

Rx For Risk

FDA Compliance is the Start of Risk Management – Not the Pinnacle

By Kevin Quinley CPCU

Many life science technology company executives believe that they are bulletproof from product liability claims because they have strong regulatory compliance programs. That is a costly mistake. Adhering to FDA and other regulatory strictures is necessary but not a sufficient condition for strong risk management and financial health. This issue of Rx for Risk explains why and urges life science technology firms to go beyond mere compliance in building effective risk management systems to safeguard their financial health.

In my 20 years of working with life sciences technology companies at Medmarc, I have seen the gamut of best practices and worst practices in product liability risk management. Those companies at the “best practice” end of the spectrum have fewer product liability claims lawsuits. Those at the opposite edge of the spectrum face expensive claims, lawsuits and regulatory headaches.

Firms which adopt best practices in their regulatory and risk management approaches reap many rewards. When they have a claim, it is much more easily and readily defended. They pay less in insurance premiums because they have their proverbial “ducks in a row.” They are more productive in pursuing their core business of developing and marketing innovative products because they spend less time distracted by defending claims, huddling with defense lawyers and figuring out how to get out of liability binds. It is amazing how much more business you can get done when you are not spending your time in court or in litigation!

One trait that separates the “best practice” companies from the “also rans” lies in their perspective on regulatory compliance. Executives at “best in class” life sciences technology firms realize that complying with FDA guidelines is a necessary but not sufficient condition for sound risk management. By the same token, though, they also understand that they must have strong compliance programs to protect against fines, jail time and lawsuits.

Merely following FDA regulations does not insulate life sciences technology companies from


product liability claims or suits. There is still a legal duty to exceed those requirements to make safe products. This includes products that are free of

- design defects
- manufacturing defects and
- defective labels and warnings.

The management teams of healthcare technology firms must make sure that they look out for patient safety, all marketing claims are true and accurate, product promotions do not illegally reward doctors and they produce products under Good Manufacturing Practices (GMP’s). With the exception of Federal preemption for certain Class III devices -- a doctrine under attack by plaintiff attorneys -- mere compliance with FDA standards will not insulate these companies against product liability claims.

The defense of, “We met all FDA standards” is no free pass in defending a product liability lawsuit. Many factors underlie this reality. One reason: the FDA faces a crisis in public confidence after revelations about drug and device safety. Some lawmakers think the FDA has become too industry-friendly. Some criticize the agency as being little more than a rubber stamp for the industry that it is supposed to regulate.

Critics point to the fact that warning letters issued by the FDA for violations of federal requirements have dropped between 2000 and 2005 by 50%, even though the number of investigations commenced during that time-span was about the same. Seizure of mislabeled, defective and dangerous products decreased by 44% during that



same time frame.¹ According to Dr. Steven Nissen, a top cardiologist with The Cleveland Clinic and an FDA advisor concedes that, “The American people no longer trust the FDA to protect their health.”²

A Summer 2006 study revealed that the independent panels which the FDA taps for advice almost always recommend approving new drugs and devices.³ Many take this as evidence that the FDA is more like a lapdog than a watchdog.

The aim here is not to dump on the FDA – only to suggest that the public hears a drumbeat of negative publicity about FDA failings. The buzz is unmistakable. Thus, it is hard to “sell” to a jury the defense that your product is good because it was approved by the FDA and met all FDA standards. This theme might sound persuasive around a conference room table but will often not “fly” in a court of law.

We can liken this situation to the aftermath of a routine traffic accident. Say my SUV collides with another car at a busy intersection. The investigating police officer does not give me a traffic ticket. Nevertheless, a month later I get sued by the other driver who alleges that I carelessly drove into her vehicle and caused her injuries. The absence of a traffic ticket does not bar the other driver from pursuing a civil lawsuit against me based on negligence. As in traffic accidents, so it is in the product liability realm. The mere fact that you did not get a “ticket” from the FDA does not insulate you from injury claims and lawsuits alleging your product was defective.

Thus, medical device, biotechnology and pharmaceutical company executives must be committed to meeting FDA standards like Good Manufacturing Practices to cement a risk management program, but they also must exceed them. While FDA compliance will not shield life sciences technology firms from liability, breaching FDA standards may be used against such companies. It may not be fair, but it is the reality.


If there is a product recall, an FDA “483”

Warning Letter, Medical Device Reports (MDR’s) or Adverse Event Reports (AER’s) – these can and will be used against life sciences technology enterprises to support claims of defect and persuade a jury that a product malfunctioned. A plaintiff attorney will throw the proverbial “stuff” up against the wall to see how much of it “sticks.” Despite objections from the companies about its relevance and admissibility, jurors get the picture and may quickly draw negative inferences. In fact, seeing how hard the defense counsel fights to exclude such information may reinforce juror perceptions that management has something to hide.

Defense lawyers can fight to keep out and render inadmissible all the “bad stuff” on the recall, Warning Letters, MDR’s or AER’s. Life sciences technology firms may or may not win such exclusionary motions. Judges like to “let it all in” and invite you to appeal if it has a prejudicial impact. Many judges think this is a “jury issue,” not a judge issue, so they will let a jury hear it and then let plaintiff and defendant spar over how much (or little) weight to give it.

Adherence to FDA regulations won’t insulate life sciences technology companies from product liability claims. Breaching FDA regulations may sink them, though. It is almost as though, “Heads I win – Tails, we flip again.” This may not be fair but that is the way the product liability game is played. FDA “baggage” on a healthcare technology company or product makes defense more problematic. This is not to downplay the importance of regulatory compliance. To the contrary. Mere FDA compliance, however, is a part of sound risk management for life sciences technology firms. It is the starting point, not the ending stage.

The takeaway is to aim for a “Caesar’s wife” record in FDA compliance. Invest in compliance and view it as a vital part of your company’s operating blueprint. Just do not let it delude you into thinking compliance makes you bulletproof from liability claims or will get a claim dismissed. It is



no “free pass” when it comes to defending product liability claims.

Highly effective risk management programs invest in strong regulatory compliance, but they do not make that the sole foundation of their risk management program. They go beyond regulatory compliance to ensure that warnings are thorough

and airtight, design changes are documented and feedback from the user environment is thoughtfully weighed. In future installments of Rx for Risk, we will discuss some of these “best practices” which cement a strong foundation for effective risk management, practices that will help bullet-proof your firm’s financial health.

1. *New York Times*, 6/26/06, “Study Shows Drop in Enforcement of FDA Laws”
2. *Cleveland Plain Dealer*, 8/4/06, “Clinic Dr. Nissen Spars with an FDA Commissioner”
3. Associated Press, 8/28/06, “Study: FDA Advisors Typically Recommend Approval for Drugs and Devices”

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