

Courting Resolution

Product Litigation is **Straining** the **Industry**

Over the past decade the number of product-liability lawsuits has escalated as plaintiff lawyers go after companies more frequently.

Experts warn that the attacks on the industry are not only harmful to individual companies but have the potential to undermine innovation, which ultimately will hurt patients.



Product litigation has become an onerous fact of life for the pharmaceutical industry.

Roughly 50 products are currently under active litigation in the United States, according to various industry sources. Legal experts say it's not so much a matter of if a company will be sued, but when — be it by a small number of people who suffer from adverse events or through a class-action suit.

“In today's environment, any product that reaches the U.S. market is a potential target for lawsuits, and almost any product is going to generate at least some legal attention,” says William L. Anderson, a partner with Crowell & Moring LLP. “The lesson: companies need to learn to plan for it.”

The problem, says Donald J. M. Phillips, Pharm.D., principal and CEO of Vox Medica, is societal rather than specific to the pharmaceutical industry.

“The phenomena of suing pharmaceutical companies for personal injury because of defective products is not unique to the pharmaceutical industry; it exists across all manufacturing and service industries,” Dr. Phillips says. “It's driven primarily by the nature of tort law in the United States.”

The pharmaceutical industry, however, has recently become a favorite target. Dr. Phillips says, in part, because of a perception that it is highly profitable and, hence, a deep-pocketed target for tort litigation.

“There also is a perception in society that providers of healthcare services carry a greater burden for safety than, say, does a ladder manufacturer or an automobile maker,” he says.

None of this comes as a surprise to pharmaceutical companies, and as such the industry



 **Jean Frydman**
Novadel Pharma Inc.

In product liability cases, companies that can prove that they provided warnings about side effects very early on are in a much better position to defend against claims of negligence.

has prepared itself to tackle these issues, company executives say.

“As one of the most heavily regulated industries in the world, with rules governing almost every phase of the business, legal issues are well integrated into the whole system and operation right from the start,” says Allen P. Waxman, senior VP and associate general counsel at Pfizer Inc.

Getting Organized

Front and center of any case is the documentation. Mary Mack, Esq., technology counsel at Fios Inc., says companies should train personnel on document-retention policies, especially when litigation or investigation arises. Companies that closely follow a document-retention policy, for example, should have records of electronic data and be in a better position to ensure that documentation is not tampered with or destroyed in the collection process. These companies are less likely to face heavy sanctions and will realize significant cost savings.

“It’s important to ensure the cross-functional product teams — the legal team, the IT staff, and so on — are trained in how to communicate and when to communicate, particularly in writing, and then how long communications



 **Allen Waxman**
Pfizer Inc.

As an industry, our mission is to provide products that help people, treat disease, prolong life, and allow people to live happier and healthier lives. As such, what should guide decisions is not the issue of lawsuits or liability; it’s medicine.

should be kept,” Ms. Mack says. “Spending time up front on organizing and training has a material effect on risk and cost down the line.”

Jean W. Frydman, VP, general counsel, and corporate secretary at Novadel Pharma Inc., says it’s crucial to have open forums where there is discussion between regulatory, litigation, and sales and marketing.

“The salesforce is the most vulnerable department because the reps are the ones in the field talking,” Ms. Frydman says. “It’s key that they’re very well-trained by all disciplines in the company early on, before the product gets launched.”

It’s important that medical, regulatory, and marketing staff effectively communicate and ensure that those in marketing recognize the importance of responding to concerns expressed by those in medical and regulatory, says Robert A. Limbacher, partner, mass torts and product liability, pharmaceutical, with Dechert LLP.

“Perhaps most importantly companies need to train, retrain, and train again all relevant personnel on the importance of carefully drafting letters, memos, and e-mails with an eye to their potential use against the company in a courtroom,” Mr. Limbacher says. “A single ill-advised sentence buried within a million pages of documents produced in discovery can make things much more difficult for the company when its lawyer is standing in front of a jury.”

Long before the specter of lawsuits begins to loom, pharmaceutical companies can protect themselves by ensuring they have comprehensive insurance in place.

“That’s something that isn’t always easy to get, and it may come at a very high cost,” says Peter S. Liaskos, a partner with Mayer, Brown,

Rowe & Maw. “The reality is that no matter how safe a drug appears, a company can expect to get sued. Even though a drug may appear perfectly safe when it enters the market, five years later it may turn out to have unexpected side effects. So a comprehensive insurance plan is vital, and it helps companies if they can negotiate a clause that allows them to control the litigation as opposed to the insurance company.”

The high cost of insurance coverage means, however, that companies will have to share the liability risk in excess of insurance limits, says Sergio Garcia, a partner in the corporate group and cochair of the life sciences group of Fenwick & West LLP.

“Product-liability insurance for drug manufacturers is being sold with high limits,” he says. “Even companies as large as Merck are self-insuring a large portion of their product liability risk. Companies should review their product liability insurance coverage at least once a year to make sure they are adequately protecting against the risks posed by their products in development — from the initiation of human clinical trials through drug approval.”

There also needs to be careful attention paid to product labeling right from the start.

“It’s important that regulatory lawyers and/or regulatory affairs when they’re negotiating the wording for approval with the FDA coordinate their efforts with the litigation department,” Ms. Frydman says. “This way the wording is acceptable from a tort perspective, as well as a regulatory perspective.”

Once a product is on the market, companies need to ensure that adverse drug events are always reviewed, consistent with regulations, appropriately analyzed, and taken seriously, Mr. Limbacher says.



 **William Anderson**
Crowell & Moring LLP

Companies need to begin to think about litigation and product liability as part of the normal life cycle of a product, just as they do marketing and research — all the things that go on with a pharmaceutical product.

One big difficulty for companies can lie in the fact that in mass tort situations, cases are generally spread out across the country.

“In the United States, because there are 50 different sets of tort laws, it’s a little hard to coordinate a strategy because what may be advantageous in one state can be disadvantageous in another state,” Mr. Liaskos says.

The in-house resources that companies need to draw on with regard to product litigation can place huge pressures on the organization.

“During a mass tort case, a company will call on many of its best scientists, marketing people, and regulatory people to help defend against the lawsuit,” Mr. Anderson says. “While these people are engaged in the courtroom, they can’t be doing what the company exists for, which is to develop, produce, and market good pharmaceutical products.”

An Honest Defense

“Doing the right thing is one of the best defenses,” Mr. Anderson says. “Juries like to hear that someone has thought about what the consequences might be and that everything that could be done to ensure the safety of the product had been done.”

Companies also need to avoid regulatory trouble since this is a flag for the plaintiffs’ bar.

“If there are allegations regarding failure to disclose testing data, manipulation of evidence, or falsifying something, that puts a target right in the center of that product for litigation,” Mr. Anderson says. “Lack of transparency turns a run-of-the-mill injury lawsuit into something that includes fraud and conspiracy and lots of ugly terms, and that’s when there are huge ver-

dicts that cost millions of dollars. Finally, what’s needed is a well-prepared, rapid response to the first signs of litigation trouble. My advice to companies is to involve their lawyers before the product ever goes to market to plan for things that might come.”

Since the attacks on a company often begin in the media, companies cannot wait to defend their cases in the courtroom, experts say.

“It’s important to think about how and when to respond to allegations made in the media rather than waiting for the courtroom,” Mr. Waxman says. “We may get only three or four lines in a media story, so companies need to have a cogent response that is communicated clearly in that limited timeframe.”

When it comes to product liability, there are two basic theories under which a company can be sued: one is strict liability and the other is negligence, Ms. Frydman says.

“Because pharmaceutical products are considered inherently dangerous, there are very few lawsuits that are brought about on a strict

liability basis; there’s always negligence involved in some way,” she says. “So it’s important that when a company is finalizing its label with the FDA, the product liability experts are involved so that they know exactly what’s included in those warnings. This information might give them some suggestions on how to better defend the company later on.”

According to Dr. Phillips, because of the very nature of pharmaceuticals, it’s up to patients and physicians to weigh the risks and benefits of taking a medicine.

“Where the industry hasn’t done a good job is keeping society aware of those risks and educating patients about whether the risk and the benefit really make sense,” he says. “The rather robust embracement of DTC over the last 10 years has somewhat misrepresented the value of pharmaceuticals.”

Legal experts advise that it is important for companies to have a consistent prelitigation approach, in terms of letting science determine their actions as opposed to a fear of lawsuits.

Patient Perception

ADVERTISEMENTS RUN BY LAW FIRMS ABOUT PRODUCT LIABILITY LITIGATION DIRECTED AT PHARMACEUTICAL COMPANIES ARE VIEWED AS COMMONPLACE BY MOST PATIENTS.

- Most patients (86%) would be concerned if they saw an advertisement for a lawsuit for a drug they were taking, and nine in 10 (90%) would consult their doctor if this happened.
- One in five (21%) patients has seen advertisements for litigation for a drug they were taking.
- One-quarter or fewer would immediately stop taking the drug (25%) or call the law firm in the advertisement (19%).
- Only one in 10 (8%) has ever had to take any of these actions.
- Almost three of four patients (72%) think that law firms commonly file product-liability lawsuits against drug companies when only a small number of people have suffered unavoidable side effects.
- Furthermore, patients believe that when other people qualify for such a lawsuit, they commonly join in, even if they themselves had not experienced any side effects (86%).
- But if the patient was in the same situation, few say they would likely join a lawsuit if they had not experienced any side effects from the drug (27%).
- Patients are concerned that product-liability litigation threatens new research and development that could benefit people with illnesses. Seven in 10 (71%) patients believe that product-liability litigation, or the fear of it, has caused pharmaceutical companies to avoid research and development in certain product areas.
- Patients are concerned (80%) that groundless litigation prevents drug companies from developing new drugs that could benefit others in the future.

Source: Pharmaceutical Liability Study Report on Findings, July 15, 2003, Harris Interactive Inc., Rochester, N.Y.
For more information visit harrisinteractive.com.



 **Dr. Donald J.M. Phillips**
Vox Medica

Companies have to make every effort to identify the potential adverse effects of the drug as early as possible and to communicate those risks to stakeholders in a forthright manner.

“As an industry, our mission is to provide products that help people by treating disease, prolonging life, or helping people to live happier and healthier lives; as such, really what should be guiding our decisions is not the issue of lawsuits or liability issues, it’s medicine,” Mr. Waxman says. “It’s making sure that our judgments are based on sound medicine and our operations are based on sound medicine.”

A troubling development is a push by plaintiffs’ lawyers to sue companies for potential or anticipated harm.

In a 2003 paper published in *The Journal of the American Medical Association* (JAMA) — titled Medical Monitoring for Pharmaceutical Injuries: Tort Law for the Public’s Health — the authors note that attorneys have begun to sue on behalf of individuals exposed to allegedly defective pharmaceutical products, although those patients have no current injury but may be at risk for developing one. The authors added a key part of this strategy seeks to make drug manufacturers pay for medical monitoring.

“Medical monitoring introduces prospective action,” the paper says. “Exposure and increased risk of disease alone are enough to trigger relief in the form of diagnostic services. Hence, medical monitoring represents an explicit attempt to prevent harms rather than merely allocating dollars to ameliorate their consequences.”

Experts warn, however, that all drugs are potentially harmful in some way or another.

“That means anyone who is taking any pharmaceutical could potentially sue the company based on at some point having an adverse reaction to a drug,” Dr. Phillips says. “That gets to be Kafkaesque.”



 **Robert Limbacher**
Dechert LLP

Companies enhance their likelihood of litigation success if they respond aggressively from the very outset of a mass tort case and are proactive rather than merely being reactive.

At present, medical monitoring appears not to have taken hold. The authors of the paper note that while courts in about 20 jurisdictions have accepted medical monitoring, most of them appear to be unsettled on the circumstances suitable for its implementation, and there are some recent signs of increased judicial resistance to the concept.

According to Dr. Phillips, efforts to drive wider use of products set the stage for the conundrum companies are now facing.

“What we saw with Vioxx — and in some cases with the other COX-2 inhibitors — was a very aggressive campaign, a substantive part of which was aimed at consumers, to drive demand for the product way beyond probably its legitimate niche in the marketplace,” he says. “This approach hurt both companies and patients because patients can benefit from these products. And I think this has caused the industry to really take a look at how it uses DTC vehicles to talk about products.”

The accumulation of growing regulatory pressures combined with the threat of litigation and the associated costs mean something has to give, experts say.

“Outside legal fees are sometimes in the billions of dollars, and companies have to have a tremendous in-house law department as well as people on the ground from a regulatory standpoint,” Ms. Frydman says. “The money to pay for this has to come from somewhere. Companies either have to let people go, or they have to absorb it in the pricing of the drug; but then there is scrutiny on drug pricing. So it’s really a catch-22 with the litigation situation.”

The very fact of having an allegation made against a product can have damaging ramifications, even when those allegations are proven to be unfounded.

“Any number of products have been taken off the market, not because they were bad or because the research said they were bad but because there were too many lawsuits to keep it out there,” Mr. Anderson says. “One good example is Bendectin, which was a morning sickness pill. Birth-defect lawsuits associated

with the product gained a life of their own in the courtroom before science ever demonstrated there was any risk. Because of the costs, Merrell Dow pulled it off the market. After that, the epidemiology studies showed there was no relationship between Bendectin and birth defects; in other words it was a perfectly safe product, but the lawsuits destroyed it.”

Legislating Litigation

The push for tort reform continues, and experts say some progress has been made on the state level.

One example is Texas, where in 2003 the state legislature passed H.B. 4 to further reform the state’s civil justice system. The bill addressed issues such as: limits on noneconomic damages; product-liability reform; punitive damages; medical-liability reform; joint and several liability; and class-action reform.

“Various bills and laws have been passed to address medical-malpractice issues and product-liability issues that focus on the primacy of the regulatory scheme in the United States for pharmaceutical companies and the primacy of the FDA in making decisions,” Mr. Waxman says. “The intention is to bring more rationality to the way damage awards get handed out.”

Efforts also have been made at the federal level, Mr. Waxman says, referring to the Class-Action Fairness Act of 2005.

“The goal is to bring more balance to the use of class actions; so rather than being used as blunt instruments to demand large sums of money, they are used appropriately for their originally intended purpose,” he says.

Legal experts believe that the need for further reform is pressing.

“For instance, we need to consider congressional tort reform that will permit the use of science-oriented, specialized juries to hear complex pharmaceutical cases,” Mr. Liaskos says. “The science in these cases is extraordinarily complex; sometimes it can even be tedious. A group of science-oriented specialists will be in a far better position than the average lay juror to weigh the value of the evidence that is presented in these types of cases. Without this type of important scientific expertise, many jury awards will continue to be based on



Sergio Garcia
Fenwick & West LLP

Companies engaged in clinical testing, development, and commercialization of drugs face special product-liability risks.



Mary Mack
Fios Inc.

sympathy for the alleged injury as opposed to actual causation by the pharmaceutical in question.”

These cases will affect not only the industry but patients because cost pressures will hurt the industry’s ability to fund research and development, ultimately resulting in fewer innovative products coming to market.

“Increasingly, we are seeing product liability theories being asserted in any case where drug safety is at issue — whether the drug is in clinical development or already on the market,” Mr. Garcia says. “This raises issues that go to the commercial viability of the drug-development process. Manufacturers may be reluctant to engage in clinical trials of potentially life-saving therapies. At the same time, insurance carriers may not be willing to insure companies against certain product-related risks, or they may raise premiums to levels that are no longer affordable, especially for emerging life-sciences companies.”

The risk to innovation from a ramp up in litigation is very real, executives say.

“In the United States, we promote entrepreneurship,” Ms. Frydman says. “We promote the ability to compete. We have anti-

trust laws, and so on. But for small companies starting out that might be in a position to move quickly on a new concept, the risk of a potential lawsuit will be too great because a lawsuit will destroy them overnight.”

Mr. Waxman says the courtroom is an inappropriate venue for dealing with the regulation of pharmaceuticals.

“The litigation environment has become another regulator of industry practices instead of being what it originally was intended to be: a compensation system for people who were injured as a result of somebody’s conduct or product,” Mr. Waxman says. “We have a regulatory system whereby experts — from biologists to chemists to statisticians — spend 10 years to 15 years looking at studies, analyzing medicines, and making very complex scientific judgments. This same information is presented in a courtroom during a three-to-five week trial, with hired experts from each side giving opinions, and then a judge and jury make their decisions around these same issues

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that experts deliberated over for 15 years. This can’t be a good thing from a healthcare-policy standpoint.” ♦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

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