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HEARING ON: 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, D.C.

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Committee Hearings

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The subcommittee met, pursuant to call, at 10:10 a.m. in room 2154, Rayburn House Office Building, the Honorable 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, Press Assistant; Ella Hoffman, Press Assistant; Zhongrui ''JR'' Deng, Chief Information Officer; Leneal Scott, Information Systems Manager; William Ragland, Staff Assistant; Miriam Edelman, Staff Assistant; Bret Schorthorst, Staff Assistant; Jen Berenholz; Jennifer Owens; Lauren Belive, Staff Assistant; Larry Halloran, Minority Staff Director; Jennifer Safavian, Minority Chief Counsel for Oversight and Investigations; Keith Ausbrook, Minority General Counsel; Jill Schmaltz, Minority Professional Staff Member; Kristina Husar, Minority Counsel; Patrick Lyden, Minority Parliamentarian and Member Services Coordinator; Brian McNicoll, Minority Communications Director; Benjamin Chance, Minority Professional Staff Member; 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?

[Prepared statement of Chairman Waxman follows:]

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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.

[Prepared statement of Mr. Davis of Virginia follows:]

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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 seven 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.

[Prepared statement of Mr. Braley follows:]

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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 tragic, 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.

[Prepared statement of Mr. Souder follows:]

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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, Massachusetts. 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 hand 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 five 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 five 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 eight-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 received. Both products are manufactured by Baxter Health Care Corporation.

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 ten 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, seven 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 Cosmetic 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.

[Prepared statement of Mr. Quaid follows:]

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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 ten 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 two 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 eight months after receiving FDA approval for the corrected device and nearly two and a half 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

Corporation 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.

[Prepared statement of Dr. Maisel follows:]

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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 follow-up 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.

[Prepared statement of Dr. Kesselheim follows:]

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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 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 time frame 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 action 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.

[Prepared statement of Dr. Kessler follows:]

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

I am now going to recognize members of the Committee to ask questions for five 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 eight-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 of 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 four or five 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 of 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 eight 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. Okay. 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 three 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 seven 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 quote, If we don't know, we are okay. 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 record-keeping 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 record-keeping 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 15th, 2006?

[No audible response.]

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

The new Baxter Pharmaceutical label was introduced in October of 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 15th of 2006 to October of 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 ten 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.

Before that quickly, though, on behalf of Congressman Cummings, who could not be here today, I wanted to seek unanimous consent to submit in the record some testimony from Ms. Laura Schmitz of West Friendship, Maryland, one of Mr. Cummings' constituents.

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

[Prepared statement of Ms. Schmitz follows:]

********** INSERT **********

Mr. SARBANES. Ms. Schmitz has taken particular interest in this hearing because her own mother passed away in February of 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 database 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 follows:]

********** COMMITTEE INSERT **********

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 1950s.

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.--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. Okay. 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. Okay. 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. Okay. Do either of the doctors know?

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

Mr. ISSA. Okay. 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 follow up and responsibilities of the manufacturers.

It is very important that we, as policy-makers, 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 follow up.

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 under-estimated 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 two years later the manufacturer submitted to the FDA the full reports of the test, including the proper statistical tests, but that was two 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 decision-making 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 1970s 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 1990s, 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 got 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 1970s she almost died. They gave her Bendectin and she learned that that was what she had to have. When it came back to the 1970s, 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 three 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 got 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.

Secondly, 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 benefitted 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 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, Missouri, Kansas City, Kansas; St. Louis, Missouri, St. Louis, Illinois; Washington, D.C. 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 five minutes.

Dr. KESSLER.--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.--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 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. Okay. 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 five 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 hand 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 of 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 of 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 of 2007. It went ahead and changed the label in October of 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.

[Prepared statement of Mr. Vladeck follows:]

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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, 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.

Another example is the diabetes drug Avandia, which after eight 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 5:00, we will publish a study on our website 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--5:00 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.

[Prepared statement of Dr. Curfman follows:]

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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 U.S.

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 decision-making 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.

[Prepared statement of Ms. Ruther follows:]

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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 policy-making 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, D.C., 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.

[Prepared statement of Mr. Clark follows:]

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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, D.C., 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 1980s 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.

[Prepared statement of Mr. Calfee follows:]

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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 dis-uniformity, 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 of 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 U.S. 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 backwards. 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 backwards. 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 got 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 cut off 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 five 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. Okay. 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. Okay. 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 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.

Secondly, 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 two minutes to get to vote.

Mr. VLADECK. Sorry.

Mr. SHAYS. That is okay. 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 five 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

STATEMENT OF RANDALL LUTTER

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 second-guessed by State courts. 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 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.

[Prepared statement of Mr. Lutter follows:]

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Chairman WAXMAN. Thank you very much, Dr. Lutter. Your whole statement is going to be in the record, and you have already taken over seven 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 1970s, 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 Seventh Amendment?

Mr. LUTTER. Yes.

Mr. BRALEY. What does that provide?

Mr. LUTTER. I am sorry, I don't know the Seventh

Amendment.

Mr. BRALEY. The Seventh 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 United States 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 Tenth Amendment to exercise their

control over things like product safety. Were you aware of that?

Mr. LUTTER. I am aware of the Tenth 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 decision-makers 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. Okay.

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. Okay. 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 okay. 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 of 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 of 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 1980s. 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. Okay. 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 got 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 record-keeping 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 ten 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. Three thousand. 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 got 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.

[Prepared statements of Ms. Levine and Ms. Goldrich follow:]

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Chairman WAXMAN. The record will be held open for other comments or any other items that wish to be added to that record.

We stand adjourned.

[Whereupon, at 3:03 p.m., the Committee was adjourned.]