states the scope of its searches if an inquiry is made or disclosure required.

The Preferred Forms and Format for ESI Preservation

In general, it is advisable to preserve ESI in native electronic format. This form preserves metadata and hidden data that may be required for production, and native formats may prove to be the most efficient form of production for some categories of ESI. For example, “print and retain” methods of preserving potentially relevant emails and attachments do not retain metadata and hidden data and may be found deficient by some courts.

Special consideration might be given to the preservation of dynamic databases and datasets that contain or constitute potentially relevant ESI. Information technology staff can provide information pertinent to the management and business retention of applications and datasets in order to make judgments regarding whether business retention schedules satisfy litigation preservation. To the extent snapshots of datasets may be required, IT personnel can determine the most cost-effective format for preservation and possible retrieval and searching.

Other E-Discovery Considerations

How and by Whom Are Reviews of Collected ESI Conducted?

Because of the likely volume of ESI, reviews are potentially costly and time-consuming. The principal issues to be resolved, in addition to costs, are: (a) the degree to which search technologies can be reliably employed to identify potentially responsive information and reduce physical reviews; (b) the personnel needed to conduct different reviews, *e.g.*, contract attorneys, outside counsel staff attorneys; (c) the use of vendors or entities other than outside litigation counsel to conduct reviews (including review by non-U.S.-based vendors); (d) the method of documenting the review; and (e) the method of retrieving and transferring the knowledge acquired in the review to litigation counsel.



In What Form or Forms Should ESI Be Produced in Litigation? What Are the Benefits of Each Form of Production?

Each form of production has benefits and drawbacks.

Native formats. Production in native formats of certain categories of ESI may offer substantial savings in production costs but present other issues, including the review of metadata (particularly for privilege); the possible need to provide the receiving party with proprietary software applications to open files; difficulties in Bates-like numbering to track produced information; ensuring the integrity of the information produced; and, if necessary, redacting information for privilege.

Images with searchable text and selected metadata. TIFF or PDF images with searchable text files resolve some of these issues while providing the searchability required by Rule 34.² The cost of conversion to image formats with associated searchable text files and selected metadata fields is an additional factor to consider.

Fixed images and hard copy. Fixed-image formats and hard copy are less searchable by automated means. They usually require agreement as to the form of production, some form of index to open the images, and possibly a searchable index as well, and they also involve costs to convert ESI to hard copy and/or image format. In addition, metadata and hidden data are excluded. The advantages of hard copy and fixed images include ease of numbering and, in general, efficiency in the review and redaction for privilege.

Are There Additional Issues to Be Considered if ESI Has to Be Collected From Foreign Locations?

If a company is required to collect and produce ESI from foreign offices or facilities or from vendors or suppliers in a foreign location, an assessment of the impact of privacy laws or regulations, data protection statutes and regulations, and so-called blocking statutes may be needed.

Are Records Retention Policies Related to ESI Discovery?

Written records retention policies and schedules that are applied in a disciplined, consistent manner can lessen ESI discovery burdens and concurrently reduce the risk of spoliation claims and possible sanctions. Records retention policies that address ESI and that cross-reference or incorporate policies pertinent to internet, email, instant messaging, PDA, and home computer usage can assist the company in specifying the reasonable scope of ESI discovery and provide the basis for the defense of spoliation allegations. These policies also can incorporate or reference litigation hold procedures that suspend ordinary-course retention schedules and identify the department or personnel responsible for issuing holds.

² Pursuant to Rule 34(b)(ii), absent agreement by the parties, the producing party must produce in a form that is “reasonably usable.” The Advisory Committee Comments to the rule state that a form of production is not reasonably usable if it is less searchable for the requesting party than it is for the producing party.

Additional Considerations:

- How should dynamic databases and datasets be preserved?
- Who should collect and process ESI for litigation?
- What needs to be done to prepare for Rule 26(f) conferences?
- Are there greater risks of inadvertently producing privileged ESI?
- Are clawback agreements or quick-peek agreements necessary?

The issues related to ESI and discovery can be overwhelming, but they cannot be ignored. The sooner a company gets control of its ESI, the easier the process will be down the road.

Discovery, records retention, and e-discovery issues are obviously not unique to product-recall situations. Every business should have good practices in place to deal with these concerns. In this era, many significant litigation matters are being profoundly affected by discovery and e-discovery issues. Employees should be sensitive to what is communicated via email. Companies must be vigilant in dealing properly and ethically with these issues as soon as litigation surfaces. In addition to being able to counsel clients on these matters in the context of product-related issues, Jones Day has established an e-discovery team that counsels clients on an ongoing basis. Needless to say, this is an area where we believe the proactive study and development of best practices will avoid costly problems later.

**For more information on this topic, please contact
Steven Bennett, chair of the Jones Day E-Discovery Committee (New York),
at 1.212.326.3939 or
Laura Ellsworth (Pittsburgh) at 1.412.391.3939.**



About Jones Day

Tracing our origins to 1893, Jones Day now encompasses more than 2,300 lawyers resident in 30 locations worldwide and ranks among the world's largest and most geographically diverse law firms. Surveys repeatedly list Jones Day as one of the law firms most frequently engaged by U.S. corporations, and many of our lawyers have achieved national recognition in their disciplines.

Our commitment to our clients has repeatedly earned the Firm the No. 1 ranking for client service by The BTI Consulting Group, including in its most recent survey. The award is based on survey results from *Fortune* 1000 corporate counsel. In fact, since the inception of the BTI Client Service Ranking seven years ago, Jones Day is the only firm to have earned top ratings year after year. In every survey, Jones Day has ranked in the top five, and our consistent high ratings have earned the Firm a place among the elite few firms elected to the BTI Client Service Hall of Fame.

The Firm was named "Labor & Employment Department of the Year" in 2008 by *The American Lawyer*. In 2004, the Firm was also named Product Liability Department of the Year by *The American Lawyer*, as well as a top-five finalist for Litigation Department of the Year. Thomson Financial, one of the foremost authorities on financial-industry performance, ranked Jones Day No. 1 for number of M&A deals completed worldwide in each quarter since the end of 2000.

The Firm acts as principal outside counsel to, or provides significant legal representation for, more than half of the *Fortune* 500 companies, as well as a wide variety of other entities, including privately held companies, financial institutions, investment firms, health-care providers, retail chains, foundations, educational institutions, and individuals.

Jones Day is an integrated partnership that operates as one firm worldwide, and this structure brings the appropriate talent and experience from across the Firm to bear on matters originating in any office. Our goal is to demonstrate sensitivity to our clients' objectives and understand the economic issues, industry trends, and client concerns implicated by the problems, transactions, and controversies brought to our attention.

Additional Information

For additional information regarding Jones Day, please contact your principal Firm representative. General email messages may be sent using our "Contact Us" form, which can be found at www.jonesday.com.



