Product Liability Cushions the Blow of Risk Management

How to Bulletproof Your Company From the Minefield in Today's Litigious Society

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"Stuff happens," to paraphrase a popular bumper sticker. Whether you work for an OEM or a contract manufacturer (CM), this "stuff" includes product liability. The legal landscape for medical product manufacturers these days is perilous. The general public is conditioned to reading headlines about medical device and pharmaceutical misadventures that harm patients, and is quick to assume that corporations place profits over patient safety considerations. Regulatory problems associated with Vioxx, Guidant implantable defibrillators and other device recalls cause the public to believe that the FDA is lax in regulating the safety of medical devices.

Enterprising personal injury attorneys are increasingly seeing medical device litigation as a lucrative niche. They are forming special litigation interest groups, sharing information, networking on the Internet and organizing seminars to give help and instruction on suing various medical products, from catheters to hip implants. Suing medical product companies has become a "sexy" niche of personal injury litigation.

The ultimate pot of gold at the end of the proverbial whiplash is a Vioxx-sized verdict a la Merck's first trial on that drug, or a multi-million (or even multi-billion) dollar class action settlement on behalf of plaintiffs situated nationwide. When listening to TV ads for personal injury attorneys, one hears similarities to the *Publishers Clearinghouse Sweepstakes* awards declaring, "You may already be a victim!" America's victim mentality—the notion that somebody must pay if a medical procedure goes awry—creates a dangerous legal environment for firms who outsource medical product manufacturing or those who perform such functions for OEMs.

Additionally, medical malpractice tort reform often has capped the amount of financial recovery possible against physicians. The net effect and unintended consequences of this reform are to make medical device firms more lucrative deep-pocket targets for an increasingly well-organized plaintiff bar. In other cases, doctors sued for medical malpractice blame the medical device and unwittingly give the personal injury attorney a "roadmap" for recovering against an additional defendant.

Exposed to Product Liability

Don't think that you are immune to product liability problems just because you haven't yet faced a claim or lawsuit. Also, do not think that you are insulated from problems because you are either an OEM or CM. Under various theories of legal liability, either type of company or both can be found responsible for an alleged injury to an aggrieved patient. Even groundless claims can exact a heavy financial toll and become a major time distraction from the responsibilities of running a profitable medical enterprise. Left neglected, product liability can threaten the financial health and even the very existence of any OEM or CM. Thus, it is even more critical that such firms look at ways to manage product liability risks for their organizations.

Medical product professionals may occasionally hear about risk management but may have only a vague idea of the phrase's meaning. Risk management is a process that involves:

- Identifying possible causes of loss—in this case, product liability loss
- Finding ways to address the causes of product liability loss
- Selecting an appropriate technique to address the cause(s)
- Implementing the technique
- Monitoring a risk management program for results

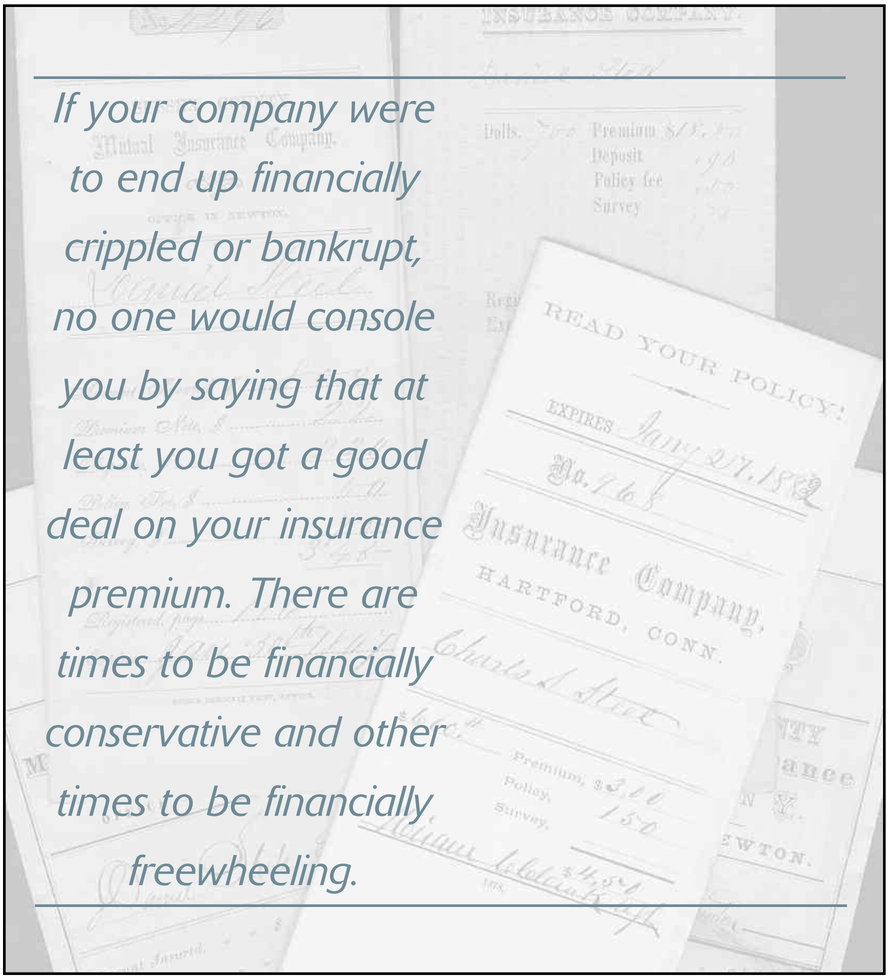
Medical device firms can also view risk management as a toolbox of techniques.

Risk Management Toolbox

Four classic risk management tactics apply in varying degrees to medical product liability claims: avoidance, control, retention and transfer.

Avoidance, as the term implies, means shying away from an activity because of its loss potential. Avoidance may involve opting out of existing manufacturing activities or deciding not to take part in other activities due to the risk of loss. Avoidance is an extreme risk management technique, reserved largely for risks that a device firm deems uncontrollable or threatening to its financial existence. For example, few firms venture into manufacturing IUDs, perhaps daunted by the litigation history of the Dalkon Shield and by Copper-7 litigation.

Control aims to reduce the frequency or severity of accidents. Loss control emphasizes safety techniques to keep adverse outcomes from occurring. For medical device firms, loss control focuses on areas such as good manufacturing practices, top-flight design systems, document manage-



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ment programs, and legal and human review of labels, warnings and regulatory compliance.

Loss control techniques benefit device firms in three ways. First, to the extent that preventive measures prevent mishaps, they save money and loss of life or limb. Second, insurance companies offer lower premiums to medical firms that demonstrate well-conceived and executed risk management plans. Many insurance companies may provide even further, deeper discounts to companies that adopt loss control measures. Finally, whatever the costs of loss control and safety measures, they are typically less than that of a single product liability claim. Expressed differently, if risk reduction steps avert one mishap for a medical device company, those measures will have paid for themselves many times over.

Five Steps of the Risk Management Process

- *Identify possible causes of loss.*
- *Find ways to address the causes.*
- *Pick the best technique to address the causes of loss.*
- *Implement the technique—execute!*
- *Monitor for results and return to step #1.*

Retention is a conscious decision to self-fund losses without transferring risk to an insurer or another risk-bearing entity. While large corporations establish "self-insurance" programs, many medical device firms may lack the means to seriously consider this.

Transfer, as the term implies, involves shifting the financial consequence of loss to another entity. The most obvious example of transfer is insurance. A medical device firm pays money—a premium—to a professional risk-bearer, ie, an insurer. An insurer exchanges a promise to pay, in return, for a stream of premium. The idea is that the premiums of the many fund the losses of the few.

Insurance is a common risk management technique, but it works optimally when blended with avoidance, control and retention—a holistic approach is best, without overt reliance on insurance as the cornerstone of a risk management program. To an extent, insurance should be the last line of defense in a well-constructed risk management program, not the end all and be all.

One key goal of risk management is asset protection. We have discussed risk management as a series of processes. While this is one useful approach, let us also explore risk management as a series of guidelines or maxims for medical device firms. These apply whether you are a CM or an OEM.

Risk Management Maxims

Once they understand the critical importance of asset protection, medical device firms should heed the following risk management advice:

Don't retain more than you can afford to lose. Fortune 500 companies can afford to "self-insure" for millions of dollars, but few medical product firms can do so. While it's great to see a premium savings from higher deductibles on the property insurance covering your office equipment and fixtures, make sure you have the funds set aside to pay any portion of a loss that is uncovered due to a deductible. Not many companies have the discipline, foresight or financial wherewithal to consciously set aside funds for future losses.

In addition, despite best intentions, they will be amateurs at it. Even the so-called professionals—the insurance companies and their actuaries—often get it wrong in terms of forecasting losses, and they are specialists in the discipline with a whole array of analytical tools at their disposal. If the pros often cannot get it right in terms of loss projections, what are the odds that an individual contract manufacturer or OEM will be able to successfully forecast losses and self-fund for them accordingly? The odds are not on the side of the device companies.

Instead, contract manufacturers and OEMs might consider retaining risk through either deductibles or self-insured retentions on insurance policies. This will usually also gain them some premium reduction.

Four Classic Risk Management Tactics

- *Avoidance*
- *Control*
- *Retention*
- *Transfer*

One key element to gauge is the risk tolerance and risk appetite of your upper management. Put differently, how much does top management value a good night's sleep? How aggressive is management toward taking risk? The answer may vary significantly depending on whether the device firm is privately held or a public company; whether it generates revenues internally and from organic growth or depends on venture capital; or whether its strategy is to go public or to seek acquisition by a larger existing entity. Factors such as the CEO's personality will even enter the equation. There is no right or wrong degree of risk appetite, but a device manufacturer's risk management program needs to factor in the risk appetite of its upper management.

Don't retain a lot to save a little. This is a corollary of the preceding tip. Risks with low frequency but high severity should generally be insured, because they are so predictable. Medical product liability claims typically have moderate to low frequency, but high severity. (Medmarc staff often say to each other, "We're in the frequency business.") In an inflationary and litigious age, one suit could financially cripple a device company and shut down its operation. One claim could cost many times the tab for one year of insurance premium and have catastrophic financial consequences. Part of what you buy is peace of mind. How much is this worth to you? For many medical device companies, the answer is ... plenty!

If your company were to end up financially crippled or bankrupt, no one would console you by saying that at least you got a good deal on your insurance premium. There are times to be financially conservative and other times to be financially freewheeling. When you ponder financial protection for your medical device enterprise, conservatism should carry the day. Don't think that just because you haven't ever had a claim or a lawsuit that you need little or no financial protection. Just because it hasn't happened yet doesn't mean that it can't or won't. The question is when rather than whether. Liability awards against device companies can total multimillions of dollars. That's not to say that you necessarily need multimillions in liability insurance coverage, but simply that the best practice is to err on the side of conservatism in buying adequate coverage limits.

Don't spend lots for very little financial protection. Spending money for premiums on low-dollar losses is called "swapping dollars" with the insurance company. Examples might be insurance to cover glass breakage, to replace damaged shrubbery on your business premises or buy extended warranty coverage on equipment you use in your manufacturing processes. These types of losses may be moderate to high frequency but low severity. They do not involve big dollar or big ticket items. Here is your opportunity to save money and capture costs. This is where it makes sense to economize and pinch pennies. Better to retain—ie, self-fund—this type of exposure and save some money.

Adopt a risk management approach to your medical enterprise to bulletproof yourself as much as possible from today's product liability minefield!

Four Risk Management Maxims

- *Don't retain more than you can afford to lose.*
- *Don't retain a lot to save a little.*
- *Don't spend a lot for little financial protection.*
- *Don't treat insurance as a substitute for safety.*

Don't treat insurance as a substitute for safety. Never view product liability risks fatalistically because, "That's what we have insurance for." Risk management and insurance go hand-in-hand. In fact, the more you invest in prevention, the less you may have to spend on product liability insurance. The best insurance rates go to medical device companies that already have the best risk management programs that incorporate thorough and regular audits of manufacturing processes; legal review of all warnings, package inserts and instructional material; prudent document control procedures; corporate sensitivity regarding e-mail communication; and a meticulous record of FDA compliance.

Insurance underwriters will fight with each other to provide coverage for businesses that they view as "good" risks. This healthy competition among insurance companies can yield for you the most favorable rates and the broadest scope of coverage. You cannot leverage this kind of influence, however, or trigger this type of competition amongst underwriters if you have a checkered regulatory history, a track record of prior claims and lawsuits or weak to nonexistent risk management systems.

Yes, the bumper sticker got it right. Stuff happens—and it can happen to medical product outsourcers and contract manufacturers. The stuff does not have to torpedo your business, however. Adopt a risk management approach to your medical enterprise to bulletproof yourself as much as possible from today's product liability minefield! ❖

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