Product safety goes global

Just as the world has seemingly shrunk and economies have become interconnected, so too have product safety and product recalls become more globally entwined. The same products sold and recalled in the United States are often sold and recalled in Europe and other countries around the world. Consistent with a global economy, many countries have enacted product safety laws and developed product recall regulations and procedures, including an EU directive now being transposed into law across the Community.

As product safety laws become more stringent throughout the world, it is essential that manufacturers, importers, distributors, and retailers assure the safety of their products and have procedures in place for deploying a product recall. It is often a challenge, however, to navigate through the maze of increasingly complex global regulatory environments. Marsh’s Global Product Recall Solutions and Prevention services can provide invaluable assistance in reducing the need for recalls, as well as minimising the challenges faced by a company when conducting one.

Overcoming the challenges

The Global Product Recall Solutions and Prevention team has identified the key elements in the manufacturing process that can reduce a company’s likelihood of producing defective products and tarnishing its brand name, while at the same time maintaining its competitive advantage.

Our team has value-added solutions and proven strategies that can provide guidance on minimising the potentially devastating effects of a recall. This includes resolving complex national and international business issues which may arise from a product recall. Marsh is the global leader offering product recall and product safety solutions in the areas of quality, safety, investigation, regulatory compliance, communication, and strategic, economic and financial analysis.
Phase I: prevention and preparation

Prevention: Our product diagnostic assesses a company’s entire product line using Six Sigma-certified staff to perform a thorough on-site evaluation of the firm’s product manufacturing/production process, whether in the U.S., UK, continental Europe or elsewhere. This also includes bioterrorism and container security assessments. By reducing product defects and tampering possibilities, the likelihood of a recall can be minimised.

Preparation: Our product preparation analysis assesses a company’s ability to comply with national and international regulatory requirements, as well as to prepare for and conduct a recall. Marsh can conduct a thorough on-site assessment, which can assist a company in developing procedures for conducting a recall. Our focus includes the following areas:

- regulatory compliance
- production management
  - Six Sigma
- technical/quality assurance
  - testing facilities (internal or external)
- recall strategy
- legal resources
- communications (internal and external)
  - public relations
  - consumer notification
- product traceability
- product loss accounting
- supply chain/distribution
- risk identification

Phase II: conducting a product recall
Marsh provides a full range of services in conducting a product recall including:

- investigating the problem
- regulatory compliance
- assessing the scope of the recall
- identifying affected product
- identifying a call centre/fulfillment centre
  - free consumer call line
- reviewing relevant insurance coverage
- time management of recall and product replacement
  - accounting
  - lost sales
  - cost of recall claim

Phase III: recovery
Recovery from a product recall entails not just the immediate action of removing product from national and international markets, but also ensuring that its reintroduction meets the expectations of regulators, shareholders, the media, and the consuming public. Our Global Product Recall Solutions and Prevention Practice can assist in the recovery process in the following areas:

- completion of all required national and international regulatory reports
- monitoring product reintroduction into affected markets
  - review of product rehabilitation costs
  - assessing reintroduction and adjusting strategy as necessary
- notification to all parties when the recall is complete
  - brokers
  - insurance companies
  - distributors
  - recall customers
  - media
  - regulators
- lessons learned assessment

Phase IV: managing product liability
Marsh provides support services to in-house lawyers, solicitors, and national and international coordinating counsel on product liability matters. These services include:

- litigation support
- expert testimony
- global document coordination
- computer forensics
- damage quantification assessment

Marsh’s Global Product Recall Solutions and Prevention services can assist your company in mitigating the financial exposure of a product recall, while protecting your brand integrity.

For more information on our Global Product Recall Solutions and Prevention services, please contact:

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MA4-11254

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With the initial glare of public scrutiny and market recoil over Vioxx behind it, Merck & Co. now is arming for another battle that will be key in determining the company’s survival.

For the beleaguered pharmaceutical giant, a looming courtroom battle entails building an expansive legal infrastructure to deal with liabilities that could be as much as $18 billion, according to a recent Merrill Lynch analysis, over its arthritis drug Vioxx. Merck took Vioxx off the market Sept. 30 after a new study showed that the painkiller may double the risk of heart attacks and stroke among its users.

The company has hired a handful of firms for its defense, but observers say that Merck’s final legal lineup could change as the litigation takes shape. The task of compiling an outside legal team may present challenges for a company that highly values privacy and prefers to turn to its in-house lawyers.

The stakes are high for Merck: Vioxx brought in sales of $2.5 billion in 2003, accounting for 11 percent of the company’s revenue. Merck also faces shareholder claims, as well as investigations by the Department of Justice, the Securities and Exchange Commission, and Congress.

Hughes Hubbard & Reed, a 300-lawyer New York firm for which Merck is already a major client, is serving as the Whitestone Station, N.J.-based company’s national counsel in the Vioxx suits. Reed Smith, Baker Botts, Dechert, and Venable have also been hired, according to court filings. Lawyers at those firms did not return calls for comment or would not comment.

A source close to Hughes Hubbard who would not allow his name to be used says that “Merck is continuing to quickly add to the infrastructure needed to deal with the litigation.” The company itself, which says that it has 115 in-house lawyers, declines to comment on its outside legal staffing.

But plaintiffs’ lawyers, who have taken out ads and mounted Internet campaigns to chase clients and held conferences to coordinate strategy, aren’t the only ones poised to get cash benefits from the Vioxx fallout. The firms lining up behind the scenes to represent Merck will also reap millions.

Merck could pay well over $100 million to outside law firms in 2005 for litigation related to Vioxx, of which the lead firm could get as much as $20 million to $50 million, says one of the company’s former legal consultants.

**Taking the Lead**

The pecking order of Merck’s outside counsel could change, but for now Hughes Hubbard holds the top spot.

Partner Norman Kleinberg has signed off on court papers in Vioxx suits nationwide, along with counsel at other, larger firms like Reed Smith. Peers say Kleinberg is better known for his work in insurance coverage litigation, rather than defending products liability suits. That could signal that other firms with specific expertise in products liability will be brought on board. Kleinberg did not return calls for comment.

In 2002, Kleinberg helped score a win for Hartford Insurance against tobacco company Liggett Group Inc., which lost a bid to force 33 insurance firms to pay hundreds of millions of dollars in defense and indemnity costs.

Hughes Hubbard lists roughly 40 lawyers in its products liability and toxic torts practice and this year was named among 20 “new elite” firms by *The American Lawyer*, a sister publication of *Legal Times*. In 1990, it was lead defense counsel in one of the largest products liability trials ever in the United States, representing a wallpaper manufacturer in claims stemming from the San Juan Dupont Plaza Hotel fire in Puerto Rico that killed nearly 100 people and injured hundreds.

However, Hughes Hubbard ultimately may end up as one of a team of national firms orchestrated by Merck to handle the defense. Embattled companies are increasingly opting to hire a
team of stars from different law firms, lining up one firm to provide lead trial counsel, another to provide special counsel for matters requiring particular expertise such as on medical issues, and another to do the grunt work, providing large numbers of associates and paralegals for tasks like document review, says corporate law department consultant Joel Henning. The more time-honored approach has been for a company to choose a single large defense firm that can hire counsel at the local level as needed.

“Increasingly, you can’t predict the model,” says Henning, who works in Chicago for Hildebrandt International.

Handling a mass tort takes manpower, which could prove difficult for Hughes Hubbard to muster.

“Firms often go in and say, ‘We’re going to do the whole thing,’ but they don’t have the bodies to do it,” says one pharmaceutical industry products liability lawyer. “It depends on how adept Hughes Hubbard is at convincing Merck that they are right for the job.”

Indeed, there are other firms poised to reap part of the Vioxx defense paycheck, including Reed Smith.

The 1,000-lawyer Pittsburgh-based firm has clinched a key role in the Vioxx defense, say lawyers familiar with the litigation. Merck confirms that it has tapped Reed Smith, which lists more than 75 lawyers in its products liability practice, but the firm declined to comment for this article.

Reed Smith’s products liability lawyers have represented American Home Products, now Wyeth, in the fen-phen diet drug suits and worked for Eli Lilly and Co., Medtronic Inc., and Pfizer Inc.

In Dechert’s Princeton, N.J., office, mass torts and pharmaceutical products liability partner Diane Sullivan says her firm is part of Merck’s Vioxx defense team, but won’t comment further.

At a drug and medical products liability conference sponsored by Dechert and Reed Smith next week in New York, Reed Smith partners are scheduled to give a presentation on “recall readiness.” And Dechert’s Sullivan is slated to moderate a session about when pharmaceutical companies should begin preparing for a mass tort, including steps that might echo Merck’s playbook, such as the how to’s of “minimizing exposure and preparing for onslaught.”

One strategy Merck has already employed is a voluntarily recall of Vioxx. In pulling a drug off the market, rather than being ordered to do so by the Food and Drug Administration, companies retain some command over their image, says Katherine Cahill, leader of the product recall group at Marsh Risk Consulting in New York. That move might ultimately play favorably before juries and help to reduce liability.

If some of the first suits filed go to trial, those juries could sit in Texas, where Baker Botts’ Houston partner Richard Josephson has represented Merck in initial court filings.

A veteran of the silicone breast implant litigation, in which he helped to represent Dow Chemical in both federal and state courts, Josephson has also successfully defended the Ciba Geigy Corp. in litigation over the effects of its drug Ritalin.

At Venable, Baltimore products liability lawyers Paul Strain and Stephen Marshall are defending Merck in Maryland. The firm also has available pharmaceutical products liability partner Bruce Parker, who has experience in multidistrict litigation, in which a mass of cases are consolidated before one judge for pretrial proceedings. Merck has asked that the Vioxx cases be consolidated in federal court in Maryland. Parker was a member of the national trial team for the Baxter Health Corp. in the breast implant litigation during the 1990s.

And some firms could try to leverage their existing relationships with Merck.

Although a deputy within Merck is likely to orchestrate outside counsel, Hildebrandt’s Henning says General Counsel Kenneth Frazier still ultimately calls the shots on which firms to use.

Frazier’s former firm, Philadelphia-based Drinker, Biddle & Wreath, which Frazier joined in 1978 and left in 1992 to go in-house at Merck, says that the pharmaceutical company is a client on other matters. The firm’s chief marketing officer, Douglas Kramer, says that he doesn’t know if the firm pitched or is pitching for the Vioxx work.

Drinker, Biddle says that it has handled products liability and antitrust work for Merck, and among the firm’s other litigation clients are two of the nation’s largest pharmaceutical companies, Pfizer Inc. and Johnson & Johnson Inc.

**BLOC PARTY**

Round 1 of the Vioxx litigation begins next month, and it could prove crucial in determining the path of the Vioxx suits.

A panel of federal judges is scheduled to decide in January whether to merge Vioxx cases against Merck around the country in one federal court for consolidated or coordinated pretrial proceedings, as well as choose the judge who will hear the case.

“It’s potentially huge,” says Carl Bogus, a professor at Roger Williams University School of Law in Rhode Island who teaches courses on products liability. “The battle will be fought in this consolidated forum.”

In multidistrict litigation, cases are returned to the jurisdictions in which they were filed after the pretrial proceedings end. But Bogus notes that many civil cases are settled before they ever reach trial, making whatever jurisdiction the panel chooses next month particularly important because the proceedings could determine the course of negotiations.

Robert Rabin, a Stanford University School of Law professor who specializes in torts, says that the number of cases that will ultimately end up before juries will depend in part on the health over the next year of Merck’s stock, which has plummeted by 40 percent since the recall.

“There is a strong impulse to see how these play out at trial,” Rabin says of corporate defendants, adding that if Merck decides that it has the luxury of time, it could try a handful of cases vigorously to gauge juries’ responses to its defenses. Settling early, he says, could be disastrous for the company.

Some industries, including tobacco and asbestos, were delayed by additional suits when they started to settle some cases early, Rabin says. “What cuts the other way, though, is if you
go to trial and lose a handful of cases with big dollar awards,” he says.

Causation may be the largest issue of contention. There is no “signature disease” that can be linked to Vioxx use; plaintiffs’ lawyers would have to prove that the drug, not some other factor like heart disease, caused a heart attack. That could make a class action more difficult to certify, Rabin says, since individual cases from members of a class would likely share few common facts.

In court filings, Merck argues that any injuries suffered by plaintiffs are due to other causes, including unrelated health conditions. In addition, Merck contends that since the company adequately warned prescribing physicians about potential risks associated with the drug, it didn’t need to warn patients directly.

Merck requested to the panel that the litigation land in Maryland federal court. Any appeals from this trial court would be heard by the 4th Circuit—one of the most conservative appeals courts in the country and a venue generally viewed as favorable to corporate defendants. As second and third choices, the company has asked for the cases to be heard in the Northern District of Illinois, or the Southern District of Indiana.

Both Indiana and Illinois are in the 7th Circuit, which would likely be favorable for Merck, particularly if many of the cases are combined as a class action, says Richard Burke, a plaintiffs’ lawyer with the Lakin Law Firm in a Chicago suburb. Burke hasn’t filed any suits against Merck.

“The 7th Circuit has been more defense-friendly than most,” says Burke of class actions.

But even if the federal litigation is consolidated, the work will require a virtual army of legal foot soldiers, says Victor Schwartz, a Shook, Hardy & Bacon partner in Washington who has defended pharmaceutical companies in mass torts.

Schwartz says it is critical for Merck’s lawyers to weed out “less-than-golden plaintiffs,” those with medical histories with whom it is not crucial for Merck to settle because their claims that Vioxx contributed to a heart attack would be so difficult to prove.

That requires time-consuming leg work, including interviewing plaintiffs about other factors in addition to Vioxx that could have caused a heart attack, such as heart disease, smoking, and eating and exercise habits.
Maintain your market: keep customers even after you pull a product. (SALES STRATEGY)

Cummings, Betsy

711 words

1 May 2005

Sales & Marketing Management

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ISSN: 0163-7517; Volume 157; Issue 5

English

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When Boston Scientific had to pull an ineffective product from the market recently, the company did so with brutal honesty. The instrument, approved for use with cardiac bypass patients, was found to be ineffective during later clinical trials, and needed to be pulled from the market two years after it was introduced, says John Groetelaars, vice president and general manager for Boston Scientific's Canadian office, based in Mississauga, Ontario.

Unfortunately, the manufacturers knew, doing so would be an inconvenience for some physicians. But for others, it was a matter of life and death. Some doctors, as it turned out, "were using the product in an area that it was not intended for," Groetelaars says. Those physicians used the instrument to enter carotid arteries in the neck rather than its intended route, veins in the heart. The problem: The doctors using the device on the necks of patients, who were often bleeding in life-threatening situations, had no other market alternative.

Yet Boston Scientific couldn't, and wouldn't, allow doctors to keep the device, given its recent ineffective status in clinical trials. In the end, the company provided those physicians with names of other companies that produced similar cardiac devices that might be alternatives. "Every client stayed with us," Groetelaars says.

Pulling products off the market is common in virtually every industry, when products become outdated due to technological advancement, become unprofitable, or are recalled due to flaws found in clinical trials. But despite the situation's frequency, many companies are left wondering how to pull the product and keep the client. Experts say a swift, honest response is crucial. Address clients immediately and let them vent, says Katherine Cahill, global managing director of product recall and liability services for Marsh Inc., a risk consulting practice based in New York.

"Get the client involved in the process," Cahill says. Explain simply and directly why the product is being removed. Then ask them what their business needs are, describe how the company is fixing the error so it won't occur in the future, and even point them to competitors if it will fix their needs for the moment. Doing so, Cahill says, can mean more credibility and greater sales in the long run.

What Should You Do?

Trying to sell like a team but a lone seller keeps breaking from the pack? Two sales managers weigh in on how they handle such a situation.

SOLUTION 1: John O'Connell, partner, Technology 2 Market, Boxford, Massachusetts

Don't ignore it. That sends the message that this guy can't be touched and teamwork doesn't mean anything. You lose the respect of the whole team because of one person.
Sit down with the seller and deal with it immediately. Explain why you are doing team-based selling. Then let him know that this is an official warning, that the behavior will not be tolerated, and that the ultimate consequence may be that you take him off the account.

If a seller doesn't realize he is breaking out of the team approach, go on a call and debrief him immediately after, in the car or back at the office, about what worked or what didn't work. If you do that later, it may come off as not that important and the seller may not remember the conversation.

SOLUTION 2: Scott Feenan, divisional sales and marketing manager, Parker Hannifin Corporation, Haverhill Massachusetts

Spend time in the field to find out why your team isn't selling like a team. Usually it's because they don't understand their role on the team or the goals of the team strategy. Sometimes even the territory manager doesn't understand his role or the purpose of the program. Ask yourself: Who should be calling on the customer up front? Who should be more involved in account planning? Who plays the leader role when meeting with clients? Conduct training or sales meetings going over key account strategies, and point out successful team-selling benchmarks. Salespeople who are reluctant to sell in teams will likely see those peers and say, “Okay, maybe I can do that.”

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