

## COVID-19 Product Liability And The 'Innocent Seller'

By **Daniel Campbell, Chalana Damron and Mimi Dennis** (June 8, 2020, 5:08 PM EDT)

To mitigate critical supply shortages throughout the country during the COVID-19 pandemic, numerous companies have stepped up to manufacture desperately needed products such as ventilators, test kits and personal protective equipment, and others to distribute these products into the supply chain and ensure that the items are available to consumers.

Most manufacturers seem to be cognizant of the inherent liability exposure associated with producing these products — especially given that many are intended for use in particularly vulnerable patient populations — and have looked to the Public Readiness and Emergency Preparedness or PREP, Act for liability protections.

The PREP Act is appealing to businesses venturing into this space, as it immunizes individuals and entities from liability associated with the use of medical countermeasures. This law, however, has specific requirements that must be met before its protections apply. For instance, there must be a governmental connection; thus PREP Act immunity is unlikely to reach companies such as retailers that sell products directly to consumers, absent a contract or arrangement with a federal agency or certain state entities.

In addition, PREP Act immunity applies to products that fall within the criteria for a "qualified pandemic or epidemic product" or "security countermeasure," including products subject to, and compliant with, an emergency use authorization. This means that PREP Act protections are unlikely to extend to all products used to reduce the spread of COVID-19, such as hand sanitizer.

Another critical limitation of the PREP Act is that its protections generally expire in October 2024. Consequently, even if a certain product is covered by the PREP Act, there is still some risk of liability should an individual claim harm after the immunity period expires.

But how do nonmanufacturers reduce their respective risks of liability if PREP Act immunity does not attach? There's at least one other option. In the event a company is unable to tap into protections under the PREP Act, or where PREP Act immunity otherwise falls short, innocent distributor statutes could provide nonmanufacturing companies additional protection from liability.



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## **Innocent Distributor Statutes**

Innocent distributor statutes, which are also known as "innocent seller statutes," "sealed container statutes," or "seller's exception statutes," generally protect nonmanufacturing product sellers or retailers from product liability claims premised solely on the seller's status as a distributor in the stream of commerce. At least 24 states have passed innocent distributor statutes.

In effect, these statutes allow distributors to obtain dismissal from product liability claims premised solely on the entity's status as a seller in the stream of commerce, and thus avoiding the need to pursue indemnity claims against the product manufacturer. In order to qualify for protection, a distributor must meet the statutory definition of a "seller" or "distributor." A seller or distributor is typically defined as a wholesaler, distributor, retailer, or other entity that is regularly engaged in selling or placing a product in the stream of commerce for a commercial purpose. Statutory protection from product liability claims typically does not extend to product manufacturers, often defined as a designer, assembler, fabricator, constructor, compounder, producer, processor, formulator or rebuilder.

Innocent seller statutes usually apply to all product liability claims, whether based in negligence or strict liability. A minority of states, however, only grant distributors immunity with respect to strict liability claims, and not negligence or breach of warranty-based claims.

Many innocent seller statutes require that the identity of the product manufacturer be known in order for the statutory protection to apply. In addition, these statutes typically contain exceptions to the liability protection for sellers. While these exceptions vary from state to state, most statutes include at least the following categories of exceptions, under which a nonmanufacturing distributor may still be held liable.

### ***Seller Involvement With the Defective Product***

If the seller was actually aware of the product defect, or the seller exercised control over the design or manufacture of the product, or otherwise modified the product, then the statutory protection will not apply in most states.

### ***Claimants Cannot Obtain a Judgment Against the Manufacturer***

If the manufacturer is not subject to the court's jurisdiction, or if the manufacturer is insolvent or otherwise not able to satisfy a judgment or settlement, and there are no other manufacturers to collect from, then the statutory protection will not apply in most states.

Other common exceptions to the statutory protection include instances where the claimant relied on an express (and allegedly incorrect) representation about the product made by the seller, or where the applicable statute of limitation bars recovery from the manufacturer.

## **Not All Innocent Distributor Statutes Are Created Equal**

Distributors should be familiar with which states' statutes are relatively more advantageous and consider choice-of-law issues when drafting contracts and agreements with upstream and downstream partners, as well as consumer warranties. For example, innocent distributor statutes differ on whether the distributor is presumed to be immune from liability or must make an affirmative showing to establish immunity.

Under Illinois' innocent distributor statute, for example, a court is required to dismiss a distributor from a product liability lawsuit once the distributor files a responsive pleading accompanied by an affidavit identifying the manufacturer of the product at issue. A plaintiff may later overcome this presumption by establishing an exception to the distributor's immunity. By contrast, Maryland's innocent distributor statute does not allow the distributor to assert immunity unless it first establishes that it did not manufacture, design or alter the product.

Innocent distributor statutes also differ with respect to the standard and mechanism for establishing a distributor's immunity. Under Kentucky's innocent distributor statute, the distributor must establish "by a preponderance of the evidence" that the product at issue was sold in its original condition. The statute does not, however, provide a particular process for doing so. Missouri's innocent distributor statute, on the other hand, requires the distributor to file an affidavit stating that it is not aware of any facts upon which the distributor could be held liable — other than its status as a distributor — and provides for a 60-day period of discovery on that issue.

Lastly, innocent distributor statutes vary widely with respect to whether and how a bankruptcy or insolvency exception may undercut a distributor's immunity. Under different versions of this exception, an otherwise innocent distributor may still be held liable if the manufacturer has been "judicially declared insolvent," if "the manufacturer is unable to satisfy any judgment as determined by the court," or the manufacturer "has been adjudicated bankrupt and a judgment is not otherwise recoverable from the assets of the bankruptcy estate." Depending on the construction of such a provision, this exception to a distributor's immunity may be more or less difficult for a plaintiff to establish.

### **Be Mindful of Innocent Distributor Statutes When Drafting Contracts**

In addition to these choice-of-law considerations, distributors should also consider how these statutes differentiate between manufacturers and distributors when drafting contracts and when establishing roles relative to other companies in the stream of commerce.

Contracts should clearly delineate manufacturing and nonmanufacturing roles and responsibilities to ensure that nonmanufacturing distributors fall squarely within the statutory definitions. Distributors should even consider incorporating the precise language of the applicable innocent distributor statute definitions into their supply and quality agreements. Finally, companies should carefully execute their roles; distributors should be careful to not engage in conduct, communication or oversight that could be construed later as participating in the design, manufacture, or alteration of products.

### **Look to Innocent Distributor Statutes in the Early Stages of Your Litigation Strategy**

In any future litigation, parties should be mindful that the burdens of proof and pleading requirements associated with innocent distributor statutes will vary from state to state. A thorough analysis of the applicable statute is thus vital to understanding any possible protections, and pleading and proof requirements, under the law. For example, some statutes place the burden on the plaintiff to prove that the seller had some active role in a product's manufacture that should negate the protections of the statute.

Conversely, some statutes place the burden on the seller to prove its lack of involvement in the manufacturing process, thereby establishing its innocence under the statute.

The burden with respect to other statutory exceptions may vary as well. In Kansas, for example, the burden is on the innocent seller to establish that the manufacturer is subject to service of process, meaning that the manufacturer is a viable defendant. Conversely, under Illinois' statute, the burden instead falls to the plaintiff to establish that the manufacturer is not subject to service of process, meaning that the seller may not be immune and may be required to remain in the case.

Finally, some courts have held that their state's innocent distributor immunity is an affirmative defense that must be asserted in a responsive pleading or is deemed waived, while other states have held that the immunity afforded by such a statute is not an affirmative defense.

In sum, an innocent distributor statute may be a vital defense tool for a blameless seller sued in product liability litigation related to the COVID-19 pandemic, should PREP Act immunity be unavailable. Innocent distributor statute procedures and requirements vary widely from state to state, so these statutes are not a one-size-fits-all tool but must instead be carefully analyzed relative to the facts of each case.

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