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Product Liability In The Age Of Global Pandemics

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Fear of a global Ebola pandemic has dominated the news this year. Travel restrictions, quarantines and the race to conduct human trials on an Ebola vaccine have been discussed everywhere, from presidential press conferences to daytime talk shows. This media reaction — and overreaction — has drawn significant attention to the public health risks associated with Ebola.

Businesses have faced a host of new health challenges and legal issues associated with the potential spread of Ebola. For instance, an emergency room nurse who participated in the treatment of a fellow nurse infected with the Ebola virus in Dallas has retained an attorney to investigate a possible claim against her employer for exposing her to the virus.[1] Airlines with passengers later diagnosed with Ebola have rushed to scrub their planes to calm customer fears about the risk of contamination.[2] And hospitals have updated their internal protocols for treating patients and staff who may have been exposed to the virus.[3]

Now, it seems that companies even further removed from the virus are a potential target, although their relationship to the spread of the virus is tangential at best.

Designing Surgical Gowns for Disaster: Shahinian v. Kimberly-Clark Corp.

One such example is a putative class action filed recently in California.[4] The plaintiff, a cranial surgeon, alleged false marketing and misrepresentation claims against Kimberly-Clark, claiming that the company falsely promoted a certain line of surgical gowns to medical professionals treating patients infected with the Ebola virus despite the company's knowledge that the gowns did not offer adequate protection against biological contaminants. The complaint alleges that internal testing by the defendant showed that the gowns failed to satisfy the standards of Association for the Advancement of Medical Instrumentation Level 4, the highest level of protection that AAMI awards, but the defendant continued to market the product with the false representation that they did.

The plaintiff also alleges that further tests show that the gowns are prone to catastrophic failures that allow liquid and bacterial and viral pathogens to penetrate the gowns, placing both the health care

professional and patients at risk. The complaint seeks certification of a class of all users of the surgical gowns, an injunction against the sale of the gowns, compensatory damages in excess of $500 million, punitive damages and attorney's fees.

Lack of Physical Injury May Not Stop Litigants from Filing Suit

Shahinian illustrates one of the many challenges facing pandemic product liability litigation: namely, if you look out your window, the sky has not yet fallen. Very few people in the U.S. have been exposed to the Ebola virus. Even fewer people have needed treatment for that exposure, and no one exposed to Ebola in the U.S. has died from that exposure. The plaintiff in Shahinian — and nearly every potential member of his class — is not among the class of people facing an actual risk of Ebola infection. As a result, the plaintiff's complaint fails to allege that the plaintiff has suffered any physical injury as a result of the gown's failure or even that the plaintiff faces any quantifiable risk of future physical injury from Ebola infection. In fact, the plaintiff fails to identify even a single incident linking the surgical gown to an Ebola infection (or any other injury).[5]

Without any injury to support a product liability claim, the complaint instead focuses on false marketing claims. This is not the first time that fears of a pandemic have unleashed their own outbreak of false marketing litigation. In Loreto v. Procter & Gamble Co.,[6] the plaintiff alleged that P&G developed special versions of its DayQuil and NyQuil cold and flu remedies which were marketed as including vitamin C, hoping to seize upon global fears about a swine flu pandemic and the common misconception that vitamin C is useful for the treatment and prevention of colds. The plaintiff alleged that P&G continued to market the products despite knowing that there was no evidence that vitamin C was effective in treating the common cold, let alone swine flu.

The court was unreceptive to such claims. It dismissed plaintiff's complaint, finding that the false marketing claims were an attempt to enforce U.S. Food and Drug Administration regulations which do not provide a private right to bring such an action. Additionally the court held that the plaintiff had failed to allege an ascertainable loss because he did not allege the products were ineffective in treating cold and flu symptoms. Thus, the plaintiff was unable to show that he failed to receive the benefit of the bargain in purchasing the medicine.

Other Risks Facing Product Manufacturers

Product manufacturers — no matter how tangentially related to Ebola or any future pandemic — run the risk of unexpectedly finding themselves facing a lawsuit with allegations that seem "ripped from the headlines."

1. Risks to Medical and Safety Product Manufacturers

Manufacturers of vaccines, medicines and medical products used by health care professionals and first responders in handling a pandemic will be on the front lines of any future pandemic litigation. Acknowledging that the risk of litigation may provide a strong disincentive to continue making such products, the federal government has already extended certain liability protections to the manufacturers, distributors, prescribers and dispensers of "covered countermeasures" (e.g., flu vaccines and anti-viral medications) when there is a federally declared emergency.[7] The U.S. Department of Health & Human Services has already announced that developers of an Ebola vaccine will be extended these protections.[8]

The experience of defendants in other mass tort cases, however, proves that "covered countermeasures" may just be the tip of the litigation iceberg. In the asbestos and silica sand litigations, respirator manufacturers have become a frequent target for new claims by the plaintiff's bar, despite the fact that the manufacturers never produced products containing asbestos or silica.[9] These companies have been targeted merely for designing protective equipment to guard against the harmful effects of prolonged exposure to such airborne contaminants, and the suits have continued unabated despite the absence of a reported mass failure of any product.

Although there are few reported verdicts against respirator manufacturers, the few that plaintiffs have received should be enough to give safety gear manufacturers pause. One Mississippi case resulted in nearly $25 million in liability to the manufacturer of two masks worn by four plaintiffs exposed to asbestos.[10] Remarkably, the jury rendered a verdict against the defendant manufacturer even as the plaintiffs' own screening doctor testified that each plaintiff had told him during the examination that he rarely, if ever, wore a mask while exposed to asbestos, or where testimony indicated that they did not use the defendant's products.[11]

2. Risks to Other Product Manufacturers

Nonmedical product manufacturers should not expect that they will be free from litigation either. Outbreaks of Legionnaires' Disease, a type of pneumonia linked to the spread of certain bacteria, have led to numerous cases against a wide swath of product manufacturers. The unique transmission system of the disease — through inhaling aerosolized water containing the bacteria — has allowed plaintiffs to target the manufacturers of everything from air conditioning and cooling systems,[12] water pumps,[13] grocery store vegetable sprinkler systems,[14] and even cruise ship hot tub water filtration systems[15] following an outbreak.

Like with Legionnaires' disease, if it could be established that a faulty air conditioning system exacerbated the spread of the pandemic through an office building or aircraft, this could lead to litigation against the manufacturer. Furthermore, professional negligence suits may be filed against architects and engineers who are alleged to have designed buildings without taking into account the risk that a building's design could lead to the spread of a virus. Plaintiffs may also argue that some normal business activities should require increased scrutiny. For instance, package delivery companies may be required to test all packages or plaintiffs' attorneys may seek to hold entertainment venues liable for not testing all guests before entering. Even the most attenuated connection to a disease may lead to litigation and potential liability.

How Can Companies Protect Themselves

Despite the ever-evolving potential for liability, there are ways that product manufacturers can protect themselves. Companies should make sure that they always exercise high due diligence standards in bringing their products to market. Companies should ensure that they employ market-leading risk assessment procedures to identify possible hazards and consider alternative designs or warnings to mitigate and control risks before litigation occurs. Additionally, companies should also confirm that they comply with the state-of-the-art in their industry, including any product safety guidelines and benchmarks.

As Shahinian demonstrates, plaintiff's counsel will seize upon a product's failure to meet the highest industry standards (particularly if the product's marketing materials allege that they do). Furthermore, companies can attempt to limit their exposure to litigation through insurance or contractual

indemnification. Finally, manufacturers may benefit from turning to trade associations or other industry groups to lobby federal and state regulators for laws that limit opportunities for plaintiffs to bring these types of speculative claims.

Conclusion

Recent litigation trends have shown that even the most insulated business can face claims related to injuries caused by diseases over which it had no control — or even in the face of a pandemic that has not materialized. The risk of litigation is, of course, part of the cost of doing business for product manufacturers, particularly when products are used in a setting where failure is potentially life threatening. It is clear, however, that the cost is increasing and will likely continue to do so as the fear of the spread of pandemic viruses becomes more publicized. Therefore, prudent manufacturers need to be prepared to address these risks.

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[1] Adolfo Pesquera, Nurse at Dallas Ebola Hospital Hires Fort Lauderdale Lawyer, Daily Business Review, Oct. 16, 2014, available at: http://www.dailybusinessreview.com/id=1202673599178/Nurse-at-Dallas-Ebola-Hospital-Hires-Fort-Lauderdale-Lawyer#ixzz3L1z3uC8E.

[2] Hugo Martin, Ebola Patient on Frontier Might Have Had Symptoms on Flight, The Los Angeles Times, Oct. 15, 2014, available at: http://www.latimes.com/business/la-fi-frontier-ebola-scare-cdc-20141015-story.html.

[3] Johnson, Carolyn & Kay Lazar, Hospitals Vary on Ebola Rules for Staff, The Boston Globe, Oct. 25, 2014, available at: http://www.bostonglobe.com/metro/2014/10/24/massachusetts-hospitals-handle-return-health-workers-from-west-africa-differently/Rras1dpiNQF9kAkSwiAYaP/ story.html

[4] Shahinian v. Kimberly-Clark Corp., No. 14-8390 (U.S. Dist. Ct., C.D. Cal., filed Oct. 29, 2014).

[5] See e.g., Clapper v. Amnesty Intern. USA, 133 S. Ct. 1138, 1151 (2013) (plaintiffs could not "manufacture" standing "merely by inflicting harm on themselves based on their fears of hypothetical future harm that is not certainly impending. ... If the law were otherwise, an enterprising plaintiff would be able to secure a lower standard for Article III standing simply by making an expenditure based on a nonparanoid fear").

[6] 737 F. Supp. 2d 909 (S.D. Ohio 2010).

[7] 42 U.S.C. §247d-6d. Public Readiness and Emergency Preparedness Act. Available at: <http://www.hrsa.gov/gethealthcare/conditions/countermeasurescomp/prepact.pdf>

[8] Julie Steenhuysen, U.S. Agency Offers Legal Immunity to Ebola Vaccine Makers, Reuters Dec. 9, 2014,

available at: http://uk.reuters.com/article/2014/12/09/us-health-ebola-vaccine-idUKKBN0JN1S920141209.

[9] According to an industry group, more than 325,000 individual asbestos and silica lawsuits have included claims against respirator manufacturers since 2000. Letter from Daniel K. Shipp, President, Int'l Safety Equip. Manuf. to Edwin G. Foulke, Jr., Asst. Sec. of Labor for Occupational Safety & Health and Leon R. Sequeira, Asst. Sec. of Labor for Policy, U.S. Dep't of Labor (May 19, 2008), available at http://www.safetyequipment.org/.

[10] See 3M Co. v. Johnson, 895 So. 2d 151, 154, 158 (Miss. 2005).

[11] Id. at 155-57, 164-65.

[12] Gross v. Baltimore Aircoil Co., No. 3:13-cv-423-DPJ-FKB (S.D. Miss. March 21, 2014).

[13] Taco Inc. v. Fed. Ins. Co., No. 07-27S (D.R.I. Nov. 30, 2007).

[14] Crowe v. Winn-Dixie of La. Inc., No. 2009 CA 0647 (La. 1st Cir. App. Feb. 12, 2010).

[15] Silivanch v. Celebrity Cruises Inc., 171 F. Supp. 2d 241 (S.D.N.Y. 2001).
