

Supply Chain Indemnification Tips For Medical Device Cos.

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Even as vaccination rates continue to increase, and the impact of COVID-19 on daily life begins to lessen, supply chain disruptions wrought by the COVID-19 pandemic and a confluence of other world events over the past two and a half years linger.

In the early days of the pandemic, we saw shortages of COVID-19-related medical products such as ventilators and masks. Now, shortages have rippled out to affect many devices that are themselves entirely unrelated to COVID-19 treatment or prevention.

For example, recent scarcity of raw materials such as plastic resins, metal, glass, semiconductors and chips has contributed to shortages of medical devices ranging from wheelchairs, IV poles and heart defibrillators to syringes, feeding tubes, exam tables and even plastic toilets.

Where at the beginning of the pandemic we saw companies in a variety of industries repurposing their facilities to produce COVID-19 products such as masks and ventilators, the same is generally not happening in response to the current medical device shortages.

To the contrary, increased demand for consumer products as the holidays approach has only compounded the medical device shortages, as raw materials have been diverted out of the medical device supply chain and into consumer products.

While these supply disruptions have many costly implications, they may also provide the opportunity for companies to reassess and revise their supply contracts. Indemnification provisions are one aspect of supply contracts that companies in the medical device industry would be well advised to review.

Product supply chains are complex networks, often involving multiple entities with distinct roles and responsibilities. While all entities in the supply chain can be targets of product liability litigation, it is not uncommon for plaintiffs to name only the most consumer-facing. That named party, however, may not be legally or factually responsible for the conduct at issue.



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Where the responsible entity is not brought into the litigation, product liability defendants can find themselves litigating claims involving products they did not themselves design or manufacture, or for which they did not create warnings or instructions. Securing indemnification from the responsible entity in such circumstances is key.

Product supply agreements typically contain provisions that define the scope and nature of indemnity obligations between supplier and distributor — including the type of claims or injuries for which indemnification is owed and procedural requirements for obtaining indemnification. Ideally, when product liability litigation occurs, tender is made to the responsible party under the terms of the agreement, and the tendered-to party accepts its contractual obligations.

But in practice, resolving tender issues is often time-consuming and expensive. Carefully drafted indemnification provisions in supply agreements are essential, both for persuading entities to accept tender in the first instance, and if necessary, for prevailing in litigation to enforce the agreement.

While indemnification disputes may arise for any number of factual and legal reasons, here are the most common ones to watch.

Lack of Timely Notice

Supply agreements may define when an entity requesting indemnification must provide notice to the tendered-to entity. Such notice provisions, when they exist, can range from specific to more general.

For example, an agreement could require notice within a certain number of days, or merely "prompt" or "reasonable" notice. Additionally, the trigger for the notice period is not always well-defined or practical.

A requirement that the tendering party provide notice once it has "reasonable notice of a claim," for example, may not account for the fact that product identification is often not available immediately upon receipt of a claim.

Claims Outside the Scope of Indemnity Provisions

While supply agreements typically describe the types of claims for which indemnification is owed, disputes can arise as to whether a particular set of factual allegations falls within the scope of available indemnification.

An agreement may cover, for example, claims for defective manufacture and design, but exclude such claims when arising from the independent conduct of one party. Determining whether a claim falls within the scope of indemnification provisions may require discovery and factual determinations.

Reciprocal Indemnification Obligations

Supply agreements often impose reciprocal indemnification obligations, which provide for indemnification flowing in either direction — to the supplier or distributor — depending on the nature of the claims at issue.

An agreement may provide, for example, that the distributor owes indemnification for claims relating to marketing or advertising of a product, but the supplier owes indemnification for claims relating to

manufacturing or design.

When a plaintiff alleges multiple product defects, or where the respective roles of the parties with respect to the product are not well-defined, disputes may arise as to which entity is owed indemnification.

Duty to Indemnify Not Ripe

Entities named in product liability litigation often seek to resolve indemnification right away, so as to avoid unnecessary time and expense. However, tendered-to entities may argue that indemnification requests are not ripe until entry of judgment.

While the law differs between jurisdictions, the crux of this issue is typically whether the contract provides for a duty to defend, in addition to a duty to indemnify. Whereas a duty to indemnify usually obligates the tendered-to party to pay the costs of any judgment or settlement ultimately paid to a claimant, a duty to defend obligates the tendered-to party to assume defense of the claim.

Further complicating matters, contractual provisions providing for indemnification only upon entry of a "judgment" may discourage settlement.

Finally, contracting parties should not discount the importance of practical considerations, such as the financial health and good faith of their business partners, and the availability of enforcement mechanisms. Bankrupt entities, or entities no longer in business, may be unable or unwilling to accept tender.

Other entities, particularly those with whom there is no ongoing business relationship, may refuse to honor their contractual obligations. And it may be more challenging to pursue entities located outside of the U.S.

Ultimately, contractual indemnification provisions must be tailored to the unique facts and circumstances of each supply relationship. But careful planning and foresight with respect to indemnification pitfalls can help set expectations, define responsibilities, and reduce costs if and when product liability litigation arises.

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