

**PROTECTING PATIENTS FROM DEFECTIVE  
MEDICAL DEVICES**

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**HEARING**  
OF THE  
**COMMITTEE ON HEALTH, EDUCATION,  
LABOR, AND PENSIONS**  
**UNITED STATES SENATE**  
**ONE HUNDRED ELEVENTH CONGRESS**

FIRST SESSION

ON

EXAMINING S. 540, TO AMEND THE FEDERAL FOOD, DRUG, AND COS-  
METIC ACT WITH RESPECT TO LIABILITY UNDER STATE AND LOCAL  
REQUIREMENTS RESPECTING DEVICES

—————  
AUGUST 4, 2009  
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Printed for the use of the Committee on Health, Education, Labor, and Pensions



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# PROTECTING PATIENTS FROM DEFECTIVE MEDICAL DEVICES

TUESDAY, AUGUST 4, 2009

U.S. SENATE,  
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,  
*Washington, DC.*

The committee met, pursuant to notice, at 2:35 p.m. in Room SD-430, Dirksen Senate Office Building, Hon. Tom Harkin, presiding.

Present: Senators Harkin, Hagan, Franken, Burr, and Hatch.

## OPENING STATEMENT OF SENATOR HARKIN

Senator HARKIN. The Committee on Health, Education, Labor, and Pensions will come to order for this hearing on protecting patients from defective medical devices.

More than 30 years ago, Senator Kennedy championed the Medical Device Amendments, a bill that gave the Food and Drug Administration long-overdue authority to regulate medical devices. In support of that bill, Senator Kennedy said, at the time:

“Today the medical device industry plays a prominent role at the very heart of American medicine. Many devices today are actually used to sustain life. We will grow more and more dependent upon medical devices in the future. We stand to benefit a great deal from them, but we must be sure that they are safe and effective in order to avoid needless injury and death.”

Well, today this committee will hear testimony on precisely the issue that Senator Kennedy sought to address, the need to ensure that the medical devices that patients rely on to stay healthy—and, in many cases, alive—are safe and effective.

We are here because last year in a U.S. Supreme Court case, *Riegel vs. Medtronic, Inc.*, the Court held that the Medical Device Amendments, a statute whose explicit purpose was, “to provide for the safety and effectiveness of medical devices,” —the Court said that this law preempts State tort claims when a medical device causes harm. This means complete immunity from lawsuits for corporations that endanger consumers with unsafe devices. The upshot is that a negligent corporation could not be held accountable and victims could not receive fair compensation, and thus, consumers are at risk.

Unfortunately, this has had catastrophic consequences for ordinary Americans. Take the example of Avery DeGroh, of McHenry, IL. She was born with an hereditary heart defect that put her at risk for arrhythmia. When she was only 2 years old, her doctor rec-

commended that, as a precaution, she have a defibrillator implanted in her chest. At age 3, she was playing in her basement when the defibrillator shocked her nine times. When her mother picked her up she felt electric shocks through her daughter's body. Avery's parents had the faulty defibrillator replaced, but Medtronic told them that the company would not cover the cost. Avery's parents are still struggling to pay off the medical bills.

And I'm told that Avery is here in the audience today. Is Avery here today?

Hi, Avery. Good to see you. I like the daisy you have in your hair, by the way.

[Applause.]

Or consider Judd Orcutt, of Oregon. During his National Guard service, where he earned the Army Commendation Medal, he sustained a spinal cord injury. In an effort to reduce pain, he had his herniated disk replaced with an artificial Charite disk—I hope I pronounced that right—manufactured by DePuy Spine. Instead of experiencing relief from the artificial disk, Judd, like hundreds of others, experienced extreme pain and bouts of paralysis. However, because of the Court's ruling in *Riegel*, Judd has no recourse to seek remedies for his injuries.

And today we'll hear from an Iowan, Michael Mulvihill, who received 22 electric shocks within a span of 53 minutes from a faulty Medtronic defibrillator. Because of the faulty device, he suffered enormous pain, was forced into early retirement, and is unable to perform basic functions, such as even driving on the Interstate. And we'll be hearing him testify here today.

As a senior member of this committee, I have worked hard, along with others here—Senator Hatch, and others—to ensure that the FDA performs its job well. While the FDA approval of medical devices is important, it cannot be the sole protection for consumers. I say that because FDA approval, as we'll hear today, is simply inadequate to replace the longstanding safety incentives and consumer protections provided by longstanding State tort law.

No matter how diligently and effectively the FDA does its job, it simply cannot guarantee that no defective, dangerous, and deadly medical device will reach consumers. As the former director of the FDA Center for Devices and Radiological Health frankly acknowledged, he said, "The FDA's system of approving devices isn't perfect, and unexpected problems do arise."

Last year 15 devices were recalled due to defects. In 2009, there have already been 10. The fact is, the FDA conducts the approval process with minimal resources and simply does not have adequate funds to genuinely ensure that devices are safe or to properly and effectively reevaluate approvals as new information becomes available. Moreover, the FDA relies on manufacturers to provide information about their products. Once on the market, the FDA relies on manufacturers to track devices and monitor for problems.

However, without the threat of any liability, there is little incentive for manufacturers to report problems to the FDA or to the public. This puts thousands of consumers at risk of harm. Indeed, thousands have already been harmed in instances where manufacturers knew of problems with the device but withheld that information from the patients.

In our system of justice, access to the court system is critical to exposing dangers and bringing about remedies. Through discovery, litigation can help uncover previously unavailable information on adverse effects of products that might not have been caught during the regulatory process. Litigants can demand documents and information on product risks that might not have been shared with the FDA. In this way, the public as a whole is alerted to dangers in these medical products.

Finally, preserving people's ability to sue when injured provides a very powerful incentive to manufacturers to use the utmost care. In short, the threat of liability is the safety net that helps repair problems when the FDA or manufacturers fail to warn consumers properly. As the U.S. Supreme Court noted in another case concerning drug companies—that's the *Wyeth v. Levine* case, "State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly." I ask, Why would we not hold device manufacturers to that same standards as we hold drug companies?

I think, sadly, the U.S. Supreme Court fundamentally misread Congress's intent in passing the Medical Device Amendments in 1976. The Court's ruling, however, is not the final say on this matter. And to quote Chief Justice Roberts,

"In every area involving an interpretation of a statute, the final say is not with the U.S. Supreme Court; the final say is with Congress. And if they don't like the U.S. Supreme Court's interpretation of it, they can change it."

And I might just add, parenthetically, aside, we found that with the Americans With Disabilities Act, when the U.S. Supreme Court, in three cases, narrowed the scope of the Americans With Disabilities Act, in clear contradiction of what we had put in our report language.

You know, when we pass a bill, we don't put in every little single thing. We add report language, to try to give guidance as to what Congress's intent is. Well, the U.S. Supreme Court just threw that overboard, they didn't pay attention to it, and so, we had to offer the Americans With Disabilities Act Amendments, 2 years ago—it took us about a year to get them through, and they got through last year, and President Bush signed them into law, which we then overturned the U.S. Supreme Court's decisions, to fully enlighten them as to what Congress really wanted to do. So, this is something that is not unheard of.

Senator Kennedy, as he did 30 years ago, is fighting to ensure that consumers are safe. He has introduced the Medical Device Safety Act, S.R. 512, which would reverse the *Riegel* decision. This bill is really about real people who have been let down—let down, sometimes catastrophically. Right now, they have no access to justice and no ability to hold those who caused them harm accountable.

And with that, I would yield to our Ranking Member, Senator Hatch.

## STATEMENT OF SENATOR HATCH

Senator HATCH. Well, thank you, Senator Harkin. We appreciate the leadership you provide, and miss our friend, Senator Kennedy.

We welcome all of you witnesses here today. This is a very important hearing and this is a very important subject—or should I say, set of subjects.

Mr. Chairman, I want to start off by discussing the context in which we are holding today's hearing. As everyone in this room knows, Congress is in the middle of debating and drafting legislation aimed at overhauling our Nation's healthcare delivery system. Obviously, we are somewhat divided over what is the best approach in this effort, but I think we all want to see something done to reduce the healthcare costs in this country.

As we all know, the Medical Device Amendments of 1976, the MDA as we call it, established a rigorous system of Federal oversight of medical devices. Under this system, devices carrying the greatest health risks are subject to premarket approval by the FDA. During this process, FDA officials spend a tremendous amount of labor-intensive time and hours reviewing a single device, consulting outside experts, and analyzing the safety-and-effectiveness profile associated with the use of the device. And I'm sure our panel will discuss this process in more detail, so I'll just say that the FDA's premarket approval process for medical devices is extremely rigorous and very costly to the manufacturers and really to those who hope for the benefits that can come from these medical devices.

And, as history has shown, the FDA is exceptionally efficient. In addition to requiring premarket approval, the MDA also requires those who manufacture and market the applicable devices to report to the FDA on the implementation and use of all approved devices. These reports include any new and relevant clinical investigations and scientific studies of which the manufacturer knows or reasonably should know. Device manufacturers must also report to the FDA any incidents, malfunctions, or adverse events that may have contributed to a serious injury. The FDA has the authority to revoke its approval, and/or order a recall, if it determines the device is unsafe under the conditions of its approval and labeling.

In addition to these rigorous approval and oversight requirements, the MDA included an explicit preemption provision prohibiting States from establishing or continuing, "any requirement," which, "is different from or in addition to," any Federal requirement applicable to the device or which, "relates to the safety or effectiveness of the device." Now, this provision was common sense. Given the rigorous and costly nature of the FDA approval process, it was in the best interests of all shareholders—or, excuse me, stakeholders, including patients and consumers, that the States be prevented from supplanting this system with their own regimes.

Now, as we're all aware, in last year's *Riegel v. Medtronic* decision that my distinguished friend has mentioned, the U.S. Supreme Court held that this explicit preemption provision also applied to tort claims filed pursuant to State common law.

Now, this was not a surprise move by the Court. It was an 8-to-1 decision that affirmed the position taken by the overwhelming

majority of the circuit courts. Yet, I'd have to say, the personal injury lawyers and their allies in Congress have painted this decision as an unexpected change in the law in order to advance their pre-existing agenda to weaken Federal preemption.

The result of this effort is the Medical Device Safety Act. The legislation we're discussing today would alter the MDA's preemption provision to state that it does not apply to actions for liability under State law.

Now, my opposition to this approach stems from many factors. First, I do not believe that randomly selected jurors have the necessary scientific and clinical knowledge to perform the same level of analysis—and review—as the analysis and review by the experts at the FDA. Yet, in essence, this legislation would supplant the findings of the FDA with those of juries in State courts.

Now, this is not only bad policy from the perspective of device safety, it will also likely have a number of unintended consequences. Once again, under the current system, device manufacturers go to considerable expense to obtain premarket approval, in part because they know that the financial risks of litigation are greatly reduced once the process is completed.

However, if this legislation is enacted, and manufacturers are required to ensure that they have approval of the FDA as well as that of any 12 random people in any one of the States. The risks of marketing a device will greatly increase and the cost of these devices will go even higher. As a result, innovation will be stifled and fewer and fewer devices will be brought to the marketplace.

Additionally, we will inevitably see a rise in the overall cost for devices as a means to offset the cost to more frivolous lawsuits. As someone who tried these suits in the past, in my early legal career, or service, I have to say that a high percentage of the lawsuits were brought to get defense costs. They were frivolous suits. They have been running up the cost of healthcare in our society, beyond belief. And frankly, when there are legitimate lawsuits, there ought to be ways of being able to arrive at just compensation for those who have been injured. But, most of them are not. And, since the cost of defense—I generally think of them as between \$50,000 and \$200,000—you know, it's, many times, in the interest of the people to just pay the cost of defense rather than to defend the cases and take a chance with a runaway jury.

Now, this is not only a detriment to healthcare reform, but, more specifically, it undermines the primary healthcare reform goal of controlling the growth curve. Not only will this adversely affect an industry that employs millions of people during a time of economic crisis, it would also harm patients, as they will not benefit from the ingenuity and continuing advancement in device technology that we currently are benefiting from, the vast majority are benefiting from.

That, in my opinion, will be the most devastating effect of this legislation. Indeed, we have one of the most, if not the most, innovative and vibrant medical device industries in the world, that provides life-saving solutions to millions of Americans and people all around the world every year. At a time when our unemployment is rapidly headed toward double digits, it would be a mistake for us to take some of the steps that are currently being discussed,

which include—on top of this legislation—taking billions out of the productive sector that employs thousands of Americans to produce life-saving treatments, to pay for an ill-advised massive government expansion and control of our healthcare system.

Now, making this proposition even worse is the fact that it's unnecessary. We all want to ensure that those who have been truly victimized by the negligence of another party are able to receive adequate compensation for their injuries. However, the current system, including the statutory preemption, does not prevent plaintiffs who have legitimate claims from being compensated.

Under the MDA, device manufacturers can only benefit from the protections of preemption if they have followed the system to the letter. If they withhold or falsify information in their disclosures to the FDA, they will be charged with defrauding the Federal Government. Similarly, if a single device is not built exactly to the FDA's approved specifications, or if it doesn't include the FDA-approved labels, the manufacturer will be liable for damages. In addition, if a device is improperly implanted or used, the MDA will not protect a doctor from being sued for malpractice.

Put simply, when a manufacturer is legitimately at fault, they will be liable under current law, but when they are not at fault, the MDA provides a narrowly crafted safe haven from costly litigation. As I've stated, this exceptionally narrow exemption has great benefits.

Indeed, the MDA has allowed for unparalleled advancement in medical device technology, due in no small part to the fact that the rules for safety and liability can't be rewritten in 50 different separate jurisdictions. If enacted, the legislation we're discussing today would remove this protection and, as a result, I believe it is the patients who are going to suffer.

I look forward to hearing the testimony from our panel today, and I hope that during this discussion we can get to the bottom of some of these issues. In particular, I'd like to hear some explanation as to why we should empower laymen on State juries to overrule the studies, analysis, and findings of our FDA experts. In addition, I hope we can debate these issues, looking toward the future, and the effects this legislation will have on the advancement of medical technology, the increased cost to our already out-of-control healthcare spending, and, of course, the lives of those who would benefit from such technology.

Let me just say that we're happy to have all of you here today. Each of you has important testimony to give to us. We're grateful you'd take time to be here.

I particularly want to mention Mr. Hutt, who is, in my opinion, the dean of all FDA lawyers, who really understands this business as well if not better than anybody in America today. Peter, we're very happy to have you here, and we appreciate you taking time, from what we know is a busy schedule, to come and help us to work through this and understand this better. But, I've known you for almost my 33 years in the U.S. Senate. You're a totally honest and decent man, but you also have written textbooks and been literally the dean for all of us in trying to understand all the intricacies of the FDA.

I particularly appreciate my friend up here, Senator Harkin. He and I have worked very closely together, not only on medical devices—I've worked very closely with the chairman, Senator Kennedy—but we've worked on all kinds of other things, including the Americans With Disabilities Act. We managed that bill on the floor, the two of us, and I remember when we walked out and saw all those folks who were just praying that we'd get that bill through, we both broke down in tears, as did all of them.

So, I want to thank Senator Harkin for chairing this hearing in the absence of our esteemed chairman of the committee. And I, again, want to thank all of our witnesses for appearing and being with us today.

Thanks, Mr. Chairman.

[The prepared statement of Senator Hatch follows:]

#### PREPARED STATEMENT OF SENATOR HATCH

Mr. Chairman, I want to start off by discussing the context in which we are holding today's hearing. As everyone in this room knows, Congress is in the middle of debating and drafting legislation aimed at overhauling our Nation's health care system. Obviously, we are somewhat divided over what is the best approach in this effort, but I think we all want to see something done to reduce health care costs in this country.

In the midst of this debate, the majority on this committee appear anxious to move forward with Senator Kennedy's Medical Device Safety Act, which is what brings us here today. Though I haven't heard it said explicitly, I can't help but conclude that it is the majority's intention to move this legislation as part of a broader health care reform effort. I hope I'm wrong on this count because, quite frankly, I don't believe this legislation will contribute at all to our efforts to make health care more affordable. Indeed, it seems that there is another agenda being advanced here.

The recurring themes in the current health care debate have been "change" and "sacrifice." According to the proponents of the President's health care plan, doctors and hospitals will have to change the way they do business. Small businesses will have to sacrifice in order to comply with the proposed employer mandates. Many of them will also have to sacrifice profitability in order to pay the higher taxes that will most certainly come with a broad government-run health care program. Seniors are going to be asked to give up benefits in order to meet the demands of bureaucrats who believe their treatment is less than cost-effective. The list of parties who will be asked to change their ways or sacrifice for the greater good goes on and on.

However, from what I've seen, there is a notable exception from these expectations. Indeed, there is one group that, if anything, will benefit more than any others if the Majority continues its present course. I'm speaking, of course, about personal injury and malpractice lawyers, who, with an apparently friendly Administration finally in office, have been lobbying Congress and the White House harder than ever. And, even at a time when so many groups are being told that they'll have to deal with increased burdens to pay for and administer a Federal health care plan, it appears that the Majority intends personal injury lawyers to go unscathed.

I'm sure we're all aware of the costs malpractice litigation imposes on our health care system, whether it's in the form of needless tests and procedures performed solely to prevent a future lawsuit or increasingly high malpractice insurance premiums charged to doctors and hospitals that are subsequently passed down to patients. However, as we've been involved in the health care debate since the start of the 111th Congress, any attempt to inject a measure of reasonableness or predictability into our tort system has been immediately rebuffed by my colleagues on the other side of the aisle.

Worse still, in this hearing today, the Majority seems poised, not only to protect the trial lawyers from having to make the same sacrifices as those in other industries, but to give them even more of what they've been asking for. It's no secret that the largest association of trial lawyers has declared the elimination of regulatory preemption its top legislative priority for this year. And, with this legislation, they'll be well on their way.

This would, of course, appear to be reasonable if there was some sort of health-related justification for this approach. However, if one takes a closer look, it seems as though the opposite is true.

As we know, the Medical Device Amendments of 1976 (MDA) established a rigorous system of Federal oversight of medical devices. Under this system, devices carrying the greatest health risks are subject to premarket approval by the FDA. During this process, FDA officials spend a tremendous amount of labor-intensive hours reviewing a single device, consulting outside experts and analyzing the safety and effectiveness profile associated with the use of the device. I'm sure our panel will discuss this process in more detail, so I'll just say that the FDA's premarket approval process for medical devices is extremely rigorous, very costly to the manufacturers, and, as history has shown, exceptionally efficient.

In addition to requiring premarket approval, the MDA also requires those who manufacture and market the applicable devices to report to the FDA on the implementation and use of all approved devices. These reports include any new and relevant clinical investigations and scientific studies of which the manufacturer knows or reasonably should know. Device manufacturers must also report to the FDA any incidents, malfunctions, or adverse events that may have contributed to a serious injury. The FDA has the authority to revoke its approval and/or order a recall if it determines a device is unsafe under the conditions of its approval and labeling.

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As we're all aware, in last year's *Riegel v. Medtronic* decision, the Supreme Court held that this explicit preemption provision also applied to tort claims filed pursuant to State common law. This was

not a surprise move by the Court. It was an 8–1 decision that affirmed the position taken by an overwhelming majority of the circuit courts. Yet, the trial lawyers and their allies in Congress have painted this decision as an unexpected change in the law in order to advance their preexisting agenda to weaken Federal preemption. The result of this effort is the Medical Device Safety Act.

The legislation we're discussing today would alter the MDA's preemption provision to state that it does not apply to actions for liability under State law. My opposition to this approach stems from many factors. First, I do not believe that randomly-selected jurors have the necessary scientific and clinical knowledge to perform the same level of analysis and review as the experts at the FDA. Yet, in essence, this legislation would supplant the findings of the FDA with those of juries in State courts. This is not only bad policy from the perspective of device safety, it will also likely have a number of unintended consequences.

Once again, under the current system, device manufacturers go to considerable expense to obtain premarket approval, in part, because they know that the financial risks of litigation are greatly reduced once the process is completed. However, if this legislation is enacted and manufacturers are required to ensure that they have approval of the FDA as well as that of any 12 random people in any one of the States, the risks of marketing a device will greatly increase. As a result, innovation will be stifled and fewer and fewer devices will be brought to the market. Additionally, we will inevitably see a rise in the overall cost for devices as a means to offset the cost to more frivolous lawsuits. This is not only a detriment to health care reform, but more specifically it undermines the primary health care reform goal of controlling the growth curve. Not only will this adversely affect an industry that employs millions of people during a time of economic crisis, it will also harm patients as they will not benefit from the ingenuity and continuing advancement in device technology. That, in my opinion, will be the most devastating effect of this legislation.

Indeed, we have one of the most, if not the most, innovative and vibrant medical device industries in the world that provides life-saving solutions to millions of Americans and people all around the world every year. At a time when our unemployment is rapidly headed towards double digits, it would be a mistake for us to take some of the steps that are currently being discussed, which include, on top of this legislation, taking billions out of this productive sector that employs thousands of Americans to produce life-saving treatments as a pay-for an ill-advised massive government expansion and control of our health care system.

Making this proposition even worse is the fact that it's unnecessary. We all want to ensure that those who have been truly victimized by the negligence of another party are able to receive adequate compensation for their injuries. However, the current system, including the statutory preemption, does not prevent plaintiffs who have legitimate claims from being compensated. Under the MDA, device manufacturers can only benefit from the protections of preemption if they follow the system to the letter. If they withhold or falsify information in their disclosures to the FDA, they will be charged with defrauding the Federal Government. Similarly, if a

single device is not built exactly to the FDA's approved specifications or if it doesn't include the FDA-approved labels, the manufacturer will be liable for damages. In addition, if a device is improperly implanted or used, the MDA will not protect a doctor from being sued for malpractice. Put simply, when a manufacturer is legitimately at fault, they will be liable under current law. But, when they are not at fault, the MDA provides a narrowly-crafted safe haven from costly litigation.

As I've stated, this exceptionally narrow exemption has great benefits. Indeed, the MDA has allowed for unparalleled advancement in medical device technology, due in no small part to the fact that the rules for safety and liability can't be rewritten in 50 separate jurisdictions. If enacted, the legislation we're discussing today would remove this protection and, as a result, I believe it is the patients who will suffer.

I look forward to hearing the testimony from our panel today. I hope that, during this discussion, we can get to the bottom of some of these issues. In particular, I'd like to hear some explanation as to why we should empower lay-men on State juries to overrule the studies, analyses, and findings of our FDA experts. In addition, I hope we can debate these issues looking toward the future and the effects this legislation will have on the advancement of medical technology, the increased cost to our already out-of-control health care spending, and the lives of those who would benefit from such technology.

Once again, I want to thank Senator Harkin for chairing this hearing in the absence of the esteemed chairman of the committee. And, I want to thank our witnesses for appearing here today.

Senator HARKIN. I thank you very much, Senator Hatch.

I'm told we have a couple of votes coming up very soon, so what we'll try to do is go down the panel. If you would just take maybe 5 minutes to summarize, then we will break to go vote, afterwards we will come back for questions and finish up the panel. I just don't know exactly how soon those votes are going to be called. Maybe right now. No, not really.

Senator HATCH. That's good.

[Laughter.]

Senator HARKIN. I also want to note for the record that we have a new member of our committee with us today. This is his first hearing, our distinguished Senator from the State of Minnesota. And we welcome you to the committee.

Senator FRANKEN. Thank you, Mr. Chairman.

Senator HARKIN. I just want to say that I started in that seat, right down there, I remember—

[Laughter.]

Senator HARKIN [continuing]. Back in the last century.

[Laughter.]

Senator HATCH. The way he used to beat me up on television, I'm very happy to see him way over there.

[Laughter.]

Senator FRANKEN. Well, it's great to serve with both of you—

Senator HARKIN. We welcome you.

Senator HATCH. We welcome you.

Senator FRANKEN [continuing]. Mr. Chairman. And you, too, Senator Burr.

[The prepared statement of Senator Franken follows:]

PREPARED STATEMENT OF SENATOR FRANKEN

Thank you, Mr. Chairman. It's an honor to be here as a new member of the HELP Committee. As I've mentioned before, this committee assignment was a top request of mine. I have to commend my colleagues for their excellent work so far on health reform. It's humbling to be joining the first committee to refer a national health reform bill out of a Senate committee in more than 15 years and most importantly, that bill—the Affordable Health Choices Act—is a first-rate bill that would bring stable, affordable health insurance coverage to millions of Americans.

Since coming to the Senate, I've had the opportunity to hold up Minnesota as an example for the rest of the country in many ways. Just a few examples are the Mayo Clinic; the low-cost, high-quality health care is available across our State; and Minnesota's requirement that health plans be not-for-profit. As the home of St. Jude, Boston Scientific, and Medtronic, Minnesota has also been a leader in the medical device industry. This industry has brought thousands of jobs to Minnesota, and life-sustaining technology to millions of people throughout the United States and the world.

Such technology and its ability to save lives is the Implantable Cardioverter Defibrillator, or ICD. Patients with fibrillation who don't have access to an ICD have a 95 percent chance of dying quickly. But *with* an ICD, chances of survival flip on their head, and 98 percent are able to live, long healthy lives. I don't think anyone questions that advances in medical device technology have improved the quality of life for Americans. However, as with all medical procedures, there are risks involved.

As others have mentioned today, we know that medical devices are distinct from drugs. These complex, finely engineered products must be designed to work in the body for many years. We know from families like the Bairds, the Meyers, and Steven Baker, who are here today with us from Minnesota, that when these devices fail, the impact on individual patients and their families is devastating. The question that we must grapple with today is *how to create public policy that puts patients' health first by protecting them from unnecessary harm, while still allowing patients to benefit from new technologies.*

The question of medical device preemption is incredibly complex and requires careful consideration by all sides. I appreciate the opportunity to hear from the witnesses assembled today, and I hope to learn from them about the steps Congress can take to help Americans be safer and healthier.

There are several steps that I believe may help strike a balance between fostering the medical benefits of devices while protecting patients from unnecessary harm:

- First, we need to *promptly* identify and disclose problems when they arise. In the case of Medtronic's Sprint Fidelis defibrillator, if the problem had been made public earlier, the harm to patients may have been greatly reduced. It seems to me that we need more

transparency from all parties to ensure that prompt reporting of potential problems. I look forward to hearing from the witnesses how we can do a better job providing accurate, timely information to patients and providers.

- Second, we need to help both patients and providers make educated decisions about healthcare decisions based on a balanced view of risk and benefit. Implantable medical devices are amazingly complex and are built to interact with the incredibly complex human body. I'm interested to hear the witnesses' recommendations on how we can help all parties make realistic, informed health care decisions about the use of these medical devices.

This hearing will begin to shed some light on these tricky issues, and when combined with the Medical Device Safety Act and the sincere participation of medical device companies in the debate, I'm confident we will make progress on this issue. I am also especially heartened that FDA Commissioner Hamburg has made medical device safety an early priority for the agency.

The guiding principle in all healthcare decisions should be: "What is best for the patient?" With medical devices, patients have much to gain. But at the same time, they also take on the small, but real risk of serious health effects.

These steps toward patient safety can take place while still allowing companies that engineer and manufacture devices to continue to innovate. Thank you Mr. Chairman. I appreciate the opportunity to participate in the discussion on this important issue.

Senator HARKIN. Thank you.

First—we'll start from the left then go to the right, over this way. First, we'll start with Dr. Maisel. He's the founder and director of the Medical Device Safety Institute at the Beth Israel Deaconess Medical Center, assistant professor of medicine at Harvard Medical School. He has an active cardiology practice and also directs the pacemaker and defibrillator service at Beth Israel Deaconess Medical Center. He received his M.D. from Cornell University, his M.Ph. from Harvard School of Public Health, completed his internal medicine and cardiovascular training at Brigham and Women's Hospital.

Dr. Maisel has served as a consultant to the FDA's Center for Devices and Radiological Health since 2003 and is a former chairman of the FDA's Circulatory System Medical Device Advisory Panel.

Dr. Maisel, welcome. As for all of the witnesses, your statements will be made a part of the record in their entirety, and if you could sum it up in 5 to 7 minutes, I'd be most appreciative.

Dr. Maisel.

**STATEMENT OF WILLIAM H. MAISEL, M.D., M.P.H., DIRECTOR,  
MEDICAL DEVICE SAFETY INSTITUTE, BETH ISRAEL, DEACONESS  
MEDICAL CENTER, HARVARD MEDICAL SCHOOL,  
BOSTON, MA**

Dr. MAISEL. Thank you, Mr. Chairman, committee members, good afternoon. Thank you very much 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 pro-

fessor of medicine at Harvard Medical School in Boston, and I direct 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 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. The U.S. Supreme Court's *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.

We are very 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. 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.

Thankfully, there are many superb FDA engineers, physicians, scientists, and public servants who work tirelessly to try to ensure that only safe and effective medical devices reach the American public. Unfortunately, it is not uncommon for unanswered questions regarding device safety and effectiveness to 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, and we'll hear more on that later, from Mr. Mulvihill.

It was then determined that the wire was prone to fracture, and a fracture of the lead, which connects the implantable defibrillator to the heart, may result in serious health consequences, including painful electric shocks or death. The Medtronic lead was approved on the basis of no human clinical data. Though Medtronic began receiving reports of lead fractures within months of initial U.S. market release, they did not recall the lead until more than 3 years later. An FDA inspection report, issued after the recall, cited Medtronic for, "objectionable conditions," noting that they failed to implement appropriate corrective and preventive action procedures related to the company's investigation of the product anomaly. In addition, when the FDA inspection team requested certain documents, according to the FDA inspection report, Medtronic would not let the FDA team view them.

The delay in issuing a product recall, the FDA citation, and the failure to provide FDA with the requested documents did nothing to eliminate Medtronic's protection under the preemption doctrine. Indeed, Medtronic claimed product liability immunity, citing the U.S. Supreme Court's *Riegel* decision, and the U.S. District Court agreed.

The FDA annually receives reports of more than 200,000 device-related injuries and malfunctions, and more than 2,000 device-related deaths. It's challenging for the agency to identify patterns of device malfunction among the deluge of adverse-events reports. The vast majority of recalls are initiated by the manufacturer, but manufacturers have an inherent financial conflict of interest, often measured in billions of dollars.

In numerous cases, manufacturers have knowingly sold potentially defective devices without public disclosure. During fiscal year 2006 alone, 651 recall actions were initiated involving 1,550 products, again reminding us that FDA product approval does not ensure device reliability or performance.

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 *Riegel* decision, that manufacturers could not be sued under State law by patients harmed by product defects from FDA-approved medical devices. As a result, consumers are unable to seek compensation from manufacturers for their injuries, lost wages, or health expenses. More importantly, a vital consumer safeguard—the threat of manufacturer liability—has been eliminated. Implanted medical devices have enriched and extended the lives of countless people, but device malfunctions have become modern diseases that will continue to occur.

Manufacturers have important responsibilities for product safety that extend well beyond FDA approval. The idea that manufacturer liability for a medical device should end at FDA approval is a dangerous policy. Additional consumer protections, as offered by the Medical Device Safety Act of 2009, are essential to minimize adverse health consequences and to improve the safety of medical devices for the millions of patients who enjoy their benefits.

Thank you.

[The prepared statement of Dr. Maisel follows:]

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

#### INTRODUCTION

Thank you for the opportunity to speak today 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 Founder and Director of the Medical Device Safety Institute ([www.medicaldevicesafety.org](http://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 I 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. 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.<sup>1</sup> 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. The Medical Device Safety Act of 2009 will re-

<sup>1</sup>*Riegel v. Medtronic*, 552 U.S. 2 (2008).

store the consumer safeguards that are necessary to ensure 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.<sup>2</sup> 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.<sup>3</sup> Thankfully, there are many superb FDA engineers, physicians, scientists, and public servants who work tirelessly to try to ensure that only safe and effective medical devices reach the American public.

#### FDA PRE-APPROVAL EVALUATION

To gain marketing 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 some products undergo testing in humans before FDA approval, it is not a requirement.

The FDA annually receives hundreds of premarket approval (PMA) and PMA supplement applications. Although this represents only approximately 61 percent of all FDA-listed devices, PMA devices are implanted into tens of millions of patients and include the highest risk devices, such as coronary stents and implantable defibrillators.<sup>4</sup>

Unfortunately, it is not uncommon for unanswered questions regarding device safety and effectiveness to 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.<sup>5</sup> 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. The Medtronic lead was approved on the basis of no human clinical data.

Mr. Sidney Engler, a patient of mine, unfortunately received this lead when he had an implantable defibrillator placed in February 2006. Mr. Engler is a decorated WWII veteran, having served in Europe from 1943 to 1945. On the night of August 14, 2008 while preparing to retire for the evening, the simple act of removing his shirt over his head caused his defective defibrillator lead to fracture. Mr. Engler suffered a cardiac arrest in front of his wife. He required CPR and received numerous unnecessary painful shocks from his defibrillator. Fortunately, due to the prompt response of his local EMTs, Sidney survived. Despite a prolonged hospital stay and months of rehabilitation, he has still not fully recovered.

Although Medtronic began receiving reports of lead fractures within months of initial U.S. market release, they did not recall the lead until more than 3 years later. An FDA inspection report, issued after the recall, cited Medtronic for “objectionable conditions” for failing to implement appropriate corrective and preventive action procedures related to the company’s investigation of the product anomaly.<sup>6</sup> In addition, when the FDA inspection team requested certain documents, FDA was told by Medtronic that “they were not able to . . . view them.”<sup>6</sup>

The delay in issuing a product recall, the FDA citation, and the failure to provide FDA with the requested documents did nothing to eliminate Medtronic’s protection under the preemption doctrine. Indeed, Medtronic claimed product liability immu-

<sup>2</sup>Maisel WH. Medical device regulation: An Introduction for the practicing physician. *Ann Intern Med* 2004; 140: 296–302.

<sup>3</sup>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 July 28, 2009 at: <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm127516.pdf>.

<sup>4</sup>Government Accountability Office. Medical Devices: FDA Should Take Steps to Ensure That High-Risk Device Types Are Approved through the Most Stringent Premarket Review Process. January 2009. Accessed July 28, 2009 at: <http://www.gao.gov/new.items/d09190.pdf>.

<sup>5</sup>Maisel WH. Semper Fidelis—Consumer Protection for Patients with Implanted Medical Devices. *N Engl J Med* 2008; 358: 985–987.

<sup>6</sup>U.S. Department of Health and Human Services. Food and Drug Administration Establishment Inspection Report FEI 2182208 Medtronic, Inc. Cardiac Rhythm Disease Management, 12/21/07. Accessed on July 28, 2009 at: <http://www.fda.gov/downloads/AboutFDA/CentersOffices/ORA/UCM133024.pdf>.

nity citing the U.S. Supreme Court's *Riegel* decision and the U.S. District Court agreed.<sup>7</sup>

#### FDA MANDATED POST-APPROVAL STUDIES

During pre-market device evaluation, several factors may limit the ability of the FDA to identify and predict which products will perform safely after approval. There may be questions that cannot be answered in the premarket stage, or an issue may arise after the device is marketed. 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 percent of the required post-market medical device studies for the years 1998–2000 and acknowledged that some of the studies were never started.<sup>8</sup> And while efforts have been made to better track these required studies, a visit to the FDA's device post-approval study Web site demonstrates that more than one-third of manufacturers with on-going post-approval study responsibilities currently have an overdue report.<sup>9</sup> In 2005, Dr. Susan Gardner, Director of the FDA's Center for Devices and Radiological 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."<sup>8</sup>

#### ADVERSE EVENTS AND RECALLS

Despite their premarket medical device evaluation, the FDA annually receives reports of more than 200,000 device-related injuries and malfunctions, and more than 2,000 device-related deaths.<sup>10</sup> It is challenging for the Agency to identify patterns of device malfunction among the deluge of adverse event reports. FDA initiatives to better integrate the premarket and postmarket workforces, to develop novel methods of surveillance, and to improve tracking of required manufacturer postmarket studies may help.

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 2,600 device malfunctions, 12 deaths, and numerous other complications related to use of its Ancure Endograft system for aortic aneurysms. The U.S. Attorney noted that "Because of the company's conduct, thousands of patients underwent surgeries without knowing the risks they faced . . ."<sup>11</sup>

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. In numerous cases, manufacturers have knowingly sold potentially defective devices without public disclosure.<sup>5 12</sup> 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.<sup>10</sup>

<sup>7</sup>In re: Medtronic, Inc. Sprint Fidelis Leads Product Liability Litigation, 592 F.Supp.2d 1147 (D. Minn., 2009).

<sup>8</sup>U.S. Food and Drug Administration, Center for Devices and Radiological Health Medical Devices Advisory Committee Circulatory Systems Devices Panel. April 22, 2005. Accessed July 28, 2009 at: <http://www.fda.gov/ohrms/DOCKETS/ac/05/transcripts/2005-4108t1.htm>.

<sup>9</sup>U.S. Food and Drug Administration. Post Approval Studies. Accessed July 28, 2009 at: [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma\\_pas.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm).

<sup>10</sup>Center for Devices and Radiological Health. CDRH FY 2006 highlights. Accessed July 28, 2009 at: <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm129258.pdf>.

<sup>11</sup>Castellucci L. Guidant subsidiary pleads guilty, settles criminal charges related to aortic aneurysm device. Accessed July 28, 2009 at: <http://www.theheart.org/viewArticle.do?simpleName=347409>.

<sup>12</sup>Maisel WH. Safety issues involving medical devices. Implications of recent implantable cardioverter-defibrillator malfunctions. *JAMA* 2005; 294: 955–958.

## PRE-EMPTION—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.<sup>1</sup> Because their lawsuits are “preempted,” consumers are unable to seek compensation from manufacturers for their injuries, lost wages, or health expenses. More importantly, however, 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. The idea that manufacturer liability for a medical device should end at FDA approval is a dangerous policy. 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. Manufacturers have important responsibilities for product safety that extend well beyond FDA approval and we have witnessed the repeated failure of manufacturers to provide the public with timely, critical information about device performance, malfunctions, and “fixes” enabling potentially defective devices to reach unwary consumers. There are 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.

Senator HARKIN. Thank you very much, Dr. Maisel.

And now we’ll turn to Professor Thomas McGarity, who holds the Joe R. and Teresa Lozano Long Endowed Chair in Administrative Law at the University of Texas School of Law. He has taught administrative law, environmental law, and torts at Texas Law School since 1980. Professor McGarity received his BA in 1971 from Rice University, his JD in 1974 from the University of Texas. After a clerkship with the Honorable William E. Doyle of the Tenth Circuit Court of Appeals, he served as an attorney advisor in the Office of General Counsel of the EPA.

Professor McGarity has written extensively about administrative law. In October 2008, he published his most recent book, “The Preemption War: When Federal Bureaucracies Trump Local Juries.”

Professor McGarity, welcome.

**STATEMENT OF PROFESSOR THOMAS O. MCGARITY, JOE R. AND TERESA LOZANO LONG ENDOWED CHAIR IN ADMINISTRATIVE LAW, UNIVERSITY OF TEXAS SCHOOL OF LAW, AUSTIN, TX**

Mr. MCGARITY. Thank you very much, Chairman Harkin and other members of the committee, for having me here.

I am very pleased to be here and to share my thoughts on this very important bill with you. I am, of course, expressing my own views on this matter, not those of the University of Texas.

The U.S. Supreme Court has frequently invoked what it calls a “presumption against preemption” in areas that are subject to traditional State regulation. And this reflects our federalist system, where we have a Federal Government but we also have 50 State governments.

Medical devices were not regulated at the Federal level at all until 1976, when the Dalkon Shield tragedy motivated Congress to

enact the MDA of 1976. The purpose of the statute was to protect the users of medical devices from future Dalkon Shields by ensuring that dangerous devices did not enter the marketplace in the first place.

Now, the Medical Device Amendments did have—and do have—a preemption clause in them, and it does use the magic word “requirement,” as the U.S. Supreme Court held in the *Riegel* opinion. Now, that was no doubt added to the statute because several States were enacting their own regulatory regimes, in the absence of a Federal regime, to fill the void. The statute lacked a savings clause for common-law claims, no doubt because in 1976 it never occurred to anyone that the word “requirement” would include State common law. But, the U.S. Supreme Court, in 1992, in the *Cipollone* opinion, held that it did, for purposes of that statute; and we’ve seen, in the *Riegel* case, that it now has interpreted the preemption clause in the MDA to mean the same thing.

Now, while the Court’s reasoning is open to criticism, the point that you made earlier is that Congress is in the position to fix this. Congress is the ultimate decisionmaker when it comes to preemption.

And I think, therefore, that taking up S. 540 is a good idea, for the reason that it preserves corrective justice for those who have been wronged. Corrective justice is a bedrock principle of civil society that goes back at least as far as Aristotle. The compensation of the common law provides corrective justice by requiring manufacturers of defectively designed or manufactured products to compensate innocent victims.

Now, tort law also provides an important backstop to the regulatory system by sending a message to potential defendants to collect the data necessary to evaluate their products and to take action to prevent future harm.

Device manufacturers that conduct the clinical trials, that are continually receiving the reports and to collect data from all sources, are in a much better position than the doctors out in the field, than the patients, certainly, or even than FDA, to evaluate the safety of their devices. They are also in a far better position to do something about it once problems do arise. The manufacturers’ incentive to comply with the common-law duty reinforces, therefore, the protective function of the Medical Device Amendments.

Now, what are the consequences of preemption? Well, on very rare occasions, Congress has, in fact, explicitly preempted common-law claims. Every time it’s done that, that I’m aware of, it has provided either a Federal cause of action or some compensation regime to provide that important compensation function. When a court interprets the word “requirement” to preempt State common-law claims, there’s a void left, there is no corrective justice. It also robs the common-law of its backstop role to back up the Federal system—the regulatory system.

Now, there are other policy considerations, as well. Institutional competence. Yes, FDA has expertise, but it is also subject to capture. And FDA approval is still relevant, and often determinative—I would say, most often determinative—in common-law litigation.

FDA has traditionally lacked resources. It can be manipulated by companies who defraud the agency. It is not the case that a party, who alleges that he's been damaged because a company's defrauded the agency, is entitled to compensation for that. Indeed, the U.S. Supreme Court, in the Buckman case, held that that claim is preempted by Federal law. So, whereas the Federal Government may pursue the frauds—or fraudulent practices—it is not something that a defendant, I mean, a plaintiff who has been harmed can seek compensation for.

We have other functions. Federalism, as already mentioned, is an important consideration in our government. And the argument that somehow allowing compensation will over deter companies just isn't supported by hard, empirical data. I've looked in—I can't find good, strong studies saying that, "Well, yes, we have fewer devices out there—or, fewer drugs, for that matter—because people are able to claim compensation when they are damaged."

The decision to preempt State common law is uniquely within the power of Congress. I commend this committee for taking up that question.

Thank you.

[The prepared statement of Mr. McGarity follows:]

PREPARED STATEMENT OF THOMAS O. MCGARITY

My name is Tom McGarity. I hold the Joe R. and Teresa Lozano Long Endowed Chair in Administrative Law at the University of Texas School of Law, where I teach courses in Torts and Environmental Law. I am also a member of the Board and immediate past president of the Center for Progressive Reform. I have recently published a book entitled *The Preemption War: When Federal Bureaucracies Trump Local Juries*, in which I explore in some detail the issues that are before your committee today. I am very pleased to be here to testify on the topic of Federal preemption of State common law claims and on the "savings clause" in S. 540 that, as I understand it, is intended to exempt State common law claims from the express preemption clause in the Medical Device Amendments to the Food, Drug and Cosmetics Act. Please note that I am expressing my own views and not necessarily those of the University of Texas or the Center for Progressive Reform.

THE MEDICAL DEVICE AMENDMENTS AND THE RIEGEL OPINION

Although the Supreme Court has frequently invoked a "presumption against preemption" in "areas of traditional State regulation,"<sup>1</sup> it has expanded the range of Federal programs that preempt State common law during the past 20 years.<sup>2</sup> This process began with the Court's 1992 holding, in *Cipollone v. Liggett Group, Inc.*, that the word "requirement" in an express preemption clause could include State common law claims.<sup>3</sup> This much-criticized opinion invited defendants to raise the Federal preemption defense in every case in which the relevant statute used the word "requirement" or similar words that could broadly be interpreted to include common law duties.

Medical devices were not regulated at the Federal level until the Dalkon Shield tragedy in the early 1970s motivated Congress to enact the 1976 Medical Device Amendments to the Food, Drug and Cosmetics Act.<sup>4</sup> The unambiguous purpose of the statute was to protect patients from future Dalkon Shield disasters by ensuring that dangerous devices did not enter the marketplace in the first place.<sup>5</sup> To accom-

<sup>1</sup>*Bates v. Dow Agrosciences, LLC*, 544 U.S. 431, 449 (2005) (quoting *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995)); *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 716 (1985).

<sup>2</sup>Thomas O. McGarity, *The Preemption War*, ch. 4 (2008); Robert L. Rabin, *Federalism and the Tort System*, 50 Rutgers L. Rev. 1, 27 (1997).

<sup>3</sup>*Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992).

<sup>4</sup>*Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996); Richard B. Sobol, *Bending the Law: The Story of the Dalkon Shield Bankruptcy* (1991).

<sup>5</sup>*Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

plish this purpose, the statute created a comprehensive regulatory regime under which medical devices in the most dangerous of three categories may not be put on the market until the manufacturer has demonstrated to FDA that there is a “reasonable assurance” that they were both safe and effective.<sup>6</sup>

The Medical Device Amendments contain an express preemption clause that uses the magic word “requirement.”<sup>7</sup> As a historical matter, the express preemption clause was added to the statute because several States, including California, were considering or enacting legislation to fill the void left by the absence of a Federal regulatory regime. The statute lacks a “savings clause” exempting State common law claims from the ambit of the preemption clause. This is no doubt attributable to the fact that prior to the *Cipollone* case, few if any lawyers imagined that the word “requirement” included State common law claims.

In the 1996 case of *Medtronic, Inc. v. Lohr*,<sup>8</sup> the Court held that the Medical Device Amendments preempted some, but not all common law claims directed toward medical devices that FDA had approved using the very abbreviated process that the statute provides for devices that are “substantially equivalent” to devices in existence in 1976.

Twelve years later, in *Riegel v. Medtronic, Inc.*,<sup>9</sup> the Court took up the issue of devices that had undergone the full FDA approval process. The Court there held that the word “requirement” in the statute’s express preemption clause encompassed *Riegel’s* common law claims. In broad dicta that defendants are relying on in currently pending cases, the Court added that “[a]bsent other indication, reference to a State’s “requirements” includes its common-law duties.”<sup>10</sup> Noting that during the full approval process “the FDA requires a device . . . to be made with almost no deviations from the specifications in its approval application,”<sup>11</sup> the Court explained that “State tort law that requires a manufacturer’s catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the Federal scheme no less than State regulatory law to the same effect.”<sup>12</sup>

While the court’s reasoning is certainly open to criticism, the fundamental flaw, in my view, dates back to the *Cipollone* opinion. It is therefore highly unlikely that the Court will revisit either decision in the foreseeable future. I take the position in my book *The Preemption War* that the best way to reverse this trend toward Federal agency preemption of State common law claims is for Congress to revisit the relevant statutes on a case-by-case basis.<sup>13</sup> That is exactly what S. 540 does, and I commend your committee for taking up this important issue.

#### THE CORRECTIVE JUSTICE AND DETERRENCE FUNCTIONS OF THE COMMON LAW

“Corrective justice” is a bedrock principle of civil society that dates back at least as far as Aristotle. Broadly stated, corrective justice requires that the State correct unjust changes in wealth that result from interactions among the members of a polity, usually by way of a financial arrangement. The compensation function of the common law provides corrective justice by requiring manufacturers of defectively designed or manufactured products to compensate innocent persons who have been injured by such products. I can think of no better example of corrective justice than the principle that the manufacturer of a defective medical device must compensate innocent patients who have been injured by the defective aspects of that device.

The accountability afforded by the civil justice system also provides a powerful incentive to companies to avoid causing harm in the first place.<sup>14</sup> To the extent that the anticipated compensatory and punitive damage awards imposed by the civil justice system are greater than the cost of avoiding the harm, a rational company will take protective action to prevent causing damage in the future.<sup>15</sup> In this way, tort law provides a valuable backstop to the regulatory system by sending a message to

<sup>6</sup> 21 U.S.C. §360e(d)(2); Richard C. Ausness, “After You, My Dear Alphonse!”: Should the Courts Defer to the FDA’s New Interpretation of §360k(A) of the Medical Device Amendments, 80 *Tulane L. Rev.* 727 (2006), at 731–33.

<sup>7</sup> 21 U.S.C. §360k(a).

<sup>8</sup> *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

<sup>9</sup> *Riegel v. Medtronic, Inc.* 128 S.Ct. 999 (2008).

<sup>10</sup> 128 S.Ct., at 1008.

<sup>11</sup> 128 S.Ct., at 1007.

<sup>12</sup> 128 S.Ct., at 1008. To the extent that the plaintiff’s claim was based on a company’s violation of FDA’s regulations, however, there was no variance between the duty imposed by the Federal Government and that imposed by the common law. Therefore, such claims were not preempted.

<sup>13</sup> Thomas O. McGarity, *The Preemption War* ch. 10 (2008).

<sup>14</sup> See Thomas O. McGarity, *The Preemption War* 32–33 (2008).

<sup>15</sup> Dan B. Dobbs, *The Law of Torts* (2000), at 19–21; Gary T. Schwartz, *Mixed Theories of Tort Law: Affirming Both Deterrence and Corrective Justice*, 75 *Tex. L. Rev.* 1801 (1997), at 1832.

potential defendants to collect data on the harm-producing potential of their products and activities and to take action to prevent future harm.<sup>16</sup> Indeed, litigation may be more effective in removing risky products from the market than regulatory controls.<sup>17</sup>

The deterrence function of State tort law is especially relevant to medical devices for two reasons. First, the device manufacturers that conduct the clinical trials and continually receive reports on their products will generally have access to more information on the risks posed by their products than doctors, patients or even FDA. Second, device manufacturers are in a far better position than doctors, patients or FDA to improve the safety of their products both before and after they enter the marketplace. The manufacturers' incentive not to violate its common law duty to market non-defective medical devices therefore reinforces the protective policies underlying the Medical Device Amendments.

#### THE CONSEQUENCES OF PREEMPTION

Congress only very rarely speaks explicitly to State common law (as opposed to State statutes and regulations) in express preemption clauses. When it does, it invariably provides an alternative route to corrective justice by creating either a separate Federal cause of action or an alternative administrative compensation regime.<sup>18</sup> Congress typically creates a national compensation regime because it concludes either that the common law of some States inadequately advances important public policies or that a national system with uniform rules is necessary to ensure the continued availability of valuable products and activities. An example of the former is the Federal Employees Liability Act, which was enacted in 1908 to replace regressive State common law doctrines that shielded railroads from liability with a more "enlightened" Federal common law cause of action for workers of interstate common carriers.<sup>19</sup> An example of the latter is the National Childhood Vaccination Injury Act (NCVI Act) of 1986, which provides swift compensation for persons injured by vaccines, while at the same time ensuring that litigation risks do not hamper the country's supply of effective vaccines.<sup>20</sup>

When a court interprets an express preemption clause that mentions State "requirements" and does not include an alternative compensation regime to include State common law claims, it deprives victims of their right to compensation from the wrongdoers who injured them. There is no alternative compensation regime available in these cases to provide corrective justice. In the case of uninsured victims, their medical expenses are as often as not picked up by the States or the Federal Government. Furthermore, a finding that a products liability claim is preempted robs the common law of the "backup" role that it plays by way of providing an incentive to device manufacturers not to market defective products.

For these reasons, I believe that Congress should be very reluctant to deprive victims of corrective justice and to deprive Federal agencies of the common law's "backstop" function behind the veil of express preemption clauses, and it should be very quick to correct the injustice that results when a court misinterprets an express preemption clause using the word "requirement" to eliminate victims' rights to corrective justice. That is why I believe that a statute like S. 540 should be on the congressional agenda in the wake of the *Riegel* opinion.

#### POLICY CONSIDERATIONS

Although much of the law of preemption derives from judicial opinions, it is important to recognize at the outset that the determination whether a Federal regulatory regime should preempt State law is entirely within the discretion of Congress. How Congress exercises that discretion is ultimately a policy question that requires Congress to balance several important considerations, many of which I highlight in chapters 7–9 of *The Preemption War*. I have already alluded to the overarching policy of preserving the capacity of the common law to provide corrective justice. I will

<sup>16</sup> See Mary L. Lyndon, *Tort Law and Technology*, 12 *Yale J. Reg.* 137 (1995), at 143; Wendy Wagner, *When All Else Fails: Regulating Risk Products Through Tort Litigation*, 95 *Georgetown L. J.* 693 (2007), at 727.

<sup>17</sup> Alexandra B. Klass, *Pesticides, Children's Health Policy, and Common Law Tort Claims*, 7 *Minnesota J. of Law, Science, & Technology* 89 (2005), at 118.

<sup>18</sup> Timothy D. Lytton, *The NRA, The Brady Campaign, & the Politics of Gun Litigation*, in Timothy D. Lytton, ed., *Suing the Gun Industry* (Univ. of Michigan Press 2005), at 152, 174.

<sup>19</sup> 45 U.S.C. §§51–60. See Dan B. Dobbs, *The Law of Torts* (2000), at 40, 312; Robert L. Rabin, *Federalism and the Tort System*, 50 *Rutgers L. Rev.* 1 (1997), at 26.

<sup>20</sup> 42 U.S.C. §300aa–11–15; *Moss v. Merck & Co.*, 381 F.3d 501 (5th Cir. 2004), at 503. See generally Thomas F. Burke, *Lawyers, Lawsuits, and Legal Rights* (Berkeley, U. California Press 2002), at ch. 4.

briefly summarize some other considerations below and explain why, in the case of medical devices, it is my view that a savings clause like that contained in S.540 represents sound public policy.

#### *Conflict Avoidance*

The most powerful policy rationale for preempting any State law is the potential for conflict between that law and Federal law. The Supreme Court has recognized that conflict comes in two varieties. First, two bodies of law may impose conflicting obligations on those who are subject to them. Thus, a State law that requires a person to take an action that violates a Federal regulation presents a conflict that renders compliance with both impossible. Although common law injunctive relief could easily bring about such a direct conflict, a common law claim for damages would present such a direct and forceful conflict only in the difficult-to-imagine case in which a Federal regulation prohibited a company from paying damages to an injured plaintiff. Nevertheless, it would usually be unfair to force a company to pay damages for violating a common law duty that directly conflicts with a Federal regulatory requirement.

Second, the two bodies of law may be at cross purposes, as when compliance with State law would present an obstacle to achieving an important policy underlying a Federal regulation. In my view, there is little risk that allowing victims of defective medical devices to seek corrective justice from manufacturers of defective devices will cause a conflict with an important Federal policy. To the extent that the device fails to comply with Federal requirements, allowing common law claims to proceed would simply reinforce the primary purpose of the Medical Device Amendments, which is to protect patients from poorly designed and manufactured medical devices, by providing an added incentive to manufacturers to be careful. There is some risk that common law actions could hinder a Federal policy favoring the availability of medical technologies if the threat of liability caused companies to withdraw FDA-approved devices unnecessarily. The magnitude of that risk, however, depends upon the ability of FDA to address previously approved devices as new information related to risk and efficacy becomes available, a topic that I discuss below.

#### *Institutional Competence*

The primary advantage that regulatory agencies have over State common law is the expertise that they can bring to bear on the scientific and technical issues. Jurors can become confused or bored by complex presentations. On issues that turn on scientific or technical evidence, they may be more easily swayed than agency experts by emotion or irrelevant policy considerations. Yet the available empirical evidence suggests that juries are capable of comprehending complex scientific and technical issues quite objectively with the help of judge-screened experts.

Agencies also develop a policymaking expertise that gives them a clear advantage over courts in addressing major issues of national policy. That form of expertise is, however, less relevant to issues related to the risks of individual products that arise in products liability litigation regarding medical devices.

At the same time, agencies are far from omniscient. They are notoriously subject to "capture" by the very interests that they are charged with regulating. FDA is almost entirely dependent on information submitted by medical device manufacturers at the initial approval stage, and that information is easily manipulated by unscrupulous companies and their consultants.<sup>21</sup> Because the device approval process is cloaked in secrecy, agency reviewers do not have the benefit of skeptical outsiders from public interest and patient advocacy groups. FDA also lacks subpoena power to obtain internal company documents that can tell a very different story than the one the agency reviewers hear in their meetings with company officials.

Common law courts have institutional advantages over Federal agencies that should also be weighed in the balance. Perhaps the strongest institutional advantage of common law litigation is its ability to force information from company files and tease it out of company employees in depositions. Courts are also better adapted than agencies to respond rapidly to developments in the real world as new information on the hazards of products and activities becomes available. Finally, courts are far less subject to capture, manipulation and political pressure than Federal agencies.

#### *Institutional Capacity*

Resource-starved Federal agencies like FDA do not have sufficient personnel to keep up with ongoing technological developments, and they are generally very reluc-

<sup>21</sup>See Marcia Angell, *The Truth About Drug Companies* (2004); Jerome P. Kassirer, *On the Take* (2005); Thomas O. McGarity & Wendy A. Wagner, *Bending Science* (2008).

tant to revisit previous decisions in light of new information. As a practical matter, the promise that they offer to bring both technical and policymaking expertise to bear on issues that are also frequently litigated in common law courts may be a hollow one. Yet the implicit assumption underlying Federal preemption of common law claims is that the Federal regulatory agencies are performing their jobs nearly perfectly. Otherwise, the common law still has a role to play in providing corrective justice to victims of defective products.

*The Common Law Backstop*

As discussed above, the common law provides a valuable “backstop” role when agencies fail to provide the degree of protection envisioned by their authorizing statutes. The threat of common law liability provides incentives for regulatees to take protective action when evolving practices and technologies create unanticipated gaps in the coverage of regulations and permit requirements that are difficult for agencies to fill on a short-term basis. It also provides a disincentive to engage in artful schemes to avoid the reach of regulatory requirements. Finally, by providing a procedural advantage to plaintiffs who can show that their harm was caused by violations of regulatory requirements, common law litigation can assist agency enforcers in their compliance assurance efforts.

*Federalism*

The States have historically played the dominant role in protecting consumers and other victims of harmful business practices and activities. In some important areas, like environmental protection, that dominance has been replaced by that of Federal agencies administering the landmark legislation of the 1960s and 1970s. In other areas, like consumer protection generally, the States remain the dominant institutional actors. And State courts have traditionally been the dominant institutions for providing corrective justice to American citizens. Since “regulatory wisdom does not reside exclusively in Federal agencies,” the experiments with lawmaking that are constantly going on in the 50 States can benefit the Nation as a whole.<sup>22</sup> Indeed, the combined resources of State courts and Federal agencies can usually accomplish a great deal more than the efforts of either one operating alone.

*“Overdeterrence”*

Some scholars have argued that the deterrence function of common law in the context of multiple sovereignties can go too far and cause manufacturers to over-invest in safety and therefore under-invest in the development of useful products.<sup>23</sup> To the extent that the amount invested in safety exceeds the value of the damage caused discounted by the probability that damage will in fact occur, the argument goes, this “overdeterrence” is economically inefficient and could delay the development of important medical technologies.

Given the strongly protective purpose of the Medical Device Amendments of 1976, I think the burden should be on the medical device industry to make that case with hard empirical evidence, and not vague allusions to a supposed “device lag.” Although think tank reports and op-ed pages are filled with claims that the American civil justice system is depriving citizens of useful technologies, I have seen very little hard empirical support for such claims in the context of either drugs or medical devices. In my view, the deterrence function of State common-law performs outweighs any speculative “overdeterrence” that might result from the possibility that device manufacturers may be called upon to compensate the victims of defective devices.

CONCLUSIONS

The decision to preempt State law is uniquely within the power of Congress, and Congress has a responsibility to speak clearly to the issue of State common law when it enacts regulatory statutes that preempt State statutes, regulations, and other “requirements.” Congress has spoken clearly in many important regulatory statutes through savings clauses articulating a congressional intent not to preempt State common law claims. Your committee has an opportunity to speak clearly to this issue in the increasingly important context of federally regulated medical devices. I would urge you to take advantage of that opportunity.

Senator HARKIN. Thank you Professor McGarity.  
And now we’ll turn to Michael Mulvihill, from Bettendorf, IA.

<sup>22</sup> Richard J. Pierce, Regulation, Deregulation, Federalism, and Administrative Law: Agency Power to Preempt State Regulation, 46 U. Pittsburgh L. Rev. 607 (1985), at 656 (regulatory wisdom quote); Nina A. Mendelson, *Chevron* and Preemption, 102 Mich. L. Rev. 737 (2004), at 767.

<sup>23</sup> See Richard A. Epstein, *Overdose* (2006).

Mr. Mulvihill is a graduate of Iowa State University, the foremost university in the entire universe.

[Laughter.]

After graduation, he worked as a golf course superintendent for 13 years. For the next 28 years, he worked for a turf equipment distributor, designing and selling golf course irrigation systems. Mr. Mulvihill is a victim of a faulty medical device, and will speak to that experience.

Mr. Mulvihill, welcome. Thank you for being here. Please proceed.

**STATEMENT OF MICHAEL MULVIHILL, PATIENT,  
BETTENDORF, IA**

Mr. MULVIHILL. Thank you for having me.

My name is Mike Mulvihill, I'm 64 years old, and live in Bettendorf, IA. I had a Medtronic EnTrust defibrillator implanted on March 28, 2006. Arrhythmia was my problem.

On June 30, 2007, I had a very painful life-changing episode. My wife and I were driving to see our son, daughter-in-law, and grandchildren in Haddonfield, NJ. On that Saturday morning, I was driving east of Springfield, Ohio, on I-70, in a construction zone, when the device went off. I first thought we'd hit some road debris, but could not understand what the blue flash was that I'd seen. I tried to navigate the car toward the shoulder of the road. The device shocked me again, and again. Mary, my wife, was calling 9-1-1. I don't remember how many times that device went off, all I recall is the excruciating pain and the fear I was feeling.

The responders showed up and took me to a small hospital in London, OH. They rolled me in on a gurney. The device went off again. I moved my head. It lifted me up off that gurney and then dropped me right back down on it. I remember looking at a—what I was assuming, a very experienced nurse. Her eyes were really, really wide open with concern. And my wife, because I was screaming so bad, she had to go outside, she told me later.

Well, I talked to Ross—Ross Heart Institute at Ohio State put a big magnet on me and transported me into Columbus, to that hospital. Checked in at the Ross Heart Institute. I was exhausted, very scared, and I hurt.

Medtronic's rep came into the room and read the device, told us it had shocked me 22 times in 53 minutes. He added that it was an electrical problem—electrical wire-lead problem, not the device. We had several doctors come in later that day and—came into the room, and one of them told my wife and I how lucky we were that I had not wrecked the car, because I had been driving.

The lead replacement surgery was scheduled for Monday, July 2, in the early afternoon. I was admitted for the 3 days, from Saturday until Tuesday, and I was discharged around noon on July 3. Mary drove us on to our son's house and the entire way back to our house in Bettendorf.

After this episode, I found that driving on freeways, highways, interstates, made me very anxious, made me very tense and fearful of the device going off. I was afraid I might wreck some other car—hit somebody, kill myself, etc. This anxiety had a huge impact on me and my job.

I've been a golf irrigation specialist for the distributor; covered 77 counties in Iowa, 17 in Illinois, and 3 in Wisconsin. Well, that's a lot of driving. And I was no longer able to properly do my job, due to the anxiety and fear that I suffered anytime I drove any distances on highways.

It also affected my personal life, this inability to drive. I had annual fishing trips planned for the fall of 2007, and they were both impacted. The first trip was to Deer River, MN. One of my fishing buddies drove the whole way up there and back, about 1,200 miles, round-trip.

While in Deer River, I experienced some chest pains, I thought, so I went to an emergency room. The doctor concluded I was likely suffering from ulcers. Upon returning home, my doctor located the ulcers and placed me on some antacid medication, etc.

About a month after that, in October 2007, was the next fishing trip. Again, one of the fellows on the trip was kind enough to do all the driving, but I was able to stay up there a day and a half out of the 9-day trip. The anxiety, nerves, whatever you want to call it—fear—got to me. The same fellow drove me home, the 380 miles from Hayward, and then went back up to finish his vacation.

It's affected our personal life, too, because Mary and I can't take those trips to see the family and friends. It's limited Mary's travel, since I worry more when she's not there to calm me down.

After all this worry and tension and anxiety that I was feeling, I decided I needed professional help, and I began seeing a psychologist, who taught me some relaxation techniques. They seemed to help calm me down.

I also, at that time, decided that the travels and pressures of my sales job were too much to handle, so I moved my retirement up to January 3, 2008, about a year and a half sooner than I'd planned.

I had several device checks in 2008, and three trips to the ER within 6 months of the lead replacement. The majority of these visits were from me feeling that something was not right. One of my biggest questions at this time is, What effect the numerous shocks from the Medtronic device have had on my heart? Any unexpected twinge or unusual feeling in the chest area makes me tense, and I begin to wonder if the device is working properly or whether I need to go to the hospital. It's not a fun way to live.

My hope is that no one else ever has to go through the pain and agony that I experienced with a fractured lead, and that Medtronic is held responsible for the injuries it has caused other patients like me.

Thank you.

[The prepared statement of Mr. Mulvihill follows:]

PREPARED STATEMENT OF MICHAEL MULVIHILL

My name is Mike Mulvihill. I'm 64 years old and live in Bettendorf, IA. I had a Medtronic EnTrust defibrillator implanted on March 28, 2006 for irregular heart beat and pulse rate.

I had a life changing episode on Saturday, June 30, 2007. My wife Mary and I were driving to see our son, daughter-in-law, and grandchildren in Haddonfield, NJ. On Saturday morning I was driving east of Springfield, OH on I-70 at about 7:30 a.m. in a construction zone when the device went off. I first thought we'd hit some road debris but could not understand the blue flash I'd seen. I navigated the car toward the shoulder of the road when the device shocked me again and I realized

what was going on. As I made it to the shoulder of the road, Mary was calling 911. I don't remember how many times the unit went off—all I recall is the excruciating pain and the fear I was feeling.

The responders took me to a rural hospital in London, OH. As they rolled me in on a gurney the device went off again—lifting me off the gurney. I remember looking at a nurse whose eyes were really, really wide open with concern. My wife had to go outside to escape my loud and continuous screaming due to the pain. The hospital transported me to Ohio State University-Ross Heart Institute.

Upon check-in at Ross Heart Institute, a Medtronic rep came into the room and read the device. He told us it had shocked me 22 times in 53 minutes. He added that it was an electrical wire lead problem. One of the several doctors who came in the room told my wife and me how lucky we were that I had not wrecked the car.

A lead replacement surgery was scheduled for Monday, July 2, 2007 in the early afternoon. I was admitted for 3 days until I was discharged on Tuesday, July 3. Mary had to drive to my son's home and all the way back to our home.

After the episode, I found that driving on freeways/interstates made me very anxious, tense and fearful of the device going off again. This anxiety had a huge impact on me and my job. My job as a golf irrigation specialist covered 77 counties in Iowa, 17 in Illinois and 3 in Wisconsin. I could no longer cover these routes due to the anxiety I suffered any time I drove on the freeway.

My inability to drive long distances also affected my personal life. I had two fishing trips planned for the fall of 2007. These were annual fishing trips that I'd gone on for over 15 years. Both trips were impacted by the anxiety I was experiencing. The first trip was in the second week of September to Deer River, MN. One of my fishing buddies drove the entire distance up and back. While in Deer River, I was afraid the device was malfunctioning. I was experiencing chest pains so we went to an emergency room where the doctor concluded that I was likely suffering from ulcers. Upon returning home, my permanent doctor located the ulcers and placed me on medication.

The second week of October 2007 was the next fishing trip. Again, one of the fellows on the trip was kind enough to do all the driving to our Hayward, WI destination. I was only able to stay for 1½ days of the 9 day trip before nerves, anxiety, and fear got to me. The same fellow drove me the 380 miles home then went back up to finish his vacation.

The anxiety that I feel, especially when traveling, has severely limited the number of trips Mary and I take to see family and friends. This anxiety has also limited Mary's travel since I worry more when she's not there to help calm me down.

I decided I needed professional help. I began seeing a psychologist who taught me some relaxation techniques. These exercises helped to calm me down. It was also at this time that I decided that the travels and pressure of my sales job were too much to handle, so I moved my retirement up to January 3, 2008. This was about a year and a half sooner than I had originally planned.

I had several device checks in 2008 and three trips to the ER within 6 months of the lead replacement. The majority of these visits were from me feeling that something was not right. One of my biggest questions is what effect the numerous shocks from the Medtronic device have had on my heart.

Any unexpected twinge or unusual feeling in the chest area makes me very tense. I begin to wonder if the device is working properly or whether I need to go to the hospital. It is not a fun way to live.

My hope is that no one else ever has to go through the pain and agony that I experienced with the fractured lead, and that Medtronic is held responsible for the injuries it has caused other patients like me.

Senator HARKIN. Thank you very much for a very profound statement, Mr. Mulvihill.

Now we turn to Peter Barton Hutt, a senior counsel in the law firm of Covington & Burling, specializing in food and drug law. He began his law practice in 1960, and has been with the firm ever since. He is also a lecturer on food and drug law at Harvard Law School, where he has taught for the last 16 years. From 1971 to 1975, he was chief counsel for the FDA. Mr. Hutt is a graduate of Yale University and Harvard Law School, earned a Master of Laws degree in Food and Drug Law from NYU School of Law.

Mr. Hutt, welcome to the committee. Please proceed.

**STATEMENT OF PETER BARTON HUTT, ESQUIRE, SENIOR  
COUNSEL IN FOOD AND DRUG LAW, COVINGTON & BURLING,  
WASHINGTON, DC**

Mr. HUTT. Thank you, Mr. Chairman.

I appear before you today, at the invitation of the committee, to present my own personal views on Section 521 of the Federal Food, Drug, and Cosmetic Act, which provides for national uniformity in the regulation of medical devices.

Section 521 was enacted, of course, as part of the Medical Device Amendments of 1976. As I relate in my prepared statement, the Medical Device Amendments of 1976, and specifically section 721, were enacted or developed during my tenure as chief counsel for FDA, and I was deeply involved in their development.

The medical device bills that were forwarded to Congress by President Nixon in 1971 and 1973 contained no provision that related to the effect of the law, or proposed law, on State law. In August 1973, however, Representative Paul G. Rogers, a Democratic Member of Congress from Florida, who was chair of the House Subcommittee on Public Health and Environment, introduced medical device legislation that, for the first time, included a national uniformity provision. On behalf of FDA, I strongly supported national uniformity in the requirements for medical device regulation, because it would strengthen the integrity, the credibility, and the primary jurisdiction of the agency.

From then on, all medical device legislation considered in both the House and the Senate included some form of national uniformity requirement. The final version was enacted as section 521, and it is that provision that would be amended by the legislation you're considering today, that would permit product liability decisions by judges and juries that are inconsistent with FDA decisions.

Mr. Chairman, because of the time constraint I will summarize my testimony with seven brief points.

First, S. 540 applies only to devices that are determined by FDA to be safe and effective under the rigorous premarket approval system. We call these premarket approval, or PMA, devices. S. 540 does not apply to devices that go through the simplified Section 510(k) procedure.

Second, PMA devices are the lifesaving and life-sustaining devices that represent the cutting edge of modern science. They are, for example, stents to keep arteries open. They are artificial hearts to keep people alive until they can get a real heart. They are the innovative new technology that should be encouraged, not hindered or discouraged.

Third, these PMA devices represent only a small fraction of all medical devices. Since 1976, only about one-half of 1 percent of all medical devices have gone through the rigorous PMA process. The U.S. Supreme Court had determined that the other 99.5 percent that go through the simplified 510(k) process are not entitled to national uniformity. And thus, this legislation does not affect those.

Fourth, the PMA devices uniquely require highly sophisticated judgment on safety and effectiveness, as Senator Hatch has pointed out. The MDs and PhDs at FDA spend more than 1,000 hours over

more than a year to review each one of these devices. No one can possibly argue that lay judges and juries can do a better job.

Fifth, allowing judges and juries to second-guess FDA decisions on PMA devices strikes at the very heart of the PMA system. If judges and juries can ignore FDA, why can't doctors, hospitals, and patients, and even companies, ignore FDA? S. 540 fosters distrust and disrespect for FDA decisions and undermines the public health protection that the PMA system is intended to provide.

Sixth, product-liability awards punish companies, there's no question about that, but they do not in any way contribute to safer or more effective PMA devices. It is the inevitable adverse events that we know will always occur with a device that lead FDA and companies to correct deficiencies and improve the device. But, by the time a lawsuit is brought and completed, the problem has been corrected and the safety issue has been resolved, to the extent that it can be, if it's not inherent in the device.

Finally, I fully support compensation of people injured by PMA devices. There's no question about that. But, the solution is not to farm out FDA decisions to juries throughout the country. The answer is not to replace national uniformity with national inconsistency and regulatory chaos. The jury system is nothing short of a lottery. Some plaintiffs win big and others come away with nothing. It is an inherently unfair system.

The goal of providing compensation can most fairly and comprehensively be addressed by a statutory procedure like the National Childhood Vaccine Injury Act of 1986. Under that system, unlike the product liability system, all patients injured by a PMA device would be fairly compensated, and not just those who are fortunate to find a persuasive trial attorney and a sympathetic judge and jury.

Thank you, sir.

[The prepared statement of Mr. Hutt follows:]

PREPARED STATEMENT OF PETER BARTON HUTT

Mr. Chairman and members of the committee, I am Peter Barton Hutt. I am a Senior Counsel at the Washington, DC law firm of Covington & Burling LLP and a Lecturer on Food and Drug Law at Harvard Law School where I have taught a course on food and drug law during Winter Term for the past 16 years. During 1971-1975 I served as Chief Counsel for the Food and Drug Administration (FDA). I appear before you today at the invitation of the Committee to present my personal views on Section 521 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which provides for national uniformity in the regulation of medical devices. section 521 was enacted by Congress as part of the Medical Device Amendments of 1976.

BACKGROUND

During my tenure as Chief Counsel for FDA I was deeply involved with the development of medical device legislation. On my very first day at FDA in September 1971, FDA Commissioner Charles C. Edwards told me that FDA had been unable to obtain clearance by the Nixon Administration of the proposed medical device legislation that the agency needed, and delegated that task to me. I was successful, and the Administration's bill was introduced in December 14, 1971.<sup>1</sup> Commissioner Edwards then delegated to me the responsibility for development of FDA policy on the legislation and for negotiation of the statutory provisions with the House and Senate. By the time I left FDA in May 1975, the legislation had twice passed the

<sup>1</sup>H.R. 12316, 92d Cong., 1st Sess. (1971).

Senate,<sup>2</sup> and the House bill<sup>3</sup> was largely in the form that was signed into law by President Ford as the Medical Device Amendments of 1976<sup>4</sup> on May 28, 1976.

The December 1971 Administration bill contained no provision addressing national uniformity. Nor did the successor Administration bill, introduced in March 1973.<sup>5</sup> In August 1973, however, Representative Paul G. Rogers (D-FL), Chair of the House Subcommittee on Public Health and Environment of the Committee on Interstate and Foreign Commerce, introduced medical device legislation that for the first time included a national uniformity provision.<sup>6</sup> On behalf of FDA, I strongly supported national uniformity in the requirements for medical devices because it strengthened the integrity, credibility, and primary jurisdiction of the agency. From then on, all medical device legislation considered in the House and Senate included some form of national uniformity requirement. The final version was enacted as Section 521 of the FD&C Act.<sup>7</sup> It is that provision that would be amended by S. 540 to make it inapplicable to decisions by judges and juries in product liability cases that are inconsistent with FDA decisions.

#### THE RISK-BASED REGULATORY SYSTEM ENACTED BY CONGRESS FOR MEDICAL DEVICES

Under the FD&C Act, as amended by the 1976 Amendments and subsequent legislation, FDA regulates medical devices according to three risk-based classifications. Class I medical devices are those simple devices for which general regulatory controls, that are applicable to all devices, are sufficient to assure safety and effectiveness. Class I devices include tongue depressors,<sup>8</sup> dental floss,<sup>9</sup> and surgical sponges.<sup>10</sup> Class II devices are those for which special controls, applicable to a particular class of device, are enough to ensure safety and effectiveness. Class II devices include vascular clamps<sup>11</sup> and powered wheelchairs.<sup>12</sup> Class III devices are those life-saving and life-sustaining devices for which general and special controls are not sufficient, and for which full premarket approval is necessary to assure safety and effectiveness. Class III devices include implantable pacemaker pulse generators,<sup>13</sup> cardiovascular stents, and artificial hearts.

Any Class I, II, or III device may lawfully be marketed if FDA clears a premarket notification (PMN) under Section 510(k) of the FD&C Act that demonstrates that the device is "substantially equivalent" to a marketed device that did not require FDA approval of a premarket approval (PMA) application.<sup>14</sup> The PMN process (commonly referred to as the 510(k) process) is a relatively simple procedure. A Class III device for which there is no marketed non-PMA substantially equivalent device, however, requires full premarket approval under section 515 for both safety and effectiveness.<sup>15</sup> This is a much more lengthy, complex, and rigorous procedure.

#### APPLICATION OF NATIONAL UNIFORMITY UNDER SECTION 521 TO THE MEDICAL DEVICE CATEGORIES

Section 521 provides that no State may impose a "requirement" on a medical device that is different from or in addition to a requirement imposed by FDA. The Supreme Court has interpreted and applied this national uniformity provision twice—once with respect to devices marketed under Section 510(k) of the FD&C Act, and once with respect to PMA devices marketed under section 515.

In *Medtronic, Inc. v. Lohr*<sup>16</sup> the Court held in 1996 that an FDA determination that a Class I, II or III device is "substantially equivalent" to a pre-1976 device is not sufficient to invoke the requirement of national uniformity. The Court concluded that FDA did not make a sufficiently detailed and searching review of the new device and did not approve the device as safe and effective. Thus, a court decision in a product liability case that was inconsistent with an FDA decision was allowed to stand.

<sup>2</sup> 120 Cong. Rec. (February 1, 1974); 121 Cong. Rec. (April 17, 1975).

<sup>3</sup> H.R. 5545, 94th Cong., 1st Sess. (1975).

<sup>4</sup> 90 Stat. 539 (1976).

<sup>5</sup> H.R. 6073, 93d Cong., 1st Sess. (1973).

<sup>6</sup> H.R. 9984, 93d Cong., 1st Sess., §704 (1973).

<sup>7</sup> 21 U.S.C. 360k.

<sup>8</sup> 21 CFR 880.6230.

<sup>9</sup> 21 CFR 872.6390.

<sup>10</sup> 21 CFR 878.4014.

<sup>11</sup> 21 CFR 870.4450.

<sup>12</sup> 21 CFR 890.3860.

<sup>13</sup> 21 CFR 870.3610.

<sup>14</sup> 21 U.S.C. 360; see also 21 U.S.C. 360c(i).

<sup>15</sup> 21 U.S.C. 360e.

<sup>16</sup> 518 U.S. 470 (1996).

In the more recent case of *Riegel v. Medtronic, Inc.*,<sup>17</sup> the Court held in 2008 that a PMA device was subject to a comprehensive review by FDA under section 515 and was explicitly determined by the agency to be safe and effective. Accordingly, the Court concluded that the national uniformity provisions of section 721 apply. A court decision in a product liability case that was inconsistent with an FDA determination was therefore struck down.

#### EXEMPTIONS FROM NATIONAL UNIFORMITY

Under section 721, any State or city may petition FDA for an exemption from national uniformity. FDA may grant the exemption if the State or local requirement is more stringent than the FDA requirement, it is required by compelling local conditions, and it would not cause the device to violate any provision of the FD&C Act. FDA has in fact granted such exemptions.<sup>18</sup>

#### NATIONAL UNIFORMITY FOR PMA MEDICAL DEVICES REVIEWED AND EXPLICITLY APPROVED BY FDA AS SAFE AND EFFECTIVE

At issue today is the narrow question of whether devices approved by FDA under the rigorous standards of premarket approval (PMA devices)—which comprise less than one-half of 1 percent of all the medical devices authorized by FDA for marketing since 1976<sup>19</sup>—should continue to be protected under section 521 from inconsistent and different standards set forth by judges and juries under State product liability law. It is important to understand that the bill under consideration—S. 540—will affect only about one-half of 1 percent of all medical devices marketed in the United States. Only about 2 percent of all devices are Class III devices, and about 80 percent of those are marketed under the simplified section 510(k) procedure. Thus, about 99.5 percent of devices come to market under the section 510(k) process. Under the Supreme Court's *Lohr* decision, national uniformity does not arise from a finding of substantial equivalence under section 510(k), even for a Class III device.

The half percent of devices that are the subject of full premarket review and approval under section 515, however, represent cutting edge science. They are the new life-saving and life-sustaining devices that are critical to the public health. They are the highest priority devices—those for which we should do everything we can to encourage investment in research and development.

It is those devices that are targeted by S. 540. The proposed legislation would allow judges and juries throughout the country not only to impose requirements that are inconsistent with FDA determinations, but that differ from one court to another. The result would be regulatory chaos.

#### THE RIGOR OF THE FDA PMA PROCESS

The PMA process is scientifically rigorous and demanding. The Supreme Court has described it as follows:

Premarket approval is a “rigorous” process. *Lohr*, 518 US at 477. A manufacturer must submit what is typically a multivolume application. FDA, Device Advice-Premarket Approval (PMA) 18, <http://www.fda.gov/cdrh/devadvice/pma/printer.html>. 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 of 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. §360e(c)(1). Before deciding whether to approve the application, the agency may refer it to a panel of outside experts, 21 CFR §814.44(a) (2007), and may request additional data from the manufacturer, §360e(c)(1)(G).

The FDA spends an average of 1,200 hours reviewing each application, *Lohr* at 477, and grants premarket approval only if it finds there is a “reasonable assurance” of the device's “safety and effectiveness,” §360e(d). 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.” §360e(a)(2)(C). It may thus ap-

<sup>17</sup> U.S. (2008), 128 S.Ct 999.

<sup>18</sup> 21 CFR part 808.

<sup>19</sup> GAO Report to Congress: *FDA Should Take Steps To Ensure That High-Risk Device Types Are Approved through the Most Stringent Review Process* at 1 (January 2009); *Lohr*, 518 U.S. at 479.

prove devices that present great risks if they nonetheless offer great benefits in light of available alternatives. It approved, for example, under its Humanitarian Device Exemption procedures, a ventricular assist device for children with failing hearts, even though the survival rate of children using the device was less than 50 percent. FDA, Center for Devices and Radiological Health, Summary of Safety and Probable Benefit 20 (2004), online at <http://www.fda.gov/cdrh/pdf3/H030003b.pdf>.

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, §360c(a)(2)(B) and must determine that the proposed labeling is neither false nor misleading, §360e(d)(1)(A).

\* \* \* \* \*

Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness. §360e(d)(6)(A)(i). If the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application. §360e(d)(6); 21 CFR §814.39(c).

After premarket approval, the devices are subject to reporting requirements. §360i. These include the obligation to inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of, 21 CFR §814.84(b)(2), and to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred, §803.50(a). The FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling. §360e(e)(1); see also §360h(e) (recall authority).<sup>20</sup>

#### NATIONAL UNIFORMITY SHOULD BE RETAINED FOR CLASS III PMA DEVICES

National uniformity for FDA requirements of design and labeling for a Class III PMA medical device is the right policy for several reasons.

*First*, national uniformity in the regulation of Class III PMA devices is essential to preserve the jurisdiction and integrity of the FDA PMA process. In two 1973 cases that I took to the Supreme Court during my tenure as FDA Chief Counsel, the Court held that FDA has "primary jurisdiction" to decide matters that have been entrusted to its implementation.<sup>21</sup> S. 540 would strike at the very heart of this doctrine. If judges and juries can summarily disregard FDA decisions on Class III PMA devices, why should physicians, hospitals, or anyone else pay attention to them? S. 540 undermines the credibility and authority of the country's most important public health agency.

*Second*, as the expert agency to which Congress delegated the responsibility for determining the safety and effectiveness of medical devices used throughout the country, FDA is in a better position to make the determinations of whether devices should be marketed than are the juries in diverse courts in the 50 States. As Justice Breyer stated during the oral argument for *Warner Lambert v. Kent*, "who would you rather have make the decision that this [product] is, on balance, going to save people or, on balance, is going to hurt people? An expert agency, on one hand, or 12 people pulled randomly for a jury role, who see before them only the people whom the [product] hurt and don't see the people who need the [product] to cure them?"<sup>22</sup> It is no defense to say that FDA is not always perfect, or is understaffed. Although no agency is perfect, FDA's expert medical reviewers are far more qualified to determine the safety and effectiveness of life-saving Class III PMA medical products than are lay juries. And if FDA is underfunded—something I have been saying for years<sup>23</sup>—the solution is not to farm FDA's work out to juries, but rather to provide adequate funding for FDA. Congress has in fact responded to FDA's need

<sup>20</sup> U.S. at \_\_\_\_\_, 128 S.Ct at 1004–1005; see also *Lohr* at 477.

<sup>21</sup> *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 627 (1973); *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 652–654 (1973).

<sup>22</sup> Transcript of Oral Argument, *Warner Lambert v. Kent*, No. 06–1948, at 30–31 (February 25, 2008).

<sup>23</sup> Peter Barton Hutt, *The State of Science at the Food and Drug Administration*, 60 Administrative Law Review 431 (Spring 2008).

for additional funds both by user fees and by an increase in appropriations from \$1.4 billion to \$2.3 billion since 2007.

*Third*, allowing juries in the 50 States to impose individualized standards would result in a chaotic system in which a manufacturer could avoid State court liability only by marketing different devices in each different State, and then on pain of violating Federal requirements set forth by FDA in the PMA approval.

*Fourth*, product liability actions can have the effect of manufacturers seeking to label their products with additional or unsubstantiated warnings, which can result not only in underutilization of valuable treatments but in confusing both physicians and their patients. “Defensive labeling” by manufacturers helps no one.

*Fifth*, allowing claims to proceed against devices that comply with FDA requirements can result in devices being removed from the market that FDA has determined are, on balance—and for the population for which they are intended—more beneficial than harmful. And it can severely deter needed innovation. In this regard, it is important to focus not only on those who may be harmed by approved devices, but also those who are helped by those same devices, and who might be harmed if the devices were removed from the market.

*Sixth*, product liability damage awards punish device manufacturers, but they do not contribute to safer devices. It is the inevitable adverse events that lead FDA and the manufacturer to correct deficiencies. By the time that a product liability lawsuit is brought and resolved, the defect has been found and corrected, and the safety issue has been resolved—assuming, of course, that there is a defect that can be corrected and that the risk is not inherent in all uses of the device. Thus, the sole rationale for product liability lawsuits is to obtain adequate compensation for the injured patient.

*Seventh*, although compensation of injured parties must be achieved, it surely is not an answer to resort to the lottery system of jury trials, where some plaintiffs win big and others lose everything because of the vagaries of judges and juries. The goal of providing compensation can most appropriately be addressed through a statutory procedure that will not drive valuable products from the market, such as the National Childhood Vaccine Injury Act of 1986.<sup>24</sup> Unlike the product liability system, *all* patients injured by a PMA device would be fairly compensated, not just those who are fortunate to find a persuasive trial attorney and a sympathetic judge and jury.

*Finally*, we must keep in mind that national uniformity is a narrow doctrine. It does not apply to claims that a Class III PMA device *failed* to meet Federal requirements—for example, a claim that the device was negligently manufactured. If, for example, a manufacturer fails to meet the specifications for the strength or composition of the device set forth in the PMA approval, national uniformity would not affect the claim advanced by a plaintiff injured by this failure. And because less than one-half of 1 percent of devices enter the market through the PMA process, it applies only to a small category of devices.

Mr. Chairman, I appreciate the opportunity to present this testimony, and would be pleased to respond to any questions.

Senator HARKIN. Thank you very much, Mr. Hutt.

And now we go to Michael Roman.

Michael Roman is from Kirkwood, MO. Well, that’s not too far from Iowa.

Mr. ROMAN. No sir.

Senator HARKIN. Mr. Roman is a Formula One racer. He is here to discuss his experience with a medical device which has enabled him to continue racing.

Welcome.

#### **STATEMENT OF MICHAEL ROMAN, PATIENT, KIRKWOOD, MO**

Mr. ROMAN. Thank you, Mr. Chairman, as well as you, Members of the committee.

My wife, Susy, and I come here today with a simple story to share with the committee, a story of help, hope, and heroes.

In 1994, while working in a hospital in St. Louis, MO, I had a knee arthroscopy done to repair a torn meniscus in my right knee,

<sup>24</sup> 100 Stat. 3755 (1986).

and developed a staph infection during that procedure. Indeed, my nightmare began that day, as well as my families'. I've endured 12 debridements, 28 weeks of IV antibiotics, 33 surgeries, three progressive amputations to try to save the leg, and the leg is now gone completely at the hip.

You see, I immediately began to experience phantom limb pain. They were so severe that I could only make it through the day with, really, increasingly large doses of medications; medications like Vicodin and OxyContin and morphine, medicines that left me with only really a hazy recollection of the last decade of my life. And it was during that time that I sought out any and all treatment options to control my pain. These included radiation, injections, implantable drug pumps. And in 2000, we even tried a spinal cord stimulator. It's a device that electrically stimulates the spinal cord to disrupt those pain signals as they travel to the brain.

The spinal cord stimulator we tried was based off of old pacemaker technology, and honestly, it was worse than the problem it was designed to treat. It replaced one type of pain with a new one, one that was far worse for me and my family. So, back on the meds we went.

Finally, in 2005 I tried a new type of spinal cord stimulator. This one did manage to provide me with some relief and hope of a recovery. The device I use is a Precision Plus spinal cord stimulator, and this is designed off of technology that is from the cochlear implant, designed to help people hear again. The system allows me to manage my pain, no matter what my activity level is, if I'm watching TV or relaxing, or on the salt flats in beautiful Utah trying to set a new record.

Once I got the device, the first thing we, as a family, did was—I needed to get off the pain medicines, and that's what we slowly started to do. I slowly started to get my life back. And because I got it back, my wife, Susy, is here with me today.

In addition to our racing, we travel all over the country and speak to pain patients and doctors about the treatment options that are out there. It was, as a result of these experiences, what allowed us to accept your invitation to be here today to talk about this. I think it's a very important issue.

We have talked to many of our veterans coming back from our conflicts in Iraq and Afghanistan, and I do know how hard it is to seek out treatments, and how scary it can be.

And the technology I had implanted in 2005 was absolutely cutting-edge technology. Was it risky? It was. Did I understand that the technology may not work? I absolutely did. Did my doctor sit down and express to me, not only all the risk of a normal operation, but the risk of this product would be? We positively did.

You know, part of our call to action was, What if Congress had enacted this Medical Device Safety Act back in 2000? For me and my family it would have been, "game over." It really does scare us to think where we would be as a family today if some researcher in 2002 decided the status quo was good enough, that the \$60 million in investment made in developing, testing, and marketing the device, and putting a cutting-edge FDA product on the market, only to have that product's value systematically reduced by lawsuits, just weren't worth it.

You see, there are millions of people out there, some of them are your family members, who one day might benefit from breakthroughs in therapies still in development. We need to think about these people and these families—parents, husbands, brothers—when we think about the consequences of this bill.

Do I want safe products? Absolutely. For me, the question is a very simple one, Senator. It's, Who decides? Is it the FDA experts, or juries, made up of people just like me? No particular expertise. And I think the hardest part is that juries see only that injured person. They don't see the thousands and thousands of patients that have benefited from a technology. To me, the choice is clear: We need safe products, we need innovation. And I think the best way to do that is, not through litigation, but through a well-funded, strong FDA.

Thank you.

[The prepared statement of Mr. Roman follows:]

PREPARED STATEMENT OF MICHAEL G. ROMAN

Good afternoon Mr. Chairman and members of the committee, I have a simple story to share with this committee. A story of help, hope and heroes.

I am a one-legged race car driver with four land speed records to my name—you might think that makes me unique. In fact, most people who spend more than 5 minutes with me come away convinced that I am a "broke-the-mold" kind of guy.

But the chronic pain that I have lived with—and now successfully manage—isn't just my story. According to the American Medical Association, 45 million Americans will seek care for persistent pain at some point in their lives.

But before I talk about those millions of people—your constituents—let me share my background.

In 1994, I was employed as an operating room technician. I underwent surgery to repair a torn knee ligament.

During that surgery a staph infection set in, and my nightmare began.

I endured 12 debridements, 28 weeks of intravenous antibiotics, 33 surgeries, and three progressive amputations of my right leg, which is now completely gone.

I immediately began to experience phantom limb pain. The pain was so severe that I could only make it through the day with increasingly large doses of pain medications—Vicodin, Percocet, OxyContin, Neurontin, Serzone, Valium and eventually Morphine—heavy drugs that left me with only hazy recollections of a decade of my life.

For that decade, I was a parent and a spouse in name only.

I cannot remember 10 years of my children's lives. I was depressed, and I even thought about ending my own life. I can only offer my sincerest thanks to my wife Susy for standing by me for those years. She helped give me hope—something I struggled not to lose.

During that time, I sought-out alternatives to manage my pain, including radiation, injections and even an implantable drug pump. In 2000 I tried a spinal cord stimulator, a device that electrically stimulates the spinal cord and disrupts the pain signals as they travel to the brain.

While different patients respond differently to therapies, for me, this spinal cord stimulator—which relied on old pacemaker technology—was worse than the problem it was designed to treat. It replaced one type of pain with a new and different type of pain that was far worse for me.

So I went back on the meds, convinced that was where my family and I would remain.

And for a time we did. But as my tolerance for medication increased, I needed increasingly larger doses of medication to manage my pain, a cycle that had to change.

A BREAKTHROUGH

Finally, on yet another trip to a new physician in 2005, I agreed to try a new type of spinal cord stimulator. I was convinced it wouldn't work, but I agreed only because my doctor said that he wouldn't give me any more increases in medications until I tried this new device out.

Unlike the device that I tried in 2000, this device did something I didn't expect.

It managed my pain and provided me with some hope for recovery!

I am not pain free today, but I can manage my pain. I use a device called the Precision Plus—Spinal Cord Stimulator System, which is designed around the same technology used to bring back people's hearing—cochlear implant technology. It's programmable, easy to use, lightweight, and it has a long rechargeable battery life.

The system I use has an electrode lead implanted into my spine. I use a wireless remote control to "talk" with and control the impulses directed through these leads with a software program that lets me deliver a specific dose of electrical current precisely where I need it. That control lets me manage my pain based on my circumstances moment-to-moment. My pain management needs change based on whether I'm relatively quiet and watching TV, or more active and exercising, even racing.

Once I got the device, the first thing we needed to do was to get me off the high doses of medication. I simply didn't need them anymore.

I slowly got my life back. And because I got my life back, I got my family back. My wife Susy is here with me today. It's safe to say that a decade ago, no one in our family would have believed that we might have the opportunity to share the story of our success with the U.S. Senate. It's an honor and a privilege to have received your invitation to be here today.

#### MY ROLE IN THE RACE AGAINST PAIN

Once I got my life and my family back, Susy calls it, "The Great Awakening," I started doing one of the things I do best, complaining.

The first people I complained to were the people that built the device. I pity (a little bit) the day that Doug Lynch got his first call from me at Boston Scientific. He got a rant from me about what a poor job the company was doing telling patients and physicians about the benefits of this device.

Little did I know at the time how lucky I was that Doug answered my call. You see, Doug was deaf, and the same cochlear implant technology that had helped me manage my pain allowed him to hear again. He took my call with an open mind, and listened to what I had to say.

I knew I was not alone, that there were lots of people sitting in living rooms, or hiding in their bedrooms, all across the country who, like me, were prisoners of their pain and could benefit from the same technology that had helped me.

"What are you, as a company, doing to help them," I said. "We got to do more to spread the word about this amazing treatment!"

I had no idea what I was getting myself into.

Ultimately, I'm not sure whether I was drafted, or I enlisted. Today, in addition to our racing, Susy and I travel the country to talk about chronic pain and what can be done to treat it, to anyone who will listen.

Boston Scientific sponsors the *Race Against Pain* Web site, a place where pain patients can find support. They are also the primary sponsor of my race team.

After speaking with thousands of chronic pain sufferers all over this Nation, I know how hard it is for patients to open up, to share what they're feeling, and especially to seek out new treatments. It's not every day that these patients meet a one-legged racecar driver, so we rarely need a conversation starter.

What I then try to do is get patients to see a different future by sharing the story of the path Susy and I have traveled. That's an important first step for many chronic pain sufferers who have given up all hope for recovery.

In 2008, my wife Susy and I had the privilege of visiting some of the wounded soldiers who were rehabilitating over at Walter Reed here in Washington, something we encourage each of you to do. We planned to stop by for an hour. We ended up spending 6 hours visiting with men and women who have been seriously injured in the service of our Nation. There I learned about the potential of medical technology. The cochlear implant technology that eventually morphed into the technology that helped me is just the beginning. We know so little about how the human brain works, but we're learning more every day about how medical technology can help not just these wounded veterans, but can lead to breakthroughs in fields like Alzheimer's research, Parkinson's treatment, and epilepsy.

Through my experience at Walter Reed, I also became familiar with the Wounded Warrior program that gets injured veterans back on track—onto bicycles and into civilian careers. Susy and I were so moved by these men and women that we placed the Wounded Warrior Project logo on our racecar to raise awareness and have participated in a number of these soldier rides to show veterans that with the right attitude and a little technology, it's possible to get your life back. These men and women remain our personal heroes.

## ABOUT THE MEDICAL DEVICE SAFETY ACT

I'm not an expert on the law, and I certainly do not have the awesome responsibility of shaping public policy. But I can assure you that in the space of just 5 short years, what may have seemed like small changes in spinal cord stimulator technology made a huge difference not just in my life, but also in the lives of my wife and children and grandchildren. They got their husband and father back, and the dad and grandfather who lost his leg once again found his purpose in life.

The technology that is implanted in me pushed the envelope when it was installed in 2005. Was it risky? Yes. Did I understand that this technology might not work, because each patient responds differently? Yes. Did I talk with my doctor about the risks and benefits of this product? Absolutely. You could say I went under the knife, as I had done some 38 times previously, with my eyes wide open.

But what if Congress had enacted the Medical Device Safety Act in 2001? For me, I'm sure it would have been game over.

It scares us to think I would lose the life I have today because a researcher decided to throw in the towel in 2002—deciding that the status quo was good enough—and that the \$60 million in development and testing costs of my device weren't worth the risk of putting a cutting edge, FDA-approved product on the market, only to have that product's value systematically reduced by lawsuits. There are millions of people out there who might one day benefit from the breakthrough therapies still in development. We need to think about those people when we think about the consequences of this bill.

Do I want safe products? Absolutely. For me, the question is who decides.

Is it scientists at the FDA who carefully study every aspect of a device and can balance the benefits of a device to patients like me versus the risks? Or is it a jury made up of people like me? One-legged race car drivers, teachers, bus drivers, bikers, veterans, waiters and waitresses—who may not have the necessary expertise to make the best decision, especially since juries see only an injured person, not all the beneficiaries of medical technology.

To me, that choice is clear. We need safe products and we need innovation, and the best way to achieve both goals is not through litigation created by this bill, but through a strong, well-funded FDA.

Senator HARKIN. Thank you very much, Mr. Roman, for a very—again, it was a profound statement and—about your experiences.

Now, I don't know when we're going to start votes, but we'll start a round of just 5-minute questions, so we can try to get everybody in. So, whoever's running the clock, start me at five. There you go. Thank you.

Well, thank you all very much for being here today. This is, obviously, an extremely important issue, and one that we are going to address, hopefully soon.

I wanted to start with Professor McGarity. Opponents claim that this law, by reexposing the medical device manufacturers to liability, would lead to a loss of innovation in the medical devices market, the kind of innovation that Mr. Roman was talking about. Is there any evidence at all to suggest this might be the case?

Mr. MCGARITY. I have not seen evidence to that effect at all. I think that a company will be looking forward to the market, and lots of considerations will affect that determination. But, the likelihood that they will be sued if they do a bad job, I don't think is one of the major considerations that play out there.

And certainly, just looking at the objective evidence of it, I don't see evidence of that, no, sir.

Senator HARKIN. I want to try to understand something.

Mr. Hutt—maybe I can get somebody else involved in this, too—I want to try to understand the difference between drug regulation—FDA drug regulation and medical devices. In Wyeth versus Levine, the Court held that the pharmaceutical regulation does not preempt State tort liability. In Wyeth, the Court held that the FDA has long maintained that State law offers an additional and impor-

tant layer of consumer protection that complements FDA regulation. So, why are medical devices different than drugs?

Mr. HUTT. Well, let me try to explain that in seven different layers. First of all, we're talking here about a statutory scheme that could be applied, but hasn't been applied, to drugs. So, on a pure legislative basis, they've been handled differently by Congress at different times. That's just setting on the statutory basis.

With regard to the difference between them, there's a huge difference between medical devices and drugs. For example, the standards for safety and effectiveness for medical devices are significantly different under the Federal Food, Drug, and Cosmetic Act. That was done purposely by the people who drafted the legislation, and I was one of those who did draft the Medical Device Amendments of 1976. And it was because medical devices are contraptions, and drugs are fixed molecules. You can change medical devices; you can't change a molecular entity that is called a drug.

So, for a wide variety of public policy reasons, Congress has seen fit to do things differently for these two types of very, very different products.

Senator HARKIN. So, it's just that Congress made that decision.

Mr. HUTT. Yes, Congress did.

Senator HARKIN. OK. So, then obviously we could make a different decision.

Mr. HUTT. Yes. There is no question. I don't disagree. This is not a constitutional issue.

Senator HARKIN. Constitutional question.

Mr. HUTT. This is a statutory issue.

Senator HARKIN. All right. OK. So, really, the difference between drugs and devices is simply a difference that we have stated, legislatively.

Mr. HUTT. Well, there's an inherent difference—

Senator HARKIN. Well—

Mr. HUTT [continuing]. In them, also. As I said, you can't change a drug; you can change a device.

Senator HARKIN. Why can't you change a drug?

Mr. HUTT. Well, it's—

Senator HARKIN. They can change it chemically. They can change it—

Mr. HUTT. Well, then it becomes a different drug. And it may lose, completely, its safety and effectiveness if you change it. But if—

Senator HARKIN. Can you change a medical device without going through a premarket approval?

Mr. HUTT. No. My point is that device technology—and this is a very interesting way that it's developed—device technology, it's very well recognized, is an iterative process. We just had a vivid description of how it develops over time. You can't change a drug over time. It is what it is.

Senator HARKIN. But, it—Professor McGarity.

Mr. MCGARITY. If I may, there are certainly differences between drugs and devices, but the issue in *Wyeth v. Levine* had to do with the warning. And the warning is much more like a device, in the sense that it's an iterative process, that you can change the warning if the product warning isn't working, or if something else has

come up that needs to be changed on the warning. It is the very same iterative process. So, I would suggest that the difference is not that great at all.

Senator HARKIN. I was just reminded by my staff that we change drugs all the time for kids—change them all the time—for dosages and recommended treatments and things, for drugs. So.

Mr. HUTT. That's changing the labeling. It's not changing the molecular entity, which is "the drug." You can change "the device" by adding something to it, by—I always say, by putting bells and whistles on it. You can't do that once you have a molecular entity, which is a drug. That drug is fixed for all time.

Senator HARKIN. It just seems to me they're changing drugs all the time. But, I'll have to think about that a second. I'm over my time.

Senator Hatch.

Senator HATCH. Thank you. One thing that I think needs to be made clear is that everybody here wants to see people who are injured be fairly compensated when they suffer injuries resulting from another person's negligence. Indeed, I don't think any of us want to prevent people who have been truly wronged from receiving fair compensation. You've expressed yourself that way, as well.

Mr. HUTT. Yes, sir.

Senator HATCH. But, it seems to me that, though the MDA, as clarified by the *Riegel* decision, provides device manufacturers some level of protection from litigation, many avenues still remain open.

Mr. HUTT. That is correct.

Senator HATCH. Yes. Under current law, a patient can still sue a manufacturer if the device fails.

Mr. HUTT. It is a very complex issue—

Senator HATCH. Right.

Mr. HUTT [continuing]. Senator Hatch, as to exactly where product liability—

Senator HATCH. Sure.

Mr. HUTT [continuing]. Would be cut off, and would not.

Senator HATCH. That's right.

Mr. HUTT. If the manufacturer follows the requirements of FDA laid down in the PMA approval—

Senator HATCH. Right.

Mr. HUTT [continuing]. Which are very specific—they set exactly how the device will be made, and how it will be labeled—if those are followed, then there could be no liability. But, if they failed to follow them, then, you're correct, there could be.

Senator HATCH. OK. If there's a manufacturing defect, what about that?

Mr. HUTT. That would mean—if you're saying, "If there is failure to follow the FDA requirement"—

Senator HATCH. Right.

Mr. HUTT [continuing]. That kind of a defect, yes.

Senator HATCH. OK. And if—

Mr. HUTT. But, please—there's one thing that we have to all understand. Devices, like drugs, often inherently have problems—they don't act perfectly in everyone. And, as a result, a drug or device that might save my life could hurt someone else, even though it's

a perfectly good device or drug. So, the fact that it hurts someone doesn't mean there's a defect. It may be working the best it can. And it may save 999 lives, and fail to save the 1,000th life. That doesn't mean it's defective.

Senator HATCH. Well, if the device is labeled in a manner that's inconsistent with the FDA's requirements, you can sue, there.

Mr. HUTT. Yes.

Senator HATCH. OK. Now, a device manufacturer may also be liable if they mislead the FDA during the premarket approval process.

Mr. HUTT. Not only would they be liable, they would be criminally liable.

Senator HATCH. Right.

Mr. HUTT. It's a criminal violation of the act, in any way to withhold information from FDA or to submit false information.

Senator HATCH. A patient can also sue for physician errors associated with an FDA-approved device, right?

Mr. HUTT. Yes.

Senator HATCH. OK. So it seems to me that those instances where a device manufacturer can truly be proved negligent or otherwise at fault, the statutory preemption in the MDA has little or no effect.

Mr. HUTT. Yes.

Senator HATCH. OK.

Now, America leads the world in the development of innovative and life-sustaining medical devices. The entrepreneurial environment, which is very unique to this industry, is the backbone of what sets medical innovation apart from other countries throughout the world—or, around the world. In fact, the medical technology industry is one of the few that has actually continued to create economic opportunities for thousands of American families, despite the challenging economic environment.

Now, the decision to develop a medical device is highly risk-dependent. For many, it begins with an entrepreneur or start-up company competing to attract venture capital and other investments to bring their product to the next stage. Now, venture capitalists are risk-focused. When deciding to invest in a promising medical technology, venture capitalists take many matters into consideration, such as patient benefit, intellectual property protection, and risk of liability. And any uncertainty in any of those elements can be a significant deterrent to investing in any kind of promising technology.

Now, I'm greatly concerned that, without the preemption and the uncertainty of the risk of liability, medical device development and innovation could be stifled. And you've indicated that you feel that way, as well.

Mr. HUTT. Senator Hatch, I have personal experience with that. I sit on the board of directors of 10 small biotechnology companies, some of which are engaged in the development of medical devices. And the decisions made by venture capitalists, based upon such issues as potential liability, directly affect every one of those companies.

Senator HATCH. OK. Well, my time's up.

## STATEMENT OF SENATOR BURR

Senator BURR. Thank you, Mr. Chairman. I'll be brief. I may not take 5 minutes, because I'm not going to ask a question.

I want to thank all of our witnesses. We've assembled quite an expertise of experience and knowledge and personal stories.

You know, several months ago we were in this room—and I have deep respect for Senator Harkin—debating tobacco. And at that point, the FDA was the only agency in the world that could regulate tobacco. They were the only ones that had the expertise. CDC wasn't good enough. There was no other agency. The FDA was the only gold standard. They had the only brain trust of employees that could wade through a complicated process.

A month ago, we were in this room debating healthcare reform. And in that healthcare reform debate we talked about the need for more drugs, more biologics, more devices, greater innovation. We needed better outcomes, we needed more investment to make sure that the outcomes of the American people were, in fact, better.

And now we're here because the result of an 8-to-1 U.S. Supreme Court interpretation of a law that was put in place in 1976 that, all of a sudden, 33, I believe, years later, this is the single most important things that we've got on our plate right now. What's changed?

Well, I trust my colleague. He said our goal is to only get safe products to market. Now, Mr. Hutt, you and I have been at FDA, you twice as long as I have. We both know that that's an impossible statement.

Mr. HUTT. Yes, sir.

Senator BURR. And let me just read from your testimony if I can, and I don't think you did it in your shortened testimony.

"It's those devices that are targeted in S. 540. The proposed legislation would allow judges and juries throughout the country, not only to impose requirements that are inconsistent with FDA determinations, but that differ from one court to another. The result would be regulatory chaos."

If anybody questioned why Mr. Roman is here, then that's the answer. If you have regulatory chaos, you have no investment, you have no innovation, you have no venture capital that's at the table trying to drive the next device. You, therefore, have no innovation, you decrease the outcome of health incidents in the country.

Now, the New England Journal of Medicine stated recently that 54 cents of every dollar paid to an injured patient is diverted to administrative cost. The majority of the administrative cost is the legal fee. It's becoming clear as to why we're here. It's because the U.S. Supreme Court has tightened where you can go to court and, more importantly, affected their pocketbooks.

Now, Mr.—Mulvihill.

Mr. MULVIHILL. Mulvihill.

Senator BURR. Listen, I want to make sure anybody injured in this country is taken care of, and I don't question your injuries one bit if there was a defective lead.

I think Mr. Hutt covered that, when a manufacturer is negligent on something, if a manufacturer does not follow that proscribed by FDA—and FDA requirements are fairly clear. They're black and

they're white. There is no gray area, I've found, in—whether it's drugs, devices, or biologics. It is pretty specific on marketing, on labeling, and on everything. If a company goes outside of that, they're basically open game.

Mr. Chairman, I'm going to conclude. I've got 40 seconds left, but I want to ask unanimous consent to enter into the record, from the Blind Veterans Association, a letter, and I'll just quote the one line, "We, therefore, strongly urge you to oppose the Medical Device Safety Act of 2009."

Also, the American Military Society, "Deciding which new medical devices are safe enough to be sold in this country is the job for doctors and scientists at the FDA, not juries."

The U.S. Veterans Hospice Committee, "Our opposition to this legislation is driven by our strong belief in the need for greater access by these veterans to many medical devices used in the end-of-life hospice-care setting."

And last, but not least, a letter signed by a number of companies—I'll just highlight a few—the American Health Care Association, American Insurance Association, American Tort Reform Association, the Business Round Table, GE Healthcare, 3M, National Association of Manufacturers, U.S. Chamber of Commerce. Their last line, "For these reasons, and others that are detailed in the attached letter from March, we strongly urge you to oppose this legislation."

I would ask unanimous consent that they be included in the record.

Once again I thank our witnesses for being here.

Senator HARKIN. Without objection.

[The information referred to may be found in Additional Materials—Letters of Opposition.]

Senator HARKIN. Thank you very much, Senator.

Senator Hagan.

#### STATEMENT OF SENATOR HAGAN

Senator HAGAN. Thank you, Mr. Chairman.

And I just want to thank all of the witnesses for being here today, and especially the two men—the patients. Thank you so much for your testimony.

I just have one question, I wanted to ask—and I'm not sure exactly who this is addressed to—but for individuals who have a defective device, and then you have to go back into the hospital and have the device removed, and other payments, whether it's the actual surgery, the hospital, the physician, who pays for that?

Dr. Maisel.

Dr. MAISEL. I think that's an excellent question, and a very important question in this era of health reform. But the answer is that patients pay for that, taxpayers pay for that, because insurers get billed. In fact, the No. 1 payer, I suspect, of medical device defects is the Federal Government, Medicare. And some might argue that we have two cash-for-clunkers programs, and this is one of them, where the Federal Government is paying for defective medical devices.

Senator HAGAN. Well, I think we're all concerned about cost and cost containment. And I think that that's a very big issue.

Yes, Mr. Hutt.

Mr. HUTT. Senator, there is a provision, in the Medical Device Amendments of 1976, that authorizes FDA to order the company to pay for a defective device, and the requirement of explanting it.

Senator HAGAN. Does the patient, individually, have to petition or—how does that process work, for the FDA to—

Mr. HUTT. The FDA can, on its own initiative, order that, or any patient could also ask for it.

Senator HAGAN. You mean like on a recall basis.

Mr. HUTT. On a petition basis.

Senator HAGAN. That's all, Mr. Chairman.

Senator HARKIN. Well, then I'll start the second round, but you can start me again on that 5 minutes.

You know, I must say for the record, that before *Riegel* was decided, the device manufacturers were subject to tort laws. In fact, there were many of them. It wasn't until the *Riegel* decision that the door shut. Am I not correct in that?

Yes. Yes, yes.

Mr. HUTT. No, sir. There were a number of court decisions before *Riegel* that held that the claim was preempted.

Mr. MCGARITY. There were a number of decisions that held otherwise, too.

Senator HARKIN. That held otherwise. So, it was back—

Mr. MCGARITY. They were certainly subject—

Senator HARKIN [continuing]. Back to—

Mr. McGarity [continuing]. To liability, and they knew it as they were designing their products.

Senator HARKIN. So, the way I see it—before *Riegel*, the device manufacturers didn't know if they'd win or lose in a tort claim, right? Well, let me just say, for the record, that the last year before *Riegel* decision—the last year before—the top 25 medical device companies had a net profit of \$173 billion. Net profit. So, they were doing quite well. And they were coming up with new devices all the time, even though they didn't know whether or not they would be subject to a tort claim, or not. So, it doesn't seem like innovation was stifled.

I must also say, regardless of the difference between drugs and devices, we're getting new drugs on the market all the time, and they are not preempted from tort claims.

Mr. Maisel, is it not true that, after Medtronic began receiving reports of these manufacturers—you State in your statement here, "within months of initial market release," they did not recall the lead until more than 3 years later. An FDA inspection report issued after recall cited Medtronic for, "objectionable conditions for failing to implement appropriate corrective and preventive action procedures related to the company's investigation of the product anomaly."

Now, Dr. Maisel, do you believe the FDA approval process is so good that manufacturers of these devices should receive immunity when they're faulty or cause injuries? You've been there, tell us what it's—tell us about that.

Dr. MAISEL. I think the FDA does an exceptional job of evaluating medical devices, and they're extremely thorough. I think the biggest issue I have is this concept that manufacturer liability

stops at device approval. I tried to outline, in my testimony, all the responsibilities of a manufacturer after the FDA approves their device. They are still manufacturing the product. They have to ensure sterility. There are many compliance guidelines that they need to follow for manufacturing. And it's simply impossible for the FDA to monitor individual companies, when there are 15,000 manufacturers and 100,000 devices that are being produced. And so, the idea that only those companies that get caught by the FDA are the ones that are going to be held liable, I think, is bad policy.

It's also interesting to note that a U.S. House committee report in June 2006 noted the decline in enforcement reports and enforcement activity of the FDA, and, in fact, the number of warning letters issued by the FDA declined 50 percent between 2000 and 2005. Every single office at the FDA had a decline, with the device center having the largest decline in the number of enforcement letters issued.

So, the concept that we're going to rely on the FDA catching manufacturers doing something wrong in order to support consumer liability is a bad policy.

Senator HARKIN. But, Mr. Hutt says that once you make a device you can change the device. You can change them. If they make a change on a device, does it have to go all the way back to the beginning again, and go through the premarket approval?

Dr. MAISEL. The manufacturers can make modifications to their device, and they need to let the FDA know about that, and submit supplements to their PMA application.

Senator HARKIN. So, it doesn't go right back and go through the whole process again.

Dr. MAISEL. Right. Well, that's an excellent point, because the Medtronic defibrillator lead in question, that we're talking about, was actually a supplement application, it was not an original PMA.

Senator HARKIN. I did not know that.

Dr. MAISEL. And that supplement application had no human clinical data. So, they made a modification to their lead, it was never implanted in a human before it was approved by the FDA—or, I should rephrase that—no human data was submitted to the FDA to support its approval. The device is approved on the basis of bench testing and animal data, and then it goes into close to 300,000 patients.

The question isn't, Why are we here? I mean—

Senator HARKIN. Yes.

Dr. MAISEL [continuing]. It's obvious why we're here. It was inevitable that something like this would happen.

Senator HARKIN. OK. Now, you've just told me something I did not know. You're saying that a device manufacturer, like this Medtronic defibrillator, when it went through the whole premarket approval and everything, and it was approved, later on they made a change to it, but it didn't have to go back and be approved, and they did no human trials?

Dr. MAISEL. It did need to be approved. The original PMA was submitted in—around 1992. The supplement that approved the Fidelis lead in question was approximately supplement 25 or 30, somewhere in that range. And each of those supplements goes back to the FDA for consideration. But, supplements often do not require

human clinical testing. And so, you're now looking at a lead 15 years removed from the original PMA, and there's not a lot of clinical data that was submitted to support its approval.

So, the idea that that lead is going to function perfectly well, and the manufacturer will never be liable for it, seems an interesting policy.

Senator HARKIN. Thank you. I'm a minute over.

Senator.

Senator HATCH. Well, thank you, Mr. Chairman.

Do you have any comments about anything that's been said, Mr. Hutt, so far?

Mr. HUTT. A supplemental PMA, which is required for any change of any kind, is required to be approved by FDA, using the same standards of safety and effectiveness as the original PMA, Senator Harkin. I don't want there to be any confusion about that.

FDA looks at the entire PMA, when the supplement is submitted, and either approves the device, as changed, as safe and effective, or not. So, there is no distinction between the original and the supplemental PMA. The FDA, in this instance—perhaps incorrectly, I do not know the facts—but, what they did was, they looked at all the data on safety and effectiveness in humans. They concluded that the new lead did not require additional human data. Now, I am not a scientist, and I cannot say they were right or they were wrong. Dr. Maisel, obviously, is more qualified than I to make that judgment. But, I don't want there to be any confusion about what the process was.

Senator HATCH. OK.

Mr. Mulvihill, did you sue, because of the difficulties you went through? Or, did you intend to sue?

Mr. MULVIHILL. When this first happened, I did not intend to sue. I like my doctors in Davenport, IA.

Senator HATCH. Right.

Mr. MULVIHILL. I didn't know there'd been a problem with the leads. I wasn't told that.

Senator HATCH. Yes.

Mr. MULVIHILL. In October of the year that I had my problem—4 months, 5 months later, whatever it was—a friend called me and said, "Did you see the paper, about Medtronics? Fractured leads."

I said, "No," I hadn't. I got thinking about it, I looked at it, my wife and I discussed it. I didn't do anything for a good long time. It was the end of January, first part of February, before I contacted a firm and they agreed to take a lawsuit.

Senator HATCH. I see. OK.

Now, Mr. Roman, I understand you'll be going right from this hearing out to the Bonneville Salt Flats, out of my home State of Utah, for the Bonneville Speed Week, to try to set your fifth land speed record, is that right?

Mr. ROMAN. Yes, sir.

Senator HATCH. I don't want to call you nuts, but—

[Laughter.]

Senator HATCH [continuing]. We're very proud of that, and we're—

Mr. ROMAN. Well, thank you—

Senator HATCH [continuing]. Very proud of you for being with—

Mr. ROMAN [continuing]. Very much. And I think one of the things we're most proud of is the second opportunity the family's been given.

Senator HATCH. Yes.

Mr. ROMAN. And one of the things we've tried to do is incorporate the Wounded Warrior project onboard, and the military onboard, this year, and—so, they come out to the Flats with us, and they're listed—the service logos go down the nose of the car. Marines are first—I get a lot of grief for this, but my rule is, First in, First to win. I'm not up for argument. So, we'll take the U.S. military with us, and we'll go set some records.

Senator HATCH. Well, you're great, I want to wish you all the best of luck in your endeavor.

But, you stated, in your testimony, that the first spinal stimulator did not work for you, and the technology from the second implanted stimulator pushed the envelope and—

Mr. ROMAN. Yes.

Senator HATCH [continuing]. Was risky. And after considering all those factors, can you explain to us what made you still decide to get the second device? And have you had any regrets since you got the second device?

Mr. ROMAN. It's plain and simple, sir. Family. I wanted my family back. I wanted a chance at a normal life. And, you know, the original trial didn't go well with the first spinal cord stimulator. Honestly, sir, it was like being electrocuted. I felt as if it—from my rectum to the top of my head, it felt—just pounding. And for me, it didn't work. Go out, 5 years later, the morphine levels are now up to 300 milligrams of morphine a day, I'm hallucinating, suicidal thoughts are pretty constant. And for me, it was desperation.

Senator HATCH. A matter of quality of life.

Mr. ROMAN. I just had nowhere else to turn.

Senator HATCH. Yes.

Mr. ROMAN. The remarkable part is, during that time, how the technology had changed. And it was like night and day. When they turned this system on, because it was based on the cochlear implant technology, it was very smooth, and I could steer it and control it a lot more than the pounding electrocution I felt in the initial system.

Senator HATCH I'm really glad you did what you did, and I'm glad you've had that result.

Mr. ROMAN. Thank you.

Senator HATCH. Mr. McGarity, I have a lot of respect for you. You've testified before the Judiciary Committee a number of times. You're clearly a very bright guy. And as you can see, you and Mr. Hutt differ—

Mr. MCGARITY. Yes.

Senator HATCH [continuing]. Quite a bit. And I'm as concerned about these issues as you are. On the other hand, I am concerned about having the best medical devices we can find. And I do know there's a balance here that has to occur.

I don't think any of us want somebody to be hurt by a medical device, and to not be compensated if it's truly the fault of the com-

pany, or anybody else for that matter. It's a tough area, and these are tough, tough decisions.

My time is up. I was going to ask you a whale of a question, but my—

[Laughter.]

Senator HATCH [continuing]. No, that's fine. I just wanted to mention that I have high respect for you.

Mr. MCGARITY. Well, thank you.

Senator HARKIN. Well, I have one other thing that I'd like to pursue. And I'm just thinking about this. I am informed—the FDA does not have subpoena power, does it?

Mr. MCGARITY. No—

Mr. HUTT. No, it does not.

Senator HARKIN. So, let's just think this through a second. If a device manufacturer knows, now, under *Riegel*, that they are not subject to tort lawsuits, therefore they're not subject to discovery that would go on in a lawsuit, and if FDA doesn't have subpoena power, and let's say that—I was thinking about this, because there's a case here, *Warner Lambert v. Kent*, which—you probably ought to know about it. It says, "Manufacturers who commit fraud on the FDA are not immune from lawsuits."

Well, OK, let's say that a device manufacturer doesn't submit all the information to the FDA. The FDA does not have subpoena power. Therefore, they approve it, goes on the market, people are injured, there's a recall. But, because they cannot sue, you cannot get discovery to find out whether or not they ever even committed fraud on the FDA.

So, I hope I've made myself clear. If a device manufacturer commits fraud on the FDA, puts a device out there, and injures people—but, they cannot sue and can't get discovery to get at these documents, then you will never know whether or not they committed fraud on the FDA or not. What's wrong with that line of reasoning?

Mr. HUTT. Well, first, Senator Harkin, you asked me a very, sort of, specific question. FDA does not have subpoena power, but any FDA inspector has the authority to obtain records inspection by visiting the company, and they can demand any form of record relating to information on safety and effectiveness in the files of the company. They have 100-percent authority to obtain that.

Moreover—and this is extremely important—it is a violation, and regarded by FDA as the most serious violation, if a company fails to submit all the relevant safety and effectiveness information as part of their PMA.

And I can assure you, when I was chief counsel, the one area that I always considered criminal sanctions was the failure of a company to report things they were required to report, either with the original application or after a drug or device was marketed, when there are also reporting requirements.

FDA's criminal authority is the strongest criminal authority under any Federal statute. It does not require knowledge or intent by the company or the individual. It is what we call "strict criminal liability," and FDA does employ that—

Senator HARKIN. Right.

Mr. HUTT [continuing]. Whenever there is a proof that someone violated those principles of reporting.

Senator HARKIN. Mr. Maisel, could you address yourself to this?

Dr. MAISEL. Sure. I'd just like to—I will read a quote from the FDA inspection report. It's page 13 of a 25-page report. And this is the FDA, "When we asked to see some in-process field product inspection reports, we were told they were not able to let us view them." That's the FDA on the Medtronic issue.

I think one could—

Senator HARKIN. So, Mr. Hutt, how can—I'm getting—

Mr. HUTT. Senator—

Senator HARKIN [continuing]. I'm getting two different things coming to me—

Mr. HUTT. Well—

Senator HARKIN [continuing]. And I can't handle this.

Mr. HUTT. The company may—

[Laughter.]

Mr. HUTT [continuing]. The company may have said that they didn't want to give it to FDA, but if they didn't give it to it, that's a violation of law. Period. Full stop.

I think the point—or, the fact—

Senator HARKIN. So, my question about—if they wouldn't give them the information, why didn't the FDA demand it, or—what could they have done?

Mr. HUTT. Well, FDA could demand it, and if the company refused, FDA could bring a lawsuit, yes.

Senator HARKIN. A lawsuit.

Mr. HUTT. Yes. They could penalize the company. They could seize the offending illegal products, they could enjoin the company against future violations, they could bring a criminal prosecution—

Senator HARKIN. So, you're saying that on this case, Dr. Maisel said—

Mr. HUTT. Yes.

Senator HARKIN [continuing]. That it's the FDA's fault that they didn't get this.

Mr. HUTT. Yes, that is true. Now, Dr. Maisel—

Senator HARKIN. Hmm.

Mr. HUTT [continuing]. Made a point earlier, that he and I are in complete agreement with.

Senator HARKIN. Wait.

Mr. HUTT. FDA needs adequate appropriations. The statistics, for example, that he—

Senator HARKIN. We're not going to give me that.

Mr. HUTT. Yes. The statistics that he quoted were from a few years ago, of the downturn in FDA inspections and other forms of enforcement action. But, in the last 2 years, FDA appropriations have increased by \$900 million, from \$1.4- to \$2.3 million, and it was precisely because the FDA Science Board report of late 2007 said that the agency was being starved to death.

Senator HARKIN. OK.

Mr. HUTT. Now they've got the funds.

Senator HARKIN. I deal with FDA a lot on another hat I wear, on Agriculture, and, I'll tell you, they don't have the resources to

monitor all the things that we ask them to monitor. But, that's for—

Mr. HUTT. Not everything, I agree.

Senator HARKIN. That's for another discussion.

Do you have any other—

Dr. MAISEL. I did want to—

Senator HARKIN. On this issue. On that—see, my point was, whether or not you could ever get to the bottom of whether or not a company gave all the information to the FDA in the first place or not, and if you don't have a lawsuit—you understand what my question was.

Dr. MAISEL. I do, and I think you've well summarized the issue. I'm not a lawyer, but the FDA does not possess the authority to, "demand" documents, other than to ask for them or to—

Senator HARKIN. But, if they don't, then Mr. Hutt says they should sue them.

Dr. MAISEL. Yes.

Senator HARKIN. That's as I understand.

Dr. MAISEL. But, I mean, that's "back to the future." That's where we were before the Medical Device Amendments, back in the 1950s and the 1960s, when the FDA regulated medical devices by trying to take them to court one at a time, and spent a lot of money, and it was very inefficient.

Senator HARKIN. I see. So, you're saying that it would almost be, I wouldn't say "next to impossible", since you've got 15,000 manufacturers out there—is that what you're saying?

VOICE. Correct.

VOICE. Yes.

Senator HARKIN. That it would be hard for them to—if they demanded, let's say, 50 of them, or 100 of them, would they have the personnel, then, to go and lawsuit every single one of them, at FDA?

Dr. MAISEL. I think you know the answer to your question.

Senator HARKIN. Yes. And I don't know where they'd get the money to hire these high-price lawyers from these big law firms.

[Laughter.]

I'm just kidding.

Mr. HUTT. Senator, in my experience, it is a rare event when a company declines to obey the law and provide the documents that FDA is entitled to.

It is a very rare event.

Senator HARKIN. I would agree with that right now. But, under *Riegel*, if there is—if they can say, "My gosh, we'll never have to give those documents up. It would be a rare instance for FDA to ever take us to court to sue. And Mr. Mulvihill can't sue us now. And his lawyers can't get discovery to get those documents." Hey, you know?

Mr. HUTT. But, Senator, their lawyers are going to tell them, "If we don't produce these documents, we can go to jail. The CEO can go to jail." That's who FDA brings criminal prosecution against, not some low-level people.

There were two U.S. Supreme Court decisions, one in 1944, one in 1975, upholding FDA authority to bring criminal prosecution

against the highest corporate officials because they are ultimately responsible for the actions of the company.

Senator HARKIN. Mr. McGarity, I went over my time, but I'll give Senator Hatch—

Mr. MCGARITY. Well, just a couple of points. One is, yes, that might happen, but it doesn't. You don't see that many criminal prosecutions. Hopefully, it's because it doesn't happen that often. But, the fact of the matter is—the underlying fact of the matter is that, when we get this information about what was going on in the drug company files and the device manufacturers files, it's not because FDA inspectors got it, it's because a plaintiff has sued and we've had discovery, we've had depositions taken, we've had, sometimes, whistle blowers within the company come forward with that information. But, it's not because FDA turned it up.

Senator HATCH. Well, let me just say this. I've had extensive experience with the FDA, and they don't miss much. And the constant complaint is they are over-regulatory, if anything. Now, I don't know the instance with the—I've heard that same point that you've made, Dr. Maisel, about Medtronics. But, if FDA wanted those materials, they'd have gotten them. And there must—I don't know what the reason was behind it, but—maybe they did, in the end. I don't know.

But, one concern that I and others have with this legislation deals with the mission of the FDA with regard to medical devices. Under the current regulatory system, the device manufacturers have to go through an extensive review process and analysis from top experts of the FDA and elsewhere. They have to strictly adhere to the FDA's labeling and marketing requirements, and even after the device is on the market, they have to report back to the FDA on the implementation and use of the device, including any adverse events.

So, what we're dealing with is a bar that is already set exceptionally high. Now, this legislation, it appears, would allow panels of randomly selected jurors, with no expertise at all in the field or any aspect of it, to overrule this entire process and create whole new standards of suitability and market readiness for medical devices.

Now, let me ask you this, Mr. Hutt, does this legislation not suggest that a jury of 12 laymen is better able to determine the future use and availability of these highly advanced medical devices than the team of highly trained experts at the FDA who approve these devices? And if so, what could be the justification for that?

Mr. HUTT. Well, that is precisely my concern, Senator Hatch. FDA is not perfect, but certainly a jury is going to be less perfect in determining what is a safe and effective medical device.

Senator HARKIN. Well, the ultimate goal is to get the very best devices we can to really help people like Mr. Mulvihill, like Mr. Roman, in ways that they've got to be helped. And we've kind of split the baby here. Is that a fair appraisal?

Mr. HUTT. I agree with you. One of the best parts of the Medical Device Amendments of 1976 was an innovative provision, under which advisory committees would be convened for every PMA device—

Senator HATCH. Yes.

Mr. HUTT [continuing]. To make certain that outside independent experts agreed with FDA that the device is safe and effective. And Dr. Maisel, who has chaired one of those committees and has obviously spent a lot of personal time, for which I think all of us should thank him—it's that kind of work that makes the system work—that's the way that FDA confirms whether a device is safe and effective, and has sufficient data to go on the market.

Senator HATCH. OK.

Mr. McGarity, in part of your written testimony you argued that the common law serves an important deterrence function. And, to some extent, I suppose I agree with that. Now, specifically, you stated that,

“To the extent that the anticipated compensatory and punitive damage awards imposed by the civil justice system are greater than the cost of avoiding the harm, a rational company will take protective action to prevent causing damage in the future.”

Now, I see some problems with the application of this reasoning to highly regulated areas like medical devices. First of all, FDA regulations make unilateral changes in labeling, design, or manufacturing processes virtually impossible. So, while it's a convenience to argue that a device manufacturer would simply and quickly update their product whenever they hear about a possible risk, the current system does not allow for this. And for good reason, because the initial process is so intensive, and sometimes intrusive, it only makes sense that any subsequent changes to a device receive similar scrutiny.

But, even if the law allowed for changes to be made so easily, how could a manufacturer ever be confident that the action they took would be sufficient to avoid a plaintiff suit?

One thing we can learn about the trial bar is that there is no shortage of legal theories on which to file a lawsuit. In your view, is there no benefit to offering limited protection for manufacturers of such highly regulated products to ensure the advancement and availability of these lifesaving products?

Mr. MCGARITY. I think that's a very good question, Senator Hatch. And the answer, I think, goes to the nature of the common law. The negligence standard—and you've alluded to it on several occasions this afternoon—is fairly uniform across the country. The standard of defective product. There's some minor variations in the States, but it is a standard of care that we ask a drug or device manufacturer to come up to.

Yes, when the manufacturer anticipates that they might be held to violate that standard of care in the future, one hopes that that affects their decision, particularly once the device is out there on the market.

Now, the fact is true that they have to go back to FDA for approval if they want to change their device. It is also the case, particularly when it comes to the label or the warning on the device, that when you go back to FDA and say, “Look, I've discovered a problem with this device. It's not as safe as it needs to be, as I've discovered from reports, or whatever, that have come to me, and I want to fix that and make it safer,” FDA doesn't get in their way. FDA doesn't say, “Oh, well, we wouldn't want you to make it safer

if that's going to take too much time or too much effort." They tend to not get in the way of safety-enhancing approvals.

But, you're right, they do have to go back to FDA, at some point, to get that approval before it actually changes things.

But, when a jury holds a defendant liable, they're not issuing an injunction, saying that, "You must do things differently." They are simply holding the defendant liable in that particular case, and the defendant then takes that message and does with it as the defendant thinks proper or appropriate.

Senator HATCH. Mr. Hutt.

Mr. HUTT. Well, in most instances, product liability lawsuits are resolved in the courts long after the safety issue is over. Because what happens is—through various mechanisms—first, doctors report problems with medical devices; they report it directly to FDA. Second, some doctors or patients report it directly to the company. As soon as those reports come in, any intelligent company starts to say, "What do we need to do? Is this inherent in the product?" like Mr. Roman was talking about with his first-generation product, that it's just the way it is; science and technology can't improve it any better? But, if there is a way of resolving it, that's done immediately. And FDA and the industry will cooperate. I agree with Tom on that.

Senator HATCH. OK.

Mr. HUTT. But, the point is that all that occurs before any product liability lawsuit arises. The product liability lawsuit punishes the company, it doesn't increase the safety or effectiveness of a single device.

Senator HATCH. Well, one last thing. There are a lot of small companies that come up with some very, very creative products. What effect would it have on that innovative process? That's what I'm concerned about. There are huge, big companies that might be able to withstand some of this stuff, but the innovation and the entrepreneurial makeup of our country—it's generally the smaller companies that come up with these devices, and I don't want that stultified.

Mr. HUTT. Yes, sir. I agree.

Senator HATCH. OK.

Well, Mr. Chairman, it's been a very interesting hearing. And I want to compliment each of you, as witnesses. Each of you has contributed a great deal to us here today. I wish I had, really, totally definitive answers to solve the problem of the three witnesses on our left, and yet still be able to have the devices for people like you, Mr. Roman, who really had a miserable life until you were able to get that device and get it to work.

Mr. ROMAN. Second chances come in all shapes.

Senator HARKIN. Well, I would just say that when the top 25 medical device companies had a net profit of \$173 billion, before the *Riegel* decision, I don't think innovation was stifled at all at that time.

Senator HATCH. Well, for the small companies, that's for sure.

Senator HARKIN. Well, they made a lot of money, Orrin.

[Laughter.]

Senator HATCH. Yes, the 25 companies—there are thousands and thousands of companies, many of them are very small. That's

where a lot of the innovative ideas come from—they'd be totally stifled if we went to a total tort system.

Senator HARKIN. Well, then I'll say this for the record. I don't—

Senator HATCH. I guarantee that.

Senator HARKIN [continuing]. I don't care how small they are, they'd better meet the most stringent standards of safety and efficacy. I don't care whether it's a drug or a device.

Senator HATCH. I agree with that.

Senator HARKIN. And if they don't adhere to that, and if it injures a person out there—now, again, it has this whole idea of preemption. And as a lawyer, I've looked at this a lot in the past, and it just seems to me that there was always, I thought, a presumption against preemption in the law. A presumption against preemption. And, quite frankly, it's—my reading of the little bit of the history of this is that the FDA's position, until the early 2000s, was basically a presumption against preemption. But, that all kind of changed. And I think it's up for us, as a legislative body, to decide.

Senator HATCH. Well, to borrow your words, if they don't adhere to that, they may have some liability under current law.

Senator HARKIN. Under criminal law.

Senator HATCH. Both.

Senator HARKIN. Under criminal law.

Senator HATCH. Both tort and current law. Depends.

Senator HARKIN. I don't know where—if it preempted—how are you going to get into court if you're preempted?

Senator HATCH. Well, if they don't abide by the rules that the FDA sets up, they may have some real difficulties.

Am I wrong, Mr. Hutt?

Mr. HUTT. You are right.

Senator HARKIN. Well—

Senator HATCH. I know I'm right.

[Laughter.]

Senator HARKIN. But, the problem is, without discovery and stuff, you won't be able to get that information. And that is the—

Senator HATCH. No, they'd be able to get—have the—

Senator HARKIN. That's the conundrum. That's the conundrum that we have here, I think, with this issue. And jury can say, "Well, the FDA can go after them criminally," and perhaps get that, but you just can't do that on every one. And the risks, you know—companies take risks, investors make risks. They say, "Well, the odds are, maybe, 10,000 to one that you'll never have to do this. Well, that's pretty good odds. I think I'll take those odds, and I'll make a lot of money off that device."

Senator HATCH. Well, thank you all for coming. We really appreciate—

Senator HARKIN. Well, just a minute, I haven't adjourned this hearing yet.

[Laughter.]

Senator HATCH. I wasn't—

Senator HARKIN. And I do have the gavel.

[Laughter.]

Senator HATCH. I was just trying to leave, that's all, in a gracious way.

Senator HARKIN. All right, Orrin.

I just wanted to ask, for the record—I have two things I want to put in the record. One is an editorial from New England Journal of Medicine. When did this article appear? Oh, March 2009, New England Journal of Medicine, in which they said that—I won't read the whole thing:

“As the law now stands, failure-to-warn and design-defect lawsuits are preempted for medical devices, but not for drugs. This perplexing State of affairs defies all logic. To address the inconsistency and to improve the safety of medical products”——

they went on to talk about the bill. And they said,

“Patients and physicians deserve to be fully informed about the benefits and risks of medical devices, and the companies making the devices should be held accountable if they fail to achieve this standard. We urge Congress to swiftly pass this legislation.”

That's the New England Journal of Medicine.

I have another article, by Margaret Jane Porter, former chief counsel of the Food and Drug Administration, and I just have one quote from that. She said that,

“Although the agency,”

meaning the FDA,

“had not formally expressed its position on the precise issue,” of preemption,

“it is clear, from the views it expressed in many other contexts, that it did not believe that State court claims were preempted under the Medical Devices Act, MDA. Indeed this was the prevailing view in the legal community into the early 1990s. No arguments were put forward that there should be preemptions of these claims.”

So, I'd just ask consent that those two articles appear in the record.

Oh, I'm sorry, I'd like to also submit for the record a 9-signature letter from victims of faulty medical devices also encouraging us to pass the Medical Device Safety Act.

[The information referred to may be found in Additional Materials—Letters of Support]

Senator HARKIN. And I would just say, off—if—you know, if I thought, for any amount of time, that this would really stifle innovation—I happen to be for innovation, I happen to be for new devices, I happen to think that these are good things, but I also believe in holding people accountable unto the strictest standards of safety and manufacture, and I am just concerned about the FDA. I've been concerned about the FDA for a long time. I have a love-hate relationship with that FDA, I can tell you that. I think sometimes they do good things, other times they don't do what they should be doing. And I think, more often than not, it's because we have not given them the resources with which to do it.

And I kind of interjected, I think, when Mr. Hutt was speaking, I said, “Well, we're not going to do that, give them the resources.” I don't mean that we don't want to give them. We should give them

the resources. We've asked them to do a myriad of things, and yet we don't give them the resources to carry it out. So, count me as one that also believes that we ought to do more, in terms of giving the FDA those resources. But, I just think, under the present budget situations and things like that, it's probably not going to happen.

Did anyone have any final comment before I go? I think we're now starting to vote, and I've got to go vote. Did anyone have any closing comment?

[No response.]

You're going to set a new land speed record?

Mr. ROMAN. Yes, sirs. Friday and Saturday.

Senator HARKIN. So, you're going to break the sound barrier.

Mr. ROMAN. Not the sound barrier. In our class, top speed's about 170 miles an hour.

Senator HARKIN. Oh, I don't know what class this is—

Mr. ROMAN. Different cars run at different records. So, our—

Senator HARKIN. Oh.

Mr. ROMAN [continuing]. Our class record's about 170, we're shooting for.

Senator HARKIN. Oh, because I thought, my gosh, would—somebody broke the sound barrier on—

Mr. ROMAN. Someone actually did break the sound barrier.

Senator HARKIN. Yes.

Mr. ROMAN. The new record is 746 miles an hour.

Senator HARKIN. Oh. Well, you're going to—

Mr. ROMAN. Everyone's got to have goals, Senators, you know.

[Laughter.]

You started out as a councilman, you moved up. Same type of thing.

Senator HARKIN. Exactly.

Well, good luck to you out there.

Mr. ROMAN. Thank you very much, sir.

Senator HARKIN. Thank you all very much.

The record will be kept open, for 10 days, for submission of other documents.

Thank you very much.

[Additional material follows.]

## ADDITIONAL MATERIAL

## LETTERS OF SUPPORT

AMERICAN BAR ASSOCIATION (ABA),  
CHICAGO, IL 60654-7598,  
December 29, 2008.

Hon. EDWARD M. KENNEDY, *Chairman,*  
*Committee on Health, Education, Labor, and Pensions,*  
*U.S. Senate,*  
*Washington, DC 20510.*

DEAR MR. CHAIRMAN: On behalf of the American Bar Association and its over 400,000 members, I write to express support for S. 3398, the "Medical Device Safety Act" that you introduced in the 110th Congress and to urge you to reintroduce this legislation in the next Congress.

Earlier this year, the Supreme Court in *Riegel v. Medtronic* ruled that a product liability lawsuit filed against *Medtronic* in a State court was preempted because the device had received approval from the U.S. Food and Drug Administration (FDA). It found that the Medical Devices Amendments of 1976 allow the FDA to preempt the State liability laws for medical devices. S. 3398 would address that decision by allowing injured patients to hold negligent medical device manufacturers liable for damages in State courts under State laws for product related deaths and injuries, as had been the case prior to the holding in the *Riegel* case. S. 3398 recognizes the value of over 30 years of experience that the United States has had in utilizing both FDA regulations and State tort laws to ensure the safety of medical devices.

State product liability law holds manufacturers accountable for injuries caused by their products when they are negligent or irresponsible. These laws permit an injured consumer to be compensated by a manufacturer found to be negligent. In addition, a manufacturer has a financial incentive to be vigilant in making its product as safe as possible and has an incentive to quickly recall a product from the market if it discovers that its product is dangerous even if the product or its label has been approved by the FDA.

S. 3398 is consistent with ABA policy supporting the continued right of the States and territories to regulate product liability law with discrete exceptions. For example, we support enactment of narrowly drawn Federal legislation on compensation that addresses the issues of liability and damages with respect to claims arising out of occupational diseases (such as asbestosis) with long latency periods in certain cases. In addition, we support Federal legislation allocating product liability risks between the Federal Government and its contractors.

The ABA is committed to sustaining a legal system in America that is not only effective and just, but also one that protects the rights of consumers and manufacturers, plaintiffs and defendants. We continually work on many fronts to develop recommendations and pursue projects aimed at improving our civil justice systems at both the Federal and State level.

We look forward to working with you toward enactment of this very important legislation in the 111th Congress.

Sincerely,

H. THOMAS WELLS, JR.

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THE NEW ENGLAND JOURNAL OF MEDICINE,  
FEBRUARY 27, 2009.

Senator EDWARD M. KENNEDY, *Chairman,*  
*Committee on Health, Education, Labor, and Pensions,*  
*U.S. Senate,*  
*Washington, DC 20510.*

DEAR SENATOR KENNEDY: The editors of the *New England Journal of Medicine* have read the "Medical Device Safety Act of 2009," which is designed to strengthen product safety in the medical device industry, and we endorse it. We think this is

critical legislation that will protect patients and help ensure the safety of medical devices in the United States.

Sincerely yours,

JEFFREY M. DRAZEN, M.D.,  
*Editor-in-Chief.*

GREGORY D. CURFMAN, M.D.,  
*Executive Editor.*

STEPHEN MORRISSEY, PH.D.,  
*Managing Editor.*

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THE NEW ENGLAND JOURNAL OF MEDICINE—EDITORIAL

THE MEDICAL DEVICE SAFETY ACT OF 2009

(By Gregory D. Curfman, M.D., Stephen Morrissey, Ph.D., and Jeffrey M. Drazen, M.D.)

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

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*,<sup>2</sup> ruled that a medical-device manufacturer cannot be sued under State law by patients alleging harm from a device that received marketing approval from the Food and Drug Administration (FDA). Until that ruling by the Court the possibility of litigation for "failure to warn or design defect served as a strong inducement for device companies to be vigilant about the safety of their products.

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

In the largest recent example, Judge Richard Kyle dismissed more than 1,000 cases filed against Medtronic in U.S. District Court in Minnesota after the failure of its Sprint Fidelis implantable cardioverter-defibrillator lead, which was withdrawn from the market in 2007. The lead was prone to fracture and it sometimes failed to deliver an appropriate shock and sometimes delivered multiple unnecessary shocks. Although Kyle stated that "the court recognizes that at least some plaintiffs have suffered injuries from using Sprint Fidelis leads, and the court is not unsympathetic to their plight," he ruled that he was compelled on the basis of the *Riegel* decision to dismiss the suits, leaving injured patients without the possibility of redress.<sup>3</sup>

And there may be many such patients: more than a quarter of a million Sprint Fidelis leads were implanted worldwide, 150,000 in the United States. The FDA has logged 2,200 reports of serious injuries from this lead, and last week Medtronic released an updated mortality report of 13 deaths; the company considers to have been related to the Sprint Fidelis.<sup>4 5</sup>

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.<sup>6</sup> The Court, in an 8-to-1 decision, interpreted this clause as demonstrating Congress's explicit intention to preempt State-law damages suits. The FDA, which until 2003 opposed preemption, in that year inexplicably did an about-face and posited that its approval of a device should be regarded as the final word and should immunize companies against legal liability. With respect to drugs, the FDA announced a broad pro-preemption position in 2006.

In marked contrast to the *Riegel* decision and to the FDA's new position on preemption, a Supreme Court ruling this month in a drug preemption case, *Wyeth v. Levine*,<sup>7</sup> 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 Cos-

metic Act contains no explicit preemption clause with regard to prescription drugs. The drug company argued that even though preemption is not specifically mentioned in the Act, it is “implied” by virtue of the supremacy clause of Article IV of the U.S. Constitution, which states that Federal law is supreme to State law. In its 6-to-3 ruling, the Supreme Court rejected this argument and found, as well, that the position put forth by the FDA in 2006 “does not merit deference.”

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

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

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#### THE *Lohr* Decision: FDA Perspective and Position

(Submitted by Margaret Jane Porter)\*

I appreciate the opportunity to participate in this meeting. Earlier versions of the program were billed as an opportunity to learn how to help reduce manufacturers’ product liability exposure. FDA was not interested in providing such advice; the program was revised to offer an opportunity to understand product liability exposure. I am glad to help put the case of *Medtronic v. Lohr*<sup>1</sup> in context from the agency’s perspective, and to explain why the agency took the position it did and why the agency regards the Court’s holding as an important victory for consumer protection.

The most important theme of this article is that the agency’s position in *Lohr* and the Court’s decision are the logical extensions of the agency’s long-standing pre-

\*Ms. Porter is Chief Counsel, Food and Drug Administration. This article is an updated version of a speech that was presented at FDLI’s seminar “After the *Lohr* Decision: What You Can Learn to Help Reduce Your Organization’s Exposure to Product Liability,” Washington, DC (Oct. 8, 1996). Beverly Rothstein of the Office of the Chief Counsel contributed substantially to these remarks.

<sup>1</sup> 116 S. Ct. 2240 (1996).

sumption against preemption in implementing section 521 of the Federal Food, Drug, and Cosmetic Act (FDCA).<sup>2</sup> The suggestion, therefore, that *Lohr* represents a significant shift is not reflective of the agency's history and practice. Rather, the *Lohr* decision is an important affirmation of the agency's historical approach. This discussion should be an opportunity for interested parties to identify areas in which more guidance would be helpful as the agency plans its implementation.

Since the passage of the Medical Device Amendments of 1976 (MDA),<sup>3</sup> it has been the agency's position that the scope of preemption under section 521 should be interpreted narrowly, with a presumption against preemption. This is true particularly when the effect of preemption would be to override a State scheme offering greater consumer protection than that currently afforded under the FDCA. Consequently, FDA's position always has been that State and local requirements are not preempted and may be enforced until FDA establishes specific counterpart requirements applicable to a particular device or class of devices.

FDA's narrow construction of the preemptive effect of section 521 is reflected in the multiple rulemakings under that section, including part 808, the regulation interpreting section 521 that was issued in 1978,<sup>4</sup> and several regulations granting or denying exemptions from preemption for various State and local requirements. Various portions of these regulations were cited by the Court in *Lohr*. For example, part 808 provides that State or local requirements that are substantially identical to an FDA requirement are not "different from" the FDA requirement and, therefore, are not preempted.<sup>5</sup> In addition, preemption is limited to instances where there are specific FDA requirements applicable to a particular device or class of devices. Even where the agency has established a detailed, comprehensive scheme regulating a particular kind of device, such as it has with hearing aids,<sup>6</sup> not all facets of State regulation of that device are preempted. Instead, only different or additional State or local requirements of the very type established by FDA are preempted. Finally, section 521 does not preempt State or local requirements of general applicability that relate either to products other than devices or to unfair trade practices not limited to devices.

Although FDA did not have occasion to address the precise issue of whether section 521 preempts State tort claims before that issue was litigated in private lawsuits, the agency did consider related questions. For example, in March 1984, the agency issued an advisory opinion stating that section 521 does not preempt the application of State law injunctive remedies to IUDs inserted in women prior to the enactment of the MDA.<sup>7</sup> With the provisions of part 808 as a basis, the agency concluded that there was no indication in the legislative history that Congress intended that the section preempt State or local requirements respecting general enforcement, including available legal remedies, or State or local statutes that only incidentally apply to devices.<sup>8</sup> Thus, in 1984 the agency's formal opinion was that rules or requirements established by States to govern the legal remedies available under State judicial systems are not "requirements with respect to a device" within the meaning of section 521.<sup>9</sup>

Similarly, in 1980, when responding to an application from the State of California for exemptions from preemption for numerous State requirements applicable to medical devices, the agency stated that penalties and remedies for violations of a State statute are general enforcement requirements, which are not preempted because they are not requirements with respect to a device.<sup>10</sup> Likewise, when responding to a congressional request for an opinion on the preemptive status of another California statute, the agency stated that requirements established by States to govern the contractual obligations of sellers and buyers, and to delineate the legal rights and remedies available to consumers under the State judicial system, are not "requirements with respect to a device" within the meaning of section 521 and, consequently, are not preempted.

Thus, although the agency had not formally expressed its position on the precise issue, it is clear from the views it expressed in many other contexts that it did not believe that State tort claims were preempted under section 521. Indeed, this was

<sup>2</sup>Pub. L. No. 75-717, § 521, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. § 360k (1994)).

<sup>3</sup>Pub.L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C.).

<sup>4</sup>See 21 CFR pt. 808 (1996).

<sup>5</sup>Id. § 808.1(d).

<sup>6</sup>21 CFR § 801.420.

<sup>7</sup>FDA Advisory Opinion to the National Women's Health Network, Dkt. No. 83-0140/AP (Mar. 8, 1984).

<sup>8</sup>Id.

<sup>9</sup>Id.

<sup>10</sup>45 Fed. Reg. 67,321, 67,322 (Oct.10, 1980).

the prevailing view in the legal community until the early 1990s; no arguments were put forward that there should be preemption of these claims.

The legislative history of section 521 contains no indication that the section was intended to preempt State tort claims. In fact, it contains no mention of product liability claims. Rather, when discussing the section, Congress focused specifically and exclusively on statutory programs administered by States and localities.<sup>11</sup> Moreover, the procedure Congress created in the statute for States to apply to the agency for exemptions from preemption does not readily encompass State tort claims. The exemption procedure is designed to accommodate State and local legislative and regulatory provisions; it does not logically accommodate judicial rulings in private tort suits.

Another significant indication that Congress did not intend section 521 to preempt State tort claims was its absolute failure to mention—or even hint at—such a result. It is clear from the legislative history of the MDA that Congress was well aware of, and indeed discussed at length, ongoing product liability litigation involving medical devices. The legislative history contains numerous references to the Dalkon Shield cases and to litigation involving catheters, artificial heart valves, defibrillators, and pacemakers. Given the harsh implications of foreclosing all judicial recourse for consumers injured by defective medical devices, FDA does not believe that Congress intended to effect so sweeping a change without even a comment. Rather, the agency believes that Congress intended to restrict preemption to positive enactments (for example, legislation or regulations) that apply to the marketing of medical devices within a State, and did not intend to preempt State tort remedies for injury to individual consumers.

While the agency was addressing the preemptive effect of section 521 on various affirmative State and local requirements, there was a suggestion in certain product liability cases, starting with *Cippolone v. Liggett Group, Inc.*<sup>12</sup> that preemption provisions in some Federal statutes could apply to State tort claims. The underlying principle relied on in *Cippolone* and echoed in a *Lohr* minority opinion was that the phrase “no requirement or prohibition” (as that language appears in the Federal Cigarette Labeling and Advertising Act)<sup>13</sup> “sweeps broadly and suggests no distinction between positive enactments and common law.”<sup>14</sup> Based on the Supreme Court’s language in *Cippolone*, courts began to interpret preemption provisions in other Federal statutes, including section 521, as preempting State tort claims.

The caselaw regarding preemption under section 521 developed quickly. Some courts narrowed the scope of preemption to areas in which FDA had imposed specific requirements on a specific device, most notably in the context of litigation involving tampons.<sup>15</sup> Many other courts, however, found broader and broader categories of product liability claims preempted under section 521, until the scope of preemption was extended well beyond what the agency believed could have been intended by the Supreme Court in *Cippolone*. Thus, tort claims were preempted based on FDA’s approval of a device, FDA’s clearance of a device, use of a device on a patient in a clinical study under an investigational device exemption, and the existence of the general labeling and manufacturing requirements. Indeed, some courts found the mere fact that a product was a device, and therefore subject to regulation by FDA, was enough to shield device manufacturers from all liability to individual consumers. These decisions were inconsistent with FDA’s long-standing position on preemption.

The first preemption case under section 521 in which FDA participated was *Talbott v. Bard, Inc.*<sup>16</sup> The defendant in that case previously had pled guilty to conspiring to defraud FDA, to filing false statements with FDA, and to shipping adulterated devices.<sup>17</sup> FDA filed an *amicus* brief with the First Circuit, stating its view that the plaintiffs’ claims were not preempted because they were premised on the same deficiencies that gave rise to the Federal enforcement action, and, therefore, would not result in the imposition of any requirement that would be in addition to or different from those under Federal law.<sup>18</sup> In its decision, the First Circuit interpreted section 521 very broadly, immunizing manufacturers from all tort liability, even in cases where a manufacturer admittedly and intentionally had violated pro-

<sup>11</sup> H. Rep. No. 94–853, at 45–46 (1976).

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

<sup>13</sup> Pub. L. No. 89–72, 19 Stat. 282 (1965) (codified at 15 U.S.C. §§ 1331–41 (1994)).

<sup>14</sup> *Lohr*, 116 S. Ct. at 2262; *Cippolone*, 505 U.S. at 521.

<sup>15</sup> See, e.g., *Moore v. Kimberly-Clarke Corp.*, 867 F.2d 243 (5th Cir. 1989) (regarding 21 CFR §801.430, regulation of menstrual tampons).

<sup>16</sup> 63 F.3d 25 (1st Cir. 1995).

<sup>17</sup> See *Talbott v. Bard, Inc.*, 848 F. Supp. 287 (D. Mass. 1994).

<sup>18</sup> Brief for the United States as Amicus Curiae at 13–14, *Talbott v. Bard, Inc.*, 63 F.3d 25 (1st Cir. 1995).

visions of Federal law intended to ensure the safety and efficacy of medical devices.<sup>19</sup>

In December 1994, the U.S. Court of Appeals for the Fourth Circuit invited FDA to file an *amicus* brief in *Duwall v. Bristol-Myers Squibb Co.*,<sup>20</sup> a case involving a claim of breach of express warranty in the context of a “510(k)d” device.<sup>21</sup> The agency filed a brief stating its view that express warranty claims are not preempted under section 521.<sup>22</sup> The agency reasoned that the statutory reference to requirements “with respect to a device” was intended to limit preemption to requirements that specifically target particular medical devices, and did not include generally applicable provisions of State law, such as those in the *Uniform Commercial Code*. In addition, the agency stated that the general requirement that devices be accompanied by a statement of intended use is not a device-specific requirement and, consequently, does not trigger preemption under section 521.<sup>23</sup> The court accepted the agency’s view and held that the express warranty claim was not preempted.<sup>24</sup>

When the issue of possible preemption of State tort claims under section 521 reached the Supreme Court in *Medtronic v. Lohr*, the agency presented its view that State tort claims generally are not preempted under section 521, a view that is consistent with its longstanding position regarding both the scope of preemption under section 521 and the presumption against preemption. The agency explained that it consistently had construed the term “requirement” to refer to substantive, but not remedial, provisions.<sup>25</sup> According to the agency, a finding of substantial equivalence should not preempt a defective design claim because that finding is not a determination that a particular design is required by the Act.<sup>26</sup> The agency also stated that the good manufacturing practice and labeling provisions under the Act should not preempt a failure to warn or negligent manufacture claim because these are general requirements applicable to all devices, rather than specific requirements applicable to a particular device.<sup>27</sup>

The agency’s position was adopted by the Supreme Court in *Lohr*. The Court accepted FDA’s narrow construction of the scope of section 521, reasoning that a finding of broad preemption would be entirely at odds with Congress’ intent in enacting the MDA—to provide greater public health protection.<sup>28</sup> The Court, like FDA, refused to find that Congress intended section 521 to usher in a sweeping preemption of traditional common law remedies against manufacturers and distributors of defective devices. There was a marked absence of such an intent on the part of legislators who were acutely aware of the high-profile product liability litigation involving medical devices. The Court emphasized the importance of not cavalierly preempting State regulation, particularly in fields traditionally left to the States.<sup>29</sup> The *Lohr* Court also distinguished *Cippolone*, and discussed the intended use of the term “requirement” in section 521. The Court stated that in enacting section 521, Congress was concerned primarily with the problem of specific conflicting State statutes and regulations rather than the general duties enforced by common law actions.<sup>30</sup> Where a regulatory scheme imposed a limited set of requirements, tort remedies could co-exist. The Court noted that Medtronic’s argument would preempt all common law obligations.<sup>31</sup>

In *Lohr*, the Supreme Court held that a finding of substantial equivalence does not amount to a specific, federally enforceable design requirement, and consequently does not preempt a negligent design claim.<sup>32</sup> The Court also held that the Act’s labeling and manufacturing requirements do not preempt claims alleging failure to warn or negligent manufacture.<sup>33</sup> The Court reasoned that the Federal requirements reflect important, but entirely generic, concerns about device regulation and that the State common law requirements were not specifically developed “with re-

<sup>19</sup> *Talbott*, 63 E3d at 26–17.

<sup>20</sup> 65 F.3d 392 (4th Cir. 1995), *vacated and remanded*, 116 S. Ct. 2576 (1996).

<sup>21</sup> See 21 U.S.C. §360(k) (FDCA §510(k)).

<sup>22</sup> Brief for the U.S. Food and Drug Admin. as Amicus Curiae, *Duwall v. Bristol-Myers Squibb Co.*, 65 F.3d 392 (4th Cir. 1995) (No. 94–1520).

<sup>23</sup> *Id.* at 1720.

<sup>24</sup> *Duwall*, 65 F.3d at 401.

<sup>25</sup> Brief for the United States as Amicus Curiae Supporting Respondents/Cross-Petitioners, *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240 (1996) Nos. 95–754, 95–886 (U.S. Mar. 13, 1996), 1996 WL 118035, at \*13.

<sup>26</sup> *Id.* at \*6.

<sup>27</sup> *Id.* at \*21.

<sup>28</sup> *Lohr*, 116 S. Ct. at 2252–53.

<sup>29</sup> *Id.* at 2250.

<sup>30</sup> *Id.* at 2252.

<sup>31</sup> *Id.* at 2251.

<sup>32</sup> *Id.* at 2254–55.

<sup>33</sup> *Id.* at 2258.

spect to” medical devices. Finally, the Court found that section 521 does not deny States the right to provide a traditional damages remedy for violations of common law duties when those duties parallel Federal requirements.<sup>34</sup> The Court reasoned that the presence of a damages remedy does not amount to the additional or different “requirement” necessary to trigger preemption under section 521, but rather merely provides another reason for manufacturers to comply with identical existing requirements under Federal law.

FDA’s view is that FDA product approval and State tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection. FDA regulation of a device cannot anticipate and protect against all safety risks to individual consumers. Even the most thorough regulation of a product such as a critical medical device may fail to identify potential problems presented by the product. Regulation cannot protect against all possible injuries that might result from use of a device over time. Preemption of all such claims would result in the loss of a significant layer of consumer protection, leaving consumers without a remedy for injuries caused by defective medical devices. Moreover, FDA’s regulation of devices would have been accorded an entirely different weight in private tort litigation than its counterpart regulation of drugs and biologics. This disparity is neither justified nor appropriate, nor does the agency believe it was intended by Congress when section 521 was enacted.

The fact that most State tort claims are not preempted under section 521 does not mean that there can be no valid defense to these claims on the merits. The existence of the Federal scheme will not *automatically* preclude these claims, however, and compliance with FDA regulations and requirements can only help a company in a product liability setting.

AARP,  
MARCH 2, 2009.

Senator EDWARD M. KENNEDY, *Chairman,*  
*Health, Education, Labor, and Pensions Committee,*  
*317 Russell Senate Office Building,*  
*Washington, DC 20510.*

DEAR SENATOR KENNEDY: On behalf of AARP’s almost 40 million members, we are pleased to endorse the Medical Device Safety Act of 2009. Your legislation would make clear that the Medical Device Amendments of 1976 (MDA) do not preempt State laws that permit individuals, harmed by devices, the opportunity for legal recourse.

The MDA was enacted by Congress in the wake of medical devices that severely injured or resulted in the death of individuals. Last year, in *Riegel v. Medtronic* the Supreme Court determined that the MDA preempted State tort law, leaving consumers the inability to obtain recourse when injured by unsafe medical devices. Your legislation would permit those who are harmed to pursue legal relief through the courts. The legislation will maintain FDA’s oversight and regulatory approval process, and provide individuals a much-needed supplement to this authority.

Consumers need to be assured that the medical devices—like heart valves, cerebral stimulators, and pacemakers—implanted into them are safe and effective. If these products cause harm, consumers should be able to pursue compensation through the legal system.

We thank you for your leadership and look forward to working with you to ensure that this much-needed legislation is enacted. If you have any questions, please contact me or have your staff contact Anna Schwamlein Howard of our government relations staff at 202-434-3770.

Sincerely,

DAVID P. SLOANE,  
*Senior Vice President,*  
*Government Relations & Advocacy.*

<sup>34</sup> *Id.* at 2255.

CALIFORNIA MEDICAL ASSOCIATION (CMA),  
SACRAMENTO, CA 95814-2906,  
March 2, 2009.

Hon. DIANNE FEINSTEIN,  
U.S. Senate,  
331 Hart Office Building,  
Washington, DC 20515.

Re: Please Cosponsor the Medical Device Safety Act

DEAR SENATOR FEINSTEIN: The California Medical Association is writing to urge you to cosponsor the Medical Device Safety Act when it is introduced by Chairmen Henry Waxman and Frank Pallone. It will protect patients and prevent increased physician exposure to medical liability claims.

Last year, the medical device manufacturers successfully applied the Federal preemption doctrine to immunize their companies from lawsuits as illustrated by the Supreme Court's ruling in *Riegel v. Medtronic*. Shortly after the *Riegel* decision was issued, congressional representatives introduced the Medical Device Safety Act to reaffirm Congress' intent that medical device manufacturers should not be immunized from lawsuits.

Physicians will likely see more claims filed against them post-*Riegel*, if the Medical Device Safety Act is not enacted. Without the ability to seek restitution from the medical device makers, patients who are injured by defective medical devices will likely pursue claims against doctors and others in the medical profession who prescribed or implanted the defective device. Patients who have suffered serious injuries, or death, due to defective medical devices will likely have significant health care costs, loss of income from extended absences from work and other expenses that will not be covered by their healthcare or disability insurance.

Attached is CMA's Amicus Brief in favor of the Respondent in *Wyeth v. Levine*, as well as a recent report issued by the U.S. House of Representatives detailing how FDA career staff objected to agency preemption policies. We also recommend viewing the JAMA article from October 21, 2008 entitled "Prescription Drugs, Product Liability, and Preemption of Tort Litigation," at <http://www.jama.ama-assn.org/cgi/content/full/300/16/1939> for more information on this issue.

The CMA would like to ask you to join us in this fight to protect patients and physicians by cosponsoring the Medical Device Safety Act when it is introduced in the 111th Congress. Without these important clarifications of congressional intent, physicians could face an economic crisis of epic proportions that would negatively affect access to health care at a time when we should be focusing on improving the state of health care.

Sincerely,

DEV GNANADEV, MD,  
President.

SENATOR JOSEPH DUNN (RET.),  
Chief Executive Officer.

March 5, 2009.

Hon. HENRY A. WAXMAN, *Chair*,  
*Committee on Energy and Commerce*.

Hon. FRANK PALLONE, JR., *Chair*,  
*Subcommittee on Health, Committee on Energy and Commerce*.

DEAR CHAIRMAN WAXMAN AND REP. PALLONE: Our groups, advocates for consumer health and safety, write to express our strong support for the Medical Device Safety Act. This bill will restore injured patients' ability to bring claims for injuries caused by defective medical devices.

The legislation was drafted in response to *Riegel v. Medtronic*, a 2008 Supreme Court decision which held that pre-market approval of a medical device by the Food and Drug Administration (FDA) under the Medical Device Amendments of 1976 immunizes the device manufacturer from tort liability. The decision removes a vital and long-standing component of the consumer safety net for medical devices and deprives injured patients of their only avenue for seeking compensation for their injuries.

Injured patients already have begun to feel the effects of *Riegel*. Recently, a Minnesota district court relied on *Riegel* to dismiss the State law claims of thousands of patients who were injured or died from Medtronic's faulty Sprint Fidelis implantable defibrillator, leaving them with no means for obtaining compensation

for their injuries. Medtronic recalled the devices in October 2007 but reportedly knew about the defects since at least January 2007. Despite this knowledge, the company launched a direct-to-consumer advertising campaign urging consumers to ask their doctors whether a defibrillator would benefit them.<sup>1</sup> Thus, Medtronic manufactured a defective device that hurts its users, continued marketing the product even after it knew that the product was injuring people, and yet escapes accountability because the FDA had approved the product before it went on the market, and well before the defect was known.

Preemption of State tort suits over medical devices is especially harmful because it places all responsibility for device regulation in the hands of the FDA, which cannot protect consumers on its own. Numerous reports list the numerous challenges that the agency faces. For example, an FDA subcommittee concluded in 2007 that the agency “suffers from serious scientific deficiencies” and “is not positioned to meet emerging regulatory responsibilities,”<sup>2</sup> while a 2008 report by the House Committee on Oversight and Government Reform shed light on the political motivations behind the agency’s efforts to immunize drug manufacturers from liability.<sup>3</sup> The FDA also has conceded that its post-approval monitoring of medical devices is “not working well.”<sup>4</sup> Although the agency has the authority to withdraw device approval, it rarely uses this tool, choosing instead to rely upon the tort system, market forces, and the threat of agency action to induce manufacturer recalls. Even when a defective device is identified and removed, the agency lacks authority to secure compensation for injured patients.

Further, the pre-market approval process for medical devices does not provide the public with foolproof protection—and was never intended to do so. It is only one part of a broader consumer protection regime, in which private tort litigation plays a critical role. Even comprehensive pre-market testing cannot uncover all defects or risks posed by a new product. Tort litigation facilitates the discovery of flaws in devices on the market and brings them to the FDA’s and the public’s attention. Damages actions also deter risky device designs, encourage continued research and testing of devices on the market, and compensate victims for deaths and injuries caused by device defects. As an October 2008 editorial in the *Journal of the American Medical Association* succinctly stated: “tort law serves in effect as a way to close regulatory gaps in the FDA premarketing approval process and to provide a mechanism for post marketing surveillance.”<sup>5</sup>

Under *Riegel*, the Medical Device Amendments immunize manufacturers from liability for injuries caused by design defects, inadequate instructions, and failure to warn of risks associated with using pre-market approved devices. With passage of the Medical Device Safety Act, Congress will restore a patient’s ability to seek to hold medical device manufacturers accountable for any wrongdoing. We strongly urge you and all Members of Congress to support this legislation.

Sincerely,

*Center for Justice & Democracy; Consumer Federation of America;  
Consumers Union; Homeowners Against Deficient Dwellings;  
National Association of Consumer Advocates; National Consumers League;  
OWL—The Voice of Midlife and Older Women; Progressive States Network;  
Public Citizen; and U.S. Public Interest Research Group.*

<sup>1</sup> Medtronic Press Release, Jan. 15, 2007. [http://www.medtronic.com/Newsroom/NewsReleaseDetails.do?itemId=1168456009954&lang=en\\_US](http://www.medtronic.com/Newsroom/NewsReleaseDetails.do?itemId=1168456009954&lang=en_US).

<sup>2</sup> Subcomm. on Sci. and Tech., U.S. Food and Drug Admin., *FDA Science and Mission At Risk* 2 (2007).

<sup>3</sup> U.S. House of Representatives Committee on Oversight and Government Reform Majority Staff Report. *FDA Career Staff Objected to Agency Preemption Policies*. (2008).

<sup>4</sup> Petitioner’s Brief at 5, *Riegel*, 552 U.S. 128 S. Ct. 999 (No. 06–179).

<sup>5</sup> Catherine D. DeAngelis; Phil B. Fontanarosa. *Prescription Drugs, Products Liability, and Preemption of Tort Litigation*. *JAMA* (2008).

CONSUMERS UNION,  
WASHINGTON, DC 20036,  
March 9, 2009.

Hon. EDWARD KENNEDY,  
U.S. Senate,  
317 Russell Senate Office Building,  
Washington, DC 20510.

Hon. PATRICK LEAHY,  
U.S. Senate,  
433 Russell Senate Office Building,  
Washington, DC 20510.

DEAR CHAIRMEN KENNEDY AND SENATOR LEAHY: Consumers Union, the non-profit publisher of *Consumer Reports*, is writing in support of your legislation, the "Medical Device Safety Act of 2009."

Your bill would reverse the Supreme Court's misguided decision in *Riegel v. Medtronic*, which misread a longstanding law and held that a consumer injured by a defective or faulty medical device could not sue the device manufacturer if the manufacturer had gotten FDA approval for the device.

As you know, the FDA has been deservedly criticized for inadequate oversight and enforcement efforts related to safety. A recent report by an FDA subcommittee found that the FDA is "not positioned to meet emerging regulatory responsibilities." The FDA has admitted that its post-approval monitoring of medical devices is "not working well," a point painfully emphasized by each injury and recall. Yet by barring lawsuits over faulty medical devices, the Supreme Court in *Riegel* has effectively placed the entire responsibility for regulating medical devices in the hands of the FDA.

Congress cannot delay in acting on this legislation. The *Riegel* decision is already being used to withhold justice from consumers who were injured by defective medical devices. Earlier this year, a Federal judge in Minnesota cited *Riegel* and dismissed numerous claims against Medtronic over a defibrillator, calling the injured consumers "sympathetic plaintiffs who are, nevertheless, without remedy by operation of law," noting that the plaintiffs' remedy now "lies with Congress, and not with this court (or any other court)."

The *Riegel* decision weakened protections available to consumers injured by faulty medical devices. Your bill would restore these protections and the original intent of the Medical Device Amendments of 1976, and ensure that consumers who suffer injuries or death can sue the manufacturers of the defective devices that harmed them.

We look forward to working with you to help restore consumers' legal rights.

ELLEN BLOOM,  
Director, Federal Policy,  
Consumers Union.

MARCH 10, 2009.

Senator EDWARD M. KENNEDY, *Chairman*,  
*Health, Education, Labor, and Pensions Committee*,  
U.S. Senate,  
317 Russell Senate Building,  
Washington, DC 20510.

Senator PATRICK J. LEAHY, *Chairman*,  
*Judiciary Committee*,  
U.S. Senate,  
433 Russell Senate Building,  
Washington, DC 20510.

Representative HENRY WAXMAN, *Chairman*,  
*Energy and Commerce Committee*,  
U.S. House of Representatives,  
2125 Rayburn House Office Building,  
Washington, DC 20515.

Representative FRANK PALLONE, JR.,  
U.S. House of Representatives,  
237 Cannon House Office Building,  
Washington, DC 20515.

DEAR CHAIRMAN KENNEDY, CHAIRMAN LEAHY, CHAIRMAN WAXMAN, AND REPRESENTATIVE PALLONE: We, the undersigned national medical and health organiza-

tions, are writing to express our support for the “Medical Device Safety Act.” This much-needed legislation addresses the Supreme Court’s recent decision in *Riegel v. Medtronic*, by restoring congressional intent and the ability of injured patients to hold negligent medical device manufacturers accountable for product-related deaths and injuries. Immunity should not be given to device manufacturers who fail to adequately warn about device risks—especially when a risk, known to the manufacturer, later causes permanent and debilitating injuries.

Under *Riegel*, manufacturers of FDA-approved medical devices are given complete immunity from liability for product related deaths and injuries. This immunity protection even extends to manufacturers who fail to warn about device problems that arise after FDA approval. By eradicating manufacturer accountability, thousands of patients injured by defective devices would be unable to receive any recourse for their injuries. An upcoming Supreme Court case (*Wyeth v. Levine*) dealing with prescription drugs could further limit the rights of patients to hold drug manufacturers accountable.

As a March 2008 *New England Journal of Medicine* editorial states,

“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.”

We know firsthand how beneficial medical devices are for patients suffering from illnesses. However, we also know there are times when devices malfunction and in those instances, it is critical for patients to be able to hold accountable the manufacturers responsible for their injuries.

The Medical Device Safety Act addresses these gaps and capitalizes on 30 years of experience under the 1976 Medical Device Amendments by utilizing both FDA regulation and State tort law to ensure the safety of medical devices. This legislation explicitly states that actions for damages under State law are preserved and makes this retroactive to the date when Congress enacted the Medical Devices Amendment of 1976.

For these reasons, we strongly support the Medical Device Safety Act. Manufacturer accountability for defective devices cannot be so easily eliminated after 30 years of proven effectiveness. Reiterating Congress’ intent and restoring manufacturer accountability is a much-needed first step towards ensuring reasonably safe medical devices. We look forward to working with you and your staff to pass this very important legislation.

Sincerely,

*Community Catalyst; Disability Rights Education and Defense Fund;  
Easter Seals; Families USA; Friends of Residents in Long Term Care;  
Pulmonary Hypertension Association; Toxic Discovery; and United Spinal.*

MARCH 12, 2009.

Hon. HARRY REID, *Majority Leader,*  
*U.S. Senate,*  
*Washington, DC 20510.*

DEAR MAJORITY LEADER REID: The above members of the Patient and Consumer Coalition strongly support the Medical Device Safety Act of 2009. This Act will restore the rights of injured patients and consumers to sue the manufacturers of defective medical devices in State courts.

Last year, the U.S. Supreme Court ruled in *Riegel v. Medtronic, Inc.* that medical devices makers are shielded from personal injury lawsuits, if their defective or unsafe product was approved by the Food and Drug Administration’s (FDA) pre-market approval (PMA) process.

The Supreme Court and the medical device manufacturing industry stated that the FDA’s “rigorous pre-market approval process” will protect patients and consumers from dangerous devices, so patients do not need State protections. However, numerous recent product recalls make it clear that many medical devices that are sold in the United States are not safe.

The Institute of Medicine and the U.S. Government Accountability Office have issued reports concluding that poor management, scientific inadequacies, and lack of resources, inspections, and post-market surveillance systems have undermined the agency’s ability to protect Americans from unsafe drugs and medical devices.

The Patient and Consumer Coalition is gravely concerned that the Supreme Court ruling will shield from lawsuits manufacturers who received FDA approval through inadequate or false data or by withholding important safety and effectiveness data. In the past, lawsuits have helped to elicit information about false or misleading

data. Without the discovery process from lawsuits, risk information that was covered-up by a company might never be made public.

It is clear that patients and consumers cannot have full confidence in the ability of the FDA to protect them from dangerous and deadly medical devices. The Supreme Court ruling has already had a negative impact on patients. Recently, a Minnesota district court relied on *Riegel* to dismiss the State law claims of more than 1,000 patients who were injured or died from Medtronic's faulty Sprint Fidelis implantable defibrillator.

According to news reports, "More than 235,000 people received the Sprint Fidelis leads before they were recalled, and many of those patients still have them in place."

The Medical Device Safety Act of 2009 would allow injured patients to seek redress in State courts, and the threat of litigation would provide a financial incentive to manufacturing companies to ensure that their products are as safe as possible. For the above reasons, the Patient and Consumer Coalition strongly supports this legislation.

Sincerely,

*Breast Cancer Action; Center for Medical Consumers; National Consumers League;  
National Research Center for Women & Families; Title II Community AIDS  
National Network; The TMJ Association; WoodyMatters.*

MARCH 31, 2009.

Hon. EDWARD M. KENNEDY, *Chairman,*  
*Committee on Health, Education, Labor, and Pensions,*  
*Dirksen Senate Office Building,*  
*U.S. Senate,*  
*Washington, DC 20510.*

DEAR CHAIRMAN KENNEDY, RANKING MEMBER ENZI, AND MEMBERS OF THE COMMITTEE: I am writing to state my support for the Medical Device Safety Act. It has been introduced in the Senate as S. 540 and in the House as H.R. 1346.

#### MY STORY

On April 13, 2007 I suffered a Sudden Cardiac Arrest. I am alive today because a doctor who was nearby administered CPR until the EMTs arrived.

I had an ICD (an internal defibrillator) implanted. It is connected to my heart by a lead that goes through an artery and is attached to the inside of my heart. Both the defibrillator and the lead were manufactured by Medtronic Incorporated.

On June 30, 2008, my Medtronic Sprint Fidelis lead failed. I received 21 incredibly painful shocks from the ICD in less than 1 hour. Other people who have received these shocks describe them as "having a cannon fired into my chest" or "being kicked in the chest by a horse that is inside and trying to get out." Those descriptions are close, but they really don't do justice to the pain.

I arrived by ambulance at Presbyterian Hospital in Charlotte, NC. A Medtronic technician was waiting for me in the emergency room. He hooked me up to a computer and almost immediately told me that:

- I had received the shocks because the lead had failed.
- He had disabled the defibrillator.
- My ICD had been detecting the impending failure since June 14—16 days earlier.

The following day I had surgery. The surgeon removed the lead and put in a new one. He implanted a Medtronic Sprint Quattro lead. The Quattro is an older model that Medtronic had replaced on the market with the Sprint Fidelis.

I work at a small, privately owned corporation. Our medical insurance was self-funded at the time. The events that occurred on June 30 and the few days following ultimately cost the company almost \$30,000, and I personally had several thousand dollars more that I had to pay out.

#### SPRINT FIDELIS LEADS HISTORY

In 2004, the FDA approved the Sprint Fidelis lead.

Medtronic described the leads as an evolutionary advance from the Quattro, and filed the application as a supplement to the already approved Quattro (which had been approved similarly based on earlier leads). Even though the wires in the lead are much thinner than in the Sprint Quattro lead, and the lead is manufactured differently, the Sprint Fidelis leads never went through the full PMA process.

During 2007, reports began coming out about doctors, most notably Dr. Robert Hauser of the Minnesota Heart Institute, who were seeing failure rates so high that they were no longer using Sprint Fidelis leads. They were advising both Medtronic and the FDA that they believed there was a problem with the Sprint Fidelis.

In March 2007—the month before I received my implant—Medtronic issued a letter to the medical community. They said that they had reports of “higher than expected conductor fracture rates” with the Sprint Fidelis leads. They went on to say they believed the problem was with how the leads were being handled while they were being implanted. They gave no indication that there might be a problem with the leads themselves.

On October 15, 2007, 6 months after my implant, Medtronic sent out another letter. They instructed doctors to stop implanting Sprint Fidelis leads and to return any unused products to Medtronic. Medtronic recommended that implanted leads not be replaced because that procedure was more dangerous than leaving them in. They also stated that 268,000 Sprint Fidelis leads had been implanted in patients.

That same day the FDA issued a “Class 1 Product Recall.” This type of recall is the highest level, and is issued when a device is likely to cause serious injury or death.

The FDA issued a document titled “*Medtronic Recalls Sprint Fidelis Cardiac Leads: Questions and Answers for Consumers.*” That document included the following:

“There are two alternatives to removing the lead. One is to continue using the lead while monitoring closely for signs of fracture. A second is to surgically add a replacement lead.”

The first alternative is clearly the less expensive, the less invasive, the less dangerous and the less expensive.

#### *Medtronic did not Heed the FDA recommendations*

I have a device called a “Medtronic Carelink Monitor” that reads the data from my implant and transmits it to Medtronic. The process is very simple—you plug in a phone line, put a device that looks like a mouse on your chest, and press a button. The entire procedure takes less than 5 minutes.

It costs me or my insurance about \$200 each time my doctor orders a transmission (to monitor whether I have had any cardiac events).

Medtronic’s computers record these transmissions and will detect lead failures. If Medtronic had advised patients to use the monitors regularly (thus “monitoring closely for signs of fracture”), their computer would have detected my lead failure in any transmission from June 14 to June 30. I would still have had the surgery, but I would not have received those shocks.

Medtronic never made that advisement!

#### THE RAMIFICATIONS OF A LEAD FAILURE

There are at least three ways that a lead failure can lead to problems:

1. A person suffers a cardiac event. The defibrillator cannot detect the event and thus does not deliver the life-saving shock. That patient probably dies.
2. A person can get multiple shocks because the lead has fractured. There might or might not be any permanent damage to the heart, but the person has suffered significant pain and significant expense.
3. A person can receive shocks because of a lead fracture, and those shocks cause the person’s heart to malfunction. This person will likely die.

#### THE NEED FOR PASSAGE OF THE MEDICAL DEVICE SAFETY ACT

In February, 2007, the U.S. Supreme Court ruled in *Reigel v. Medtronic*. Charles Reigel was undergoing an angioplasty procedure. A catheter, manufactured by Medtronic, burst during the procedure. Mr. Reigel died from complications that arose from that catheter failure.

In the ensuing civil trial, Medtronic claimed that they could not be sued for a **possibly** defective device because the catheter had received PMA approval from the FDA. They maintained that the approval preempted any civil suits because of the Medical Device Amendment of 1976, which Congress had enacted to delineate the FDA’s authority and obligations in regard to medical devices. The Supreme Court agreed.

It’s no surprise that people started civil suits in various State courts against Medtronic on the Sprint Fidelis leads. The federal court system put these cases into a Multi-District Legislation so that they would all be heard in the Federal District Court in Minnesota.

Earlier this year, Judge Richard Kyle Sr. dismissed the more than 1,400 cases, accepting Medtronic's assertion that all of the particulars in the complaints were preempted by the Medical Device Amendment of 1976.

In Judge Kyle's decision, he stated:

"Congress has decided to limit medical-device manufacturers' liability in order to spur innovation, even though individuals are sometimes injured when using medical devices. Plaintiffs' remedy, therefore, lies with Congress, and not with this Court (or any other court)."

The FDA, until early in this decade, had supported the concept that the ability of victims of medical device problems to sue Medical Device Manufacturers was a significant factor in making manufacturers do their best to produce safe devices and to correct problems with the devices.

Yet now, the Supreme Court and Judge Kyle have made it essentially impossible for victims to sue the manufacturers.

I don't know whether what happened to me was the result of a defective design, or defective manufacturing of the lead. That can only be determined in Discovery if I am able to sue Medtronic! I do know, however;

- Medtronic probably knew well before my lead was implanted that there were problems with the Sprint Fidelis leads.
- My doctor could have used a different product such as the Quattro lead had he known that there was a problem with the Sprint Fidelis.
- According to the estimates that have appeared in the press, there are still 150,000 people with Sprint Fidelis leads implanted. I don't know what happened to the other 118,000, but those 150,000 people are walking around with "ticking time bombs" in their chests.
- Medtronic is still doing nothing to protect those 150,000 people.
- Sprint Fidelis leads are continuing to fail. The FDA's MAUDE database shows more failures every month.
- I am out several thousand dollars, and my employer is out \$30,000.
- I cannot sue Medtronic to recover the costs I and my company incurred.
- The Sprint Fidelis leads are just one of numerous Class 3 medical devices approved by the FDA through the PMA process. People with any of the other devices, should there be problems, are in the same situation as I and the other victims of the Sprint Fidelis leads.

As Judge Kyle pointed out, my remedy lies with Congress.

The Medical Device Safety Act is the remedy I need to restore my right to sue Medtronic.

I am begging you to support the Medical Device Safety Act.

- Restore the law to what existed prior to *Reigel v. Medtronic*.
- Restore the law to what was originally intended by Congress.
- Restore to victims the ability to seek recompense from the manufacturers.
- Restore the incentive to manufacturers to produce the best devices they can and to protect their customers when there are problems.

DON FERNBACH.

JULY 30, 2009.

Hon. EDWARD M. KENNEDY, *Chairman,*  
*Committee on Health, Education, Labor, and Pensions,*  
*Dirksen Senate Office Building,*  
*U.S. Senate,*  
*Washington, DC 20510.*

DEAR CHAIRMAN KENNEDY, RANKING MEMBER ENZI, AND MEMBERS OF THE COMMITTEE: My name is Michael Collins. I am 43 years old and a resident of Georgetown, TX. My son Joseph Collins and I have both been injured by a Medtronic defibrillator. My 14-year-old son Joe collapsed in July 2006 during baseball practice for his team and his heart was in ventricular fibrillation. It was discovered he had HCM, which is a genetic defect of the heart that can cause sudden death. He was implanted with a Medtronic defibrillator and a Sprint Fidelis lead model #6949.

Since this disease is genetic, the family was tested and I found that I had the same defect. I am very active and my cardiologist was concerned that I may have an event similar to my son. On September 6, 2006, I was implanted with a Medtronic defibrillator with the Sprint Fidelis model #6931. In both cases, I was told the device life would be up to 10 years for each of us based on how often it had to administer a shock. The batteries can not be recharged so the more it is used, the quicker it has to be replaced.

On June 20, 2007 (9 months after the implant surgery), I was exercising at the gym and the defibrillator shocked me six times. The first shock felt as if someone had hit me in the head and chest extremely hard. It blurred my vision and caused me to be confused for a moment. I actually thought someone had purposely hit me with something. A few seconds later, the same pain was felt again. At this point I realized what was happening but knew the shocks were not necessary. The device continued to shock me four more times. Each shock caused me to become more concerned about how many times I would need to endure the pain. I was taken from the gym by ambulance to a local hospital for evaluation. It was determined that the defibrillator lead had shorted. If I simply moved my left arm the device improperly sensed that my heart was having problems. The device was disabled and surgery was scheduled to replace the broken lead. There was nothing medically wrong with me, the device failed. On June 27, 2007, I underwent surgery that removed the entire lead from my heart to upper chest and replaced it again with a Sprint Fidelis lead model #6931. At the time, I was told my situation was extremely rare and the odds of having future issues were incredibly high. I again would have to endure a 6-week recovery period from the surgery.

On October 23, 2007, I received the letter regarding the recall of the Sprint Fidelis leads. They had recalled the first lead that my son had implanted and both of the leads I had implanted. I visited my doctor's office on Saturday, November 10, 2007 to make the changes to the defibrillator as outlined in the Medtronic letter to doctors dated October 15, 2007. I found it incredibly unfair that I was charged a co-pay and my insurance was billed for an office visit when I only met with a Medtronic Representative at their request to check their faulty device. This is another example of how a defective product creates profit for companies and creates no responsibility.

On April 1, 2008, my son Joe was shocked twice when his lead failed while he was walking down the driveway at our home. Joe and I were repairing a sprinkler head at our home. He had gone to get a tool that was needed and as he was returning, he received a shock from the device. I observed the entire incident and came to his aid. My wife took Joe inside and attempted to have his device transmit information electronically over the phone to determine what happened. Joe was standing still with the transmitting device over his chest when he was shocked a second time. We immediately contacted the Doctor and we were instructed to take him directly to the emergency room. Joe was visibly shaken and concerned about enduring repeated shocks. Upon arrival at the emergency room, we were met by a Medtronic Representative. After some testing he told me that Joe's lead had short circuited. Like me, my son had to undergo an explant surgery to remove the device and fractured lead. Joseph was placed in ICU since his device had to be turned off and the surgery was scheduled for the next day. Joe underwent surgery that removed the entire lead from his heart to upper chest. The new lead would be a Medtronic lead that was not involved in the recall. A new defibrillator was also implanted at this time. Joe was released to go home the following day. He would again endure a 6-week recovery period. Unfortunately, about a week after the surgery the defibrillator sensing was too high and it actually paced Joe's heart into stopping and then administered a shock to restart his heart. Joe did lose consciousness during this event. The doctor modified some settings in the device and we have not had any issues since.

Once Joe's lead shorted I became very concerned about my replacement lead. The "extremely rare" event had happened twice in one home and I now still had a recalled lead in my chest. I was very concerned my wires would fail again. At this time my Doctor prescribed the antidepressant Zoloft to help me deal with my anxiety. I am still taking the medication today. I also requested a magnet to disable the device if it began administering shocks needlessly. I honestly live in more fear of the leads failing than I do of my heart actually having a problem. I exercise regularly and play some sports but I am constantly concerned the device might fail during exertion, as it did before. As you would also understand, after this event I had many questions from friends and bystanders about what had happened at the gym. People to this day still look at you different and treat you different than before the lead failure.

When Joe's lead shorted, he was trying really hard to get his life back to normal. He put everything he had into playing the game of golf since that was the only sport all the doctors would allow him to participate in. We paid for many golf lessons and supported him in every way we could to try to keep his spirits up. He was looking forward to playing school golf and had worked hard enough to make the High School Team. Joe was excited for once in a long time. Consequently, Joe was very upset when he had to undergo the replacement surgery just 20 months after the first time. He also was angry he was going to miss the first District Tournament that was to

take place on April 2, 2008, the next day. Joe would have to make up all missed school work and endure 6 weeks of rehabilitation. School would be over once his rehabilitation was complete and once again he would be let down, not being able to participate in High School sports. That would mean 6 more weeks of not playing golf and putting him further behind once again on his golf skills. This resulted in additional lessons and most important trying to keep Joe's spirits high and positive. Unfortunately, what may seem to be minor to those that do not have to deal with these issues is pretty huge to a 16-year-old who had dreams, made new ones and had to start over again and again. Joe is not taking any medication at this time for anxiety but we have had multiple episodes where Joe has thought he received a shock while he was sleeping. We have contacted the doctor more than once to check the situation and in all cases it was only in his mind. He still has reoccurring dreams of being shocked.

As for the financial impact, the total cost of just the two replacement surgeries was in excess of \$135,000 with me having to personally cover \$6,000 of the expense in deductibles and co-pays. It is inconceivable that I would be held responsible to pay for both of these lead failures. With the use of credit cards and personal savings I have made the entire payment but endured threatening Collection Notices on my son's second surgery. The insurance implications are also important as the total cost of each surgery is counted towards our lifetime caps. Given the fact that I am 43 and my son is now 17, it is critical to manage our medical insurance so we do not find ourselves without coverage due to cap limits.

I urge you to pass the Medical Device Safety Act. As described above, my family has endured significant suffering related to the lead failures and I have no recourse in the situation. **It is important that companies are held responsible for their decisions and do not continue to profit from devices that they know are faulty but are very profitable and carry no liability once FDA approved.** With any other product in the United States, the manufacturer is responsible for it's safety and held accountable for it. I find it unconscionable that a device can be developed, marketed and sold that's purpose is to save a human life and the manufacturer has no liability or motivation to insure it's quality because of FDA approval. Many experts have argued that the FDA does not have the resources to make this evaluation. My replacement lead was billed at \$17,000 and my son's replacement lead was \$20,000. This cost is simply for the wire that runs from the defibrillator to the heart, not for any of the surgery. Medtronic was aware there were failure issues with the Sprint Fidelis leads at the time of my replacement surgery but continued to sell and implant the leads without conscious. However, Medtronic's fiscal year profits in the year ended April 25, 2008, the same timeframe of both replacement surgeries, were \$2.23 billion. Without any accountability, there will be no motivation to produce high quality medical devices or to remove the faulty products from distribution.

Sincerely,

MICHAEL COLLINS,  
Georgetown, TX 78628.

JULY 30, 2009.

Hon. EDWARD M. KENNEDY, *Chairman,*  
*Committee on Health, Education, Labor, and Pensions,*  
*Dirksen Senate Office Building,*  
*U.S. Senate,*  
*Washington, DC 20510.*

DEAR CHAIRMAN KENNEDY, RANKING MEMBER ENZI, AND MEMBERS OF THE COMMITTEE: I would like to thank you for your support of the Medical Device Safety Act. The passage of this act will make a positive impact on our family. My wife, both my children, Avery and Oliver, and 17 members of my wife's family, have a genetic heart condition called Long Q-T Syndrome. One of the symptoms of Long Q-T Syndrome is cardiac arrest without warning. Following our doctor's medical advice Avery, our daughter was implanted with a Medtronic Defibrillator with a Sprint Fidelis shocking coil.

Less than a year after the defibrillator was implanted, Avery was playing in our basement when she started screaming, convinced that there were monsters getting her. My wife picked her up and could feel the shocks through her body. When the paramedics came, they assured us that her heart beat was in a normal sinus rhythm at a mere 110 beats per minute, which is well below her shocking threshold. When we got to the hospital she was shocked simply sitting there in triage. By the time the Medtronic Representative got there to turn off the device, Avery had been

shocked nine times without warrant. For months afterwards Avery was scared of sudden sounds like a garbage truck backing up or a cell phone chime and insisted on wearing a hood or hat everywhere to muffle the potential for sound. It was a long time before we even saw her smile again. We were very lucky that the 911 response was quick and we were able to have the device deactivated relatively quickly or the outcome could have been far more severe.

Once we discovered the malfunction, our doctor thought that it was best to replace the device with a more efficient model, thankfully not implanting another Sprint Fidelis lead. About a month later Medtronic issued a recall on devices using the Sprint Fidelis leads. We expected that we would be reimbursed for our replacement expenses but Medtronic said that we violated warranty by following our doctors orders and using a different device.

When it became clear that Medtronic would not work with us individually, we filed a lawsuit to hold Medtronic accountable. Relying on the preemption doctrine in the *Reigel* case, Medtronic denies any legal responsibility and the District Court has dismissed many cases. My son Oliver just turned 2 years old and will need a device implanted soon. I am extremely concerned about the surgery without knowing whether we will have any legal recourse if the device proves defective. To some, that may seem an unlikely scenario. However, I know from personal experience that recalls are common. Multiple devices implanted in our family and relatives have been recalled.

Thank you again for your support. I hope we can help make the world a little safer place for people who need the assistance of medical devices.

Sincerely,

ALEX AND MOLLY DE GROH,  
McHenry, IL 60050.

JULY 30, 2009.

Hon. EDWARD M. KENNEDY, *Chairman,*  
*Committee on Health, Education, Labor, and Pensions,*  
*Dirksen Senate Office Building,*  
*U.S. Senate,*  
*Washington, DC 20510.*

DEAR CHAIRMAN KENNEDY, RANKING MEMBER ENZI, AND MEMBERS OF THE COMMITTEE: My name is Crystal Wahl. I am 56-years old and a resident of Davenport, IA. It was on a Friday evening, about 5:30 p.m., and I had just taken a shower. I was sitting on the edge of my bed, putting on lotion when I got really dizzy and began feeling nauseated. Just then, my phone rang. I answered it, and then I heard this clicking sound. I have a CareLink Monitor in the bedroom, which monitors the Medtronic device implanted in me. The monitor was trying to transmit, so I told my daughter I had to hang-up. When I hung up, I heard the alarm going off on my pacemaker, so I knew something wasn't right. I left the bedroom and sat down at the table, and right after I sat down, I was shocked. We called 911 right away. I am 100 percent dependent on the pacemaker, and was really scared at this point, since it was shocking me. I was afraid it was trying to quit.

While I was talking to the lady on the 911 call, I was shocked a second time. Then after the paramedics got to my home, they had me hooked up to another monitor. They asked if I could take a couple of steps over to their gurney. As soon as I sat down on the gurney, I was shocked a third time. This whole time I was definitely very afraid that my pacemaker was going to quit and that I was going to die.

They got me to the hospital and a Medtronic Representative was called into the hospital room. When he came in, the first thing he said was, "Don't move. Don't move your left arm. I think you've got a fractured wire." After checking his computer he confirmed that I had a fractured wire. At that point, he turned the shocking mechanism off.

I asked the Medtronic Representative when they would have found out about the wire being fractured, since it was transmitted. He replied, "Well, since it was a Friday evening and the doctor's office was closed, they wouldn't even have known until Monday."

The following morning, I went into surgery and they replaced the wire. It was a very frightening experience, one I never want to have to go through again.

Sincerely,

CRYSTAL WAHL,  
Davenport, IA 52804.

AUGUST 4, 2009.

Hon. EDWARD M. KENNEDY, *Chairman,*  
*Senate Committee on Health, Education, Labor, and Pensions,*  
*Dirken Senate Office Building,*  
*U.S. Senate,*  
*Washington, DC 20510.*

DEAR CHAIRMAN KENNEDY, RANKING MEMBER ENZI, AND MEMBERS OF THE COMMITTEE: Writing this letter is not easy, even after 3 years. Our son's name was Robert Wallace Baird. He died on September 14, 2006 at the age of 16. Robert died with a Medtronic Sigma series pacemaker implanted in his body, a device we would come to find out was subsequently recalled by the FDA for what appears to be the exact problem that was found with the device at the time of Robert's death.

On July 29, 1994, at 4½ years of age, Robert was diagnosed with second degree heart block. On September 6, 1996, at 5 years of age, Robert received his first pacemaker, a Thera VDD-i. We were told that our son would live a full life and were advised not to worry about the pacemaker.

On October 26, 2002, Robert's pacemaker failed due to a lead fracture. Robert received his second pacemaker, a Sigma SDR303 on November 5, 2002. At that time Robert was diagnosed with complete heart block. We were told that the key to Robert living a long, productive life was dependent upon a pacemaker.

In November, 2005 a small subset of Robert's pacemaker, the Sigma series, was recalled due to "separation of redundant interconnect wires." The recall stated, "This subset of Sigma series pacemakers that may fail due to separation of interconnect wires from the hybrid circuit may present clinically as loss of rate response, premature battery depletion, intermittent or total loss of telemetry, or no output." In addition, the recall noted that "Hybrid circuits used in this subset of devices were cleaned during manufacture with a particular cleaning solvent that could potentially reduce the strength of the interconnect wire bond over time." Unfortunately, we were not made aware of this recall.

On September 3, 2006, while on vacation, my son took an afternoon nap. While I told myself that Robert never takes afternoon naps, I thought nothing of it. He was a teenager and he had an active day. Robert was not one to complain because he was busy living his life as all teenage boys do.

On the morning of September 14, 2006, Robert's sister and brother, Mary and Jeremy, awoke to noises coming from Robert's room at 5:30 a.m. Mary walked into his room and then rushed to wake Janis and myself. The paramedics spent several hours trying to revive Robert and transported him to the hospital where he was pronounced dead.

On October 3, 2007, we received a letter from Medtronic regarding Robert's pacemaker. It had this to say: "The generator was opened for further testing. Analysis found the wire(s) connecting the battery to the hybrid had lifted at the bond pads."

On June 11, 2009, the FDA issued a Class I recall on the remaining Sigma series pacemakers "due to a separation of wires that connect the electronic circuit to other pacemaker components, such as the battery." This is the same flaw that caused our son's death!

The loss of a child is the greatest loss that a father and mother can suffer. We are born into this world and are told that this is the order of life. We marry and have children. We teach our children about life and try to protect them. They graduate to many important steps in their lives, teenager, young adult, college, love, marriage, and children of their own, each step verifying our success as parents, bringing us great joy and purpose in our lives. Our children are supposed to bury us. They are supposed to grieve their loss of us, not us of them. Instead we are left with memories, questions and a heavy emptiness that we must carry with us as we learn to live this new life, to find peace in our hearts so that we may live again, so that we can bring meaning to Robert's life.

Where do we go from here? How do we find the answers to our questions? How do I seek justice for my son? Unfortunately, as a result of preemption, and the *Riegel* decision, we are denied the opportunity to discover the answers to these questions. That is why the passage of the Medical Safety Device Act is so important to our family.

Manufacturers of medical devices say that our courts cannot handle cases involving medical devices because they are too complex. If that is true, then why are our courts capable of handling complex murder cases with complex forensic evidence or DNA evidence? Why are the courts capable of handling tire defect cases, pharmaceutical cases or any other non-medical device cases that harm people? Specifically, as to my son's case, what is so complex about the use of a cleaning solvent that may have weakened the bond that held my son's device to the battery? What is so

special about medical devices that their manufacturers are granted immunity from being responsible to those that they injure or kill?

My son, Robert, knew of one truth in life at a young age, a truth that many of us fail to see early in our lives or for that matter much later in our lives. In the tenth grade Robert had to write an essay titled "Who Am I". He started with: "Who am I? This is a question I can now answer." He then wrote down everything that he loved in life, coming to one simple conclusion. "I have many goals in life. But they all add up to one big simple one: live happily."

This father had taught his son many important lessons in this lifetime, justice being one of them. Should Robert have justice in this lifetime for the life he cannot live? Saying that justice is giving each person what he or she deserves does not take us very far in this world. How do we determine what people deserve? What criteria and what principles should we use to determine what is due to this or that person? That is not for me to answer, it never has been as I am only one man. I leave that answer in the hands of others and in the faith of our courts. I only ask for my day in court. That is all I can ask for. That is all I can hope for. Is that too much to ask in this life time?

The wrongs that can be committed amongst individuals and groups are virtually unlimited. It is the principles of justice, the judges and a jury of our peers that apply these principles to determine what is right and what is wrong. We only ask that all of us have the opportunity for those principles of justice to work in a system that those that came before had the wisdom to give us.

My son died quietly in his room. Robert did not die in a collapsed bridge, but his life is no less important. "Equal Justice Under Law" is the inscription on the west pediment of the Supreme Court building. Those words were coined from Chief Justice Melville Fuller when he said "no State can deprive particular persons or classes of persons of equal and impartial justice under the law." It is not the State of Minnesota that is depriving us of justice; it is the concept of complete corporate immunity and the *Riegel* decision.

Thank you for your time and efforts. We can only hope that you will restore the law back to what it was before February 2008, or the *Riegel* decision, and once again hold medical device manufacturers responsible for the safety of the products that they produce.

Sincerely,

MARK AND JANIS BAIRD,  
Oakdale, MN 55128.

AUGUST 4, 2009.

Hon. EDWARD M. KENNEDY, *Chairman,*  
*Committee on Health, Education, Labor, and Pensions,*  
*Dirksen Senate Office Building,*  
*U.S. Senate,*  
*Washington, DC 20510.*

DEAR CHAIRMAN KENNEDY, RANKING MEMBER ENZI, AND MEMBERS OF THE COMMITTEE: In May 2009, President Obama called for a reversal of the Bush administration policy that prevented consumers from holding companies accountable when their products cause harm. Under the Bush policy of complete immunity preemption, companies could claim that if a Federal agency, like the Food and Drug Administration, approved a product, the company could not be sued in State court by injured consumers. As the mother of a victim of a faulty medical device, I was relieved to hear Obama's remarks, but there is still much work that needs to be done to protect Americans.

My daughter, Katherine "Katie" Meyer was engaged to be married and just 3 days from her 31st birthday when she died from complications from a surgery to remove a defective medical device. She needed the device, a heart defibrillator manufactured by Medtronic, because of a cardiac condition she developed while undergoing treatment for bone cancer. Katie beat cancer, but in the end, it was the device she had implanted to save her life that would ultimately end it.

Katie's lead to her defibrillator fractured, causing three painful jolts to shock her body, a sensation similar to being electrocuted, three different times. The lead had been recalled after Medtronic reported over 120 incidents of fractures and malfunctions to the Food and Drug Administration (FDA). Medtronic reported these incidents at least 7 months *after* the company had known about problems with the device, but continued to sell and profit from the leads anyway rather than report the truth to the FDA.

In Katie's case, the surgery to remove the faulty lead had complications that led to emergency open heart surgery. Further complications during the surgery resulted in Katie spending most of the next 8 months in a hospital bed, until she passed away in December 2008. Her medical expenses were nearly \$1.5 million, all paid by Medicare, or in other words, by the average taxpayer, and all associated with complications experienced to remove a defective medical device, a device the FDA had recalled. Under the current state of preemption, as Medtronic has told our Courts in Minnesota, it has no intention of, nor does it have the responsibility to, reimburse Medicare for any of these medical expenses related to its defective, recalled products.

Unfortunately, that's not all there is to the story. In February 2008, in line with the Bush administration's "preemption" policy, the Supreme Court ruled in *Reigel v. Medtronic* that, because the FDA had approved a medical device through the pre-market approval process, families like ours do not have any recourse to hold manufacturers like Medtronic accountable when their products cause injury or death.

Strangely enough, had Katie been harmed by a prescription drug, the story would be quite different. Just 1 year later, the Supreme Court ruled in *Wyeth v. Levine* that patients harmed by prescription drugs can hold manufacturers accountable in State courts, creating a major double standard between prescription drugs and medical devices. In *Wyeth*, the Court ruled FDA approval of prescription drug labels does not provide the manufacturer with complete immunity preemption. So right now in America, it is acceptable for medical device companies to hurt you, but not acceptable for prescription drug companies. This makes no sense. Manufacturers need to be held accountable for the safety of their products, whether it is a drug or a device.

Had Medtronic pulled their faulty product sooner when they first knew of the devices' problems, maybe Katie would not have had the deadly defibrillator lead. And while nothing will bring Katie back, we can do something.

Thankfully, the Medical Device Safety Act has been introduced in Congress. This legislation would extend the protections of the civil justice system recognized by the Court in *Wyeth v. Levine* to medical device patients, too.

I traveled to Washington, DC earlier this year seeking support for the Medical Device Safety Act. I am here again for these hearings because I am convinced that holding manufacturers accountable for the quality of their products is the only way to ensure the safety of Americans, like my daughter. Thank you for doing the right thing by restoring the rights of injured consumers to hold negligent medical device manufacturers accountable when their products cause injury or death.

Sincerely,

MICHELE MEYER,  
Cambridge, MN 55008.

AUGUST 4, 2009.

Hon. EDWARD M. KENNEDY, *Chairman,*  
*Committee on Health, Education, Labor, and Pensions,*  
*Dirksen Senate Office Building,*  
*U.S. Senate,*  
*Washington, DC 20510.*

DEAR CHAIRMAN KENNEDY, RANKING MEMBER ENZI, AND MEMBERS OF THE COMMITTEE: I have been blessed with very good health. I do not typically even get colds or flus. But just as heredity factors are often favorable, they can also be unfavorable. Blocked arteries are common with the men in my Dad's family. Although I was an active man, in April 2001, I suffered a heart attack due to a blockage in the main artery to the left side of my heart. Angioplasty was performed and a stent was placed, but there was damage to the mitral valve. I continued to work and maintain an active life, but in 2005, the cardiologist I was assigned to at the time determined that I should have a combination pacemaker/defibrillator implanted.

I did not have any difficulties with the surgery and continued an active life. I began to hear about the recall of the Sprint Fidelis lead and my records indicated that this was part of my implant. Eventually, I was notified that I should schedule an appointment to have the implant checked. Following the assessment, I was told there appeared to be no concern. Due to my own concerns, however, I asked that the lead be replaced. I was told that would not be done because Medtronic said that there was only a remote chance that I would ever have any problems with the lead. I was scheduled for an assessment every 3 months and was given the same response each time I raised my concerns.

I spent the summer of 2008, in an old, small mobile home in the mountains near Palm Springs, CA. I've always enjoyed walking and walked the mountain roads in and around the village of Idyllwild. I walked 2 to 6 miles everyday. I returned to my home in the desert on October 1, 2008. I had an appointment to have the unit checked on October 7 and planned to leave for a trip to Iowa on October 8. At 3:30 a.m. on October 6, 2008, I awoke from a shock that I thought was a bolt of lightning. I went straight up out of bed and received another shock. Needless to say, I knew the cause. I walked down the hall to the living room to call 911 and was shocked again. The shock knocked the phone from my hand. After completing the call, I called my neighbor and left a message requesting that she take care of my dogs for the day as I would probably be in the hospital. She arrived before the medics and witnessed more shocks. When the medics arrived, the device continued to shock me, and I was taken to the hospital. By that time, I had received 19 shocks of 800 volts each, but they ceased and the technician from Medtronics arrived 3 hours later and turned off that part of the device.

I spent 3 days in the hospital and a new unit and leads were implanted. After returning home, I began to "panic" any time I heard a sound. I was prescribed anti-anxiety medication and later anti-depression medication. Four weeks later, I experienced a severe anxiety attack and was returned to the emergency room. As time passed, I felt that I was making good progress and requested that the physician allow me to start lessening the medication. In July 2009, I traveled to Iowa for several reunions and began to experience anxiety difficulties. After a visit with the physician upon my return home, he restored my medications to the original amounts and indicated that I should possibly expect to be on them for several years.

Due to my own curiosity, I went through the medical expenses related to this experience from October 6 to March 9. The cost to Medicare and supplemental insurance was approximately \$168,048.70—all incurred as a result of Medtronic's faulty, recalled device. I understand that approximately 187,000 recalled Sprint Fidelis leads were implanted in the United States. I also understand that the failure rate may be as high as 8 percent. If everyone's expenses were comparable to mine, could you imagine what this costs Medicare, Medicaid, and private health insurers, all of which will be passed on to taxpayers and other businesses, to pay for Medtronic's faulty products? And this is just for Medtronic's Sprint Fidelis recall. Now can you imagine the additional costs associated with all of Medtronic's other recalled, defective products or all of the other medical device manufacturers who have put defective, now recalled products into the market? This type of "corporate welfare" is particularly shocking as we, as a nation, are currently debating the cost of health care.

I'm hopeful that the passage of this legislation would make it less likely that anyone else will ever have to go through this experience. I'm generally considered a very calm, composed, organized person. I don't feel that way much of the time since this episode.

I hope this is helpful in providing you with some understanding of what has happened to many people and will happen to many more if manufacturers of medical devices are not held accountable for the products that they manufacture.

Thank you.

Sincerely,

KEITH SEIFERT,  
Palm Springs, CA 92262.

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Hon. EDWARD M. KENNEDY, *Chairman,*  
*Committee on Health, Education, Labor, and Pensions,*  
*Dirksen Senate Office Building,*  
*U.S. Senate,*  
*Washington, DC 20510.*

DEAR CHAIRMAN KENNEDY, RANKING MEMBER ENZI, AND MEMBERS OF THE COMMITTEE: Your work on the Medical Device Safety Act (S. 540/H.R. 1346), is appreciated. At age 72, I was diagnosed as having cardiomyopathy, which is weakness of the muscles on one side of the heart, and an ICD (implantable cardiac defibrillator) was implanted in my chest in March 2005. It made a big difference in the way I felt. I had more energy, did not have the shortness of breath I had experienced before and was less tired.

In April 2008, I received two shocks from the device. While they were not as severe as I had expected a shock to be, it was a frightening experience, especially since they happened in the night and I live alone. The doctors checked the device by way of the phone and said I should go to the hospital right away, as the right lead had fractured. When the surgeon removed the broken lead, the vein closed and

the new lead could not be inserted. Two surgeons attempted to insert the new lead but could not accomplish it. The ICD was removed and another one implanted on the right side of my chest, running the new lead across to the heart and bringing the left lead across to the ICD. (The original left lead was apparently long enough to do that.) This resulted in a 5-hour surgery instead of the anticipated 2-hour surgery.

Except for the usual precautions following such a procedure, i.e., not lifting the arm on the side where the ICD is above your shoulder for 2-3 weeks, always holding a cell phone on the side opposite of the ICD, and never going through the electronic detection devices at airports, or other security buildings, everything seemed to be fine for a few weeks. At that time, the left lead apparently slipped, and I was suddenly receiving "STEM" (don't know the medical term) which was a constant light shock in my diaphragm. This was extremely uncomfortable, making sleep impossible. The only way they could eliminate this was to turn the device down so low I was actually not receiving any daily therapy. After 2 months, an ultrasound showed my heart function was worsening. It was then decided to go with another company's device, which was implanted at the end of August. However, when the slipped lead was removed, the new one would not go in properly and the next day, an epicardial was performed. This procedure was an incision under my left breast, attaching the lead to the outside of the heart and running it across to the device. Apparently they had to spread my ribs to do this, and for about 2 weeks following, each time I bent down, turned from the waist, got up out of a chair or sat up to get out of bed, I had a very sharp pain in my side, similar to extreme pleurisy. Thankfully, since then I have had no complications.

I am not saying Medtronic is a bad company, but I strongly believe any company or any person who produces a product should be held liable if it fails. The leads of an ICD actually enter the heart, and we should be able to depend on it working properly.

Again, I greatly appreciate your working on this bill and taking the time to listen to those of us who have had frightening experiences because of the malfunction of a Medtronic ICD.

ANNA L. NAVIN,  
Polk City, IA 50226.

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Hon. EDWARD M. KENNEDY, *Chairman,*  
*Committee on Health, Education, Labor, and Pensions,*  
*Dirksen Senate Office Building,*  
*U.S. Senate,*  
*Washington, DC 20510.*

Hon. HENRY WAXMAN, *Chairman,*  
*House of Representatives,*  
*Energy and Commerce Committee,*  
*2125 Rayburn House Office Building,*  
*Washington, DC 20515.*

Re: Medical Device Safety Act of 2009

DEAR CHAIRMAN KENNEDY, RANKING MEMBER ENZI, AND MEMBERS OF THE COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS; AND CHAIRMAN WAXMAN, RANKING MEMBER BARTON, AND MEMBERS OF THE ENERGY AND COMMERCE COMMITTEE: **The undersigned organizations committed to women's health and safety, ask you to prioritize passage of S. 540 and H.R. 1346, the *Medical Device Safety Act of 2009*.** This important legislation corrects the U.S. Supreme Court's recent decision in *Riegel v. Medtronic*, 128 S. Ct. 999 (2008), by reflecting congressional intent to allow patients harmed by negligent medical device manufacturers to access the court system in order to obtain compensation and hold companies accountable. Immunity should not be given to device manufacturers that fail to adequately warn about or prevent device risks; especially when the manufacturer knows, or should know, that the device could cause serious injuries or death.

For 30 years, the Federal medical device law and State tort law have coexisted without problem, and with the support of many FDA officials. In fact, in the important case *Wyeth v. Levine*, decided on March 4, 2009, the U.S. Supreme Court acknowledged the "longstanding coexistence of State and Federal law and FDA's traditional recognition of State-law remedies." It also noted that "the FDA long maintained that State law offers an additional, and important, layer of consumer protection that complements FDA regulation." The Court recognized that lawsuits are especially important since "the FDA has limited resources to monitor the 11,000 drugs

on the market and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge.”

The same reasoning should apply to the risky medical devices considered in *Riegel*. Unfortunately, due to the Supreme Court’s confusion regarding whether Congress intended to preempt claims for medical devices, in *Riegel*, manufacturers of Class III FDA-approved medical devices were given complete immunity from liability for product-related deaths and injuries. *This immunity protection even extends to manufacturers who fail to warn the FDA and consumers about device problems that arise after obtaining FDA approval.* By eradicating manufacturer accountability, thousands of patients injured by defective devices now have no remedy for their injuries.

As advocates for women’s rights and women’s health, we have a heightened interest in restoring congressional intent to allow for State tort suits by injured women and their families, and believe that all persons unfairly harmed by faulty medical devices should have their day in court. Medical devices marketed primarily to women, many of which relate to women’s reproductive health, have a record of safety problems. The FDA’s handling of these devices, as well as manufacturers’ development and marketing of the product, can be prone to inappropriate corporate pressure and interference.

As with other drugs and devices, those devices marketed to women have caused significant harm, even after FDA approval. A recent report by the Center for Justice & Democracy (CJ&D) chronicles the harm that FDA-approved drugs and devices have caused women. The CJ&D report, entitled *The Bitterest Pill: How Drug Companies Fail to Protect Women and How Lawsuits Save Their Lives* (issued October 2008), details the harm caused by drugs and devices marketed only to women, such as the Ortho-Evra birth control patch, the Dalkon Shield IUDs and high-absorbency tampons. The damage has been severe in many instances (including heart attacks, blood clots, and death). Moreover, this report shows that it is often damages awarded by juries rendering verdicts in favor of patients harmed by these devices that have led to manufacturers withdrawing unsafe products, or altering the marketing of these devices.

The *Medical Device Safety Act* will restore women’s ability to be compensated, and hold device manufacturers accountable. This serves three crucial functions: it allows women to mitigate their injuries; it helps to deter misleading and careless marketing of devices to women; and it provides an extremely important incentive (in addition to the FDA’s regulatory authority) to manufacturers to strive to monitor and improve the safety of their products. The *Medical Device Safety Act* also takes the vital step of making its clarification of congressional intent retroactive to the date when Congress enacted the *Medical Devices Amendment of 1976* (the statute the Supreme Court wrongly interpreted to accord immunity to manufacturers) to protect consumers whose claims will otherwise be barred by *Riegel*.

In the three decades leading up to the 2008 *Riegel* decision, women were able to count both on FDA regulation and State tort law to ensure the safety of devices. As supporters of women, we urge you to quickly enact the *Medical Device Safety Act of 2009*.

We look forward to working with you and your staff to pass this very important legislation.

Sincerely,

*Alliance for Justice; American Medical Women’s Association (AMWA); Center for Justice & Democracy; Center for Medical Consumers; Center for Science in the Public Interest; Clearinghouse on Women’s Issues; Dalkon Shield Information Network; DES Action USA; Government Accountability Project (GAP); InjuryBoard.com; National Asian Pacific American Women’s Forum; National Capital Area Union Retirees National Congress of Black Women; National Consumers League; National Council of Women’s Organizations; National Organization for Women (NOW); National Women’s Health Network (NWHN); Northwest Women’s Law Center; Ovarian Cancer National Alliance; OWL—The Voice of Midlife and Older Women; US PIRG; Women’s International Public Health Network; Women’s Research and Education Network.*

## ATTACHMENT

## THE BITTEREST PILL—HOW DRUG COMPANIES FAIL TO PROTECT WOMEN AND HOW LAWSUITS SAVE THEIR LIVES

(By Amanda Melpolder, Amy Widman and Joanne Doroshov)

## EXECUTIVE SUMMARY

Women across the country have suffered tremendously as a result of defective and dangerous drugs and medical devices. History shows that many FDA-approved drugs and devices that have caused some of the most serious injuries and death have been marketed specifically for women. This is largely due to the number of products routinely prescribed to otherwise healthy women to control some aspect of their reproductive system. In addition, some drugs have had a disproportionate impact on pregnant women and their children.

Many drugs and devices were made safer only after women and their families filed lawsuits against those responsible. Sometimes, companies that have been hit with large verdicts or settlements act immediately to change their unsafe product or practice. Lawsuits also have had a tremendously beneficial role spurring medical research and alerting the public—and ultimately pressuring regulators—to act on larger health risks and problems. As a result, the lives of countless other women have been saved.

In addition, unlike the regulatory scheme, which provides no direct benefit to victims, civil cases hold companies directly accountable to those whom they have hurt, and provide their victims with compensation to help rebuild their lives. Drug company immunity would remove the most significant and effective financial consequence to a company for choosing to keep a dangerous drug or device on the market.

The following are some examples that illustrate these points:

## HAZARDOUS BIRTH CONTROL

- *Ortho-Evra Patch*. This weekly birth control patch, approved by the FDA in 2002 and marketed to young women with sexy television commercials and fashion runway shows, caused blood clots, heart attacks and strokes. Both the company and FDA knew of major problems with the patch but kept the information quiet until documents, including those produced in litigation, forced the information out.

- *Dalkon Shield IUD*. This IUD caused at least 17 American deaths and over 200,000 injuries including pelvic inflammatory disease, perforated uteruses, and infertility. The FDA suspended distribution of the IUD after 3 years but did not recall existing stock or require the company to tell doctors to remove them. For the next 10 years, the company continued to promote the device. It took several lawsuits and the threat of larger punitive damages awards for the company finally to urge women to have the Dalkon Shield removed and offered to finance the removal.

- *Copper-7 IUD*. Like the Dalkon Shield, this IUD led to deaths and injuries. It was pulled from the market after numerous lawsuits, coupled with the company's inability to obtain products liability insurance. Actual injuries and deaths of women, which came years before the devices were withdrawn, never had that effect.

- *Ortho-Novum 1/80 Birth Control Pill*. This pill contained extremely high and dangerous levels of estrogen leading to blood clots and blood disorders. One woman suffered life-threatening injuries after taking this pill. As a result of this case, the manufacturer lowered estrogen levels in the pill.

## LETHAL HORMONES

- *DES was a synthetic estrogen approved by the FDA to prevent miscarriages*. DES did not work but instead caused cancer, infertility and other serious physical problems for the women who took it, and the children they carried. For almost two decades after the drug was proven ineffective, manufacturers continued to push the drug and expose hundreds of thousands of women and their off-spring to risk. Until women started bringing lawsuits, many DES-exposed women did not know about the risks they faced.

- *Estrogen replacement therapy (ERT) or hormone replacement therapy (HRT)*. Hormones were approved by the FDA and heavily promoted by the pharmaceutical industry beginning in the 1960s to women experiencing menopause. Yet evidence had existed since the 1930s and 1940s that estrogen therapy caused cancer. After years of struggle by consumer groups and women's health organizations to bring attention to the cancer and other risks, in 2002 NIH researchers finally confirmed a significant increase in the risk of breast cancer, heart attacks, blood clots and

strokes. By then, an untold number of women had been harmed or killed from being over-prescribed HRT.

OTHER HARMFUL DRUGS AND DEVICES

- *High-absorbency tampons.* These tampons cause “toxic shock syndrome” resulting in many deaths. A woman died from toxic shock syndrome after using super-absorbent tampons, and her family sued. The company stopped making these tampons only after the jury’s punitive damage award.
- *Parlodel.* The FDA approved this drug in 1980 to suppress lactation after birth. It caused heart attacks and strokes. The FDA requested the drug’s five manufacturers to voluntarily take it off the market. One company refused and for the next 5 years, continued to promote the drug and persuaded hospitals to prescribe it. Only after a large jury award and petitions by consumer groups to force the FDA to act, did the company withdraw the drug from the market.
- *Accutane.* Accutane is an acne drug to which the FDA gave fast track approval despite knowing it caused severe birth defects as serious as Thalidomide if taken by pregnant women. As a result of the company’s continuously failed policies to prevent women who were or could become pregnant to take the drug, hundreds of severely deformed babies have been born. Juries have now started to hold the company accountable in these cases.

LETTERS OF OPPOSITION

Re: Medical Device Safety Act of 2009

TO WHOM IT MAY CONCERN IN THE U.S. SENATE AND THE HOUSE OF REPRESENTATIVES: I am writing to voice my opposition to the proposed “Medical Device Safety Act of 2009.”

The proposed H.R. 1346 and S. 540, “Medical Device Safety Act of 2009” will have little to no impact on patient safety. Instead, it substitutes a strong, consistent, expert-based FDA regulatory system with a lawsuit-driven, 50 different State-court-based compliance scheme based on litigation and the resulting cost of multi-jurisdictional compliance. In other words, chaos would replace the current system at the expense of physicians and patients in favor of trial lawyers’ who profit from litigation at the expense of patient access to health care and new technology.

It is my belief that eliminating preemption protection for medical devices will impact:

1. Patient access and public health;
2. Medical technology innovation rates;
3. Industry employment; and
4. Government expenses as a healthcare payer, regulator and judicial funder.

Good patient care is of utmost importance to me and I believe that this legislation will not improve the quality of treatment for those seeking medical care.

Sincerely,

*Samuel W. Wiesel, M.D.; John Klimkiewicz, M.D.; Paul Cooper, M.D.;  
Brett Wiesel, M.D.; Brian G. Evans, M.D.; John Delahay, M.D.;  
Scott Edwards, M.D.; Mark Zawalsky, M.D.; Benjamin Osborne, M.D.*

MARCH 31, 2009.

Hon. HARRY REID,  
U.S. Senate,  
Washington, DC 20510.

Hon. MITCH MCCONNELL,  
U.S. Senate,  
Washington, DC 20510.

Hon. NANCY PELOSI,  
U.S. House of Representatives,  
Washington, DC 20515.

Hon. JOHN BOEHNER,  
U.S. House of Representatives,  
Washington, DC 20515.

DEAR MAJORITY LEADER REID AND SPEAKER PELOSI, MINORITY LEADER MCCONNELL AND MINORITY LEADER BOEHNER: As a group, we represent thousands of indi-

viduals and companies that develop medical technology as well as the venture capitalists who help to provide the essential financing for innovations that save lives and provide greater value in health care. We are writing to express our concerns about the policy implications of the Medical Device Safety Act (S. 540 & H.R. 1346).

***We believe this legislation does not advance patient safety, will limit patient access to lifesaving medical technologies, increase health care costs by delaying innovation, and dilute the regulatory effectiveness of the FDA.***

The Medical Device Amendments of 1976—the law that helped to create the modern medical device industry has balanced the interests of patient safety and patient access to medical technology extremely well for more than three decades. Only a subset of all medical devices reviewed by the FDA each year is subject to preemption. These products are developed to treat the most complex and most debilitating conditions and have been subjected to an assessment of safety and effectiveness by FDA and specific regulatory requirements including post-marketing surveillance. In addition, the preemption protection is not blanket immunity—there are circumstances under which patients can and have been suing manufacturers.

The impact of removing preemption on the integrity of this process and our industry will be significant.

#### NEED FOR A STRONGER, CENTRAL FEDERAL AUTHORITY

As former FDA Chief Counsel and Carter-appointee Richard Cooper recently testified before Congress:

“Totally unpreempted regulation through product-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 drugs and devices.”—(Statement before the Senate Committee on the Judiciary, June 11, 2008)

The creation of a lawsuit-driven, State court-based compliance scheme imposes two potentially significant costs on our industry: multi-jurisdictional compliance, as well as the additional costs of mass tort litigation.

This flawed legislation contemplates a regulatory scheme that would undermine the safety and effectiveness determinations of the FDA with respect to complex medical devices—for reasons that may or may not be medically and scientifically sound. The manufacturer of a product with the potential to save millions of lives, but with known and properly disclosed risks, will no longer be able to create tomorrow’s next wave of medical technology on the fair playing field of a national standard set and enforced by the FDA.

It is much more effective to continue to make the FDA more independent, stronger and accountable than it is to allow States to create a patchwork of regulations that preempt innovation and fail to protect the safety and rights of all Americans.

#### IMPACT ON PATIENTS

Beyond the harm to innovation, Congress should also consider the harm done to the health and rights of patients who will no longer be assured a national standard for safety under the FDA. Eliminating preemption will create a patchwork system of State laws and regulations that may help some citizens and leave others without options depending on where they live.

For nearly 30 years, the current system for regulating medical technology has worked extremely well in three areas: it has fostered the development of an industry in which the United States has unparalleled leadership; it has fostered innovations that have safely enhanced and prolonged patients’ lives; and it has provided avenues for recovery in the tort system for injured patients.

#### IMPACT ON SMALL BUSINESSES

A significant percentage of these costs will be borne by small businesses. For example, from 2003–2007, nearly one-in-five applications for pre-market approval were submitted by a small business. These small businesses are not only catalysts for growth and innovation within our industry, but in these challenging economic times—when access to capital already threatens their business model—their success is critical to our Nation’s overall economic recovery.

These small companies develop cutting-edge technologies such as devices to close heart defects, non-invasively treat uterine fibroids, non-invasively manage diabetes, better detect fetal heartbeats, and destroy contaminated needles. Such products

allow for the better management of chronic disease, the better treatment of expectant mothers and their babies, and the better management of cardiovascular diseases such as strokes.

If preemption is rolled-back, many of these businesses will face two equally unappealing alternatives. They can bring products to market with the harbinger of unfettered tort litigation on the horizon, a prospect nearly guaranteed to drive higher insurance premiums, or they can shelve the product. The notion, suggested by some, that only unsafe products would go on the shelf is nonsensical. Venture capital firms will be less willing to fund even the most promising and safe breakthroughs unless there is the level playing field of a national standard for safety. In this case, innovation wouldn't be shelved, it would never get off the drawing board.

We would urge you to exercise your respective leadership positions in Congress to ensure that no action is taken on this harmful legislation—and that the FDA is given the resources it needs to guarantee the health and safety of the Nation.

Sincerely,

*Advanced Medical Technology Association (AdvaMed); Arizona BioIndustry Association; BioOhio; BIOCOM; California Healthcare Institute (CHI); Florida Medical Manufacturers' Consortium; The Health Industry Council; HealthCare Institute of New Jersey; Indiana Health Industry Forum; Indiana Medical Device Manufacturers Council (IMDMC); LifeScience Alley; Massachusetts Medical Device Industry Council (MassMEDIC); Medical Device Manufacturers Association; MedTech; National Venture Capital Association; North Carolina Biosciences Organization; Texas Healthcare and Bioscience Institute; Washington Biotechnology & Biomedical Association.*

RETIRESAFE,  
WASHINGTON, DC 20006,  
July 31, 2009.

Hon. EDWARD M. KENNEDY, *Chairman,*  
*Committee on Health, Education, Labor, and Pensions,*  
*U.S. Senate,*  
*Washington, DC 20510.*

Hon. MICHAEL B. ENZI, *Ranking Member,*  
*Committee on Health, Education, Labor, and Pensions,*  
*U.S. Senate,*  
*Washington, DC 20510.*

DEAR CHAIRMAN KENNEDY AND RANKING MEMBER ENZI: On behalf of Retiresafe, an organization of over 400,000 supporters dedicated to preserving and enhancing the options, benefits and lives of older Americans, I write to express our strong opposition to the so-called "Medical Device Safety Act of 2009" (S. 540).

We are concerned that S. 540 would threaten the preeminence of our health care system by needlessly subjecting medical device manufacturers to a flood of costly, burdensome and meritless lawsuits without providing any real safety benefits to American consumers.

S. 540 is intended to undo long-standing Federal law that prevents lawsuits regarding certain innovative medical devices that have gone through the FDA's rigorous safety review procedures. If S. 540 is enacted, juries will decide which innovative medical devices should be available on the market—instead of leaving that decision to the medical experts at the FDA.

This outcome would be devastating for many senior citizens who rely on cutting-edge medical devices and technologies—such as heart valves, pacemakers, arterial stents, and orthopedic joints—so that they can live longer, healthier and more comfortable lives. By encouraging lawsuits against FDA-approved medical devices, S. 540 would discourage companies from investing in innovative devices that are critically needed by senior citizens and other Americans. Put simply: this legislation would slow the pace of medical breakthroughs that not only save lives, but also improve the quality of life for our aging population.

For these reasons, we strongly urge you to oppose the Medical Device Safety Act of 2009.

Sincerely,

THAIR PHILLIPS,  
*President, Retiresafe.*

AMERICAN MILITARY SOCIETY,  
UPPER MARLBORO, MD 20774,  
August 3, 2009.

Hon. EDWARD M. KENNEDY, *Chairman,*  
*Committee on Health, Education, Labor, and Pensions,*  
*U.S. Senate,*  
*Washington, DC 20510.*

Hon. MICHAEL B. ENZI, *Ranking Member,*  
*Committee on Health, Education, Labor, and Pensions,*  
*U.S. Senate,*  
*Washington, DC 20510.*

DEAR CHAIRMAN KENNEDY AND RANKING MEMBER ENZI: On behalf of the veterans who we collectively represent, many of whom are recipients of life saving and life improving medical devices, we write to express our strong opposition to the "Medical Device Safety Act of 2009" (S.540), which would limit access to innovative medical devices and technologies that can dramatically improve quality of life for aging and ailing veterans.

Under the guise of improving the safety of medical devices, S.540 would repeal a Federal law that prevents State-court lawsuits over medical devices that have been approved under the FDA's stringent safety and efficacy review standards. The legislation would thus invite personal-injury lawyers to barrage medical device manufacturers with costly, meritless lawsuits, diverting resources away from essential research and development of medical breakthroughs and discouraging manufacturers from investing in new, innovative medical devices and technologies.

Deciding which new medical devices are safe enough to be sold in this country is a job for doctors and scientists at the FDA—not juries. By encouraging lawsuits against medical-device makers and stifling innovation in the critical area of medical technology, S.540 will hamper efforts to deliver cutting-edge, lifesaving medical devices and technologies to our Nation's veterans.

For these reasons, we ask that you oppose the Medical Device Safety Act of 2009. Sincerely,

*The American Military Society; The Army and Navy Union, U.S.A., Inc.; Military Order of Foreign Wars; U.S. Veterans Hospice Committee.*

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BLINDED VETERANS ASSOCIATION,  
WASHINGTON, DC 20001-2694,  
August 3, 2009.

Hon. TED KENNEDY, *Chairman,*  
*U.S. Senate,*  
*Committee on Health, Education, Labor, and Pensions,*  
*428 Senate Dirksen Office Building,*  
*Washington, DC 20510.*

Re: The Medical Device Safety Act of 2009

DEAR CHAIRMAN KENNEDY: On behalf of the Blinded Veterans Association (BVA), the only national veterans' organization congressionally chartered and exclusively dedicated to blinded veterans and their families for 64 years, I write to express our concern and opposition to H.R.1346 and S.540, the Medical Device Safety Act of 2009.

BVA represents over 12,000 members and families, many of whom are recipients of life saving and life improving medical devices including (among other things) heart stents, orthopedic joints, neuro-stimulators and retinal implant research that in early clinical trials offer promise of restoration of partial vision. We are very concerned that enactment of this legislation as written, which would throw open State-based litigation against the medical device manufacturing community and weaken FDA safety approval and technology research review, further stifle innovation, and ultimately limit the availability of many critical medical devices that are of vital importance to advancing the health and improving the quality of life of our disabled veterans.

While BVA has often opposed efforts to reduce the access of individuals to remedies for grievances by means of resort to the Federal Courts, in this case we believe that such a State-torts expansion would be detrimental to the interests of future medical technology research, particularly small biotechnology companies that would face increased risk of State common-law courts and multitude of more State regulations.

Many of our members hold hope for these new medical devices to improving their quality of life from their service-related visual injuries and some have benefited from significant neuro-visual-technological breakthroughs in this field. But legislation resulting in increased litigation against biotechnology manufacturers of these devices, will only diminish future advances in this area.

We therefore strongly urge you to oppose the Medical Device Safety Act of 2009 as written and request Class III FDA devices are preempted by common-law claims. BVA appreciates your support of veterans' issues in the past and requests that you strongly consider the negative impact of this proposed legislation on future research and development.

Sincerely,

THOMAS ZAMPIERI, PH.D.,  
Director, Government Relations BVA.

U.S. VETERANS HOSPICE COMMITTEE,  
WASHINGTON, DC 20005-3514,  
August 3, 2009.

Hon. EDWARD KENNEDY, *Chairman,*  
*Committee on Health, Education, Labor, and Pensions,*  
*U.S. Senate,*  
*428 Senate Dirksen Office Building,*  
*Washington, DC 20510.*

Hon. MIKE ENZI, *Ranking Member,*  
*Committee on Health, Education, Labor, and Pensions,*  
*U.S. Senate,*  
*428 Senate Dirksen Office Building,*  
*Washington, DC 20510.*

Re: The Medical Device Safety Act of 2009

DEAR CHAIRMAN KENNEDY: On behalf of the U.S. Veterans Hospice Committee, I am writing this letter to express our opposition to S. 540, the Medical Device Safety Act of 2009. If enacted, we believe this legislation will spark costly lawsuits against device manufacturers, limiting the availability of many critical medical devices important to advancing the health and improving the lives of our constituency. We urge you to reject this misguided legislation.

The U.S. Veterans Hospice Committee is dedicated to educating the American public about the plight of the nearly 70,000 veterans of U.S. military service who are simultaneously homeless and suffering a chronic or terminal illness. It is our mission to advocate policies in the public interest that serve this constituent population. Our opposition to this legislation is driven by our strong belief in the need for greater access by these veterans to the many medical devices used in end-of-life hospice care settings.

Thank you for the opportunity to express our views on this important matter.

Sincerely yours,

GERALD B. JOHNSON,  
*Executive Director.*

THE 60 PLUS ASSOCIATION,\*  
ALEXANDRIA, VA 22314,  
August 3, 2009.

Hon. EDWARD M. KENNEDY, *Chairman,*  
*Committee on Health, Education, Labor, and Pensions,*  
*U.S. Senate,*  
*Washington, DC 20510.*

Hon. MICHAEL B. ENZI, *Ranking Member,*  
*Committee on Health, Education, Labor, and Pensions,*  
*U.S. Senate,*  
*Washington, DC 20510.*

DEAR CHAIRMAN KENNEDY AND RANKING MEMBER ENZI: On behalf of the 60 Plus Association, a non-partisan seniors advocacy group, I write to express our strong opposition to the so-called "Medical Device Safety Act of 2009" (S. 540).

\*The 60 Plus Association is a 17-year-old nonpartisan organization working for death tax repeal, saving Social Security, affordable prescription drugs, lowering energy costs and other

Continued

The 60 Plus Association is a network of more than 5.5 million seniors committed to improving the quality and accessibility of health care. We are concerned that S. 540 would threaten the preeminence of our health care system by needlessly subjecting medical device manufacturers to a flood of costly, burdensome and meritless lawsuits without providing any real safety benefits to American consumers.

S. 540 is intended to undo long-standing Federal law that prevents lawsuits regarding certain innovative medical devices that have gone through the FDA's rigorous safety review procedures. If S. 540 is enacted, juries will decide which innovative medical devices should be available on the market—instead of leaving that decision to the medical experts at the FDA.

This outcome would be devastating for many senior citizens who rely on cutting-edge medical devices and technologies—such as heart valves, pacemakers, arterial stents, and orthopedic joints—so that they can live longer, healthier and more comfortable lives. By encouraging lawsuits against FDA-approved medical devices, S. 540 would discourage companies from investing in innovative devices that are critically needed by senior citizens and other Americans. Put simply: this legislation would slow the pace of medical breakthroughs that not only save lives, but also improve the quality of life for our aging population.

For these reasons, we strongly urge you to oppose the Medical Device Safety Act of 2009.

Sincerely,

JAMES L. MARTIN.

3800 RESEVOIR ROAD,  
WASHINGTON, DC 20007,  
August 3, 2009.

Hon. EDWARD M. KENNEDY, *Chairman,*  
*Committee on Health, Education, Labor, and Pensions,*  
*U.S. Senate,*  
*Washington, DC 20510.*

Re: S. 540

DEAR CHAIRMAN KENNEDY: On behalf of the many physicians I am associated with, we are writing to express our strong opposition to the so-called "Medical Device Safety Act of 2009" (S. 540).

These physicians are committed to improving the quality and accessibility of health care to all Americans. We are concerned that S. 540 would threaten the preeminence of our health care system by needlessly subjecting medical device manufacturers to a flood of costly, burdensome and meritless lawsuits without providing any real safety benefits to the American consumer.

S. 540 is intended to undo long-standing Federal law that prevents lawsuits regarding certain innovative medical devices that have gone through the FDA's rigorous safety review procedures. If S. 540 is enacted, juries will decide which innovative medical devices should be available on the market—instead of leaving that decision to the medical experts at the FDA.

This outcome would be devastating for many seniors, veterans and American citizens who rely on cutting edge medical devices and technologies—such as heart valves, pacemakers, arterial stents, and orthopedic joints—so that they can live longer, healthier and more comfortable lives. By encouraging lawsuits against FDA-approved medical devices, S. 540 would discourage companies from investing in innovative devices that are critically needed by senior citizens, veterans and other Americans. Put simply: this legislation would slow the pace of medical breakthroughs that not only save lives, but also improve the quality of life for our aging population.

For these reasons, we strongly urge you oppose the Medical Device Safety Act of 2009.

Sincerely,

JOHN KLIMKIEWICZ, M.D.

(On behalf of: Stephen Baker, M.D.; Scott Edwards, M.D.; Brett Wiesel, M.D.; Mark Zawalsky, M.D.; Benjamin Osborne, M.D.; John Delahay, M.D.; Brian G. Evans, M.D.; Samuel W. Wiesel, M.D.; and Paul Cooper, M.D.)

issues featuring a less government, less taxes approach. 60 Plus calls on support from nearly 5.5 million citizen activists. 60 Plus publishes a magazine, SENIOR VOICE, and a Scorecard, bestowing awards on lawmakers of both parties who vote "pro-senior." 60 Plus has been called "an increasingly influential senior citizen's group."

AUGUST 4, 2009.

Hon. EDWARD KENNEDY, *Chairman,*  
*Committee on Health, Education, Labor, and Pensions,*  
*U.S. Senate,*  
*Washington, DC 20510.*

Hon. MIKE ENZI, *Ranking Member,*  
*Committee on Health, Education, Labor, and Pensions,*  
*U.S. Senate,*  
*Washington, DC 20510.*

DEAR CHAIRMAN KENNEDY AND RANKING MEMBER ENZI: On behalf of the undersigned companies and related organizations, and the thousands of members they collectively represent, we write to again express our strong opposition to S. 540, the so called "Medical Device Safety Act of 2009," which will be the subject of a hearing that has been noticed by the committee for August 4, 2009. As many of us raised in the attached letter to Congress dated March 30, 2009 (attached below), this misguided legislation would, among other things, stifle innovation, compromise the safety of American consumers, and threaten the preeminence of the U.S. medical device industry in the world community.

We are particularly concerned that this legislation represents one of several troubling attempts to dilute the preemptive authority of the Federal Government to regulate interstate commerce. As we collectively seek to restore our economy to strong fiscal health, we are concerned about efforts to devolve regulatory authority to State tort systems. Such efforts, if successful, would inevitably lead to more litigation and less opportunity for American businesses to stimulate job creation in this country.

For these reasons and others that are detailed in the attached letter (below) from March, we strongly urge you to oppose this legislation.

Sincerely,

*Medtronic, Inc.; Abbott; Acorn Cardiovascular; AdvaMed; Alcon Laboratories, Inc.; American Healthcare Association; American Insurance Association; American Tort Reform Association; ATS Medical, Inc.; B. Braun Medical Inc.; Bayer Healthcare; Beckman Coulter; Biomet, Inc.; Boston Scientific Corporation; Business Roundtable; Cardinal Health; CaridianBCT, Inc.; Celera Corporation; Covidien; Edwards Lifesciences, LLC; Eli Lilly and Company; GE Healthcare; Greatbatch, Inc.; HemCon Medical Technologies, Inc.; Hill-Rom; Hollister Incorporated; Hospira, Inc.; Integra LifeSciences Corporation; Johnson & Johnson; LifeCell Corporation, a KCI Company; 3M; Medical Device Manufacturers Association; National Association of Manufacturers; National Association of Mutual Insurance Companies; RoundTable; Smith & Nephew, Inc.; St. Jude Medical; STERIS Corporation; U.S. Chamber of Commerce; U.S. Institute for Legal Reform; Welch Allyn; Zimmer, Inc.*

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ATTACHMENT

MARCH 30, 2009.

TO THE MEMBERS OF THE UNITED STATES CONGRESS: On behalf of the undersigned companies and organizations and the thousands of members they collectively represent, we are writing to express our concern with what is likely a series of efforts to dilute the preemptive authority of Congress to regulate interstate commerce. As we collectively seek to restore our economy to strong fiscal health, we are especially concerned about efforts to devolve regulatory authority to State tort systems.

These systems serve an important role in redressing wrongs and compensating injured persons, but they are a poor proxy for a strong, uniform regulatory environment that sends clear prospective signals to businesses and consumers about the integrity of the products they develop, market, sell, and buy. The creation of a lawsuit-driven, State-court-based compliance scheme would impose potentially significant costs on our companies and members in the form of State-based litigation and the cost of multi-jurisdictional compliance. Moreover, we believe that such State-based litigation would limit the availability of many, including life-saving, products for Americans.

Given this broad concern, we write specifically to express opposition to H.R. 1346 and S. 540, the "Medical Device Safety Act of 2009," which represents the opening salvo of a broader campaign by personal injury lawyers to replace uniform Federal regulation with tort litigation. This bill seeks to undo the U.S. Supreme Court's 2008 nearly unanimous ruling in *Riegel v. Medtronic*, which held that certain State tort suits based on injuries from medical devices that were approved through the

FDA's premarket approval (PMA) process are expressly preempted by Federal law. See *Riegel v. Medtronic*, 128 S. Ct. 999 (2008). As set forth below, we believe that enacting legislation to repeal the preemption provision at issue in the *Riegel* case would stifle innovation, compromise the safety of American consumers, and threaten the preeminence of the U.S. medical device industry in the world community.

In 1976, Congress enacted the Medical Device Amendments Act (MDA) to create a uniform national process for evaluating the safety and efficacy of medical devices. Prior to enactment of the MDA, medical device manufacturers were subject to various State regulatory regimes and were frequently sued over alleged device failures in State courts around the country. Congress enacted the MDA and incorporated an express preemption provision in that statute in response to this hopelessly complex regulatory environment. Thus, the MDA ensures intensive Federal review of new and innovative medical devices and provides manufacturers with clear guidance from a single source, the Food and Drug Administration (FDA), on the safety and efficacy standards applicable to new medical devices. Under the MDA's uniform regulatory environment, medical innovation has thrived and patients have received cutting-edge medical technologies like pacemakers, arterial stents, and heart valves.

Last year, the Supreme Court confirmed in *Riegel* the MDA's uniform regulatory framework by holding in an 8-1 decision that the express preemption clause in the MDA limited certain State tort lawsuits against medical devices that have gone through PMA review, a particularly rigorous FDA approval process. The decision clearly allows claims to move forward in a variety of instances including in cases where the device was not manufactured to specification, or a company mislead FDA. The Medical Device Safety Act of 2009 seeks to undo the *Riegel* decision by amending the MDA to revoke preemption with respect to such medical devices.<sup>1</sup>

We strongly urge you to reject the proposed legislation for several reasons:

**First**, the pending legislation would stifle innovation of new medical devices thus limiting the availability of lifesaving technologies. As it currently stands, the PMA approval process Congress established in 1976 (which is specific for certain medical devices) benefits both manufacturers and consumers. Consumers are protected by a rigorous safety review procedure conducted by expert regulators. The approval process is an intense one, during which the FDA typically spends over a thousand hours reviewing volumes of clinical and safety data about a proposed device. Even after a device is approved, regulatory review is not complete. Rather, the manufacturer is required to report to the FDA on any changes to the device and provide a summary of new information from scientific literature and unpublished reports about that device. This regulatory scheme assures that only products whose benefits to potential patients outweigh their risks can go to market. Although the process is extremely burdensome on manufacturers, the MDA's express preemption provision assures that manufacturers that complete the PMA process will not be subject to later tort liability. This balance of intense regulation, coupled with protection from State law liability, has fostered the invention and marketing of countless devices that have saved American lives.

The proposed legislation would upend this comprehensive regulatory framework. Many manufacturers would inevitably determine that it is too costly to go through the PMA approval process and still be forced to comply with 50 different State tort regimes. Thus, they will simply stop developing new, innovative medical devices, preferring to market older technologies for which the litigation risks are known. Such a result would hurt not only manufacturers and their employees but it would also prevent patients from gaining access to life-saving, cutting-edge medical devices.

**Second**, the proposed legislation, notwithstanding its title, would provide no real safety benefits to American consumers. Instead, the result of the legislation would be to replace the judgment of expert regulators with that of lay juries. Under the current regime, FDA is able to weigh the risks and benefits of a particular device, and to assure that when the former are outweighed by the latter, the device reaches the market. Replacing expert regulators with lay jurors would result in conflicting and suboptimal regulation and ultimately prevent important medical technologies from reaching the patients who need them.

**Finally**, the pending legislation would impose significant additional costs on American business at a time of economic crisis. Many medical device manufacturers

<sup>1</sup>The Supreme Court's recent decision in *Wyeth v. Levine*—which rejected a claim of implied preemption with respect to prescription drugs—has no relevance to the pending legislation. The question in *Wyeth* was whether certain FDA regulation had preemptive effect *absent* express preemption by Congress. The *Wyeth* Court did not make any policy judgments regarding whether and to what extent preemption of State tort claims against either drug or medical device manufacturers was appropriate.

are relatively small companies without large research and development budgets. These companies rely on often-scarce, venture capital to fuel innovation and cannot afford the risk of increased lawsuits. *See* S. Rep. No. 33, 94th Cong., 2d Sess. 18 (1976) (noting the importance of the MDA for “small manufacturer[s] of medical devices,” with “limited financial resources”). In fact, in 2002, Congress created a mechanism for small device manufacturers to receive a discount on the application fees associated with a PMA. In the last 5 years, 20 percent of all PMA applications were from small businesses. For more than 30 years, the United States has been a leader in innovation in medical technology. Now is not the time to threaten the viability of an important American industry—especially one that has saved countless American lives.

For all of these reasons, we strongly urge you to oppose the Medical Device Safety Act of 2009.

Sincerely,

*Medtronic, Inc.; Abbott; Acorn Cardiovascular; AdvaMed; Aesculap, Inc.; American Health Care Association; American Insurance Association; American Tort Reform Association; ATS Medical, Inc.; B. Braun Medical Inc.; Bayer; Beckman Coulter; Biomet, Inc.; Boston Scientific Corporation; Business Roundtable; C. R. Bard, Inc.; Cardinal Health; CaridianBCT, Inc.; ConvaTec Inc.; Edwards Lifesciences; Elemé Medical, Inc.; Eli Lilly and Company; GE Healthcare; Hill-Rom; Hollister; Hospira, Inc.; Icaria; Johnson & Johnson; 3M; Medical Device Manufacturers Association; MicroCube, LLC; National Association of Manufacturers; RetireSafe; Roche Diagnostics; Sleep Solutions; Smith and Nephew; St. Jude Medical, Inc.; STERIS Corporation; U.S. Chamber of Commerce; U.S. Chamber Institute for Legal Reform; Vietnam Veterans of America; Welch Allyn; Zimmer, Inc.*

[Whereupon, at 4:25 p.m., the hearing was adjourned.]

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