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MANAGING PRODUCT LIABILITY IN THE CHEMICALS SECTOR

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Rivkin Radler LLP's chemical product litigators vigorously defend claims asserted in class action, mass tort, and individual settings, intertwining legal strategy with the development of scientific evidence and proofs. Putting to work our philosophy of early and thorough preparation for our clients, we stay abreast of the science as it develops, utilising our long-term existing relationships with experts in toxicology, epidemiology, biostatistics, environmental fate and transport, and medical specialties. As a result, we have successfully represented manufacturers in matters involving chemical and products such as: Agent Orange, dioxin, herbicide and pesticide products, asbestos, silica, mold, lead, pentacholorophenol, and others.

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Stephen Harburg focuses his practice on complex civil litigation, particularly in the defence of product liability and consumer fraud class actions, mass torts and multidistrict litigation proceedings. He served as national coordinating counsel in numerous MDL proceedings, including the Welding Fume MDL proceeding on behalf of the industry defence group, and the Ford Explorer/Firestone tire MDL proceeding on behalf of Ford Motor Company. He currently is serving as national coordinating counsel in the Pinnacle hip MDL proceeding on behalf of DePuy Orthopaedics, Inc.

CD: What are some of the key trends in product liability that have affected the chemicals sector over the last 12-18 months?

Hitchcock: Over the last 18 months there has been a general increase in regulatory interventions arising from whistleblowing and competitor complaint. The chemical sector has so far seemed to have come off relatively lightly in this respect. Actual intervention by enforcement authorities seems to have focused more heavily on other sectors, whereas regulatory preoccupations of the chemical sector have focused more on compliance with legislation such as the REACH regulation which involves a significant degree of self-regulation by suppliers. However, businesses in the sector should not be complacent. The impact of REACH has seen chemical manufacturers hit the spotlight and their products be more acutely scrutinised. Non-compliance with REACH or other regulations can have not only recall consequences but also criminal liability issues. There are also significant business implications if a product cannot be released until it is shown to be compliant. This is just as damaging, if not more so, than the consequences of a controlled specific batch recall, for example.

Akyurek: The chemical sector is not perceived well by the public. At a time when health is considered a high priority, chemical companies have been increasingly criticised. Several dramatic industrial and chemical accidents have reinforced this idea. As a consequence, changing the vision that public opinion may have about the chemical sector has become necessary. In May 2014, the French General Assemblies of the chemical sector took place in Paris. Emphasis was placed on transparency and liability of chemical industry stakeholders. Chemical sector companies are willing to improve their external communication, especially with regard to consumer information on components used in chemical products.

Majkowski: Two interrelated areas affecting product liability in the chemicals sector are the science and the regulatory arena, insofar as these are the building blocks of a claim or lawsuit, where the battleground is typically causation. While many courts have held the line on the proposition that regulatory standards do not satisfy proof of causation, the more expansive the regulatory schemes, the greater influence their influence on legal outcomes. In these regards, two aspects are noteworthy. The first is the increasing prevalence of state regulation of chemicals – whether this will be resolved by TSCA modernisation, and the outcome of the pre-emption dispute being waged within that debate, remains to be seen. The second aspect is greater attacks on industry-sponsored science as being unreliable and biased. Relying on the fundamentals, good science and appropriate

regulation based on good science are keys for the chemical sector in confronting product liability.

Harburg: Plaintiffs' counsel have increasingly turned to mass tort strategies in pursuing product liability litigation. This involves the filing of often thousands of cases in a relatively short period of time with the goal of forcing a company into a quick settlement in order to avoid potentially ruinous litigation exposure. Product recalls provide a natural hunting ground for plaintiffs' counsel seeking to create a mass tort because they create both a perception that there is a risk with the product and publicity that makes it easy to recruit plaintiffs. Courts, particularly in the United States, have become more receptive to the creation of mass tort proceedings through the MDL (multi-district litigation) device and its state law equivalents. While plaintiffs' counsel have focused much of their attention on the pharmaceutical and medical device industries, the chemical sector provides another target for exposure-based mass tort product liability litigation.

CD: Have there been any recent legal or regulatory developments in this area? If so, what are the implications for companies?

Majkowski: A key regulatory development is, or will be, the state of TSCA modernisation in Congress, and the interplay with the growing body of state regulations. Modernising TSCA through the adoption and implementation of a model of performing safety assessments and determinations within a rigorous scientific framework, using the 'best available science', will be a positive step; although in the course of such assessments, we can foresee substantial scientific debate when it comes to applying developing areas of science such as biomonitoring and epigenetics. Again, a key to managing product liability is good science. Another development potentially affecting product liability will be the evolving standards for jurisdiction in the United States. A theory that bears watching is that the parent company's selection of chemical formulas for its global brand is conduct within the

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>
> *Stephen Harburg, Skadden, Arps, Slate, Meagher & Flom LLP*

United States, even if the alleged chemical exposure occurs elsewhere, allowing foreign plaintiffs to make an end-run around US jurisdictional limitations. Even so, complementing this potential trend, global product liability might continue to emerge with the development of plaintiff bars and the implementation of class action devices.

Akyurek: There is no recent legal or regulatory development that can be highlighted. The chemical sector is mainly regulated by European Law, which has not been amended for several years. However, given the particular features of the chemical sector, case law provides certain product liability rule that may have a major impact for companies. As an example, a French court has established the principle of 'market share liability' in a matter involving two pharmaceutical companies for the commercialisation of Diethylstilbestrol (DES), a synthetic substance designed as a treatment to prevent miscarriages in pregnant women. Thus, companies may be required to share pharmaceutical product liability claims for damages, proportionally to their respective market shares. It should be noted that the two defendants have lodged an appeal against this decision and the matter is still currently pending.

Hitchcock: Recent regulatory developments in the EU, notably under the REACH regulation and the reconfiguration of the WEEE and RoHS Directives, have placed responsibilities on industry, in line with the system of CE marking of products, on the basis that industry has technical resources not always available to enforcing authorities. Furthermore, it is considered preferable for manufacturers to bear the cost of assessing the conformity of their products with EU safety requirements. Most recently, attention has focused on the increasingly lengthy candidate list for substances of very high concern. This has involved companies in a great deal of work reviewing the use of such substances in their products and considering the feasibility of alternatives, with a view to being in a position to propose 'sunset dates' for their use.

CD: How important is it for chemicals companies to plan in advance for the possibility of a product recall? What aspects should such a plan entail?

Harburg: Advance planning is crucial to managing and minimising the litigation risks associated with a product recall. The documents created by a company leading up to a recall will be among the most important in any ensuing product liability litigation. These documents are a discovery target of plaintiffs' counsel hoping to find concessions by the company about the need for the recall. Controlling the process by which documents related to the recall are created by various people and organisations within the company can help to

minimise the opportunities for plaintiffs' counsel to exploit the company's own documents in subsequent litigation. Just as important to plaintiffs' counsel in today's litigation environment as the documents they do find are those they don't. Spoliation claims have become a standard fixture in product liability litigation. Ensuring that an effective document retention notice goes out to prevent the destruction of documents related to a product recall will avoid having this issue become a sideshow in any ensuing product liability litigation.

Majkowski: It is vital for companies to plan in advance of a recall, both for purposes of coordinating the complicated logistics and multiple players involved in a recall, and ensuring that a media relations plan is in place to protect the company's reputation and brand and that the record for any potential claims or lawsuits is maintained. This cannot be done on the fly, and once the company loses control of the situation, it will be difficult to regain it. The company would do best by having in place a recall committee, which would include elements from management, consumer affairs and public relations, distribution and supply, legal counsel, records management, and regulatory affairs. A recall plan should designate a key company official as a point of contact, so that messaging is consistent. The company's recall plan should also incorporate planning for the monitoring and use of social media. A recall plan might provide for drills or a mock recall.

Hitchcock: If a decision has been taken to recall a product, the key factor to success and ultimate closure of the process is traceability. Inevitably, this requires attention before the product passes into the distribution chain. Good traceability will mean that product can be easily and quickly identified, even to the end consumer, although this is usually the most difficult part of the tracing process. With chemicals, often they will be used in the work environment and on that basis all reasonably practicable steps will need to be taken to ensure the safety health and welfare of individuals exposed to them. To demonstrate this it will require clear and concise procedures to be put into place which begin with effective traceability. It is also of benefit to have good contractual protection and clear responsibilities defined between any contracting parties, so that the recall process is not delayed by contractual squabbles. This will require pre-planning, as will the establishment of a crisis management team.

Akyurek: Anticipation regarding product recall enables companies to avoid panic and to be ready the day they face this kind of specific situation. The aim is to act quickly and to communicate effectively. It is recommended to be far-sighted by implementing a policy of product recall. To that end, it is important that companies have a team in charge to perform

this work, in particular the monitoring of information on product safety. Companies must also inform their business partners about how they will implement their policy in case of a product recall. Companies must be able at any time to ensure a product's traceability and to identify end users. A good communication with commercial partners, authorities or end users is essential.

CD: If a product recall is deemed necessary, how should companies go about managing the crisis to avoid some of the common pitfalls?

Akyurek: Companies should assess the risk in a general way, at all levels of the market process. For this reason, companies must monitor whether the recall involves products located in the supply chain or products held by end customers. It is also necessary to inform public health authorities and dealers so that they can relay this information on a large scale. Most importantly, companies need to set an appropriate communication program. The alert should be clear, simple and widespread. Formal features of such an alert are essential, in particular the selection of appropriate means of communication, the mention of detailed information so as to identify easily the defective products and, eventually, security guidelines that should be followed by customers. The establishment of a dedicated hotline is also highly recommended.

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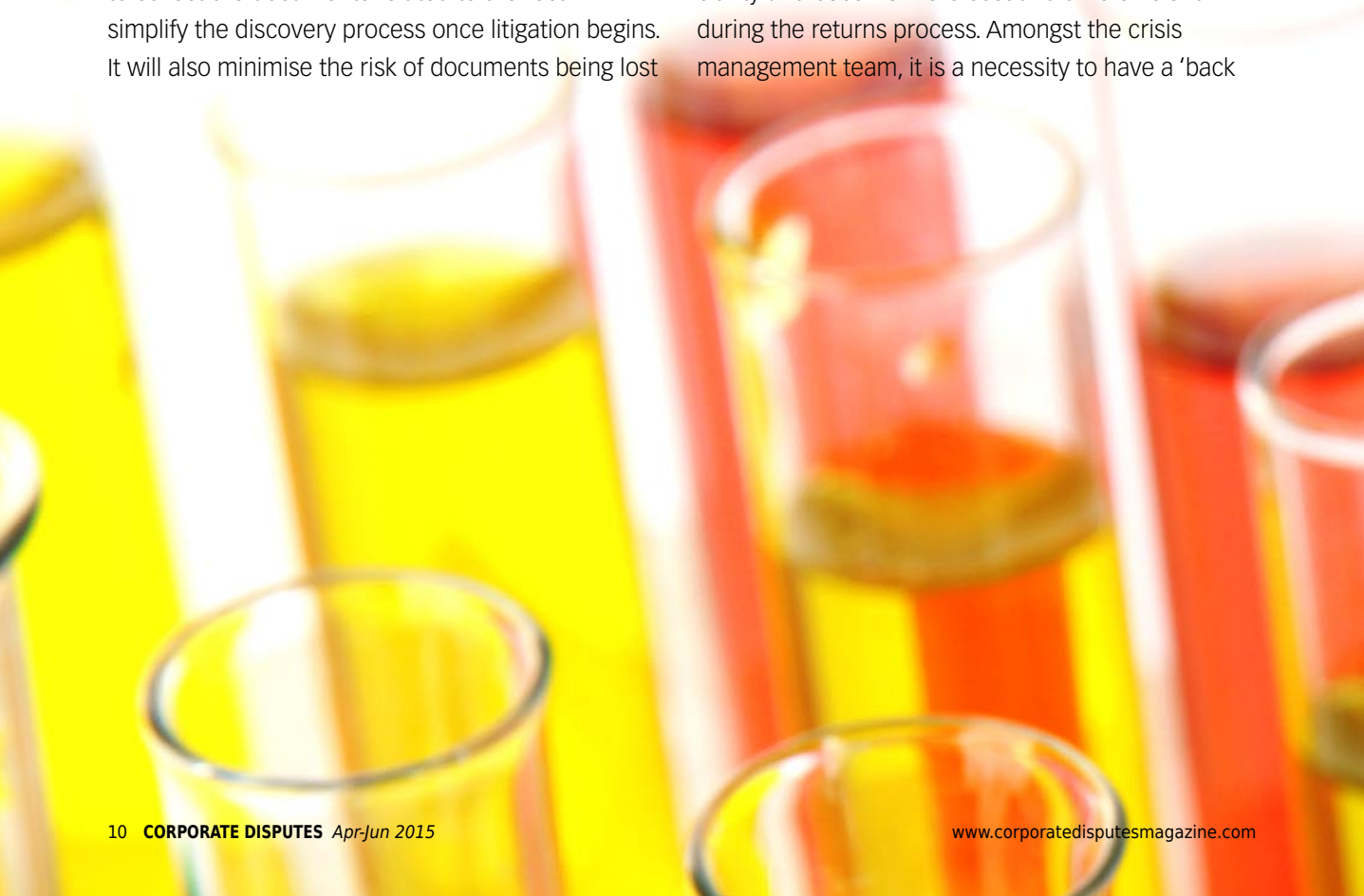
>
> *Paul V. Majkowski, Rivkin Radler LLP*

Majkowski: One of the key elements to managing a product recall crisis is to have a key messenger, who is trained in media relations, to speak on behalf of the company. In some circumstances, it may become necessary for a senior executive to speak on behalf of the company, so appropriate training for those individuals should be undertaken as well. Finally, the company would develop procedures, as part of the recall plan, to ensure that it is collecting and maintaining documents relating to the product at issue and the recall activity.

Harburg: Managing the litigation risk associated with a product recall should begin well before the actual recall. Setting up a team that includes

legal counsel and public relations personnel in addition to the company employees responsible for the product at issue is important to ensure that the company is maintaining a consistent position on the reasons for the recall, both internally and externally. The company's internal documentation should clearly set out the basis for the recall, but should avoid speculative claims about potential risks of the product that are not an essential part of the justification for the recall. Taking early steps to collect the documents related to the recall will simplify the discovery process once litigation begins. It will also minimise the risk of documents being lost or destroyed, which can avoid unnecessary disputes in the litigation.

Hitchcock: The management of costs and the exercise of recall has its foundations in preplanning. The quicker you can trace products, the less cost will be involved. The clearer the supply contract on procedure and responsibility, the less the costs involved in the mechanics of a recall. Internal or external return logistics will also benefit from this clarity and become more cost and time efficient during the returns process. Amongst the crisis management team, it is a necessity to have a 'back



to business' focus so that a group of nominated individuals are pushing to remediate the fault, test the product and re-emerge into the marketplace. That will reduce contractual claims for non-supply and downtime.

CD: What additional challenges apply if a product recall is necessary across borders, in multiple jurisdictions?

Hitchcock: With the European RAPEX system, the process of information exchange and common principles is much easier than used to be the case. Once the decision to recall has been made and communicated by the RAPEX medium, the biggest issue is the coordinated logistics of return and replacement of product throughout a number of jurisdictions. Chain of custody and security will be key factors in any return of chemicals together with consideration of any other regulatory regimes that are European in nature or jurisdiction-specific and which apply to discarded product. Complications may arise if different jurisdictions determine that different standards apply to the product or some jurisdictions are not content with, for example, withdrawal of batches as opposed to all product.

If this is not carefully handled it could expose the company to criticism and claims relating to what is perceived to be unsafe product in the marketplace in some jurisdictions. Brand and reputation could be affected with consequent loss of market share.

Harburg: Cross-border recalls raise the risk of product liability claims being filed in multiple jurisdictions. While the product liability laws in most countries are not as developed as in the United States, plaintiffs' counsel in recent years have become more aggressive in filing cases in those jurisdictions, particularly as US courts have become more willing to dismiss claims brought by foreign nationals on *forum non conveniens* grounds. Multi-jurisdiction recalls also increase the discovery burdens on the company, particularly given the breadth of discovery permitted in US litigation, which can often encompass documents in the possession of non-US subsidiaries and affiliates. Conflicts between US discovery rules and non-US countries' privacy rules can also create real headaches for companies trying to comply with both.

Akyurek: A company facing a product recall in different countries, for example within the European Union, should immediately notify an alert to every national public health authority in each territory where a defective or dangerous product has been marketed. This alert must be translated into the language of each identified country.

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>
> *Ozan Akyurek, Jones Day*

Majkowski: Apart from the logistical challenges of a multijurisdictional recall, the company's media and public relations response is complicated insofar as the company's messaging needs to account for local cultural differences. Additionally, in some venues, a product recall issue might involve more direct governmental involvement than others; for example, we know of an instance in Korea where a defective product resulted in the company's CEO being required to appear before the National Assembly during its annual audit hearings. Circling back to recall planning and ensuring the maintenance of records, in civil law jurisdictions where discovery is not common, the thought to maintain records might not be as second nature as

in the United States, so provisions should be worked into the recall plan for that contingency.

CD: Are potential class actions arising from product liability a major risk for chemicals companies? What steps can companies take to mitigate this risk?

Majkowski: Although personal injury class actions for chemical exposures are difficult to certify under the Federal Rules – for example, due to a lack of commonality in the allegedly toxic dose across the class and individualised issues concerning alternate causes of injuries – other theories pose class action risks. For example, medical monitoring may be claimed, particularly as better diagnostic tests and capabilities to detect chemicals are developed and refined. The expanding scope of consumer chemical products regulations also pose risks, based on claims for failure to satisfy such regulations and sounding in a failure to warn. Companies need to have the requisite infrastructure to track regulations and ensure compliance, and reiterating the good science theme, be prepared to elucidate the science when confronted with a claimed exposure.

Akyurek: The law implementing class actions in France came into force on 1 October 2014. Despite the lack of hindsight due to the recent introduction of class actions in France, it is unlikely that class actions would represent a major risk for chemical companies since such claims may only be filed to obtain damages in respect of pecuniary loss resulting from material injuries suffered by the consumers. As a result, claims based on health protection issues do not fall within the scope of class actions, which exclude moral and bodily injuries. The risk of class actions can be mitigated by chemical companies through the setting up of a communication strategy managing the company's reputation, the use of ADR clauses in terms and conditions, the setting up of a team dedicated to class action risk management, the involvement of consumers in trade policy, and the renegotiation of insurance policies.

Hitchcock: Class actions arising from product liability are a major risk for chemicals companies in the US, where the contingency fee system and jury awards of damage combined with common law rules on discovery of evidence, which require defendants to reveal information relevant to the case against them, provide a major incentive for specialist plaintiff law firms to organise litigation by large groups of claimants. Although the EU Product Liability Directive has copied the US system of strict liability, awards of damages are generally assessed by judges and are not on the same scale as in the US. Furthermore, the procedural rules in EU countries do not in general encourage speculative actions by lawyers representing claimants. Group litigation, which is the version of class actions more common in the UK,

is only likely to be a major problem for companies in areas where there is a genuine safety issue with the product. Prudent companies are proactive and prepare for product recalls in order to avoid the risks of such litigation.

Harburg: US courts have generally rejected attempts to allow personal injury claims to proceed as class actions due to the variability in proof of individual causation. The Class Action Fairness Act allows most product liability class actions to be removed to federal court, where the class action limitations are typically more strictly applied. Plaintiffs' counsel have tried to get around the difficulty of certifying personal injury class actions in two ways. The first is to try to certify what is known as a medical monitoring class. In these cases, the plaintiffs are claiming that they need to be monitored for potential future harms from an alleged toxic exposure. Although most states have imposed restrictions on medical monitoring claims that make them difficult to certify for class treatment, plaintiffs' counsel continue to push courts to expand the reach of such claims. The second way that plaintiffs' counsel seek to avoid the limitations on product liability personal injury class actions is by filing multiple cases, often numbering in the thousands, to create what is known as a mass tort or mass action. Plaintiffs' counsel use this tactic in the hopes of overwhelming a defendant and forcing a quick settlement. Defendants typically try to counter this tactic by aggressively removing cases to federal court and then seeking to have the cases consolidated before a single judge in a MDL proceeding. While MDL proceedings provide many benefits in preventing plaintiffs' counsel from subjecting a defendant to a multi-front war in courts around the country, they also can have the unintended consequence of driving up the number of cases. This can happen by encouraging plaintiffs' counsel to file numerous claims without conducting adequate due diligence with the expectation that there will be a settlement before the plaintiffs are required to support their claims. Thus, defendants need to be careful in evaluating the benefits and risks of creating an MDL proceeding.

CD: How can product liability insurance help? What should a company consider when choosing the right policy to meet its needs?

Harburg: Product liability insurance can help to offset the cost of product liability claims arising from a product recall. However, companies need to carefully assess the terms of the coverage as insurers attempt to limit the scope of coverage available to exposure-based claims through provisions such as pollution exclusions. Another issue that needs to be addressed is whether the insurance policy will allow the company to select defence counsel. While this is not as significant

an issue when a company is facing an individual product liability claim, it becomes more important as the scope and risks of the litigation increase. In defending against the high volume of claims that a product recall can draw, defendants will need to create a large defence team, often involving multiple law firms across multiple jurisdictions. In this situation, it is important for the company's ability to effectively manage the litigation to be able to control the selection of defence counsel.

Hitchcock: Plainly, product liability litigation can result in large sums being awarded against the manufacturers of products which are found to be defective even outside jurisdictions such as those in the United States where damages awards are considered to be unreasonable. An appropriate product liability policy can mitigate at least some of the risks, though many policies have exclusion clauses which exclude cover from the greatest risks. It is important to consider whether liabilities for consequential losses as opposed merely to physical damage are covered. As claims may occur long after the event that caused damage or injury, policies may need to be on a claims-made rather than on an occurrence basis. An important point is that product liability insurance often excludes the costs of voluntary recalls to avoid damage occurring and a special policy may need to be purchased to cover this. It is also standard for policies to exclude liability in respect of recalls made under compulsion from the regulator. Again, it is important to consider the extent of the cover, for example whether it covers liability for loss of profits resulting from a recall or the loss to third parties. Finally, it is crucial for businesses to ensure that it will be in a position to meet all the requirements imposed by the policy as a pre-condition for making a successful claim.

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Teresa Hitchcock, DLA Piper UK LLP

Majkowski: One of the important aspects of insurance for product liability risks in the chemical sector is an understanding that the defence provided under the policy encompasses the science work necessary to defend against a docket or set of controversies relating to a particular substance. Chemical products commonly do not generate one-off, *sui generis* cases, but more frequently associated

cases, and the theories of those cases, evolve and develop along with the science. The defence of those cases is best made with an integrated legal and science team, and the development and understanding of the scientific evidence on an ongoing basis, and the defence handling provisions applicable to the coverage should afford for that. While insurers might be reluctant to provide for such a proactive approach as part of the defence, they should recognise that they benefit as well.

Akyurek: Even if it is highly recommended, it must be emphasised that French companies are not obliged to have general civil liability insurance. However, most French companies do have contract insurance policies. By contracting an insurance policy, companies' purpose is to cover two important aspects of their business: their professional civil liability and the risks arising out of commercial operations. Those insurance policies usually cover personal injury and property damage claims from product liability, subject to specific exclusions. They may also include other costs that may arise, such as product recall costs from the market or emergency measures such as temporary withdrawal.

CD: What final advice can you offer to chemicals companies on managing product liability?

Akyurek: Companies that market their products through a subsidiary or independent dealers should set up a cooperation process in case of a product recall. Coordination may be useful for notifying the relevant local authorities of any risk identified by the manufacturing company or its dealer. Such cooperation can be all the more important in case of product liability that could result in dramatic damages. In this situation, it is likely that manufacturers, sub-contractors and dealers will be acting as co-defendants if a claim were to be filed by a victim.

Hitchcock: Companies need to be prepared. There may well be a temptation to delegate management time and effort to activities which appear to be likely to bring more immediate profit. However, ensuring in advance that all the necessary procedures and information are in place in respect of the company's product range can save enormous amounts of time and money in the event of a problem emerging.

Harburg: In today's litigation environment, product recalls have become one of the most common triggers for product liability litigation. The publicity that typically surrounds a product recall makes it easy for plaintiffs' counsel to recruit potential plaintiffs, and the mere fact of the recall can create a perception of a problem that can slant a jury's perception of the product. Plaintiffs'

counsel have developed a business model which allows them to both generate large numbers of claims quickly, often through online and television advertising, and to pool resources in order to exert maximum pressure for settlement on a company that has announced a recall. As a result, preparing for the fallout from a product recall in advance is crucial in order for a company to respond effectively to the product liability litigation that is almost certain to follow.

Majkowski: Managing product liability for a chemical company starts with the basics: good science. Good science helps shape appropriate regulation. Good science produces just results in court. But, that integrated science and legal approach and team needs to be in place, in advance, because the companies' adversaries are working on their own tracks, producing their own science, assailing industry-sponsored science, and lobbying for increased regulation, all of which can lead to product liability allegations against the companies. CD