Stent Concerns Are Galvanizing Plaintiffs' Bar

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While a panel of experts from the Food and Drug Administration weighs the safety of a popular heart device at a meeting concluding today, another group is paying close attention: personal-injury lawyers.

At issue are drug-coated stents -- tiny scaffolding that holds arteries open and emits a medication that prevents them from closing up. Such stents were considered one of the hottest treatments for heart disease until recently, when concerns developed that they may cause potentially fatal blood clots.

Some patients and lawyers aren't waiting to file lawsuits, claiming the manufacturers of the devices failed to warn them of the possible clotting risks, and of a severe itching problem caused by a hypersensitive reaction that they allege can develop after stent implantation.

The cases come amid a surge of lawsuits against pharmaceutical and medical-device companies. The shift has taken place as massive lawsuits against tobacco and asbestos companies have dried up and health-care companies have been dogged by safety concerns. But plaintiffs and their attorneys face a much higher bar for these cases than with similar lawsuits brought in relation to drugs that proved risky. A key hurdle: Unlike drugs, medical devices that have been approved by federal regulators are generally protected from personal-injury suits.

When Johnson & Johnson and then Boston Scientific Corp. introduced drug-coated stents in the U.S. some three years ago, they were considered a huge improvement over their bare-metal predecessors. The older wire-mesh contraptions held open clogged arteries, but the procedure often had to be repeated several times because scar tissue would re-clog the vessel. The new stents were coated with a drug that retards scarring.

Drug-coated stents won't provide the plaintiffs' attorneys with their next Vioxx, the Merck & Co. painkiller that was pulled from the market and has attracted more than 28,000 lawsuits claiming billions of dollars. And the FDA panel so far hasn't handed plaintiffs attorneys -- some of whom are attending the meeting to learn more -- a silver bullet.

The FDA panel said yesterday that while drug-coated stents could carry a small risk of clotting, that risk doesn't translate into a higher rate of heart attack and death. When used as directed, the panel indicated that the benefits of drug-eluting stents outweigh the risk. The talk today will continue to look at off-label use of drug-eluting stents.

There are almost five million patients world-wide who have the devices in their chests, and patients have an average of 1.5 stents each, according to Matthew Dodds, an analyst at Citigroup Inc. The common remedy to reduce clotting risk is taking the anticoagulant Plavix, which is jointly marketed by Bristol-Myers Squibb Co., of New York, and Sanofi-Aventis SA, of Paris. But that can cause problems too. Patients getting coated stents tend to be older and in need of more surgeries -- including repeat stent procedures -- but undergoing surgery requires that patients stop taking blood-thinning drugs, opening up the clotting risk anew.

Last week, Sean O'Shea, a 46-year-old retired police officer from West Palm Beach, Fla., filed a complaint in state court there against Johnson & Johnson and its Cordis Corp., which makes the Cypher stent. The suit alleges that the stent causes clots that the companies were aware of, or should have been aware of, and failed to communicate the risk to doctors and patients.

Mr. O'Shea received two Cypher stents after an October 2003 heart attack. He was put on Plavix to prevent clotting, he says, but suffered another heart incident and was implanted with four more stents, making a total of six. Of the six, says Mr. O'Shea, five are Cypher drug-eluting stents.

The Plavix that he has had to take in the interceding 2½ years causes him to bleed profusely from small scratches. He had to retire early from his job, as being in the line of fire was no longer safe, he says.

"It's a time bomb," Mr. O'Shea says. "How long is it going to be before I break a bone or need surgery, and I have to make the decision to go off the Plavix so they can open me up, or stay on and take the chance of bleeding to death?"

Christopher Allman, a spokesman for Miami-based Cordis, said that the company doesn't comment on matters of pending litigation. It has said that there is not a significant difference in the clotting risk between Cypher and bare-metal stents.

"Obviously, a slam dunk for our case would be to have all these esteemed cardiology experts come out and say this is a health-care nightmare," said Stephan Le Clainche, a lawyer at Babbitt, Johnson, Osborne & Le Clainche, the West Palm Beach, Fla., law firm representing Mr. O'Shea. "That's not going to happen, but what's interesting is the strongly divergent opinions of many of the panelists. It's an unfolding issue that's going to take time."

Contributing to the complexity of the legal situation, a 1976 federal law largely pre-empted state law in cases involving medical devices. Concerned that fears of litigation could stifle innovation among device manufacturers, Congress established protections that thwart lawsuits brought against most medical devices that have received FDA approval. It's rare for a court to deny device makers that pre-emption -- though last week a federal judge overseeing a case involving Neutronic's defibrillators did just that.

The high legal hurdles for medical-device cases have deterred some plaintiffs' attorneys from bringing suits. "I think the general perception is that device cases have been the subject of increasing scrutiny" in light of the pre-emption issues, says Thomas R. Kline, of Kline & Specter in Philadelphia, who isn't participating in the litigation.

Some of the lawyers who are moving ahead with drug-coated stent cases say their cases have merit because of alleged off-label marketing, and the fact that drug-eluting stents are a combination of drugs and devices, among other claims. Another factor plaintiffs might have in their favor: Unlike a drug, whose effects are diffuse, it's fairly easy to determine if a stent causes a heart attack because it often can be determined with either an angiogram or an autopsy whether the culprit clot had formed in the stent or not.

A handful of other cases filed recently in state and federal courts, some seeking class-action status, allege that manufacturers failed to warn of potentially fatal blood clots. A suit filed last month in federal court in the Southern District of Florida claims that Boston Scientific, which makes the Taxus stent, didn't warn that the stents could increase the risk of potentially fatal blood clots, don't always prevent arteries from relocating and could cause a hypersensitivity reaction. If a judge certifies it for class-action status, and the plaintiffs win, the case could bring damages in the millions from wrongful deaths, and in the hundreds of thousands for plaintiffs with increased risk of clotting or hypersensitivity, according to Gary Betensky and Gary Rosner, the lead lawyers on the case.

Paul Donovan, a spokesman for Boston Scientific, said: "We don't believe there is any basis for the claims that are being made in this litigation, and we think the case is without merit." Boston Scientific previously has acknowledged a small but significant risk of late clotting has said it has seen no increase in heart attacks or death linked to Taxus.

Plaintiffs' attorneys say they are fielding dozens of calls each day and are signing up patients. Mike Papantonio, a partner at Levin Papantonio Thomas Mitchell Echsner & Proctor, a large personal-injury firm, has received about 100 inquiries and said he plans to file suit on behalf of about five plaintiffs by year end.

And John Driscoll, a lawyer in charge of mass torts with Brown & Crouppen in St. Louis, is waiting to see what the FDA concludes. "My father has a Taxus stent, and now it appears he will have to be on Plavix for the rest of his life," he said.