THIS IS IT: Mark Lanier, attorney for one of the plaintiffs in the most recent Vioxx trial, holds up a sample packet of the drug as he speaks during opening arguments of the proceedings in March.

AP/Wide World Photo/Mel Evans

After Vioxx

The national focus on the Merck & Co. trials is calling attention to product liability insurance and its future with large drug manufacturers.

by Bonnie Brewer Cavanaugh

Key Points

- Underwriting for product liability insurance for pharmaceuticals and related products has changed due to the ongoing Vioxx litigation.
- Insurers are making lists, some several pages long, of drugs and compounds they are unwilling to cover.
- Major pharmaceutical companies have begun to forgo product liability coverage.

In April, jurors in the latest Vioxx trial in Atlantic City, N.J., delivered a split decision. One plaintiff emerged victorious with a $13.5 million award, including $9 million in punitive damages. The second plaintiff received what amounted to nothing.

At stake during the myriad of Vioxx trials, however, is not just whether manufacturer Merck & Co. of Whitehouse Station, N.J., will emerge mostly victorious or downtrodden. For the insurance industry, at stake is whether such high-profile trials will trigger tribulations for product liability insurers and those who seek liability protection.

"There's no question that underwriting has changed," said Jim Walters, national managing director of Aon's life sciences and chemical group. But clearly not just because of Vioxx; negative trends in product liability have been ongoing for years. "Most of the pain in our world was inflicted between 2001 and 2004. Now we're seeing the market somewhat stabilize, but at a much different level than [it was] at a few years ago."

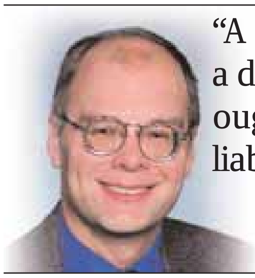
Aon handles commercial product liability for pharmaceutical, biotechnology, genomics, medical device and diagnostic companies. Merck, the world's third-largest drug maker, has been a client of Aon and its predecessor firms since the late 1920s, Walters said. Aon is not involved in the current Vioxx litigation; the identity of Merck's insurers has not been disclosed.

Speed to Market

"In recent years, going back to the Clinton administration and continued by both the Bush administrations, there has been a push to get drugs into the market sooner and to reduce the amount of government-supervised testing and safety and effectiveness that goes in the drug approval process," noted Mark Rahdert, a law professor at Temple University's Beasley School of Law, Philadelphia. He teaches insurance law, impact and regulations.

The *Los Angeles Times* reported in December 2000 that the demand for AIDS drugs changed the political climate in the early 1990s, when Congress advised the Federal Drug Administration to work closely with pharmaceutical firms in getting new medicines to market faster. In 1988, only 4% of new drugs introduced into the world market were approved first by the FDA. By 1998, the FDA's approvals had soared to 66%. By the end of the 1990s, the FDA was approving more than 80% of the industry's applications for new products.

"If that is the case, that, I think, does actually materially increase the risk that undetected defects with drugs will materialize once the drugs are mass marketed. That is a real change in the risk profile of pharmaceutical drugs," Rahdert said. "If it continues to be national policy, it should actually produce an increase in liability insurance premiums—a sustained increase, because the risk of future liability is actually greater."



"A single instance like the Vioxx incident—of a danger like that occurring, in theory—ought not to have a substantial impact on liability insurance rates generally."

—Mark Rahdert, Temple University

Getting a new drug from the idea phase to the drug counters is a big process; any drug manufactured in the United States is developed under highly regulated circumstances and goes through layers of FDA approval directed toward the drug's efficacy and safety, Rahdert said.

"The thing that's thought of as perverse by the drug companies is they can adhere to every single government requirement, the entire FDA approval process, have it tested in multiple studies and have the drug approved—and then still be sued out of existence," said Robert Hartwig, chief economist at the Insurance Information Institute. "From a public policy perspective, is the greater good being done?"

Hartwig would like to see a cost-benefit analysis done for new drugs so consumers can take a particular drug if they choose to, with all the risks exposed.

Vioxx, a Merck pain reliever taken by more than 20 million Americans, was pulled from the market in late September 2004 after the company revealed that the COX-2 inhibitor could cause cardiac problems in some patients. The FDA followed with a public health advisory.

Merck's stock dropped by 3% in after-hours trading following the April 5 verdict, according to the *New York Times*. Lawyers for the plaintiffs forecast a surge in similar lawsuits following the multimillion dollar award, the second against Merck in the four cases that have reached juries. In mid-August 2005, the pharmaceutical giant's stock plunged 7.7% in one day after a Texas jury delivered a $253 million judgment against the company in the death of a man who used Vioxx. At last count, Merck still faces some 9,600 total lawsuits, 4,000 of which will take place in federal court.

> "The phenomenon that we're faced with here is major pharmaceutical companies have basically stopped buying product liability insurance."
>
> *—Jim Walters, Aon Corp.*

Seal of Approval

What pharmaceutical manufacturers ultimately would like to see is immunity from litigation for products that already have been approved by the FDA, Hartwig said.

"If they've adhered to all the FDA guidelines in the approval process, clinical trials and so on, the government effectively, by rendering that decision, would have to say, 'We understand that this drug has some great benefits but also has some side effects,'" Hartwig said. "And for the greater good, put the drug on the market with full disclosure."

"I think it's actually getting through to juries and justices around the country," Hartwig added. "We're in a somewhat different tort environment today that is not so automatically predisposed to produce enormous judgments against a particular defendant."

The *National Law Journal* reported in its annual review released February 20 that total awards among the top 100 verdicts in 2005 decreased for the third straight year, indicating that "juries are becoming ever stingier toward plaintiffs, at least with regard to the punitive damages they dole out." Juries awarded $8.2 billion in compensatory and punitive damages in 2005, the lowest total since NLJ started tracking the top 100 verdicts in 2001.

However, U.S. tort costs, which grew to a record $260 billion in 2004, are expected to climb at a higher rate for 2005 and 2006, according to a recent report by consulting firm Tillinghast. The company forecasts growth rate in U.S. tort costs would increase from 5.9% in 2004 to 6.5% in 2006 and 2007. The firm believes 2005 costs could reach $277 billion.

Rates and Withdrawals

While product liability results have been improving, they're still not very good, Hartwig said. "Pharmaceuticals is a very tough business in every respect. It can cost hundreds of millions of dollars and decades to bring a new drug to market. It's a very, very risky business. You get a blockbuster drug, which happens very rarely, and it winds up blowing up because of medical concerns. The loss of revenue simply can't be replaced by insurance."

This continued assault on pharmaceutical manufacturers and medical manufacturers means that product liability rates will remain high, but by no means as high as they were three-to-four years ago, he added. Yet, he fears American drug companies could wind up like the U.S. vaccine business, which "has been sued out of existence," Hartwig said. "We can't produce vaccine for flu in this country. We have to get it from France or Canada or somewhere else."

In 1967 there were 26 companies in the United States manufacturing vaccines until "a litigation crisis in the 1980s drove many companies away from the vaccine business," according to Congressional findings supporting the National Childhood Vaccine Compensation Act of 1986. Today, there are just four companies that make the vast majority of vaccines used in the United States.

Adding Exclusions

Part of what's happening in the pharmaceutical product liability arena is that carriers and reinsurers have changed the way they are underwriting the business, Walters said. Insurers have made multiple-page lists of drugs and compounds they are unwilling to cover.

"They're starting the negotiations with an exclusion," Walters said. "Right now they have basically looked at the pharmaceutical products and any product they think has had a problem, even if it's not on the major list, or if they believe it may have some problems in the future, they're starting the insurance negotiations on those drugs with absolute exclusions."

Yet, several pharmaceuticals have been excluded for a long time, he said. "Thalidomide, DES, the swine flu vaccine are all standard exclusions on insurance policies," Walters said. "But now again, the list is longer than your arm."

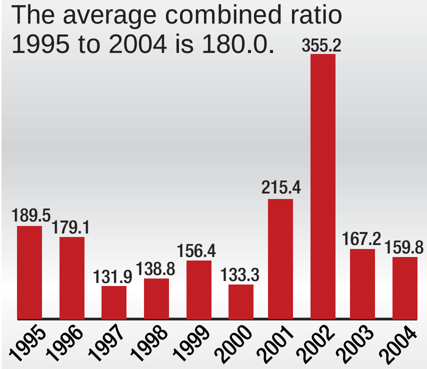
One of the bigger problems looming over the marketplace is that some large pharmaceuticals have decided they can live without coverage.

"The phenomenon that we're faced with here is major pharmaceutical companies have basically stopped buying product liability insurance," Walters said. That's because insurers are telling pharmaceutical companies they must retain the first $300 million to $500 million or more of risk. "Upwards of eight of the top 10 [pharmaceutical manufacturers] have stopped buying conventional product liability insurance," Walters said. Major pharmaceutical companies are finding that paying $10 million to $20 million for $100 million of insurance coverage that excludes half their products is no longer a viable transaction, he added.

If the current tort environment continues, "Major pharmaceuticals, the large companies, will continue to basically stop buying insurance," Walters said. "As we experienced with the insurance crisis of the mid-'80s, once companies

Product Liability Combined Ratio

The average combined ratio 1995 to 2004 is 180.0.



Source: Insurance Information Institute, A.M. Best get comfortable retaining more of their risk, they tend to never return to the insurance industry. I think that creates a big hole in their premium volumes that will probably never return. Whether that will ultimately hurt or benefit smaller companies remains to be seen."

Merck said previously that it gave up seeking product liability insurance last year for certain products, after evaluating its risk and determining that the cost of obtaining insurance outweighs the likely benefits of the available coverage. Currently, the drug maker has product liability insurance for claims brought in the Vioxx lawsuits of up to approximately $630 million after deductibles and coinsurance, the company disclosed in regulatory filings.

"A single instance like the Vioxx incident—of a danger like that occurring, in theory—ought not to have a substantial impact on liability insurance rates generally across the industry," Rahdert said. "It should have been taken into account with the calculus of the premium to begin with. It ought not to have an appreciable effect."

Drug recalls and lawsuits are an inevitable part of the market of pharmaceutical drugs; therefore, they should be an inevitable part of the insurance industry's calculus of premiums for liability insurance, he added.

"This is not unusual," Hartwig said. "There's always some drug out there that's under a microscope; there's always someone being sued." He does not expect insurers will shy away from providing product liability insurance for pharmaceuticals and other government-regulated products. "Whether it's Vioxx or Fen-Phen or a variety of other drugs that have been brought to the market, there's always something like this going on."

"If Merck can be successful in this litigation, then effectively, trial lawyers will lose interest in this," Hartwig said. Then, "hopefully, with the approval disclosure, [such] drugs would be available to people around the world who have no other means of relief."

The plaintiff lawyers who are presenting these cases seem to now have the upper hand, Walters said. "Clearly, they are so much better organized. They're on the Internet and so much more willing to share their expertise on these cases. Look them up on the Internet; Google any one of the 'problem' drugs and up will pop attorneys and seminars where they will explain their litigation strategies and give other lawyers a road map on how to try these cases. They're very willing to share. The common belief is if there is a groundswell of victories, that will help their individual cases as well."

"The balance of power has shifted from the hand of corporate America to the plaintiffs and the trial attorneys a great deal," Walters added. Fifteen major products have been withdrawn from the market between 1997 and 2005, compared with only eight withdrawals in the previous 26 years, he said. "The market was concerned long before Vioxx was withdrawn." BR