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The Art of Product Liability Defense

> *Though the enemy be stronger in numbers, we may prevent him from fighting. Scheme so as to discover his plans and the likelihood of their success.* – Sun Tzu, The Art of War

Product liability lawsuits have surged over the last few years. Recent high-profile lawsuits involving medical devices have caused plaintiffs' attorneys to set their collective sights on the orthopaedic industry. Generally, product liability lawsuits against orthopaedic companies attempt to transform a known risk, e.g., revision surgery, into a claim that the orthopaedic device is defective.Weak on science and credible experts, plaintiffs' attorneys will often rely on other strategies to bolster their case or to gain settlement leverage. Knowing their strategies and preparing against them is the art of defending medical devices in product liability cases.

> *Security against defeat implies defensive tactics; ability to defeat the enemy means taking the offensive.* – Sun Tzu, The Art of War

Know that plaintiffs' attorneys will request all complaints about your product. They may have researched your complaint handling and reporting obligations. They likely have searched the MAUDE database. They definitely are relying on liberal discoveryrules to make their request, and they are looking for a fight. Give them a fight, but not one they expect. Use your complaint handling system as a defensive tool to narrow their request appropriatelyand then go on the offensive to show the clinical success of your product.

First, be prepared to narrow a request for complaints that likely will be overly broad. It can be argued that other product failures are not discoverable unless the other product failures are substantially similar to those involved in your case.[1] Legal arguments for narrowing a request are more effective if you are in a position to specifically identify which complaints are substantially similar and which are not. An effective complaint handling system will assist you in identifying substantially similar complaints relating to the specific product at issue. Complaint information should describe specifically the product and failure. If the failed product is a component in a system, identify the component. Use objective terms to describe the failure. Avoid using conclusive, legal terms of art, like "defect."
Second, take the offensive using that same effective complaint handling system. You have already identified a limited number of substantially similar complaints relating to the specific product at issue. Now compare that number to the number of total product sales. If you are able to determine through your complaint handling system that you have had relatively few substantially similar complaints compared to the number of implanted products, you can build a case against a design defect allegation.

> *It is the business of a general to be quiet and thus ensure secrecy; upright and just, and thus maintain order.*
> – Sun Tzu, The Art of War

Know that you may also be asked for reports generated through Medical Device Reporting to the FDA. Consider objecting to the production of MDRs. Medical device manufacturers have successfully blocked plaintiffs' attorneys from obtaining MDRs through discovery. For example, one federal court of appeals in a product liability action prohibited any discovery of information contained in or gleaned from voluntarily submitted MDRs.[2]

> *Carefully guard your line of supplies.*
> – Sun Tzu, The Art of War

Know that plaintiffs' attorneys may attempt to name your raw materials supplier as a party to the lawsuit. Consider using the Biomaterials Access Assurance Act to guard your supplier against harassment. The Biomaterials Access Assurance Act of 1998 provides immunity to suppliers of raw materials and component parts of medical devices that are implanted in the human body. The Act preempts state law on the subject and applies to any civil action brought in any court, state or federal, for harm allegedly caused, directly or indirectly, by a medical implant.[3]

The threshold issue for using the Biomaterials Access Assurance Act is whether the supplier is a "biomaterials supplier" as defined by the Act. A "biomaterials supplier" is an entity that directly or indirectly supplies a component part or raw material for use in the manufacture of an implanted medical device.[4] A "biomaterials supplier" is immune from liability for harm to a person allegedly caused by an implanted medical device unless the supplier: (1) is a manufacturer of the implant, (2) is a seller of the implant, or (3) furnished raw materials or component parts that failed to meet applicable contractual requirements or specifications.[5] If suit is brought against a biomaterials supplier for harm caused by an implant, the supplier may assert its statutory immunity right under the Act by filing a motion to dismiss or for summary judgment. Likewise, a medical device manufacturer could use the Biomaterials Access Assurance Act to oppose adding a supplier as a party to the lawsuit.

We can form a single united body, while the enemy must split into fractions. Hence there will be a whole pitted against separate parts of a whole, which means that we shall be many to the enemy's few.
– Sun Tzu, The Art of War

Know that plaintiffs' attorneys will try to play the orthopaedic surgeon against the orthopaedic company. Their strategy is for the orthopaedic surgeon and the orthopaedic company to blame each other for the failed medical device and thus to build the plaintiffs' case. Do not succumb to this strategy, and lay the groundwork with orthopaedic surgeons ahead of time so that you are united against the liability claims made by the plaintiffs' attorneys. A united front generally makes good business and litigation sense. Appropriate product warnings and a network of expert orthopaedic surgeons can go a long way in defeating product liability claims based on defective design and failure to warn theories.

Plaintiffs bringing product liability claims generally must prove that the product is defective and unreasonably dangerous. Courts often interpret "unreasonably dangerous" as dangerous beyond that which is contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics.[6] Reliance on consumer expectation, however, is only appropriate when the product is simple enough for a lay person to have safety expectations based on common everyday experience. In cases involving complex products, such as prescription orthopaedic implants, the expectation of an ordinary consumer is not an appropriate standard. Prescription medical products can be so complex that an ordinary consumer cannot rely on everyday experiences to determine the safety of the product. You must know and be prepared to use judicial doctrines or standards concerning product defects which apply specifically to prescription medical products.

For example, the learned intermediary doctrine has arisen in response to the common theory of product liability that the manufacturer of a prescription drug or medical device failed to provide adequate warnings regarding the risks associated with the product.[7] The learned intermediary doctrine requires that the manufacturer warn the health care provider, not the patient. One of the underlying principles of the learned intermediary doctrine is that a treating physician, rather than the patient, is in the best position to evaluate the risks and benefits of the prescription medical product.

The orthopaedic surgeon can also be an ally in defeating a design defect claim. A number of jurisdictions have adopted the principle that prescription medical products are unavoidably unsafe products and, thus, that prescription medical products are neither defective nor unreasonably dangerous when they are properly prepared and accompanied with proper warnings.[8] Again, implicit in this principle is that the orthopaedic surgeon is in the best position to evaluate the risks of the orthopaedic product and to decide whether it is appropriate for the patient after weighing the risks and benefits.

A similar approach, provided by commentators in the Third Restatement of Torts, expressly places the risk/benefit determination for prescription drugs and medical devices on health care providers:

> A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.[9]

In other words, under the Third Restatement approach, if an orthopaedic surgeon would use your device for any class of patients, the device is not defectively designed. Therefore, the favorable opinion testimony of an orthopaedic surgeon, who would use your device for certain patients, could be outcome determinative in your product liability lawsuit.

The art of war teaches us to rely not on the likelihood of the enemy's not coming, but on our own readiness to receive him; not on the chance of his not attacking, but rather on the fact that we have made our position unassailable.
– Sun Tzu, The Art of War

To be ready for a product liability claim means to prepare for the product liability claim before it is filed. The strategies discussed here may not apply to your case and certainly are not intended to be an exhaustive list. Additional strategies should be considered. Like the art of war, the art of defending medical devices in product liability cases varies based on the (factual and legal) territory. Consult with counsel who knows the territory.

[1] *See, e.g., Piacenti v. General Motors Corp.*, 173 F.R.D.221 (N.D.Ill.1997).
[2] *In re Medtronic*, 184 F.3d 807 (8th Cir. 1999).
[3] 21 U.S.C. §§ 1601 et seq.
[4] 21 U.S.C. § 1602 (1)(A).
[5] 21 U.S.C. § 1604 (a)(1)-(3).
[6] RESTATEMENT (SECOND) OF TORTS § 402A cmt. i(1965).
[7] RESTATEMENT (SECOND) OF TORTS § 402A, cmt. k.
[8] RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(c).

Editor: With 350 legal professionals in seven offices in Indiana, Washington, D.C. and China, and a federal affairs consulting subsidiary in Washington, Baker & Daniels serves client needs around the globe. Baker & Daniels has extensive experience successfully defending medical device companies in product liability lawsuits and currently serves as national product liability counsel for an orthopedics manufacturer. Baker & Daniels also offers counseling on compliance with regulations concerning GMPs, labeling, packaging, advertising, public disclosures, and trademarks. Baker & Daniels serves as counsel to the Indiana Medical Device Manufacturers Council, Inc. J. Stephen Bennett concentrates his practice at Baker & Daniels in product liability defense, particularly medical device cases, and he is a member of the Drug and Medical Device Committee of the Defense Research Institute.

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