what's HOT & what's not

Medical device, pharmaceutical litigation

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As medical technology continues to advance, so to do lawsuits over allegedly defective medical devices and drugs. Among the many lawyers in Minnesota representing plaintiffs or defendants in medical device litigation is Kim M. Schmid, who recently discussed what's hot and what's not with Minnesota Lawyer associate editor Barbara L. Jones. Schmidt and other attorneys at her firm, Bowman and Brooke, will present a seminar on drug and medical device litigation, addressing both litigation and regulatory issues, on Sept. 30 at the Metropolitan in Golden Valley.

WHAT'S HOT

■ Mass tort litigation

"We are looking at a number of mass torts being filed concerning both medical devices and pharmaceuticals. I don't see the mass tort litigation going anywhere, but [instead] continuing," Schmid said.

Some of the cases achieve multi-district litigation status, and there has been a steady increase in the number of cases involving pharmaceuticals and devices granted by the MDL panel in the past six or seven years. "It's still not a large number but it's certainly an increase," said Schmid.

The advantage of MDL to both sides is coordinated discovery. Devices or drugs now the object of MDL include: Fleet phospho-soda; Bextra; Vioxx; Kugel hernia mesh patches; Medtronic defibrillator leads; Fosamax; hormone replacement therapy; stents, Ortho Evra birth control patches; and Fentanyl pain patches.

"Minnesota sees more than its fair share of medical device and pharmaceutical filings," said Schmid. She attributes this phenomenon to the six-year statute of limitations on negligence and the caliber of the federal bench.

According to the United States Judicial Panel on Multi-District Litigation, 8,156 MDL cases came into court nationwide in the 12 months ending Sept. 30, 2008, with 3,632 of those being in the 8th Circuit. More than 3,000 went into the Eastern District of Arkansas. (Arkansas is the venue for MDL involving Prempro and now has over 8,000 cases.) Of the remaining 8th Circuit cases, the majority went to Minnesota. Minnesota has MDLs involving eight products or defendants.

MDL and mass tort litigation defendants are often employing national coordinating counsel to manage these cases, Schmid said. "It has become far more cost-effective to have one person at the helm," she said.

■ Allegations of forum-shopping

Defense lawyers claim that plaintiffs' lawyers file in inconvenient venues where the plaintiff does not reside or the surgery did not take place, forcing defendants to incur the expense of motions to change venue.

■ Pain pumps

Pain pumps deliver a continuous flow of anesthetic, so pain-pump claims involve both devices and drugs that are delivered. Schmid is the national coordinating counsel for Breg, Inc., where the plaintiffs have filed hundreds of cases alleging injury from the use of a pain pump after arthroscopic shoulder surgery. Plaintiffs allege that the anesthetic, which the pain pump delivers directly into the shoulder joint, eats the cartilage, resulting in a bone-on-bone condition called chondrolysis.

"This is the newest mass tort that we have seen from the plaintiffs' bar," said Schmid. To date, plaintiffs have not been granted MDL status, but have organized into a national consortium to pursue these cases in state and federal courts.

■ Pre-emption

The U.S. Supreme Court held in 2008 in *Riegel v. Medtronic* that a pre-emption clause enacted in the Medical Device Amendments of 1976, 21 U. S. C. sec. 360k, bars common-law claims challenging the safety and effectiveness of a class III medical device given premarket approval by the Food and Drug Administration. (Medical devices are divided into three classes, with the most invasive devices assigned to class III.)

The response to *Riegel* has been two-fold, according to Schmid. From the plaintiffs' bar, a new theory alleging manufacturing defects, rather than design defects, in class III devices has been developed to allow state court lawsuits. From Congress, legislation has been drafted to undo *Riegel*. The Medical Device Safety Act of 2009, currently in the hearing stage, would overrule *Riegel* in favor of state tort law, said Schmid.

(The Supreme Court reached a different conclusion on pre-emption in *Wyeth v. Levine*, which held that the FDA's labeling approval of a drug does not pre-empt state laws or shield companies from legal damages as part of liability claims.)

■ Daubert challenges

The defense bar has stepped up its use of *Daubert* challenges to plaintiffs' experts' causation opinions. The defendants argue that the expert's opinion should be based on science that was available when the device was manufactured, Schmid explained. "You have to judge [the device] by the state of the prevailing art available at the time of the manufacture," she said. Additionally, Schmid sees federal court judges as being increasingly willing to accept the role of gatekeeper as required by *Daubert*.

■ E-discovery

The extent to which plaintiffs are able to obtain electronically stored information from defendants and their employees, and what defendants perceive as discovery abuses by the plaintiffs' bar, is a very hot topic, Schmid said. The lawyers for both sides should agree on a protocol for keeping the search reasonable in scope, time and production, she said.

WHAT'S NOT

■ Class actions

Class actions involving medical devices or pharmaceuticals are becoming less common. "In large part, that's due to the fact that the defense bar was very aggressive about objecting to class certification standards ... early on," said Schmid. Taking the place of class actions are MDLs or individual mass tort filings, she said.

Minneapolis attorney Kim Schmid handles medical-device litigation at Bowman and Brooke. (Photo: Bill Klotz)

■ Off label usage doctrine

Lawsuits based on off-label use of devices or pharmaceuticals have waned as lawyers and judges recognize that physicians will often prescribe off-label uses. That is acceptable to the FDA if the use is in the physician's best considered judgment. But some lawsuits continue based on marketing for off-label use, Schmid said.