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SHOULD FDA DRUG AND MEDICAL DEVICE REGULATION BAR STATE LIABILITY CLAIMS?

HEARING

BEFORE THE

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

SECOND SESSION

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SHOULD FDA DRUG AND MEDICAL DEVICE REGULATION BAR STATE LIABILITY CLAIMS?

WEDNESDAY, MAY 14, 2008

HOUSE OF REPRESENTATIVES,
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:10 a.m. in room 2154, Rayburn House Office Building, Hon. Henry A. Waxman (chairman of the committee) presiding.

Present: Representatives Waxman, Cummings, Kucinich, Tierney, Watson, Lynch, Higgins, Yarmuth, Braley, Norton, McCollum, Sarbanes, Welch, Davis of Virginia, Burton, Shays, Souder, Platts, Issa, McHenry, and Bilbray.

Staff present: Kristin Amerling, general counsel; Karen Nelson, health policy director; Karen Lightfoot, communications director and senior policy advisor; Andy Schneider, chief health counsel; Sarah Despres, senior health counsel; Ann Witt, health counsel; Steve Cha, professional staff member; Earley Green, chief clerk; Caren Auchman and Ella Hoffman, press assistants; Zhongrui "JR" Deng, chief information officer; Leneal Scott, information systems manager; William Ragland, Miriam Edelman, Bret Schorthorst, Jen Berenholz, and Lauren Belive, staff assistants; Larry Halloran, minority staff director; Jennifer Safavian, minority chief counsel for oversight and investigations; Keith Ausbrook, minority general counsel; Jill Schmaltz and Benjamin Chance, minority professional staff members; Kristina Husar, minority counsel; Patrick Lyden, minority parliamentarian and Member services coordinator; Brian McNicoll, minority communications director; John Ohly, minority staff assistant; and Meredith Liberty, minority staff assistant and correspondence coordinator.

Chairman WAXMAN. The meeting of the committee will please come to order.

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

Currently, when Americans are injured by any sort of defective product they have a remedy. In most States, they can sue the manufacturer of a product in a State court. Under a radical legal doctrine being advocated by the pharmaceutical and device industries and the Food and Drug Administration under the Bush administration, this will change. Patients hurt by defective drugs and medical devices would no longer have the ability to seek compensation for their injuries. This doctrine is known as preemption. The result is

that one of the most powerful incentives for safety, the threat of liability, would vanish.

One of our witnesses today will describe the case of Joshua Oukrop, a 21 year old student who died in 2005 when his cardiac defibrillator malfunctioned. Joshua's device failed because of a design flaw. The manufacturer knew about this flaw at the time of Joshua's death, but neither Joshua, his physician, nor his parents did.

Three years elapsed between the time the manufacturer first learned of the defect and the time the manufacturer withdrew the defibrillator from the market. All the while, doctors, who didn't have any other information, continued to implant this device known to the company to be defective. Ultimately the defect was linked to seven deaths.

In the lawsuits that followed, the manufacturer argued that it should be immune from liability because FDA approved the defibrillator. This type of argument received a significant boose when the Supreme Court ruled earlier this year that FDA approval of a complicated medical device preempts most liability claims.

Think of the message that the manufacturer is trying to send. Even if a company withholds information about potentially fatal defects from physicians, patients, and the FDA, it is still going to be immune from liability for its actions.

This morning we will have two expert panels to help us understand the implications of this legal doctrine of preemption. We will also have the chance to question FDA about why it is now taking the side of the manufacturers on this crucial public safety issue.

For decades the Food and Drug Administration believed that State liability cases actually helped the agency regulate drugs and medical devices, but under the Bush administration FDA has reversed course. Now FDA advocates that once a product receives FDA approval, the manufacturer should be absolved of the responsibility for injuries caused by their products. This is exactly the wrong time for FDA to be saying, Trust us.

As a result of chronic under-funding and weak leadership, FDA's ability to protect the public is plummeting. FDA's own Science Board just issued a report that said the agency is so starved of resources that American lives are at risk. But even with an FDA with more funding and better leadership, there would still be a compelling need for our system of State liability laws.

Some drug and device companies have hidden and manipulated important safety data. Some have failed to report serious adverse events, and some have failed to disclose even known defects. If manufacturers face no liability, all the financial incentives will point them in the wrong direction, and these abusive practices will multiply.

And there is another problem. The clinical trials upon which FDA relies to approve drugs or devices are often too small to detect the risks. Some risks can only be detected when the drug or medical device is used in the population at large. Without the risk of liability, companies would have little incentive to give FDA timely reports about these dangers. All the resources in the world will not fix these inherent problems.

Patients who are injured by approved drugs and devices deserve compensation to help them deal with their permanent disabilities, their inability to work, and their costly medical procedures, but the only way patients can obtain compensation is to bring a lawsuit under State laws.

Today we will be considering a fundamental question with high stakes for everyone in America who depends on drugs and medical devices: should the companies that produce these products be absolved of their legal obligation to ensure the safety of their products?

[The prepared statement of Chairman Henry A. Waxman follows:]

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Opening Statement of Rep. Henry A. Waxman
Chairman, Committee on Oversight and Government Reform
Should FDA Drug and Medical Device Regulation Bar
State Liability Claims?
May 14, 2008

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

Currently, when Americans are injured by any sort of defective product, they have a remedy. In most states, they can sue the manufacturer of that product for damages in state court.

Under a radical legal doctrine being advocated by the pharmaceutical and device industries and the Food and Drug Administration (FDA), this would change. Patients hurt by defective drugs and medical devices would no longer have the ability to seek compensation for their injuries. This is known as "preemption."

The result is that one of the most powerful incentives for safety — the threat of liability — would vanish.

One of our witnesses today describes the case of Joshua Oukrop, a 21-year-old college student who died in 2005 when his cardiac defibrillator malfunctioned. Joshua's device failed because of a design flaw. The manufacturer knew about this flaw at the time of Joshua's death, but neither Joshua, his physician, nor his parents did.

Three years elapsed between the time the manufacturer first learned of the defect and the time the manufacturer withdrew the defibrillator from the market. All the while, doctors continued to implant this device known to the company to be defective. Ultimately, the defect was linked to seven deaths.

In the lawsuits that followed, the manufacturer argued that it should be immune from liability because FDA had approved the defibrillator. This type of argument received a significant boost when the Supreme Court ruled earlier this year that FDA approval of complicated medical devices preempts most liability claims.

Think of the message that the manufacturer is trying to send: even if a company withholds information about potentially fatal defects from physicians, patients, or the FDA, it is still immune from liability for its actions.

This morning we will have two expert panels to help us understand the implications of this legal doctrine of preemption. We will also have a chance to question FDA about why it is now taking the side of the manufacturers on this crucial public safety issue.

For decades, FDA believed that state liability cases actually helped the agency regulate drugs and medical devices. But under the Bush Administration, FDA has reversed course. Now FDA advocates that once a product receives FDA approval, the manufacturers should be absolved of responsibility for injuries caused by their products.

This is exactly the wrong time for FDA to be saying: "Trust us."

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

But even with an FDA with more funding and better leadership, there would still be a compelling need for our system of state liability laws.

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

If manufacturers face no liability, all the financial incentives will point them in the wrong direction, and these abusive practices will multiply.

And there's another problem: The clinical trials upon which FDA relies to approve drugs or devices are often too small to detect less frequent risks. Some risks can only be detected when the drug or medical device is used in the population at large. Without the risk of liability, companies would have little incentive to give FDA timely reports about these dangers.

All the resources in the world will not fix these inherent problems.

Patients who are injured by approved drugs and devices deserve compensation to help them deal with their permanent disabilities, their inability to work, and their costly medical procedures. But the only way patients can obtain compensation is to bring a lawsuit under state law.

Today we will be considering a fundamental question with high stakes for everyone in America who depends on drugs and medical devices: Should the companies that produce these products be absolved of their legal obligation to ensure the safety of their products?

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

Chairman WAXMAN. I am grateful to our witnesses for being with us today to discuss this issue, and I look forward to their testimony, but before we call upon them I want to recognize my colleagues for opening statements.

Mr. Davis.

Mr. DAVIS OF VIRGINIA. Thank you, Mr. Chairman.

The title of today's hearing asks a controversial question: should FDA drug and medical device regulation bar State liability claims? But framing the issue as an either/or proposition offers an illusory choice between non-existent absolutes, between total Federal preemption and unrestrained litigation of medical claims in 50 State court systems. The real, harder question is: when in the interest of public health must FDA regulations preempt liability claims under State law.

Finding that answer means threading a course around the horror stories of both sides of the debate and finding the right balance between Federal regulatory reinforcement of interstate standards and plaintiff's recourse to separate State tort systems to pursue claims against drug and device makers.

At stake in striking that balance: the health of patients and the protection of consumers too often caught in the cross-fire between predatory trial lawyers and FDA regulated companies trying to shield themselves from post-approval claims.

If either side wins, we all lose. Total preemption means dangerous and defective products could hide behind narrowly based FDA findings of safety and effectiveness. Total litigation would raise medical costs, stifle drug and device development, and subject both companies and patients to an endless labyrinth of conflicting standards.

Already dense product labeling would become a State-by-State legal litany for lawyers rather than a clinical guide for doctors and patients.

In a letter to Congress five former FDA general counsels who served in Republican and Democratic administrations dating back to 1972 put it this way: "If every State, judge, and jury could fashion their own labeling requirements for drugs and medical devices, it would be regulatory chaos for these two industries that are so vital to the public health and FDA's ability to advance the public health by allocating scarce space in product labeling to the most important information would be seriously eroded."

That by consensus among FDA lawyers also effectively rebuts those who claim the current administration has somehow skewed longstanding FDA policy toward preemption. FDA took affirmative steps to preempt State interference in drug and device warnings under Presidents, and FDA will have to do so under future administrations.

Current preemption policy is nothing novel or radical, but a dynamic response to an increasingly litigious environment that undermines the effectiveness of the long-established FDA regulatory system.

Those same FDA legal experts concluded: "There is a greater need for FDA intervention today because plaintiffs and courts are intruding more heavily on FDA's primary jurisdiction than ever before."

Some might argue State court awards provide a layer of consumer protection FDA regulation alone does not offer. That is true when the manufacturer hides relevant data from the FDA or otherwise violates Federal regulations on drug abuse review. But when the regulated company is in compliance with all key Federal requirements, allowing State judges and juries to second-guess FDA experts and scientific advisory panels adds instability, not protection, to a system the Nation relies upon for vital medical advances.

Criticism of the FDA process as under-funded, understaffed, or too limited in scope argue for changes at the Federal level, not for replacing one consistent regulatory standard with 50 fragmented approaches.

The hard truth is drug and devices will always pose some level of risk, but that cold fact will never comfort those that are harmed. The suffering caused by inadequate safety warnings on drug and devices or by practitioners' negligence in misusing those products can be heart-wrenching. We will hear such an account from Mr. and Mrs. Quaid this morning. But even the most compelling individual stories can't overthrow the collective judgment that the national weighing of benefits and risks best serves the public health.

Striking a pose on one side of an emotional debate is easy, but maintaining the appropriate balance between public health and private relief is more difficult.

We appreciate that Chairman Waxman has agreed with our request to bring some balance to today's witness panels by inviting testimony from the Food and Drug Administration and the American Enterprise Institute.

The reach of expressed and implied Federal preemption of drug and device regulation is an important evolving issue, and we very much appreciate the chairman's continued focus on this, as well as other public health matters.

Thank you.

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

While it is usually the practice for just the chairman and the ranking member to give opening statements, I do want to recognize other Members who may wish to make a brief opening statement.

Mr. Braley.

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

This doctrine of Federal preemption has been around a long time, and it historically evolved to be used in very limited circumstances where Congress clearly expressed an intent to preempt a field of law that the States historically have had the ability to enforce in their own jurisdictions, but in the past 7 years under the Bush administration we have seen a radicalization of the use of Federal preemption, not just in the courts but in Federal agencies who have taken it upon themselves to include in preambles language that effectively preempts the role of Congress under the Constitution to decide when and where to preempt State law.

This is the real radical threat that is endangering the lives of consumers all over this country, and it is time this Congress started to wake up and focus on this problem. Our role in the Constitutional framework is being usurped by administrative appointees, many of whom come out of academic and research backgrounds

that have been long advocating a doctrine called tort reform. All you have to do is look at where they come from and the advocacy of those interest groups to find out what their true motivation is. It is no accident that the President has mentioned tort reform in every single State of the Union Address he has given, including the State of the Union this year.

It is time for us to talk about what is going on here. My friend talked about the increasingly litigious environment, but that is completely contrary to documented evidence which shows that in State courts across this country the number of products liability claims is declining every year, and there is a doctrine already in place in those State court claims called the state-of-the-art defense, which is a total defense to product liability cases, and in order to prove that defense you simply have to show that the product and the language used to describe it conform to the state-of-the-art at the time it was manufactured and distributed.

When the FDA has an extensive approval process like the one we are talking about here today, that is a fundamental component of a state-of-the-art defense, so there is already substantial opportunity in State court proceedings to assert the very defense that we are here to talk about today.

I look forward to the testimony of our witnesses and the opportunity to explore this in greater detail.

Thank you.

Chairman WAXMAN. Thank you, Mr. Braley.

Mr. Souder.

Mr. SOUDER. Thank you, Mr. Chairman.

I want to associate myself with Mr. Davis' comments. I believe that, as you look at the industry, not only do you have a proliferation of variations of State laws, as we all know, most things don't go to trial. You negotiate and settle out of court. The variations, the potential will sit on innovation.

In the hip, knee, and joint replacement I have three of the four largest manufacturers in the world in my congressional district. They have bought the biggest manufacturers in Germany and Switzerland. We have soldiers killed in Iraq or people who would have been killed but now come back with shoulder and hip, knees. They are not 80 years old, they are 18 to 22 years old. We are trying to figure out how to do skin grafting. We are into types of things that we know little about how this is going to project. You try to do as much science as you can.

You cannot deal in technical innovation with variations of politicized State regulations. You have to have increasingly in this world some kind of standard or, quite frankly, they won't pursue new innovations. We ran into this with the orphan drug laws that innovations in flu prevention, innovations in AIDS, that unless you have some kind of ability to estimate your cost in areas where you don't know what return you are going to have, you have to have some sort of logical method to keep the lawsuits down.

At the same time, there have to be protections that, when companies conceal, abuse, that there is clear warning, because it is unbelievably tragic when it happens to you that there is a byproduct, something that costs a life, that costs damage out of something because of a product that was supposed to help. That is terribly trag-

ic, but when we look at this balance—I want to read Justice Breyer's as it came to print. She said, "You came up and began and said this drug has side effects that hurt people, and that is a risk when you have a drug and it is a terrible thing if the drug hurts people."

There is a risk on the other side. There are people who are dying or seriously sick, and if you don't get the drug to them, they die. So there is a problem: you have to get drugs to people, and at the same time the drug can't hurt them.

Now, would you rather have to make that decision as to whether a drug is on the balance going to save people or in the balance going to hurt people, an expert agency on the one hand or 12 people pulled randomly for a jury from a jury roll who see before them only the people the drug hurt and don't see those people who need the drugs to cure them? That is one of our dilemmas when we go into a court situation as opposed to a research area or, quite frankly, why you have people at the FDA trying to balance this.

Yes, there needs to be a legal appeal. The question is: where should the legal appeal be, how organized should it be? And one of the challenges is, if you are trying to deal with 50 courts, in addition to the international, what you will do is stop the innovation. What we have is a balance.

I have been critical of FDA on the other side of being too cautious at times, but here I believe there has to be some weighing of this balance which will get lost if it is just going to be decided in 50 States by basically jury trial.

I yield back.

Chairman WAXMAN. Thank you, Mr. Souder.

Any other Members with to make opening statements? Mr. Tierney. Ms. Watson. Mr. McHenry.

[No audible response.]

Chairman WAXMAN. If not, we will proceed to recognize our first panel of witnesses.

Dennis Quaid is the parent of newborn twins, Thomas Boone Quaid and Zoe Grace Quaid, who were victims of a heparin overdose due to inadequate safety warnings by the manufacturer. Today Mr. Quad will explain the impact that this event had on his family and share his views on the need for patient access to the State court system.

Dr. William H. Maisel is a cardiologist and the director of the Medical Device Safety Institute within the Department of Medicine at Beth Israel Deaconess Medical Center in Boston, MA. Dr. Maisel previously chaired two FDA advisory panels and has been a consultant to FDA since 2003. He will be providing testimony regarding the FDA's approval process for medical devices, as well as medical-device-related safety issues he has encountered as a physician.

Dr. Aaron S. Kesselheim is both a lawyer and an internal medicine physician. Dr. Kesselheim is a clinical fellow in the Department of Medicine in Harvard School of Public Health and an associate physician in the Division of Pharmacoepidemiology at Brigham and Women's Hospital. Dr. Kesselheim will be testifying about the role of litigation in defining drug risks.

Dr. David Kessler served as FDA Commissioner from 1990 until 1997. He is currently a professor of pediatrics and epidemiology

and biostatistics in the School of Medicine at University of California, San Francisco. As a former FDA Commissioner, Dr. Kessler will be providing testimony regarding FDA's historical stance on the issue of preemption.

We are delighted to have all of you here today to present your testimony and your views to us.

It is the policy of this committee that all witnesses that testify do so under oath, so if you would please stand and raise your right hands I would like to administer the oath.

[Witnesses sworn.]

Chairman WAXMAN. The record will show that each of the witnesses answered in the affirmative.

You have presented to us prepared statements, and those prepared statements will be part of the record in full. We would like to ask if you would to try to limit the oral presentation to 5 minutes. We have a timer where the red light showing right now, which would indicate that the time has expired. It will be green, and the last minute it will turn yellow, and then eventually turn red after 5 minutes.

Mr. Quaid, we are delighted to have with us. You are one of my constituents, and so I especially want to welcome you today.

STATEMENTS OF DENNIS AND KIMBERLY QUAID, PARENTS OF NEWBORN TWINS, THOMAS BOONE QUAID AND ZOE GRACE QUAID, WHO WERE VICTIMS OF A HEPARIN OVERDOSE DUE TO INADEQUATE SAFETY WARNINGS BY THE MANUFACTURER; WILLIAM H. MAISEL, M.C., M.P.H., DIRECTOR, MEDICAL DEVICE SAFETY INSTITUTE, DEPARTMENT OF MEDICINE, BETH ISRAEL DEACONESS MEDICAL CENTER, BOSTON; AARON S. KESSELHEIM, M.D., J.D., HARVARD MEDICAL SCHOOL, DIVISION OF PHARMACOEPIDEMIOLOGY; AND DAVID A. KESSLER, M.D., J.D., PROFESSOR OF PEDIATRICS AND EPIDEMIOLOGY AND BIOSTATISTICS, SCHOOL OF MEDICINE, UNIVERSITY OF CALIFORNIA, SAN FRANCISCO, FORMER FOOD AND DRUG ADMINISTRATION COMMISSIONER

STATEMENT OF DENNIS QUAID

Mr. QUAID. Thank you, Mr. Chairman, and thank you for inviting me here today to share my family's story. My wife couldn't be here. She is at home taking care of our twins. But it is our hope that these proceedings may raise public awareness about the issue that is here before us, and that is preemption of suits concerning injuries or death caused by FDA-approved drugs.

This is an issue I am sure most Americans are not aware of, but it is one that could adversely affect all Americans, my family included.

I am sure that many of you already know that our newborn twins recently received a near-fatal overdose of blood-thinning medication, heparin, at Cedars-Sinai Medical Center in Los Angeles. Our twelve-day-old infants were mistakenly injected not once but twice over an 8-hour period with a massive overdose of 10,000 units of the anti-coagulant drug heparin, which is 1,000 times the normal does of 10 units of Hep-Lock that our twins should have re-

ceived. Both products are manufactured by Baxter Health Care Corp.

How could this have happened? Well, the answer became very clear to us after talking with the doctors and nurses and doing a little bit of research on our own. The 10 units of Hep-Lock and Baxter's 10,000 unit of Heparin are deadly similar in their labeling and size. The 10,000-unit label, which I believe you have there, Mr. Chairman, is dark blue, and the 10-unit bottle is light blue. If the bottles are slightly rotated, which they often are when they are stored, they are virtually indistinguishable. The similar labeling is what led to the tragic deaths of three infants and severe injuries to three others in Indianapolis the year before, and it was also the major factor in the overdosing of our twins.

After the Indianapolis incident, Baxter sent out a warning to hospitals, and afterward, 7 months later, even changed the label of their Heparin to distinguish it from Hep-Lock. But Baxter failed to recall the deadly misleading bottles that were still on the market and stocked in hospitals, including Cedars-Sinai.

We consider this to be a dangerous decision by Baxter made for financial reasons, and our feelings are they recall automobiles, they recall toasters, they even recall dog food, but Baxter failed to recall a medication that, due to its labeling, had already killed three infants and severely injured three others just a year earlier, and then a year after the Indianapolis incident, the very same incident happened to our 12-day-old infants.

However mistakes did occur at Cedars, the overdosing of our twins was a chain of events of human error, and the first link in that chain was Baxter. Baxter's negligence, the cause of that, was an accident waiting to happen.

Now, since this brush with tragedy my wife and I have found out that such errors are, unfortunately, all too common. Up to 100,000 patients in the United States, alone, die in hospitals every year because of medical errors.

We have also learned a lot about the legal system in a very short time, and it was very surprising, I must tell you. Like many Americans, I have always believed that a big problem in this country has been frivolous lawsuits. But now I know that the courts are often the only path that families have that are harmed by a drug company's negligence.

Now we face something that could cause grave harm to all Americans. The Supreme Court is about to decide whether the law preempts most lawsuits concerning injuries from drugs and their labeling simply because the drug was approved by the Federal Food and Drug Administration.

In our case against Baxter, the company is relying on this very same argument before the Supreme Court, that when the FDA allowed Baxter's Heparin onto the market, the FDA also immunized Baxter from any liability. So says Baxter. Our case may not even be heard before a judge or a jury, no matter how negligent it was in designing its labels or in failing to take the Heparin with the old label off the shelves after it knew about the tragedy in Indianapolis.

Now, it is hard for me, Mr. Chairman, to imagine that this is what Congress intended when it passed the Food, Drug, and Cos-

metic Act in 1938. Did Congress intend to give appointed bureaucrats in the FDA the right to protect a drug company from liability, even when that company cuts corners and jeopardizes public safety?

Federal ban on lawsuits against drug companies would not just deny victims compensation for the harm that has been done to them; it would also relieve drug companies of the responsibility to make drugs as safe as they can be, and, moreover, to correct problems after that drug has been on the market.

Now, let's hope that the Supreme Court will not put barriers in front of patients who are harmed by drug companies, but if the court does decide for the drug companies, in favor of them, I respectfully ask this Congress to pass corrective legislation on an emergency basis.

I thank you for your time.

[The prepared statement of Mr. Quaid follows:]

Testimony of Dennis Quaid and Kimberly Quaid Before the Committee on Oversight and Government Reform of the United States House of Representatives

May 14, 2008

Chairman Waxman and Members of the Committee:

Thank you for inviting my wife, Kimberly, and me here today to share our experience as parents of two infants harmed by the negligence of a prescription drug manufacturer. As I'll explain, our newborn twins nearly died because of a drug company's failure to put safety first. It is our hope that these proceedings will raise public awareness of the issue before the Committee today: When the U.S. Food and Drug Administration (FDA) approves the sale of pharmaceutical drugs, does that preempt the right of consumers to sue the manufacturer if the drug later causes injury or death? This is an issue, I'm sure, most Americans are not aware of, but it is one that could adversely affect all Americans, our family included. As many of you already know, our twins received a potentially fatal overdose of the blood-thinning medication Heparin last year.

Our Life-Altering Story

Thomas Boone and Zoë Grace Quaid were born on November 8, 2007. They were four weeks premature, but healthy and beautiful, and, after three days in the hospital, we took them home to begin our new life as a happy, much-expanded family.

On their eleventh day of life, Kimberly noticed an irritation on T-Boone's belly button and Zoë Grace's finger. Being nervous new parents, we took T-Boone and Zoë to the pediatrician immediately, and, after examining them, he sent us to Cedars-Sinai Medical Center – one of the top hospitals in Los Angeles – for a more in-depth diagnosis. Lab tests at Cedars revealed that both of our twins had a staph infection, and we were told that they would have to be admitted to the hospital to be put on a continuous intravenous drip of antibiotics. Our hearts sank as we accompanied the twins to the pediatric ward, where they were placed in a room to begin their treatment.

At about 11:00 am the next day, a nurse came to the room and said she needed to replace the now empty bags of antibiotic. According to standard procedure, the nurse was supposed to clean the IV lines connected to our twins' little arms with 10 units of a blood thinner medication called Hep-Lock, the idea being that the very small dose of heparin contained in Hep-Lock allows the IV to flow freely. What was not standard procedure was that she mistakenly injected the twins with a massive overdose of 10,000 units of the drug Heparin, which is *1,000 times* the normal 10-unit dose of Hep-Lock our babies should have received. This happened while Kimberly and I were present in the room.

Unaware of the catastrophe that had just occurred, Kimberly and I spent the afternoon and early evening standing vigil over our twins until our doctor suggested we go home and get some rest. We were exhausted, not having slept the night before. The twins seemed to be resting comfortably, so we decided to go home, but not before leaving express instructions to the doctors and nurses to call us if anything changed in our infants' condition. We had no way of knowing at that point that the potentially lethal quantity of Heparin in their tiny bodies was turning their blood to the consistency of water.

After we left, a nurse on duty noticed that Zoë Grace had an abnormal seepage of blood coming from a place on her foot where blood had been drawn. No alarms were raised. Incredibly, sometime after 7:00 pm, both babies were injected with yet another 10,000-unit overdose of Heparin. One nurse prepared the medication, and then handed it to the instructor nurse, who then handed it to the nurse in training as the instructor lectured the trainee on how infants must only receive a 10-unit dose of Hep-Lock. They then left the room and continued their rounds.

At about 9:00 pm, Kimberly and I were at home trying to get some restless sleep when Kimberly was suddenly struck with a hammer blow of overwhelming dread. She became inconsolable, crying out with a mother's intuitive certainty that our babies were in trouble: "They're passing," she said. This did not make sense to me. I had called the nurse's station an hour and a half earlier and had been told that the twins were fine. But, to calm Kimberly's fear, I called again and was put through to the nurse in our room. Kimberly wrote down the time for some reason. The nurse told me in a measured tone that the twins were fine. I was assured. Kimberly became less frantic, and we both eventually fell into a fitful sleep.

But the twins were not fine. In fact, they were fighting for their lives. Their now water-thin blood was flowing out of every place that they had been poked or prodded. They faced the very real possibility of hemorrhaging through a vein or artery, causing massive brain damage or failure of one of their vital organs.

Our babies could have died that night, and we would not have been there for them.

Early the next morning, Kimberly and I arrived at the hospital, only to be met at our babies' room by our pediatrician and hospital staff. We were taken aside and told what had happened. Suffice it to say, it was the beginning of the most frightening day of our lives. It was spent helping tend to our infants who were still bleeding profusely and severely bruised from internal bleeding. They were both screaming in pain, and God only knows what they were feeling. I am not sure even a lab rat had ever received such a high dose of the Heparin that was causing them to bleed out. At one point as the doctors tried to clamp shut a bleeding wound in the remnant of T-Boone's umbilical cord, blood spurted six feet across the room and splattered on the wall. The bleeding went on all day. Although the twins had been administered Protamine, a medication to counteract the Heparin overdose, their blood's inability to coagulate literally remained off the charts all day and into the night. Kimberly and I did a lot of praying.

Finally, after more than forty hours, their coagulation levels dropped into the measurable scale and continued to fall, eventually back into the normal range. T-Boone and Zoë Grace had survived, apparently with no damage so far, thank goodness. But we have no way of knowing what the long-term effects may be.

We Were Not Alone

How had this happened? The answer became apparent after interviewing the doctors and nurses. We discovered that the bottle of 10-units of Hep-Lock and the 10,000-unit bottle of Heparin – both manufactured by Baxter Healthcare Corporation – were deadly similar in labeling and size. The 10,000-unit label is dark blue, and the 10-unit bottle is light blue. And if the bottles are rotated slightly, as they often are when stored, they are virtually indistinguishable.

We later learned that the similarity of the labels for the two products had led to the overdose of infants at a hospital in Indianapolis little more than a year earlier, in September 2006. Just like with T-Boone and Zoë Grace, hospital staff used the 10,000-unit Heparin product, rather than the 10-unit Hep-Lock, to flush the infants' IV lines. Tragically, three infants died, and three others were severely injured.

More than four months after the Indianapolis incident, Baxter sent out a warning to hospitals concerning the potential for deadly mix-ups in the two products. A full seven months after that – in August 2007 – Baxter submitted changes in the labeling of the higher-concentration Heparin to the FDA. Baxter was permitted by FDA regulations to revise its labels, without prior FDA approval, to add or strengthen a drug warning or precaution, or to enhance drug safety by strengthening an instruction about a drug's dosage and administration. So, although the FDA did not approve the changes to the Heparin label until December 2007, Baxter starting using its new labels in October 2007. Baxter described the changes to the Heparin labels as "an increase of 20 percent font size, a unique color combination, and a large cautionary tear-off label" warning that the product is not intended for "lock-flush."

Baxter explained that the new labeling was designed to help reduce the risk of medication errors. But, shockingly, Baxter failed to recall the misleadingly labeled bottles that were still on the market and stocked in hospitals ready for use. Kimberly and I think that this was a dangerous, potentially deadly decision, made by Baxter for financial reasons. Companies recall automobiles, they recall toasters, they even recall dog food, but Baxter failed to recall a medication that, due to its labeling, had killed three infants and severely injured three others. More than a year after the Indianapolis tragedy, the same medical nightmare happened to our twelve-day-old infants – and all because Baxter had not acted as a responsible corporate citizen.

Baxter knew that an estimated 7,000 Americans die each year as a result of medication errors, knew that 61 percent of life threatening or lethal errors involve intravenous drugs such as Heparin, and also knew that Heparin was among eight high-alert products that were involved in more than 31 percent of all medication errors that caused harm to patients. Yet, even with all of this knowledge, Baxter did not change the labeling of its Heparin injection

products until months after the Indianapolis tragedy. And Thomas Boone and Zoë Grace would have to fight for their lives because the new product labeling, introduced by Baxter only one month before, had not yet made it to the shelves of Cedars-Sinai, and Baxter had done nothing to see that the look-alike Heparin products were removed from pharmacy shelves immediately.

Although mistakes occurred at Cedars-Sinai hospital, doctors, nurses, pharmacists, or other staff who make medical errors are not bad people. Indeed, choosing a career devoted to curing the sick and easing the suffering of others is one of life's highest callings. But the overdosing of our twins was the result of a chain of events, and the first link in that chain was Baxter Healthcare. Because of Baxter's inaction, a tragedy was waiting to happen again.

What Can Be Done?

Since this brush with tragedy, I have found out that medication errors are unfortunately all too common. Approximately 100,000 U.S. patients die every year because of medical errors in hospitals alone. It's a toll we would never tolerate in aviation, nearly the equivalent of a full 747 crashing every single day.

I have also learned a lot about the legal system – and it was surprising, I have to tell you. Like many Americans, I believed that a big problem in our country was frivolous lawsuits. But now I know that the courts are often the only path to justice for families that are harmed by the pharmaceutical industry and medical errors. Yet the law is stacked against ordinary people. For instance, in my home state of California, a 1975 law caps compensation to malpractice victims. The cap has never been raised for inflation. The practical effect is that people without the wealth to pay legal fees up front are unable to get their cases before a judge or jury.

Now we face something with potential to be even more sweeping and even more unjust: federal preemption. The Supreme Court is about to decide whether to bar most lawsuits over drugs and their labeling, as long as the drug was approved for marketing by the FDA. After many years of rejecting arguments that FDA actions should preempt lawsuits involving injuries from products regulated by the FDA, White House appointees at the FDA reversed that position in 2002, and now argue that FDA approval immunizes

the manufacturers of dangerous products from liability for the deaths and injuries they cause.

We sued Baxter Healthcare Corporation in November 2007. Baxter has filed a motion to dismiss the case, relying on the same preemption argument that the drug industry and the FDA has made before the Supreme Court – that when the FDA allowed its Heparin drug onto the market, it gave Baxter the government's seal of approval – a "get out of jail free" card that denies us the right to hold the company accountable. (Of course, Baxter never mentions the FDA regulations that encourage and sometimes require manufacturers to fix their drug labels immediately, without getting the FDA's permission first.) So, says Baxter, our suit may not be heard by a judge or jury.

It is hard for me to imagine that this is what Congress intended. You tell me, Mr. Chairman: When it passed the Food, Drug, and Cosmetic Act in 1938, did Congress intend to give appointed bureaucrats at the FDA the right to protect a drug company from liability, even when the company cuts corners and jeopardizes our safety?

A federal ban on lawsuits against drug companies would not just deny victims compensation for the harm they experience. It would also relieve drug companies of their responsibility to make products as safe as possible, and especially to correct drug problems when they are most often discovered – years after their drugs are on the market.

Permitting bureaucrats who are under pressure from their bosses and the drug companies themselves to yank our access to the courts is incomprehensible. We have all heard about understaffing and backlogs at the FDA, and about drug-safety scrutiny that is patchy at best. If the Supreme Court rules in favor of the drug companies, it will eliminate one of the most effective deterrents to letting the bottom line win out over public health and safety.

I am in the entertainment industry, but what happened to us, and what is happening in the courts of our country, is no fiction. It is all too real. That is why I have decided to speak out and try to do something.

Kimberly and I have established a non-profit foundation to call attention to medical safety issues and seek ways to improve medical safety from the

bedside up. Everybody gains from a safer health care system—from patients to nurses and doctors to hospitals and insurance companies.

We are meeting with experts from all over the country to formulate a strategy for safer health care. Americans pioneered the safest aviation system in the world; though highly complex, it is 99.9% error free. The human body is also very complex and hard to perfect. But we should strive for perfection, and we know that at the very least we can do much better.

We can hope that the Supreme Court will not put more barriers in front of patients who are harmed by drug companies. But if the Court goes along with the FDA and rules for the drug companies, I respectfully ask this Congress to pass corrective legislation on an emergency basis, just as it should do immediately to correct the recent Supreme Court decision immunizing the makers of defective and mislabled medical devices. We Americans need some balance on the scales of justice in our country.

My family blessedly survived a huge drug error, triggered by the misconduct of a drug manufacturer. Others are not so fortunate. If they are denied access to our courts, they will have no compensation for their injuries, and society will lose one of the most effective incentives for safer drugs.

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

Dr. Maisel.

STATEMENT OF WILLIAM H. MAISEL

Dr. MAISEL. Thank you, Chairman Waxman. Good morning. Ranking Member Davis, distinguished committee members. My name is Dr. William Maisel.

I am a practicing cardiologist at Beth Israel Deaconess Medical Center and assistant professor of Medicine at Harvard Medical School in Boston. I also direct the Medical Device Safety Institute, an industry independent organization dedicated to improve the safety of medical devices. I have served as a consultant to the FDA Center for Devices and Radiologic Health since 2003, and have previously chaired the FDA's Post-Market and Heart Device Advisory Panels.

I hope that by the conclusion of my brief comments today you will appreciate that FDA marketing clearance or approval of a medical product does not guarantee its safety. For this reason, it is critical that patients receive accurate, timely, easily understood information to assist them in making informed decisions. Manufacturers' responsibilities for product safety extend well beyond initial FDA approval, and it is apparent that additional consumer safeguards are needed if we are to improve the safety of medical devices for the millions of patients who enjoy their benefits.

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

Mark Gleeson is a man whose very life depends on one of these implanted medical devices, in his case a pacemaker. Pacemakers are implanted to treat dangerous slow heart rhythms, and in Mr. Gleeson's case every single beat of his heart comes from his device.

The pacemaker itself consists of a battery and computer circuitry sealed together in a metal housing. Pacemaker batteries typically last five to 10 years, so you can imagine how Mr. Gleeson must have felt when he required surgery to replace his defective pacemaker after just 12 months due to a short circuit that caused his battery to wear out prematurely. Fortunately, Mr. Gleeson was able to safely have his new pacemaker fitted.

St. Jude Medical, the manufacturer of Mr. Gleeson's pacemaker, had become aware of the short circuit problem 2 years prior to Mark Gleeson's pacemaker failure, because other faulty pacemakers had been returned to the manufacturer. After studying the problem for over a year and validating the fix, St. Jude asked for and received FDA approval for a modified version of the device that corrected the problem. Although the approval came several months prior to Mr. Gleeson's device failure, St. Jude Medical continued to distribute the already manufactured potentially faulty pacemakers.

Mark Gleeson was unlucky enough not just to receive the faulty pacemaker, but also to receive a potentially faulty device when his

first faulty pacemaker was replaced, even though corrected pacemakers had been built and were marketed and were available.

Ultimately, St. Jude Medical issued the recall of 163,000 pacemakers, including Mark Gleeson's new unit, but not until 8 months after receiving FDA approval for the corrected device and nearly 2½ years after initially learning of the problem.

Mr. Gleeson wrote a letter to me, and he said, "I have been on a journey through the Food and Drug Administration trying to determine why an incident dealing with a medical device was allowed to happen to me." He adds, "Although my present pacemaker is working fine, every day I expect something to fail."

While Mark Gleeson's case occurred several years ago, it is not an isolated event. Other manufacturers have knowingly sold potentially defective devices without public disclosure. We heard earlier from Chairman Waxman about Guidant Corp. who identified and corrected a design flaw that could result in the short-circuit of an implantable defibrillator, a device that treats both dangerous slow and dangerous fast heart rhythms. Although the company reported the malfunctions to the FDA and received approval for the device modification, it continued to sell its inventory of potentially defective devices without public disclosure.

The FDA annually receives reports of more than 200,000 device-related injuries and malfunctions and more than 2,000 device-related deaths, and it is challenging for them to identify patterns of malfunction among the deluge of adverse event reports. In the majority of cases, FDA relies upon industry to identify, correct, and report the problems, but there is obviously an inherent financial conflict of interest for the manufacturers, sometimes measured in billions of dollars.

Implanted medical devices have enriched and extended the lives of countless people, but device malfunctions and software glitches have become modern diseases that will continue to occur. The failure of manufacturers and the FDA to provide the public with timely critical information about device performance, malfunctions, and fixes enables potentially defective devices to reach unwary consumers. Patients like Mark Gleeson are sometimes forced to make life-changing decisions with insufficient and sometimes inaccurate information.

We have consumer protections for airline passengers, for cable television customers, and for cellular telephone users, but few for patients who receive life-sustaining medical devices. Additional consumer safeguards are needed if we are to minimize adverse health consequences and improve the safety of medical devices for the millions of patients who are fortunate enough to enjoy their benefits.

Thank you.

[The prepared statement of Dr. Maisel follows:]

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

BEFORE THE
HOUSE COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

SHOULD FDA DRUG AND MEDICAL DEVICE REGULATION
BAR STATE LIABILITY CLAIMS?
MAY 14, 2008

INTRODUCTION

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

I hope that by the conclusion of my brief comments today you will appreciate that FDA marketing clearance or approval of a medical product does not guarantee its safety. For this reason, it is critical that patients receive accurate, timely, easily understood information to assist them in making informed decisions. Manufacturers' responsibilities for product safety extend well beyond initial FDA approval and it is apparent that additional consumer safeguards are needed if we are to improve the safety of medical devices for the millions of patients who enjoy their benefits.

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

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

St. Jude Medical, the manufacturer of Mr. Gleeson's pacemaker, had become aware of the short circuit problem 2 years prior to Mark Gleeson's pacemaker failure because other faulty pacemakers had been returned to the manufacturer[3]. After studying the problem for over a year and validating a fix, St. Jude asked for and received FDA approval for a modified version of the device that corrected the problem[4]. This approval came several months prior to Mr. Gleeson's device failure although the reason for the

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[1] Maisel WH. Medical device regulation: An Introduction for the practicing physician. Ann Intern Med 2004; 140: 296-302.
[2] Tillman D-B. Report from ODE. Accessed May 12, 2008 at: **http://www.fda.gov/cdrh/present/advamed-052405-tillman-ode.ppt**
[3] US Food and Drug Administration. *Consumer Complaint/Injury Report.* Rockville, Md; June 10, 2000. LOS-9364.
[4] Fleckenstein JR. United States Food and Drug Administration: Los Angeles District. *Memorandum: F/U to Consumer Complaint.* Irvine, Calif; September 18, 2000. LOS-9364.

device modification and a patient warning were not publicly provided at that time. Furthermore, St. Jude Medical continued to distribute the already manufactured potentially faulty pacemakers[5]. Mark Gleeson was unlucky enough to receive one as his replacement device – even though corrected pacemakers had been built and were available. Eight months after receiving FDA approval for the corrected device and nearly 2.5 years after initially learning of the problem, St. Jude Medical issued a recall of 163,000 pacemakers, including Mark Gleeson's new unit[6].

Mr. Gleeson writes "...I have been on a journey through the Food and Drug Administration trying to determine why an incident dealing with a medical device was allowed to happen to me." He adds, "Although my present pacemaker is working fine...every day I expect something to fail."

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

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

While Mark Gleeson's case occurred several years ago, it is not an isolated event. Other manufacturers have knowingly sold potentially defective devices without public disclosure[7]. For example, Guidant Corporation identified and corrected a design flaw that could result in the short circuit of an implantable defibrillator, a device that treats both dangerous slow and dangerous fast heart rhythms. The company, however, continued to sell its inventory of potentially defective devices without public disclosure[8]. The FDA sometimes permits a potentially flawed product to be marketed unbeknownst to the consumer while the manufacturer submits a revised marketing application and awaits approval of the amended product design and manufacturing plan[7].

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[5] Maisel WH. Malfunctions of implantable cardioverter defibrllators. JAMA 2005; 295: 161-2.
[6] St. Jude Medical. Technical memo: Important advisory information: Premature battery depletion in the Trilogy family of pacemakers. July 9, 1999.
[7] Maisel WH. Semper fidelis – Consumer protection for patients with implanted medical devices. N Engl J Med 2008; 358: 985-987.
[8] Maisel WH. Safety issues involving medical devices. Implications of recent implantable cardioverter-defibrillator malfunctions. JAMA 2005; 294: 955-958.

FDA PRE-APPROVAL EVALUATION

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

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

FDA MANDATED POST-APPROVAL AND POST-CLEARANCE STUDIES

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

Despite the obvious importance of these studies in assessing device safety, the FDA and manufacturers have struggled to handle this responsibility. In 2005, the FDA reported that they "couldn't find" 22% of the required post-market medical device studies for the years 1998-2000 and acknowledged that some of the studies were never started[9]. And while efforts have been made to better track these required studies, a visit to the FDA's device post-approval study website on May 6, 2008 demonstrated that 22% of manufacturers had submitted a report late and that nearly 1 in 20 manufacturers with on-going post-approval study responsibilities currently had an overdue report[10]. Lest you think that this problem applies only to medical devices, it was reported in April 2008 that 1,044, or 62 percent, of incomplete studies for conventional drugs and biotechnology medications had

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

[10] U.S. Food and Drug Adminsitration. Post approval studies. Accessed May 12, 2008 at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm

yet to be started[11]. In 2005, Dr. Susan Gardner, Director of the FDA's Center for Devices and Radiologic Health Office of Surveillance and Biometrics, spoke about the medical device post-approval studies observing that, "it looks like we have a fairly poor track record in getting these studies done"[9].

ADVERSE EVENTS AND RECALLS

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

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

CONCLUSIONS

Implanted medical devices have enriched and extended the lives of countless people, but device malfunctions and software glitches have become modern "diseases" that will continue to occur. The failure of manufacturers and the FDA to provide the public with timely, critical information about device performance, malfunctions, and "fixes" enables potentially defective devices to reach unwary consumers. Patients like Mark Gleeson are sometimes forced to make life-changing decisions with insufficient and sometimes inaccurate information. We have consumer protections for airline passengers, cable-television customers, and cellular-telephone users, but few for patients who receive life-sustaining medical devices. Additional consumer safeguards are needed if we are to minimize adverse health consequences and improve the safety of medical devices for the millions of patients who enjoy their benefits.

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[11] Blum J. Drugmakers didn't begin 1,044 promised U.S. studies. Accessed May 12, 2008 at: http://www.bloomberg.com/apps/news?pid=20601124&sid=acu6znqklhBo&refer=home

[12] Center for Devices and Radiologic Health. CDRH FY 2006 highlights. Accessed May 12, 2008 at: http://www.fda.gov/cdrh/annual/fy2006/fy2006.pdf

[13] Castellucci L. Guidant subsidiary pleads guilty, settles criminal charges related to aortic aneurysm device. Accessed May 12, 2008 at: http://www.theheart.org/viewArticle.do?simpleName=347409

Chairman WAXMAN. Thank you very much, Dr. Maisel.

Dr. Kesselheim.

STATEMENT OF AARON S. KESSELHEIM

Dr. KESSELHEIM. Thank you. Chairman Waxman, Ranking Member Davis, and members of the committee, my name is Aaron Kesselheim. I am an internal medicine physician in the Division of Pharmacoepidemiology at Brigham Women's Hospital and an instructor of medicine at Harvard Medical School in Boston, and I conduct research on the ways that legal and regulatory issues affect medical practice, in particular related to the uses of prescription drugs.

It is an honor to have the opportunity today to talk to you about the important role litigation plays in the drug safety system. Lawsuits against pharmaceutical manufacturers usually involve charges that the manufacturer failed to exercise proper care in warning about the risks of their drug products. Preempting or blocking such lawsuits, in my view, would to great harm to the public health. The reason is that a drug's manufacturer plays the central role in the development and dissemination of knowledge about its product.

After FDA approval of a drug, important new data about adverse events often arise, but the FDA does not have the resources to fully monitor the uses and outcomes of all approved drugs. As a result, the FDA cannot certify a drug's ongoing safety. The drug's manufacturer is often in a position to identify emerging safety problems with its own product, but it has an inherent conflict of interest in that role. Manufacturers have a strong financial incentive to promote their drugs' effectiveness and increase sales of their products. Manufacturers may also sometimes be faced with data that suggests limiting the use of their product or withdrawing it from the market altogether.

Manufacturers faced with this conflict of interest can make poor decisions that adversely affect the public health.

First, manufacturers have misrepresented findings in medical publications. For example, in the case of the anti-inflammatory Vioxx, a manufacturer-organized study was criticized because the authors did not accurately represent all the safety data they had regarding serious cardiovascular side effects. The exclusion of that data minimized the appearance of cardiovascular risks to physicians reading the study and using it as a basis for prescribing decisions.

Second, manufacturers have minimized safety signals in their reports to the FDA. When Vioxx was associated with an increased risk of mortality in two manufacturers' studies, the manufacturer delayed communication of certain findings to the FDA and ultimately reported it in a way that clouded the appearance of risk.

In the case of a cholesterol-lowering medicine, Baycol, the manufacturer received early reports suggesting an increased risk of a rare form of muscle breakdown and kidney failure, but the company did not conduct timely followup analyses or pass along internal analyses of drug safety signals to the FDA. A company memorandum reportedly stated, "If the FDA asks for bad news, we have to give; but if we don't have it, we can't give it to them."

At the same time, when manufacturers promote a drug to physicians and patients, they tend to inflate its benefits and downplay its risks. Vioxx's manufacturer continued actively promoting its wide use, even after it reportedly knew about the drug's association with cardiovascular adverse events.

The Vioxx and Baycol cases are just two recent examples illustrating how a manufacturers' dual role as the promoter of drug sales and the collector of safety information led to decisions detrimental to the public health. In this context, our research shows that litigation plays an important oversight role aside from helping people injured by dangerous products obtain financial recoveries.

First, lawsuits can help bring important data to light so that physicians can make better prescribing decisions. Second, lawsuits help reveal improper business tactics, punish such actions, and hopefully prevent such similar behavior from occurring on other occasions in the future. Third, lawsuits can help reveal gaps in FDA policies and procedures in the oversight of drug safety.

In sum, FDA approval does not end the process of information development about drug risks and benefits that define the safety of a drug and how a drug should properly be used. Without the possibility of litigation against manufacturers and their executives, we are likely to see greater misrepresentation of safety-related data and more potentially inappropriate use of harmful medications.

Manufacturers continue to have a key role in the development and organization of safety and efficacy data about their products, but they also have an inherent conflict of interest when evaluating their own products.

In my view, it is therefore important to continue to encourage manufacturers to act responsibly by subjecting their decision-making to judicial review.

Thank you, and I welcome your questions.

[The prepared statement of Dr. Kesselheim follows:]

BRIGHAM AND
WOMEN'S HOSPITAL

HARVARD
MEDICAL SCHOOL

Testimony of:

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Brigham and Women's Hospital

Harvard Medical School

Boston, MA

United States House of Representatives
Committee on Oversight and Government Reform
May 14, 2008
Washington, D.C.

BRIGHAM AND WOMEN'S HOSPITAL

HARVARD MEDICAL SCHOOL

Chairman Waxman, Ranking Member Davis, and Members of the Committee:

My name is Aaron Kesselheim. I am an Internal Medicine physician in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham & Women's Hospital in Boston and am an Instructor in Medicine at Harvard Medical School. I am also a lawyer and I spend most of my time conducting research on the ways that legal and regulatory issues affect medical practice, in particular related to uses of prescription drugs. It is an honor to have the opportunity to share my thoughts with you today about the important role litigation plays in the drug safety system.

The subject of the hearings today is federal preemption of lawsuits against pharmaceutical manufacturers, usually brought by injured patients or state attorneys general on behalf of their citizens. Most of the time, these lawsuits involve charges that the manufacturer failed to exercise proper care in warning about the risks of their drug products. Blocking such lawsuits, in my view, would do great harm to the public health. These lawsuits are important because in the current US regulatory system, a drug's manufacturer plays the central role in the development and dissemination of knowledge about its product, and therefore exerts considerable influence over what is known about its product and how it is used in the marketplace. When a drug is approved by the FDA, it is approved on the basis of a small number of studies in a modest number of subjects, some of whom may be healthy volunteers and many of whom are far healthier than the patients for whom we usually write prescriptions. Often, the effect that forms the basis of approval is improvement of a laboratory test rather than real clinical outcomes. Requiring a drug to be studied in tens or hundreds of thousands of patients over a number of years could delay important new products from entering the market. But as a result, when a drug is approved for marketing, the FDA cannot fully certify its ongoing safety. As many more patients are prescribed the drug in the post-approval setting, new data about adverse events often arise, and the FDA does not have the resources to fully monitor the uses and outcomes of all approved drugs. The drug's manufacturer is often in an excellent position to identify emerging safety problems with its own product, but has an inherent conflict of interest in that role. Manufacturers have a strong financial incentive to promote their drugs' effectiveness and increase sales of their products, but manufacturers may also sometimes be faced with their own safety-related data that suggest limiting use of their product, or withdrawing it from the market altogether.

In the past few years, we have seen how manufacturers faced with this conflict of interest can make poor decisions that adversely affect public health. First, manufacturers have misrepresented safety and efficacy findings in published medical literature in ways that favor their products.[1] For example, in the case of Vioxx, an early study organized by the manufacturer showing the drug's effectiveness was criticized because the authors did not accurately represent all the safety data regarding serious cardiovascular side effects available to them as the study was being reviewed by a leading medical journal.[2] The exclusion of that data minimized the appearance of the cardiovascular risks to physicians reading the study and using it as a basis for prescribing decisions.

Second, manufacturers have minimized safety signals in their reports to the FDA to avoid raising concerns from regulators about their products. Again using Vioxx as an example – although many others could be cited – the manufacturer conducted several randomized trials of its drug in patients with cognitive impairment. In analyses conducted by company biostatisticians, Vioxx was associated with an increased risk of mortality in two studies. Yet the manufacturer delayed communication of the findings to the FDA and ultimately reported it in a way that minimized the appearance of risk. When FDA regulators noted the increased mortality and raised questions about the ethics of continuing one of the studies, the manufacturer dismissed the findings as "chance fluctuations."[3] In the case of cerivastatin (Baycol), a cholesterol-lowering medication that substantially increases the risk of a rare form of muscle breakdown and kidney failure, the

manufacturer received reports suggesting this increased risk as early as 1999. A study of internal company documents indicated that the company did not conduct timely follow-up analyses or pass along internal analyses of drug safety signals to the FDA.[4] A company memorandum reportedly stated "If the FDA asks for bad news, we have to give, but if we don't have it, we can't give it to them."[5] These behaviors can impede the ability of the FDA to recognize early safety-related signals and be able to judge whether a drug is potentially dangerous.

At the same time, a drug's manufacturer manages how the drug is promoted to physicians and patients. Numerous studies show that these promotional messages are extremely powerful in influencing physicians' prescribing practices. However, like any sales messages, they also tend to inflate the benefits of a medication and downplay its risks. Vioxx's manufacturer continued actively promoting its wide use even after it reportedly knew about the drug's association with cardiovascular adverse events. Such promotional tactics included specific instructions to its detailers how to dodge questions from physicians concerned about these side effects.[6] Similar marketing tactics occurred in the case of Baycol, where one of the manufacturer's executives, aware of potential safety concerns about its product, instructed its marketing department to "promote the hell out of this product."[7]

The Vioxx and Baycol cases are just two recent examples illustrating how manufacturers' dual role as promoter of drug sales and collector of safety information led to decisions detrimental to the public health. In this context, litigation plays an important oversight role, aside from helping people injured by dangerous products obtain financial recoveries.[8] First, lawsuits can help bring important data to light so that physicians can make more well-informed prescribing decisions in the future. Second, lawsuits help reveal improper business tactics, punish such actions, and hopefully prevent similar behavior from occurring on other occasions in the future. Third, lawsuits can help reveal gaps in FDA policies and procedures in the oversight of drug safety.

In sum, FDA approval does not end the process of information development about drug risks and benefits that define the safety of a drug and how a drug should properly be used. In our research group at Harvard Medical School, we contribute to this process in a number of ways. We conduct research, sometimes at the request of drug manufacturers, looking at large databases of patient experiences with drugs in order to determine if there are associations between the drugs and important side effects that bear further investigation. We also educate physicians about how to make optimal drug use decisions through a process of academic detailing. But our work, and the work of similar drug safety researchers across the country, can be readily undermined if pharmaceutical companies manipulate or restrict access to patient safety data.[9]

Applying the principle of preemption in these cases would treat FDA approval and labeling decisions as the final word on knowledge about a drug's safety, when substantial experience shows that they are not. Preempting lawsuits against pharmaceutical manufacturers would remove a check on pharmaceutical manufacturers that is essential to prescription drug safety and the public health. Without the possibility of litigation against manufacturers and their executives, we are likely to see greater misrepresentation of safety-related data and more inappropriate use of potentially harmful medications. Manufacturers should not be absolved of blame when they inadequately evaluate or report their products' risks. Manufacturers continue to have a key role in the development and organization of efficacy and safety data about their products, but they also have an inherent conflict of interest when evaluating their own products. In my view, it is therefore important to continue to encourage manufacturers to act responsibly by subjecting their decision making to judicial review.

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Chairman WAXMAN. Thank you very much, Dr. Kesselheim.

Dr. Kessler.

STATEMENT OF DAVID A. KESSLER

Dr. KESSLER. Mr. Chairman, I would like to discuss why the FDA system of drug and medical device regulation is not entirely adequate for assuring the protection of the public health.

There are two very different aspects to drug review, and it is important to understand each in the debate on preemption. First is the period leading through approval. Manufacturers are supposed to submit all pre-clinical and clinical data. FDA has to review that data. FDA makes an affirmative decision that the drug can go on the market if the drug meets the statutory standards for safety and efficacy.

Let me move on to the second phase of a drug's life. The drug is on the market. If a drug is studied in a few thousand patients and a serious and life-threatening drug reaction occurs in an incidence of 1 in 10,000, it is likely that serious and life-threatening risk will not have been seen in the clinical trials and will only emerge after the drug is on the market.

Companies have to file adverse reaction reports. Thousands of adverse reaction, drug and device adverse reaction reports, come into the agency each year.

Those who favor preemption focus on the first part of a drug's life, the approval process. They suggest that the FDA's approval of a drug's labeling reflects the agency's definitive judgment, but I believe it is wrong to focus on the moment of approval as the determination of the preemption question. The relevant timeframe is post-approval as much as it is pre-approval, and the question is: what did the FDA and the drug company know about a drug's risk at the time the patient sustained the injury?

As I just discussed, the FDA's knowledge base of the risks posed by a new drug is far from static. At the time of approval, the FDA's knowledge base may be close to perfect for that moment in time, but it is also highly limited, because at that point the drug has been tested on a relatively few small population of patients. The fact is that companies will always have better and more timely information about their products than FDA will ever have at its disposal.

Moreover, there are real limits on FDA. There are limits on FDA authority that prevent it from acting quickly in some settings, and, most importantly, there are real limits imposed by the limited resources the agency has available. Even if FDA's funding were doubled or tripled, its resources and ability to detect emerging risks on the thousands of marketed drugs and devices would still be dwarfed by those of the drug and device companies who manufacture those products.

For that reason, the tort system has historically provided a critical incentive to drug and device companies to disclose important information to physicians, patients, and the FDA about newly emerging risks. My greatest concern with preemption is that it would, I believe, dramatically reduce the incentives for manufacturers to act quickly and responsibly to detect, analyze, investigate, and take ac-

tion on potentially serious and life-threatening adverse reactions once a drug is on the market.

Mr. Chairman, I need to stress that it is the manufacturers, not the agency, that are in a far better position to know when a new risk emerges from a drug or device, and it is the manufacturer that has the ability to make swift changes to a drug or device's warning or product features.

Thank you, Mr. Chairman.

[The prepared statement of Dr. Kessler follows:]

TESTIMONY

FORMER COMMISSIONER

UNITED STATES FOOD AND DRUG ADMINISTRATION

BEFORE THE HOUSE COMMITTEE ON

OVERSIGHT AND GOVERNMENT REFORM

HEARING ON:

SHOULD FDA DRUG AND MEDICAL DEVICE

REGULATION BAR STATE LIABILITY CLAIMS?

MAY 14, 2007

Mr. Chairman and Members of the Committee, thank you for inviting me to be here today to set forth my views on the question of whether FDA regulation of drugs and medical devices should preempt state liability cases.

My colleague Professor David Vladeck of the Georgetown Law School and I have recently coauthored a law review article titled, "*A Critical Examination of the FDA Efforts to Preempt Failure-To-Warn Cases.*" I request that article be included in the Committee's record.

Let me speak today from my personal experience having had the privilege to serve two Presidents in the role of Commissioner of Food and Drugs.

In 1996, Margret Jane Porter, a career public servant, who served as the agency's chief counsel while I was Commissioner, summed up the Agency's position at a Food and Drug Law Institute conference.

She was talking about medical devices, but the position was equally applicable to prescription drugs. Let me quote:

> "FDA's view is that FDA product approval and state tort liability usually operate independently, each providing a significant yet distinct layer of consumer protection. FDA regulation of a device cannot anticipate and protect against all safety risks to individual consumers. Even the most thorough regulation of a product such as a critical medical device may fail to identify potential problems presented by the product. Preemption of all such claims would result in the loss of a significant layer of consumer protection leaving consumers without a remedy caused by defective medical devices."

So, in general, I believe, as did my general counsel, that the two systems should operate in a complementary but independent manner.

FDA, under the current Administration, has a different point of view.

I would like to discuss why the FDA system of drug and medical device regulation is not entirely adequate for assuring the protection of the public health.

But first let me discuss federal preemption more generally. I am not opposed to federal preemption in certain cases, but I think there should be specific criteria governing when it is deemed appropriate.

There are three elements that I believe should be met if FDA regulation is going to preempt state law in a given case.

First, the Agency took substantive and definitive action.

Second, there is a direct conflict between state action and agency action which would thwart the ability of the agency to achieve its statutory goals.

And third, there is a public health reason to favor preemption.

Let me give you two examples in an area outside of drug and medical device regulation -- the area of food regulation.

In the 1980's, food companies were making a lot of outlandish health claims on the food label. FDA could have acted and concluded that the claims were false and misleading, but it did not, for whatever reason -- bureaucratic intransigence, other regulatory priorities, concern about being able to sustain its enforcement actions in court, regulatory philosophy, or simply being asleep at the switch.

The state attorneys general stepped in under state food and drug laws and took action.

Applying the criteria I listed, in this food example there was no substantive and definitive agency action, no direct conflict, no public health reason to stop the AGs.

Let me give you a second example -- the food label.

In 1992, FDA promulgated final rules for the Nutrition Facts panel, implementing the Nutrition Labeling and Education Act of 1990—a statute that you, Mr. Chairman, were a key architect. Based on decades of study, including that by the National Academy of Sciences, and after hundreds of thousands of public comments, the Agency, along with its sister agency in the Department of Agriculture, promulgated with great specificity the requirements for what should be included on all packaged food labels.

What should happen if a state issued a different rule requiring a nutrition facts panel but specifying that the information be disclosed in a different way than mandated by federal law? I believe that preemption would be in order, and Congress expressly instructed that be the case. Going through the above criteria, FDA acted in a substantive and definitive way, there is a conflict between state and federal action, and the public health would be served with greater consistency and public familiarity.

Now let me shift to prescription drugs.

There are two very different aspects to drug review and it is important to understand each in the debate on preemption.

First is the period leading through approval. Manufacturers are supposed to

submit all preclinical and clinical data. FDA has to review all that data. FDA makes an affirmative decision that the drug can go on to the market if the drug meets the statutory standards for safety and efficacy. FDA must approve the drug's label, which is the equivalent of the physicians' package insert.

Let me move on to the second phase of a drug's life. The drug is on the market. If a drug is studied in a few thousand patients and a serious life threatening drug reaction occurs at an incidence of one in ten thousand, it is likely that this serious and life threatening risk will not have been seen in the clinical trials and will only emerge after the drug is on the market.

In fact, it has been noted that only a fraction of adverse reactions that appear on the label occur in the first seven years. Adverse reactions continue to occur during the postmarketing period. Companies have to file adverse reaction reports. Thousands of adverse drug and device reports come in to the Agency each year.

Those who favor preemption focus on the first part of a drug's life, the approval process. They suggest that the FDA's approval of a drug's labeling reflects the Agency's definitive judgment, regarding risks that must be shielded from the possible second-guessing that might take place in a failure-to-warn case. Otherwise, court rulings adverse to drug companies might force companies to add warnings not approved, or even rejected, by the FDA, thereby upsetting the balance of risks and benefits set by the FDA when it approves a drug label.

Of course, the moment the FDA approves a new drug is the one moment the Agency is in the best position to be the exclusive arbiter of a drug's safety and effectiveness. On that day, assuming the drug sponsor has fully and accurately provided all the data and appropriate analyses to the Agency, the FDA has had access to and has devoted considerable resources to reviewing carefully the health and safety data relating to the drug.

But I believe it is wrong to focus on the moment of approval as determinative of the preemption question. The relevant timeframe is *post*-approval, and the question is: What did the FDA and the drug company know about a drug's risks at the time the patient-plaintiff sustained the injury. As I just discussed, the FDA's knowledge-base of the risks posed by a new drug is far from static. At the time of approval, the FDA's knowledge-base may be close to perfect for that moment in time, but it is also highly limited because, at that point, the drug has been tested on a relatively small population of patients. Once the drug enters the marketplace, risks that are not overly common, that manifest themselves only after an extended period of time, or that affect vulnerable subpopulations begin to emerge. These are often risks not foreseen by the drug's manufacturer or the FDA and, for that reason, are not addressed on the label. The FDA's statutory and regulatory tools for gathering post-approval information are relatively crude and often ineffective, especially when contrasted with its tools for information gathering prior to approval. The expectation that even an enhanced FDA post-market surveillance program will detect all emerging safety problems with drugs or devices is not realistic.

The fact is that companies will always have better, and more timely information about their own products than FDA will ever have at its disposal. Moreover, there are real limits on FDA: There are limits on FDA authority that prevent it from acting quickly in some settings, *e.g.*, lack of drug recall authority and, as implemented by FDA, very slow device recall authority. In the drug advertising arena, FDA is never able to monitor what the thousands of drug representatives are saying to doctors that may be encouraging unsafe uses. Moreover, FDA usually gets the raw adverse reaction data, and does not have the benefit of all the analyses, review, thinking, and back and forth communication that occurred within the companies.

And, most importantly, there are real limits imposed by the limited resources the

Agency has available. The case for preemption must be examined in light of a clear-eyed appraisal of the FDA's ability to assure the safety of the drugs being marketed in the United States. As we all know, the reality departs from what we would all wish could be the resources allocated to the Agency. The Institute of Medicine (IOM) reported in 2006 that the FDA "lacks the resources needed to accomplish its large and complex mission today, let alone position itself for an increasingly challenging future." FDA doctors and scientists share this view -- many believe that the FDA lacks sufficient resources to protect the public health, and many worry that the FDA is not adequately monitoring the safety of drugs once they are on the market. The FDA has long been hamstrung by resource limitations. Even if FDA's funding were doubled or tripled, its resources and ability to detect emerging risks on the thousands of marketed drugs and devices would still be dwarfed by those of the drug and device companies who manufacture those products

For that reason, the tort system has historically provided a critical incentive to drug and device companies to disclose important information to physicians, patients, and the FDA about newly emerging risks.

My greatest concern with preemption is that it would, I believe, dramatically reduce the incentives for manufacturers to act quickly and responsibly to detect, analyze, investigate, and take action on potentially serious and life threatening adverse reactions once a drug is on the market.

While there are adverse reaction reporting requirements for the manufacturers to give the data on adverse reactions to the Agency, that does not mean that the Agency knows as much as the companies and in as timely a fashion as the companies. We limit the incentives for a company to uncover potentially serious and life threatening reactions if there is no liability for harm the drug or device causes. We limit the incentives to do anything more than be a passive transfer of adverse product reports that come within the company's knowledge. We limit the

incentives to do, in a timely and expeditious manner, the type of epidemiological studies to discover patterns and links between a drug, or a device, and the potential harm it causes. The tort system has always provided those incentives. Congress has recently given the Agency new tools to require more post marketing studies, but the Agency still needs to know what the potential risks are so that it is in a position to require such studies. And if the companies have little incentive on their own to undertake such post marketing studies, much harm can occur until the agency is in a position to act.

Mr. Chairman, I need to stress that it is the manufacturers, not the Agency, that are in a far better position to know when a new risk emerges from a drug or device. And it is the manufacturer that has the ability to make swift changes to a drug or device's warning or product features.

Doing away with the incentives to act responsibly and expeditiously to correct potential risks, incentives that are the result of state liability cases, would, I believe, jeopardize the public's health.

Chairman WAXMAN. Thank you very much, Dr. Kessler.

I am now going to recognize members of the committee to ask questions for 5 minutes, and I will start with myself.

Mr. Quaid, to understand what happened to your twins, you had on the screen earlier—and I hope they will put it back up—a picture of the two vials. I do have them right here. They look very, very much alike, but one is 10,000 times the potency of the other.

Mr. QUAID. Sorry to correct you, but it is 1,000 times the potency.

Chairman WAXMAN. But the one that was 1,000 times more was the one that was administered to your children, is that right?

Mr. QUAID. Yes, sir. Not once but twice over an 8-hour period.

Chairman WAXMAN. Not once, but twice?

Mr. QUAID. Yes.

Chairman WAXMAN. And I imagine what happened is, if you look at the two bottles they look so closely alike that busy nurses and doctors and others in the hospital made the mistake of confusing one for the other.

This wasn't the first time this mistake was made, because in September 2006 there was a tragic situation in Indianapolis when two Heparin vials were confused for each other and six babies were injured and three babies died. So you would think if something like this already happened there would have been action spurred all around the country to inform people about it.

The time line suggests that action took a very long time. It took 5 months just to get a letter out to warn health care professionals, 13 months to issue a new label. What do you think of that length of time to get some action by the manufacturer?

Mr. QUAID. Well, I think there is too much time, sir. The incident in Indianapolis, when that occurred, although I can't speak with the full knowledge of that case, but I think that may have been at the point of what was referred to earlier as the state-of-the-art. No one was aware at that time that it was really a problem. This was a case that got reported and received attention because of the deaths of the incidents.

At that time I do believe that it would have been prudent for Baxter to recall all the Heparin that they had out there in the 10,000-unit bottles or/and the Hep-Lock to differentiate them for use. This was not done.

As you said, it took 4 or 5 months to get a warning out to hospitals, and I think it was 11 to 13 months before they actually changed the bottle of the Heparin to differentiate it from the Hep-Lock.

Chairman WAXMAN. The label was supposed to have been changed. Baxter didn't recall the product. They kept the vials with the old labels on the shelf, even though they were going to change the labels, but they didn't recall those that were already out.

You brought a case against Baxter in the State court, and then Baxter filed a motion to dismiss your case because on the facts the drug had been approved originally by the FDA. So what Baxter is arguing is that your case should be dismissed because FDA preempted the whole area of regulation of Heparin and it seems that what they are doing now in this decision is to try to say you can't even go to the State court to seek redress of your grievances. Your

children were overdosed, and you want to get action against the manufacturer that had some responsibility.

If we go along with this preemption theory, it seems to me we are giving a company a free pass when they know there is a problem with one of its products, when it drags its feet in letting the consumers know about the problem and fixing it, and when someone gets hurt by the product during that time just because the product had originally been approved by FDA.

I want to ask Dr. Kessler, you are a former FDA Commissioner. You may not know the details of this case, but according to the time line Baxter changed its Heparin label in October 2007, but it wasn't until December of that year that FDA approved the label change.

What significance is there? How is this possible? How could Baxter change the label and then later get approval for the change by the FDA?

Dr. KESSLER. Mr. Chairman, both drug and device law allow manufacturers to make safety changes on their label, and those changes should not be delayed.

Chairman WAXMAN. So the company can make the change on its own? They don't need FDA approval?

Dr. KESSLER. They need to submit at the time they make the change, they need to tell the agency, and then the agency can review it subsequently. But this is about safety, Mr. Chairman.

Chairman WAXMAN. Why wouldn't FDA have recalled the product or told Baxter to recall the product that had the old labels on them?

Dr. KESSLER. Well, the agency can act subsequently, but there is an interim period of time where the company can take action, deal with the safety. FDA can learn about it, but there is that period of time that it takes the agency to review. It is about information, Mr. Chairman, and when does the agency get that information. Here the company has that information. It can act. It submits it to the agency. But then the question is what that period of time is.

Chairman WAXMAN. Thank you very much.

Mr. Davis.

Mr. DAVIS OF VIRGINIA. Thank you very much.

Thank you very much, Mr. Quaid. Thank you. You put a face to the problem, which is helpful to us in terms as we try to understand. I think if this had been my kids, I would be suing everybody in sight. This kind of thing should not happen. But I am curious to understand why you are just suing Heparin. Why not the hospital and the nurses, as well, who took the wrong vials off? I think this is after the hospital had gotten a letter. I mean, wouldn't you get everybody? There is culpability to go around here.

Mr. QUAID. Yes, sir. Those letters that were sent out, warnings, they are sent out to hospitals. There are so many warnings that are sent out that stack up on desks, and not everyone is aware of them completely.

To address your question about pursuing the hospital, we have 8 years to sue the hospital. Our twins survived, and apparently with no damage to them, although we really don't know what the long-term effects may be.

I am hesitant to sue people. As I say, I did not believe in frivolous lawsuits and I certainly don't consider this to be one, but we don't want to bring down our medical institutions. We really need them. What we are seeking at the present time is to get Cedars to work with us to help solve this problem and improve patient safety.

Mr. DAVIS OF VIRGINIA. OK. Thank you very much.

Dr. Kessler, fellow Lord Jeff, you support preemption when there is a direct conflict between State and regulatory action. In the case of *Wyeth* v. *Levin,* phenergan, an injectable anti-nausea medication included in its label warnings included the mode of administration. The label stated that intramuscular injection was preferred, and intra-arterial injection can cause gangrene and extreme care should be exercised.

Now, the manufacturer requested changes to its label to prohibit this mode of injection, but FDA rejected those changes because in some specific instances intra-arterial injection may be appropriate.

Now, my question is this: do you think the Vermont Supreme Court requiring a labeling change that was rejected by the FDA is an example where preemption should be allowed because of the direct conflict?

Dr. KESSLER. I think, Congressman Davis, I think you summed it up well in your opening statement. I don't want to get into the very specific facts of a particular case, but I do believe there are times and there are criteria when there is a case for preemption, and I have supported in several instances case of preemption. I think when an agency takes substantive and definitive action, I think when there is a direct conflict between the State action and the agency action that would thwart the ability of the agency to achieve its statutory goals, and I think when there is a public health reason to favor preemption, I think there are criteria.

Mr. Davis, the Congress supported, for example, take the nutrition facts panel that is on all packaged foods. It wouldn't makes sense for States to be enacting a separate nutrition facts panel. So there are times when the agency acts.

The important thing to understand is that at the moment the agency has the NDA, assuming the company has told them everything. The agency is in a good position to know everything. But that is not the kind of cases we are talking about.

Much of this happens as you see people learn information after the drug is on the market.

Mr. DAVIS OF VIRGINIA. That is right.

Dr. KESSLER. And who is in the position to act and what are the appropriate incentives? I am concerned that if you have preemption, if you have blanket preemption, preemption across the board, then you are going to take away incentives for the companies to act quickly.

Mr. DAVIS OF VIRGINIA. I agree. I would note that the only regulatory action—regulatory action, I am not talking about their legal preference—by the current administration is a proposed rule relating to the circumstances under which manufacturers can make a label change without prior FDA approval, so when they find a problem they can fix it without FDA approval. I think that is moving in the right direction.

Dr. KESSLER. But I would urge that when we are talking about safety—and that is what we are talking about—and a company has information, FDA is going to want that company to act quickly and expeditiously.

Mr. DAVIS OF VIRGINIA. I would hope so.

Dr. KESSLER. I have never yet been in a position where a company says, we want to put something on that label because we are concerned about safety, and the FDA says, No, hold it. We are not concerned as you are about safety.

So we want to create the incentive for companies to act expeditiously and responsibly.

Mr. DAVIS OF VIRGINIA. Can I just make one comment? I remember, though, with antidepressants, when they all of the sudden put the labels on, for a while there was a hiatus. People quit taking antidepressants. Teen suicides went up. It is a balance where you want FDA involved, as well.

Dr. KESSLER. You are exactly right. They are complex questions, and no one is saying that if the agency has considered the matter and has looked at the evidence and said the evidence doesn't support that association with that risk, of course that should be evidence.

Juries and judges, those cases, if the agency has acted definitively, that is important evidence that should give the manufacturers comfort.

Mr. DAVIS OF VIRGINIA. Thank you all. I appreciate the testimony. It is helpful. Thank you.

Chairman WAXMAN. Thank you, Mr. Davis.

Mr. Braley.

Mr. BRALEY. Mr. Quaid, I want to applaud you and your wife for your efforts to improve patient safety. This is an issue that has been known to the Federal Government for a number of years. In 2000 the Institutes of Medicine came out with a seminal comprehensive study called To Err is Human, which concluded that every year 44,000 to 98,000 people die in hospitals due to preventable medical errors. That is just the deaths, not the injuries like your children. And then 3 years later they came out with a comprehensive study on patient safety and things the Federal Government should be doing to improve patient safety. So thank you for using your tragedy to put a human face on this issue.

My question for the physicians on the panel, and in order to give us a better understanding of exactly what happened, is we are talking here about a mix-up with a drug called Heparin. Are you three familiar with complications known as Heparin-induced thrombocytopenia or white clot syndrome?

Dr. KESSELHEIM. Yes.

Mr. BRALEY. And can you describe for us what the devastating consequences of those complications are for a patient who has been administered Heparin therapy?

Dr. KESSELHEIM. They can clot in all different veins and arteries and receive end organ damage to their kidneys and brain and heart, and it can ultimately be fatal.

Mr. BRALEY. And also can lead to severe limb amputation, correct?

Dr. KESSELHEIM. Yes.

Mr. BRALEY. Dr. Maisel, I want to talk to you about the St. Jude's pacemaker that you discussed briefly in your opening statement. Do you remember that?

Dr. MAISEL. Of course.

Mr. BRALEY. One of the patients you discussed was a Mr. Gleeson whose pacemaker failed due to some device that was prone to short circuiting?

Dr. MAISEL. Yes.

Mr. BRALEY. Do you remember that? One of the things that we all know is that occasionally there are medical devices that just don't work. That doesn't necessarily mean they are defective, does it?

Dr. MAISEL. I think it does mean that they are defective, but it doesn't mean that the manufacturer is at fault.

Mr. BRALEY. That is exactly right.

Dr. MAISEL. So we should make a distinction between malfunctions that are inevitable for complex devices that a manufacturer may have done due diligence and done their best to try to get those devices to market and have them safe. The distinction here is that the manufacturer was aware of a problem. It was a problem that they fixed and they failed both to notify the public about that fix and they also failed to retrieve from inventory the devices that they knew were prone to malfunction, and there were a number of devices that were implanted into patients. Those implants could have been prevented. So a number of patients were unnecessarily exposed to a defective, potentially defective, device.

Mr. BRALEY. And one of the things that we hear a lot about and we have heard here today at this hearing is predatory trial lawyers and frivolous lawsuits, but in this case Mr. Gleeson never even filed a suit, did he?

Dr. MAISEL. In his letter to me he said that no law firm would take his case, and he actually said, "I should have died to have had a better case." He was somewhat frustrated. Obviously he had received a defective device and then had been re-implanted with a potentially defective device, but he did not seek legal redress.

Mr. BRALEY. Let's talk about that. Let's talk about who bears the ultimate burden of taking care of patients who are injured or killed. Well, if they are killed obviously they are no longer with us, but if they are severely injured due to a defective medical device and there is no source of recovery under State law because of Federal preemption, and that family does not have the means to provide for the medical care that is necessary, who ultimately pays the price for that defective product?

Dr. MAISEL. I think you and I pay that price, the taxpayers pay that price. Many of the medical expenses are paid by Medicare or other insurers. In Mr. Gleeson's case he received a letter that said that his maximum benefit from St. Jude, the maker of his device, would be $600, plus he would get a "free" pacemaker. The expenses associated with a surgical procedure to replace a pacemaker are typically over $10,000, so we all pay for that.

Mr. BRALEY. And going up every year, correct?

Dr. MAISEL. Yes.

Mr. BRALEY. So one of the things that we know is when we have a radical shift in a Federal application of a policy like preemption is that there is a cost shifting that goes along with that.

Dr. MAISEL. I think that is right. I think it is not like these things are not paid for.

Mr. BRALEY. And the cost shifting winds up in the laps of the taxpayers of this country?

Dr. MAISEL. I think that is right.

Mr. BRALEY. Now, one of the other issues you talked about was the Guidant defibrillator. Do you remember that?

Dr. MAISEL. Yes.

Mr. BRALEY. And you testified about the problems with that device, and according to your testimony the company had known about those problems years before it came to public light. Did it ever tell the FDA about the problems that it discovered?

Dr. MAISEL. Guidant first modified their device in April 2002 after they were aware of two or three malfunctions of the device. Guidant did submit adverse event reports through the medical device reporting system that the FDA has, but that is a needle in a haystack. There are over 200,000 adverse event reports that the FDA receives annually. For pacemakers and defibrillators, alone, there are tens of thousands of malfunctions over the last 15 or 16 years, so it is very difficult for the FDA, even if they receive an individual case report, to connect the dots. That responsibility falls on the manufacturer.

Ultimately, Guidant mitigated their device, meaning that they fixed it, they put a new device out onto the market, and it wasn't until a New York Times story was pending because the parents and physicians of Jeffrey Oukrop, who was harmed by the device, went to the New York Times, did the story actually become public.

It is interesting. Guidant had an independent panel that they put together to review the whole process related to this device, and it is a 133-page report that is very comprehensive, and I found this one sentence very sobering. They say in this case the criteria would not have triggered an FDA recall if not for the New York Times article. If those parents and those physicians had not gone to the New York Times, it is quite likely we wouldn't be here talking about this today.

Mr. BRALEY. Thank you.

Chairman WAXMAN. Thank you, Mr. Braley.

Mr. Souder.

Mr. SOUDER. Thank you, Mr. Chairman.

I want to start with a simple point here, and that is that once again we are faced with a hearing that presumes to talk about an issue that has eight Democrat-selected witnesses and two Republican. We appreciate the two Republican, but that is not a balanced hearing.

The first panel that gets the most attention at every hearing has no balance. How can I ask questions and hear debate? I have no one on the one side. Everybody is advocating the legislative position that the chairman supports. We can't have a debate.

I want to raise some questions, because apparently nobody is going to raise the other side in this first panel unless I do it.

Chairman WAXMAN. Will the gentleman yield to me?

Mr. SOUDER. Yes.

Chairman WAXMAN. I do want to indicate that we have taken all the recommendations of the Republican side of the aisle for witnesses. There are witnesses on subsequent panels. These witnesses are capable of answering your questions, and others that have been recommended by your side will be available, as well, to answer your questions.

Mr. SOUDER. Mr. Chairman, did the minority ask if there would be a witness on the first panel?

Chairman WAXMAN. The answer is no.

Mr. SOUDER. So your position is the minority doesn't care if they have a witness on the first panel, or did you——

Chairman WAXMAN. I didn't specify panel, but we have taken all the witnesses that were recommended. We have always taken recommendations of witnesses and accommodated the request.

Mr. SOUDER. Thank you, Mr. Chairman. I have been on both sides of this as a staffer and a Member, and, quite frankly, I know the chairman is open to taking minority witnesses, but when you bury them further in the hearing, as a former staff director who knows how to set up hearings, I can see what is done in front of me, and it is frustrating. Of course I can ask questions later. Of course I can do this type of thing. The question is on the first panel that we have had, one approach here——

Chairman WAXMAN. Mr. Souder, your time is going, and when you get the majority and become chairman you can design the hearings as you see fit. Regular order means Mr. Souder is recognized.

Mr. SOUDER. Will I get the time that you used on my time?

Chairman WAXMAN. Without objection, the gentleman will be given one additional minute.

Mr. SOUDER. When we were in the majority we did have more balanced hearings, and we gave one-third of the witnesses, and I always included in my hearings on the first panel a minority witness unless there was agreement otherwise, and we did do that when we were governed.

Here is the question. Here is my problem, that real concerns have been turned into simplistic, silly policy. I understand the concerns you are raising. It is not addressed, in my opinion, by proliferating lawsuits; that we have substantive questions here on labeling. It would be embarrassing. Mr. Quaid handled the question. It would be embarrassing for the others on the panel and it would be hypocritical self-interest if you didn't include doctors and nurses in the same charges that you do pharmaceutical companies and medical device companies. I didn't hear that.

We have never seen cost containment or innovation come from lawsuits. Yes, lawsuits can discourage risk, but it does not address the fundamental question of whether you get innovation and cost control.

In my District I met a man that was Lincoln Reinsurance because every doctor in every hospital knows this, as well as pharmaceutical companies, that the company only assumes part of it. They get insurance to cover this if there is not legal protection. And the insurance companies get protection through reinsurance. I met a man in a little office who is trying to figure out 40 years from now

what the legal risk is of genetic modification drugs that are trying to get breakthroughs. Now, he is trying to set a cost. The greater you set the risk and the lawsuit risk and the proliferation of lawsuits and the negotiated settlements and trying to make all this proof and jury trials followed by appeals, the greater that insurance company charges the greater the reinsurance and you escalate the cost of health care, which reduces innovation and reduces this.

We need fundamental questions of how to provide product safety, but it is silly to suggest that proliferating lawsuits and having 50 States address this in any kind of medicine, whether it is nurses, doctors, hospitals, or others, that yes, the ability to sue will, in fact, particularly if you think you can get to an executive, result in very over-reactive behavior, which helps some individuals, as I mentioned in Justice Breyer's point, will help some individuals, but it will also hurt thousands of individuals, because in the over-reaction and in the cost process of how things are made in America and how things are delivered in America in the real world of finances is an incredible risk.

I also am frustrated that if there is willful neglect, clearly willful neglect, that I heard possible, that there may be damage and companies didn't pull something on, but willful neglect is not immunized. If you have deliberately provided false information to the FDA, you are accountable now.

Let me ask, Mr. Kessler, isn't that true? Not debatable, but willful distortion by the companies of data can be prosecuted?

Dr. KESSLER. U.S. 1001, false statements are a crime.

Mr. SOUDER. The debate here is what about the areas of tolerable risk, and is it going to be decided by the courts or the process, and if we have companies that are willfully—everybody believes that. We are at the margins here.

Dr. KESSLER. Congressman, you ask a very good point, but rarely is this about willful, intentional, criminal behavior. I ran the agency for 7 years, and yes, we had an Office of Criminal Investigations, but I don't sit here and believe that the kind of cases that we are talking about are people—I mean, at these companies they want to do good. They don't sit there wanting to engage in criminal behavior. That is not what we are talking about.

The issue is, though, where are the incentives. It is not only lying, but there is the issue. You heard this, "If we don't know, we are OK."-+ So where do you create the incentives? I mean, is the ostrich defense: I am not going to undertake those studies, I am going to be willfully blind.

Mr. SOUDER. Isn't the FDA and consumer product safety and other types of advertising questions because you want to say that this should be solved at the lowest level courts appealing through four court processes in 50 States when these businesses are internationally doing it, taking capital risk, and you know full well it would be a disincentive, because when you were there we saw this in orphan drugs. We saw this in the medical license.

Chairman WAXMAN. The gentleman's time has expired, but please go ahead and answer the question.

Dr. KESSLER. I wish I could sit here, Congressman, and tell you that with all the agency resources you gave the agency, the agency

could ever be in a position as good as the company to deal with those risks.

But the agency is always racing after, especially when one is talking about once the drug is on the market, new information comes. It is somewhere. The company knows about it. So the question is do you want to incentivize that behavior of the company. So it is not just FDA doesn't control all the behavior after a drug is on the market. I mean, how the company acts in that interval until the agency gets the information, until the agency has been able to review all that information, those are the kind of cases that I think that you are seeing, so it is that gray zone, Congressman, that really is—I mean, those are the hard questions, and that is what we are talking about today. It is not about criminal behavior.

Chairman WAXMAN. Mr. Tierney.

Mr. TIERNEY. Thank you, Mr. Chairman.

Chairman WAXMAN. Mr. Quaid, did you want to say something?

Mr. QUAID. Yes, sir, I just wanted to address that because he brought up about the hospital, and that is I certainly don't believe in frivolous lawsuits, myself, sir, but I do believe that the tort system that exists in States is a good balance between the drug companies and the FDA and what we are talking about today.

The FDA, to my understanding, is, in part, funded by the drug companies who pay a fee sometimes to expedite the marketing of their product. That seems to me to be a conflict of interest, and the tort system has traditionally created a balance for this.

What we are talking about really is a balance between business expediency and public safety, and the tort system does exist to inform the public about—that is where a lot of the public learns about what are the dangers of some products out there.

Without the tort system, there is not going to be as much motivation and impetus, and certainly I don't believe the people at the drug companies are evil people, as well. Everybody is trying to do their job in the best way, but we are talking about business here.

For instance, Baxter would answer to why didn't they recall the Heparin when they knew there was a problem with it, with the labeling, would say that it was because it was a very important drug and they did not want to create a shortage that was out there. But at the same time recently we had the events that happened in China with the tainted Heparin that was out there that was also a Baxter product, and what happened was that Baxter's competitor wound up taking up the slack and there was absolutely no shortage of the product.

Chairman WAXMAN. Thank you.

Mr. Tierney.

Mr. TIERNEY. Thank you, Mr. Chairman.

I thank all the witnesses so far.

It is all very interesting what Mr. Souder was proposing over there, but I think the last two statements from witnesses hit it right on the head: this is really about who is going to bear the burden when a corporation isn't as careful as they should be or makes a bad decision. Is it going to be the family of the patient or is it going to be spread out on the party that had the most control over the information.

There is pretty much agreement, the Government Accountability Office, which is Congress' investigatory arm, the Institute of Medicine, they all agree there is a problem with the safety of products that the FDA regulates, but I think, Dr. Kessler, you said it right: no matter how many resources we give the FDA, or no matter how much authority we give them—we can never give them unlimited authority or resources—the company is always going to have more information than the FDA has. Where should the burden fall on that?

Let me just ask, please, Dr. Kesselheim, do you think preemption will help or harm drug and device safety?

Dr. KESSELHEIM. I think preemption will harm drug safety, and that is what my conversation earlier was focused on. When a manufacturer is allowed to discharge their duty of safety to patients merely by presenting something to the FDA, which we know is under-staffed and which we know may not be able to pick up on safety signals that are masked in the presentation of the data, and meanwhile the company continues to promote its product, it doesn't do that with presenting the risk and benefits to physicians and patients that they need to do to make fully informed prescribing decisions.

Mr. TIERNEY. Thank you.

Dr. KESSELHEIM. So that would harm the public health.

Mr. TIERNEY. Thank you.

Dr. Maisel, do you agree?

Dr. MAISEL. I do agree that preemption would harm drug and device safety. And I think it is interesting to point out, in the Guidant example, for instance, the FDA actually conducted inspections, seven inspections of the Guidant manufacturing plant during the time period that these malfunctions were occurring. They had received reports of the adverse events, and they still were incapable of detecting the problem and reporting it publicly.

So even with the best resources, the FDA is still not going to be able to pick up on all the important safety signals.

Mr. TIERNEY. Dr. Kessler, I gather from your testimony, as well, that you don't think the FDA's oversight is so reliable that manufacturers should be given a free pass on any of this?

Dr. KESSLER. No, I don't believe the companies should be given a free pass, and I think if you go back and you look at what we said when general counsel, back in 1996, my general counsel, if I could just put it in the record, Congressman, Margaret Jane Porter, in 1996, said, "FDA's view is that FDA product approval and State tort liability usually operate independently, each providing a significant yet distinct layer of consumer protection."

She was talking about devices, but I think it applies also to drugs. "FDA regulation of a device cannot anticipate and protect against all safety risks to individual consumers. Even the most thorough regulation of a product such as a critical medical device may fail to identify potential problems presented by the product. Preemption of all such claims would result in the loss of a significant layer of consumer protection, leaving consumers without a remedy caused by defective medical devices." That was what my general counsel said in 1996 to the Food Drug Law Institute. I still think that is the wisest policy, Congressman.

Mr. TIERNEY. Thank you.

Somebody mentioned the word frivolous several times. I think there is nothing more frivolous that I can think of than any assertion that anyone believes in frivolous lawsuits. I mean, obviously that is not the case in general, but, Mr. Quaid, I understand you have done a number of things as a result of what happened to your twins. You have spoken out publicly, obviously made statements on that. You have created a foundation and you filed a lawsuit on that.

Why are you suing Baxter, Mr. Quaid? Is it all about the money? Is it frivolous?

Mr. QUAID. Yes, sir. Also, to answer Mr. Souder as far as the makeup of the panel, I, myself, have considered myself to be a Republican most of my life, but I am on the other side of this issue.

Mr. TIERNEY. That may not be conservative enough for Mr. Souder. You may want to talk about that.

Mr. QUAID. But we are pursuing Baxter because Baxter, like I said before, this was a chain of events in human error, and part of that human error was in the design and labeling of the bottle and the label of this Heparin. Even after the Indianapolis incident where three infants were killed and three others were severely injured, Baxter did send out a warning. They eventually, although not in a timely manner, changed the label of the bottle of Heparin, but 13 months after the fact. But they failed to recall the existing bottles that were already out there and that had already been proven to be dangerous and possibly lethal and almost were to my 12-day-old newborn twins.

So we are going to the source, starting at the source, and that is why we are suing Baxter, sir.

Mr. TIERNEY. Again, I thank all the witnesses for their testimony; Mr. Quaid, you for bringing your family's situation to a good cause. We are trying to get a resolution on that.

I yield back, Mr. Chairman.

Chairman WAXMAN. Thank you, Mr. Tierney.

Mr. McHenry.

Mr. MCHENRY. Thank you, Mr. Chairman.

Mr. Quaid, I appreciate your being here. I know it is taking time out of your personal schedule, but it shows your commitment to the issue at hand. I certainly appreciate that.

I think, regardless of where we stand on State preemption, your story is a very moving one, and I appreciate your taking your awareness. The American people know you. We all feel like we know you and your family to some degree, and so I appreciate your actually taking that for a proactive approach to something you feel very sincerely about, so thank you.

Mr. QUAID. Thank you, sir. When the twins were in the hospital and they finally made it to the 41-hour period where their blood was basically turned to the consistency of water, and severely bruised and bleeding out of every place they had been poked or prodded, and they had made it, it made me feel that they had survived for a reason. First off, I really thank God that they had pulled through, but they had survived for a reason, that they were maybe going to change the world in a little way that might wind up saving more lives.

We were lucky. Our twins survived. Those people in Indianapolis were not so lucky. I believe if preemption is allowed to prevail, it will basically make all of us, the public, uninformed and uncompensated lab rats.

Mr. MCHENRY. Is a part of what you are advocating an awareness about medical errors, too, because in hearing your story certainly there is a component on legal action?

Mr. QUAID. Yes, sir. It is not the issue that is before us today, but really we want to concentrate on one thing at a time in our foundation, and part of that is bringing some sort of recordkeeping and checks and balances and backups into the 21st century in medical care, and part of that would include bar coding in bedside and in pharmacies and in recordkeeping in hospitals by someone who is hospitals, sir, where by someone who is administering medicine to a patient when they are in the room, they could basically scan the bracelet of the patient, scan the medicine, itself, scan in their own i.d. tag, and there would be a record and there would be a warning if the wrong medication was being administered.

There is resistance to this because a lot of people say it is way too expensive, especially people in the hospitals and medical industry, but yet my question is: there is a bar code reader in every checkout stand in every supermarket in America; why can't there be one in hospitals?

Mr. MCHENRY. And so part of that is technology and making sure medical records are digitized and really in keeping with our society?

Mr. QUAID. Yes, sir. There was a study done not too long ago where it was shown that, because a lot of times the doctors scribble down prescriptions that are sent to the pharmacy, and by using the bar code system and computerized technology they lowered the mistakes of pharmaceutical mistakes by more than 98 percent.

Mr. MCHENRY. Because I think beyond this issue I think medical errors and making sure hospitals and the medical industry updates in terms of technology, I think a lot of us can work together.

Mr. QUAID. This is doable.

Mr. MCHENRY. Yes.

Mr. QUAID. This is something that would actually wind up saving the American public money. This is something that eventually I think the insurance companies, themselves, would welcome because it would lower their liability, because fewer mistakes would be made.

I relate it to the airline industry, one of our safest. Why is it so safe? It is because every time there is a crash the NTSB goes out and they find out the exact cause of that crash, and usually always whether it is design or pilot or whether—it comes down to human error somewhere along the way, and they minimize the impact of human error in aviation to where it is the safest form of travel today.

But if you relate it to what is going on with how many patients die needlessly every year because of medical mistakes, it is 100,000 patients. That is the equivalent of one major airline crash a day every single day of every year. Because it happens over such a broad, disconnected area, the public isn't really aware of it, but it

is something that if people were really aware of we would not tolerate.

Mr. MCHENRY. Thank you, sir.

Mr. QUAID. Thank you.

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

Mr. Burton.

Mr. BURTON. Thank you, Mr. Chairman.

In Indianapolis six children were injured at Methodist Hospital after receiving an adult dose of the blood thinner Heparin on September 15, 2006. That is correct, isn't it, September 15, 2006?

[No audible response.]

Mr. BURTON. Well, I have already checked. It is.

The new Baxter Pharmaceutical label was introduced in October 2007, which was 13 months later, and in November 2007 your twins received the wrong dose at Cedars-Sinai Hospital?

Mr. QUAID. Yes, sir.

Mr. BURTON. My question is I can't understand if anybody reads the newspapers, because the tragedy that took place in Indianapolis was all over the country in the newspapers and it seems to me that the FDA and Baxter Pharmaceuticals would have known immediately that this problem existed and they wouldn't have waited around from September 15, 2006 to October 2007 to start taking any action, and the action that was taken in October 2007 really wasn't known about when your twins were hurt in November.

So this idea that people weren't informed and that is why this tragedy occurred with your twins just doesn't make any sense to me because it was publicized all over the country.

If I were talking to the FDA right now I would like to ask them, don't you have some kind of a part of your agency that reviews these kinds of cases that are publicized in the newspapers, and if it does take place don't you act immediately?

And I would also like to say if the pharmaceutical company has a product where someone is injured, I am sure they know about it right away, and it seems to me logically that they would want to move as soon as possible to preempt any further problems like that occurring.

I can't understand why it was 14 months between the Indianapolis case and your case and nothing was done. I just don't understand it. That is not a question, it is just a statement.

Mr. QUAID. Well, myself as a part of the general public, I have a lot more knowledge now than I did before. I wasn't aware of the Indianapolis case, myself. I am sure Baxter Pharmaceutical was aware of it.

Mr. BURTON. Mr. Quaid, I am sure you weren't, but the FDA was or should have been, and the pharmaceutical company I am sure was, because it was their product. That is the point I am trying to make. Action should have been taken much quicker, which would have preempted the problem which you faced.

I would like to say this to Mr. Chairman. Mr. Chairman, we have been working for years to try to make the Vaccine Injury Compensation Fund more user friendly. We have about $3 billion in that fund. You were one of the authors of that, as I recall. I would like to work with you to make that more user friendly and maybe to expand it to take in cases that may occur similar to this one.

I know you have legislation you are going to be introducing that would make tort reform changes, but the Vaccine Injury Compensation Fund, if it was properly handled and we expanded it to deal with these kinds of problems, would protect the pharmaceutical industry and yet still give people like Mr. Quaid recourse. I think that is extremely important. We are not doing that right now and we could legislatively.

I am very sympathetic to your problem. It is incomprehensible to me that this kind of thing could occur in Indianapolis, in my area—I represent part of Indianapolis—and it was reported widely, and the FDA and the pharmaceutical company had to know about it, and no action was taken for 13 months, and 14 months later your children were injured.

I think that we need to hold them accountable for their inaction, but also, in order to protection the pharmaceutical industry so they aren't hit with thousands of lawsuits, we need to come up with an answer like the Vaccine Injury Compensation Fund which could take care of this kind of problem without going through the courts.

With that, thank you very much.

Mr. QUAID. Thank you, sir.

Chairman WAXMAN. Some of our Members have responded to a vote that is pending on the House floor. We will take a short recess, probably around 10 minutes or so, and then we will reconvene so other Members may have their chance to ask questions.

We stand in recess.

[Recess.]

Chairman WAXMAN. We would like to reconvene the committee hearing. We have the Members but we don't have all of the witnesses for the first panel, but I think they are going to be joining us now.

Mr. Sarbanes, I would like to recognize you now for questions.

Mr. SARBANES. Thank you, Mr. Chairman. I do have some questions.

Mr. SARBANES. Ms. Schmitz has taken particular interest in this hearing because her own mother passed away in February 2006 from an adverse reaction to a medical device. She was a healthy, active 74-year-old woman who went in for routine surgery, and tragically her surgeon used a medical device that the FDA's own data base revealed had been subject to several complaints. Unfortunately, that information never came to light. The manufacturer was never required to change its labeling of the device. If that had happened, Ms. Schmitz' mother would be alive today.

Now, with the FDA's preemption of lawsuits regarding medical devices, Ms. Schmitz has no legal remedy at her disposal.

This, Mr. Chairman, is another illustration of the need for Congress to act on this critical issue.

Dr. Kesselheim, I wanted to ask you a few questions that relate to the importance of litigation, which, after all, is simply an individual or family's recourse when they have suffered a tragedy in many instances, the importance of that in terms of bringing information forward, when often the focus is on the damage end of the equation, and that is where we have a lot of the rhetoric that goes around, but in the process of these lawsuits moving forward there is a lot of very valuable information that does come to light.

There have been some recent publications revealing safety problems with Vioxx for patients who suffer dementia. Your testimony I think indicated that the manufacturer delayed communication and known risks to the FDA and minimized those risks in its communication. How exactly did that happen? How did they sort of minimize that?

Dr. KESSELHEIM. So what the litigation does in a number of circumstances is it brings to light both information that the manufacturer had kept internally and also brings to light the manufacturer's practices and the way that they address safety concerns, so it brings information to light in a number of different ways that can help affect both knowledge about drugs and knowledge about the proper use of drugs.

In the specific case of Vioxx that I referred to earlier, the manufacturer had conducted a number of studies in using Vioxx in patients with cognitive impairment and had found in two different studies an increased rate of mortality in the Vioxx arm as compared to the placebo arm, and what they did was they chose a statistical method regarding the interpretation of the safety data that purposefully or, in the best case scenario, just improperly helped mask the risk that those studies resulted in when they presented that data initially to the FDA.

FDA regulators in one case did pick up on the possibility that there might have been an increased mortality risk and directly queried the manufacturer about whether or not they should continue one of the studies on ethical grounds, and the manufacturer dismissed the FDA's concerns as simple chance fluctuations, when, as we found out later in the litigation, the manufacturer was internally very concerned about these safety risks and had done its own calculations indicating that they were legitimate.

Mr. SARBANES. So basically the manufacturer was able to present the data or manipulate the presentation of the data in a way that made it difficult to discern what some of the risks were. I gather FDA tried to piece some of that together. But it sounds like without the litigation that was involved we wouldn't have gotten a full picture of what the risk was.

Dr. KESSELHEIM. I think that is correct, and I would just add that it isn't necessarily that the manufacturer's actions in this case rise to the level of fraud. These are just decisions that the manufacturer made in how to interpret and how to present risk. That may not rise to the level of fraud, and therefore would be preempted.

Mr. SARBANES. It is interesting because Mr. Quaid talked about bringing checks and balances into the hospital, but if you think about it, litigation is really a check and balance, itself, in its ability to bring to the surface information, two kinds of information, Mr. Chairman, and then I will stop because I know my time is out.

There are two kinds of information that the litigation can help to surface. One is information that maybe folks know about but they are hiding, and that is an important result. But the other, frankly, is information that maybe nobody has yet realized is important, because in a particular case the facts of a particular case might be such that you would only see it in that instance, and so

it is critical to bring that forward in the litigation context in order to promote safety going forward.

Thank you, Mr. Chairman.

Chairman WAXMAN. Thank you, Mr. Sarbanes.

Mr. Issa.

Mr. ISSA. Thank you, Mr. Chairman.

Mr. Chairman, I would ask unanimous consent to have a number of items, we have already given them to your staff and they have read them, included in the record, particularly one from the Manhattan Institute on Policy Research, and another one, a letter to Mr. Conyers from Leader Boehner.

Chairman WAXMAN. Without objection, those will be made part of the record.

[The information referred to follows:]

ABOUT THE LEADER

NEWS

ISSUES

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FLOOR ACTION

2008 Legislative Calendar

MONDAY, MAY 5, 2008
The House will convene at 12:30 pm

TUESDAY, MAY 6, 2008
The House will convene at 10:30 am

WEDNESDAY, MAY 7, 2008
The House will convene at 10 am

THURSDAY, MAY 8, 2008
The House will convene at 10 am

FRIDAY, MAY 9, 2008
The House is not in session.

Press Release

Boehner & Smith Call for Congressional Hearings on Milberg Weiss Trial Lawyer Scandal

Warning of Economic Threat, GOP Leaders Call on Democrats to Set Hearing by May 19, When William Lerach Reports to Federal Prison

Washington, May 2 - Saying Congress has ignored "a steadily unfolding scandal that points to a cancerous growth within our nation's economy," House Republican leaders John Boehner (R-OH) and Lamar Smith (R-TX) today called on House Judiciary Committee Chairman John Conyers (D-MI) to schedule a hearing on the trial lawyer scandal that has engulfed the once-powerful class action law firm formerly known as Milberg Weiss.

Boehner, the House Republican Leader, and Smith, the ranking Republican on the House Judiciary Committee, said a hearing should be scheduled by May 19, 2008 – the date when former Milberg Weiss leader William Lerach is expected to report to federal prison after pleading guilty to charges of criminal conspiracy in conjunction with a class action scheme. Lerach told the *Wall Street Journal* earlier this year that his crimes were an "industry practice."

"If in fact Mr. Lerach's crimes are an 'industry practice,' then the Milberg Weiss scandal has revealed a clear and present threat to our nation's prosperity," Boehner and Smith said in a letter to Conyers, a copy of which was sent to House Speaker Nancy Pelosi (D-CA). "Congress is sitting idle while criminal behavior in the trial lawyer industry threatens American jobs and feeds like a parasite on the prosperity of working families."

A recent report by *Congressional Quarterly* noted that reform advocates have called for a congressional investigation of unethical conduct in the trial lawyer industry – but also observed that "[t]he majority Democrats in Congress, so many of whom are beholden to the financial largesse of trial lawyers, are unlikely to undertake that investigation." (Jost, Kenneth; "Courts & the Law: Stones Left Unturned," *CQ Weekly*, April 21, 2008)

The full text of the Boehner-Smith letter follows:

Congress of the United States
House of Representatives

May 2, 2008

The Honorable John Conyers, Jr.
Committee on the Judiciary
2138 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Conyers:

On May 19, 2008, trial attorney William Lerach is expected to report to federal prison to begin serving the prison term he received after pleading guilty to charges of criminal conspiracy in conjunction with a class action scheme involving his former law firm, formerly known as Milberg Weiss. This development will be the latest milestone in a steadily unfolding scandal that points to a cancerous growth within our nation's economy – an economic threat the United States Congress has a responsibility to address at a time when middle class families and small businesses are struggling.

According to federal investigators, Milberg Weiss officials masterminded a $250 million illegal kickback scheme involving their clients, and then lied in court about their actions. "The scope and the breadth of this conspiracy was breathtaking," said U.S. District Judge John Walter, who sentenced Mr. Lerach, adding that the crimes involved go "to the core of our judicial system."

More disturbingly, Mr. Lerach himself told the *Wall Street Journal* his illegal conduct and that of his law partners was an "industry practice." At his sentencing, one of his supporting letters quoted Mr. Lerach as saying, "Everybody was paying plaintiffs so they could bring their cases."

The Milberg Weiss trial lawyer scandal has implications for every American, particularly at a time when our economy is struggling and the triple threat of excessive regulation, taxation, and litigation is pushing jobs overseas. The costs of the crimes involved in the Milberg Weiss scandal are ultimately borne by innocent American taxpayers, workers, and employers -- the very Americans being tossed about in the current economic storm. If in fact Mr. Lerach's crimes are an "industry practice," then the Milberg Weiss scandal has revealed a clear and present threat to our nation's prosperity. The United States Congress has an obligation to take action -- by holding hearings to determine the extent of the trial lawyer scandal and the threat to our economy, identifying appropriate legislative remedies, and sending them to the President without delay.

It has already been documented that securities class action lawsuits such as those that bankrolled Milberg Weiss are cheating American taxpayers by disproportionately clogging the court system and consuming a wasteful share of judicial resources. Federal securities class actions are brought more than four times as often as any other single type of federal class action, and account for almost half of all such class actions in the United States (*Comm. on Capital Markets Regulation, Interim Report 74, Nov. 2006*).

Securities class action lawsuits are also on the rise, with the number of filings in 2007 increasing 58 percent over the previous year's number *(Stephanie Plancich et al., NERA Econ. Consulting, Recent Trends in Shareholder Class Actions: Filings Return to 2005 Levels as Subprime Cases Take Off; Average Settlements Hit New High 2; Dec. 2007).*

Evidence also exists that the threat of such litigation has been preventing the creation of new American jobs and pushing them instead to other nations. International employers with the potential to invest and create high-paying jobs in the United States have been turning elsewhere, driven away from America's shores by the fear of becoming ensnared in the sort of bogus, predatory litigation perfected by Milberg Weiss during its rise to power. A recently-released study by the London-based firm Lovells found that international employers believe the threat of becoming embroiled in frivolous, job-killing litigation is greater in the United States than in any other major nation *(Lindeman, Ralph; "In-House Counsel for EU Companies Cite Disputes in U.S. as Key Concern," Bureau of National Affairs' Daily Report for Executives; March 20, 2008).* The study, according to BNA, indicated international employers are troubled by "the complex relationship [in the United States] between state and federal courts, legal costs, the time involved, the extreme and demanding discovery process, the inability to recover costs even if one is successful and the potential for punitive damages." Respondents also cited the "multiplicity of courts, prosecutors and regulators at the state and federal levels as well as a tradition of targeting corporations as well as individuals in criminal cases -- effectively using criminal investigation and prosecution as a form of regulation," according to BNA.

Even the far-left publication "Mother Jones" has written that "[l]arge corporations have long argued that class action lawyers are nothing more than extortionists who shake down big companies every time their stocks fall, forcing them to settle or risk fiscal ruin from a big jury verdict. Given what's known now about how Lerach operated his law firm, it's hard to say that the perception is only spin." *(Mencimer, Stephanie; "The Fall of a Corporate Crime Fighter," Feb. 14, 2008)*

The Republican-led Congress responded aggressively to the Enron and WorldCom scandals earlier this decade. Now the Democrat-led Congress needs to do its job and examine the scandal at Milberg Weiss, which potentially has deeper and more far-reaching implications. Nearly three months have passed since Mr. Lerach was sentenced, but this Congress has yet to conduct even a single hearing to determine the extent to which crimes such as his are occurring in the rest of the industry.

If in fact the crimes committed by Mr. Lerach and his colleagues are an "industry practice," as Mr. Lerach himself confessed, then the United States Congress is sitting idle while criminal behavior in the trial lawyer industry threatens American jobs and feeds like a parasite on the prosperity of working families. The American people deserve answers.

- How many of these cases are brought as a result of illegal payments to plaintiffs?
- What other types of conflicts exist between trial lawyers and the injured investors they purport to represent?
- What reforms should Congress enact to eradicate these abuses from our judicial system?

We respectfully request that the House Committee on the Judiciary schedule a hearing by May 19 to begin the process of answering these questions in a complete and bipartisan way. Thank you for your attention to this important matter.

Sincerely,

/s/

Rep. John Boehner
Republican Leader

/s/

Rep. Lamar Smith
Ranking Republican
Committee on the Judiciary

cc: The Honorable Nancy Pelosi (D-CA)
Speaker of the House

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Global Liability Issues
Vol. 2 February 2002

How should the Law of Products Liability be Harmonized? What Americans Can Learn from Europeans

Stephen B. Presser,[1]

EXECUTIVE SUMMARY

As the twenty-first century unfolds and commerce becomes more and more globalized, there is a need to harmonize the law of products liability across nations. So far, unfortunately, efforts at harmonization have too often been in the direction of reproducing the costly features of United States tort doctrines—doctrines that have imposed spiraling costs on American manufacturers.

Even though the European Community recently altered its tort doctrines from a pure fault-based system to strict products liability, there are features of the European legal system that lessen the effects of even strict liability. Consequently, European courts are much less likely to hand out unpredictable and disproportionate damage judgments—unlike American courts, where ruinous verdicts are a potential in too many lawsuits.

Europe has escaped an American style litigation explosion by erecting barriers to excessive litigation. Such barriers include:

- Absence of contingent fees
- Loser pays winner's attorney fees
- Discouragement of massive discovery filings
- Lower damage judgments
- Absence of punitive damages
- Non-use of juries in civil cases
- Lower expectations of damages

Unless similar barriers to excessive litigation are created in the U.S., American companies face an ongoing competitive disadvantage relative to European manufacturers who operate in a more predictable, less costly, and less litigious legal environment. In one case, probably typical, Dow Chemical Corporation estimates that it spends *100 times* as much on litigation costs in the U.S. as opposed to Europe.

America prides itself on being the world's pre-eminent economic superpower, but if American economic preeminence is to survive in a highly competitive global marketplace, there must be changes in the American legal system. We should seek to reproduce here some of the features of the European system of litigation. It is time, in short, to give American firms the same legal protections that European firms enjoy, rather than waiting for Europeans to harmonize

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SUMMARY:
Professor Presser argues that if America is to remain an economic superpower, we must curb America's penchant for expensive litigation. In the U.S., Dow Chemical Corporation estimates that it spends $1 on litigation costs for every $71 in sales, while in Europe their litigation costs dwindle to $1 for every $7,000 in sales. Europe has escaped an American style litigation explosion by erecting barriers to frivolous litigation. Unless similar barriers are created in the U.S., American companies face a competitive disadvantage in global markets relative to European manufacturers, who operate in a less litigious legal environment.

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their legal systems with their aberrant American cousins.

In the course of our efforts to reshape the way Americans think about product liability law it will be necessary to examine, question, and eventually correct the way in which American courts have—over the last thirty years—usurped the law-making function of American legislatures. Achieving these changes will not be easy. However, critical reflection on the legal culture of the United States should begin with a global perspective on products liability law. Much work remains to be done in this vein: in particular there is a great need for empirical research and outreach education to American consumers, investors, and workers about the actual nature of the American Civil Justice System and its deficiencies compared to those found in other parts of the globe, particularly in Europe.

Harmonization of the American Civil Justice system with the European model must be achieved, however, if American manufacturers are going to be able to compete effectively in the global marketplace and if American consumers are going to continue to enjoy the benefits of technological innovation.

INTRODUCTION: HARMONIZATION, STRICT PRODUCTS LIABILITY, AND THE LITIGATION TAX

As the twenty-first century unfolds, there should be further progress toward a global marketplace for American manufactured goods, and, accordingly, American policy makers in and out of government will need strategically to plan for commercial success in a global economy. One trend that seems already to be underway is the effort to harmonize the laws governing commerce both within geographical areas (such as the North American Free Trade Agreement and the European Community), and even across the entire community of nations. A particular problem which has preoccupied legal scholars, judges, and lawyers since the second half of the twentieth century has been the proper treatment for liability of manufacturers to consumers injured by their products. This law of "products liability" underwent drastic change since the nineteen-sixties, in America, from a rule that held that manufacturers were not liable unless they had been negligent in the manufacture of their products to a (mostly judge-imposed) rule that manufacturers were liable (even if there had been no negligence) if products left the factory in an "unreasonably dangerous" condition.2 No one knows beforehand what an "unreasonably dangerous" condition is, and manufacturers' liability, in the twentieth century, became one of the most litigated areas of contemporary jurisprudence.

The new, judicially imposed and judicially expanded products liability rules,3 which generally go by the name "strict liability," eventually resulted in million and billion dollar jury verdicts on a previously unimaginable scale. Coping with these jury verdicts, and the threat of future ones, has considerably added to the costs of manufacture of products for American businesses. These costs are generally passed on to the American consumer, and have been often described as a "litigation tax." This "tax" increases the price of American consumer goods to Americans and to all other customers of goods produced by American corporations.4

The American law of products liability might also be described as a "high jackpot lottery" where some plaintiffs (and their lawyers)

There has been considerable dispute about the precise amount of the "litigation tax." Still, when one considers the litigation and regulation that has imposed hundreds of billions of dollars in costs through damage judgements, settlements, and regulatory compromises, it is impossible to conclude that these costs have been anything but considerable.5 Because of the uncertain standards in the American judge-made strict liability rules, both in

have reaped huge rewards, but where the costs of complying with an uncertain, and, in some cases, biased law, have unfairly impacted most Americans.

the content of the rules and the manner in which they have been applied in jury trials, American businesspersons have often been forced to settle products liability litigation at considerable cost. The result has been an American law of products liability that imposes unprecedented expense on businesses and consumers. The American law of products liability might also be described as a "high jackpot lottery" where some plaintiffs (and their lawyers) have reaped huge rewards, but where the costs of complying with an uncertain, and, in some cases, biased law, have unfairly impacted most Americans.6

Curiously, in recent years, as efforts internationally to harmonize laws have proceeded, the trend in substantive law, at least with regard to the European Community, seems to have been toward the imposition of a rule of strict liability (along the American model), and toward creating the kind of climate for litigation that has imposed considerable costs on American manufacturers and consumers.7 Even so, because of some characteristics of the European legal systems, a regime of strict liability is not as costly in Europe as it has proven to be in America.8 Because of this favorable economic circumstance, it seems likely that American and foreign firms may determine that, all other things being equal, it makes more sense to sell manufactured goods in Europe (or other parts of the global marketplace) than it does to sell them in the increasingly-unfriendly litigation climate of the American market.9 Alternatively, because of peculiarities in the United States Court System, foreign manufacturers may be in a better position to market products in America than are American firms.10

In order to avoid circumstances in which American consumers would miss out on product development, circumstances in which American businesses would be inclined to shift operations out of the country, or circumstances in which foreign firms would be at a competitive advantage over American firms when selling products in America, it is now necessary to consider whether the factors that mitigate a law of strict products liability in Europe might be reproduced in America. Accordingly, though we might describe what has happened so far (in Europe at least) as a harmonization toward greater manufacturers' liability and greater costs imposed on consumers and manufacturers,11 it is time to consider the feasibility and desirability of harmonizing in a different direction. It is now crucial to consider harmonization of the law in America with that of the European Community,12 to reproduce, insofar as possible, the factors in Europe which have the potential for Americans to reduce the litigation tax and restrain the operation of our litigation lottery.

Thus, while so far virtually all the talk about "harmonization" seems to have resulted in moves to increase liability and costs in other countries, it is now time to consider a different kind of "harmonization," one that may reduce the uncertainty and unpredictability of the American law of products liability.13 Such a form of harmonization will not only bring our rules more into line with those in place in other parts of the globe, but result in a system that is fairer both to American businesses and to consumers. Such harmonization might also reduce the likelihood that because of treaty obligations such as those of NAFTA, the United States itself could end up liable to foreign corporations because of the eccentric manner in which our tort system operates.14

How, then, might such a fairer system of "harmonization," one that is more "business and consumer friendly," be achieved? In a key article arguing that strict liability rules, even if applied by European courts, are not likely to result in dramatically increased costs to American corporations doing business in Europe, Professors Sandra N. Hurd and Frances E. Zollars point to the most

significant factors in Europe which mitigate the effects of such rules. Their analysis of European practice serves as a framework for considering how American law might be "harmonized" with the European. While it might be difficult to accomplish "harmonization" with each and every one of these European practices, all are well worth considering. The salient features of what we might regard as the "mitigating aspects" of European products liability law, discussed by Hurd and Zollars, will now be considered in turn.

A POLITICAL AND SOCIAL CLIMATE WHICH DISCOURAGES LITIGATION

Hurd and Zollars first note that "The political and social climate in the European Community discourages litigation," because "[I]n many situations of product-related injury . . . there are no damages, or only minimal damages," and thus there is little incentive to sue to recover, because product-related injury is treated through "national health plans [which]provide free medical care, and [through governmentally-provided] employment compensation systems [which] protect against lost earnings."15

There seems to be considerable reluctance, on the part of many Americans, to adopt a nationalized system of health-care provision along the European model. When this was attempted in the early years of the Clinton administration, it seems to have been a "spectacular failure."16 It does appear, however, that efforts in this country are underway to provide relief for injury through private insurance systems in a manner that may eventually alleviate the need for lawsuits to recover damages.17

Perhaps those who wish to protect American consumers from the adverse effects of the American system of products liability law should enlist in the effort to provide health insurance coverage for a greater percentage of Americans, to help duplicate this advantage of the European system. But even if we can duplicate in America the situation where there is adequate health-care provision for all, we also need further reform, to eliminate our "collateral source rule" in Tort actions. That rule now permits "double-recovery," because it prevents evidence of health insurance benefits that have been paid to plaintiffs from being introduced to reduce amounts recovered against defendants.18 If the primary goal of our tort system is compensation for the injured, and if, as is generally argued here, American industry and American consumers can benefit if we can more closely harmonize our civil litigation system with that prevailing in Europe, the modest reform of eliminating the collateral source rule seems wise, but there is a risk that such reform efforts will be frustrated by American courts.19

By driving up the costs of products through the litigation tax . . . products liability rules probably redistributed wealth from most consumers to a few lucky plaintiffs and their lawyers, hardly a result in keeping with our democratic system.

The precise strategies for the more general provision of health insurance, and, indeed, the current national controversy over the provision of health-care services is too complex to receive complete treatment here, though, and it seems wise to move on to other concerns.

Most telling, in the analysis of Hurd and Zollars, is their sensible observation that European countries "rely on legislation, not litigation, to bring about broad social change. Because there is relatively little expectation [in Europe] that reforms in consumer protection will be accomplished through policy making by the courts, there is no tradition of using them for that purpose."20 The implication is that harmonization of the operation of the product liability rules between Europe and America would require changing the very "litigation culture" of this country.21

It is notorious that we have more lawyers as a percentage of population than any other nation,22 and, in the last half of the twentieth century, at least, it does seem clear that litigation, especially in matters of constitutional law, was a means of bringing about broad social change. The results of that litigation, insofar as it moved America toward greater equality in the provision of education, in the exercise of the franchise, and in the equality of opportunity for Americans of different races and genders, were certainly salutary. Still, there are those who question whether courts are the best means of achieving social change,23 and America's reliance on the courts in the late twentieth century may have had the unintended and harmful consequence of cheating Americans of the benefits of thoughtful social policy formulated by legislatures.24

In any event, it is much less certain that the social policy that has been made through American courts reformulating the rules of private law, such as the law of products liability, has been as salutary as the social policy courts have imposed in the area of constitutional law. There are very good grounds for believing that the law of products liability, insofar as it has imposed increased costs on American businesses and consumers has harmed many of the people it was designed by judges to protect.25 By driving up the costs of products through the litigation tax (or the "tort tax," as it has also been called),26 a regressive tax measure at best, products liability rules probably redistributed wealth from most consumers to a few lucky plaintiffs and their lawyers,27 hardly a result in keeping with our democratic system.

Worse, because of the widespread ownership of stock in manufacturing corporations on the part of most Americans (through participation in pension plans, through investment in mutual funds, or through attendance at endowed universities) the reduction in profits as a result of the costs imposed by American liability rules have been felt by the majority of Americans who are investors.28 As this is written the country seems to be experiencing marked stagnation if not decline in the stock market, and most Americans have seen their retirement funds and other stock portfolios dramatically decline in value.29 Much of this decline is due to overly optimistic assessments of firms during the dot-com boom of the 1990's,30 but it still seems reasonable to attribute part of it to a litigation climate in which billion-dollar verdicts and settlements have become almost common. Accordingly, it is appropriate to consider whether there might be some means of shifting America away from a "litigation culture" inclined to solve social problems through the courts, towards one closer to the European model. In order to do this it is necessary to consider the specific "legal rules and procedures" which Hurd and Zollars note "create barriers to litigation" in Europe.31

THE ERECTION OF "BARRIERS" TO LITIGATION

Contingent Fees. The first of these "barriers" is that "Contingent fees are virtually unknown in Europe; indeed, they are prohibited in most [European Community] countries [footnote omitted]." "Contingent Fees" are arrangements whereby lawyers can be retained by allegedly injured plaintiffs, but no fees are due to counsel unless counsel produces a monetary settlement or judgement for the plaintiff. Counsel's fees are then taken from the settlement or judgement, and will generally be a substantial portion of the recovery, as much as 30-40%, or more.32 Since any recovery is supposed to be based on damage to the plaintiff, it should be obvious that paying a substantial percentage of recovery to lawyers short-changes plaintiffs, unless damage figures are inflated. There is evidence that plaintiffs who retain lawyers on a contingency fee basis receive less than 50% of any recoveries,33 and the reality in America is also that high lawyers' contingency fees are driving up the amounts of damage recoveries. This is true because inflated amounts are being inserted for non-economic

There is evidence

that plaintiffs who retain lawyers on a contingency fee basis receive less than 50% of any recoveries, and the reality in America is also that high lawyers' contingency fees are driving up the amounts of damage recoveries.

damages such as pain and suffering,34 and perhaps also because plaintiffs lawyers' will inevitably lose some cases, and must recover substantial sums in those they win to cover their costs.35

Hurd and Zollars state that in Europe, "The unavailability of contingent fee arrangements means that many fewer cases are litigated. There is no incentive to litigate a case in which the amount of the plaintiff's recovery would not be enough to cover the costs of prosecuting the case."36 The availability of contingent fees in this country, of course, means that a plaintiff often incurs no costs in bringing an action.37 Explaining why contingent fees are prohibited in Europe and encouraged in America is not particularly easy, and the prospects for eliminating them are daunting.

Contingent fees were not permitted in the early years of the United States, just as they are not now permitted in most countries, because they were regarded as unduly encouraging litigation. 38 Nevertheless, the argument for contingent fees—that people who would otherwise not be able to have the benefit of legal assistance in bringing lawsuits had real claims that needed redressing and would otherwise not have their day in court39 —proved compelling in all American jurisdictions.

Perhaps it is true that contingency fees help the otherwise helpless, but it seems at least equally plausible that those who benefit the most from contingent fees are the lawyers who comprise the Plaintiffs' Bar in this country.40 Since their influence over state and federal legislatures, or at least state courts, is now quite powerful,41 there may not be much of a chance of eliminating contingent fees in most American jurisdictions. Still, it does not now seem to be generally understood by the American public that a products liability system in which contingent fees play a prominent role (1) encourages the bringing of suits that may be without merit, (2) encourages the settling of suits as a relatively inexpensive means for defendants of dealing with claims that may even be frivolous (settling them for their "nuisance value," as it is often called),42 and (3) finally results in a situation where the aggregate costs of such "nuisance settlements," in adding to the "litigation tax," are considerable. If these facts ever were to become generally known, perhaps American public sentiment might turn against contingency fees, and some legislation might discourage them.43

It seems likely that the existence of contingency fees, by raising the costs to the public of manufactured goods, damages the public. But even so, since it is the poor (who cannot afford to pay lawyers on a non-contingency basis) who allegedly benefit from the availability of contingency fees, to argue against contingency fees risks being characterized as "anti-democratic," or at least insensitive to the needs of the economically challenged. Neither of these are risks that many in the American academy or in American politics are willing to take. It is probably for this reason that contingency fees have rarely been subjected to sustained criticism in the American press, or in legislative chambers. Again, however, if the existence of contingency fees could be demonstrated convincingly to have an adverse economic impact for most Americans, this might change, and politicians and scholars might dare more easily to criticize them.

There is clearly a need for empirical data on the effects of contingency fees, or for the promulgation of what data exists.44 Nevertheless, because of what we might call the prevailing "democratic" justification in America for contingency fees—that they permit poor people to take on large and powerful

In effect, then, by lowering the potential costs of unsuccessful lawsuits, the American legal system encourages the bringing of lawsuits of dubious merit.

corporations—eliminating or reducing the availability of contingent fees for legal services might be the most difficult aspect of achieving harmonization with European norms. It is something of a paradox, if the democratic justification for contingency fees is strong in this country, why there seems no pressure to adopt it in Europe, where democratic arguments are, of course, now the *sine qua non* of politics.45 One wonders whether Europeans have figured out that the costs imposed by contingency fees have anti-democratic implications, or whether Europeans are simply more hostile to lawyers and lawsuits than we are. Certainly the Europeans have grave reservations about the costs of lawsuits, especially on prevailing parties, as is indicated by another clear trend in European law.

Loser Pays Winner's Attorney's Fees. Another "barrier" to the bringing of expensive products liability suits in Europe is that there "the losing party is, in most cases, responsible for paying the [prevailing party's] litigation costs," and "attorney's fees typically are awarded to the prevailing party."46 Hurd and Zollars remark that

> A plaintiff [in Europe] who is faced with the possibility of having to pay not only his or her own costs and attorney's fees but those of the other party as well if the lawsuit is unsuccessful will be effectively discouraged from initiating a lawsuit unless the likelihood of prevailing is very high. This is particularly true when a consumer is suing a corporate defendant who has the ability and resources to make litigation extremely expensive.47

For reasons that are obscure, the custom of imposing all costs, including attorneys fees of the winning party, on the losing one, never really took hold in this country. There were some exceptions to the "American Rule" where the successful party cannot recover his or her fees (as distinguished from the "English Rule" where such recovery takes place), but, generally, in the United States, the American rule has prevailed to this day.48

In effect, then, by lowering the potential costs of unsuccessful lawsuits, the American legal system encourages the bringing of lawsuits of dubious merit. Again, because of the thinness of the empirical literature on the topic, one is driven to speculation,49 but it appears that the same motives that may have led to the availability of contingency fees—the sympathy for wronged plaintiffs —may have argued for the American practice of not imposing all the costs of litigation on the losing party.

If an American plaintiff knows that he will not have to bear the costs of any attorney's fees, neither his own nor the other party's, there is more of an incentive to participate in a lawsuit, more of an opportunity to vindicate his purported legal rights, and, indeed, more of an opportunity to gain the help of a lawyer. Conversely, if American plaintiffs had to run the risks of the payment of attorneys fees for the other side if they lost, even contingent arrangements with lawyers for their own fees might not be enough to induce them to bring lawsuits in doubtful cases. This would be particularly true, if defendants had the resources to pay their own (probably fairly expensive) counsel.

The only way such suits might still be brought is if plaintiff's lawyers were able to indemnify potential plaintiffs from the possible liability for defendant's legal costs. But if this were to happen it would be even more clear than it already is that the American Plaintiffs' Bar has a vested interest in litigation (especially in its settlement value), and the Plaintiffs Bar might find itself in a difficult social and political position.50

If one is inclined to try to reduce the "litigation tax," by discouraging the bringing of lawsuits, it is clear that there would be substantial merit in the adoption of the European solution of having the losing party pay the winner's legal costs. Indeed, there is already powerful statutory precedent for such a solution in the availability of legal fees from losing parties for prevailing parties in civil rights litigation, and some other forms of litigation which public policy seeks to promote. 51 This might be an area where the analogies to public law practice would work in favor of lowering the costs to American business, and these analogies ought to be pursued.52

Discovery Discouraged. Hurd and Zollars also believe that the different rules regarding discovery procedures provide another "barrier" to litigation in the European Community. In America discovery is now widely available, but in the European Community "Some countries do not permit discovery [footnote omitted] and some allow only very limited discovery closely supervised by the court."53 Hurd and Zollars conclude that "The inability to acquire information through the discovery process may make it more difficult for the plaintiff to prove his or her case or to ascertain additional causes of action."54 By reducing the availability of discovery, then, litigation is discouraged. The costs of discovery in this country, particularly for defendants, are very high indeed, and it seems likely that it is the avoidance of these costs, in large part, that raises the "nuisance value" as a result of which settlement often occurs. Perhaps it is the threat of substantial costs in the discovery phase of litigation which is the most profound inducement to settle early.55

It would appear, then, that if discovery were to be made more difficult in America, this would be advantageous to defendants in products liability lawsuits both in discouraging "nuisance value" settlement of frivolous litigation,56 and in discouraging the bringing of lawsuits (as in Europe) because of the lack of information on which they could be grounded. The increased availability of discovery seems to be a twentieth century phenomenon (as well as many of the other features of products liability litigation in America that we have examined), and, perhaps, is as driven by the interests of the Plaintiffs' Bar as are some of the other features of current American products' liability practice. 57 Again, because of the substantial political wherewithal of these lawyers, elimination of easy discovery seems unlikely, unless the costs to the public of the settlement of "nuisance suits" can be made more evident. Discovery works both ways, however, and it may have value in helping defendants to determine when plaintiffs' cases are without merit. The merits of discovery must be weighed against its costs before there is any wholesale campaign to cut back on it, a campaign with a dubious chance of success, at best.

Lower Damage Judgements. Still another "barrier" to excessive damage awards in the European Community, even if there is now a standard of "strict liability," is the fact that there is very little occurrence there of judgments that are of great monetary value. The kind of multi-million, or even multi-billion dollar damage awards that have recently become common in American courts simply do not seem to happen with great frequency in Europe. Hurd and Zollars explain this phenomenon, "in part" because "salary scales and health care costs are generally lower in the EC, making damages much lower in an absolute sense."58 More important, perhaps, as Hurd and Zollars indicate, "allowable damages [in Europe] often do not include the non-economic damages permissible under the law in the United States. [And, further, even when non-economic damages for items such as pain and suffering are allowed, they are significantly limited by law or tradition."59 There have been some attempts, in the state legislatures and in Congress, to enact civil justice reforms that would limit damage amounts for non-economic damages such as pain and suffering. These attempts have so far failed in the United States Congress, and have had, at best, uneven success in the states because of state court decisions that have questioned their permissibility under the state or federal

Constitution.60 It is only fairly recently that American courts have allowed substantial damage judgements for non-economic injury. Nevertheless, perhaps because of the powerful influence of the plaintiff's bar, changing our "law and tradition" to reject huge damage judgments (or, more properly, returning our "law and tradition" to the prior status of allowing only modest amounts for "non-economic" damages) is proving to be quite difficult.

Punitive Damages. There is one particular element of "non-economic" injury that may be the most important difference between what is done in the European community and what often occurs in America, and that is "punitive damages." Punitive damages are those which are not based on the economic injury to the plaintiff, or even on noneconomic injury, but rather on an amount sufficient to "punish" the defendant for allegedly wrongful conduct by deterring him and others from future wrongdoing.61 Hurd and Zollars state that of all the Member States of the European Community "only Ireland permits punitive damages in products cases." What are the chances of "harmonizing" American tort law in the direction of eliminating or reducing punitive damages?

There seems to be little doubt that the punitive damages element is the most unpredictable and most substantial factor in crippling damage assessments in American products liability cases.62 Indeed, the potentially arbitrary use of punitive damages has led the United States Supreme Court to conclude that under some circumstances punitive damage awards may violate the United States Constitution because they are not in accordance with due process.63 There have also been some legislative reform efforts that have sought to reduce punitive damage awards, but like other attempts at damage limitations by state and federal legislatures, they have only met with limited success.64 Even the Supreme Court's condemnation of punitive damages awards as potentially violative of due process holds little promise of elimination of the proliferation of punitive damage awards.

There seems to be little doubt that the punitive damages element is the most unpredictable and most substantial factor in crippling damage assessments in American products liability cases.

The greatest difficulty of eliminating punitive damages, in the end, flows from another crucial difference between the European and American civil justice systems—the heavy reliance, in America, on juries for the resolution of products liability claims. It is the juries, in recent years, that have been awarding massive products liability claims, and, in particular, punitive damages.65 If there is to be "harmonization" between European and American practice, there may have to be some serious rethinking, on the American side, about the role of juries generally, or at least the role of juries in products liability litigation.

Non-use of Juries. As Hurd and Zollars stress, "European courts do not use juries for tort suits at either civil or common law; damages are determined by the court."66 The difficulty with using juries for determining damages in products liability lawsuits, we are now beginning better to understand, is that juries may be subject to rhetoric which will sway them, especially against corporate defendants. Particularly where jurors are themselves persons of modest means—and this is common, as anyone who has participated in a jury understands—the temptation to engage in a bit of redistribution to a similarly situated plaintiff may be all but irresistible. 67 Anyone who has been involved in the defense of products liability litigation has observed this phenomenon of jury demographics and retributive human nature, and it is a difficulty that, in this country, may be one of the most intractable.

It is at least theoretically possible to suggest that members of juries could be made aware that when they render excessive verdicts against corporations they

are damaging the real human stakeholders in the corporations—the shareholders, the employees, the consumers of products, and the members of the communities in which the corporations are located.68 Still, it seems far easier for jurors, swayed by the rhetoric of clever plaintiff's counsel, to reify corporations and see them as inhuman, bloodless lucre-seeking monsters.69 Or, if there is a human aspect of corporations that can be discerned by members of a jury, at trial at least, it may be only the well-educated and elegantly coiffed and clothed appearance of corporate officers and directors, or their lawyers. In short, large jury verdicts in products-liability actions have become a kind of class-warfare, celebrated in fiction,70 and promoted by demagogic politicians for their particular partisan purposes.71 Sadly, even some law professors appear to have praised the use of judgements in tort cases as political tools in a struggle of weak individuals against evil corporations.72

In any event, if there is to be "harmonization" of American products liability law and practice in a manner that brings it closer to that of Europe, there is going to have to be a national discussion about the role of the American jury in products liability cases. That discussion ought to consider how the behavior of juries in products liability cases accords with not only current policy needs in this country, but also with the Constitutional design.

Consider the original conception of the jury's role that existed at the time of the Constitution. Defenders of the jury have a strong argument to make that jury discretion is a fundamental attribute of American Constitutional law, as indicated by the fact that the Seventh Amendment to the United States Constitution guarantees jury trial in suits at common law involving more than $20. Aside from the problem that $20 in 1789, when the Constitution was adopted, may have meant something quite different from $20.00 now, it does seem clear that this provision in the federal Constitution still permits some experimentation by the states in altering the performance of the traditional jury.73 Moreover, the insistence on the importance of the jury in the Bill of Rights may have reflected a very different conception of the job of the jury from that it now seems to be engaged in.

Both before and after the American Revolution, the jury was regarded as a safeguard from government oppression, as a protection against a government which sought to infringe on the rights of property or person of the American colonists, and, later, the citizens of the early American republic.74 There is some suggestion that jurors were originally used because of their particular knowledge of the facts of a given legal dispute, but by the end of the eighteenth century their role was to be that of impartial citizen arbitrators in a trial, charged with the objective determination of the facts of particular disputes.75 By the early Nineteenth century it had become clear that even in criminal cases, while the jury had the power to ignore the legal instructions of the judge, it had no right to do so, and the jury's job was neutrally to apply the law as given to them by the judge.

By the beginning of the Nineteenth century, we Americans had adopted a conception of popular sovereignty whereby the democratic underpinnings of our Constitution were to be secured by reposing law making power in only two categories of popular institutions. One of these, to be used for regular law making, was the state and federal legislatures, where the people or their representatives elected the members. The other repositories of popular law making power were the institutions used for making and Amending Constitutions. These were the bodies of representatives chosen expressly for the purpose of Constitutional conventions, or the state and federal legislatures which eventually approved such Amendments, or, occasionally, the people voting *en masse* to approve Constitutions or Amendments.

These were the means by which regular and fundamental law was to be made, and, most important, neither juries, nor courts, were supposed to have the

power to make law. This was especially true with regard to the taxing power, which power was at the core of our revolutionary war, as the slogan "no taxation without representation" suggests. It seems evident that our current law of products liability, especially insofar as it adopts "strict liability" as the rule, is pretty clearly judge-made. It follows, then, that allowing juries total discretion to apply virtually unlimited punitive damages with redistributive effects, in effect allowing juries to levy a "litigation tax," is completely—we might say doubly—counter to our tradition.

Not only does the current manner in which products liability juries operate interfere with the legislature's prerogative to make law, it imposes taxation without the traditional form of representation. Moreover, by the middle of the Nineteenth century, the American common law of torts had pretty clearly arrived at a firm rule that there ought to be no liability imposed without some form of fault, a fault such as negligence for example.76 If it is true, then, that at common law liability is based on fault, then resting jury discretion in products liability cases, where "strict liability" is now the rule, is not the way it was done at common law, and there is no basis for resting claims about jury prerogatives on the Seventh Amendment.77

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Lower Expectations. Hurd and Zollars conclude their treatment of the differences between the American and European approaches to damages in products liability cases by observing that even with strict liability, damage judgements in Europe are likely to be smaller because, since there is an absence of contingency fees, there is no need for plaintiffs lawyers' to seek larger damage judgements in order to offset those occasions when they lose, and thus collect no fees.78 Summing up, Hurd and Zollars make the obvious point that the countries in the European Community "in contrast to the United States, simply have lower expectations of what is a reasonable level of damages."79

Taking into account that Europeans have lower expectations of damages, unless there is some movement to "harmonize down" American damage judgements in products liability cases, at least where all other things are equal, simple cost-benefit analysis will lead American, European, and other manufacturers to market their goods in Europe rather than the United States. Manufacturers, owing a duty to shareholders to maximize profits, ought, quite properly, to sell goods where costs are lower. Should this happen, the result will be not only that fewer products will be available here, there is a risk that manufacturing itself may be moved closer to the markets where costs are lower, and, eventually this could lead to loss of jobs for Americans, and loss of revenue to American communities.

RECONSIDERING STRICT LIABILITY

There are reasons to wonder whether a strict liability regime makes any sense in a nation where technology is still being developed (or, indeed, in any other).80 The idea behind strict liability is to further the creation of a regime of "enterprise liability." In such an economic regime—theoretically at least—all the costs of production, including damages caused by defective products, are borne by the industry itself.81 Pursuant to this notion, goods are priced in manner that allows industry to pass the costs of the enterprise on to consumers. This has a surface appeal, but is not necessarily the best way to encourage the development of new technologies.

There are reasons to wonder whether

New technologies, it has been convincingly argued,

a strict liability regime makes any sense in a nation where technology is still being developed (or, indeed, in any other).

need a sort of capital subsidy during the take-off stages of their growth.82 One of the most prominent American legal historians has argued that such a subsidy was, in effect, provided to American industry, in the Nineteenth century, through the tort system. Harvard Law School Professor Morton Horwitz argued that the costs of development of national transportation systems, and the development of commerce and manufacturing was aided by the implementation of the "fault" or "negligence" principle (and the abandonment of earlier English and colonial strict liability standards).83 Similar subsidization, by lowering the costs of doing business in Nineteenth Century America, was supplied by the development of the doctrine of shareholder limited liability for corporations.84

If it was true that all Americans eventually benefited from the explosive economic growth of this country in the Nineteenth and Twentieth centuries, and if it is true that limiting liability generally made it possible for American commercial, manufacturing, and technological progress (which progress is now the envy of the world), perhaps we should be hesitant about adopting the "enterprise liability" notions as new technologies emerge. The very idea of strict products liability, then, ought to be questioned, and even more the American version, which raises the costs of damage judgements far beyond what is now occurring in other parts of the world.85

There are some encouraging signs that the doctrine of strict products liability is being critically reexamined. Some American courts, recognizing the deleterious consequences of our strict products liability doctrines, are refashioning the law of products liability back toward a fault-based system, or at least one in which the law is not stacked in favor of plaintiffs.86 Similar concerns appear to have led to changes in the ALI's Restatement of Torts (Third) adopted in 1997, which appears to ameliorate somewhat the application of strict liability for manufacturers.87 Nevertheless, there is still reason to worry that the depths of the problems facing American businesses and consumers have not been sufficiently appreciated by lawmakers and commentators. As a recent very perceptive student note observed, "In the wake of a new millennium where our world thrives on job opportunities, consumer products and services, and the revenue of large corporations, it would be in our nation's best interest to protect corporate defendants [against excessive damage awards, particularly from arbitrary punitive damages] yet this has not occurred."88

CONCLUSION: ACHIEVING HARMONIZATION AND RETHINKING THE JUDICIAL ROLE

Civil Justice Reformers in the United States who might seek constructively to harmonize American products liability law and legal institutions with European ones face a daunting task. After all, American courts have not only been responsible for the shift to strict liability in the late twentieth century, but lately they have also managed to throw up roadblocks to many civil justice reform efforts.89 Legislation can be altered when a majority can be elected which is sensitive to the need for legislative reform, but even where judges are elected, if a bench is bent on finding particular forms of civil justice reforms unconstitutional the task of replacing them is almost Herculean. Judicial elections are generally for longer terms than those of legislators, and public interest in judicial elections, as opposed to those for legislators, is minimal. Generally speaking, it is easier for the Plaintiffs' Bar, or other interested parties, to finance judicial election campaigns, and place judges on the bench sympathetic to their views, than it is for the proponents of Civil Justice

reform.90

In the late twentieth and early twenty-first centuries, moreover, there is widespread belief (especially in the academy) that judges ought to exercise wide discretion in Constitutional interpretation, in order to promulgate rules in keeping with American democratic ideals. This is what led to the imposition of strict liability, but, as already indicated, it is not at all clear that this is in accordance with the long-term needs of America. It is time for Americans to give more thought to whether American courts ought to continue to exercise what amounts to the discretion to make law. There are some champions of the bench's role in overturning civil justice reform who embrace this role for the bench as a way of preserving the current prerogatives of tort plaintiffs and their lawyers,91 but when courts make law it runs counter to the concept of popular sovereignty itself.

It is time to recognize . . . that the bench can also be captured by "special interests," and in some cases those special interests may be members of the plaintiffs' bar determined to preserve the status quo of large damage judgements.

There has been a tendency, even among conservative academics, virtually to deify American judges, to champion their discretionary role, and even to suggest that it is better to trust them to make law than the legislatures, since the latter are more subject to capture by "special interests."92 It is time to recognize, however, that, especially where there are elections for judges, that the bench can also be captured by "special interests," and in some cases those special interests may be members of the plaintiffs' bar determined to preserve the status quo of large damage judgements.93

In the last Presidential election, one of the most important issues was over the kind of people who ought to be placed on the federal bench. Then Governor Bush promised to appoint more judges who would be committed to "interpreting" rather than making the law, and he gave as his models Supreme Court Associate Justices Antonin Scalia and Clarence Thomas, the two Justices who had written most consistently in support of such a position. Vice-President Gore and his supporters, by contrast, railed against Scalia and Thomas, and made them campaign issues.94

In order to harmonize American products liability law with the European, it will be necessary not only to educate legislators, and secure the passage of civil justice reform legislation, but also to continue this political debate and to educate the American public about what needs to be done about State court judges who are frustrating such reform efforts. The issues of the rule of law and the importance of who sits on the bench are beginning to be more important concerns in national politics, and, because most American products liability law is likely to remain state law, these issues ought to receive more consideration in state political campaigns, particularly for judges.

It would be easier if the American law of products liability could be harmonized with the European simply on the basis of passage of federal legislation, and while there might still be some hope for such a solution,95 the Supreme Court's recent federalism jurisprudence makes it likely that any broad-based federal reform efforts could be found unduly to trench on the states' traditional domestic authority.96 The struggle properly to harmonize American products liability law with European approaches, then, will be a difficult one, to be fought on many fronts. It is a worthy struggle, however, and the outcome will be of profound significance for the future of the American economy and the well-being of the American consumer.

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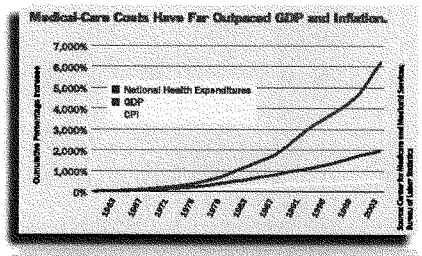
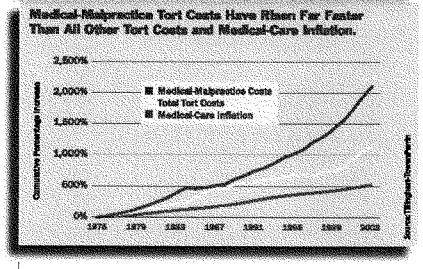
A Message from the Director

This report is the third entry in the Manhattan Institute Center for Legal Policy's Trial Lawyers, Inc. project. Our initial report, *Trial Lawyers, Inc.: A Report on the Lawsuit Industry in America, 2003*,[1] examined how the litigation industry operates in the U.S. Sensing a need to explore how the plaintiffs' bar operates on an individual state basis, we released *Trial Lawyers, Inc., California, 2005*,[2] which examined how the litigation industry operates in the nation's largest state.

Trial Lawyers, Inc.: Health Care represents a logical extension of this project. In our original report, we explained the business model of the plaintiffs' bar and described how Trial Lawyers, Inc.—like any other big business—had various "business lines" crucial to its current and future profitability. Since our closer look at a particular state's litigation industry proved so useful, we decided that an in-depth exploration of one of Trial Lawyers, Inc.'s many business lines might be equally revealing. For our first such effort, the health-care sector is a sensible starting place: health care represents over 15 percent of the U.S. economy, up from only 5 percent in 1961.[3]

While the excesses of the litigation industry alone cannot explain America's mounting medical costs, litigation is a large, and growing, contributor to our health-care bill. As the graph below shows, medical malpractice liability—the "tort tax" on doctors and hospitals, whose costs constitute the majority of health expenses—has grown much faster than health-care inflation.[4] Indeed, medical-malpractice liability alone constitutes over 10 percent of the entire U.S. tort tax, which by 2003 represented over $3,300 for a family of four.[5]





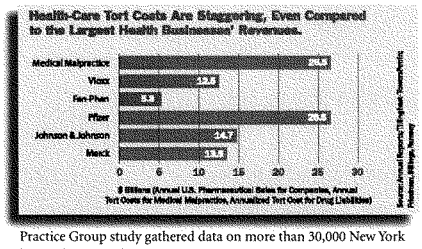
Although medical-malpractice liability provides Trial Lawyers, Inc. with its largest health-care sector revenue stream, litigation over pharmaceuticals and medical devices exacts a staggering cost on an increasingly important part of the U.S. economy. Wyeth's massive reserve for Fen-Phen litigation is $21 billion,[6] and Merck's exposure to Vioxx lawsuits may total as much as $50 billion.[7] Such figures are astronomical in comparison with these companies' individual budgets, representing nine to twelve times each company's annual research and development costs.[8] In fact, since each drug was only widely used for about four years, the approximate annualized liability cost of these two drugs comes to almost $18 billion—equivalent to 10 percent of the annual revenues *for the pharmaceutical industry as a whole*.[9]

As this report will detail, far from limiting its attacks to doctors and drug makers, the plaintiffs' bar is attacking all levels of the health-care distribution chain. Some of Trial Lawyers, Inc.'s favorite targets, nonprofit hospitals and nursing homes, are the health-care providers that minister to our nation's most vulnerable—the poor and the elderly. And as if its effects on health costs were not bad enough, the litigation industry has focused its crosshairs on managed-care providers, who, while politically unpopular, are crucial to dispersing risk and providing for health care at affordable cost.

It is also important to emphasize that the direct costs of health-care litigation only begin to scratch the surface of the toll that these predatory lawsuits exact on our economy—and on our health itself. Med-mal lawsuits tend to inflate health-care costs by encouraging "defensive medicine"—unnecessary procedures and referrals that doctors and hospitals prescribe in order to limit their exposure to future litigation. Studies suggest that defensive medicine costs are several times higher than the direct liability costs themselves.[10]

Nor are we made safer by product-liability litigation over drugs and medical devices. Such suits inevitably drive innovation from the marketplace that would lead to net health improvements not only for U.S. society but for the entire world. Since any drug manufacturer might be held accountable for unanticipated liability of the magnitude of Vioxx and Fen-Phen, every drug company will consider such numbers in its research and investment decisions, and many drugs that would otherwise save lives or improve the quality of lives will never reach the market.

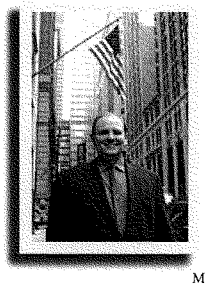
Trial Lawyers, Inc.'s defenders typically will assert that tort litigation has a deterrent effect on risky or negligent activity, which it undoubtedly does, but in our current civil justice system it also deters any activity that might lead to high-cost lawsuits, *which is not at all the same thing as actual risk*. For instance, a seminal Harvard Medical



Practice Group study gathered data on more than 30,000 New York hospital patients from a weighted sample of more than 2.5 million and found that the vast majority of medical-malpractice suits did not involve actual medical injury—and that most cases in which there was actual injury involved no doctor error[11]—which makes the claim that medical-malpractice litigation serves mainly to deter doctor misconduct a peculiar argument indeed. When our liability system punishes so indiscriminately, it does not efficiently deter bad conduct but rather reduces health-care access by reducing the supply of doctors; encourages expensive, unnecessary, and often dangerous procedures; and lowers the expected return from research into new medicines and medical devices that save lives.

Finally, it is worth noting that the litigation industry does a very poor job compensating the victims it professes to be protecting. Not only are most medical-malpractice claimants not harmed by avoidable doctor error, but most medical-malpractice victims never sue, and plaintiffs typically wait years to recover damages—then getting less than 50 cents on the dollar, with lawyers' and administrative fees soaking up the majority of settlements and verdicts.[12] When Trial Lawyers, Inc. pursues mass tort drug liability claims like Fen-Phen by gathering large numbers of highly questionable cases using attorney-sponsored screenings, and settles those along with legitimate claims, actual victims of drug side effects receive insufficient compensation.[13]

With *Trial Lawyers, Inc.: Health Care*, the Manhattan Institute hopes to shed light on the unwholesome effects of lawsuit abuse on our wallets and our well-being. In the concluding section, we'll offer prescriptions for restoring sanity to the system; while the current prognosis for U.S. health care is bleak, thoughtful reform can help protect medical innovation, reduce costs, improve efficiency, and ensure that the truly injured are compensated in a fair and timely fashion.



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Visit TrialLawyersInc.com for an online version of this report, the full 2003 report, and other resources.

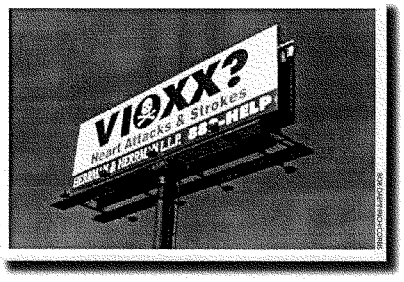
Introduction

HAZARDOUS TO OUR HEALTH

Trial Lawyers, Inc. hurts consumer health with its full-fledged assault on the U.S. medical system.

Last November, hundreds of trial lawyers converged on Las Vegas to plot a strategy for their assault on Merck Pharmaceuticals and its besieged painkiller Vioxx.[14] They divvied up key tasks and traded marketing and legal ploys in a confab worthy of a Fortune 500 company launching a major new product.[15]

Meet the health-care division of Trial Lawyers, Inc., which regularly delivers outsize profits for the plaintiffs' bar at the expense of doctors, hospitals, consumers, and the health-care system itself. Trial lawyers have honed their health-care playbook to a simple but devastating formula—gin up public outrage, recruit intimidating hordes of plaintiffs, and rewrite medical science to fit the claims of injury.



Drug Torts: A Massive Pain

Trial Lawyers, Inc.'s highly effective business model has undone corporations from Armstrong World Industries to W. R. Grace,[16] but arguably nowhere have the litigation industry's tactics been more aggressive and sophisticated than in the mass product-liability suits that have dogged pharmaceutical manufacturers for two decades. The plaintiffs' bar and its allies in consumer lobbies like Public Citizen have torpedoed dozens of drugs, driving many off the market.[17] Of 39 pending product-liability cases currently before the Judicial Panel on Multi-District Litigation, which determines jurisdictional issues for mass torts, 22 involve drugs or medical devices.[18] To be sure, some drugs have harmful side effects, but they are often exaggerated and avoidable. Others, such as Norplant, a long-term reversible contraceptive, have been hounded off the market despite evidence that its side effects are little more than a nuisance.[19]

Bolstered by its success, and spurred on by the pharmaceutical industry's prolific development of useful and profitable new drugs, Trial Lawyers, Inc. has been stepping up its assault. The litigation industry is using increasingly sophisticated plaintiff-recruiting techniques, which include not only traditional advertising—fully 46 percent of all trial-lawyer advertising on television is directed at culling plaintiffs for drug lawsuits (see graph)[20]—but also new tactics that vary from hitting daytime talk shows that attract the poor and unemployed to running Internet ads that can reach more sophisticated audiences.[21]

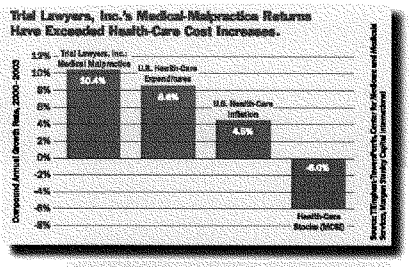
It's no surprise that the plaintiffs recruited by such techniques usually have feeble cases. Nor does it really matter. Trial Lawyers, Inc. needs only to get a couple of multimillion-dollar verdicts—usually in tort-friendly courts where judges are in the pocket of the plaintiffs' bar—and it can begin to make the real money from cowed defendants who settle the thousands of weaker claims—often for billions of dollars.

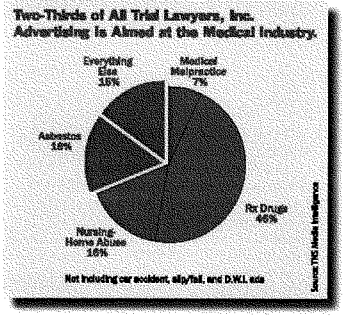
Consider the Fen-Phen mass tort, for example: a Mayo Clinic study found that the widely used diet drug appeared to cause heart-valve damage in 24 individuals, which prompted the Food and Drug Administration to pull the drug from the market;[22] soon after, Trial Lawyers, Inc. set up echocardiogram mills in hotels across the country that churned out thousands of class-action claimants.[23] An audit of a sample of plaintiffs' echocardiograms found 70 percent ineligible for compensation, many of them having been doctored to produce evidence of disease.[24] Nevertheless, once Fen-Phen's maker, Wyeth, lost two verdicts totaling more than $120 million, it began to settle.[25] So far, Wyeth has forked over $14 billion and estimates its total liability at $21 billion.[26]

Doctors Under Siege

Their deep pockets make drug companies sitting ducks for Trial Lawyers, Inc., but the litigation industry has also found less well-heeled defendants, such as doctors, to be easy targets. The cost of these legal attacks is increasingly unaffordable liability insurance for doctors: according to the Congressional Budget Office, medical internists saw their malpractice premiums climb 50 percent between 1993 and 2002, and 33

While the trial bar gets rich, the average consumer loses—through higher costs, reduced access, fewer products, and less innovation.





percent from 2000 to 2002 alone.[27] Vulnerable medical specialties like obstetrics and neurology have buckled under the ceaseless pressure from the trial bar. Skyrocketing malpractice-insurance premiums—and, in some cases, the inability even to buy insurance—have driven neurologists to refuse to staff emergency rooms and OB-GYNs to stop delivering babies.[28]

Obstetricians continue to fall prey to suits alleging that the doctor's failure to perform a Cesarean section caused oxygen deprivation during delivery, which in turn caused cerebral palsy in the newborn. These suits, long a staple of the malpractice bar, have grossed millions in fees for trial lawyers like former senator and vice presidential candidate John Edwards.[29] Notwithstanding the fact that research has shown that cerebral palsy is only rarely attributable to birth asphyxiation[30]—and that the dramatic increase in C-section rates has led to no decrease in the percentage of infants born with cerebral palsy[31]—plaintiffs' attorneys continue to flog this theory to gullible juries. Last year, one of the highest jury awards ever in a medical malpractice case—$112 million (later settled for $6 million based on a pre-verdict agreement)—went to a New York couple who claimed that doctors failed to act on signs of fetal distress during the mother's protracted labor.[32]

The cost of such litigation industry tactics is lower-quality health care. Trial Lawyers, Inc.'s cerebral palsy suits not only have helped spur an increase in unnecessary C-sections, at a cost to mothers' health,[33] but also have succeeded in shutting down maternity wards—Philadelphia has lost three in recent years[34]—thus forcing pregnant women in certain parts of the country to travel hours for treatment.

The Litigation Industry's New Health-Product Lines

Any well-run business must constantly explore new product lines, and the health-care division of Trial Lawyers, Inc. is no exception. In recent years, the plaintiffs' bar has been busily expanding its portfolio of health-care products. Having successfully persuaded some judges to accept novel theories of elder abuse, the trial bar has driven up the malpractice premiums of nursing homes.[35] Hospitals have long been accustomed to malpractice suits over surgical mishaps and birth defects, but now litigation-industry leaders like Dickie Scruggs, who led the states' suits against the tobacco companies, have made class-action defendants out of nonprofit hospitals that serve the nation's poorest citizens.[36]

Yet Scruggs's nonprofit hospital suits are small potatoes compared with his ventures alleging, on behalf of 145 million patients, that health maintenance organizations were guilty of fraud and racketeering.[37] Copying a page from the playbook he used against Big Tobacco, Scruggs cozied up to Wall Street analysts and investors, intimating what the fallout of an adverse verdict might be.[38] Although the biggest cases ultimately were dismissed, two insurers—after watching their stock prices tank—settled for half a billion dollars each.[39]

Ultimately, while Scruggs and his buddies in the plaintiffs' bar get rich, the average health-care consumer loses—through higher costs, reduced access, fewer products, and less innovation. Bloodletting was a core medical treatment from the time of Hippocrates to well into the last century, but if today's leeches in the litigation industry are not constrained, they may suck the lifeblood out of the American health-care system.

SAYING NO TO DRUGS

Breakthrough pharmaceuticals have driven medical progress for decades. Litigation may grind it to a halt.

Bolstered by war chests amassed in tobacco and asbestos suits and by an increased spirit of cooperation among law firms, Trial Lawyers, Inc. is going after drug companies and medical-device makers with new intensity. And it is busily trolling for customers: "You may be entitled to money," blares the website ClassActionConnect.com, targeting Merck & Co.'s popular painkiller Vioxx.[40] A similar site claims to "give you all the facts you need to stake your claim to the billions of dollars sitting in financial accounts right now."[41]

Vioxx, the first of a class of COX-2 inhibitor drugs, was created as a useful treatment for the many older individuals who suffer from debilitating rheumatoid arthritis and other painful chronic conditions but who are at risk for life-threatening reactions to medicine-chest standbys aspirin and ibuprofen, which themselves take thousands of lives a year.[42] Last year, Merck voluntarily withdrew Vioxx from the market after a study showed an increased risk of heart attack and stroke after using the drug in heavy doses for 18 months.[43]

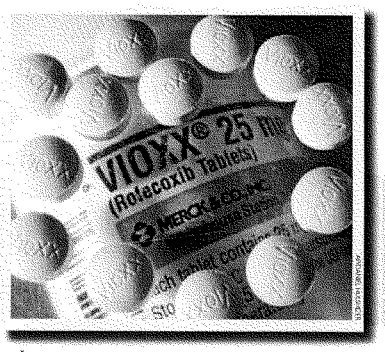
What has followed has been the biggest bonanza for the trial bar since 2001 (when Wyeth put aside $13 billion to settle lawsuits over the diet drug Fen-Phen—a number that subsequently climbed to $21 billion).[44] More than 20 million Americans have taken Vioxx since it was introduced in 1999.[45] By this fall, Merck was facing almost 5,000 federal and state lawsuits stemming from the drug's use, not to mention a slew of shareholder suits.[46] While financial estimates last year suggested that the Vioxx litigation could wind up costing Merck $18 billion,[47] the overall take for the litigation industry could be much higher if the first Vioxx jury verdict (see box, p. 7) is any indication, and some analysts are now projecting that Merck could lose up to $50 billion.[48]

Junk Science in the Courts

While at least some Vioxx suits seek compensation for actual injury[49]—Merck's scientific tests did show an increased incidence of heart attack for some individuals who took a certain dosage over time—medical-products liability cases often seek compensation for "phantom risks" that are nonexistent, or at least unproven.[50] Trial Lawyers, Inc. has cashed in for billions of dollars with such claims of injury, lacking any real scientific evidence, by relying on what Manhattan Institute legal scholar Peter Huber calls "junk science"—assertions presented as scientific fact but in reality more like astrology than astronomy, more like alchemy than chemistry, and more like numerology than mathematics.[51] By exploiting loose evidentiary requirements, clever lawyers have been able to use junk-science testimony to dupe unsophisticated juries into believing their far-fetched claims.[52]

For example, in 1995, 400,000 women registered for a $4.25 billion fund established to compensate them for injuries allegedly caused by silicone breast implants—notably, an increased risk of breast cancer and connective tissue diseases—despite any scientific evidence that such implants were harmful.[53] The settlement followed two 1992 studies "showing that breast implants were associated with a *reduced* rate of breast cancer"[54] and just preceded a major 1994 epidemiological study published in the *New England Journal of Medicine* that found "no association between implants and the connective tissue diseases and other disorders that were studied."[55] Why would Dow Corning enter into bankruptcy

By exploiting loose evidentiary requirements, clever lawyers use "junk science" to dupe juries into believing far-fetched claims.



and a multibillion-dollar settlement, given such evidence and the total absence of studies establishing the litigation industry's allegations? After losing a $7.5 million lawsuit to a woman claiming illness caused by breast implants,[56] Dow was flooded with suits—from some 20,000 women from 1992 to 1994—and lost, in trial and on appeal, tens of millions of dollars in jury verdicts to Trial Lawyers, Inc.[57]

Though breast-implant litigation may strike some as trivial, since the device's typical purpose is cosmetic, drugs and devices with genuine lifesaving and life-enhancing effects have also been driven off the market by the litigation industry's junk-science lawsuits. Take, for instance, the morning-sickness drug Bendectin, which greatly improved the daily lives of pregnant women and by 1980 was used by as many as 25 percent of all expectant mothers.[58] Trial lawyers generated such a national panic over the claim that the drug was associated with birth defects—despite any evidence—that many women who had been taking the drug aborted their unborn fetuses.[59] By 1983, the manufacturer of Bendectin pulled the drug in the face of $18 million in annual legal bills—against only $20 million in total sales.[60] Though Bendectin is on the market elsewhere around the world, it remains unavailable to pregnant American women,[61] despite more than 30 published studies—examining more than 130,000 patients—that have failed to find a link between the drug and birth defects.[62] Since Bendectin was pulled from the market, the percentage of pregnant women hospitalized each year for morning sickness has doubled; the incidence of birth defects has not changed.[63]

Compensating the Unsick

Even when there is scientific evidence that a drug can cause injury, our courts do a very poor job of distinguishing between creditable and meritless cases, as demonstrated most recently in *Ernst v. Merck* (see box). So unscrupulous operators within the litigation industry can (and do) flood courts with mass tort claims that group together many claimants—most of whom have no recognizable medical injury—and settle claims that compensate the unsick, undercompensate the sick, and produce astronomical fees for themselves.

This tactic was pioneered by Trial Lawyers, Inc. in its long-established product line of asbestos litigation,[64] and today it drives product-liability claims over drugs and medical devices. A case in point is the litigation industry's attack on Fen-Phen, the diet drug that has already cost Wyeth $14 billion in litigation expenses and damages (and is expected to cost $7 billion more).[65] Doctors at the Mayo Clinic discovered a link between Fen-Phen and a heart-valve disorder.[66] According to Wyeth's initial models, the association was strongest for aortic valve damage, a rare condition.[67] Most of the plaintiffs, however, claimed that Fen-Phen had caused mitral valve damage, "a much more common condition among overweight people generally."[68]

You might ask how this could happen. So did Judge Harvey Bartle III, of the Eastern District of Pennsylvania.[69] In one case, he held a six-day

THE IMPORTANCE OF BEING ERNST

Carol Ernst, the widow of a 59-year-old who had taken the pain-relieving drug Vioxx and died shortly after, was handed a $253 million verdict from a Texas jury this August.[85] Texas attorney **Mark Lanier**, who moonlights as an evangelical minister when he's not leading Trial Lawyers, Inc.'s pharmaceuticals division, scored the big win.[86] Although the verdict will likely be reduced under Texas's punitive-damages cap,[87] the cap will not affect the jury's award of damages for the mental anguish suffered by the deceased's wife (of one year), which the jury determined to be $24 million.[88]

ARTHUR SULLIVAN

Ernst had taken Vioxx for only eight months, less than the 18 indicated as potentially unsafe in Merck's study; he had 70 percent blockage in his arteries; and the original diagnosis for his cause of death was heart arrhythmia, which has not been linked to Vioxx.[89] The Texas jury was apparently not persuaded by these facts.

The verdict in the *Ernst* case highlights the significant problems that American lay juries have in assessing complex medical claims of causation. One juror in the case told the *Wall Street Journal*, "Whenever Merck was up there, it was like wah, wah, wah. . . . We didn't know what the heck they were talking about."[90] Without the ability to assess competing scientific claims with any precision, jurors can be persuaded by charismatic plaintiffs' attorneys like Mark Lanier to accept legal claims that a more sensible legal system would deny.

inquiry focusing on 78 claimants who had been screened by one of only two doctors.[70] The first of these doctors "was working on contingency for the Hariton firm; he received an extra $1,500 whenever a claimant he'd evaluated submitted a green form to the trust."[71] As for the second doctor, the judge stated that her "mass production operation would have been the envy of Henry Ford" and that her lead sonographer had been trained by an employee of the plaintiffs' firm.[72]

Drug Lawsuits Cost More than Money

By exploiting the legal system to sue manufacturers of drugs and medical devices that do not actually cause plaintiffs' injuries, Trial Lawyers, Inc. deters companies from researching and manufacturing legitimate lifesaving and life-improving products.[73] Manufacturers try to maximize profit—they're not charities—so they will only research and produce goods whose expected sales exceed expected costs.

Of course, were our legal system functioning efficiently, lawsuits would force pharmaceutical companies to internalize the costs of side effects caused by the drugs that they produce—which would encourage the manufacturers to withhold more dangerous products and which in turn would lower the net social cost of accidents.[74] But the legal system doesn't function efficiently, and the evidence strongly suggests that tort lawsuits have done little to lower accident rates. Rather, seminal research from Yale's George Priest showed two decades ago that accident rates fell significantly throughout the twentieth century—and indeed, fell even *faster* before tort law was expanded in the 1960s and 1970s than they did thereafter.[75] A more recent study, forthcoming from the Manhattan Institute, examines accident rates and tort reforms from 1980 through 2000 and shows that reforms designed to limit the scope of tort law—including noneconomic- and punitive-damage caps, higher evidentiary standards, and product-liability reform—are actually associated with *lower* accident rates.[76]

In the drug context, these results should hardly be surprising, given that the system as we know it has punished safe products from breast implants to Bendectin and overpunished other drugs such as Fen-Phen and Vioxx. Pharmaceuticals and other products that improve health and save lives have been indiscriminately driven from the marketplace. As Peter Huber has explained, "When all is said and done, the modern [tort] rules do not deter risk: they deter behavior that gets people sued, which is not at all the same thing."[77]

The harmful side effects of overactive litigation go far beyond the actual products that are taken off the market. Countless other potentially useful drugs sit in petri dishes because companies hesitate to spend hundreds of millions of dollars on products that could land them in court, costing hundreds of millions more.

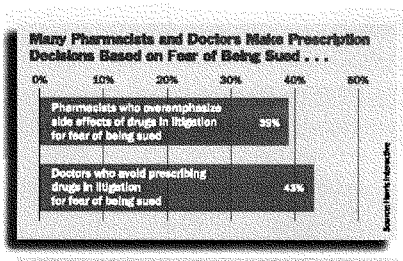
For example, lawsuits have prompted a virtual cessation in contraceptive research.[78] Following on the heels of successful lawsuits against the manufacturers of IUDs, Trial Lawyers, Inc. managed to kill off other contraceptives such as Norplant, a long-term reversible contraceptive that was used by a million women in the United States and that is still used by millions more in other countries.[79] Sued for alleged complications caused by Norplant's silicone applicator, its maker, Wyeth, withdrew the product from the U.S. market in 2002 after five years of litigation and over $50 million in legal costs—despite the fact that plaintiffs produced no evidence of harm.[80] Indeed, when lawyers couldn't prove Norplant a health threat, they took to attacking Wyeth for failing to warn patients of its side effects.[81] The upshot: U.S. companies have made no new contraceptive drugs since, and spend 20 times more money on cosmetics research than on developing new contraceptives.[82]

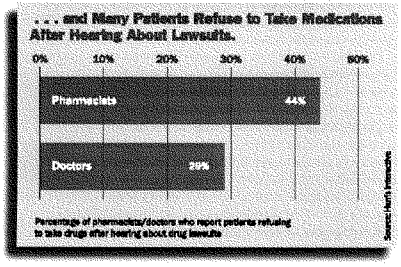
The Vioxx case itself is a good example of how litigation exposure

THE NEW DRUG LORD

The new CEO of the drug division of Trial Lawyers, Inc.'s health-care practice might well be **Christopher A. Seeger**. Seeger recently wrung a $700 million settlement out of Eli Lilly in a national suit over its antipsychotic drug Zyprexa, which his suit alleged caused diabetes[87]—a side effect deemed worth the risk by the Food and Drug Administration for a medication that effectively treats schizophrenia and manic depression:[88] when untreated, sufferers from these conditions face far more serious threats to their quality of life than regular insulin injections. Seeger now serves as a lead counsel or member of the plaintiffs' steering committee in many of the most prominent drug mass torts in the country—including suits against anti-diabetes drug Rezulin, anti-heartburn drug Propulsid, and weight-loss drug Dexatrim—and in April, plaintiffs' lawyers unanimously elected him to serve as co-lead counsel for the multidistrict litigation over Vioxx.[89] Shortly after the decision in *Ernst v. Merck*, Seeger began his opening arguments in the second Vioxx case alleging that the drug caused a heart attack, a New Jersey lawsuit still pending as this publication went to press.[90]

ARTHUR FINEBERG





Do we really want schizophrenics to stop taking Zyprexa because they saw the trial bar's TV ads recruiting plaintiffs who had taken the drug?

can stifle potentially lifesaving research, since Vioxx had been shown experimentally to prevent the growth of precancerous lesions in people at risk of developing colon cancer.[83] Given the threat posed by such cancers, many patients would accept a moderately increased risk of heart attack to have an effective cancer treatment. But if trial lawyers have their way, people with real health needs won't have such choices, and Vioxx's potential efficacy as a cancer preventative may die along with its use as a painkiller.[84]

In addition to removing lifesaving drugs from the market and stifling research, the specter of drug litigation can adversely affect health by changing patient and doctor behavior. More than 40 percent of doctors say they don't prescribe drugs that are under threat of litigation for fear that they will be drawn into the suit (see graph, above left).[85] Even more frightening, 40 percent of pharmacists report that patients have refused to take prescribed medications that they knew were the subject of litigation (see graph, below left).[86] Given the millions of dollars spent on drug-lawsuit advertising across the country (see graph, p. 5), such risks are very real, and when patients stop taking medications without legitimate medical reasons, they endanger their own health and, in some cases, the public at large: do we really want individuals with schizophrenia and bipolar disorder to stop taking their Zyprexa because they saw one of Trial Lawyers, Inc.'s thousands of television advertisements recruiting plaintiffs who had taken the drug?

An Attack on Democracy

Finally, Trial Lawyers, Inc.'s assault on the drug industry has undermined the democratic authority of Congress itself, which vests the Food and Drug Administration with responsibility for pharmaceutical regulation. [87] The FDA has been scrambling to reassert itself as the arbiter of drug safety as lawyers and juries usurp its role and increasingly make cost/benefit decisions that are rightly left to patients and their doctors. Necessarily, lawsuits such as those against Fen-Phen and Vioxx undermine the FDA's regulatory mandate from Congress to oversee drugs and patient health, as the agency itself has recently argued.[88] Though the FDA is far from perfect and needs reform, its onerous approval processes are specifically designed to test drugs' safety and efficacy with an eye toward the big picture: they determine whether the costs of allowing a drug into the marketplace are higher or lower than the benefits that the drug is expected to bring.

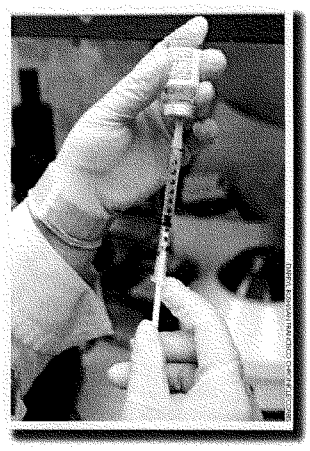
In contrast, juries that decide lawsuits over drug side effects can consider only the case at hand, not the broader cost/benefit analysis. Such juries can impose punitive damage awards to "send a message" to drug companies, notwithstanding other juries' decisions to send the same message—or indeed, other juries' decisions that the message need not be sent. And Trial Lawyers, Inc. can exploit lax venue and jurisdiction rules to shop cases to the most lenient state courts, which not only have much looser evidentiary rules but also see lawsuits against out-of-state manufacturers as a cottage industry.[89] These venues are what plaintiffs' attorney Dickie Scruggs, a longtime Trial Lawyers, Inc. executive, calls "magic jurisdictions"—where "judges are elected with verdict money" and "it's almost impossible to get a fair trial if you're a defendant."[90]

Effectively, the litigation industry is imposing its own national health-care policy, case by case—a policy not primarily concerned with the public's health but with the trial bar's power and wealth. The legal assault on the makers of our medicines and medical devices threatens our health and that of our children and grandchildren. We all need to just say no to Trial Lawyers, Inc.'s war on drugs.

Special Focus: Vaccines

VACCINATION LITIGATION

After almost killing the childhood vaccine market, Trial Lawyers, Inc. takes another stab at these vital medications.



Vaccines are among the greatest accomplishments of modern medicine, eliminating the widespread scourge of killer diseases like diphtheria, polio, and smallpox. Each year, millions of American children are vaccinated against many such infectious diseases, an essential precaution for the broader public health.[101] Unfortunately, a very small percentage of vaccinated children can develop side effects, or even die.[102] Thus it was that, beginning in the 1960s and accelerating in the early 1980s, the market for vaccines faced a new plague that threatened its very existence—one that continues to infect vaccine manufacturing today and that has proven itself resistant to statutory remedy. The plague, of course, is the virulent lawsuit abuse sponsored by Trial Lawyers, Inc.

The 1980s Vaccine Litigation Explosion

The sordid story of lawsuits targeting vaccine side effects is one of the most compelling examples of what ails our liability system. As late as 1965, the Second Restatement of Torts opined that drug and vaccine manufacturers could not be held strictly liable for selling unavoidably dangerous products, since such products are "apparently useful and desirable . . . with a known but apparently reasonable risk."[103]

In the 1960s and 1970s, however, courts loosened these requirements in permitting liability for the Sabin live-virus polio vaccine under a "failure to warn" theory.[104] Moreover, the federal government assumed liability for side effects caused by the swine-flu vaccine in the 1970s and soon faced more than 4,000 claims, upon which it paid out over $72 million.[105] As the courts continued to apply novel liability theories, vaccine manufacturers were flooded with lawsuits, which, in the case of the diphtheria, pertussis, and tetanus ("DPT") vaccine, escalated from one suit in 1979 to 255 in 1986.[106]

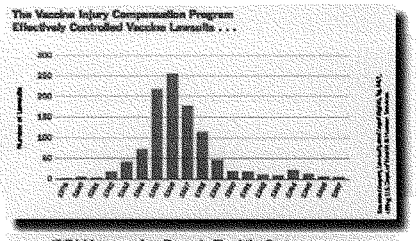
A watershed was breached in 1984, when juries slapped vaccine makers with huge verdicts over two individual claims: the first—against a manufacturer of the DPT vaccine—was for over $1 million;[107] and the second—against a manufacturer of the Sabin polio vaccine—was for $10 million, including $8 million in punitive damages.[108] Each case was predicated on the theory that alternative vaccines were available or could have been developed[109]—an interesting irony. Although the latter verdict was subsequently overturned, the damage had been done. Claims multiplied: vaccine maker Lederle estimated that total sales of its 1983 polio vaccine were only one-twelfth the value of claims filed against it;[110] its 1983 DPT vaccine sales were dwarfed by claims 200 to 1.[111]

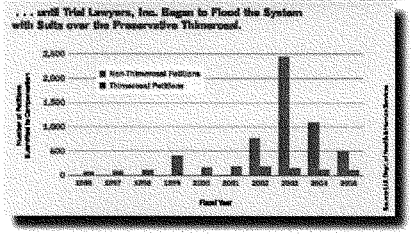
Vaccine manufacturers responded predictably to this avalanche of lawsuits. First, they exited the market: of the 26 vaccine manufacturers in business in 1967, 15 were still extant in the early 1980s, but the number plummeted to three by the middle of the decade.[112] Second, they raised prices: DPT vaccine cost 10,000 percent more in 1986 than it did in 1980.[113] The few remaining suppliers reported that they were having trouble finding liability insurance at all, and the Centers for Disease Control, fearing a shortage, asked doctors to delay giving children DPT booster shots.[114]

Congress Steps In

Responding to the crisis, Congress passed legislation in 1986 establishing the Vaccine Injury Compensation Program ("VICP"), which bars all tort claims until parents of children allegedly injured by a vaccine have exhausted a no-fault remedy.[115] In essence, the system makes the federal government the insurer for vaccine-related injuries, with payouts coming from a fund supported by a small vaccine surtax.[116] Claimants appear before a special master and have the burden of establishing injury, according to a "vaccine injury table," and if successful, the Justice Department has the option of contesting the finding if it can show that the injury was not caused by the vaccine.[117]

There are now only two flu-vaccine makers worldwide—down from five in 1994—and supply shortages are an annual rite of winter.





The VICP largely stemmed the tide of vaccine lawsuits. Having ɜached a high of 255 suits in 1986, the number of DPT suits fell to only 9 by 1990 (see graph).[118] In general, the program effectively compen-ıted those legitimately injured and rejected bad claims.[119] The average ward under the system has been high—$824,463—for the minority of laims that have been compensated,[120] but with much lower adminis-ative costs than traditional tort litigation—only 9 percent under the 'ICP, compared with 54 percent for the average tort claim.[121]

With the liability climate more stable and predictable, research into ew vaccines began to proliferate: safer "whole cell" DPT vaccines re-laced older versions, and several new vaccines were widely adopted.[122] laving only recently been a dead-end field for R&D, the vaccine indus-y was now attracting new entrants, including biotechnology firms.[123]

rial Lawyers, Inc. Fights Back

While the VICP has been successful in protecting those vaccines designed for childhood diseases, Trial Lawyers, Inc. has continued to attack ıe supply of vaccines that fall outside the law's ambit. In 1999, less than a year after GlaxoSmithKline introduced LYMErix, an adult vaccine for yme disease (the multi-symptom inflammatory and neurological ailment that has affected more than 150,000 people since 1982), Trial Lawyers, ıc. brought a class-action suit claiming that the vaccine causes chronic arthritis.[124] By 2002, LYMErix was off the market—and reported cases f Lyme disease, stable since the vaccine's introduction, jumped 40 percent.[125]

Trial Lawyers, Inc. has also sued flu-vaccine manufacturers, despite the fact that influenza kills 36,000 people annually and costs the U.S. :onomy over $12 billion each year in lost work time.[126] Unsurprisingly, there are now only two vaccine makers worldwide—down from five in 994—and supply shortages are now an annual rite of winter.[127]

Trial Lawyers, Inc.'s latest gambit is to claim injury caused not by vaccines themselves but by thimerosal, the mercury-based compound used › preserve them.[128] Unsurprisingly, the litigation industry's claims lack solid scientific foundations. The thimerosal furor erupted in 1999, when ıe Environmental Protection Agency hypothesized that, theoretically, a combination of infant vaccines could lead to blood mercury levels above PA guidelines.[129] That same year, the Clinton administration recommended removing thimerosal from vaccines, and drug manufacturers began oing so when possible.[130]

While high doses of mercury can indeed cause neurological damage, subsequent research has concluded that "mercury was cleared from the lood in infants exposed to thimerosal faster than would be predicted for methyl mercury," such that "[b]lood levels of mercury did not exceed EPA] safety guidelines for methyl mercury for all infants in these studies."[131] Moreover, last year the Institute of Medicine's Immunization Safety eview Committee issued a definitive report concluding that the "body of evidence favors rejection of a causal relationship between thimerosal-ontaining vaccines and autism,"[132] the ailment typically associated with the preservative in suits by Trial Lawyers, Inc.[133] Little wonder that the merican Academy of Pediatrics continues to advise giving thimerosal-preserved flu shots to children as young as six months old,[134] and that the Vorld Health Organization still recommends using thimerosal as a vaccine preservative.[135]

Regardless of the scientific evidence—and despite the fact that a vaccine's preservative plausibly fits within the statutory protection that ongress erected against vaccine litigation—the lawsuits came. In 2001, four Oregon families filed a class-action suit against 12 drug companies, leging that 6 million children in the United States received potentially toxic doses of mercury from thimerosal-laced vaccines.[136] In another ıit, plaintiffs are seeking $30 billion in damages—from an industry with total annual sales of barely $6 billion.[137] Such continuing outbreaks f vaccine litigation, even in the face of congressional action designed to stop them, show just how difficult it is to inoculate society against the ıfectious reach of Trial Lawyers, Inc.

MALPRACTICE MALADIES

Doctors continue to flee states with out-of-control medical-injury verdicts.

Over the last two years, many state legislatures have responded to the crisis in medical-malpractice insurance rates by trying to rein in out-of-control medical-liability lawsuits.[138] While several states have been successful in enacting substantial reforms, the American Medical Association continues to list 20 states "in crisis" over malpractice litigation.[139] Overall, then, these efforts have yet to derail the med-mal gravy train that has been one of Trial Lawyers, Inc.'s longest-running and most lucrative business lines.

Trial Lawyers, Inc.'s medical-malpractice lawsuits are legion: of the 46,000 members of the American College of Obstetricians and Gynecologists, 76 percent have been sued at least once, 57 percent at least twice, and 41.5 percent three times or more.[140] And the litigation industry tends to file far more cases than actually have merit: nearly half of malpractice suits—49.5 percent—are dropped, dismissed, or settled without payment.[141] Indeed, in a study of medical-malpractice cases filed against New York hospitals, the Harvard Medical Practice Group found that in the majority of medical-malpractice claims, the plaintiff exhibited no medical injury whatsoever; the plaintiff was injured by doctor negligence only 17 percent of the time.[142]

The High Costs of Malpractice Liability

So if Trial Lawyers, Inc.'s suits against doctors are wide-ranging, and often meritless, just how much do they cost? By 2003, medical-malpractice liability costs in the United States had reached an astounding $26 billion annually.[143] That staggering sum represents a 2,000 percent increase over costs in 1975.[144] At 12 percent per year, the growth rate in medical malpractice costs since 1975 is four times the rate of inflation and twice the rate of *medical-care* inflation.[145]

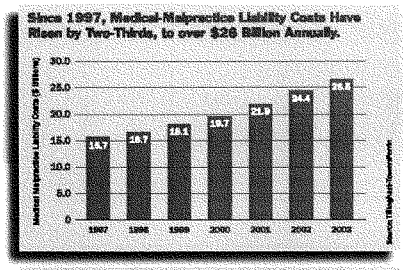
In jury trials, million-dollar verdicts are now the norm. Fifty-two percent of all awards exceed $1 million while the average award now weighs in at $4.7 million.[146] In crisis states, jury verdicts can be truly astronomical. For example, in 2002 in New York State, where juries delivered five of the top ten malpractice awards,[147] insurers incurred losses of over $1 billion and paid out $747 million in claims.[148] Though such outsize verdicts are often reduced by pretrial agreements and constitute only 4 percent of all med-mal case resolutions,[149] they establish a benchmark for future settlements. Between 1997 and 2003, the average settlement climbed 93 percent, to $1.9 million.[150]

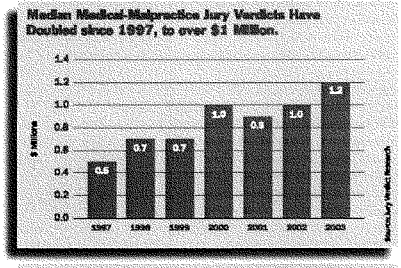
An Insurance Crisis

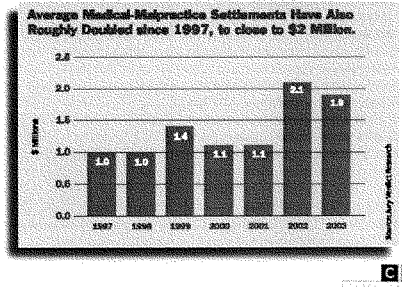
These legal-defense and settlement costs are driving doctors' insurance premiums into the stratosphere. Trial Lawyers, Inc.'s carpet-bombing tactics helped drive average premiums up 18 percent in 2003 alone[151]—more than twice the rate of growth of total health-care spending per person.[152] Doctors in plaintiff-friendly states and those in high-risk specialties like obstetrics, orthopedics, surgery, and neurology have borne the brunt of the assault. In plaintiff-friendly Cook County, Illinois, obstetricians paid $230,428 for coverage in 2004, up 67 percent from 2003 and nearly 12 times what they would pay in nearby Minnesota.[153] In St. Clair County, Illinois, where 1,100 defendants were named in more than 400 lawsuits between 2001 and 2003, neurosurgeons last year paid an average of $228,396, five times the going rate in Wisconsin.[154]

Even so, these sky-high premiums have not kept pace with payouts and with the costs of defending the 70 percent of suits that are spurious.[155] In 2003, insurers paid out $1.38 for every premium dollar they took in.[156] Little wonder that many of them are running for the exits. SCPIE Indemnity Company stopped selling medical-liability insurance in every state but California in 2003.[157] American Physicians Assurance pulled out of Nevada early last year even after the state legislature passed reforms.[158] In 2002, MIIX Insurance in New Jersey declined to renew 7,000 policies because it had lost over $200 million in 2000 and 2001.[159] In Maryland, where cowed legislators prefer to tax HMOs to pay for doctors' insurance rather than take on the plaintiffs' bar, there are only four medical-liability insurers left, down from 14 in 1995.[160]

The exodus of viable insurers has left doctors scrounging for coverage. Facing the huge increases, some doctors are forgoing insurance, taking their chances against being sued. Others, loath to put everything they own at risk, are retiring, moving out of plaintiff-friendly jurisdictions, or abandoning procedures—including delivering babies—that are the favorite targets of the plaintiffs' bar. In Illinois, three Park Ridge obstetricians recently decamped for Wisconsin after their 2004 premiums jumped 48 percent, to more than $500,000 a year.[161] In Kenosha, which then had caps on pain-and-suffering awards (see p. 18), they would pay only $50,000.[162] Kentucky, another AMA crisis state, lost a third of its obstetri-







As the AMA journal has recently observed, "It has never been safer to have a baby and never more dangerous to be an obstetrician."

cians between 1999 and 2003.[63] Pennsylvania—with total malpractice payouts at twice the national average—lost 36 percent of its general surgeons and 16 percent of its neurosurgeons between 1995 and 2002.[64]

The Human Costs of Malpractice-Liability Excess

As doctors have abandoned lawsuit-prone states and given up procedures most likely to land them in court, those most vulnerable—pregnant women and accident victims requiring specialists' care—have been left in the lurch. The human costs of Trial Lawyers, Inc.'s excesses are tragic, even deadly.

For example, Palm Beach County, Florida, is one of those tort-friendly locations where doctors increasingly shun risky cases. In five of the county's 13 hospitals, there are no neurologists working in the emergency room, and accident victims and stroke and seizure patients must be transferred to hospitals in Gainesville and Tampa for treatment, over 100 miles away.[65] Last year, 53-year-old Barbara Masterson died of a stroke while a hospital searched desperately for an out-of-county doctor to treat her; no local neurosurgeon would do it.[66] Similarly, maternity patients in some parts of the country have to travel long distances because many obstetricians have stopped delivering babies. In upstate New York, seven counties have no OB/GYNs at all.[67] The *Journal of the American Medical Association* recently observed in an article entitled "Who Will Deliver Our Grandchildren?" that "It has never been safer to have a baby and never more dangerous to be an obstetrician."[68]

The gaps in coverage are not just in sparsely populated rural areas, as trial lawyers like to contend. When Methodist Hospital stopped delivering babies in 2002 because of the rising cost of liability insurance, South Philadelphia lost its only maternity ward.[69] In Manhattan, Elizabeth Seton Childbearing Center—30 percent of whose patients were on Medicaid—shut down in 2003 when its liability premiums soared to $2 million a year.[70]

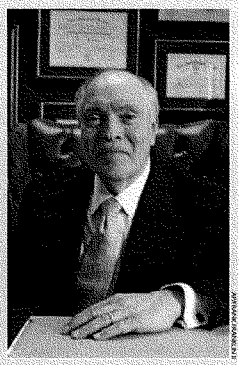
The Push for Reform

Recently, pressure from doctors and hospitals and consumer uproar over doctor shortages have emboldened some lawmakers to enact

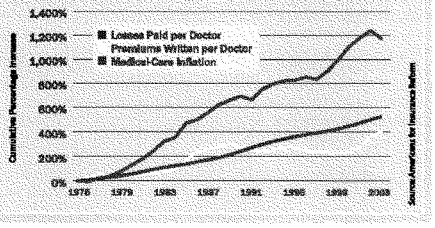
An Ohio jury awarded $3.5 million to the family of a heart-attack victim whose doctor failed to help the man lose weight and quit smoking.

DR. TRIAL LAWYER

Doctor and lawyer **Harvey F. Wachsman** is one of the most prominent leaders of Trial Lawyers, Inc.'s medical-malpractice division, along with erstwhile partners Steven Pegalis and Stephen Erickson.[169] Their firm shocked the legal community in 1998 and 2001 by pulling out two jury verdicts of over $100 million for birth-defect cases, the two largest medical-malpractice verdicts in New York State history.[170] In the public debate over the medical-malpractice crisis, Wachsman regularly delivers Trial Lawyers, Inc.'s favorite (and falsifiable: see below) sound bite, one well-honed by the litigation industry's coterie of "consumer group" surrogates (see box, p. 19): "Blame insurance companies."[171]



Medical-Malpractice Tort Costs Have Risen Far Faster than Insurance Premiums and Medical-Care Inflation.



reforms. Since 2002, 15 states have made at least some progress against runaway lawsuits.[171] The benefits are starting to show. In Texas, where new statutes cap pain-and-suffering damages at $250,000, Texas Medical Liability Trust lowered its premiums 12 percent the first year and another 5 percent the second.[172] In Los Angeles (where 30 years ago lawmakers limited noneconomic damages to $250,000), 2004 OB/GYN premiums were half as large as those in Texas and less than a third of those in Dade County, Florida.[173]

Even at that, it's an uphill battle. Many of the new laws are riddled with loopholes that allow payouts to exceed the new statutory limits. Trial lawyers have already taken Florida, West Virginia, and Ohio to court over new caps on noneconomic damages.[174] Similarly, federal efforts to rewrite the rules of medical-liability practice have foundered; reform measures have died multiple times in the Senate, and it's far from clear that the Bush administration can secure the necessary votes to win passage.[175]

Trial Lawyers, Inc. Fights Back

All the while, the plaintiffs' bar is busy conjuring up new causes of action. Last April, trial lawyers successfully overturned 20 years of case law when the New York Court of Appeals held that a patient could be compensated for the emotional distress of a miscarriage or stillbirth if it was caused by malpractice.[176] With 19,000 miscarriages and stillbirths a year in New York, beleaguered obstetricians are bracing for a new flood of lawsuits.[177]

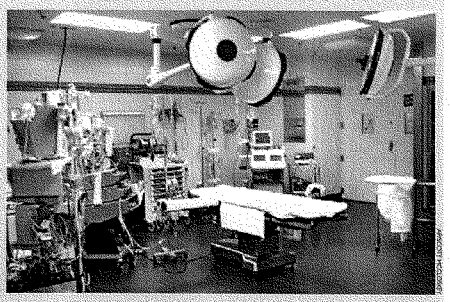
Ever resourceful, lawyers also are coming up with new categories of medical negligence. In 2003, a jury in Ohio awarded $3.5 million to the family of a man who died of a heart attack, claiming that the man's doctor failed to help the man lose weight and quit smoking.[178] Such outcomes promise to inflate the already staggering cost of defensive medicine, the $60 billion to $108 billion spent annually on costly and unnecessary tests that doctors order to forestall lawsuits.[179] If such verdicts become a trend, expect doctors to refuse to treat overweight smokers—for anything.

INHOSPITABLE TREATMENT

Trial Lawyers, Inc.'s medical-malpractice operations today include suits against not only individual doctors but also health-care facilities such as hospitals, nursing homes, and clinics. Juries tend to have less sympathy for what they perceive to be impersonal, faceless institutions. Accordingly, hospitals lose over half of malpractice cases—doctors lose only one-third—and the average compensation in suits against hospitals is over $6 million, a healthy 225 percent more than the average verdict against doctors.[40]

As a result of the litigation industry's relentless assault, hospitals are seeing their medical-liability premiums soar as payouts escalate. In 2002, 44 percent of the hospitals in the country saw premium increases in excess of 50 percent—without any corresponding increase in coverage.[84] Hardest hit were places like New York, which is now deemed one of the "medical liability crisis states" by the American Medical Association.[85] In New York, premiums rose 51 percent in 2004 on top of a 23 percent increase in 2003.[86] In crisis states, hospitals pay an average of $11,435 in malpractice-insurance costs per staffed bed, compared with $4,228 in states that have instituted medical-liability reforms.[87]

Hospitals' soaring costs and their inability to attract or retain willing physicians have caused many of them to shut down high-risk services (see, e.g., the idle West Virginia heart-surgery operating room, below) or shelve plans for new ones. In Philadelphia and its suburbs, eight maternity units have closed their doors in the past three years.[88] One of them, at Darby Mercy Fitzgerald Hospital, closed in June 2003 after the 17-bed unit had lost $2 million in each of the previous two years.[89] In 2003, Florida Hospital in Orlando abandoned plans to build a $55 million, 60-bed full-service satellite facility 20 miles from its main campus in Orlando because it couldn't find the doctors to staff it.[90] At Winter Park Memorial Hospital near Orlando, the number of surgeons willing to do emergency appendectomies and gall-bladder removals dropped from 14 in 2000 to zero in 2003, forcing the hospital to transfer to other facilities patients who required immediate treatment.[91]



Nursing homes, too, are staggering under medical liability costs, as lawsuits against them have become one of the fastest-growing markets for the plaintiffs' bar. Nationally, long-term-care facilities saw malpractice costs per bed increase 700 percent between 1992 and 2003.[92] If such trends continue, it will become increasingly difficult to care for our aging population.

As if targeting care for the elderly were not enough, tobacco mastermind Dickie Scruggs has put the poor in his crosshairs in a series of class-action suits that he has led against nonprofit hospitals.[93] Notwithstanding that nonprofit hospitals delivered $23 billion in free care in 2003 alone, Scruggs alleges that they have abused their tax-exempt status by overcharging the poor while discounting the cost of care to other patients.[94]

Thus far, federal judges hearing these cases have given them the treatment that they justly deserved, throwing out suits in Alabama, Michigan, and New York.[95] New York judge Loretta Preska went so far as to rebuke Scruggs for his "orchestrated assault on scores of nonprofit hospitals, necessitating the expenditure of those hospitals' scarce resources to beat back meritless legal claims," which she characterized as "part of the litigation explosion that has been so well documented in the media."[96] Nevertheless, some hospitals have been sufficiently intimidated that they have capitulated; one six-hospital system in Mississippi and Alabama, North Mississippi Health Services, has already agreed to refund money to poor, uninsured patients.[97]

Finally, even as new reforms capping noneconomic damages have put a damper on some suits, they've also generated creative new causes of action against hospitals. In Ohio, lawyers now sue hospitals for corporate negligence—claiming, for example, that a doctor should not have been permitted to perform a certain surgery.[98] Similarly, in Texas, lawyers have alleged that patients are being harmed because in its drive to make money, a hospital neglected safety.[99] By casting run-of-the-mill malpractice claims as claims against corporate malfeasance—which lie outside the statutory limits that several states have placed on malpractice damages—the litigation industry is performing an end run around those states' democratically instituted tort reforms. When it comes to protecting its bottom line, Trial Lawyers, Inc. can be downright inhospitable.

New Line of Business: Health Maintenance Organizations

THE TRIAL BAR'S HMO RACKET

Trial Lawyers, Inc.'s smooth talkers paint HMOs as gangsters, and cash in on subscriber dissatisfaction.

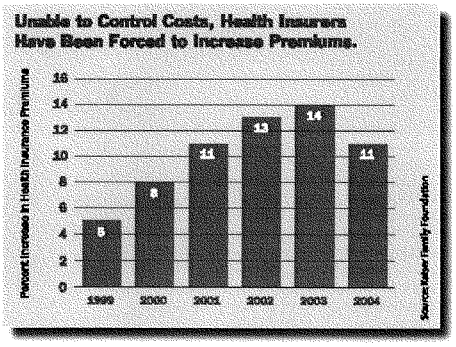
Essential to Trial Lawyers, Inc.'s business model is its constant search for new products—and new villains. Lately cast in the role of the heavy are managed-care providers such as health maintenance organizations, insurers that work to regulate the dispensing of health care by channeling subscribers into their approved networks of specialists and influencing the selection of treatment options. Once seen as a fulcrum for health-care reform, HMOs have become—along with drug companies—an industry that Americans love to hate, thanks in no small part to the litigation industry's propaganda machine. Homing in on the public's disenchantment with HMOs, lawyers have managed to all but decimate the cost-control tools that are at the heart of the benefits that managed care confers on the health-care system.

Treating Broken Legs with Brain Surgery

In 1993, Memorial Sloan-Kettering Cancer Center in New York City sued Empire Blue Cross Blue Shield for $12 million, including $10 million in punitive damages, for refusing to pay for bone-marrow transplants for breast-cancer patients, despite the fact that the treatment was unproven.[200] Later that year, a California jury awarded $89.3 million, including $12 million for emotional distress, to the family of a deceased woman whose HMO declined to pay for a similar treatment.[201] Thus rebuked, insurers started routinely doling out $100,000 per treatment for bone-marrow therapy for breast-cancer patients—an estimated 30,000 women received the treatment during the 1990s.[202] Insurers finally stopped providing the treatment in 1999—after wasting $3 billion—when four separate studies proved the treatment to be a failure, and the lone South African study that suggested effectiveness was exposed as having been based on falsified data.[203]

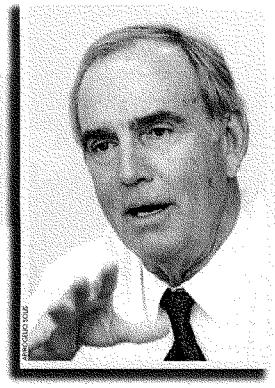
The suits against HMOs for refusing to cover speculative bone-marrow treatments were just the beginning of Trial Lawyers, Inc.'s all-out assault on medical cost-control measures. In the late 1990s, the litigation industry began to leverage its powerful government-relations divisions in states such as Texas and California to enact new "patients' rights" laws.[204] These statutes typically created direct causes of action against HMOs for "negligent misconduct"—a catchall phrase that made managed-care providers not only liable for treatment and non-treatment decisions but also for any medical malpractice of doctors covered under the plan.[205] Thus emboldened, trial lawyers increasingly turned subscribers' gripes into lucrative lawsuits.

Fortunately, the United States Supreme Court last year shut down this particular trial-lawyer profit stream when it ruled that the Employee Retirement Income Security Act preempted such state laws.[206] The Court unanimously determined that Congress had set up clear national rules that funneled aggrieved patients into federal courts, where they could recover only the cost of treatments denied—not punitive and other damage awards.[207]



Who's the Racketeer Here?

Trial Lawyers, Inc.'s other big assault on the HMO industry used the riskier but potentially more lucrative tactics the plaintiffs' bar honed to a science in its wars against Big Tobacco. Beginning in 1999, plaintiffs' lawyers have mounted some three dozen class actions against HMOs under the federal anti-racketeering RICO statute that allows for treble damages—all the time insisting that their real motive is to change the managed-care industry's alleged moneygrubbing ways.[208]



The cost of family coverage has soared a whopping 59 percent since 2000, making it increasingly unaffordable for employers.

The biggest of these suits was led by Dickie Scruggs (pictured left), the Mississippi lawyer who masterminded the state lawsuits against tobacco companies, and David Boies, the litigator of *Bush v. Gore* fame.[209] Their massive class action, consolidated as *In re Managed Care* in U.S. District Court in Miami, alleged that ten HMOs committed fraud by, among other things, cheating doctors out of their rightful fees and delivering inferior health care because of their undue attention to the bottom line.[210] The potential damage to the industry—and to the public, which will ultimately pay the price in higher premiums—is mind-numbing. Brought on behalf of 600,000 doctors and 145 million subscribers, the suits seek disgorgement of profits, recovery of part of subscribers' premiums, and the treble damages allowed by RICO.[211]

In 2002, the court threw out the subscriber claims of substandard care as too speculative, dealing Scruggs and Boies a painful rebuke.[212] But the court allowed some of the doctors' claims to go forward, under the leadership of attorneys including the Trial Lawyers, Inc. securities litigation powerhouse Milberg Weiss.[213] Wary of the resentful juries they would likely face if the cases went to trial, some insurers have settled, including Aetna and Cigna—who in 2003 forked over $470 million and $540 million, respectively—handing Trial Lawyers, Inc. a major victory—and over $100 million in legal fees.[214]

Those settlements are sure to spawn more lawsuits, especially against smaller, regional HMOs and against other types of managed-care organizations, such as prescription-benefit managers. Dentists have already piled on, having filed a class-action suit in 2001 in Miami federal district court alleging RICO violations against numerous HMOs.[215] Aetna, for one, settled with the 147,000 dentists last July, agreeing to speed up claims payments and reduce administrative requirements, among other things, as well as ponying up $5 million for the dentists, the American Dental Association Foundation—and their lawyers.[216]

The Costs of HMO Regulation by Litigation

The real cost of litigation against HMOs is borne by the average consumer. Managed-care organizations are nothing more than private insurance providers. Their treatment decisions, while often controversial, are the only mechanism of imposing cost discipline on health-care provision when consumers and their doctors do not directly bear the cost of procedures.

In the face of the litigation industry's charges of HMO profiteering, managed-care companies increasingly relaxed the guidelines that had kept a lid on costs. The court-approved settlement with Aetna specifically "requires changes and commitments in Aetna's business practices," policy modifications estimated to cost at least $300 million.[217]

The result? For the past four years, the cost of health insurance has risen annually between 10.9 percent and 13.9 percent, five times faster than inflation and wage growth.[218] The cost of family coverage has soared a whopping 59 percent since 2000, making it increasingly unaffordable for employers.[219] Indeed, between 2001 and 2004, the percentage of workers who get health-care insurance through their employers dropped from 65 percent to 61 percent, according to the Kaiser Foundation Employer Health Benefits 2004 Summary.[220] Much of the drop took place in the small firms that employ the majority of American workers and where medical coverage fell from 68 percent to 63 percent.[221]

Though review of HMO treatment decisions might be at times appropriate, such oversight should not be in the hands of lay juries liable to be swayed by the emotional pleas of smooth-talking, self-interested trial lawyers. Should the litigation industry's assault on managed-care providers continue to succeed, the tragic cost will be less affordable health care for most Americans.

READY MONEY

Trial Lawyers, Inc. finds politics a lucrative investment.

Tort reform is a bitter pill for Trial Lawyers, Inc. to swallow, and the litigation industry gives lavishly to buy the support of legislatures and judges. At the national level, Trial Lawyers, Inc. wins over politicians with concentrated political-action-committee giving and bundled individual contributions. In the last political cycle, lawyers and law firms again led all industries in federal political giving, spending a staggering $182 million on federal campaigns alone—outspending the corporate health-care sector by more than 50 percent (see graph, p. 19).[223] Although no comprehensive numbers are available for state-by-state trial-lawyer giving, anecdotal evidence from some of the nation's largest states suggests that the litigation industry's political influence at the state level exceeds, if anything, its influence at the federal level.[232]

Federal Giving: Trial Lawyers, Inc. Stands Apart

PAC donations from the Association of Trial Lawyers of America (ATLA)—Trial Lawyers, Inc.'s government-relations "home office"—are perennially among the nation's highest to the Democratic Party.[224] Democrats receive 93 percent of ATLA's contributions, which helps explain why every Democratic senator opposed the president's medical-malpractice reform bill in the last Congress.[225]

PAC gifts, however, only scratch the surface of litigation-industry giving, which Trial Lawyers, Inc.'s leaders and their firms bundle and distribute directly to candidates. Senator John Edwards's presidential campaign was almost wholly funded by the lawsuit industry,[226] and when he joined John Kerry's ticket, much of that fund-raising apparatus followed: the Texas law firm of Fred Baron, who chaired the Kerry-Edwards campaign's fund-raising efforts, has made a princely fortune in Fen-Phen litigation.[227] Other major 2004 contributors included Waters & Kraus, a firm whose suits have targeted Vioxx, vaccines containing thimerosal, and the cholesterol-lowering drug Crestor;[228] and SimmonsCooper, a firm in Madison County, Illinois (the nation's worst jurisdiction, according to the American Tort Reform Association),[229] which has a major practice suing the manufacturers of painkiller OxyContin and hormone-replacement therapy Prempro.[230]

While 74 percent of lawsuit-industry contributions go to Democrats[231]—including almost all those given by the large donors mentioned above[232]—Trial Lawyers, Inc.'s health-care division funds key Republicans, as well. The Senate judiciary committee chairman, Republican Arlen Specter, has been called "the favorite senator of the trial lawyers."[233] Small wonder: Specter's son Shanin (pictured with his parents below)—one of Pennsylvania's most successful medical-malpractice lawyers—is also one of Trial Lawyers, Inc.'s top fund-raisers.[234] Florida's newest senator, Mel Martinez, is also a former plaintiffs' lawyer, as are his fellow Republican senators Lindsey Graham of South Carolina and Mike Crapo of Idaho.[235] And Trial Lawyers, Inc. is keen to recruit more GOP candidates, particularly in the populist, socially conservative South.[236]

A Multipronged State-by-State Attack

Tort law is largely in the jurisdiction of the states, and the trial bar has diligently cultivated its influence over state legislatures. West Virginia's legislature is so beholden to the trial bar that the American Tort Reform Association calls its entire legal system a "judicial hellhole."[237] In larger states, the litigation industry targets political giving to maximize influence. Trial lawyers gave $10 million to legislative and statewide-office candidates in California's last two political cycles, including over $1 million for state attorney general Bill Lockyer's last two campaigns.[238]

When Trial Lawyers, Inc. loses in the legislature, it falls back on the courts, using its most seasoned strategy—litigation—to block reform. For years, the lawsuit industry has packed the courts with friendly judges who not only liberally interpret rules to the trial bar's advantage but also unabashedly engage in judicial activism to strike down tort-reform measures as unconstitutional, often on tendentious legal grounds. Just this summer, the Wisconsin Supreme Court struck down the state's statutory $350,000 cap on noneconomic damages in medical-malpractice actions.[239] Why? In an opinion authored by chief justice Sarah Abrahamson—who receives almost half her campaign funding from the trial bar[240]—the court found the statute to be "unreasonable and

JOSEPH KACZMARCZYK

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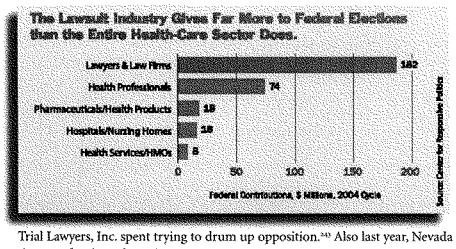


arbitrary because it is not rationally related to . . . lowering medical malpractice insurance premiums."[241] The court disregarded the General Accounting Office's explicit finding that "medical malpractice suits are one of the leading costs for insurance carriers."[242]

Frustrated by Trial Lawyers, Inc.'s influence over both the legislatures and the courts, reformers in states with referendum and initiative powers have taken to the ballot box to attempt to reduce lawsuit abuse. These efforts sometimes succeed—e.g., last year in California, where citizens reformed the state's notorious "shakedown statute," despite the $4 million Trial Lawyers, Inc. spent trying to drum up opposition.[243] Also last year, Nevada citizens voted in limits on pain-and-suffering awards and contingency fees in malpractice cases.[244]

While voter-referendum drives have met with success, the litigation industry often counters with initiatives of its own. Last year, for example, Florida's citizens passed an initiative limiting excessive contingency fees in medical-malpractice suits.[245] Trial lawyers responded with two succesful initiatives, including a "three-strikes" rule that strips the license of doctors who lose three malpractice suits.[246] A three-strikes provision sounds sensible—until one considers that doctors already settle thousands of groundless suits and that legal outcomes in medical-malpractice cases bear little or no relationship to actual doctor error, so that doctors who wish to stay in practice face a powerful incentive to settle even the weakest claims, for sizable amounts. While it's unclear whether the trial bar will generate enough new settlements to recoup its lost contingency fees, experts like law professor Lester Brickman argue that, with this counter-initiative, the lawyers have "trumped the doctors."[247] As the Florida story shows, Trial Lawyers, Inc.'s sophisticated government-relations operations make it difficult for reformers to keep the upper hand for long.

PUBLIC PITCHMEN

To block reform, Trial Lawyers, Inc. goes beyond its direct political contributions to influence public, legal, and academic opinion with its well-oiled public-relations machine. Trial Lawyers, Inc. targets the media with allied "consumer groups" bearing innocuous names like Consumers Union, Public Citizen, the Center for Justice and Democracy (CJD), and CJD's subsidiary, Americans for Insurance Reform. But these "public interest" groups have deep connections to the litigation industry. Consumers Union receives between 9 and 20 percent of its budget from unclaimed class-action funds.[248] Public Citizen Foundation's board looks like a Trial Lawyers, Inc. leadership meeting, including Lisa Blue of plaintiffs' firm Baron & Budd and Joseph Cotchett, who's also on the Association of Trial Lawyers of America board;[249] Public Citizen boasts its own litigation division,[250] and group founder Ralph Nader has come under fire from other consumer advocates for his deep financial ties to the trial bar.[251] While the CJD closely guards its donor list, its sole stated mission is to "educate the public about the importance of the civil justice system and the dangers of so-called 'tort reforms,'"[252] and its board is populated with the trial bar's most zealous advocates in the academy, as well as media hounds Michael Moore and Erin Brockovich.[253]

In taking on big pharmaceutical companies, the lawsuit industry is helped immeasurably by Public Citizen's scare tactics. They led the fight against breast implants and Bendectin, both of which have been shown repeatedly to pose little health risk. Sidney Wolfe,[254] the director of Public Citizen's Health Research Group, calls prescription drugs a "massive public health problem" costing 100,000 lives per year[255]—without mentioning the millions more lives saved and improved by modern drug technology. Public Citizen produces an annual report, "Worst Pills, Best Pills," which paints scores of prescription and over-the-counter medications as too dangerous for public use: their "do not use" list now numbers 185 and includes such medicine-chest standbys as the cough syrup Robitussin, the decongestant Sudafed, and the antacid Mylanta.[256] While urging consumers to avoid these common medicines "under any circumstances" may seem bizarrely extreme, consider that Public Citizen's "health letter" last year extravagantly suggested that "[w]eapons of mass destruction are hard to find in Iraq [but] in modern medicine they are abundant."[257]

Beyond attacking pharmaceuticals, Public Citizen and its allies issue disingenuous reports designed to obscure the very real danger posed by medical-malpractice litigation. Since April, Public Citizen, CJD, and Americans for Insurance Reform have each issued separate "studies" that blame the med-mal liability crisis on insurance companies.[258] Long-term statistical analysis of the groups' own numbers, however, shows that medical-malpractice payouts have risen far faster than insurance premiums (see graph, p. 14).[259] While these "public interest" groups resort to statistical misrepresentation to make their case, their reports are still uncritically trumpeted by mainstream media outfits like the *New York Times*[260]—lending unearned credibility to Trial Lawyers, Inc.'s public-relations flacks.

Outlook and Conclusion

PRESCRIPTIONS FOR CHANGE

Reformers look for healthy solutions to rein in Trial Lawyers, Inc.

Reforming the legal system to facilitate better health care is a delicate—but not impossible—operation. The aggressive public- and government-relations arms of Trial Lawyers, Inc. work tirelessly to oppose change; America's federalist system makes reform a state as well as a national concern; and the highly complex issues involved in civil justice reform are not easily understood by elected representatives and policymakers—even those not beholden to the trial bar's campaign financiers. Still, after the high costs of medical-malpractice-lawsuit abuse galvanized doctors, who raised tort reform's visibility through well-publicized demonstrations and strikes,[261] the public has begun to understand that an out-of-control legal system has serious real-world health effects. Aggressive grass-roots efforts have the litigation industry on the defensive, but reformers need to capitalize on this momentum by prescribing comprehensive solutions to effectively treat a health-care system ravaged by Trial Lawyers, Inc.

States Push for Change

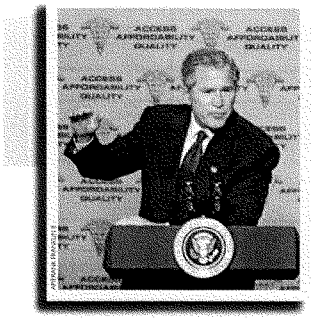
Tort law rests primarily in the states, and the states have been at the forefront of reform. State capitols around the country now have medical liability reform on the agenda: in 2005, legislators in 48 states introduced more than 400 bills on the issue.[262] More than 60 of these bills are now law, including measures to cap noneconomic damages, establish standards for expert witnesses, and set statutes of limitation on filing malpractice suits.[263] In all, 27 states now limit noneconomic damages in medical-liability cases.[264]

While states' laws vary in their effectiveness, in those states where damage caps and other broad reforms have passed, malpractice premiums have generally come down and doctors' shingles have stayed up. Since Texas legislators imposed a $250,000 limit on noneconomic damages in 2003, malpractice suits have dropped by half, and the five largest insurers have announced rate cuts that will save doctors and hospitals $50 million a year.[265] An Agency for Healthcare Research and Quality study found that rural counties in states with such caps saw a 3.2 percent rise in doctors per capita.[266] Over the long run, medical-malpractice reforms have been highly successful: since California passed its $250,000 noneconomic damages cap in 1975, its medical-malpractice premiums have risen "only" 245 percent, versus 750 percent nationwide.[267]

Federal Reform: What's on the Table

Success at the state level, however, cannot by itself fix the health-care liability problem. Trial Lawyers, Inc. shops its cases to the most lenient forums, so suits against drug and medical-device manufacturers—whose products are sold nationwide—often wind up in "magic jurisdictions" that function as cash registers for the plaintiffs' bar (see p. 9).[268] Critics of federal tort reform often point out, rightly, that tort law is a historical province of the states. But products-liability law has expanded dramatically in the last 50 years,[269] and the litigation industry's forum-shopping enables plaintiff-friendly states to impose costs on other states, even when those states have conflicting regulations or statutes.[270] Thus, federal products-liability reform fits easily within the ambit of Congress's power to regulate interstate commerce.[271] The case for federal reform of medical-malpractice liability is less clear-cut; but considering that Medicare and Medicaid constitute close to half of medical spending, taxpayers nationwide bear the costs of outlier states' plaintiff-friendly tort systems, so the case for federal remedy is compelling.[272]

Understanding the national implications of the issue, President Bush has led the fight for medical-liability reform at the federal level and has proposed legislation to limit liability on medical malpractice as well as on pharmaceuticals and medical devices.[273] The bill—the Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act of 2005—would place a $250,000 cap on noneconomic-damage awards, limit attorneys' fees, enact a three-year statute of limitations for malpractice cases, and mandate standards for expert witnesses.[274] Also, the federal legisla-



The litigation industry's assault on American health care is a threat both to our wealth and our health, and effective reform requires bold action.

tion borrows from Michigan's salutary law—now under siege by Trial Lawyers, Inc.—that prohibits certain suits against companies that have complied with their regulators:[275] the HEALTH Act would prohibit punitive damages against a manufacturer whose product has been approved by the Food and Drug Administration.

The president's proposed remedy, however, will be a hard prescription to fill. Although the House passed the president's bill in July—as it has seven times before—the legislation remains stalled in the Senate.[276] Trial Lawyers, Inc. is spending millions to keep it there and has hired additional lobbyists to turn up the heat on lawmakers who might be considering voting for it. Democrats are lined up against the bill, ready to mount a filibuster if necessary, and won't let the bill go anywhere without changes, such as increasing the damages cap.[277] Even then, its passage is not assured unless the president can convert some key opponents of the legislation, Republicans as well as Democrats.[278]

What's Missing: A Comprehensive Plan for Reform

In calling for the elimination of punitive-damage awards for FDA-approved drug litigation, the HEALTH Act administers a much-needed antidote of reason for Trial Lawyers, Inc.'s feverish public-relations campaign against the pharmaceutical industry, but the legislation really does not go far enough. As shown in *Ernst v. Merck*—where the jury gave a $24 million compensatory award for mental anguish[279]—it is far too easy for juries to use noneconomic damages like "pain and suffering" to punish companies even where punitive damages are limited by law. An effective federal reform must limit all noneconomic damages—not just punitive awards—that juries could extract from drug companies that have complied with the FDA.

Moreover, a strong case can be made that Congress should preempt state drug suits altogether.[280] Whether assessing the causal link between Vioxx and Robert Ernst's death, or the general safety of breast implants and Norplant, lay juries have demonstrated enormous difficulty in assessing complex scientific claims. When juries make unpredictable, often wrong, decisions in the thousands of state drug lawsuits led by Trial Lawyers, Inc., they interfere with federal regulatory schemes designed to foster innovation, and they endanger medical progress.

Preempting state drug suits need be neither unsafe nor unfair. As demonstrated throughout this report, the haphazard system of drug litigation tends not to efficiently deter bad behavior, but certainly deters research and innovation. By eliminating a system in which tort suits are shopped to judges beholden to Trial Lawyers, Inc. and tried before juries unable to make accurate scientific judgments, federal preemption would lower the tax on drug research and prevent the litigation industry from interfering with the FDA's role of protecting public safety. Furthermore, preempting state suits against drug makers who comply with the FDA does not mean that individuals injured by drugs or medical devices must go uncompensated: the existing federal no-fault Vaccine Injury Compensation Program offers a template for fairly and efficiently compensating those harmed by drug side effects.[281]

To improve the handling of medical-malpractice liability claims, states would be well advised to experiment with comprehensive solutions of their own. One model would establish special health courts in which judges with experience in adjudicating medical issues would vet expert witnesses and try cases without juries.[282] Juryless courts already exist in family law and for tax and bankruptcy cases, and focus on equitable treatment of the parties involved rather than meting out blame and punishment to wrongdoers. By eliminating junk science, sympathetic juries, and grandstanding lawyers, such courts could dramatically reduce costs while expediting the process of compensating injured patients. They would establish precedents to guide future adjudication and discourage the groundless, scattershot suits that fill court dockets today.

The litigation industry's assault on America's health-care system is a threat to both our wealth and our health, and effective reform requires bold action. The reforms outlined above would improve our legal system to better deter accidents while encouraging innovation, allow consistent standards that would award uniform compensation to similar claimants, and lower the steep tax that Trial Lawyers, Inc. levies on the U.S. health-care system. But the plaintiffs' bar will fight even marginal reforms. No magic pill will eliminate the tort plague, but effective curatives exist if the American people can muster the will to administer them.

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208. *See* Beck, *supra* note 37.
209. *See id.*
210. *See In re Managed Care Litigation*, MDL No. 1334, 2003 WL 22850070 (S.D. Fla. Oct. 24, 2003).
211. *See* Beck, *supra* note 37.
212. *See id.*
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268. *See* Scruggs, *supra* note 90.

269. *See generally* HUBER, *supra* note 73.

270. *See, e.g.*, John H. Beisner et al., *One Small Step for a County Court . . . One Giant Calamity for the National Legal System*, 7 CIV. JUST. REP. (Manhattan Inst. Center for Legal Pol'y, Apr. 2003), *available at* http://www.manhattan-institute.org/pdf/cjr_07.pdf.

271. Such activity should fall under "the particular restraints imposed on the authority of the States, and certain powers of the judicial department," which James Madison noted were an essential constitutional function to "provide for the harmony and proper intercourse among the States." *Federalist* 42.

272. A federal scheme for handling all medical-malpractice claims is less feasible, and perhaps less desirable, than one for drugs. Doctors are regulated by the states, not the federal government. Furthermore, cross-state forum shopping is much less common for medical malpractice than for drug litigation; typically, doctors are sued in the plaintiff's home state or where the alleged injury occurred. So, if a state has bad medical-malpractice laws, it will lose doctors to its neighbors, and thus its citizens bear much of the cost of their own inadequate legislation. Still, the fraction of health spending assumed by the federal government—of $1.7 trillion in U.S. health expenditures in 2003, over $500 billion came from the federal government, *see* National Health Expenditures, *at* http://www.cms.hhs.gov/statistics/nhe/historical/t3.asp—certainly gives the federal government a constitutional nexus for overarching reform. *Cf.* South Dakota v. Dole, 483 US 203 (1987).

273. *See* Press Release, Office of the Press Secretary, President Discusses Lawsuit Abuse at White House Economy Conference (Dec. 15, 2004), *available at* http://www.whitehouse.gov/news/releases/2004/12/20041215-11.html.

274. *See* H.R. 534, 109th Cong. (2005).

275. Michigan House Bill 4981, introduced June 21, 2005, proposes to amend section 4 of the Michigan Consumer Protection Act, MICH. COMP. LAWS § 445.901 *et seq* (2004), which provides statutory defenses to product liability claims, including adherence to government standards, FDA standards, and sellers' defenses.

276. *See* Sandra Lee Breisch, *BOC Measures Professional Liability Concerns*, AM. ACAD. OF ORTHOPAEDIC SURGEONS BULL., June 2002, *available at* http://www.aaos.org/wordhtml/bulletin/jun02/flinc1.htm (citing six prior passages, not including the subsequent 108th Congress).

277. For instance, Senator Feinstein, one of the Senate Democrats most amenable to tort reform, supports a $500,000 noneconomic-damages cap. *See* http://www.feinstein.senate.gov/03Releases/r-medmal.htm.

278. *See* Drinkard, *supra* note 225 (noting majority opposition to the 2003 HEALTH Act, including Republican Senators Lindsey Graham and Richard Shelby).

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Other Resources

Medical

American Medical Association
www.ama-assn.org

Pharmaceutical Research and Manufacturers of America
Billy Tauzin, President
www.phrma.org, (202) 835-3400

Physician Insurers Association of America
Lawrence E. Smarr, President
www.piaa.us, (301) 947-9000

General

Manhattan Institute Center for Legal Policy
James R. Copland, Director
Peter W. Huber, Senior Fellow
Walter K. Olson, Senior Fellow
www.manhattan-institute.org/clp, (212) 599-7000

American Enterprise Institute Liability Project
Ted Frank, Director and Resident Fellow
www.aei.org, (202) 862-5820

American Justice Partnership
Dan Pero, President
www.americanjusticepartnership.com, (517) 371-5256

American Legislative Exchange Council
Kristin Armshaw, Director, Civil Justice Task Force
www.alec.org, (202) 466-3800

American Tort Reform Association
Sherman Joyce, President
www.atra.org, (202) 682-1163

Common Good
Philip K. Howard, Founder and Chairman
www.cgood.org, (212) 576-2700

Federalist Society for Law and Public Policy Studies
Leonard Leo, Executive Vice President
www.fed-soc.org, (202) 822-8138

National Association of Manufacturers
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RAND Institute for Civil Justice
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www.rand.org/icj, (310) 451-6979

U.S. Chamber of Commerce Institute for Legal Reform
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Mr. ISSA. Thank you, Mr. Chairman.

Dr. Kessler, I guess I will begin with you. Fairly straightforward. You have had a very long career at the FDA. This drug has been on the market since most people in the room hadn't been born. This basically goes back, I understand, to the 1950's.

Dr. KESSLER. This drug?

Mr. ISSA. Heparin.

Dr. KESSLER. Sure.

Mr. ISSA. If I believe what one side has given me, there has been somewhere north of 70 million uses, one confusion. When you became aware of that, when you were still at the FDA, would you have sponsored an immediate recall, since that was reported in a timely fashion within the 15-day rule?

Dr. KESSLER. Under the drug——

Mr. ISSA. I apologize. I just want to know your personal. You are no longer in that position. I really just want to know would you have recalled all the Heparin based on that event?

Dr. KESSLER. I don't believe I would have had the authority——

Mr. ISSA. No, no.

Dr. KESSLER [continuing]. Under the law.

Mr. ISSA. I am going to make you the chairman and CEO of Baxter. Would you have recalled it all based on that one event?

Dr. KESSLER. Again, the experience I have had is at FDA. You would have to give me a little more information and the context.

Mr. ISSA. Exactly what occurred. Three innocent children died, three more were severely hurt using a drug based on a misapplication of two different drugs at a hospital before Mr. Quaid's children suffered the same.

Dr. KESSLER. So if you made me CEO of Baxter and there were three deaths, and the labels looked like they look like on the screen, I would want those changed. I would want to make sure that no other nurses or doctors were put in that position.

Mr. ISSA. And I appreciate that, because they did just that. They began the process of making changes in labels. I asked you would you immediately recall and lead potentially to a shortage, immediately recall all these drugs.

Dr. KESSLER. Three deaths? I would certainly give it very serious consideration.

Mr. ISSA. When you were at the FDA did you ever recommend a recall based on products which were not defective but, in fact, if not read, could be misunderstood as to the two distinctly different drugs?

Dr. KESSLER. FDA doesn't have the authority, Congressman, to recall drugs.

Mr. ISSA. OK. I am going to make a small statement, which is I don't believe you would if you had the authority. I think when you look at decades of the use of this drug, the two different doses, and the fact that you would have to do every drug which had a similar label but different doses, if you were to do that, that you would have said that is Congress' authority or that is something which we could research. I don't think, in 15 or 30 or even 180 days, you would have recalled it.

The reason I am bringing this up is that this is an important hearing. People died, and people die every day. More people die in

hospitals, based on these kinds of mistakes, than die in car accidents, as you are well aware. They did that before you came to your office and they continued to do it after you leave this office. Mr. Sarbanes even noted one. People die in hospitals of the mistakes in hospitals very, very often, don't they?

Dr. KESSLER. People die in hospitals.

Mr. ISSA. OK. And this was a mistake to have this drug in the pediatric ward to begin with, wasn't it?

Dr. KESSLER. I don't know the answer.

Mr. ISSA. OK. Do either of the doctors know?

Mr. QUAID. Sir, I can answer that question.

Mr. ISSA. OK. Just one more thing, and then I really would like to ask you. Do any of the doctors know? Is there a valid, common use of the full-strength drug in a pediatric ward?

Mr. QUAID. Yes, sir.

Mr. ISSA. Yes, Mr. Quaid?

Mr. QUAID. In a pediatric ward you are going to have children from infants all the way up to 18 years of age who are adult size, and those minors would take an adult dose, which is much more.

Mr. ISSA. Good. Well let me ask you a question, Mr. Quaid. And I am very sorry for what has happened to Zoe and Thomas. You came here because you want to make a change. Everyone on the dias, certainly myself, came here because we want to make changes. Is the change you want to make, separate from a lawsuit, is the change you want to make to get overall better labeling, clearer, and, with all due respect, places like Cedars-Sinai to use the bar coding that was already on this drug so as to prevent this mistake even if the person tries to carelessly read?

I looked at both the bottles. They are both bar coded. I think you have probably long since over-studied this more than I have.

Mr. QUAID. Yes, sir. I would like to see bar coding and all of that, what you just mentioned I would like to see changes in. But the real reason that I am here today is not because of our foundation or because of that issue, which is a separate issue which we are going to continue on with, but I am here today because of the preemption law that is coming up before the Supreme Court, which I believe in the end will be, if it goes through in favor of the drug companies, there will be less motivation to change certain problems that arise with drugs and their applications in the after-market process. That is why I am here today.

Chairman WAXMAN. Thank you, Mr. Issa.

Mr. ISSA. Thank you. Thank you for being here.

Chairman WAXMAN. Ms. Watson.

Ms. WATSON. I want to thank all the witnesses, and particularly you, Mr. Quaid, for coming today and putting a real face on what the dangers are of the kinds of labeling and the fact that we don't have enough people in the FDA to really followup and responsibilities of the manufacturers.

It is very important that we, as policymakers, understand and thoroughly review so we can hold whichever the responsible parties are accountable so that we will protect the health and safety of the public.

Thank you for being here, all of the witnesses, and your patience.

I would like to deal with Vioxx, which was a product that all of you are aware of, was finally recalled, and a product that was highly advertised on television. You know, most people get their information today from television. That is why the ads are so frequent, because that is the way of giving the public their information.

So, Dr. Kesselheim, I would like to talk about the importance of litigation in bringing information about drug safety to light. Recent publications have revealed safety problems with the drug Vioxx for patients with dementia. According to your testimony, the manufacturer delayed communications of known risk to the FDA and minimized those risks in its communication. So, Dr. Kesselheim, how did it do this? And can you respond, and then I will followup.

Dr. KESSELHEIM. Sure. As I indicated in more detail in my written testimony, the manufacturer selected certain statistical tests that have been shown to mask the types of outcomes and the adverse events that were showing up in the trials of Vioxx in patients with cognitive disability, and by choosing those statistical tests in its presentation to the FDA led the risks of the drug to be underestimated by the FDA regulators who would then read that report.

Ms. WATSON. All right. And what did the FDA do? Did they pick up on the risk?

Dr. KESSELHEIM. The FDA did, at the end of 2001, send a note to the manufacturer asking them about the possibility that there were increased cardiovascular adverse events in one of the trials, and the manufacturer dismissed the FDA's qualms, calling the results chance fluctuations, when, in fact, the manufacturer, as the litigation files show, was internally concerned about these problems and had performed its own analyses suggesting that these were not simply chance fluctuations.

In addition, the manufacturer had a whole separate second study. You know, in science when a result appears in a test and it might be a result of chance fluctuations, the normal course of action is to conduct a second test to evaluate it, and the manufacturer already had in front of them a second whole trial that showed the same results, an increased hazard ratio for cardiovascular adverse events of upwards of two to four times normal.

Ms. WATSON. Now, would this information come to light without litigation?

Dr. KESSELHEIM. Well, ultimately 2 years later the manufacturer submitted to the FDA the full reports of the test, including the proper statistical tests, but that was 2 years later and very close to the removal of Vioxx from the market.

Ms. WATSON. Yes.

Dr. KESSELHEIM. So the role of litigation after the fact was sort of to show both improper decisionmaking on behalf of the manufacturer and to reveal to the FDA the need to be more concerned in future instances when these sorts of cases occur. They need to be more vigilant and potentially try to dig deeper.

Again, as we have heard from Dr. Kessler, the resources of the FDA in many circumstances, try as hard as they might, may be limited in terms of both their authority to require different statistical testing be done or different analysis to be done or to punish the manufacturers if they don't respond to the FDA's requests.

Chairman WAXMAN. Thank you, Ms. Watson. Time has expired.

Mr. Bilbray.

Mr. BILBRAY. Thank you, Mr. Chairman.

You know, Mr. Quaid, this hearing is kind of tough for some of us, but your experience just brings back a lot of memories to me. With your two twins less than a year old, I am sure every time you go home and are able to pick up that baby, one of them or both of them, you will never take it for granted again.

David, have you been able to talk to your staff about the Bendectin issue?

Dr. KESSLER. Bendectin was before my time, Congressman.

Mr. BILBRAY. I know. You are all so young, it is all before your time. I only point out here that there is a cost here not just in dollars and cents, but there is a cost here in lives we are talking about. The Bendectin during the 1970's was available to consumers, right, and then there was a lot of litigation. As far as I remember, the FDA looked at it, looked at it, looked at it, and never removed it. Is that fair to say?

Dr. KESSLER. I wasn't there, Congressman, so you know a lot more about Bendectin than I.

Mr. BILBRAY. Well, in the 1990's, when you were there, you did not remove Bendectin from the market?

Dr. KESSLER. I didn't deal with Bendectin. No, I did not.

Mr. BILBRAY. And in only want to say this because what happened with Bendectin is something we have to be very careful of. It is like what has happened with the implant issue that required the Titus bill, a young man who desperately needed to have shunts to be able to live. Annie Eschew and I actually authored a bill to hold the manufacturers of products harmless, because what happened was the litigation was going after the manufacturer of the material, like Union Carbide, the plastic that went into the implant, and was going after deep pockets that basically were going to deny the manufacturers, that the people making the product wasn't going to be able to get the product to make the implant, and thus it was not going to be available for the consumers, and young man like Titus and kids would then be doomed because somehow litigation had deprived them of what they desperately needed.

I will say this, Mr. Quaid, in my situation my wife was acutely reactive to pregnancy. She had morning sickness so bad that when she had her first child in the 1970's she almost died. They gave her Bendectin and she learned that was what she had to have. When it came back to the 1970's, the product was taken off the market, not because the FDA ever found that the product was defective, but because of litigation after litigation was going after deep pockets.

Sadly, when my first boy was born, the product wasn't available to my wife. My wife almost died, and thank God there was a doctor who was willing to find old product to be able to give to my wife. That was one of those things that it is sad that, not because of science, but because of litigation and the deep pockets my wife almost died then.

Now, there is no way for me to say there was a nexus, but 3 months later the baby didn't wake up, and physicians feel that the trauma of the first trimester contributes severely to crib death. I cannot prove it, but I know in my heart that my child died because

the proper product wasn't available because the science wasn't driving the issue, but the greed for money was.

I will say, Mr. Quaid, I totally feel where you are. Thank God you didn't end up in our situation. But I just hope as we look at this that we understand, just as we address the litigation limitations for implants, that we do not think that trial lawyers in a courtroom is the best way to maintain quality health care.

I just want to say to be careful here, because there are two ways to kill somebody: inappropriate treatment, and denial of treatment. I will go to my grave believing my child is dead because he was denied the product that he desperately needed in his first trimester because of litigation.

Mr. Quaid, I will open it up for your comments. I know this is basically between you and me today.

Mr. QUAID. I certainly feel for you, sir, of the tragedy that occurred to you. My feeling is, of course, science should drive the products that are out there and they should become available to the general public. But at the same time, the general public needs to be protected, because really, after market, with the public, it is basically ongoing clinical trials only its out there and the public are the ones who are conducting the trials.

I would say to that I don't believe that drug companies are evil people, but I do believe that some check and balance needs to be in place to motivate the drug companies that changes come about in the after-market or before-market process, that would be harmful to people, that they needed to be identified and the public needs to be informed about it.

And, just like what we have in our system of Government where we have checks and balances between the three parts of our Government—Congress and the courts and the Presidential—there needs to be, I think, the tort system, and the State tort system serves as a check and balance for sometimes the businesses, the drug companies, because sometimes decisions are made for business expediency. There also could be a conflict of interest between public safety and business expediency.

Mr. BILBRAY. Thank you, Mr. Chairman.

I just wanted to say that the conflict of interest exists in the tort system, too, even more so in my opinion.

I come from a family of lawyers that have never made life and death decisions and never had that, but the fact is I would rather see our resources going to the FDA to front end to avoid the problem than to depend on courts and lawyers and lawyers and rogues to make the quality issue settle down. There has to be a more cost-effective way of doing that.

Mr. QUAID. I agree with you, sir, but, as I mentioned also before, the FDA is largely funded by the drug companies in order to expedite their products to the market. That seems to me to be a conflict of interest.

Chairman WAXMAN. The gentleman's time has expired.

Mr. BILBRAY. Thank you, Mr. Chairman.

Chairman WAXMAN. I want to recognize Mr. Lynch.

Mr. LYNCH. Thank you, Mr. Chairman. I thank the ranking member, as well.

I want to thank, first of all, the panelists who have come here to help us with our work. Mr. Quaid, I want to thank you for the power of your example. I also appreciate the comments of the gentleman, Mr. Bilbray, in bringing his own personal experience here, as well.

I want to just make a couple of quick observations. A number of Members have made the point today that Mr. Quaid did not name the hospital involved here as a defendant in this case. I, for one, am thankful for that, and I appreciate the spirit in which it was done, but I do want to point out it is a simple procedure of cross-claim by which the drug company can bring the hospital in as a defendant, so it is not a simple case where the deep pocket is being targeted here. The deep pocket can bring all the possible and likely parties on the basis of either superseding liability or shared liability. So I do not ascribe any motive on the part of Mr. Quaid other than not wanting to bring the hospital in on this occasion.

Second, I just want to make another observation, and that is one about power, power here in this Congress. This is really a hearing on whether or not this whole liability and tort process should be Federalized. I just want to remind all the Members not too long ago—well, first of all I read recently that there are more pharmaceutical company lobbyists on Capitol Hill than there are Members of Congress, and if there is any doubt about the power of the drug companies, pharmaceutical companies, one only needs to look back to the last Medicare reform bill.

It seems to me unbelievable, but the pharmaceutical companies were able to get a provision put in the Medicare Reform Act that said that the Secretary of Health and Human Services shall not negotiate lower drug prices with the pharmaceutical companies. Now, that was a provision that benefited a very small number of people, the pharmaceutical companies, and acted to the detriment of every senior citizen, the 32 million people without health care, and it was clearly against the best interest of consumers, but that happened.

So any attempt here to Federalize this process lays itself open to the same disparity in power, I believe, that opened up that example. That is one of my main fears.

The last issue I would like to touch on—and I want to leave this for the doctors—there was an argument made earlier today from a gentleman in the minority who I have great respect for who argued that acts of willful negligence would not be preempted. We have talked here at length this morning about the incentives for causing drug companies and these device companies to exercise the proper duty of care.

Now, I just want to remind people we are talking about drug companies and people who manufacture medical devices. Their customer is almost always compromised health-wise. These people are either afflicted with a disease that requires them to need this drug, or, as in the case of Mr. Quaid, his two young children were unable to protect themselves, were unable to complain, and so in my opinion the drug companies and the device manufacturers have a tremendous duty of care here because of the people that they are treating and the quality of what they are providing.

These drugs are going to be ingested or administered to people who are in a compromised position.

I want to ask the doctors: is willful negligence where we want to set the bar here? In other words, the only time it won't be preempted is if the plaintiff's attorney can prove, which is very difficult, that the drug company acted or the defendant acted with willful negligence, they did it basically on purpose. That is *New York Times* v. *Sullivan.* That is just a very hard standard to meet.

I just want to ask the doctors: is that where we are at here? Is this where we want to set the bar for incentives of providing safe products to consumers in America? Please?

Dr. KESSLER. I think the responsibilities of manufacturers do not end with the approval of their medical device. In fact, I think it would be much easier to argue that is really where they begin.

There are a number of requirements that the FDA puts on manufacturers when their device or drug is approved, and I will talk about devices as a specific example, but post-approval studies, for example, oftentimes when a device is approved we don't know how it is going to behave in people over many years, and the FDA, recognizing that, requires manufacturers to complete studies.

Well, if you go back and look at how many manufacturers actually complete the studies that they were "required" to complete, more than 20 percent of those studies aren't completed. At least that is data from 1998 to 2000. So is that willful neglect? Is that bad management at the company? I think there are a lot of factors that go into what causes a company not to meet the requirements that are expected of them or that are put on them by the FDA.

I think other neglect, if you will, can be much more subtle than that. In the Guidant case that we talked about earlier with the implantable defibrillators, the independent analysis demonstrated that the company relied on product performance engineers to recognize safety issues within the company and the product line of implantable defibrillators. Well, during this period of time, at times only one of three positions were actually staffed, so they were under-staffed. Is that willful neglect? Is that bad management? I think it is a very murky line that we are trying to paint.

Chairman WAXMAN. Thank you, Mr. Lynch.

Mr. Shays.

Mr. SHAYS. Thank you, Mr. Chairman, for holding this hearing.

I used to chair the subcommittee, we had a Health Subcommittee. Dr. Kessler, you came before my subcommittee on many occasions, and I was taught not to like FDA Administrators, but I thought you did a really fine job and I thought you were always a very candid and helpful witness. So I appreciate your service with the FDA. Obviously, your participation here has particular import, even though you are not longer with the FDA.

Mr. Quaid, let me say, as well, I can't imagine anything worse than seeing your children suffer, and then to think that they are suffering because of a mistake. I always appreciate people who have gone through this kind of experience to not let it die but to learn from it and try to be helpful.

But I actually don't know where I come down on this issue, because it is almost to me like everything is on its head. Republicans are taking the absolute opposite view that they usually take, and the Democrats seem to be taking the exact opposite view they take. I mean, we are usually not for the central Government and the

FDA, and usually my chairman and others have argued very strongly for the FDA and the role it plays.

And then I will just say I wonder, in a trial with a jury of people that aren't experts, they say how should they have a role, but honestly, when I look at this, I say, you know, why in the world did they look so much alike. So I don't have to be a doctor, I don't have to be a researcher. I can apply my own logic and say this is pretty dumb, this here.

But then again I think it could be dumb for there to be lots of different requirements in lots of different States. I think uniformity matters.

So I wonder, and I will ask you, Dr. Kessler, to start. Kansas City, MO, Kansas City, KS, St. Louis, MO, St. Louis, IL; Washington, DC, and the metropolitan area of D.C., Virginia, Maryland. So you live in Virginia and your doctor is in D.C. How does the doctor prescribe the drug? I mean, how does that function? Let's say you have three different requirements in those three different locations, or at least two. Tell me how it works.

Dr. KESSLER. Congressman, I have been licensed in New York, Connecticut, Maryland, California——

Mr. SHAYS. And all different requirements?

Dr. KESSLER. But I have not acted differently as a physician.

Mr. SHAYS. Right.

Dr. KESSLER. I have been trained——

Mr. SHAYS. But what I am wondering is, Does the manufacturer, if in one jurisdiction, Virginia, a trial of laymen determine that there needs to be a change, will the manufacturer make that change nationwide because they now expose themselves? So in essence would there be uniformity because in essence wherever you had a jury you just add to the label?

Dr. KESSLER. I think my colleague, David Vladeck, and I deal with that issue, because that is one of the arguments that are being used——

Mr. SHAYS. Tell me the answer. I only have 5 minutes.

Dr. KESSLER [continuing]. For preemption. No, it doesn't. A jury's finding doesn't require that the label be changed; a jury's finding only deals with compensation for the individual.

Mr. SHAYS. But in effect, though, they have been found guilty because they didn't warn, so in effect it would strike me that then they are going to have to put that label in every State.

Dr. KESSLER. Not necessarily.

Mr. SHAYS. Well, it doesn't seem logical to me because they could be sued again.

Dr. KESSLER. They could look at the jury's finding. They can ask the FDA to opine, and if the FDA says, Boy, that is a stupid thing. We don't see that association. If I were the company, just because a jury does it——

Mr. SHAYS. Let me ask you another question, and this gets to something that we have dealt with a lot with autism. The lay folks, me included, think that the immunizations have had an impact on autism. The medical community seems to disagree. If there was a court determination that it did, in fact, have an impact, what would be the impact on the supplier of these various drugs? And how would the FDA respond to that?

Dr. KESSLER. In general, Congressman, this is about information. If information comes to light in that trial, I would argue——

Mr. SHAYS. But we may not have expertise.

Dr. KESSLER [continuing]. The FDA should look at that information and be able to bring the best science to bear on that information and be able to help answer the scientific issues that arise from that information that comes out at that trial.

Mr. SHAYS. What I wrestle with, whether you win me over or not, is this: I am not sure that a trial of laymen, a jury of laymen, have the capability to decide whether immunizations have, in fact, caused autism, but they may make that decision in a court. The implication would be that somehow it would have a tremendous implication on the manufacturer and the labeling and so on.

Dr. KESSLER. This is a very important point.

Chairman WAXMAN. Mr. Shays' time has expired, but if you want to answer that point.

Dr. KESSLER. It is a very important point that you raise, but it is important for the record to understand that jury, that trial is not a requirement and doesn't require that label to be changed. If you look at the Supreme Court in *Bates* v. *Dow Agra Science,* they say that a requirement is a rule of law that must be obeyed, and that is not the case with a jury verdict.

If there is information that comes out of that trial—and I have been in that situation—I at FDA would want to be able to look at that and evaluate that, but it is FDA that has the ability to require what goes on the labels.

Chairman WAXMAN. It is the science and not the jury's opinion that will dictate what will happen at FDA; is that correct?

Dr. KESSLER. As far as the requirement, yes, Mr. Chairman.

Chairman WAXMAN. Thank you. Thank you, Mr. Shays.

Ms. Norton, did you have questions?

Ms. NORTON. Not at this time.

Chairman WAXMAN. OK. Well, that completes the questioning for this panel. You have been terrific and very patient, and I think it has been very helpful for Members as they think through this whole question and we look at this very important public policy discussion. Thank you so much for being here.

For our second panel the Chair would like to call forward David Vladeck, professor of law and co-director for the Institute for Public Representation at Georgetown University Law Center. He also serves as the director of the Center on Health Regulation and Governance of the O'Neill Institute for National and Global Health Law. He will be providing an overview of the current legal landscape of preemption in the context of FDA-approved drugs and medical devices, as well as implications for the future.

Dr. Gregory Curfman is an internal medicine physician, currently the executive editor of the New England Journal of Medicine. Dr. Curfman will be providing testimony regarding his views on the effect of preemption on the safety of FDA-approved drugs and medical devices.

Christine Ruther is a biomedical engineer and the president and chief engineer of C&R Engineering, Inc. She will be testifying today regarding her views on the impact of preemption in medical device and product liability cases.

Representative David Clark has served in the Utah State House of Representatives since 2001 and is currently a member of the National Conference of State Legislatures Executive Committee. As a State legislator he will be sharing his views on the impact of preemption on State interests.

Dr. John E. Calfee is a resident scholar for the American Enterprise Institute for Public Policy Research, where he studies pharmaceuticals, the FDA, health care policy, advertising, the tort liability system, and tobacco. He will be testifying on his views regarding the preemption in the context of FDA-approved drugs and medical devices.

Thank you all for being here. We are pleased that you have been willing to come and share your views on this subject with us.

Your prepared statements will be in the record in full. What we would like to ask you to do is to, as you noticed with the previous panel, try to stay within the 5-minutes for the oral presentation.

It is the policy of this committee that all witnesses that testify before us do so under oath, so if you would please stand and raise your right hands I would like to administer the oath.

[Witnesses sworn.]

Chairman WAXMAN. The record will indicate that each of the witnesses answered in the affirmative.

Mr. Vladeck, let's start with you.

STATEMENTS OF DAVID VLADECK, J.D., PROFESSOR OF LAW, GEORGETOWN UNIVERSITY LAW CENTER; GREGORY CURFMAN, M.D., EDITOR, NEW ENGLAND JOURNAL OF MEDICINE, ACCOMPANIED BY STEPHEN MORRISSEY, M.D., MANAGING EDITOR, NEW ENGLAND JOURNAL OF MEDICINE; CHRISTINE RUTHER, PRESIDENT AND CHIEF ENGINEER, C&R ENGINEERING, INC.; STATE REPRESENTATIVE DAVID CLARK, NATIONAL CONFERENCE OF STATE LEGISLATURES; AND JOHN E. CALFEE, PH.D., AMERICAN ENTERPRISE INSTITUTE

STATEMENT OF DAVID VLADECK

Mr. VLADECK. Thank you, Mr. Chairman, members of the committee. I want to thank you for inviting me here today to present my views on FDA preemption.

My view is this: FDA's new position on preemption, namely that the regulation of drugs and medical devices broadly displaces State liability law, is wrong both as a matter of law and a matter of policy. If accepted, it gives consumers the worst of both possible worlds.

Why? First, preemption undermines safety. Experience has shown that, despite the FDA's claims to the contrary, the FDA alone cannot be counted on to keep dangerous drugs and devices off the market or to correct errors or mistakes once devices and drugs get on the market.

Drug companies and device companies must do their part. They, too, must be kept accountable for their acts. Giving drug manufacturers and device manufacturers immunity from liability weakens their economic incentives to protect the public.

Second, preemption leaves injured parties with nothing, no compensation, no recompense for the injuries, no medical expenses, nothing.

FDA's policy is not a good one and will undermine public health. Fortunately, the courts have made clear that the ultimate choice is not for the courts, it is not for the FDA, it is for Congress to make.

So first I would like to urge Congress to work to reverse the Supreme Court's ruling in *Riegel* v. *Medtronic.* As I have explained elsewhere, the ruling in *Riegel* v. *Medtronic* is wrong as a matter of law, but what I would like to do for a moment is focus on the policy issues underlying Riegel.

Riegel should be overturned because it deals a body blow to people like Joshua Oukrop, who we have heard about today. Joshua was 21 years old. He had a heart condition that could be treated with a defibrillator. His defibrillator failed him and he died.

Now, the manufacturer of the defibrillator knew back in 2002 that this particular device was prone to malfunctioning. It did not tell the doctors who installed the defibrillator into Joshua's chest. It did not, as far as we know, alert the FDA of the fact other than to bury it in an enormous submission. And so by the time Joshua died in March 2005, 25 other malfunctions had been reported with this particular brand of defibrillator. Guidant had continued to sell those that it knew were prone to malfunction, even though it knew of the defect and even though it had developed a new and more effective model.

Seven other deaths have been linked to this particular defibrillator. There were probably others. Other people were injured.

This manufacturer was sued and settled after a court rejected its preemption defense.

Now fast-forward to today. In the wake of Riegel, Guidant would be immunized for its errors, no matter how egregious, no matter how knowing, and no matter how lethal. Riegel takes away the manufacturers' incentive to protect the public by preventing or correcting errors as soon as they become manifest. And Riegel deprives people like Joshua and his family of any remedy at all. That just isn't right. That is not the way we do things in this country.

Congress should act to restore the rights of people injured by dangerous and defective medical devices like Joshua Oukrop to bring State liability actions.

Let me turn briefly to drug preemption. In my view the argument for drug preemption is just as weak if not weaker for medical devices. The Federal Government has regulated drugs for 100 years, tracing back to the Bureau of Chemistry in 1908. For all of that time there has been concurrent Federal regulation of drugs and State liability actions. Indeed, State liability actions for failure to warn predate Federal regulation by at least 60 years. So there is nothing new about product liability litigation, there is no argument that for the last 100 years product liability litigation has stifled innovation. We have the most robust medical device and drug industry in the world.

Nonetheless, in 2002 the FDA, which had previously supported and encouraged the existence of State liability, litigation, as a way of promoting the values the Food, Drug, and Cosmetic Act served,

reversed field and has now taken the position that there ought to be broad preemption.

Now, what has changed other than the change of administrations? As far as I can tell, nothing. There is simply no public health justification for this about-face, as the examples of Heparin indicate.

I want to take one more minute, if I may, Mr. Chairman, to talk a little about the change of being affected regulations that the FDA has proposed, which would weaken the ability of drug manufacturers like Baxter to quickly change their labels. If the FDA changes that rule, what Baxter did in changing its label in October 2007 would be forbidden by the FDA rule because it would not have been based on any newly discovered evidence.

If you look at the time line that you put up on the monitors earlier, Baxter asked the FDA, notified the FDA that it wanted to change its rule in August 2007. It went ahead and changed the label in October 2007. The FDA did not approve that labeling change until December.

So under the new proposed rules, the FDA will inhibit the ability of drug manufacturers to respond promptly to serious, urgent public health needs by changing labels and doing other things to protect the public.

Thank you.

[The prepared statement of Mr. Vladeck follows:]

TESTIMONY OF DAVID C. VLADECK

PROFESSOR OF LAW
GEORGETOWN UNIVERSITY LAW CENTER
AND
SCHOLAR
CENTER FOR PROGRESSIVE REFORM

BEFORE THE HOUSE COMMITTEE ON
OVERSIGHT AND GOVERNMENT REFORM

HEARINGS ON:

SHOULD FDA DRUG AND MEDICAL DEVICE
REGULATION BAR STATE LIABILITY CLAIMS?

May 14, 2008

Mr. Chairman and Members of the Committee, thank you for inviting me to be here today to set forth my views on whether FDA regulation of drugs and medical devices should bar state liability claims. This is a subject I have thought about a great deal. I am a Professor of Law at Georgetown University Law Center and also serve as a Scholar with the Center for Progressive Reform. I have written extensively on regulatory preemption, with an emphasis on the question the Committee examines today.[1]

My views are these: FDA's new position on preemption — namely, that FDA regulation of drugs and certain medical devices broadly displaces state liability law — is wrong as a legal matter. I will discuss in some detail the basis for my conclusion. I also want to emphasize why FDA's position is wrong as a matter of public policy, since the ultimate decision about preemption is for Congress, not the courts, to make. Here's the bottom line: If accepted by the courts and not overturned

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[1] Submitted along with this testimony are copies of a recent law review article I co-authored with David A. Kessler, M.D., former Commissioner of the Food and Drug Administration, entitled *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 Geo. L.J. 461 (2008), a law review article I wrote a few years ago that focused on medical device preemption, *Preemption and Regulatory Failure*, 33 Pepp. L. Rev. 95 (2005), and a White Paper I prepared jointly with other scholars with the Center for Progressive Reform entitled *The Truth About Torts: Using Agency Preemption to Undercut Consumer Health and Safety* (CPR White Paper # 704, July 2007). I would also refer the Committee to testimony I submitted to the Senate Judiciary Committee for a hearing entitled "Regulatory Preemption: Are Federal Agencies Usurping Congressional and State Authority," on September 12, 2007. My recent writings on preemption also include a book chapter entitled *Preemption and Regulatory Failure Risks*, which will be published in PREEMPTION CHOICE: THE THEORY, LAW, AND REALITY OF FEDERALISM'S CORE QUESTION (William Buzbee, ed., Cambridge Univ. Press 2008) (forthcoming) and an essay entitled *The FDA and Deference Lost: A Self-Inflicted Wound of the Product of a Wounded Agency?* 93 Cornell L. R. __ (2008) (forthcoming), both of which will be published this summer.

by Congress, FDA's pro-preemption position gives consumers the worst of both worlds. On one hand, despite FDA's claims otherwise, FDA cannot single-handedly accomplish the Herculean job of assuring the safety of the 11,000 drugs and thousands of medical devices on the market. Thus, consumers cannot depend on FDA regulation alone to protect them from unsafe or defective drugs and medical devices. That is why, until recently, FDA saw the discipline the liability system places on the market as an essential complement to its work.

Despite FDA's inability to safeguard the marketplace by itself, FDA claims that consumers injured by unsafe drugs or defective medical devices should be denied the ability to seek compensation for injuries they sustained through no fault of their own. That is a right that the liability system has guaranteed to the American people since the founding of the Republic. Let's be clear about this: Under FDA's view, consumers are forced to assume the risks of unsafe drugs and medical devices. At the same time, manufacturers of drugs and medical devices who fail to take reasonable steps to assure their drug or device is safe are immunized from liability, and, these days, essentially immune from FDA enforcement. This result is not only unfair, it is bad policy. Removing economic incentives for drug and device manufacturers to act responsibly serves no legitimate end, but instead jeopardizes the health and well-being of the public.

What makes this result all the more indefensible is that the decision to wipe away state liability law was not made by Congress through legitimate, democratic means. Instead, it was made by unelected and unaccountable agency officials —

many of whom worked for drug and device companies before their government service and have returned or will return via the revolving door to represent the same companies.[2] These decisions were not made in a transparent, publicly accountable way. Rather, they were made in obscure regulatory documents, with no opportunity for public input, and with no regard for the clear-cut requirements of Executive Order 13,132, which disfavors preemption and requires agencies to consult with states, local governments and the public before making preemption decisions.[3]

Because the question posed by the Committee relates to both drugs and medical devices, and I will address those questions separately. First, I will address medical device preemption and urge Congress to act swiftly to overrule the Supreme Court's recent ruling in *Riegel v. Medtronic, Inc.*[4] Here, I start with a brief history of the Medical Device Amendments of 1976 and explain why that history demonstrates that Congress quite clearly intended to *preserve* state liability law. I

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[2] *See, e.g.*, Anne C. Mulkern, *Watchdogs or Lapdogs? When Advocates Become Regulators*, The Denver Post, May 23, 2004.

[3] Executive Order 13,132 provides that "[w]hen an agency foresees the possibility of a conflict between State law and Federally protected interests within its area of regulatory responsibility, the agency shall consult, to the extent practicable, with appropriate State and local officials in an effort to avoid such a conflict." *Id.* §(4)(d). The Order also directs agencies to construe federal law to preempt State law "only where the statute contains an express preemption provision or there is some other clear evidence that Congress intended the preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute." *Id.* §(4)(d). The Executive Order is available at 64 Fed. Reg. 43,255, 43,257 (Aug. 10, 1999). FDA has simply ignored these requirements in accomplishing its about-face on preemption.

[4] *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008).

will then turn to the Court's ruling in *Riegel* and address why the Court's wooden textual approach to the Amendments — which ignored their purpose — led the Court to conclude, wrongly, that *Congress* intended the Amendments to *preempt* state liability claims for devices approved by FDA through the pre-market approval process.

I will then turn to a discussion of the debate that is raging in the courts over FDA's new contention that its approval of a drug's labeling broadly preempts state liability claims. The lower courts are deeply divided on drug preemption, although the majority of courts have rejected FDA's pro-preemption position. This question will be considered by the Supreme Court in October in *Wyeth v. Levine*, and a decision can be expected by early 2009.

In my view, the question in *Wyeth* is not a close one. The federal government has regulated the sale of drugs for one hundred years without any hint that state liability actions interfered with FDA's ability to do its job. Nothing in the statutes FDA administers suggests that they oust state liability actions for drug products. Indeed, FDA has long taken the view that state liability litigation for pharmaceuticals is an important, independent discipline on the market. And Congress has not acted to preempt or limit state liability actions, even though Congress has long been aware of the steady procession of liability actions against drug makers — including those that pre-date FDA and its forerunners. For these and other reasons I address later in my testimony, I remain hopeful that the Court will find that Ms. Levine's claim is not preempted. Should the Court reach the

wrong conclusion, however, Congress should be ready to respond with legislation to restore the right of individuals harmed by dangerous drugs to bring state liability actions for redress.

I. FDA Preemption and Medical Devices.

Preemption cases involve more than dry and arcane questions of law. They invariably involve a story like Joshua Oukrop's — a tragic death or serious injury to someone caused by a product that failed them. Joshua Oukrop, a college student, was on a spring break trip to Moab, Utah, with his girlfriend. They went for a bike ride, but Joshua soon complained of fatigue, fell to the ground, and died of cardiac arrest. Why? Joshua had a common genetic disorder that causes erratic heartbeats that, if untreated, can trigger sudden cardiac arrest. But Joshua was able to lead a normal life because of a small, pocket-watch-sized, defibrillator that had been implanted in his chest. The defibrillator — a Guidant Prizm 2 — was programmed to deliver an electrical impulse to Joshua's heart when it went into arrest and jolt his heart back into a normal rhythm. But on that day in March 2005, instead of delivering a life-saving charge to his heart, Joshua's defibrillator short-circuited and failed. A wire in the device was too close to a component, causing an arc between them when the device fired.[5]

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[5] David C. Vladeck, *Preemption and Regulatory Failure*, 33 Pepp. L. Rev. 95 (2005); Thomas McGarity, *The Preemption War* (New Haven, Conn.: Yale Univ. Press 2008) (forthcoming); Barry Meier, *Maker of Heart Device Kept Flaw From Doctors*, N.Y. Times (May 24, 2005) at A1; Barry Meier, *Repeated Defect in Heart Device Exposes a History of Problems*, N.Y. Times (Oct. 20, 2005) at A1.

Joshua's doctors determined that the defibrillator's malfunction caused his death. This was no surprise to Guidant. By the time Joshua died, Guidant had received 25 reports of other failures of the device for exactly the same reason. Guidant had fixed the problem in 2002, three years *before* Joshua's death, but decided to sell its existing inventory, without first fixing the flaw. After all, defibrillators cost $25,000. Thousands of these faulty defibrillators were sold *after* Guidant had developed a new and safer device. Nor did Guidant tell physicians or patients about the defect. Word of the defect might frighten patients into opting for potentially risky surgery to replace the device. And in Guidant's view, its data still showed the Prizm 2 to be "a highly reliable life-saving product."[6]

Shortly after his death, Joshua's doctors met with Guidant officials to discuss what the company would do for the 24,000 patients who depended on the same device. Guidant offered to replace the devices Joshua's doctors had implanted in their patients. But Guidant was unwilling to inform other doctors, fearing that they too might want replacement devices. Guidant's efforts to keep the defect quiet did not succeed. The media disclosed that the short-circuiting problem had affected other Guidant defibrillators, and that Guidant had concealed the defect. Ultimately, three years after learning of the defect, after dozens of failures (including at least one other death and several heart attacks), and prodding from FDA, Guidant decided to "recall" the Prizm 2, as well as several other defibrillator models, affecting more

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[6] *See, e.g.*, Barry Meier, *Maker of Heath Device Kept Flaw From Doctors*, N.Y. Times (May 24, 2005) A1; *The Preemption War*, at 135.

than 50,000 patients.[7] As I'll explain in a minute, the Supreme Court's recent ruling in *Riegel v. Medtronic, Inc.*, will immunize companies like Guidant from liability for conduct such as this, notwithstanding the grave harm that it inflicted on Joshua and his family.

The statute that governs medical devices — the Medical Device Amendments of 1976 (MDA) — was enacted in response to a series of highly-publicized public health catastrophes caused by defective medical devices, like the Guidant defibrillator. Most notorious was the Dalkon Shield. It was an intrauterine device introduced and widely marketed by the A.H. Robins Company without FDA approval. At the time, FDA had limited authority over medical devices. In producing the device, Robins ignored its own experts, who urged that both ends of the device's "sheath" be sealed to prevent "wicking" of bacteria-laden fluids into the uterus. Robins touted the Dalkon Shield as a safe and effective alternative to birth control pills. Soon after it hit the market, however, women began contracting infections that caused death, infertility, and other serious injuries. Robins kept the device on the market for an additional year, but finally stopped selling it in 1974.

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

Litigation by thousands of injured women brought to light the nature and severity of the problem and afforded women the only compensation that was available to them.[8]

To avoid a recurrence of this and similar tragedies, Congress enacted the MDA to give FDA regulatory authority over all medical devices.[9] The MDA reserves the most rigorous regulation for "Class III" devices — devices, like defibrillators, heart valves, and pacemakers, that sustain life or pose a serious risk to patients if they malfunction. As a general rule, before marketing a Class III device, a manufacturer must submit a pre-market approval (PMA) application asking FDA's permission to market the device for the specific uses identified in the application. There are two exceptions. First, any device manufactured prior to the passage of the MDA — a "grandfathered" device — is not subject to the PMA requirements. Second, a device manufactured *after* 1976 may bypass the PMA process if the manufacturer can show that it is "substantially equivalent" to a grandfathered device. Before granting a PMA, FDA must find that there is a "reasonable assurance" that the device is safe and effective for its intended use.

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

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

Because FDA lacked authority over medical devices before 1976, states had filled the regulatory void. By the time the MDA was enacted, a number of states, especially California, were engaging in robust regulation of devices. Accordingly, to formalize the allocation of responsibilities between FDA and state regulators, Congress included an express preemption provision in the MDA. It provides that "no State . . . may establish or continue in effect with respect to a device intended for human use any *requirement* (1) which is different from, or in addition to, any *requirement* applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device . . .."[10] This language is important. Nothing in it says that Congress is acting to nullify existing state damages claims. There are federal statutes that do just that. But they do so in unmistakable terms and generally provide a federal remedy in lieu of displaced state remedies.[11]

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[10] 21 U.S.C. § 360k(a) (emphasis added). In an earlier ruling finding that the MDA did not preempt liability actions for devices not subject to full-scale FDA premarket approval, the Court had observed that the MDA's preemption provision "was primarily concerned with the problem of specific, conflicting state statutes and regulations rather than the general duties enforced by common-law actions." *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 489 (1996).

[11] *See, e.g.*, 42 U.S.C. §§ 2210 *et seq.* (Price-Anderson Act, which federalizes all claims for personal and property damage arising from significant accidents at civilian nuclear power plants); 42 U.S.C. §§ 300aa-1*et seq.* (Vaccine Act, which federalizes all claims arising from personal injuries relating to the administration of vaccines); Air Transportation Safety and System Stabilization Act of 2001, Pub. L. No. 107-42, 115 Stat. 230 (2001) (9/11 Compensation Fund, which substitutes a federal remedy for tort claims 9/11 victims and their families could have asserted against the airlines whose planes were hijacked); 29 U.S.C. §§ 1001 *et seq.* (Employee Retirement Income Security Act of 1974, which federalizes disputes over employment related benefits).

Nor was there any indication that Congress, which enacted the MDA in response to tragedies like the Dalkon Shield — brought to light because of liability litigation — wanted to deprive persons injured by defective devices the compensation they could obtain only through liability actions. And, for most of the MDA's history, FDA took the position that the MDA did not preempt state liability actions.[12]

All of that changed in 2002 when the agency made a 180-degree shift in position. Abandoning its decades-old stance, FDA aggressively sought to participate in private state liability cases on behalf of device manufacturers to argue that the MDA's preemption provision immunized device manufacturers from liability under state law. Without informing the public, states or local governments, or seeking their views on its new position, FDA filed *amicus* briefs in several cases — always on the side of the manufacturer, never on the side of the injured patient — urging the courts to find the injured patient's claim preempted. As a result of FDA's reversal of field, lower courts began adopting FDA's new position, which created a split of authority among lower courts. To resolve the question, the Supreme Court granted review in *Riegel v. Medtronic, Inc.*

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

On February 20, 2008, the Court ruled that the MDA expressly preempts state liability actions for PMA devices.[13] The majority opinion does not address the *purpose* of the MDA, let alone suggest that preemption is right as a policy matter. Instead, the majority relied on the word "requirement," which, the Court held, is a term of art that may, and in the MDA does, encompass state liability actions.[14] The majority reasoned that because state liability actions seek to impose "requirements" on device manufacturers "different from, or in addition to," those imposed by FDA, they are preempted under a literal reading of the MDA. In the majority's view, Congress' selection of the word "requirement" demonstrates that *Congress* made the choice to preempt state law.[15]

As a result of *Riegel*, thousands of cases like the one that Joshua Oukrup's family brought against Guidant and settled will no longer be viable. FDA's premarket approval of a device would, standing alone, require dismissal of the case, even if the device proves to be unsafe, and even if the device's label fails to provide physicians and patients with adequate information to assess the device's

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[13] The Court's ruling in *Riegel* applies *only* to PMA devices. As noted, the Court had previously ruled in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), that state liability actions involving non-PMA devices approved by FDA were not preempted.

[14] *Riegel*, 129 S.Ct. at 1007-10.

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

risks. The one exception noted by the *Riegel* Court is where the manufacturer violated duties imposed by FDA. In those instances, the *Riegel* ruling would "not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements."[16]

Riegel deals a body blow to injured consumers and their families. The device industry tries to minimize *Riegel*'s impact by making two points. One is that *Riegel* applies only to PMA devices, which comprise a very small fraction of the devices on the market. The second is that *Riegel* does not preclude actions based on the manufacturer's breach of federal duties.

To be fair, both of these points are correct. But they overlook the real-life consequences of the decision. Make no mistake, the impact of *Riegel* on consumers will be severe and far-reaching. The devices specifically approved by FDA are generally the ones that sustain or support life, and failure of those devices all too often leads to dire, and at times, fatal consequences. Thus, the fact that FDA also permits other, non-PMA devices on the market is beside the point. The devices that matter most are PMA devices. Nor is the remote prospect that someone injured by a PMA device might have a claim based on a violation of a *federal* requirement much comfort. In most cases, a finding of preemption with respect to life-saving or life-sustaining PMA devices simultaneously immunizes manufacturers for their errors, removes incentives to prevent or correct errors,

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[16] *Riegel*, 129 S.Ct. at 1011.

and deprives consumers injured through no fault of their own of compensation that historically has been available under state law. None of these consequences is defensible as a matter of public policy.

Let me make one last point about medical devices. FDA has had to strain to suggest that its approval of a device is a warrant for its safety. In fact, premarket approval is a one-time licensing decision based on whether the device's sponsor has shown a "reasonable assurance" of safety — a standard far less rigorous than for drugs, which must be shown to be safe and effective for their intended use. Unlike drugs, which are extensively tested, medical devices are often approved on the basis of a single clinical trial, in part because of the ethical problems in testing experimental medical devices on human subjects. Once on the market, FDA engages in only limited surveillance. There is no provision in the MDA for devices to be periodically re-certified by FDA. As a result, defective devices typically remain on the market until the manufacturer commences a "voluntary" recall, often in response to adverse publicly generated by state liability litigation.

FDA's track record demonstrates the agency's inability to single-handedly protect the American people against defective and dangerous medical devices. Just in the past few years, we have seen massive recalls of defibrillators,[17]

[17] Consider the case of the Guidant defibrillators, discussed in my Pepperdine article. By the time they were withdrawn from the market, more than 24,000 of the defective devices had been implanted in patients, who then faced the daunting decision of whether to have replacement surgery. *See generally In Re Guidant Corp. Implantable Defibrillators Prod. Liab. Litig.*, 2007 WL 1725289 (D. Minn.

pacemakers,[18] heart valves,[19] and heart pumps[20] — which have exacted a terrible toll on the patients who have had them implanted in their bodies, and who often face the daunting prospect of explantation and replacement surgery. Post-*Riegel*, these patients will now be left with no remedy at all: no compensation for the pain and suffering they endure, no reimbursement for the expenses of surgery and a replacement device, and no recompense to their loved-ones should they die as a result of a defective device. Making matters worse, manufacturers will have little economic incentive to recall swiftly defective devices, since they are immunized

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June 12, 2007); Barry Meier, *FDA Expanding Inquiry into Heart-Device Company*, N.Y. Times (Aug. 25, 2005), at C3.

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

[19] The St. Jude Silzone heart valve is another instructive case. This valve was approved on the basis of only scanty testing involving 20 human subjects. After St. Jude starting selling the valve, testing revealed that its silver coating not only did not protect against infection, but it also caused the valves to leak. Litigation publicized the risk and forced St. Jude to recall the problem valves, but not until they had been implanted in over 36,000 patients. *See generally In re St. Jude, Inc. Silzone Heart Valves Prod. Liab. Litig.*, 2004 WL 45503 (D. Minn. Jan. 5, 2004); *see also Bowling v. Pfizer*, 143 F.R.D. 141 (S.D. Ohio 1992) (class action involving 55,000 patient implanted with different defective heart valve).

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

from liability in tort, and virtually certain to face no enforcement sanction from FDA, which has essentially withdrawn the regulatory cop from the beat.[21]

Premarket approval is an important process intended to put an end to the marketing of devices without meaningful testing and with no assurance of safety. But PMA process, by itself, cannot replace the continuous and comprehensive safety incentives, information disclosure, and victim compensation that state liability law has traditionally provided.

The Court's opinion in *Riegel* makes it clear that the decision about preemption is one for Congress. The ball is squarely in Congress' court. I would urge Congress to act swiftly to restore the historic availability of state liability law protections both to ensure that compensation is available to people injured through no fault of their own and to place economic incentives on device manufacturers to take reasonable measures to protect consumers from defective or unsafe devices.[22]

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

[22] Overturning the result in *Riegel* will require Congress to amend the MDA to make clear that the preemption provision, 21 U.S.C. 360k(a), does not preempt state liability action. One approach would be to define the word "requirement" to mean only positive state law (i.e., statutes and regulations); another would be to insert a "savings clause" to make explicit that nothing in the provision should be construed to displace state liability law.

II. FDA Preemption and Drugs.

As noted above, FDA's reversal of field on device preemption was part of a broad realignment by FDA on preemption more generally. Pushed by the agency's political, non-career appointees, FDA now asserts that virtually every one of its regulatory actions — from setting standards for sun-screen products to the labeling of over-the-counter drugs — preempts state law.[23]

The most important and inexplicable of these shifts was FDA's about-face on the agency's long-expressed position that its regulation of drug labeling does not immunize drug manufacturers from failure-to-warn claims. FDA's prior position was not surprising. The Federal Food, Drug and Cosmetic Act does not contain, and never has contained, a preemption provision for drug products. Indeed, when the 1938 Act was being debated, Congress was told that the bill did not need to create a federal claim for damages because state law already permitted such actions to be brought.[24] And the Act has been amended repeatedly since then, but Congress has never given the pharmaceutical industry the immunity from liability it has long coveted. Indeed, the one preemption provision in the Act applicable to drugs cuts decidedly against FDA's position. When Congress added the efficacy requirements to the Act in 1962, it added a provision

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[23] *See* FDA, *Sunscreen Drug Products for Over-the-Counter Human Use, Proposed Amendment of Final Monograph; Proposed Rule*, 72 Fed. Reg.49070, 47109-10 (Aug. 27, 2007); FDA, *Over-the-Counter Human Drugs; Labeling Requirements; Proposed Rule*, 71 Fed. Reg. 74474, 74481 (Dec. 12, 2006).

[24] *See* Hearings on S. 1944 before a Subcomm. of the Sen. Comm. on Commerce, 73d Cong., 2d Sess. 400 (1933) (statement of W. A. Hines).

that states: "Nothing in the amendments . . . shall be construed as invaliding any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law."[25]

Nonetheless, FDA now maintains that state failure-to-warn litigation threatens its ability to protect the public health. A determination in civil litigation that an FDA-approved label fails adequately to warn of risks may force manufacturers to add warnings not approved by FDA, or even warnings that FDA considered and rejected. For that reason, FDA asserts that most failure-to-warn litigation is preempted.[26] As noted, FDA's change of position has triggered a substantial wave of preemption litigation over drug claims, with the vast majority of courts rejecting FDA's pro-preemption position.[27] The Supreme Court will address this issue in October 2008 when it reviews *Wyeth v. Levine.*

This seismic shift in policy must be viewed against the backdrop of the agency's long-held, and repeatedly expressed, position to the contrary. Let's be clear about one thing: Litigation against drug manufacturers for failing to warn physicians and patients about the risks that attend the drug is nothing new.

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[25] *See* 76 Stat. 780, 793 (1962).

[26] *See* FDA, *Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Products,* 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006).

[27] *See also Riegel v. Medtronic, Inc.*, 199 S. Ct. at 1019 & n.16 (Ginsburg, J., dissenting) (noting that "[c]ourts that have considered the question have overwhelmingly held that FDA approval of a new drug application does not preempt state tort suits," and citing cases so holding).

Perhaps the most celebrated failure-to-warn case — *Thomas v. Winchester* — was decided by the New York State Court of Appeals in 1852.[28] Since *Thomas*, there has been a steady stream of failure-to-warn litigation against drug companies, both pre- and post-dating the creation of the modern FDA in 1938, and its forerunner in 1908.[29] Notwithstanding FDA's awareness of this litigation, until recently, FDA steadfastly took the position that its regulation of drug labeling did not preempt state failure-to-warn litigation.[30] Indeed, FDA took exactly the

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[28] 6 N.Y. 397 (1852). In *Thomas*, the court held that, even though the consumer purchased the mis-labeled drug from a pharmacist, the consumer could sue the manufacturer of the drug which was responsible for the mislabeling.

[29] These cases are legion, but a sample includes: *Blood Balm v. Cooper*, 83 Ga. 457, 10 S.E. 118 (1889); *Valmas Drug Co. v. Smoots*, 269 F. 356 (6th Cir. 1920) (applying Michigan law); *Hruska v. Parke, Davis & Co.*, 6 F.2d 536 (8th Cir. 1925) (applying Missouri law); *Halloran v. Parke, Davis & Co.*, 245 A.D. 727, 280 N.Y.S. 58 (N.Y. App. Div. 1935); *Wechsler v. Hoffman-La Roche*, 198 Misc. 540, 99 N.Y.S.2d 588 (N.Y. App. Div. 1950); *Wright v. Carter Products*, 244 F.2d 53 (2d Cir. 1957) (applying Massachusetts law). By 1964, the pace of drug litigation had accelerated to the point that one commentator called the 1960s "the era of the drug" and observed that "drugs are being withdrawn from the market in unprecedented numbers because of undesirable side effects which are deemed to outweigh whatever therapeutic value the drugs may have." Paul Rheingold, *Products Liability – The Ethical Drug Manufacturers' Liability*, 18 Rutgers L. Rev. 947 (1964). The reasons for this growth in litigation were (1) the fact that states had abandoned defenses based on lack of privity; and (2) the 1962 amendments to the FDCA required manufacturers to show that the drug was not just safe, but was also effective for its intended use. Post-1960, representative cases include: *Gottsdanker v. Cutter Laboratories*, 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (Cal. Dist. Ct. App. 1960); *Sterling Drug v. Cornish*, 370 F.2d 82 (8th Cir. 1966) (applying Missouri law); *Love v. Wolf*, 226 Cal. App. 2d 379, 38 Cal. Rptr. 183 (Cal. Ct. App. 1964); *Lake v. Konstantinu*, 189 So. 2d 171 (Fla. Dist. Ct. App. 1966). *See also Riegel v. Medtronic, Inc.*, 199 S. Ct. at 1017 n.11 (canvassing state law drug liability cases).

[30] *See, e.g.* FDA, *Final Rule: Labeling and Prescription Drug Advertising: Content and Format for Labeling for Human Prescription Drugs*, 44 Fed. Reg. 37434, 37447 (June 26, 1979) (making clear that FDA regulation for labeling "do not

opposite position, emphasizing that it did "*not* believe that the evolution of state tort law will cause the development of standards that would be at odds with the agency's [drug labeling] regulations."[31] Thus, FDA's current argument that state liability actions — which turn on claims that the manufacturer withheld important safety information from physicians and patients — impair FDA's ability to protect the public health deserve especially close scrutiny.

In an article recently published in the *Georgetown Law Journal*, former FDA Commissioner David A. Kessler, M.D., and I make three key points why, in our view, FDA's position on drug preemption cannot be sustained.

1. Failure-to-warn litigation does not challenge FDA's decision to approve a label for a new drug, or even the agency's final say over the form and contents of drug labeling. Instead, failure-to-warn litigation challenges the *company*'s failure to revise its labeling to warn physicians and patients about risks unknown at the time of approval, or risks that turn out to be graver than the company and FDA originally thought.

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prohibit a manufacturer . . . from warning health care professionals whenever possibly harmful adverse effects associated with the use of the drug are discovered. The addition to labeling and advertising of additional warnings . . . is not prohibited by these regulations."); FDA, *Prescription Drug Product Labeling; Medication Guide Requirement*, 63 Fed. Reg. 66378, 66384 (Dec. 1, 1988) ("FDA does not believe that the evolution of state tort law will cause the development of standards that would be at odds with the agency's [drug labeling] regulations. FDA's regulations establish the minimal standards necessary, but were not intended to preclude the states from imposing additional labeling requirements"); *see also* Margaret Jane Porter, *The Lohr Decision: FDA Perspective and Position*, 52 Food & Drug L.J. 7 (1997).

[31] FDA, *Prescription Drug Product Labeling; Medication Guide Requirement*, 63 Fed. Reg. 66378, 66384 (Dec. 1, 1988) (emphasis added).

FDA's own regulations impose a duty on drug manufacturers to modify labeling without delay when hazards emerge, and expressly authorize labeling changes without the agency's advance approval. When FDA approves a new drug, it also approves the drug's proposed labeling. The manufacturer must follow the FDA-approved label and must submit a supplemental new drug application (NDA) to FDA if it wishes to change the label.[32] Ordinarily, the manufacturer waits for FDA approval before making the change. However, FDA rules create an exception in cases where a manufacturer makes a labeling change "[t]o add or strengthen a contraindication, warning precaution, or adverse reaction," or "[t]o add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product."[33] In those cases, manufacturers may

[32] It is important not to overstate FDA's authority over labeling. Until the 2007 amendments, FDA lacked authority to dictate labeling changes to manufacturers. As a result, it took FDA over a year to force Merck to place a warning for heart attack and stroke on Vioxx, and even then the agency acceded to Merck's demand that the warning be a weak one and not the stronger warning the agency favored. *See FDA's Drug Approval Process: Up to the Challenge?* Hearings before the S. Comm. on Health, Educ., Labor and Pensions, 109th Cong., 23 (2005) (testimony of Sandra Kweder, M.D., Deputy Dir., Office of New Drugs, FDA) (explaining that Merck "rejected many of our proposals," and defending the lengthy delay in the labeling change by observing that "we don't have the authority to tell a company, this is how your label has to look."). To be sure, the FDA Amendments Act of 2007 makes explicit that FDA has authority to compel labeling changes, but it also requires the agency to first negotiate with the company, a process that will likely take months, even if the agency accelerates it. *See* FDAAA, Tit. IX, sec. 901(a), § 505(o)(4), 121 Stat. 924-26.

[33] *See* 21 C.F.R. § 201.80(e) (requiring labels to contain requisite warnings); 21 C.F.R. § 314.70(b)(2)(v)(A) (setting forth general rule that drug labeling must be approved by FDA); *Id.* § 314.70(c)(6) (setting forth exceptions that permit manufacturers to change the label without first obtaining FDA approval).

change labeling without first securing FDA's permission, so long as they file a supplemental NDA at the same time they make the labeling change.

Thus, the common law duty enforced in failure-to-warn litigation — namely a drug company's duty to take all reasonable measures to alert physicians and patients to previously unknown hazards — is no different than the duty FDA itself imposes on drug manufacturers. That is why the steady procession of failure-to-warn cases has not interfered with FDA's regulatory efforts for all of these years: the duties imposed by state and federal laws are parallel and mutually reinforcing.[34]

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[34] The Vermont Supreme Court's decision in *Levine v. Wyeth,* 2006 Vt. 107 (Vt. 2006), *cert. granted,* 128 S. Ct. 1118 (2008), is a good illustration of the utility of state law in enforcing broader public policy norms. Ms. Levine was a musician who suffered through two amputations, ultimately losing an arm that ended her career, because the anti-nausea drug Phenergan, was administered through the "Push IV" method, inadvertently introducing Phenergan directly into her artery. The corrosive nature of Phenergan can lead to catastrophic tissue damage if it enters a patient's arterial blood flow. This risk was realized when an error in Levine's IV- Push procedure injected the drug into her arteries and caused her injuries. Wyeth was well aware of this risk. Yet its labeling did not clearly warn physicians or patients. Wyeth's defense was that it had submitted proposed labeling changes to FDA, which rejected them. But the Vermont Supreme Court found neither proposal sought to change the warning regarding administering the drug by intravenous injection, and thus the submissions did not provide Wyeth a defense. *Levine,* ¶ 23. FDA approved Phenergan's label over twenty-five years ago. Even assuming that Phenergan's label appropriately balanced the drug's known risks when approved, there is no evidence that FDA revisited its assessment of the IV-Push method to verify that the warnings were appropriate in light of new adverse-reaction information. Yet, by 1976, both the agency and Wyeth were aware of the risk. *See id.* The jury's verdict assessed liability for Wyeth's failure to improve the warning as the risk became increasingly clear. Because FDA never took definitive action with respect to new information about this increased risk of arterial damage, no possible conflict exists between any FDA decision and a jury verdict requiring Wyeth to pay damages. The verdict provides incentives for Wyeth to improve its warnings, but it does not *require* the

There is one more point to make about these FDA regulations, which are known as the "change being effected," or CBE, regulations. Apparently in response to industry pressure, FDA has recently proposed modifications the CBE regulations to limit the ability of manufacturers to make changes without first securing FDA's approval to situations in which the change is based on "new" information that had not been available previously to the manufacturer. *See* 73 Fed. Reg. 2848 (Jan. 16, 2008). Not only does this proposal run counter to fundamental notions of public health — public health is threatened if manufacturers have to wait for an FDA greenlight to warn physicians and patients of a serious, undisclosed risk — it is also transparently an effort to fortify industry's position in *Wyeth v. Levine*. I would urge this Committee to find out whether, as many suspect, this proposal was initiated by industry and not FDA, perhaps by demanding all FDA correspondence, emails, and other records reflecting communications with individuals outside FDA on this matter.

2. More fundamentally, FDA's preemption argument presupposes that the agency has the resources to perform the monumental task of ensuring that the labeling of drugs on the market reflects current safety information. It does not. According to the November 2007 report of a blue-ribbon panel appointed by the FDA Commissioner, "[t]he scientific demands on the Agency far exceed its capacity to respond. This imbalance is imposing a significant risk to the integrity

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manufacturer to do anything that is inconsistent with that which FDA has instructed it to do.

of the . . . regulatory system, and hence the safety of the public."[35] The Institute of Medicine reported in 2006 that FDA "lacks the resources needed to accomplish its large and complex mission today, let alone to position itself for an increasingly challenging future."[36] These reports are no surprise. FDA regulates products that amount to one-quarter of consumer spending in the United States,[37] but it has only 9,000 employees nationwide.[38] According to the most recent statistics, FDA's Office of New Drugs, which reviews new drug applications, employs over 1,000 physicians and scientists to review the approximately 100 new drug applications each year and to supervise post-marketing studies. In contrast, FDA's Office of Drug Safety, the unit charged with monitoring adverse events associated with the 3,000 prescription drugs (and 11,000 drugs altogether) on the market, has about 100 professional employees.[39]

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[35] FDA SCIENCE AND MISSION AT RISK: REPORT OF THE SUBCOMMITTEE ON SCIENCE AND TECHNOLOGY 1.1 (2007).

[36] INST. OF MED., THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC 193 (National Academies Press 2006).

[37] FDA News, *The Food and Drug Administration Celebrates 100 Years of Service to the Nation* (Jan. 4, 2006).

[38] Food and Drug Administration, *An Overview of the FDA*. In addition to drug safety, these employees also review applications to market new medical devices, monitor the safety of the medical devices on the market, inspect drug and device manufacturing facilities, inspect virtually all of the non-meat food products sold in this country (including a rising flood of imported foods), inspect food processing and storage facilities, regulate dietary supplements, oversee the safety of the blood supply and tissues for transplantation, regulate radiologic and biologic products, and regulate veterinary medicines and cosmetics. *Id.*

[39] *FDA's Approval Process: Up to the Challenge?*, Hearings before the S. Comm. on Health, Education, Labor and Pensions, 109th Cong., 10 (2005) (Joint

I recognize that Congress has recently enacted comprehensive amendments to the Food, Drug, and Cosmetic Act, which will bolster the agency's statutory authority and shore-up, to some extent, the agency's flagging resources. But as Senator Ted Kennedy warned, even with added resources, "[t]he resources of the drug industry to collect and analyze . . . safety data vastly exceed the resources of the FDA, and no matter what we do, they will always have vastly greater resources to monitor the safety of their products than the FDA does."[40]

3. State liability litigation helps uncover and assess risks that are not apparent to the agency during a drug's approval process, and this "feedback loop" enables the agency to better do its job. FDA approval of drugs is based on clinical trials that involve, at most, a few thousand patients and last a year or two. These trials cannot detect risks that are relatively rare, affect vulnerable sub-populations, or have long latency periods. For this reason, most serious adverse effects do not become evident until a drug is used in larger population groups for periods in excess of one year.[41] Time and again, failure-to-warn litigation has

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Statement of Sandra L. Kweder, M.D., Deputy Director, Office of New Drugs, and Janet Woodcock, M.D., Acting Deputy Commissioner for Operations, Food and Drug Administration, to the Committee on Health, Education, Labor and Pensions, U.S. Senate) (March 1 & 3, 2005) (reporting that for fiscal year 2005 the Office of Drug Safety had about 90 full time employees, but projecting for fiscal year 2006 an increase to about 110 full time employees).

[40] 153 CONG. REC. S11,832 (2007) (statement of Sen. Kennedy).

[41] *See, e.g., Hearings on Risk and Responsibility: The Roles of the FDA and Pharmaceutical Companies in Ensuring Safety of Approved Drugs, Like Vioxx,* Before the H. Comm. on Government Reform, 109th Cong., 23, 55 (2005) (testimony of Steven Galston, Acting Director, Center for Drug Evaluation and Research, FDA).

brought to light information that would not otherwise be available to FDA, to do+ctors, to other health care providers, and to consumers. And failure-to-warn litigation has often preceded and clearly influenced FDA decisions to modify labeling, and, at times, to withdraw drugs from the market.[42]

Congress is, of course, acutely aware of the shortcomings in FDA's ability to police the marketplace on drug safety, which have been driven home by the recent public health failures involving widely-prescribed drugs like Vioxx, Bextra, Baycol, Rezulin, Celebrex, Avandia, and Evra Ortho. FDA's current claim that it, and it alone, can single-handedly discipline this market is a difficult claim to accept.

For the Committee's purposes, however, the key point here is that the agency's claim that it is authorized to direct the preemption of state law is not based on any mandate from Congress. Congress has not dictated preemption with respect to drug products, nor has it delegated to FDA the authority to define the borderline between federal regulation and state tort law. Nonetheless, the agency claims authority to cut off state law *now* because, at some point in the future, a state court *might* issue a ruling that undercuts the agency's regulatory authority. With all respect, that is a decision for Congress, not agency officials, to make. Congress should stand ready to ensure that its decision not to preempt state liability law is respected by both FDA and the courts.

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[42] *See, e.g.,* Lasser, *et al.*, *Timing of New Black Box Warnings and Withdrawals for Prescription Medications*, 287 J. Am. Med. Ass'n 2215, 2218 (2002); Aaron Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks,* 287 J. Am. Med. Ass'n 308, 310 (2007) (citing examples).

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

Dr. Curfman.

STATEMENT OF GREGORY CURFMAN

Dr. CURFMAN. Thank you, Mr. Chairman, members of the committee. My name is Greg Curfman. I am the executive editor of the New England Journal of Medicine. I am here with my colleague, Dr. Stephen Morrissey, the managing editor, to provide testimony from our Journal. We will argue that preemption of common law tort actions against drug and medical device companies is ill advised and will result in less-safe medical products for the American people.

For nearly 200 years the New England Journal of Medicine has published articles on new drugs and medical devices. Some have succeeded, but others have failed, in most cases owing to problems with safety. We have learned that approval of a new product by the FDA by no means guarantees its safety, and FDA approval is just one step in the assessment of long-term safety.

Let me give some specific examples.

Now, we have heard a lot about Vioxx today, and I want to tell you a little bit more about Vioxx, a drug used to treat arthritis pain which was approved by the FDA in 1998. In 2000 we published in the Journal a clinical trial showing that Vioxx relieved pain while causing less gastrointestinal bleeding than traditional pain killers; however, we were disturbed by something that we learned later. What was not revealed in that article was that for each episode of serious gastrointestinal bleeding prevented by the use of Vioxx, one heart attack, stroke, or other serious cardiovascular problem was caused by Vioxx.

The FDA was provided with the missing data after the article was submitted, but it was not until 2002 that the label for Vioxx was revised to reflect these cardiovascular risks and it was not until 2004, 6 years after the drug was approved by the FDA, and after millions of people had taken it, that it was finally removed from the market, in part owing to the mounting threat of product liability litigation.

Another example is the diabetes drug Avandia, which after 8 years on the market was shown in a New England Journal article to be associated with an increased risk of cardiovascular problems.

And tonight, Mr. Chairman, at 5, we will publish a study on our Web site showing that Trasylol, a drug that has been used for 15 years to control bleeding after open heart surgery, results in an increased death rate in heart surgery patients—5 tonight.

What do we learn from these examples? First, together the drugs I have described have placed millions of Americans at risk, but those who have been harmed have had the right to seek legal redress. Preemption would erase that right.

Second, drugs are approved by the FDA on the basis of short-term efficacy studies, not long-term safety studies.

Third, and importantly, manufacturers may not immediately make public information indicating safety problems with their drugs.

Fourth, the FDA is hampered by a lack of resources and may be slow in resolving drug safety concerns. I say that with a lot of respect for the good work of the FDA.

If drug and device companies are shielded against tort actions by preemption, medical products will surely be less safe. The possibility of litigation is a strong inducement for companies to be especially diligent about the safety of their products. If they are immunized against product liability suits, they will surely be less vigilant.

The purported benefit of making drugs and devices available quickly should not outweigh the possibility of redress for patients when safety flaws are discovered later.

Patients injured by unsafe drugs and devices should not be stripped of their right to seek redress through due process of law. Preemption will seriously undermine the confidence that doctors and patients have in the safety of drugs and devices, and preemption will have a chilling affect on the doctor/patient relationship, which is built on a foundation of trust.

Mr. Chairman, members of the committee, we urge you and your colleagues to pass legislation that will eliminate the possibility of preemption of common law tort actions for drugs and medical devices. Removing the right of legal redress is not only unjust, but will also result in less-safe drugs and medical devices for the American people.

Thank you, Mr. Chairman.

[The prepared statement of Dr. Curfman follows:]

TESTIMONY
House Committee on Oversight and Investigations
Wednesday, May 14, 2008
Preemption – Drugs and Medical Devices

My name is Gregory Curfman, and I am the executive editor of the *New England Journal of Medicine*. I am here today along with my colleague, Dr. Stephen Morrissey, the managing editor, to provide testimony from our *Journal*. We will make the case that preemption of common-law tort actions against drug and medical device companies is ill advised and will result in less safe medical products for the American people.

The *New England Journal of Medicine* is nearly 200 years old. Our mission is to publish important advances in medical research, including research on new drugs and medical devices. During my 23 years at the *New England Journal of Medicine*, I and my colleagues have published many articles on new drugs. Some of these drugs have succeeded, but others have failed, in most cases owing to problems with safety.

We have learned over the years that approval of a new drug by the FDA by no means guarantees its safety. It is not uncommon for drugs to be approved by the FDA without long-term studies of their safety. Indeed, FDA approval of a drug is just one milestone along a path to the assessment of long-term safety. It is essential that a drug's safety continue to be carefully monitored during the post-marketing period, because we know that serious safety issues may come to light only after a drug has entered the market. I will give three specific examples that I have encountered in my work at the *New England Journal of Medicine*.

The first is rofecoxib, or Vioxx, a COX-2 inhibitor used to treat arthritis pain, which was approved by the FDA in 1998. In 2000, we published in the *New England Journal of Medicine* a clinical trial called the VIGOR study, which showed that Vioxx effectively relieved pain while causing less gastrointestinal bleeding than traditional nonsteroidal painkillers.

However, something that the *Journal* editors learned later was disturbing. What was not adequately conveyed in that article was the fact that for each episode of serious gastrointestinal bleeding *prevented* by the use of Vioxx, one heart attack, stroke, or other serious cardiovascular problem was *caused* by Vioxx. There was a one-to-one trade-off, but the authors of the article, two of whom were employees of the manufacturer of Vioxx, left most of those data out, and therefore the *Journal*'s readers and the public were not fully informed about this serious problem.

The FDA was provided with the missing data after the article was submitted, but it was not until 2002 that the label for Vioxx was revised to reflect these cardiovascular risks; and it was not until 2004, six years after the drug was approved by the FDA and after millions of people had taken it, that it was finally removed from the market, in part owing to the mounting threat of product-liability litigation.

Example 2 is rosiglitazone, or Avandia, which was approved by the FDA in 1999 for the treatment of type 2 diabetes. It was approved solely on the basis of its ability to lower blood sugar. Whether it would make a difference to patients with diabetes by reducing the risk of cardiovascular disease, the major complication of type 2 diabetes, was unknown, because long-term clinical trials to study cardiovascular end points had not been done.

It came as a surprise when, in 2007, researchers from the Cleveland Clinic reported in the *New England Journal of Medicine* that, on the basis of a meta-analysis of data from multiple studies, Avandia appeared to be associated with an *increased* risk of cardiovascular events, not a decrease. This was a worrisome finding for fragile type 2 diabetics.

Even more surprising, was the revelation that the manufacturer of Avandia had commissioned a similar study in 2005 that showed the same result. To meet legal requirements arising from a lawsuit in New York, the company placed the results of that study on a section of its Web site, but those results were never publicized and never published in a medical journal. Today, nine years after FDA approval, Avandia remains on the market, but in November 2007 a warning about potential cardiovascular risks was added to its label, and its use has declined substantially. Last month the FDA sent a warning letter to the manufacturer for failure to submit reports on a large number of studies on Avandia to the FDA, as required by law.

The third example involves a drug called aprotinin--the brand name is Trasylol--which was approved by the FDA in 1993 and is used to control bleeding in patients undergoing cardiac surgery. In January 2006 a study in the *New England Journal of Medicine* suggested that the use of Trasylol was associated with an increase in heart attack, stroke, kidney failure, and death.

Later in 2006 the FDA held an advisory committee meeting to reexamine the safety of Trasylol. Shortly after the meeting, FDA officials were stunned to learn that the manufacturer had commissioned a similar study, which confirmed the findings in the *New England Journal* article, but had withheld the results from the advisory committee.

Tonight at 5:00 p.m., we will publish on the *New England Journal of Medicine* Web site a large clinical trial that shows definitively that Trasylol, as compared with other drugs used to control bleeding, results in higher mortality in patients undergoing high-risk heart surgery. The editorial accompanying the article states that, after 15 years, in all likelihood this is the end of the story for Trasylol.

What do we learn from these examples?

1. Together, these three drugs have placed millions of Americans and other people around the world at substantial risk. But patients who have been harmed by a drug have had the right to seek legal redress. Preemption would erase that right.

2. Serious adverse drug effects may not become apparent until *after* drugs are granted FDA approval, sometimes *long after* approval.

3. FDA approval by no means guarantees the safety of drugs.

4. The Congress's FDA reform efforts in 2007 made it clear that approval is usually based on short-term efficacy studies, not long-term safety studies.

5. Manufacturers may not immediately make public information indicating safety problems with their drugs.

6. Despite the usually admirable work of the FDA, the agency is hampered by lack of resources in addressing drug safety concerns and may be slow in resolving them.

If drug and medical device companies are shielded against common-law tort actions by preemption, what will be the effect on the safety of our drugs and devices? The answer is intuitively obvious. We recently wrote in an editorial in the *New England Journal of Medicine* that the safety of drugs and devices in our country will almost certainly be diminished. If drug and device companies are immunized against product-liability suits, companies will surely focus less attention on the safety of their products. The possibility of litigation serves as a strong inducement for companies to be especially diligent in scrutinizing their products for safety problems. It is questionable that the purported benefit of making drugs and devices available more quickly should outweigh the possibility of redress when safety flaws are discovered later.

Patients injured by unsafe drugs and devices should not be stripped of their right to seek redress through due process of law. Preemption will undermine the confidence that doctors and patients have in the safety of drugs and devices and will have a chilling effect on the doctor-patient relationship, which has traditionally been built on trust.

Mr. Chairman and members of the Committee, we urge you and your colleagues to pass legislation that will unambiguously eliminate the possibility of preemption of common-law tort actions for drugs and medical devices. Removing this patient right would not only be unjust, but will also result in less safe drugs and medical devices for the American people.

Thank you, Mr. Chairman.

The NEW ENGLAND JOURNAL of MEDICINE

EDITORIALS

A Pivotal Medical-Device Case

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

This spring the Supreme Court of the United States will decide whether premarketing approval of a medical device by the Food and Drug Administration (FDA) immunizes the manufacturer against product-liability litigation in state courts. This decision, we believe, is a matter of particular importance to patients and the medical community.

On December 4, 2007, the Supreme Court heard oral arguments in *Riegel v. Medtronic*.[1] In May 1996, Charles Riegel underwent coronary angioplasty in Albany, New York. During the procedure, the balloon ruptured, and advanced cardiac life support and emergency coronary bypass surgery were needed. Mr. Riegel and his wife subsequently sued Medtronic in a New York court, claiming that the device was defective and the labeling inadequate. Medtronic claimed, however, that any state lawsuit was preempted by a section of the Medical Device Amendments of 1976 to the Food, Drug, and Cosmetic Act.[2]

The 1976 law arose out of the Dalkon Shield disaster. Like all medical devices introduced before 1976, the Dalkon Shield intrauterine device underwent no premarketing assessment of safety or efficacy by any federal agency. In the wake of the thousands of deaths and serious injuries caused by the device, Congress took action, empowering the FDA to regulate all medical devices. To avoid conflict with state laws that, given the absence of any federal oversight, had been enacted to regulate medical devices, the 1976 law included a section that preempted certain state-law requirements that differed from federal (FDA) requirements with respect to the safety and efficacy of devices. This section, §360k(a), was used for two decades to prevent the enactment of state legislation that might conflict with FDA regulation.

In a 1996 Supreme Court case, however, Medtronic attempted to extend preemption beyond the enactment of state laws to include all product-liability claims against medical-device manufacturers in state courts. In a Florida court in 1993, Lora Lohr and her husband had sought damages for an allegedly faulty pacemaker lead manufactured by Medtronic. The company argued that the Medical Device Amendments preempted any damages claims because the device had been approved for marketing by the FDA. In *Medtronic v. Lohr*,[3] the Court's majority opinion, written by Justice John Paul Stevens, held that none of the Lohrs' damages claims were preempted by the 1976 law. Thus, in the *Lohr* case the Court ruled that FDA approval of a medical device did not preclude subsequent product-liability suits in state courts, and the Lohrs' lawsuit (in which a settlement was eventually reached) was allowed to proceed.

In *Riegel v. Medtronic* the company has resurrected the argument dismissed by the Court in *Lohr*. What, then, is the difference between the two cases? In *Lohr*, the pacemaker lead had been approved by the FDA in a "substantial equivalence" process in which, because the design of the lead was deemed to be "equivalent" to that of an existing lead, no further study of the safety and efficacy of the specific device was required. Furthermore, the existing pacemaker lead to which the new lead was judged equivalent had itself never undergone full premarketing assessment and had instead been "grandfathered." In *Riegel*, on the other hand, the angioplasty catheter had received premarketing approval from the FDA in accordance with current standards on testing for efficacy and safety. Medtronic argues that, given the rigor of the FDA approval process, any action at the state level, including tort litigation against the company, would represent a further requirement and thus be preempted under §360k(a) of the Medical Device Amendments. Medtronic ar-

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gues, in effect, that the granting of FDA approval shields any device manufacturer from state tort liability.

Congress worked long and hard last year to reform the FDA in its mission to improve the safety of drugs and medical devices. Congressional scrutiny of the FDA raised serious questions about whether the agency has the authority and resources necessary to do its job. A recent report from the Office of Inspector General of the Department of Health and Human Services reinforced this concern.[4] Thus, a question that the justices will address in *Riegel v. Medtronic* is just how reliable the FDA premarketing approval process is and how much weight to give it. For its part, the FDA in *Lohr* interpreted the Medical Device Amendments as providing no basis for the preemption of state lawsuits. However, in *Riegel*, the FDA has reversed itself and now interprets the same statute as allowing the preemption of state lawsuits.

The decision of the justices in *Riegel v. Medtronic* will be critical for patients' rights and will have enormous impact on manufacturers' responsibilities and the safety of medical devices. Whether drug manufacturers might enjoy the same immunity that device manufacturers are claiming is a question that will also soon come before the Court. Next month the Court will hear a case (*Warner-Lambert v. Kent*)[5] involving the diabetes drug troglitazone, which was withdrawn from the market in 2000 because of liver toxicity. The Court will be asked to decide whether FDA premarketing approval of the drug preempts liability claims in state court.

Ultimately, we believe that the pivotal question for the justices in *Riegel v. Medtronic* resides in what is in the best interest of American society. Is it in the people's interest to shield medical-device companies from product-liability claims? Would such a decision benefit patients by making more lifesaving medical devices available, or would there be adverse effects on the overall safety of devices? Is the FDA premarketing approval process sufficiently rigorous and comprehensive to justify immunization of the industry against tort claims? And if medical-device manufacturers are shielded from liability, what about drug manufacturers? Or would society be better served if patients retained their right to seek legal redress when they believed they had been damaged by a faulty medical device? In the long run, would this result in safer medical devices for patients?

If Congress later concludes that the Supreme Court has come to the wrong conclusion — that is, a conclusion that is too restrictive of patients' legal prerogatives and does not serve the public interest — Congress can then act to clarify the law and leave open the possibility that patients injured by devices or drugs can seek legal redress.

But by rejecting Medtronic's plea for immunity, the Supreme Court can act now to protect patients. From time to time, the Court agrees to hear a case that may have major, even momentous, implications for health care. *Riegel v. Medtronic* is such a case.

1. Donna S. Riegel, Individually and as Administrator of the Estate of Charles R. Riegel, Petitioner, v. Medtronic, Inc.
2. 1976 Medical Device Amendments, 21 U.S.C. § 360c et seq., to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq.
3. Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996),
4. The Food and Drug Administration's oversight of clinical trials. Washington, DC: Office of Inspector General, Department of Health and Human Services, September 2007. (Document no. OEI-01-06-00160.)
5. Warner-Lambert Co., LLc, et al., Petitioners, v. Kimberly Kent, et al.

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Survival after Tachyarrhythmic Arrest — What Are We Waiting For?

Leslie A. Saxon, M.D.

Approximately 225,000 out-of-hospital cardiac arrests occur annually in the United States. It is a little-known fact that at least double that number of cardiac arrests occur in hospitalized patients.[1] Survival after cardiac arrest due to ventricular tachycardia or ventricular fibrillation requires prompt defibrillation, regardless of the setting in which it occurs.[2,3] Therefore, it is clear that timely defibrillation in the hospital is an important determinant of the quality of cardiovascular care.

If out-of-hospital cardiac arrest from ventricular tachycardia or ventricular fibrillation occurs

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Chairman WAXMAN. Thank you very much, Dr. Curfman.

Ms. Ruther.

STATEMENT OF CHRISTINE RUTHER

Ms. RUTHER. Thank you. My name is Christine Ruther, and I am a medical device engineer with over 15 years experience in testing and designing medical devices, and in compiling information for regulatory submissions such as those filed with the FDA.

I am appearing today to speak as an engineer and as a Republican in support of legislation to ensure that all medical devices are subject to market forces, including the possibility of lawsuits by injured patients, which I believe is critical to help ensure the safety and effectiveness of those medical devices.

I have two main reasons for this position.

First, the FDA has a prescribed list of information that must be provided for pre-market review. In very general terms, we provide a description of the device and its intended use, as well as top level engineering documents. It is important to note that FDA does not directly test our products, so we also provide safety testing data, as well as clinical data, to the FDA.

The FDA reviewers inspect the data, ask questions, and then make the decision on whether our device can be sold in the United States.

I believe manufacturers are generally being truthful and are not necessarily trying to hide information, and I believe the FDA reviewers are diligent in their duties; however, not all manufacturers understand the level of care that should be taken in testing and other areas, and sometimes seemingly irrelevant data is omitted that would make a difference to FDA's review.

An analogy may help. Let's say that I am in a State where I am required to show that my car is safe to drive. In other words, that it is roadworthy. I select a mechanic to review the engine while I inspect the body and the tires. I send these reports off to the States Car Division where an inspector reviews the paperwork. After writing to ask me additional questions, the inspector makes a decision without having personally inspected my car that my car is, in fact, safe to drive.

The inspector relies completely not only on my integrity, but also on my ability to select a competent mechanic, my ability to evaluate my own tires, and to make other judgments. And it is possible that some key information that I deemed irrelevant and the inspector never asked for was omitted. For instance, if it doesn't bother me if I only take short drives, I may not mention that the car tends to stall after it has been running for about an hour.

The review is an excellent first step, but even the most rigorous review does not ensure that my car is safe, and a rigorous FDA review, unfortunately, cannot fully ensure that a device is safe and effective.

On a second point, as designers and manufacturers we are constantly balancing conflicting goals. Getting to market quickly and maximizing profit creates a tension with taking sufficient time to consider and test for possible risks, and, when necessary robustly addressing issues.

After arising at a resolution for such a conflict, a colleague of mine will generally ask us to proceed that argument with, Ladies and gentleman of the jury. He is not asking us to determine if the choice is legally defensible, but rather he wants to make sure that we are comfortable publicly defending our choices.

We often collect data that FDA does not ask for and therefore we do not submit. I believe that it is vitally important to keep the possibility of public disclosure of all data and our decisionmaking processes, especially with regards to risk and remediation, in front of those of us who design and manufacture medical devices.

The concept of preemption can cause a fundamental shift in the risk/benefit equation. We go from, Ladies and gentlemen of the jury, to potentially, What is the minimum the FDA will accept? And if we no longer need to consider the ladies and gentlemen of the jury, do we then diminish the regulatory manager's argument for testing beyond the FDA requirements to ensure that we really are selling a great product? Does Dilbert's pointy-haired boss see preemption as a get-out-of-jail-free card and as a license to push for the minimum?

Finally, the reality is that, despite the very best efforts of designers, manufacturers, and the FDA, not all device problems are identified in pre-market testing. The potential for being held liability is a key force in assuring the most conscientious testing and the prompt correction of hazards when they are identified.

I hope this information allows you to better weigh the advantages and disadvantages of any proposed legislation, and I will remain at your disposal to answer any questions.

Thank you.

[The prepared statement of Ms. Ruther follows:]

Christine Ruther
President & Engineer
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My name is Christine Ruther, and I am a medical device engineer. I am appearing today to speak in support of legislation to ensure that all medical devices are subject to market forces, including the possibility of lawsuits by injured patients, which I think is critical to help ensure the safety and effectiveness of medical devices. As a medical device engineer, I believe that it is important to keep the possibility of liability in front of those of us who create and maintain medical devices.

My testimony will focus on 3 points:

1. Lawsuits create a market force that puts pressure on those of us who design or market engineers to achieve and maintain safe and effective medical devices.
2. As good as FDA reviewers are, they will never be in a position to know for certain that any particular device is as safe and effective as the manufacturer's data seems to show.
3. Pre-emption of patients' lawsuits has had and may continue to have unintended consequences.

First (regarding market forces): As a medical device engineer, I believe that it is important to keep the possibility of liability in front of those of us who create and maintain medical devices. When hearing a possibly suspect approach, a colleague of mine is fond of asking, "If you precede that explanation with 'ladies and gentlemen of the jury', are you still satisfied with your position?" He's not really asking if the position is defensible from a legal standpoint. Rather, he wants his fellow engineers to consider if they would be comfortable defending their position should the specific decision become public.

There are a variety of routine pressures that designers and manufacturers face each day. Typical pressures include: wanting to be the first to market for a novel device or a new feature, fulfilling all demands for product, and wanting to contain costs. These pressures sometimes conflict with our goals of ensuring that we release only the absolutely highest quality, most reliable products. As we try to balance these pressures, the words that draw our attention are not "what would the FDA think," but "ladies and gentlemen of the jury." If we are comfortable that a design is adequate from a safety and effectiveness perspective when considered in light of "ladies and gentlemen of the jury," we proceed. Whether or not losing the threat of liability would lower the overall safety and effectiveness of devices, it will remove an important weapon in the battle to ensure a reasonable degree of safety and effectiveness.

Second (regarding limitations of FDA's review): FDA has talented reviewers who undoubtedly work tirelessly to ensure safe and effective medical devices reach the market. However, they are not (and can never be) as familiar with the nuanced issues associated with any one particular device as the designers and manufacturer are. The fullest understanding is (and will always be) limited to those of us who are intimately involved with the particular product.

The FDA has a prescribed list of information that device manufactrurers must provide. In very

general terms, manufacturers seeking marketing approval provide a description of the device and what it is intended to do. So that the FDA can evaluate the details of the design, we provide our top level engineering specifications, risk analyses, and similar information. We also provide laboratory and clinical test data so that the FDA can determine if we have met our design goals and if the overall device is safe and effective for its intended use. The FDA reviewers perform diligent reviews and ask many relevant questions which we respond to, providing additional information and test data. But throughout the process, we the manufacturers are the ones providing the information, and we always have more information than is submitted to the FDA. We don't lie, but we may omit information that we don't believe to be relevant to FDA's concerns. Such information might include features that were dropped from the project due to time or cost constraints, patent application information, or additional engineering level tests performed outside of the formal test plans. All are reasonable data to omit, but might provide insight that, if known, would sway FDA's opinion or result in additional questions. Or, for example, sometimes additional engineering testing is in progress to address issues that the FDA might raise. If the FDA asks, the manufacture will have (or soon will have) the data to address the concern. If the FDA doesn't ask, the data will not necessarily be shared with the agency.

On any given day with any given manufacturer and any given FDA reviewer, an important issue may be missed. Pre-emption, inappropriately limits a manufacturer's focus to satisfying the FDA, whereas lawsuits expand a manufacturer's focus to broader concerns about whether a device is really as safe and effective as it can be. Stated differently, as designers, we do not generally fear that the FDA will find fault with our designs, risk analyses, or other work. Irrespective of the FDA, we respect the prospect of liability, where a fellow engineer who is perhaps either highly competent in our type of product or very knowledgeable in the details of the design control techniques we use could find fault in our approaches or results

Third (regarding unintended consequences of pre-emption): Pre-emption of claims based on injuries from premarket approved medical devices may skew market forces or encourage companies to seek more rigorous review than needed, thereby unnecessarily using valuable FDA resources. Pre-emption also eliminates and possibly even discourages an important incentive for companies to make changes to improve products as real-world use demonstrates that such changes are needed. The reality is that, despite the best efforts of designers, manufacturers, and the FDA, not all device problems are identified in premarket testing. The potential for being held liable is a key force to ensure the most conscientious testing and to prompt correction of hazards as soon as they are identified.

And finally, would the pre-emption line tend to expand over time? Could one make the argument that what really makes the PMA process unique is the need to provide clinical data? If so, then it would be a reason to expand pre-emption to devices reviewed under FDA's 510(k) process where clinical data was, as an exception, required. And, if these devices make that hurdle, how far behind would be all medical devices reviewed under FDA's 510(k) process? If this happens, do we then have the unintended consequence of the majority of medical devices not being subject to market forces? It seems this could be a slippery slope.

Summary: It is my opinion that:

1. Allowing market forces to maintain pressure to achieve and maintain safe and effective

medical devices is desirable,

2. FDA reviewers cannot know for certain that any particular device is safe and effective based on the data presented to it by the manufacturer before the device is on the market, and
3. Pre-emption has had and may continue to have unintended consequences.

If no approved device had ever been recalled and if no approved device had ever injured a patient due to design or manufacturing failures, then pre-emption would be appropriate. But some devices have been recalled, and these and other devices have injured patients. As long as injuries and defective devices remain a reality, the possibility of liability will help ensure that designers, manufacturers, and others involved with medical devices remain vigilant.

I hope the information I've provided allows you to better weigh the advantages and disadvantages of any proposed legislation on the matter. Thank you.

My Background: I received my BS in Physics at Xavier University and MS in Biomedical Engineering at The Ohio State University. I have over 15 years experience in the medical device industry. I have worked in a variety of companies and with a wide range of medical devices, from relatively simple suction pumps to high tech implants. I currently assist medical device manufacturers in compliance & safety engineering, and in quality & regulatory affairs on a consulting basis.

Chairman WAXMAN. Thank you very much, Ms. Ruther.

Mr. Clark.

STATEMENT OF DAVID CLARK

Mr. CLARK. Thank you. Good afternoon. I am Utah House Majority Leader David Clark and Chair of the National Conference of State Legislators Standing Committee. The standing committees of NCSL are the policymaking entities of that organization. I am grateful to Chairman Waxman, Ranking Member Davis, and other members of the House Oversight and Government Reform Committee for inviting me here to speak to you about the impact of regulatory preemption on States.

From NCSL's vantage point and that of the States, Federal agencies have taken inappropriate liberties with the regulatory process. The preemptive regulatory actions of the Federal agencies have been steadily on the rise over the past several years and show no signs whatsoever of decreasing.

There are many troubling aspects of this trend for States.

First, unlike State legislatures, Federal agencies are comprised of unelected Federal bureaucrats with no constituency. Agency bureaucrats have no real accountability to those impacted by the agency's preemptive regulations. Conversely, State legislatures do answer to their constituents.

Second, Federal agencies have gone so far to preempt established bodies of State law without even having enabling legislation passed by Congress to do so. FDA did this in the prescription drug labeling rule. This type of preemption is an affront to our Federalist system. It is dishonest and ignores the rules and the role of the States as implementers of these regulations.

In my State, if an agency were to preempt local ordinances in the absence of State statutory authority, I, as a State legislator and majority leader of my chamber, would hear about it right away. My legislature would take immediate action to reign in that agency and correct the problem.

In Utah we have a Legislative Review Committee whose job it is to examine rules submitted to it by our agencies. After examining each rule, this committee must present a report to the presiding office of the Utah House and Senate. If the rule is not proper, we act upon it.

Third, agency preemptions have sought to regulate in areas that have traditionally been left by Congress for the States to address. Again, FDA prescription drug labeling rule falls into this category, as it seeks to prohibit State lawsuits and erode State tort and consumer protection laws.

In Utah, State product liability law has been around for decades, and our products have careful consideration of court decisions and statutory laws. Unelected Federal bureaucrats in Washington, DC, should not—repeat, should not—get to tell my legislature and my judges how to address these topics.

Finally, NCSL, in concert with other States and local government national associations, sought to increase communication between our Federal and State governments by refining the provisions of Executive Order 13–122, better known as the federalism Executive order. This Executive order requires agencies to consult with State

and local elected officials or their national associations like NCSL whenever a proposed rule contains preemption provisions.

The purpose of this consultation is for agencies to better understand the preemptive impact of a proposed regulation and to minimize the preemption. Agencies like FDA, however, have chosen to ignore it.

I have written in length about NCSL's experience with the FDA during the promulgation of this prescription drug rule in my written testimony. That experience was not a positive one, and the State's impact of the FDA final rule has undermined State policy in several States. Federal agencies do not seem to care that the entire body of State law out there that has been passed by legislatures and handed down by State court judges that represents the balancing of competing interests on a particular subject.

In the absence of congressional authority and without even knowing what the State impact of these actions would be, Federal agency bureaucrats should not have the authority to swipe laws out with a single stroke of the pen. However, and even moreover, Congress should not let them.

Mr. Chairman, I sincerely hope that you will introduce and move the medical device safety act that you have drafted and will seek to restore some of the traditional State authority with agencies, and now even the Supreme Court has stripped away, move it back to the States.

NCSL is prepared to work with you to pass this important first step legislation. My hope is that, with your leadership, more legislation to address the States' concern on preemption will be introduced and passed. Our States, your States deserve this respect.

I would be happy to answer any questions that you might have and thank you for your time today.

[The prepared statement of Mr. Clark follows:]

The Honorable David Clark
Majority Leader, Utah House of Representatives

Standing Committee Chair,
National Conference of State Legislatures

Testimony
Before the Committee on Oversight and Government Reform
United States House of Representatives

May 14, 2008

Good morning. I would like to thank Chairman Waxman, Ranking Member Davis and the members of the House Oversight and Government Reform Committee for inviting me here this morning to speak to you about the preemption crisis facing states today. My name is David Clark and I am the Majority Leader of the Utah House of Representatives and the current Chair of the National Conference of State Legislatures Standing Committees. NCSL is a bipartisan organization representing the legislatures from the 50 states and the U.S. Territories. I ask that my written testimony be accepted and incorporated into the record.

NCSL is troubled by the growing trend in Congress, the federal agencies and now the United States Supreme Court to pass legislation, promulgate rules and render decisions that have a substantial detrimental impact on states because of their intrusively preemptive nature. NCSL has tracked these preemptions in our Preemption Monitor, a publication that we initiated to alert state legislators nationwide to the alarming number of federal legislative, regulatory and judicial preemptions. As a result of federal preemption, a significant part of the policy jurisdiction of state legislatures and of city and county officials has been lost or compromised. States and localities cannot legislate in response to their citizens' needs when the federal government has preempted the policy field. What is lost is the capacity for regional and local self-government.

The cornerstone policy of NCSL is our Federalism policy. Set forth in this policy resolution are the building blocks for a sound and robust state-federal partnership. The NCSL Federalism policy makes several important observations about the role of the states and federal government in our federal system of which we should all take note. Specifically, our policy recognizes that individual liberties can be protected by dividing power between levels of government; in other words, division of power among federal and state governments also serves

as a check on the power of each. As the Supreme Court properly stated in *New York v. United States* (1992): "When one level of government becomes deficient or engages in excesses, the other level of government serves as a channel for renewed expressions of self-government."

Our Federalism policy also recognizes the importance of state innovation and creativity. As Justice Brandeis wrote in his dissenting opinion in the case of *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932)(Brandeis, J., dissenting):

"It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country." Finally, our federalism policy speaks to the role of federal agencies in our system of government and states. Our policy states that it is inappropriate for unelected bureaucrats in federal agencies to preempt the laws of the sovereign states. Additionally, federal agencies should not preempt state law absent clear congressional authority to do so.

NCSL believes that states are often in the best position to act quickly on a given issue and, in so acting, be more sensitive to the needs of the American people. NCSL believes that federalism allows for greater responsiveness and innovation though local self-government. State and local legislatures are accessible to every citizen. They work quickly to address problems identified by constituents –much more quickly than Congress. It is also worthy of mention that states have different ways of solving these problems. The diversity found within our state laws helps refine our democratic system. When those state policy decisions are overridden by Congress, the agencies or the Supreme Court, the results are significant to states.

Enhancing NCSL's broad federalism policy are our policies regarding product liability and tort reform. Our product liability policy opposes federal preemption of state product liability

laws in the absence of comprehensive evidence demonstrating that state product liability laws are inadequate thereby requiring federal intervention. In fact NCSL believes that if there were uniform federal product liability laws, and state laws were indeed preempted, state tort liability laws, insurance regulations and workers' compensation laws would all be negatively impacted. NCSL's tort reform policy states that it is particularly improper for the federal government, either through legislation or agency regulation, to restrict or redefine when a citizen may access state courts. All of these policy resolutions are longstanding ones and were passed by NCSL's general membership in a bipartisan fashion. Together, they represent NCSL's core belief that states should maintain authority over areas of product liability and general tort law and that the three branches of the federal government should tread carefully when it comes to preemption of state authority in these areas.

NCSL is committed to the goal of restoring balance to our dual system of government by inviting Congress to reexamine some of its own recent preemptive actions. We also call upon Congress to provide appropriate oversight and scrutinize some of the more recent federal agency actions that have frustrated this policy goal. We also ask Congress to pass legislation to reverse the disturbing trend of regulatory and judicial preemptions of state laws. We at NCSL hope that this hearing will serve as an important first step toward repairing the damage that has been done to states through ill-considered preemptive actions.

Agency Actions and State Implications

In recent years, agency preemptions of state law without legislative foundation, through the rulemaking process are rampant. Everyone from the National Highway Traffic Safety Administration (NHTSA) to the Internal Revenue Service seems to be jumping onto the preemption bandwagon. Perhaps the most insidious preemptions have occurred at the Food and

Drug Administration. Every state has well developed bodies of product liability and consumer protection laws that may even date back prior to the establishment of FDA as an agency. Indeed, product liability and consumer protection issues have always been subjects reserved to the states to figure out. In Utah, there are various protections for citizens who are harmed by defective products. These statutes can be found in the Utah Product Liability Act contained in Title 78, Chapter 15 of the Utah Code. This portion of our Code was first enacted in 1977, but caselaw on issues of product liability date back to at least 1953. Over the last fifty-five years, the Utah legislature has refined our product liability statutes and our state courts have addressed issues of product liability, further refining our state common law. As a result, there is a robust body of product liability laws in our state. If these laws are federally preempted, more than a half century of discussion and debate on what laws best meet the needs of Utah's citizens and businesses will be totally lost. Cases decided by the Utah Supreme Court such as *Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 2003 UT 43; 79 P.3d 922; 485 Utah Adv Rep 16; 2003 Utah LEXIS 105 *Grundberg v. Upjohn* , 813 P.2d 89; 160 Utah Adv. Rep. 20; 1991 Utah LEXIS 44, *Barson v. E. R. Squibb & Sons*,682 P.2d 832; 1984 Utah LEXIS 799, and *Reeves v. Geigy Pharmaceutical, Inc.*, 764 P.2d 636; 95 Utah Adv. Rep. 19; 1988 Utah App LEXIS 177 would have been barred, and the further evolution of product liability law in our state would be halted. Is this what was contemplated by our Founding Fathers?

There have been recent rulemakings by FDA that have undermined entire bodies of state consumer protection laws. An example of this type of rulemaking in which NCSL was unfortunately involved occurred in December, 2005. At this time, the FDA determined that it was time to finalize a rule on prescription drug labeling which had lain dormant for five years. NCSL was aware of this rule, but did not submit comments because the original language of this

NPRM expressly stated that there would be no federalism implications because the proposed rule would not preempt state law. See, Federal Register, Vol. 65, No. 247, p. 81103, December 22, 2000. Because of the express statement of non-preemption, the consultation requirements of Executive Order 13132, the Executive Order on Federalism, were not triggered. Executive Order 13132 is a guidance document to agencies and "requires" them to consult with elected officials or their representative national organizations to discuss preemptive impact of proposed rules with the goal of minimizing the preemptions.

On December 30, 2006, NCSL learned that the FDA planned to finalize its rule and include a policy statement that the provisions of the prescription drug labeling rule would preempt state product liability laws. NCSL approached FDA officials and asked for three things: a consultation meeting pursuant to the Federalism Executive Order, a copy of the proposed language, and that the FDA re-open the comment period to allow NCSL to file formal comments on this very significant and preemptive change. The FDA ignored the first request. The second and third requests were denied. However, it is interesting to note that during this rule's 5-year dormancy period, the FDA had allowed certain pharmaceutical companies to submit comments pertaining to preemption after the expiration of the comment period. States, however, were not given the same deference, and the FDA finalized this rule in mid-January, 2006. Perhaps the most shocking aspect of this rulemaking is that the preemption of state law took place not through an act of Congress, but rather by unelected federal bureaucrats who basically usurped state tort law policy over the objections of the states. Last year, an unsuccessful legislative attempt to undo the impact of this rule was made in S. 1082, the "Prescription Drug User Free Act of 2007 (PDUFA) which was part of The Food and Drug Administration Revitalization Act. Unfortunately, just before passage, language was stripped from all ten House drafts of the

PDUFA legislation which, if included, would have provided a safeguard against FDA preemption of state laws and would have undone the FDA Prescription Drug Labeling Rule preamble preemption which I discussed above.

Mr. Chairman and committee members, creative solutions to public problems can be achieved more readily when states are accorded due respect. Uniformity for uniformity's sake does not justify preemption.

NCSL believes that the preemption of state product safety and consumer protection laws is tantamount to an unfunded federal mandate on the states. Federal preemption is not just an affront to state policy choices. It also carries a price tag for the states. If citizens of my state of Utah cannot go to state court to obtain redress for injuries suffered as a result of a defective product or a file a failure to warn case against a drug company their only recourse is to turn to the state for help through my states'social service agencies. The cumulative result of this is a financial burden on Utah and every other state as well. Here's an example of how the cost of preemption plays out in the states. NCSL was involved in a NHTSA rulemaking that proposed to preempt state wrongful death laws in vehicle rollover cases. To thwart this proposed rule, NCSL contracted with the Pacific Institute for Research and Analysis to conduct an analysis of how much a federal preemption of this nature would cost states. The ensuing report found that the financial burden placed on State governments as a result of the preemption provision contained in the NHTSA rule would be between $49 and $71 million per year, primarily as a result of increased state-paid medical and disability costs.

Proposed Solutions to Excessive Preemptions

In 1999, NCSL and other state and local government national associations worked closely with the Clinton Administration to revise and refine the Federalism Executive Order,

Executive Order 13132. Although the Federalism Executive Order is a noble first step in increasing agency awareness and accountability for preemptive regulations, as my testimony has shown, it does not go far enough for one main reason: an executive order is a guidance document that does not carry the weight of statute and, therefore, cannot be enforced. There are no consequences for its violation. There is no incentive for agencies to adhere to the Federalism Executive Order's requirements in any meaningful way. NCSL has found that in the years following the effective date of the Federalism Executive Order, overall agency adherence to its provisions has been spotty at best. As I have illustrated, agencies like the FDA have, at times, chosen to ignore its requirements altogether. Other agencies, like the Department of Homeland Security and the Department of Health and Human Services, choose to circumvent it by issuing interim rules so that the Federalism Executive Order cannot be applied; and independent agencies, like the Consumer Product Safety Commission, are expressly exempted from its requirements.

NCSL believes that the Federalism Executive Order should be codified into statute to protect elected state policymakers from the uninformed actions of unelected federal agency bureaucrats. Additionally, we believe that the provisions of this new law should be extended to legislative actions undertaken by Congress. Specifically, NCSL would like to see a new piece of congressional legislation that contains the following principles:

1. **Partnership and enhanced consultation**. NCSL supports provisions to provide for consultation with state and local elected officials or their representative national associations prior to the consideration of any legislation or federal regulations that would interfere with or intrude upon historic and traditional state and local rights and responsibilities.

2. **Rule of Construction.** NCSL supports provisions to ensure that, absent any explicit statement of intent to preempt or absent any irreconcilable conflicts with state law, any ambiguities would be construed in favor of state law.

3. **Enforcement.** NCSL supports provisions to ensure congressional and agency accountability and enforcement. The point of order in the Unfunded Mandates Reform Act (UMRA) has made members of Congress increasingly aware of potential impacts of federal laws and regulations on state and local taxpayers. We believe that a mechanism to ensure this recognition regarding preemption in both the legislative and the regulatory arenas is critical.

4. **Legislative Report.** NCSL supports efforts to include a federalism assessment in every committee and conference report. This will help members appreciate the potential impact on our levels of government, our taxpayers, and our programs.

5. **Agency Impact Statement.** Early in the rulemaking process, it is essential to codify the provisions of the Federalism Executive Order to ensure that <u>every</u> federal agency engages in a meaningful consultation process with elected state and local officials or their national associations, as well as with other impacted stakeholders. This will help to determine the potential impact of final administrative rules on our partnership.

NCSL recognizes that passing this type of broad legislation will be no easy task and in the alternative suggests that bills like the Medical Device Safety Act of 2008 cosponsored by Representative Pallone and the Chair of this Committee, Representative Waxman, is an important first step toward reversing the troubling trend of agency and judicial preemptions of

state law. This legislation is supportive of state product safety laws and reinstates the primacy of state laws for product safety. The bill recognizes that some decisions, such as how to protect people from defective products, are best made by the state legislatures, not by the federal government. NCSL applauds your leadership and willingness to support the states in achieving a more harmonious federalism system.

NCSL believes that these recommendations, taken in the cumulative, will benefit everyone – state and local governments, the federal government and the general public -- because they foster greater transparency, greater cooperation between governmental units and more information sharing all around. NCSL is prepared to work with you, Chairman Waxman, Ranking Member Davis and members of the House Oversight and Government Reform Committee Committee, to make these policy considerations a legislative reality. I believe that this type of legislation will serve to strengthen and fortify the intergovernmental partnership. My hope is that with your leadership, legislation to address the states' concerns on preemption will be introduced soon so that it can successfully make its way through the legislative process during this session. Thank you for this opportunity to testify.

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

Dr. Calfee.

STATEMENT OF JOHN E. CALFEE

Mr. CALFEE. Mr. Chairman, I am honored to testify in today's hearings. I am John E. Calfee. I am an economist with the American Enterprise Institute here in Washington, DC, where I do research and writing on tort liability and FDA regulation and other topics. I am the ninth witness today. I would like to offer a different perspective.

I support limited FDA preemption of State tort law, and I do so basically for three reasons: First is the issue of compensation. Contrary to what is often assumed, the liability system is an extremely inefficient way to provide compensation for harm from drugs, partly because of the increasingly important role of punitive damages and damages for pain and suffering. Attempts to use the liability system for comprehensive compensation essentially transforms the tort system into an insurance system, with corresponding increases in drug prices. Because this insurance tends to be worth less than its cost to consumers, the net effect can be to discourage the use of even very valuable drugs.

This was demonstrated vividly in the 1980's when liability suits nearly destroyed the childhood vaccine market. Preemption would serve to ameliorate these adverse effects of liability litigation.

Second is the issue of information. Liability litigation has proved to be a very poor tool for improving product information. Mass litigation for Vioxx, for example, has failed to improve public information about that drug, and here I depart somewhat from the views of some of the other witnesses.

In the case of tobacco, where the product is essentially unregulated and where litigation has been massive, the result has not been to improve information about the product, itself.

A particularly serious problem is liability litigation based upon allegations of failure to warn about the dangers of approved drugs. This kind of litigation is likely to trigger unnecessary contra-indications and other forms of over-warning to the detriment of patients.

On the other hand, there is little evidence that litigation will actually improve the pharmaceutical information environment. This is partly because the FDA already tends the require excessively detailed safety disclosures and warnings.

Finally, there is the issue of drug safety. Contrary to what is often assumed, there is no evidence of a drug safety crisis today, or even a decline of drug safety in recent years, nor is there evidence of the FDA's slighting of drug safety. In fact, there are compelling reasons to believe that, if anything, the FDA tends to be overly cautious in its emphasis on safety at the cost of delaying the approval of new drugs and new indications. This is mainly because the FDA is criticized far more for problems with approved drugs than it is for being too slow to approve new drugs or new indications.

Liability suits tend to reinforce these adverse tendencies toward over-caution. Preemption, on the other hand, would tend to ameliorate this negative effect from liability litigation.

On the whole then, I suggest that more liability litigation is not always a good thing. In certain situations, liability lawsuits could even cause harm. This is particularly likely to occur when juries are given the power to overrule FDA deliberations on label contraindications and other warnings. Preemption is a useful tool to prevent this from happening.

Thank you, Mr. Chairman. My written testimony has considerably more detail on these three points.

[The prepared statement of Mr. Calfee follows:]

Written testimony before the

United States House of Representatives

Committee on Oversight and Government Reform

In Public Hearings on

FDA Preemption of State Tort Liability Lawsuits

on FDA-Regulations Drugs and Devices

Wednesday, May 14, 2008

John E. Calfee, Ph.D.

email: calfeej@aei.org – tel: 202-862-7175

American Enterprise Institute

1150 17th St., NW

Washington, D.C.

I am honored to testify in these hearings on FDA preemption of state product liability lawsuits relating to FDA-approved drugs and medical devices. I will focus mainly on pharmaceuticals. In doing so, I will address the practical consequences of FDA preemption of liability litigation, and will largely ignore the complex legal issues to be discussed by other witnesses. By way of background, I am an economist who has specialized in government regulation, tort liability, information, and FDA regulation, beginning with my experience in the Bureau of Economics at the Federal Trade Commission in the 1980s.

The central issue in these hearings is whether state tort litigation against FDA-approved drugs and devices – especially lawsuits alleging failure to warn – should be preempted by FDA regulation including the content of the labels that accompany all approved drugs and devices. A current case now before the Supreme Court, *Wyeth v. Levine*, may strongly affect the role, if any, of preemption.

A commonly held view is that state tort liability litigation can do much good and little harm because such litigation provides added protection to patients and consumers through compensation for injury, better information in the form of new warnings and disclosures, and improved drug safety (e.g., Kennedy 2008; Glantz and Annas 2008). I believe these views are largely unsupported, however. Economic reasoning and historical experience strongly suggest that FDA preemption, if it becomes standard law, would actually tend to improve patient welfare.

Tort Liability Suits as a Compensation Mechanism

The original function of the tort liability system was to deter unsafe activity by causing firms and others to internalize the full costs of their actions. Since the 1960s, compensation has come to play an equal or perhaps predominant role. In the meantime, punitive damages, once rare, have assumed a crucial role in liability litigation, especially in shaping the many settlements through which most liability suits are resolved (Priest

1991; Rubin, Calfee, and Grady 1997; Moore and Viscusi 2002). Punitive damages are of course paid in addition to compensatory damages.

A substantial stream of research demonstrates that liability litigation is an extraordinarily inefficient tool for compensating patients. In asbestos litigation, which has been studied more than any other kind, plaintiffs have received only about forty percent of total damages payouts. Transaction costs including attorney and expert fees accounted for the rest (Hensler 1993). Some of the research critical of tort liability as a compensation mechanism has appeared in medical journals, sometimes accompanied by proposals to replace some components of the liability system (Studdert and Brennan 2001). An additional problem is the increasing role played by damages for pain and suffering (i.e., nonpecuniary losses). Here, the problem is that systematic use of pain and suffering damages amounts to a form of mandated insurance. There are compelling arguments that such insurance is often not worth its cost to consumers (Calfee and Winston 1993). The problem is worse for products (including virtually all pharmaceuticals) that usually prevent far more harm than they cause. Burdening pharmaceutical manufacturers with full compensation for apparent harm from their products would dramatically increase prices, transferring the burden to patients and payers generally. This can work to suppress even very valuable products, as recognized by former FDA Commissioner Mark McClellan (McClellan 2003). That this is more than a theoretical possibility became clear when liability engulfed the child vaccine market in the 1980s. As it became clear that the extra insurance bundled with childhood vaccines was worth far less than its cost, shortages ensued and manufacturers abandoned the market. The situation was resolved by replacing the liability system altogether (Manning 1994, 1996, 1997).

Information and Preemption

Much if not most litigation subject to FDA preemption involves allegations of failure to warn. The effects of preemption on drug information are therefore a central issue. It would be a mistake to assume that because liability suits would induce

pharmaceutical manufacturers to provide additional information and warnings, litigation is bound to improve information for patients and physicians. Experience has provided little reason to expect this kind of improvement in the wake of liability litigation. For example, a detailed and largely favorable assessment of the role of litigation in pharmaceutical markets noted that Vioxx litigation has done little or nothing to improve knowledge about that drug (Bernstein 2007, p. 1055). Even in the case of massive litigation sponsored by state governments and non-profit organizations – that relating to tobacco – there little if any evidence that public knowledge of the health effects of smoking was improved even though cigarettes are among the least regulated products (while pharmaceuticals are arguably the most regulated) (Schuck 2008, n. 104, citing Rabin 2001, p. 201).

Given that we cannot assume that tort liability litigation will improve product information, we must pay attention to how it actually works in pharmaceutical markets, where regulation is already exceptionally strong. In *Wyeth v. Levine*, for example, the dispute was essentially over whether Wyeth should have strengthened the warning for the drug Phenergan in order to contra-indicate a specific way to administer this drug in emergency situations. It seems clear from the record that the FDA itself had issued detailed warnings about administration but had also declined to contra-indicate this particular method because physicians would probably decide it was in fact the best method in some circumstances.

Rather than focusing narrowly on the debate over one particular contra-indication, however, we must pay attention to the larger effects limiting or prohibiting FDA preemption. An unwise contra-indication is an example of the more general problem of over-warning. It has become clear that liability worries encourage manufacturers to propose very detailed warnings and even to resist emphasis on relatively greater dangers for fear of being held accountable for downgrading rarer but still dangerous risks. Some of this was described in a series of *Wall Street Journal* articles that noted, for example, that the three erectile dysfunction drugs on the market each carried labels more than 20

pages long (Hensley 2005a, 2005b). The FDA has for many years sought to modify and improve drug labels while avoiding the constant danger of over-warning (Galson 2005).

Many new warnings and contra-indications are bound to be considered for a wide variety of drugs and devices. In the absence of preemption, firms will know that they (and physicians) may be subject to large damages verdicts at the will of juries that necessarily focus on a highly specific personal tragedy rather than on societal trade-offs. This applies with particular force to possible contra-indications. Physicians are likely to treat contra-indications as outright bans because to prescribe in the face of a labelled contra-indication is to court a malpractice lawsuits and punitive damages if anything goes wrong no matter how extensive the warnings might be. The result is that patients who would have benefitted from the contra-indicated use will be denied those benefits even if the expected net benefit greatly exceed the likelihood of harm.

If the FDA tended to provide too little in the way of warnings and contra-indications, one might doubt that preemption would serve a useful role. But there no reason to expect this problem. The FDA is legendary for its detailed probing and assessment of nearly anything related to drug safety, and does this under intense scrutiny from Congress, medical academia, the public press, and many others (cf. Schuck 2008, p. 14-15). It clearly seeks to balance the costs and benefits of information provided on drug labels and through other means. In fact, the agency probably tends to require too much of this kind of information. For example, the label for Rotateq, the rotavirus vaccine, was recently amended to include a warning against intestinal blockage, a rare but genuine problem with an earlier rotavirus vaccine since removed from the market. It did so even though extremely large clinical trials involving tens of thousands of subjects had revealed no excess likelihood of blockage for the vaccine compared to a placebo (*Wall Street Journal*, May 2, 2008).

Perhaps the most vigorous wave of criticism of the agency for inadequate warnings in recent years arose in connection with "suicidality" (roughly speaking, suicidal thinking) among youthful users of the SSRI class of antidepressants. Facing relentless criticism from litigators, politicians, popular press editorialists, and elite

medical journals, the FDA implemented its strongest "black box" warning for all antidepressants, not just SSRIs (because there was little reason to think that older drugs, which can cause fatal overdoses, are safer). Subsequent research taking a variety of approaches has found that SSRI use is strongly associated with lower, not higher, suicide rates, and that the highly publicized warnings probably did more harm than good by reducing antidepressant use. In particular, a series of reports has found that there is a striking, inverse relationship between SSRI prescriptions and youth suicides in a variety of data sets and that the imposition of new FDA warnings (beginning with public health alerts) is strongly associated with reduced antidepressant prescribing for children (and younger adults) and higher suicide rates (Shogren 2004; McKeown, Cuffe, and Schulz 2006; Ludwig, Marcotte, and Norberg 2007; Brent 2007; Gibbons et al. 2007; Lubell et al. 2007; Bridge et al. 2007; Pfeffer 2007).

The reasons why FDA is more likely to lean toward over-warning rather than under-warning become clearer when one looks at drug safety itself.

Drug Safety and Preemption[1]

Those who oppose FDA preemption of tort liability lawsuits for failure to warn and other reasons often seem to assume that the FDA has tolerated an unduly low level of drug safety (Glantz and Annas 2008). There is essentially no systematic evidence for this view. In its widely cited 2006 report on drug safety, the Institute of Medicine began by noting, "The committee did not attempt to document whether or not a drug safety crisis exists, and this report should not be interpreted as commenting on that claim one way or the other" (p. 1-1). Even when looking at the leading anecdotes that have aroused intense criticism of drug safety in the past few years, there is little reason to think drugs have become less safe or are unduly unsafe. I have already mentioned antidepressants. Also informative is the lengthy and exhaustively studied series of events that began with the

[1] This section draws upon my written testimony in the Feb. 27, 2008 hearings on drug safety and the FDA before the House Committee on Appropriations, Subcommittee on Agriculture and FDA.

withdrawal of the arthritis pain reliever Vioxx at the end of September 2004. As the FDA presciently pointed out at the time, it was far from clear that Vioxx or its competing Cox-2 inhibitor, Celebrex, was significantly riskier than the much older non-steroidal anti-inflammatory drugs (NSAIDs) they replaced, given that these older drugs had never been subjected to rigorous clinical trials like the one that brought Vioxx down. Subsequent research has largely vindicated that view, with the entire class of NSAIDs (old and new, Cox-2s or not) now bearing heart attack warnings (Calfee 2005; Kearney et al. 2006; Warner and Mitchell 2008).

This is hardly surprising. Even for products that are subject to far less regulation, no systematic evidence has emerged that the U.S. liability system in the U.S. improves safety (Moore and Viscusi 2002; Rubin and Shepherd 2007). In fact, there are compelling reasons to think that in balancing safety against the benefits of new drugs, the FDA tends to give too much weight to safety and not enough to benefits. The reasons lie in the biased incentive structure facing the FDA staff. The unrelenting criticism visited on the FDA since the Vioxx withdrawal illustrates a profound disparity how the public penalizes two different kinds of regulatory error. When FDA staff members decide whether the benefits of a proposed new drug exceed its risks, they know that if they commit what is often called a Type I error – the approval of a drug that turns out to be insufficiently safe once marketing begins – their error will usually become known (a "public error"). This can and often does lead to impassioned criticism of the agency and to correction of the error (although more often than not, critics fix upon something that was probably not an error at all). On the other hand, a Type II error – the failure to permit marketing of a drug that would in fact provide benefits in excess of harms – is typically detected by relatively few people (a "private error"), and its deleterious effects can persist more or less indefinitely.

The effect is to bias even the most conscientious FDA regulators toward exercising excessive caution and requiring excessive drug testing. This first became apparent in a stream of research on the "drug lag" of the 1960s and 1970s, when FDA approvals trailed far behind those in European nations. This research revealed no

consumer benefit in terms of safer drugs, yet similar approval lags continued for years afterward (Peltzman 1973, 1974; Wardell and Lasagna 1975; Katin and Brown 1995). Yet slow drug approvals here did not bring extra safety. An analysis of the United States, Spain, and the United Kingdom yielded essentially identical drug-withdrawal rates despite the more rapid drug-approval timelines in the European countries (Bakke, et al. 1995). Also, research has made clear that the advent of user-fee funding via the 1992 Prescription Drug User Fee Act has worked to the benefit of patients by accelerating the arrival of new drugs (Philipson, et al., 2005).

There is anecdotal evidence that soon after the Vioxx withdrawal and ensuing criticism, the FDA began to be even more cautious in approving new drugs and new indications (Harris 2005). Last year, for example, the FDA refused to approve the pain reliever Arcoxia and the weight-loss drug Accomplia even though both had been approved by the European Union and many other nations (Gottlieb 2007; Wadman 2007). The FDA has also been unreceptive to some promising new drugs for advanced cancer, including Provenge, Genasense, and others (Usdin 2007a; Miller and Henderson 2007; Miller 2007; Pardoll and Allison 2004). The 2007 FDAAA legislation, which is rooted in the view that the FDA staff has consistently neglected drug safety, has probably reinforced the FDA's innate tendency toward over-caution (Calfee 2007).

Finally, too little attention has been paid to another potent force: market-driven manufacturer incentives to maintain drug safety. Such incentives operate with powerful effect in far less regulated high-tech industries such as automobiles, petroleum, and electronics. As in other industries, pharmaceutical manufacturers rely heavily upon maintaining their reputation among customers (especially physicians) for product safety and efficacy. Post-approval clinical trials play a central role in this process. These trials are undertaken to expand markets, but they necessarily open the door to new and possibly alarming (as well as reassuring) safety information. Often, post-approval trials are bigger, longer, and more informative than the trials undergirding drug approvals. Often, they force revisions in accepted views of such basic matters as, for example, the benefits of

lowering serum cholesterol or the safety of all NSAID pain relievers (Topol 2004a; Wadman 2007).

Conclusions

The question of whether FDA regulatory rulings should preempt state or common law tort liability litigation for failure to warn and similar allegations turns on the question of whether such litigation would improve the pharmaceutical market in terms of compensation, information, and product safety. For three reasons, the absence of preemption is likely to worse markets and harm patients on the whole. First, the liability system is an extraordinarily inefficient mechanism to achieve compensation for harms from pharmaceuticals. The attempt to provide compensation through comprehensive liability litigation is likely to burden pharmaceuticals with excessive costs that would raise prices and tend to discourage the use of valuable drugs.

Second, the absence of preemption would make it far easier for litigation to induce new contra-indications and other warnings that on the whole are more likely to cause over-warning and under-use of essential drugs instead of improving the pharmaceutical information environment. One reason is that the pressure for excessive warnings is sufficiently intense that the FDA is unlikely to forego useful warnings, and will sometimes mandate excessively detailed warnings. And third, there is little reason to think that drug safety has suffered in recent years or that FDA incentives are such as to cause the agency to slight drug safety. Indeed, strong forces exert pressure to give too much weight to safety in comparison to approving new drugs and new indications. Further growth in liability litigation would reinforce these tendencies, to the disadvantage of patients, while preemption can provide a valuable check on these adverse consequences of litigation.

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Chairman WAXMAN. Thank you. Your written testimony, of course, is part of the record in full.

Mr. Vladeck, let me start my questions with you. These lawsuits are by people who are injured, and they are claiming that the manufacturer of a drug or device didn't do what would be required of them, what a reasonable company would do. Isn't that what the issue is all about in these lawsuits?

Mr. VLADECK. Right. That is the question that the jury or the judge would have to decide.

Chairman WAXMAN. So there are two reasons for lawsuit, one for compensation. The company didn't do right, therefore the injured person should be compensated. The second reason for these lawsuits is that it makes companies concerned in advance that if they did something wrong they could be sued, and therefore incentivize them, as we might say, to make sure they are doing everything right.

Mr. VLADECK. That is right. I think Ms. Ruther put it about as well as anyone has, which is it makes companies worry about suppose they don't play by the rules and they get caught. Is it going to cost them some money?

Chairman WAXMAN. The question that I want to ask you is why don't we have all these lawsuits at the Federal level? Why should they be at the State level? If we had a Federal law, like FDA approving drugs, and there turns out to be a problem with the drugs or devices, why should we have this at the State level?

Mr. VLADECK. Congress considered that very question 70 years ago when the first Food and Drug Act was enacted, the Food, Drug, and Cosmetic Act was enacted. Congress decided not to put in a right of action in to the Federal food and drug laws because the States already permitted these kinds of suits, and so Congress made a deliberate decision 70 years ago to let Mr. Clark's State, or Senator Clark's State, to set its own liability rules.

But let me make one quick point about that. Concerns about disuniformity, which have cropped up repeatedly, and I believe Congressman Shays raised that, that is a red herring. If the drug company loses a case, it doesn't have to change its label. Ultimately, of course, the FDA will exercise final control over the label. But what will happen is the company will have to go back and take a hard look and say, Is this a risk that needs to be warned about? And if so, how do we go about making sure there is no recurrence?

Perhaps this is what Mr. Shays was driving about. If the company decides this is just an aberrational jury verdict that was wrong and the product is safe and it doesn't pose the risk, then the company will probably just ignore it.

Chairman WAXMAN. What if I were concerned about the fact that 50 States are going to have different label requirements? Should I be concerned about this matter?

Mr. VLADECK. It can't happen. The Food and Drug Administration does exercise final control, but the problem generally arises from the other direction. We talked a lot about Vioxx. It took the FDA over a year to force Merck to put a warning on Vioxx, a serious warning on Vioxx, about the heart attack and stroke risk. Why did it take the FDA a year? Because it didn't have the authority then to tell Merck that it had to place that warning on its label.

Now, I know Congress has changed the law to explicitly give the FDA the authority, but even under the new legislation it is going to take months. Even if the FDA goes through the process and accelerates it, the way the new statute permits it to do, it will take months.

Chairman WAXMAN. So preemption would say that we shouldn't just rely on FDA; we should hold the manufacturer accountable, and if we were going to rely on the FDA, there are going to be so many delays at FDA that we may not have a very good system at FDA to protect us, so we ought to be able to use the tort system, as well.

Is all this premised on the idea that the FDA can be relied on and has the capacity to regulate drugs and medical devices effectively?

Mr. VLADECK. The FDA does a great job, given its resources, but it is not perfect. Since this issue first surfaced 30 or 40 years ago, the FDA consistently took the position that it needed State liability actions to give it information and to place an important discipline on the market that it could not possibly place.

Chairman WAXMAN. And that has always been the position of the FDA until the Bush administration, hasn't it?

Mr. VLADECK. Right.

Chairman WAXMAN. So FDA is not complaining that their powers are being limited and they are not going to be able to make sure that the drugs are as safe as possible?

Mr. VLADECK. Well, they are now complaining.

Chairman WAXMAN. Well, now. It is interesting that they are now complaining, when at the same time we have seen a dramatic drop of enforcements by the FDA against drug companies. They used to send warning letters from the agency that there are violations of the Federal requirements, but these warning letters have fallen over 50 percent 2000 to 2005. It is a 15-year low. During the same period of time the number of seizures of mislabeled, defective, and dangerous products declined by 44 percent. A rational drug and medical device company would take a look at FDA's lack of diligence and say, Well, I shouldn't worry about it because the FDA is not ever going to go after me. They are not even enforcing the law.

Mr. VLADECK. Right. The shrinkage of FDA enforcement is nothing short of stunning. In the last several years the FDA has brought no criminal prosecutions, the number of enforcement actions had declined more sharply than is imaginable, so the regulatory cop is off the beat.

We have talked about a lot of regulatory failures here today, the Guidant heart defibrillator. We have talked about Vioxx. There has been no sanction imposed by the FDA. The only discipline on the marketplace that is meaningful these days is the tort system. The statistics are there for anyone to see. The report was commissioned by the FDA, and this part of it was written by a preeminent food and drug lawyer who represents the food and drug industry, and so these are the statistics he complied based on the FDA's own records. They are astonishing.

Chairman WAXMAN. Thank you very much.

Mr. Braley.

Mr. BRALEY. Thank you, Mr. Chairman.

We have a mutual friend who is a constituent of mine who shares your passion for oversight of the FDA, and that is Republican Senator Charles Grassley. Senator Grassley initiated an effort that led to Congress mandating that the Centers for Medicare and Medicaid Services sponsor a study by the Institutes of Medicine to address the problem of medication errors. It is the third publication in the quality chasm series that I was holding up earlier called Preventing Medication Errors.

I was shocked when Dr. Calfee testified there is no evidence of a drug safety crisis, because this publication that was released on July 20, 2006 by the Institutes of Medicine reached a very different conclusion. It found that every year there are 7,000 deaths due to medication errors, and that the increased cost of preventable adverse drug events affecting hospitalized patients cost us $2 billion every year.

They also talked in this Institutes of Medicine Study about the disparity of resources for new drug approval and monitoring of drug safety.

So, Dr. Curfman, in light of that Government study, can you explain to us whether you believe that this is a serious problem and whether you are concerned about the safety of drugs and medical devices in a post-preemption world.

Dr. CURFMAN. Well, Mr. Braley, I think that you have set the frame very beautifully here today by pointing out that in the last few years there has been a national effort to look at patient safety, hospital safety, drug safety. This is very much on the minds of physicians, hospital administrators. We have published in our own Journal numerous articles dealing with the issue of patient safety. So this is a national effort that is going on.

Now, preemption of tort litigation is simply going to be a way of attempting to undermine what I see as a national effort that our Journal has been a part of to try to improve the safety of patients. So I want to thank you for having set the frame so nicely.

Mr. BRALEY. Thank you.

Ms. Ruth, you gave some eloquent testimony about your role in actually processing the medical devices that are some of the subject of the conversation here today. As an engineer and a potential patient, do you share Dr. Curfman's concerns about the fact that if there is no preemption, device manufacturers will be unable to innovate?

Ms. RUTHER. I disagree that the lack of preemption stalls innovation. We haven't had preemption, and if you look at the innovation of devices over the last 50 years it is stunning.

What we don't want is that people look at innovation as just the next cool toy and how do we get it through the FDA. We really want the best, which is what we have always had in the United States. Starting with the FDA is a fantastic base. Keeping the liability there helps keep us on our toes.

Chairman WAXMAN. Thank you, Mr. Braley. Your time has expired.

Ms. Watson.

Ms. WATSON. I have no questions.

Chairman WAXMAN. You pass. Ms. Norton, are you ready to ask your questions?

Ms. NORTON. Thank you very much, Mr. Chairman. Since I have been here I have heard some fairly frightening testimony. I am pleased I was able to come in for part of this hearing.

I have a question for Mr. Vladeck.

I want to thank all the witnesses. Mr. Vladeck is a colleague of mine at Georgetown, where I am still a member of the faculty, and I was drawn perhaps because, like him, I look at the legal implications of this, to the Riegel decision, which, of course, is the problem, preempting of Federal law and shielding medical devices from State suits, even without an up-to-date warning. It seems to me pretty harsh.

Let me ask you, first of all, it was decided eight-to-one. I would like to know, a court that tends to be fairly divided, I would like to know your view of that. And then, of course, the industry says, So what? It only applies to 1 percent of all devices. I would like to hear your view on that.

Mr. VLADECK. Thank you very much.

First, let me talk about the court's ruling in Riegel. What the court says in Riegel is that when Congress passed the Medical Device Amendments in 1976 it included a preemption provision that used the word requirements. The preemption provision was included because by 1976 there was already robust State regulation of medical devices, and Congress had to figure out how to allocate responsibility between the Federal and the State governments. So what Congress did was preempt State requirements that are different from or in addition to Federal requirements.

The Supreme Court in Riegel said in the Medical Device Amendments the word requirements includes State tort law, and therefore Congress, not the courts, but Congress made a calculated decision back in 1976 to preempt State tort law.

I think the court had it backward. I think the court intended to preserve, not to preempt, State tort law in 1976. But ultimately, of course, that is a question for Congress.

The court makes it quite clear that the ball is in Congress' court, so this is a problem that Congress could fix tomorrow, assuming you could get the votes.

Now, with respect to, Don't worry about Riegel, it only applies to PMA devices, these pre-market approval devices which are 1 percent, well, that is not a fair argument. PMA devices are the devices that are life-sustaining, life-supporting, or, if there is a problem with them, might kill people. These are the most important devices. These are the devices that sustain life. These are the devices that Ms. Ruther was talking about earlier. These are the devices we depend on to keep our loved ones safe and healthy.

So to simply suggest that Riegel is somehow less important because it only applies to these is I think to get it backward. Riegel is especially important because it immunizes the people who make the most important medical devices from liability, and it removes the incentives to play straight.

Ms. NORTON. Yes, and I have a question, particularly since we have the Wyeth case now and Riegel can serve something of a

precedent for the case that is now before the Supreme Court on drug labeling.

By the way, concerning your last answer, very often, still to this very day, we will seek to leave intact State laws, because very often they are stronger than laws we are able to pass here. That has been a habit of Congress since long before I came, so I am not particularly surprised there. There may be some wording that has to be adjusted if they get it wrong, as I believe they did.

But here we have the next step. We have a recent decision here. We are going to go on to a case to come before the court I believe in October. This case takes us to the next step, to the largest number of cases that would be involved, and that is whether or not the regulation of a drug's labeling preempts State law claims when the manufacturer failed to warn both the patients or either the patients or physicians.

I would like to know your view on what you think will happen in this case.

Mr. VLADECK. Well, I hope the court gets it right.

Ms. NORTON. Your testimony seemed to indicate that you thought we had a better chance in this case.

Mr. VLADECK. Well, there are several reasons why I believe we do. First and foremost, there is no preemption provision in the drug part of the Food, Drug, and Cosmetic Act. The industry has long coveted preemption. It wants immunity, but Congress has never given it to it. This is a statute that has been repeatedly amended and reviewed by Congress. Congress is well aware of the backdrop of State liability litigation, and Congress has never acted to give the industry the immunity it wanted. In fact, when Congress added the efficacy requirements to the statute in 1962, it made clear that it would only cutoff State law that was positively and directly contrary to what the FDA did. So, to the extent there had been any signals in the statute from Congress, the signals had been strongly anti-preemptive.

The second thing is there is a long history of product liability litigation over failure to warn claims in State courts, dating back since 1852. This is an area that the States have historically exercised their police power in, and the court has, at times at least, been respectful of State prerogatives in this area.

Third and foremost, I think the arguments for preemption are its absolute weakest here. If you take a look at the case before the court, this is a case in which a woman, a musician, lost her arm because of the way a drug was administered to it. Now, what the plaintiff said was there ought to be a warning to doctors, don't administer this drug directly into the veins, because it is incredibly corrosive to the veins. That is what caused the amputation.

There is no such warning on the drug label. The FDA has never sat down and considered whether there ought to be. There were some proposed changes to the drug label that the manufacturer submitted, none of which would have done what the plaintiff asked for and what the jury said should have been done. So I think this is exactly the kind of case where State liability law complements, not thwarts, the achievement of the FDA's goal, which is to protect the American people.

This kind of litigation simply calls for the disclosure of material safety information. It is hard for me to fathom that anyone thinks that is a bad idea.

Mr. BRALEY [presiding]. Thank you.

Mr. Shays is recognized for 5 minutes.

Mr. SHAYS. Thank you.

Attorney Vladeck and Professor Vladeck, you have great passion, but you are also, I think, someone who believes in fairness. We have eight witnesses who take your view, and we have one witness who doesn't, and it is a little frustrating because you are making certain claims that I am told by my staff are not correct, but I don't have the expertise. In other words, you are giving part of the story but not all of the story.

Dr. Calfee, what would you want to say with the time I have allocated to counteract eight witnesses?

Mr. CALFEE. And I am not a lawyer.

Mr. SHAYS. Use it wisely.

Mr. CALFEE. A further disadvantage.

I think we have to bear in mind that, first of all, we don't want to confuse Institute of Medicine reports. There are reports showing that a lot of people die as a result of things, bad things that happen when they are given drugs in hospitals and clinics and so on, but that is not usually an inherent problem with the drug; the problem is with the way the drug is being used. That has happened with a number of people, including a Boston Glob columnist who died from an overdose of chemotherapy.

The Institute of Medicine report that specifically addressed FDA oversight of drug safety said very clearly at the outset that they had made no attempt to determine whether or not there was a drug safety crisis or even whether drug safety is worse than it used to be. This has been a largely anecdote-driven episode.

Mr. SHAYS. Let me just jump in.

Mr. CALFEE. Sure.

Mr. SHAYS. Professor Vladeck, where I have my problem first is I believe that we have a litigious society. I believe that lawyers get too freaking much. I don't think that the public ultimately benefits. That is the bias I take to the table. It just seems to me that if the FDA has made certain findings and those warnings are proper, and that in the end it is administered incorrectly, I don't know why the drug company should be the one to be liable. So just give me the short version.

Mr. VLADECK. OK. The short version is this: the FDA does not have the capacity to keep up with the current information post-approval about the safety of a drug. For decades what the FDA has said——

Mr. SHAYS. OK. That is a fine point. Now tell me this: how does a lay person have the expertise to do and know more than the FDA? How do they have that expertise, because you are basically having this decided by laymen.

Mr. VLADECK. But, with all respect, I don't believe that is the way to frame the question. If I might answer this way, the FDA recognizes this, and what the FDA's regulations have said is that manufacturers have a duty to update their label without first securing the FDA's approval, without having this conversation with

the FDA, when there is a safety problem, and that regulation has been in effect for a long time.

Mr. SHAYS. Let me ask you this. In the case didn't the FDA deny the company the ability to change it, and doesn't the drug company have to get approval from the FDA to change its——

Mr. VLADECK. Not with respect to safety issues. The drug company can make the change first and then get the FDA's approval.

In the case before the Supreme Court, yes, the agency denied two suggestions by Wyeth about changing a label, but the courts and the jury found that the changes in the label were not the ones that would have addressed the issue. The issue in that case was a route of administration, and nothing in the labeling changes.

Mr. SHAYS. I honestly don't know where I fall down on this issue, but my inclination is that to suggest that somehow if a court rules against you, you still don't have to change your label in other States to me sounds foolish, because you have been found guilty in a particular State. So tell me why I am looking at it incorrectly.

Mr. VLADECK. I think that is a fair question. Let me answer it in three ways.

First, it is very hard to find a case in which a drug company wanted to strengthen the warnings and the FDA said no. That is certainly not what happened in the case from Vermont.

Second, in a case that came up like that where the company said, We want to add a stronger warning, and the FDA said no, no lawyer in their right mind would take that case because I would lose that case.

Mr. SHAYS. Let me ask you one last question while I still have the yellow light. What happens if laymen make a determination that it is simply false?

Mr. VLADECK. And they do, just like everybody makes mistakes.

Mr. SHAYS. But, no, they are not just everybody; they are laymen.

Mr. VLADECK. And that is why we have judges and that is why we have appellate courts.

Mr. SHAYS. No, no. With all due respect, judges aren't medical experts. They are not experts on the issue. They are lawyers.

Mr. VLADECK. But in a case like this, both sides puts on experts.

Mr. SHAYS. I ask one question: what happens if they make a mistake?

Mr. VLADECK. My answer to you is two-fold. First is there are error correction devices embedded in the judicial system to correct errors. Many jury determinations are set aside by trial judges or overturned on appeal, so one answer is trust the judiciary to do its job. That is the first answer.

The second answer is assume for the moment your worst hypothetical, where a jury reaches a bad decision and it is not corrected on appeal. In that case the company would have the discretion to——

Mr. SHAYS. I don't mean to be rude. I have 2 minutes to get to vote.

Mr. VLADECK. Sorry.

Mr. SHAYS. That is OK. Thank you.

Mr. BRALEY. I want to thank all of the panel for coming and testifying today. Your testimony has been deeply appreciated.

Before we adjourn this panel I just want to make a comment about the issue of appellate review, because there was a point brought up during the hearing about the role of punitive damages and tort liability. One of the things we know is recent U.S. Supreme Court decisions have restricted severely the right to recover punitive damages. They have set a very high bar in order to recover from punitive damages. They have limited the evidence that can be submitted in support of a punitive damage award and have required mandatory appellate review of State court determinations of punitive damages.

So one of the things we want to do is continue to consider your helpful testimony as we go further.

With that we will adjourn until 2:15. We have a series of votes. And then we will take up the third panel.

[Recess.]

Chairman WAXMAN [presiding]. The hearing will please come back to order.

For our third panel we are pleased to welcome Dr. Randall W. Lutter, Deputy Commissioner for Policy at the U.S. Food and Drug Administration. Dr. Lutter will present the FDA's current view regarding preemption in the context of FDA-approved drugs and medical devices.

We are pleased to have you with us today. Your full statement will be part of the record in its entirety. We are going to ask you to try to limit your presentation to 5 minutes.

It is the practice of this committee that all witnesses that testify before us do so under oath, so if you would please rise and raise your right hand.

[Witness sworn.]

Chairman WAXMAN. The record will indicate that the witness answered in the affirmative.

I would like you to now commence your oral presentation.

STATEMENT OF RANDALL LUTTER, PH.D., DEPUTY COMMISSIONER FOR POLICY, FOOD AND DRUG ADMINISTRATION

Mr. LUTTER. Good afternoon, Chairman Waxman and members of the committee. I am Dr. Randall Lutter, Deputy Commissioner for Policy at the U.S. Food and Drug Administration. Thank you for the opportunity to discuss issues relating to the safety of medical products regulated by FDA and the importance of accurate information about those products.

FDA is the public health agency charged by Congress with ensuring that drugs, biologics, and devices are safe and effective and that the labeling of drugs, biologics, and devices adequately informs users of the risks and benefits associated with the use of those products.

We believe, based on the authority provided by Congress and the scientific expertise of the agency, that FDA's qualifications to make important judgments about the safety, effectiveness, and labeling of medical products are unsurpassed.

We have heard today about the importance of balance in deciding the roles of Federal regulation by FDA and of State tort law, and I would like to speak to that.

FDA is concerned that State product liability lawsuits that challenge the agency's careful determination of safety, efficacy, and appropriate labeling can have detrimental effects on public health in a number of ways, including limiting patient and doctor choices and decreased patient access to beneficial products and increased confusion over warnings or statements that can deter the use of beneficial medical products.

Of course, if a plaintiff claims to have been harmed because a sponsor, meaning a manufacturer, did not meet the conditions of FDA's approval for a drug, biologic, or device, then State law liability on that basis wouldn't interfere with Federal law and manufacturers would get no protection from such claims. But both to protect the public health and as a matter of law, State law claims are preempted if they challenge a design or a labeling that FDA approved after being informed of the relevant health risk based on its expert weighing of the risks and the benefits of requiring additional or different warnings.

A critical part of the FDA's mission is its review of the adequacy of labeling. The agency carefully controls the content and labeling of medical products because such labeling is our principal tool for communicating to health care professionals and consumers the risks and benefits of approved products so as to help ensure safe and effective use. FDA employs scientists and other experts to review the information submitted by the manufacturer on a product's risk and carefully calibrate warnings and other information that should be placed on the labeling.

FDA continuously evaluates the latest available scientific information to monitor the safety of products and to incorporate new information into product labeling when appropriate. FDA takes care that labeling neither under-warns nor over-warns. We work to ensure that approved labeling not omit important risk information that patients and physicians should consider in making health care decisions.

FDA engages in extensive post-market surveillance to detect and respond to emerging information about approved products after they have been on the market.

After a drug has been approved and marketed, the manufacturer must investigate and report to FDA any adverse events associated with the use of the drug in humans, and must periodically submit any new information that may affect FDA's previously conclusions about the safety, effectiveness, or labeling of the drug.

Device sponsors similarly have obligations to report certain adverse events. FDA is currently modernizing its post-marketing surveillance and risk communication efforts through its implementation of the Food and Drug Administration Amendments Act of 2007 and other major initiatives. FDA believes its teams of scientists are unsurpassed in ensuring that labeling meets patients' needs.

Congress authorized FDA to apply its scientific expertise to determine in the first instance whether a medical product is safe and effective and what labeling, including warnings, is appropriate and necessary for particular product; therefore, FDA's determinations about safety, efficacy, and labeling are paramount.

FDA believes that the important decisions it makes about the safety, efficacy, and labeling of medical products should not be sec-

ond-guessed by State courts. Recent documents clarify FDA's long-standing position that it has primary responsibility to review the safety, efficacy, and labeling of medical products.

In particular, FDA has reiterated the basis for this position in its Supreme Court brief in *Wyeth* v. *Levine,* and before that in the preamble to the Physician Labeling Rule.

Early regulation, preambles from 1982 dealing with tamper resistance, 1986 dealing with over-the-counter aspirin, and 1994 on protecting the identity of adverse event reporters, all may be construed to extend to State tort judgment, although they are primarily directed to State legislative law.

In the preamble to the Final Physician Labeling Rule, which has been discussed earlier today, FDA describes some examples of instances in which it believes preemption is appropriate; for example, where there are claims that a sponsor breached an obligation to warn but where FDA had considered the substance of the warning and decided that it shouldn't be required.

FDA also recognized that FDA's regulation of drug labeling would not always preempt State law actions, noting that the Supreme Court has held that certain State law requirements that parallel FDA requirements may not be preempted.

FDA is concerned that State product liability lawsuits that challenge FDA's careful determination of safety, efficacy, and appropriate labeling can have detrimental effects to public health, and such effects include decreased consumer access to beneficial products through decreases in availability, or even removal of beneficial products from the market, thereby limiting patient and doctors' choices, and the requirement for additional and conflicting warnings or statements that could cause confusion or deter the use of beneficial medical products.

Of course, if a patient claims to have been harmed by a sponsor's failure to use the specific design or labeling approved by FDA, then State liability would not interfere with Federal requirements and preemption would not apply. But public health is not served if tort litigation has the unintended consequence of decreasing or eliminating access to a beneficial product.

The agency is concerned that State tort actions, in conflict with FDA's authority, would create requirements on manufacturers to increase labeling warnings, to include speculative risk or warnings that do not accurately communicate FDA's careful evaluation of the risks and benefits of the product. Including warnings in a labeling without a determination by FDA that they are well grounded in science can have the effect of over-warning and confusion, as well as deterring use of a beneficial drug. Thus, FDA interprets and implements its responsibility under the act as establishing both a floor and a ceiling for risk information, and that additional disclosures of risk information by the manufacturer can violate the act if the statement is unsubstantiated or otherwise false or misleading.

As FDA articulated in the Physician Labeling Final Rule, the public health risk associated with over-warning can be as great as the health risk associated with under-warning. Over-warning can cause patients not to use beneficial medical products and doctors not to prescribe them.

Over-utilization of a product based on dissemination of scientifically unsubstantiated warnings so as to deter patients from undertaking beneficial, possibly life-saving treatment, could well frustrate the purposes of Federal regulation as much as over-utilization resulting from a failure to disclose a drug's scientifically demonstrable adverse effects.

[The prepared statement of Mr. Lutter follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

WRITTEN STATEMENT FOR THE RECORD BY

THE U.S. FOOD AND DRUG ADMINISTRATION

BEFORE THE

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

U.S. HOUSE OF REPRESENTATIVES

"Should FDA Drug and Medical Device Regulation Bar State Liability Claims?"

MAY 14, 2008

RELEASE ONLY UPON DELIVERY

INTRODUCTION

Good morning, Chairman Waxman, Ranking Member Davis, and Members of the Committee. I am Dr. Randall Lutter, Deputy Commissioner for Policy at the U.S. Food and Drug Administration (FDA or the Agency) in the Department of Health and Human Services (HHS). Thank you for the opportunity to discuss issues relating to the safety of medical products regulated by FDA and the importance and accuracy of the information associated with those products.

Under the Federal Food, Drug & Cosmetic (FD&C) Act, FDA is the public health agency charged by Congress with ensuring that drugs, biologics, and devices are safe and effective, and that the labeling of drugs, biologics, and devices adequately informs users of the risks and benefits of the product. FDA considers not only complex clinical issues related to the use of the product in study populations, but also important and practical public health issues pertaining to the use of the product in day-to-day clinical practice, such as the nature of the disease or condition for which the product will be indicated, and the need for risk management measures to help assure in clinical practice that the product maintains its favorable benefit-risk balance. FDA believes, based on the authority that Congress has given it and the scientific expertise that resides in the Agency, that it is uniquely qualified to make important judgments about the safety, effectiveness and labeling of medical products.

FDA is concerned that state product liability lawsuits that challenge FDA's careful determination of safety, efficacy and appropriate labeling can have detrimental effects to

public health in a number of ways, including limiting patient and doctor choices and decreased patient access to beneficial products, and increased confusion over warnings or statements that can deter the use of beneficial medical products. Of course, if a plaintiff claims to have been harmed by a sponsor's *failure* to meet the conditions of FDA's approval for a drug, biologic, or device, then state-law liability on that basis would not interfere with Federal law and manufacturers would get no protection from such claims. But to both protect the public health and as a matter of law, state law claims are preempted if they challenge a design or labeling that FDA approved, after being informed of the relevant health risk, based on its expert weighing of the risks and benefits of requiring additional or different warnings.

FDA'S ROLE IN ENSURING THE SAFETY AND EFFICACY AND APPROPRIATE LABELING OF MEDICAL PRODUCTS

FDA extensively reviews drugs for safety and efficacy using standards specified in statute, regulations and guidance.[i] FDA review teams consisting of medical doctors, chemists, statisticians, microbiologists, pharmacologists, and other experts evaluate whether the studies the sponsor submitted show that the drug is safe and effective for its proposed use. FDA reviewers analyze study results and look for issues with the application, such as weaknesses of the study design or analyses. Reviewers determine whether they agree with the sponsor's results and conclusions, or whether they need any additional information to decide whether benefits outweigh risks for intended uses. The process for pre-market approval of medical devices is similarly rigorous.[ii]

A critical part of FDA's mission is its review of the adequacy of labeling. FDA carefully controls the content and labeling of medical products, because such labeling is FDA's principal tool for educating health care professionals and consumers about the risks and benefits of the approved products to help ensure safe and effective use. FDA employs scientists and other experts to review the information submitted by the manufacturer on a product's risk and carefully calibrate warnings and other information that should be placed on the labeling. FDA continually evaluates the latest available scientific information to monitor the safety of products and to incorporate new information into product labeling when appropriate.

FDA takes care that labeling neither underwarns nor overwarns. FDA works to ensure that approved labeling not omit important risk information that patients and physicians should consider in making healthcare decisions. FDA further works to ensure that less important risks not be presented in a way that detracts from important risk information, and that risk information not adequately supported by scientific information not be presented in labeling, as such unsupported information could deter beneficial use of medical products.

In addition to its comprehensive pre-market review of medical product safety and efficacy, FDA engages in post-market surveillance to detect and respond to emerging information about approved products after they have been on the market. After a drug has been approved and marketed, the manufacturer must investigate and report to FDA any adverse events associated with use of the drug in humans, Title 21, *Code of Federal Regulations* (CFR), 314.80, and must periodically submit any new information that may affect FDA's previous

conclusions about the safety, effectiveness, or labeling of the drug, 21 CFR 314.81. (See 21 *United States Code* (U.S.C.), 355(k) (post-approval reporting and record-keeping requirements). Device sponsors similarly have obligations to report certain adverse events, see 21 CFR 803.10(c)(1), 803.50(a)(1)-(2), and to file annual reports. 21 CFR 803.55(b), 814.84.

FDA receives signals of post-marketing problems from individual adverse event reporting, surveillance networks, inspections, and various other resources. FDA directs internal and external data analysis, laboratory research, post approval studies and problem assessment groups in order to assess post-marketing problems. FDA's response includes communication of important risk information to the public and enforcement action where appropriate. FDA is currently in the process of modernizing its post-marketing surveillance and risk communication efforts through its implementation of the Food and Drug Administration Amendments Act of 2007 and other major initiatives.[iii] FDA believes its teams of scientists are unsurpassed in ensuring that labeling meets patients' needs.

FEDERAL PREEMPTION

Congress authorized FDA to apply its scientific expertise to determine, in the first instance, whether a medical product is safe and effective and what labeling, including warnings, is appropriate and necessary for a particular product. Therefore, FDA's determinations about safety, efficacy and labeling are paramount. The legal basis for Federal preemption of state law is the Supremacy Clause of the United States Constitution (U.S. Constitution Article VI,

clause 2). One form of preemption is express preemption, where Congress explicitly states in statute that Federal law supersedes state law in a particular area. For example, Congress has expressly preempted state lawsuits concerning certain medical devices. The Supreme Court recently ruled that an express preemption provision of the FD&C Act was properly interpreted to preempt state-law tort claims premised on allegations that a medical device that has received FDA pre-market approval is unsafe or ineffective.[iv] Even in the absence of an express preemption provision, however, implied conflict preemption principles still function to preempt state law in some circumstances. This type of preemption arises when there is conflict between Federal and state law, and the preemptive effect can occur with any Federal regulation. Under implied preemption doctrine, a state may not force a manufacturer to choose between compliance with Federal law and state law; Federal law prevails. State laws are also impliedly preempted if they stand as an obstacle to the accomplishment of Federal objectives[v] Where state law would force a drug sponsor to pay damages for failing to include a warning in labeling that FDA had rejected, for example, the state-law claim would be preempted. More generally, state law claims are preempted if they challenge a design or labeling that FDA approved, after being informed of the relevant health risk, based on its expert weighing of the risks and benefits of requiring additional or different warnings.[vi]

FDA believes that the important decisions it makes about the safety, efficacy, and labeling of medical products should not be second guessed by state courts. As the Supreme Court has stated with regard to medical devices,

> 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. Indeed, one would think that tort law, applied by juries under a negligence or strict-liability standard, is less deserving of

> preservation. A state statute, or a regulation adopted by a state agency, could at least be expected to apply cost-benefit analysis similar to that applied by the experts at the FDA: How many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm? A jury, on the other hand, sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.[vii]

FDA abides by standards set forth in regulations and guidance documents that are issued through a public process. FDA is the scientific regulatory body that is publicly accountable for effectively executing its mission of protecting and promoting the public health. FDA also believes, as explained in more detail below, that state court actions that undermine FDA decisions may have the consequence of serving to hinder, rather than help, public health.

Recent documents clarify FDA's longstanding position that it has primary responsibility to review the safety, efficacy, and labeling of medical products. In particular, FDA has reiterated the bases for this position in its Supreme Court brief in Wyeth v. Levine, No. 06-1259, and before that in the preamble to the physician labeling rule.

Physician Labeling Rule

The FD&C Act gives FDA the authority to determine when drug products are misbranded[viii]. FDA, therefore, is the appropriate arbiter of whether a drug's labeling is considered false and misleading. The Department of Justice (DOJ) has participated on behalf of FDA in preemption cases, and FDA has advanced this position in rulemakings. FDA rules dating back to 1979 reflect the Agency's view that the ultimate decision whether to require a warning on a drug label rests with FDA.

In the preamble to the final Physician Labeling Rule, FDA described some examples of instances in which it believes preemption is appropriate, for example, where there are claims that a sponsor breached an obligation to warn, but where FDA had considered the substance of the warning and decided that it should not be required. FDA also expressly recognized that FDA's regulation of drug labeling would not always preempt state law actions, noting that the Supreme Court has held that certain state law requirements that parallel FDA requirements may not be preempted.

The 2006 preamble sets out FDA's understanding of some of the ways in which a state tort judgment can interfere with FDA's implementation of Federal law. FDA's regulation of prescription drugs and biologics labeling and Federal preemption over conflicting state requirements are important to FDA's ability to protect the public health. The Agency's regulation of drugs and biologics is designed to ensure the optimal use of medical products by requiring scientifically substantiated warnings.

Changes Being Effected—CBE Proposed Rule

On January 16, 2008, the Agency published a proposed rule titled, "Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices." These supplemental applications are commonly referred to as "changes being effected supplements" or "CBE supplements." This document proposes to amend the regulations on CBE supplements to reflect FDA's longstanding policy to allow CBE changes only (1) when a sponsor has new evidence not previously submitted to FDA; and (2) when there is sufficient evidence supporting the change. This policy dates back as far as 1982,

when the Agency stated with regard to the proposal to implement the CBE rule: "[S]ome information, although still the subject of a supplement, would no longer require agency preclearance. These supplements would describe changes placed into effect to correct concerns about *newly discovered* risks from the use of the drug." (47 *Federal Register* (FR) 46622, 46623, October 19, 1982) (emphasis added).

This proposed rule, if finalized, would not alter the Agency's existing practices with respect to accepting or rejecting labeling changes proposed by a CBE supplement. The proposed rule was drafted so it would avoid inhibiting appropriate and timely submissions of new safety information, or the Agency's ability to review supplements in a prompt manner.

In several products liability cases, FDA/DOJ have taken the position that state law claims for failure to warn are preempted by Federal regulation of drug or device labeling. In those cases, FDA/DOJ have taken the position that CBE supplements are appropriate only in situations when a sponsor has new evidence and there is sufficient evidence supporting the change. This proposed rule, if finalized after FDA's review of the public comments, would simply codify that position.

To be clear, the proposed rule, if finalized, would not affect a sponsor's obligation to amend product labeling under FDA regulations (for instance, drug manufacturers are required to include "a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not be established.").[ix]

Further, the proposed rule would not affect this responsibility to bring appropriate safety information to FDA's attention – through a CBE supplement or other mechanism.

STATE PRODUCT LIABILITY LAWSUITS THAT UNDERMINE FDA'S EXPERT DETERMINATIONS MAY THREATEN PUBLIC HEALTH

Medical products are inherently risky. FDA evaluates evidence of a medical product's risks and benefits in the prevention or treatment of disease *across populations*. An FDA approval means that, on average and across the target population, the benefits of the product outweigh the risks for the intended uses. However, this does not mean that for each *individual* who uses the product the benefits of using a medical product will always outweigh the risks, and any system of regulation that required the benefits to outweigh the risks for every individual who might use the product would result in few or no medical products for the public. The use of the product is a decision that each patient must make in consultation with his or her doctor, who must apply the known risks and benefits of the product to their patient's particular situation. In some cases, even with the best information and judgment, a patient may still be hurt. Even so, because of the product's benefits to users as a whole, in FDA's judgment the product should be available with the appropriate labeling in order to best improve public health.

FDA is concerned that state product liability lawsuits that challenge FDA's careful determination of safety, efficacy and appropriate labeling can have detrimental effects to public health. Such effects include (1) decreased consumer access to beneficial products

through decreases in availability or even the removal of beneficial products from the market, limiting patient and doctor choices; and (2) the requirement for additional and conflicting warnings or statements that can cause confusion or deter the use of beneficial medical products. Of course, if a plaintiff claims to have been harmed by a sponsor's failure to use the specific design or labeling approved by FDA, then state liability would not interfere with Federal requirements and preemption would not apply.

Decreased Consumer Access

The public health is not served if tort litigation has the unintended consequence of decreasing or eliminating access to a beneficial product. In the case of childhood vaccines in the 1980's, tort liability contributed to a threat to public health that compelled Congress to act.[x] After a series of lawsuits were filed against vaccine manufacturers and administrators in the 1970's, the number of manufacturers of the DTP (diphtheria and tetanous toxinoids and pertussis) vaccine fell from seven to two, the manufacturers of OPV (Sabin oral poliovirus vaccine) from three to one, and the manufacturers of the measles vaccine from six to one.[xi] Prices of the DTP vaccine rose from 19 cents to $12 in six years. Rising prices, uncertainty about the results of vaccine research and development and the possibility of disease outbreaks were the impetus for the National Childhood Vaccine Injury Act, which shielded individual vaccine manufacturers from liability while compensating individuals from vaccine-related injuries.[xii]

Some commentators have observed the relationship between tort liability and the lack of available types of birth control in the U.S., and suggested it is in part causal.[xiii] For instance, Dalkon shield lawsuits led to the removal of other IUDs (intrauterine devices) on the market

by manufacturers, even though FDA had not raised questions about their safety. Randall reported in the Journal of the American Medical Association (JAMA) in 1992 that all but one major U.S. pharmaceutical company (Ortho Pharmaceutical Corporation) had withdrawn from the field of contraceptive research and development and that the U.S. was lagging behind other countries in the availability of modern contraceptives.

Confusion and Deterrence Due to Conflicting Labeling Requirements

FDA is also concerned that state tort actions would create requirements on manufacturers to seek to amend labeling to include warnings of speculative risks or warnings that do not accurately communicate FDA's careful evaluation of the risks and benefits of the product. Including warnings in the labeling without a determination by FDA that they are well-grounded in science can have the effect of overwarning and confusion as well as deterring use of a beneficial drug. Thus, FDA interprets and implements its responsibility under the act as establishing both a "floor" and a "ceiling" for risk information. Additional disclosures of risk information by the manufacturer can violate the act if the statement is unsubstantiated or otherwise false or misleading.

An example of such a state law requirement was in *Dowhal v. Smithkline Beecham Consumer Healthcare*. In *Dowhal*, the plaintiffs argued that a nicotine replacement therapy was required to bear a warning under California's Proposition 65 for pregnant women. FDA believed that the warning label required by Proposition 65 did not properly communicate the benefits of the product, and might deter women from using the product in lieu of smoking, an

activity that would be far less healthy than using the product. The California Supreme Court ultimately agreed with FDA that the state requirement was preempted.[xiv]

In the recent case of *Colacicco v. Apotex*,[xv] plaintiffs brought a state tort action alleging that the manufacturers of a class of antidepressant medications known as selective serotonin reuptake inhibitors (SSRIs) failed to appropriately warn about risks of suicidality associated with the drugs. FDA had extensively considered and adjusted the warnings regarding suicidality for these drugs, balancing the information about risk suicidality with the benefits of these products of lowering rates of suicide overall. FDA had considered and rejected certain warnings regarding suicidality; a state tort suit sought to punish a drug sponsor for failing to include such a warning that FDA had rejected. T he Court of Appeals for the Third Circuit Court found such claims preempted.

Another case about SSRIs involved labeling for the drug PAXIL. Though FDA had reviewed advertisements claiming PAXIL was "non-habit forming" and had concluded they were not false or misleading, a Federal district court applying California law enjoined GlaxoSmithKline (GSK) from running advertisements that had this language.[xvi] Though the parties ultimately settled out of court, this serves as an illustration of where states have attempted to undermine FDA's careful assessment of risk-benefit medical product information.

As FDA articulated in the Physician Labeling Final Rule, the public health risks associated with over-warning can be as great as the health risks associated with under-warning. Over-

warning can cause patients not to use beneficial medical products and doctors not to prescribe them. Under-utilization of a product based on dissemination of scientifically unsubstantiated warnings, so as to deter patients from undertaking beneficial, possibly lifesaving treatment, could well frustrate the purposes of Federal regulation as much as over-utilization resulting from a failure to disclose a drug's scientifically demonstrable adverse effects. Further, allowing unsubstantiated warnings may also diminish the impact of valid warnings by creating an unnecessary distraction and making even valid warnings less credible.

CONCLUSION

Mr. Chairman, Congress has given FDA the responsibility for ensuring the safety, effectiveness, and proper labeling of medical products, and Federal preemption of state standards that are different from the design or labeling approved by FDA is the inevitable consequence of our carrying out that important mission. FDA is committed to helping ensure the safety and efficacy of drug products in the U.S. marketplace and the communication of appropriate risk information to the public.

Thank you for the opportunity to discuss this very important topic. I am happy to answer any questions.

ENDNOTES

[i] Under the FD&C Act, 21 U.S.C. 301 *et seq.*, a drug manufacturer may not market a new drug unless it has submitted a new drug application to the Food and Drug Administration (FDA) and received the Agency's approval. 21 U.S.C. 355(a). An application must contain, among other things, "the labeling proposed to be used for such drug," 2 21 U.S.C. 355(b)(1)(F) (Supp. V 2005); see 21 CFR 314.50(c)(2)(i) and (e)(2)(ii); "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is * * effective in use," 21 U.S.C. 355(b)(1)(A) (Supp. V 2005); and "a discussion of why the benefits exceed the risks [of the drug] under the conditions stated in the labeling," 21 CFR 314.50(d)(5)(viii); see 21 CFR 314.50(c)(2)(ix). The FD&C Act also requires that drugs not be misbranded. 21 U.S.C. 331(a) and (b). A drug is misbranded if, among other things, the drug's "labeling is false or misleading in any particular;" the labeling does not provide "adequate directions for use" or certain "adequate warnings;" the drug "is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof;" or the labeling does not comply with certain FDA regulations. 21 U.S.C. 352(a), (f) and (j). FDA has established specific requirements for prescription drug labeling. 21 CFR Pt. 201. FDA will approve a new drug application if it finds, among other things, that (i) the drug is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof," (ii) there is "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof," and (iii) the proposed labeling is not "false or misleading in any particular." 21 U.S.C. 355(d). After a drug has been approved and marketed, the manufacturer must investigate and report to FDA any adverse events associated with use of the drug in humans, 21 CFR 314.80, and must periodically submit any new information that may affect FDA's previous conclusions about the safety, effectiveness, or labeling of the drug, 21 CFR 314.81. See 21 U.S.C. 355(k) (post-approval reporting and record-keeping requirements); Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 901 *et seq.,* 121 Stat. 922 (enhancing FDA's authority to require post-market studies and surveillance). FDA "shall" withdraw its approval of an application if it finds, among other things, that the drug is not safe or effective under the conditions of use specified in the drug's labeling. 21 U.S.C. 355(e). Following FDA's approval of an application, the manufacturer generally may not make changes to the drug, including "[c]hanges in labeling," without first submitting a supplemental application to FDA and securing the agency's prior approval for the change. 21 CFR 314.70(b)(2)(v)(A). A manufacturer must submit such a supplemental application "to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug." 21 CFR 201.57(c)(6). "An applicant may ask FDA to expedite its review of a supplement for public health reasons." 21 CFR 314.70(b)(4). In addition, a manufacturer may change a drug's labeling after FDA has received the supplemental application, without waiting for the agency's approval of the change, if, among other things, the change "add[s] or strengthen[s]" a warning or a statement about administration of the drug in order to promote safety. 21 CFR 314.70(c)(6)(iii)(A) and (C). FDA interprets that regulation to permit changes without prior approval only to address "newly discovered risks." 47 FR. 46,623 (1982). If a manufacturer makes a change before receiving FDA's approval, the Agency may later reject the change and order the manufacturer to cease distribution of the changed product. 21 CFR 314.70(c)(7).

[ii] Class III devices are subject to premarket review. The Medical Device Amendments of 1976 (MDA), 21 U.S.C. 360c *et seq.*, to the FD&C Act, 21 U.S.C. 301 *et seq.*, sort medical devices into three classes. See 21 U.S.C. 360c(a)(1). Class I and II devices are subject to regulatory controls or standards, but do not require pre-market approval. See 21 U.S.C. 360c(a)(1)(A) and (B); *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 476-477 (1996). A device falls within Class III if (i) it "presents a potential unreasonable risk of illness or injury," or is purported to be used to sustain or support human life or to have substantial importance in preventing impairment of human health, and (ii) there is inadequate evidence for FDA to determine that controls or standards authorized for Class I or II devices would provide reasonable assurance of safety and effectiveness. 21 U.S.C. 360c(a)(1)(C). In general, a Class III device requires pre-market approval (PMA) by FDA unless it was marketed for use before the MDA's enactment or it is "substantially equivalent" to a device that is already lawfully on the market. 21 U.S.C. 360e(a) and (b)(1)(A) and (B), 360(k). Fewer than 1% of new devices require pre-market approval. FDA's PMA process for the relatively few devices that require it is "rigorous." *Lohr*, 518 U.S. at 477. A manufacturer must submit: full reports of all studies and investigations, including clinical investigations, of the device's safety and effectiveness; a full statement of the components, ingredients, properties,

and principles of operation of the device; a full description of the methods used in, and facilities and controls used for, the manufacture, processing, packing, and installation of the device; a reference to any performance standard that would apply if the device were a Class II device, and information showing that the device satisfies that standard or justifying any deviation from it; any sample of the device or its components requested by FDA; and the proposed labeling. See 21 U.S.C. 360e(c)(1); 21 CFR 814.20. FDA may request additional information from the manufacturer, and may also consult with a scientific advisory committee made up of outside experts. See 21 CFR 814.44, 814.20(b)(13). The Agency conducts an in-depth review of requests for pre-market approval, devoting an average of 1,200 hours to each application. See *Lohr*, 518 U.S. at 477.

FDA may grant pre-market approval for a Class III device only if it finds, among other things, that (i) there is "reasonable assurance" of the device's "safety and effectiveness" under the conditions of use included in the proposed labeling, and (ii) the proposed labeling is neither false nor misleading. 21 U.S.C. 360e(d)(1)(A), (2)(A), (B) and (D). In determining safety and effectiveness, FDA must "weigh[] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. 360c(a)(2)(C). FDA may impose restrictions on the sale or distribution of the device as a condition of pre-market approval, see 21 U.S.C. 360e(d)(1)(B)(ii); 21 CFR 814.82(a)(1), and it may also impose device-specific restrictions by regulation, see 21 U.S.C. 360j(e)(1). Following FDA's pre-market approval, a manufacturer must submit a supplemental application to FDA and receive its approval before making any changes to a device that affect its safety or effectiveness. See 21 U.S.C. 360e(d)(6)(A)(i); 21 CFR 814.39(a). The same process that applies to an original PMA application generally applies to a supplemental application. See 21 U.S.C. 360e(d)(6)(B); 21 CFR 814.39(c). With only narrow exceptions, the manufacturer also must receive FDA's approval before making any changes to the labeling of a device. See 21 CFR 814.39(a) and (d)(1). Manufacturers are also required to collect and report to FDA information on certain adverse events related to the device after it has been approved. See 21 U.S.C. 360i(a); 21 CFR Pt. 803.

The manufacturer must report within 30 days any incident in which a device may have caused or contributed to a death or serious injury, or in which the device malfunctioned in a manner that would likely cause or contribute to serious injury if the malfunction recurred. See 21 CFR 803.10(c)(1), 803.50(a)(1)-(2). The manufacturer must report such an incident within five days if remedial action is required "to prevent an unreasonable risk of substantial harm to the public health." See 21 CFR 803.10(c)(2)(i). A device manufacturer is also required to provide annual reports to FDA. See 21 CFR 803.55(b), 814.84. Among other things, an annual report must identify any reports in the scientific literature about the device, as well as any unpublished reports of data from clinical investigations or nonclinical laboratory studies involving the device about which the manufacturer knows or reasonably should know. See 21 CFR 814.84(b)(2).

Based on new information reported to FDA or other information known to the agency, FDA may withdraw premarket approval of a Class III medical device if it finds, among other things, that the device no longer satisfies the standards for premarket approval. 21 U.S.C. 360e(e)(1).

[iii] *See* FDAAA, Public Law 110-85, sec. 901-921; The Future of Drug Safety — Promoting and Protecting the Health of the Public, *available at* http://www.fda.gov/oc/reports/iom013007.html; Ensuring the Safety of Marketed Medical Devices: CDRH's Medical Device Post-market Safety Program, available at *http://www.fda.gov/cdrh/postmarket/mdpi-report.pdf*

[iv] Riegel v. Medtronic, 128 S.Ct. 999 (2008).

[v] Federal preemption would affect a state requirement that, for example, a sponsor of a medical product include in labeling a statement not supported by the level of evidence required by Federal labeling regulations, or a requirement that a sponsor include a statement in labeling that FDA has rejected. 71 FR. 3922, 3936. Preemption would not block a claim against a sponsor for an injury alleged to be caused by a product's noncompliance with a design or labeling requirement of FDA's approval (for example, a claim that a patient was injured by a sponsor's non-compliance with the ingredient requirements of FDA's drug approval).

[vi] Colacicco v. Apotex, 521 F.3d 253 (3d Cir. April 8, 2008) ("we agree that the FDA's rejection of the warning plaintiffs proffer preempts a state-law action premising liability on a drug manufacturer's failure to include such a warning in the drug labeling"); compare Riegel v. Medtronic, 128 S.Ct. 999, 1008 (2008) ("Absent other indication, reference to a State's 'requirements' includes its common-law duties.").

[vii] Riegel v. Medtronic, 128 S.Ct. 999, 1008 (2008).

[viii]See 21 U.S.C. 352

[ix] 21 CFR 201.57(c)(6).

[x] Evans, Geoffrey. Update on vaccine liability in the United States: presentation at the National Vaccine Program Office Workshop on strengthening the supply of routinely recommended vaccines in the United States, 12 February 2002. Clin Infect Dis. 2006 Mar 1;42 Suppl 3:S130-7.

[xi] Evans G, Harris, D. and Levine, E, Legal Issues in Plotkin SA, Orenstein WA, eds. Vaccines. 4th ed. Philadelphia: WB Saunders, 2003:1591-617.

[xii] Pub. L. No. 99-660 sec. 311 et seq., 100 Stat. 3755, codified at 42 U.S.C.A. sec. 300aa-1 et seq. (1989).

[xiii] Randall, Terri, *United States Loses Lead in Contraceptive Choices, R&D; Changes in Tort Liability, FDA Review Urged.* JAMA, 268(2):176-179.

[xiv] Dowhal v. Smithkline Beecham Consumer Healthcare, 32 Cal. 4th 910 (Cal. 2004).

[xv] Colacicco v. Apotex, 521 F.3d 253, (3d Cir. 2008)

[xvi] In re PAXIL Litigation, Case No. CV01-07037 MRP (C.D. 2002).

Chairman WAXMAN. Thank you very much, Dr. Lutter. Your whole statement is going to be in the record, and you have already taken over 7 minutes. We have some questions for you. And we have had an opportunity to review your statement in advance.

I want to recognize Mr. Braley to start off the questions.

Mr. BRALEY. Thank you, Mr. Chairman.

Dr. Lutter, I want to talk to you about the change in FDA's position on preemption and your role in that change. Before 2002, FDA took the position that the regulation of drugs and medical devices did not preempt State court product liability cases. The FDA's view was that State liability cases actually helped it to protect consumers from unsafe drugs and medical devices because they brought new safety information to light, information the FDA might not otherwise get.

In fact, in 1997 former FDA Chief Counsel Margaret Porter stated, "FDA's view is that FDA product approval and State tort liability usually operate independently, each providing a significant yet distinct layer of consumer protection. FDA regulation of a device cannot anticipate and protect against all safety risks to individual consumers. Preemption would result in the loss of a significant layer of consumer protection."

And your former FDA Commissioner David Kessler testified in a previous panel that this was the agency's longstanding view.

Yet in early 2006 the FDA issued a final Drug Labeling Rule whose preamble announced a brand new position. The preamble declared that the agency now believed that FDA approval of labeling preempts State failure to warn lawsuits. And in that preamble the FDA claimed that the preemption is the agency's longstanding position.

So you will have to forgive me, Dr. Lutter. I am a little confused. We know from our previous witnesses that the FDA's longstanding position was against preemption of State court cases, yet your agency now claims the opposite. Please tell us the date and time when the FDA decided to reverse its longstanding position on preemption and the persons involved in that decision.

Mr. LUTTER. The position on preemption has been articulated in a number of amicus briefs over the years and also in various regulations in their preambles. With respect to the positions pertaining to statutory law by States, these go back all the way to the 1970's, and there has been, I believe, no change with respect to FDA's position on preemption in that regard.

I mentioned in my oral testimony several regulations where preambles have articulated a position on preemption that goes back a couple decades.

Mr. BRALEY. Do you hold yourself out at this hearing as an expert in the Federal Doctrine of Preemption as it has evolved over time?

Mr. LUTTER. I am not an attorney by training. I have been briefed on the matter here and I come to you as a representative of FDA on its current policy position on preemption.

Mr. BRALEY. Well, are you aware that long before the FDA was ever created by act of Congress that State tort liability claims involving medications and drugs and drug devices were already taking place?

Mr. LUTTER. Yes.

Mr. BRALEY. Did you have to take an oath when you became Deputy Administrator at the FDA?

Mr. LUTTER. Yes.

Mr. BRALEY. Did you have to swear to uphold the Constitution of this country?

Mr. LUTTER. Yes, sir.

Mr. BRALEY. Are you familiar with the Constitution?

Mr. LUTTER. Yes, sir.

Mr. BRALEY. Including the 7th amendment?

Mr. LUTTER. Yes.

Mr. BRALEY. What does that provide?

Mr. LUTTER. I am sorry, I don't know the 7th amendment.

Mr. BRALEY. The 7th amendment provides that suits at common law, which is what we are here talking about today, the right to trial by jury shall be inviolate. So can you explain to me how it is that the FDA has suddenly decided that it is going to completely turn the Doctrine of Federal Preemption on its head by having Federal agencies stand in the role of Congress, which normally has the exclusive jurisdiction to preempt State law claims?

Mr. LUTTER. I think there is also a Supremacy Clause, sir, in the Constitution that deals with the relationship between Federal law and State law, and the Supremacy Clause speaks also to the question of FDA's authority relative to other authorities exercised by State law.

Mr. BRALEY. The Supremacy Clause of the U.S. Constitution you claim speaks to the FDA's authority?

Mr. LUTTER. It speaks to the relationship between Federal law and State law.

Mr. BRALEY. Because you realize the FDA did not exist when the Supremacy Clause was added to the Constitution?

Mr. LUTTER. Yes, sir.

Mr. BRALEY. And, in fact, that was one of the whole points of the Constitution and Bill of Rights was to distinguish those issues where the States had the right under the Savings Clause of the 10th amendment to exercise their control over things like product safety. Were you aware of that?

Mr. LUTTER. I am aware of the 10th amendment. Yes, sir.

Mr. BRALEY. Now, one of the things that we are concerned about here is it seems to us that the FDA has changed its position on preemption 180 degrees, because we know that there was a preamble to the final rule on drug labeling, but the proposed rule was issued back in 2000, and there was absolutely nothing in the proposed rule that signaled that FDA intended to address preemption, much less that the agency was going to reverse its longstanding position. So can you tell us what happened between the issuance of the proposed rule and the later final rule and the change in the preamble?

Mr. LUTTER. We received public comments asking us to articulate a position in this regard, and we took those public comments into account and developed the language in the preamble based in part on those.

Mr. BRALEY. And did some of those public comments come from Agencies or associations or trade groups who have been at the vanguard of the tort reform movement?

Mr. LUTTER. I presume they come from a variety of sources, including industry.

Mr. BRALEY. Including bodies like the American Enterprise Institute that you worked for?

Mr. LUTTER. I don't know if the AEI filed a brief. I did work at AEI. I was not involved in any brief on this issue at the time that I was there.

Mr. BRALEY. Were you aware that AEI had been influential in trying to push an agenda of tort reform?

Mr. LUTTER. I know that AEI has been involved in tort reform.

Mr. BRALEY. Thank you. That is all I have at this time.

Chairman WAXMAN. Thank you, Mr. Braley.

Mr. Shays.

Mr. SHAYS. Thank you. And, Mr. Chairman, thank you for inviting a representative from the FDA, as well.

I want to just be clear. The FDA's position is that the FDA should be the ultimate decider, and that they should not have State courts, juries, override a decision of the FDA; is that correct?

Mr. LUTTER. Yes, sir. Our key position is that we have been entrusted by Congress to have expertise in the regulation and labeling of medical products in a manner that ensures that the communication through labeling of the safety and effectiveness of those products best protects and promotes public health. We believe we are uniquely well-qualified to do that, and our position with respect to preemption is that State law claims are preempted if they challenge a design or labeling that FDA has approved after being informed of the relevant health risks based on our expert weighing of the risks and the benefits of requiring additional or different warnings.

Mr. SHAYS. So basically we are talking about experts making a decision versus a court, whether it is a judge who does not have expertise in the field or a jury of lay people who do not have expertise, and so your argument is that the experts should trump the lay officials and the judges, correct?

Mr. LUTTER. Yes. The labeling decisions made by FDA are made by teams of doctors, pharmacologists, scientists, epidemiologists who review the information about safety, who take it into account, often on public venues such as our Advisory Committee meetings, and then make decisions about what information should be conveyed on the label about risks and the effectiveness of the product.

Mr. SHAYS. Yes. The irony of this hearing has been that Republicans usually are not great fans of the FDA, at times for a variety of reasons, and Democrats usually are there arguing that the FDA should be given more credibility than sometimes people on my side of the aisle want to do. I mean, that is the irony that I am saying. You are not saying that, I realize. But in asking the question of our first panel, the chairman said, well, we go where the science takes us, and that the courts are basing it based on science. But, without offending the chairman, how do you respond to that? And maybe I didn't say it correctly.

Mr. LUTTER. I don't remember exactly the chairman's remarks in that regard, but our view is that we look carefully at all the adverse events that are associated with the product.

Mr. SHAYS. Let's look at the courts, though. The argument is the courts go where the science takes them. How do you respond to that?

Mr. LUTTER. They lack the technical, scientific, and medical expertise that we use in making decisions about the labeling of products that we regulate.

Mr. SHAYS. What is the danger of having the courts or the jury basically override the FDA?

Mr. LUTTER. Well, fundamentally there is a conflict between law imposed by the courts and the law that we impose on the sponsors in terms of their labeling. In particular, if we say that a label must describe the risks in a particular manner and the State court reaches a conclusion that those risks were associated with the failure to warn and an alternative label was appropriate, there is a conflict between that legal judgment by the court and our judgment. And we think that, from a public health standpoint, we have more expertise in conveying and regulating those risks.

Mr. SHAYS. Let me just say, Mr. Chairman, thank you for allowing a third panel, because I think it is important that we get the position of the FDA and I think it is very persuasive.

I thank you, Doctor, for your testimony.

Mr. LUTTER. Thank you.

Chairman WAXMAN. Thank you, Mr. Shays.

FDA was set up in 1906, I believe. From 1906 to the present time, FDA has had responsibilities to make sure drugs are safe. That was the first job of the FDA. Then later FDA was empowered to decide whether drugs were effective.

Now, throughout all that period of time there is always this dual system of FDA assuring drug safety by following the science and using their expertise, but we have always had during that same period of time a system where individuals could sue in State courts if they were injured.

Now, in courts all the time experts come in and give their opinion. FDA isn't the only expert on drug safety; there are others who can give opinions on drug safety. Isn't that true?

Mr. LUTTER. There are other experts. The decisionmakers in State courts are the judges and the juries.

Chairman WAXMAN. Yes, but the decisions that FDA is making is not in an individual case; the decision FDA is making is whether a drug ought to be approved and marketed as a safe product, and, after it is out, to review whether it still should stay on the market if there is a safety problem that arises. Isn't that correct?

Mr. LUTTER. Yes.

Chairman WAXMAN. OK.

Mr. LUTTER. We make decisions on the safety for the population that is intended to use the drug.

Chairman WAXMAN. So we have never had this preemption before. Suddenly FDA, under the Bush administration, has decided to insert FDA preemption in the law. This was done in a rather tricky way, it seems to me, because there was a proposed regulation that didn't mention it at all. In fact, it had a provision saying this won't affect preemption. And then at the last minute FDA put in a preamble that said, oh, by the way, we are preempting the States from even having court cases to resolve the disputes where people are

injured and feel that the manufacturers didn't live up to their legal responsibilities.

Now, I am offended by that. I am offended by it all the time by this administration because I know there is a unitary theory of the executive branch that you are the supreme branch, but there is a branch of Government under the Constitution that is supposed to make laws, and Congress was never asked to change the law. Suddenly FDA decided to change the law.

Now, if FDA is going to say we are the only ones that can decide these things for the safety risks for individual consumers, you would have to work on the assumption that FDA is on top of tens of thousands of drugs and medical devices that it regulates, not only to have approved them, but to make sure that they continue to be safe.

Now, FDA doesn't have the capacity to do that. There is just no way in the world FDA can do that, and to say that you are doing it is to accept the notion of the Federal Government bureaucracy being supreme over everybody else in the country in deciding whether an injured person has the ability to go in court and say that I was unfairly treated, and as a result I have lost my arm, I have lost my livelihood, I have suffered enormously. That person will be denied even the opportunity to go in and get redress from their injuries.

Mr. LUTTER. Sir, we are not opposed to all State lawsuits, and it is important to——

Chairman WAXMAN. You are opposed to any lawsuit that is based on the manufacturer not living up to a reasonable standard of care that deviates once FDA has approved them.

Mr. LUTTER. State law claims are preempted if they challenge a design or labeling that we have approved after being informed of the relevant——

Chairman WAXMAN. OK. After being informed. That is a very interesting point, because when we heard this morning about the Heparin that nearly killed the Quaid family children and, in fact, did kill some other children, what we learned was that the company knew about the problem but FDA didn't, and the company wanted to change its label and, in fact, did change its labels, and then wrote to the FDA or appealed to the FDA saying, We want you to approve that label.

Now, if the company found out that its product was doing harm to children and they decided they wanted to change the label, under this Doctrine of Preemption they would have to wait for FDA to decide it is OK. That could take a long period of time, wouldn't it?

Mr. LUTTER. I can't speak to the specifics of that.

Chairman WAXMAN. You can talk to the specifics of a situation where the company knows about the harm, FDA does not. The company wants to take action to prevent this harm from occurring again, and under the Doctrine of Preemption they would have to wait for FDA to decide to adopt a change in the label. The reason they would have to do that is otherwise they are not going to be protected against a State lawsuit.

Mr. LUTTER. We have a practice which has been in place for a couple decades called changes being affected, and we have issued a new proposed regulation that speaks a little bit to——

Chairman WAXMAN. Where was FDA in September 2006 when three babies in Indianapolis died from an overdoes of Heparin? They didn't know about it. Why did it take FDA until December 2007 to approve a label change to address this very serious and very real risk? That is over a year. If the company knew about the problem, they could have done something about it earlier. Why shouldn't they be held responsible if they didn't?

Mr. LUTTER. I would have to get back to you on the specifics of that case, sir.

Chairman WAXMAN. Well, I am telling you the specifics of a case like that would mean that people in the interim would not be able to sue, even though FDA didn't act and the manufacturer didn't act. In effect, we are just telling them, Well, that is just too bad. You are out of luck. You pay the penalties. This seems to me a radical change in direction. From 1906 to 2008 we have never had preemption.

Now, the medical device law, there was a specific reference to preemption, but never in the FDA law, and suddenly FDA is trying to do it by regulation. You don't have the power to do it by regulation. If you want it changed, come to Congress and make an argument. I think you have a weak one, and you certainly don't have the power to do it on your own.

I have exceeded my time, and I will be glad to recognize any Members who want to ask further questions.

Mr. Shays.

Mr. SHAYS. Thank you, Mr. Chairman. Just for that basic point, to just say, though, that it might be wise to bring more officials of the FDA and the legal side of the office to respond to I think a question you raise, which I think is debatable.

Chairman WAXMAN. What is the question that is debatable?

Mr. SHAYS. Whether or not they have ever had preemption.

Chairman WAXMAN. Well, you can answer that. Have you ever had preemption before?

Mr. LUTTER. I would like to speak a little bit, sir, if I may——

Chairman WAXMAN. No, no. Have you ever had preemption before?

Mr. LUTTER. I am not sure exactly in what context you are asking it. I have alluded to different regulations going back to 1980 where we have articulated a Doctrine of Preemption against State statutes in the preambles and regulations going back into the 1980's. Yes.

Chairman WAXMAN. Those were States' efforts to regulate the products or to design the label. Have you ever had preemption against State lawsuits by injured people against manufacturers of products?

Mr. LUTTER. In 2000 FDA issued an amicus brief in——

Chairman WAXMAN. Amicus briefs do not make the law change. You might have asked the court to accept it. Did the court accept it in that case?

Mr. LUTTER. I don't know the decision of the court case.

Chairman WAXMAN. OK. So it is 2008 that you are now suddenly deciding that the law is going to be preemption and people are out of luck, they can't go to the State courts. You may think that the preemption was always there, but it has never been acted upon in that way. Suddenly you are making the law out of FDA. Where were you before FDA? Were you at a think tank?

Mr. LUTTER. I was at the American Enterprise Institute before I joined the FDA.

Chairman WAXMAN. That is a think tank with a particular point of view. And I don't care what the point of view is, but why should a think tank person come into Government and then be able to write laws when we have a Congress to do that?

Mr. SHAYS. Mr. Chairman.

Chairman WAXMAN. Yes, Mr. Shays. It is your time.

Mr. SHAYS. I think that you feel very convinced about your argument. My point is it would strike me that we would get a number of folks from the FDA to respond. I think some of the power has been implicit for a very long period of time. I am just struck by your basic argument about——

Chairman WAXMAN. Are you talking about me or him?

Mr. SHAYS. I am talking about the FDA's arguments. I think the power is implicit in the powers we have given them. I think this has become an issue that has come to the forefront, but the fact that you are questioning whether they have this power or not and never had this power to me is a debatable issue. That is all. And I am just suggesting we bring in some of the legal folks in the FDA to make this argument.

We have had eight people who have given testimony one way and we had one individual give testimony the other way, and now we have the FDA. I think we should bring in more from the FDA. I think it would be interesting.

I just make this point to you: I don't have a dog in this fight, but as I listen to it I think it is a debatable issue. Then the next question is: what should we do about it? Should we pass a law to make it clear or not? I think that is something that is a debatable issue, as well.

Chairman WAXMAN. Would the gentleman yield to me?

Mr. SHAYS. Absolutely.

Chairman WAXMAN. There is some strange notion I don't have a dog in this fight. If the products are less safe as a result of preemption, then you and I both have a vested interest in it in a personal way and also as a public policy matter, because it could turn out that you or I or our loved ones will go and need drugs and find out that the drugs are not as safe as they could be.

Mr. SHAYS. Just reclaiming my time, because I wouldn't want you to distort what I mean by that, what I mean by that is that I am very open to this debate. Other than someone who has a very strong opinion one way, I don't have a strong opinion either way, but as I listen to this debate I don't think having eight witnesses who make your argument and having one witness who argues differently gives an accurate and fair presentation. I am just making the point to you. You have the FDA disagreeing with you.

You are not a lawyer, correct, sir?

Mr. LUTTER. That is correct.

Mr. SHAYS. Your capabilities is as an expert, and you are expressing your opinion as an expert.

Mr. LUTTER. I am representing FDA here and its positions, yes.

Mr. SHAYS. Right. And all I am saying is we are getting more into a legal fight, and I think it is unfair to Dr. Lutter to be arguing the legal aspects of it. That is all.

Chairman WAXMAN. Thank you, Mr. Shays.

Mr. Braley.

Mr. BRALEY. Well, Mr. Chairman, I may be the only person who is participating in these hearings today who has actually researched, briefed, and argued Federal preemption questions in Federal and State court, and this gets to the basic core of the Doctrine of federalism, and that is whether or not we are going to allow a Federal agency to substitute its judgment for the judgment of Congress in deciding whether or not to attempt to preempt State law claims.

Now, Dr. Lutter, have you ever been a witness in a product liability case?

Mr. LUTTER. No.

Mr. BRALEY. Drug you know what the standard of proof is in a State tort claim to recover damages for a defective product?

Mr. LUTTER. I think it varies State by State.

Mr. BRALEY. Not usually, because it is based upon the restatement of torts, which are generally acceptable in State court cases all over the country. You have to prove that the product was defective, that there was something wrong with it, and then you have to prove that it was unreasonably dangerous. And in every case that I have ever been involved in involving a defective product the defense always comes in and presents every piece of evidence that they can to prove the product was not unreasonably dangerous at the time it was placed into the stream of commerce.

If you have an FDA ruling on your warning, don't you think that would be a critical piece of evidence offered by the defense to try to avoid even any liability in those State tort claims?

Mr. LUTTER. I think that speaks to the issue at hand, which is what is the relationship by a State court's finding that products are unreasonably unsafe given that we have found that they are safe and effective. That is really the inconsistency between the——

Chairman WAXMAN. Would the gentleman yield?

Mr. BRALEY. Of course.

Chairman WAXMAN. What troubles me is that you at FDA can agency this product appears to us, based on the science that has been presented to us by the manufacturer, that it is safe. And you approve it for use by the public. And then it turns out it is not safe, it is defective, and somebody is injured by this defective product, a drug let's say. Well, should we tell the injured person, you might have been injured by a defective product, but you can't go and sue the manufacturer, who might have even known it was defective, because the FDA said it was not defective when they approved it? That to me is an absurd position.

Thank you for yielding.

Mr. BRALEY. And, reclaiming my time, there is a doctrine that already exists in product liability law called post-sale duty to warn. It focuses on newly discovered information that has come to the

knowledge of the manufacturer or potentially in this case to the FDA that raises concern about some information that was not known at the time that product was placed or approved. So I don't understand how the agency can contend that once you pass your Good Housekeeping seal of approval on a drug label that some subsequent problem, like the problem we saw today with the Heparin labels, could not bring about a change in the need for labeling requirements. Can you explain that?

Mr. LUTTER. We think there are already requirements on manufacturers to make label changes and recordkeeping and to report adverse events to us, and we think these go a long way toward ensuring the safety of the product.

Chairman WAXMAN. Would the gentleman yield to me?

Mr. BRALEY. Yes.

Chairman WAXMAN. It is voluntary. A manufacturer of a drug does not have to report to you an adverse impact that they are informed of. It is voluntary.

Staff PERSON. It is voluntary for physicians.

Chairman WAXMAN. Oh, I see. But the company is still required. So the physicians may know about an adverse impact of a drug.

Mr. LUTTER. It is mandatory, sir, the manufacturers must report to us the information that they collect. It is not mandatory that the physicians report to anybody. They may or may not do that.

Mr. BRALEY. But getting to the point the chairman was raising, the manufacturer does not have a representative in the hospital room or the physician's office to monitor every adverse outcome, so how, if it is a voluntary reporting requirement for the people on the front line using the device or the medication, how is it possible that you can guarantee every adverse reaction or every adverse outcome with an approved medical device is going to get reported through your adverse system?

Mr. LUTTER. We cannot do that guarantee. Absolutely cannot.

Mr. BRALEY. Isn't that the problem?

Mr. LUTTER. Well, that is the world that we live in, that we only have this information available to us. Given this information——

Chairman WAXMAN. Would the gentleman yield?

Mr. BRALEY. As soon as I finish this point I will be happy to.

Mr. LUTTER. But I think, given this information, the question is we are still asked, nonetheless, given the information that we have, to make judgments about adequate labeling of the products that we regulate.

Mr. BRALEY. Let me put a fine point on this. Are you familiar with the Joint Commission on Accreditation of Health Care Organizations?

Mr. LUTTER. Yes.

Mr. BRALEY. They are charged with collecting data on patient safety based upon the same type of medical mishaps we were talking about earlier in the hearing, and it is a voluntary reporting requirement, and they have had a system in place called a sentinel event reporting system that requires any sentinel event that results in serious injury or death to be reported, that a root cause analysis to be performed of what led to that event and an action plan be created to prevent that event from occurring in the future.

In the 10-years that system has been in place, do you know how many sentinel event reports have been filed with JHACO?

Mr. LUTTER. I don't know.

Mr. BRALEY. 3,000. That works out to 300 a year, and, given the numbers we were talking about, deaths only, 44,000 to 98,000 a year due to preventable medical errors, I think you can appreciate how there is a huge gap between the number of adverse incidents and a voluntary reporting system. That is why some of us are so passionate about not allowing the FDA to be the last safeguard for these procedures.

With that I will be happy to yield.

Chairman WAXMAN. Will you yield to me?

Mr. BRALEY. Yes.

Chairman WAXMAN. And then I am going to yield to Mr. Shays.

Look, you have companies that make these drugs. They have so much more resources to follow whether there are problems with their drugs. They have the marketers who talk to the doctors who can tell them about adverse impacts. They have reasons to want to improve their drugs, and they are following this information. They may know about it but FDA may not.

Now, if someone is injured because a manufacturer decided, Well, I have already been approved by FDA, so therefore if somebody is hurt they can't sue me, they can't even get into court to sue me, why should I want to get so active in trying to do anything more to improve the safety of my drugs, and I will just take it, see if this is as big a problem as it may be.

That is very little solace to somebody who is injured. Somebody who is injured by a drug that is defective has to be told the bureaucracy in Washington called the Food and Drug Administration approved this drug with the knowledge that we had at the time we approved it, and therefore you have been injured, you suffer. It is your hard luck. You pay for all the consequences.

Now, that individual may pay for it, their insurance may pay for it, or all the taxpayers will pay for it. Who will not be liable and responsible is the manufacturer of the drug, who may have some culpability under all the tort laws in this country, which is not different from one State to another but generally the standard to which they are held.

Mr. Shays.

Mr. SHAYS. Thank you.

My point in this is it is a fascinating debate, but, Mr. Sarbanes, you are making my point because you are saying you are the only one who has this expertise, that basically you have dealt with preemption issues, you have filed briefs, and so on, and you are dialoguing as a trial lawyer against a medical expert. All I am saying is I would learn more from having someone who has the same knowledge that you appear to have.

And I would say to you, Mr. Chairman, when you were instrumental in 1986 in enacting the 1986 National Childhood Vaccine Injury Act, I don't want people to think that we don't want people to be dealt with fairly. There are just some of us who think this hearing today, with all due respect, is more about trial lawyers than it is about the health of our young people and our older people. That is the debate that we begin to wonder about.

Shouldn't we find a way to compensate people without having to go through the courts, but do exactly what you did as it related to vaccines, which was landmark legislation. That, to me, is the kind of issue we should be debating.

Chairman WAXMAN. Would the gentleman yield to me?

Mr. SHAYS. Sure.

Chairman WAXMAN. The Vaccine Compensation Act provided a system where, in rare cases, because it is mandated that every child be immunized, when there is an adverse impact, as there are going to be, very rare, but it is going to be, and we wanted to provide a compensation system for them, but we never ever precluded them from going to court. We never said now there is a preemption and the court cases will not be allowed, first of all.

And second of all, you want to have a compensation system for everyone in this country with all the thousands of drugs and devices if anybody is injured without any showing of responsibility that suddenly they are going to be compensated? That is called universal health care. Great, but we don't have it, and a lot of people are going to be left in the lurch, injured, having to bear the burden of their injuries without any compensation from anybody.

Mr. SHAYS. Let me just tell you what I wrestle with, though, because this is what you said in talking about the act. This is a quote I think that you made. "No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable, even though the vaccine was properly prepared and was accompanied by proper directions and warnings."

I think what you did was you took it out of the courts, you took it out of the trial lawyers, and you made sure that people would get the full benefit and not have to share it with anyone else. I think that made sense.

Chairman WAXMAN. It is interesting you are quoting a statement from me from I don't know when, but I will tell you what the law requires, because that is the way I intended it to be. There is a compensation system because vaccines for children are a unique product. It is mandated that every child be immunized for childhood diseases, and because of that, in order to——

Mr. SHAYS. I need to correct something. I am sorry. This was not your quote, it was taken directly from the act, itself. I apologize.

Chairman WAXMAN. And the act provides that this compensation system will compensate a child who has an adverse impact, but it does not preclude that child from going into the courts and suing under tort law in the State in which that child resides. We did not preempt the courts in that legislation, even though we tried to provide another alternative. There is no other alternative for the adults and children who use drugs that are not vaccines. If they are injured and it is the fault of the manufacturer, they should be able to go into court and prove it. They have a job to prove it. And if they can't prove it, they don't recover it.

If the drug has been approved by the FDA, that will be introduced in evidence. But this preemption idea precludes that person from ever getting into court in the first place. The manufacturer can just simply say, You can't sue me. There is a bureaucracy in

Washington called the FDA. They approved this product, and even though there are problems with the product that they didn't know about, that means I am home free.

Well, trial lawyers, people who are injured usually get lawyers to represent them. They don't have a good chance on their own to represent themselves. There is nothing wrong with people having representation. I am sure you will fight to the end to make sure that the rich and powerful are represented here in Washington and elsewhere. The poor often are represented by trial lawyers who take the case because they realize that they can recover damages and they should recover damages.

This is not a trial lawyer issue, this is a consumer issue. I think it is a red herring to say the trial lawyers. It is the consumers who are going to be left out in the cold.

And if you want to be mean about it you could say perhaps some postal are more concerned about—and I am not saying this about you—some people are more concerned about the drug manufacturers than they are about the people who may be injured by those products.

Well, unless anybody else has another thought to throw into the stew, I think we have had an interesting hearing, a lot to think about, and I wish Congress had this before us to decide and debate, not the FDA Bureaucrats to make a decision on their own based on some ideology of power that they don't really have and an ideology to put in place their view of the world.

We want to keep the record open for any other submissions that Members may wish to make. There are two statements, one by Dianna Wynn Levine, and I would like that statement to be made part of the record, and testimony of Cybil Nighten Goldrich, as well.

[The prepared statement of Ms. Levine follows:]

Statement of Diana Winn Levine

Musician and Children's Record Producer

Marshfield, Vermont

Before the
House Oversight and Government Reform Committee

For a hearing entitled
"Should FDA Drug and Medical Device Regulation Bar State Liability Claims?"

May 14, 2008

Today, big business, led by the drug manufacturers, is seeking to stop everyday citizens who have been hurt by a dangerous product that was approved by the federal government from being able to hold those powerful corporations accountable through the application of a legal theory known as "pre-emption."

The companies, supported in many cases by the Bush Administration, argue that, if the federal government approves a product that goes on to hurt somebody, the victims of the product cannot use the legal system to hold the company behind the product accountable – even in cases where a company knows, and does not disclose to the federal government or public, that its products will harm people.

I am one of those people.

Almost eight years ago, I was wheeled into a Vermont health clinic with a severe migraine headache and nausea. I ended up having my hand and half my forearm amputated because of the failure of Wyeth Pharmaceuticals to change its label so that only the safe ways of administering the anti-nausea drug Phenergan were provided to the medical caregivers – even though Wyeth was aware that the drug was being administered improperly.

The loss of my body parts ended my 30-year career as a professional musician. It is nearly impossible to play the guitar, bass, or piano with only one hand. In 2004, I took Wyeth to court to hold the company accountable for their conduct. A Vermont jury ruled in my favor, requiring Wyeth to compensate me for my economic losses, damages, and medical expenses.

Wyeth, in the appeal of the Vermont court's decision, has argued that, since the Food and Drug Administration (FDA) had approved the drug's labeling instructions, victims such as myself are barred – what they call "pre-empted" – from being able to hold them accountable regardless of the fact that the company knew its warnings were not adequate.

In other words, Wyeth's argument boils down to the idea that since the FDA approved of the drug and warning label – I am out of luck despite the fact Wyeth's action caused me to lose my hand through absolutely no fault of my own and despite the fact that the company knew its instructions were causing injuries to the public.

The case is now before the United States Supreme Court where it will be determined whether claims like mine are pre-empted or not.

Historically, courts have considered government-issued warnings on a product as reflecting a minimal standard of care – the baseline, not the top line. Victims of dangerous products have long had the right to hold companies accountable through our court system. Not only does this well established system allow individual victims to hold businesses accountable when they do wrong, it is the primary way that society has encouraged companies to use reasonable care in designing and marketing products. If you put out something that will hurt people, you can be held responsible.

However, if the Supreme Court rules for the drug company in my case, it will mean that big business will be given immunity when it sells products that hurt people so long as they have

been "approved" by a federal agency – even in cases where companies know for a fact that their products are unsafe and will cause fatal injuries.

Given the performance of the FDA under the Bush Administration, I for one am not ready to give up my individual rights to hold a company accountable merely because a government agency has issued a minimal safety standard for a product.

Over the last several years, we have seen report after report of drug companies impacting the approval process of the FDA to produce a label warning that is inherently flawed. In some cases, it was through a cozy relationship with the regulators issuing the approvals. In other matters, a political relationship existed between a company and a political appointee at FDA that helped grease the wheels for the approval. And there have been times where drug companies simply did not disclose negative information about a drug's safety record, while it was going through the approval process.

The Supreme Court's decision will have enormous ramifications far beyond my case, my hand, my musical career or even the drug industry. It will mean that virtually every industry that has a product that requires federal approval could be given protection from lawsuits. Essentially, a decision for Wyeth will be akin to giving corporate America a "get out of jail free" card – and it will leave everyday Americans exposed. Congress must prevent that result, which would be devastating for victims of unsafe products.

Chairman WAXMAN. The record will be held open for other comments or any other items that Members wish to add to that record.

We stand adjourned.

[Whereupon, at 3:03 p.m., the committee was adjourned.]

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