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AVOIDING PRODUCT RECALLS

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ONE-ON-ONE INTERVIEW

AVOIDING PRODUCT RECALLS



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Alison Newstead is a specialist in product safety. She advises on compliance and regulatory issues and often guides clients through the complexities of international product recalls. She also represents clients in regulatory investigations and prosecutions and handles products liability litigation arising out of recalls.

CD: How would you gauge the extent of product liability risks that manufacturers face? Have any recent legal and regulatory updates heightened this risk?

Newstead: Products are becoming ever more complicated and the markets in which they are sold often span the globe. This presents a plethora of challenges in terms of minimising both pre-and post-market risk. Consumer safety is high on the agenda of governments and regulation is increasing across all product sectors, along with the level of scrutiny by regulators. Several recent cases have highlighted that regulators are willing to take manufacturers and individuals to task for failing to act swiftly and effectively to address safety issues. Prison sentences for late notification of safety issues and regulators forcing manufacturers to take prescribed action – both of which have been seen in the past year – may well become commonplace.

CD: What are some of main causes of a product recall in today's market?

Newstead: What may prompt a product recall has evolved significantly over the past decade. Historically, recalls commonly arose from defects in design or materials used to manufacture products. These still remain common reasons for the recall of many products. However, we are increasingly seeing

products recalled due to shortcomings in labelling – in particular in relation to food allergens. Several fatal reactions to allergens in food have heightened manufacturers' awareness of the need to label products correctly. Recalls due to cyber risks are also on the rise – we have seen medical devices, vehicles and children's toys recalled due to potential hacking risks.

CD: What legal, financial and reputational consequences exist for manufacturers in connection with a product recall?

Newstead: The risks posed by recall are multifaceted. When consumer safety is at stake, there are inevitable reputational risks. If not managed correctly, a recall can have a devastating effect on brand reputation, share price and sales. It is imperative that a business is open and honest about the potential risk posed, how it arose and what is going to be done to address it. Consumers, regulators and the media respond well to a timely, well-managed and transparent response. A slow or evasive response or failure to take adequate action quickly can have a seriously negative effect on the business. Legally, the business will have obligations to notify regulators of the risk and what action will be taken. The time limits for making such notifications are commonly very short and prosecutions can arise for any delay. In addition to regulatory obligations,

there will also be an inevitable risk of civil claims arising out of any injuries caused by the recalled product. In addition to the financial implications of a loss of sales, the cost of defending civil claims and potential fines arising out of regulatory action, businesses need to consider the costs of conducting the recall itself. The daily activity of the business will be impacted by the demands of the recall process. The costs of external legal advice, logistical support, managing repairs or returns of products, destroying unsafe products and implementing an effective media strategy all have cost implications. With many businesses having a global presence, consideration should certainly be given to obtaining recall insurance.

CD: Could you highlight any recent, high-profile product safety and liability cases that exemplify the prevailing challenges for manufacturers?

Newstead: In the UK, 2019 saw the first example of a regulator indicating that it would force a manufacturer to take specific action to address a safety issue. This came in the light of intense pressure from consumers and the media, who considered that a recall rather than repair action was appropriate. Manufacturers are commonly faced with logistical challenges when a safety issue arises. Producing replacement parts and

scheduling engineers to repair products frequently pose challenges. Until now, regulators have often recognised such challenges and the difficulties that manufacturers face in their response. This may be changing with consumers finding an ever-stronger voice in respect of safety.

“Consumer safety is high on the agenda of governments and regulation is increasing across all product sectors, along with the level of scrutiny by regulators.”

*Alison Newstead,
Shook, Hardy & Bacon L.L.P.*

CD: In your experience, do manufacturers pay enough attention to product liability risk? Does more need to be done to raise awareness and more effectively manage this risk?

Newstead: Manufacturers of products that are aimed at vulnerable individuals, such as children, the elderly or the sick, or whose products are likely to create a serious risk if they fail in some way are commonly attuned to the potential consequences of product liability issues – both in terms of claims

and recall risk. However, in my experience, it is more common for businesses not to have a recall policy and plan than to have a tried and tested policy and process in place. In the UK, regulators have taken steps to encourage businesses to implement recall plans and have indicated that they will be actively looking at whether a business has a recall plan in place when a safety incident arises.

CD: What proactive steps should manufacturers take to mitigate product recall risk and ensure compliance throughout a product's lifecycle?

Newstead: There are many steps that a business can take, both pre- and post-marketing, to minimise the risk of recall. Pre-market, it is important to ensure that the business has robust quality assurance procedures in place with regard to materials and processes used to manufacture the products. Quality assurance checks are extremely important, both planned and random. Be aware that there have been instances where overseas third-party manufacturers have manufactured product batches specifically for inspection. Post-market, it is important that manufacturers keep a close eye on customer complaints and escalate them effectively. Warranty claims, legal claims, repair records and social media posts can all give an indication of a potential safety problem. Ensure that these are all

reviewed effectively and in a joined-up way and that appropriate action is taken.

CD: How important is it for manufacturers to regularly assess policies and procedures, to ensure they keep pace with regulatory requirements and help to avoid the need for a product recall?

Newstead: Manufacturers need to approach a product recall on the basis of when, not if, it is going to happen to their business. Having a well-rehearsed recall policy and plan is key. The policy needs to be a live document. Training should be rolled out across the business, with the scope of relevant roles, responsibilities and financial authority confirmed in advance of a recall situation. Recall action is fast-paced and decisions with far-reaching implications often need to be taken swiftly and under time pressure. Once a potential safety issue has arisen, it is less than ideal to be spending valuable time allocating roles and determining who has the legal or financial authority to take the lead. It is crucial that the business has a robust process to monitor and react to changes in regulatory requirements, and that the impact of those changes is considered well in advance of their implementation. **CD**