

Classes of Medical Devices in the United States

The Food and Drug Administration has recognized three classes of medical devices based on the level of control necessary to assure the safety and effectiveness of the device.^[1] The classification procedures are described in the Code of Federal Regulations, Title 21, part 860 (usually known as 21 CFR 860).

Class I: General Controls

Class I devices present minimal potential for harm to the user and are often simpler in design than Class II or Class III devices. These devices are subject only to general controls. General controls cover such issues as manufacturer *registration* with the FDA, good *manufacturing* techniques, proper *branding* and *labeling*, *notification* of the FDA before marketing the device, and general reporting procedures.^[2] (Most Class I devices are exempt from the good manufacturing practices and/or the FDA notification regulations.)^[2] These controls are deemed sufficient to provide reasonable assurance of the safety and effectiveness of the device; or the device is not life-supporting or life-sustaining and does not present a reasonable source of injury through normal usage. Devices in this category include tongue depressors, bedpans, elastic bandages, examination gloves, and hand-held surgical instruments and other similar types of common equipment. Depending on the "stated/purported use" of a device, it may be necessary to obtain a Premarket Approval or 510K for the device, which is otherwise classifiable as a Class 1 device. Such devices are referred to as "reserved devices". The electrically powered arthroscope (which is really an endoscope powered electrically) is a case in point. While endoscopes are Class 1 devices, the electrically powered arthroscopes need a pre-market notification (510K) although the manual arthroscopes do not. Pre-market notified devices are marketed as "at least as safe and effective, that is, substantially equivalent, to a legally marketed device."

Class II: General Controls with Special Controls

Class II devices are those for which general controls alone are insufficient to assure safety and effectiveness, and additional existing methods are available to provide such assurances. Therefore,

Class II devices are also subject to special controls in addition to the general controls of Class I devices. Special controls may include special labeling requirements, mandatory performance standards, and postmarket surveillance.^[2] Devices in Class II are held to a higher level of assurance than Class I devices that they will perform as indicated and will not cause injury or harm to patient or user. Devices in this class are typically non-invasive and include x-ray machines, PACS, powered wheelchairs, infusion pumps, surgical drapes, surgical needles and suture material, and acupuncture needles.

Class III: General Controls and Premarket Approval

A Class III device is one for which insufficient information exists to assure safety and effectiveness solely through the general or special controls sufficient for Class I or Class II devices. Such a device needs premarket approval, a scientific review to ensure the device's safety and effectiveness, in addition to the general controls of Class I. Class III devices are described as those for which "insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness or that application of special controls ... would provide such assurance and if, in addition, the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury."^[3]

Examples of Class III devices which require a premarket approval include replacement heart valves, silicone gel-filled breast implants, implanted cerebral stimulators, implantable pacemaker pulse generators and endosseous (intra-bone) implants (with the exception of root-form endosseous dental implants which were recently reclassified as Class II).



The Medical Device Amendments of 1976 (MDA)

21 U. S. C. § 360k. State and local requirements respecting devices

(a) General rule [21 U. S. C. §360k(a)]

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

- (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
- (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

- (1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or
- (2) the requirement—
 - (A) is required by compelling local conditions, and
 - (B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.



LEGISLATION

Safe Medical Devices Act Of 1990

by Frank E. Samuel, Jr.

The Safe Medical Devices Act of 1990 (P.L. 101-629) was signed by President Bush on 28 November 1990. It is the first important device amendment to the federal Food, Drug, and Cosmetic Act since the Medical Device Amendments of 1976. The new law caps eight years of congressional review of implementation of the 1976 statute and gives to the Food and Drug Administration (FDA) significant new authority for regulating the safety and effectiveness of medical devices and diagnostic products.

The 1976 device law established a regulatory system based on the degree of risk posed by a product, as classified by FDA.

New high-risk products were subjected to a premarket procedure similar to that for new drugs. This procedure required FDA approval based on clinical experience before a device could be marketed. “Me-too” products and product modifications were not required to adhere to this process if the product as introduced or modified was substantially equivalent to a product on the market before the 1976 enactment date. High-risk products on the market prior to that date were “grandfathered” but were supposed to be subjected eventually to premarket approval requirements. All products, regardless of the category of risk, were subject to a variety of controls, chief of which were adherence to good manufacturing practices and reporting of defects related to product *Frank Samuel, a lawyer and consultant in Washington, D.C., was president of the Health Industry Manufacturers’ Association from 1984 through 1989.*

Malfunction or patient death or injury

The first major congressional complaint about device regulation under the 1976 law concerned the process for determining substantial equivalence. The manufacturer initiates this process by notifying FDA under section 510(k) of the act. If FDA determines that the product subject to the notification is substantially equivalent to an existing product, the product may be marketed without undergoing complete premarket approval.

After reports by the General Accounting Office (GAO) and its own review, Congress concluded that the 510(k) procedure had evolved into a loophole that allowed untested products onto the market without adequate regulatory oversight. The second major criticism was that FDA lacked sufficient information about actual experience with devices following their introduction to be able to make informed regulatory decisions. The congressional testimony taken to prepare a basis for the new legislation depicted several instances in which device use had resulted in patient harm. In addition, GAO noted that providers reported only a small percentage of incidents involving devices. Reasonable people can differ over the force of this testimony. It is at least arguable whether the amendments enacted in 1990, if in place earlier, would have prevented the incidents cited or resulted in a noticeably greater degree of usable regulatory information. Criticisms usually focused on disagreement with FDA over the timing or nature of FDA action, not over its legal authority to take

a step Congress thought necessary. The basis for device law changes was, it appeared, due as much to the conclusion that implementation had not turned out the way Congress had thought it would as it was to widespread public health problems attributable to legal inadequacies.

Another factor contributed to the environment of congressional policy making: the revelation of bribery and submission of false and inaccurate information in connection with generic drug approvals. Although a variety of investigations continue into FDA's internal procedures, no information made publicly available during consideration of the new device law suggested that these problems existed in the device area (or in any other, for that matter). Nor has any come to light since. Even though such evidence did not exist, Congress still appeared sufficiently concerned to augment greatly FDA's penalty and postmarket authority.

The new law requires some seventeen sets of new regulations, many with specific timetables. For convenience, I group the changes into the following four categories: premarket approval, postmarket surveillance, penalties, and miscellaneous. I describe only the major features of this complex new law.

Premarket approval

Despite criticism of the 510(k) notification process, the legislative history of the new law explicitly confirms FDA's treatment of product modifications and authorizes certain FDA practices that have grown up over the past fourteen years. These include comparing new product modifications to products introduced after 1976 and requiring submission of clinical information to support a 510(k) notification. Manufacturers had opposed the latter practice at first on the grounds that the 1976 device law did not authorize FDA to require clinical data to support a 510(k) notification. But as experience with that provision grew, the 510(k) process evolved so that the amount of information required by the agency varied in relation to the significance of the product modification in question. In sum, FDA matched its requirements for clinical information with its perception of the degree of risk posed by the product. This was congruent with the fundamental structure of device regulation established in 1976, even though disagreement could exist over whether it was specifically authorized or over FDA decisions in specific cases.

In addition to confirming these two important, evolutionary aspects of FDA's device regulation, the new law requires a summary of safety and effectiveness in connection with a 510(k) submission. Review of pre-1976 devices is spurred by requiring submission, prior to 1 December 1995, of adverse safety and effectiveness data for the highest-risk products. Under certain circumstances, FDA is allowed to use clinical and preclinical data in a premarket approval application to support its decision on subsequent applications for premarket approval. The data issue was exceedingly controversial for manufacturers. Firms that considered themselves to be innovators felt that any use of their data reduced unfairly the regulatory barriers for subsequent competitors. Proponents of change argued that repetitive clinical testing posed unneeded public health risks and, furthermore, that the proper determinant of competitive position was the patent law, not a regulatory law designed to advance public health. The result was a compromise that protects premarket approval data until four manufacturers of the same product type have received FDA approval.

Overall, the new law encourages FDA to continue the 510(k) process for the vast majority of device and diagnostic product changes and to begin seriously to address high-risk products that were on the market prior to 1976.

Postmarket surveillance

Here there are four major changes. With existing law, they mean that devices are subject to more scrutiny than any other FDA-regulated product class, including pharmaceuticals. (1) Highrisk products introduced after 1 January 1991 must be subject to an FDA-approved protocol that provides for postmarket surveillance. (2) Manufacturers are required *to* adopt methods for tracking high-risk devices. (3) Product corrections or removals must be reported to FDA if the action was taken to reduce health risks. (4) Hospitals, nursing homes, ambulatory surgery centers, and outpatient treatment facilities (but not doctors' offices) are required to report to FDA whenever a device is thought to have caused or contributed to the death of a patient. In cases where 194 HEALTH AFFAIRS | Spring 1991 the device is related to serious illness or injury, reports must be made to the manufacturer (who in turn has the duty, under existing law, to report to FDA). This is the first time that providers have been required to report to FDA about incidents occurring in their facilities. Because these reports will be publicly available, greater scrutiny of provider behavior can be expected. It will be some time, however, before the effects of this novel requirement are understood.

Penalties

The law carries three new penalty provisions. The first allows FDA to suspend temporarily an approved premarket application in cases of serious adverse health consequences or death. The second authorizes FDA to order a manufacturer to recall a device and notify patients, hospitals, or physicians. Finally, for the first time, FDA is authorized to impose fines for violations of many device provisions of the act. These range up to \$15,000 per occurrence, with a maximum of \$1 million per proceeding. This authority has been urged for many years (although not by FDA), and its inclusion in the new law appears to have been facilitated by the generic drug scandal. Adding this civil penalty provision (with related subpoena authority) to device law is probably a precedent for extending similar FDA authority to other regulated products.

Miscellaneous

Several other provisions give FDA the opportunity to adjust device regulation to changing circumstances. First, FDA is given increased latitude to classify devices and to suit the degree of regulation to the risk posed by the device. (These changes mainly affect products in the intermediate risk category, the so-called standards class.) The agency is also required to address a small but resource-intensive group of products known as transitional devices, with the intent of reducing the burden these products have posed on agency operations.

For products that partake of the characteristics of devices and other products (for example, drugs and biologics), FDA is required to determine the primary mode of action and assign the product to the FDA office responsible for products that act in that way. Lastly, the agency is authorized to add requirements for design validation to existing good manufacturing practices.

One new provision is the device equivalent to orphan drug legislation. Called the “humanitarian device exemption,” it provides limited exemptions from the device law for devices intended to treat or diagnose rare diseases or conditions (affecting fewer than 4,000 persons). This provision lacks the product development incentives that have been enacted for orphan drugs. Finally, the new device law establishes an Office of International Relations within the Department of Health and Human Services (HHS), whose only specific authority is to enter into agreements with foreign countries to facilitate commerce in devices.

FDA is in the early stages of implementing the law. Unanswered questions abound. Definitions, priorities, and the locus of decision making are key issues to be resolved in the fullness of time—which, if the past is any guide, is likely to be full indeed.

The legislative process

The first congressional oversight hearing was in July 1982 before the House Commerce Subcommittee on Oversight and Investigations. A report followed in 1983, pointing to deficiencies in FDA’s implementation of the 1976 law. Congressional discussions with FDA, industry, and other representatives began in August 1985. These discussions were led by staff of the House Commerce Subcommittee on Health and the Environment but with steady, active participation of full committee staff. They continued, with only the usual number of fits and starts, until final congressional action in October 1990. The House passed a bill in July 1988, which arrived in the Senate during the hectic period that customarily precedes congressional adjournment in a presidential campaign year. The Senate committee had not reviewed device law implementation, so the Senate leadership had only two choices: approve the House bill without much consideration, or postpone action. Given the lack of preparation and the Senate’s views of its own prerogatives, it is not surprising that action did not occur before the 100th Congress adjourned in October 1988. The Senate committee resumed device law consideration in the 101st Congress, and, after it UPDATE 195 became clear that the Senate was seriously moving forward, House activity resumed as well. Both bodies worked roughly in parallel (if a geometric term is apt to describe a legislative process) through final congressional passage in October 1990.

The roles of certain key players deserve comment. FDA was active in briefing congressional staff in the early stages of the process and from time to time thereafter. During the key period in the House, late 1987 and early 1988, the agency became convinced that legislation could not pass in that Congress nor for some time, so it effectively withdrew from any day-to-day involvement in the negotiation process. Even though it gave technical support and formal legislative testimony in the late drafting stages, FDA was simply not a full participant in consideration of this key legislation. Also, no administration position on the final legislation was sent to Congress. Early on, the administration submitted bills narrowly focused on certain standard-writing and classification provisions. All in all, there was a remarkably low level of participation, given the significance of the statutory changes under consideration. The lack of administration interest undoubtedly had an effect on FDA’s involvement.

The industry’s position was ambivalent. At first, it had opposed the need for any legislation. As congressional activity continued, industry leaders gradually came to the conclusion that passage of a bill was inevitable. When the House passed its bill in July 1988, industry for the most part

acquiesced unenthusiastically. A few industry representatives strongly opposed the bill, arguing that a better bill could be expected from the Senate. With House action occurring late in a politically charged year with no Senate preparation, this industry division was not the sole reason for the failure of legislation before Congress adjourned in 1988, but it certainly did not smooth the process then or later and probably had a detrimental effect on the final bill. In the 101st Congress, industry predictions of propitious Senate action proved illusory. The enacted law includes several provisions adverse to industry interests that were not in the bill passed by the House in 1988.

Health care providers were notable by their absence; for them, regulatory legislation rarely ranks above the financial problems posed by Medicare proposals. The only exception was the modest involvement of hospital organizations in consideration of the new provider reporting requirements.

The Safe Medical Devices Act authorizes or requires significant additional agency action affecting medical devices. From the preliminary comments of FDA leaders, it is clear that this action cannot be carried out within existing capacities. The outlook for significant new resources is far from clear. In 1988, prior to passage of the House bill, a comparatively serious congressional effort was made to ascertain the resources needed for implementation. But FDA's estimates were not adopted, and no serious effort was made thereafter to come to grips with the discrepancies between FDA and Congressional Budget Office estimates.

As is typical with regulatory statutes, there was no provision for appropriations. Nor was there any attempt to estimate the size or distribution of the new cost burden that will be imposed on the health care system and its users.

In conclusion

The Safe Medical Devices Act has been placed on the books at a time when many factors are complicating FDA's life. A new FDA Commissioner, David A. Kessler, took office in early December 1990. There is new leadership as well in several top positions in the Center for Devices and Radiological Health. The international dimensions of regulatory decisions are changing, especially with respect to imports and an emerging regulatory system in the European Community. In addition to the device law, the 101st Congress passed an important food labeling program and some twelve other laws that affect FDA operations. An HHS Advisory Committee on FDA is expected to issue its report in May 1991. Technological innovation and demanding, often conflicting, public expectations continue unabated. The new device law, in sum, creates important new challenges for FDA at a difficult and complex juncture.



SUPREME COURT OF THE UNITED STATES

Syllabus

MEDTRONIC, INC. *v.* LOHR *et vir*

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

No. 95-754. Argued April 23, 1996 -- Decided June 26, 1996

Enacted "to provide for the safety and effectiveness of medical devices intended for human use," the Medical Device Amendments of 1976 (MDA or Act) classifies such devices based on the risk that they pose to the public. Class III devices pose the greatest risk and, thus, are subject to a rigorous premarket approval (PMA) process. However, most Class III devices on the market have not been through the PMA process due to two statutory exceptions. Realizing that existing devices could not be withdrawn from the market while the Food and Drug Administration (FDA) completed PMA analyses, Congress included a provision allowing pre-1976 devices to remain on the market without FDA approval until the requisite PMA is completed. The Act also permits devices that are "substantially equivalent" to pre-existing devices to avoid the PMA process until the FDA initiates the process for the underlying device. The FDA uses a "premarket notification" submitted by all manufacturers (§510(k) process) to determine substantial equivalence for Class III devices. Petitioner Medtronic, Inc.'s pacemaker is a Class III device found substantially equivalent under the §510(k) process. Cross petitioners Lohrs filed a Florida state court suit alleging both negligence and strict liability claims in the failure of her Medtronic pacemaker, but Medtronic removed the case to the Federal District Court. That court ultimately dismissed the complaint as having been pre-empted by 21 U.S.C. § 360k(a), which provides that "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under [the MDA] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the Act]." The Court of Appeals reversed in part and affirmed in part, concluding that the Lohrs' negligent design claims were not pre-empted, but that their negligent manufacturing and failure to warn claims were.

Held: The judgment is reversed in part and affirmed in part, and the case is remanded.

56 F. 3d 1335, reversed in part, affirmed in part, and remanded.

Justice Stevens delivered the opinion of the Court with respect to Parts I, II, III, V, and VII, concluding that the MDA does not pre-empt the Lohrs' common law claims. Pp. 12-13; 19-30; 31.

(a) While the Court need not go beyond §360k(a)'s pre-emptive language to determine whether Congress intended the MDA to pre-empt at least some state law, see *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517, "the domain expressly pre-empted" by that language must be identified. *Ibid.* Interpretation of the text is informed by the assumptions that the States' historic police powers cannot be superseded by a Federal Act unless that is Congress' clear and manifest purpose, *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, and that any understanding of a pre-emption statute's scope rests primarily on "a fair understanding of *congressional purpose*," *Cipollone*, 505 U. S., at 530, n. 27. Pp. 12-13.

(b) The Lohrs' negligent design claims are not pre-empted. The FDA's "substantially equivalent" determination as well as its continuing authority to exclude a device from the market do not amount to a specific, federally enforceable design requirement that cannot be affected by state law pressures such as those imposed here. Since the §510(k) process is focused on *equivalence*, not safety, substantial equivalence determinations provide little protection to the public. Neither the statutory scheme nor legislative history suggests that the §510(k) process was intended to do anything other than maintain the status quo, which included the possibility that a device's manufacturer would have to defend itself against state law negligent design claims. Pp. 20-22.

(c) Section 360k(a) does not pre-empt state rules that merely duplicate the FDA's rules regulating manufacturing practices and labeling. That the state requirements may be narrower than the federal rules does not make them "different" under §360k. Nor does the presence of a damages remedy amount to an additional or different "requirement"; it merely provides another reason for manufacturers to comply with identical existing federal law "requirements." This view is supported by the regulations of the FDA, to which Congress has delegated authority to implement the MDA. Pp. 22-25.

(d) The Lohrs' manufacturing and labeling claims are not pre-empted. Although the statutory and regulatory language may not preclude "general" federal requirements from ever pre-empting state requirements, or "general" state requirements from ever being pre-empted, it is impossible to ignore its overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest. State requirements must be "with respect to" medical devices and "different from, or in addition to" federal requirements. They must also relate "to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device," and the regulations provide that state requirements of general applicability are pre-empted only where they have "the effect of establishing a substantive requirement for a specific device." Federal requirements must be "applicable to the device" in question, and, according to the regulations, pre-empt state law only if they are "specific counterpart regulations" or "specific" to a "particular device." The federal manufacturing and labeling requirements at issue reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements. Similarly, Florida's common law requirements were not specifically developed "with respect to" medical devices and, thus, are not the kinds of requirements that Congress and the FDA feared would impede implementation and enforcement of specific federal requirements. Pp. 25-30.

Justice Stevens, joined by Justice Kennedy, Justice Souter, and Justice Ginsburg, concluded in Part IV that Medtronic's argument that any common law cause of action is a "requirement" under §360k(a) is implausible, for it would grant complete immunity from design defect liability to an entire industry that, in Congress' judgment, needed more stringent regulation. It would take language much plainer than §360k's text to do that. The word "requirement," which appears to presume that the State is imposing a specific duty upon the manufacturer, would be an odd term to use to indicate the sweeping pre-emption Medtronic urges here. *Cipollone*, 505 U. S., at 521-522, distinguished. The legislation's basic purpose and history entirely support the rejection of such an extreme position. Pp. 13-19.

Justice Breyer concluded that, although the MDA will sometimes pre-empt a state law tort suit, it does not pre-empt the claims at issue here. First, since the MDA's pre-emption provision is highly ambiguous, Congress must have intended that courts look elsewhere for help as to just which federal

requirements pre-empt just which state requirements, as well as just how they might do so. Second, in the absence of a clear congressional command as to pre-emption, courts may infer that the relevant administrative agency possesses a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive effect. See *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 721. Third, the FDA's regulations indicate that the FDA does not consider that its requirements pre-empt the state requirements at issue here. Fourth, ordinary principles of "conflict" and "field" pre-emption support the conclusion that plaintiffs' tort claims are not pre-empted. Pp. 1-7.

Stevens, J., announced the judgment of the Court and delivered the opinion of the Court with respect to Parts I, II, III, V, and VII, in which Kennedy, Souter, Ginsburg, and Breyer, JJ., joined, and an opinion with respect to Parts IV and VI, in which Kennedy, Souter, and Ginsburg, JJ., joined. Rehnquist, C. J., and O'Connor, Scalia, and Thomas, JJ., joined the opinion of Stevens, J., in part. Breyer, J., filed an opinion concurring in part and concurring in the judgment. O'Connor, J., filed an opinion concurring in part and dissenting in part, in which Rehnquist, C. J., and Scalia and Thomas, JJ., joined.



SUPREME COURT OF THE UNITED STATES

RIEGEL, INDIVIDUALLY AND AS ADMINISTRATOR OF ESTATE OF RIEGEL v. MEDTRONIC, INC.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

Argued December 4, 2007—Decided February 20, No. 06–179. 2008

The Medical Device Amendments of 1976 (MDA) created a scheme of federal safety oversight for medical devices while sweeping back state oversight schemes. The statute provides that a State shall not “establish or continue in effect with respect to a device intended for human use any requirement—... (1) which is different from, or in addition to, any requirement applicable under [federal law] to the device, and ... (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under” relevant federal law. 21 U. S. C. §360k(a). The MDA calls for federal oversight of medical devices that varies with the type of device at issue. The most extensive oversight is reserved for Class III devices that undergo the premarket approval process. These devices may enter the market only if the FDA reviews their design, labeling, and manufacturing specifications and determines that those specifications provide a reasonable assurance of safety and effectiveness. Manufacturers may not make changes to such devices that would affect safety or effectiveness unless they first seek and obtain permission from the FDA.

Charles Riegel and his wife, petitioner Donna Riegel, brought suit against respondent Medtronic after a Medtronic catheter ruptured in Charles Riegel’s coronary artery during heart surgery. The catheter is a Class III device that received FDA premarket approval. The Riegels alleged that the device was designed, labeled, and manufactured in a manner that violated New York common law. The District Court held that the MDA pre-empted the Riegels’ claims of strict liability; breach of implied warranty; and negligence in the design, testing, inspection, distribution, labeling,

marketing, and sale of the catheter, and their claim of negligent manufacturing insofar as the claim was not premised on the theory that Medtronic had violated federal law. The Second Circuit affirmed.

Held: The MDA’s pre-emption clause bars common-law claims challenging the safety or effectiveness of a medical device marketed in a form that received premarket approval from the FDA. Pp. 8–17.

(a) The Federal Government has established “requirement[s] applicable ... to” Medtronic’s catheter within §360k(a)(1)’s meaning. In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 , the Court interpreted the MDA’s pre-emption provision in a manner “substantially informed” by an FDA regulation, 21 CFR §808.1(d), which says that state requirements are pre-empted only when the FDA “has established specific counterpart regulations or there are other specific requirements applicable to a particular device” under federal law. Premarket approval imposes “specific requirements applicable to a particular device.” The FDA requires that a device that has received premarket approval be marketed without significant deviations from the specifications in the device’s approval application, for the reason that the FDA has determined that those specifications provide a reasonable assurance of safety and effectiveness. Pp. 8–10.

(b) Petitioner’s common-law claims are pre-empted because they are based upon New York “requirement[s]” with respect to Medtronic’s catheter that are “different from, or in addition to” the federal ones, and that relate to safety and effectiveness, §360k(a). Pp. 10–17.

(i) Common-law negligence and strict-liability claims impose “requirement[s]” under the ordinary meaning of that term, see, e.g., *Lohr, supra*, at 503–505, 512, *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 . There is nothing in the MDA that contradicts this normal meaning. Pp. 10–12.

(ii) The Court rejects petitioner’s contention that the duties underlying her state-law tort claims are not pre-empted because general common-law duties are not

requirements maintained “with respect to devices.” Petitioner’s suit depends upon New York’s “continu[ing] in effect” general tort duties “with respect to” Medtronic’s catheter. Title 21 CFR §808.1(d)(1)—which states that MDA pre-emption does not extend to “[s]tate or local requirements of general applicability [whose] purpose ... relates either to other products in addition to devices ... or to unfair trade practices in which the requirements are not limited to devices”—does not alter the Court’s interpretation. Pp. 14–17.

(c) The Court declines to address in the first instance petitioner’s argument that this lawsuit raises “parallel” claims that are not pre-empted by §360k under *Lohr, supra*, at 495, 513. P. 17.

451 F. 3d 104, affirmed.

SCALIA, J., delivered the opinion of the Court, in which ROBERTS, C. J., and KENNEDY, SOUTER, THOMAS, BREYER, and ALITO, JJ., joined, and in which STEVENS, J., joined except for Parts III–A and III–B. STEVENS, J., filed an opinion concurring in part and concurring in the judgment. GINSBURG, J., filed a dissenting opinion.



Thursday, March 19, 2009

Health Leaders Introduce Legislation Reversing Supreme Court's Medical Device Decision



U.S. Reps. Frank Pallone, Jr. (D-NJ), Chairman of the Energy and Commerce Subcommittee on Health, and Henry A. Waxman (D-CA), Chairman of the Energy and Commerce Committee, today introduced legislation in the House that will reverse a U.S. Supreme Court decision that denies injured patients the ability to seek compensation for their injuries and gives medical device makers blanket immunity.

In February 2008, the U.S. Supreme Court, for the first time, immunized medical device companies from lawsuits brought by patients who are injured by certain medical devices. In *Riegel v. Medtronic, Inc.*, the Court found that those claims are barred by a preemption clause included in the Medical Device Amendments of 1976 (MDA). This decision ignores both congressional intent and 30 years of experience in which federal regulation, through the U.S. Food and Drug Administration (FDA), and tort liability played complementary roles in protecting consumers from device risks.

The Court's decision has left consumers without any ability to seek compensation for their injuries, medical expenses and lost wages resulting from injuries caused by defective premarket approval (PMA) devices or inadequate safety warnings. It also removed one of the industry's most important incentives to maintain product safety after approval and disclose newly-discovered risks to patients and physicians.

The Medical Device Safety Act of 2009 protects patients from dangerous and defective devices by correcting the Court's flawed interpretation of the MDA. The legislation explicitly clarifies that state product liability lawsuits are preserved.

"Yesterday the Supreme Court rightfully upheld a patient's right to legal recourse after sustaining an injury from a pharmaceutical product," Pallone said. "Today, we introduce legislation that gives patients that same right when injured by a medical device. This legislation puts safety first and eliminates the blanket immunity that medical device companies currently enjoy thanks to an unfortunate Supreme Court decision last year. We introduce this legislation today with strong bipartisan support, and I look forward to moving it through my subcommittee quickly."

"As the Supreme Court affirmed in its Wyeth decision yesterday, lawsuits by injured consumers play a critical role in helping to ensure safety," said Chairman Waxman. "The Court noted that these lawsuits 'uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly.' The same is true for medical devices. We must act quickly to enact this important legislation that will restore the ability of patients injured by defective medical devices to seek compensation, and realign the incentives for manufacturers to ensure the ongoing safety of their products."

The Court premised its decision on the theory that approval by the FDA adequately protects patients from unsafe medical devices, but the two lawmakers said that theory has proven false time and again. They point to numerous recent stories of patients who have suffered serious injuries from defective FDA-approved devices or devices without adequate safety warnings, like implantable cardiac defibrillators and pacemakers.

The Medical Device Safety Act of 2009 is endorsed by the National Conference of State Legislatures, the New England Journal of Medicine, the American Bar Association, AARP, the Center for Justice & Democracy, Consumer Federation of America, Consumers Union, Homeowners Against Deficient Dwellings, National Association of Consumer Advocates, National Consumers League. OWL - The Voice of Midlife and Older Women, Progressive States Network, Public Citizen, and the National Research Center for Women & Families

A companion bill has been introduced in the U.S. Senate by Sens. Edward Kennedy (D-MA), Chairman of the Senate Health, Education, Labor & Pensions Committee, and Patrick Leahy, Chairman of the Senate Judiciary Committee.



NEJM Supports Medical Device Safety Act of 2009 Passage would hold medical device manufacturers to same legal standards as drug manufacturers
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The Medical Device Safety Act of 2009

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Patient safety is a national concern. Major stakeholders throughout our health care system agree that every step must be taken to ensure that medical interventions, used with the intention of improving patients' health, are as safe as possible. But every medical intervention has benefits and risks. Patient safety can be ensured only when the makers of drugs and devices fully and openly disclose both the benefits and the potential adverse effects associated with an intervention. As the Institute of Medicine has made clear, medical devices and drugs need to be assessed for risks and benefits throughout their life cycles.¹

Unfortunately, one major stakeholder, the medical-device industry, has been shielded from the potential consequences of failing to adequately disclose risks. Just over a year ago, the U.S. Supreme Court, in *Riegel v. Medtronic*,² ruled that a medical-device manufacturer cannot be sued under state law by patients alleging harm from a device that received marketing approval from the Food and Drug Administration (FDA). Until that ruling by the Court, the possibility of litigation for "failure to warn" or design defect served as a strong inducement for device companies to be vigilant about the safety of their products.

Since the Supreme Court ruling in *Riegel*, thousands of lawsuits against medical-device manufacturers have been tossed out of court by judges following the Court's lead in deeming such lawsuits to be preempted. We contend that preemption will result in medical devices that are less safe for the American people.

In the largest recent example, Judge Richard Kyle dismissed more than 1000 cases filed against Medtronic in U.S. District Court in Minnesota after the failure of its Sprint Fidelis implantable cardioverter-defibrillator lead, which was withdrawn from the market in 2007. The lead was prone to fracture and it sometimes failed to deliver an appropriate shock and sometimes delivered multiple unnecessary shocks. Although Kyle stated that "the court recognizes that at least some plaintiffs have suffered injuries from using Sprint Fidelis leads, and the court is not unsympathetic to their plight," he ruled that he was compelled on the basis of the *Riegel* decision to dismiss the suits, leaving injured patients without the possibility of redress.³

And there may be many such patients: more than a quarter of a million Sprint Fidelis leads were implanted worldwide, 150,000 in the United States. The FDA has logged 2200 reports of serious injuries from this lead, and last week Medtronic released an updated mortality report of 13 deaths the company considers to have been related to the Sprint Fidelis.^{4,5}

The Supreme Court's ruling in *Riegel* was based not on considerations of what is best for the health of the public, but rather on a point of statutory law. The Medical Device Amendments of 1976 (MDA) to the Food, Drug, and Cosmetic Act provide that a state may not "establish with respect to a device intended for human use any requirement . . . which is different from, or in addition to, any requirement applicable" to a medical device under federal law.⁶ The Court, in an 8-to-1 decision, interpreted this clause as demonstrating Congress's explicit intention to preempt state-law damages suits. The FDA, which until 2003 opposed preemption, in that year inexplicably did an about-face and posited that its approval of a device should be regarded as the final word and should immunize companies against legal liability. With respect to drugs, the FDA announced a broad pro-preemption position in 2006.

In marked contrast to the *Riegel* decision and to the FDA's new position on preemption, a Supreme Court ruling this month in a drug preemption case, *Wyeth v. Levine*,⁷ dismissed Wyeth's argument that failure-to-warn suits against drug companies are preempted by FDA approval of the drug's label. The Food, Drug, and Cosmetic Act contains no explicit preemption clause with regard to prescription drugs. The drug company argued that even though preemption is not specifically mentioned in the Act, it is "implied" by virtue of the supremacy clause of Article IV of the U.S. Constitution, which states that federal law is supreme to state law. In its 6-to-3 ruling, the Supreme Court rejected this argument and found, as well, that the position put forth by the FDA in 2006 "does not merit deference."

As the law now stands, failure-to-warn and design-defect lawsuits are preempted for medical devices but not for drugs. This perplexing state of affairs defies all logic. To address the inconsistency and to improve the safety of medical products, Congressmen Henry Waxman (D-CA), chair of the House Committee on Energy and Commerce, and Frank Pallone (D-NJ), chair of the Health Subcommittee, recently introduced the Medical Device Safety Act.⁸ This bill, along with a companion bill introduced by Senators Edward Kennedy (D-MA) and Patrick Leahy (D-VT), would nullify the Court's ruling in *Riegel* by adding language to the Medical Device Amendments to make explicit that the law does not preempt suits against device companies, and thereby to place medical devices and drugs on a level playing field with respect to patient lawsuits.

Patients and physicians deserve to be fully informed about the benefits and risks of medical devices, and the companies making the devices should be held accountable if they fail to achieve this standard. We urge Congress to swiftly pass this legislation and to allow lawsuits by injured patients, which have been an important part of the regulatory framework and very effective in keeping medical devices safe, to proceed in the courts. The critical issue of preemption, which directly affects the disclosure of risks and thus the safety of the nation's supply of medical devices and drugs, should properly be decided by officials elected by the people, with whom the responsibility for the health of the public rightfully resides.

Source Information

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References

1. Challenges for the FDA: the future of drug safety — workshop summary. Washington, DC: National Academies Press, 2007.
2. Riegel v. Medtronic, 552 U.S. 2 (2008).
3. Kyle RH. In re Medtronic, Inc. Sprint Fidelis leads products liability litigation. Multidistrict litigation no. 08-1905 (RHK/JSM). Memorandum opinion and order. U.S. District Court of Minnesota. January 5, 2009. (Accessed March 17, 2009, at <http://www.mnd.uscourts.gov/MDL-Fidelis/Orders/2009/090105-08md1905ord.pdf>.)
4. Meier B. Medtronic links device for heart to 13 deaths. New York Times. March 13, 2009.
5. Medtronic letter to physicians: Sprint Fidelis model 6949 lead performance. (Accessed March 17, 2009, at <http://www.medtronic.com/product-advisories/physician/sprint-fidelis/PHYSLETTER-2009-03-13.htm>.)
6. Medical Device Amendments of 1976, codified at 21 U.S.C. §360(k)(a).
7. Wyeth v. Levine, 555 U.S. 2 (2009).
8. Committee on Energy and Commerce. Health leaders introduce legislation reversing Supreme Court's medical device decision. (Accessed March 17, 2009, at http://energycommerce.house.gov/index.php?option=com_content&task=view&id=1518.)



THURSDAY, March 19 (HealthDay News) -- Passage of the Medical Device Safety Act of 2009 would nullify the U.S. Supreme Court's 2008 *Riegel v. Medtronic* decision -- which shielded medical device manufacturers from the potential consequences of failing to adequately disclose risks -- and significantly improve patient safety, according to an editorial published online March 18 in the *New England Journal of Medicine*.

Gregory D. Curfman, M.D., and colleagues cited the consequences of *Riegel v. Medtronic*, including the recent dismissal of more than 1,000 cases filed against Medtronic in U.S. District Court in Minnesota after the failure of its Sprint Fidelis implantable cardioverter-defibrillator lead, which was withdrawn from the market in 2007.

The authors argue that *Riegel v. Medtronic* was based on a point of statutory law instead of patient-safety considerations, leading to a legal situation in which failure-to-warn and design-defect lawsuits are preempted for medical devices but not for drugs.

"Patients and physicians deserve to be fully informed about the benefits and risks of medical devices, and the companies making the devices should be held accountable if they fail to achieve this standard," the authors conclude. "We urge Congress to swiftly pass this legislation and to allow lawsuits by injured patients, which have been an important part of the regulatory framework and very effective in keeping medical devices safe, to proceed in the courts. The critical issue of preemption, which directly affects the disclosure of risks and thus the safety of the nation's supply of medical devices and drugs, should properly be decided by officials elected by the people, with whom the responsibility for the health of the public rightfully resides."

