H.R. 1346, THE MEDICAL DEVICE SAFETY ACT OF 2009

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

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H.R. 1346, THE MEDICAL DEVICE SAFETY ACT OF 2009

TUESDAY, MAY 12, 2009

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 2:12 p.m., in Room 2123, Rayburn House Office Building, Hon. Frank Pallone, Jr., [chairman of the subcommittee] presiding.

Present: Representatives Pallone, Dingell, Matheson, Christensen, Castor, Sarbanes, Murphy of Connecticut, Braley, Waxman (ex officio), Deal, Shimkus, Blunt, Buyer, Pitts, Burgess, Blackburn, Gingrey, and Barton (ex officio).

Staff Present: Rachel Sher, Legislative Counsel; Sarah Despres, Legislative Counsel; Eric Flann, FDA Detailee; Alvin Banks, Special Assistant; Lindsay Leshin, Special Assistant; Ryan Long, Minority Chief Health Counsel; Clay Alspach, Minority Counsel; and Chad Grant, Minority Legislative Analyst.

OPENING STATEMENT OF HON. FRANK PALLONE, JR.

Mr. PALLONE. Good morning. I am so out of it. I have been having too many speeches and too many meetings. I apologize. Good afternoon.

The subcommittee today is a meeting to review H.R. 1346, the Medical Device Safety Act of 2009. We have made huge advances in medicine over the last few decades. New and emerging technologies hold promises that our great grandparents could never have imagined. Many illnesses that were once a death sentence are now preventable, curable, or are at least manageable through modern medical treatments. However, though these medical advances offer huge benefits, they also present a certain amount of risk.

For example, there have been recent stories of patients who have suffered serious injuries from defective FDA-approved devices like implantable cardiac defibrillators and pacemakers. To use an example from my home State of New Jersey, there was a young girl who was 14 years old who was one of the victims affected by a faulty medical device. Last year, she felt a very strong pain through her body that she described as "a horse trampling me." Eventually, she realized that her implantable cardiac defibrillator was shocking her, and it continued to do so 18 times. When the paramedics arrived at the scene, they found this little girl lying on the floor, begging for someone to remove the device from her body. She spent the next 4 days at a Children's Hospital, waiting to have

the surgery to remove the device. Though the faulty device is no longer inside her body, she still suffers from significant anxiety triggered by the slightest heart palpitation or any beeping sound she hears. The medical costs this family in New Jersey now bears as a result of the surgery and side effects are tremendous.

Unfortunately, I use that example of the little girl from New Jersey, but the problem is that she and her family have no opportunity for legal recourse, and she is not alone in this problem.

In February of last year, the U.S. Supreme Court deliberated the Riegel v. Medtronic case and made a decision that, in effect, relieved medical device companies from the responsibility of ensuring the safety of their products. The Supreme Court ruled that patients could not receive compensation for their injuries—medical expenses and lost wages—caused by defective premarket approval, PMA devices, or inadequate safety warnings. Now, this decision, in my opinion, ignores congressional intent and is contrary to the Medical Device Amendments or at least the way they have been interpreted since the legislation was passed in 1976.

For the past 30 years, Federal regulation through the FDA, together with tort liability, played crucial roles in protecting consumers from risky devices. Already, this Supreme Court decision has had a devastating impact on patients who have been harmed by defective medical devices. For example, a Federal judge in Minnesota threw out more than 1,400 lawsuits filed by patients who had defective heart defibrillator wires or leads implanted. Many of them died as a result. The judge based his decision on the Riegel case and noted that the only way to remedy the situation was for Congress to step in.

It is crucially important that all of the major stakeholders involved in manufacturing medical devices make patient safety their main priority. We must be certain that we are taking every step necessary to ensure that the technologies designed to save lives are not placing people in danger. Much of the data used by the FDA in premarket approvals for both drugs and devices is limited in the number of individuals who are monitored as well as in the time frames that they are collected. These studies are vital in making safety and efficacy determinations while, at the same time, getting life-saving treatments to patients in a timely fashion.

However, the Institute of Medicine has recommended that the risk and benefits of these treatment options should be monitored through the entire life cycle. This means that the manufacturer has a responsibility for the safety of their product for as long as it is being used by patients, not just during pre-approval trials.

Until last year, the State court system provided an additional incentive for companies to actually follow this recommendation. Unfortunately, the Riegel v. Medtronic case and its effects have removed that incentive and have provided medical device companies with blanket immunity. The court premised its decision on the theory that FDA approval adequately protects patients from unsafe medical devices. That theory, in my opinion, has proven false time and again.

So that is why I, along with Mr. Waxman, our full committee chairman, introduced the Medical Device Safety Act of 2009, the bill we are examining today. This bill protects patients from dan-

gerous and defective devices by correcting the Court's flawed interpretation of the Medical Device Amendments of 1976. The bill explicitly clarifies the State product liability lawsuits are preserved and puts safety first by eliminating the blanket immunity that medical device companies currently enjoy.

There is precedence for this as the Supreme Court just a few months ago ruled in favor of a plaintiff in a case against a drug company. In that case, the Court upheld congressional intent and placed the responsibility for making the safe products squarely within the company's purview; and it is crucial, in my opinion, that we act now to provide patients in need of a medical device with that same certainty.

So I want to thank all of you. I will introduce you after we have the opening statements from the rest of the committee.

I now recognize my colleague from Georgia, Mr. Deal.

Mr. DEAL. Thank you, Mr. Chairman. Thank you for having this hearing today; and thanks to the witnesses who have come to share their positions and opinions on this legislation, H.R. 1346.

Although the legislation is less than one page in length, the legislative impact of the legislation is significant and I think cannot be discontinued based on its own brevity.

The United States is and should remain at the forefront of medical device innovation, a position which I believe would be undermined by this bill. The medical industry in the United States has grown as a worldwide leader in innovation and development, providing therapeutic advances for patients and their physicians to treat complicated medical conditions as the advance of science and medicine in our country continues to grow. This has been shared around the world.

Critical life-saving devices such as neurostimulation devices, cardiac defibrillators, and pacemakers have improved the longevity and the quality of life for countless Americans who depend on these technologies every day. What must be considered when evaluating the merit of legislation to eliminate preemption of State tort claims with respect to these critical devices is the resulting impact which will occur on the development of new products.

Eliminating preemption will stifle innovation. In my opinion, it will increase the risk among manufacturers who are on the cutting edge of medical device development; and it will prove detrimental to patients in dire need of innovative solutions to complex, hard-to-treat medical conditions.

In the case that the chairman referred to of Riegel v. Medtronic, the United States Supreme Court, as well as six out of seven Federal circuit courts, confirmed the widely held view that the Medical Device Amendments Act, MDA, does indeed preempt State common law claims with respect to devices approved through the premarket approval process, which is the most rigorous approval process for medical devices. What seems to have been forgotten is that the vast majority of State common law claims involving most medical devices are still permitted.

First, the preemption provision provided under the MDA applies to approximately 2 percent of devices approved by the FDA each year, those which are approved under the premarket approval pathway. The majority of medical devices each year, those which

are approved through the 510(k) process, are not preempted under current law.

Second, it is also important to remember that if a device is improperly manufactured or the source company withholds information from the FDA or it misleads the FDA and consumers about the safety and effectiveness of the product, the MDA does not preclude common law tort liability cases in State court. Patients who incur harm are fully capable of pursuing such just recourse for their harm.

I urge the members of this subcommittee to take the same approach which the FDA takes in approving these devices by evaluating the risk versus benefits of this legislation. Given the detrimental impact H.R. 1346 will likely pose on the development and innovation of promising new technologies promoted by heightened litigious environments surrounding these products, we will be instituting roadblocks contrary to the overall mission of this committee and of the Food and Drug Administration, which has the responsibility of improving the health of American patients across the country.

Thank you, Mr. Chairman. I look forward to the testimony of the witnesses, and I yield back.

Mr. PALLONE. Thank you, Mr. Deal.

Chairman Waxman.

OPENING STATEMENT OF HON. HENRY A. WAXMAN

Mr. WAXMAN. Thank you very much, Mr. Chairman.

I welcome the witnesses to today's hearing as well.

Until February of last year, when Americans were injured by defective medical devices they had a remedy. In most States, they were able to sue the manufacturer of that product for damages in State court. In fact, the only way patients could obtain compensation was to bring a lawsuit under State law.

But in February, 2008, the Supreme Court dramatically altered this landscape in its Riegel v. Medtronic decision. The court ruled that, so long as the FDA has approved a medical device, patients injured by that device could no longer seek compensation to help them deal with their permanent disabilities, their inability to work, and their costly medical procedures.

Ironically, the decision applies only to the most dangerous and most complex devices, the kind of devices that, when they malfunction, often result in death or in severe physical impairment. This decision has already had a devastating impact in the over 1,400 cases brought by injured patients that have been thrown out. We learned that another 300 cases were terminated under Riegel and that countless other lawsuits will never be brought.

In the wake of the Court's decision, it does not matter how badly a defective device has harmed a patient. It does not matter how egregious the device manufacturer's conduct was in marketing a defective device. Patients have no recourse and no ability to be compensated for their injuries.

The Court's decision was bad for Americans in another way, too. It has destroyed one of the most powerful incentives for safety, the possibility of liability. We know that some device companies have hidden and have manipulated important safety data. Some have

failed to report serious adverse events. Some have failed to disclose known defects. Yet, under the Court's decision, even if a company withholds information about potentially fatal defects from physicians, patients, or the FDA, it is still immune from any liability for its actions.

In the absence of liability, all of the financial incentives will point medical device companies in the wrong direction. Tragically, the end result is that these abusive practices will undoubtedly multiply.

Now, some would counter the FDA will be there to protect against these abuses. The FDA approved these devices, so why should we have juries second-guessing the FDA's expert judgment? Well, as a result of chronic underfunding and weak leadership, the FDA's ability to protect the public has plummeted. In fact, the FDA's own science board issued a report saying that the agency is so starved of resources that "American lives are at risk."

Even if we were to give the FDA every penny it needs, there would still be a compelling argument for our system of State liability laws. That is because we operate on a model that relies on the industry to innovate, research, develop, and market their products. The FDA is not the only one playing this role, so the device companies themselves will always know more about their products than will the FDA.

Here is another problem. The clinical trials upon which the FDA relies to approve drugs or devices are often too small to detect less frequent risks. Some risks can only be detected when the drug or medical device is used in the population at large.

I was here, as well as Mr. Dingell and very few others on the committee, when the medical device law was adopted; and at no point in the consideration of that legislation did we expect that the preemption language, which was that the FDA has the sole responsibility to approve a product, meant that we were trying to preempt the States from the liability laws. Liability laws have always been in place to serve a very important role; and I was disappointed to see the Supreme Court come up with the decision it did, using that language, which of course they did not find in the medical drug section, to preempt the State liability laws.

I hope that we will overturn the decision of the Supreme Court and will allow State laws to continue to play an important role in protecting consumers.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Waxman follows:]

Opening Statement of Rep. Henry A. Waxman
Chairman, Committee on Energy and Commerce
H.R. 1346, The Medical Device Safety Act of 2009
Subcommittee on Health
May 12, 2009

This morning, the Subcommittee will hear testimony on an issue that affects all of us: the legal liability of manufacturers that produce dangerous medical devices.

Until February of last year, when Americans were injured by defective medical devices, they had a remedy. In most states, they were able to sue the manufacturer of that product for damages in state court. In fact, the only way patients can obtain compensation is to bring a lawsuit under state law.

In February 2008, the Supreme Court dramatically altered this landscape in its *Riegel v. Medtronic* decision. The Court ruled that, so long as FDA has approved a medical device, patients injured by that device can no longer seek compensation to help them deal with their permanent disabilities, their inability to work, and their costly medical procedures.

Ironically, the decision applies only to the most dangerous and most complex devices. The kind of devices that, when they malfunction, often result in death or severe physical impairment.

This decision has already had a devastating impact. Well over 1,400 cases brought by injured patients, have been thrown out. Ironically, just today, we learned that another 300 cases were terminated under *Riegel.* Countless other lawsuits will never be brought.

In the wake of the Court's decision, it doesn't matter how badly a defective device harmed a patient. It doesn't matter how egregious the device manufacturer's conduct was in marketing a defective device. Patients now have no recourse and no ability to be compensated for their injuries.

The Court's decision was bad for Americans in another way too. It has destroyed one of the most powerful incentives for safety — the possibility of liability.

We know that some device companies have hidden and manipulated important safety data. Some have failed to report serious adverse events. And some have failed to disclose known defects.

Yet, under the Court's decision, even if a company withholds information about potentially fatal defects from physicians, patients, or the FDA, it is still immune from any liability for its actions.

In the absence of liability, all the financial incentives will point medical device companies in the wrong direction. Tragically, the end result is that these abusive practices will undoubtedly multiply.

Some would counter: FDA will be there to protect against these abuses. FDA approved these devices, so why should we have juries second-guessing FDA's expert judgment?

As a result of chronic underfunding and weak leadership, FDA's ability to protect the public has plummeted. FDA's own Science Board issued a report saying that the agency is so starved of resources that "American lives are at risk."

But even if we were to get FDA every penny it needs, there would still be a compelling need for our system of state liability laws. That's because we operate on a model that relies on industry to innovate, research, develop, and market their medical products. FDA is not the one playing this role. So the device companies themselves will always know more about their products than the FDA.

And here's another problem: The clinical trials upon which FDA relies to approve drugs or devices are often too small to detect less frequent risks. Some risks can only be detected when the drug or medical device is used in the population at large. Without the risk of liability, companies would have little incentive to give FDA timely reports about these dangers. We have seen such risks arise, over and over, with devices and drugs. And, over and over, we've seen companies fail to disclose such risks to patients and physicians. Yet preemption gives companies a free pass on any safety problems discovered after approval.

All the resources in the world will not change the nature of this system. Congress needs to enact the Medical Device Safety Act of 2009 to correct this dangerous situation.

Let me briefly address another argument that is often made against the bill: that the bill will somehow destroy medical device innovation.

Keep in mind that patients have long had the ability to bring product liability cases under state tort law for all types of consumer products, including medical devices. That is, until the Supreme Court's decision last year. Until last year, medical device manufacturers had always operated with the knowledge that they might have to deal with lawsuits over injuries caused by their products — and, over the years, thankfully for all of us, device innovation has flourished.

The Medical Device Safety Act does nothing more than to simply return things to the status quo before last year's Court decision.

I am grateful to our witnesses for being with us today to discuss this issue, and I look forward to their testimony.

Mr. PALLONE. Thank you, Chairman Waxman.

The gentleman from Illinois, Mr. Shimkus.

Mr. SHIMKUS. Thank you, Mr. Chairman.

We are going to hear many difficult, tough stories today, but I know we have Mr. Kinsley here to talk about the other side, and I would just plead for people to remember the thousands of people who have greatly benefited from—the one aspect I know is the cerebellar or the spinal cord stimulators.

Now, I had a chance to visit with a couple of individuals today—Mike Roman from Des Peres, Missouri, and Adam Homhammon, who was an Army guy. I had a chance to visit with them, and their stories are just as compelling of the serious pain which they were under, to a point where they were of no benefit, only to the pharmaceutical companies who had to medicate them severely to ease their pain. They were not able to function in today's society. Because of this technological advance, one walked into my office. The other one jumped off the wheelchair and talked to me about how his life had been changed for the good.

Now, the doctors have the Hippocratic oath, which says, "first do no harm." We had better be very, very, very careful that, in trying to fix the problems of some, we do not turn over the opportunity for this really new, life-giving technology to be available for people who desperately need it.

So, Mr. Chairman, I would preach caution and concern for both sides as we move forward; and I yield back the balance of my time.

Mr. PALLONE. Thank you, Mr. Shimkus.

Chairman Dingell.

OPENING STATEMENT OF HON. JOHN D. DINGELL

Mr. DINGELL. Mr. Chairman, I thank you for holding today's legislative hearing on H.R. 1346, the Medical Device Safety Act of 2009. I am an original cosponsor of this legislation, and I strongly believe that it is necessary to reinforce congressional intent on a very important policy matter.

I want to thank the witnesses who have joined us today, and I look forward very much to hearing their testimony.

Prior to 1976, in the absence of Federal regulation, States enacted their own laws governing medical devices. So, in an effort to streamline medical device safety policy, the Congress acted. In 1976, we passed the Medical Device Amendments. Our legislative intent was to give the FDA the power to regulate the approval of medical devices for U.S. consumers. We concluded that it was necessary to include a preemptive clause to make sure that Federal regulation, through the FDA, preempted State regulation on medical devices. We included no other preemptions. We did not, I note, however, expressly nor implicitly do away with State liability actions.

Unfortunately, the U.S. Supreme Court in Riegel v. Medtronic, Inc. in 2008 decided to create legislative intent where there was none and immune medical devices from State product liability law. Now, people complain about activist judges. Here is a fine example of people who are running out to find congressional intent where none existed.

I urge my colleagues to remember that there are three coordinate and coequal branches of the Federal Government with distinctive duties and responsibilities. The appropriate application of Federal preemption should be determined by the Congress, not concocted in preambles to Federal regulations or decided through case law. Though, in 2008, with the Riegel decision, an activist judiciary decided to constrict State authority in the way Congress never intended. Therefore, it is time for the Congress to act properly, to exercise our authority, and to correct this clear judicial overreach.

In this instance, the use of tort litigation is beneficial, because it will protect consumers where Federal regulation fails to anticipate latent danger in medical devices. When the Congress wants to preempt, I think it has the great talent in saying so in the legislation. None, I repeat, is here to be found.

The Food and Drug Administration, I want to note, has been starved for resources for a number of years. This has made it almost impossible for them to adequately ensure the safety of the products they regulate. All you have to do is look back at the flood of unsafe foods, commodities, pharmaceuticals, and of other things coming in from China and elsewhere abroad, as well as things that are slipping into our American economy because of the total inability of the FDA to properly protect American consumers.

It is to be noted that the FDA does not have the ability to ensure the safety of the products they regulate. The FDA's IT systems are antiquated, its science base has eroded, its laboratories are a joke, and it does not have adequate personnel or, quite honestly, adequate authority to deal with its responsibilities.

I will note, parenthetically, I have a good bill, H.R. 759, that will go a long way in addressing this issue, and we can get back to protecting our people in the way we should. Until this can be done, we, very frankly, need to see to it that citizens and Attorneys General have the capacity to properly protect American consumers. So, until we properly equip the FDA with the resources to do its job, consumers should have the ability to seek redress under the law.

I would note that, as of late, we have seen many instances where a lot of do-gooders have run out and have stripped Federal agencies of the authority to regulate either legislatively or in courts. We saw it in securities, and we saw Enron follow, and a lot of other bad things happened. We have seen them do it with regard to banks in the repeal of Glass-Steagall, in the deregulation of the securities industry, and in the deregulation of banks. Then, all of a sudden, we found that we had a magnificent depression on our hands because of the abuses of the banks in their repeating the same things that they did in 1920 and in 1929.

Having said this, there may be a day come when we will no longer need State liability to protect consumers from defective medical devices. Unfortunately, that day is not here, and it is not likely to come until we have dealt with the weaknesses of the FDA in its inadequate budget and in its total inability to properly protect American consumers.

For those who paid attention in 1976, we made our intent clear. For those unfortunates needing clarification, we can point to H.R. 1346. It tells people what we had in mind then and what we have in mind now.

Thank you, Mr. Chairman, for holding this hearing. I look forward to receiving the testimony of our witnesses.

Mr. PALLONE. Thank you, Chairman Dingell.

The gentleman from Missouri, Mr. Blunt.

Mr. BLUNT. Thank you, Mr. Chairman. Thank you for holding this hearing on the Medical Device Safety Act of 2009.

It is certainly important that we carefully consider the possible impacts this legislation could have on patients and on the companies that produce life-saving and life-changing devices for those patients. It is extremely important that any medical device on the market undergoes a thorough and appropriate approval process to ensure the safety of the patients who need them.

If a company fails to ensure they are manufacturing the highest quality devices and that there are adverse impacts on a patient, then they should be held responsible. On the other hand, if the manufacturer has done everything in its power to put a device through the proper approval processes, to correctly manufacture the device and to properly inform its customers, it cannot be held responsible for situations beyond its control.

We need to make sure, as we look at this bill and this subject, that companies are not subject to overly burdensome regulations, because this would ultimately cause patients to suffer in the form of decreased access and decreased innovation of medical devices.

I look forward to working with you, Mr. Chairman, with Mr. Deal, and with the subcommittee as we move forward on this issue. I also look forward to the panel today.

Mr. PALLONE. Thank you, Mr. Blunt.

Mr. Murphy of Connecticut.

Mr. MURPHY OF CONNECTICUT. Thank you very much, Mr. Chairman.

Just very briefly, I would like to thank you for holding this hearing today. I understand that the focus of much of our discussion today is going to be the precedence set in Riegel, but, as someone new to this debate, I look forward to hearing from the panel about their ideas on how to truly make the fundamental reforms to the FDA process that Mr. Dingell and many others have referenced.

I absolutely believe that tort law can be an effective check against unsafe products, but I also understand that it can be a patchwork check on those products. So I look forward to hearing today both about the precedent that has been set and about our opportunity to transform it, but I also look forward to hearing from this panel and from those who will come before this committee in the future to hear about how we can truly put teeth into the FDA. There is no reason to give up on that process; and I stand ready, at the very least, to be part of a process by which we can make that approval process work once again.

Thank you, Mr. Chairman.

Mr. PALLONE. Thank you.

The gentleman from Indiana, Mr. Buyer.

OPENING STATEMENT OF HON. STEVE BUYER

Mr. BUYER. Thank you, Mr. Chairman.

I want to comment on two points. One came from my dear friend, Mr. Waxman. The reason I need to make this point is that he

talked about how the FDA, right now being an underfunded agency, is ill-equipped to protect the public because it has been woefully underfunded. All right. Let us stop and think about that for a moment: woefully underfunded.

Mr. Waxman, what did you just do and this committee just do with regard to tobacco legislation? You gave it a new mission on top of a core mission that is counter to its culture. If, in fact, we have an agency that is underfunded, we should be funding the agency and should be making sure that it does its job so that the best minds in the world can assess these products to make sure that we have the gold standard of safety, not to turn it over to juries and to judges and to the cleverness of trial lawyers. That is the wrong place. That is the wrong venue. It is the wrong jurisdiction to have the supervision of medical devices. So that is a bizarre logic for me.

The second point is with regard to my other dear friend, Mr. Dingell, who was talking about activist judges. Boy, this is in the hands of the beholder when conservative courts are now considered to be activist courts because of their interpretation of the law. Now whom are they embracing? No, who they are embracing is the circuit, the 11th circuit that is out of step with all other circuits is who Mr. Waxman is embracing.

For the years that I served on the Judiciary Committee, I sought to sever the 11th circuit. I would break it into six parts if I could. It is the most bizarre circuit with regard to its judgments for the country. So for us as a committee to embrace the 11th circuit as though that is, in fact, the judgment that should be made for the whole of the country, I think it is twisted logic.

Now, I agree with the judgments of the Supreme Court. I think they made the right decision. I think they brought clarity to the issue.

The other point I want to make is that, in the Court's decision in Riegel, it confirmed, yes, that the MDA does preempt State common law with respect to devices approved for the premarket approval process, but it further confirmed that the manufacturer, if it engages in wrongful conduct, can be held liable.

Now, think about if some of us wanted to go to the marketplace at risk, pool our capital, and push the bounds of science. We have created something. We go through the approval process, and we do everything that the FDA says we are supposed to do. Yet what? We want to turn that over, even though we have done everything we are supposed to do, to all of these State court jurisdictions?

If I am the manufacturer and I have got a State out there that is out of step and bizarre, I will not market that product in that State. Then the people who live in that State will suffer.

Is that the type of equity we bring to America? I do not think so.

I yield back.

Mr. PALLONE. Mr. Braley of Iowa.

OPENING STATEMENT OF HON. BRUCE L. BRALEY

Mr. BRALEY. Thank you, Mr. Chairman, for holding this important hearing.

It is a very important distinction to draw that what we are talking about today is a restoration of rights that existed in this country for over 100 years, not the creation of some new cause of action. In fact, Justice Ginsburg, in his dissenting opinion, referred to this as a radical curtailment of State common law remedy.

As someone who has not only researched, briefed, and argued Federal preemption cases in both State and Federal courts, I can tell you from personal experience that the key issue in every Federal preemption case is the original intent of Congress as expressly stated and that, in the application of the law to that issue, the question is always a presumption against preemption, because it is such an extraordinary action to take.

In fact, the Court, in its opinion, cited the legislative history, which is always one of the first things you look at in determining congressional intent, and it referred specifically to the Senate sponsor of the bill, Senator Kennedy, who noted at the time the bill was introduced that the legislation is written so that the benefit of the doubt is always given to the consumer. After all, it is the consumer who pays with his health and with his life for medical device malfunctions.

It also quoted Chairman Waxman, who I am sure would be surprised that he was being cited as one of the contributing members whose congressional intent shaped the Court's eventual outcome.

One of the things that was also mentioned in the dissenting opinion was the perverse effect of immunity. The Court focused on fact that, at the time this Act was brought before Congress in 1976, it was at a time when the entire industry, according to the judgment of Congress, needed more stringent regulation. If you look at Justice Scalia's opinion, he notes that, when these devices enter the market, they have never been formally reviewed under the MDA for safety or efficacy.

Mr. Chairman, I would like to note, as Chairman Waxman referred to earlier, that just today, in the United States District Court for the District of Minnesota, 300 additional people who were injured or killed by defective medical devices had their cases thrown out because of this decision.

I would ask unanimous consent for the ruling that was handed down today to be included as part of the record.

Mr. PALLONE. Without objection, so ordered.

[The information follows:]

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation,

This document relates to:
ALL CASES

Multidistrict Litigation
No. 08-1905 (RHK/JSM)
ORDER

This matter is before the Court on Plaintiffs' Motion for Leave to File an Amended Master Consolidated Complaint for Individuals (Doc. No. 248). For the reasons set forth below, the Court will deny the Motion.

The background of this case is set forth in detail in the Court's January 5, 2009 Order dismissing Plaintiffs' Master Consolidated Complaint for Individuals (the "MCC") and will not be repeated here. See In re Medtronic, Inc. Sprint Fidelis Prods. Liab. Litig., 592 F. Supp. 2d 1147 (D. Minn. 2009). In short, the Court previously concluded that all of the claims alleged in the MCC were preempted under 21 U.S.C. § 360k(a), and it dismissed those claims with prejudice. With the Court's approval, however, Plaintiffs later filed the instant Motion, seeking leave to file an Amended MCC; Plaintiffs also submitted a proposed Amended MCC to the Court, which they subsequently revised. Medtronic opposes Plaintiffs' Motion to Amend, arguing the proposed amendments are futile and that many are untimely.

Amendment generally is governed by Federal Rule of Civil Procedure 15. Under that Rule, courts "should freely give leave [to amend] when justice so requires." Fed. R.

Civ. P. 15(a)(2). But "different considerations apply to motions [to amend] filed after dismissal," United States *ex rel.* Roop v. Hypoguard USA, Inc., 559 F.3d 818, 823 (8th Cir. 2009) (quoting Briehl v. Gen. Motors Corp., 172 F.3d 623, 629 (8th Cir. 1999)), because "[a]fter a complaint is dismissed, the right to amend under Fed. R. Civ. P. 15(a) terminates." Parnes v. Gateway 2000, Inc., 122 F.3d 539, 550 (8th Cir. 1997) (citation omitted). Courts have "considerable discretion" to deny such "disfavored" motions. Drobnak v. Andersen Corp., 561 F.3d 778, 788 (8th Cir. 2009) (quoting Roop, 559 F.3d at 824).

Plaintiffs argue they should be permitted to amend, and that the Court erred in dismissing the MCC with prejudice, because "dismissal with prejudice is a drastic sanction." (Pl. Mem. at 3 (quoting Omaha Indian Tribe v. Tract I-Blackbird Bend Area, 933 F.2d 1462, 1468 (8th Cir. 1991)).) But as the quoted language suggests, Omaha Indian Tribe addressed dismissal as a *sanction* for failing to comply with court orders, not (as here) dismissal for failure to state a claim under Rule 12. There is simply no support for Plaintiffs' assertion that dismissals under Rule 12 "should be" without prejudice. See Pet Quarters, Inc. v. Depository Trust & Clearing Corp., 559 F.3d 772, 782 (8th Cir. 2009) (no abuse of discretion in dismissing complaint with prejudice and without opportunity to amend); Gunderson v. ADM Investor Servs., Inc., Nos. C96-3148, C96-3151, 1997 WL 570453, at *11 (N.D. Iowa Apr. 17, 1997) (rejecting "the notion that a party putting forward inadequate pleadings must automatically be given leave to amend when the court finds that the opposing party's Rule 12(b)(6) motion should be granted").

Indeed, plaintiffs do not enjoy an absolute or automatic right to amend. E.g., United States *ex rel.* Lee v. Fairview Health Sys., 413 F.3d 748, 749 (8th Cir. 2005); Meehan v. United Consumers Club Franchising Corp., 312 F.3d 909, 913 (8th Cir. 2002). That is particularly true where, as here, a plaintiff does not request leave to amend before an adverse ruling. See Drobnak, 561 F.3d at 787 ("A district court does not abuse its discretion in failing to invite an amended complaint when plaintiff has not moved to amend and submitted a proposed amended pleading.") (quoting Meehan, 312 F.3d at 913).

In addition, the basis for Plaintiffs' Motion is a host of allegedly "newly discovered" facts they claim add substance to their allegations. But many of those so-called "new" facts were available to Plaintiffs before the MCC was filed on July 2, 2008. (See, e.g., Proposed Revised Amended MCC ¶¶ 49, 134.) Plaintiffs have failed to explain why those facts were omitted from the MCC. See, e.g., United States *ex rel.* Joshi v. St. Luke's Hosp., Inc., 441 F.3d 552, 557 (8th Cir. 2006) (appropriate to deny amendment for undue delay). Moreover, Plaintiffs seek to assert several new claims, but "a post-judgment motion for leave to assert an entirely new claim is untimely." Roop, 559 F.3d at 825. A litigant cannot simply lie in wait with plans to amend his or her complaint and change the theory of the case should it be dismissed. See Briehl, 172 F.3d at 629.

In any event, even if not untimely the Court would deny Plaintiffs' Motion because the proposed amendments would be futile. "Futility is a valid basis for denying leave to amend." Roop, 559 F.3d at 822. In the Court's view, all of the claims in the Proposed

Revised Amended MCC (including the newly asserted ones) are preempted for the reasons stated in the January 5, 2009 Order. While suffused with some greater detail than the MCC, the Proposed Revised Amended MCC largely reiterates and rehashes the allegations previously made. For instance, Plaintiffs continue to adhere to the view that "[b]ecause the Sprint Fidelis leads have been recalled, the FDA approval no longer exists" (Proposed Revised Amended MCC ¶ 1), a proposition the Court has squarely rejected. See In re Medtronic Sprint Fidelis, 592 F. Supp. 2d at 1155. Similarly, Plaintiffs repeat their assertion that Medtronic was negligent in failing to change the Sprint Fidelis Leads' product label after adverse events were reported. (See Proposed Revised Amended MCC ¶¶ 68, 228.) Yet, federal law merely *permits*, but does not *require*, such product-label changes. As the Court previously held, "[w]here a federal requirement permits a course of conduct and the [claim alleged would] make[] it obligatory, the [claim] is preempted." In re Medtronic Sprint Fidelis, 592 F. Supp. 2d at 1160 (citation omitted).

Simply put, the Court believes that the flaws endemic to the MCC are equally endemic to the Proposed Revised Amended MCC because the very premise underlying Plaintiffs' claims is faulty. As the Court noted when it dismissed the MCC:

> The theory of Plaintiffs' case is that Medtronic did not adequately manufacture the Sprint Fidelis leads, not because it failed to comply with the specifications in the leads' PMA, but rather because the manufacturing methods Medtronic opted to use rendered all of the leads defective. In other words, Plaintiffs' claims are predicated on a defect in the method of manufacture approved by the FDA when it granted the leads PMA. . . . [S]uch claims are by their very nature preempted under Section 360k(a).

Id. at 1166.

Plaintiffs, however, argue that the Court's preemption ruling misapplied 21 U.S.C. § 360k(a) (the express preemption provision for medical devices in the Federal Food, Drug, and Cosmetic Act) and Riegel v. Medtronic, Inc., __ U.S. __, 128 S. Ct. 999 (2008). They cite a recent decision from the United States District Court for the Southern District of Indiana, Hofts v. Howmedica Osteonics Corp., No. 1:08-CV-855, 2009 WL 331470, at *3 (S.D. Ind. Feb. 11, 2009), in which the medical-device defendant's motion to dismiss on preemption grounds was denied. Of course, Hofts is not binding on this Court, and the undersigned respectfully disagrees with that decision. See also Horowitz v. Stryker Corp., __ F.R.D. __, 2009 WL 436406, at *9 n.5 & *10 n.6 (E.D.N.Y. Feb. 20, 2009) (favorably citing this Court's preemption decision and concluding that Hofts wrongly applied Riegel and Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007)). Since the preemption decision in January, several other courts have confirmed Riegel's teaching that Section 360k(a) broadly preempts tort and other claims concerning FDA-approved medical devices. See, e.g., Heisner v. Genzyme Corp., No. 08-C-593, 2009 WL 1210633, at *3 (N.D. Ill. Apr. 30, 2009); Dorsey v. Allergan, Inc., No. 3:08-0731, 2009 WL 703290, at *5-7 (M.D. Tenn. Mar. 11, 2009); Horowitz, 2009 WL 436406, at *8-12; Blunt v. Medtronic, Inc., 760 N.W.2d 396, 403-09 (Wis. 2009). The Court remains of the view that Plaintiffs' claims are preempted, notwithstanding Hofts. See In re Sulzer Hip Prosthesis & Knee Prosthesis Liab. Litig., 455 F. Supp. 2d 709, 716 (N.D. Ohio 2006) (case law "reveal[s] that § 360k(a) preempts almost every type of state law claim that

seeks to hold a defendant liable for a PMA- approved medical device").[1]

For all of these reasons, the Court concludes that Plaintiffs' proposed amendments would not survive a motion to dismiss on preemption grounds and, hence, are futile. See, e.g., Cornelia I. Crowell GST Trust v. Possis Med., Inc., 519 F.3d 778, 782 (8th Cir. 2008) ("[W]hen the court denies leave on the basis of futility, it means the district court has reached the legal conclusion that the amended complaint could not withstand a motion to dismiss."). Accordingly, the Court will deny Plaintiffs' Motion for Leave to Amend.

The foregoing begs the question: What now? Previously, the Court had suggested it might certify its preemption decision to the Eighth Circuit for review under 28 U.S.C. § 1292(b). Upon reflection, the Court concludes that certification would be improper for several reasons. First, certification is rarely appropriate. See Caraballo-Seda v. Municipality of Hormigueros, 395 F.3d 7, 9 (1st Cir. 2005). Moreover, as Medtronic has previously noted, there are at least 229 cases pending in this MDL that have simply adopted the MCC without any additional claims. (See Doc. No. 237 & Ex. B.) Because the MCC has been dismissed and the Court has denied Plaintiffs leave to amend, each of those 229 cases is subject to outright dismissal. And, were the Court to dismiss those

[1] In a letter seeking reconsideration of the January 5, 2009 Order, Plaintiffs suggest that the preemption landscape has changed due to the Supreme Court's recent decision in Wyeth v. Levine, __ U.S. __, 129 S. Ct. 1187 (2009). But Wyeth addressed implied preemption of claims concerning prescription drugs, which are treated differently than medical devices. See id. at 1200 ("[D]espite its 1976 enactment of an express pre-emption provision for medical devices, Congress has not enacted such a provision for prescription drugs.") (citations omitted). In the Court's view, Wyeth does not alter the preemption analysis.

cases, the preemption decision could be brought to the Eighth Circuit via appeal. If this Court were to certify the preemption decision, however, there is no guarantee that the appellate court would accept it for review. See 28 U.S.C. § 1292(b) (court of appeals "may . . . in its discretion" accept certified question); Caraballo-Seda, 395 F.3d at 9 (review of interlocutory order certified to appellate court is discretionary). Therefore, the Court determines that the appropriate action at this juncture is to dismiss the 229 cases that have adopted the MCC for the operative Complaint. Because the Court believes that at least some of the plaintiffs in those cases will appeal, and because the Eighth Circuit's decision in those cases will impact the remaining cases in this MDL, it is the Court's view that the remaining cases comprising this MDL should be stayed in the interim.

Based on the foregoing, and all the files, records, and proceedings herein, **IT IS ORDERED** as follows:

1. Plaintiffs' Motion for Leave to File an Amended Master Consolidated Complaint for Individuals (Doc. No. 248) is **DENIED**;

2. Plaintiffs' March 6, 2009 letter request to file a Motion for Reconsideration of the Court's January 5, 2009 Order is **DENIED**;

3. The Complaints in each of the 229 cases listed in the attachment hereto are **DISMISSED WITH PREJUDICE** and **JUDGMENT SHALL BE ENTERED ACCORDINGLY** in each of those cases; and

4. The remaining cases comprising this MDL, including any cases subsequently transferred here by the Judicial Panel on Multidistrict Litigation, are

STAYED pending further Order of the Court. The parties shall promptly notify the Court (1) when one or more plaintiffs in the 229 dismissed cases have filed a notice of appeal to the Eighth Circuit or (2) the time for doing so has expired without any plaintiff having appealed.

Dated: May 12, 2009

s/Richard H. Kyle
RICHARD H. KYLE
United States District Judge

Mr. BRALEY. Now, one of the things we often hear about are reasons that this bill should not be passed. Let me give you four conservative reasons to support the passage of this bill.

Number one, it holds corporate wrongdoers accountable when they injure or kill people with defective devices.

Number two, when you provide immunity to medical device manufacturers, you create greater exposure for the physicians who install them and for the hospitals where they are installed.

Number three, as Dr. Maisel noted last year during our hearing, it results in the cost shifting to U.S. taxpayers, who end up paying for the care of these patients who have no other remedy.

Number four, we see a flood of defective medical devices flowing in from overseas.

Those are conservative reasons right there, and that is why we need to pass this bill.

Mr. PALLONE. Thank you.

The gentleman from Pennsylvania, Mr. Pitts.

OPENING STATEMENT OF HON. JOSEPH R. PITTS

Mr. PITTS. Thank you, Mr. Chairman. Thank you for convening this hearing.

The bill we are discussing today, H.R. 1346, would overturn the 8–1 Supreme Court decision in Riegel v. Medtronic. In this 2008 decision, the Court held that the preemption clause contained in the Medical Device Amendments Act bars common law claims challenging the safety of a medical device granted premarket approval by the FDA. This decision is extremely limited in scope. Only those devices that receive premarket approval, or PMA—approximately 2 percent of the new medical devices marketed per year—have express preemption.

Riegel also makes it clear that preemption does not apply to PMA devices if the manufacturer withholds information from the FDA, if it misleads the FDA about the safety or effectiveness of its product, or if the company manufactures a product improperly. In such case, a company can be sued for its wrongful behavior.

The PMA process is scientifically rigorous. The FDA spends an average of 1,200 hours reviewing each application, including a device's proposed labeling. In granting PMA, the FDA has determined that the probable benefit to help from the use of the device outweighs any probable risk of injury or of illness from use.

Once a device is approved through the PMA process, the manufacturer is subject to reporting requirements, including informing the FDA of new clinical or scientific studies regarding a device and reporting incidents in which the device failed or contributed to significant injury.

The FDA can withdraw its approval if a device is found not to be safe or effective. The FDA can order a recall if it is determined that a reasonable probability exists that a device could cause serious injury or death.

What would the consequences be if these life-saving, complex devices did not receive express preemption as would be the case if H.R. 1346 became law?

Companies that manufactured and labeled their products according to FDA-approved standards could be sued in State courts and

found at fault if a device causes injury or harm. A lay jury would be presented with a case in which an individual was harmed by a device, and its judgment would be substituted for that of the FDA's. Fifty courts in fifty States could each determine what standard a device should meet. Innovation would be stifled. Venture capital could dry up with the threat of litigation once a product hits the market. Manufacturers could pull products from the market or could refuse to sell them in certain States as a result of court cases. People who desperately need these life-sustaining devices may not have access to them.

No device, no matter what the approval process, will ever be 100 percent safe and effective, but when the FDA grants premarket approval, it has judged that the benefits of the population at large outweigh the risk to the population at large.

The Riegel case was decided properly, and H.R. 1346 is simply bad policy. We all want only those medical devices that are safe and effective to be on the market. H.R. 1346 will not help us to achieve that.

I look forward to hearing the witnesses today.

I yield back.

Mr. PALLONE. Thank you, Mr. Pitts.

The gentleman from Texas, Mr. Burgess.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS

Mr. BURGESS. I thank the chairman. I thank our witnesses for being here with us today and for listening to our opening statements. We will listen to yours in just a moment.

Certainly, the Food and Drug Administration categorizes devices into three categories: Class I devices are subject to minimal requirements. Some easy examples of that would be latex gloves, bedpans, and urinals. Class II devices are subject to more requirements that include such items as hearing aids.

H.R. 1346 is not aimed at Class I and Class II devices. It is aimed at high-risk devices known as Class III. Class III devices are considered high risk because they are complex and are used to support or to sustain human life or whose use is of substantial importance in preventing the impairment of human health. They are most certainly life-changing devices with no 100 percent guarantee of safety or efficacy. With Class III devices, there are calculated risks involved.

Now, when weighing the interests of a manufacturer against the life of a human being, there is no question about what side you would come down on. You would come down on the side of the human being. But preemption does not do that, nor does preemption bar State common tort laws. Preemption is not a get-out-of-jail-free card for bad actors taken to court. If a medical device manufacturer violated the essential premise of producing a safe product, there are still remedies, despite the Supreme Court's 8–1 ruling in Riegel v. Medtronic.

What the Supreme Court recognized in Riegel v. Medtronic are two things:

First, the Supreme Court found that premarket approval for devices by the Food and Drug Administration is rigorous, even arduous, with 1,200 hours or more of review for each potential device

and with the undergoing of clinical trials, and a company must give countless pages of documentation to the scientific experts of the Food and Drug Administration.

A review by the Food and Drug Administration does not end with the premarket studies. Postmarket approval is continuous and frequent. If a manufacturer fails to maintain the Food and Drug Administration's standard of approval by being disingenuous or by the failure to be transparent, then approval can be rescinded.

The strenuous nature of the premarket approval process is evident in the exponential rise in the 510(k) applications where a device is allowed to go to market if there are what are known as "substantially equivalent devices."

Now, Mr. Chairman, I requested a hearing on the 510(k) process in March of this year. I am concerned about how devices are being approved at the FDA. If the FDA is broken, if the FDA is underresourced, as Chairman Waxman suggested, if the FDA is understaffed and underwater, if the FDA is ill-equipped, inadequate or severely underachieving in its Class III medical device process, then let us do what is within our power and fix the FDA.

This subcommittee is not tasked with fixing the legal system. H.R. 1346 is tort reform, but it is tort reform at its very worst, utilizing the worst possible mechanism. H.R. 1346 would create a haphazard system, a virtual patchwork of device standards where lay jurors are elevated to the same standard of expertise, knowledge, and grasp of science as someone on an FDA advisory panel.

Furthermore, an Attorney General in California or an ambitious Attorney General in New York or an even-keeled Attorney General in Alabama could each create their own sensational trial with sensational damage figures, regardless of what the Food and Drug Administration does.

If there ever were congressional intent in the enactment of the Medical Device Act of 1976, it would be this: Federal ceilings to tort liability, as it relates to medical devices, must exist as a necessity to encourage innovation and healthy progress in medicine. Without a ceiling, no doctor will ever use a medical device and risk his or her entire professional future to a jury, and no manufacturer will ever undertake the risk of producing a single device where a single error will result in the destruction of the entire livelihood of that company.

The science of devices should not be in the judicial branch. The judicial branch should determine the law, and the law here is written by Congress. So the solution regarding medical devices is to give the Food and Drug Administration the resources that they need to do the job that they have been tasked to do and not to enact H.R. 1346.

I thank you, and I will yield back the balance of my time.

Mr. PALLONE. Thank you.

The ranking member, the gentleman from Texas, Mr. Barton.

Mr. BARTON. Thank you, Mr. Chairman.

I am going to submit my full statement for the record, but I do want to read one paragraph from the Republican staff committee brief for this hearing about H.R. 1346.

Before I do that, let me say I do appreciate that we are having a legislative hearing. I wish it were on another bill, but at least we are having a hearing.

Let me just put in a nutshell what my position is and what I think the positions are of most of the Republicans on this subcommittee.

Enacting H.R. 1346 will not only overturn the Supreme Court's 8–1 decision in Riegel v. Medtronic. It will also severely disrupt the innovation in the medical device industry that has existed since the enactment of the Medical Device Amendments Act of 1976 and of the Federal Food and Drug and Cosmetic Act.

This disruption will decrease patient access to life-saving medical devices, threaten the U.S.'s status as a global leader in medical device innovation, and it will dramatically increase the number of lawsuits against device companies.

So, Mr. Chairman, again, thank you for holding the legislative hearing. We will certainly listen to our witnesses, but I would hope that you have no intention of moving this bill. There are more important bipartisan issues that we can work on together for the good of the country. This is not one of them.

With that, I yield back.

Mr. PALLONE. Thank you, Mr. Barton.

Next is the gentlewoman from Tennessee, Mrs. Blackburn.

OPENING STATEMENT OF HON. MARSHA BLACKBURN

Mrs. BLACKBURN. Thank you, Mr. Chairman; and I thank our witnesses for their patience today. We have had a lot of conversation so far about the bill that you are going to testify on. I think it is important to make just a couple of notes as we move forward to your testimony.

I will submit my full statement, Mr. Chairman.

As Chairman Dingell said, it was over 30 years that Congress enacted the Medical Device Amendments. They were there to create a uniform national process for evaluating the medical devices. They have done that.

Subsequently, the FDA successfully implemented the premarket approval process, which gives to the medical technology companies specific guidance that they follow to ensure the safety of those devices. They have spent an average of 1,200 hours reviewing every single application. That is a lot of time on every one of those applications.

Now, common sense would dictate that the FDA and the medical technology companies are committed to making available the safest devices possible to save lives. Anyone who believes that these companies are out to purposefully make poor performing products ought to return to Business 101 and realize that companies know if you put bad products into the marketplace it will eventually lead to a company's collapse. So, in order to stay competitive, medical technology companies like Medtronic, Smith & Nephew, and Wright Technologies, which are all in my district, continue to develop and to produce innovative technologies in order to save lives.

Also, I am troubled that some in Congress would weaken the current device review system in the name of consumer safety. I do

think that Act is misnamed. It would be a boon for trial lawyers at the expense of public safety.

I think the other provision we have to look at is that the device sector is responsible for almost two million jobs, for thousands of jobs in my district alone. I have personally toured many of the facilities and am continually impressed by the innovation, by the research, and by the commitment to saving and to bettering lives that I have found at each one of the facilities.

Thank you, Mr. Chairman. I yield back.

Mr. PALLONE. Thank you.

The gentleman from Georgia, Mr. Gingrey.

Mr. GINGREY. Thank you, Mr. Chairman.

Today, as a result of advances in medical technology, Americans enjoy access to a quality of health care that most nations do not. While some countries restrict or ration the types or the amounts of drugs and devices that patients can access, American patients can receive the latest and the most advanced medical technology, such as an artificial hip or the latest cancer medication, that will drastically improve and extend their lives.

Mr. Chairman, ensuring the safety of medical devices is an absolute necessity for our continued access to quality health care. The FDA is charged with making certain that all medical devices have been thoroughly tested for safety and effectiveness before coming to the market. It is one of the FDA's primary responsibilities, and I support increased efforts in this area.

Unfortunately, modern medical procedures inherently have risks associated with them, regardless of advances in technology or of effective oversight. It goes without saying there are very few absolutes in this world. With this thought in mind, I look forward to the testimony of our witnesses today.

I yield back. Hopefully, we will use some of this additional time for questions. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you, Mr. Gingrey.

That is the end of our opening statements, so we are now going to turn to our witnesses. We have just one panel, and I want to welcome you all for being here today. Let me introduce each of you, from my left to right.

First is Professor David Vladeck, who is a Professor of Law at Georgetown University Law Center here in D.C.

Next is Dr. William Maisel, who is Director of the Medical Device Safety Institute for the Department of Medicine at Beth Israel Deaconess Medical Center in Boston.

Then we have Dr. Gregory Curfman, who is Editor of the New England Journal of Medicine.

And Bridget Robb, who is—I know that is that Welsh name. I always get it wrong. Gwynedd.

Ms. ROBB. Gwynedd.

Mr. PALLONE. Gwynedd, Pennsylvania.

Then we have Mr. Richard Cooper, who is a partner at Williams & Connolly.

Finally, we have Michael Kinsley from Seattle, Washington.

Thank you all for being here today.

Now, the way we work it is we have 5-minute opening statements. They become part of the hearing record. You may, at the

discretion of the committee, submit additional statements in writing for inclusion into the record after your testimony.

STATEMENTS OF DAVID VLADECK, J.D., PROFESSOR OF LAW, GEORGETOWN UNIVERSITY LAW CENTER; WILLIAM H. MAISEL, M.D., M.P.H., DIRECTOR, MEDICAL DEVICE SAFETY INSTITUTE, DEPARTMENT OF MEDICINE, BETH ISRAEL DEACONESS MEDICAL CENTER, BOSTON; GREGORY CURFMAN, M.D., EDITOR, NEW ENGLAND JOURNAL OF MEDICINE; BRIDGET ROBB, GWYNEDD, PENNSYLVANIA; RICHARD COOPER, PARTNER, WILLIAMS & CONNOLLY LLP, AND MICHAEL KINSLEY, SEATTLE, WASHINGTON

Mr. PALLONE. I am going to start on my left again with Professor Vladeck.

STATEMENT OF DAVID VLADECK, J.D.

Mr. VLADECK. Mr. Chairman and members of the committee, thank you very much for inviting me to be here today.

The bill, H.R. 1346, proposes to restore consumers injured as a result of defects in life-supporting or life-sustaining medical devices the right to sue medical device manufacturers.

My views are these:

Mr. PALLONE. Professor, just move the mike a little closer; and I am going to ask everyone to do the same. It will be easier to hear you.

Mr. VLADECK. I think it is on.

Mr. PALLONE. It is on, but it is better to speak a little closer to it.

Mr. VLADECK. All right.

My views are these:

Riegel v. Medtronic provides very broad immunity from tort liability to manufacturers of medical devices, and the ruling gives consumers the worst of both worlds.

On the one hand, the FDA cannot single-handedly ensure the safety of the thousands of medical devices on the market today. Too many serious defects have emerged with FDA-approved devices, and too many patients have been killed or injured by defective devices to contend otherwise.

On the other hand, in the aftermath of Riegel, patients injured by devices are left with no remedy at all, with no compensation for the pain and suffering they endure, with no reimbursements for the costs of surgery and of medical care, and with no recompense to their loved ones should they die. Making matters worse, manufacturers have little economic incentive to swiftly recall devices or to repair defective devices in their market since they are immunized from liability in tort.

I recognize that Riegel ruled that Congress, in passing the Medical Device Amendments, conferred immunity from tort liability to device manufacturers. In my view, Riegel is wrong as a matter of history, as a matter of law, and as a matter of policy, and Congress ought to swiftly overrule it.

First, Riegel is wrong as a matter of history. As Chairman Waxman and Mr. Dingell confirmed, the Members of Congress who enacted the Medical Device Amendments know that Congress never

intended the Medical Device Amendments' very narrow preemption provision to restrict the rights of injured parties to sue for compensation. Cutting off tort liability was not Congress' goal in that statute.

Second, it is wrong as a matter of law. The Medical Device Amendments were passed to strengthen consumer protection. The statute was passed in the wake of the notorious failure of the Dalkon Shield, an intrauterine device that harmed and killed many women. The legislation was intended to strengthen consumer remedies, and it is odd in the extreme to say that Congress intended to insulate manufacturers from the tort liability that was instrumental in bringing justice to people injured by defective medical devices.

The last point and the most important point is that Riegel is wrong as a matter of policy. Immunizing device manufacturers—and device manufacturers alone in terms of the manufacture of medical products—harms the public in several ways:

First, immunity removes the incentive to manufacturers to fix devices quickly and to get defective devices off the market. Time and again, we have seen device manufacturers find defects in their devices, make important safety improvements, and yet continue to sell their older, riskier devices until they sell out their inventory. Tort law would constrain that practice.

Second, immunity weakens the incentives to disclose defects to physicians and to patients without delay. Again, time and again, we have seen device manufacturers fail to do that. Again, tort liability would constrain that practice.

Third, immunity eliminates the compensatory justice role served by the civil liability system. It shifts all of the costs of injuries and deaths from the manufacturers on to consumers, who can ill afford it, to insurance companies and, ultimately, to taxpayers. What we have done is simply shift the burden of risk off the manufacturer onto the shoulders of the taxpayers.

The arguments that defend Riegel are off target, and history proves this point. Life-saving and life-sustaining medical devices have been marketed for decades. For all but a very brief period, there has been no preemption. Preemption is a fleeting phenomenon. It has not been the norm with respect to medical devices, yet for virtually all of the time FDA regulation and State tort litigation have coexisted, each placing an important but complementary discipline on the marketplace without impairing the FDA's function and without any of the harms the defenders of Riegel fear.

For instance, the United States' industry for medical devices remains and has always been the most innovative in the world. The American manufacturers of medical devices dominate the international market, even though there has long been a backstop of tort liability.

I see my time is up. Let me just make one last point.

The Supreme Court in Riegel said that preemption was decreed by Congress. Congress has the power to fix it. I urge that, without delay, Congress restores consumers to the place they were prior to Riegel. Thank you very much.

Mr. PALLONE. Thank you, Professor.

[The prepared statement of Mr. Vladeck follows:]

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.[1] 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.[2]

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

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[1] 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.

[2] 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.,[3] 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'

[3] 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.[4]

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[4] 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."[5]

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.

[5] *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.[6] 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

[6] "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.[7]

To avoid a recurrence of this and similar tragedies, Congress enacted the MDA to give FDA regulatory authority over all medical devices.[8] 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

[7] 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).

[8] 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 . . .."[9] 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.[10]

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[9] 21 U.S.C. § 360k(a) (emphasis added).

[10] *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.[11]

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*.[12] *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.[13] Following *Cipollone*, medical device manufacturers began routinely to assert preemption defenses, and some courts sided with industry.

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

[11] *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).

[12] 505 U.S. 504 (1992).

[13] 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,*[14] 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.[15]

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

[14] *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 489 (1996).

[15] *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.[16] 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."[17] 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

[16] 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.

[17] 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.[18] 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.[19]

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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[18] 128 S. Ct. at 1008.

[19] 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.[20]

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.[21] 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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[20] 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).

[21] 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.[22] 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 serous 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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[22] 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,"[23] 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.[24] 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

[23] 592 F. Supp. 2d at 1149.

[24] 592 F. Supp. 2d at 1152.

surgery.[25] 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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[25] *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 protheses); *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.[26]

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

[26] 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 tesimony 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.[27]

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,"[28] 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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[27] 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).

[28] *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."[29] 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 . . . ."[30]

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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[29] House Staff Report, at 6.

[30] 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 publicly 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,[31] pacemakers,[32] heart valves,[33] heart pumps,[34] and prostheses[35] — which have exacted a terrible toll on the patients who

[31] 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.

[32] 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 (6th Cir. 2005) (finding claims preempted) *with Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) (finding no preemption).

[33] 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).

[34] *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).

[35] 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.[36]

4. The Supreme Court's recent ruling in *Wyeth v. Levine*,[37] 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).

[36] 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.*

[37] 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.[38]

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.[39] 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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[38] 129 S. Ct. at 1197-98.

[39] 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.[40] 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 decis ion 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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[40] 129 S. Ct. at 1202.

Mr. PALLONE. Dr. Maisel.

STATEMENT OF WILLIAM H. MAISEL, M.D., M.P.H.

Dr. MAISEL. Thank you, Chairman Pallone and distinguished members of the committee. Thank you for the opportunity today to speak about the importance of the Medical Device Safety Act of 2009.

My name is Dr. William Maisel. I am a practicing cardiologist at Beth Israel Deaconess Medical Center and am Assistant Professor of Medicine at Harvard Medical School in Boston. I am also Director of the Medical Device Safety Institute, an industry independent, nonprofit organization dedicated to improving the safety of medical devices. I have served as a consultant to the FDA's Center for Devices and Radiological Health since 2003, and I have previously chaired the FDA's Postmarket and Heart Device Advisory Panels.

I hope that by the conclusion of my brief remarks today you will appreciate that the FDA marketing approval of a medical device does not guarantee its safety. In particular, manufacturers' responsibilities for product safety extend well beyond initial FDA approval, and it is apparent that additional consumer safeguards are needed if we are to improve the safety of medical devices for the millions of patients who enjoy their benefits.

We are fortunate to have the preeminent medical regulatory system in the world. The U.S. Food and Drug Administration regulates more than 100,000 different medical devices that are manufactured by more than 15,000 companies. They receive several thousand new and supplemental device applications annually, and they are mandated by Congress to complete their premarket evaluations in a timely fashion.

Mark Gleeson is a man whose very life depends on one of these implantable medical devices—in his case, a pacemaker. Pacemakers are implanted to treat dangerous slow heart rhythms; and, in Mr. Gleeson's case, every single beat of his heart comes from his device. The pacemaker itself consists of a battery and of computer circuitry and is sealed together in a metal housing. Although pacemaker batteries typically last 5 to 10 years, Mr. Gleeson required the surgical replacement of his pacemaker after just 12 months due to a short circuit that caused the battery to wear out prematurely.

St. Jude Medical, the manufacturer of Mr. Gleeson's pacemaker, had become aware of the short-circuit problem 2 years earlier because other faulty devices had been returned to the manufacturer. St. Jude asked for and received FDA approval for a modified version of the device that corrected the problem, although they continued to distribute already manufactured, potentially faulty pacemakers with the FDA's knowledge but without public disclosure.

When Mr. Gleeson needed his faulty pacemaker replaced, he received another potentially faulty device, even though corrected pacemakers had been built and were available. Ultimately, St. Jude Medical issued a recall of 163,000 pacemakers, including Mark Gleeson's new unit, but not until nearly 2–1/2 years after initially learning of the problem.

As Mr. Gleeson wrote to me, "It is unacceptable that St. Jude Medical was permitted to continue to sell known defective inventory of a device with impunity." One possible conclusion is that St.

Jude Medical weighed the likelihood of death or of serious injury against the cost of pulling defective inventory off the market.

While Mr. Gleeson's case occurred several years ago, it is not an isolated event. Other manufacturers have also knowingly sold potentially defective devices without public disclosure. The FDA annually receives reports of more than 200,000 device-related injuries and malfunctions and more than 2,000 device-related deaths, and it is challenging for them to identify patterns of malfunction among the deluge of adverse event reports. In the majority of cases, the FDA relies on industry to identify, to correct, and to report the problems, but there is obviously an inherent financial conflict of interest for the manufacturer that is sometimes measured in the billions of dollars.

The U.S. Supreme Court, with their February, 2008, decision of Riegel v. Medtronic, removed an essential consumer safeguard—the threat of manufacturer liability. Implanted medical devices have enriched and have extended the lives of countless people, but device malfunctions and software glitches have become modern diseases that will continue to occur. The failure of manufacturers to provide the public with timely critical information about device performance and malfunctions enables potentially defective devices to reach unwary consumers. Patients like Mark Gleeson are sometimes forced to make life-changing decisions with insufficient and sometimes inaccurate information.

We have consumer protections for airline passengers, for cable television customers, and for cellular telephone users but surprisingly few for patients who receive life-sustaining medical devices. The Medical Device Safety Act of 2009 provides important and necessary consumer safeguards that will minimize adverse health consequences and will improve the safety of medical devices for the millions of patients who enjoy their benefits.

Thank you.

[The prepared statement of Dr. Maisel follows:]

STATEMENT OF
WILLIAM H. MAISEL, MD, MPH
DIRECTOR, MEDICAL DEVICE SAFETY INSTITUTE
BETH ISRAEL DEACONESS MEDICAL CENTER
HARVARD MEDICAL SCHOOL

BEFORE THE
HOUSE COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON HEALTH

H.R. 1346, THE MEDICAL DEVICE SAFETY ACT OF 2009
MAY 12, 2009

INTRODUCTION

Chairman Pallone, Ranking Member Deal, Distinguished Members of the Committee. Thank you for the opportunity today to speak about the importance of the Medical Device Safety Act of 2009. My name is Dr. William Maisel. I am a practicing cardiologist at Beth Israel Deaconess Medical Center and Assistant Professor of Medicine at Harvard Medical School in Boston. I am also Director of the Medical Device Safety Institute (www.medicaldevicesafety.org), an industry-independent, non-profit organization dedicated to improving the safety of medical devices. I have served as a consultant to the FDA's Center for Devices and Radiological Health since 2003 and have previously chaired the FDA's Post Market and Heart Device Advisory Panels.

I hope that by the conclusion of my brief remarks today you will appreciate that FDA marketing clearance or approval of a medical device does not guarantee its safety. In particular, manufacturers' responsibilities for product safety extend well beyond initial FDA approval and it is apparent that additional consumer safeguards are needed if we are to improve the safety of medical devices for the millions of patients who enjoy their benefits.

We are fortunate to have the preeminent medical regulatory system in the world. The U.S. Food and Drug Administration regulates more than 100,000 different medical devices manufactured by more than 15,000 companies[1]. They receive several thousand new and supplemental device applications annually and they are mandated by Congress to complete their premarket evaluations in a timely fashion[2].

Mark Gleeson is a man whose very life depends on one of these implantable medical devices – in his case a pacemaker. Pacemakers are implanted to treat dangerous slow heart rhythms – and in Mr. Gleeson's case, every single beat of his heart comes from his device. The pacemaker itself consists of a battery and computer circuitry, sealed together in a metal housing. Although pacemaker batteries typically last 5-10 years, Mr. Gleeson required surgical replacement of his pacemaker after just 12 months due to a short circuit that caused the battery to wear out prematurely. Luckily, Mr. Gleeson was able to safely have a new pacemaker fitted.

St. Jude Medical, the manufacturer of Mr. Gleeson's pacemaker, was aware of the short circuit problem. In fact, they had known about the problem for 2 years because other faulty devices had been returned to the manufacturer[3]. Although St. Jude asked for and received FDA approval for a modified version of the device that corrected the problem, they continued to distribute already manufactured potentially faulty pacemakers and

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[1] Maisel WH. Medical device regulation: An Introduction for the practicing physician. Ann Intern Med 2004; 140: 296-302.

[2] U.S. Department of Health and Human Services. Food and Drug Administration. Center for Devices and Radiological Health. Office of Device Evaluation: Annual Report – Fiscal Year 2006 and Fiscal Year 2007. Accessed May 10, 2009 at: http://www.fda.gov/cdrh/annual/fy2007/ode/report.pdf.

[3] US Food and Drug Administration. *Consumer Complaint/Injury Report.* Rockville, Md; June 10, 2000. LOS-9364.

provided no public patient warning at that time[4, 5]. When Mr. Gleeson needed his faulty pacemaker replaced, he received another potentially faulty device – even though corrected pacemakers had been built and were available. Eight months after receiving FDA approval for the corrected device and nearly 2.5 years after initially learning of the problem, St. Jude Medical finally issued a recall of 163,000 pacemakers, including Mark Gleeson's new unit[6].

I do not recount this story to suggest that St. Jude Medical broke any laws or failed to follow the FDA's rules and regulations. Instead, the story highlights how patients may fail to receive critical information about their medical device's performance and how they may be unnecessarily exposed to potentially faulty products despite the FDA's approval process.

In 1998, the Advisory Commission on Consumer Protection and Quality in the Health Care Industry adopted a Patients' Bill of Rights whose primary tenet is that patients have "the right to receive accurate, easily understood information to assist them in making informed decisions."[7] Regrettably, patients like Mark Gleeson who are undergoing medical device implantation, often fail to receive critical information on device safety. The failure to publicly disclose adverse information about device safety subverts the process of informed consent and prevents patients from making educated treatment choices in consultation with their physician and family.

While Mark Gleeson's case occurred several years ago, it is not an isolated event. Other manufacturers have knowingly sold potentially defective devices without public disclosure[7]. For example, Guidant Corporation identified and corrected a design flaw that could result in the short circuit of an implantable defibrillator, a device that treats both dangerous slow and dangerous fast heart rhythms. The company, however, continued to sell its inventory of potentially defective devices without public disclosure[8].

FDA PRE-APPROVAL EVALUATION

To gain marketing clearance or approval from the FDA for a medical device, a manufacturer must demonstrate reasonable assurance of safety and effectiveness. During the pre-approval evaluation, several factors may limit the ability of the FDA to identify and predict which products will perform safely after approval. Product evaluation may include computer simulations, engineering analyses, non-clinical laboratory testing, animal testing, and human clinical studies. Although many products undergo testing in humans before FDA approval, it is not a requirement.

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[4] Fleckenstein JR. United States Food and Drug Administration: Los Angeles District. *Memorandum: F/U to Consumer Complaint.* Irvine, Calif; September 18, 2000. LOS-9364.

[5] Maisel WH. Malfunctions of implantable cardioverter defibrillators. JAMA 2005; 295: 161-2.

[6] St. Jude Medical. Technical memo: Important advisory information: Premature battery depletion in the Trilogy family of pacemakers. July 9, 1999.

[7] Maisel WH. Semper fidelis – Consumer protection for patients with implanted medical devices. N Engl J Med 2008; 358: 985-987.

[8] Maisel WH. Safety issues involving medical devices. Implications of recent implantable cardioverter-defibrillator malfunctions. JAMA 2005; 294: 955-958.

Unanswered questions regarding device safety and effectiveness often remain at the time of FDA approval. This creates the potential for a large number of patients to be rapidly exposed to a newly approved product in the absence of long-term follow-up data. For example, close to 268,000 patients had been implanted with the Medtronic Sprint Fidelis implantable defibrillator lead before it was recalled in October 2007 after it was determined that the wire was prone to fracture[8]. A fracture of the lead, which connects the implantable defibrillator to the heart, may result in serious health consequences, including painful electrical shocks or death. Human clinical testing had not been required during the Sprint Fidelis pre-approval process.

FDA MANDATED POST-APPROVAL AND POST-CLEARANCE STUDIES

The FDA may require manufacturers to perform post-approval studies as a "condition" of approval to provide on-going evaluation of the device's safety, effectiveness, and reliability after initial marketing approval. These post-approval studies are most often used to: 1) monitor device performance and safety during the transition from clinical trial to real-world use, 2) assess the long term safety, effectiveness, and reliability of the device, and 3) look for infrequent but important adverse events. These studies may also be initiated to evaluate an emerging public health concern in response to reported adverse events.

Despite the obvious importance of these studies in assessing device safety, the FDA and manufacturers have struggled to handle this responsibility. In 2005, the FDA reported that they "couldn't find" 22% of the required post-market medical device studies for the years 1998-2000 and acknowledged that some of the studies were never started[9]. And while efforts have been made to better track these required studies, a visit to the FDA's device post-approval study website on May 10, 2009 demonstrated that more than 1 in 10 manufacturers with on-going post-approval study responsibilities currently had an overdue report[10]. Lest you think that this problem applies only to medical devices, it was reported in April 2008 that 1,044, or 62 percent, of incomplete studies for conventional drugs and biotechnology medications had yet to be started[11]. In 2005, Dr. Susan Gardner, Director of the FDA's Center for Devices and Radiologic Health Office of Surveillance and Biometrics, spoke about the medical device post-approval studies observing that, "it looks like we have a fairly poor track record in getting these studies done"[9].

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[9] U.S. Food and Drug Administration, Center for Devices and Radiologic Health Medical Devices Advisory Committee Circulatory Systems Devices Panel. April 22, 2005. Accessed May 12, 2008 at: http://www.fda.gov/ohrms/dockets/ac/05/transcripts/2005-4108t1.htm

[10] U.S. Food and Drug Administration. Post approval studies. Accessed May 10, 2009 at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm

[11] Blum J. Drugmakers didn't begin 1,044 promised U.S. studies. Accessed May 10, 2009 at: http://www.bloomberg.com/apps/news?pid=20601124&sid=acu6znqklhBo&refer=home

ADVERSE EVENTS AND RECALLS

The FDA annually receives reports of more than 200,000 device-related injuries and malfunctions, and more than 2000 device-related deaths[12]. Although manufacturers are required to report medical device-related adverse events and malfunctions that caused or could cause serious injury or death, not all manufacturers reliably report these events to the FDA. For example, EndoVascular Technologies, a subsidiary of Guidant Corporation, was charged with failing to report more than 2600 device malfunctions, 12 deaths, and numerous other complications related to use of its Ancure Endograft system for aortic aneurysms. In announcing the nearly $100 million dollar settlement, the US Attorney noted that "Because of the company's conduct, thousands of patients underwent surgeries without knowing the risks they faced…"[13]

Although the FDA can theoretically order a product recall in response to observed adverse events or device malfunctions, the vast majority of recalls are voluntarily initiated by the manufacturer. Because of the manufacturers' inherent financial conflict of interest, the timing and extent of the product recalls are often controversial. During fiscal year 2006, 651 recall actions were initiated involving 1,550 products – again reminding us that FDA product approval does not ensure device reliability and performance[12].

PREEMPTION – LOSS OF AN IMPORTANT CONSUMER SAFEGUARD

It is clear that medical device manufacturers have responsibilities that extend far beyond FDA approval and that many companies have failed to meet their obligations. Yet, the U.S. Supreme Court ruled in their February 2008 decision, *Riegel v. Medtronic*, that manufacturers could not be sued under state law by patients harmed by product defects from FDA-approved medical devices[14]. Because their lawsuits are "preempted", consumers are unable to seek compensation from manufacturers for their injuries, lost wages, or health expenses. Most importantly, the *Riegel* decision eliminates an important consumer safeguard - the threat of manufacturer liability – and will lead to less safe medical devices and an increased number of patient injuries. Due to limited resources, the FDA cannot identify every company that fails to fulfill its post-approval obligations. Therefore, additional consumer protections, as offered by the Medical Device Safety Act of 2009, are essential.

CONCLUSIONS

Implanted medical devices have enriched and extended the lives of countless people, but device malfunctions and software glitches have become modern "diseases" that will continue to occur. The failure of manufacturers and the FDA to provide the public with timely, critical information about device performance, malfunctions, and "fixes" enables

[12] Center for Devices and Radiologic Health. CDRH FY 2006 highlights. Accessed May 10, 2009 at: http://www.fda.gov/cdrh/annual/fy2006/fy2006.pdf

[13] Castellucci L. Guidant subsidiary pleads guilty, settles criminal charges related to aortic aneurysm device. Accessed May 10, 2009 at: http://www.theheart.org/viewArticle.do?simpleName=347409

[14] Riegel v. Medtronic, 552 U.S. 2 (2008).

potentially defective devices to reach unwary consumers. Patients like Mark Gleeson are sometimes forced to make life-changing decisions with insufficient and sometimes inaccurate information. We have consumer protections for airline passengers, cable-television customers, and cellular-telephone users, but surprisingly few for patients who receive life-sustaining medical devices. The Medical Device Safety Act of 2009 provides important and necessary safeguards for consumers that will minimize adverse health consequences and improve the safety of medical devices for the millions of patients who enjoy their benefits.

Mr. PALLONE. Thank you.
Dr. Curfman.

STATEMENT OF GREGORY CURFMAN, M.D.

Dr. CURFMAN. I want to thank you for inviting me to participate in this important hearing. My name is Gregory Curfman. I am the executive editor of the New England Journal of Medicine. I will argue that preemption of common law tort actions against medical device companies is ill-advised.

Preemption puts the interest of corporations before the interest of patients. It denies patients their rights and will result in less safe medical devices for the American people.

For nearly 200 years, the New England Journal of Medicine has been publishing articles on innovative drugs and medical devices. We strongly support medical innovation. We are a medical journal. But we are a patient-focused medical journal, and we are committed to patient safety.

Now, Mr. Chairman, innovation and safety are not mutually exclusive. We can and we must have both. 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 are as safe as possible.

Unfortunately, one major stakeholder, the medical device industry, has been shielded from the potential consequences of failing to adequately disclose risks. This was the result of the U.S. Supreme Court decision in Riegel v. Medtronic. Until that ruling, the possibility of litigation for failure to warn or design defect served as a strong incentive for device companies to be vigilant about the safety of their products.

Medical devices are often approved on the basis of only small, short-term clinical trials, and a number of devices have been approved through a fast-track process that does not require any clinical testing at all. The approval process leaves patients vulnerable to safety problems that have gone unrecognized during the premarketing period only to emerge during the postmarketing period. Since the Riegel ruling, as Chairman Waxman has mentioned, thousands of lawsuits against medical device manufacturers have been tossed out of court by judges following the Supreme Court's lead.

Now, litigation or the threat of litigation has been effective in removing potentially harmful medical products from the market, and there are a number of examples. They include the diet pill, dexfenfluramine, or Redux; the COX–2 inhibitor, Rofecoxib or Vioxx; and the cholesterol-lowering drug, cerivastatin or Baycol.

But the examples are not limited to drugs. A number of medical devices have been removed from the market after injuries and litigation, among them, the Dalkon Shield that Professor Vladeck mentioned, the Bjork-Shiley heart valve and recently the Sprint Fidelis cardioverter defibrillator lead that we will hear more about.

Mr. Chairman, let me be clear, I am not here to promote lawsuits. I am here to promote the interest of patients. I oppose preemption because it removes a legal mechanism by which patients who have been harmed can be compensated, and because it will inevitably result in less safe medical devices for the American people.

The way to prevent lawsuits is to put safe medical products on the market.

The Supreme Court's ruling in Riegel was not based on considerations of what is best for the health of the public, but rather on a point of statutory law. In marked contrast to Riegel, the Supreme Court ruling last March in the drug preemption case, Wyeth v. Levine, dismissed Wyeth's argument that failure-to-warn suits against drug companies are preempted by FDA approval of the drug's label.

Now, as the law stands, failure-to-warn and design-defect lawsuits are preempted from medical devices, but not from drugs. This perplexing state of affairs defies all logic.

The Medical Device Safety Act of 2009 addresses this legal inconsistency. The bill would nullify the Court's ruling on Riegel and would thereby place medical devices and drugs on a level playing field with respect to patients' rights. I urge you and your colleagues in Congress to swiftly pass this legislation. The critical issue of preemption should be decided by officials elected by the people.

Mr. Chairman, I hope that this testimony is informative and I look forward to answering any questions that you may have.

Mr. PALLONE. Thank you, Doctor.

[The statement of Dr. Curfman follows:]

The NEW ENGLAND JOURNAL of MEDICINE

TESTIMONY OF GREGORY D. CURFMAN, M.D.
EXECUTIVE EDITOR
NEW ENGLAND JOURNAL OF MEDICINE
BOSTON, MASSACHUSETTS

HEARING: MEDICAL DEVICE SAFETY ACT OF 2009

SUBCOMMITTEE ON HEALTH
HOUSE COMMITTEE ON ENERGY AND COMMERCE

TUESDAY, MAY 12, 2009

Chairman Pallone, Ranking Member Deal, and other distinguished members of the Health Subcommittee, I want to thank you for inviting me to participate in this important hearing. My name is Gregory Curfman, and I am the executive editor of the *New England Journal of Medicine*. I will argue that preemption of common-law tort actions against medical-device companies is ill advised. Preemption puts the interests of corporations before the interests of patients. It denies patients their rights and will result in less safe medical devices for the American people.

For nearly 200 years, the *New England Journal of Medicine* has been publishing articles on new drugs and medical devices. Some have succeeded, but others have failed, in most cases owing to problems with safety. We are a patient-focused medical journal, and much of our work is directed toward ensuring that the potential hazards as well as benefits of medical products are transparently presented in the articles we publish.

Patient Safety: A National Concern

Patient safety is a national concern. But 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] Devices, however, are often approved on the basis of only small clinical trials, and a number of devices have been approved through a fast-track process that does not require any clinical testing at all. The approval process leaves patients vulnerable to safety problems that have gone unrecognized during the premarketing period and emerge only during the postmarketing period.

Preemption and the Medical-Device Industry

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. 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 incentive 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 believe that preemption not only strips patients of their rights but also results in medical devices that are less safe for the American people.

The Case of Sprint Fidelis

In the most 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, 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]

Tort Litigation and the Public Health

Litigation, or the threat of litigation, has been effective in removing potentially harmful medical products from the market. Examples include the diet pill dexfenfluramine (Redux), the COX-2 inhibitor rofecoxib (Vioxx), and the cholesterol-lowering drug cerivastatin (Baycol). But the examples are not limited to drugs. A number of medical devices have been removed from the market after injuries and litigation, among them the Dalkon Shield, the Bjork-Shiley heart valve, and more recently, as just discussed, the Sprint Fidelis cardioverter-defibrillator lead.

We do not promote lawsuits. We nonetheless oppose preemption, because it removes a legal mechanism by which patients who have been harmed can be

compensated and because it will inevitably result in less safe medical devices for the American people. The way to prevent lawsuits is to put safe medical products on the market.

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.[4] The Court, in an 8-to-1 decision, interpreted this clause as demonstrating Congress's explicit intention to preempt state-law damage 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 last March in a drug preemption case, *Wyeth v. Levine,*[5] 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 VI of the U.S. Constitution, which states that federal law is supreme over 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."

Preemption: Drugs versus Devices

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. In contrast, in the FDA Amendments Act of 2007,[6] there is parity between drugs and devices. In establishing a registry for the results of clinical trials, the act made it explicit that the registry applied to clinical trials of not only drugs but also devices.

The Medical Device Safety Act of 2009

To address the legal inconsistency with regard to preemption and to improve the safety of medical products, Congressmen Henry Waxman, chair of the House Committee on Energy and Commerce, and Frank Pallone, chair of the Health Subcommittee, recently introduced the Medical Device Safety Act of 2009.[7] This bill 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 in the interest of the public health, 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 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.

I hope that this testimony is informative, and I look forward to answering any questions that you may have.

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. (http://www.mnd.uscourts.gov/MDL-Fidelis/Orders/2009/090105-08md1905ord.pdf.)
4. Medical Device Amendments of 1976, codified at 21 U.S.C. §360(k)(a).
5. Wyeth v. Levine, 555 U.S. 2 (2009).
6. Food and Drug Administration Amendments Act of 2007, §1102 (codified at 21 U.S.C. §524) (2007).
7. Committee on Energy and Commerce. Health leaders introduce legislation reversing Supreme Court's medical device decision. (http://energycommerce.house.gov/index.php?option=com_content&task=view&id=1518.)

Mr. PALLONE. Ms. Robb.

STATEMENT OF BRIDGET ROBB

Ms. ROBB. Chairman Pallone and members of the Health Subcommittee, thank you for inviting me to speak to you about my personal experiences with the faulty medical device and my reasons for supporting the Medical Device Safety Act, H.R. 1346.

My name is Bridget Robb, and I am a 35-year-old mother and resident of Gwynedd, Pennsylvania. On December 31, 2007, I suffered greatly and thought I was going to die because of a defective heart device implanted in my body. I am thankful to be here today, and I am pleased that Chairman Pallone has reintroduced medical safety—the Medical Device Safety Act which would restore the right of patients like me to hold manufacturers accountable when their products cause injury and sometimes even death.

Approximately 5 years ago, I was diagnosed with nonischemic viral cardiomyopathy and congestive heart failure. In May of 2005, to prevent me from dying from a fatal arrhythmia, I had a Medtronic cardiac defibrillator implanted in my chest. This heart device is a small metal case that contains electronics and a battery. Its components work much like a pacemaker, but unlike a pacemaker, an ICD delivers an electrical shock to the heart when the heart rate becomes dangerously fast.

On December 31, 2007, I was awoken from my sleep by a series of shocks in my heart which felt as if a cannon was being repeatedly shot at my chest at close range. Along with these recurrent shocks was a strong electrical current racing through my body.

After feeling the first shock, I immediately phoned 911 for help. My then 6-year-old daughter, Emma, had snuck into bed with me that night and was present during this horrific experience. I remember Emma being scared and confused. She crouched down in front of me, hugging her cat and saying, Mommy is dying. She was present during the entire 7 minutes I was on the telephone with the 911 operator until the EMS arrived. I cannot imagine how terrified she must have been to see her mother in such pain.

My doctors have told me that I received a total of 31 dangerous shocks to my heart in a matter of minutes that morning. Each time I was shocked, I saw my life flash before my eyes. It was excruciating pain. At one point I began to pass out and thought that I would never see Emma again.

Every day since then, I have been unable—ever since that day, I have been unable to sleep in my own bed due to the trauma that I have experienced. I later learned that the agonizing shocks and electricity coursing through my body was caused by a defective cardiac lead implanted in my heart, the Sprint Fidelis lead manufactured by Medtronic. A lead is a thin wire that connects the ICD to the heart and delivers the actual shock to the heart when is beating too fast. Medtronic's Sprint Fidelis lead was recalled on October 15, 2007, because of its potential to fracture. Despite receiving over 1,000 complaints about the defective lead, it took Medtronic 3 years to issue this recall.

Since this terrifying experience, my health has declined significantly. I visit doctors weekly because of my ongoing health issues due to this event. After the inappropriate shocking from my lead,

I underwent surgical replacement of my defibrillator and defective lead and a second surgery to adjust the new lead. My second surgery resulted in an extended hospital stay where I had to undergo a blood transfusion.

Most recently in September of 2008, my incision ulcerated and became extremely painful. I was hospitalized a series of times, once for 2 weeks straight, in an effort to cure this problem. To prevent an infection to the hardware in my chest, my doctors ultimately decided to remove my defibrillator altogether. Right now, my doctors continue to try and stabilize my decreased heart function, and I take various medications that carry serious health risks which I never took before.

As you would expect, I risk serious harm each time another procedure is performed. From the time between my diagnosis in 2004 and the horrifying shocking in December of 2007, I was never hospitalized for my heart failure except to have my defibrillator implanted. My heart function had significantly increased due to my medications, and I had a good outlook from my doctors. However, since my defective lead misfired, I have been hospitalized at least 8 times, mostly for 1 to 2 weeks at a time, and my heart function is much lower than it used to be.

I am a single mother, so as you can imagine, this has been trying for both my daughter Emma and myself. Each time I am hospitalized, it becomes more difficult on my daughter, since she is afraid that one of these times I won't come home.

Even though Medtronic's defective device caused my injury, my health insurance plan has been paying for the cost of my medical care. It is wrong to shift the cost of medical care from the responsible party to private insurers, patients and, in some cases, to taxpayer-sponsored programs like Medicare and Medicaid.

I would like to have the opportunity to hold Medtronic accountable for the injuries that I suffered that day and the physical and emotional aftereffects that I continue to experience on a daily basis. I find it discouraging and demoralizing that I have no recourse for my injuries and that a company that manufactured a defective product that has harmed me and thousands of other individuals has no accountability.

I encourage Congress to act quickly and pass the Medical Device Safety Act. It is extremely important that injured patients have a remedy for their injuries and that the cost of their medical expenses and other needs are not borne by Medicare, private insurance, employees and patients themselves. The medical device industry should be accountable for their products just like the drug companies or any other industry.

Thank you for your commitment to this critical issue. I am happy to answer any questions that you may have.

Mr. PALLONE. Thank you, Ms. Robb. Thanks so much for being here.

[The statement of Ms. Robb follows:]

Statement of Bridget Robb

Gwynedd, PA

Before the Health Subcommittee of

the House Energy and Commerce Committee

For a hearing on the Medical Device Safety Act of 2009

Tuesday, May 12, 2009

Chairman Pallone and Members of the Health Subcommittee:

Thank you for inviting me to speak to you about my personal experiences with a faulty medical device and my reasons for supporting the Medical Device Safety Act, H.R. 1346.

My name is Bridget Robb, and I am a thirty-five year old mother and resident of Gwynedd, Pennsylvania. On December 31, 2007, I suffered greatly and thought I was going to die because of a defective heart device implanted in my body. I am thankful to be here today and am pleased that Chairman Pallone has reintroduced the Medical Device Safety Act, which would restore the rights of patients like me to hold device manufacturers accountable when their products cause injury and sometimes, even death.

Approximately five (5) years ago, I was diagnosed with non-ischemic, viral cardiomyopathy and congestive heart failure. In May 2005, to prevent me from dying from a fatal arrhythmia, I had a Medtronic cardiac defibrillator implanted in my chest. This heart device is a small metal case that contains electronics and a battery. Its components work much like a pacemaker, but unlike a pacemaker, an ICD delivers an electrical shock to the heart when the heart rate becomes dangerously fast. My particular device combined a pacemaker and ICD in one unit.

On December 31, 2007, I was awoken from my sleep by a series of shocks to my heart which felt as if a cannon was being repeatedly shot at my chest at close range.

Along with these recurrent shocks was a strong, electrical current racing through my body. After feeling the first shock, I immediately phoned 9-1-1 for help. My then six-year old daughter, Emma, had snuck into bed with me that night and was present during this horrific experience. I remember Emma being scared and confused. She crouched down in front of me hugging our cat, saying "Mommy's dying." She was present during the entire seven minutes that I was on the telephone with the 911 operator until the EMS arrived. I cannot imagine how terrified she must have been to see her mother in such pain.

My doctors have told me that I received a total of thirty-one (31) dangerous shocks to my heart in a matter of minutes that morning. Each time I was shocked, I saw my life flash before my eyes. It was excruciating pain. At one point, I began to pass out and thought that I would never see Emma again. Ever since that day, I have been unable to sleep in my own bed due to the trauma I experienced.

I later learned that the agonizing shocks and electricity coursing through my body was caused by a defective cardiac lead implanted in my heart, the Sprint Fidelis lead manufactured by Medtronic. A lead is a thin wire that connects the ICD to the heart and delivers the actual shock to the heart when it is beating too fast. Medtronic's Sprint Fidelis lead was recalled on October 15, 2007, because of its potential to fracture. Despite receiving over a thousand complaints about the defective leads, it took Medtronic three years to issue this recall.

Since this terrifying experience, my health has declined significantly. I visit doctors almost weekly because of my ongoing health issues due to this event. After the inappropriate shocking from my lead, I underwent surgical replacement of my defibrillator and defective lead, and a second surgery to adjust the new lead. My second surgery resulted in an extended hospital stay where I had to undergo a blood transfusion.

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I would like to have the opportunity to hold Medtronic accountable for the injuries that I suffered that day and the physical and emotional after-effects that I continue to experience on a daily basis. I find it discouraging and demoralizing that I have no recourse for my injuries, and that a company that manufactured a defective product that has harmed me and thousands of other individuals has no accountability.

I encourage Congress to act quickly and pass the Medical Device Safety Act. It is extremely important that injured patients have a remedy for their injuries and that the costs of their medical expenses and other needs are not borne by Medicare, private insurance, employers and the patients themselves. The medical device industry should be accountable for its products just like drug companies or any other industry.

Thank you for your commitment to this critical issue. I am happy to answer any questions that you may have.

TRANSPERFECT

TRANSCRIPTION OF AUDIO

9-1-1 CALL

[Audio Begins]

Dispatch Operator: 9-1-1, where's your emergency?

Caller: Oh, God, help. 9-1-1.

Dispatch Operator: Okay, what's goin' on?

Caller: Oh (unintelligible), my defibrillator went off.

Dispatch Operator: Okay, where do you live, ma'am?

Caller: Help, I'm in the cottage.

Dispatch Operator: Okay, what's your address?

Caller: 404 Swedesford Road. Hold on, my defibrillator, I'm young, I don't wanna die.

Dispatch Operator: Okay, okay, okay.

Caller: Can you call my uncle?

Dispatch Operator: Ma'am, how old are you?

Caller: Please? I'm 33.

Dispatch Operator: You're 33?

Caller: Yeah. Ow, damn it, (edited), (edited), please, 9-1-1, please.

Dispatch Operator: Ma'am, what's your -- what's your closest cross streets?

Caller: (Unintelligible) help (unintelligible).

Dispatch Operator: Okay, ma'am, while I'm talkin' to you, I have the ambulance being dispatched, okay?

Caller: (Unintelligible) hang up.

Dispatch Operator: Okay, they're on their way, okay?

Caller: Alright, bye.

Dispatch Operator: Ma'am?

Caller: Yes?

Dispatch Operator: What's your name?

Caller: Bridget.

Dispatch Operator: Bridget?

Caller: Yeah.

Dispatch Operator: What's your last name, Bridget?

Caller: Robb.

Dispatch Operator: And you're at 404 --

Caller: Oh, God help me. It's going off (unintelligible) on me. Oh, no.

Dispatch Operator: You're -- Bridget, Bridget, they're on their way.

Caller: Ow, oh, God. It won't stop.

Dispatch Operator: Okay is anybody there with you?

Caller: My daughter is five, six.

Dispatch Operator: Your daughter is five or six?

Caller: I -- I love you, I'm sorry, I keep dropping the phone and --

Dispatch Operator: No, no, it's okay listen to me. Listen to me, okay?

Caller: Uh --

Dispatch Operator: Are you in Upper Gwynedd Township?

Caller: Yes.

Dispatch Operator: Okay listen, they're on their way while --

Caller: Ow, (edited). I'm sorry.

Dispatch Operator: No, it's okay. When did this start?

Caller: Like when I woke up last week. Ow, (edited), how long does it out there. This hurts. Am I dying?

Dispatch Operator: They're -- they're on their way.

Caller: God, please don't die.

Dispatch Operator: Okay, how long have you --

Caller: I don't wanna die.

Dispatch Operator: -- how long have you had this? When did you get this defibrillator?

Caller: Uh, (unintelligible).

Dispatch Operator: When did you get it?

Caller: Ah, in five months -- I've been living here two years.

Dispatch Operator: You've had it for two years?

Caller: Yeah, I'm so dizzy. Ah.

Dispatch Operator: Okay, Bridget? Bridget?

Caller: I'm trying to call my uncle, hold on. Are you there? Can you come over quickly? I need help, help, please. Yeah, ow, (edited), oh my God.

Dispatch Operator: Bridget, Bridget.

Caller: Huh?

Dispatch Operator: I'm gonna keep you on the phone.

Caller: Are they coming? Are they coming?

Dispatch Operator: Yes, they're on their way, Bridget, while I'm talking to you.

Caller: Ow, (edited), oh my gosh, I can't handle this anymore. It hurts so bad.

Dispatch Operator: They're -- they're on their way, Bridget.

Caller: How do you stop this?

Dispatch Operator: I know, it feels like forever. They're on their way.

Caller: Oh, I'm not gonna die. I'm sick. They're getting stronger.

Dispatch Operator: Okay.

Caller: They're getting stronger.

Dispatch Operator: The shocks are getting stronger?

Caller: Yes. Where's the ambulance? Hurry.

Dispatch Operator: It's on its way.

Caller: How, how far away?

Dispatch Operator: I, I don't know how far, but it -- trust me, it's on its way, okay?

Caller: I'm gonna pass out. I'm 'bout to pass out.

Dispatch Operator: I want you to stay on the phone with me. Stay with me as long as you can, okay?

Caller: I can't. I'm gonna pass out.

Dispatch Operator: Trust me.

Caller: Ow, ow. This thing hurts. Ow. Ow. My defibrillator keeps going off. 9-1-1, coming.

Dispatch Operator: Who's there with you?

Caller: Ow, I'm dying. Oh my God (unintelligible). Stop this thing.

Dispatch Operator: Bridget?

Caller: Huh?

Dispatch Operator: Who's there with you?

Caller: My uncle.

Dispatch Operator: Your uncle's there with you?

Caller: I think I'm dying. Everything I did is gonna be like 10 times now. You don't understand how this hurts.

Dispatch Operator: I, I, I can understand that, Bridget and they are on their way. I know it feels like forever. They are on their way.

Caller: Oh, I'm about ready to die. God, please don't take me, God, please.

Dispatch Operator: Bridget, why did you get the defibrillator?

Caller: I, I have cardiomyopathy.

Dispatch Operator: Card - myopathy?

Caller: Cardiomyopathy, congestive heart failure.

Dispatch Operator: Okay, okay. Is it below your skin?

Caller: Oh my heart hurts. It's under my chest.

Dispatch Operator: It's under your chest? Okay and you got it two years ago?

Caller: Yeah.

Dispatch Operator: Okay.

Caller: Oh, God this is so bad. It's gonna be okay.

Dispatch Operator: They're on their way.

Caller: How far away are they?

Dispatch Operator: I wanna keep you on the phone, okay?

Caller: Okay.

Dispatch Operator: While I'm talkin' to you, I know it feels like forever.

Caller: It hurts.

Dispatch Operator: I know it does. I'm sure.

Caller: Ah.

Dispatch Operator: Bridget, where's your uncle?

Caller: He's right next to me.

Dispatch Operator: Okay and where's your -- you have a young daughter?

Caller: I have my daughter, yeah.

Dispatch Operator: Okay and she's there with you?

Caller: Yeah.

Dispatch Operator: Okay, you haven't gotten shocked in these last couple minutes?

Caller: No -- not since I last told you.

Dispatch Operator: Okay, okay and I want you to deep -- deep breaths for me that last --

Caller: I'm (unintelligible) pretty much hazy.

Dispatch Operator: I'm, I'm sure you are.

Caller: Ah. What hospital are they takin' me to?

Dispatch Operator: You'll have to talk to them about that Bridget, okay?

Caller: Okay.

Dispatch Operator: That's gonna be -- that's gonna be up to them.

Caller: Okay.

Dispatch Operator: I actually have a police officer who is almost there to you.

Caller: All right, hurry.

Dispatch Operator: And the ambulance shouldn't be too far behind him, okay?

Caller: Okay. Ah. How long we been on the phone?

Dispatch Operator: We've only been on the phone for a few minutes. I know it feels like forever, especially when you don't feel good. It feels like they take forever, but trust me, they don't take forever. I know it --

Caller: Oh, I'm gonna die.

Dispatch Operator: I know it feels that way. They're gonna get there and they're gonna help you, okay? Can your uncle get your med -- are you on medication?

Caller: Yeah, I'm on a lot of medicine.

Dispatch Operator: Can -- can you ask him to get your medication together so when the ambulance gets there?

Caller: Yeah.

Dispatch Operator: Okay.

Caller: Can you get my medicine for me?

Dispatch Operator: Just so they have it right there.

Caller: It's on the kitchen counter.

Dispatch Operator: They can look at it when they get there, okay?

Caller: Okay.

Dispatch Operator: All right.

Caller: Yeah, I'm on the phone. Hi, how are you? The police just got here.

Dispatch Operator: Okay, Bridget, I'm gonna hang up with you, okay?

Caller: Okay.

Dispatch Operator: All right.

Caller: Bye.

Dispatch Operator: Bye.

[End of Audio]

Mr. PALLONE. Mr. Cooper.

STATEMENT OF RICHARD COOPER

Mr. COOPER. Thank you, Mr. Chairman, members of the subcommittee for inviting me to testify here today. I am here on my own, not representing any organization.

I would like to make three points. The first is, a number of the opening statements refer to what the members called defective devices. The fundamental issue here is who ultimately decides whether a device is defective. Is it the physician, the engineers, the material scientists, the chemists, the statisticians and other experts at FDA; or is it juries and judges in the 50 States and other jurisdictions that will hear products-liability cases?

By what process should that decision be made? By people who review enormous volumes of data, who over time, even after approval, receive reports from manufacturers of malfunctions or injuries, who can commission special studies, who can send inspectors into manufacturing plants to review all of the manufacturing records and interview the employees who design and manufacture the products? Or should it be people who listen to a couple of lawyers rant at them and observe witnesses being examined and cross-examined?

And what perspective should guide that decision-making? The perspective of people who look at all those who will use a device, those who will benefit from it as well as those who will suffer from malfunctions? Or a group that spends day after day in court observing an injured plaintiff?

I submit to you that the ultimate decision should be made by the Food and Drug Administration which, if properly funded and subject to proper oversight, is a national treasure.

Second, products-liability law is not insurance; it is about fault. And a manufacturer that puts on the market a product with a design approved by the Food and Drug Administration with the perspective I have described, by the experts I have described and with the procedure I have described is not at fault for marketing a device with that design and, similarly, for other aspects of a device that FDA approves.

Third, the concern about the effect of products-liability litigation on incentives for innovation is not mere theory. It is real.

A number of years ago, I served on a committee of the Institute of Medicine that issued a report. The report came out in 1990, called Developing New Contraceptives: Obstacles and Opportunities. And one of the principal obstacles to innovation in that medical field that the committee, which included primarily physicians—that the committee identified was products-liability.

It summarized its conclusion from its analysis as follows; I quote from its report: "Without changes in the products-liability rules and procedures, it appears likely that even fewer firms will allocate even fewer resources to contraceptive research and development," closed quote. That is just one small medical field, and indeed a field that probably doesn't involve devices to which preemption under Riegel would apply.

But the effects of products-liability risks are great. Most medical device companies are small. To develop a product in a field that

has great risks of litigation is to bet the company on every product, and that is imprudent when there are other things that can be done.

Since 1990 and this report was issued, there hasn't been a lot of innovation in contraception. And there are other medical fields which are underserved due to liability risks. So that is something I would suggest you consider.

This isn't corporations versus people. This is how best to serve people, how best to serve patients who need medical devices, whose lives are supported or sustained by medical devices and whose adverse health conditions can be greatly alleviated by them if companies have the incentive to develop them and they are presented to FDA for its review.

Thank you.

Mr. PALLONE. Thank you, Mr. Cooper.

[The statement of Mr. Cooper follows:]

BEFORE THE SUBCOMMITTEE ON HEALTH
OF THE HOUSE COMMITTEE ON ENERGY AND COMMERCE

MAY 12, 2009

STATEMENT OF RICHARD M. COOPER

Mr. Chairman and Members of the Subcommittee, thank you for inviting me to testify on H.R. 1346, The Medical Device Safety Act of 2009, a bill to amend the Federal Food, Drug, and Cosmetic Act ("FDCA") with respect to liability under State and local requirements respecting devices. Although the law firm of which I am a partner represents a number of companies interested in the topic of this hearing, I was invited to appear, and I am appearing, on my own, and not on behalf of my law firm or any client.

I was Chief Counsel of FDA during the Carter Administration. Since then, I have practiced food and drug law at the law firm of Williams & Connolly LLP, have taught food and drug law at Georgetown University Law Center, and have served on committees, published articles, and edited or co-edited books in the field.

H.R. 1346 would overturn the Supreme Court's decision last year in *Riegel v. Medtronic, Inc.*[1] That decision interpreted a provision of the FDCA that expressly preempts any state-law requirement with respect to a device that (i) is different from or in addition to any requirement applicable

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1 128 S. Ct. 999 (2008).

under the FDCA to the device and (ii) relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the FDCA.[2] The Court held that the FDCA's preemption provision bars common-law claims challenging the safety or effectiveness of a medical device marketed in accordance with a premarket approval application ("PMA") approved by FDA.

I want to make seven points.

First, the supremacy of federal law over state law, operating through the doctrines of express and implied preemption, is fundamental to our federal system, and is expressly authorized by the Constitution. Without preemption, the 50 States and other American jurisdictions would apply their own bodies of law, businesses and other organizations operating in interstate commerce could be subjected to conflicting duties, and the many benefits of a national legal system and a national economy would be greatly diminished.

Second, *Riegel* was not an innovation in the law, and was decided correctly. It was not a close case. Eight Justices concurred in the Court's judgment, and seven joined the opinion of the Court. The decision was anticipated by a substantial majority of the federal courts of appeals that had considered the issue.[3]

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[2] 21 U.S.C. § 360k(a) (2006).

[3] Richard A. Nagareda, *FDA Preemption: When Tort Law Meets the Administrative State*, 1 J. Tort L. 1, 14 (2006).

Riegel also was plainly foreshadowed by prior decisions of the Supreme Court that stretch back to the period before the enactment of the Medical Device Amendments of 1976 ("MDA").[4] In 1959, the Court observed that "regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy."[5] *Cipollone v. Liggett Group, Inc.*, decided in 1992,[6] confirmed that, under the Supremacy Clause of the Constitution,[7] theories of liability that support judgments in products-liability cases can constitute state-law requirements that are preempted by federal action. A majority of the Court adhered to that holding in *Medtronic, Inc. v. Lohr* in 1996.[8] In 2002, a unanimous Court in *Sprietsma v. Mercury Marine* stated in *dictum*: "Of course, if a state common-law claim directly conflicted with a federal regulation promulgated under the Act, or if it were impossible to comply with any such regulation without incurring liability under state common law, pre-emption would occur."[9]

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4 Pub. L. No. 94-295, 90 Stat. 539 (1976).

5 *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 246-47 (1959).

6 505 U.S. 504 (1992).

7 U.S. Const. art. VI, cl. 2.

8 518 U.S. 470 (1996). *See id.* 503-04 (Breyer, J., concurring in part and concurring in the judgment), 509-12 (O'Connor, J., joined by Rehnquist, C.J., Scalia & Thomas, JJ., concurring in part and dissenting in part).

9 537 U.S. 51, 65 (2002).

Moreover, *Riegel* and the cases that foreshadowed it did not come out of the blue. Rather, they reflect widely-supported mainstream trends in judicial and scholarly understanding of products-liability law and of the role of federal agencies in administering regulatory statutes enacted by the Congress.

Products-liability theories are widely understood as a type of regulation of manufacturers' conduct. That system of regulation is administered by judges and juries *ad hoc* and with a focus on a particular allegedly injured plaintiff or group of plaintiffs, and without the presence in the courtroom of those users of the product who have benefited from it.[10] Thus, products-liability theories constitute a kind of regulation "in disguise."[11]

It has long been obvious that regulatory agencies such as FDA are far more expert in their areas of regulatory activity than are judges and juries, and that they have the advantage of being able to apply criteria of effectiveness and safety to product design and criteria of truthfulness and adequacy to product labeling *ex ante* and with all potential users in mind, in contrast to the *ex post* perspective presented to judges and juries by an individual plaintiff or group of plaintiffs complaining of a grievous injury. In

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10 *See generally* Nagareda, *supra* note 3, at 38-39.

11 *See id.* at 38 & n. 143 (internal quotation omitted).

addition, since the Supreme Court's decision in *Chevron* in 1984,[12] it has been clearly understood that federal agencies administering regulatory statutes are more politically accountable as regulators (including to congressional committees and subcommittees, such as this one) than are judges and juries, and that therefore courts are to defer to them not only in their application of expertise to technical matters but also in their institutional interpretations of statutory ambiguities.[13]

The *Harvard Law Review*, after a thorough analysis, concluded that *Riegel* strikes the proper balance between the interest of patients generally in having a single, authoritative federally-managed system for regulating medical devices and the interest of individual patients in receiving from state tort systems compensation for injuries from devices:

> Despite criticisms that it leaves tort victims uncompensated, preemption is necessary to ensure that federal regulatory agencies, like the Food and Drug Administration (FDA), are the only governmental actors able to impose requirements on manufacturers — thereby ensuring a nationally standardized system of safety regulations without myriad local variations. *Riegel* extends an evolving MDA jurisprudence that empowers this federal system, while preserving common law claims when the regulation systematically provides inadequate safety assurances . . . .
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> . . . .
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> *Riegel* is the most recent step in a body of preemption precedent pertaining to medical devices; these cases must balance the effective regulatory power of the federal government and the ability of tort victims to seek compensation for their injuries.

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12 *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984).

13 *See generally* Nagareda, *supra* note 3, at 38-39.

While acknowledging the supremacy of federal regulation, the Supreme Court's preemption jurisprudence has recognized that the FDA does not strictly regulate all medical devices on the market, nor can it ensure safety in all situations. Common law claims have thus been allowed to proceed when the federal regulatory system is systematically avoided — as when the device is not subject to regulation — or when it is unable to protect the public — as with manufacturer noncompliance. The Court has repeatedly decided cases according to the underlying principle that state law claims are only precluded if federal safety requirements have been satisfied . . . .

Through the MDA, Congress created a superseding federal system of regulation to ensure the safety of medical devices. In so doing, Congress vested the FDA with the power to approve — through a rigorous process — new devices before they may be marketed. Through its express preemption, the MDA made the FDA the only arbiter of appropriate regulation. (In fact, some commentators have suggested increasing the role of the FDA in determining the outcome of product liability suits.) As Justice Scalia argued, to allow state common law claims to proceed against a properly screened medical device in the face of the preemption provision would grant a single jury greater power than even state legislatures — a "perverse distinction" not mandated by the MDA. By precluding some tort suits, *Riegel* accepted that some consumers hurt by pre-approved products will be uncompensated, which is a necessary cost of prioritizing the federal system.

However, preemption does not automatically apply to all medical devices. As a threshold matter, the MDA does not preempt suits relating to devices that are not subject to the extensive federal regulation at issue in *Riegel*. If the device was not required to comply with the most stringent federal safety requirements, its manufacturer cannot use FDA approval as a liability shield. As the *Riegel* majority discussed, the *Lohr* Court preserved causes of action against products that did not go through the premarket approval process, but only through "substantial equivalence" review . . . . Thus, if the federal regulatory system has not approved the medical device, regulation through common law claims is allowed — and expected — to fill this gap.

Even if a device has been screened by the premarket approval process, the tort system catches some cases that fall through the cracks in federal safety regulation — if the cracks are

> the result of manufacturer noncompliance. Manufacturers are not immunized from tort suits if they violate FDA regulations. Importantly, the MDA does not preempt "parallel" state claims; nothing in the statute "prevent[s] a State from providing a damages remedy for claims premised on a violation of FDA regulations." . . .
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> . . . .
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> Although *Riegel* appears to be a broad preemption precedent, its scope is couched within a system of supreme federal regulation and supplementary common law claims. The Court's finding that the MDA's express preemption provision precluded the Riegels' state tort claims was the next step in a jurisprudence that finds preemption when federal requirements have been satisfied. However, this preemption only applies to medical devices that undergo the extensive premarket approval process; manufacturers who do not comply or who perpetrate fraud are likely to find themselves still subject to tort liability. Rather than completely deprive consumers of the protection provided by state common law actions, the Supreme Court's MDA-related decisions have struck a balance — protecting consumer safety through a complementary system of federal regulation and state civil actions.[14]

The Supreme Court also held in *Lohr* that the generality of the requirements applicable in FDA's clearance of medical devices under the section 510(k) process[15] precluded preemptive effect for such clearances, but it explained that that generality

> make[s] this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.[16]

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14 *The Supreme Court 2007 Term – Leading Cases*, 122 Harv. L. Rev. 405, 410-12, 414-15 (2008) (footnotes omitted), *available at* http://www.harvardlawreview.org/issues/122/nov08/leadingcases/riegel_v_medtronic.pdf.

15 *See* 21 U.S.C. § 360(k) (2006).

16 518 U.S. at 501.

Riegel presented that very case.

Third, as interpreted and applied in *Riegel*, medical device preemption of products liability claims has very limited scope. *Lohr* and *Riegel* leave unchanged the availability of products-liability claims relating to devices that have not gone through the PMA process, but, rather have gone through the section 510(k) process or are exempt from both – and those are all of the class I and class II devices and the vast majority of class III devices.[17] Thus, as to all but a very small percentage of devices – less than 1%[18] – *Lohr* and *Riegel* provide no preemption defense based on FDA approval.

Moreover, under those cases, if a manufacturer materially violates a relevant condition of its approval, or violates some other requirement under the FDCA, it may be held liable under a traditional state-law products-liability theory that seeks to enforce a state-law requirement that adopts, or otherwise is the same as, the federal condition or requirement.[19] Thus, those cases leave intact the regulatory function of traditional products-liability law in providing incentives for compliance with state-law requirements that, in effect, enforce FDA requirements. In sum,

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17 *See Riegel*, 128 S. Ct. at 1004; *Lohr*, 518 U.S. at 479; *see also* 21 U.S.C. § 360e(a) (2006); 21 C.F.R. § 807.85 (2008).

18 Statement of Dr. Randall Lutter before the H. Comm. on Oversight and Government Reform 7 n.2 (May 14, 2008), *available at* www.fda.gov/ola/2008/stateliability051408.html.

19 Not every "violation of the FDCA will support a state-law claim," however. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001).

Riegel and the current overall judicial interpretation of medical-device preemption do not grant manufacturers blanket immunity. Far from it: as to most devices and as to most violations of traditional state-law requirements that seek to enforce FDA requirements, they leave products-liability law free to operate.

H.R. 1346 is not needed to provide appropriate compensation under products-liability law for injured users of medical devices. Under products-liability law, manufacturers are not insurers. Their liability to compensate injured plaintiffs always is to be based on some type of fault – most commonly, their marketing of a product that is defectively designed, manufactured or labeled or their negligence with respect to one or more of those aspects of a product. Under products liability law properly applied, where a manufacturer is not at fault, it should not be liable. A manufacturer that complies with requirements imposed by FDA through the PMA-approval process is not at fault for so complying without doing something additional or different. Thus, *Riegel* is fully consistent with the limited compensatory purpose of products-liability law.

Fourth, as described by FDA, the PMA process under section 515 of the FDCA[20] is

> the most stringent type of device marketing application required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient

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20 21 U.S.C. § 360e (2006).

> valid scientific evidence to assure that the device is safe and effective for its intended use(s)."[21]

The Supreme Court has described the process as "rigorous"[22]:

> A manufacturer must submit what is typically a multivolume application. It includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a "full statement" of the device's "components, ingredients, and properties and the principle or principles of operation"; "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device"; samples or device components required by the FDA; and a specimen of the proposed labeling. Before deciding whether to approve the application, the agency may refer it to a panel of outside experts and may request additional data from the manufacturer.
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> The FDA spends an average of 1,200 hours reviewing each application and grants premarket approval only if it finds there is a "reasonable assurance" of the device's "safety and effectiveness." The agency must "weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." It may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives . . . .
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> The premarket approval process includes review of the device's proposed labeling. The FDA evaluates safety and effectiveness under the conditions of use set forth on the label and must determine that the proposed labeling is neither false nor misleading.[23]

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21 FDA Device Advice, Review Process Overview (Nov. 21, 2002), *available at* http://www.fda.gov/cdrh/devadvice/pma/.

22 *Lohr*, 518 U.S. at 477.

23 128 S. Ct. at 1004 (citations omitted).

Thus, FDA approval of a PMA for a medical device constitutes FDA approval of the physical aspects of the device and its labeling, results from a comprehensive review of the scientific and medical information relevant to the effectiveness and safety of the device, and reflects FDA's detailed resolution of tensions between those aspects of the device that confer therapeutic benefits and those that present risks to safety. Such a federal decision presents the strongest case for preemptive effect.

Where an adequately informed FDA has weighed the advantages and disadvantages of, and has approved, the design and labeling of a particular product, decision-makers applying state law should not be permitted to second-guess FDA's approval – or re-weigh benefits and risks FDA has already weighed, or revise trade-offs FDA has already found acceptable – by finding the product's design or labeling inadequate. Permitting decision-makers applying state law to do so would create conflicts with FDA-imposed requirements, and would create obstacles to the achievement of the objectives of the FDCA.

Fifth, FDA has broad authorities and regulatory systems to monitor the safety of medical devices after approval, to require changes to enhance safety, and to bring about withdrawal of a product from the market if new information warrants such action.[24] The means available to FDA to

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[24] *See generally* FDA, Center for Devices and Radiological Health, *Ensuring the Safety of Marketed Medical Devices[:] CDRH's Medical Device Postmarket Safety Program* (Jan. 18, 2006), *available at* www.fda.gov/cdrh/postmarket/mdpi-report.pdf.

obtain safety-related information include: FDA inspections[25]; mandatory reports of adverse experiences by device user facilities, manufacturers, and importers[26]; other reports by manufacturers[27]; voluntary reports of adverse events by healthcare providers and patients; postmarket surveillance[28]; review of medical literature, monitoring certain listservs, and cooperative arrangements with other organizations, both governmental and private, that are concerned with public health. Remedial actions available to FDA include: restrictions on distribution[29]; notification, repair, replacement, refund, and recall.[30] The agency can conduct a variety of risk-communication and other educational activities directed to manufacturers, healthcare providers, and patients. FDA can bring about changes in labeling through enforcement action against a device it considers misbranded.[31] As a practical matter, FDA can end the use of a product immediately by exercising its authority to call publicly for an end to such use.[32] The agency can also suspend or withdraw

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25 *See* 21 U.S.C. § 374 (2006).

26 *See* 21 U.S.C. § 360i(a)-(c) (2006); 21 C.F.R. pt. 803 (2008).

27 See 21 U.S.C. § 360i (2006); 21 C.F.R. pt. 806, § 814.84 (2008).

28 *See* 21 U.S.C. § 360l (2006); 21 C.F.R. § 814.82, pt. 822 (2008).

29 *See* 21 U.S.C. § 360j(e) (2006).

30 *See* 21 U.S.C. § 360h (2006); 21 C.F.R. pt. 810 (2008).

31 *See* 21 U.S.C. §§ 331(a), 332-334, 337, 352 (2006).

32 *See* 21 U.S.C. § 375 (2006).

its approval of a device,[33] or ban it.[34] Congress has also specifically provided for FDA to make use of an advisory committee on communication of information on product-related risks.[35]

Products-liability litigation sometimes brings to light information about medical products that was not previously known. The discovery process in litigation, however, is very costly and inefficient. FDA could obtain much the same information through effective use of tools it already has – mandatory reporting of adverse events and submission of periodic reports by manufacturers,[36] and use by FDA of its authority to inspect in a manufacturing establishment

> all things therein (including records, files, papers, . . .) bearing on whether . . . restricted devices which are adulterated or misbranded . . . or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale . . . have been or are being manufactured . . . in any such place, or otherwise bearing on violation of [the FDCA].[37]

Thus, without dependence on private products-liability litigation, FDA has broad authority to obtain from manufacturers information they have and it needs to monitor the safety of marketed prescription restricted devices. FDA can also receive voluntary reports of adverse events associated with devices

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33 *See* 21 U.S.C. § 360e(e) (2006).

34 *See* 21 U.S.C. § 360f (2006); 21 C.F.R. pt. 895 (2008)

35 *See* 21 U.S.C.A. § 360bbb-6(a) (West 2009).

36 *See* 21 C.F.R. §§ 803.1-.58, 814.82, 814.84 (2008).

37 21 U.S.C. § 374(a)(1) (2006).

from physicians, healthcare facilities, and patients. That better systems and methods are needed generally to monitor the safety of medical products after they have been approved is a problem that is independent of the preemption doctrine, and is not solved by litigation. Significant improvements are likely, moreover, when medical records are stored and transmitted electronically rather than in hard copies, and FDA's Sentinel Initiative seeks to make such improvements.[38]

Sixth, H.R. 1346 is not justified by arguments that FDA is ill-equipped to protect the public, that the agency is under-funded, inadequately managed, and makes mistakes.[39] The proper response to those criticisms is not to declare open season for unrestrained regulation by judges and juries (who lack FDA's expertise and broad public-health perspective), but for the Congress to fund FDA adequately and to conduct effective oversight of its management and performance, so as to reduce mistakes to the minimum humanly achievable. The Congress has already taken steps, in the Food and Drug Administration Amendments Act of 2007 ("FDAAA"), to provide FDA with additional tools to improve its performance[40]; and the President's budget

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38 *See* FDA's Sentinel Initiative, *available at* www.fda.gov/oc/initiatives/advance/sentinel/.

39 *See generally*, David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts To Preempt Failure-To-Warn Claims*, 96 Geo. L.J. 461 (2008).

40 Pub. L. No. 110-85, 121 Stat. 823 (2007).

for FY 2010 proposes significant additional resources for FDA's safety-related activities.[41]

Seventh, *Riegel* also is sound from the perspective of policy, and does not short-change patients. The patients to be considered are all patients – those who need and benefit from devices, as well as those who experience adverse events and become plaintiffs.

Riegel implements the Congress's central policy in the FDCA as to medical devices. That policy has several components. There is to be a nationally centralized agency with relevant medical, scientific, engineering, statistical, and other expertise. That agency is to conduct individualized product-by-product reviews of certain devices. Those reviews are to occur initially before marketing, and are to be in the interest of all prospective patients and for the benefit of the public health generally. Each review is to be based on substantial scientific information as to the aspects of the device that bear on its effectiveness, safety, and labeling. Each review is also to weigh a device's therapeutic benefits and risks, is to consider trade-offs between effectiveness and safety in its design and labeling, and is to take into account both what is known and what is unknown about the device's effectiveness and safety.

FDA's statutorily prescribed mission is to "promote the public health by promptly and efficiently reviewing clinical research and taking

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41 Press Release, FDA, President's FY 2010 Budget for FDA Invests Substantially in Food and Medical Product Safety (May 7, 2009), *available at* www.fda.gov/bbs/topics/NEWS/2009/NEW02013.html.

appropriate action on the marketing of regulated products in a timely manner."[42] That formulation implicitly recognizes that, just as the public health is harmed by medical products that turn out to be ineffective or unsafe, the public health benefits by timely marketing of medical products that are effective and safe.

That policy serves patients well, but has unavoidable limitations. It serves patients well because FDA, under congressional oversight, does a far better job of deciding on product designs and labeling than judges and juries could do. Totally unpreempted regulation through products-liability litigation would erode FDA's uniform national regulatory system, would lead to inconsistent requirements from state to state and jury to jury, would create powerful incentives for inclusion in labeling of numerous additional warnings that plaintiffs' lawyers persuaded juries and judges to impose, and thereby would diminish the overall effectiveness of labeling in guiding physicians in the proper use of medical devices. The diminished effectiveness of labeling – indeed, the diminished willingness of physicians to wade through labeling drafted to provide legal protections as well as to guide medical decision-making – would make devices in actual use less effective and less safe than they would be if considerations of products liability did not intrude. The totally unpreempted tort system would also increase the costs of medical devices by building in additional costs not only

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42 21 U.S.C. § 393(b)(1) (2006).

to compensate plaintiffs injured through no fault of the manufacturer but also to pay for lawyers' fees and other costs incurred in litigation.

H.R. 1346 might well lead to a reduction in medical device effectiveness and safety. Increased manufacturer exposure to litigation risks might well lead to increased defensive statements in product labeling and, as a result, decreased usefulness of such labeling and decreased willingness of doctors to consult such labeling. It might also deter the development of devices for medical needs that carry high risks of litigation.

As FDA has stated with respect to drugs, in language equally applicable to devices:

> [A]dditional requirements for the disclosure of risk information . . . can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use. Exaggeration of risk could discourage appropriate use of a beneficial drug. . . . [L]abeling that includes theoretical hazards not well-grounded in scientific evidence can cause meaningful risk information to "lose its significance." (44 FR 37434 at 37447, June 26, 1979). Overwarning, just like underwarning, can similarly have a negative effect on patient safety and public health.[43]

The problem of potentially inconsistent jury verdicts in multiple states is worse as to devices than it is as to drugs. Devices share with drugs the risk of claims of inadequate labeling, inadequate testing, and inadequate manufacturing. Because devices are engineered products, however, they face a much greater risk of claims of inadequate design. Thus, without preemption, a design that FDA experts have approved as constituting an

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[43] Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006).

appropriate trade-off between aspects that provide therapeutic effectiveness and aspects that present risks of harm, juries could conclude that the FDA-approved design is inadequate. Different juries could find different inadequacies; one jury could find that a design different in one respect should have been adopted, and other juries could find that designs different in other respects should have been adopted. The result would be chaos – or, perhaps the withdrawal of the FDA-approved device from the market, even though FDA would still find it effective and safe.

This congressional policy for approval of devices has limitations because there is always a trade-off between approving a device for use by patients who need it and may benefit from it now and waiting for additional data that may clarify further how a device may be made safer or more effective or may be labeled so as to be used more safely or more effectively, or that may show, contrary to earlier data, that a device has additional risks that make it unsafe. Thus, every approved device is marketed with less than complete information about its optimal use and, consequently, presents risks of harm, through no fault of its manufacturer or FDA.

In sum, current Supreme Court jurisprudence as to device preemption is sound and well serves the public. H.R. 1346 would destroy the balance achieved by current device jurisprudence and, overall, would harm the interests of patients who need and use medical devices that have gone through the PMA process.

Mr. PALLONE. Mr. Kinsley.
Mr. KINSLEY. Does this work?
Mr. PALLONE. Good idea to switch seats.

STATEMENT OF MICHAEL KINSLEY

Mr. KINSLEY. Thanks for this opportunity to testify, Mr. Chairman. I am here because I was approached last week by Medtronic, but I am here representing myself. I am not accepting anything from this except for Xeroxing of copies of my testimony.

I also have—I am not an expert on Federal preemption issues, and I don't even have a view about the question of whether standards should be similar between drugs and devices. I also have no view about the goings-on in the 11th Circuit, although it sounds pretty exciting.

I am here for two reasons, first, as a grateful customer of the pharmaceutical and medical device industry. I have had Parkinson's, and I have had it for over 15 years. As I hope you can see for yourself, my symptoms are pretty mild. After all that time they have not affected my ability to work, to travel or to enjoy life.

This is true thanks in part to drugs, including many that have just come on the market in the years since I was diagnosed. And it is true especially because of the surgery I had 3 years ago called deep brain stimulation. Now I walk around with wires in my head and two pacemaker-type batteries in my chest. But thanks to these devices and these pills, I am walking around, which is encouraging to me.

I am also here as a journalist who has written quite a bit about the damage done to our economy and to our country by excessive litigation in general and product and medical liability lawsuits in particular; and with all due respect to Dr. Curfman, if he thinks that companies can avoid litigation simply by producing safe products, I think he is naive. We all want the government to protect us from dangerous drugs and devices, but we don't want the government to prevent us from getting helpful or life-saving drugs and devices.

And the central problem is that those are the same devices, the ones that threaten us with harm sometimes and the ones that help us most of the time. And you do not want a system even if you could have it, that only allowed safe devices to be produced because that would be too far over on the scale.

You need to have—in order for maximize the benefit, you have to tolerate some risk. And the danger of using litigation to solve these problems is that we—it forces us as a society to be overcautious.

I think I will even stop there.

Mr. PALLONE. Thank you, Mr. Kinsley.

[The statement of Mr. Kinsley follows:]

Testimony of Michael Kinsley
Subcommittee on Health
House Committee on Energy and Commerce
May 12, 2009

Thanks for this opportunity to testify. I'm here because I was approached last week by Medtronics. But I don't represent Medtronics or anyone except myself. I don't claim to be an expert on federal pre-emption issues or to even have a view on the specific question of different standards for medical devices and pharmaceuticals.

I am here for two reasons. First, as a grateful customer of the pharmaceutical and medical device industries. I have had Parkinson's disease for over 15 years. As I hope you can see for yourselves, my symptoms are pretty mild. They have not affected my ability to work, to travel, to enjoy life. This is true thanks in part to drugs—including several that did not exist when I was first diagnosed. And it is true thanks especially to surgery I had three years ago called Deep Brain Stimulation. Now I walk around with wires in my head and two pacemaker-type batteries in my chest. But if not for these pills and devices, I might not be walking around at all.

I am also here as a journalist who has written quite a bit about the damage done to our economy and to our country by excessive litigation in general and lawsuits over medical care gone wrong in particular. This goes back 30 years to a piece in The New Republic about a pregnancy drug called DES, and includes a column in the Washington Post just a few weeks ago about the Wyeth case.

So here's the problem. We all want the government to protect us from dangerous drugs and devices. But we don't want the government to prevent us from getting helpful or even lifesaving drugs and devices. Yet the most important drugs and devices are both. They save lives, and they can cost lives. The government's job is to weigh the risks against the benefits.

And here's where it gets messy. We have two completely independent systems for making the same decision of whether a drug or device should be approved for sale.

One is the Food and Drug administration-- a national government agency staffed by experts and mandated to take into account both the potential benefits and the potential dangers. The decisions it makes set a uniform standard for everyone in every state.

The other system is tort law, administered by thousands of non-expert judges and jurors in 50 state courts. The same issue can and does get relitigated dozens of times. Differences in state law or just the randomness of juries produce dozens of different answers. Some plaintiffs hit the jackpot; most victims never even sue. The direct cost is horrendous: delivering a dollar to a victim costs far more than a dollar in expenses—mostly lawyers' bills.

The indirect cost is immeasurable. Lawsuits focus on the victim of some medical product. By their nature, they undervalue the benefit that same product has brought to other users, or even to the victim herself.

Forced to choose between these two systems for making essentially the same decision, I believe that anyone sensible would choose the FDA. But in real life, the situation is even crazier: we have both systems simultaneously. And basically, whichever one draws a more restrictive line, wins. Add to this the fact that product manufacturers have no idea when or how the standard might change, and you have a perfect arrangement for discouraging drug and device manufacturers from developing new products, like the ones that allow people like me to go about our business, which is making trouble for people like you.

Thank you again.

"Truth in Testimony" Declaration:

I am testifying on behalf of myself (though at the request of Medtronics Corp). I have received no compensation from Medtronics or anyone else for this testimony. I also have received no compensation from and signed no contracts with the United States Government for at least ten years.

Here is my bio:
Michael Kinsley is a columnist for the Washington Post. For many years he was the Editor of The New Republic. He was the founding Editor of Slate. He also served as Editor of Harper's, Editorial and Opinion Editor of the Los Angeles Times, American editor of The Economist, and Managing Editor of The Washington Monthly. He has written regular columns for Time Magazine, the Los Angeles Times, the Wall Street Journal and the Times of London. His writing has appeared in the New Yorker, the Readers Digest, the Daily Beast, Conde Nast Traveler, and other publications. For six years he was co-host of the CNN program "Crossfire," appearing five nights a week opposite Pat Buchanan, John Sununu and Robert Novak. He also was William F. Buckley's regular interlocutor on Firing Line and moderator of the Firing Line debates on PBS.

Kinsley was born in Detroit in 1951. He attended Harvard College, Oxford University and Harvard Law School. He is a member of the District of Columbia Bar and the Screen Actors Guild. He lives in Seattle with his wife, Patty Stonesifer.

Mr. PALLONE. Thank you all. We are going to proceed to questions from the members of the committee now, and I will start with my own questions and I guess I will start with Professor Vladeck if I may.

Many people looked at the fact that the Riegel decision was decided with an 8-to-1 vote by the Supreme Court in favor of preemption as evidence that it is clear that all FDA product liability cases should be preempted. I wanted to ask you, how could the court be wrong about that when it was such an overwhelming margin?

Can you explain why the Riegel decision was 8-to-1?

Mr. VLADECK. I can take the Court at its word. What the Court said was—and this goes back to an earlier decision by the Court in a case involving cigarette labeling alone.

Many statutes that have preemption provisions use the same language, and the language is, requirements are different from or in addition to those proscribed by Federal law. And the battleground since 1992, if you can believe it, has been over the word "requirement." And in Cipollone, where Congress itself wrote the warning label, the Court said that it would be odd to hold a tobacco company liable for failing to add a warning that Congress itself did not write. And so there in Cipollone the Court said the word "requirement" could, in some cases, include common law remedies under tort. And since then there has been a series of decisions discussed in both my testimony and Mr. Cooper's testimony which the Court has vacillated on what the word "requirement" meant.

Finally—and Justice Stevens' concurrence makes this quite clear. Finally, in Riegel, the Court simply gives up the ghost and says, going forward, the word "requirement" should be understood to include common law tort remedy.

Mr. PALLONE. What about—some of my colleagues made statements that they were here at the time, that wasn't the intent. Was that—any of that information, they just ignored it or what?

Mr. VLADECK. Yes, the Court just ignored it and this is part of the Court's new practice pushed by some of the justices on the Court to look simply the attacks to the statute and not to look at the statute's purpose or the underlying legislative history.

The legislative history of the statute is quite clear. Congress did not mean to wipe away tort remedy for people injured by medical devices. And there is no argument on that score.

Mr. PALLONE. I appreciate it. I think it is important.

Now, the device industry is arguing that a bill overturning the Riegel decision like mine would dramatically change the legal and financial landscape for device companies.

But would this bill really change the status quo? My understanding is that the device companies faced State tort suits right up until the Riegel decision. So what is your opinion on that?

Mr. VLADECK. Right. I think that is true with a caveat.

Prior to Riegel, the courts were divided on whether there was preemption of these kinds of cases. The majority of the Federal circuits had ruled that there was preemption, but none of these decisions however, came before the mid-1990s. All of them are post-Cipollone, post-1992 decisions. None of the device manufacturers even argued preemption until post-Cipollone. So it is true that in some jurisdictions and in many circuits from maybe the mid-1990s

through 2008, there was a preemption defense available to these kind of devices.

But if you look at the history of medical devices in the United States, they predate by decades the medical device amendments of 1976. We have had life-supporting and life-sustaining medical devices on the market for 50 or 60 years, and only in that one brief interval, that maybe 10 years post-Cipollone and pre-Riegel was their real preemption available. And even then there was no guarantee because device manufacturers could be sued in some jurisdictions, including what some have colorfully referred to as the "crazy 11th Circuit."

Mr. PALLONE. Let me ask you this. You have heard some of my colleagues say that the most frequently repeated objection to my bill is that it will create 50 State FDAs, and the devices will be regulated differently in different States. And then I think Mr. Cooper stated that products-liability cases constitute a kind of regulation in disguise.

What is your opinion about that?

Mr. VLADECK. I think that is an overstated argument. For every other consumer product, except where Congress has expressly preempted State tort law, we see parallel enforcement of State regulation—excuse me—of Federal regulation of products—car, cell phone, virtually any other consumer product that complements State tort law. They serve distinct functions although they are somewhat overlapping.

I think it is an overstatement to say that a State tort judgment is regulation in my meaningful sense. It isn't. It is not device specific. It doesn't tell the manufacturer that they must do anything, and for that reason, we have seen tort law and Federal regulatory law coexist in virtually every sphere of government and private industry that we have in the United States.

And this complementary role serves an important purpose. One is, it compensates people injured through no fault of their own; and second, it deters excessive risk-taking.

We can go up and down the list in terms of massive recalls of medical devices; and here, remember, most of these recalls are where—Mr. Cooper talked about who makes the decision about defect. In virtually all of these cases, it is the manufacturer and the FDA.

The Sprint Fidelis lead is being recalled because both agreed it should be recalled; Bjork-Shiley, the heart valve, 55,000 people; the Sulzer heart valve, another 35,000 people; the Medtronic pacemakers. All of these products were recalled after serious defects emerged, and both the FDA and all of the experts there and the company agreed it was time to get the product off the market.

That serves—in most of these instances tort law served an incredibly important informational function. That is, we learned about the severity and pervasiveness of the defect through tort litigation, not through the imperfect, adverse reporting mechanisms that the FDA has.

Mr. PALLONE. Thank you, Professor. Thank you for your enthusiasm too.

The gentleman from Illinois, Mr. Shimkus.

Mr. SHIMKUS. As much as you don't want to go to me—no. Thank you for the panel and compelling testimony.

I left—one of the challenges of our jobs as a Member of Congress is we hear tough stories all the time, especially in the Health Subcommittee. I left here to go to—it is ALS lobbying day. I had folks in my office. So we are—these are things we deal with on a daily basis, maybe multiple times. So we appreciate you all being here.

Ms. Robb, can you give me a time line? You were diagnosed—the implantation occurred in 2005?

Ms. ROBB. I was diagnosed in February of 2004, and the implantation was in May of 2005.

Mr. SHIMKUS. What would have been your health condition if you had not had implantation?

Ms. ROBB. The device was implanted simply as a safety net; it didn't do anything on a daily basis. I didn't use the pacemaker portion of it. It just was simply there in case I was to have a fatal arrhythmia to, hopefully, shock me out of it and save my life.

I was on a course of medication that was increasing my heart function, and I was doing really well.

Mr. SHIMKUS. Yes, good. I think that is helpful, and I appreciate that.

Let me turn to Mr. Kinsley from the St. Louis area, a Member of Congress from Illinois. Of course, those of us who follow the St. Louis Cardinals are huge Jack Buck fans, who suffered from Parkinson's; and you would not have known that had you not seen him and—because his voice was still strong.

When you moved from your chair from where your seat was to Mr. Cooper's seat, had you not had the implantation, how long would that have taken you to do?

Mr. KINSLEY. Well, it would have taken a few seconds longer probably. I mean, I can't be more specific than that.

Mr. SHIMKUS. So the implantation for you has been pretty much as you stated in your testimony, very helpful in obtaining a livelihood and your standard of living?

Mr. KINSLEY. Yes. It has been essential, I would say.

Mr. SHIMKUS. In your testimony, you also talk about the problem of having two independent systems, the FDA and tort law, for making the decision on whether a device should be on the market.

Can you talk about this and explain this analysis of the problem?

Mr. KINSLEY. Well, you have got the FDA ruling and you have got tort law essentially trying to do the exact same thing, which is to balance the risks against the benefit. And I was amazed to hear that—well, let me start again.

I think that surely tort law does draw a line under the behavior effect—affects the behavior of companies that manufacture devices. And any company that loses a case and then—and then continues to manufacture the device anyway would lose—would do very badly both in the market and before this committee. That would be crazy.

So I think it is undeniable that these are both systems that affect the decisions of medical device companies; and I think, in effect, the company does whatever, between the two, is the most restrictive.

Mr. SHIMKUS. Thank you. Let me go to Mr. Cooper real quick.

Does a patient have a right to sue the device company if it fails to follow FDA requirements in manufacturing the device?

Mr. COOPER. Yes. The Riegel decision, following the lower decision, made it absolutely clear that States——

Mr. SHIMKUS. Let me go to the next one. That is fine. Does a patient have the right to sue if the device labeling is inconsistent with FDA requirements?

Mr. COOPER. Yes.

Mr. SHIMKUS. Let me go to the next one. Does the patient have the right to sue if the company withholds data from the FDA?

Mr. COOPER. Probably not.

Mr. SHIMKUS. Does the patient have the right to sue if the company misleads the FDA as to the device's safety and effectiveness?

Mr. COOPER. Same answer. But the FDA has tools, including criminal prosecution, to deal with that kind of problem.

Mr. SHIMKUS. And I was going to follow up, Mr. Chairman, with a question for Mr. Cooper.

Can you expound on the small business implications of this legislation?

Mr. COOPER. Yes. I will give you an example.

One of the areas that at least some years ago was grossly underserved was medical devices, including breathing instruments and the like for prematurely born babies. That is a high litigation risk area, a company that develops a product—and there are some products. But a company that develops a product in that area is taking an enormous risk of litigation because nothing that humans make is perfect, nothing in medicine is perfect.

I am not a doctor, but that is my understanding. Not medical device, not drugs, not surgical procedure, not laboratory test, nothing is perfect. They all fail sometimes. And if you get failures in that area, you are going to get litigation, and you are going to get enormous judgments. And small companies, that doesn't—that is where the innovation is, mostly in small companies.

Mr. SHIMKUS. Thank you.

Thank you, Mr. Chairman. If I could ask unanimous consent to submit two letters one from the Vietnam Veterans of America and also from a Mr. Albert Daum, who is in a similar situation of the benefits of this type of technology.

Mr. PALLONE. Without objection, so ordered

[The information appears at the conclusion of the hearing.]

Mr. PALLONE. Mr. Braley of Iowa.

Mr. BRALEY. Thank you, Mr. Chairman. One of the comments that was made earlier in the hearing was that preemption is not a get-out-of-jail card.

Professor Vladeck, that is not true, is it? That is exactly what preemption is; it is a bar to the courthouse door. In fact, Justice Ginsberg mentioned that in the concluding paragraph of her dissent where she writes the Court's broad reading of section 360(k)(A) saves the manufacturer from any need to urge these defenses. Instead, regardless of the strength of a plaintiff's case, suits will be barred as an issue; that means before they are even filed.

Mr. VLADECK. They will be dismissed as soon as they are filed.

Mr. BRALEY. Exactly. And if this is a well-known legal doctrine, then people aren't going to take those cases and they are not going to file them.

One of the other comments was, this was going to dramatically increase the number of lawsuits against medical device companies, but until the Riegel decision clarified this conflict within the circuit, there was nothing that prohibited somebody from pursuing this type of relief.

So the same pace of claims is likely to occur whether or not this act is passed?

Mr. VLADECK. Right, which is why we are seeing so many cases dismissed in light of Riegel.

Mr. BRALEY. Exactly.

Now, one of the other comments that was made—I think it was by Ranking Member Barton, who was quoting from the Republican staff committee brief. And he would—he mentioned that this act, if passed, would severely disrupt innovation in a medical device industry that has existed since 1976.

But you pointed out this same dual enforcement mechanism has existed literally since the act was passed. So any innovation that has been proceeding at pace since 1976, should not in any way be affected by this.

Mr. VLADECK. That is correct. And even well prior to 1976 we had medical devices prior to Congress' passage of the medical device amendment.

Mr. BRALEY. Thank you.

Mr. Kinsley, I want to ask you a little bit about what your concerns are, specifically related to the role that tort liability litigation plays in medical device and pharmaceutical claims.

Based upon your background, I assume that you are a firm believer in the Constitution.

Mr. KINSLEY. Yes.

Mr. BRALEY. That includes the Bill of Rights which, as we know, includes the right to free speech and the right to freedom of the press which gives you the ability to do what you do for a living?

Mr. KINSLEY. Right.

Mr. BRALEY. Are you supporter of the 7th amendment of the Bill of Rights?

Mr. KINSLEY. Which one is that?

Mr. BRALEY. It is the one that says, in suits at common law, where the value in controversy exceeds $20, the right to trial by jury shall be preserved.

Do you believe in that amendment?

Mr. KINSLEY. Well, it doesn't—it is not one that gets my heart beating faster.

Mr. BRALEY. Well, let us talk about that, because you understand the historical perspective that led to the passage of the Bill of Rights.

Mr. KINSLEY. Well, let me say something about the Bill of Rights.

I am the one in the street that is protected from malpractice lawsuits which are called libel suits in the world of the press. And the Supreme Court, as I am sure you know, has said that because of the First Amendment, we are protected even when we have com-

mitted malpractice by making a mistake, New York Times v. Sullivan. Every other industry does not have that advantage.

This is just the opposite of most countries, such as in England where journalists live in terror of lawsuits, and everybody else is rather calm about it because they somehow or other manage to have a system that brings justice in most cases without a lot of the absurdities that, in my view, attach to product liability in this country.

Mr. BRALEY. Well, you understand that even journalists are subject to liability under certain circumstances when they engage in libel and slander, and there are differing degrees of proof, whether you are a public figure or not; and that all factors into determining whether there is accountability that, in fact, some journalists have been held accountable because they took unreasonable risks in what they say about people.

Mr. KINSLEY. Yes, you have to try really hard to be sued.

Mr. BRALEY. Let's talk about that. Because one the things we know is, if you are going to sue the manufacturer of a defective medical device, not anybody can do that. Did you realize that?

Mr. KINSLEY. What do you mean?

Mr. BRALEY. In order to bring that claim, you have to prove the manufacturer made a defective device that was unreasonably dangerous, that caused direct harm to someone. And even if you can prove that and you are the device manufacturer, you have an absolute defense to those claims if you can prove that the product you introduced into the stream of commerce conformed to the state of the art at the time that product was manufactured.

Mr. KINSLEY. As I said in the beginning, I am not an expert in this field. But I do think that, as a general rule, our society is overly risk averse; and we pay for that.

Mr. BRALEY. But in this case, if you are the device manufacturer and this state of the art is an affirmative defense that gives you complete immunity, you can walk into court and say, Hey, the FDA preapproved my product. That was state of the art at the time that manufacture—that product was introduced, that is my get-out-of-jail-free card.

Mr. KINSLEY. Well, that seems like a good get-out-of-jail-free card to me.

Mr. PALLONE. We are a minute over.

Mr. BRALEY. Thank you, Mr. Chairman.

Mr. PALLONE. You two were having such a good time here that I didn't really want to stop you. But thank you.

Mr. Burgess.

Mr. BURGESS. Thank you, Mr. Chairman. I was enjoying it. It took me back 15 years ago when I was a physician in practice and every night would tune in Crossfire and watch you and Bob Novak go at each other; and I used to enjoy those exchanges as well. What concerns me today is, I agree with you more than I recall agreeing with you 15 years ago. I must admit I guess things have changed in 15 years.

Let me start with Dr. Curfman. I probably need to ask Dr. Maisel the same question, both physicians.

Can you help us understand the physician's role in helping to evaluate and helping an appellant understand the risks and bene-

fits associated with any complex medical technology? That role does fall to the physician, does it not?

Dr. MAISEL. It is a common role for physicians to serve as counsel for patients when determining the risks and benefits of any therapy, whether it is a medical device, a drug or some procedure. I think it is incumbent upon physicians to have accurate and timely information, and one of the things I, as a physician, have struggled with is dealing with medical device malfunctions with incomplete information, inaccurate information or a lack of timely information in handling these cases.

Mr. BURGESS. And, of course, we all rely upon the Food and Drug Administration to help us with those determinations.

Do you ever find yourself in the course of clinical events reviewing court cases to find out if a device—if you should be counseling your patient based upon what has happened in the legal system?

Dr. MAISEL. I am not sure I am the right person to ask that question. I do review the court cases. I find them extremely interesting. I think there is a lot of very interesting information about device reliability that is in those court cases. I think a lot has been learned from those court cases, and there are things in those court cases that are released because of the court cases that otherwise wouldn't be released, including FDA documents.

Mr. BURGESS. Let me ask Professor Vladeck, in response to a question posed by Chairman Pallone about the 8-to-1 decision of the Supreme Court, was this consistent with what had been the decisions of lower courts or did they depart from lower court decisions?

Mr. VLADECK. I think it is fair to say that many lower courts had reached the same conclusion that the Supreme Court did. I think it is also fair to say that there were many courts, particularly State courts that did not. And so you had a deep division within our judicial system about the proper reading of the preemption provision of the medical device amendment.

Mr. BURGESS. But it was not inconsistent with what the lower courts had ruled, so in that aspect did not alter the regulatory environment?

Mr. VLADECK. Remember, no court had ruled that there was preemption under the medical device amendments until the mid-1990s. So to the extent there was preemption during this period, one is, it was recent; and second, it was incomplete because plaintiffs could engage in forum shopping, and where possible they would sue in the jurisdictions that permitted these cases to go forward.

So it is not as though prior to Riegel any medical device manufacturer had an assurance that a claim would be preempted.

Mr. BURGESS. Who would engage in the forum shopping?

Mr. VLADECK. The plaintiffs, yes.

It is only bad when the other side does it.

Mr. BURGESS. Mr. Cooper, let me ask you a question if I could. There is some suggestion that the effect of the Riegel decision to provide broad-based immunity in instances where the medical device failed, a get-out-of-jail-free card, versus a don't-get-out-of-jail-free. So do you agree with that? Do you think that is true?

Mr. COOPER. No, I would not agree with it, Mr. Burgess. The Riegel decision applies only to devices that have gone through the PMA approval process. That is about 30 products a year, less than 1 percent of all the devices on the market.

Mr. BURGESS. Under current law, does the patient have the right to sue the manufacturer if the device fails?

Mr. COOPER. People can always sue. Whether they will win is another matter. And if a manufacturer has—as I discussed earlier in answering some question, if a manufacturer fails to comply with FDA requirements and the conditions on the PMA approval or the manufacturing process, Riegel would not provide any defense.

The real problem, I think we are grappling with here, is that medical devices are going to fail even if they are the best that human beings can make; and how do we take care of the people in whom they fail or for whom they fail? And that is matter of health insurance, disability insurance or life insurance. It is an insurance system.

And the products-liability system is not intended to be an insurance system. It is based on fault or defect. And if the product isn't defective, if the manufacturer is not at fault, then the plaintiff should lose. That is our legal system.

Mr. BURGESS. And just in the brief time I don't have left, if, on the physician's part—the physician utilizing the device, if they commit an error either in diagnostics or in application of the device, under Riegel, can they be sued?

Mr. COOPER. Yes. And in Levine, for example, the doctor—the clinic, I guess it was—settled.

And if you look at the facts in the Riegel case, the physician who was applying the catheter, the balloon catheter, misapplied it in violation of the labeling. Nevertheless, the plaintiff sued the device manufacturer.

Mr. PALLONE. OK. We are going to move on. Thanks.

The gentlewoman from Florida, Ms. Castor.

Ms. CASTOR. Thank you, Mr. Chairman.

Thank you all very much for being here today. Some device companies have argued that the premarket—that the impact of the Riegel decision is limited numerically because it only applies to PMA devices. Mr. Cooper just made the argument that it only represents 1 percent of all medical devices reviewed by the FDA.

But is this a fair representation of Riegel and all of the devices? Dr. Maisel, does that 1 percent figure accurately represent the actual usage and importance of PMA devices?

Dr. MAISEL. The best term I can come up with to describe that number is "propaganda." The repeated use of the 1 percent we heard or the 2 percent number is fuzzy math.

The devices that we care about are not tongue depressors and bedpans and stethoscopes which are included in the 99 percent. We care about the important, life-sustaining devices whose safety patients rely on.

And those devices—we have also heard a number of approximately 30 new PMA applications a year. The FDA actually sees over 1,000 PMA and PMA supplement applications each year, so it is much higher than that number. And if you think about the number of patients affected by these devices, it is in the millions.

There are more than 10 million Americans living with permanent implanted devices right now, and there are hundreds of thousands if not millions implanted each year.

Ms. CASTOR. What type of injuries and what type of patients?

Dr. MAISEL. Well, these devices are—in many cases are life-sustaining devices. We have heard from a patient today here on our witness stand that received painful shocks.

There are devices that can fail to deliver life-sustaining therapy when needed. There are pumps that can underdeliver or overdeliver medication. There are stents that can malfunction. Every product has the potential to malfunction.

I would like to clarify. I don't think a malfunction should equal liability for a manufacturer. That is not what we are talking about here. We are talking about a manufacturer that fails to meet their—the standard of care, that fails to produce a product that is as reliable as it should be.

Ms. CASTOR. And, Professor Vladeck, it is unclear to me, does the preemption apply even when the corporation or folks in the company knew or had knowledge that the device was defective even after they received the FDA approval?

Mr. VLADECK. Yes. Even where the companies misleads the FDA, it fails to provide information to the FDA.

There would be preemption not under Riegel, but under Buchman v. Plaintiffs.

Ms. CASTOR. So, Mr. Kinsley, I would ask you about those cases when folks in the corporation, or the corporation or personnel knew of the danger; does it make sense that consumers are barred from seeking compensation from their injuries and lost wages?

Mr. KINSLEY. When you say "knew of the danger," if this company has met FDA standards and what they knew was that there is something—I mean, either it meets the standards or it doesn't. And if it meets FDA standards, then you shouldn't have to meet a whole other set of standards.

Ms. CASTOR. Even if they knew that the device was faulty and could cause injuries, you are saying if the FDA signed off on that——

Mr. KINSLEY. Yes.

Presumably what they knew was—well, if what they knew was that the device didn't meet FDA standards, yes, of course, they should be liable.

Ms. CASTOR. I think the case is that if they receive the premarket approval and approval from the FDA, that it is supposed to mean something. But even in the cases they had knowledge that the device could cause injury?

Mr. KINSLEY. Well, I think some things I have heard today and things I knew even before suggest, then I think everyone here agrees that the FDA could use a little bit of improvement. But——

Ms. CASTOR. It would seem to me that the companies in those—in that case, have a responsibility to be truthful in the FDA process.

Mr. KINSLEY. Well, sure. I would say if the company is lying, even if it is lying about a product that does meet FDA standards, that is not good, and they should maybe lose this immunity they get.

Ms. CASTOR. Thank you very much.

Mr. PALLONE. Thank you.

The gentleman from Indiana, Mr. Buyer.

Mr. BUYER. Mr. Kinsley, I will be your lifeline.

Mr. KINSLEY. Thank you.

Mr. BUYER. I will be your lifeline because I disagree with the professor's testimony. The professor's testimony said that Federal preemption will give protection to a manufacturer if, in fact, they voluntarily withhold information, i.e., that is wrongful conduct or lying, that is wrongful conduct.

So if a corporation is involved in wrongful conduct, they are outside of the Federal preemption as according to the Supreme Court decision. Is that not correct, Professor?

Mr. VLADECK. The decision I was referring to——

Mr. BUYER. Or is my analysis not yet—is that not correct?

Mr. PALLONE. Professor, do you have the mic on?

Mr. VLADECK. I do. It would be correct under the Supreme Court's prior ruling.

Mr. BUYER. Professor, time out.

The analysis that I just gave according to Riegel; is that not yet correct?

Mr. VLADECK. Preceding Riegel is Buchman. Every lower court to address what I believe is the question you are posing has said that that is essentially a fraud on the FDA claim, which is preempted.

And maybe I am misunderstanding your question.

Mr. BUYER. It is clear—I believe it is clear after Riegel that if a manufacturer of a device, in fact, commits wrongful conduct, it can be held liable. That is my lifeline to you, sir, that if somebody is lying, they voluntarily withhold that information, you do not get the shelter of the law.

If you participate in wrongful or criminal or conduct that would be harmful to our society, you don't get the shield of the law. That is Riegel; is it not?

Mr. VLADECK. I would hope you are right. Let me just make two caveats. With all respect, I think the lower courts have not read Riegel to overrule or to in any way affect Buchman. And if you look at the cases cited at footnote 25 of my testimony, many of them discuss precisely that issue.

I would agree with Mr. Cooper that the sanction that would be available would be the FDA bringing an enforcement action against the company. And the FDA plainly would have the authority to go after the company for doing that conduct and could proceed criminally. I am sorry.

Mr. BUYER. Is your background in tort law?

Mr. VLADECK. I have done tort law, yes, sir.

Mr. BUYER. Under products-liability law—now, help me. I am just a country lawyer. So under products-liability law, a device manufacturer's liability must be based on some type of fault; is that not true?

Mr. VLADECK. That is correct.

Mr. BUYER. Some type of fault. So if a manufacturer, though, abides by the rules, the regulations, the procedures, the law, where are they then at fault?

Mr. VLADECK. They are not at fault.

Mr. BUYER. Right. And that, in fact, is the importance of the preemption, the shield to that manufacturer in the premarket approval process, correct?

Mr. VLADECK. I think I understand you. Yes.

Mr. BUYER. Yes. So that is basically—that is why I am say, All right, Supreme Court, I understand why you then have made that as a ruling, to bring clarity then to all of the other courts and jurisdictions around the country, excepting the hiccup of the 11th Circuit.

Mr. VLADECK. You are correct that only the 11th Circuit in the Federal courts——

Mr. BUYER. I am referring to the Federal courts. And you agree with that?

Mr. VLADECK. I am sorry?

Mr. BUYER. You would agree with what I just said, with regard there is one circuit out of balance?

Mr. VLADECK. That is correct.

Mr. BUYER. So back to my lifeline to you.

I just want to be very clear to you here that if, in fact, there is a manufacturer, Mr. Kinsley, that in fact has lied, they don't get the protection of the law. And I don't think any good manufacturer out there wants there to be protection against anyone who is not playing by the rules.

If they play outside the foul line, they should feel the full wrath of the law. Do you not agree?

Mr. KINSLEY. Thank you. Thank you for that lifeline.

Mr. BUYER. I just don't remember that on Crossfire. I will remember that.

Here is the other point that I make in my opening. It really does concern me because in the year, the 17 years I have been up here, I have been a strong advocate of our country being able to attract great minds from all over the world to place—come to the marketplace, at risk capital, push the bounds of science for the benefit of our society and then under the world.

If, in fact, we pass a law like this, what are the consequences—let me turn to you, Mr. Cooper—what are the consequences going to be upon not only innovation, but what—will there be a quilt, sort of a patchwork in the marketplace with regard to where manufacturers are going to go to sell their products for fear that one State may, in fact, have a different litigious environment?

Mr. COOPER. There may well be some of that.

I think the major impact would be lack of development of products where there is great need but also great liability risk. The—I think the experience of lawyers who try products-liability cases is that juries will do what they need to do to compensate an injured plaintiff. Even if the manufacturer had a warning that said, Don't do this, it will kill you, the jury will find that that was inadequate because it could have said, It will kill you for sure.

That is a natural human reaction and it is a problem. And the effect of it is on people who need medical devices and they are not there. Or they haven't been improved to the extent that they could be if more investment were made, but the manufacturers decided to put the investment somewhere else, which presents less liability risk.

Mr. BUYER. Thank you. Thank you, Professor.

Mr. PALLONE. Thank you.

The gentleman from Utah, Mr. Matheson.

Mr. MATHESON. Thank you, Mr. Chairman. I think this topic is certainly an important issue. It represents an intersection of a number of key dynamics, including patient safety and health care and innovation. And while we all agree that patient safety should be a top priority, I think it is also—I think we all probably agree that if the device maker has done something wrong, they should be held accountable.

What I am concerned about is that a blanket approach could have some far-reaching consequences. If the problem lies elsewhere, say, with the review process at FDA, then this committee needs to have a larger conversation beyond this preemption discussion we are having today. I don't think we should take this issue very lightly, and I think we ought to be really careful and not rush to legislative action.

I had a number of questions, all of which have all been covered except one, and I will ask real quickly to Mr. Cooper.

How should we address this issue with the FDA? Do they need more power, more authority? Do we need to change the way they are structured to protect consumer safety related to medical devices?

Mr. COOPER. I think they need additional resources. I think, as several members have said, the Agency has been underfunded for a very long time. The President's budget makes some headway on that with some substantial increase, including for safety-related projects. More needs to be done, and there also needs to be good oversight.

My experience at the FDA was that nothing concentrates the mind like an upcoming congressional hearing, particularly one by the Oversight Subcommittee or by the Health Subcommittee of this committee, which has a long and distinguished record of very effective oversight of the agency. I think that is needed as well.

The FDA has wonderful public servants, dedicated career people, who could make a lot more money doing something else but derive much value in their lives from serving the public. On the whole, I think they do a very good job. It still could be improved, because the problems they deal with are immense.

Mr. MATHESON. Thanks, Mr. Chairman. I yield back.

Mr. PALLONE. Thank you.

The gentleman from Georgia, Mr. Gingrey.

Mr. GINGREY. Mr. Chairman, thank you.

I want to address my first question to Mr. Cooper.

The medical devices we are talking about and how they are regulated by the FDA, if you would just walk me through the process to approve one of these new devices and would discuss the types of postmarket surveillance that is typical of these devices in order to identify higher-than-expected complication rates and to notify patients and physicians of any failures.

Mr. COOPER. Well, to try to do it very briefly——

Mr. GINGREY. Yes, please.

Mr. COOPER.—as has been stated, the applications tend to be voluminous. The FDA needs to understand the ingredients or mate-

rials, the components of the device, the principle of operation, what its intended use or uses are, and what kinds of problems it has to deal with. There will be clinical studies, preclinical studies. There will be laboratory studies.

The raw data of all of that and the analyses all go to the FDA. The FDA does its own review, its own statistical analyses. It can require the companies to do additional studies, to propose labeling as submitted. The FDA can ask for samples. So it does a truly comprehensive review of all that is known.

As has also been pointed out, the studies are limited in terms of the number of patients and of the duration of the studies. If you waited forever, you would never have any devices approved. So you have to cut it off and make a reasonable judgment at some point.

Then the FDA has to conclude and people have to sign their names and be accountable—and they are accountable—for concluding that there is an assurance, a reasonable assurance, that the device is effective for its intended use and that it is safe. And "safe" means not that it is harm-free or risk-free but that the benefits of the product outweigh those risks.

Then it approves it; and it can approve it with various kinds of conditions, including the conditions for further studies as the patient population using the device expands, sometimes exponentially, beyond the limits of the clinical trials, which are the primary bases for the approval.

Manufacturers are required to submit promptly to FDA reports of malfunctions or adverse events associated with the use of the device. Device user facilities—hospitals, clinics and the like—are also required to report. Physicians, patients and others are encouraged to report. Then you can go to the FDA Web site and do that. The medical literature is reviewed both by the manufacturer and by the FDA; and, in their annual reports, the manufacturers are supposed to update the FDA in that area.

Mr. GINGREY. Mr. Cooper, thank you. I will reclaim my time. Thank you for that response.

Ms. Robb, I wanted to ask you—and thank you so much, of course, for being a witness. I am sure it is very difficult for you to describe that harrowing experience that you went through several years ago, but let me understand:

As to the defibrillator that was implanted, I am assuming that the physician—your cardiologist—decided that you were at great risk, because of this cardiomyopathy and, I guess, because of some congestive heart failure as well, of going into what we in the medical field call "ventricular fibrillation," not atrial fibrillation, not super-ventricular but ventricular fibrillation, and I am sure you were told that this could result in sudden death. So you had this surgical procedure.

You had this defibrillator inserted because if, all of a sudden, you went into ventricular fibrillation, without that device to give you that shock, which was a pretty good jolt, as you described, when it started shocking you, maybe inappropriately—but if it had shocked you in the appropriate manner that would have been because, truly, your heart would have gone into ventricular fibrillation. That device would have or it certainly was intended to save your life, was it not?

Ms. ROBB. It was definitely implanted in me to save my life. I had never been shocked before December 31 when it malfunctioned. That was the first time that I had ever been shocked, and it was 31 times, but it was put in as a safety net in case I were to go into V-tach.

Mr. GINGREY. Would you agree that you had that put in because it was better to have it not needed than to need it and not have it?

Ms. ROBB. Definitely. I would say that, you know, at the time, I knew that—they have sort of a cutoff limit with your heart function. When it gets below a certain level, you are at an increased risk to go into V-tach, and they recommend to get a defibrillator as a life-saving safety net.

Mr. GINGREY. Well, let me reclaim my time. Thank you for that.

Mr. Chairman, I just want to say that this is a great hearing, and it was an opportunity to hear from some real experts and to hear anecdotal testimony from Ms. Robb and, actually, from Mr. Kinsley as well.

It is not easy. This is tough. I am a physician member. Some of my colleagues on this panel or on this committee and subcommittee are physician members, and we understand that this is a tough issue, so I appreciate your being here and for giving testimony and for helping us weigh the pros and cons of this legislation.

With that, Mr. Chairman, I will yield back.

Mr. PALLONE. Thank you.

I think we have finished with our questions, but I do want to thank all of you for being here today. I agree with what Mr. Gingrey just said, that this is, you know, something that we obviously take very seriously, and we have to decide what is the best course of action. I think all of you have really helped us in, you know, commenting on this legislation as we move forward. So thank you all very much.

What happens procedurally is, if members have questions, they can submit them in writing, and you should be notified within the next 10 days if there are questions of that nature. Then we would ask you to respond in writing. That is the way we proceed.

Again, thank you so much.

Without objection, the meeting of the subcommittee is adjourned.

[Whereupon, at 4:16 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

Statement of the Honorable Anna G. Eshoo
House Committee on Energy and Commerce
Hearing on the *Medical Device Safety Act*
May 12, 2009

Mr. Chairman: Thank you for holding this hearing today on the *Medical Device Safety Act.*

Class III medical devices, or implantable devices, have brought amazing breakthroughs into the field of healthcare. Heart valves, defibrillators, and pacemakers have transformed the way patients live their lives. Fostering innovation is critical to getting these products onto the market and the FDA has the responsibility is to review and approve devices for safety and efficacy.

Once the FDA approves a class III device, a device if manufacturer follows the manufacturing and labeling guidelines, patients reap the intended benefits from the device. Unfortunately, there are rare instances where a patient will have an adverse reaction even when FDA guidelines are followed.

The *Medical Device Safety Act* will allow affected patients to sue for damages in state court, despite the FDA's determination of safety and efficacy. Patients and families should generally have the right to seek redress for injuries but I worry about undermining the FDA's authority in 50 separate states and the impact this legislation could have on the development of new devices.

It's also important to recognize that we want the FDA to be the premier food, drug, and device regulating agency in this country and the gold standard around the world, we *must* give them the necessary resources to carry out the duties we expect from them. The American people expect their drugs and devices to be safe and we owe that to them.

Albert J. Dahm
13615 Puff Road
Fort Wayne, Indiana 46845

May 11, 2009

The Honorable Henry A. Waxman
Chairman
United States House of Representatives
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Joe Barton
Ranking Member
United States House of Representatives
Committee on Energy and Commerce
2322A Rayburn House Office Building
Washington, D.C. 20515

Re: The Medical Device Safety Act of 2009

Dear Chairman Waxman and Ranking Member Barton:

I write to express my concern and opposition to H.R. 1346 and S.540, the so called Medical Device Safety Act of 2009.

On Palm Sunday, 2006, when I was 47 years old, I awoke at 4:10 a.m. in excruciating pain. I gently nudged my wife to tell her that something was wrong with my heart. Her first instinct was to drive me to the hospital because she did not want an ambulance to frighten our four children. The pain was so severe, however, that I thought I should dial 911, which I did.

A few minutes later, EMTs were in our kitchen. A neighbor arrived to watch the kids, and I was loaded into the ambulance. My wife rode up front with the driver and watched the red lights light up the darkened road.

Upon my arrival at the hospital I was taken to an emergency room area. A nurse asked me if I knew where I was. I replied that I was in the hospital's ER. And then, nothing. My wife told me later that my arms and legs started to shake as if I was having a seizure. Indeed, the ER physician asked my wife if I had a history of seizures. When she replied in the negative, the cardiologist on duty realized my heart had started to shut down.

The next thing I knew I was floating down a tunnel toward a very bright, peaceful light. I found myself asking, "Where am I?" Before I reached the light, a voice told me, "You have more to learn." I then floated backward, and upward. Gradually, I started to hear the doctor's voice saying "Stay with us Bert," "Stay with us."

I had experienced what the doctors call a "widow-maker." One of the critical arteries supplying blood to my heart was 99% blocked and my heart had shut down. Fortunately, I suffered the "widow maker" at the hospital. Most people die, but I survived because the doctors were able to restart my heart. I'll never forget the look on my kids' faces later that day in the hospital.

Unfortunately, my artery was still blocked, so I had to undergo an angioplasty the next day. The cardiologists inserted a drug-eluting stent into my groin (the femoral artery) and threaded it to the blocked heart artery. That stent, a Class III medical device, has given me three more years with my wife and our four children, currently aged 18, 16, 13, and 10.

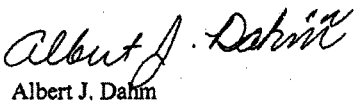
If the so-called Medical Device Safety Act of 2009, H.R. 1346 and S.540, were the law of the land before my heart attack, it is highly unlikely my cardiologists would have had the option of providing me with a device that has added years to my life and more time with my kids.

A scientific debate exists about drug eluting stents. This proposed bill would allow juries across the country to weigh in on that scientific debate. As a lawyer who has spent his entire career in the civil justice system, I do believe in juries. Some decisions, however, should not be handed over to them, and the decision regarding the safety or efficacy of certain Class III devices like drug eluting stents is one of them.

Given the track record of some juries, it is highly likely companies would not be selling that stent if the question of the safety and efficacy of stents was left to a jury. I want these legitimate scientific debates kept out of the courtrooms and instead resolved by the dedicated people at the FDA. Passage of this bill likely will mean that cardiologists will have fewer treatment options when confronted with future sufferers of "widow makers." Can you image the look on that widow's face or the faces of her children?

In summation, my opposition to the Medical Device Safety Act of 2009 is heartfelt. Please, if we have more to learn in the area of stents, let us allow science to be our teacher.

Very truly yours,



Albert J. Dahm

cc: Congressman Mark A. Souder
Members of the House Energy & Commerce Committee

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May 11, 2009

The Honorable Henry A. Waxman, Chairman
United States House of Representatives
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

Re: The Medical Device Safety Act of 2009

Dear Chairman Waxman:

On behalf of the Vietnam Veterans of America (VVA), the only national Vietnam veterans' organization congressionally chartered and exclusively dedicated to Vietnam-era veterans and their families, I write to express our concern and opposition to H.R. 1346 and S.540, the so called Medical Device Safety Act of 2009.

VVA represents over 50,000 individual members, many of whom are recipients of life saving and life improving medical devices including (among other things) heart stents, orthopedic joints and neuro-stimulators. We are concerned that enactment of this legislation as written, which would open state based litigation against the medical device manufacturing community despite FDA approval and supervision, would stifle innovation and ultimately limit the availability of many critical medical devices that are of vital importance to advancing the health and improving the lives of our members.

While VVA has often opposed efforts to reduce the access of individuals to remedies for grievances by means of resort to the Courts, in this case we believe that such an expansion would be detrimental to the interests of all, particularly our members.

Many of our members rely heavily on medical devices to mitigate pain associated with their service related injuries and have benefitted greatly from significant technological breakthroughs in this field. But legislation resulting in increased litigation against manufacturers of these devices, particularly small manufacturers, will only diminish future advances in this area.

We therefore strongly urge you to oppose the Medical Device Safety Act of 2009.

Sincerely,

John Rowan
National President
Vietnam Veterans of America

cc: Members of the House Energy & Commerce Committee

May 11, 2008

The Honorable Joe Barton
Ranking Member
United States House of Representatives
Committee on Energy and Commerce
2322A Rayburn House Office Building
Washington, D.C. 20515

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Sincerely,

John Rowan
National President
Vietnam Veterans of America

cc: Members of the House Energy & Commerce Committee

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