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HEADLINE: Suits roll in over recalled drugs;
China may factor in heparin actions.

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BODY:

Plaintiffs' attorneys have filed dozens of lawsuits in recent months involving two recalled drugs, generic blood thinner heparin and prescription medication Digitek, that could signal a clean break from past actions that were far less successful against drugs Vioxx and Paxil.

In short, it's a different legal ballgame, attorneys say.

In contrast to past pharmaceutical tort litigation, plaintiffs' lawyers aren't alleging that a company's "failure to warn" about possible risks of a drug caused injuries and deaths.

In recent years, those arguments have been challenged in court, where several judges have sided with manufacturers in upholding federal pre-emption, or the concept that U.S. Food and Drug Administration (FDA) regulations override state liability claims.

Lawyers anticipate that the new defective-product claims could duck the federal pre-emption argument altogether, increasing the chances of success for more plaintiffs.

Also, plaintiffs' attorneys may have another edge: The heparin suits are the first to be brought against a pharmaceutical manufacturer with ties to China, which has been linked in other litigation to dangerous products such as toys, pet food and toothpaste.

"This is going to be the tip of the potential iceberg in terms of Chinese manufacturing and drugs," said William M. Audet of Audet & Partners in San Francisco, a plaintiffs' lawyer who has brought several drug cases and anticipates filing up to 60 lawsuits involving heparin and Digitek.

But the recent drug lawsuits aren't all easy to swallow.

Theodore Mayer, a partner at New York's Hughes Hubbard & Reed who defends pharmaceutical companies, said that plaintiffs' attorneys are likely to face challenges of causation.

"Part of the challenge here is to distinguish between the cases that are actually caused by this contamination and the cases where the patient is just one of many, many patients in hospitals on heparin whose outcome may or may not be good for reasons that have nothing to do with the heparin," he said.

Up to 700 cases

More than 40 lawsuits have been filed against the manufacturers of heparin, which is used to thin blood during surgeries. In the past six months, about a dozen manufacturers, primarily Baxter International Inc., as well as their distributors and suppliers, have recalled much of the nation's supply of heparin after a contaminant was discovered in the drug. The contaminant was tied to a supplier in China.

In recent weeks, the lawsuits against Baxter, filed on behalf of those who claim that their loved ones died following a rapid drop in blood pressure, or that they suffered allergic reactions to the contaminated drug, have been consolidated in federal court in Ohio. According to the FDA, 124 deaths have been associated with the contaminated heparin.

David Zoll, a partner at Toledo, Ohio-based Zoll, Kranz & Borgess, and liaison counsel in the heparin cases, said he expects 300 to 700 claims to eventually be brought involving heparin.

"We think there are important ramifications on pre-emption that are raised by this case," he said. "The doctrine of pre-emption holds that we can rely on the FDA to keep us safe from dangerous drugs; the FDA will make sure the manufacturer does its job. This case shows that was not the case."

Meanwhile, the U.S. division of generic pharmaceutical manufacturer Actavis Group hf. recently announced a nationwide recall of Digitek, a prescription drug used to treat congestive heart failure and abnormal heart rhythms, after several of the bottles contained more than the dosage as labeled.

More than 40 lawsuits have been filed in federal and state court in Alabama, California, Louisiana, New Jersey, Ohio and West Virginia on behalf of patients who were injured or died.

Tony O'Dell of Berthold Tiano & O'Dell in Charleston, W.Va., a lead plaintiffs' lawyer in the cases involving Digitek, said Actavis "ran the pill back through the process twice and ended up having twice the amount of active ingredient."

He said his firm alone is evaluating about 100 potential lawsuits.

The suits have few similarities to other drug cases in which he has been involved, O'Dell said. In those cases, the allegations against the drug were focused on "the way it was being marketed or being used or the fact that they had tested enough and had reactions," he said. Digitek has "been around for a long time. And it's a drug that has very good therapeutic reasons for its use. But it's a drug [for which] this company had very poor quality assurance in place."

Matthew Moriarty, a partner at Cleveland-based Tucker Ellis & West, who represents Actavis and the other defendants in the case, declined comment.

In the cases involving both drugs, plaintiffs' lawyers argue that a product defect, not a "failure to warn" about possible risks, caused injuries and deaths. Although heparin and Digitek were approved by the FDA, those drugs were never intended to be sold as they were -- allegedly with contaminated ingredients or in incorrect dosage amounts.

The claims mark a shift in drug liability cases. "Most pharmaceutical litigation is based on a failure to warn," said Roger Drake, an attorney in the Los Angeles office of Baum, Hedlund, Aristei & Goldman who serves on the multidistrict litigation plaintiff's steering committee in the heparin cases.

"This is a manufacturing defect, a different type of cause of action not subject to pre-emption problems that some of the failure-to- warn cases have," he said. "Because of that, it's unique in that respect from some of the pharmaceutical litigation out there."

Although most lawyers agree that federal pre-emption could be a more difficult argument to prove in manufacturing defect cases, the legal defense remains a potentially major factor in all pharmaceutical products liability cases.

Federal pre-emption has been successful in a substantial number of cases against pharmaceutical manufacturers. Even the FDA issued a preamble two years ago supporting federal pre-emption in cases involving the labeling of approved drugs.

Earlier this year, the U.S. Supreme Court ruled that products liability claims against a medical device manufacturer were pre-empted by the Medical Device Amendments to the federal Food, Drug and Cosmetic Act. **Riegel v. Medtronic**, 128 S. Ct. 999 (2008).

While the ruling is limited in scope -- addressing whether claims challenging the approved design and label of a catheter that burst during surgery were subject to a specific pre-emption clause -- some lawyers have interpreted the decision as having broader implications that could influence products liability claims involving drugs.

Mark Robinson of Newport Beach, Calif.'s Robinson, Calcagnie & Robinson, and a member of the steering committee in the consolidated heparin cases, said the pre-emption issues in failure-to-warn cases and in cases accusing companies of design defects have little or no relevance in cases involving manufacturing defects, which allege entirely different claims.

"We're not claiming they designed it that way. This Chinese subsidiary, or Chinese supplier, changed the ingredients from the actual ingredient that makes the blood thin to an ingredient that looks like the same ingredient," he said. "But in reality, it's a lot cheaper version, and it doesn't thin your blood. In effect, that's a manufacturing defect."

The suits involving heparin also are the first involving a pharmaceutical drug with ties to China. With the recent prevalence of defective-product cases involving China, plaintiffs' attorneys filing heparin lawsuits could have a stronger case than those concerning other drugs.

Jeffrey Killino, a partner at Philadelphia's Woloshin & Killino who filed a heparin suit against Covidien Ltd., a supplier of medical devices and drugs, primarily handles cases involving defective tires and toys made in China. He said he anticipates jurors to be more receptive to the heparin cases than they were to previous pharmaceutical lawsuits.

"Juries are outraged about what happened in China," he said.

"These pharmaceutical lawyers will get in a courtroom on a Chinese product case and be happy campers," Killino said.

Zoll, liaison counsel of the heparin suits, said there is a potential for more liability suits against pharmaceutical drug manufacturers with links to China because the growth of companies in that country is "huge."

"Will there be another case coming out of China? Absolutely," he said.

Mayer, the defense attorney, hesitated to suggest that more suits would be filed outlining a similar set of facts that surround the heparin recalls. But, he said, the heparin suits could attract more pharmaceutical litigation, in general, involving Chinese suppliers.

"There's a lot of copycat effect in litigation," he said. "Once you see one of these lawsuits where people make an allegation that the Chinese supplier didn't do what it was supposed to, people may look harder at other such situations whether or not there is any basis for it."

Baxter's lawyer, Leslie Smith, a partner at Chicago's Kirkland & Ellis, referred calls to a company spokeswoman, Erin Gardiner. In an e-mailed statement, Gardiner said that products liability suits generally involve allegations of a design defect, manufacturing defect or failure to warn. In this case, the heparin contaminant was the result of "deliberate and sophisticated tampering" that evaded internal tests of the drug.

"Because of the insidious nature of the heparin contamination that surprised heparin manufacturers around the world, we do not think the traditional product liability claims are valid," she said in the statement.

Gardiner also said that, unlike other pharmaceuticals that have been on the market for years, the heparin at issue was in use for less than six months. Not all the heparin on the market was contaminated, either.

Finally, she said, "we believe that only a very small number of people who received the heparin suffered significant injury caused by the contaminant, while the vast majority suffered no adverse event or only a transient reaction."

A call to Michael Moeller, a partner at Kansas City, Mo.-based Shook, Hardy & Bacon, who represents Covidien, was returned by spokesman David Young, who declined to comment on the litigation.

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