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Energy and Commerce, 111th Cong., May 12,  
2009 (Statement of David C. Vladeck, Prof. of Law,  
Geo. U. L. Center)

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**TESTIMONY OF DAVID C. VLADECK**

**PROFESSOR OF LAW  
GEORGETOWN UNIVERSITY LAW CENTER**

**BEFORE THE SUBCOMMITTEE ON HEALTH,  
HOUSE ENERGY AND COMMERCE COMMITTEE**

**HEARINGS ON H.R. 1346  
THE MEDICAL DEVICE SAFETY ACT OF 2009**

**May 12, 2009**



Mr. Chairman and Members of the Committee, thank you for inviting me to be here today to set forth my views on H.R. 1346, the Medical Device Safety Act of 2009.<sup>1</sup> The bill proposes to restore to consumers injured as a result of defects in life-supporting or life-sustaining medical devices the right to sue medical device manufacturers under state tort and product liability law. I have written extensively on regulatory preemption, with an emphasis on preemption of claims for medical devices and drugs, and have given the question of device preemption considerable thought.<sup>2</sup>

My views are these: The Supreme Court's recent ruling in *Riegel v.*

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<sup>1</sup> I am a currently a Professor of Law at Georgetown University Law Center. On June 15, 2009, I will take a leave of absence from the Law Center to join the staff of the Federal Trade Commission as Director of the Bureau of Consumer Protection. My testimony represents my views alone and I do not appear today as a representative of the Commission.

<sup>2</sup> Submitted along with this testimony are copies of a law review article I wrote a few years ago that argued against medical device preemption, *Preemption and Regulatory Failure*, 33 *Pepp. L. Rev.* 95 (2005), and a White Paper I prepared jointly with other scholars with the Center for Progressive Reform entitled *The Truth About Torts: Using Agency Preemption to Undercut Consumer Health and Safety* (CPR White Paper No.704, July 2007). I would also refer the Committee to testimony I submitted to the House Committee on Oversight and Government Reform for a hearing entitled "Should FDA Drug and Medical Device Regulation Bar State Liability Claims?", on May 14, 2008, and to the Senate Judiciary Committee for a hearing entitled "Regulatory Preemption: Are Federal Agencies Usurping Congressional and State Authority?," on September 12, 2007. My recent writings on preemption also include a recent law review article I co-authored with David A. Kessler, M.D., former Commissioner of the Food and Drug Administration, entitled *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 *Geo. L.J.* 461 (2008), a book chapter entitled *Preemption and Regulatory Failure Risks*, published in *PREEMPTION CHOICE: THE THEORY, LAW, AND REALITY OF FEDERALISM'S CORE QUESTION* (William Buzbee, ed., Cambridge Univ. Press 2008), and an essay entitled *The FDA and Deference Lost: A Self-Inflicted Wound or the Product of a Wounded Agency?* 93 *Cornell L. Rev.* 981 (2008).

*Medtronic, Inc.*,<sup>3</sup> which provides broad immunity from tort liability to manufacturers of medical devices specifically approved by FDA, gives consumers the worst of both worlds. On the one hand, FDA cannot single-handedly accomplish the Herculean job of assuring the safety of the thousands of medical devices on the market. Too many serious defects have emerged with FDA-approved medical devices to contend otherwise. On the other hand, in the aftermath of *Riegel*, consumers cannot turn to the tort system for compensation if they are injured, let alone count on the liability system to deter excessive risk-taking by device manufacturers.

I recognize that *Riegel* ruled that Congress, in passing the MDA in 1976, conferred immunity from tort liability to device manufacturers whose devices are individually approved by the FDA. In my view, *Riegel* is wrong as a matter of history, law, and policy, and Congress ought to act swiftly to overrule it.

\* ***Riegel* is wrong as a matter of history.** Members of Congress who served when the Medical Device Amendments (MDA) were enacted in 1976 know that Congress never intended the MDA's narrow preemption provision to restrict the right of persons injured by medical devices to sue for compensation. The preemption provision was included to make sure FDA-imposed device-specific requirements displaced conflicting state requirements. But cutting off tort liability was not Congress' goal.

\* ***Riegel* is wrong as a matter of law.** The Court's ruling turns Congress'

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<sup>3</sup> 128 S. Ct. 999 (2008).

intent to strengthen consumer protection on its head. The MDA was passed in the wake of litigation over the notorious Dalkon Shield intrauterine device — litigation that brought the defective device to public attention and provided compensation for women injured by the device. There is no hint in the language or history of the MDA that Congress intended to insulate device manufacturers from the tort liability that was instrumental in bringing justice to people injured by defective medical devices.

**\* *Riegel* is wrong as a matter of policy.** Insulating device manufacturers from tort litigation harms the public by (1) removing incentives to manufacturers to fix defective devices quickly and remove defective devices from the market; (2) weakening incentives to manufacturers to disclose defects to physicians and patients without delay; and (3) eliminating the compensatory justice role served by the civil liability system and shifting the costs of injuries from defective devices to consumers, insurers and the federal government.

To explain these conclusions, I start with a brief history of the Medical Device Amendments of 1976 and explain why that history demonstrates that Congress quite clearly intended to *preserve* state liability law, not wipe it away. I will then turn to the Court's ruling in *Riegel* and address why the Court's wooden, textual approach to the Amendments — which ignores their purpose — led the Court to conclude, wrongly, that *Congress* intended the Amendments to preempt state liability claims for devices approved by FDA through the pre-market approval process. Next, I discuss the impact *Riegel* has had in the courts, resulting in the

wholesale dismissal of device-related tort litigation and the denial of redress to thousands of patients injured by defective devices. Finally, I address the policy arguments against preemption and point out that the Court's more recent decision in *Wyeth v. Levine* underscores the need for Congress to overturn *Riegel*.

### **I. FDA Preemption and Medical Devices.**

Preemption cases involve more than dry and arcane questions of law. They invariably involve a story like Joshua Oukrop's — a tragic death or serious injury to someone caused by a product that was supposed to sustain their life but failed them. Joshua Oukrop, a college student, was on a spring break trip to Moab, Utah, with his girlfriend. They went for a bike ride, but Joshua soon complained of fatigue, fell to the ground, and died of cardiac arrest. Why? Joshua had a common genetic disorder that causes erratic heartbeats. If untreated the disorder can trigger sudden cardiac arrest. But Joshua was able to lead a normal life because of a small, pocket-watch-sized, defibrillator implanted in his chest. The defibrillator — a Guidant Prizm 2 — was programmed to deliver an electrical impulse to Joshua's heart when it went into arrest and jolt his heart back into a normal rhythm. But on that day in March 2005, instead of delivering a life-saving charge to his heart, Joshua's defibrillator short-circuited and failed. A wire in the device was too close to a metal component, causing an arc between them when the device fired.<sup>4</sup>

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<sup>4</sup> David C. Vladeck, *Preemption and Regulatory Failure*, 33 Pepp. L. Rev. 95 (2005); Thomas McGarity, *The Preemption War* (New Haven, Conn.: Yale Univ. Press 2008) (forthcoming); Barry Meier, *Maker of Heart Device Kept Flaw From Doctors*, N.Y. Times (May 24, 2005) at A1; Barry Meier, *Repeated Defect in Heart Device*

Joshua's doctors determined that the defibrillator's malfunction caused his death. This was no surprise to Guidant. By the time Joshua died, Guidant had received 25 reports of other failures of the device for exactly the same reason. Guidant had fixed the problem in 2002, three years *before* Joshua's death, but decided to sell its existing inventory, without first fixing the flaw. After all, defibrillators cost \$25,000. Thousands of these faulty defibrillators were sold *after* Guidant had developed a new and safer device. Nor did Guidant tell physicians or patients about the defect. Word of the defect might frighten patients into opting for potentially risky surgery to replace the device, although for young and otherwise healthy patients like Joshua, replacement surgery might have been a sensible option. But there was no notice. In Guidant's view, its data still showed the Prizm 2 to be "a highly reliable life-saving product."<sup>5</sup>

Shortly after Joshua's death, his doctors met with Guidant officials to discuss what the company would do for the 24,000 patients who depended on the same device. Guidant offered to replace the devices Joshua's doctors had implanted in their patients. But Guidant was unwilling to inform other doctors, fearing that they too might want replacement devices. Guidant's efforts to keep the defect quiet did not succeed. The media disclosed that the short-circuiting problem had affected other Guidant defibrillators, and that Guidant had concealed the defect.

Ultimately, three years after learning of the defect, after dozens of failures

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*Exposes a History of Problems*, N.Y. Times (Oct. 20, 2005) at A1.

<sup>5</sup> See, e.g., Barry Meier, *Maker of Heath Device Kept Flaw From Doctors*, N.Y. Times (May 24, 2005) at A1; *The Preemption War*, at 135.



(including at least one other death and several heart attacks), and prodding from FDA, Guidant decided to “recall” the Prizm 2, as well as several other defibrillator models, affecting more than 50,000 patients.<sup>6</sup> As I’ll explain in a minute, the Supreme Court’s recent ruling in *Riegel v. Medtronic, Inc.*, will immunize companies like Guidant from liability for conduct such as this, notwithstanding the grave harm that it inflicted on Joshua and his family and thousands of other patients and their loved-ones.

The statute that governs medical devices — the Medical Device Amendments of 1976 — was enacted in response to a series of highly-publicized public health catastrophes caused by defective medical devices, like the Guidant defibrillator. Most notorious was the Dalkon Shield. It was an intrauterine device introduced in 1972 and widely marketed by the A.H. Robins Company without FDA approval. At the time, FDA had limited authority over medical devices, and had no authority to require devices to undergo premarketing review. In producing the device, Robins ignored its own experts, who urged that both ends of the device’s “sheath” be sealed to prevent “wicking” of bacteria-laden fluids into the uterus. Robins touted the Dalkon Shield as a safe and effective alternative to birth control pills. Soon after it

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<sup>6</sup> “Recalling” a medical device implanted into a patient’s body presents its own complications. For many cardiac patients, the risk of additional surgery to explant a defective defibrillator, pacemaker or heart valve outweighs the risk of retaining a defective product. See, e.g., Barry Meier, *Maker of Heath Device Kept Flaw From Doctors*, N.Y. Times (May 24, 2005) at A1. Many patients decide not to undergo replacement surgery, but then endure the risk of life-threatening product failure. A young and otherwise healthy patient like Joshua likely would have opted for replacement surgery. See generally Barry Meier, *Faulty Heart Devices Force Some Scary Decisions*, N.Y. Times (June 20, 2005) at A1.

hit the market, however, women began contracting infections that caused death, infertility, and other serious injuries. Robins kept the device on the market for an additional year, but finally stopped selling it in 1974. Litigation by thousands of injured women brought to light the nature and severity of the problem and afforded women the only compensation that was available to them.<sup>7</sup>

To avoid a recurrence of this and similar tragedies, Congress enacted the MDA to give FDA regulatory authority over all medical devices.<sup>8</sup> The MDA reserves the most rigorous regulation for “Class III” devices — devices, like defibrillators, heart valves, pacemakers, and prostheses (*e.g.*, knee, hip and shoulder replacements) that support or sustain life or pose a serious risk to patients if they malfunction. As a general rule, before marketing a Class III device, a manufacturer must submit a pre-market approval (PMA) application asking FDA’s permission to market the device for the specific uses identified in the application. There are two exceptions. First, any device manufactured prior to the passage of the MDA — a “grandfathered” device — is not subject to the PMA requirements. Second, a device manufactured *after* 1976 may bypass the PMA

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<sup>7</sup> Morton Mintz, *At Any Cost: Corporate Greed, Women, and the Dalkon Shield* (New York: Pantheon Press 1985); Richard B. Sobol, *Bending the Law: The Story of the Dalkon Shield Bankruptcy* (Chicago, Ill.: U. Chi. Press 1991).

<sup>8</sup> The term “medical device” includes an array of products, from cotton swabs to artificial heart valves. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996). Medical devices are categorized into three classes, based on the potential risk of harm posed. Class I devices, like swabs, are subject only to general controls that provide a reasonable assurance of safety. *Id.* at 477. Class II devices, such as hearing aids, are subject to somewhat stricter controls, to ensure that they are both safe and effective for their intended use. *Id.* Class III devices are used to sustain human life or pose a serious risk to patients. *Id.* at 477-78.

process *if* the manufacturer can show that it is “substantially equivalent” to a grandfathered device. Before granting a PMA, FDA must find that there is a “reasonable assurance” that the device is safe and effective for its intended use.

Because FDA lacked authority over medical devices before 1976, states had acted to fill the regulatory void. By the time the MDA was enacted, a number of states, especially California and Massachusetts, were engaging in robust regulation of devices. Accordingly, to formalize the allocation of responsibilities between FDA and state regulators, and to ensure that FDA had the final say over a PMA device’s design, Congress included an express preemption provision in the MDA. It provides that “no 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 . . .”<sup>9</sup> This language is important. Nothing in it says that Congress is acting to nullify existing state damages claims. There are federal statutes that do just that. But they do so in unmistakable terms and generally provide a federal remedy in lieu of displaced state remedies.<sup>10</sup>

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<sup>9</sup> 21 U.S.C. § 360k(a) (emphasis added).

<sup>10</sup> *See, e.g.*, 42 U.S.C. §§ 2210 *et seq.* (Price-Anderson Act, which federalizes all claims for personal and property damage arising from significant accidents at civilian nuclear power plants); 42 U.S.C. §§ 300aa-1 *et seq.* (Vaccine Act, which federalizes all claims arising from personal injuries relating to the administration of vaccines); Air Transportation Safety and System Stabilization Act of 2001, Pub. L. No. 107-42, 115 Stat. 230 (2001) (9/11 Compensation Fund, which substitutes a federal remedy for tort claims that 9/11 victims and their families could have asserted against the airlines whose planes were hijacked); 29 U.S.C. §§ 1001 *et seq.*

Nor was there any indication that Congress, which enacted the MDA in response to tragedies like the Dalkon Shield — brought to light because of liability litigation — wanted to deprive persons injured by defective devices the compensation they could obtain only through liability actions. And, for most of the MDA’s history, FDA took the position that the MDA did not preempt state liability actions.<sup>11</sup>

Indeed, the question of preemption of state tort claims under the MDA did not arise until after the Supreme Court’s 1992 ruling in *Cipollone v. Liggett Group*.<sup>12</sup> *Cipollone* addressed a question under the Federal Cigarette Labeling and Advertising Act, which expressly preempted state “requirements” for the labeling of cigarette packages and advertising in addition to, or different from, requirements prescribed by Congress. The Court ruled that the word “requirements” could, and in that case did, reach state tort cases, and thus held that some failure-to-warn claims against cigarette companies were preempted.<sup>13</sup> Following *Cipollone*, medical device manufacturers began routinely to assert preemption defenses, and some courts sided with industry.

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(Employee Retirement Income Security Act of 1974, which federalizes disputes over employment related benefits).

<sup>11</sup> See, e.g., Brief for the United States as Amicus Curiae, *Smith Indus. Med. Sys. v. Kernats* (No. 96-1405) (arguing on behalf of FDA that the MDA preemption provision was narrow and did *not* preempt state liability cases).

<sup>12</sup> 505 U.S. 504 (1992).

<sup>13</sup> The Court has recently emphasized that its ruling in *Cipollone* did not preempt state fraud cases against cigarette companies and made clear that *Cipollone* was a narrow ruling. *Altria v. Good*, 129 S. Ct. 538 (2009).

The Supreme Court first addressed preemption under the MDA in 1996. In *Medtronic, Inc. v. Lohr*,<sup>14</sup> the Court ruled that the Amendments do not preempt liability actions for devices not subject to full-scale FDA premarket approval. The Court observed that the MDA’s preemption provision “was primarily concerned with the problem of specific, conflicting state statutes and regulations rather than the general duties enforced by common-law actions.” Indeed, the Court said that Medtronic’s argument would have

the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation in order “to provide for the safety and effectiveness of medical devices intended for human use,” 90 Stat. 539 (preamble to Act). It is, to say the least, “difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct,” *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251(1984), and it would take language much plainer than the text of § 360k to convince us that Congress intended that result.<sup>15</sup>

But the Court reserved the question whether tort claims involving devices that had been subject to the premarket approval process would be preempted — a question that continued to divide the lower courts.

All of that changed in 2002 when FDA made a 180-degree shift in position. Abandoning its decades-old stance that the MDA did not preempt state tort law even with regard to PMA devices, FDA aggressively sought to participate in private state liability cases on behalf of device manufacturers to argue that the MDA’s preemption

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<sup>14</sup> *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 489 (1996).

<sup>15</sup> *Id.* at 487.

provision immunized device manufacturers from liability under state law. Without informing the public, states or local governments, or seeking their views on its new position, FDA filed *amicus* briefs in several cases — always on the side of the manufacturer — urging the courts to find the injured patient’s claim preempted. As a result of FDA’s reversal of field, lower courts began adopting FDA’s new position, which further deepened the split of authority among lower courts. To resolve the question, the Supreme Court granted review in *Riegel v. Medtronic, Inc.*

## II. *Riegel*.

On February 20, 2008, the Court ruled that the MDA expressly preempts state liability actions for PMA devices.<sup>16</sup> The majority opinion does not address the *purpose* of the MDA, let alone suggest that preemption is right as a policy matter. Indeed, the Court explicitly rejects the idea that it is “our job to speculate upon congressional motives.”<sup>17</sup> Instead, the majority relied on the word “requirement,” which, the Court held, is a term of art that ordinarily encompasses state liability actions. Building on the Court’s ruling in *Cipollone*, the majority reasoned that because state liability actions can impose “requirements” on device manufacturers “different from, or in addition to,” those imposed by FDA, they are preempted under

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<sup>16</sup> 128 S. Ct. 999. The Court’s ruling in *Riegel* applies only to PMA devices. As noted, the Court had previously ruled in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), that state liability actions involving non-PMA devices approved by FDA were not preempted.

<sup>17</sup> 128 S. Ct. at 1009.

a literal reading of the MDA. The Court took this approach because “Congress is entitled to know what meaning this Court will assign to terms regularly used in its enactments,” and that the Court’s prior rulings had suggested that the term “requirement” embraced tort litigation.<sup>18</sup> What the Court leaves out is an acknowledgment that the Court did not say that the word “requirement” in a preemption provision could include state tort law until it decided *Cipollone* in 1992 — sixteen years *after* Congress enacted the MDA. Nonetheless, in the majority’s view, Congress’ selection of the word “requirement” demonstrates that *Congress* made the choice to preempt state law, a choice Congress is free to revisit.<sup>19</sup>

### **III. The Landscape Post-*Riegel*.**

As a result of *Riegel*, thousands of cases like the one that Joshua Oukrup’s family brought against Guidant and settled are no longer be viable. FDA’s premarket approval of a device would, standing alone, require dismissal of the case, even if the device proves to be unsafe, even if the manufacturer is slow to warn doctors and patients of the defect, and even if the device’s label fails to provide

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<sup>18</sup> 128 S. Ct. at 1008.

<sup>19</sup> 128 S. Ct. at 1008. Justice Stevens filed a concurring opinion, in which he acknowledges that the majority’s decision is in tension with Congress’ intent in the MDA, but he nonetheless concurred in the majority’s focus on the word “requirement” and its conclusion that Congress’ use of that word expressed *Congress’* intend to preempt. *Id.* at 1011-12. Justice Ginsburg filed a dissent, arguing that the majority’s opinion “effect[s] a radical curtailment of state common-law suits seeking compensation for injuries caused by defectively designed or labeled medical devices” — a result that Congress did not intend. *Id.* at 1013.

physicians and patients with adequate information to assess the device's risks.<sup>20</sup>

*Riegel* thus deals a body blow to injured consumers and their families. There are many devices on the market that have not performed as anticipated and have exacted a serious toll on the well being of patients. Let me use one example, although, unfortunately, there are many to choose from.

Consider the problems that have plagued Medtronic's Sprint Fidelis defibrillator cable.<sup>21</sup> A quarter of a million people received the Sprint Fidelis cable in the three years from its introduction in 2004 until Medtronic "recalled" the product in 2007 because of its high failure rate. Fractures in the cable can result in a

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<sup>20</sup> The one exception noted by the *Riegel* Court is where the manufacturer violated duties imposed by FDA. In those instances, the *Riegel* ruling would "not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 129 S.Ct. at 1011. There are, however, other barriers to this kind of argument. For the most part, claims that manufacturers failed to comply with federal requirements are greeted by motions to dismiss arguing that such claims are really fraud-on-the-FDA claims, which are preempted under *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). Lower courts have read *Buckman* broadly. See, e.g., *Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961 (6th Cir. 2004).

<sup>21</sup> The factual background relating to Medtronic's Sprint Fidelis cable is drawn from several sources, including a series of articles in the New York Times, all written by Barry Meier, including *Removing Medtronic Heart Cables is Hard Choice*, Apr. 7, 2009; *Medtronic Links Device for Heart to 13 Deaths*, Mar. 13, 2009; *Heart Device Dispute Renews Push for User Registry*, Feb. 26, 2009; *Study Finds More Failure of Heart Device*, Feb. 24, 2009; *Test of Heart Devices to Get Review*, Oct. 18, 2007; and *In Data for Heart Devices, Parts Are a Blind Spot*, Oct. 16, 2007; as well as federal District Court Judge Richard H. Kyle's decision dismissing the claims of about 2,000 patients injury from the Spint Fidelis cable on preemption grounds. See *In re Medtronic, Inc., Sprint Fidelis Leads Product Products Liability Litigation*, 592 F. Supp. 2d 1147 (D. Minn. 2009) (MDL Proceeding).



defibrillator failing to deliver a life-saving shock to a patient experiencing an erratic heart beat, or firing for no reason at all, causing the patient pain and serious psychological harm, since patients are taught that the device fires only when they are in cardiac distress.<sup>22</sup> At this point, Medtronic acknowledges that the cable is no longer functioning in about 5 percent of the patients, even though no patient has had the cable for more than 45 months. An independent analysis, however, puts the failure rate at 12 percent. The failure rate is expected to rise over time.

I put the word “recalled” in quotation marks above because, although Medtronic has recalled the lead, the extreme difficulties of extracting the cable and replacing it with a safer one makes the decision whether to replace the cable a daunting one for patients. Most patients have not yet had the faulty cable extracted, and many may choose not to undergo risky extraction surgery. Already four patients have died during extractions, and at least nine others have died as a result of the device’s defect. The FDA has received 2,200 reports of serious injuries associated with the cable’s failure.

Further complicating the problem for patients is the high cost of extraction and replacement surgery. Although Medtronic has admitted that the Sprint Fidelis

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<sup>22</sup> In one case, a 68-year-old grandmother in Minnesota was shocked 54 times in one hour as a result of a fracture in her Sprint Fidelis cable; she said that she felt like a horse was kicking her in the chest. Another patient, a 54-year-old-male, was shocked 17 times in a ten minute period, and the shock was so severe that he was thrown across the family room of his home. He said “it’s like being hit by a car.” Janet Moore, *Seeking Relief From Medical Device Makers*, Minneapolis StarTribune, Feb. 7, 2009.

cable has a dangerously high fracture rate, it has offered patients no financial assistance at all other than the cost of the replacement cables. Patients alone must bear the full costs of the surgery — which can run as high as \$15,000 — the recovery, the lost time from work, and the pain and suffering they endure. The most patients can hope for is that some of their medical costs will be offset by private insurance or by Medicare. Medtronic has offered nothing more to patients and post-*Riegel* patients stuck with a Sprint Fidelis cable cannot compel Medtronic to do more.

In his decision dismissing the action of those injured by the Sprint Fidelis lead, Judge Kyle acknowledged at the outset that the preemption doctrine “leaves some plaintiffs without judicial recourse to pursue claims for damages,”<sup>23</sup> but he concluded that, following *Riegel*, he had no choice but to dismiss the claims of the Sprint Fidelis patients. In so ruling, he noted that since *Riegel* was decided, courts across the country have applied the ruling “broadly,” to preempt “all manner of claims” relating to PMA devices.<sup>24</sup> He is right. *Riegel* has already been invoked to dismiss claims involving defective defibrillators, defibrillator cables, hip replacements (even though the model was recalled), knee replacements, heart valves (also subject to recall), silicon breast implants, and “adhesion barriers” used in

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<sup>23</sup> 592 F. Supp. 2d at 1149.

<sup>24</sup> 592 F. Supp. 2d at 1152.

surgery.<sup>25</sup> All of these cases would have been viable prior to *Riegel*.

#### **IV. Congress Should Overturn *Riegel*.**

As my remarks thus far make clear, I favor the Medical Device Safety Act of 2009 (MDSA), H.R. 1346, and urge its swift enactment, for five distinct reasons:

1. As discussed above, passage of MDSA will simply restore the regulation of medical devices to the *status quo ante* and return to Congress' initial understanding of the limited role served by MDA's preemption provision. No one has argued or could argue seriously that Congress in 1976 intended to strip away tort remedies for PMA devices. The MDSA is needed to align the statute with Congress' original intent.

2. *Riegel's* impact on consumers is severe and far-reaching. Consumers, like the thousands of patients struggling to decide whether to undergo risky extraction surgery with the Sprint Fidelis cable, are left with the worst of both worlds — an FDA premarket approval system that cannot possibly guarantee the safety of devices and no recourse if their devices fail.

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<sup>25</sup> See, e.g., *Clark v. Medtronic, Inc.*, 572 F. Supp. 2d 1090 (D. Minn. 2008) (defibrillator); *Bausch v. Stryker Corp.*, No. 08 C 4248, 2008 WL 5157940 (N.D.Ill. Dec. 9, 2008); *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298 (D.Colo.2008); *Horowitz v. Stryker Corp.*, 2009 U.S. Dist. LEXIS 13321 (E.D.N.Y. 2009) (hip prostheses); *Despain v. Bradburn*, 372 Ark. 272, --- S.W.3d ----, 2008 WL 1067202 (2008) (hearing device); *Dorsey v. Allergan*, 2009 U.S. Dist. LEXIS 26235 (M.D. Tenn. 2009); *Link v. Zimmer Holdings, Inc.*, --- F. Supp. 2d ----, 2008 WL 5047677 (N.D.Ill. Nov. 26, 2008) (knee replacement); *Blanco v. Baxter Healthcare Corp.*, 158 Cal.App.4th 1039, 70 Cal. Rptr. 3rd 566 (2008) (heart valve), *Heisner v. Genzyme*, 2008 WL 2940811 (N.D. Ill. 2008) (surgical adhesion barrier).

The device industry tries to minimize *Riegel's* impact by pointing out that *Riegel* applies only to PMA devices, which comprise a very small fraction of the devices on the market. That is so. But make no mistake, PMA devices are generally the ones that sustain or support life, and failure of those devices all too often leads to dire and at times fatal consequences. Thus, the fact that FDA also permits other, non-PMA devices on the market is beside the point. The devices that matter most are PMA devices.

The device industry also argues that overturning *Riegel* and restoring to patients the right to sue if they are harmed by defective devices may stifle innovation. History refutes this argument. From 1976 to at least the mid-1990s, the medical device industry flourished *even though* there was no suggestion that the MDA preempted state tort law. And from the mid-1990s to 2008, when *Riegel* was decided, the courts were divided on preemption. As a result, manufacturers have had a reliable liability shield for at most a year. Nonetheless, the industry remained highly innovative and profitable. Nor it is reasonable to place so much emphasis on preemption; preemption is just one of many defenses available to device manufacturers. Overturning *Riegel* hardly guarantees patients victory in litigation. Even when a device proves to be riskier than the manufacturer or the FDA anticipated, device manufacturers have a range of defenses and the burden remains on the plaintiff to prove causation. Defendants win many of these cases. And finally, the idea that state tort law stifles innovation is an old shibboleth trotted out

whenever industry wants a liability shield. But American drug and device manufacturers have been the most innovative in the world and have done so with the ever-present backstop of potential tort liability. The simple fact is that the tort system provides a constructive discipline on the market-place, forcing manufacturers to develop safer, newer and more effective products as technology moves forward, which makes their products more competitive and rewards innovation.<sup>26</sup>

Taking a cue from the drug industry, the device industry also argues that if immunity from tort liability is withdrawn, device manufacturers will rush to add warnings to their devices that might deter doctors and patients from using beneficial devices. Once again history refutes that argument. The reality is that rarely, if ever, device manufacturers (who are trying to sell their devices) want *stronger* labeling than FDA does, and FDA (which is trying to safeguard public health), *resists* the change. Time and again, FDA has struggled to force manufacturers to add warnings that FDA thought necessary. For instance, it took FDA over a year to force Merck the manufacturer of Vioxx, to add a statement about Vioxx's cardiovascular risks to the drug's label. Merck fought hard against the labeling change because it had determined that a "warning" rather than a "precaution" on Vioxx's label could lead to a 50% reduction in Vioxx's sales. During the year-long negotiation between

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<sup>26</sup> This is not just my view, it is also the view of those in the field. *See generally* Testimony of Christine Ruther, President and Engineer, C & R Engineering, Inc., before the House Committee on Oversight and Government Reform for a hearing entitled "Should FDA Drug and Medical Device Regulation Bar State Liability Claims?", on May 14, 2008. Ms. Ruther's testimony is available here: <http://oversight.house.gov/documents/20080514124817.pdf>.

FDA and Merck, no change was made to the label, and in the end, the FDA accepted a compromise: The statement about cardiovascular risk was added to the “precaution” section of the label, as Merck urged, not to the “warning” section notwithstanding FDA’s judgment that a warning was appropriate.<sup>27</sup>

The argument the availability of tort remedies for those injured by defective medical devices would encourage device companies to add warnings indiscriminately is also counter to the experience of senior FDA staff. When the FDA made the same argument in support of preemption in *Wyeth*, the Majority Staff of the House Committee on Oversight and Government Reform conducted an investigation to see whether the FDA career doctors and scientists who work day-to-day on labeling agreed with the preemption position taken by the agency’s political appointees. The Report, entitled “FDA Career Staff Objected to Agency Preemption Policies,”<sup>28</sup> makes clear that they did not. In responding to the over-warning argument, Dr. Jane Axelrad, Associate Director for Policy in the Center for Drug Evaluation and Research, said that “We rarely find ourselves in situations where sponsors want to disclosure more risk information than we think is necessary. To the contrary, we usually find ourselves dealing with situations where sponsors want to minimize risk

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<sup>27</sup> See, e.g., Kessler & Vladeck, 96 Geo. L. J. at 480 (and authorities cited therein); *In re Vioxx Products Liability Litig.*, 501 F. Supp. 2d 776, 779, 783 (E.D. La. 2007).

<sup>28</sup> See House Committee on Government Oversight and Government Reform, Majority Staff Report, FDA Career Staff Objected to Agency Preemption Policies 14-15 (2008)). The Report is available here: <http://oversight.house.gov/story.asp?ID=2266>. Hereinafter (“House Staff Report”).

information.”<sup>29</sup> Dr. Jenkins, Director of the Office of New Drugs in the Center for Drug Evaluation and Research, and the FDA’s most senior official in the new drug review process, was even more critical of the argument: “The entire argument put forward that sponsors are insisting on exaggerated statements of risk information is naïve as to what actually occurs in practice. While I do not believe that most sponsors deliberately attempt to obscure risk information . . . in the product labeling, I also believe that it is true that sponsors attempt to present the information in a way that does not put their product at a competitive disadvantage to other products . . .”<sup>30</sup>

3. The claim made by preemption proponents — that the FDA premarket approval process is a sufficient guarantee of safety to justify shedding the deterrent value of the tort system — is misguided. In assessing whether it is wise to forego the background market discipline imposed by state tort law, it is critical to understand the strengths and limitations of the PMA process. The strength of the PMA process is that, by and large, it has averted the introduction of a plainly unsafe device — like the Dalkon Shield — onto the market.

But the PMA process is no guarantee of safety. Far from it. PMA approval is

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<sup>29</sup> House Staff Report, at 6.

<sup>30</sup> House Staff Report, at 5. Dr. Jenkins added: “I think the whole argument that liability concerns drive inaccurate labeling is false and misleading. . . . [T]he whole argument that liability concerns leads to decreased product innovation or product withdrawals is not supported by adequate data.” *Id.* (ellipsis and bracket in original).

a one-time licensing decision based on whether the device’s sponsor has shown a “reasonable assurance” of safety — a standard far less rigorous than for drugs, which must be shown to be safe and effective for their intended use. Before drugs are allowed on the market, they are extensively tested in at least two, but often several, clinical trials, involving thousands of subjects. In contrast, medical devices are often approved on the basis of a single clinical trial, involving far fewer subjects, in part because of the ethical problems in testing experimental medical devices on human subjects. Once on the market, FDA engages in only limited surveillance of devices. There is no provision in the MDA for devices to be periodically re-certified by FDA. And FDA has only limited recall authority over defective devices — authority so limited it is rarely invoked. As a result, defective devices typically remain on the market until the manufacturer commences a “voluntary” recall, often in response to adverse publicity generated by state liability litigation.

Because of the structural limitations in the preapproval process, FDA’s track record demonstrates the agency’s inability to single-handedly protect the American people against defective and dangerous medical devices. Just in the past few years



we have seen massive recalls of defibrillators,<sup>31</sup> pacemakers,<sup>32</sup> heart valves,<sup>33</sup> heart pumps,<sup>34</sup> and prostheses<sup>35</sup> — which have exacted a terrible toll on the patients who

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<sup>31</sup> Consider the case of the Guidant defibrillators, discussed in my Pepperdine article. 33 Pepp. L. Rev. 95. By the time they were withdrawn from the market, more than 24,000 of the defective devices had been implanted in patients, who then faced the daunting decision of whether to have replacement surgery. See generally *In re Guidant Corp. Implantable Defibrillators Prod. Liab. Litig.*, 2007 WL 1725289 (D. Minn. June 12, 2007); Barry Meier, FDA Expanding Inquiry into Heart-Device Company, N.Y. Times (Aug. 25, 2005), at C3.

<sup>32</sup> Although Medtronic's 4004M pacemaker was approved by FDA, it was later determined to be defectively designed. Some patients died when the pacemaker's defective lead failed; many patients were forced to undergo open-heart surgery to replace the defective lead. Prior to Riegel, the courts were split on whether the plaintiffs' claims were preempted. Compare *Cupek v. Medtronic, Inc.*, 405 F.3d 421 (6<sup>th</sup> Cir. 2005) (finding claims preempted) with *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11<sup>th</sup> Cir. 1999) (finding no preemption).

<sup>33</sup> The St. Jude Silzone heart valve is another instructive case. This valve was approved on the basis of only scanty testing involving a handful of human subjects. After St. Jude starting selling the valve, testing revealed that its silver coating not only did not protect against infection, but it also caused the valves to leak. Litigation publicized the risk and forced St. Jude to recall the problem valves, but not until they had been implanted in over 36,000 patients. See generally *In re St. Jude, Inc. Silzone Heart Valves Prod. Liab. Litig.*, 2004 WL 45503 (D. Minn. Jan. 5, 2004); see also *Bowling v. Pfizer*, 143 F.R.D. 141 (S.D. Ohio 1992) (class action involving 55,000 patient implanted with different defective heart valve).

<sup>34</sup> See *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004) (finding claim against manufacturer of device heart pump preempted, even though evidence showed that it was defectively designed and that the pump had been redesigned to correct design defect).

<sup>35</sup> The FDA granted approval to the Sulzer hip and knee implants, but it soon turned out that a manufacturing defect kept the implants from bonding properly with patients' bones. See *In re Sulzer Hip Prosthesis & Knee Prosthesis Liab. Litig. (In re Sulzer I)*, 455 F. Supp. 2d 709, 712 (N.D. Ohio 2006). Testimony in litigation exposed the fact that the problem was caused by unsanitary conditions at the manufacturing facility. See J. Scott Orr & Robert Cohen, *Messy Plant Made Faulty Hip Joints*, TIMES-PICAYUNE (New Orleans), Aug. 13, 2002, at A-1. In December 2000, Sulzer finally notified the FDA that it recalled about 40,000 defective hip

have had them implanted in their bodies, and who often face the daunting prospect of explantation and replacement surgery.

Post-*Riegel*, these patients will now be left with no remedy at all: no compensation for the pain and suffering they endure, no reimbursement for the expenses of surgery, no reimbursement for lost wages, and no recompense to their loved ones should they die as a result of a defective device. Making matters worse, manufacturers will have little economic incentive to swiftly recall defective devices, since they are immunized from liability in tort, and, at least during the prior Administration, virtually certain to face no enforcement sanction from FDA, which had withdrawn the regulatory cop from the beat.<sup>36</sup>

4. The Supreme Court's recent ruling in *Wyeth v. Levine*,<sup>37</sup> provides further

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implants, 26,000 of which had been implanted in patients. *In re Sulzer Hip Prosthesis & Knee Prosthesis Liab. Litig. (In re Sulzer II)*, 268 F. Supp. 2d 907, 910–11 (N.D. Ohio 2003). Among the failed implants were approximately 6,100 units that Sulzer, with the FDA's permission, reprocessed and sold. *See id.* at 911. Many of the victims needed to undergo multiple additional surgeries to remove the faulty devices and replace them with more effective ones. *See, e.g., Orr & Cohen, supra*, at A-10 (describing the procedures undergone by one plaintiff; also noting that many members of the class had similar experiences).

<sup>36</sup> The decline in enforcement activities by FDA is nothing short of stunning. In 1991 through 1993, the agency brought a total of 468 civil seizure actions, 75 injunction cases, and 121 criminal prosecutions. *See* Peter Barton Hutt, *The State of Science at the Food and Drug Administration*, in *FDA SCIENCE AND MISSION AT RISK: REPORT OF THE SUBCOMMITTEE ON SCIENCE AND TECHNOLOGY* app. B, B-22-23 (2007). However, from 2004 to 2007, the agency brought a total of only 53 civil seizure actions, 57 injunction cases, and no criminal prosecutions. *Id.* The decline in FDA warning letters is just as steep: from 1,788 in 1993 to only 467 in 2007. *Id.*

<sup>37</sup> 129 S. Ct. 1187 (2009).

support for the swift passage of the MDSA. *Wyeth* spotlights the anomaly of giving PMA device manufacturers alone immunity from tort liability. Of the drugs and medical devices regulated by FDA, only the manufacturers of PMA devices have been granted this coveted insulation from tort liability. But the standards for approving PMA devices are significantly less stringent than for drugs. Thus, preemption for PMA device manufacturers cannot be defended on grounds of principle.

*Wyeth* also stands as a symbol of the reaffirmation of tort litigation as a valuable complement to federal regulation. *Wyeth* rejects emphatically the idea that federal regulation shifts the ultimate responsibility for ensuring that a product is reasonably safe for its intended use on to the federal government. That responsibility, says the Court, falls squarely on the shoulders of the manufacturers, who have superior access to information about their product's performance in the market, and for that reason, bear responsibility for their product's safety.<sup>38</sup>

*Wyeth* also underscores the important role tort law plays in providing information about product hazards that might escape the attention of regulators, or come to the regulators' attention well after the manufacturer is alerted to the risk.<sup>39</sup> The Court points out that tort litigation "provide[s] incentives for drug manufacturers to disclose risks promptly" as a means of avoiding adverse tort rulings. The Court also makes clear that it values the compensatory function of tort

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<sup>38</sup> 129 S. Ct. at 1197-98.

<sup>39</sup> 129 S. Ct. at 1202.

law, not just as an aid those injured by drugs that prove to be unsafe, but to “motivate injured persons to come forward with information” about those risks.<sup>40</sup> The Court’s focus on the informational role tort litigation serves was not inadvertent. To the contrary, the Court was using it to underscore the point that federal preemption comes at a cost — not just to the unfortunate person, injured through no fault of her own, but to society as a whole, that benefits when injured people stand up and use the courts not just to redress their own grievances, but also to alert regulators, doctors and patients that a widely used device like the Sprint Fidelis cable poses an unreasonable risk of grievous harm.

5. The Court’s opinions in *Wyeth* and *Riegel* make it clear that the decision about preemption is one for Congress. The ball is squarely in Congress’ court. The *Riegel* Court justifies its decision by underscoring that it is simply carrying forward Congress’ clearly expressed intent to preempt. I would urge Congress to act swiftly to restore the historic availability of state liability law protections both to ensure that compensation is available to people injured through no fault of their own and to place economic incentives on device manufacturers to take reasonable measures to protect consumers from defective or unsafe devices.

I would be glad to answer any questions the Committee may have.

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<sup>40</sup> 129 S. Ct. at 1202.