

## Device Safety and Risk Management After Supreme Court's Riegel v. Medtronic Ruling

As noted in this column in the last issue of *Medical Product Outsourcing*, the Supreme Court's Riegel v. Medtronic decision might make the product liability arena tougher for medical device firms engaged in outsourcing. The ruling underscores the need to invest in strong safety and risk management programs.

### Risk Management Strategies

All the same risk management strategies that made sense pre-Riegel still make sense. For life science firms engaged in medical product outsourcing though, supply chain management becomes even more vital. Those firms outsourcing manufacturing of components or products—or who outsource manufacturing—can and should undertake these risk management steps:

1. **Have due diligence.** Carefully investigate and continually re-evaluate business partners and suppliers. This applies whether a company outsources or receives outsourced jobs.

At multiple points, conduct visits—perhaps unannounced—and independent product testing at various stages of the production process. Verify that the business partner makes products in accordance with the proper specifications and with the quality of materials specified. If faced with a product liability claim, plaintiff attorneys will scrutinize this in microscopic detail.

2. **Require that your “partner” carry liability insurance coverage.** Mandate contractually that each party procure its own product liability protection from reputable insurance providers. Further, insist that each be listed on each other's insurance policy.

Outsourcing does not mean go without insurance coverage. Do not “go bare” because the business partner has coverage. Both partners need their own poli-

cies. Some reasons:

- The partner's insurance policy may have inadequate limits (e.g., a \$2 million claim versus a \$1 million insurance policy).

- He/she may have coverage with an insurer that has weak financials (e.g., a rating downgrade by A.M. Best).

- The claims-paying ability of the partner's insurer is suspect (e.g., insurer flirts with insolvency).

- The claim service of the partner's carrier is sub-par (losses are slow to get assigned or your adjuster is a recording on a toll-free number).

- The partner's insurance company has no business relationship with you and won't look out for your interests if a claim arises (other insurer assigns you a jackleg attorney to save money).

There are many reasons why you should not feel fully protected just because your partner has his/her own insurance. Also, your business partner might produce for you a document called a Certificate of Insurance. That is fine, but device firms must beware of bogus or out-of-date insurance certificates or business partners who cancel policies as soon as manufacturing starts.

3. **Create dispute resolution mechanisms before a claim or controversy.**

What if, say, an infusion pump claim arises and one party thinks the culprit is a manufacturing defect, but the other party thinks it received flawed specifications? What if each company points the finger at the other when a patient is hurt, and an expensive bodily injury claim arises? These are not purely theoretical concerns. When a deal is done, handshakes and high-fives abound. Later, when a claim surfaces or a product firestorm hits, the atmosphere can be very different. Even promising marriages take place against the backdrop of “prenup” agreements. (Just ask Paul McCartney or Madonna.) Get your prenup in place when outsourcing



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medical device manufacturing.

Draft in advance a written dispute resolution mechanism. Also, due to the difficulties of litigating against some foreign companies, have agreements require arbitration of any disputes flowing from the relationship. When it comes to prenups for medical device businesses, it's better to have them and not need them than to need it and not have it.

**4. Regularly review product instructions with qualified legal counsel.** Craft and draft thorough warnings to ensure that consumers and users are properly told how to use devices and are warned of any product hazards. Get warnings, packaging, labels and ads screened in advance by an attorney who specializes in product liability; this is a subspecialty. Seek references in the medical device field, and ask counsel if he or she is credentialed to analyze product warnings from a litigation mitigation standpoint.

**5. Keep your regulatory "house" in order.** Know your FDA regulatory and re-

porting obligations. Not only know them, but follow them to the letter. Regulatory "baggage" such as recalls, medical device reports, warning letters, etc. will be grist for the trial lawyers' mill.

Attorneys can and will scour the Internet to see if you have any regulatory sanctions. Having them does not sink your product liability defense, but—depending on the nature of the "baggage"—it may be an albatross that hinders the defense of a defect claim.

## Your business partner's insurance policy may not be enough to protect you against claims.

**6. Prepare contingency plans for product meltdowns.** "Dig your well before you're thirsty." Implement procedures and prepare response plans to handle obligations timely and efficiently in the event of recalls or litigation. Do crisis simulations such as:

- "The FDA just shut down our Ohio manufacturing plant. What will we do?"
- "Two hospitals have reported three patient deaths associated with our device. What's next?"
- "We just got a class action lawsuit in

California. What is our first step?"

• "Our product was just skewered on the TV news show 'Dateline.' What now?"

Identify, play out and rehearse responses in various scenarios. Be ready to marshal resources to retrieve products or respond to lawsuits in an organized and cost-effective way if a product problem develops.

Medical device outsourcing companies cannot control what they cannot control. Instead, they must focus on those factors in their business environment that they can influence. Given the shifting sands of political changes, judicial uncertainty and legislative reform, medical product outsourcers are best off investing in the "basics" of building strong risk management and safety programs. ❖

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**The 2008 Riegel v. Medtronic decision by the Supreme Court could make liability tougher for medical device makers involved in outsourcing.**

*This article, which does not purport to offer legal advice, is adapted from his November 2008 presentation at the Medical Product Outsourcing Symposium in Waltham, Mass.*