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PRODUCT SAFETY, PREVENTIVE COUNSEL AND MANAGING RECALLS

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MINI-ROUNDTABLE

PRODUCT SAFETY, PREVENTIVE COUNSEL AND MANAGING RECALLS



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CD: Reflecting on recent months, what trends and developments have you observed impacting manufacturers and the product liability risk they face?

Spilker: One major development that has impacted manufacturers is the rapid development of technology. It is both promising and challenging for manufacturers. On the one hand, manufacturers are able to utilise technology to further develop their products and capabilities. On the other, the development of 'smart' products often leads to different and more complex causes of product liability. One of the most recent examples is autonomous driving. There are many potential liability risks arising from the advent of autonomous driving, as demonstrated by the recent accidents involving autonomous Uber and Tesla vehicles. The development of 'smart' tech is particularly demanding for manufacturers. More complex and connected interactions between 'smart' products require companies to develop an evolving level of technical knowledge, which must be implemented and observed by manufacturers. Non-implementation or non-observation may lead to serious product liability risks, as in many jurisdictions design and monitoring obligations are key duties of manufacturers, which must comply to avoid product liability cases.

Smith: The variety of product liability claims continues to expand, as plaintiffs increasingly pursue new industries and new kinds of product liability claims. For example, in recent months plaintiffs have continued to expand litigation against the automotive industry. From air bag and ignition switch claims to emissions litigation, plaintiffs have increased the number and type of claims filed against automobile manufacturers and expanded the scope of the litigation faced by this industry. Likewise, plaintiffs continue to expand the scope of product liability litigation alleging economic losses. While traditionally plaintiffs have pursued claims for personal injury, increasingly plaintiffs seek to obtain payment for alleged product defects that they claim decrease the value of products they have purchased.

Williams: Manufacturers have expressed increasing concerns about how the courts will apply existing product liability laws to new and emerging technologies. There is uncertainty over liability for connected, artificial and autonomous technologies – including the Internet of Things, machine-assisted diagnostic tools and driverless vehicles – as well as decentralised technologies that include blockchain and digital ledgers. At the same time, we have seen an increase in class action claims as the plaintiff's bar targets product manufacturers under state consumer protection laws even when no actual injury has occurred.

Beisner: Although certainly nothing new, controversies, including recalls, involving allegations that what is inside a product container is not consistent with what is stated on the labelling have been increasing in frequency recently. Sometimes the concerns involve food products or over-the-counter medicines in which manufacturing errors result in unintended product formulations, which may or may not pose health risks. In other instances, the issue may be food products containing materials not referenced on the container – for example, substances unintentionally added during the production process. There has also been a dramatic increase in allegations of misleading product packaging, such as the use of ‘all natural’ products. Such allegations normally implicate only consumer choice issues, not safety risks. There has also been an increase in the number of allegations that products do not perform ‘as advertised’, giving rise to both consumer expectation and safety concerns.

Swinehart: I see a number of developments. First, there is continued regulatory pressure, with long-term trends demonstrating increasing growth in regulatory regimes and related enforcement. For example, in the US, the largest fine in the Consumer Product Safety Commission’s (CPSC) history was issued in the second calendar quarter of this year. Second, the global web of component and ingredient manufacturers, wholesalers, agents, third-party testers and transporters in a

company’s ever-expanding supply chain creates tremendous challenges in maintaining, tracking and documenting product integrity. In that regard, companies face an ocean of data that they have responsibility to use and maintain for product safety purposes. The complexity of that data management and corresponding signal detection challenge is enormous. And finally, consumer behaviours, reactions and attitudes – and their platform to globally express those views or experiences – have changed dramatically in the age of social media. In all, each one of these trends indicates ‘more’ for a company to react to.

CD: What are some of the legal factors that manufacturers need to consider in connection with product safety and liability claims?

Smith: Product safety and liability claims can involve a variety of complex legal considerations. The applicable regulatory requirements and compliance with those requirements can be important. Failure to comply with regulatory requirements can lead to further liability or the initiation of litigation. Likewise, consistent communication about product liability and safety issues is important. A consistent message is important to avoid increased liability. Failing to communicate accurate information regarding product defects may lead to additional liability, such as securities claims filed against the company.

Williams: Meeting the standards in the industry of yesterday will likely not be sufficient to meet the standards in the industry of tomorrow, and leading manufacturers need to engage in the process to be aware of the change and to participate in creating appropriate standards by which manufacturers will be measured tomorrow. Manufacturers that challenge or even lead the industry in innovation and technology can improve their position by demonstrating affirmative steps were taken to achieve product safety through thoughtful, customer-forward design and warnings elements to accompany their cutting edge product offerings which exceed the industry standards yet to come.

Beisner: One of the most important factors is identifying the markets in which a product is likely to be sold or utilised. The variations in applicable product liability laws among countries, and among the states, provinces or other political subdivisions within countries, are growing. Thus, in designing a product, and developing instructions and warnings, it is critical for the manufacturer to have a clear understanding of where the product is likely to be sold and to be circumspect about the 'rules of the road' in each of those markets. This knowledge is particularly important when designing a product and developing instructions and warnings, as small adaptations in

either could lessen the risk of claims in particular geographies. Further, unless the manufacturer has firm control over distribution – for example, through a dealer network – the company must also assess the extent to which a product might be purchased on a cross-border basis and therefore used in

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jurisdictions where it is not available for retail sale. In short, the laws of a country may become relevant to product liability claims even if the manufacturer does not plan to sell the product there.

Swinehart: To avoid safety or quality issues, and thus reduce the risk of a product liability claim, there are a set of things a company should consider. Fundamentally, executive and operational leadership should set the tone that safety and quality matter. In that sense, most companies are interested in the safety and quality of their products,

and have systems, processes and people dedicated to these issues. In other words, the foundation is there. So where is there opportunity to enhance that foundation? For one, companies need to have strong data management and signal detection practices specifically related to these issues. This includes data-rich and objective decision-making frameworks for action and reporting when they get evidence that there is a safety issue with one of their products. They need to know their suppliers and manufacturing processes and keep good records. And they need strong post-sale feedback mechanisms. In order to mitigate issues once they are a reality, companies can consider investing in state-of-the-art sensing technologies. The benefits of an early warning system can be immense in terms of avoided remediation costs and customer satisfaction. For example, I am aware of consumer products companies that use real-time text analytics from call centre and social media to detect early signals related to product problems.

Spilker: Manufacturers need to consider the safety requirements of a product and that the preconditions for liability claims differ within different legal systems. Therefore, manufacturers should make themselves aware of the legal requirements of the countries in which they sell their products. Non-compliance with product safety regulations can cause severe liability risks and thus are a huge cost risk. They must ensure that their suppliers do the

same. In addition, recall obligations may also change from one jurisdiction to another. A product warning can be sufficient in one country while a recall is compulsory in another. Similar considerations should be made regarding liability claims. This is especially challenging for specialised product liability lawyers when drafting contracts. Manufacturers need to keep in mind that they have to fulfil their obligation to inform the competent authorities of certain product defects in time. If they fail to comply with this obligation, they also face administrative fines.

CD: To what extent do manufacturers tend to manage product liability risks in an ad hoc, reactive and localised manner?

Williams: Some manufacturers are caught flat-footed when faced with a product liability issue that attracts national media attention and generates thousands of 'cut-and-paste' legal claims in state courts. Often manufacturers do not have policies or plans for crisis response and management or for the investigation and defence against the claims and lawsuits. The plaintiff's bar often leverages the element of surprise, amassing facts, witnesses and scientific experts before filing claims and lawsuits and then pressing for rapid resolution of the cases. In many instances, manufacturers and their product liability counsel are confronted with looking for information and documents and identifying potential witnesses while at the same

time trying to determine the validity of the claims and assess the risk and exposure to the company. In some cases, we are seeing these lawsuits localise in jurisdictions where the company does not do business but the courts are perceived as more favourable to plaintiffs. Companies should anticipate the impact of forum shopping on their potential litigation portfolio and make sure that their products comply with localised regulations and labelling requirements, such as California's Safe Drinking Water and Toxic Enforcement Act and Illinois' Biometric Information Privacy Act (BIPA). We have also seen many manufacturers get swept up in lawsuits affecting one of their component suppliers. This scenario has become more common as product companies anticipate design defects or failure to warn claims, but are less prepared to defend against manufacturing claims arising from faulty materials or components made by third parties, especially those located outside the country of manufacture.

Beisner: Although manufacturers prefer to manage product liability risks in a well-planned, comprehensive manner, this is not always possible. This is largely because plaintiffs' counsel and corporate critics are becoming increasingly creative about 'identifying' and publicising concerns about products they choose to target. On occasion, those concerns turn out to have some merit. But in far too many instances, the criticisms lack foundation. Often, the complaints are so fanciful that they could

not possibly be anticipated by a manufacturer. In those instances, companies have no choice but to respond on a relatively ad hoc, reactive basis. And that response must be market-specific, dealing with the unfounded allegations in the geography where they are raised. Manufacturers can tie themselves in knots trying to anticipate these sorts of allegations, and generally there is little benefit in trying to do so.

Spilker: Manufacturers tend to react in an ad hoc manner. Whenever product liability risks arise, in our experience, the vast majority of manufacturers comply with their information duties and take voluntary and comprehensive recall actions in order to protect their customers from any risks. Averting damage to the company's image and ensuring the highest possible level of customer satisfaction is further motivation. Suppliers, by contrast, tend to be more reactive. Normally, they do not have any business relationships with end customers. Image and reputation in the consumer market is important to them but it is not as important as it is for manufacturers. Preventing the end customer from suffering any harm is relevant, however. In part, manufacturers also act in a localised manner. This is due to the fact that the requirements for product safety, the preconditions for a recall and also the product liability risks, such as liability for damages and criminal liability, vary in different legal systems.

Swinehart: I think management of product liability risks varies considerably from company to company. I am aware of companies that have a strong tone at the top, leading class processes, early detection systems and disciplined decision-making mechanisms. I am also aware of companies that are missing one or more of these critical components. There are certainly publicly-known examples of situations when it was determined that a company could have or should have acted earlier or have kept better records. I also see differences across sectors. For example, the automotive sector is effective with dealing with recalls given that consumer and regulatory expectations around safety are central to that business. On the other hand, some companies in certain other consumer sectors do not face product safety, liability or recall issues as frequently. However infrequent, when something does come up, such companies may not have effective processes in place, thus causing them to in fact or appearance be reactive, ad hoc, or localised in their response.

Smith: Many manufacturers have sophisticated procedures in place to monitor product safety and quality. Manufacturers in certain industries have put in place procedures to ensure that when safety or quality issues arise they are addressed in a prompt

and efficient manner. This is particularly true in industries that are subject to significant regulation. Such procedures and infrastructure can be useful not only in heading off potential litigation but in responding to regulatory requirements. Nonetheless, in other industries where product claims are not as common, the approach may be more ad hoc. There

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*John Beisner,
Skadden Arps Slate Meagher & Flom LLP*

may also be differences in corporate culture among companies that make them more or less responsive to quality and safety issues.

CD: Could you highlight any recent, high-profile product safety and liability situations that exemplify prevailing issues and challenges?

Swinehart: Without getting into company-specific examples, I can provide some themes and trends

that I see. For one, many companies are challenged when they do not have true mastery or insight into their own information. For example, not correlating supply chain testing data with product failures, or not expediently detecting and elevating clearly emerging signals from call centres. I have also seen problems escalate because of a company's apparent slowness in responding to an identified issue. This gets to decision making. It is sometimes a difficult judgment call, especially with emerging or ambiguous signal, as to when to take action with

respect to a suspected defective product, especially a product recall or notification to a regulator. However, compiling complete data from disparate but correlated sources and conducting objective analytical techniques to interpret that data can go a long way to informing good decision making.

Beisner: Although not particularly high profile, two recent recalls illustrate a major trend in recalls that simply address a problem with the contents of a product container not matching what is described



on the outside. One example is the May 2018 recall in the US of frozen 'buffalo chicken' calzones distributed in boxes bearing 'ham and cheese' calzone labels. At first glance, one may wonder why a recall was necessary to deal with what looks like more of a customer relations problem. But concerns about allergen issues likely caused the manufacturer to conclude that a formal recall was prudent. Interestingly, consumers were told not to consume the product, regardless of whether they had allergies. Around the same time, another

US manufacturer recalled a substantial amount of 'Southwestern style corn chowder' that was shipped in containers with a 'chicken tortilla soup' label. These two recalls illustrate the heightened sensitivity to any deviations between product content and labelling, even though health risks seem relatively remote.

Smith: One recent example illustrates the potential pitfalls of addressing product defects. When Samsung introduced its Galaxy Note 7 phone,



it quickly began to receive reports of overheating. Attempting to respond quickly to the issue with its product, the company initiated a recall. However, it soon began receiving reports of similar problems with the replacement products it shipped to consumers. This episode illustrates the tension between responding quickly to a product defect and ensuring that the response is effective. While the company responded promptly to reports of product defects, its response was not effective and may have further damaged its reputation with consumers.

bankruptcy in 2017, citing tens of billions in costs, liabilities, fines and criminal penalties. The juridical

“Proactive steps can be taken by manufacturers which affect the entire product lifecycle, from development and design to production and after sales.”

*Matthias Spilker,
Bird & Bird*

Spilker: The biggest recall in automotive history, the Takata airbag case, is particularly notable. A failure in the inflation mechanics and the rupture or explosion of Takata airbags, especially in hot and humid conditions, has reportedly led to over 230 injuries and 22 deaths globally to date. Takata’s engineers allegedly identified the issue in 2004, but the company did not immediately inform their customers about the issue. Even after the first recall in 2008, the scope of the issue was not made public. Car manufacturers continued to install the defective airbags until 2017. In the US, more than 37 million vehicles have been affected by recall measures, and car manufacturers have paid billions in fines and damages since they allegedly did not act despite knowing about the problem. Takata filed for

procedure is still ongoing, as are recalls. Apart from the severe consequences, this case also exemplifies the need for transparent communication.

Williams: Manufacturing is an industry at the forefront with respect to embracing new and emerging technologies in the production process. Companies are utilising technologies such as 3D printing, biometric monitoring, the Internet of Things, wearable devices, and virtual and augmented realities to streamline operations. Manufacturing and distribution are also utilising emerging technologies which rely on artificial intelligence (AI) such as autonomous vehicles, unmanned airborne vehicles (UAVs), also known as drones, and robotics. The pace and breadth of the non-product class action litigation

in the last two years under Illinois' BIPA illustrates the potential magnitude of litigation exposures generated by emerging technologies. Additionally, litigation risks and exposures will clearly extend to AI-based products such as robots. The *Holbrook v. Prodomax Automation Ltd.* manufacturing death case involving a robotic machine is one case in point, while a series of commercial drone crashes provides a set of other illustrative cases. The testing of autonomous vehicles in the US and the EU may provide a third set of potential circumstances that lead to high-profile product liability issues.

CD: What proactive steps can manufacturers take to mitigate the safety and compliance risks they face throughout a product's lifecycle?

Smith: It is important to have robust procedures in place to monitor a company's products and identify defects promptly when they occur. Routine monitoring should take into consideration not only foreseeable consumer uses of the product but also consumer misuse of the product along with applicable voluntary standards and required regulatory standards. Companies can monitor not only their own products, but similar products sold by competitors. Consumer complaints, reports from retailers, insurance claims, testing reports, and public reports can be monitored to collect information to provide advance warning regarding

product defects. In addition, establishing procedures to deal with product defects in advance of a problem can ensure that the company's response is efficient and effective.

Spilker: Proactive steps can be taken by manufacturers which affect the entire product lifecycle, from development and design to production and after sales. A good way to mitigate safety risks throughout a product's lifecycle is to establish 'product integrity management'. This process should be established independently from any concrete recall actions. The purpose of this process is to identify potential risk, carry out a risk assessment, prepare decisions, comply with reporting obligations within the specified deadline and organise market measures. Hence, this process can help to identify and assess potential risks throughout a product's lifecycle. In addition to this, an optimised compliance management system (CMS) can also help to mitigate safety and compliance risks connected to products.

Williams: Manufacturers that engage a litigation risk assessment can be less reactive and more proactive and can exercise greater control over their risk and exposure by taking advance steps to mitigate both and establish a plan to effectively respond when an incident happens. A risk assessment takes a 360-degree analysis of the product life cycle and the manufacturer's approach

to each phase of that life cycle. A risk assessment identifies gaps, hidden issues, and opportunities to remedy and improve the outcomes of the design, supply, manufacture, sale and post-sale phases of the life cycle. From validating specifications on component parts from suppliers to doubling-down on documentation of quality checks before the product leaves the manufacturer's control, a risk assessment can help ensure manufacturers meet the high bar set by consumers for product manufacturers.

Swinehart: I think that prioritising for early action is important. Companies should identify high-priority quality and safety concerns, systematically generate alerts and prioritise alerts based on a risk-ranking process. Alert prioritisation can help companies more efficiently conduct research and investigations by proactively planning workload requirements and better allocating time and resources toward remediation. Cross-correlating data sources is certainly central to actionable alert generation. Companies can gather, examine and find common links between unstructured data, including technician reports, call centre notes, surveys and social media postings, as well as structured data from warranties, repair orders and sensor readings. Self-learning advanced analytics can scan millions of data points to help determine the likelihood of a product defect based on textual feedback, historical data patterns, statistical expectations and many

other techniques. Patterns generated can enable manufacturers to monitor and detect the faint signals that might point to an eventual consumer threat and potential liability risks.

Beisner: Perhaps the most important steps involve monitoring 'field' experiences and consumer commentary. Obviously, one of the most important steps is to monitor warranty claims carefully to discern any volume spikes or other patterns that may signal areas warranting closer scrutiny. Of course, many products are sold without repair warranties, or have warranties of limited duration, and for those, assessing other communications from the field, such as dealer questions and customer complaints, will have greater importance. Increasingly, consumer concerns about a product are not communicated directly to the manufacturer. For example, websites are sometimes created on which consumers may air their gripes about the performance of particular products. Unfortunately, such forums are often created by persons trying to generate litigation claims or by critics seeking to stir up grievances, regardless of whether they are well founded.

CD: How can legal involvement and preventive counsel during product development contribute to an improved defence in the event of a claim down the line?

Spilker: Legal advice is necessary to identify and mitigate possible liability risks. Legal counsel should be involved from the beginning of contract negotiations regarding the development and supply of a product. This enables counsel to influence the contract in order to avoid detrimental provisions for the manufacturer on the one hand, and include provisions to protect the manufacturer, such as indemnifications, on the other. This is essential for mitigating liability risk even at this early stage. Companies would be required to identify potential product risks, which are often technical risks, in close cooperation with all relevant departments at the manufacturer, particularly quality and development. If, as is usual, several parties are involved in the development process, it may be useful to conclude third-party agreements in order to ensure that legal measures can be taken against every party involved.

Williams: Counsel must be able to head off future liability risks by understanding the new innovations that drive their clients' industries. A design that was deemed reasonably safe one year with no viable alternative might be judged defective the next year in light of rapidly advancing technology. This is especially true for applications that are becoming increasingly autonomous. For instance,

a plaintiff might argue that a car made today that does not include newly available safety features – such as a rear-view camera, blind-spot warning system or automatic braking – is defective by design.

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*Greg Swinehart,
Deloitte Financial Advisory Services LLP*

Preventative counsel can help companies anticipate and adapt their designs to reduce liability later in the product life cycle. A litigation risk assessment considers existing and anticipated risks from materials, suppliers and technology, the process and life cycle, and the end customers' product use – and foreseeable misuse – as well as the external factors impacting a manufacturer's risk, such as the consumer litigation environment, emerging regulations and laws, and impact of third parties acting on or against the product, such as hijacking of technology. The risk assessment provides an opportunity to create a holistic solution to the

problems now existing and to prevent or mitigate future problems before they occur.

Swinehart: Having legal perspective and counsel early in the development cycle is a leading practice. Understanding the relevant regulatory regimes, emerging legal trends, including product liability trends, and documentation of leading practices can be valuable in the development process and help reduce costly errors.

Beisner: Obviously, counsel should not 'run' a company's product development process, but attorneys certainly can play a valuable role in establishing product development, testing protocols and guaranteeing compliance. Ensuring an accurate and complete recording of a product's development process is of paramount importance. Experienced product litigation counsels know that plaintiffs' counsel often endeavour to take unfair advantage of gaps in a written product development record when prosecuting product liability claims. For example, product development team members will sometimes write emails or memos expressing design or performance concerns they feel require attention. Typically, these concerns are fully and satisfactorily addressed by other team members. But if those responses are not properly documented, it may allow plaintiffs' counsel to suggest that a concern

was ignored or handled sloppily. Again, attorneys should not act as product designers or otherwise function outside their field of expertise.

"Familiarity with the regulatory reporting and compliance requirements in the relevant jurisdictions is critical."

*Doug Smith,
Kirkland & Ellis LLP*

Smith: Legal involvement and preventive counsel can assist companies in putting in place procedures so that when product safety and quality issues arise, companies can respond quickly and effectively. Familiarity with the regulatory reporting and compliance requirements in the relevant jurisdictions is critical. Many jurisdictions require that product defects be reported immediately. Failure to comply with such regulatory requirements can lead not only to regulatory liability, but may weaken a company's position in any ensuing litigation. Periodically assessing recall procedures can ensure that they are updated to reflect applicable regulatory and compliance requirements. An effective recall

can head off litigation by rendering moot claims that might be filed for economic losses.

CD: What strategies should be deployed by manufacturers to plan for and manage the recall of a defective product?

Williams: Manufacturers and their counsel should prepare in advance to meet the demands of a crisis, including a product recall. Equipped with a well-rounded plan, manufacturers can more effectively and efficiently implement the plan and endure and recover as a company following the product recall. Thoughtful planning of who needs to be involved, what needs to be addressed, and how reporting, communications and programme actions will be executed, makes a manufacturer recall-ready in the event a recall is required. Manufacturers must implement a recall policy and plan, regularly review supply chain contracts, identify an incident management and communications team, train staff, conduct readiness exercises, and ensure that adequate traceability systems are in place. Blockchain is one area of new technology that is being explored as a way to provide real-time traceability and transparency in food and medical supply chains to help companies pinpoint and address any issues that might occur on a product's path to the consumer.

Beisner: First and foremost, manufacturers should have response and reaction plans that can be activated immediately when the potential for a recall becomes apparent. The most important part of that plan is to identify the membership of a relatively small group of company personnel, and possibly outside consultants, who will be responsible for decision making and implementation, subject to management review. Their availability to convene and respond immediately is critical. In most instances, that group will be interdisciplinary, including company managers with product-specific knowledge, such as engineers, media experts, legal counsel and regulatory specialists. Depending on the type of product involved, a specialist in distribution and dealership relations may be critical as well. The nature of a recall, or of the product involved, may cause a particular effort to focus more on some of these specialists, while rendering others more or less irrelevant. But that core team should be identified and should respond quickly.

Swinehart: Manufacturers should be prepared and have a risk management plan if the need for recall arises. This includes designating a well-trained team that has the required expertise to expedite the process and the ability to reduce costs while executing the recall strategy with minimal brand erosion. I have also found that conducting simulations or 'war gaming' can pay huge dividends for two significant reasons. First

and most importantly, such exercises can identify process gaps that can be addressed before a real crisis emerges. Secondly, such preparation can make the actual execution faster and smoother. This type of war gaming exercise typically considers common themes, such as managing recall communications, with a high focus on being transparent, consistent and responsive; being proactive with open lines of communication with customers; using social media and other innovative ways of notifying customers; educating customers about the potential hazards of the product's defects; offering full refunds whenever possible; and, of course, cooperating with third-party regulators and arbitrators.

Smith: It is important to develop a plan for product recalls before a recall occurs in order to be able to quickly and effectively respond to quality or safety issues. A recall plan should identify the responsible individuals within the company and the procedures that should be followed in the event of a recall so that when needed, these procedures can be promptly employed. The goals of the recall plan may include identifying the product defect, identifying which products or batches are affected, notifying appropriate regulatory authorities regarding the defect, communicating with the public and other constituencies, and implementing the recall in an efficient manner. Establishing clear procedures for communicating with a unified message is important. Inconsistencies in the message communicated to

the public and regulators can lead to additional liability or damage to the company's brand.

Spilker: Manufacturers should, independent of specific recall actions, have a recall management system or product integrity management system that complies with reporting obligations within the specified deadline and allows them to organise market measures. Comprehensive batch management can limit the effort and cost of a recall. In addition, the advantage of building a permanent recall management system or product integrity management framework is that the structure of the process and the distribution of tasks within this system are already planned and recorded in the event of a recall. The manufacturer should therefore have a recall team in place, tasked with operational implementation. All relevant information, documentation and contact information required in the event of a recall should be available at all times.

CD: What considerations should manufacturers make when reviewing their existing product safety, preventive counsel and recall procedures? How important is it to regularly assess and amend these processes?

Beisner: Perhaps the most important consideration is to ensure that safety-related information, generated both in the field and by

the manufacturer, is reaching personnel within the company who are capable of recognising product performance events and trend-lines that may require responsive action and who are empowered to initiate such action. The volume of such data is increasing, and manufacturers would be well advised to have robust processes for analysing it. Frequent review of these processes is important because the methods by which these communications occur are evolving rapidly.

Smith: It is important that responsibilities be clearly defined and that procedures are tested to ensure that when a recall occurs it can be executed promptly and effectively. Regular assessment of these procedures is important to ensure that they are up to date. When a recall occurs, it is frequently necessary to act promptly. Having a recall plan in place helps ensure an efficient and prompt response in the event a recall is necessary. However, ongoing assessment of recall procedures is necessary to ensure that the plan is current. Companies can assess on an ongoing basis whether their recall plan takes into account regulatory requirements in the applicable jurisdictions, which may change over time. Likewise, the identity of the recall stakeholders such as distributors, retailers and employees may change, necessitating updates to the recall plan.

Spilker: It is important to regularly assess and amend processes. In many jurisdictions,

manufacturers face product observation obligations after a product has been placed in the market. If safety issues are identified, the manufacturer is obliged to eliminate these risks. Regarding products that are already in the market, customers must be warned and recall measures must be taken. In order to make a product safe, the manufacturer must change the product design, or stop manufacturing it if a change is not possible, and cease production and sale of the product. If the manufacturer fails to do so, it could be liable for damages. When reviewing existing product safety, preventive counsel and recall procedures, both the technical and scientific standards that must be observed, such as ISO-Norms, as well as the legal and regulatory requirements of product safety, must be respected.

Swinehart: It is very critical to review and update existing product safety and recall procedures on a periodic basis to prevent potential compliance violations and litigation issues. Periodic reviews of processes and procedures can also help avoid or reduce corruption, fraud, waste, counterfeiting, financial statement misrepresentation and regulatory investigations in the long run. As the standards and regulations that define product safety are constantly changing, evolving and adapting to new consumer needs and demands is equally critical. By staying on top of these changes and conducting frequent product test and supplier audits, manufacturers

may be better poised to avoid future recalls or legal penalties.

Williams: The best way to measure the quality and effectiveness of a recall plan is to test the plan. Manufacturers should routinely review and update their policy and plan, but more importantly, manufacturers should actively test their plan through table-top and real world crisis management and product recall exercises. Having product liability counsel observe and provide candid lessons learned feedback after a test event will help manufacturers ensure their recall policy and plan is robust and effective both in theory and in practical execution.

CD