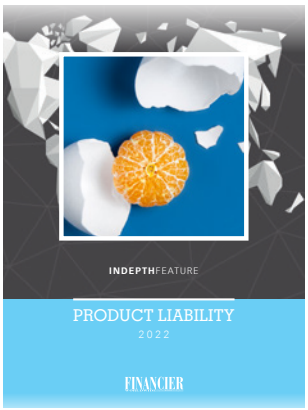

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Published by Financier Worldwide Ltd

INDEPTH FEATURE Reprint February 2022

PRODUCT LIABILITY

Financier Worldwide canvasses the opinions of leading professionals around the world on the latest trends in product liability.

UNITED STATES

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Jennise Stubbs has extensive experience representing Fortune 100 companies in the pharmaceutical and medical device, manufacturing, automotive, retail, professional, medical and service industries. She has served as trial counsel in numerous cases from complex mass tort litigation to individual disputes. She has helped achieve numerous defence verdicts and other favourable resolutions for her clients. She specialises in product liability. She serves as national counsel for clients involved in multidistrict product liability litigations. She also provides litigation risk counselling and assessment, as well as due diligence review and recommendations for her clients.

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Q. Could you outline some of the key trends shaping product liability claims in the US? How would you describe the current level of product liability claims?

A. The level of product liability claims in the US remains high, with more than half of pending federal cases consolidated in multidistrict litigations (MDLs). As of December 2021, there were more than 408,000 product liability cases in 60 MDLs. While MDLs often collect meritless cases, they also present opportunities for litigation-ending motions. In the Zofran MDL, for instance, a summary judgment motion was filed based on the FDA's repeated rejection of the warnings plaintiffs sought. The court granted the motion, agreeing that the claims were preempted by federal law, and dismissed all pending cases. A similar motion involving Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) preemption was filed in the Roundup MDL. While it was denied by the lower courts, the decision has been appealed to the US Supreme Court. A favourable Supreme Court decision will change the course of the entire Roundup litigation.

Q. Could you highlight any recent, high-profile cases which shed light on the nature of this type of dispute? What are some of the common causes of product liability claims within the US?

A. Product liability litigation often stems from a publication claiming that a product's use may result in injuries. To combat this, the defence must focus on the actual data pertaining to the product, particularly as it relates to design and causation. For example, plaintiffs filed thousands of cases based on media reports regarding the number of 'adverse events' associated with the Mirena intrauterine device. After years of litigation, the plaintiffs designated purported experts to opine that the device was, generally speaking, capable of causing their injuries. Presenting the comprehensive scientific data, the defence demonstrated that the plaintiffs' general-causation opinions lacked a scientific basis. The court excluded these opinions, which ultimately resulted in the termination of the entire litigation. This was a positive result, but it took many years to get there.

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Q. Have any recent legal or regulatory developments affected product liability cases?

A. Due to variations in law, judges, and juries, plaintiffs often file lawsuits in state courts they deem favourable. The US Supreme Court has held that if case-specific facts do not provide a court with personal jurisdiction over the defendant, the state court may only exercise general jurisdiction over a defendant 'at home' in that state. While this sounds limiting, there is a history of state courts exercising general jurisdiction in a broad manner, relying on state statutes. Aided by such a statute allowing general jurisdiction over companies registered in the state to do business, Pennsylvania has become a hotbed for litigation. However, in the 2021 case of *Mallory v. Norfolk Southern Railway Co.,* Pennsylvania's Supreme Court recently found the state's statutory expansion of general jurisdiction to be unconstitutional. The ruling limits Pennsylvania's outsized role in product liability litigation and supports arguments that similar statutes are unconstitutional.

Q. What are some of the specific challenges for companies facing a product liability claim, including class actions? What steps should form part of their initial response?

A. Companies facing product liability claims, including class actions, frequently confront a lack of information based on vaguely drafted complaints. These complaints may refer generally to manufacturing or design defects with no specific information about the defects alleged. Similarly, plaintiffs often bring failure-to-warn claims without specifying how the warnings are inadequate and fraud claims without pleading a misstatement or omission. When possible, companies should remove state court cases to federal court – which is generally more favourable to defendants – and then use the inadequate allegations to their advantage by moving to dismiss for failure to comply with federal pleading standards, including Rules 8 and 9(b), or the state equivalent. These challenges educate the court about the weaknesses of the case at an early stage. The result is often abandonment of nonviable claims while providing critical information about

plaintiffs' viable theories, allowing for the development of a comprehensive defence strategy.

Q. When assessing a claim arising from a defective product, how should manufacturers go about calculating potential damages? What aspects need to be examined?

A. Plaintiff-specific factors, such as the severity of the alleged injuries, pre-existing risk factors for the injury, and the strength of the data supporting the causation claims, are a critical starting point for any damage estimate. Manufacturers should also consider the company conduct defence. Can the plaintiff weave a compelling story that the manufacturer was aware of the product defect and failed to act? Company documents are critical to this analysis. The existence of unfavourable documents, or neutral documents taken out of context, which savvy plaintiffs' attorneys use to further themes such as 'profits over safety', have the potential to inflame juries and significantly increase punitive damages awards. Jurisdictional factors, including the likely makeup of the jury pool, representative jury verdicts in

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the jurisdiction at issue, and any applicable caps or limits on damages, should also be factored into the potential damage calculation.

Q. Could you outline the proactive steps that companies need to take to prepare for a potential product liability claim, such as identifying product defects, planning for recalls, responding to investigations and managing reputational fallout?

A. Any manufacturer conducting business in the US may be subject to product liability litigation. However, identifying and managing risk may allow a company to lessen liability or avoid litigation. Companies should determine potential areas of risk from product planning and development to distribution, and then assess ways to mitigate those risks. Some areas to examine and monitor for possible litigation risk include distribution and supplier agreements, quality control and standard operating procedures, training and promotional materials, adverse events in development and post-marketing, regulatory agency interaction and compliance, media and public-facing communications, attorney advertising, and related publications or studies. Identifying issues seen in litigation or regulatory action involving similar products, along with monitoring new developments with the company's own product, allows the company to mitigate and prepare, putting it in a stronger position to avoid or combat litigation.

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

A. Even prior to developing a product, it is important to determine the potential liability risk associated with development, marketing and distribution. Similar products in development or already on the market are the best predictors for a company's product's performance and course. We recommend companies examine and keep abreast of regulatory action, literature, studies and other publications, sales and litigation of similar products prior to development. As development begins, ensuring regulatory compliance and open communication is important. Development can identify

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known possible adverse events or uncover unknown issues. It is important to continually examine adverse events and develop a strategy of mitigation to address issues early and completely. Knowledge and swift action are the best tools in preparing for litigation and resolving possible claims later. ❑

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SHOOK, HARDY & BACON's reputation as an international powerhouse is founded on longstanding collaborations with industry leaders in science, health and technology. In addition to fielding the largest product liability practice in the world, Shook promotes the interests of clients in business and employment litigation, intellectual property disputes and corporate transactions. Working at the intersection of litigation, regulation and public policy, Shook attorneys stay ahead of emerging issues to help companies execute their long-term objectives.

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