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REGULATORY OUTLOOK

Protecting PMA Devices and Their Makers

Critics of preemption may be overstating their case.

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In February 2008, the U.S. Supreme Court decided that medical devices that receive premarket approval (PMA) from FDA are protected from product liability lawsuits brought in state courts. However, members of Congress have introduced legislation to overturn the Court's decision and to make PMA devices vulnerable to attack.



In *Riegel v. Medtronic*, the Court found that federal preemption prohibits state law claims that challenge the safety or effectiveness of PMA devices. Federal preemption is a legal principle based on the U.S. Constitution; it prohibits a plaintiff from prevailing on state law claims when state and federal laws conflict. Because medical devices in the PMA process must meet federal requirements, state laws cannot later be used to challenge their safety or effectiveness. This rule could change, however, if Representatives Henry Waxman (D-CA) and Frank Pallone (D-NJ), Senators Edward Kennedy (D-MA) and Patrick Leahy (D-VT), and other critics of preemption get their way.

On June 26, 2008, Representatives Waxman and Pallone introduced the Medical Device Safety Act of 2008 (HR 6381) in the House of Representatives. The bill is intended to amend the Medical Device Amendments of 1976—which made extensive changes to the Federal Food, Drug, and Cosmetic Act and which is the law at issue in *Riegel*. The proposed bill states that the Medical Device Amendments will no longer prevent plaintiffs from pursuing judgments against the makers of PMA devices in state courts.

The bill has 71 cosponsors and is being considered by the House Committee on Energy and Commerce. On July 31, 2008, a companion bill was introduced in the Senate (S 3398). The bill has 15 cosponsors and is being considered by the Senate Committee on Health, Education, Labor, and Pensions.

The proposed legislation and several related high-profile legal cases, including *Riegel*, have put preemption in the spotlight. Although *Riegel* determined the effect of preemption on device cases, the outcome for pharmaceutical cases has yet to be decided. Later this year, the Court will decide *Wyeth v. Levine*, which will determine whether FDA's authority to regulate drug labels preempts failure-to-warn actions based on state law.

In May 2008, in the wake of *Riegel* and in anticipation of *Wyeth*, the House Committee on Oversight and Government Reform, which Waxman currently chairs, heard testimony regarding preemption. Many who were involved in the hearing had grim predictions for the post-*Riegel* world. They claim that the *Riegel* decision jeopardizes public health and bars injured patients from having their day in court. Waxman characterized *Riegel* as "an unfortunate Supreme Court decision that denied victims any legal recourse."

Despite such doomsday proclamations from Waxman and other preemption critics, preemption is ultimately beneficial to the public. Preemption encourages innovation, enabling device makers to enhance existing technologies and make discoveries. Litigation, in contrast, impedes access to certain medical treatments.

Preemption opponents caution that it eliminates state court oversight of devices. They do not mention, however, that states are poor guardians of the public health when it comes to device regulation, as federal lawmakers discovered prior to 1976, when FDA did not yet receive premarket approval authority.

Preemption critics want the public to believe that preemption leaves injured plaintiffs without recourse against device makers. Yet, despite the positive effect that the *Riegel* decision can have on the development of lifesaving technologies, the decision does little to change medical device litigation.

Preemption and Public Health

Before a device may be marketed, FDA must approve it. There are two routes to approval: the PMA process and the 510(k) review. Only certain Class III medical devices are subject to the PMA process, and this group, by definition, consists of the newest and most innovative technologies.

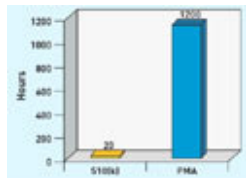


Figure 1. (click to enlarge) A comparison of the average time for reviews for 510(k)s and PMAs. It takes 60 times longer to review a device through the PMA process than through a 510(k) review.

Bringing a Class III, PMA device to market is a costly endeavor in various ways. The U.S. Government Accountability Office (GAO) found that premarket reviews cost device manufacturers \$239,000 per device in 2005. On average, it takes FDA 1200 hours to review each PMA device (see [Figure 1](#)). By comparison, it takes FDA 20 hours to determine whether a device may be brought to market under 510(k) review. As such, it is far more onerous for a device maker to market a PMA device than a 510(k) device, meaning that there is a systemic disincentive to develop new, innovative technologies.

Preemption, on the other hand, is an incentive for a device maker to undertake the pricey and time-consuming PMA process. Preemption, in a sense, protects the device maker's investment in obtaining premarket approval. As a result of the assurance that premarket approval provides—namely that device makers will be somewhat sheltered from litigation—device makers are free to pursue innovations, propelling technology beyond its current limitations. As such, preemption fosters advances and discoveries that ultimately benefit the public.

How Litigation Limits Access to Treatments

A lawsuit focuses on the highly specific, possibly unique experience of a single plaintiff. By design, the U.S. tort system focuses a jury's attention on the safety of a medical device with respect to its effect on one individual patient (the plaintiff). As Justice Scalia pointed out in *Riegel*, a jury "is not concerned with [the device's] benefits; the patients who reaped those benefits are not represented in court." A device that could potentially benefit the public as a whole can be withdrawn from the market and withheld from patients due to litigation, even if the expected benefits of the device outweigh the likelihood of harm.

Borrowing an example from the world of pharmaceuticals, in the 1980s, a series of lawsuits targeted the manufacturers of children's vaccines. As a result, many manufacturers ceased producing vaccines, leading to shortages and driving up prices. (The vaccine for DTP (diphtheria, tetanus, and pertussis) rose from 19 cents to \$12 in six years.)

In commentary made during the hearing before the House Committee on Oversight and Government Reform, Representative Brian Bilbray (R-CA), a member of the committee, provided another example of the effect that litigation can have on the availability of lifesaving treatments.

Bilbray's wife experienced severe morning sickness while pregnant with their first child and was unable to get the drug, Bendectin, which had been withdrawn from the market by its maker, Merrell Dow Pharmaceuticals. More than 300 lawsuits had been filed against Merrell Dow by plaintiffs who claimed that the drug caused birth defects. FDA conducted a review of the drug in 1980, in the midst of the litigation, and determined that there was no connection between Bendectin and birth defects.

However, the cost of defending Merrell Dow and large jury awards caused Merrell Dow's insurance premiums to skyrocket (reportedly to \$10 million a year, just \$3 million less than its profits from the sale of the drug), leading the company to withdraw Bendectin from the market. Bilbray told the committee that his son died shortly after birth, allegedly as a result of trauma he experienced during his first trimester. Bilbray stated, "I will go to my grave believing that my child is dead because he was denied the product that he desperately needed in his first trimester."

With respect to devices, litigation surrounding the Dalkon Shield led other IUD manufacturers to remove their devices from the market even though FDA had not raised questions about their safety. The Dalkon Shield was an intrauterine contraceptive device (commonly referred to as an IUD). During the committee's hearing, the Dalkon Shield litigation was cited as the reason that the United States lags behind other countries in the availability of modern contraception.

Similarly, Norplant, a contraceptive, was withdrawn from the U.S. market in 2000 in the wake of several unsuccessful lawsuits that were filed against the manufacturer, which ultimately decided to stop marketing Norplant to avoid continued litigation costs. Allegations from the plaintiffs' bar notwithstanding, FDA, the World Health Organization, and the American Society of Reproductive Medicine had all determined that Norplant was safe.

Critics of preemption advocate a position that conflicts with public outcry to make medical treatments accessible to patients as rapidly as possible. FDA is frequently castigated as an overly cautious gatekeeper. It is accused of being slow to release medical products to the public and, thus, responsible for unnecessary suffering and death. Uproar arises from the perception that existing, effective (though unapproved) medical treatments are locked away by FDA from patients who would benefit from their immediate use. Yet, as the history of Bendectin and Norplant illustrate, litigation can have a far more profound effect when it forces device makers to yank otherwise effective and beneficial devices from the market.

Effective Oversight of Devices

Preemption critics who claim that state courts are essential to protecting patients from allegedly defective devices overlook important lessons from the era before Medical Device Amendments. The purpose of the tort system is to compensate individual plaintiffs for harm—not to police the device market for the benefit of the general public. Perhaps it is for this reason that state courts, historically, have not been effective keepers of the public health when it comes to oversight of medical devices.



Prior to 1976, FDA had little authority with respect to devices and had no power to approve devices prior to their marketing. Instead, regulation of devices was left to the states, largely through litigation (though at least 13 states had also enacted laws to regulate devices). This system failed to protect more than 700 people who died during a 10-year period as a result of poor medical device oversight. That's according to a 1970 government study, which also found that

10,000 people were injured when state litigation, rather than federal oversight, was supposedly protecting consumers.

After hundreds of deaths were attributed to artificial heart valves and the public was reeling from the Dalkon Shield litigation, President Nixon publicly called for federal legislation to ensure the safety of devices. An editorial that appeared in the Washington Post in 1973 called for federal oversight of the device market, noting that the "casualness with the public's health needs to be replaced with [appropriate] surveillance... Obviously, not all the medical devices are unsafe; rather, the issue is that the public's health should not be left to chance."

At the time, lawmakers recognized that state oversight was not working and expert scientific review of devices prior to their marketing was necessary. Ultimately, FDA received premarket approval authority from the Medical Device Amendments, the very law that preemption critics now attack.

Bringing scientific expertise to the oversight of medical devices is not the only justification for the enactment of the Medical Device Amendments. In the era before the amendments, through litigation, states could impose varying requirements on a single medical device. Imagine a system in which courts in all 50 states could dictate the content of a device's warning label, resulting in 50 different versions of the label. Complying with each state's requirement could be extremely onerous, if not impossible. Preemption, however, ensures national uniformity for device requirements and thus makes it more efficient for device makers to bring lifesaving technologies to market.

Preemption also assures medical device makers that they will not be held liable for complying with FDA requirements. For example, without preemption, a device maker could be required by FDA to reduce certain warnings because of concern for overlabeling, and then later the device maker could be sued in state court for failure to warn. Preemption, on the other hand prohibits state law claims and protects a device maker's efforts to build and market a device that meets FDA's requirements. Therefore, the legislation currently being considered by Congress could stifle innovation and discourage the marketing of new devices.

Litigation Despite *Riegel*

During the recent congressional hearing on preemption, Representative Waxman described preemption as a "radical legal doctrine" that "strips consumers of the rights they've had for decades." In fact, PMA devices have been shielded from most state court litigation for quite some time. The *Riegel* decision merely affirmed the existing law of most states. State courts heard numerous preemption cases prior to *Riegel*, and most found that the Medical Device Amendments barred claims brought by plaintiffs. In this respect, *Riegel* does little to change the legal landscape. The legislation pending in both the House and Senate, on the other hand, is a major departure from the law of most U.S. jurisdictions. To borrow a word from Representative Waxman, the pending legislation is "radical."

Critics of preemption would have the public believe that *Riegel v. Medtronic* will completely insulate device makers from tort liability, forcing courts to turn away all injured plaintiffs. This is a scare tactic. Most devices do not enter the market through the PMA process and, as a result, are not affected by the *Riegel* decision.

In the *Riegel* opinion, the Supreme Court noted, "In 2005, for example, FDA authorized the marketing of 3148 devices under 510(k) and granted premarket approval to just 32 devices." (See [Figure 2](#)) Most claims—suits against non-PMA devices—will survive, as will claims for manufacturing defects.

Plaintiffs may also pursue claims for injuries sustained because medical devices do not conform to the specifications approved during premarket review or because device manufacturers deceived regulators by providing false information to attain premarket approval. As such, the bleak picture painted by preemption critics is overstated. In fact, most device litigation will continue in the post-*Riegel* world. Instead of tilting the scales in favor of the medical device industry, as some critics have asserted, *Riegel* affects only a narrow slice of device lawsuits.

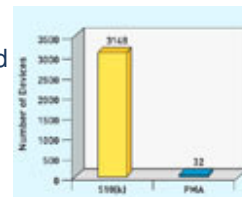


Figure 2. (click to enlarge) The number of devices approved in a year by process. Most devices are approved through 510(k). Because preemption applies only to devices approved through PMA, most products will remain subject to

Despite the inflated commentary of preemption critics, the *Riegel* decision does little to change medical device litigation. Nevertheless, *Riegel* shores up preemption and, in doing so, protects PMA device makers from a patchwork, state-based regulatory scheme. Most importantly, preemption fosters innovation and thus ensures that consumers will lead longer and better-quality lives as a result of the development and availability of new technologies. **state law claims.**

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