S. HRG. 110–497

SHORT-CHANGE FOR CONSUMERS AND SHORT-SHRIFT FOR CONGRESS? THE SUPREME COURT'S TREATMENT OF LAWS THAT PROTECT AMERICANS' HEALTH, SAFETY, JOBS AND RETIREMENT

HEARING

BEFORE THE

COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

ONE HUNDRED TENTH CONGRESS

SECOND SESSION

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SHORT-CHANGE FOR CONSUMERS AND SHORT-SHRIFT FOR CONGRESS? THE SUPREME COURT'S TREATMENT OF LAWS THAT PROTECT AMERICANS' HEALTH, SAFETY, JOBS AND RETIREMENT

WEDNESDAY, JUNE 11, 2008

U.S. SENATE,
COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The Committee met, Pursuant to notice, at 10:02 a.m., in room SD–226, Dirksen Senate Office Building, Hon. Patrick J. Leahy, Chairman of the Committee, presiding.

Present: Senators Leahy, Whitehouse, Specter, and Hatch.

OPENING STATEMENT OF HON. PATRICK J. LEAHY, A U.S. SENATOR FROM THE STATE OF VERMONT

Chairman LEAHY. Good morning. I am glad to see everybody here. I called this hearing today to shine a light on how the Supreme Court's decisions affect Americans' everyday lives. We sometimes see a headline, the Court rules this way or that way, and I recall when I was a law student, it was always an interesting thing to then discuss the pros and cons of a decision. But it is well beyond that. It goes into how it affects real people in those decisions.

We know that the Court's rulings will come into focus if they involve divisive cultural issues. But, lately, many Court observers have noticed that business interests have been the big winners over workers and consumers. In a worsening economy, mothers and fathers are struggling with health care coverage, the uncertainty of retirement, credit card payments, and mortgages, and, of course, gasoline prices that are going off the charts. Congress has passed laws to protect Americans in many of these areas, but in many cases, the Supreme Court, I believe, has ignored the intent of Congress in passing these measures, sometimes turning these laws on their heads and making them protections for big business rather than for ordinary citizens.

For almost two decades, to give one example, Lilly Ledbetter worked as the sole female supervisor in a major national corporation. Her diligence helped send her children to college and helped her and her husband plan for the future. Before her retirement, Ms. Ledbetter received an anonymous note showing the salaries of her male counterparts, the men in her business that were doing the same work she was doing. And even the lowest-paid of the male supervisors was earning 20 percent more than she was, de-

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spite having far less experience and seniority than she did. She would later learn that the pay difference was even greater because she was also short-changed on bonuses, retirement benefits, and overtime pay. Now, she clearly proved to a jury that she had been illegally discriminated against. There was no question in the jury's mind, no question in the lower court she was discriminated against. But the Supreme Court reversed the verdict and created a bizarre interpretation of the law. As a result, her employer is never going to be held accountable for the illegal discrimination against her. The Court's ruling tells other corporations very clearly go ahead and discriminate because you can get away with it, as long as they keep their illegal activity hidden long enough.

Now, a majority of Senators support overturning the Court's decision, but we have 43 Senators who are preventing us from even proceeding to consider this remedy. They have filibustered having the ability to reverse what the Supreme Court did. And by filibustering the Lilly Ledbetter bill, those Senators are standing behind the Supreme Court's terrible interpretation of our antidiscrimination laws.

At today's hearing, we are going to focus on several laws designed to protect Americans' health, safety, and retirement. We will hear testimony today from two brave women who, like Ms. Ledbetter, have or will be denied relief and justice as a result of Supreme Court rulings. There are thousands more of them outside this hearing room who have been adversely affected by rulings that slam the courthouse door shut and encourage corporate misconduct.

Years ago, Congress passed a landmark law known as ERISA. It was done to ensure that workers with employer- sponsored health insurance or retirement benefits could benefit from them when they needed them. But the Supreme Court has so distorted this law, so changed what was intended by Congress, that it provides no relief for individual beneficiaries when the companies and insurers entrusted with administering their benefit plans violate the law or the terms of the employees' plans. Can you imagine? People are entrusted to handle these retirement plans, and if they violate the law, the Supreme Court has given them a get-out-of-jail-free card.

Moreover, the Court has held that it was the intent of Congress to take away preexisting State law remedies for workers, even though Congress never intended that. The result: Congress' bill passed with Republican and Democratic support, a monumental effort to safeguard workers and their families has literally left them more vulnerable than they were before the law was passed. Congress passed the law to protect them, and the Supreme Court says not only does it not protect them, but we are taking away any other protections you might have had. Great jurists from the late Justice White to Justice Ginsburg have decried how preposterous, unjust, and incompatible with Congress' true intent this result is. The late Judge Ed Becker, former Chief Judge of the Third Circuit, a friend to many of us here in this Committee, best captured the impact of this line of cases when he observed that the interpretation had devolved from the protection of ordinary Americans that was intended into a catch–22 and "into a shield that insulates

HMOs from liability for even the most egregious acts of dereliction...directly contrary to the intent of Congress."

The Supreme Court has narrowly interpreted another law designed to protect Americans who rely on medical devices to keep them alive. Unfortunately, here again the Supreme Court's interpretation has transformed the law into one that takes away protections from people by extinguishing longstanding State law remedies which hold corporations accountable when they are aware of potential dangers but hide them from consumers, and we are going to hear what happens in real life.

The last set of laws to be examined here today involves lending institutions used by Americans to finance their homes and credit cards used for everyday purchases. In this context as well, the Court has interpreted Federal legislation in such a way that strips consumers of the right to benefit from more protective State laws. These decisions also serve to shield corporations from their misconduct. This is something that potentially affects the pocketbook of every working American man and woman in this country.

Now, the Supreme Court rulings have occurred with little public attention, except for the lives of Americans that it impacted. There has been plenty of academic discussion about the radical changes that this Court is making to preemption and federalism. But the health and retirement guarantees provided by Congress were not meant to be merely rhetorical commitments. They are essential to give every American the chance to lead a rich and full life.

So in light of the troubling Supreme Court rulings we are going to examine today, Congress may be again required to step in with remedial action to clarify our intent, as we did in 2006 with the Voting Rights Act reauthorization. Congress is seeking to do the same with the Lilly Ledbetter bill if we can get past the filibuster. And to paraphrase my friend and civil rights hero Congressman John Lewis, in our system of checks and balances we have to meet every judicial step backward with a legislative step forward. The problem, however, with any legislative fix is that the Supreme Court might again strip it of its purpose.

So I hope today's hearing will be a first step in contributing to the understanding of the impact the Supreme Court has on our daily lives.

[The prepared statement of Senator Leahy appears as a submission for the record.]

Senator Specter?

STATEMENT OF HON. ARLEN SPECTER, A U.S. SENATOR FROM THE STATE OF PENNSYLVANIA

Senator SPECTER. Thank you, Mr. Chairman.

This is a very important hearing as a significant step for the Congress of the United States to establish the law on this subject contrary to what the Supreme Court has ruled. This is a matter of statutory interpretation, not a constitutional ruling. So it is a matter for congressional decision.

This issue involves very fundamental questions of federalism on the tradition of leaving it to the States to make decisions which are particularly applicable for State court decisions as opposed to control out of Washington, D.C.

When we deal with the subject of the FDA and preemption, the FDA under the existing law will grant approval only if it finds there is a reasonable assurance of the device's safety and effectiveness. The grave problem with that is that the FDA has become a joke. It does not have the funds to begin to carry out its responsibilities, and that has been highlighted in the course of the past several weeks on strenuous efforts by Members of Congress to find out from the FDA what money it needs. But the FDA will not tell, and the reason the FDA will not tell is because it is run by the Office of Management and Budget, and they have overall targets, and they do not want a needy agency communicating to Congress where Congress really needs to know what is going on.

I have gotten to know Commissioner von Eschenbach well. Perhaps it is the Philadelphia connection. But I finally got from him, as a result of a letter I wrote on May 1st, a figure of $275 million. Now, that is a start, candidly, but not a very good start. Well, we have worked to put the $275 million in an emergency appropriation bill, supplemental appropriation. Yesterday I found out that the administration, Secretary Leavitt, HHS, has come in with a different approach, wants to have an amendment to next year's budget. And Secretary Leavitt is quoted in the New York Times yesterday as "urging Congress to act promptly."

Well, the emergency appropriation would put the money in FDA's hands in the next week or two if we finally get around to acting on that bill, which involves Iraq funding. What the administration and Secretary Leavitt are doing is to defer it until next March or April. Really, it is an effort to sabotage getting the funds in hand at the present time. So it seems to me really ludicrous to talk about having preemption by an agency which is dysfunctional, does not have the capacity to pass on safety.

We are dealing here with a wide variety of products, and I think back to my days as district attorney, and I think that Senator Leahy will agree and Senator Whitehouse may also, and I think Senator Hatch will as well. Malice is established when someone acts or fails to act in a context of subjecting an individual to the unreasonable risk of bodily injury or death. That is the definition for malice and murder in the second degree. And I believe if the Federal Government does not fund the FDA on matters like the tomatoes and others, harsh language, but I think it really does amount to criminal negligence.

So it is hard for me to see how Congress can sit back and let preemption exist with the FDA when the FDA cannot do its job. And the administration is sabotaging under a cover of urging Congress to act, when the Secretary and the administration are submitting legislation which will delay it for 8 or 9 months.

I was pleased to see the Chairman quote Judge Becker. Judge Becker was a preeminent jurist, did a lot of work with the Committee on asbestos, and I would like to quote Judge Becker a little more on the subject about preemption on ERISA, where he said, "A plan participant whose claim is denied by an HMO is often in the throes of a life-or-death medical crisis, hardly a feasible time to retain counsel and prosecute an injunctive lawsuit." He concluded, as have many critics, that ERISA and its preemption provisions "have become virtually impenetrable shields that insulate plan sponsors

for any meaningful liability for negligent or malfeasance acts committed against plan beneficiaries in all too many cases."

So I do think it is high time that the Congress got into this field with both feet and undertook some significant action.

Just one more point in passing, and I do want to agree with the Chairman on what he had to say about the Ledbetter case. Ms. Ledbetter was denied an opportunity to go to court on a claim of discrimination by a Supreme Court ruling that the statute of limitations of 6 months precluded her going to court when she did not even know she had a cause of action within the 6 months. But I want to differ with my distinguished colleague Senator Leahy on what is happening in the Senate on it.

The bill was introduced, and I am for it, but a procedure was employed known as "filling the tree," which is arcane within the Beltway, and nobody could offer any amendments. And I voted against cloture to go forward because I am not about to move ahead on the bill if I cannot offer amendments. The same thing happened with global warming. The same thing has happened repeatedly. And it is a procedure which has been employed by both Republicans and Democrats. One thing, when you find partisanship around here, you find an even 50–50 split. Senator Mitchell used it nine times years ago; Lott and Frist used it nine times; and Senator Reid is now up to 12. But we are going to have to revert to the days when a Senator could offer amendments on any subject, and we will take up Ledbetter, and we will reverse the Supreme Court decision, giving the woman a right to a remedy.

We really are facing enormously serious issues here beyond any question.

Mr. Chairman, I would ask consent that my letter to Commissioner von Eschenbach be included in the record and my letter to Secretary Leavitt yesterday be included in the record.

Chairman LEAHY. Without objection.

Senator SPECTER. Secretary Leavitt and I traded called. He called me twice, and I called him back twice, so I finally ended up writing him a letter in the afternoon to move ahead on the record.

Chairman LEAHY. This falls in the category of strong letter.

Senator SPECTER. Well, every now and then a strong letter is in order.

Secretary Leavitt is a great public servant, and he is following the work of the administration. But there comes a time when the public interests are so pronounced that people in Congress ought to be told what is going on so that we can protect the public, and not hide behind a shield. But to say "urging Congress to act" when the administration is delaying it for 8 or 9 months is unconscionable. It is sabotage.

Mr. Chairman, I regret that I cannot stay, but I have other commitments, one of which is to move ahead on this FDA funding, trying to get it into the emergency supplemental. And I am especially sorry not to stay because we have witnesses from Pennsylvania who have come a long way, and I would like to be here to question them. But I am leaving the Republican side in very goods hands with former Chairman Hatch.

Chairman LEAHY. Thank you, Senator Specter, and I am glad to hear you quote Judge Becker. I know what a close friend he was

of yours, and he became a close friend of so many of the rest of us. Let us hope we can get over any procedural things because 57 Senators have voted to overturn Ledbetter. And let us hope before the year is out we find a way that all 100 can, because it was an egregious, egregious misstep on the part of the Supreme Court.

Our first witness is Bridget Robb, who was diagnosed 4 years ago with congestive heart failure. To save her life, doctors implanted a medical device in her chest. A few months ago, she experienced a horrific malfunction of that device. I want to let her tell the Committee the story.

Incidentally, there is a 911 call that she made. We have a tape of that. The 911 call is very disturbing. It may be difficult for many to hear, especially the sound of her child begging her not to die. I cannot think of an easier way of putting it, but that is basically it. Your child was begging, "Mommy, don't die."

We will put an edited version of the transcript in the record, without objection, and I will make the audio recording available to all members of the Committee and their staffs.

Ms. Robb, thank you very much for being here. Please go ahead with your testimony.

STATEMENT OF BRIDGET ROBB, GWYNEDD, PENNSYLVANIA

Ms. ROBB. Chairman Leahy and members of the Senate Judiciary Committee—

Chairman LEAHY. Pull the microphone a little bit closer, please. We want to make sure that that little red light is on.

Ms. ROBB. Is that better?

Chairman LEAHY. Yes, that is better.

Ms. ROBB. Chairman Leahy and members of the Senate Judiciary Committee, thank you for the invitation to speak on the topic of laws that protect Americans' health and safety. In a time when big business and corporate profits seem to take precedence over individuals' rights, we tend to forget the reasons why certain laws were, in fact, enacted and why it remains important for people who have been injured by defective products to be able to hold companies accountable and to have their day in court. I am here today not only because of my own tragedy, but also to protect the rights of those who have or may suffer similar events such as mine.

My name is Bridget Robb. I am a 34-year-old mother and resident of Gwynedd, Pennsylvania. On December 31, 2007, I suffered greatly and thought I was going to die because of a defective heart device implanted in my body. I am thankful to be here today and to be able to share my experience with you.

Approximately 4 years ago, I was diagnosed with non- ischemic viral cardiomyopathy and congestive heart failure. In May 2005, to prevent me from dying from a fatal arrhythmia, I had a Medtronic cardiac defibrillator with pacemaker implanted in my chest. This heart device is a small metal case that contains electronics and a battery. Its components work much like a pacemaker, but unlike a pacemaker, an ICD delivers an electrical shock to the heart when the heart rate becomes dangerously fast. My particular device combined a pacemaker and an ICD unit in one.

On December 31, 2007, I was awoken from my sleep by a series of shocks to my heart which felt as if a cannon was being repeat-

edly shot at my chest at close range. Along with these recurrent shocks was a strong electrical current racing through my body. After feeling the first shock, I immediately phoned 911 for help. My 6-year-old daughter, Emma, had snuck into bed with me that night and was present during this horrific experience. I remember Emma being confused and scared. She crouched down in front of me hugging her cat, saying "Mommy's dying." She was present during the entire 7 minutes that I was on the telephone with the 911 operator until the EMS arrived. I cannot imagine how terrified she must have been to see her mother in such pain.

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

I later learned that the inappropriate shocking and electrical feeling throughout my body was caused by a defective cardiac lead implanted in my heart, the Sprint Fidelis lead manufactured by Medtronic. A lead is a thin wire which connects the ICD to the heart and delivers the actual shock to the heart when it is beating too fast. Medtronic's Sprint Fidelis lead was recalled on October 15, 2007, because of its potential to fracture. Unfortunately, Medtronic never notified me that my lead was recalled, and I did not learn of the recall until after this "life-saving" medical device seriously hurt me.

Since this terrifying experience, my health has declined significantly. I have been visiting doctors almost weekly for followup appointments and testing and have suffered from severe anxiety. I have since undergone surgical replacement of my defibrillator and the defective lead, and a second surgery to revise the lead. My second surgery resulted in an extended hospital stay where I had to undergo a blood transfusion. As you would expect, I risk serious harm each time another procedure is performed. Even though Medtronic's defective device caused my injuries, my health insurance plan has been paying for the cost of my medical care.

I would like to have the opportunity to hold Medtronic accountable for the injuries that I suffered that day and the emotional aftereffects that I continue to experience on a daily basis. Medtronic knew that its Sprint Fidelis lead was faulty, yet the company never took responsible steps to notify me that this lead needed to be replaced. Instead, I suffered indescribable pain that day and continue to suffer from the emotional toll of my near-death experience.

However, my attorneys tell me that a jury may never hear my case due to a legal doctrine known as "preemption," which the Supreme Court recently discussed in another Medtronic medical device case, *Riegel* v. *Medtronic*. In that case, the Supreme Court found that any claims brought by people injured by another Medtronic device were preempted and that the company would have complete immunity from any claims brought against it given that the FDA approved the device. My attorneys are concerned that the *Riegel* decision also may apply to my case, and as a result, I would have no recourse for my injuries. I find this discouraging and demoralizing.

In addition, the considerable costs for my health care have been shifted from Medtronic, the company that knew about this problem but failed to take action, to my health insurance provider. This may result in an increase in the cost of my insurance. It is wrong to shift the cost of medical care from the responsible party to private insurers, patients, and in some cases to taxpayer-sponsored programs like Medicare and Medicaid.

Therefore, I am asking Congress to pass legislation to ensure that victims of faulty medical devices, like me, will continue to have the ability to hold a medical device manufacturer accountable for their injuries. I find it hard to believe that Congress ever intended to prohibit me from having the opportunity to go to court to obtain justice.

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

[The prepared statement of Ms. Robb appears as a submission for the record.]

Chairman LEAHY. Thank you very much, Ms. Robb. I would urge the Senators on this Committee and their staffs to listen to the 911 call. It is chilling, to say the least.

Maureen Kurtek—did I pronounce that correctly, Ms. Kurtek? She has been battling lupus for almost 20 years. She is here to tell her compelling story about an HMO that delayed approving health care treatment under the Supreme Court's ERISA case law, which I believe is misguided, and I also believe not what was intended by either the Democrats or Republicans who voted for the ERISA law. Ms. Kurtek has no avenue of recovery for significant medical injuries.

Ms. Kurtek, please go ahead, and make sure that is on. Go ahead, please.

STATEMENT OF MAUREEN KURTEK, POTTSVILLE, PENNSYLVANIA

Ms. KURTEK. Chairman Leahy and members of the Committee: A health insurance company should never be allowed to jeopardize a person's health while they look for ways to save money. But when they do they should be held accountable.

My name is Maureen Kurtek. I have lupus, and I was diagnosed in 1989. My doctors agreed that a therapy called IVIG would be beneficial to me.

IVIG helps to fight infection by building up a patient's resistance. People with autoimmune diseases such as myself do not have a normal resistance to germs, which is comparable to a person undergoing chemotherapy.

Periodic IVIG therapy improved my condition. It raised my platelet count and boosted my immunities. My first series of treatments in 1998 cost about $14,000 and was paid for by Pennsylvania Blue Cross and Blue Shield through my husband's employer. Although I had six treatments in 3 years, in January of 2003 my doctor recommended another IV treatment. At the time, my husband had changed jobs, and our health insurance company was now Capital Blue Cross.

I immediately called them to preauthorize the treatment, which according to the plan they would pay for as long as it was medically necessary.

I first called Capital on January 17, 2003. The first representative wanted to look into whether the treatment would be provided at home health instead of in the hospital, which I had got it all the time before in the hospital.

The next person told me she thought the treatment was experimental. Well, that put up a red flag to me.

I repeatedly asked to speak with a supervisor and was told that Capital was continuing to look into this and would report back to me once a decision was made.

Every time I called, I was told that "someone was working on it and that the supervisor had a note on her desk with my name and number on it.

Capital did not call any of my doctors. It took the insurance company 53 days to authorize my treatment. By then I had nearly died. Due to not receiving my treatment, I became septic. I developed an infection my body that I could not fight,

On March 1, 2003, I was taken by ambulance to the hospital for an acute flare-up of my lupus. According to my doctor, this condition could have been prevented or dramatically diminished if I had received the medically necessary IVIG treatment.

The very first treatment I received after being admitted to that hospital was emergent IVIG. While at the hospital, I was in critical condition. The doctors told my husband I had a 5-percent chance of survival.

After going into septic shock, I went into kidney failure. My body also started to throw clots at the same time as I was bleeding bled out. I had blood clots in my hands and feet. I also suffered uncontrollable hemorrhaging of the sinuses causing blood to enter my lungs. I was bleeding from every orifice in my body, including my eyes and mouth.

I was in respiratory failure and required ventilation on a respirator and within 24 hours had an emergency tracheotomy due to bleeding from my sinuses into my lungs. I almost died because of this injustice, and parts of me actually did die: my fingertips; I lose half of my right foot.

Eleven days after I was admitted to the hospital, the insurance company approved the treatment. As a result of the extraordinary delay in the approval of the IVIG therapy, like I said, I had lost half my right foot, amputated. I had developed osteomyelitis to that right foot. I had lost five fingertips. I had difficulty breathing through my nose and had undergone many surgeries. I am required to take Lovenox, two injections daily, and have developed peripheral neuropathy, and I am required to wear special shoes.

I filed a lawsuit against the insurance company, but the judge decided my case was covered under the ERISA law, which does not allow people like me to sue for the harm the insurance company caused me. The ERISA law, as the late Judge Becker stated, "has evolved into a shield that insulates HMOs from liability for even the most egregious acts of dereliction committed against plan beneficiaries."

Because of ERISA, there is a monetary incentive for insurance companies to mistreat people like me who have health problems.

I am privileged to be here today to tell you about how the ERISA law has hurt me and my family. I am wearing a tear-shaped necklace given to me by my family members who had to watch me cry tears of blood.

At the time I was sick, I had a 13-year-old son who did not know whether his mom would even make it through the night. I had a husband who didn't know whether in a few days he would be a single parent and have to raise a child while trying to support a family on a modest income. And all of this pain and suffering was caused by an insurance company that failed to timely authorize the treatment that I had received six times before. This treatment was necessary for me.

As I stand before you today, I can tell you that life ceased as I had known it. I am no longer able to jog or dance. I cannot wear stylish shoes on special occasions. And I have to wear an orthopedic shoe, which I can assure you is not any woman's dream. During my time in the hospital, I missed my son's spelling bee, piano recital, his confirmation at church, and many baseball games. These are events I can never get back.

Due to this law, insurance companies can get away with denying care and delaying treatment without any consequences. This is wrong. We need to change this law so no families will have to suffer the way mine did.

Thank you for your time.

[The prepared statement of Ms. Kurtek appears as a submission for the record.]

Chairman LEAHY. Thank you, Ms. Kurtek. I know it is not easy to tell your story, the same as Ms. Robb.

Ms. KURTEK. I have pictures here if you would like to see them.

Chairman LEAHY. Thank you. We will make sure they are available to all the Senators.

Ms. KURTEK. Thank you.

Chairman LEAHY. What I am going to do is go through the testimony of each of you, and then we will open it to questions.

Andy Anderson is of counsel for the international law firm of Morgan Lewis. He is testifying today on behalf of the U.S. Chamber of Commerce.

Mr. Anderson, welcome, and go ahead, please.

STATEMENT OF ANDY R. ANDERSON, OF COUNSEL, MORGAN, LEWIS & BOCKIUS LLP, CHICAGO, ILLINOIS

Mr. ANDERSON. Chairman Leahy and members of the Committee, I am pleased and honored to be here today. As you indicated, I am here to testify on behalf of the United States Chamber of Commerce regarding Supreme Court decisions under the Employee Retirement Income Security Act of 1974, commonly known as "ERISA."

My name is Andy Anderson, and I am of counsel at Morgan Lewis. My practice focuses on advising single-employer and multiemployer benefit plans on employee benefits matters and specifically on their health benefit programs. I have worked in the area of employee benefits since 1984. I chair my firm's Health and Wel-

fare practice, and I participate on the Chamber's Employee Benefits Committee.

ERISA uniformity and limited recovery is intended and necessary. All employers—except for certain religious and government organizations—who voluntarily choose to offer retirement or health benefits are governed by ERISA.

ERISA was the subject of a long and detailed legislative process. Included among the myriad provisions of ERISA are two concepts that cut to the heart of today's hearing. These concepts work in unison to encourage employers to voluntarily extend health benefits to their employees with a high degree of uniformity and without unnecessary exposure to liability.

These provisions are ERISA Section 514, which generally preempts State jurisdiction over employer-provided health benefits, and ERISA Section 502 that outlines the rules associated with the civil enforcement of ERISA.

The ERISA provisions in these sections have a long and detailed legislative, regulatory, and judicial history that extends all the way back to the initial legislative proposals that eventually became ERISA. It was no accident that resulted in these provisions but, rather, a careful balance of competing interests and incentives to encourage employers to voluntarily offer retirement and health benefits.

Our judiciary, including the Supreme Court, has heard many cases related to ERISA uniformity and remedies. While sometimes chafing under the statutory provisions of ERISA or bemoaning yet another ERISA case on their docket, our judiciary has usually reached the correct decision regarding both the specific facts of a given case and the broader principles and tradeoffs embodied in ERISA. These decisions should be respected and upheld.

Changes to ERISA will decrease employer-provided voluntary health care

Employers engage in a complicated calculus when they determine whether or not to offer health benefits. Included in this calculus is whether they retain control over the fundamental provisions of their plans, such as eligibility and which benefits are covered under the plans. Employers are also concerned about the risk of liability associated with offering a health plan and the judicial forums and rules applicable to the plan.

Of the 160 million Americans who have employer-provided health coverage, 132 million receive health benefits that are subject to the provisions of ERISA. The large numbers of Americans covered by ERISA-regulated health plans shows how successful ERISA has been at encouraging employers to voluntarily offer benefits.

This success is due in large part to ERISA Sections 514 and 502, since these rules ensure that employers—and particularly employers who self-insure their health benefits—are able to provide uniform medical plans in every State in which they operate, that disputes associated with ERISA-governed health plans are heard in Federal court, and that successful litigants generally receive the benefits owed to them under the terms of their employer's plans.

I firmly believe that interposing the determination of a State legislature—or a State judge—regarding the eligibility and benefit rules for an employer's health plan will begin to make this vol-

untary program much less appealing and far more complicated for employers. Further, if employers have to begin weighing the increased risk of broader participant recoveries, we will quickly see a number of employers stop providing health coverage to their employees or merely reimburse employees for individually purchased coverage. As a result, we will wind up with fewer Americans who are covered under traditional employer- provided health plans.

While a few will benefit, many will lose.

We are already witnessing the reduced retirement income security associated with the legislative, regulatory, and judicial environment surrounding defined benefit plans. This lesson is reason enough for Congress to build on the strengths of employer-provided health care, maintain ERISA uniformity and recovery rules, and encourage—rather than discourage—our system of voluntary employer-sponsored health plans.

Mr. Chairman and members of the Committee, thank you for the opportunity to testify today and for your attention to this very important issue. I would be happy to answer any questions that you may have during the balance of this hearing.

[The prepared statement of Mr. Anderson appears as a submission for the record.]

Chairman LEAHY. Our next witness is Thomas O. McGarity. Professor McGarity teaches at the University of Texas School of Law, a leading scholar in the fields of torts, administrative law, and environmental law. He has written a number of influential books on Federal regulation, including the forthcoming book "The Preemption War: When Federal Bureaucracies Trump Local Juries."

Mr. McGarity, thank you for being here. Please go ahead, sir.

STATEMENT OF THOMAS O. MCGARITY, PROFESSOR OF LAW, UNIVERSITY OF TEXAS SCHOOL OF LAW, AUSTIN, TEXAS

Mr. MCGARITY. Mr. Chairman and members of the Committee, thank you for having me here. As mentioned, I hold the Long Chair in Administrative Law at the University of Texas School of Law. I am board member and immediate past president of the Center for Progressive Reform, which is an organization of legal scholars throughout the country that is working on preemption, among other issues. My forthcoming book, just mentioned, will be out in October, and is being published by Yale University Press.

Although the Supreme Court quite correctly is insulated from the pulls and tugs of day-to-day politics, its decisions do have a powerful impact on the lives of ordinary Americans. Our written testimony highlights the serious injustices that can result when the Court exercises its power to interpret Federal statutes narrowly to reach a result that Congress never intended and then employs the doctrine of Federal preemption to impose that questionable interpretation on the State common law courts.

An increasing number of sitting Justices, in my view, seem more willing to interpret laws that Congress enacted to implement protective social goals in ways that really advance their less protective views of public policy. For example, the longstanding presumption against preemption that the Supreme Court has honored for years seems more honored in the breach these days, as at least some sitting Justices, demonstrate their willingness to accommodate the in-

terest of the business community in nationally uniform implementation of weak Federal regulations. Ms. Kurtek's experience is sadly but one of hundreds of similar instances of medical benefit plan errors that have resulted in uncompensated mental damage and physical harm to the erstwhile beneficiaries of such plans.

The injustice that Ms. Kurtek and Ms. Robb have felt here in the case of ERISA stems from two lines of Supreme Court precedent that were just moving off in different directions from each other and the Department of Labor's failure to exercise its rulemaking power to address the problem of medical benefit plans.

The first line of cases narrowly interpreted the clause Mr. Anderson just referred to, providing civil remedies, to exclude common law damages. So all you get by way of a remedy is the benefits that you would have otherwise been entitled to, no matter how negligent the health care provider.

A second line of cases, broadly interprets the express preemption provisions of ERISA to displace all Federal laws, including, though not mentioned explicitly in the statute, State common law.

The Department has consistently failed to fill the gap which it does have the power to do by promulgating regulations that would limit negligence on the part of health care providers. The net effect has been to substitute a virtually content-free Federal regulatory regime for what would otherwise be a rich body of State common law. The message to the HMOs and insurance companies is to ignore their fiduciary obligations and deny legitimate requests for coverage, and my testimony mentions where that has actually been instructed to the medical service folks.

Justice Ginsburg, Judge Becker, Second Circuit Judge Guido Calabresi have all expressed concern about the state of ERISA law as interpreted by these two lines of Supreme Court cases.

Now, ERISA is not the only Federal statute. My book goes into several Federal statutes where Federal agencies promulgate weak regulations that then preempt State common law actions. The Medical Device Amendments that resulted in the approval of the medical device—the full approval of the medical device that Ms. Robb described to you is another instance of injustice coming about by a recent Supreme Court case saying that all claims involving fully approved devices are preempted.

The arcane law of Federal preemption has a profound effect on the rights of ordinary citizens. First, it deprives innocent plaintiffs of the corrective justice to which I believe all Americans are entitled. Second, it replaces the common law jury, perhaps that most democratic of legal institutions, with an unelected Federal bureaucracy. And, third, it undercuts the backstop role that State common law litigation can provide to back up the Federal law.

Just in passing, the ERISA law preempts even claims based on violations of ERISA, not just claims that are inconsistent with ERISA.

So when the Supreme Court concludes that Congress meant for the questionable judgment of Federal bureaucracies to supersede the common-sense wisdom of a common law jury, it leaves behind a hole in the law that has enormous potential for injustice.

Thank you.

[The prepared statement of Mr. McGarity appears as a submission for the record.]

Chairman LEAHY. Thank you, Professor.

Richard Cooper, our next witness, was chief counsel of the FDA during 1977 to 1979. He is currently a partner at the Washington law firm of Williams & Connolly, where his principal area of practice is food and drug law, with an emphasis on medical products.

Mr. Cooper, welcome. Please go ahead, sir.

STATEMENT OF RICHARD M. COOPER, PARTNER, WILLIAMS & CONNOLLY LLP, WASHINGTON, D.C.

Mr. COOPER. Thank you, Mr. Chairman. I thank you and the Committee for inviting me to testify here this morning.

The fundamental question that is put at issue by preemption in the food and drug field is who gets to decide whether a medical device or drug is safe and effective and who gets to decide what information will be put into labeling to guide doctors in prescribing and administering the medical product.

Under our Federal system, the supremacy of Federal law over State law is fundamental. The *Riegel* decision earlier this year involved express preemption. Congress in 1976, as part of the Medical Device Amendments, included a section that provides, in substance, that no State shall establish or continue in effect with respect to a device any requirement—any requirement—that is different from or in addition to a requirement with respect to the device under the Food, Drug, and Cosmetic Act and that relates to the safety or effectiveness of the device.

As early as 1959, long before the current Supreme Court, the Supreme Court recognized that State common law damages remedies have a regulatory effect and, thus, in effect, impose requirements. That was 17 years before the Medical Device Amendments of 1976. That understanding was reiterated and applied to product liability, a part of the common law, in the *Cipollone* decision in 1992. And in the *Sprietsma* case, another product liability case, in 2002, that recognition was endorsed by a unanimous Court.

In *Riegel*, the Supreme Court applied that established body of jurisprudence to FDA approval decisions with respect to a medical device. And although FDA has many problems, whether it is tomatoes or pharmaceutical factories in China, I am not aware of evidence that FDA is inadequately staffed or has inadequate resources to perform its review function with respect to medical devices or reviews of new drug applications.

When FDA reviews a Pre-Market Approval application for a medical device, it reviews a vast amount of data. It assesses effectiveness and safety and makes tradeoffs between design features that affect safety or effectiveness. It decides on the basis of the medical needs in the best interest of all potential users of the product and takes into account, as far as can be foreseen, those who are likely to derive a net benefit from it, whether it is saving life, whether it is maintaining health, whether it is enhancing quality of life, as well as those who are likely to suffer adverse experiences with the device. It takes into account what is known and what is unknown. And when FDA approves a product, it approves it with conditions that, together with the applicable statutory and regulatory require-

ments, must be obeyed by the manufacturer with very, very limited exceptions.

FDA could always hold the product off the market until there is more information to guide use, to make it safer and more effective, possibly to change design, or even to reveal new risks that might make one conclude that the product is unsafe. You could hold the product off the market forever until you had perfect information. If you waited for perfect information, if you insisted that no device ever malfunction, no drug ever cause an adverse reaction, we would have no devices and we would have no drugs. There are no perfect medical products.

The PMA products are only a very small proportion of the medical devices on the market today. All Class I devices and Class II devices and the vast majority of even Class III devices do not go through the PMA process, and *Riegel* and the other preemption decisions have no effect on the ability of harmed patients to seek legal redress.

Riegel is also consistent with the scope, the limited scope, for compensation from manufacturers under products liability law. Manufacturers are not insurers. In general, they are liable only if their product is defective or they are negligent, if they are at fault in some way. Once FDA has decided that a design is safe and acceptable and what is to be in the labeling, there is no fault in a manufacturer that markets that product with that design and with that labeling. Under the Supremacy Clause, State law requirements that would change the design or would change the labeling are preempted.

In general, this system benefits consumers as the flow of life-saving and life-enhancing products used by people, some of whom may be in this room, this hearing room, most of whom, millions of whom, are not in this hearing room this morning. Preemption also gives full respect to Congress by taking fully seriously the words that Congress enacted in the preemption provision of the Food, Drug, and Cosmetic Act.

Thank you.

[The prepared statement of Mr. Cooper appears as a submission for the record.]

Chairman LEAHY. Thank you very much.

Our next witness is Robert Lawless. Professor Lawless teaches at the University of Illinois College of Law. He is an expert in bankruptcy and corporate law, has published numerous articles on these topics. Professor Lawless has previously testified before this Committee on the implementation of the Bankruptcy Abuse Prevention and Consumer Protection Act, and we welcome him back here again.

Professor, please go ahead.

STATEMENT OF ROBERT M. LAWLESS, PROFESSOR OF LAW AND GALOWICH-HUIZENGA FACULTY SCHOLAR, UNIVERSITY OF ILLINOIS COLLEGE OF LAW, CHAMPAIGN, ILLINOIS

Mr. LAWLESS. Thank you, Mr. Chairman and members of the Committee. Thank you very much for inviting me to testify today.

As Senator Leahy indicated, my name is Robert Lawless. I am a professor of law at the University of Illinois College of Law,

where I study bankruptcy and financial services law, and my research focuses especially on how those laws, how those legal institutions affect the American family. And I really commend the Committee for having this hearing today and shedding light on the many ways the U.S. Supreme Court has decisions that happen outside the blur of the usual media headlines, but that really can dig into the pocketbooks of everyday Americans.

I am here today to talk about cases about credit cards, about bankruptcy, about consumer loans, some areas that we have not heard about yet this morning. But in the same way, what we have seen is a series of Supreme Court decisions that have centralized regulatory authority in the Federal Government and taken away the power of the States to provide protections for their citizens.

In my written testimony, I refer to a citizen of Maryland who has written some comments to the Federal Reserve's recent regulations on credit cards. And he complains about being charged an extremely high, exorbitant rate. Penalty default rates now on credit cards can run into the 30s. This gentleman was complaining about a rate, as he characterized it, in the "high 20s." The State of Maryland prohibits a creditor from charging more than 24 percent interest. An interest rate higher than 24 percent is considered usurious. Why can't a citizen of Maryland rely on their State law to protect them? Because of a decision of the U.S. Supreme Court known as *Marquette*.

Why do we have so much consumer debt in this country? Why do we have over $50,000 in consumer debt for every man, woman, and child in the United States? Again, because of that same decision, because of the *Marquette* decision, involving an interpretation of something known as the National Bank Act, which gives a bank the authority to charge interest at the rate allowed where the bank is located. This law had been passed 114 years before the case had reached the Supreme Court. At the time it was passed, this country was in the midst of the Civil War. The purpose of the National Bank Act was to establish a strong national banking system. The purpose of that particular section was to prevent a State like Nebraska, as was involved in that case, from ganging up on a Federal bank and driving federally chartered banks out of the State in favor of State-chartered banks.

What had been a section that was there to protect Federal banks was used in *Marquette* as now a sword for a bank in the State of Nebraska to go into the State of Minnesota and make consumer loans that were above the legal rate allowed by the State of Minnesota, but because they were within the rate of the laws of the State of Nebraska, the Supreme Court upheld the bank's actions.

Now, reasonable people can differ over whether this was a good idea or not. The effect of the *Marquette* decision was effectively to deregulate interest rates. But the important point here that we have been hearing over and over is that this ultimately was a decision for Congress to decide. By ruling in favor of the banking interest, Congress essentially locked in a regulatory policy. I do not think anybody realistically expected that consumer interests were going to be able to effectively come into Congress after the *Marquette* decision and seek to have it overturned.

I talked about some other decisions in my written testimony. Let me just focus on one more from last term, the *Watters* decision. Why can't States right now, especially State Attorneys General, enforce their own State consumer laws against national banks, the *Watters* decision? The Office of the Comptroller of the Currency issued a regulation defining the scope of its own authority to displace State law. In that regulation, the Office of the Comptroller of the Currency preempted State consumer protections as they applied to national banks. The *Watters* decision upheld the authority of the OCC to do this. Again, reasonable people might differ over this, but, again, this would be a policy decision for Congress to consider.

Because of the *Watters* decision, the New York Attorney General would not have been able to undertake an investigation into overbilling practices that was undergoing as that *Watters* case began its way through the Federal court system. The New York Attorney General was not investigating consumers who were trying to escape responsibility for loans, whether the New York Attorney General was trying to investigate cases of overbilling where the lender acknowledged receiving payments over and above the amount they were contractually entitled to. Such an investigation today would be preempted because of the U.S. Supreme Court's decision.

We have heard a lot about problems. Let me try to offer one solution, and that would be for Congress to start adopting an interpretive rule, either broadly or in particular statutes, that any ambiguity be resolved in favor of consumer interests. That would stop the problem of lock-in. That would stop the problem of having a decision from the Supreme Court that cannot effectively be overturned. If the tipping rule were to be adopted, then the burden of legislative change would rest with the financial services industry and the business interests were most able to come to Congress and have their interests represented.

Thank you for letting me speak this morning, and I will be happy to answer any questions you have.

[The prepared statement of Mr. Lawless appears as a submission for the record.]

Chairman LEAHY. Thank you, Professor Lawless. Let me ask my first question of Professor McGarity, and I should note that each of you will have a copy of the transcript; if you want to expand on your answers, feel free to. We are also going to probably have some questions for the record afterward.

Professor, you heard Ms. Robb's testimony, and here she has this 911 call, a malfunctioning device implanted in her chest, a malfunctioning device that the company knew could malfunction. She thought she was dying because of the severe pain, and probably as traumatically, her 6-year-old daughter thought her mother was dying. And yet she finds that nobody is accountable. The company knew the device was improper. They are not accountable.

Now, I wonder—they know they are not accountable, they are given this kind of blanket immunity—what is out there that might give them the incentive to do something right? We have laws on the books that for your conduct. If you drive down the road, you have got speed limit laws, and most people will follow them. Some do not. But if you had a sticker on your license plate which said

Professor McGarity does not have to follow these laws, there is no real incentive to follow them.

Now, some claim that the Supreme Court's *Riegel* decision is going to allow an injured consumer to go to court to enforce Federal agency regulations. That should be sufficient to protect consumers, but there is no compensation. So do you really think that is going to allow consumers to be protected? Is there anything in there that gives a real incentive for corporations to even notify consumers when they know there is not a heck of a lot consumers can do to them?

Mr. MCGARITY. I think there is very little—I mean, there is nothing there if there is no common law action available at all, which is the case now for fully approved devices. Now, what you have, of course, is the approval process so that the device is supposed to be shown to be safe and effective when it is approved.

That could have happened years ago. It could have happened decades ago. In the case of some agencies, it did happen back in the 1950s. The agency has never gone back and revisited the regulation or the approval, even though we have lots more information that has come in by way of adverse event reports in the case of FDA and other such sources of information, including academia, that show that various aspects are unsafe and that safer technologies are there. Until the agency withdraws that regulation or takes some action, there is no incentive for the company to do anything to even come up with safer technology.

Chairman LEAHY. Look at the results of this. I mean, Congress spent, I believe, a decade studying the problems of protecting workers' pensions and benefits before passing a sweeping law intended to increase protection of the vulnerable American workers. But Justice Scalia has taken the lead and ignored congressional intent, gutted the law that is supposed to ensure that workers with employer-sponsored health insurance and retirement benefits can count on them. But listen to Ms. Kurtek's testimony, we see what Judge Becker, the late Judge Becker, described as the "perverse effects" of Justice Scalia's cramped interpretation. Doesn't this, instead of protecting people within HMOs—as Mr. Anderson and others testify. Doesn't this really create a strong incentive for HMOs to deny claims? There does not seem to be anything that can happen to them if they do.

Mr. MCGARITY. Well, in fact, it can be a profit maximizer to deny the claims. The fact is that your employer and you have paid into the insurance company. The money is in their bank account drawing interest while they are denying the claim so that the entire time that that is happening, they are investing that money at the same time they are denying the claim. If there is no consequences, no accountability, as Ms. Kurtek pointed out, for doing that, there is exactly that. And I mentioned in my testimony a training session that was conducted in the late 1990s of these basically nurses who make the decision whether or not something is covered or not, and they train them that if it is an ERISA-covered claim, draw it out. If it is not ERISA, we might be held liable, so go ahead and get that thing taken care of.

Chairman LEAHY. Well, you know, I think about last week, Colorado's Governor, Bill Ritter, signed into law major crippling pen-

alties for health insurers who delayed or denied authorizing payments of a covered benefit without a reasonable basis for it. But doesn't Justice Scalia's line of ERISA decisions threaten to override such State laws?

Mr. MCGARITY. That is not so different from the Texas law that President Bush signed when he was Governor of Texas that was at issue in the *Davila* case, which did give a private right of action when your claim was unreasonably denied. The Supreme Court held that that was preempted. I expect that the Supreme Court—one hesitates to predict always, but my prediction would be that this provision is DOA, dead on arrival.

Chairman LEAHY. I am going to yield to Senator Hatch, and I have other questions. We could spend hours and hours with each one of you on this. I will submit questions to you. And Senator Whitehouse is going to chair. I must admit—and this, I agree, will be somewhat editorial commenting, but you hear this buzz word of "activist" judges. I cannot think of any more activist judges than many on the Supreme Court who have overturned congressional actions that were intended to protect consumers, when basically they end up overturning them to protect multinational corporations, and that is one Senator's opinion. But I thank each one of you for being here.

Ms. Robb and Ms. Kurtek, you are not people who are used to testifying before congressional committees, and I thank you for being here. I hope your son, Ms. Kurtek, still goes to the spelling bees and does those things. Ms. Robb, I hope your daughter still wants to hug her mom.

Senator Hatch?

Senator HATCH. Well, thank you, Mr. Chairman. I appreciate you holding this hearing. It is an interesting hearing to me. And as many things in the law, we find a lot of situations that are very difficult to resolve. I empathize with both of you, Ms. Robb and Ms. Kurtek. Did either of you sue the doctors or the hospitals?

Ms. KURTEK. No.

Senator HATCH. Did you, Ms. Robb?

Ms. ROBB. No, I did not.

Senator HATCH. OK. Well, it seems to me there was some potential there, but, still, these issues are important issues.

Now, Mr. Cooper, I want to thank you for your testimony. Reading your resume, and, of course, knowing a lot about you, it is obvious that you are not only the expert on FDA law, but you were chief counsel for the FDA during the Carter administration. And you have a real sense of how the FDA works, and it is a practical sense. So I want to commend the Chairman and the Ranking Member for inviting all of you to testify, but especially you since you have this broad background at the FDA. And this seems to be a major, major aspect of at least this one part of this problem.

Now, Mr. Cooper, is there any way that Ms. Robb, based upon the statement that she made today, could have sued the insurance company under the Medical Device Act?

Mr. COOPER. You mean the manufacturer?

Senator HATCH. Yes, the manufacturer. Excuse me. The manufacturer.

Mr. COOPER. I cannot comment on the details of her case without knowing a lot more about it—

Senator HATCH.—that she could not.

Mr. COOPER. Yes, I can speculate. The preemption doctrine under *Riegel* applies to the FDA approval decision, so I think it protects against lawsuits challenging the design of the product or the labeling of the product. But if, for example, the malfunction she described resulted from a defect in manufacturing, if the product was not manufactured to its design specification—

Senator HATCH. The law allows an opening for that, doesn't—

Mr. COOPER. Pardon?

Senator HATCH. The laws allows an opening to sue for that.

Mr. COOPER. That is a possible opening. I don't know whether that happened, but that is a possible opening.

Senator HATCH. I just wanted to make that clear, that there may be a cause of action there if there was negligence on the part of the manufacturer or a defect in the product that they—

Mr. COOPER. In the manufacturing.

Senator HATCH. Right, in the manufacturing, which bothers me a lot because she has gone through an awful lot of pain. It is more difficult to see how the ERISA laws would be overturned in the case of Ms. Kurtek, but, nevertheless, these are matters of great concern.

Mr. Cooper, what would happen to a company if it ignored the requirements for use set by the FDA? The requirements the FDA set, would it be liable under State tort law? What would be its exposure under Federal law?

Mr. COOPER. Well, if a company violated one of the conditions of approval of its product, it could be liable under both Federal and State law. If it manufactured a product that differed in a material way from the design that FDA had approved, the product would be adulterated. If it materially changed the labeling from what FDA had required in its approval, the product would be misbranded. It would also be—in the case of a device, an unapproved product and would be adulterated. In the case of a drug, if the company changed the formula for the drug, for example, without FDA approval, the drug would become an unapproved product, and there is a separate prohibited act in Section 301 of the Federal Food, Drug, and Cosmetic Act that would make the shipment of that drug in interstate commerce unlawful. In addition, the Supreme Court has been very clear in all of its FDA preemption decisions that a State law theory of liability that, in effect, enforces a Federal requirement is not preempted.

Senator HATCH. Now, the distinguished Chairman kind of indicated that the *Riegel* case was an activist decision. After all the sturm and drang over the *Riegel* decision, I think it is important to keep in mind that it was an 8–1 decision. This was not some 5–4 decision. This was an 8–1 decision.

Mr. COOPER. That is correct, and it was clearly foreshadowed in prior Supreme Court decisions and by the vast majority of courts of appeals decisions that had considered the question. It was not a bolt from the blue.

Senator HATCH. Well, could you elaborate on that decision, what it does and does not say? And also, in your view, did the decision come as a surprise to the experts in the legal community?

Mr. COOPER. I think it was not a surprise, and I would emphasize that it protects only a very small percentage of the medical devices—the thousands and thousands of medical devices that are marketed. It protects only those that go through the PMA route to the market and have been approved by FDA in accordance with what the Supreme Court correctly described as a "very rigorous process," backed up by lots of data.

Senator HATCH. Could I ask one more question, Mr. Chairman.

Senator WHITEHOUSE. [Presiding.] Of course. Please take your time.

Senator HATCH. This is important stuff because, you know, I am one of the authors of some of the subsequent aspects of the Medical Device Act, and I want to have it right. I certainly do not want to see people suffer. And I would appreciate any advice you could give to the Committee as to whether we should change some aspect of the law to make this more workable and to make it more fair, if there is, in fact, unfairness.

Now, I agree with you, there are millions and millions of people who benefit from these devices, and there is no way you could absolutely be sure that any device is perfectly harmless or that any pharmaceutical is perfectly harmless. They all have risks, and they all have adverse events to a degree, and this is part of this.

But let me ask you this question: Mr. Anderson in his testimony—and I do not mean to not give you this question, Mr. Anderson, but I would like to—since I have been asking Mr. Cooper, I would like to just ask this of him.

In his testimony, he stated that legislative efforts to undermine ERISA preemption would discourage employers from providing health benefits to their employees.

Do you agree or disagree with that?

Mr. COOPER. I am really not an expert on ERISA.

Senator HATCH. OK. Well, then, let me ask the question of Mr. Anderson. I do not think there are very many experts on ERISA, I tell you. It is a very complicated set of laws.

Mr. COOPER. We should treasure the one we have.

Senator HATCH. Yes, that is right. But let me tell you, your testimony there is a matter of great concern to me. The fact of the matter is that we are finding that employer-provided health care is diminishing gradually in a rapid fashion, and there are many reasons for that. But I for one want to do everything we can to give incentives to employers to provide health care. So if you care to expand on your testimony there so that we all know exactly what you think will happen.

Mr. ANDERSON. Thank you, Senator. I would be pleased to.

As you point out, ERISA is a voluntary statute. Employers choose to offer employer-provided health coverage, and, unfortunately, in recent years, fewer and fewer employers have been able to afford to offer health coverage. There are a lot of costs associated with or bundled into delivering medical benefits—medical advances, liability concerns, so on and so forth. And I think anything that exposes employers to additional risk related to their employer-

provided health coverage will lead to those employers beginning to exit the system.

I would also like to clarify what I think was a misrepresentation earlier in today's testimony. It is easy to demonize health insurers here, that they are looking to line their pockets or some such thing. But what is often overlooked is somewhere in the neighborhood of 73 million Americans who have employer-provided health insurance enjoy self-insured health insurance. What that means is, while there may be an insurer who handles some of the paperwork or provides the doctors or the network, every single dollar associated with the cost of that employer-provided coverage comes exclusively out of the employer's pocket. This is not a scheme to enrich insurance companies for those 73 million Americans.

Senator HATCH. Well, let me interrupt you for a second. Ms. Kurtek's case is the—I would hate to go through what she went through. I think anybody sitting and listening to this would just hate to have to go through the terrible pain, suffering, amputations, and so forth that she has gone through. Do you see no way that her case could be brought under ERISA?

Mr. ANDERSON. Well, I see a couple things—

Senator HATCH. Would it be preempted completely under the ERISA laws? Or is there some way around the ERISA laws that would give her a cause of action?

Mr. ANDERSON. I think the United States in the—or the Supreme Court in the *Davila* case, which we heard before, unanimously concluded that cases like that should be the sole province of the Federal judiciary, not State law.

Senator HATCH. Could she have brought her case in the Federal judiciary?

Mr. ANDERSON. She sure could have, and while I am not aware of—

Senator HATCH. Could she—OK.

Mr. ANDERSON.—her case, there has been a lot of regulatory effort in this area recently by the Department of Labor. The last 5 or 8 years has seen a huge expansion of the rules associated with ERISA claims and appeals in the area of health plans. Had a physician determined that a patient was suffering from some medical condition which rises to the level of urgent care, that claim has to be heard in 3 days; that appeal has to be heard in 3 days. On the seventh day, that individual could make their way to Federal court to receive an injunction to receive that benefit.

I don't know the particulars of this case. I just want to highlight that our Government has been very active in this area, ensuring that Americans have quick access to medical care and medical decisions when they are suffering from life-threatening illnesses or diseases.

Senator HATCH. Could I just ask one more? Then I am going to have to leave.

Senator WHITEHOUSE. Sure.

Senator HATCH. The Chairman has been very gracious to me. I really appreciate it. But I would like to ask just one other question of Mr. Cooper, because I am concerned about these two women, and others who are like them. I agree the vast majority of cases probably could not be brought. But, Mr. Cooper, you were forthright in

your testimony acknowledging that no product goes to the market absent any risk. And you explained, however, that this risk does not emerge through the fault of the FDA or the manufacturer. If that is the case, it seems that negligence claims in State court might not be the best way to compensate persons injured by properly approved and used products.

Now, have you given any thought and could you give us the benefit of your thinking here on this Committee to alternative remedies that Congress might pursue to provide compensation to these persons?

Mr. COOPER. I have given it some thought, Senator, and have a couple of possible answers. One is a system of compensation quite different from most of our compensation system would be a no-fault system. We have that, I think, for some childhood vaccines. We may have that in some other circumstances. Under traditional tort law, the plaintiff has to show that the manufacturer was somehow at fault. Either the design, the manufacturing, or the labeling of the product had some defect—this is any kind of product, not limited to medical products—or that the manufacturer was negligent. That is a kind of fault.

If the manufacturer was not at fault, then there is no recovery, and you could have people who go through these kinds of experiences, and the manufacturer is not at fault. It just happened, because no drug or medical device is perfect. There are always going to be some people who will have adverse experiences, and it is nobody's fault.

My father died in surgery or as a result of surgery, shortly after surgery. Something went wrong in the surgery. But it was not clear that anybody was at fault. So there was no lawsuit. That happens in life. And if you do not have a no-fault system, then you need a network or set of networks for insurance, for health insurance, for disability insurance, for life insurance, to cover the bad things that can happen to people. You need a social safety net, because, if you put it all on the manufacturer, then you are going to drive the prices of goods way up.

Senator HATCH. Well, I apologize to you other two professors for—I have a couple questions I would like to ask both of you, and I appreciate the testimony you have given as well. This has been an extremely interesting hearing to me and one that causes me great concern on both sides of the equation. And I can easily see why this is—having worked on both of these laws, trying to get them right, we had to balance a lot of interests. There is no question about it. And we have an illustration here of where, you know, I wish we could have done a better job of solving these things. But, on the other hand, our current tort system does not solve a lot of things either.

Thank you, Mr. Chairman. You were very gracious to allow me to ask these extra questions.

Senator WHITEHOUSE. It is my pleasure. As the audience well knows, the distinguished Senator from Utah is a former Chairman of this Committee who served with great distinction. He is one of the leading trial lawyers in the history of Utah, and his thoughts and observations are most welcome. And I was very pleased to lis-

ten and have you take the time that you needed, Senator, since there was nobody else competing for our attention here.

Senator HATCH. If you would yield for just one further comment, I agree with Mr. Cooper that the FDA—I agree with Senator Specter that the FDA needs more money, that we really treat it like a wicked stepsister rather than doing what we should when it handles up to 25 percent of all consumer products in America. But I also agree with you, Mr. Cooper, that the FDA is very diligent and has the capacity and the ability to do the work in this area in an extremely refined and good manner. And I do not particularly go along with people who do not believe the FDA can do a high-quality job. I know it can, and especially if we get that—you know, I passed the FDA Revitalization Act back in 1992 to build the plaza out there, to get everything under one roof with the highest ability computer-wise and every other scientific instrumentation-wise so that we would attract the top people there. And we are gradually getting there, but we are still—now, that was in 1992, and we are still only beginning getting that whole White Oak plaza going. But I really appreciate people like you who have served so long and hard in these areas.

Mr. COOPER. If I may just say, Senator, your work on FDA matters has been a very important contributor to such success as the agency has had.

Senator HATCH. Thank you.

Mr. COOPER. That should be acknowledged.

Senator HATCH. Thank you.

Senator WHITEHOUSE. I would like to start on a historical note, because the question of the role of the common law in this country is at issue when Federal administrative regulatory preemption is the topic, and so is the role of the American jury system. And I know that there are people who could go on at considerable and exhaustive length about this, and I am not inviting that at this late stage in the hearing. But I do think it is important that the hearing should in some fashion reflect the importance to the founders of this country of the American common law and of the American jury system.

If you read from the Revolutionary Era of the various principles that America was fighting for, if you would ask any of the Founding Fathers to put together a top-ten list of the principles that they were willing to put their lives, their reputations, and their sacred honor—their lives, their fortunes, and their sacred honor on the line for, I suspect every single one of them would have had the common law and the jury system in that top-ten list. And I am not, however, a professor so, if I may, I will turn to Professor McGarity and Professor Lawless to see if they have an observation along those—in that context.

Mr. MCGARITY. Well, I think you are absolutely right that the common law jury is written into the Seventh Amendment of the United States Constitution in civil cases, not just in criminal cases, and most State Constitutions recognize a right for a jury. So, yes, absolutely. And we trust juries. And the fact of the matter is the jury has been over the last 15 or 20 years severely maligned and, in my view, quite inappropriately so, too, usually through anec-

dotes, like the McDonald's case and things like that that just get repeated over and over and over again—

Senator WHITEHOUSE. Often with critical relevant facts omitted.

Mr. MCGARITY. That is right, omitting the fact that she was not in the car as it was driving down the street, that she was sitting in a parked car, and lots of other things. And the fact of the matter is, if you look at the objective evidence, that is, collected data on juries, one they do not vary that much from judges in their decisions on the merits. So there are very few instances of juries off the reservation, so to speak. And if they do go off the reservation, the judges can correct that by various procedural devices that are available.

They tend to view plaintiffs quite skeptically these days—in fact, more skeptically these days than judges do, no doubt in part due to the advertisements that they have been hearing about all the abuse of the common law system that they get on their daily TVs. But the fact of the matter is the jury is a profoundly democratic institution. I, unfortunately, have never served on one because I always get excluded. I always go down and try. But my wife has served on them, and she was most impressed with the seriousness with which they take their job.

Senator WHITEHOUSE. Well, as somebody who has been a lawyer through a significant portion of his life, I have developed a very strong confidence in the American trial jury as a collective group to sift through facts and legal arguments and come to, almost every time, a very fair and correct decision. But in addition to that, I think there is another point that is worth exploring a little bit, and that is that, again, those Founding Fathers who set up this country were keenly interested in the abuse of power. And they were keenly interested in the passions of politicians and containing them. They were keenly interested in trying to diffuse political power in such a way that Americans essentially were safe from their Government.

I see the common law backdrop that they fought for and the jury system that they fought for as a part of that system of checks and balances. And a word that has not yet been mentioned, or at least I did not notice it if it was—I apologize—is "regulatory capture." And I would like to talk about that just for a minute and ask for your thoughts. For people who are listening, to me, anyway, regulatory capture means when an agency that purports to be a public agency representing the general public in fact gets taken over politically by the organizations that it was designed to regulate. It is a widely known phenomenon through administrative law particularly because it is a little bit more under the radar then. And it strikes me that if you are doing your best to deprecate and to diminish the jury system, and if you are doing your best to eliminate the common law, and if you are doing your best to set as much power as you possibly can in the hands of an administrative agency that is not elected but is appointed by political actors, you are creating a very grave risk. And, indeed, it strikes me that special interests would be particularly encouraged to focus the full force and might of their political and economic strength on administrative agencies that enjoy preemptive authority, because they know that if they can capture that regulatory agency, they have won the day.

The prize is a tantalizing one: no more juries, no more liability, no more State regulation, no more accountability to the law, just a regulatory agency that you now own.

And it is a horrible thing for the general American public, but from a highly self-interested point of view, there can almost be no greater prize for a special interest than to own or control or dictate terms to its regulatory agency. And that prize is even more valued and the risk of that happened I would think goes up even more once you have put all the eggs in that basket.

Mr. LAWLESS. I completely agree with that, Senator. What we are talking about, the modern administrative state was unknown to the Founders, but you are absolutely right about their genius in that they set up checks and balances that are still with us today—

Senator WHITEHOUSE. I am afraid—I am sorry. I have to interrupt this hearing. Certain checks and balances have just been deployed in the U.S. Senate. This hearing has gone beyond 2 hours. There is a rule that requires hearings to conclude within 2 hours unless unanimous consent, which is ordinarily provided as a matter of courtesy and formula, is given. A Republican Senator has invoked the 2-hour rule, which means that this Committee hearing cannot take place for more than 2 hours after the Senate was called into session, and the Senate was called into session at 9:30 this morning. It is now just after 11:30.

I regret that this tactic has been deployed again. It was done yesterday when a Committee was exploring questions of torture and of abusive interrogation techniques. It has now been employed here. But the hearing must be suspended due to an objection of an unnamed Republican Senator.

This is an important hearing. I thank the witnesses for their testimony. I particularly thank Ms. Robb and Ms. Kurtek for this testimony. And I consider it an embarrassment on the part of my institution that after the effort that you have taken to come here today and after the nature of the testimony that you have given that we should be put in this position and obliged to interrupt the hearing. So on behalf of the U.S. Senate, I apologize to you.

The hearing is now recessed.

[Whereupon, at 11:33 a.m., the Committee was adjourned.]

[Questions and answers and submissions for the record follow.]

QUESTIONS AND ANSWERS

JOHN W. VARDAMAN
PAUL MARTIN WOLFF
JOHN G. KESTER
WILLIAM E. McDANIELS
BRENDAN V. SULLIVAN, JR.
RICHARD M. COOPER
GERALD A. FEFFER
JERRY L. SHULMAN
ROBERT B. BARNETT
DAVID E. KENDALL
GREGORY B. CRAIG
JOHN J. BUCKLEY, JR.
TERRENCE O'DONNELL
DOUGLAS R. MARVIN
JOHN K. VILLA
BARRY S. SIMON
KEVIN T. BAINE
STEPHEN L. URBANCZYK
PHILIP J. WARD
F. WHITTEN PETERS
JAMES A. BRUTON, III
PETER J. KAHN
LON S. BABBY
MICHAEL S. SUNDERMEYER
JAMES T. FULLER, III
BRUCE R. GENDERSON
CAROLYN H. WILLIAMS
F. LANE HEARD III
STEVEN R. KUNEY
GERSON A. ZWEIFACH
PAUL MOGIN
HOWARD W. GUTMAN
MARK S. LEVINSTEIN
VICTORIA RADD ROLLINS
DANIEL F. KATZ
WILLIAM R. MURRAY, JR.
EVA PETKO ESBER
STEPHEN D. RABER
DAVID C. KIERNAN
LON E. MISSLEWHITE
ROBIN E. JACOBSOHN
HEIDI K. HUBBARD
GLENN J. PFADENHAUER
GEORGE A. BORDEN
ROBERT J. SHAUGHNESSY
DAVID S. BLATT
ARI S. ZYMELMAN
DANE H. BUTSWINKAS
LAURIE S. FULTON
DENNIS M. BLACK
PHILIP A. SECHLER
LYNDA SCHULER
PAUL K. DUFFERT
R. HACKNEY WIEGMANN
ROBERT M. CARY
KEVIN M. HODGES

LAW OFFICES
WILLIAMS & CONNOLLY LLP
725 TWELFTH STREET, N.W.
WASHINGTON, D. C. 20005-5901
(202) 434-5000
FAX (202) 434-5029
www.wc.com
EDWARD BENNETT WILLIAMS (1920-1988)
PAUL R. CONNOLLY (1922-1978)

DAVID M. ZINN
JOSEPH G. PETROSINELLI
STEVEN M. FARINA
KEVIN M. DOWNEY
THOMAS G. HENTOFF
PAUL B. GAFFNEY
ROBERT A. VAN KIRK
MARGIE R. ZIEGLER
KENNETH C. SMURZYNSKI
JOHN E. SCHMIDTLEIN
CRAIG D. SINGER
JAMES L. TANNER, JR.
J. ANDREW KEYES
GILBERT O. GREENMAN
M. ELAINE HORN
ENU MAINIGI
MICHAEL F. O'CONNOR
PAUL T. HOURIHAN
WILLIAM J. BAUMAN
MARGARET A. KEELEY
MEGAN E. HILLS
EDWARD J. BENNETT
TOBIN J. ROMERO
BETH A. LEVENE
THOMAS G. WARD
WILLIAM T. BURKE
LISA M. DUGGAN
JOHN E. JOINER
NICHOLAS J. BOYLE
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ANDREW W. RUDGE
DENEEN C. HOWELL
ALEX G. ROMAIN
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JONATHAN M. LANDY
CHRISTOPHER N. MANNING
RYAN T. SCARBOROUGH
JENNIFER G. WICHT
STEPHEN D. ANDREWS
MALACHI B. JONES
THOMAS H. L. SELBY
KEVIN HARDY
EDWARD C. BARNIDGE
JOSEPH M. TERRY
AARON P. MAURER
JON R. FETTEROLF
OF COUNSEL
RAYMOND W. BERGAN
JEREMIAH C. COLLINS
DAVID POVICH
J. ALAN GALBRAITH
ROBERT P. WATKINS
MARY G. CLARK
STEVEN A. STEINBACH
JACQUELINE E. MAITLAND DAVIES

July 3, 2008

By 1st Class and Electronic Mail

Office of Honorable Patrick Leahy
Chairman, Committee on the Judiciary
Washington, DC 20510-6275
Attention Justin Pentenrieder, Hearing Clerk

Dear Mr. Pentenrieder:

My answers to the questions posed to me by Senator Grassley and Senator Specter, and sent to me in the letter of June 19, 2008 from Sen. Leahy, are attached.

Sincerely,

Richard M. Cooper

44331.111

Senator Grassley's Written Questions for Judiciary Committee Hearing "Shortchange for Consumers and Short-shrift for Congress? The Supreme Court's Treatment of Laws that Protect Americans' Health, Safety, Jobs and Retirement", June 11, 2008

1. It took nearly 2 years after the manufacturer and the Food and Drug Administration first became aware of a cardiovascular risk for a change to be made in the drug labeling for Vioxx. More recently, based on a review of documents from recent litigation against the manufacturer of Vioxx, several researchers found selective presentation of data to the FDA that minimized the appearance of an increased risk of death and the manipulation of scientific literature through ghost writers.

a. If individuals cannot pursue claims against manufacturers even after a federal agency has failed to act in a timely fashion to inform the public of emerging safety risks, what is the recourse for individuals who are injured by prescription drugs and/or medical devices?

b. In your opinion, are there any situations related to individuals being injured by medical devices and/or drugs where state laws and interests in citizens' safety and welfare would be appropriate?

c. Are private tort claims warranted when drug companies and/or device manufacturers have been less than forthcoming about the risks of their products? Please explain your answer in detail.

Answer

The law firm at which I am a partner, Williams & Connolly LLP, represents Merck in litigation related to Vioxx. I, therefore, would prefer to address your questions outside the context of particular allegations or premises, except to note my understandings (a) that Merck has consistently stated that it thoroughly and properly disclosed to FDA safety information, including the actual data, from its extensive studies of Vioxx so that FDA could conduct its own analyses and (b) that, as to any "delay" in changing the labeling, Merck reported the results of the VIGOR study – the clinical study that led to the labeling change – to FDA within weeks of the unblinding of the results, and thereafter published those results, which received extensive public debate prior to the change in the labeling, including a review by an Advisory Committee of leading scientists convened by FDA in February 2001 to analyze and consider the ramifications of the VIGOR results and to assist FDA and Merck in determining the language that should be included in revised labeling.

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a. Through no fault of a manufacturer or FDA, there is always a trade-off between approving a drug or device for use by patients who may benefit from it now and waiting for additional data that may clarify further how a drug or device may be made safer or more effective or may be labeled so as to be used more safely or more effectively. FDA does a far better job at conducting this analysis than judges and juries could do because FDA is able to conduct its analysis from the perspective of the public's health and not solely from the perspective of the effect of a drug or device on a particular individual. Moreover, FDA is in a far better position than the tort system to determine the contents of the official labeling of a drug or device and to calculate the consequences of a labeling change with respect to both the use of the particular drug or device and alternative therapies to which doctors and patients could be driven by a change in the labeling for a particular drug or device. It is important that the Congress adequately fund FDA and conduct effective oversight of its management and performance, so as to reduce mistakes and delays in conducting these analyses to the minimum possible. In sum, patients using drugs and devices are best served by an adequately funded and properly performing FDA. Some other aspects of this question are addressed in my prepared statement.

b. As explained in my prepared statement, the tort system provides compensation only where a manufacturer has been at fault; if a manufacturer has not been at fault, the tort system provides no compensation to an injured patient. The purpose of the preemption doctrine in the field of food-and-drug regulation is to protect the role of FDA as the national agency for setting the standards for determining whether a manufacturer is at fault with respect to the design and labeling of its FDA-approved drug or device.

If a manufacturer has materially violated a relevant condition of the approval of its drug or device, or violates some other requirement of the Federal Food, Drug, and Cosmetic Act ("FDCA"), there may be liability under a traditional products-liability theory that seeks to enforce a state-law requirement that is "parallel" (presumably, identical, except that it is based on state rather than federal law) to the federal condition or requirement that the manufacturer violated. The Supreme Court did not address that kind of situation in *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008). *See id.* at 1011. Such a theory of liability would limited by *Buckman Co. v. Plaintiffs' Legal Committee*, 521 U.S. 341 (2001),

c. As noted below in my answer to Senator Specter's first question, FDA has the authority to obtain from a manufacturer information FDA needs to assess the safety, effectiveness, and labeling of a drug or device. As a practical matter, FDA's authority also is broad enough to enable it to determine whether a manufacturer has provided information that is misleading or has withheld required safety information.

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In *Buckman*, Justice Stevens, joined by Justice Thomas, expressed the view that an injured individual should be able to pursue a tort claim based on fraud on FDA where FDA has previously determined that fraud has occurred and that such fraud requires removal of the product involved from the market. *Id.* at 354. The reasoning of Court did not support that view, but the type of situation hypothesized by Justices Stevens and Thomas was not presented in *Buckman* and might be presented in a future case.

2. The Supreme Court held in Buckman Co. v. Plaintiffs' Legal Committee that "the plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, the FDCA [Food, Drug, and Cosmetic Act], as amended by the MDA [Medical Devices Amendments of 1976]" and found that "would-be applicants may be discouraged from seeking § 510(k) approval of devices with potentially beneficial off-label uses for fear that such use might expose the manufacturer or its associates (such as petitioner) to unpredictable civil liability." What, in your opinion, is the recourse for individuals who are injured by a device that was approved based on fraudulent and/or misleading data/information to the FDA?

Answer

Knowing and willful submission to FDA of fraudulent data or information is a crime under 18 U.S.C. § 1001 and, depending on the circumstances, may violate other federal statutes as well. In a successful prosecution for such fraud, an individual injured by a product the approval of which was procured by the fraud may benefit from an order of restitution under 18 U.S.C. §§ 3556 and 3663. Under section 3663(b)(2), in the case of an offense resulting in bodily injury to a victim, for example, the defendant may be sentenced to pay an amount equal to the cost of necessary medical and related professional services and devices, necessary physical and occupational therapy and rehabilitation, and lost income.

3. When the Food and Drug Administration proposed its prescription drug labeling rule in December 2000, the Agency explicitly stated that "this proposed rule does not preempt State law." Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81082, 81103 (proposed Dec. 22, 2000). Further, the FDA stated, "FDA has determined that this proposed rule does not contain policies that have federalism implications or that preempt State law." Yet in the preamble to the final rule, the FDA states, "FDA believes that under existing preemption principles, FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary State law." Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922,3934 (Jan. 24,2006). In your opinion, did the FDA act appropriately? Please explain your answer in detail.

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Answer

I believe that FDA acted appropriately, although its action might have been more widely accepted had it given further opportunity for public comment on the preemptive effect of its drug-labeling regulations. Between the proposed rule and the final rule, significant developments had occurred in preemption jurisprudence. *See, e.g., Sprietsma v. Mercury Marine,* 537 U.S. 51 (2002); *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). In addition, I think FDA's final rule gave adequate reasons for the Agency's change of view.

Of course, there was also a change of Administration between the time of publication of the proposed rule and the time of publication of the final rule. Whether and to what extent federal regulations shall have preemptive effect is a matter of policy on which, within the scope permitted by applicable statutory provisions, an elected Administration may properly express its intent and its views.

Questions for the Record from Senator Specter

"Short-change for Consumers and Short-shrift for Congress? The Supreme Court's Treatment of Laws that Protect Americans' Health, Safety, Jobs and Retirement."

1) In your written testimony, you assert that the discovery process in litigation is inefficient and the FDA could obtain the same information through effective use of tools it already has. What are these tools? In your opinion, has the FDA made effective use of the tools you refer to?

Answer

Section 704(a) of the FDCA, 21 U.S.C. § 374, provides in part:

> In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, or restricted devices are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, or restricted devices which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data

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> as to qualifications of technical and professional personnel performing functions subject to this Act), and research data (other than data relating to new drugs, antibiotic drugs, and devices and subject to reporting and inspection under regulations lawfully issued pursuant to section 505(i) or (k) section 519, or 520(g), and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j)).

Thus, with certain exceptions, FDA has statutory authority to inspect all records and other things bearing on whether a manufacturer is shipping prescription drugs, OTC drugs for human use, or restricted devices that are adulterated, misbranded, or lacking a required approval, or bearing on some other type of violation of the FDCA. The data that are outside that authority are not needed for the Agency to be able to determine whether a drug or device is in violation of the FDCA. Thus, FDA's inspectional authority enables it to determine whether such a product's design, manufacturing, and labeling accord with applicable requirements.

In addition, FDCA § 519(a), 21 U.S.C. § 360i(a), provides in part:

> Every person who is a manufacturer or importer of a device intended for human use shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such device is not adulterated or misbranded and to otherwise assure its safety and effectiveness.

Under that authority, FDA can require device manufacturers to gather such information as the Agency needs to determine whether devices are adulterated or misbranded and to assure the safety and effectiveness of devices; and FDA can require device manufacturers to organize and present the information in the manner most useful to the Agency. That provision also directs FDA to issue regulations requiring device manufacturers to submit information about malfunctions that may cause or contribute to, or that may have caused or contributed to, a death or serious injury. FDA has issued such regulations. *See* 21 C.F.R. pt. 803 (2007). FDA requires holders of approved premarket approval applications ("PMAs") to submit periodic reports containing specified types of information. *See* 21 C.F.R. § 814.84 (2007). The Agency has also reserved authority to require holders of particular PMAs to maintain records and submit additional information as the Agency may require. *See* 21 C.F.R. 814.82 (2007).

As to approved new drugs, FDCA § 505(k), 21 U.S.C. § 355(k), provides in part:

> (1) In the case of any drug for which an approval of an application filed under subsection (b) or (j) is in effect, the applicant shall establish and

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> maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section [providing for withdrawal of approval]. Regulations and orders issued under this subsection and under subsection (i) shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.
>
> (2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

Under that authority, FDA can require holders of approved new drug applications to gather such information as the Agency needs to determine whether approved new drugs are adulterated or misbranded, and to assure their safety and effectiveness; and FDA can require such holders (which generally are pharmaceutical manufacturers) to organize and present the information in the manner most useful to the Agency.

FDA has issued regulations that require manufacturers to report adverse events and to submit periodic reports containing specified types of information. *See* 21 C.F.R. §§ 314.80, 314.81 (2007).

My general sense is that FDA has made effective use of its authority to issue regulations requiring disclosure to it of information relating to drugs and devices, but I am not in a position to assess the agency's general use of its inspectional authority or its processing of information submitted to it.

2) Some argue that the FDA is "captured" by the industries it is supposed to be regulating. As a result, the FDA makes decisions that are favorable to the medical device and pharmaceutical industries. As a former Chief Counsel at the FDA and someone who has worked closely with the FDA over the past few decades, do you believe this is accurate?

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Answer

I believe it is not accurate to say that FDA has been "captured" by the industries it is supposed to regulate. FDA has very few political appointees, and those political appointees generally are concerned with matters of broad policy and budget. With only rare exceptions, decisions about approvals and other actions as to individual products are made by career employees with the relevant professional qualifications. I believe that the most significant outside influences on those career employees are opinion leaders (generally, academics) in their respective medical, scientific, and other professional disciplines and congressional committees that take an interest in product approvals and other agency decisions about products. I believe that regulated firms do not have undue or otherwise improper influence on FDA decisions about individual products or on FDA enforcement decisions in individual cases.

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UNIVERSITY OF ILLINOIS
AT URBANA-CHAMPAIGN

College of Law
504 East Pennsylvania Avenue
Champaign, IL 61820

August 21, 2008

Mr. Justin Pentenreider
Hearing Clerk
United States Senate
Committee on the Judiciary
Washington, DC 20510

Dear Mr. Pentenreider:

This letter responds to questions posed by Senator Dianne Feinstein following my testimony at the June 11 hearing of the Senate Judiciary Committee on "Short-Change for Consumers and Short-Shrift for Congress." I will answer each of the questions in order.

Question One: I have been concerned for a long time about the rising levels of consumer debt in our country. According to the Federal Reserve, Americans owed a total of $39 billion in revolving debt – primarily credit card debt – in January 1978. The data for April 2008, which are the most recent data available, show that Americans owed $949 billion in revolving debt.

In your view, how strong is the connection between the Supreme Court's 1978 decision in the *Marquette* case and the massive increase in credit card debt?

A: The statistics you cite are a troubling indication of our deeply indebted consumer society. Over the course of a generation, we have gone from a nation where consumers considered debt as something unusual, an almost dangerous financial device that could bring disaster if not used responsibly, to a nation where debt is part of everyday life. Our media are full of reports about consumers in over the heads, and radio stations run contests promising to repay the debt of a lucky winner. Most every American can relate a story about someone from their neighborhood, their church, or their school who has encountered financial ruin because of excessive debt. The change in attitude toward debt is one of the greatest cultural shifts of our generation. American society will be feeling the effects of this shift for many years to come. *Marquette*[1] was a necessary condition but not sufficient alone to cause all of these changes.

Allow me to take both of those ideas separately; how *Marquette* was necessary but also not sufficient alone. First, how was *Marquette* a necessary condition to these changes? At its most fundamental level, the *Marquette* decision was a decision to let states export their own regulation for consumer interest rates. The inevitable consequence was that states with the least to lose and the most to gain would loosen their regulatory scheme and then export that scheme to other states. Specifically, low-population states could remove their usury caps, an action which might visit some misery on their own citizens, but the losses from this misery would be far less than the

[1] *Marquette National Bank v. First of Omaha Service Corp.*, 439 U.S. 299 (1978).

phone 217-333-0931 · *fax* 217-244-1478

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revenues flowing from the increased banking services and income that would occur in the state. On the other hand, high-population states faced a different policy calculus. The repeal of usury laws might bring new revenues to the high-population states, but offset against those revenues would have to be the increased financial loss that would accrue to a broad population base and that usury laws had sought to prevent for hundreds of years.

In the wake of the *Marquette* decision, it is not surprising that less populous states were the first movers in repealing their usury laws and then exporting their new laws across the country. Faced with a world where lenders could prey on their citizens even if their usury laws were left unchanged, it made little sense for any state to keep these caps. If usury laws stayed in place, large states would still suffer the misery without any chance of offsetting benefit through increased banking activity. Thus, we have the world today where many states of all sizes have usury laws on the books that provide no effective regulation of consumer interest rates.

With the usury laws effectively gone, consumer lenders exponentially expanded the amount of consumer credit available. Formerly unprofitable loans became profitable. In the decade after *Marquette*, consumer borrowing was said to have become "democratized," meaning that consumers across all social strata now had access to credit but also owed more to more lenders than ever before. That increased access has come with a price, however, as Senator Feinstein's question suggests. We are now a nation of indebted consumers. The total amount of consumer debt and mortgage debt exceeds the annual personal income of American citizens. If we devoted our nation's entire income for the next year toward the repayment of our personal debts—forgoing housing, food, utilities, and all the other necessities of life—it still would not retire this debt.[2]

Marquette was a necessary condition that set in motion a series of events that established the market conditions for an explosion of consumer credit. Still, it would be folly to suggest that a Supreme Court decision alone is responsible for almost $13 trillion in consumer and mortgage debt that exists today. The marketing and advertising of the consumer financial industry had to change American attitudes toward borrowing.[3] Other regulatory decisions had to be taken to remove regulatory borrowers on home mortgage loans (although it should be noted that *Marquette* created the regulatory climate that made these changes seem inevitable). New financial instruments and financial markets had to arise to bundle loans and to provide the constant flow of capital from which consumers could borrow. Changes in computer technology and credit reporting had to make more individualized credit decisions possible. *Marquette* put us on track to become a nation of indebted consumers, but these other events also had to happen for us to reach that destination.

Question Two: 2. As you know, this nation is in the grips of a major crisis in home foreclosures. Five of the 10 metropolitan areas with the highest rates of foreclosure in the nation are in California. More than 481,000 homes in California entered foreclosure in 2007, and 500,000 more foreclosures are expected in the state in the next two years.

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[2] Bob Lawless, "One to Lie Awake at Night About," posted on *Credit Slips* at http://www.creditslips.org/creditslips/2007/05/one_to_lie_awak.html (May 14, 2007).
[3] *See, e.g.*, Louise Story, "How Home Equity Was a Bank Ad Come True," N.Y. Times, Aug. 14, 2008, at A1.

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In your view, is there a connection between the increase in consumer debt and the problem of home foreclosures?

Have the Supreme Court's decisions in the area of preemption affected the ability of states to respond to the foreclosure crisis? If so, how?

A: In addition to Senator Feinstein's foreclosure statistics, I would add that California is experiencing the highest increased bankruptcy rates in the country. These two datapoints are undoubtedly related. In my answer to the previous question, I mentioned how the explosion of consumer credit helped to contribute to changing cultural attitudes. These attitudes have led to an increase in mortgage debt as well, but there are also more direct links between increased consumer debt and higher mortgage and more home foreclosures.

There are many connections between consumer debt and the problem of home foreclosure, and the first connection is that mortgage debt must be seen as part of an increasingly indebted society. Beginning in approximately 1998 and continuing until the foreclosure crisis hit quite recently, Americans have substituted mortgage debt for consumer debt. According to figures from the Federal Reserve, the growth in mortgage debt outpaced the growth in consumer debt during this time, and a significant part of this growth in mortgage debt occurred through home equity lines of credit or HELOCs. From 1997 to 2008, the value of outstanding HELOCs more than tripled to over $1 trillion. By their nature, HELOCs are not there to help finance home ownership but represent a cashing in of savings represented by home value. The HELOCs represent consumer credit that otherwise might have been incurred but now are mortgage claims that put consumers' homes at risk.

A second connection is that increased consumer debt is another drain on consumer resources that must compete with the financial demands of a mortgage. At the end of the day, a financially strapped consumer often will have to choose between repaying the mortgage or repaying a consumer debt. For years, the conventional wisdom was that a consumer always would choose to repay the mortgage debt first so as to save home. In recent months, reports have surfaced that some consumers are prioritizing their consumer debt. Paying down high-interest consumer debt rather than relatively lower interest mortgage debt can sometimes be a wise strategy for the consumer looking to climb out of a deep financial hole and avoid bankruptcy.

Senator Feinstein also asks about preemption, which in my view has greatly affected the states to respond to the foreclosure crisis. In *Watters v. Wachovia Bank*[4] the Supreme Court upheld the power of the Office of the Comptroller of the Currency (OCC) to preempt state consumer regulation. The OCC had acted under its authority to protect the safety and soundness of national banks, which the OCC apparently believes is inconsistent with state consumer protection laws. The *Watters* case itself involved the power of the state of Michigan to oversee a mortgage subsidiary of Wachovia Bank. The Supreme Court's ruling means the Wachovia subsidiary is not subject to the rules that apply to other mortgage lenders in the state.

[4] 127 S. Ct. 1559 (2007)

44331.011

Mr. Justin Pentenreider
August 21, 2008
Page 4

In my written testimony, I also related some anecdotes of other, simple state enforcement actions stopped by federal preemptive power. For example, based on a newspaper account, I wrote:[5]

> For example, before *Watters*, the New York attorney general had brought a proceeding to investigate overcharging by mortgage lenders. The investigation was not about fees that were too high or about debtors who were trying to escape responsibility for loans. Instead, the investigation was triggered by a modest $27,000 home loan, incurred in 1974 and paid off over 25 years. Despite its own paperwork that showed the loan had been completely paid off, the lender had collected over $9,400 in extra payments. After *Watters*, the New York attorney general would not be able to bring this investigation, and the affected consumer will have to turn to the OCC for whatever help it is inclined to offer.

The OCC stands among the most "captured" federal agencies in terms of leaning toward the industry it is supposed to regulate.[6] Instead of fifty state attorneys general on watch, we have only one regulatory cop that has become known for its friendliness toward potential offenders rather than their victims.

Question 3: Since 2005, I have sponsored legislation that would require credit card companies to tell consumers about the consequences of making only the minimum payments on their credit cards. My bill would require companies to tell their customers, on each monthly statement, how long it would take to repay their balance if only the minimum payments are made. The disclosure would also have to show the total amount of interest that the customer would pay if they made only the minimum payment each month.

In your view, would consumers benefit from getting this type of disclosure on their monthly credit card statements?

A: I supported that legislation in 2005 and have continued to support it. It is difficult to argue against better disclosure that makes it easier for consumers to understand the credit decisions they have made. Yet, as Senator Feinstein may have encountered with this legislation, the financial services industry has continually fought better disclosures. Disclosure interferes with their profit model.

The real profits in consumer lending come from the systematic mistakes that science tells us humans will tend to make when confronted with complex decisions with many alternative and that need predictions about future outcomes. We will systematically overestimate the probability that our incomes will go up and underestimate the chance of health problems or financial ruin. We will tend to anchor decisions on numbers that are predominantly presented, like an envelope with "**0% INTEREST**" emblazoned on the front, and ignore fine print disclosing the true cost actually may be much higher. We will only make purchasing decisions on a small number of variables and not the mandatory arbitration clause buried on page four of the contract. We will overestimate the likelihood we will use frequent flier miles and bonus points and underestimate the likelihood we will forgetfully mail a payment one day late. These decision-making heuristics mean consumers will

[5] *See* Jathon Sapsford, "Bank-Cop Fight: Spitzer Takes on U.S. Regulator," Wall St. J., Mar. 22, 2004, at C1.
[6] *E.g.*, Zvika Krieger, "The Nefarious Bureaucrat Who's Helping Banks Rip You Off," The New Republic, July 2, 2007, at 14.

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make mistakes, and those mistakes translate into fees and profits for the consumer lenders. Disclosure undercuts that profit model, so it is not surprising that the industry resists more disclosure.

At the same time, disclosure is not a panacea. No amount of disclosure will ensure that consumers will use the information wisely. Indeed, as I just discussed, it is virtually certain that many consumers still will make systematically unwise decisions. Nonetheless, Senator Feinstein's proposed disclosures are simple directives that would greatly increase the ability of consumers to understand the true cost of the credit they are purchasing. The cost of these disclosures would be low; the benefits would be great. This legislation should be enacted.

Thank you for the opportunity to present my testimony to the Senate Committee on the Judiciary and thank you again for allowing me to follow up with these questions. If you need any further information, please do not hesitate to contact me.

Sincerely,

Robert M. Lawless
Professor of Law and Galowich-Huizenga Faculty Scholar

SCHOOL OF LAW
THE UNIVERSITY OF TEXAS AT AUSTIN
727 East Dean Keeton Street • Austin, Texas 78705 • (512) 471-5151 • Facsimile (512) 471-6988

June 20, 2008

Senator Patrick J. Leahy
Chairman, Committee on the Judiciary
U.S. Senate
Washington, DC 20510-6275

Re: McGarity's Testimony at the U.S. Senate Committee on the Judiciary hearing: "Short-change for Consumers and Short-shrift for Congress? The Supreme Court's Treatment of Laws that Protect Americans' Health, Safety, Jobs and Retirement" on June 11, 2008

Dear Senator Leahy:

I have attached my responses to the written questions that members of the committee have addressed to me.

I very much appreciate your inviting me to testify, and I hope that the hearing produced information that was useful to you and the other members of the committee.

Please let me know if there is more that I can do to assist the committee.

Sincerely

Thomas O. McGarity
Joe R. and Teresa Lozano Long Endowed Chair
in Administrative Law

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Encls. (3)

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Senator Patrick J. Leahy
June 20, 2008

Page 2

Responses to Questions Posed by Senator Specter

1. Even after Riegel, *a variety of state tort claims, including those asserting a manufacturing defect, would not be pre-empted, correct?*

That is correct. The Supreme Court in *Medtronic v. Lohr*[1] unanimously held that design defect claims regarding devices that received only the abbreviated "substantial equivalence" approval were not preempted. A clear majority of the Court also agreed that claims based on conduct that violated FDA regulations were not preempted because they merely reinforced the federal requirements, and the lower courts have allowed many such claims to proceed. The Court in *Reigel* reaffirmed the latter holding. In neither case did the Court find that manufacturing defect claims were preempted.

2. In your written testimony you go into great detail regarding a regulated entity "bending science to their economic and ideological ends." Is this a real problem? Do you have evidence of regulated entities regularly engaging in fraud or manipulating scientific, economic, and statistical information to trick regulatory agencies?

I believe that this is a very real problem. In our recently published book, *Bending Science*, my co-author Wendy Wagner and I have documented and discussed at great length many cases in which regulated entities engaged in fraud or manipulation of scientific, economic and statistical information in support of the safety and efficacy of their products in dealing with regulatory agencies, courts and the public. Thomas O. McGarity & Wendy Wagner, *Bending Science* (Harvard University Press 2008).

3. In Mr. Cooper's written testimony, he states "It has long been obvious that regulatory agencies such as FDA are far more expert in their areas of regulatory activity than are judges and juries, and that they have the advantage of being able to apply criteria of effectiveness and safety to product design and criteria of truthfulness and adequacy ex ante and with all potential users in mind." Do you disagree with Mr. Cooper's assertion?

I would certainly agree with Mr. Cooper that regulatory agencies generally have more expertise in their areas of regulatory activity than judges and juries. I would also agree that regulatory agencies have an advantage in applying statutory criteria of effectiveness and safety to product design *ex ante* and with all potential users in mind for purposes of determining whether a particular product meets those statutory criteria. I would not agree that agencies are better able than common law juries to apply the common law tests relevant to products liability claims.

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[1] Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996).

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I would also agree with Mr. Cooper that it is a considerable advantage from the perspective of protecting public health and safety for an agency to review prospectively the potential safety and efficacy of potentially dangerous products. The ex ante regulatory controls that the regulatory system provides are unquestionably necessary to protect public health and safety, but they are not sufficient. A robust common law can provide a backstop for situations in which the ex ante regulatory controls fail, and it also provides what is typically the only vehicle through which injured victims may seek corrective justice from the entities that are responsible for those injuries.

I would not agree that regulatory agencies are any better qualified, whatever their expertise, to determine "truthfulness" of statements or claims. In my view, juries are at least as adept at evaluating the truthfulness of testimony as experts in regulatory agencies, and they are usually better equipped to determine whether a person is telling the truth or lying. The common law jury functions in a procedural context in which witnesses testify under oath and are subject to cross-examination and other procedures specifically designed to elicit the truth. An agency official typically evaluates cold documents or, at most, observes representatives of affected parties in informal meetings where the representatives are not testifying under oath and are not subject to cross-examination. In my opinion, the jury has withstood the test of time as an accurate, albeit imperfect, institution for getting to the truth of the matter at hand.

I would also disagree with the proposition that agencies are better at determining "adequacy" than juries. The term "adequacy" is value-laden and, as such, depends as much on one's view of the appropriate social goal as on any particular expertise. If, for example, the question is whether a particular scientific study is "adequate" for purposes of supporting particular scientific conclusions, an expert employee of an agency may well be more qualified to make that determination. If, on the other hand, the question is whether the evidence supporting the proposition that a particular product is "defectively dangerous" is "adequate," then expertise plays only a limited role in the policy-dominated balance that goes into that determination, and a jury is, in my view, better qualified to make that determination than an agency.

4. Won't repealing ERISA's preemption provisions increase the cost or lessen the availability of health care coverage for employees?

Repealing ERISA's preemption provisions may well increase the cost of health care coverage to employers to the extent that insurance companies incur greater costs in assessing the merits of pre-authorization requests and to the extent that they may in turn pass those costs on to their customers. In my view, the corrective justice and the added incentive to behave reasonably that would result from repealing ERISA's preemption provisions for purposes of common law liability would clearly justify those added costs. Whether the added costs would lessen the availability of health care coverage for

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employees is a very complex question that depends upon the elasticity of the demand curve, the degree of competition in the industry, and the profitability of the industry and is generally outside my range of expertise.

McGarity's Responses

Senator Patrick J. Leahy
June 20, 2008

Page 5

Responses to Questions Posed by Senator Grassley

1. It took nearly 2 years after the manufacturer and the Food and Drug Administration first became aware of a cardiovascular risk for a change to be made in the drug labeling for Vioxx. More recently, based on a review of documents from recent litigation against the manufacturer of Vioxx, several researchers found selective presentation of data to the FDA that minimized the appearance of an increased risk of death and the manipulation of scientific literature through ghost writers.

a. If individuals cannot pursue claims against manufacturers even after a federal agency has failed to act in a timely fashion to inform the public of emerging safety risks, what is the recourse for individuals who are injured by prescription drugs and/or medical devices?

b. In your opinion, are there any situations related to individuals being injured by medical devices and/or drugs where state laws and interests in citizens' safety and welfare would be appropriate?

c. Are private tort claims warranted when drug companies and/or device manufacturers have been less than forthcoming about the risks of their products? Please explain your answer in detail.

First, I would like to point out the obvious fact that the documents from recent litigation to which the question refers would not have been available to the researchers were it not for the fact that damaged plaintiffs brought lawsuits against the manufacturer of Vioxx. Common law litigation has the great virtue of shedding light on information that would otherwise remain buried in the files of drug manufacturers, because the attorneys for plaintiffs have a strong incentive to find out what the defendants knew and when they knew it.

a. If individuals cannot pursue claims against manufacturers of products after a federal agency has failed to act in a timely fashion, injured individuals ordinarily have the option of filing a common law tort action against those manufacturers. During the past twenty years, the Supreme Court has interpreted the term "requirements" and similar terms in the preemption clauses of federal regulatory statutes to include state common law claims. When common law claims come within the terms of such express preemption clauses, the common law option is no longer available to injured individuals. The Supreme Court has also held in some, but not all cases that have come before it, that common law claims are impliedly preempted because they pose an obstacle to the relevant federal agency's efforts to achieve the applicable statutory goals. When common law claims are held to be impliedly preempted, the common law option is no longer available to injured individuals.

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Injured individuals deprived of the right under state common law to seek damages from manufacturers of defective drugs and devices can sometimes seek reimbursement of their medical expenses under their health insurance coverage, Medicare or Medicaid. This is usually not sufficient to make the injured individuals whole, because it fails to compensate them for pain and suffering and for economic loses that directly result from their injuries. Injured individuals can, of course, seek revenge through extralegal means. The common law was designed, among other things, to provide an alternative to self-help, but when the common law option is unavailable because it has been preempted, self-help may prove more attractive to injured individuals and the groups representing them.

b. In my opinion, the positive statutes and regulations that states have put into place to protect their citizens' safety and welfare should in most cases be respected by the federal courts under the "presumption against preemption" that the Supreme Court has on numerous occasions applied to areas of the law that have traditionally been subject to state regulation. In the absence of a federal statute that expressly preempts state law and explicitly addresses state common law claims, the federal courts should, in my opinion, rarely find such claims to be preempted for reasons that I explore in great detail in Chapter 10 of *The Preemption War*, where I suggest criteria and rules of thumb for courts to apply in individual cases.

c. I strongly believe that private tort claims are warranted when drug companies and/or device manufacturers have been less than forthcoming about the risks of their products. However, the Supreme Court in the *Buckman* case, described in my testimony, has held otherwise. I have attached for the committee's files a reprint of an article that I wrote not long after the *Buckman* case was decided in which I criticize that holding at some length. Thomas O. McGarity, *Beyond Buckman: Wrongful Manipulation of the Regulatory Process in the Law of Torts*, 41 Washburn L. J. 549 (2002). I also critique the *Buckman* case and related lower court cases in Chapter 7 of *The Preemption War*.

2. You state in your written testimony that the Supreme Court found that "state common law claims based upon alleged fraud on the FDA could increase the regulatory burdens on potential applicants who might be 'discouraged from seeking expedited approval of devices with potentially beneficial off-label uses for fear that such use might expose the manufacturer or its associates (such as petitioner) to unpredictable civil liability.'" What, in your opinion, is the recourse for individuals who are injured by a device that was approved based on fraudulent and/or misleading data/information to the FDA?

Individuals who are injured by a device that was approved based on fraudulent and/or misleading data may request FDA to consider filing a civil or criminal enforcement action against the manufacturer or other entity responsible for the fraud under the federal

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statutes (listed in the Supreme Court's *Buckman* opinion) that are applicable to such conduct. Ordinary citizens may not, however, bring such enforcement actions on their own. Otherwise, the injured individual may resort to self-help remedies mentioned above.

3. When the Food and Drug Administration proposed its prescription drug labeling rule in December 2000, the Agency explicitly stated that "this proposed rule does not preempt State law." Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81082, 81103 (proposed Dec. 22, 2000). Further, the FDA stated, "FDA has determined that this proposed rule does not contain policies that have federalism implications or that preempt State law." Yet in the preamble to the final rule, the FDA states, "FDA believes that under existing preemption principles, FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary State law." Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006). In your opinion, did the FDA act appropriately? Please explain your answer in detail.

In my view, FDA did not act appropriately when it changed its long-standing position on preemption of state common law failure to warn claims in the above-quoted preamble. I provide a detailed analysis and critique of the preamble in Chapter 6 of *The Preemption War*. In that discussion, I make the following points. First, the position articulated in the preamble was contrary to many past agency pronouncements on that question. Second, that position was contrary to the position adopted by the vast majority of courts that had addressed the preemption question. Third, since the contents of the warnings associated with prescription drugs are largely within the control of the manufacturer and since the manufacturer may unilaterally change the drug's label to "add or strengthen a contraindication, warning, precaution, or adverse reaction," subject to the rarely invoked power of FDA to disapprove the change, the label does not generally represent the agency's considered judgment on the content of the warning that should be required. Fourth, the determination of whether a drug is mislabeled within the meaning of the Food, Drug and Cosmetic Act is, in any event, ultimately made by a jury in a civil enforcement action brought by FDA and therefore does not differ greatly from the determination of a jury in common law litigation that a warning is inadequate.

4. What is your response to the argument that private claims may lead drug and/or device companies to over-warn and patients not to take needed drugs?

I address the "overdeterrence" argument in Chapter 8 of *The Preemption War*. I conclude that the argument is generally persuasive in the context of product warnings,

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because factfinders, be they judges or juries, can in hindsight usually identify some way in which the manufacturer could have been more specific or could have featured the warning more prominently. This, in turn, gives the manufacturer an incentive to provide every conceivable warning with the resulting risk of "information overload" to the consumer.

I also point out, however, that very little empirical evidence supports the proposition that patients have been "overdeterred" during the decades before FDA adopted its new preemption policy and plaintiffs during which were free to pursue failure to warn claims. Indeed, some scholars have concluded that there is a far greater risk of "underdeterrence," because of the difficulties that plaintiffs typically encounter in bringing such claims successfully and the general reluctance of U.S. citizens to resort to litigation when they have not suffered serious debilitating damage. The overdeterrence argument also assumes that federal agencies otherwise provide "optimal" deterrence, and this erroneously assumes that underfunded and overworked federal agencies are capable of inducing the degree of deterrence that the statute demands. Finally, it is worth noting in the context of prescription drug litigation that the deterrent function of drug labels can easily be overwhelmed by the massive direct-to-consumer advertising campaigns that drug companies typically employ to promote widely used drugs.

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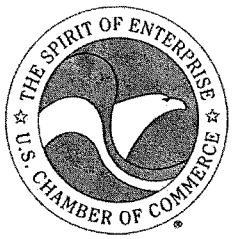
SUBMISSIONS FOR THE RECORD



Statement of the U.S. Chamber of Commerce

ON: **"SHORT-CHANGE FOR CONSUMERS AND SHORT-SHRIFT FOR CONGRESS? THE SUPREME COURT'S TREATMENT OF LAWS THAT PROTECT AMERICANS' HEALTH, SAFETY, JOBS AND RETIREMENT"**

TO: **THE SENATE COMMITTEE ON THE JUDICIARY**

BY: **ANDY R. ANDERSON**

DATE: **JUNE 11, 2008**

The Chamber's mission is to advance human progress through an economic, political and social system based on individual freedom, incentive, initiative, opportunity and responsibility.

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The U.S. Chamber of Commerce is the world's largest business federation, representing more than three million businesses and organizations of every size, sector, and region.

More than 96 percent of the Chamber's members are small businesses with 100 or fewer employees, 70 percent of which have 10 or fewer employees. Yet, virtually all of the nation's largest companies are also active members. We are particularly cognizant of the problems of smaller businesses, as well as issues facing the business community at large.

Besides representing a cross-section of the American business community in terms of number of employees, the Chamber represents a wide management spectrum by type of business and location. Each major classification of American business -- manufacturing, retailing, services, construction, wholesaling, and finance -- is represented. Also, the Chamber has substantial membership in all 50 states.

The Chamber's international reach is substantial as well. It believes that global interdependence provides an opportunity, not a threat. In addition to the U.S. Chamber of Commerce's 105 American Chambers of Commerce abroad, an increasing number of members are engaged in the export and import of both goods and services and have ongoing investment activities. The Chamber favors strengthened international competitiveness and opposes artificial U.S. and foreign barriers to international business.

Positions on national issues are developed by a cross-section of Chamber members serving on committees, subcommittees, and task forces. More than 1,000 business people participate in this process.

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Statement of Andy R. Anderson

Morgan, Lewis & Bockius LLP

On behalf of the United States Chamber of Commerce

Before the Senate Committee on the Judiciary

June 11, 2008

Chairman Leahy, Ranking Member Specter and Members of the Committee, I am pleased and honored to be here today. I am here to testify on behalf of the United States Chamber of Commerce concerning recent Supreme Court decisions under the Employee Retirement Income Security Act of 1974 (ERISA).

The maintenance of the voluntary, employer-provided system under ERISA is of critical concern to the Chamber and its members. As such, the Chamber is on the Steering Committee of the National Coalition on Benefits (NCB). The NCB is dedicated to working with Congress to maintain employers' ability to provide uniform health and retirement benefits to employees and retirees across state and local lines, and to ensure that federal health reform initiatives preserve Employee Retirement Income Security Act (ERISA) benefits.

Introduction

My name is Andy R. Anderson and I am Of Counsel at the law firm of Morgan, Lewis & Bockius LLP. My practice focuses on advising single-employer and multi-employer benefit plans on employee benefits matters and specifically on their health benefit programs. I have worked in the area of employee benefits since 1984. I chair my firm's Health and Welfare practice and I participate on the Chamber's Employee Benefits Committee.

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ERISA Uniformity and Limited Recovery Is Intended and Necessary

All employers (except for certain religious and government organizations) who voluntarily choose to offer retirement or health benefits are subject to the Employee Retirement Income Security Act of 1974, which is commonly known as ERISA.

ERISA was the subject of a long and detailed legislative process. Included among the myriad provisions of ERISA are two concepts that cut to the heart of today's hearing. These concepts work in unison to encourage employers to voluntarily extend health benefits to their employees with a high degree of uniformity and without unnecessary exposure to liability.

These provisions are ERISA Section 514, which generally preempts state jurisdiction over employer-provided health benefits, and ERISA Section 502 that outlines the rules associated with the civil enforcement of ERISA.

ERISA Section 514 states that, with a few exceptions, ERISA overrides any and all state laws that relate to employee benefits plans. Particularly as applied to employers with self-insured benefits, Section 514 allows employers to design uniform health plans that treat all of their employees the same regardless of where the employees may happen to live or work. The ability to maintain a uniform benefit plan, particularly for large employers who have operations in many different states, allows employers to reap the design cost savings associated with large covered groups and the administrative costs savings created by streamlined and uniform plan rules. These cost savings, in turn, make health coverage more affordable for employees who pay a portion of the cost of their health coverage and for former employees, surviving spouses, and older children who pay the full cost of continued health coverage under the terms of COBRA.

ERISA Section 502 states, among other things, that a participant may bring a civil action in federal court to recover benefits due under the terms of a health plan or to enforce rights under the terms of the plan. This right is the exclusive remedy for the wrongful denial of plan benefits and is only available to a participant after exhausting the ERISA claims and appeals process that is comprehensively detailed in ERISA Section 503 and associated regulations.

The ERISA provisions found in these Sections have a long and detailed legislative, regulatory, and judicial history that extends all the way back to the initial legislative proposals that eventually became ERISA. It was no accident that resulted in these provisions, but rather a careful balance of competing interests and incentives to encourage employers to voluntarily offer retirement and health benefits.

Our judiciary, including the Supreme Court, has heard many cases related to ERISA uniformity and remedies. While sometimes chafing under the statutory provisions of ERISA or bemoaning yet another ERISA case on their docket, our judiciary has usually reached the correct decision regarding both the specific facts of a given case and the broader principles and trade-offs embodied in ERISA. These decisions should be respected and upheld.

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Changes To ERISA Will Decrease Employer-Provided Voluntary Health Care

Employers engage in a complicated calculus when they determine whether or not to offer health benefits. Included in this calculus is whether they retain control over the fundamental provisions of their plans, such as eligibility and which benefits are covered under their plans. Employers are also concerned about the risk of liability associated with offering a health plan and the judicial forums and rules applicable to the plan.

Of the 160 million Americans who have employer provided health coverage, 132 million receive health benefits that are subject to the provisions of ERISA. The large numbers of Americans covered by ERISA-regulated health plans shows how successful ERISA has been at encouraging employers to voluntarily offer health benefits.

This success is in large part due to ERISA sections 514 and 502, since these rules ensure that employers (and particularly employers who self-insure their health benefits) are able to provide uniform medical plans in every state in which they operate, that disputes associated with ERISA-governed health plans are heard in federal court, and that successful litigants generally receive the benefits owed to them under the terms of their employer's plans.

I firmly believe that interposing the determination of a state legislature--or a state judge--regarding the eligibility and benefit rules for an employer's health plan will begin to make this voluntary program much less appealing and far more complicated for employers. Further, if employers have to begin weighing the increased risk of broader participant recoveries, we will quickly see a number of employers stop providing health coverage to their employees or merely reimburse employees for individually purchased coverage. As a result we will wind up with fewer Americans who are covered under traditional employer provided health plans.

While a few will benefit, many will lose.

We are already witnessing the reduced retirement income security associated with the legislative, regulatory and judicial environment surrounding defined benefit plans. This lesson is reason enough for Congress to build on the strengths of employer-provided health care, maintain ERISA uniformity and recovery rules, and encourage--rather than discourage--our system of voluntary employer-sponsored health plans.

Mr. Chairman and members of the Committee, thank you for the opportunity to testify today and for your attention to this very important issue. I would be happy to answer any questions that you might have during the balance of this hearing.

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STATEMENT OF STEVE BARTLETT

Introduction

Good morning, Chairman Leahy and Senator Specter, my name is Steve Bartlett and I am President & CEO of The Financial Services Roundtable. The Financial Services Roundtable represents 100 of the largest integrated financial services companies providing banking, insurance, and investment products and services to the American consumer. Our companies account directly for $50.5 trillion in managed assets, $1.1 trillion in revenue, and more than 2.4 million jobs.

The American consumer is the lifeblood of the economy and it is in the best of interests of Roundtable member companies to have well-educated consumers who manage debt prudently.

Testimony

It is highly beneficial for both consumers and lenders to have a uniform set of rules governing the granting of consumer credit. I will use testimony to explain how federal preemption creates a regulatory and legal framework that benefits consumers by creating the conditions under which national banks can grant credit with full confidence that there will not a crazy quilt of conflicting and ambiguous state law regulations or tort liability standards. Obviously, it defies reason and commonsense to expect national

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banks to grant credit on favorable terms if each loan faces different, and sometimes contradictory, regulations or standards for tort liability. Consistent and fair access to credit depends on predictability and predictability depends on uniform rules.

Should this Congress reverse the court cases that have correctly interpreted prior Congress' decisions to promote economic growth through uniform national standards, the admirable progress to date in democratizing credit would also be reversed. We have come a long way as a society from the time when minorities and the low income were shut out of the credit markets. It would be a shame to roll back the tide of progress.

In 1978, the Supreme Court correctly interpreted Section 85 of the National Bank Act to shield national banks from tort suits and state regulation regarding interest rates. See Marquette National Bank v. First Omaha Serv. Corp., 439 U.S. 299 (1978). This decision allowed national banks, with their considerable economies of scale, to offer credit across state lines on favorable terms for qualified borrowers. It is inconceivable that Congress would reverse this thirty year old ruling and inject considerable risk and uncertainly into the marketplace at a time when some Americans are finding it harder and harder to obtain credit.

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In 1996, the Supreme Court provided further certainty to borrowers and lenders by preventing similar conflicts over late fees. See Smiley v. Citibank, 517 U.S. 735 (1996). For the reasons I discussed earlier, this legal trend should be encouraged to continue, not reversed or stymied.

In 2007, the Supreme Court once again reaffirmed the Congressional decision not to subject national banks to contradictory state laws. In Watters v. Wachovia, 127 S. Ct. 1559 (2007), the Court prevented state attorneys general from enforcing state laws against national banks. I would ask the Committee to imagine if this case had turned out differently - if fifty state attorneys general could enforce the laws of fifty states against national banks, even where the laws might conflict with each other or conflict with federal law. The uncertainty and confusion that would ensue would create an incentive to tighten credit standards in a dramatic way. This outcome would surely harm the economy and consumers.

Fortunately, this Congress has already wisely rejected the idea that the Supreme Court's Nobleman decision be reversed. In this case, the Supreme Court helped reduce upward pressure on mortgage interest rates by correctly interpreting Section 1322 of the Bankruptcy Code to forbid bankruptcy courts from converting home mortgages of primary residences into partially unsecured debt. In 1978, a Congress controlled by Democrats enacted

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Section 1322 specifically to encourage mortgage lending to traditional underserved populations. See Nobleman v. American Savings Bank, 508 U.S. 324 (1993). Again, it is inconceivable that Congress would reverse this decades-old policy – especially at this time, when many Americans are finding it difficult to obtain mortgages. In fact, overturning Nobleman, according to the non-partisan CBO, would increase interest rates. See Letter to the Honorable Kent Conrad, Congressional Budget Office April 11, 2008 p. 21.

Conclusion

As our country moves into the 21st century, it will be important to make further progress in establishing a level playing field for lenders and borrowers alike. Reverting to outdated and discredited interpretations of federal law will subject businesses of nationwide scope to a regulatory and legal environment that is murky, where aggressive trial lawyers would be newly empowered and where credit will ultimately become more difficult to obtain. The Roundtable urges Congress not to turn back the clock to the bad old days when only the well-off had access to credit.

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Statement of Senator Tom Coburn, M.D.

Hearing: *"Short-change for Consumers and Short-shrift for Congress? The Supreme Court's Treatment of Laws that Protect Americans' Health, Safety, Jobs and Retirement"*

United States Senate Committee on the Judiciary

June 11, 2008

We absolutely need FDA to have all the tools necessary to ensure the safety and efficacy of drugs, but doctors need tools as well, and one of those important tools is new drugs on the market.

The FDA should have broad and exhaustive authorities to ensure that drug companies are doing the right and scientifically-justified thing when it comes to drug safety and the labeling of their drugs. This authority is placed rightly in the hands of highly-trained scientists at the FDA. It's clear that Congress relies on the scientists at the FDA to assess safety risks and drug labeling, which should be solely the FDA's role. The role of the FDA does and should pre-empt State law when it comes to drug safety and labeling. In order to ensure scientific drug safety the last thing that we need is the regulatory nightmare of every state court being a mini-FDA.

Let me be clear, the FDA is the expert Federal agency charged by Congress with ensuring that drugs are safe and effective, and that product labeling is truthful and not misleading. Appropriate preemption of State law includes not only claims against manufacturers, but also against health care practitioners for claims related to dissemination of risk information to patients beyond what is included in the labeling. Unless State law is preempted in this area, State law actions can conflict with the FDA's interpretations and frustrate the FDA's implementation of its statutory and scientific mandate.

Should the FDA's scientific judgment on drug safety and labeling be set aside, we would risk eroding and disrupting the truthful representation of benefits and risks that medical professionals need to make decisions about drug use. As a physician, I know that exaggeration of risk can discourage the important and correct use of a clinically therapeutic drug. Superfluous liability concerns can create pressure on manufacturers to expand labeling warnings to include merely speculative risks, and limit physician appreciation of potentially far more significant contraindications and side effects.

Furthermore, if not preempted in drug safety information and labeling, State law could conflict with achieving the full objectives of Federal law if it precludes a firm from including certain labeling information. If a manufacturer then complies with State law, the firm would be omitting a statement required under § 201.100(c)(1) as a condition on the exemption from the requirement of adequate directions for use, and the omission would misbrand the drug under 21 U.S.C. 352(f)(1). The drug might also be misbranded on the ground that the omission is material within the meaning of 21 U.S.C. 321(n) and makes the labeling or advertising misleading under 21 U.S.C. 352(a) or (n).

While it's true that a manufacturer may, under FDA regulations, strengthen a labeling warning on its own, it's important to understand that in practice manufacturers typically consult with FDA before doing so. Otherwise they could risk enforcement action if the FDA disagrees.

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Some misunderstand the FDA's labeling requirements to be a minimum safety standard, and thus have used State law to force manufacturers to supplement safety regulation beyond that required by FDA. I want to be clear that the FDA's labeling requirements establish both a ''floor'' and a ''ceiling.'' Therefore, risk information beyond what is required by the FDA could be considered unsubstantiated or otherwise false or misleading. Given the comprehensiveness of FDA regulation of drug safety, effectiveness, and labeling—additional requirements for the disclosure of risk information are not necessarily more protective of patients.

There is an overriding Federal interest in ensuring that the FDA, as the public health body charged with making these complex and difficult scientific judgments, be the ultimate arbiter of how safety information is conveyed.

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BEFORE THE SENATE COMMITTEE ON THE JUDICIARY

JUNE 11, 2008

STATEMENT OF RICHARD M. COOPER

Mr. Chairman and Members of the Committee, thank you for inviting me to testify on the *Riegel* decision and federal preemption in the field of food and drug regulation. Although the law firm of which I am a partner represents a number of companies interested in the topic of this hearing, I was invited to appear, and I am appearing, on my own, and not on behalf of my law firm or any client.

The supremacy of federal law over state law, operating through the doctrines of express and implied preemption, is fundamental to our federal system. The Supreme Court's recent decision in *Riegel v. Medtronic, Inc.*[1] interprets a statute that expressly preempts any state-law requirement with respect to a device that (i) is different from or in addition to any requirement applicable under the Federal Food, Drug, and Cosmetic Act ("FDCA") to the device and (ii) relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the FDCA.[2]

Riegel was decided correctly. It was not a close case. Eight Justices concurred in the Court's judgment, and seven joined the opinion of

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1 128 S. Ct. 999 (2008).

2 21 U.S.C. § 360k(a) (2000).

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the Court. The decision was anticipated by a substantial majority of the federal courts of appeals that had considered the issue.[3]

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

The Court also held in *Lohr* that the generality of the requirements applicable in FDA's clearance of medical devices under the

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3 Richard A. Nagareda, *FDA Preemption: When Tort Law Meets the Administrative State*, 1 J. Tort L. 1, 14 (2006).
4 *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 246-47 (1959).
5 505 U.S. 504 (1992).
6 U.S. Const. art. VI, cl. 2.
7 518 U.S. 470 (1996). *See id.* 503-04 (Breyer, J., concurring in part and concurring in the judgment), 509-12 (O'Connor, J., joined by Rehnquist, C.J., Scalia & Thomas, JJ., concurring in part and dissenting in part).
8 537 U.S. 51, 65 (2002).

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section 510(k) process[9] precluded preemptive effect for such clearances, but it explained that that generality

> make[s] this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers on producers.[10]

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

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

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9 *See* 21 U.S.C. § 360(k).
10 518 U.S. at 501.

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with FDA-imposed requirements and would create obstacles to the achievement of the objectives of the FDCA.

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

Products-liability theories are widely understood as a type of regulation of manufacturers' conduct. That system of regulation is administered by judges and juries *ad hoc* and with a focus on a particular allegedly injured plaintiff or group of plaintiffs and without the presence in the courtroom of those users of the product who have benefited from it.[11] Thus, products-liability theories constitute a kind of regulation "in disguise."[12]

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

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11 *See generally* Nagareda, *supra* note 3, at 38-39.
12 *See id.* at 38 & n. 143.

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grievous injury. In addition, since the Supreme Court's decision in *Chevron* in 1984,[13] it has been clearly understood that federal agencies administering regulatory statutes are more politically accountable as regulators than are judges and juries, and that therefore courts are to defer to them not only in their application of expertise to technical matters but also in their institutional interpretations of statutory ambiguities.[14]

Although products-liability theories are a form of regulation, they also can be a basis for compensation for injured plaintiffs. *Riegel* and similar decisions,[15] however, are consistent with the proper compensatory role of products-liability litigation.

Manufacturers are not insurers. Their liability to compensate injured plaintiffs must be based on some type of fault – most commonly, their marketing of a product that is defectively designed, manufactured or labeled or their negligence with respect to one or more of those aspects of a product. Where a manufacturer is not at fault, it should not be liable. The law of products liability is not intended to be a social safety net for all patients harmed by medical products. It is not intended to be a substitute for health, disability, and life insurance. Thus, the compensatory purpose of products-liability law is limited.

Where a properly informed FDA has specifically approved the design and labeling of a particular product, and the manufacturer is barred

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13 *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984).
14 *See generally* Nagareda, *supra* note 3, at 38-39.
15 *See, e.g.*, *Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3d Cir. 2008).

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by federal law from changing the product or its labeling without prior FDA approval,[16] the manufacturer is not at fault in marketing that product, so designed and so labeled, and therefore should not be liable to a plaintiff alleging a defective design or inadequate labeling. Preemption in such circumstances is consistent with the limited compensatory purpose of products-liability litigation.

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

Moreover, under those cases, if a manufacturer materially violates a relevant condition of its approval, or violates some other requirement under the FDCA, it may be held liable under a traditional state-law products-liability theory that seeks to enforce the federal condition or requirement.[18] Thus, those cases leave intact the regulatory function of traditional products-liability law in providing incentives for compliance with state-law requirements that enforce FDA requirements.

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16 *See* 21 C.F.R. §§ 310.3(h), 314.70, 814.80 (2007).

17 *See Riegel*, 128 S. Ct. at 1004; *Lohr*, 518 U.S. at 479; *see also* 21 U.S.C. § 360e(a) (2000); 21 C.F.R. § 807.85 (2007).

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

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As to drugs, biologics, and devices, FDA regulations permit manufacturers to make changes in labeling to enhance information about risk where new information warrants such changes.[19] FDA has stated that this permission extends only to situations involving information about a newly discovered risk or important new information about a known risk, where there is sufficient evidence of causal association with the drug, biologic, or device.[20] *Lohr* and *Riegel* leave open the potential for liability if a manufacturer fails to update its labeling in the narrow circumstances permitted by FDA's regulations. State courts adjudicating claims of such liability, however, would have to interpret FDA's regulations correctly.

Thus, as a practical matter, *Lohr* and *Riegel* have only a quite limited preemptive effect. As to most devices and as to most violations of traditional state-law requirements that seek to enforce FDA requirements, they leave products-liability law free to operate.

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

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19 21 C.F.R. §§ 314.70(c)(6)(iii)(A) & (C), 601.12(f)(2), 814.39(d)(2) (2007).

20 New Drug and Antibiotic Regulations, 47 Fed. Reg. 46,622, 46,623 (proposed Oct. 19, 1982) (to be codified at 21 C.F.R. pts. 310, 312, 314, 430, 431 & 433); Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 2848 (proposed Jan. 16, 2008) (to be codified at 21 C.F.R. pts. 314, 601 & 814).

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

Finally, FDA's statutorily prescribed mission is to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner."[21] That formulation implicitly recognizes that, just as the public health is harmed by medical products that turn out to be unsafe or ineffective, the public health benefits by timely marketing of medical products that are safe and effective.

That policy serves patients well, but has unavoidable limitations. It serves patients well because FDA does a far better job of

[21] 21 U.S.C. § 393(b)(1) (2000).

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deciding on product designs and labeling than judges and juries could do. Totally unpreempted regulation through products-liability litigation would erode FDA's uniform national regulatory system, would lead to inconsistent requirements from state to state and jury to jury, would create powerful incentives for inclusion in labeling of numerous additional warnings that plaintiffs' lawyers persuaded juries and judges to impose, and thereby would diminish the overall effectiveness of labeling in guiding physicians in the proper use of drugs and devices. As FDA has stated:

> [A]dditional requirements for the disclosure of risk information . . . can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use. Exaggeration of risk could discourage appropriate use of a beneficial drug. . . . [L]abeling that includes theoretical hazards not well-grounded in scientific evidence can cause meaningful risk information to "lose its significance." (44 FR 37434 at 37447, June 26, 1979). Overwarning, just like underwarning, can similarly have a negative effect on patient safety and public health.[22]

That congressional policy has limitations because there is always a trade-off between approving a device or drug for use by patients who need it and may benefit from it now and waiting for additional data that may clarify further how a device or drug may be made safer or more effective or may be labeled so as to be used more safely or more effectively, or that may show, contrary to earlier data, that a device or drug has additional risks that make it unsafe. Thus, every approved device and drug is marketed with less

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

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than complete information about its optimal use and, consequently, presents risks of harm, through no fault of its manufacturer or FDA.

Preemption sometimes is opposed on the ground that FDA is ill-equipped to protect the public, that the agency is under-funded, inadequately managed, and makes mistakes.[23] The proper response to that criticism is not to declare open season for unrestrained regulation by judges and juries, but for the Congress to fund FDA adequately and to conduct effective oversight of its management and performance, so as to reduce mistakes to the minimum humanly achievable. The Congress has already taken steps, in the Food and Drug Administration Amendments Act of 2007 ("FDAAA"), to provide FDA with additional tools to improve its performance.[24]

Products-liability litigation sometimes brings to light information about medical products that was not previously known. The discovery process in litigation, however, is very costly and inefficient. FDA could obtain much the same information through effective use of tools it already has – not only required post-approval surveillance and studies,[25] and reporting of adverse events and submission of periodic reports by manufacturers,[26] but also use of its authority to inspect in a manufacturing establishment

> all things therein (including records, files, papers, . . .) bearing

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[23] *See generally*, David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts To Preempt Failure-To-Warn Claims*, 96 Geo. L.J. 461 (2008).
[24] Pub. L. No. 110-85, 121 Stat. 823 (2007).
[25] *See* FDAAA §§ 901-09, 121 Stat. at 922.
[26] *See* 21 C.F.R. §§ 314.80, 314.81, 803.1-.58, 814.82 814.84 (2007).

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> on whether prescription drugs . . . or restricted devices which are adulterated or misbranded . . . or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale . . . have been or are being manufactured . . . in any such place, or otherwise bearing on violation of [the FDCA].[27]

Thus, without dependence on private products-liability litigation, FDA has broad authority to obtain from manufacturers information they have and it needs to monitor the safety of marketed prescription drugs and restricted devices. That better systems and methods are needed generally to monitor the safety of medical products after they have been approved is a problem that is independent of the preemption doctrine and is not solved by litigation.

It has been argued, contrary to *Garmon* and other decisions and to other scholarly understanding of products-liability theories, that court judgments embodying such theories do not impose requirements that might conflict with FDA's requirements because the judgments merely compensate injured plaintiffs, the judgments operate against companies and not against FDA, and manufacturers can maintain their compliance with FDA requirements and satisfy court judgments by paying damages. These arguments have no merit.

Court judgments awarding damages in products-liability cases do not merely compensate plaintiffs; they order defendants to make payments due to a finding that those defendants violated requirements imposed by state law. That those requirements operate on companies rather

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[27] 21 U.S.C. § 374(a)(1) (2000 & Supp. V 2005).

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than FDA certainly does not entail that the requirements do not conflict with contrary requirements imposed on those companies by FDA. To say that products-liability judgments don't conflict with FDA requirements because companies could continue to comply with FDA requirements and pay damages is analogous to saying that a state criminal statute that prohibited conduct required by FDA does not conflict with the FDA requirement because companies could continue to comply with the FDA requirement and pay fines and their executives could direct compliance with the FDA requirements while in state prison.

In sum, current Supreme Court jurisprudence as to preemption in the field of food-and-drug law is sound and well serves the public.

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Statement of Sen. Russ Feingold
Hearing of the Senate Judiciary Committee

Short-change for Consumers and Short-shrift for Congress?
The Supreme Court's Treatment of Laws that Protect
Americans' Health, Safety, Jobs and Retirement

June 11, 2008

Mr. Chairman, thank you for calling this hearing. This Committee has a unique and important role to play in educating the public about the effect of Supreme Court decisions. The Court has made numerous decisions interpreting federal banking, health care, and consumer protection statutes that have far reaching implications for the health and personal finances of millions of Americans. Decisions on controversial social issues typically get the headlines, and there is no denying that they are important. But the impact on ordinary people of the decisions that our witnesses will discuss today is often much greater.

Some of today's testimony is truly tragic. Particularly in the area of ERISA preemption, the Court's decisions have a very real effect on Americans' health and well-being. That's because, when the Court decides that state tort claims are preempted, it isn't just deciding that certain people will not get the compensation they deserve through lawsuits. Rather, it is creating incentives for insurance companies and HMOs to deny coverage and prevent people from getting the treatment or the medication that they need to survive. As hard as it is to hear these stories, I'm glad this hearing is focusing attention on the real victims of these decisions by the Supreme Court.

I wanted to highlight one area that is briefly mentioned by one of the witness, but not explored in much detail in the testimony – mandatory arbitration. One very good example of a very old federal statute that has been interpreted in a way that causes great harm to consumers is the Federal Arbitration Act. That statute was passed in 1925 to give legal approval to a process that had been developed to allow businesses to adjudicate their disputes with each other outside of the regular legal system. Arbitration was in its infancy and participants in it needed the certainty that they could enforce the decisions of arbitrators in court. The FAA decreed that contracts to arbitrate could be enforced in court like any other contract.

In decisions beginning in the 1980s, the Supreme Court began to very broadly interpret the FAA, turning it into a tool for corporations to abuse their greater bargaining power in their dealings with consumers and employees. The *Southland* case in 1984 held that the FAA preempted state laws that prohibited

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arbitration provisions in certain contracts. The *Circuit City* case in 2001 narrowly interpreted the exemption from the FAA for employment contracts. As Justice Stevens noted in his dissent in *Circuit City*:

> "[N]either the history of the drafting of the [Federal Arbitration Act] by the ABA, nor the records of the deliberations in Congress during the years preceding the ultimate enactment of the Act in 1925, contain any evidence that the proponents of the legislation intended it to apply to agreements affecting employment."

The result of these and other decisions has been to encourage and approve the use of mandatory arbitration in a whole range of contracts that average citizens and consumers are pretty much forced to accept if they want a credit card, a cell phone, health coverage from an HMO, care for an aging parent in a nursing home, or to invest in the stock market. Through its decisions, the Supreme Court has essentially looked the other way as a parallel legal system has developed – a system that lacks due process protections and that, in too many cases, is not fair to both sides of a dispute. Most important, that system has not been voluntarily chosen by both parties.

While the subject of today's hearing is the Supreme Court, I think we would be remiss if we didn't note Congress's role in these issues. The federal statutes that the Court has misinterpreted were passed by Congress. They can be amended by Congress. I hope that one result of this hearing will be to refocus attention on legislation that is desperately needed to reverse some of the Supreme Court's most damaging decisions, including those on equal pay, medical device preemption, ERISA, and mandatory arbitration. In the end, while we can complain about the Court's unwillingness to properly interpret congressional enactments, if we don't act to correct the mistakes the Court has made, we have only ourselves to blame.

Thank you Mr. Chairman.

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One Johnson & Johnson Plaza
New Brunswick, NJ 08933
June 17, 2008

Thank you for your introduction, Mr. Chairman. On behalf of the nearly 120,000 employees of the Johnson & Johnson Family of Companies, thank you for the opportunity to speak here today.

Let me briefly tell you about Johnson & Johnson.

Our consumer health care businesses are responsible for many familiar personal products used in baby care, skin care, oral care, wound care and women's health, including familiar brands such as JOHNSON'S® Baby and BAND-AID® Brand. We also market an extensive line of over-the-counter medicines that include such well-known names as TYLENOL® and MOTRIN®.

Our medical device and diagnostic businesses supply professional products to physicians, surgeons, consumers, and laboratories for many uses, including patient care, wound closure, diagnosis, blood testing and surgery. Surgical implants, needles, sutures, endoscopic instruments, orthopedic products, infection control products, cardiovascular monitoring and vascular access products are among our wide array of products used by medical professionals.

Our pharmaceuticals businesses develop and have brought to market prescription products including products for psychiatry, infection control, cancer, immunotherapy, family planning, and cardiovascular disease. We discover and manufacture both traditional and small molecule medicines, as well as biotechnology-derived products.

Counterfeit healthcare products present an extraordinary risk to patients and consumers.

According to the United States Food and Drug Administration (FDA), the United States pharmaceutical supply chain is one of the safest in the world. Nonetheless, counterfeiting of healthcare products is a growing concern for society. The World Health Organization estimates that 8-10% of pharmaceutical products outside the United States are counterfeit. In some countries, counterfeit products may represent 50% of medicines in the marketplace.

Until recently lifestyle and biological products have been primary targets of counterfeiters. Counterfeit heart, arthritis, asthma, HIV and AIDS, diabetes, and cancer medications have been found. Even relatively low cost consumer products such as shampoo and toothpaste have been counterfeited.

Medical devices are not immune to counterfeiting. A *Gray Sheet* article dated June 2, 2008, stated, "Counterfeiting of medical devices, including sophisticated implantable devices, is a growing threat to patient safety and manufacturers' reputations." Medical device businesses of Johnson & Johnson have experienced counterfeit medical devices.

The Internet is becoming the marketplace of choice for the counterfeiter. Counterfeit pharmaceutical products can be purchased from a wide variety of unregulated Internet pharmacies. These Internet pharmacies are in many cases shams, selling potentially ineffective or unsafe products. The counterfeiter can easily sell their products via a website and distribute them into the U.S. via the U.S. postal or private express mail services to their unsuspecting customers. Counterfeit and diverted medical devices can be purchased via on-line auction sites.

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These scams are so widespread that according to the Pharmaceutical Security Institute, "seizures of bogus prescription medicines jumped 24 percent to 1,513 incidents in 2007, and illicit versions of 403 different prescription drugs were confiscated in 99 countries." The FDA Office of Criminal Investigations (OCI) and border inspection officials make many seizures of illicit products each year, but the federal resources cannot catch every package containing an illegal product.

Another avenue for counterfeiters to introduce fakes or substandard product into the supply chain is diversion. Diversion refers to merchandise that is distributed into markets other than originally intended in violation of a contract, law or regulation. Diverted product, commonly referred to as "grey market" product, is frequently past dated or expired, had been previously marked for destruction, had not been properly stored, or is counterfeit product. When product is diverted, authentic and grey market products travel together through the supply chain creating confusion. For example, a hospital could receive legitimate and diverted product in the same shipment. The diverted product is stocked on the same shelf beside the legitimate product. A surgeon could unknowingly select the diverted product and implant a substandard product into the patient. The patient could experience a wide range of medical complications.

Counterfeiters show total disregard for the safety of consumers, patients, doctors and nurses who unwittingly encounter the counterfeit product. Counterfeiters don't care about product quality, safety, or efficacy. People who use a counterfeit healthcare product run the risk of a wide variety of medical problems ranging from experiencing no therapeutic benefit, to new illnesses, and even death.

Counterfeiters have no regard for intellectual property (IP) rights. They take advantage of countries with gaps in IP laws or where enforcement of these laws are nonexistent or lax. Some countries do not enforce IP laws for products made for export only. These countries provide the counterfeiter a safe haven for their operations. The active ingredient can be manufactured in one country, exported to a second where the product is packaged, exported to a third country where it is labeled and finished packaged, and exported for final sale.

Johnson & Johnson supports Sen. Evan Bayh (D-IN) and Sen. George Voinovich (R-OH) for co-sponsoring legislation that strengthens patent enforcement overseas to help prevent the very lucrative and shady business of product piracy and counterfeiting.

Both healthcare manufacturers and governmental regulators have begun taking action to combat counterfeiting and to protect our consumers and patients. Many healthcare manufacturers have invested in measures to tighten the security of supply chains and products. These measures are multifaceted with IP and trademark protection being just two key areas of focused effort.

While much work remains, here are some examples where manufacturers are focusing their efforts:

- Renegotiating trade agreements with authorized distributors of record (ADR's) to ensure ADR's only buy directly from the manufacturer or a manufacturer's approved source.
- Conducting market monitoring activities and auditing trading practices to identify sources of illicit trade.
- Collaborating with customs and police to investigate suspected cases of counterfeit or tampering activities, and aggressively prosecuting the offenders.
- Working with governmental agencies to ensure trademark and IP laws are enforced and prosecuting infringements.
- Applying overt and covert features to products and product packaging to aid in product identification.
- Deploying communication programs to healthcare professionals and downstream supply chain partners encouraging them to buy from approved sources and alerting them to the dangers of counterfeit or tampered products.

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- Investigating and piloting track & trace and pedigree systems to communicate the product's chain of custody. These systems are intended to improve visibility into the supply chain and gain greater clarity into where products have been and where they are moving to in the supply chain.

Pedigree documents the chain of custody of a specific product after it leaves the ownership of the manufacturer. Regulators have been working on regulations at state and federal levels, and in other countries requiring pedigree on pharmaceuticals. Over 30 U.S. states have enacted pharmaceutical pedigree legislation. Countries as diverse as Turkey, Japan, Brazil, Serbia and Slovenia have, or are considering, legislation requiring tracking and tracing of pharmaceutical products. As a result, we have a patchwork quilt of pedigree laws and regulations that could defeat the purpose of improving supply chain security.

We believe that the Senate Judiciary Committee should be interested in eliminating the complexity of multiple pedigree laws, which may result in fraudulent - and even counterfeit - pedigrees, and in its place implement a simple and potentially effective solution: the electronic pedigree (ePedigree). Making distributors produce ePedigrees for law enforcement when products are questioned would increase the effectiveness of law enforcement in combating counterfeiting. Immediate information about the authenticity of a product puts powerful information in the hands of law enforcement for enforcement action. Within the U.S., a federal standard is required for electronic pedigree. This is an area where the federal government can and should take the lead.

We cannot over emphasize that the integrity of the pharmaceutical and medical device supply chain is essential to the well being of all of our citizens. Patients and consumers rely on our medicines, medical devices and personal products everyday to improve the quality of their lives and, in many cases, to save their lives. Healthcare manufacturers depend upon the integrity of our supply chain to ensure that patients and consumers receive genuine products from approved sources.

As the healthcare supply chain becomes increasingly global, coordination across manufacturers, distributors, pharmacies, hospitals, and a wide variety of governmental agencies will be imperative to ensure the integrity of the healthcare supply chain.

There is a critical and concerted effort to maintaining supply chain integrity across the industry. Yet, as counterfeiters increase their activity and sophistication in creating fake products, industry must also increase resources to address this criminal activity. This requires a diversion of industry resources that otherwise would be applied to drive medical innovations that will address some of today's most pressing health care challenges.

Here are some examples where we believe Congress could encourage governmental agencies to work together to protect patients and consumers from counterfeit products.

Congress should....

- Pass legislation that would enable the FDA to establish industry-wide implementation dates for federal pedigree standards. The FDA should be encouraged to work with state and international regulators to develop effective, practical pedigree and track & trace standards for the United States and globally.
- Support a review of the FDA's Office of Criminal Investigation's procedures and organizational capacity for handling enforcement actions. OCI is an important FDA resource to help manufacturers combat counterfeit products.
- Encourage the FDA's regulatory and OCI divisions to develop a common approach for working with the healthcare industry on investigation and enforcement actions.

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- Enact legislation that ensures manufacturers can protect their products no matter where they are in the supply chain so that consumers are protected from unwittingly receiving adulterated products. Including requiring that all returned product be sent back to the manufacturer.
- Provide sufficient resources to the Patent and Trademark Office to work with their international counterparts to ensure proper IP protection and the enforcement of existing IP laws.
- Sponsor a nation-wide awareness campaign aimed at consumers to warn them about the dangers of opportunistic purchases of medications from non-licensed health care providers.

As I stated earlier in my comments, we are fortunate to be living in the United States and to be served by one of the most secure healthcare supply chains. Johnson & Johnson believes it is our responsibility to help ensure that all people receive genuine, unadulterated products from trusted authorized trading partners. All people deserve the right to be protected from the dangerous effects of counterfeit products.

Johnson & Johnson is pleased to work with Congress, the FDA and any other governmental agencies whether Federal, State or International to develop effective laws and regulations to protect patients and consumers from counterfeit products. We are ready to make our company experts available to these legislative and regulatory efforts.

Thank you for allowing Johnson & Johnson to share our perspective on this critical issue with you today. If we can be of any further assistance, we are available to help this committee. I am happy to answer your questions.

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Statement of Maureen Kurtek
Pottsville, Pennsylvania

Senate Judiciary Hearing entitled:
"Short-change for Consumers and Short-shrift for Congress? The Supreme Court's Treatment of Laws that Protect Americans' Health, Safety, Jobs and Retirement"

June 11, 2008

Chairman Leahy, Ranking Member Specter and Members of the Committee:

A health insurance company should never be allowed to jeopardize a person's health while they look for ways to save money. But when they do they should be held accountable.

My name is Maureen Kurtek. I am 44 years old and live in Pottsville, Pennsylvania. I am a registered nurse by training and last worked in an ICU.

I have lupus. I was diagnosed in 1989 when I was 25 years old. I suffer from complications of thrombocytopenia, which is a low platelet count and antiphospholipid syndrome (APLS) which means I produce blood clots.

For the low platelet count I began treatment with large doses of steroids. Because of the negative effects of chronic steroid use, I was evaluated at Thomas Jefferson University Hospital in Philadelphia. My doctors agreed that a therapy called IVIG would be beneficial to me and enable me to taper the use of steroids.

IVIG (Intravenous Immunoglobulin IG) is the IGG portion of the blood which helps to fight infection by building up a patient's resistance. People with autoimmune diseases such as myself do not have a normal resistance to germs, which is comparable to a person undergoing chemotherapy.

My doctors were right. Periodic IVIG therapy enabled me to avoid high dose steroids. IVIG therapy raised my platelet count and boosted my immunities.

IVIG therapy is expensive. My first series of treatments in 1998 cost about $14,000.00 and was paid for by Pennsylvania Blue Cross and Blue Shield through my husband's employer.

I had two more treatments, one in 1999 and one in 2001, paid for by Pennsylvania Blue Cross and Blue Shield.

In January 2003, my platelet count was very low and my doctor recommended another IVIG treatment. At the time, my husband had just changed jobs and our health insurance company was now Capital Blue Cross.

I immediately called Capital Blue Cross to preauthorize the treatment, which according to the Plan; they would pay for as long as it was medically necessary.

It was indeed medically necessary for me.

I first called Capital Blue Cross on January 17, 2003. The first representative wanted to look into whether the treatment could be provided by home health instead of in a hospital.

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The next Capital representative on the same day told me she thought the treatment was "experimental."

I repeatedly asked to speak with a supervisor and was told that Capital was continuing to look into this and would report back to me once a decision was made.

Every time I called, I was told that "someone was working on it." I was also told that the supervisor had a note on her desk with my name and number.

Capital knew I had received this treatment three times in the past, and Pennsylvania Blue Cross paid for it.

Capital did not call any of my doctors.

Due to the fact I could not receive the IVIG, my doctor increased my dose of prednisone, which suppresses the immune system and keeps my platelet count up, so that I would not bleed to death while I was waiting to hear from the insurance company.

It took the insurer 53 days to determine that IVIG therapy was necessary for my medical condition.

By then I had nearly died. Due to not receiving my treatment, I became septic with a white blood count of 24,000 and a low blood pressure of 69/34. I developed an infection my body could not fight since my platelet count was so low.

On March 1, 2003, I was taken by ambulance to Pottsville Hospital and thereafter transferred on an emergency basis to Reading Hospital for what proved to be an acute flare up of my lupus and catastrophic APLS. According to my doctor, this condition could have been prevented or dramatically diminished had I received the medically necessary IV IG therapy during the time period when I requested pre-approval.

It was not until March 11, 2003 while I was an inpatient at the Reading Hospital that I received a voice mail message at home from Capital that the IV IG therapy would be covered under Capital's comprehensive health coverage under the Blue Cross portion of the contract and would be covered at 100% as long as the services are medically necessary.

The very first treatment I received after being admitted to the hospital was emergent IV IG therapy. While at Reading Medical Center, I was in critical condition in septic shock with multi system organ failure. The doctors told my husband I had a five percent chance of survival. My platelet count was 20,000.

After going into septic shock, I went into kidney failure and due to having Systematic Lupus Erythemous with A/B syndrome, my body also started to throw clots at the same time as it bled out. I had blood clots in my hands and feet while I also suffered uncontrollable hemorrhaging of the sinuses causing blood to enter my lungs. I was

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bleeding from every orifice in the body including the eyes and mouth at the same time as I suffered from blood clots. All of this could have been prevented had I received the IVIG treatment I had received many times before.

During my hospitalization, I was in respiratory failure and required ventilation on a respirator and within 24 hours had an emergency tracheotomy due to bleeding into my sinuses. My extremities were clamped down and clotted, and I experienced excruciating pain in my fingers and feet. I was so weak it took four nurses to roll over in bed. I couldn't do anything. I could not even hold a toothbrush I almost died because of this injustice and parts of me actually did die.

As a result of the extraordinary delay in approval of IV IG therapy, I had half of my right foot amputated, have developed osteomyelitis of my right foot, have lost the tips of five fingers, I have discoloration and redness in my face, including scarring of my nose, have difficulty breathing through my nose, have undergone surgeries, am required to take Lovenox, 2 injections daily, have developed peripheral neuropathy, and am required to wear special shoes.

There is no doubt the insurance company unnecessarily delayed approval of IVIG therapy while trying to find a way to deny coverage, and my family and I paid a heavy price.

I filed a lawsuit against the insurance company not only because of the harm they caused me but also to prevent them from doing this to someone else. The judge dismissed my case because the ERISA law does not allow people like me to sue for the harm the insurance company caused me. Because the law insulates them from any liability for their conduct, they have every incentive to delay or deny treatment in an effort to try to save money. Instead the ERISA law as the late Judge Becker stated "has evolved into a shield that insulates HMOs from liability for even the most egregious acts of dereliction committed against plan beneficiaries"

Because of ERISA, there is a monetary incentive for insurance companies to mistreat people like me who have health problems and are unaware of our rights. According to the law, the only remedy in court for me would have been to file an injunction to force the insurance company to pay for the treatment. I did not know I could do that and even if I did, I did not have the time or money to hire a lawyer. I relied on the insurance company who kept telling me someone would get back to me soon.

I am privileged to be here today to tell you about how the ERISA law has hurt me and my family. I'm wearing a tear shaped necklace given to me by family members who had to watch me cry tears of blood. Instead of protecting the American people, this law favors the insurance industry.

At the time I was sick, I had a 13 year old son who did not know whether his mom would even make it through the night. I had a husband who didn't know whether in a few days he would be a single parent and have to raise a child while trying to support a family on a modest income. And, all of this pain and suffering was caused by an insurance company

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that failed to provide me with a treatment that I had received six times prior at the same hospital under the same insurance provider with good effective results. Previously, this treatment had helped my body increase its ability to fight infection and keep my platelet count at a normal level. This treatment was prescribed for me by at least seven doctors and two specialists and was never considered to be experimental by them. This treatment, although expensive, was necessary for me. And, my insurance company delayed my treatment.

I stand before you today with a tracheotomy scar on my neck, five amputated finger tips and an amputated right foot where I still experience phantom pains. Life ceased as I had known it. I can no longer jog or dance. I can not wear stylish shoes on special occasions such as my son's graduation, and I have to wear an orthopedic shoe which I can assure you is not the dream of any woman. During my time in the hospital, I missed my son's spelling bee, piano recital, his confirmation at church and baseball games. These are events I can never get back.

Due to this law, insurance companies can get away with denying care and delaying treatment without any consequences. This is wrong. We need to change this law so no families will have to suffer the way mine has.

Thank you for your time. I would be happy to answer any questions.

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WRITTEN TESTIMONY OF PROFESSOR ROBERT M. LAWLESS
University of Illinois College of Law
June 11, 2008

My name is Robert Lawless, and I thank you for extending me the privilege to speak with you today. In my work as a Professor of Law and the Galowich-Huizenga Faculty Scholar at the University of Illinois College of Law, I study bankruptcy and financial services law. My research includes surveys and interviews with everyday Americans that help to tell us how these laws and the courts' applications of these laws puts economic pressure on families. Also, I have had opportunity to write about the role of the Supreme Court in financial services and offer academic commentary on the changing economic nature of the American family on our jointly authored blog, *Credit Slips*.[1]

This work shows how very technical and dry regulatory issues—issues that only a lawyer could love—can end up as Supreme Court cases that dig into the pocketbooks of consumers. These cases are litigated outside the blare of the media spotlight, followed closely only by experts and obscure to the millions of consumers who will bear the brunt of the decisions. The committee is to be commended for convening this hearing and casting some light on the importance of these underappreciated cases.

This is not a partisan issue, not a matter of the justices or some subset of the justices sitting in a room and deciding to be "pro-business" or "anti-consumer." Instead, it is a simple fact of our political system that cases are going to end up in the Supreme Court where business

[1] *See* Robert M. Lawless, *Bankruptcy* in ENCYCLOPEDIA OF THE SUPREME COURT OF THE UNITED STATES, forthcoming 2008; Robert M. Lawless, *Marquette National Bank v. First of Omaha Service Corp.*, in ENCYCLOPEDIA OF THE SUPREME COURT OF THE UNITED STATES, forthcoming 2008; Robert M. Lawless & Dylan Lager Murray, *An Empirical Analysis of Bankruptcy Certiorari*, 62 MO. L. REV. 101 (1997) ; Robert M. Lawless, *Legisprudence Through a Bankruptcy Lens: A Study in the Supreme Court's Bankruptcy Cases*, 47 SYRACUSE L. REV. 1 (1996); Charles J. Tabb & Robert M. Lawless ,*Of Commas, Gerunds, and Conjunctions: The Bankruptcy Jurisprudence of the Rehnquist Court*, 42 SYRACUSE L. REV. 823 (1991). The *Credit Slips* blog can be found at http://www.creditslips.org.

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interests will have systematic advantages. The good news is that there are measures Congress could take to restore some of the balance. This is not the place for a dry recitation of dozens of case holdings, but it is appropriate to begin with an overview of a few illustrative examples.

I. Some Examples of Supreme Court Cases Where Business Won Big

a. *Credit Card Debt, Interest Rates, and Fees*

In his comments to the Federal Reserve's proposed regulations to prohibit unfair credit card practices, Mr. Michael Rosado of Elkton, Maryland, writes about how a credit card company's mistake resulted in penalty rates that rose into the "high 20's."[2] As a citizen of Maryland, Mr. Rosado is protected by a usury law that prohibits a creditor from charging more than 24% interest.[3] How is it possible, then, for Mr. Rosado to be charged interest over 24%? Because of the Supreme Court's decision in *Marquette National Bank v. First of Omaha Serv. Corp.*,[4] the Maryland usury statute is virtually worthless to Mr. Rosado and every other Marylander. National consumer lenders operate in an environment that is free of usury restrictions because of the *Marquette* decision.

Marquette's legacy is not just about the cost of consumer debt but also the amount of it. There is now more than $53,000 in mortgage and consumer debt for every man, woman, and child in the United States. That figure represents an average across everyone—those with credit card debt and those without, adults and children, the young and the old; homeowners and renters. Our personal debt is outstripped by our annual personal income, which was not true as recently

[2] *See* Comments of Michael L. Rosado to Proposed Regulation AA, available at http://www.federalreserve.gov/SECRS/2008/May/20080527/R-1314/R-1314_730_1.pdf (May 19, 2008).
[3] Maryland Code, Commercial Law § 12-903.
[4] 439 U.S. 299 (1978).

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as 2003.[5] If, as a nation, we devoted all of our personal income this year to debt repayment—forgoing things like shelter, food, health care, and all other necessities—we still would not retire our outstanding personal debt.

In *Marquette*, the issue revolved around the interpretation of five words in section 85 of the National Bank Act.[6] Other than experts in the banking industry, few people would have any idea of what section 85 provides or, for that matter, what the National Bank Act provides. Passed in 1864, the National Bank Act created a national banking system and was intended to help create a stable national currency amidst the financial chaos of the Civil War. Section 85 of that law allows a national bank to charge an interest rate allowed by the state "where the bank is located." By enacting section 85, Congress wanted to protect nationally chartered banks from predatory state legislation designed to drive the nationally chartered banks out of business to the benefit of state-chartered. In 1864, bank lending was primarily a local business. Banks lent on the strength of personal relationships with members of the local community. The idea that a bank in one state would seek out lending business with citizens in another state was simply not something an 1864 Congress would have considered.

By 1978, information technology had dramatically changed the potential meaning of section 85. The *Marquette* case had its genesis in the decision of a Nebraska bank to expand its operations and lend to Minnesota citizens at an interest rate greater than allowed under Minnesota law but less than the amount allowed under Nebraska law. First of Omaha Bank argued that section 85 allowed it to charge the interest rate allowed by Nebraska law, the interest rate allowed by the state where First of Omaha was physically located. Although Congress had intended section 85 as a shield for national banks, First National Bank of Omaha now wanted to

[5] *See* Bob Lawless, "One to Lie Awake at Night About," *Credit Slips* (May 14, 2007) (http://www.creditslips.org/creditslips/2007/05/one_to_lie_awak.html).
[6] 12 U.S.C. § 85.

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use section 85 as a sword to export Nebraska's interest rate into Minnesota. Ignoring the purpose of the National Bank Act and Congress' original intentions, the Supreme Court agreed with First National Bank.

The effect of the *Marquette* decision cannot be understated. Because a national bank now could charge whatever interest rate its own state allowed, some states simply repealed their interest rate caps. The national banks flocked to these states, set up operating subsidiaries, and began issuing credit cards at interest rates that would have been illegal under the state law where consumers were using these credit cards. Whichever states were willing to race to the bottom and offer the fewest consumer protections would win all of the consumer credit business. When consumers wonder how it can possibly be legal to get charged an interest rate that would have been considered usurious a generation ago, they can look to the *Marquette* decision

With banks able to charge whatever interest rate they could get customers to pay, household debt exploded, and this increase in household debt is one of the greatest changes of our generation. We have come from a society where consumer debt was unusual to a society where consumer debt is ubiquitous. Where our parents would have been shocked to hear a neighbor owed a great deal of money, we now have conversations where permanent indebtedness is discussed a way of life. All of these effects can be traced to a decision of the United States Supreme Court.

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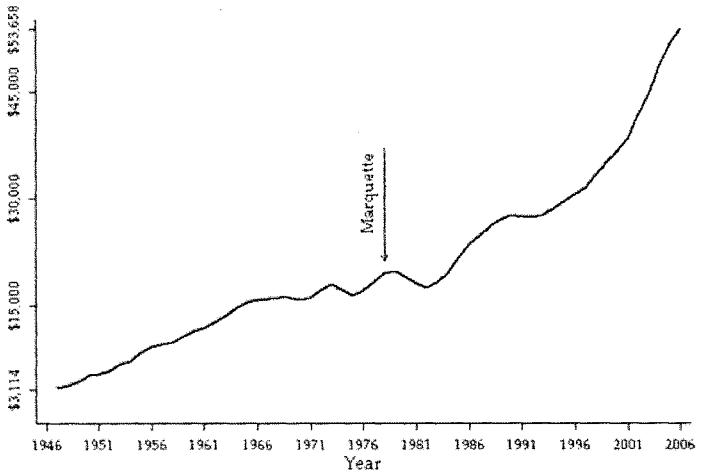
Growth in Mortgage and Consumer Debt per Adult Population, 1946-2006

Figure 1



Figures represent inflation-adjusted (to 2006 dollars) amount of debt outstanding for the adult population. Sources: Federal Reserve, Census Bureau, Department of Labor

Today's consumers know that it is not just the interest rates that credit card companies charge but also the fees. For example, late fees on credit cards average close to $35 and have more than doubled since 1996.[7] What happened in 1996? In *Smiley v. Citibank (South Dakota)*,[8] the Supreme Court extended the logic of *Marquette* to credit card fees.

In *Smiley*, a citizen of California sought the protection of California state law against late fees Citibank charged on top of the exorbitant penalty default interest rates that *Marquette* already had allowed. Citibank again turned to the same words in the National Bank Act as had been at issue in *Marquette*. The difficulty for Citibank was that the National Bank Act said the bank could charge "interest" as allowed by the law where the bank was located and a late "fee"

[7] *See* Government Accountability Office, *Credit Cards: Increased Complexity in Rates and Fees Heightens Need for More Effective Disclosures to Consumers*, at 18 (September 2006)
[8] 517 U.S. 735 (1996).

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did not seem to be the same as "interest." Nevertheless, Citibank was able to cite an interpretive regulation of the Office of the Comptroller of the Currency (OCC) that said the term "interest" included any compensation paid to a lender including late fees. The OCC had equated "interest" and "fees," which was quite helpful to Citibank's legal case. Although the Supreme Court viewed the question as close, it placed particular emphasis on the OCC's regulation and ruled for Citibank.[9]

Smiley led to the same dynamic as happened after *Marquette*: when it came to fees banks simply exported the law most favorable to the banks, meaning an Illinois or Pennsylvania consumer would have to pay whatever fee the law of another state allowed. When consumers pay a $39 late fee, a 3% currency conversion fee, or a 3% balance-transfer fee, they can look to the *Smiley* decision for the reason why.

b. No Help for Homeowners in Bankruptcy

It is hardly novel to point out that America is in the middle of a debt crisis. According to newly released statistics from the Mortgage Bankers Association, nearly one in ten Americans are experiencing difficulty with their home loans, either facing foreclosure or behind in their payments.[10] Many of these homeowners owe more than their home is worth.

For these homeowners, bankruptcy court does not provide the relief it could. As committee members are probably aware, Senator Durbin has introduced S. 2136 to address this shortcoming and give bankruptcy judges the tools they need to help keep financially troubled Americans in their homes. Bankruptcy is no shortcut and only gives a second chance to the honest but unfortunate debtor. It does not wipe out obligations for which a lender holds

[9] *See Smiley*, 517 U.S. at 739-45.
[10] Michael Grynbaum, "Nearly 1 in 10 Homeowners Face Loan Problems," N.Y. Times, June 6, 2008 (available at http://www.nytimes.com/2008/06/06/business/06mortgage.html?hp).

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collateral. Failure to pay a car loan or home mortgage, even after bankruptcy, will result in foreclosure and repossession. To receive a discharge, debtors have to turn over all of their assets to the bankruptcy trustee or devote all of their disposable income for three to five years to repayment of creditors. Moreover, bankruptcy judges have discretion to provide more limited relief or to dismiss cases where particular circumstances indicate abusive behavior by a debtor. What bankruptcy judges lack are effective tools to deal with the home mortgage mess in which we find ourselves.

Senator Durbin's bill addresses this imbalance and simply would put a lender in the same position it would be outside of bankruptcy if it had gone through a foreclosure and extended another loan on the property. Homeowners would have to pay off the value of the home over time at the current market rate of interest. If the payments were not completed, the bank would still have the right to take the home. Senator Durbin and his cosponsors—including Senators Biden, Feinstein, Schumer, and Whitehouse of this committee—are to be commended for sponsoring this important piece of legislation.

Senator Durbin's legislation would have been unnecessary had the Supreme Court not taken this power from the bankruptcy judges in a case called *Nobelman v. American Savings Bank.*[11] In that case, a married couple owed more than $71,000 on a condominium that no one disputed was worth more than $23,500. Using chapter 13, they asked a bankruptcy court to put the bank in the position it would be in a foreclosure—requiring them to pay the value of $23,500. If the Nobelmans could not make this payment, the bank would still have the power to take the condominium. The dollar amounts tell us this was not an extravagant spender seeking protection on a multimillion dollar mansion. This was a modest home for which the debtors turned to the bankruptcy courts in an attempt to keep it.

[11] 508 U.S. 324 (1993).

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By the time they got to the Supreme Court, these everyday realities had turned into a legal debate that would keep only a bankruptcy lawyer's interest. At issue was the interaction of complex statutory provisions scattered throughout the Bankruptcy Code, and beyond a narrow circle of bankruptcy specialists, the case received little attention at the time. A Senate committee hearing room is not the place to dissect the statutory language at issue, and my students might even contest whether they should hear about it in the law school classroom. The interpretive issues in *Nobelman* were truly complex, and it is fair to say that there were reasonable arguments on either side of the issue.

Although fair-minded justices could reach either outcome, the Supreme Court unanimously sided with the banking interests. In doing so, the Court reached a decision that was contrary to the majority view in the lower federal courts. In doing so, the Court strengthened special advantages home lenders had managed to get in the enactment of the original Bankruptcy Code. In doing so, the Court barred relief on a modest principal residence that would be available for vacation homes or investment property. In doing so, the Court left the burden of legislative change with the consumer. The reception that Senator Durbin's bill has received gives some indication of the relative powers of banking interests and consumer interests in the legislative process. By reaching a decision in favor of banking interests, the Court essentially locked in the law and now has led to a situation where bankruptcy judges are deprived of a potentially important tool in a financial crisis.

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c. Taking Away Enforcement Power of State Attorneys General

My final example comes from just the last Supreme Court term. In *Watters v. Wachovia Bank*,[12] the Court deprived the state attorneys general of the power to enforce state consumer law against the operating subsidiaries of national banks. Rather than dispersed among fifty state attorneys general, the responsibility for enforcing consumer protection against national banks now rests solely with the OCC. This is the same agency that took the banking industry's side by issuing favorable regulations leading to the *Smiley* decision, and the same agency whose industry favoritism has been the subject of recent media attention.[13] Why does responsibility for consumer protection now rest solely with the OCC?—because the OCC had issued regulations saying it did. The issue in *Watters* was whether the Court should uphold these OCC regulations, and a majority of the Court agreed that the OCC could issue regulations that defined the scope of its own authority to displace contrary state law.

Watters will be a case that consumers will feel in the years to come. Even if the OCC suddenly became interested in more strictly enforcing consumer protections, it will lack the resources and interest that fifty state attorneys general could bring. For example, before *Watters*, the New York attorney general had brought a proceeding to investigate overcharging by mortgage lenders. The investigation was not about fees that were too high or about debtors who were trying to escape responsibility for loans. Instead, the investigation was triggered by a modest $27,000 home loan, incurred in 1974 and paid off over 25 years. Despite its own paperwork that showed the loan had been completely paid off, the lender had collected over $9,400 in extra payments. After *Watters*, the New York attorney general would not be able to

[12] 127 S. Ct. 1559 (2007).
[13] *E.g.*, Zvika Krieger, "The Nefarious Bureaucrat Who's Helping Banks Rip You Off," The New Republic, July 2, 2007, at 14.

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bring this investigation, and the affected consumer will have to turn to the OCC for whatever help it is inclined to offer.

Another example of how *Watters* will come to affect consumers comes from the cover story of a recent issue of *Business Week.*[14] The city of San Francisco has sued the National Arbitration Forum (NAF) alleging it "is actually in the business of operating an arbitration mill, churning out arbitration awards in favor of debt collectors and against California consumers."[15] *Business Week* tells the story of Laurie Raymond, an Oregon attorney who had to fight a $16,000 arbitration award from NAF. Raymond had not incurred the debt, which had to be the result of a fraud or a mistake. The credit card company at times had even admitted Raymond did not owe the money. An attorney herself, Raymond had the resources and knowledge to wage a two-year fight with the NAF. Others will not be so lucky. Because of the broad authority upheld in *Watters*, attempts to fight unjustified arbitration awards from credit card debt collections like that of the San Francisco city attorney will be met by claims they are precluded by federal law. Reports are even beginning to surface that some lenders are using *Watters* to argue they are exempt from basic state foreclosure laws.[16]

II. Why Business Tends to Win

These cases illustrate the tilted playing field in favor of big business. No one would seriously suggest that the justices sit down in a back room and consciously decide to be "pro-business" or "anti-consumer." Instead, these results come more from a litigation system that

[14] Robert Berner and Brian Grow, "Banks vs. Consumers (Guess Who Wins)," Business Week, June 5, 2008 (available at http://www.businessweek.com/magazine/content/08_24/b4088072611398.htm).
[15] Sam Zuckerman, "S.F. Sues Credit Card Service, Alleging Bias," S.F. Chron., Apr. 8, 2008 (available at http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2008/04/08/BU2S101CV2.DTL).
[16] *See* Elizabeth Warren, "Banks: State Laws Not for Us," *Credit Slips* (available at http://www.creditslips.org/creditslips/2008/05/banks-state-law.html).

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produces systematic advantages for big business by the time cases get to the highest court in the land.

In the financial services area with which I am most familiar, the cases that make it to the Supreme Court typically involve very technical and complex statutory schemes in which the justices are unlikely to have had a deep background prior to assuming the bench. Moreover, the justices are unlikely to come to the Court with deeply held ideological convictions on the proper scope of the chapter 13 cramdown—as was at issue in *Nobelman*—or the preemptive scope of the National Bank Act—as was at issue in *Marquette* and *Smiley*. Unanimity (or near unanimity) in these cases often will reflect these realities. An individual justice does not have much to gain from being a lone dissenter on the meaning of five words in section 85 of the National Bank Act and can gain more by trading votes or joining an opinion to display collegiality that later might be severely tested by a dissent in a higher-profile decision.

For these reasons, Supreme Court litigation is especially susceptible to the dynamics of litigation and the regulatory process that especially help big business. In my areas of specialty, I see two inescapable parts of the institutional structure that play a role. First, on a highly technical regulatory issue, the position of the agency involved or the brief of the Solicitor General often sways the outcome in the Supreme Court. Second, because they often will be simultaneously litigating the same issue in dozens of the same cases, a big business like a credit card company can choose to take to the Supreme Court whichever case has facts that present its position in the best possible light.

As part of the Department of Justice, the Solicitor General's views will come and go with changes in administrations. An administration with a tin ear toward the concerns of consumers is likely to have a Solicitor General with similar views. Even beyond the ideological slant of any

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particular Solicitor General, that officer is charged with protecting the interests of the United States, and as a tax collector and creditor to many Americans, the Solicitor General often will see the interests of the United States as consonant with the interests of financial institutions. There is particular reason to believe this happens in bankruptcy cases, where the United States has appeared in the Supreme Court often to protect its interest as a creditor (generally a tax creditor).[17] As to agencies, it is an inescapable fact of the modern administrative state that they will come to identify with the industries they regulate. One need look no further than the examples of *Smiley* and *Watters* for friendly regulatory interpretations that were particularly persuasive to the Supreme Court.

As to the repeat player effect, one would hardly expect anything different from the expert and high-priced legal advice large business can command. In my work, I have found not only that institutional creditors are more able to get the Supreme Court to hear their cases in the bankruptcy area but that the same is also true for the state and federal governments.[18] Although there are undoubtedly multiple explanations, one commonality among these institutional creditors, state governments and the federal government as litigants is that they all are likely to have multiple disputes on the same issue. Repeat litigants, such as big consumer lenders, always can be expected to choose which case is the one they will take on appeal to the Supreme Court and can be expected to choose the case where they expect they will win. It also is worth noting that once they get to the Supreme Court, business interests will be able to call on far more resources than consumer interests on the other side of the courtroom.

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[17] Ronald J. Mann, *The Supreme Court, The Solicitor General and Bankruptcy*: BFP v. Resolution Trust Corp. in Bankruptcy Law Stories (Robert K. Rasmussen ed. 2007).
[18] *See* Robert M. Lawless & Dylan Lager Murray, *An Empirical Analysis of Bankruptcy Certiorari*, 62 MO. L. REV. 101 (1997).

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It is not that financial interests will always win every case, and consumers always are doomed to lose. Rather, it is matter of the deck being stacked. Big business will tend to win, and consumers will tend to lose. The result will be more of what we have seen—decisions immunizing financial institutions from state control, decisions tearing down consumer protections states have enacted for their own citizens, and decisions that free financial institutions to charge what rate, fee, or penalty they dare.

III. Solutions

One solution is for consumers to pay closer attention to what happens at the Supreme Court. This hearing is a useful step and will help draw attention to the many ways the Supreme Court's financial services decisions affect the everyday lives of Americans. These decisions, however, always will come from cases that appear to present mundane, dry, and technical regulatory issues, meaning these decisions will fare poorly in the competition for attention among the blare of other media stories. The diffusion of information made possible by the Internet has helped. I am continually heartened by the many persons who write into our *Credit Slips* blog to offer their own comments on legal and regulatory issues of the day, but our audience is still a specialized audience of persons who are particularly interested in the financial services issues we discuss. On a good day, we reach a few thousand, while news coverage on the hot button social issues that reach the Supreme Court will reach millions.

A more permanent solution might be for Congress to help even the playing field. All of the cases discussed above involved tough interpretive issues of technical statutory language where reasonable arguments could be made on either side of the case. We have seen that agency positions or systematic advantages tipped the statutory ambiguities in favor of businesses and

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against consumers. To even the playing field, Congress might adopt an interpretive rule that any ambiguity in a statute should be resolved in favor of consumer interests. This rule would place the burden of legislative change on the party most able to affect that change. When the Supreme Court decides an ambiguity in favor of financial interests, the practical result is that the rule is now locked in, given the advantages financial interests enjoy in the legislative process. Financial interests can and will lobby Congress to overturn statutory decisions, but consumer groups have less ability to organize and affect the legislative process. Moreover, interpreting rules that tip statutory ambiguities in one direction or another are hardly unprecedented. For example, the courts have a long tradition of resolving statutory ambiguities to avoid constitutional issues or resolving ambiguities in criminal statutes in favor of the accused. An interpretive rule that ambiguities should be resolved in favor of consumers could be enacted as a blanket rule or on a statute-by-statute basis. It would go a long way to helping alleviate some of the concerns expressed at this hearing.

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Statement Of Senator Patrick Leahy
Chairman, Senate Judiciary Committee
Hearing On
"Short-change For Consumers And Short-shrift For Congress?
The Supreme Court's Treatment Of Laws
That Protect Americans' Health, Safety, Jobs, And Retirement"
June 11, 2008

I called this hearing today to shine a light on how the Supreme Court's decisions affect Americans' everyday lives. Often, the Court's rulings come into focus when they involve divisive cultural issues. Lately, however, many Court observers have noticed that business interests have been the big winners, over workers and consumers. In this worsening economy, mothers and fathers are struggling with health care coverage, the uncertainty of retirement, credit card payments and mortgages. Congress has passed laws to protect Americans in these areas, but in many cases, the Supreme Court has ignored the intent of Congress in passing these measures, oftentimes turning these laws on their heads, and making them protections for big business rather than for ordinary citizens.

For almost two decades, Lilly Ledbetter worked as the sole female supervisor in a major, national corporation. Her diligence helped send her children to college, and helped her and her husband plan for the future. Before her retirement, Ms. Ledbetter received an anonymous note showing the salaries of her male counterparts. Even the lowest paid male supervisor was earning 20 percent more than she was for the same job, despite having far less experience and seniority than she did. She would later learn that the pay difference was even greater, because she was also shortchanged on bonuses, retirement benefits, and overtime pay. Ms. Ledbetter clearly proved to the jury that she had been illegally discriminated against. But the Supreme Court reversed the verdict, and created a bizarre interpretation of the law. Her employer will never be held accountable for its illegal actions. The Court's ruling tells other corporations that they can discriminate with impunity, so long as they keep their illegal actions hidden long enough. A majority of Senators support overturning the Court's decision, but 43 Senators on the other side of the aisle are preventing us from even proceeding to consider this remedy. By filibustering the Lilly Ledbetter bill, those Senators are standing behind the Supreme Court's terrible interpretation of our anti-discrimination laws.

At today's hearing, we will focus on several laws designed to protect Americans' health, safety and retirement. We will hear testimony today from two brave women who, like Ms. Ledbetter, have or will be denied relief and justice as a result of Supreme Court rulings. There are thousands more like them outside this hearing room who have been adversely affected by rulings which slam the courthouse door shut and encourage corporate misconduct.

Years ago Congress passed a landmark law known as ERISA to ensure that workers with employer-sponsored health insurance or retirement benefits could count on them when they needed them. But the Court has so distorted this law that it provides no relief for individual beneficiaries, when the companies and insurers entrusted with administering their benefit plans violate the law or the terms of the employees' plans. Moreover, the Court has held that it was the intent of Congress to take away pre-existing state law remedies for workers. The result: Congress' monumental effort to safeguard workers and their families has literally left them more vulnerable than they were before the law was passed. Great jurists from the late Justice White to

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Justice Ginsburg have decried how preposterous, unjust, and incompatible with Congress' true intent this result is. The late Judge Ed Becker, former Chief Judge of the Third Circuit, best captured the impact of this line of cases when he observed that the interpretation had devolved from the protection of ordinary Americans that was intended into a catch-22 and "into a shield that insulates HMOs from liability for even the most egregious acts of dereliction...directly contrary to the intent of Congress."

The Supreme Court has narrowly interpreted another law designed to protect Americans who rely on medical devices to keep them alive. Unfortunately, here again, the Supreme Court's interpretation has transformed the law into one that takes away protections from people by extinguishing long-standing state law remedies which hold corporations accountable when they are aware of potential dangers but hide them from consumers. As a result, Americans are not only deprived of a remedy under state law but are offered no replacement remedy under Federal law.

The last set of laws to be examined here today involves lending institutions used by Americans to finance their homes, and credit cards used for everyday purchases. In this context as well, the Court has interpreted Federal legislation in such a way that strips consumers of the right to benefit from more protective state laws. These decisions also serve to shield corporations from their misconduct. This affects everyone's pocketbook.

These Supreme Court rulings have occurred with little public attention, but have had a tremendous impact on the lives of many Americans. There has been plenty of academic discussion about the radical changes that this Court is making to preemption and federalism. But the health and retirement guarantees provided by Congress were not meant to be merely rhetorical commitments. They are essential to give every American the chance to lead a rich and full life.

In light of the troubling Supreme Court rulings we will examine today, Congress may be again required to step in with remedial action to clarify our intent, as was done in 2006 with the Voting Rights Act reauthorization. Congress is seeking to do the same with the Lilly Ledbetter bill. To paraphrase my friend and civil rights hero Congressman John Lewis, in our system of checks and balances we must meet every judicial step backward with a legislative step forward. The problem, however, with any legislative fix is that the Supreme Court might again strip it of its purpose. I hope today's hearing will be a first step in contributing to the understanding of the impact the Supreme Court has on our daily lives. I look forward to the testimony of our witnesses and thank them for traveling to be with us today.

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TESTIMONY OF

THOMAS O. MCGARITY
Joe R. and Teresa Lozano Long Endowed Chair in Administrative Law
University of Texas School of Law

on

Short-change for Consumers and Short-shrift for Congress? The Supreme Court's Treatment of Laws that Protect Americans' Health, Safety, Jobs and Retirement

United States Senate
Committee on the Judiciary

June 11, 2008

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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. With my colleague Wendy Wagner, I have recently published a book entitled *Bending Science: How Special Interests Corrupt Public Health Research* (Harvard Univ. Press 2008). My forthcoming book, entitled *The Preemption War: When Federal Bureaucracies Trump Local Juries*, will be published by Yale University Press in October of this year. I am very pleased to be here to testify on the importance of the Supreme Court as the ultimate interpreter of the statutes that Congress enacts to address serious social problems and the serious injustices that can result when the Court exercises its power to interpret federal statutes to reach a result that Congress arguably never intended and then employs the doctrine of federal preemption to impose its questionable interpretation on state common law courts.

Although the Supreme Court is quite correctly insulated from the pull and tug of electoral politics, its decisions can have a powerful impact on the lives of ordinary citizens. Most citizens are well aware of the Court's controversial decisions interpreting the United States Constitution in the areas of abortion, equal protection, freedom of speech and religion, and the death penalty. But we hear much less of the Court's power to shape our lives in its role as the interpreter of last resort of the laws that Congress enacts to protect citizens from the risks to health, safety and well-being posed by dangerous products, fraud in the marketplace, and environmental pollution.

In recent years, the Supreme Court has been far less vigilant than in the past in ascertaining the purpose underlying federal statutes when it exercises its power to interpret those statutes. An increasing number of the sitting justices appear to limit their inquiry to the words of the statute and the dictionary. At the same time, they seem more willing to interpret laws that Congress enacted to implement humanitarian and protective social goals in accordance with their views of sound public policy to reach results that are at odds with those goals. Long-standing judicial doctrines, like the "presumption against federal preemption" of state statutes and common law are either tacitly ignored or artfully avoided by some justices in their willingness to accommodate the interest of the business community in nationally uniform implementation of weak federal regulations.

Yet when the Supreme Court narrowly interprets the substantive protections provided by federal statutes to limit their range or when the Court broadly interprets preemption clauses in those statutes to restrict the ability of state court juries to award damages to innocent victims of negligence and fraud, the suffering and pain that results is no less real because it is hidden from public view.

To illustrate this point, I will focus my attention primarily on the injustice that has resulted from the Court's narrow interpretation in several cases of the remedial provisions of the Employee Retirement Income Security Act of 1974 (ERISA) and its broad interpretation of the statute's express preemption clause to preempt long-standing

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common law remedies that would otherwise be available to victims of negligence (often bordering on medical malpractice) on the part of insurance companies and health maintenance organizations when they arbitrarily deny coverage to beneficiaries of employer-sponsored employee benefit plans. Ms. Kurtek's experience is, sadly, but one of hundreds of similar instances of medical benefit plans errors that have resulted in uncompensated physical and mental damage to the erstwhile beneficiaries of such plans.

I will also briefly discuss how recent Supreme Court holdings that federal regulatory agency action preempts state common law claims deprive innocent plaintiffs of corrective justice and undercut the "backstop" role that the common law courts play in encouraging companies to behave responsibly. In this connection, I will focus particularly on recent Supreme Court holdings in cases involving medical devices, such as the defibrillator that malfunctioned in Ms. Robb, and cases involving regulated companies that have defrauded federal agencies as they attempt to implement their regulatory responsibilities.

The Supreme Court's ERISA Muddle.

The committee has just heard about the injustice suffered by Ms. Maureen Kertek. In my forthcoming book, *The Preemption War*, I relate the story of Buddy Kuhl, a Kansas City resident who died unnecessarily as a result of the inexcusable indifference of the administrator of his medical benefit plan. The designated primary care physician under Mr. Kuhl's employer-sponsored medical benefit plan recommended that he see a heart specialist after he suffered a serious heart attack. Two different specialists in turn recommended that Mr. Kuhl undergo heart surgery at a St. Louis hospital, because the local Kansas City hospitals lacked the proper equipment for the prescribed surgery. After Mr. Kuhl and his primary care physician scheduled the necessary surgery, his plan's "utilization reviewer" refused to approve his pre-certification request. Because Mr. Kuhl could not afford to pay for the operation out of his own pocket, the surgery was therefore canceled. After a third specialist agreed that surgery in St. Louis was necessary, the plan did pre-certify the operation. But Buddy's heart had deteriorated by then to the point at which surgery was no longer a feasible option. When the St. Louis specialist recommended a heart transplant instead, the plan refused to pre-certify that surgery as well. Within three months, Mr. Kuhl succumbed to the heart affliction. Buddy's family sued the medical benefit plan for malpractice, negligent infliction of emotional distress, and tortious interference with contract. At the plan's request, the federal court dismissed the case, holding that it was preempted by the ERISA.[1]

The Statutory Language.

Congress enacted the ERISA in 1974 to address mounting public concerns stemming from numerous reports of abuse of employee pension funds by employers, unions and

[1] Kuhl v. Lincoln National Health Plan of Kansas City, Inc., 999 F.2d 298 (8th Cir. 1993).

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other entities with fiduciary responsibilities for administering those funds.[2] In that statute, Congress delegated to the Department of Labor (DoL) broad authority to promulgate regulations defining relevant terms and establishing standards for administering pensions and other employee benefit plans, including those that, "through the purchase of insurance or otherwise," provide for medical care for covered employees through insurance companies and Health Maintenance Organizations (HMOs).[3] The statute also establishes a fairly elaborate civil enforcement regime that empowers the federal government, employer participants and beneficiaries to obtain relief when fiduciaries violate such plans or otherwise mishandle their fiduciary responsibilities. In particular, a participant or beneficiary may bring a civil action in federal court "to recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan" and "for appropriate relief under" the section establishing the fiduciary duties of plan administrators.[4]

Unlike many federal laws, the ERISA contains an express preemption clause stating that the Act's provisions "shall supercede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan." A savings clause provides that nothing in the Act "shall be construed to exempt or relieve any person from any law of any State which regulates insurance, banking, or securities." Neither clause explicitly mentions state common law claims of the sort that Ms. Kurtek and Mr. Kuhl brought against their medical benefit plans.[5] The courts were therefore left to determine both the scope of the express preemption clause and the reach of the savings clause.

The Supreme Court Interprets ERISA.

The injustice that Ms. Kurtek and Mr. Kuhl suffered at the hands of medical benefit plans resulted from two lines of Supreme Court precedent and the Department of Labor's failure to exercise its rulemaking power effectively to address the problem of medical benefit plans.

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[2] 29 U.S.C. § 1001(b). Aetna Health, Inc. v. Davila, Brief of United Policyholders as Amicus Curiae, January 22, 2004, at , at *24-*29; Donald T. Bogan, Protecting Patient Rights Despite ERISA: Will the Supreme Court Allow States to Regulate Managed Care? 74 Tulane L. Rev. 951 (2000), at 996; Stacy Roberts Sharp, Note, ERISA Preemption and MCO Liability: The Court's Search in Aetna Health, Inc. v. Davilla for Congress's Elusive Intent, 84 Tex. L. Rev. 1347, 1351 (2006).

[3] 29 U.S.C. § 1002(1). See Pilot Life Insurance Co. v. Dedeaux, 481 U.S. 41, 44 (1987); John H. Langbein, What ERISA Means by "Equitable": The Supreme Court's Trail of Error in Russell, Mertens, and Great-West, 103 Colum. L. Rev. 1317 (2003), at 1325 n. 52.

[4] 29 U.S.C. § 1132(a)(1)-(3).

[5] 29 U.S.C. § 1144(a) (preemption clause); 29 U.S.C. § 1144(b)(2)(A) (savings clause); 29 U.S.C. § 1144(b)(2)(B) (deemer clause).

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In the first line of cases, the Supreme Court interpreted the language in the statute providing a private remedy for violations of ERISA and its implementing regulations. In several cases, the Court drastically limited the relief available under the statute.[6] In particular, the Supreme Court held that the "equitable relief" available to a plaintiff did not include money damages. The Court majority based this strained interpretation on the hypertechnical ground that nineteenth century equity courts did not entertain claims for consequential damages attributable to violations of fiduciary obligations.[7] Yale Law School Professor John Langbein, a prominent legal historian, has concluded that this holding was probably wrong as a historical matter. The Court, in his opinion, "rendered the protections of ERISA illusory in any case in which the victim of ERISA-proscribed wrongdoing needs damages for consequential injury in order to be made whole."[8]

The second line of precedent stemmed from the Supreme Court's interpretation of the ERISA's preemption clause. In *Pilot Life Insurance Co. v. Dedeaux*, the Court held that ERISA's broad preemption clause applied to state common law claims, as well as state statutes and regulations. In particular, Congress meant for "all suits brought by beneficiaries or participants asserting improper processing of claims under ERISA-regulated plans [to] be treated as federal questions governed by" the ERISA's civil action provision.[9] In the Court's view, the ERISA established "a federal common law of rights and obligations under ERISA-regulated plans" that displaced state common law on any issue "related to" such plans.[10] The Court later held in *Metropolitan Life Insurance Co., v. Massachusetts* that Congress intended the ERISA and its implementing regulations "to displace all state laws that fall within its sphere, even including state laws that are consistent with ERISA's substantive requirements."[11] This had the effect of displacing not only state common law claims based on conduct that complied with ERISA, but also conduct that amounted to gross violations of ERISA's requirements. The Court greatly expanded the ERISA's preemptive "sphere" when it broadly construed the words "related

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[6] Great-West Life and Annuity Insurance Co. v. Knudson, 534 U.S. 204 (2002); Mertens v. Hewitt Associates, 508 U.S. 248 (1993); Massachusetts Mutual Life Insurance Co. v. Russell, 473 U.S. 134 (1985).

[7] Great-West Life and Annuity Insurance Co. v. Knudson, 534 U.S. 204 (2002); Mertens v. Hewitt Associates, 508 U.S. 248, 255 (1993).

[8] John H. Langbein, What ERISA Means by "Equitable": The Supreme Court's Trail of Error in Russell, Mertens, and Great-West, 103 Colum. L. Rev. 1317, 1362 (2003).

[9] Pilot Life Insurance Co. v. Dedeaux, 481 U.S. 41 (1987). See also Donald T. Bogan, Protecting Patient Rights Despite ERISA: Will the Supreme Court Allow States to Regulate Managed Care? 74 Tulane L. Rev. 951, 956 (2000).

[10] Pilot Life Insurance Co. v. Dedeaux, 481 U.S. 41 56, 58 (1987).

[11] Metropolitan Life Insurance Co., v. Massachusetts, 471 U.S. 741, 749 (1985). See also Ingersoll-Rand Corp. v. McClendon, 498 U.S. 133 (1990) (holding that ERISA preempted state common law claims); Catherine L. Fisk, The Last Article About the Language of ERISA Preemption? A Case Study of the Failure of Textualism, 33 Harv. J. Legis. 35, 60-66 (1996).

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to" quite literally to reach any common law claim that "has a connection with or reference to such a plan."[12]

The reach of the ERISA's preemption provision soon exceeded the statute's substantive grasp. Congress drafted the statute with *pensions* in mind, and it addressed "employee welfare benefit plans" providing medical and disability coverage only as an afterthought.[13] The Department of Labor could fill this gap by promulgating substantive regulations for welfare benefit plans restricting the power of unqualified HMO and insurance company "reviewers" to deny pre-certification of coverage for medical procedures recommended by qualified doctors. Fearing that such restrictions would discourage employers from adopting medical benefit plans in the first place, however, the Department has consistently failed to promulgate regulations safeguarding the rights of medical benefit plan beneficiaries.[14] Since welfare benefit plans clearly "relate to" employee benefit plans, there is a disconnect between the limited scope of the substantive requirements relating to medical coverage in welfare benefit plans and the much broader scope of the statute's express preemption provision, as interpreted by the Supreme Court.

The net effect of the combination of Supreme Court holdings and DoL inaction has been to substitute a virtually content-free regulatory regime for a rich body of common law in which fiduciaries who negligently fail to perform their fiduciary obligations are subject to injunctive relief and liability for damages caused by such failures.[15]

The ERISA Train Wreck.

These judicial trends converged with disastrous consequences for some beneficiaries in the 1990s when employers began to replace traditional insurance policies providing "fee-for-service retrospective pay" with Health Maintenance Organizations (HMOs), Preferred

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[12] Shaw v. Delta Airlines, Inc., 463 U.S. 85, 97 (1983); District of Columbia v. Greater Washington Board of Trade, 506 U.S. 125, 129 (1992) (quoting Black's Law Dictionary 1288 (6th ed. 1990)). See Donald T. Bogan, Protecting Patient Rights Despite ERISA: Will the Supreme Court Allow States to Regulate Managed Care? 74 Tulane L. Rev. 951, 986 (2000), at; Catherine L. Fisk, The Last Article About the Language of ERISA Preemption? A Case Study of the Failure of Textualism, 33 Harv. J. Legis. 35, 64 (1996).
[13] Aetna Health, Inc. v. Davila, Brief of United Policyholders as Amicus Curiae, January 22, 2004, at *14; Donald T. Bogan, Protecting Patient Rights Despite ERISA: Will the Supreme Court Allow States to Regulate Managed Care? 74 Tulane L. Rev. 951 (2000), at 964-72, 974, 976-77.
[14] Aetna Health, Inc. v. Davila, Brief for the United States as Amicus Curiae, December 18, 2003, at *25-*26; Aetna Health, Inc. v. Davila, Brief for the Chamber of Commerce of the United States as Amicus Curiae, December 18, 2003, at *13, *25-*26.
[15] See Donald T. Bogan, Protecting Patient Rights Despite ERISA: Will the Supreme Court Allow States to Regulate Managed Care? 74 Tulane L. Rev. 951, 958 (2000); Catherine L. Fisk, The Last Article About the Language of ERISA Preemption? A Case Study of the Failure of Textualism, 33 Harv. J. Legis. 35, 39 (1996).

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Provider Plans (PPOs), and other types of "prospective pay" managed care plans."[16] The latter plans were popular with employers because they were supposed to reduce the costs of unnecessary treatment. However, they "often ignore[d] the individual needs of a patient in order to improve the HMOs' bottom lines."[17] Most important for present purposes, these new cost-containment devices permitted the fiduciary to determine whether or not to pay for the prescribed health care in advance of treatment.[18] As one court noted, "a system of prospective decisionmaking influences the beneficiary's choice among treatment options to a far greater degree than does the theoretical risk of disallowance of a claim facing a beneficiary in a retrospective system."[19]

When plaintiffs like Ms. Kurtek and Mr. Kuhl who are damaged by gross mismanagement of employee medical benefit plans sue under the exclusive "federal common law" created by the ERISA and its implementing regulations, they first encounter an empty body of substantive law, because the statute and implementing regulations by-and-large ignore such plans. The rare plaintiffs who can prove violations of the regulations cannot recover compensatory damages for bodily injury or emotional distress or punitive damages.[20] Beneficiaries who attempt to opt out of a system that is clearly rigged against them quickly discover that the statute's preemption provisions deprive them of any state common law remedies as well. The result is that health care for thousands of Maureen Kurteks and Buddy Kuhls throughout the country is determined not by their doctors, but by anonymous nurses working phone banks for an HMO or insurance company who have every incentive to deny expensive medical procedures and no incentive to allow them.

The message to HMOs and insurance companies is to ignore their fiduciary obligations and deny legitimate requests for coverage from patients who are, in the words of one court, "often in the throes of medical crises and entirely unable to assert what meager rights they possess."[21] HMOs and insurance companies receive a fixed income stream that they may invest as it comes in from employers, but their payouts depend on the number of claims they honor and the amounts that they allocate to those claims. Since

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[16] Donald T. Bogan, Protecting Patient Rights Despite ERISA: Will the Supreme Court Allow States to Regulate Managed Care? 74 Tulane L. Rev. 951, 998 (2000).
[17] Pegram v. Herdrich, 530 U.S. 211, 220 (2000).
[18] Jonathan J. Frankel, Note, Medical Malpractice Law and Health Care Cost Containment: Lessons for Reformers from the Clash of Cultures, 103 Yale L. J. 1297 (1994), at 1303.
[19] Corcoran v. United Healthcare, 965 F.2d 1321 (5th Cir. 1992), at 1332. (quote). See Stacy Roberts Sharp, Note, ERISA Preemption and MCO Liability: The Court's Search in Aetna Health, Inc. v. Davilla for Congress's Elusive Intent, 84 Tex. L. Rev. 1347 (2006), at 1354-56.
[20] Nancy Mansfield, Joan T.A. Gabel, & Laurie B. Jablow, Evolving Tension Between HMO Liability Precedent and Legislation, 36 Tort & Ins. L. J. 949 (2001), at 951.
[21] DiFelice v. Aetna U.S. Healthcare, 346 F.3d 442 (3d Cir. 2003) (Becker, J. concurring).

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the money otherwise paid to satisfy claims remains in the HMO's account to be invested by the HMO, the company can make money by denying or delaying claims. The only serious consequence of even gross breaches of fiduciary obligations is the highly unlikely prospect of injunctive relief or the contingent prospect of a court order to reimburse the rare beneficiary who elects to undergo treatment at his own expense. While the matter is being litigated, the employer's premiums are still piling up interest in the HMO's account.[22]

The HMOs and insurance companies that administer employee benefit plans are, of course, well aware of the positive effects of denying claims on the bottom line. A 1990s-vintage training video for claims handlers for one provider instructed them on the critical difference between ERISA-covered claims and non-ERISA claims. The lawyers stressed that claims in the latter category required a "reasonable investigation" and review by a "Specialty Review Team" before being denied because wrongful denials could result in state common law "bad faith failure to settle" claims with possible punitive damages. Handlers of ERISA-covered claims, on the other hand, should make the claimants undertake the investigation, and if they did not present precisely the right proof or filed the claim late, the handlers were to deny the claim. Since ERISA beneficiaries cannot sue at common law and cannot receive compensatory damages under federal law, "[a]fter we send the final letter, it doesn't matter what they send us any more."[23]

The American Medical Association and numerous state medical examination boards have concluded that when claims handlers render prospective judgments about whether or not the treatment recommended by a beneficiary's doctor is "medically necessary," they are engaged in medical decisionmaking that should be subject to the same ethical and common law principles that constrain the prescribing physician's judgment.[24] Yet, absent the threat of common law liability, a claims handler with little or no relevant expertise is free to second-guess highly credentialed medical experts. By the late 1990s, the ERISA juggernaut had yielded hundreds of horror stories, several of which I relate in *The Preemption War*.

The Court's Missed Opportunity to Fix the Problem.

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[22] DiFelice v. Aetna U.S. Healthcare, 346 F.3d 442 (3d Cir. 2003) (Becker, J. concurring), at 454; Aetna Health, Inc. v. Davila, Brief Amicus Curiae of California Consumer Health Care Council, Congress of California Seniors and California Coalition for Ethical Mental Health Care, January 22, 2004, at *29.

[23] Jane Bryant Quinn, Health Insurance Firms Shielded Against Most Suits, Florida Sun-Sentinal, November 24. 1998, at D3; Patients' Right to Sue Needed Check on Health Care Industry, USA Today, October 19, 1998, at A26.

[24] Aetna Health, Inc. v. Davila, Brief Amicus Curiae of the American College of Legal Medicine, January 20, 2004, at *9-*11; Aetna Health, Inc. v. Davila, Brief of the Council of State Governments, National Conference of State Legislatures, National Association of Counties, and International City/County Management Association as Amicus Curiae, January 22, 2004, at *11.

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The Supreme Court had an opportunity to adjust the ERISA's misguided course when it agreed in 2004 to hear two consolidated appeals in *Aetna Health, Inc. v. Davila*.[25] In one of the cases, Juan Davila's treating physician prescribed the painkiller Vioxx for his arthritis pain, but his employer-provided HMO refused to pay for that drug because it was deemed to be too expensive. When Mr. Davila took the generic drug Naproxen that the HMO was willing to pay for as a suitable alternative, he suffered a severe reaction that required extensive hospitalization and left him unable to take any orally administered painkillers at all.[26] Davila sued the HMO under a Texas statute, signed by then-Governor George W. Bush, that authorized a common law claim for tort damages against HMOs for failure to use ordinary care in making coverage determinations. Twenty states, the National Council of State Legislatures, and a number of consumer groups filed amicus curiae briefs urging the Court to correct its past mistakes and allow the lawsuits to proceed.[27]

The Court held that the ERISA preempted all of Mr. Davila's claims. The majority opinion reasoned that the "limited remedies available" under the ERISA "are an inherent part of the 'careful balancing' between ensuring fair and prompt enforcement of rights under a plan and the encouragement of the creation of such plans."[28] State common law tort claims against HMOs, even for violations of the statute's substantive requirements, could undermine that "careful balance" by recognizing rights or providing remedies that might discourage employers from creating such plans in the first place. The Court believed that the ERISA's enforcement tools could adequately protect the legitimate

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[25] Aetna Health, Inc. v. Davila, 542 U.S. 200 (2004).

[26] Aetna Health, Inc. v. Davila, Brief Amicus Curiae of California Consumer Health Care Council, Congress of California Seniors and California Coalition for Ethical Mental Health Care, January 22, 2004, at *6-*7.

[27] Aetna Health, Inc. v. Davila, Brief of United Policyholders as Amicus Curiae, January 22, 2004; Aetna Health, Inc. v. Davila, Brief for Amicus Curiae Senators Edward M. Kennedy, John McCain, Bob Graham and Representatives John D. Dingell, Charlie Norwood, George Miller and Charles B. Rangel, January 22, 2004; Aetna Health, Inc. v. Davila, Brief of Amicus Curiae Health Administration Responsibility Project, January 22, 2004; Aetna Health, Inc. v. Davila, Brief Amicus Curiae of the American College of Legal Medicine, January 20, 2004; Aetna Health, Inc. v. Davila, Brief Amicus Curiae of California Consumer Health Care Council, Congress of California Seniors and California Coalition for Ethical Mental Health Care, January 22, 2004; Aetna Health, Inc. v. Davila, Brief of the Council of State Governments, National Conference of State Legislatures, National Association of Counties, and International City/County Management Association as Amicus Curiae, January 22, 2004; Aetna Health, Inc. v. Davila, Brief of Texas, California, Connecticut, Delaware, Illinois, Kansas, Louisiana, Maryland, Minnesota, Missouri, Montana, Nevada, New Mexico, New York, Ohio, Oklahoma, Oregon, Puerto Rico, Utah, Vermont, Washington as Amicus Curiae, January 22, 2004.

[28] Aetna Health, Inc. v. Davila, 542 U.S. 200 (2004), at 215; Aetna Health, Inc. v. Davila, Brief for the United States as Amicus Curiae, December 18, 2003, at *9, *25-*26.

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rights of plan beneficiaries.[29] For example, Mr. Davila could have sued the HMO for an injunction requiring it to provide those benefits in advance of treatment, or he could have "paid for the treatment [himself] and then sought reimbursement" in an action under ERISA's claims procedures.[30]

In my view, the Court's analysis is wildly unrealistic. Mr. Davila was in no position to forego the generic drug proffered by his HMO, hire a lawyer at his own expense, and endure his arthritis pain while the lawyer sought injunctive relief.[31] Maybe it would not have been too burdensome to expect him to dip into savings and purchase his own Vioxx until he could sue for reimbursement after the fact, assuming that he could persuade a lawyer to take the case for what would have been a very small contingency fee. But the reason that most employees join their employers' health benefit plans is that they cannot afford to pay for medical treatment in advance.[32] As one doctor noted, "[t]he economic reality is that, if these insurance companies are not going to pay for something, it won't get done."[33] Taking the time to write a special concurring opinion, a frustrated Justice Ginsburg "join[ed] 'the rising judicial chorus urging that Congress . . . revisit what is an unjust and increasingly tangled ERISA regime.'"[34]

The "rising judicial chorus" alluded to in Justice Ginsburg's outraged concurring opinion includes some very prominent occupants of the federal courts of appeals. For example, Judge Edward R. Becker, who until his death last year was the Chief Judge of the United States Court of Appeals for the Third Circuit, wrote that "ERISA, generally, and § 514(a) particularly, have become virtually impenetrable shields that insulate plan sponsors from any meaningful liability for negligent or malfeasant acts committed against plan beneficiaries in all too many cases." He noted that "ERISA's remedial scheme gives HMOs every incentive to act in their own and not in their beneficiaries best interest while simultaneously making it incredibly difficult for plan participants to pursue what meager remedies they possess, a confounding result for a statute whose original purpose was to protect employees."[35] Similarly, Second Circuit Judge Guido Calabresi, a former dean

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[29] Aetna Health, Inc. v. Davila, Brief for the United States as Amicus Curiae, December 18, 2003, at *16-17.

[30] Aetna Health, Inc. v. Davila, 542 U.S. 200, 211-12 (2004).

[31] See Andrews-Clarke v. Travelers Ins. Co., 984 F. Supp. 49, 59 (D. Mass. 1997).

[32] Stacy Roberts Sharp, Note, ERISA Preemption and MCO Liability: The Court's Search in Aetna Health, Inc. v. Davilla for Congress's Elusive Intent, 84 Tex. L. Rev. 1347 (2006), at 1376; Aetna Health, Inc. v. Davila, Brief of the Council of State Governments, National Conference of State Legislatures, National Association of Counties, and International City/County Management Association as Amicus Curiae, January 22, 2004, at 3.

[33] Under Fire, St. Louis Post-Dispatch, August 30, 1998, at A1.

[34] Aetna Health, Inc. v. Davila, 542 U.S. 200, 222 (2004) (Ginsburg, J., concurring) (quoting DiFelice v. Aetna U.S. Healthcare, 346 F.3d 442, 453 (3d Cir. 2003)).

[35] DeFelice v. U.S. Healthcare, 346 F.3d 442, 456, 459 (3d Cir. 2003) (Becker, J., concurring).

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of the Yale Law School, has observed that "the injury that the courts have done to ERISA will not be healed until the Supreme Court reconsiders the existence of consequential damages under the statute, or Congress revisits the law to the same end."[36] More recently, Judge Michael McConnell has quoted Justice Ginsburg's opinion at length in holding that an insurance company's determination that the appropriate drug for the plaintiff's condition was Ritalin, rather than the less risky drug Provigil fell within the scope of ERISA's express preemption clause.[37]

Justice Ginsburg's plea was, however, somewhat unrealistic. Congress undoubtedly has the power to fix the problem with appropriate amendments to the ERISA. However, when the demand for reform comes from a diffuse or economically disadvantaged segment of society and status quo arrangements are congenial to a concentrated and economically powerful segment, the prospects for reform are best in periods of social ferment following a long history of past injustice and abuse. Proponents for the victims of managed care abuse thought the late 1990s and early 2000s was a propitious time to address the injustices brought on by the Supreme Court's strained interpretations of the ERISA. But their efforts to enact a "Patient's Bill of Rights" that would have, among other things, amended the ERISA's express preemption provision to allow state common law claims against managed care providers for unreasonable denial of coverage were unsuccessful.

Other Preemption Hurdles.

The ERISA experience is an especially disturbing example of the power of the Supreme Court to undermine the protective policies underlying federal remedial legislation through aggressive federal preemption of state common law. But it is by no means the only such example. I discuss may more areas in which the Court has interpreted express preemption clauses in federal regulatory statutes to hold that state common law is preempted. Another area that has received a great deal of recent attention is the preemptive effect of the Medical Device Amendments to the Food, Drug and Cosmetics Act.

Express Preemption of Claims Addressed to Medical Devices.

Although the Supreme Court has frequently invoked a "presumption against preemption" in "areas of traditional state regulation,"[38] it has nevertheless expanded the range of federal programs that preempt state common law during the past 20 years.[39] Its 1992

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[36] Cicio v. Does, 321 F.3d 83, 106 (Calabresi, J., dissenting in part).

[37] Lind v. Aetna Health, Inc., 466 F.3d 1195 (10th Cir. 2006).

[38] 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).

[39] McGarity, Preemption War, ch. 4; Robert L. Rabin, Federalism and the Tort System, 50 Rutgers L. Rev. 1, 27 (1997).

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holding, in *Cipollone v. Liggett Group, Inc.*, that the word "requirement" in an express preemption clause included state common law claims[40]invited defendants to raise a federal preemption defense in every case in which the relevant statute used the word "requirement" or a closely related word.

The Medical Device Amendments to the Food, Drug and Cosmetics Act contain an express preemption clause that uses the magic word "requirement" and does not have a savings clause.[41] In the 1996 case of *Medtronic, Inc. v. Lohr*,[42] the Court held that that the Medical Device Amendments preempted some, but not all common law claims directed toward medical devices that FDA had approved using a very abbreviated process for devices that are "substantially equivalent" to devices in existence in 1976. The Court took up the harder issue of devices that had undergone the full FDA approval process earlier this year in *Riegel v. Medtronics, Inc.*[43]

The Court held that Riegel's common law claims came within the meaning of the word "requirement" in the statute's express preemption clause. In broad dicta that defendants will no doubt rely on in future cases, the Court added that "[a]bsent other indication, reference to a State's 'requirements' includes its common-law duties."[44] 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,"[45] 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."[46]

Implied Preemption of Claims Based on Fraud on Federal Agencies.

The Court has not limited its propensity to preempt to statutes containing express preemption clauses. In several other areas, the Court has found state common law claims to be "impliedly" preempted by a federal statute that does not explicitly address preemption one way or the other.

First, "[i]f Congress evidences an intent to occupy a given field, any state law falling within that field is pre-empted." This form of implied preemption, referred to as "field preemption," is rarely applicable to state common law claims. Second, "[i]f Congress has

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[40] Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992).
[41] 21 U.S.C. § 360k(a).
[42] Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996).
[43] Riegel v. Medtronics, Inc. 128 S.Ct. 999 (2008).
[44] 128 S.Ct., at 1008.
[45] 128 S.Ct., at 1007.
[46] 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.

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not entirely displaced state regulation over the matter in question, state law is still pre-empted to the extent it actually conflicts with federal law."[47]

The second category of "conflict preemption" is further subdivided into two subcategories. The first, called "impossibility" preemption, exists when compliance with both the state law and the federal law is impossible because complying with state law will cause the actor to violate federal law and visa versa. The second, called "obstacle preemption," preempts state law to the extent that it conflicts with federal law because "the state law stands as an obstacle to the accomplishment of the full purposes and objectives of Congress."[48]

A good example of implied obstacle preemption is *Buckman v. Plaintiffs' Legal Committee*, a case involving a common law claim based upon a medical device company's alleged fraud in obtaining FDA approval of its spinal screws.[49]

An entity subject to a federal licensing requirement, like the FDA drug and device approval process, can affect the outcome of the regulatory process by manipulating the information available to the agency and managing public perceptions about the implications of the relevant information. Professor Wagner and I discuss this ability of regulatees to "bend" science to their economic and ideological ends in our recently published book *Bending Science*.

First, a regulated entity may engage in overt fraud by submitting fraudulently conducted studies to the agency or by withholding relevant information. Second, it can covertly "massage" or otherwise manipulate the scientific, economic and statistical information in misleading ways to fit the company's view of the scientific facts. Third, it can affect agency decision-making by finding flaws with or otherwise attempting to undermine scientific, economic and statistical studies from sources over which the company has no control. Finally, it can attempt to bring pressure to bear on an agency to take lenient regulatory action through public relations exercises aimed at manipulating public perceptions of publicly available scientific information. Some of these techniques are clearly unlawful under federal law; others are clearly lawful; and still others fall into grey areas that require further analysis and investigation.[50]

It is, of course, very difficult for the relevant federal agency to know at the time that it is being misled or defrauded, and it may never uncover the deception. After-the-fact prosecution of fraud can protect the government's interest in the integrity of the regulatory process and provide incentives to regulatees not to dissemble with federal agencies in the future. But that happens only very rarely.

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[47] Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 248 (1984).
[48] Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 248 (1984).
[49] Buckman Co. v. Plaintiffs' Legal Committee 531 U.S. 341 (2001). Except where otherwise noted, the facts and the Court's analysis are drawn from Id., at 341, 346-51.
[50] Thomas O. McGarity & Wendy E. Wagner, Bending Science (2008).

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The Supreme Court resolved the question in the context of FDA device regulation in a fairly unique factual setting in *Buckman Co. v. Plaintiffs' Legal Committee.*[51] In that case, a class consisting of more than 2300 plaintiffs claimed that its members had been damaged by defective orthopedic bone screws that doctors had installed in the pedicles of their spines. Like the pacemaker in *Lohr*, the bone screws went through the "expedited" FDA approval process that is available for devices that are "substantially equivalent" to "predicate" devices that were on the market prior to 1976.[52] During the approval process, the submitter had to certify that "all data and information submitted" during the expedited process were "truthful and accurate" and that "no material fact" had been omitted.[53]

After FDA twice found that the screws were riskier than pre-1976 spinal-fixation devices and therefore not substantially equivalent, the manufacturer hired the Buckman company, a consultant with experience in the expedited approval process, to assist in a third try. On Buckman's advice the manufacturer split the device into its component parts, renamed them, and filed separate applications for approval for use in the long bones of the arms and legs instead of in the spine. Both Buckman and the manufacturer fully expected that doctors would prescribe the screws for "off-label" use in spinal-fixation systems.[54] This time the FDA approved the devices as substantially equivalent to predicate devices used in long bone surgery.[55]

The plaintiffs settled their claims against the manufacturer,[56] but they litigated their claim that Buckman's misleading manipulation of the regulatory process violated its common law duty to the plaintiffs as foreseeable victims of the alleged fraud.

The Supreme Court held that the Medical Device Amendments impliedly preempted the plaintiffs' claims. The Court reasoned that although the plaintiffs' common law claims were not clearly inconsistent with FDA's authority to regulate medical devices, they presented a subtler conflict with the "delicate balance of statutory objectives" that the agency had to strike in deciding whether or not to investigate and punish fraud. Since doctors could lawfully prescribe approved medical devices for unapproved uses, FDA faced an especially difficult balancing job in "regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals." The Court

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[51] Buckman Co. v. Plaintiffs' Legal Committee 531 U.S. 341 (2001). Except where otherwise noted, the facts and the Court's analysis are drawn from Id., at 341, 346-51.
[52] 21 U.S.C. § 360e(b)(1)(A), (B).
[53] 21 C.F.R. § 807.87(k).
[54] 21 U.S.C. § 360aaa (prohibition on marketing drugs for off-label uses).
[55] The agency much later approved the bone screws for use in spinal-fixation systems. Orthopedic Devises: Classification and Reclassification of Pedicle Screw Spinal Systems, 63 Fed. Reg. 40025, 40032 (July 27, 1998).
[56] Buckman Co. v. Plaintiffs' Legal Committee, Brief of Amicus Curiae of Public Citizen, October 23, 2000, at 2.

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concluded that Congress did not intend to allow common law juries to second-guess the agency's discretion in striking this balance.

The Court also found that state common law claims based upon alleged fraud on the FDA could increase the regulatory burdens on potential applicants who might "be discouraged from seeking expedited approval of devices with potentially beneficial off-label uses for fear that such use might expose the manufacturer or its associates (such as petitioner) to unpredictable civil liability." In addition, they could "deter off-label use despite the fact that the [statute] expressly disclaims any intent to directly regulate the practice of medicine . . . and even though off-label use is generally accepted." Finally, a common law claim based on fraud on the FDA would "cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the [agency], will later be judged insufficient in state court." Alternatively, massive prophylactic submissions by applicants concerned about state tort liability could tie up the agency and slow down the flow of approved predicate devices, thus impeding competition and delaying health care professionals' ability to prescribe appropriate off-label uses. Since all of these possibilities had the potential to erect serious obstacles to the agency's efforts to implement the statutory goals, the Medical Device Amendments impliedly preempted the plaintiffs' claims.

Apart from its rather speculative "deluge of information" concern, the Court did not cite any evidence suggesting that the plaintiffs' claims would interfere with the agency's regulatory efforts. Significantly, the Court's opinion did not pay even passing deference to the statute's *primary* purpose, which is "to provide for the safety and effectiveness of medical devices intended for human use."[57] Rather than reflecting the statutory policy of protecting consumers, the Court implemented a policy of protecting the ability of doctors to prescribe drugs for unapproved uses and an even more dubious policy of protecting drug companies from burdensome investigations into the bona fides of their FDA filings.

From the perspective of consumers, who have a strong interest in both corrective justice and ensuring corporate accountability for misleading agencies into approving dangerously defective products, *Buckman* moves the law in exactly the wrong direction.

Conclusion.

Although the arcane law governing federal preemption of state common law claims is rarely featured in daily news reports, it has a profound effect on the rights of ordinary citizens to seek justice at the hands of a jury of their peers. The common law jury is a profoundly democratic institution that has been a part of the American civil justice system from the first and remains one of the American institutions best able to protect individuals against the tyranny of government and the marketplace. When the Supreme Court concludes that Congress meant for the questionable judgment of a federal bureaucracy to supercede the common sense wisdom of the common law jury, it leaves

[57] Pub.L. No. 94-295, 90 Stat. 539, 539 (1976) (preamble).

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behind a hole in the law has an enormous potential for injustice. It is imperative that the public become aware of this potential and for this Committee to perform its critical confirmation role conscientiously.

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44331.088

State Options for Expanding Coverage That Do Not Affect ERISA

States can, and should, play an important role in expanding healthcare coverage for the uninsured, and they have significant authority to do so. Health reform does not require unraveling or harming the Employee Retirement Income Security Act (ERISA), which has expanded access to employer-sponsored coverage.

For example, some states already do and other states can do the following:

Provide Subsidies for Health Insurance Offer subsidies to low-income individuals and families to help pay for health insurance premiums for individual or employer-sponsored coverage. Offer subsidies to small employers for providing coverage to their employees.

Offer Tax Subsidies for Health Insurance Related to option 1, provide tax credits (which reduce the amount of taxes owed) or tax deductions (which reduce the amount of taxable income) for the individual purchase of health insurance. Offer tax credits to small employers who offer health coverage to their employees.

Create State Reinsurance Programs Allow small employers to participate in state reinsurance programs to reduce their financial risk for high cost cases and lower their overall cost of health coverage for employees.

Establish High Risk Insurance Pools Establish a state high risk pool to provide coverage for individuals who are otherwise unable to obtain health coverage.

Permit Small Employers to Join Purchasing Pools Allow small employers to join together to purchase insurance.

Permit State Residents to Purchase Health Insurance in Other States Allow state residents to buy insurance approved in other states.

Permit Insurers to Offer Low-Cost Insurance Options Permit insurers to offer low-cost, basic benefit plans, including high-deductible health plans.

Permit Insurers to Offer Targeted Health Coverage Offer low-cost health insurance for young adults or other targeted populations.

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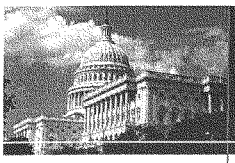
Continued from front

Reduce or Eliminate Mandated Benefits Allow insurers to offer health insurance without mandates to allow consumers to choose from more affordable coverage options. Require that any state mandate undergo an independent cost analysis that assesses the impact of the mandate on health insurance costs and coverage prior to becoming law.

Expand Public Programs and Outreach Expand state Medicaid, State Child Health Insurance Programs (SCHIP) and other state health programs and expand outreach efforts to reach eligible residents who have not yet enrolled in these programs.

Reallocate State and Federal Medicaid Funds Use State and Federal Medicaid funds innovatively to expand healthcare coverage to targeted populations, including the uninsured, underinsured and low-wage working residents.

44331.090



Details

OF THE NATIONAL BUSINESS GROUP ON HEALTH'S POSITION

Supporting the Federal Framework of ERISA

Support The Federal Framework of ERISA for Employer-Sponsored Health Benefits and Oppose Federal Waivers for State Health Reform

Employers must continue to have the flexibility to determine the types of benefits they offer and to tailor benefit plans to the specific needs of their employees and the circumstances of their companies.

States can, and should, play an important role in expanding coverage, and they have significant resources and authority to adopt innovative programs to do so. They do not have to unravel or harm employers' ERISA plans in order to offer coverage for the uninsured (see supporting document for a list of options that states can consider to expand coverage without amending ERISA).

States should not be permitted to regulate employer-sponsored benefit plans under waivers or carve-outs of ERISA's national framework.

The Federal Framework of ERISA is Essential to Employers' Ability to Offer Affordable Coverage and to Innovate in Health Benefits

Waivers or carve-outs of ERISA's national framework will discourage employers from offering benefits and reestablish the same problems that ERISA corrected.

Permitting states to regulate employer-sponsored benefits would eliminate two essential elements of ERISA that encourage employers to offer health benefits to employees—national uniformity and employer autonomy—and jeopardize health benefits for more than 130 million people.

National uniformity enables employers to offer and maintain uniform benefit plans across state lines and across local jurisdictions for their employees and retirees. It keeps benefit costs lower through greater economies of scale, purchasing leverage, and administrative efficiencies. Without ERISA preemption, employers would have to offer different benefits to employees based on where they work or live and to administer each plan separately, making it incredibly costly to administer benefit plans and creating issues of equity among employees. Employers would have the nearly impossible burden of navigating a patchwork of regulation, significantly raising compliance costs and risks of noncompliance and they would lose the ability to choose effective benefits to offer to employees.

About ERISA

ERISA provides the national framework that enables employers to find innovative health care and benefits solutions that benefit us all when they improve health care delivery and others adopt them. Subjecting employer plans to state laws rather than to regulations of the federal Department of Labor is likely to stifle innovation, raise costs and harm quality.

Statement of Bridget Robb
Gwynedd, PA

Before the
Senate Judiciary Committee

For a hearing entitled
"Short-change for Consumers and Short-shrift for Congress? The Supreme Court's Treatment of Laws that Protect Americans' Health, Safety, Jobs and Retirement"

Wednesday, June 11, 2008

44331.092

Chairman Leahy and Members of the Senate Judiciary Committee:

Thank you for the invitation to speak on the topic of laws that protect Americans' health and safety. In a time when big business and corporate profits seem to take precedence over individuals' rights, we tend to forget the reasons why certain laws were in fact enacted, and why it remains important for people who have been injured by defective products, to be able to hold companies accountable and to have their day in court. I am here today not only because of my own tragedy but also to protect the rights of those who have or may suffer similar events such as mine.

My name is Bridget Robb. I am a thirty-four year old mother and resident of Gwynedd, Pennsylvania. On December 31, 2007, I suffered greatly and thought I was going to die because of a defective heart device implanted in my body. I am thankful to be here today and to be able to share my experience with you.

Approximately four (4) years ago, I was diagnosed with non-ischemic, viral cardiomyopathy and congestive heart failure. In May 2005, to prevent me from dying from a fatal arrhythmia, I had a Medtronic cardiac defibrillator with pacemaker implanted in my chest. This heart device is a small metal case that contains electronics and a battery. Its components work much like a pacemaker, but unlike a pacemaker, an ICD delivers an electrical shock to the heart when the heart rate becomes dangerously fast. My particular device combined a pacemaker and ICD in one unit.

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On December 31, 2007, I was awoken from my sleep by a series of shocks to my heart which felt as if a cannon was being repeatedly shot at my chest at close range. Along with these recurrent shocks was a strong, electrical current racing through my body. After feeling the first shock, I immediately phoned 9-1-1 for help. My six-year old daughter, Emma, had snuck into bed with me that night and was present during this horrific experience. I remember Emma being scared and confused. She crouched down in front of me hugging her cat, saying "Mommy's dying." She was present during the entire seven minutes that I was on the telephone with the 911 operator until the EMS arrived. I cannot imagine how terrified she must have been to see her mother in such pain.

The doctors have told me that I received a total of thirty-one (31) inappropriate shocks to my heart in a matter of minutes that morning. Each time I was shocked, I saw my life flash before my eyes. At one point, I began to pass out and thought that I would never see Emma again.

I later learned that the inappropriate shocking and electrical feeling throughout my body was caused by a defective cardiac lead implanted in my heart, the Sprint Fidelis lead manufactured by Medtronic. A lead is a thin wire which connects the ICD to the heart and delivers the actual shock to the heart when it is beating too fast. Medtronic's Sprint Fidelis lead was recalled on October 15, 2007, because of its potential to fracture. Unfortunately, Medtronic never notified me that my lead was recalled and I did not learn of the recall until after this "life-saving" medical device seriously hurt me.

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Since this terrifying experience, my health had declined significantly. I have been visiting doctors almost weekly for follow-up appointments and testing, and have suffered from severe anxiety. I have since undergone surgical replacement of my defibrillator and the defective lead, and a second surgery to revise the lead. My second surgery resulted in an extended hospital stay where I had to undergo a blood transfusion. As you would expect, I risk serious harm each time another procedure is performed. Even though Medtronic's defective device caused my injuries, my health insurance plan has been paying for the cost of my medical care.

I would like to have the opportunity to hold Medtronic accountable for the injuries that I suffered that day and the emotional after-effects that I continue to experience on a daily basis. Medtronic knew that its Sprint Fidelis lead was faulty, yet the company never took reasonable steps to notify me that this lead needed to be replaced. Instead, I suffered indescribable pain that day and continue to suffer from the emotional toll of my near-death experience.

However, my attorneys tell me that a jury may never hear my case due to a legal doctrine known as "preemption," which the Supreme Court recently discussed in another Medtronic medical device case, *Riegel v. Medtronic*. In that case, the Supreme Court found that any claims brought by people injured by another Medtronic device were "preempted" and that the company would have complete immunity from any claims brought against it given that the FDA had approved the device. My attorneys are

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concerned that the *Riegel* decision also may apply to my case and, as a result, I would have no recourse for my injuries. I find this discouraging and demoralizing.

In addition, the considerable costs for my healthcare have been shifted from Medtronic, the company that knew about this problem but failed to take action, to my health insurance provider. This may result in an increase in the cost of my insurance. It is wrong to shift the cost of medical care from the responsible party to private insurers, patients, and in some cases to taxpayer sponsored programs like Medicare and Medicaid.

Therefore, I am asking Congress to pass legislation to ensure that victims of faulty medical devices, like me, will continue to have the ability to hold a medical device manufacturer accountable for their injuries. I find it hard to believe that Congress ever intended to prohibit me from even having the opportunity to go to court to obtain justice. Thank you for your attention to this critical issue. I am happy to answer any questions that you may have.

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44331.096

TRANSPERFECT

TRANSCRIPTION OF AUDIO

9-1-1 CALL

[Audio Begins]

Dispatch Operator: 9-1-1, what is your emergency?

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

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

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

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

Caller: Help, I'm in the cottage.

Dispatch Operator: Okay, what's your address?

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

Dispatch Operator: Okay, okay, okay.

Caller: Can you call my uncle?

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

Caller: Please? I'm 33.

Dispatch Operator: You're 33?

Caller: Yeah. Ow, damnit, ... please, 9-1-1, please.

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

Caller: (Unintelligible) help (unintelligible).

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

Caller: (Unintelligible) hang up.

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

Caller: Oh, my.

44331.113

Dispatch Operator: Ma'am?

Caller: Yes?

Dispatch Operator: What's your name?

Caller: Bridgett.

Dispatch Operator: Bridgett?

Caller: Yeah.

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

Caller: Robb.

Dispatch Operator: And you're at 404 --

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

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

44331.099

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

Dispatch Operator: Okay is anybody there with you?

Caller: My daughter is five, six.

Dispatch Operator: Your daughter is five or six?

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

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

Caller: Uh --

Dispatch Operator: Are you in upper Gwinnett County?

Caller: Yes.

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

Caller: Ow, ... I'm sorry.

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

44331.114

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

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

Caller: God, please don't die.

Dispatch Operator: Okay, how long have you --

Caller: I don't wanna die.

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

Caller: Uh, (unintelligible).

Dispatch Operator: When did you get it?

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

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

44331.115

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

Dispatch Operator: Okay, Bridgett? Bridgett?

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

Dispatch Operator: Bridgett, Bridgett.

Caller: Huh?

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

Caller: Are they coming? Are they coming?

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

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

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

44331.116

Caller: How do you stop this?

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

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

Dispatch Operator: Okay.

Caller: They're getting stronger.

Dispatch Operator: The shocks are getting stronger?

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

Dispatch Operator: It's on its way.

Caller: How, how far away?

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

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

44331.103

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

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

Dispatch Operator: Trust me.

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

Dispatch Operator: Who's there with you?

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

Dispatch Operator: Bridgett?

Caller: Huh?

Dispatch Operator: Who's there with you?

Caller: My uncle.

Dispatch Operator: Your uncle's there with you?

44331.104

Caller: I think I'm dying. Everything I did is gonna be like 10 times now. Well and (unintelligible) this hurts.

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

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

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

Caller: I, I have cardiomyopathy.

Dispatch Operator: Heart -- heart (unintelligible)?

Caller: Cardiomyopathy, congestive heart failure.

Dispatch Operator: Okay, okay. Did it discolor your skin?

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

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

44331.105

Caller: Yeah.

Dispatch Operator: Okay.

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

Dispatch Operator: They're on their way.

Caller: How far away are they?

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

Caller: Okay.

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

Caller: It hurts.

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

Caller: Ah.

44331.106

Dispatch Operator: Bridgett, where's your uncle?

Caller: He's right next to me.

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

Caller: I have my daughter, yeah.

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

Caller: Yeah.

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

Caller: I -- not since I last told you.

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

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

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

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

44331.107

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

Caller: Okay.

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

Caller: Okay.

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

Caller: All right, hurry.

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

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

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

Caller: Oh, I'm gonna die.

44331.108

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

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

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

Caller: Yeah.

Dispatch Operator: Okay.

Caller: Can you get my medicine for me?

Dispatch Operator: Just so they have it right there.

Caller: It's on the kitchen counter.

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

Caller: Okay.

44331.109

Dispatch Operator: All right.

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

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

Caller: Okay.

Dispatch Operator: All right.

Caller: Bye.

Dispatch Operator: Bye.

[End of Audio]

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