

Confessions of a Claims Adjuster: Product Liability Defense Lessons for Life Sciences Technology Firms

By Cindy Khin CPCU and Kevin Quinley CPCU

Sidebar/Abstract: Medmarc's Kevin Quinley and Cindy Khin have between them over a half-century of claims-handling experience, the vast majority of which consists of managing healthcare technology products liability claims. These two practitioners who are up to their proverbial elbows in these claims step back from the "trees" to assess the "forest" of life sciences product liability claims. In this installment of "Rx for Risk," they prepare life science firms for what to expect from the liability system. They close with nine specific tips that life science firms can embrace to navigate the minefield of today's product liability tort landscape.

Staples may have an Easy Button, but life sciences technology companies should be so lucky! Unfortunately, firms dodging the product liability minefield while introducing new medical devices have no "Easy Button." From the moment a product is conceived to the time of its market launch, the threats of product liability claims and lawsuits loom. The confusing and wacky world of litigation and product liability can stunt the development of innovative technologies and at its worst thwart the introduction of much needed life-saving and life-improving diagnostic and therapeutic technologies.

Let us distill product liability into basic fundamentals, in as plain English, non-legalese. (Disclaimer: we are not lawyers, and do not play them on TV.) Most claims against life sciences technology companies have common themes and turn on the following questions:

- Did the manufacturer provide a product that was free of manufacturing and design (formula)

defects?

- Was the product suitable for its intended use and purpose?
- Did the company establish an effective system to monitor and analyze post-sale intelligence?
- Did the company follow up on its knowledge of hazards with appropriate and adequate action?

Let's look at each component in turn.


Did the manufacturer provide a product that was free of defects? The key to a products liability claim is determining or ruling out a product defect. Much litigation has revolved around this definition, but simply put, a product is defective when it is unfit for the use it was sold for, or if, when it was sold, there was a *reasonably* foreseeable potential for misuse. Admittedly, this is subjective. Many a case is won or lost when experts deconstruct a product's formulary or design. Liken this to Monday morning quarterbacking. In hindsight, it is easy to see traps and fumbles and assess what could have been done differently. It's not so easy when you are in

the game!

Was the product suitable for its intended use or purpose?

This question is at the heart of the legal doctrine of strict liability. It is based on the premise that when a healthcare technology manufacturer places a product into the market, the company represents to the medical community and public that it is safe and effective if used as directed and intended. Of course, courts allow injured patients to weigh in on the reasonableness of those instructions, warnings and the unreasonableness of the danger the product presented – even if used as intended. Here, the focus shifts from the manufacturer's or distributor's actions to the product itself and whether or not it was in fact, unsafe.

Did the company establish an effective system to monitor and analyze post-sale intelligence? In short, what did you know and when did you know it? Product complaints are a life sciences technology firm's "early warning system." Tracking complaints and identifying trends can provide opportunities to prevent



small problems from becoming major litigation headaches. Product complaint tracking systems and internal decision-making can be used against company's in a product liability lawsuit to show that management could have prevented the incident giving rise to the claim, thus preventing injury or harm.

Did the company follow up on its knowledge of hazards with appropriate and adequate action? Defining words like *risk*, *hazard* and *danger* is tough. These words can mean different things to different people. Certainly these words (and supportive theories) have been litigated repeatedly in various states. In some cases, juries have held a manufacturer responsible based on allegations that a manufacturer should have known about the potential for an injury but failed to act. Then, the same case can be litigated in another state and the outcome is completely different, with the manufacturer found not liable. Documenting decisions, supporting the decision making process with analysis and acting immediately will help bullet-proof your defense.

No Good Deed Goes Unpunished

Admittedly, this is a broad and oversimplified view of products liability. Having witnessed thousands of products liability claims against life sciences technology companies over the last twenty years – we now see the commonalities and have seen many good intentions get punished. There are few winners

when it comes to protracted litigation. Litigation is neither quick nor cheap. Courts provide no vindication or exoneration; more likely they provide . . . exhaustion. Along these lines, here are key points for managing claims and litigation

1. Understand the rules. Civil procedures follow common rules. The process will basically consist of discovery, motion practice and trials.

2. Surround yourself with talent you can trust. Medmarc has a network of nearly 200 attorneys around the world that have expertise in life sciences product liability defense. The attorneys undergo a rigorous approval process that includes reference checks. We also employ a simple philosophy: we hire lawyers, not law firms.

3. Doing something is generally better than doing nothing. Claims, unlike fine wine, do not improve with age. You should expect proactive investigations by your insurer and management of your case by the attorney hired to defend your company.

4. Pursue continuous improvement – be open to new and better ways to do what you do and get done what needs to be done. Cookie-cutter claims and litigation management has some appeal. But, beware that not every injury in every state will bring you the same claims, allegations or ultimately, the same result. Defense counsel and your claim representative will recommend a strategy. Stay informed and involved!


5. Read and reflect before responding. Even great questions

will not lead to sound decisions if you have not “listened” to the message. Take time to reflect on what decisions should be made. If you have reservations or questions, discuss them openly with your defense counsel or your claim representative.

6. Leverage your talent. The plaintiff's bar is very organized and is capable of an attack on an industry or a product. Medmarc has met this challenge head on by organizing a specialized panel of attorneys through an internet listserv and by hosting annual meetings for developing strategies to meet the defense needs of the medical device, biotechnology and pharmaceutical industries.

7. Be passionate. Oversight of claims and litigation at your company probably is not going to be 100% of what you do all day, everyday (we hope!). Your involvement and commitment will be imperative, however, to successfully defending your company! Your corporate passion will be infectious to the defense team. In fact, the more you want to “win,” the harder your team will work to deliver results. In product liability litigation, a “win” may be a pre-trial settlement, a deeply discounted resolution, an early dismissal of a claim or a defense verdict at trial.

8. Trust, but verify. Many insurance companies have developed defense counsel guidelines. Often, though, they become window-dressing as overworked adjusters with huge caseloads abandon files to defense attorneys. Medmarc follows a different path. Its defense panel has agreed, in advance



of every assignment, to abide by its Guidelines. Infractions will cost the firms money in the short term, and potentially business in the long term. The panel is aware of Medmarc's philosophy and approach and is not alarmed by adjusters that get involved and move cases along.

9. Sweat the details, but keep the Big Picture in view. The rules of engagement in litigation are simple; tell the truth and strategize. Every question posed by an

opponent has a desired outcome in mind. To best defend you, we must know everything about the product – from product conception to every change and rationale for change in between. This could mean foraging for every little scrap of paper the engineers have in their files, to handing over documents that you know look bad, but for which you have an explanation. It is never a good idea to hold back. Rest assured, there may come a time to panic, but never let your opponent

see it! Plaintiff attorneys feed on the fear!

Life sciences technology firms get no Easy Button when dealing with a perilous tort and court system. No magic wand can make the headache of product liability go away. However, the problem can be effectively managed by embracing the steps noted above and aligning with the right business partners who can leverage their strengths to preserve your financial health!

Cindy Khin is Assistant Vice President, Insurance Operations, Medmarc Insurance Group. Kevin Quinley is Senior Vice President of Medmarc Insurance Group, Chantilly, VA.

Created in 1979 by the healthcare technology industry, Medmarc's purpose is to be the superior provider of liability insurance protection and related risk management services at consistently fair prices and to support the development, testing and delivery of products that save lives and improve the quality of life. Further, through a strategic alliance with The Hartford, Medmarc policyholders benefit from all-lines property and liability insurance protection, loss prevention services and claims management tailored to the needs of life sciences technology companies.

From Ideas and Prototypes to the Reality of Commercialization,
We Can Meet the Changing Needs of Life Science Technology Companies

www.medmarc.com

Inquiries regarding Medmarc should be directed to:

Eastern & Midwestern States
Bill Igoe
(800)-356-6886 ext 330
bigoe@medmarc.com

Western & Pacific States
Cindy Melocik
(800)-356-6886 ext. 337
cmelocik@medmarc.com

Please contact your broker for additional information regarding what Medmarc can do for you.