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Risk Allocation For Drug And Device Cos. And Their Suppliers

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Entities in the medical device and pharmaceutical industries are doubtlessly familiar with the disruption COVID-19 has wrought on supply chains, with shortages or threatened shortages of a wide range of products.

In response to this crisis, entities are continue to reevaluate their supply chains and business relationships, noting the need for increased flexibility and resiliency — which might mean changing or diversifying suppliers, renegotiating contracts and the like

While many pandemic-related supply chain disruptions have been consumer-facing — i.e., shortages of finished products — a less visible but equally essential part of the supply chain that has faced disruption is the supply of materials or components that product manufacturers use to make those finished products.

For example, at the onset of the pandemic, the scarcity of hand sanitizer products prompted the U.S. Food and Drug Administration to temporarily relax its regulations on the active ingredients incorporated into hand sanitizers, allowing manufacturers to make hand sanitizers using fuel or technical grade alcohol, so long as the product complied with certain specifications.

It is generally well known that entities engaged in the upstream supply of material to intermediary purchasers — such as medical device or pharmaceutical companies who incorporate those materials into finished products — have a number of defenses available to them in the product liability context. More often than finished product manufacturers, such entities can successfully shield themselves from liability related to the finished products into which their materials are incorporated.

While the interests of supplying entities and intermediate purchasers may at times diverge, their business relationship also presents opportunities to allocate potential liability appropriately — and, where possible, minimize shared risk. Keeping potential product liability defenses in mind as efforts to revamp supply chains move forward can help achieve this goal.

PREP Act Immunity

Immunity under the Public Readiness and Emergency Preparedness, or PREP, Act substantially limits product liability litigation against manufacturers of covered COVID-19 countermeasures, which include a wide variety of products used to treat, diagnose, cure, prevent or mitigate COVID-19.

This protection extends not only to finished-product manufacturers, but also to manufacturers of components or constituent materials incorporated into covered countermeasure products. However, there may be circumstances in which entities will not be able to rely on PREP Act immunity.

For example, one notable limitation of the PREP Act is that its protections generally expire in October 2024. This being the case, there is some risk of liability exposure should claims arise after the immunity period expires.

Raw Materials and Component Parts Doctrine

Suppliers of raw materials or component parts incorporated into finished products are not ordinarily liable for injuries resulting from the use of a finished product into which their raw material or component part is incorporated. These common law doctrines, often referred to as the raw materials and component parts doctrines, exist in some form in many states.

The raw materials and component parts doctrines may provide a defense to a variety of product liability claims, including design defect and failure to warn claims, in both negligence and strict liability settings. These doctrines are premised on the idea that the supplier of raw materials or component parts is typically not in a position to scrutinize the finished products into which its materials or parts are incorporated.

Often, materials and parts suppliers sell to companies in a variety of industries, which then incorporate the materials into products that the supplier had no role in designing. In some cases, suppliers may not even know what products their raw materials are ultimately incorporated into.

Materials and parts suppliers can, however, be liable to the end user of a finished product in certain limited circumstances — namely, if the raw material or part itself is defective (for example, if a raw material is contaminated), or where the supplier substantially participated in the integration of the material or part into the design of the finished product, and the integration of the material or part rendered the finished product defective.

Bulk Supplier and Sophisticated Intermediary Doctrines

In the failure to warn context, raw material or part suppliers may also be relieved of liability to end users of finished products into which their materials or parts are incorporated by two additional common law defenses: the bulk supplier and sophisticated intermediary doctrines.

Under these doctrines, a supplier of materials or parts to a sophisticated intermediary purchaser — such as a manufacturer of medical devices — discharges its duty to warn by providing warnings to the intermediary purchaser. The intermediary, rather than the supplier, is charged with passing on those warnings to the ultimate user of the finished product, so long as the supplier reasonably relied on the intermediary to do so.

Similar to the raw materials and component parts doctrines, the bulk supplier and sophisticated

intermediary doctrines derive from the idea that suppliers of materials or parts to intermediary purchasers, who incorporate those materials or parts into finished products, are not well-positioned to warn end users. Such suppliers are not typically labeling the finished product, do not have direct contact with end users and may have their materials put to a wide variety of commercial uses.

Biomaterials Access Assurance Act

A lesser-known defense available to suppliers of biomaterials — i.e., raw materials or component parts used in the manufacture of an implant — is the Biomaterials Access Assurance Act, or BAAA.

Though suppliers may often be able to extricate themselves from product liability litigation on the basis of the raw materials, bulk supplier or sophisticated intermediary doctrines, this often requires first enduring expensive discovery. The BAAA creates a procedural mechanism for biomaterial suppliers to be dismissed from litigation in advance of significant discovery.

Where it applies, the BAAA provides that a biomaterials supplier is not liable for harm caused by an implant, unless they are liable as a manufacturer or seller of the implant, or if the material itself failed to meet applicable contractual requirements or specifications. However, the BAAA is of relatively narrow applicability and, even where applicable, comes with important caveats to consider.

The applicability of the BAAA is complex and not always intuitive, hinging largely on the definitions found within the statute. For example, whether a device is a covered implant depends both on the length of time it is intended to be placed in the body and whether it is intended to be placed in a surgical opening versus naturally formed body cavity.

Some devices generally thought of as implants do not meet the BAAA definition, such as a urinary catheter only inserted for a period of a few days. Covered raw materials, in turn, include only materials that have a generic use and may be used in applications other than an implant.

Additionally, suppliers contemplating seeking BAAA dismissal should be aware that while dismissal is with prejudice, they may be subject to post-judgment impleader where their negligence or intentionally tortious conduct is found to be the proximate cause of a plaintiff's harm.

The BAAA specifically allows for a supplier to be brought back into a case, even after final judgment, if their negligence or intentionally tortious conduct caused harm, to assess proportionate liability or otherwise bear some of the cost, where the claimant is unlikely to be able to recover the full amount of its damages from the remaining defendants.

What Entities Should Keep in Mind When Evaluating Supply Relationships

In many cases, both suppliers and purchasers can best position themselves for potential litigation by ensuring that the parties' respective responsibilities and activities are clearly outlined and documented at every step of the business relationship. Anticipating potential litigation even before entering a supply agreement — in the sales and negotiation stages — can present an early opportunity to minimize risk, and set the stage for clear communication and documentation for the duration of the business relationship.

For example, to best position themselves to use the raw materials/component parts doctrine, suppliers can ensure that they do not substantially participate in design of the finished product, by refraining from

advising about particular materials that should be used in a finished product, even in the sales context.

On the other hand, awareness of activities that the supplier can participate in without incurring substantial litigation risk can be important too — for example, manufacturing a component part to a purchaser's specifications, or offering mechanical or technical services exclusive to the raw material or component part.

Similarly, suppliers might evaluate potential business partners and materials applications, with the understanding that the end product into which their component is incorporated can affect liability. For example, where the raw material or component part at issue has multiple uses, a court may be less likely to find that the supplier substantially participated in design of the finished product for purposes of the raw material and component parts doctrines.

Knowing the end products into which their material or parts are being incorporated may also allow suppliers to assess the availability of other defenses, such as the BAAA.

From the purchasing intermediary's perspective, contract terms may provide a mechanism to ensure that they have access to the information needed to defend against lawsuits that actually involved defects in the raw materials or component parts, rather than finished products.

A purchaser might seek to negotiate access to supplier's testing data, for example. Or, to the extent a supplier does participate in design of the finished product, the purchaser might consider indemnification provisions for lawsuits involving those applications of the raw material or component part.

Finally, frequent communication between a supplier and a purchasing entity can be mutually beneficial when it comes to discharging duties to warn. Under the bulk supplier and sophisticated purchaser doctrines, for example, suppliers need only warn the intermediary purchaser — not the end user of the finished product. But the purchasing intermediary, charged with passing on warnings from the supplier, has an interest in ensuring end users obtain those warnings.

The entire supply chain benefits from robust warnings and communications of risk to end users, and well-informed end users are less likely to misuse products and experience harm. Robust communication between suppliers and purchasers — including about updating warnings and disclaimers or monitoring buzz about known and emerging materials-related risks — can aid both suppliers and intermediaries in fulfilling their warning obligations and keeping end users safe.

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