Monday, March 3, 2008

The Reflex Hammer Falls

The U.S. Supreme Court shields makers of medical devices from lawsuits

By Daniel E. Cummins

On Feb. 21, the U.S. Supreme Court handed down a resounding 8-1 decision that has essentially almost entirely wiped out an injured patient's ability to sue a manufacturer of a medical device for damages arising out of the use of an allegedly defective device.

Writing for the majority in the case of *Riegel v. Medtronic, Inc.*, No. 06-179, Justice Antonin Scalia held that manufacturers of medical devices were immune from liability for personal injuries as long as the Food and Drug Administration (FDA) approved the device for marketing and as long as the device continued to meet the agency's specifications.

Justice Ruth Bader Ginsburg was the sole dissenter in the case.

Commentators reviewing the decision have indicated that the opinion could serve to bar pending and future claims for personal injuries arising out of the use of such devices as defibrillators, heart pumps, balloon catheters, drug-coated stents, artificial heart valves, spinal cord stimulators, prosthetic hips and knees, or breast implants, just to name a few.

The Supreme Court's decision in *Riegel v. Medtronic Inc.* represents the crashing down of a legal tidal wave of an analysis that all but one appellate circuit court had agreed upon, i.e. that when Congress created an express pre-emption clause with respect to the federal regulation of new medical devices, it clearly also sought to bar state law tort claims against medical device manufacturers.

In Pennsylvania, the joinder in this analysis was previously voiced by the Third Circuit Court of Appeals in the case of *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004). In *Horn*, the plaintiff's claims against maker of heart pump for defective design and failure to warn were found to be barred under the same analysis as set forth by the Supreme Court in its just released opinion in *Riegel*.

The Device's Alleged Failure

The case of *Riegel v. Medtronic, Inc.* itself began as a products liability lawsuit brought on behalf of Charles Riegel, who underwent a coronary angioplasty in 1996, shortly after suffering a heart attack.

During the surgery, the doctor inserted an Evergreen Balloon Catheter into the coronary artery in an effort to dilate, even though the labeling for the device warned that the device's use was contraindicated for the type of condition at issue. The device also came with a warning that the catheter should not be inflated beyond a certain level. Nevertheless, the doctor inflated the device beyond that level during the surgery and the catheter ruptured as a result. Riegel developed a heart block, was placed on life support and underwent emergency coronary bypass surgery.

Thereafter, the Riegels commenced a lawsuit in a New York Federal District Court alleging that the catheter manufactured by Medtronic was designed, labeled, and manufactured in a manner that violated New York common law, and that these defects resulted in the plaintiff's injuries.

At the time the lawsuit was filed there was in place a pre-emption clause in the Medical Device Amendments of 1976, 21 U.S.C.Section 360k, that was relied upon by the Court to support its finding that Congress intended to bar any common-law claims challenging the safety and effectiveness of a medical device given premarket approval by the FDA.

Regulatory Scheme

According to the background on the regulatory scheme set forth in Justice Scalia's opinion, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, had long required the FDA's approval for the introduction of new drugs into the market. However, until the subject Medical Device Amendments were enacted in 1976, the introduction of new medical devices into the market was largely left to the states to regulate as they each deemed fit.

In the 30 to 40 years before the passage of the Medical Device Amendments in 1976 many complex medical devices were invented, developed, and placed into the stream of commerce with some notable failures. The Court referenced a notorious example of a failed device, which most lawyers may recall from their law school case studies, as being the failed Dalkon Shield intrauterine device. That product was introduced in 1970 and which was eventually linked to serious infections and several deaths, not to mention many unwanted pregnancies before it was taken off of the market.

The Supreme Court noted that, with the Dalkon Shield failure and its aftermath, it became the general consensus that the common-law tort system was unable to sufficiently manage the risks associated with potentially dangerous medical devices. As such, Congress tackled the issue with the passage of the Medical Device Amendments of 1976. According to Scalia, these amendments swept back some state imposed obligations and put in its place a detailed program of different classes or levels of federal oversight of new medical devices, with the extent of the regulation of the device depending upon the risks imposed by the device.

Although the Medical Device Amendments set forth a rigorous process for the approval of new devices by the FDA, the law also grandfathered out of the process many devices that were already on the market. The law allowed devices already on the market before 1976 to remain in the stream of commerce until the FDA promulgated a regulation requiring a premarket approval for that particular device. Another part of the law sought to limit the resultant competitive advantage to those grandfathered devices by providing that a new device did not have to undergo the premarket approval process if the FDA found that it was "substantially equivalent" to another device that was already exempt from the premarket approval requirement.

The *Riegel* case concerned only medical devices that were subject to and had gone through the premarket approval process specified by the Medical Device Amendments of 1976.

Regulations Trump Common Law

To support its 8-1 decision that the Medical Device Amendments pre-empted any states' common law requirements and tort remedies, and thereby provided immunity to manufacturers for liability for any injuries caused by such pre-approved medical devices, the Supreme Court went to great lengths in opinion to explain in detail the rigorous and time-consuming FDA approval process of the medical devices.

In essence, the majority suggested that the premarket approval process is no small matter and, as a result, it appeared that Congress had determined that if a manufacturer was mandated to meet so many rigorous FDA requirements before its product was allowed to be on the market, the FDA may as well be deemed the final arbiter of the products' safety.

Turning back to the Riegel's claims which were based upon common law tort principles, Scalia noted that the problem presented by such lawsuits was that if the claims of product defects such as, for example, that the product should have been made differently or that the warning should have been otherwise stated, were accepted by a jury in a verdict for the plaintiffs, that would be tantamount to the creation of state common law requirements on a federally regulated product.

Another potential problem could be that different jury verdicts in separate cases on the same type of product (i.e. finding in one case, for example, that the product should have been more flexible or larger and another jury finding in another case that the same product should have been less flexible or smaller) would result in inconsistent state common law requirements which would also be in violation of the single federal scheme of FDA regulation created by Congress.

In the words of Scalia, to permit state court juries to impose liability on the manufacturer of an FDA approved medical device would "disrupt the federal scheme" that mandates that the FDA have the ultimate responsibility of assessing the risks and benefits of a new device and ensuring that it is safe and effective before it enters the stream of commerce.

The Supreme Court did specify that state requirements in this regard are pre-empted by the Medical Device Amendments only to the extent that they are "different from, or in addition to" the requirements imposed under federal law for medical devices. As such, it was held that the amendments did not prevent a state from providing a damages remedy for claims premised on a violation of an FDA regulation or regulations. Therefore, in cases containing allegations that the device at issue was made improperly or in violation of the FDA specifications, the state created duties are permissibly "parallel" to the federal requirements, rather than in addition to those requirements, and such suits could proceed.

Although the Riegels argued in this matter that their claims were of a nature that paralleled the federal requirements, the Supreme Court found this issue to have been waived on appeal. The Court also noted that, in any event, the District Court in *Riegel* had recognized in its trial opinion that parallel claims would not be pre-empted, but had nevertheless interpreted the plaintiff's claims to impermissibly assert that Medtronics device violated state tort law notwithstanding compliance with the relevant federal requirements, i.e., the court decided that the plaintiff's claims did not parallel the federal requirements.

The Supreme Court's decision in *Riegel v. Medtronic Inc.* affirmed the dismissal of the lawsuit by the District Court, as well as the Second Circuit Court of Appeals' affirmance of that dismissal.

In other words, all of the courts that addressed Riegel's claims consistently ruled that the claims presented against the manufacturer were pre-empted, or barred, by the Medical Device Amendments. By the conclusion of the case before the United States Supreme Court, it was affirmed that the pre-emption clause of the Medical Device Amendments did indeed bar common-law claims challenging the safety and effectiveness of a medical device given premarket approval by the FDA. As stated above, this is the position that had also been taken by all but one Federal Circuit Court of Appeals.

Sparking a Firestorm

According to a Feb. 21 *New York Times* article written by Linda Greenhouse reporting on the Court's opinion, it is unclear how many thousands of lawsuits against medical device manufacturers would be affected, but it was certain that at least some pending cases would be dismissed as a result.

The article also noted that the decision could spark a political firestorm in this election year. The Supreme Court's decision was being viewed as a victory for the Bush administration, which had been seeking broad authority to pre-empt tougher state regulations in this regard. It was also reported that the Bush administration will be continuing its push to for pre-emption in another FDA case, *Wyeth v. Levine*, No. 06-1249, that the Supreme Court has accepted for review for its next term of court. The issue in that case will address whether the FDA's approval of a drug, as opposed to a device, pre-empts a personal injury suit based upon a drug.

The *Times* also reported that, on the other side of the aisle, some high profile Democratic lawmakers, such as Sen. Edward M. Kennedy, D-Mass., who was actually the sole Senate sponsor of the 1976 legislation in question, have sided with the position set forth in the dissent issued in *Riegel* by Ginsburg that Congress never intended that the FDA approval process would give blanket immunity to manufacturers from liability for injuries caused by defective medical devices. Foreshadowing that the issue has not ended, Kennedy was quoted as saying, "Congress obviously needs to correct the Court's decision."

The article also noted that U.S. Rep. Henry Waxman, a California Democrat and member of the House of Representatives who was on the House panel that approved the 1976 bill at issue was equally strong in his condemnation of the Court's decision, stating, "The Supreme Court's decision strips consumers of the rights they've had for decades. This isn't what Congress intended, and we'll pass legislation as quickly as possible to fix this nonsensical situation."

Meanwhile, as reported in the *Times* article, the Bush administration is also supporting a manufacturer's position in another FDA pre-emption case that was set to be heard by the Court last week. In that case, the issue is whether a state case can be based on a claim that a drug maker committed fraud by misrepresenting or withholding information from the FDA during the approval process. That case is entitled *Warner-Lambert Co. v. Kent*, 06-1948 and concerns the diabetes drug Rezulin. •