

Legal Landscape Heats Up for Life Science Companies

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ABSTRACT

Drawing on their success with asbestos and tobacco litigation, trial lawyers are aggressively targeting pharmaceutical and medical device companies with class action lawsuits that seek billions of dollars for thousands of plaintiffs. While the largest and wealthiest companies stand first in the line of fire, smaller companies are vulnerable, too. This article discusses how biotechnology and life science companies can reduce the risk of product liability litigation and the prudent risk management steps that can be taken to improve their defense posture and reduce their exposure to large jury verdicts.

INTRODUCTION

Drawing on their success with asbestos and tobacco litigation, trial lawyers are aggressively targeting pharmaceutical and medical device companies with class action lawsuits that seek billions of dollars for thousands of plaintiffs. While the largest and wealthiest companies stand first in the line of fire, smaller companies are vulnerable, too.

Even companies that have not been sued directly will feel the effects as the insurance industry responds to today's litigation trends. Insurance premiums for large pharmaceutical and medical device companies have risen dramatically while policy limits have shrunk. Insurance companies are also requiring much higher deductibles or self-insured retentions. While these price increases started with the larger companies, they have begun trickling down to middle-market and smaller businesses.

While no company can entirely eliminate its risk of product liability litigation, all pharmaceutical and medical device businesses can take prudent steps to improve their defense posture and reduce their exposure to large jury verdicts.

FRUITFUL TERRITORY

Lawsuits concerning the adverse events of drugs and medical devices are not new; however, unlike the more common isolated claims of the past, today's lawsuits involve more plaintiffs and seek greater damages. The lawsuits also extend beyond product liability. Several publicly held drug and device companies face shareholder lawsuits for failing to disclose adverse information about their products to investors. And a few face civil and criminal investigations by state and

federal authorities alleging that their marketing and pricing practices defrauded government-financed health care programs. In May 2003, the Schering-Plough Corp. told investors it could be indicted in a federal investigation into its marketing practices and could face charges that employees destroyed documents to impede the investigation.¹

Pfizer and Wyeth are two in a long list of companies facing litigation. By the spring of 2003, 8,900 people sued Pfizer over Rezulin, a diabetes drug that the Food and Drug Administration (FDA) linked to liver injury and pulled from the market. Another 1,100 have indicated their intent to sue, and the statute of limitations was recently extended for another 30,900 users. As of the end of last year, Wyeth set aside \$13.65 billion to resolve claims by people who allege that they were injured by its diet drugs, which were withdrawn from the market in 1997. The company also faces 16 class actions, 13 multi-plaintiff actions and 40 individual suits in various courts for injuries such as breast cancer, heart disease and stroke allegedly caused by Pembro, the company's hormone replacement therapy.²

Medical device companies are not immune to litigation. In June, a widow filed the first in an expected wave of class actions over the Ancure Endograft System, a device developed by Endovascular Technologies Inc. to repair abdominal aortic aneurysms. Days earlier, the Guidant Corp. subsidiary agreed to pay civil and criminal fines of \$92.4 million to settle charges stemming from its failure to report problems with the device to the FDA.

Though plaintiffs' lawyers attribute the rise in lawsuits to profit-driven drug and device makers who hide the risks of dangerous products, other factors contribute to the growing

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wave of litigation. Trial lawyers bring a wealth of cash and experience gained from successful mass torts against other industries to their battle against drug and device makers. Today's more sophisticated and innovative plaintiffs' attorneys collaborate, each assuming different responsibilities in a complicated case, with the expectation that their investment in long and expensive pretrial work will pay off with multi-billion-dollar settlements.³

Rapid growth in prescription drug and device utilization also plays a role in the rising tide of product liability litigation. The pool of potential plaintiffs increases greatly as more people are diagnosed with conditions that can be treated with pharmaceuticals and medical devices and as the industry develops innovative drugs and devices for conditions afflicting millions of people.⁴

Shifting perceptions also influence the industry's exposure to product liability lawsuits and larger verdicts. While all drugs have side effects, there is a perception that newer drugs are more risky than older drugs.⁵ Perceptions of the industry have changed, too. Even as medicines help more people, the altruistic allure of the pharmaceutical industry has been tarnished by its wealth, marketing practices and pricing. A suspicious public makes it easier for plaintiffs' attorneys to recruit clients and persuade juries.

AVENUES OF ATTACK

Plaintiffs' attorneys drive cracks in traditional defenses and find avenues of attack in areas where drug and device companies are most vulnerable. The discussion below highlights some of the most common allegations in product liability litigation.

Overstating Benefits While Understating Risks

The risk of overstating a products' benefits or minimizing its risks is exacerbated as pharmaceutical companies invest greater resources to promote their products directly to consumers. While the lion's share—about 80 percent—of promotional spending is directed toward doctors, spending on direct-to-consumer (DTC) advertising of prescription drugs has more than doubled since 1998, growing to \$2.6 billion in 2002.⁶

Although drug maker consumer advertising is regulated by the FDA, a Government Accounting Office report published in October 2002 concluded that the FDA's limited oversight does not deter some companies from repeatedly disseminating misleading advertisements. According to the FDA, several common problems appear in consumer advertisements: minimized or omitted risk information, misleading communication of the indication or overstatement of efficacy, and unsubstantiated comparative claims.

In a growing number of product liability cases, plaintiffs are arguing successfully that an advertisement's message about a drug's benefits outweighed physicians' warnings about its risks. The exposure is greatest with TV ads, which provide little opportunity to adequately warn of major side

effects. TV ads represent almost two thirds of DTC ad spending, up from 29% in 1997.

Drug manufacturers who are aggressive in their use of DTC advertising may forfeit one of the most potent defenses in product liability lawsuits. The "learned intermediary" doctrine provides an exception to the general rule imposing a duty on manufacturers to warn consumers about the risks of their products. Applying the learned intermediary rule, courts have held that manufacturers have a duty to warn only medical professionals, not the ultimate consumer, of the risks of most prescription drugs. Since consumers must consult with and receive approval from a physician or other health care provider in order to purchase prescription drugs and devices, the provider serves as a learned intermediary between the manufacturer and the consumer.

While most states still apply the learned intermediary doctrine, the New Jersey Supreme Court carved out an important exception. In *Perez vs. Wyeth Laboratories Inc.*, the court refused to apply the doctrine because Norplant, an implantable contraceptive device, was advertised directly to consumers in popular magazines. The court determined that these advertisements allow patients to actively participate in the choice of medication and that they alter the doctor-patient relationship by encouraging patients to ask for specific products by name. The court stated that "when mass marketing of prescription drugs seeks to influence a patient's choice of a drug, a pharmaceutical manufacturer that makes direct claims to consumers for the efficacy of its product should not be unqualifiedly relieved of a duty to provide proper warnings of the dangers or side effects of the product."

Though limited to one state, the Perez decision is influencing litigation in other jurisdictions. A growing number of lawsuits allege that physician warnings are less effective because of DTC advertising, thus weakening the defenses available to manufacturers.

Failure to Warn

A growing number of lawsuits allege that manufacturers were aware of risks and adverse effects but failed to take appropriate steps to warn physicians and consumers. Lawsuits filed against Glaxo Smithkline Corp. allege that the company has ignored studies indicating that Paxil is more addictive and causes more severe withdrawal symptoms than other drugs in its class, thereby misleading doctors and consumers about its true risks.

Under federal law, a company is required to report to the FDA any incident in which a drug or device may have caused or contributed to a death or serious injury. Medical device makers also must report if a medical device experiences a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. Last year, the FDA faulted Abbott Laboratories for failing to make timely reports on potentially serious reactions—including deaths—on several of its drugs, including Meridia, a diet drug that is the subject of litigation.

The guilty plea by Endovascular Technologies in June

exposed a serious example of a company not properly reporting adverse events. The Guidant subsidiary sold 7,632 Ancure devices during the 19 months before they were recalled in March 2001. During that period, the company filed 172 reports of injuries or malfunctions with the FDA. In its guilty plea, the company admitted that it failed to file an additional 2,628 reports describing incidents in which the device malfunctioned or its use was associated with death or serious injury.

Off-Label Use

Off-label use has become a greater exposure since the FDA was pressured into modifying some of its regulatory actions concerning off-label dissemination of information on unapproved uses for drugs and medical devices. The decision has emboldened some manufacturers to push the limits on off-label promotion or to turn a blind eye to sales representatives who do.

The lack of safety and efficacy data and the lack of instructions or warnings could damage a company's defense in a product liability lawsuit, especially if the information provided by the manufacturer was a primary factor in the physician's decision to prescribe the off-label use. Juries are also more likely to punish manufacturers who do not attempt to test the safety of a widely prescribed off-label use, even if the company doesn't actively promote it.

Even before the FDA modified some of its regulatory actions on off-label promotion, Parke-Davis, a division of Warner-Lambert, allegedly launched a campaign to promote its epilepsy drug, Neurontin, for about a dozen unapproved uses, including bipolar disorder, pain management and restless leg syndrome. The company reportedly paid dozens of doctors thousands of dollars each to speak to other physicians about how Neurontin could be prescribed for many other uses that had not been approved by the FDA, according to documents in a whistle-blower lawsuit.⁷ In many cases, the lawsuit claims, the information was misleading or inaccurate, though the campaign seemed to have long-term success. About 80 percent of Neurontin's sales were for off-label uses in 2000, according to published reports. U.S. prosecutors, in a brief supporting the suit, said the whistle-blower, Dr. David P. Franklin, presented evidence of an "illegal off-label marketing scheme that is rife with false statements and fraudulent conduct."⁸

The off-label use of adult medications for children may increase a manufacturer's vulnerability in a product liability lawsuit. In June 2003, the FDA warned that pediatric patients should not take Paxil for depression. The warning followed reports by British drug-safety regulators that new

evidence showed the drug did not work in children and showed an increase in the risk of self-harm and potentially suicidal behavior. Claims of violent behavior and suicidal thinking have been part of the wave of litigation concerning Paxil and several other antidepressants.

COUNTERMOVES

As product liability litigation against drug and device makers has grown, some efforts to curtail abuses show promise. In June, the House passed legislation that expands the jurisdiction of federal courts, allowing them to more easily hear large class action lawsuits involving plaintiffs and defendants from different states. The Senate Judiciary Committee approved a similar bill in April. One aim of the legislation is to limit "venue shopping," in which trial lawyers file suits in a handful of states that render disproportionately large jury verdicts. The Insurance Information Institute refers to judicial "hellholes" in Texas, Mississippi, Alabama, California, New York, Florida, Illinois and Louisiana.

In another favorable development, courts in a few states have upheld the concept of preemption—an important defense providing that FDA approval preempts state product liability claims as long as that approval was not obtained fraudulently. This doctrine was upheld as recently as May by a U.S. District Court in Michigan.⁹ And the 1993 Daubert decision—in which the U.S. Supreme Court determined a new standard for the admissibility of scientific testimony in federal trials—still stands strong.

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RISK MANAGEMENT TECHNIQUES

While such legal and legislative developments may improve the overall position of the industry, they do not insulate individual companies from having to defend against aggressive lawsuits. Insurance underwriters, therefore, must assess the defensibility of each company they insure. Experienced underwriters analyze their claim data to develop a framework for understanding what companies can do to reduce their vulnerability to similar allegations. Here are some of the factors underwriters will contemplate as they assess the exposure of a drug or device company.

Advertising and Promotional Activities

Underwriters want to determine if a company is overstating its product's benefits or understating the risks without adequate regard for patient safety. Underwriters might want to know:

- What percentage of the advertising budget is direct-to-

consumer?

- Have there been any FDA or FTC violations concerning promotional activities?
- What is the process for developing promotional materials? What kind of legal review is done? Does the process include representation from medical affairs, safety surveillance, etc.?
- What is the marketing and sales department's philosophy? Does it emphasize quality over speed? Are product liability and regulatory issues emphasized?
- Are the company's promotional activities viewed as being very aggressive or conservative?

In essence, underwriters try to discern if a company's promotional activities are dangerously aggressive or thorough and clear. They want to see that marketing managers consider it their responsibility to let people know about their product but in a fair and balanced fashion that puts patient safety first.

Off-Label Use

Underwriters will want to determine how a company reacts when it becomes aware of a pervasive off-label use. Is it reported to the FDA? Does the company try to communicate with health care professionals to remind them that the product hasn't been approved for that use? If the unapproved use continues, does the company give serious consideration to conducting clinical trials for this off-label indication to determine if the use is safe and effective?

Safety Surveillance

Underwriters are looking for a very robust safety surveillance team that has the autonomy, clout and the resources it needs. It should be comprehensive in its effort to collect information, looking at any person or organization doing studies or commenting on its product. The safety surveillance team needs the capability for sophisticated analysis so it can extrapolate as precisely as possible from the data it collects. The team also must have the ability to carry out any remedial actions that it considers necessary, from minor labeling or dosage changes to a major labeling change or product withdrawal.

Product Testing and Manufacturing

Underwriters will look at the manufacturer's track record.

The suggestion of systemic problems often becomes part of litigation. Is the company's relationship with the FDA cooperative or adversarial? Companies that strive to exceed rather than to meet regulatory requirements are less likely to have a manufacturing defect and to find it quickly if they do. It is helpful in cases alleging inept testing and manufacturing to show a history of strong performance with only minor incidents. Underwriters will be looking at whether or not the company has formalized procedures concerning risk analysis.

Document Management


Companies frequently get into trouble when they don't have good systems for managing documents. Underwriters look for evidence that employees are well-trained in document management and understand that everything they say or do will be included in discovery. Taken out of context, a casual e-mail can create a host of problems.

Crisis Management

Underwriters will try to determine if the company has a crisis management plan. The plan should include comprehensive and effective steps for notifying and communicating with physicians and patients using the product in the event of a labeling change or product withdrawal. If a company does not manage a crisis well, the company may be perceived as dragging its feet and incompetent—and that can become part of a negligence allegation.

CONCLUSION

Every drug and medical device has risks, and, before a product reaches the market, companies must do their best to identify risks and demonstrate that its benefits outweigh them. Yet, despite thorough clinical trials, undiscovered side effects may not appear until long after the product is on the market and used by large numbers of people over long periods of time.

No company can completely eliminate the risk of product liability litigation. But drug companies and medical device manufacturers should expect a much higher degree of scrutiny on how the risks of their products stack up against the benefits. And with an honest self-assessment of their vulnerabilities, prudent companies can shore up their defense and reduce their exposure to large settlements. 

ENDNOTES

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