

Product Liability Insurers Raise The Bar On Risk Management

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Device firms large and small must do even more to satisfy commercial insurers than what the government requires. In fact, FDA may be of limited concern to companies faced with plaintiffs' suits and escalating premiums, device industry insurance experts say.

Commercial plans provide key protections for companies, such as product liability policies that defend firms and pay on their behalf when negligence claims are made. They can also head off future lawsuits by showing firms where their vulnerabilities lie. Yet companies are often so focused on FDA compliance that they ignore liability issues, according to device and diagnostics insurance firm Medmarc (see chart: "[Product Liability Insurance 101](#)").

"Companies get lulled into believing that if they get that FDA stamp of approval, everything's going to be fine," said Sara Dyson, loss control manager at Medmarc. "Regulatory compliance needs to be your floor, not your ceiling. You absolutely need to comply, but you can't stop there."

"There's always a product liability problem lurking around the corner that the FDA's quality regulations aren't going to address," Dyson told "The Gray Sheet."

The issue remains despite relief from the recent U.S. Supreme Court *Riegel v. Medtronic* ruling in favor of PMA approval pre-empting state personal injury suits, liability insurance reps say (²["The Gray Sheet" Feb. 25, 2008](#), p. 3).

Medmarc, along with other device insurers such as Chubb Group and Travelers, are offering more value-added services such as "loss control" and "risk mitigation" programs to attract companies looking to improve their product liability defenses, says Dan McDonough, medical device insurance broker at Britton-Gallagher & Associates.

According to the Cleveland, Ohio, brokerage firm, an insurer's idea of risk management goes beyond FDA's. More sophisticated buyers may need to adjust their practices to lower premiums and reduce the likelihood of a claim.

"Insurance underwriters will always charge more if they don't understand a product, or there's some subjectivity in their opinion of what a risk is for a company," McDonough said in an interview.

Ultimately, underwriters want to know: "In the event that there's a breakdown, what's your response," says McDonough.

When setting a policy, Medmarc says it looks at the technology (Is it brand new, or similar to existing products?); risk of adverse events (What is likely to go wrong and how will the company respond?); management experience (How knowledgeable and focused on risk management is the executive team?); and financial condition (How healthy is the firm, and who are its financial backers?).

"We would give discounts for evidence that there is an organization-wide mindset to patient safety," Tom Konopka, Medmarc's senior VP-business development and marketing, told "The Gray Sheet." "We would give discounts for experience of management."

Some risk mitigation strategies involve broad, system-wide processes, such as adequately training employees and creating a thorough document management program.

In other cases, insurers offer discounts for adopting specific standards such as the medical device risk management standard, ISO [International Organization for Standardization] 14971.

Medmarc does not overtly guarantee a discount for companies that are ISO compliant, "but we look at those types of controls in concert with the loss prevention control dynamics," Konopka said.

Risky Business Raises Premiums

Businesses can be broken down into various areas of risk, Dyson explains, including "damning documents," off-label promotion and direct-to-consumer advertising.

"You can splice these companies in various ways in terms of where do you expect to find risk? That's what we try to do, and if we find something that looks questionable, we try to correct it," she said.

For example, when a company starts advertising directly to consumers - a practice that device firms are more frequently engaging in (³["The Gray Sheet" Feb. 18, 2008](#), p. 5) - it erodes certain legal liability protections such as the "learned intermediary doctrine," wherein the manufacturer warns physicians of the potentially harmful effects of a product and is therefore not also obligated to warn the user.

"The whole notion of moving to direct-to-consumer advertising is going to have some significant longer-term effects, and only time will tell if the cost-benefit proportions are worth it," Konopka says.

Firms, Hospitals And Vendors Trade Risk

In addition, Britton-Gallagher says companies do not pay enough attention to contracts, especially as a way of sharing liability among all involved parties.

"A lot of [large] companies are self-insuring and they have a policy that may not step in until a very high level, up to \$5 million to \$10 million," said McDonough. "They're trying to distribute as much of that risk as they can to the hospitals, to the distributors."

On the other hand, hospitals and distributors are becoming savvier about transferring risk back to manufacturers, too, McDonough notes.

"Distributors are seeing requests from hospitals, for example, to show them certificates of liability with very high levels, whereas five years ago no one even asked them if they had insurance," McDonough says. "Some won't let them in the door unless they can show a certificate."

Start-ups More Vulnerable, But Not Powerless

Smaller start-up firms may find it difficult, though not impossible, to secure affordable liability insurance, the brokers note.

The policymaker's decision will hinge on whether the management team comes with sufficient experience, and whether the technology is brand-new and therefore unpredictable.

For companies developing well-characterized product types, there are risk mitigation practices in place that underwriters are aware of, even if small firms are not, McDonough says.

Occasionally, small companies cannot make their case to insurers in order to secure a policy. However, "carriers will be very forthcoming in what their objection is," he said. "If it's correctable, we'll certainly help them do that."

Additionally, manufacturers can negotiate with insurance companies on matters such as deductibles and policy limits. Device makers can also ask hospitals to adjust their insurance requirements on a case-by-case basis and exclude certain unnecessary coverage items to save money, McDonough suggests.

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