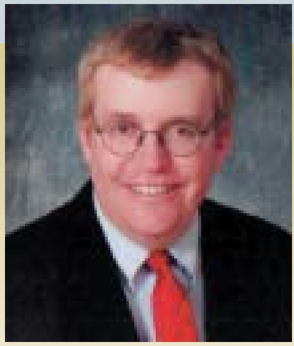

Kevin M. Quinley, CPCU
Senior Vice President, Risk Services
Medmarc Insurance Group

From the BoneZone to the Safety Zone—
Ten Questions for Your Liability Coverage

Orthopedic device firms—whether OEM's or contract manufacturers—face a tough legal climate and perilous tort landscape. Invasive devices must function perfectly or else a swarm of enterprising personal injury attorneys are ready to pounce with product liability lawsuits. Mass tort litigation involving pedicle screws or SulzerMedica hip implants foster the appetite of attorneys who are looking out for the Next Big Thing in medical product liability litigation. The tort climate for orthopedic firms tickles no one's funny bone. To address the financial risks of product liability, firms making orthopedic products need the protection of insurance as a cornerstone of their risk management program.

Whether you are designing an orthopedic device, planning a new business expansion or shopping for financial protection, fortune favors the prepared. One major product liability claim can spell financial ruin for the orthopedic product manufacturer who is inadequately prepared. Since device companies risk lawsuits simply by operating in their chosen fields, they must prudently have insurance to cover this contingency. Orthopedic device manufacturers, known for their exactitude, must have comparable specifications when shopping for product liability insurance.

Insurance policies are two-party deals between a device manufacturer and an insurance company. In the contract, both parties agree to certain terms of protection. Those terms should cover the specifics of a manufacturer's operations and activities. Since an insurance company's literature rarely discloses everything you need to know to decide if a policy is right for you, be sure to ask the company's representative the following ten questions before signing on the dotted line:

1. "How does the insurer determine my premium cost?" Insurers may base premiums on your sales volume and the nature of your manufacturing activities. Insurers consider some product lines riskier than others, so be sure to provide clear, accurate information about the types of manufacturing in which you are engaged. Honesty is the best policy. Withholding any pertinent information either about your operations or involvement in previous litigation may result in later denial of coverage.

Applications may list the areas the insurance company considers high risk: life support equipment, silicone implants, etc. One mid-west company in the mobility business was considering products for disposing of AIDs-patient waste and supplies. This is akin to a life insurance policyholder changing vocations from accountant to paratrooper. If a company makes low-risk products when it applies for coverage but switches later on, it should inform the insurance company. Failure to do so could cause the insurer to deny coverage later in the new area.

Also, let the insurer know if company officers or executives serve on any professional accrediting, design or licensing board or similar formal committee and confirm that it will cover you for any related liability. If not, buy directors and officers (D&O) liability coverage or reconsider the liabilities you may unwittingly be assuming by such activities.

2. "Will I have "claims-made" or "occurrence" coverage?" An "occurrence" policy covers the manufacturer for any loss occurring while the company was insured by that policy. A claims-made policy, however, covers manufacturers only if they are still insured by the same policy when a claim arises. Under most claims-made policies, the date of loss must occur during the policy dates PLUS the claim must be made within the policy dates. Each state has a time limit—statute of limitation—within which claimants can file a suit. With statutes of limitation varying widely among states, a claims-made form forces companies to think twice before switching insurers.

As a manufacturer stays with the same insurer from year to year, the differences between occurrence and claims-made policies start to blur. However, jumping from one insurer to another when you have a claims-made policy, or moving from claims-made to occurrence can be a very tricky business. Caveat: occurrence coverage may be more expensive than claims-made coverage or, in a "tight" insurance market, unavailable.

3. "How financially strong is the insurance company writing this coverage?" The cheapest coverage quote is no bargain if the insurer goes belly-up, leaving you with worthless paper to cover real claims. Sometimes things are cheap for a reason. Check the financial strength of any insurers who give you quotes. An insurance agent or broker can help. Many sources exist, such as the A.M. Best Company or Standard & Poor's. Look for an insurer with a strong capital base, a history of consistent claims-paying ability, and a long operating history. If you are presented with an insurance company you have never heard of, check the financials carefully!

4. "How much is my coverage or limit of liability?"
Normally, the policy section titled, "Declarations of Coverage" lists the amount of liability insurance as well as the effective and expiration date of coverage. Coverage of $1 million per loss—$3 million aggregate, for instance, means that you have coverage for up to $1 million per claim, up to a total of $3 million per year.

Other policies have a combined single limit, where the total coverage is $3 million. Whether you have one $3 million claim or six claims valued at $500,000 apiece, $3 million is the maximum the policy will pay. Ask also if the policy includes incidental professional as well as product liability.

5. "Can I get unlimited or generous defense provisions?"
Find out whether the insurer includes expenses incurred in defending a lawsuit—such as legal fees—in the stated amounts, or whether they are outside of the policy's liability limits. The average product liability claim may take thousands of dollars to defend. Ten years ago, most liability insurance policies provided unlimited defense costs. Insurers, hit hard by skyrocketing legal fees, now often seek to limit their maximum liability for defense expenses. Device manufacturers should seek coverage with generous defense provisions, since this dictates how much real coverage they have. Note that some liability policies may state that the policy does not obligate the insurer to defend you. Moral: read the fine print before snapping up the cheapest premium quotation.

6. "How strongly are you committed to orthopedic device risks?" Some insurers dabble in writing products or medical device liability coverage; a few specialize in it. Grabbing the cheapest premium quotation is no bargain if the insurer later cancels or non-renews your coverage because:
- You have a large claim or a run of bad luck;
- You have a voluntary recall or the FDA takes regulatory action against you;
- Insurance company management no longer considers orthopedic device risks attractive;
- "20/20" or "Dateline" runs a medical "expose" on your device or ones like it, and the insurer presumes guilt by association.

Orthopedic device professionals need insurers with proven track records in writing medical product liability coverage. Some insurance underwriters wouldn't know the difference between Class I and Class III devices or couldn't differentiate a 510(k) from a 401(k). Therefore, ask carriers:
- "How long have you been writing medical product liability coverage?"
- "Give me the names and phone numbers of existing clients in the medical device field."
- "How can I be sure that your company will remain a stable market for my insurance needs and won't abandon me."
- "What long-term pricing trends can I expect?" [*Caveat: Some insurers give a low-ball price as a loss leader to lure new business. Later, they hike premiums when you have claims. If a deal is too good to be true, there is probably a reason!*]

Specific or vague answers are litmus tests for whether a prospective insurer is a good match with your needs.

7. "What protection does the policy give me?" The policy sections titled "Coverages" and "Limits" disclose what actions the insurer covers and for how much. Find out whether or not the policy covers you (and for how much):
- during arbitration
- for loss or damage to the personal property of others
- for damage to employee's property
- for loss of earnings, and for any other expenses you incur while helping the company investigate or defend claims.

8. "Am I adequately insured?" A million dollars in coverage may sound like a lot, but when seven-figure jury verdicts are common, medical device firms may have scant protection if they pick thin limits to save premium costs. No formula can determine the level of insurance limits a nursing home should carry. An experienced insurance agent or broker can help you decide, factoring in such variables as your firm's financial health, claims history and even your risk tolerance.

9. "How do I notify the company when a problem arises?"
The policy's "Conditions" include your specific duties if a claim or lawsuit surfaces. All insurers require prompt reporting of potential suits and may deny coverage if you ignore the rules for reporting such events. Do not take this reporting requirement lightly! Often, this section lists what you must do at the insurer's request: agreeing to settlements, attending hearings and trials, producing witnesses, and helping the insurer enforce any right of contribution if another party caused or contributed to the accident. "Conditions" also tell you what NOT to do. For example, you "must not voluntarily make any payments, assume any obligations, or incur any expenses without the company's consent."

Most policies also include language about the insurer's right to settle out of court. Right now, without a claim, that may mean little to you. Faced with a lawsuit, however, you may be uneasy with the admission or implication of guilt. If you refuse to settle, the policy may let the insurer relinquish its duty to defend. You might then have to defend a claim at your own expense. Discuss this with the insurer, before—not after—you buy coverage and face a claim!

continued on page 50

Liability Coverage, continued from page 49

10. "Can I use deductibles or retentions to cut my costs?" Some product liability policies have deductibles. The higher the deductible you are willing and able to absorb, the lower your insurance premium. Negotiate deductibles with the insurance company to obtain rate concessions.

Finally: read the policy! If anything differs from what the company's representative told you, question it and keep careful records of all correspondence and conversations.

With a little forethought, orthopedic device professionals can design their insurance program as carefully as they would plan a new product rollout. For orthopedic firms and professionals willing to invest the time, broader coverage and lower premiums will be their rewards.

Editor: Medmarc Mutual Insurance Company was founded in 1979 by the medical technology industry for the express purpose of providing stable and predictable products liability insurance. The Company operates exclusively as a reinsurer of primary insurance company partners in national programs. Medmarc Casualty Insurance Company was acquired in 1995 and recapitalized. It is an admitted insurance company in 50 states and the District of Columbia.

Kevin Quinley is a leading authority on claims, product liability losses and litigation management. He manages claims and litigation throughout the world as a senior executive for a cutting edge casualty insurance carrier. Managing claims and litigation throughout the world as a senior exectutive for Medmarc, Mar. Quinley is also the author of over 500 published articles and nine books on various aspects on insurance, claims, product liability, risk management and litigation. He is also a skilled CPCU and IIA Course Leader, specializing in Commercial Liability, The Legal Environment of Insurance and the CPCU Management courses.

Medmarc Insurance Group
14280 Park Meadow Drive, Ste 300
Chantilly, VA 20151-2219
P.O. Box 10809
Chantilly, VA 20153-0809
703-652-1300 (phone)
703-652-1389 (fax)
www.medmarc.com
kquinley@medmarc.com