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The Shifting Landscape of Product Liability Litigation in the Life Sciences Space

March 26, 2024

By Matthew Zagwoski, Product Leader, Global Life Sciences & Russell Chibe, Claims Manager, Life Sciences

In recent years, there has been a significant transformation in how product liability cases are evaluated within the life sciences sector in the US. Fifteen to twenty years ago, the criterion was relatively straightforward: do the facts of a particular case support a finding of liability against a manufacturer? If so, you looked to provable damages to evaluate the risk. However, the landscape has evolved, and the focus has shifted. Today, less emphasis is placed on the specific facts of a plaintiff's allegations and more on whether a manufacturer is an attractive target of the plaintiffs' bar in general.

Driven primarily by the high severity and the ease of multidistrict litigation (MDL) and US-based class actions, this evolution underscores the importance for life sciences policyholders, risk managers, executives, and their brokers to understand the shifting landscape and its potential impact. Even if an organization is not at fault, they may still face a costly lawsuit. While this may not be a welcome message for life sciences companies, it is one they cannot afford to ignore.

This article examines recent legal tactics employed by the plaintiffs' bar, analyzing their effect on defense costs and underwriting considerations. We also consider the importance for life sciences organizations to stay informed about the current liability landscape.

Changing plaintiffs' bar tactics

In recent years, plaintiffs' legal representatives have significantly evolved their strategies, particularly in cases that fall into a gray area. By employing tactics such as emphasizing a "profits over patients"

narrative and other strategies to portray defendants in a negative light, the plaintiffs' bar has been able to effectively leverage the widespread distrust of both life sciences corporations and the Food and Drug Administration (FDA) to advance their agenda.1

Using aspects of environmental, social, and governance (ESG), public relations, and regulatory history to influence public perception of a company's culture has become a common tactic for plaintiffs' firms. Any aspect that can cast the defendant organization in a negative light is utilized to influence jury pools and judgments against clients who may not have otherwise been found culpable.

Plaintiffs' firms have also shifted to a 'failure to warn' litigation approach, largely because of its nebulous nature.2 Previously plaintiffs' firms asserted actual defects in the device as the basis of their case, whereas a more subjective 'failure to warn' strategy is increasingly proving more effective than defective design or manufacture. As by emphasizing what the life sciences organization knew or should have known, any indication of the defendant's failure to share information with the public can influence the outcome of the liability case against them.

The impact of plaintiff litigation funding

The rise of plaintiff litigation funding has also altered the liability landscape significantly. This funding, which has become more prevalent in the US in recent decades, enables plaintiffs to pursue complex litigation cases in an exploratory manner.3 Previously, the high costs associated with preparing a mass tort claim deterred plaintiffs from pursuing less certain cases and increasing their risk. As a result of this change in funding, defendants now face substantial litigation costs, and once litigation commences, it is harder to use the defenses' ability to handle burdensome discovery (previously an advantage) to persuade plaintiffs to settle weaker lawsuits at favorable terms.

These tactics used by the plaintiffs' bar are fostering a societal belief that plaintiffs deserve compensation regardless of a defendant's culpability, and these lawsuits are gaining traction. The public's perception of life sciences defendants is becoming pivotal in influencing the proceedings and final decisions, often overshadowing the actual evidence and influencing juries and verdicts, irrespective of true culpability.

Claims costs are rising

With the power dynamic shifting in favor of plaintiffs, defense strategies for life sciences organizations are increasingly focused on navigating forced settlements, particularly regarding when and at what amount to settle. Within MDLs, many judges perceive their role to be one of steering parties towards settlements4, rather than achieving resolutions that accurately reflect culpability. This trend can have costly implications for defendants.

As a result, defense costs are significantly influencing strategic decisions, often determining the outcome of larger claims based purely

on these expenses rather than apportioned liability. Furthermore, the rising costs of specialty defense counsel and subject matter experts, coupled with plaintiffs' firms' ability to expand the plaintiff pool, are contributing to a significant escalation in defense costs.

The impact of defense strategy and underwriting process

From an underwriting perspective, insurers are increasingly focusing on the perceived integrity of life sciences companies and their defenciblity. They are scrutinizing their clients' public relations and marketing activity, posing challenging questions before issuing policies. Firms should expect to answer questions such as - How has the organization enhanced its public image as a responsible corporate entity? What measures have they taken to demonstrate prioritization of patient safety over shareholder interests? Is there a formal ESG policy in place, and if so, what is their stance? Does the organization's mission statement reflect a humanitarian ethos?

Even an organization's regulatory track record is now considered during the underwriting process. Underwriters scrutinize the company's past engagement with regulatory agencies (especially the FDA), as a history marked by notable public disagreements with the FDA can cast the client in an unfavorable light.

How should life sciences organizations respond?

In today's litigious environment, investing in public relations and aligning communication strategies with messages that emphasize social responsibility can yield significant returns on investment. Simple adjustments, like crafting mission statements to highlight a patient-centric approach or implementing reputation management through online activity monitoring, can make a substantial impact. Not only can such efforts potentially secure better insurance terms, but they can also better position a life sciences organization in the event of future litigation.

Ultimately, staying informed and mindful of shifting litigation trends is crucial. Drawing from extensive experience with claims litigation in this field, your insurance carrier serves as a valuable resource for understanding trends in the courts. Life sciences organizations should also utilize their insurance partners' insight and knowledge of the shifting liability landscape so that they are informed and comprehend the evolving risk landscape they face.

[1] https://www.managedhealthcareexecutive.com/view/many-americans-feel-us-healthcare-puts-profit-over-patients

[2] https://scholarship.law.cornell.edu/cgi/viewcontent.cgi?article=2551&context=facpub

[3] https://instituteforlegalreform.com/what-you-need-to-know-about-third-party-litigation-funding/

[4] https://irlaw.umkc.edu/cgi/viewcontent.cgi?article=1016&context=lawreview

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