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Testing Manufacturer Liability in FDA-Approved Device Malfunction

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In 1996, an Evergreen Balloon Catheter, marketed by Medtronic, Inc., burst during Charles Riegel's angioplasty [1]. The catheter had been granted premarket approval (PMA) from the Food and Drug Administration (FDA) in 1994. While the manufacturer's instructions recommended that physicians inflate the catheter to only 8 atmospheres, the treating physician in Riegel's case inflated the catheter to 10 atmospheres before it burst. As a result, Riegel developed a heart block, was placed on life support, and underwent emergency coronary bypass surgery.

Riegel and his wife filed a product liability complaint against Medtronic. A federal district court dismissed the complaint, holding that federal legislation—the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act [2] preempted the state negligence and liability claims the Riegels cited in their case against Medtronic. The case eventually made its way to the U.S. Supreme Court.

Riegel v. Medtronic, Inc. brings to light a conflict between manufacturers who have obtained FDA approval and injured patients who want to retain the option of seeking restitution for damages resulting from defective medical devices [3]. Patients who believe defective devices caused their injuries take little comfort in knowing that the devices had FDA approval. Conversely, device manufacturers who received FDA approval after extensive review want to avoid repeating the review process in the courts. In *Riegel*, the Supreme Court addressed whether the preemption clause of the Medical Device Amendments bars state law claims that challenge the safety and effectiveness of a medical device given premarket approval by the FDA.

Summary of the Medical Device Amendments of 1976

The Medical Device Amendments (MDA) of 1976 established three regulatory classes of medical devices. Class I medical devices, which include elastic bandages and examination gloves, are subject to "general controls," such as labeling requirements [4]. Class II medical devices, which include powered wheelchairs and surgical drapes, are subject to "special controls," such as performance standards [4].

The most regulated medical devices are those in Class III, which the amendments define as devices that support or sustain human life, are "of substantial importance in preventing impairment of human health" or "present a potential, unreasonable risk of illness or injury" [4]. Class III medical devices include replacement heart valves and the catheter used on Charles Riegel. These devices are subject to a rigorous premarket approval (PMA) process that includes:

- full reports of all studies and investigations of the device's safety;
- a complete statement of the device's components, ingredients, and properties;

- a detailed description of the methods used in, and the facilities and controls used for, the manufacture and processing of the device;
- samples of device components required by the FDA; and
- a specimen of the proposed labeling [1].

The FDA grants premarket approval to Class III devices only after determining that there is reasonable assurance of their safety and effectiveness [5]. In making this determination, the FDA weighs any probable benefit to health from the use of the device against any probable risk of injury in light of available alternatives. For example, a ventricular assist device for children with heart failure was approved, despite a survival rate of less than 50 percent in children using the device, because no other device had a higher survival rate [1]. However, a Class III device that fails to meet PMA requirements is considered unmarketable [4].

At issue in *Riegel* was the Medical Device Amendments' preemption clause. In general, preemption clauses provide that federal laws that conflict with state laws will trump, or "preempt" them [6]. The preemption clause in the Medical Device Amendments prohibits states from establishing a requirement with regard to any device intended for human use that is different from, or in addition to, any federal requirement applicable to the device [5]. The preemption clause also forbids states from establishing any requirement that relates to the safety or effectiveness of a device intended for human use [5].

How Safe is Safe Enough?

The dispute in *Riegel* centered on the amount of regulation necessary to ensure the safety and effectiveness of medical devices. Medtronic argued that letting state claims proceed against devices that had passed the premarket approval process would usurp the power of the FDA, because the PMA process was designed to assure the safety and effectiveness of medical devices [7]. The Riegels countered that Congress never intended the FDA's power to regulate medical devices to negate the right of private citizens to sue negligent manufacturers [8].

The Riegels also contended that FDA regulations alone were not enough to protect consumers, since no amount of rigor in the premarket approval process could predict all possible outcomes or problems with a device and its use. Without the threat of litigation, the Riegels argued, manufacturers could attempt to hide safety flaws from the FDA [9].

Medtronic challenged the plaintiffs' assertion that the threat of litigation would improve product safety. Instead, it argued, state restrictions would reduce innovation in the development and availability of beneficial medical devices [7]. Moreover, Medtronic argued, because manufacturers factor the cost of potential litigation into product prices, increasing the threat of litigation would increase the cost of health insurance and put some devices out of reach of potential consumers [10].

Interpreting the Medical Device Amendments and Applicable Precedent

To settle this dispute, the Supreme Court turned to judicial precedent and the plain text of the Medical Device Amendments' preemption clause. In particular, the Court relied on its 1996 decision in *Medtronic v. Lohr*. In *Lohr*, the Supreme Court had ruled that the Medical Device Amendments preempt state requirements only when the FDA has established “specific counterpart regulations or there are specific requirements applicable to a particular device” [11]—in other words, only when the FDA has a regulation that covers the same safety aspect or the same device that the state requirement covers. The Court rejected the Medtronic contention that general labeling requirements for all medical devices fall under this “specific counterpart” description [10].

Unlike general labeling requirements, premarket approval entails an in-depth review of a specific medical device. Writing for the majority, Justice Scalia stressed that the premarket approval process for medical devices is one that is rigorous and highly individualized [1]. The Court held that because “premarket approval is specific to individual devices” it constitutes “federal safety review” which, under the Medical Device Amendments, preempts state law [1]. Because the Medtronic catheter that burst during Charles Riegel's angioplasty had premarket approval from the FDA, state claims against its manufacturer were invalid under the Medical Device Amendment and *Lohr* [1]. In support of this holding, Justice Kennedy emphasized during oral arguments that, if state law damage claims were not preempted by federal regulations, state juries would be asked to repeat the demanding review process already completed by the FDA for any potentially hazardous device [3].

The Effect of the Ruling

By ruling against the Riegels, the Supreme Court refused to allow injured patients to sue device manufacturers whose products pass the FDA's findings of adequate safety. This ruling prevents courts from enforcing state regulations on medical devices with premarket approval unless those restrictions are identical to corresponding FDA restrictions. Going forward, this may prevent consumers injured by such devices from receiving adequate compensation [8]. Though consumers are not completely without legal recourse—they can still bring suit against negligent manufacturers under state laws identical to FDA requirements or against negligent physicians—the Supreme Court has immunized PMA medical devices from many product liability suits founded in state law, leaving some injured consumers without a common source of judicial remedy [1, 10].

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