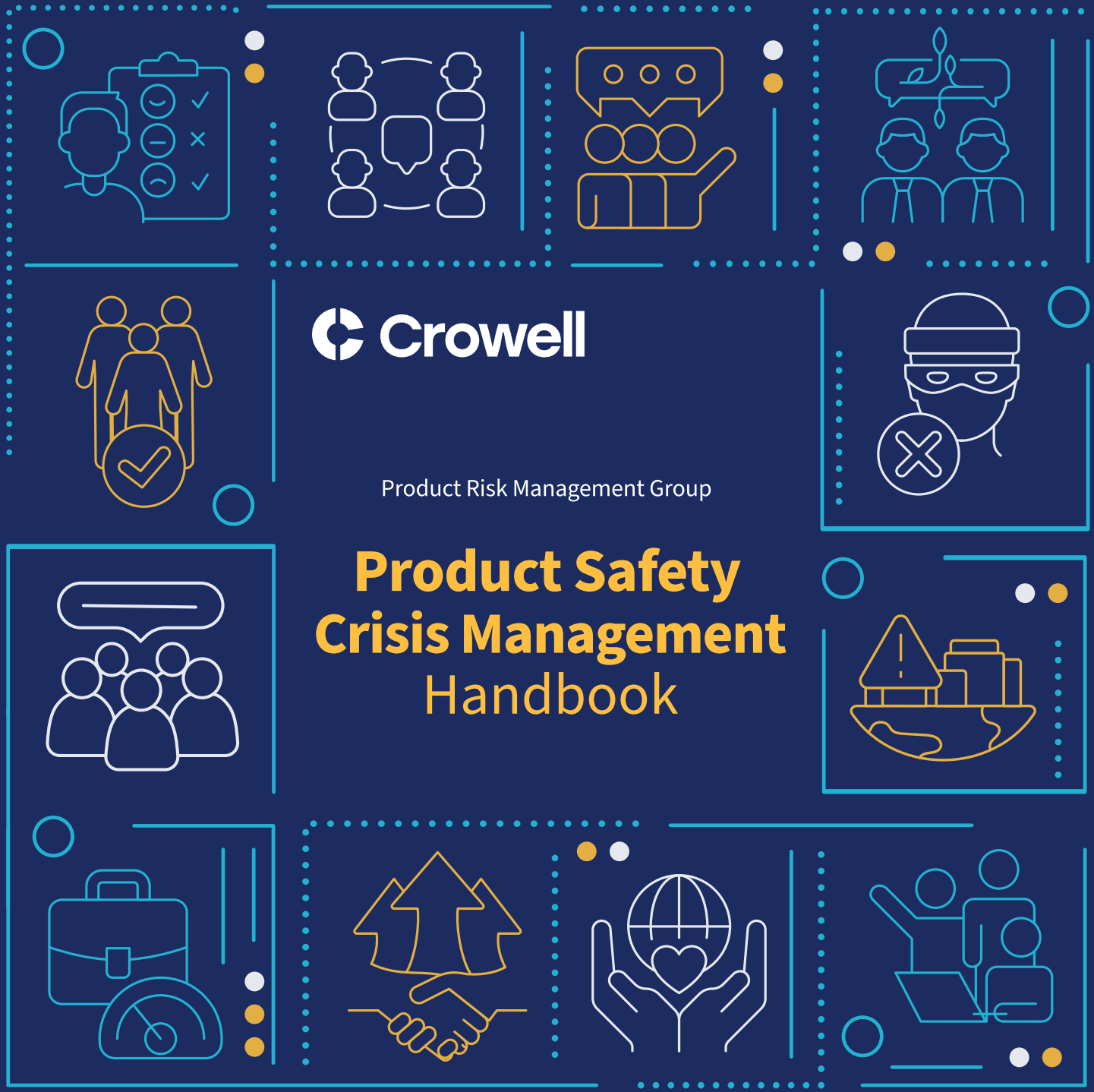

Crowell

Product Risk Management Group

Product Safety Crisis Management Handbook

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ABOUT CROWELL'S PRODUCT RISK MANAGEMENT GROUP

Crowell & Moring's multidisciplinary Product Risk Management team assists companies with identifying and managing the legal risks associated with bringing a consumer product to market and the full product life cycle thereafter. Our practice, the first of its kind, combines over 40 product risk management lawyers and policy professionals. We empower clients with navigating complex legal and regulatory regimes, both domestically and internationally, applicable to the design, manufacture, promotion, and sale of their products and services. Many of our lawyers contributed to authoring sections of this crisis management handbook over the years.

We have a track record of successfully litigating federal and state product liability, consumer protection, and product safety matters, defending federal and state consumer class action litigation, and counseling on product safety regulatory matters, such as mandatory reporting and recall issues.

Business-Focused Support

Embrace Technology. Many of our clients are transforming their businesses from being grounded in traditional product spaces to embracing the latest digital and analytics capabilities. As consumer goods and services become increasingly digitized, our team stays ahead of the curve, from tackling emerging product issues in new technologies to providing advice on the use of artificial intelligence and data analytics for tracking incidents and safety regulatory compliance.

Minimize Risk. We assist clients in developing legal strategies that support business growth and minimize risk in the food, cosmetics, consumer products, and transportation industries. This includes advising and counseling on matters of product safety and liability, advertising and marketing, and intellectual property.

Maximize Value. We work with clients to maximize the value of their products and services, as well as their brands, at every step of the distribution chain, and to minimize unpleasant surprises, whether from litigation, adverse regulatory action, or damage to brand reputation. We manage product recalls and other corrective action from start to finish.

Manage Safety. We help champion the safety of products throughout their lifecycle, reporting to legal departments, senior management, and Boards of Directors on product safety, both before and after product launch. This counseling includes advising clients on how to build and continuously improve product safety compliance programs tailored to industry needs and how to audit their success.

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Cheri Falvey leads Crowell's Product Risk Management practice and is a former general counsel of the Consumer Product Safety Commission (CPSC). A hallmark of Cheri's practice is helping clients launch innovative new products while protecting their brand and reputation, avoid and defend liability in the marketing of their products, build safety and security into their products with science-based risk assessment, and successfully navigate product safety challenges with rapid response. She represents clients on litigation and counseling matters, including product recalls conducted in cooperation with NHTSA, CPSC, and FDA, defending clients in agency enforcement actions, advising manufacturers faced with the potential release of unfair and inaccurate information by the government, and counseling and defending clients on the sale and marketing of consumer products on the Internet, including compliance with the Children's Online Privacy Protection Act, the FTC's Green Guides, and state and federal privacy laws.

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Rachel Raphael advises clients on a range of consumer protection issues with a particular focus on consumer product safety and regulatory compliance. In this role, she helps clients identify and analyze risks associated with new and existing ventures or products; and navigate consumer complaints about the products they manufacture, import, distribute, and sell. Rachel also represents clients in response to inquiries from and enforcement actions by State Attorneys General, the Consumer Product Safety Commission, the National Highway Traffic Safety Administration, and other regulators throughout the globe. She has significant experience litigating commercial disputes on behalf of clients in a wide range of industries. Her practice focuses on a broad spectrum of complex commercial, consumer, and retail litigation, including defending class actions and multi-district litigation.

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Consumer and other product manufacturers lean on Rebecca Chaney's keen understanding of the consumer product industry and the legal landscape to advance their businesses. Rebecca applies her commercial-focused product risk lens to represent product manufacturers facing litigation, commercial, and regulatory challenges. She is an industry-recognized force in litigating complex product-related warranty, defect, indemnity and contractual commercial disputes, and consumer litigation, including in class actions and mass tort proceedings. She counsels her commercial clients on product disputes, risk mitigation, and crisis management matters. Rebecca also serves as co-head of the firm's Transportation Practice.

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Scott L. Winkelman is a partner in the firm's Mass Tort, Product, and Consumer Litigation Group. Scott is co-founder of the Product Risk Management Practice, and co-head of the firm's Transportation Practice. Scott represents clients in class actions, multidistrict proceedings, arbitrations, and other complex litigation in products and commercial matters nationwide. Scott also represents clients in agency proceedings before the National Highway Traffic Safety Administration, the Consumer Product Safety Commission, and related product regulatory bodies. Scott has been recognized by BTI Consulting Group as a 2020 Client Service All-Star. The honor, bestowed by corporate counsel, recognizes attorneys who "stand above all the others in delivering the absolute best in client service. Amid all the changes and unexpected events—they stand tallest."

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Matthew regularly counsels clients on compliance with consumer product safety statutes, regulations, and standards, including the Consumer Product Safety Act (CPSA), Consumer Product Safety Improvement Act of 2008, Federal Hazardous Substances Act, and Poison Prevention Packaging Act. He advises companies on navigating product safety reporting obligations under Section 15(b) of the CPSA, recalls and other corrective action plans, product safety investigations, civil penalties, internal compliance programs and trainings, FOIA requests, and consumer reports filed on the CPSC's safer products database. As a product safety lawyer, Matthew represents manufacturers, importers, and retailers, including those in the following industries: children's products; home appliances; electrical equipment and component parts; fitness equipment; furniture; and emerging and innovative technologies including smart and IoT devices and micromobility products.

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Kieran defends Fortune 500 companies involved in complex products liability and toxic tort litigation pending in federal and state courts across the country. A natural investigator, Kieran often acts as a lead analyst in charge of building the factual record for his clients. He is adept at mining a corporation's archive and synthesizing complex records for use in responding to discovery, preparing both fact and expert witnesses, and developing defenses for his clients. Building on his personal and professional interest in scientific developments, Kieran routinely tracks scientific literature of interest to the Toxic Tort bar, and is adept at quickly understanding complex scientific issues involved in the defense of his clients. He often applies this knowledge to the development and preparation of scientific experts used in litigation.

FOREWARD

When your Brand is at Stake: Developing a Comprehensive, Lasting Approach to Product Risk Management

Worrying about a possible business crisis to a marquee product line or innovation can certainly keep any executive or in-house counsel up at night. Being in the middle of an actual crisis is even more of a nightmare. Whether it is an alleged safety issue, problems with your supply chain, false and misleading competitive advertising claims, seizures at the border, regulatory agency investigations, or full-fledged litigation (just to name a few), product- and brand-related crises can have devastating effects on the bottom line and your company's goodwill with customers and shareholders. Dealing with these crises also creates major disruptions to your business. The good news is that proactive measures do exist and they can position your business to reduce the chances that crises hit, and be ready to act swiftly and effectively to minimize negative fallout when crises are unavoidable.

We intend this handbook to be a guide and an essential reference before you launch a new product line or other innovation–to help you identify potential legal risks throughout the product's anticipated lifecycle and use the tools discussed to minimize, where possible, these potential risks. We also encourage you to consult this book for product lines and innovations already in production, because it is never too late to implement risk avoidance and mitigation tactics. Building risk management into the lifecycle of your innovations, from design and testing through marketing and distribution, is addressed throughout the ensuing chapters. Key issues that arise along the way such as document creation and product stewardship policies are also covered.

In addition, should you find yourself in the middle of a full-fledged legal crisis involving your product, brand, or innovation, this handbook provides quick resources to assist in identifying issues and considerations key to an effective and appropriate response. We have specific chapters devoted to meeting regulatory compliance obligations, primarily focused on the United States but referencing international obligations as well, since products are increasingly sold globally. And the chapters dedicated to government enforcement actions and class action risks provide the ammunition to get C-suite attention to avoiding product safety risks and meeting compliance obligations.

Of course, there is no "one size fits all" approach to legal risk management. Every business and every product or service presents its own unique issues. But the hypotheticals and general principles discussed in this book can help businesses think creatively about ways to minimize—or, better yet, avoid—potential negative impacts.

The purpose of any legal risk management strategy is to help the business grow and achieve its goals with minimal obstacles. Businesses that integrate legal risk management throughout the full lifecycle of their innovations are often best prepared to thrive in any storm. Crowell & Moring's Product Risk Management Group approaches legal risk management from a multi-disciplinary and product life cycle approach, bringing expertise from inside regulatory agencies, the Hill, and the courtroom. Should you have any questions about developing a comprehensive legal risk management strategy for your company, or about any of the issues addressed in this handbook, please feel free to contact us for more information.

Disclaimer

Product Innovation Done Well: Designing Away Risk

Be Proactive: Design in Safety to Design Away Legal Risks

Identifying and addressing hazards proactively at the product design stage can mitigate, or even eliminate, future legal risk, including reducing potential exposure to costly class action litigation. For example, design defect claims feature prominently in product liability lawsuits, with a plaintiff (or class of plaintiffs) claiming that the design of a product is inherently defective or dangerous, rendering every unit of the product defective. Failure to warn claims are also common, alleging that the inherent risk of a design could have been mitigated with proper warnings, but that the manufacturer failed to include such warnings on the product. Because all units of a mass-produced product typically share the same design and bear the same warnings, these claims have the potential to generate costly and burdensome class action lawsuits and personal injury cases. Companies can mitigate these legal risks from the outset by proactively identifying and designing away potential risks, and working with experts, including an attorney, experienced in balancing business goals, consumer demands, and a company's legal risk tolerance, while ensuring compliance with the myriad state and federal applicable laws and regulations.

In designing away risk, carry out a risk assessment to determine how best to reduce the risk and what actions need to be taken. The goal is to be practical, but also informed and aware of potential hazard scenarios that could lead to legal landmines. In some cases, it may be possible to identify alternatives to full-blown risk assessment that can keep costs down and speed the innovation process for a new product. For example, similar products often have similar risk profiles, and compliance with industry standards may serve as whole or partial surrogates in some cases for independent risk assessment.

There are a number of considerations to a design risk assessment, including:

- Ensuring compliance with applicable industry standards, laws, and regulations;
- Identifying inherent risks and dangers in the design and assessing the obviousness of those risks and dangers;
- Gauging the reliability of component part suppliers and identifying critical-to-safety manufacturing processes;
- Developing warnings/education to mitigate inherent risks and dangers;
- Considering the availability/feasibility of safer alternative designs;
- Adding safeguards or other product enhancements to prevent risk; and
- Evaluating the litigation profile of similar products and risks.

Identify, gather, evaluate, and synthesize the relevant information, being mindful about document creation that reflects safety-conscious and defensible decision-making. Document the design specification process to ensure that information is available to be used during subsequent risk evaluation activities and for traceability, product redesign, and legal and regulatory compliance. Consider consulting with technical, scientific, legal, or medical specialists concerning safer design alternatives where appropriate.

Sometimes risks are inherent to the product, cannot be eliminated, and no safeguard is technologically feasible. At that point, a hazard assessment should guide consideration of whether warnings will suffice to reduce potential legal risks within the company's level of tolerance.

An assessment of the potential frequency and severity of possible injuries aids in prioritizing warnings. Evaluate whether proposed warnings, labeling, and advertising comply with state and federal laws, whether they effectively communicate risks of use and reasonably foreseeable misuse, and whether they must comply with or be guided by industry standards or government guidelines. The assessment may also include other considerations affecting comprehension, such as whether the label should include pictures, whether warnings should be in more than one language, and the placement of labels and warnings on the product and packaging. Focus groups of users or consumers can help inform decision-making on warning issues and aid in prioritizing the priority and placement of warnings. Finally, the ANSI Z535 Committee has created six standards to help develop safety and accident prevention information in labeling, product manuals, and instructions.

Design Products with Potential Regulatory Regimes in Mind

A product's design may influence whether and to what extent it is regulated by a local, state, federal, or international agency. For example, a product may be deemed a "children's product" based on certain design features, subjecting it to heightened regulatory standards and a heightened risk profile, even though the manufacturer did not intend the product primarily for children. Expanding into new product areas may warrant consulting with experts experienced in counseling manufacturers and retailers on regulatory compliance to help avoid unintentional (and unwanted) product regulation.

In addition to the design itself, the materials from which a product is made should be chosen carefully, as they may increase or decrease the level of legal risk associated with the product. For example, California has many state-specific requirements concerning the chemicals contained in products sold in the state. Proposition 65 requires the state to publish a list of chemicals known to cause cancer or birth defects or other reproductive harm. This list has grown to approximately 800 chemicals. Companies doing business in the state of California have a duty to provide "clear and reasonable" warnings before knowingly and intentionally exposing anyone to a listed chemical. Any product which could ultimately end up in the state of California is subject to Proposition 65 requirements, even if they are not directly sold in the state.

Warnings can be given in a variety of different ways, including product labeling or posting signs. Penalties for violating Proposition 65 by failing to provide notices can be as high as $4,500 per violation per day, so compliance is critical.

Awareness and consideration of state chemical regulation is playing an increasingly important role in product design. Michigan and California were among the first states to establish a policy encouraging the use of safer, less toxic, chemical alternatives. In addition, Washington, Connecticut, Maine, and Minnesota, among other states, have enacted "green chemistry" legislation, some of which is specifically targeted at promoting safer children's products. Maine and Minnesota have enacted laws that completely ban the sale of any product containing any PFAS chemical, starting in 2030 and 2032, respectively. Considering the potential for state obligations early in the design process may help to avoid expensive alternative analysis down the road, especially if substitute components can be incorporated.

Post-Design Effective Product Stewardship

Pre-launch design risk management doesn't end once the design and materials are finalized. Product stewardship includes conducting product safety and compliance testing, and documenting those efforts as well as monitoring customer complaints and effectiveness of warnings and instructions. Some jurisdictions have imposed an independent "duty to test" in product liability cases, and manufacturers have been held liable where courts have found that defects would have been discovered with reasonable testing. At a minimum, test products to the applicable standards. Good practice, however, may dictate going beyond the standards, such as by simulating foreseeable use and misuse, testing to failure, or simulating a full product lifecycle to evaluate the effect of environmental factors. In addition, monitoring consumer returns or complaints can provide early warning signs of potential issues.

Establish and follow appropriate and legally required documentation and record retention pertaining to design, manufacturing, and product stewardship. Maintaining batch and lot records can help limit the scope of a recall in the event of an unanticipated manufacturing defect or chemical contamination of a product. Documenting the risk assessment process is important, as it captures the company's thinking as to potential problems, and provides evidence of the company's commitment to minimizing and preventing risks and to designing and creating safe products.

Robust risk management that begins at the design stage cannot guarantee a risk-free product. It can, however, reduce exposure to regulatory sanctions and product liability lawsuits, as well as create a more defensible product and a more defensible corporate commitment to product safety, in the event problems do arise.

How Internal Policies and Practices Can Prevent or Fuel a Crisis: Developing an Effective Corporate Crisis Plan

Your company learns that its only product has been reportedly involved in several serious injuries and deaths across the country. Regulatory authorities are aware of the reported incidents, and plaintiffs' attorneys are in contact with your company's counsel. The press is calling corporate headquarters seeking information and requesting a statement. How does your company respond?

This scenario is not uncommon. Developing a corporate crisis response plan—that includes effective communication with various stakeholders—in advance gives your company a greater likelihood of successfully weathering a crisis. These events typically arise quickly, require the expenditure of significant resources, both talent and dollars, and could have long-term effects on the business if not handled properly, reputationally and otherwise. Your company should understand the risks inherent in its business and develop a workable response plan.

Critical Elements of a Crisis Response Plan

Crisis Team. A cross-functional crisis team should be assembled, and team members assigned roles. Clear lines of decision-making authority for the duration of the crisis should be established. The team should brainstorm the scope of the crisis; anticipate all that could go wrong as the crisis unfolds; and engage in contingency planning. A crisis team may include outside consultants with special expertise in public relations, government affairs, communications, or otherwise.

Internal Investigation and Remediation. One of the first steps your company should take in the face of a crisis is to determine the root cause of the problem and develop a plan to address it. The investigation may be handled internally, by an outside firm, or by a combination of the two. In addition, involving outside legal counsel early in the crisis will make it more likely that the investigative work and analysis will be covered by the privilege and/or work product doctrine and protected from disclosure to a third party, such as a regulator or litigant, in the future.

At the outset, your company should consider whether it should stop sale, shipment, or even manufacturing of the product at issue during the investigation. Communicating that message through the supply and distribution chain may be a complicated and sensitive process that should be planned before a crisis hits and handled with the utmost care.

Once the root cause has been determined, your company may need to determine how to fix the problem and implement controls to prevent it from happening again. At this stage, it may be necessary to involve external experts, engineering, human factors, or otherwise and, in some cases, regulatory authorities. Counsel should also be closely involved at this stage to strategize how these decisions affect legal liabilities.

Public Relations. The media often aggressively pursues stories about product safety crises and may publicize and shape public opinion about a crisis early on, even before a company fully understands what has happened. In most cases, a company in the midst of a crisis should talk to the press based on a carefully crafted plan.

External public relations consultants may be hired to take the lead on press inquiries, and the work of those consultants may be privileged if hired by outside counsel. It is important to understand that any statement provided to the media may later dictate the company's position in the face of a government enforcement action or civil litigation. Your company should thus carefully develop the theme of its responses at the earliest stages and ensure it provides consistent messaging.

Regulatory Notice. Federal regulatory agencies, such as the United States Consumer Product Safety Commission (CPSC), National Highway Traffic Safety Administration (NHTSA), Food and Drug Administration (FDA), or state Attorneys General, for example, may be involved during a product safety crisis, particularly when a recall or other corrective action is required. Thus, it is important to understand the laws and regulations applicable to your company's products and operations and whether it has any obligation to report defects and/or alleged incidents to any government agencies long before a crisis takes place.

This plan may include designating employees who are in charge of compliance obligations, as well as consultation with outside legal counsel. If the product has been sold internationally, those reporting obligations must be considered as well.

Corporations should also be aware of potential enforcement actions and penalties that may result from a crisis. Corporate officers and employees may be exposed to civil and criminal liabilities for their involvement in the underlying crisis. Your company may benefit from consulting with legal counsel when communicating with the government.

Litigation. The company might not be sued until after it has dealt with its investigation, remediation, public relations, and regulatory action, but how a company conducts itself during a crisis and, in particular, interacts with regulatory authorities, will directly impact litigation risk and strategy. It is usually beneficial to have legal counsel forecast the nature of any potential litigation that may develop as a result of the crisis (including class actions), identify possible defenses, and project exposure to damages. That could be critical information for a business in evaluating its tolerance for risk in navigating a crisis.

Your company cannot predict when or where a crisis may hit or fully prevent negative legal or reputational fallout. However, thinking through critical issues, taking the time to develop a response plan before a crisis occurs, and being ready to respond in a nimble way will increase your company's chances of successfully weathering the storm.

Executing on a Crisis Plan: CPSC Reporting

Sometimes the unforeseen can happen. A company can give its very best efforts at designing products to be free of risk, and it can have the best crisis management plans in operation. But when that product is out in the stream of commerce things that cannot be anticipated happen. And you may have a product safety risk that requires immediate and decisive attention. Understanding reporting obligations is a critical part of mitigating these unforeseen risks.

When to Report. The Consumer Product Safety Act (CPSA) requires you to report if you are a manufacturer, importer, distributor, and/or retailer of consumer products who obtains information that reasonably supports the conclusion that a product:

- Fails to comply with an applicable consumer product safety rule or with a voluntary consumer product safety standard upon which the Commission has relied under Section 9 of the CPSA;
- Fails to comply with any other rule, regulation, standard, or ban under the CPSA or any other Act enforced by the CPSC;
- Creates an unreasonable risk of serious injury or death; or
- Contains a defect that could create a "substantial product hazard."

A Company must report to the Commission within 24 hours of obtaining reportable information. The Commission has suggested that it is advisable to report a potential substantial product hazard, even while an internal investigation is continuing. The CPSC's maxim is "when in doubt, report."

What is a Substantial Product Hazard? Section 15(b)(3) of the CPSA requires a manufacturer, importer, distributor, or retailer to report to the CPSC whenever a product "contains a defect which could create a substantial product hazard." The two types of "substantial product hazards" are:

1. a failure to comply with an applicable consumer product safety rule under the CPSA or a similar rule, regulation, standard, or ban under any other Act enforced by the CPSC that creates a substantial risk of injury to the public; and
2. a product defect that creates a substantial risk of injury to the public.

In assessing whether or not a product is defective the CPSC will consider:

- What is the utility of the product? What is it supposed to do?
- What is the nature of the risk of injury that the product presents?
- Is the risk obvious to the consumer?
- What is the need for the product?
- What is the population exposed to the product and its risk of injury?
- Are there adequate warnings and instructions that mitigate the risk?
- What is the Commission's experience with the product?
- What does the products liability case law suggest?
- Is the risk of injury the result of consumer misuse, and is that misuse foreseeable?
- Finally, what other information sheds light on the product and patterns of consumer use?

In *United States v. Spectrum Brands, Inc*., 218 F. Supp. 3d 794 (W.D. Wis. 2016), a Federal Court in Wisconsin considered the limits of what is a reportable "substantial product hazard." 15 U.S.C. § 2064(a) and 16 C.F.R. § 1115.12(g) both describe the considerations that factor in to identifying a reportable product hazard including the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, and "other considerations." Id. at 809. In that case, the court seemed particularly influenced by the fact that company engineers had discovered the issue with the product, the handle on a coffee carafe, and fixed it with a design change without reporting to the CPSC.

With respect to the "severity of risk" factor, the Court stated "Commission and its staff will consider the number of injuries reported to have occurred, the intended or reasonably foreseeable use or misuse of the product, and the population group exposed to the product (e.g., children, elderly, handicapped)." Id. at fn. 11. While there is very little case law interpreting the severity of risk factor, the District Court in Spectrum Brands explicitly stated that a common-sense interpretation applies. The Court found that 1,600 complaints of coffee carafe handles breaking over three-and-a-half years, some of which involved severe coffee burns, were sufficient to put the company on notice of an issue. In rejecting defense arguments that the reporting standard was too subjective, the court pointed out by way of example the type of injury that would not be reportable under the statute stating, "of course paper cuts pose no risk of a 'serious' injury", even to hemophiliacs. Id. As a result, such incidents would not be reportable under the CPSA.

How and What to Report. Reports should be filed with the Office of Compliance and Field Operations and can be made:

- Electronically (using SaferProducts.gov)
- By mail
- By telephone

When providing a Section 15 report, a company should be prepared to provide:

- Identification and description of the product;
- Name and address of the manufacturer and/or importer of the product if known, or if not known, then the names and addresses of all known distributors and retailers of the product;
- Nature and extent of the possible defect, the failure to comply, or the risk;
- Nature and extent of injury or risk of injury associated with the product;
- Name and address of the person informing the Commission;
- If reasonably available, the other information specified in Section 1115.13(d) of the Commission's regulations; and
- A timetable for providing information not immediately available.

What Happens Next? After a company files a Section 15(b) report the following process typically applies:

1. The CPSC's Office of Compliance and Field Operations undertakes its own product hazard analysis. First it will look to see if there is a defect. If the staff identifies a defect it will assess whether or not there is a substantial risk to the public and make a "preliminary determination" about whether or not a product creates a substantial product hazard.
2. Not all reports result in a recall. If a product is determined to be a substantial product, the company must enter into a "Corrective Action Plan" (CAP) developed in conjunction with the CPSC. Elements of a CAP include:
    - A plan to locate all defective products as quickly as possible;
    - A process to remove defective products from the distribution chain and from the possession of consumers; and
    - A plan for communicating accurate and understandable information in a timely manner to the public about the product defect, the hazard, and the corrective action. Companies should design all informational material to motivate retailers and media to get the word out and consumers to act on the recall.
3. The company conducting the recall has the obligation to monitor and apprise the CPSC of the status of the recall. This includes:
    - Submission of monthly progress reports to the Office of Compliance and Field Operations, including information on the number of products remedied, number of consumers notified of the recall, and any post recall announcement incidents and injuries;

- Being aware that the CPSC may conduct recall verification inspections and retail visits to monitor implementation of the corrective actions undertaken; and
- Providing the CPSC with notification of the intent to dispose or destroy recalled products. CPSC may request to witness disposal activities.

4. When a recall is complete, a company should be prepared to demonstrate what actions were taken regarding the CAP in the event they are visited by a regional CPSC inspector. The company should have readily available:
   - Copies of all notifications to consumers and any other documents sent out regarding the recall;
   - Copies or other demonstration that agreed social media was posted;
   - If the company agreed to monitor wholesale/auction websites, records to show that such a process has been established;
   - Records to demonstrate what the total number of units in the recall population, what inventory exists, or what was done with any units under the company's control at the start of the CAP; and
   - Incident records to confirm the total number of incidents, whether there have been new incidents discovered post-recall, and when the company first learned of incidents that gave rise to the CPSC filing.

The Company Knows It Wants to Provide a Consumer Remedy–the Fast Track Product Recall Program. In some instances, a company can tell that it has an issue with a product that can be remedied to prevent possible injury. In those instances, the CPSC has designed a program called the "Fast Track Product Recall Program." If a company reports a potential issue and, within 20 working days of the filing of the report, implements with the CPSC approved voluntary recall, the CPSC will not make a preliminary determination that the product contains a defect which creates a substantial product hazard.

To participate in the Fast Track Product Recall Program, a company must:

- Provide all of the information required for a full report under 16 C.F.R. § 1115.13(d) through the CPSC's online reporting portal;
- Request to participate in the program and agree to stop sale immediately pending the announcement of the recall; and
- Submit a proposed corrective action plan with sufficient time for the Commission staff to analyze any proposed repair, replacement, or refund offer and to evaluate all notice material before the implementation (announcement) of the CAP, which is to occur within 20 working days of the report.

Participating in the Fast Track recall program enables consumer to get a remedy, whether that is a repair, replacement, or refund, without any admission that a product is defective.

Managing Documents Created Before, During, and After a Product Liability Crisis

Creating the Right Documents During the Product Life Cycle and Preserving Them in the Ordinary Course of Business

Take care not to draft "problematic" documents: assume every document you create will be used against you in litigation, will be an exhibit at trial, or quoted in the press. Some additional thoughts to consider include:

- Avoid sarcasm, humor, contempt, or expletives.
- Don't speculate, offer unsupported opinions, or misrepresent facts.
- Don't express legal opinions if you're not a lawyer.
- Don't create or send unnecessary documents.
- Don't exaggerate.

Take steps to maintain legal privileges and protections over documents. Possible steps include:

- Use outside counsel to attach and protect legal privilege over testing and studies.
- Involve counsel in communications with experts.
- Know and operate within parameters of local privilege rules.

Preserving Your Documents in the Ordinary Course of Business

Create and implement a comprehensive document retention policy that establishes and describes how company employees are expected to manage company electronic and physical data from creation through destruction. There are many reasons why a company should implement a document retention policy:

Efficiency in Determining Whether Materials Still Exist. In the event of litigation or a government investigation, a well-administered retention policy can help a company more efficiently locate whether documents from a particular time period still exist and how they may be located.

Protecting the Company in Litigation. Federal Rule of Civil Procedure Rule 37 permits a Court to impose sanctions when a party has destroyed or altered evidence. Courts have discretion in the nature of the sanction ordered, ranging from an adverse evidentiary inference to the entry of a default judgment against the spoliating party. If documents that are relevant to a lawsuit or government investigation were destroyed by the company before it reasonably anticipated the investigation or lawsuit, having a company-wide document retention policy may help demonstrate to a judge or government agency that the company had a legitimate purpose for the document destruction.

Confidence in Compliance. Companies are required to retain certain legal and official documents. For example, the CPSA requires that for five years, a manufacturer must maintain records of its certificates of compliance and testing results. Failure to comply with the applicable regulations can lead to penalties. An effective retention program is the first step in ensuring that a company does not destroy records that must be retained.

In developing a document retention policy, a company should consider:

- Selecting a point person or committee of departmental representatives to manage to process of document preservation.
- Consult with data management and IT personnel to ensure that all the different forms of documents and data are created, stored, preserved, and backed up at your company.
- Identify the electronic and physical documents produced by the company and list every possible type of information that the company could have in its possession and the required retention period. Identify who is responsible for these records and determine whether this responsibility should be centralized in a dedicated individual or department, decentralized among representatives of the company's business units, or shared among employees in a records compliance task force.
- Review state and federal rules to ensure that the retention policy complies with applicable federal, state, and regulatory requirements.

- Provide detailed instructions on how to organize, where to store, how long to retain, and when to back up documents. Describe the method in which to organize and store documents so that they can be retrieved effectively and expediently. Describe the categories and types of documents that are confidential or sensitive and cover the steps necessary to protect this type of information.
- Set guidelines on how to handle data when the retention period expires. Specify the procedure to dispose of documents once their retention period is up.
- Train your employees on the retention policy and communicate the process. Plan to answer questions pertaining to a process for special requests and irregular events (e.g. legal holds). Training and implementing the document retention policy should be consistent, systematic, and feasible.
- Clearly communicate that the employee has a responsibility to follow protocols established in the retention policy.
- Periodically review the retention policy and update as needed.

When Litigation is Anticipated, Send Out Legal Hold Orders

In the event of a crisis, the document retention policy may be supplemented with a Legal Hold. This is the practice of ensuring evidence is preserved in anticipation of and during a regulatory or legal challenge. In practice, Legal Holds are notifications sent by an organization's legal team to employees or other owners of data ("custodians"), instructing employees to not delete information relevant to a legal case. The goal is to preserve any possible evidence, both in the form of electronically stored information (ESI) and physical documents. The following best practices should be considered:

When Do Legal Hold Orders Need to Be Sent? Legal or Litigation Holds should be activated when litigation commences, or can be anticipated. Legal cases don't typically arise out of the blue, so a company's legal team should be able to prepare accordingly. Developing issues with a supplier, competitor, or disgruntled employee, past or present? It is best to prepare for litigation by sending out hold orders to the custodians who have relevant data in place. The Legal Hold process should simply start as soon as reasonable, to avoid being caught by surprise and getting hit with sanctions or adverse jury inference during litigation.

Who Should Receive the Legal Hold Order? A Legal Hold should be sent to "anyone who might possess relevant data." In practical terms, the legal team investigating the litigation issues should create a list or overview of possible data sources and custodians. This is an ongoing process, and as investigations progress, more custodians can de discovered and added to the Legal Hold.

What are the contents of a Legal Hold order? There are no mandatory rules for the content of a Legal Hold. They should be clear and set out what is asked of the custodians, what data they need to preserve, and how to contact the legal team if they have questions regarding the Legal Hold. When specifying the data that should be preserved, it is usually smart to include date ranges, names, and key terms associated with the case. Also, make sure custodians understand what types of data you want them to preserve.

Ensuring Compliance with a Legal Hold Order. A sound Legal Hold process has ways to track custodian compliance by allowing (or requiring) custodians to acknowledge notifications, and having a reminder system in place for those who do not acknowledge receipt. Additionally, having a procedure in place for dealing with unresponsive custodians is important to have a defensible process.

The End of a Legal Hold. Generally, Federal Courts apply the same standard to assess whether a party's obligation to preserve information has ceased: a party can cease preserving information when it is no longer "reasonably foreseeable" that litigation will occur. Generally, a company may be in the safe zone when the litigation is dismissed with prejudice, or the underlying litigation is settled. A company may also be in the safe zone when the applicable statute of limitations period for litigating a claim has expired. It is advisable to consider the relevant statutes of limitations periods in all territories in which the company conducts business. However, a company should also consider the prospect of repeat litigation when releasing a Legal Hold.

Front Page Problems: Using Offensive and Defensive Strategies to Protect Your Brand from Reputational Harm in the Press

Hypothetical

A popular parenting blog posts a story discussing how your new, best-selling product–a small indoor swing for babies and toddlers–is allegedly collapsing during use, resulting in injuries to small children. The original post reports only a few occurrences involving bumps and scrapes, without additional injury. The story attracts attention, however, and others respond to report a few similar incidents, one of which involves more serious harm. The blog discussion is circulated widely across Facebook and Twitter, and is eventually picked up by traditional news media outlets. The blog discussion and related press are the first reports you have received of any such problems with your product. You are approaching a period of expected high sales volume, and your biggest competitor sells a similar product but was not mentioned in the blog or the subsequent press.

Issues

Consumer reports of product problems raise a variety of issues, particularly in the age of social media and the Internet. When faced with negative public reports about a product, especially a marquee product, the potential risk of reputational–and legal–harm may be high. Some immediate issues that arise include:

Fact Gathering. Before you can determine how best to respond, it is important to gather as much information about the reported incidents as possible. What information is being reported? What is the source of the information, and what biases or accuracy issues might impact the information shared? Is the problem a genuine one, or one of false reporting, competitively motivated misinformation, or mistake?

Risk Analysis. After gathering the facts, determine what risks are involved and brainstorm various potential responses. How serious is the reported injury? What is the likelihood of another occurrence? How sure are you of the problem, and what are the costs and benefits of waiting to find out more? What potential financial and reputational impact could result from various corrective actions or inaction?

Message Management. As you determine the scope of the risk and plan responses, develop a communications strategy targeted to address concerns of the various stakeholders. Who within the company will have what information, and when? What information will be given to customers? To retailers? In response to media inquiries? To the general public?

Commercial Impact. If you face competition in the relevant product category, consider what impact this media crisis may have on your sales and competitive position. Do other manufacturers have any involvement in the information being reported? Do other market participants face similar risks? Is there any opportunity for joint action? Is there any need for offensive/defensive action vis-à-vis other market participants?

Regulatory Obligations. Regulatory agencies often mandate short reporting deadlines and voluntary self-reporting obligations when certain safety issues arise. Does any agency have jurisdiction over your product, and if so, do you owe a legal duty to report? What are the risks of failing to timely report? What might be the benefits and risks of reporting even if not necessarily under a legal obligation to do so, especially in light of the publicity of the incidents?

Litigation Risk. When product issues attract media attention, they may also attract the attention of the plaintiffs' bar. You should consider developing a litigation defense response plan. Have any lawsuits been brought, or threatened? What protocol will be followed if a complaint is filed? Are there ways to reduce litigation and class certification risks now?

Identify Solutions. If a problem with the product is identified, consider whether to develop ideas for an effective and practical solution that resolves the issue. Engaging technical experts inside and outside the company may be necessary, but proceed with caution in memorializing plans and analyses in writing as these may be discoverable in litigation or by government agencies. In developing potential remedies, weigh the scope of the problem, the population involved, and the desired outcome against the cost and feasibility of potential fixes. In addition, consider how the offered remedy can be communicated effectively and to the right audience to achieve the desired result.

Offensive Considerations

Some offensive steps to consider in developing an affirmative public relations message and crisis response plan may include:

- Issuing your own affirmative press release;
- Publicly identifying flaws in news reports or their sources;
- Publicly identifying flaws in similar products manufactured or sold by others;
- Affirmatively contacting distributors, retailers, and customers; and
- Issuing a safety campaign or other affirmative informational campaign promoting the product and its correct use.

Defensive Considerations

Some defensive considerations to avoid reporting violations, future safety issues, and uncontrolled messaging may include:

- Issuing a litigation hold;
- Developing a strategy for additional testing (either in-house or third-party testing);
- Reviewing the quality control on raw materials, component parts, assembly, and finished product;
- Reviewing design protocol, testing, and safeguards;
- Reviewing prior incident reports for any overlooked information;
- Analyzing regulatory reporting duties;
- Preparing PR responses to press and customer inquiries;
- Developing a possible corrective action (with regulatory agency, if necessary);
- Considering how to ensure corrective action is adequate to resolve underlying issue; and
- Implementing corrective action and follow-up messaging.

Avoiding Reputational Damage During Congressional Investigations and Agency Enforcement Matters

Government scrutiny, whether of an individual firm or an entire industry, is rarely welcome. When it comes, however, it is essential that you respond appropriately and avoid unintended missteps that can have potentially disastrous consequences for your company, not to mention individual reputations.

Most likely, a government investigation will come from one of two places: from Capitol Hill, where high-profile events and good old-fashioned politics may prompt congressional committees to spring into action; or from regulatory agencies, which may monitor industry and inspect firms as a matter of course or in response to external pressures, such as political pressure from the Hill or state Attorneys General offices. Because of their different origins and investigative tools, unique approaches may be warranted when developing an effective response strategy for each while also considering the possibility of responding to simultaneous or "piggy-back" investigations.

Congressional Investigations

Congressional investigations are a hybrid of legal investigations, media events, and lobbying campaigns with procedures and methods unique to the committee that initiates the investigation. Their purpose is usually to investigate and call attention to issues of importance within the jurisdiction of a particular committee. In this way, they are not only for examination but also incitement. Beyond effecting regulation or enforcement, the goal of a hearing could be to energize consumers, interest groups, or industry, or it could be to embarrass a company or government agency.

An effective response to a congressional investigation should include both a long-term legal strategy and a short-term public relations plan. Not all inquiries result in hearings and not all interrogatories become part of the public record, but it is important to prepare for those possible outcomes. While most congressional inquiries come without the force of a subpoena, a failure to take even an informal request seriously could result in a range of larger problems.

If you receive a congressional request letter, some steps to consider include:

- Demands for documents as well as the scope of questions can and should be negotiated with Committee staff. This will help protect your interests while satisfying the oversight interests of the Committee.
- Seek to avoid exposing trade secrets or other information that demand confidentiality. Committee findings will be made public in all but the most sensitive matters.
- Determine a press and public relations strategy for your company and any witnesses that might be called, in addition to answering Congressional inquiries.
- Develop and always keep in mind the big picture legal strategy.
- Recognize that anything submitted or said in testimony can be used as evidence in a civil or criminal proceeding later.

Agency Enforcement Actions

Usually less dramatic, but no less of a risk to company brands, are agency regulatory actions. They often arise after a violation has been brought to an agency's attention by a routine inspection, a consumer complaint, or congressional pressure.

Some steps to consider in handling agency investigations include:

- Examine your compliance program—make sure you are in compliance with applicable statutory and regulatory requirements before an agency inspection or investigation hits. Don't rely on government investigators to be your compliance auditors.
- Assess and ensure knowledge and control of all aspects of the manufacturing and distribution of your product throughout your supply chain. Require documentation from your suppliers demonstrating they are meeting all applicable regulatory and legal requirements. Maintain detailed records of manufacturing, testing, and sales by batches to facilitate efficient and effective traceability and isolation of products in the marketplace.
- Review your compliance history—make sure you have responded to and corrected any previously observed violations.
- Stay current—standards evolve. What was sufficient for compliance ten years ago, may not be sufficient today.

Limiting reputational damage during an agency investigation is important given the long-term relationship most companies have with their regulator. Some steps to consider to preserve that relationship include:

- Don't panic, but prepare to respond quickly.
- Be honest with yourself, and prepare to be contrite. Enforcement resources are limited, and though agencies won't get everything right, they rarely bring actions that are not supported by some evidence of significant violations.
- Retain the appropriate scientific and legal experts. Agencies are data driven organizations. You should consider sharing data to contain and control the investigation. Assess whether you also need manufacturing, recall, and public relations experts.
- Address product in the marketplace—if it poses a risk to consumers, capture it before it causes harm (or more harm).
- Show the government agency and the public that you are on top of the problem and, if necessary, you know how to fix it. Often the difference between brief adverse regulatory events and long regulatory quagmires is whether a company can demonstrate the competence to solve a problem quickly itself, or if the government agency determines that it must step in, supervise, and solve the problem for the company.

Keep in mind that an investigating agency may escalate from informal inquiry to citation to warning letter after a series of investigations or adverse findings, or it may jump directly to aggressive action seeking a civil injunction and other civil penalties—or even criminal proceedings—depending on the severity of the violation. Don't assume an agency won't respond dramatically just because it has never taken enforcement action against you before.

Minimizing Your Litigation Exposure

Every year, manufacturers have to take thousands of products off the market over potential safety hazards. Companies are often concerned that the publicity of a product recall announcement will quickly lead to a class action or mass action lawsuit. But when a company learns of a possible issue with one of its products out in the field, how quickly it gets up to speed on what is going on, how effectively it communicates what it knows to key stakeholders, and the actions it takes from that point forward, are critical to a company's chances of defeating a subsequent legal challenge. A quick and comprehensive response, whether that includes a product recall or otherwise, can make all of the difference.

Best Practices

Early Preparation: Cross Ts and Dot Is. One of the best ways to minimize litigation exposure is to prepare for a lawsuit from the outset, starting with the early stages of product development. Before a company puts a product on the market, it must identify and comply with any regulatory or licensing requirements; test the product for safety and efficiency; identify and evaluate any potential risks associated with the product (including those associated with foreseeable misuse); and make considered decisions about what risks to address in the product label and associated product materials. A lapse in any of these areas opens a door that a plaintiff's attorney can, and will, exploit.

Know Your Business Partners and Prioritize Quality Control. Using contract manufacturers—third parties that produce some or all of another company's products—makes sense for a lot of industries. It can often result in cost savings, faster times to market, and access to advanced skills, new technology, or different markets. But there are also risks, particularly in the form of lost quality control. Companies that outsource production must thoroughly vet any contract manufacturers that they use (and, as a practical matter, any other third party in the supply chain, from raw ingredient suppliers to distribution outfits). Companies also need to insist upon a robust contract manufacturing agreement that clearly sets forth, among other things, applicable quality control standards, processes, and procedures. And they need to exercise their audit rights to ensure that any contract manufacturers are meeting expectations. A lapse in quality control, particularly one that the company knew or should have known about, is bound to create problems in a product-related lawsuit.

Stay on Top of Customer Complaints. Tracking customer complaints is one of the most critical aspects of business management and the best way to stay up to speed with what is going on with products in the field. But when a company starts to learn of alleged problems, merely tracking complaints is not enough. Upon identifying a pattern of potential issues with its products, a company will likely need to conduct an internal investigation to determine whether any complaints have merit and, if so, why the company (and/or other responsible parties) missed these issues during the product development and validation process. Of course, the last thing a company wants to do when investigating potential issues is to connect all of the dots for plaintiffs in the form of discoverable materials. As a result, the company should take special precautions, including consulting with and involving counsel from the outset, to ensure that it best preserves any and all privileges applicable to both the investigation process and any work product created and disseminated as a result.

Act Quickly and Thoughtfully. Any company considering an investigation into one of its products, will need to carefully structure and conduct any investigation to ensure that it does not create evidence that will be used against it in a future lawsuit. The company must customize its response, taking into litigation and business concerns. Just because a response has worked for others in the industry, or with another company product, it does not mean it will be the most appropriate way to handle the issue at hand. Additionally, every aspect of the investigation will need to be carefully vetted (by legal) to ensure that any messaging will not escalate tensions with customers and their counsel, making them more likely to sue.

Strategic Considerations

Defend Against the Litigation. In the event of a lawsuit, the best option may be for the company to stand behind its product and defend itself in court. A number of early strategic decisions will shape the course of any litigation: Should the company conduct additional product testing, and run the risk of creating bad evidence? Should the company retain a third-party public relations firm to navigate potential bad press, even though information shared with them will probably be discoverable? If the company is facing a putative class action, there are additional considerations: Should the company seek to bifurcate merits and class discovery? Should it proceed with merits discovery with an eye toward defeating the case on the science without briefing class certification?

The answers to these questions will depend on the facts of the case, and in particular how strong of a defense the pre-launch product stewardship provides.

Recall the Product and Launch a Claims Process. After investigating the issue, the company could decide that its business is better served by pulling the product from the market and launching a voluntary process to pay claims. This may be because the company discovers its product actually is responsible for the damage alleged. Or the company may determine that the costs of litigation (and the reputational costs of defending it and continuing to market the product) are too steep.

Depending on the number and complexity of claims, a voluntary claims process could be time-consuming and expensive to design and implement, and it would not cut off the prospect of an eventual lawsuit. However, an effectively communicated recall and a successfully run claims process can cut the legs out from any subsequent litigation. In a class action context, for example, plaintiffs would have difficulty showing that a class action is the superior method of resolving the matter—a prerequisite under federal law and the laws of many states. And if the product involved is regulated by a federal agency such as the FDA, CPSC, or NHTSA, a consumer level recall executed in cooperation with the agency can have a similar effect, and lead to dismissal early on in the litigation.

Of course, any form of settlement (through a company's own claims process or otherwise) does not necessarily guarantee finality. Should a company choose to settle claims, it must use care to minimize the possibility of claimants "reopening" their settlements in the future (e.g., based on allegations that the company withheld information and defrauded them into accepting a lower payment). When a potential plaintiff reopens a claim, these suits have the potential to be costlier than any initial litigation, as plaintiffs in these situations tend to assert fraud-based claims or claims under RICO or parallel state statutes that have treble damages or punitive damages.

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