AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

S. HRG. 109–421

DEFECTIVE PRODUCTS: WILL CRIMINAL PENALTIES ENSURE CORPORATE ACCOUNTABILITY?

HEARING

BEFORE THE

COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

ONE HUNDRED NINTH CONGRESS

SECOND SESSION

MARCH 10, 2006

Serial No. J–109–63

Printed for the use of the Committee on the Judiciary

U.S. GOVERNMENT PRINTING OFFICE

27–707 PDF WASHINGTON : 2006

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2250 Mail: Stop SSOP, Washington, DC 20402–0001

COMMITTEE ON THE JUDICIARY

ARLEN SPECTER, Pennsylvania, *Chairman*

ORRIN G. HATCH, Utah
CHARLES E. GRASSLEY, Iowa
JON KYL, Arizona
MIKE DEWINE, Ohio
JEFF SESSIONS, Alabama
LINDSEY O. GRAHAM, South Carolina
JOHN CORNYN, Texas
SAM BROWNBACK, Kansas
TOM COBURN, Oklahoma

PATRICK J. LEAHY, Vermont
EDWARD M. KENNEDY, Massachusetts
JOSEPH R. BIDEN, JR., Delaware
HERBERT KOHL, Wisconsin
DIANNE FEINSTEIN, California
RUSSELL D. FEINGOLD, Wisconsin
CHARLES E. SCHUMER, New York
RICHARD J. DURBIN, Illinois

MICHAEL O'NEILL, *Chief Counsel and Staff Director*
BRUCE A. COHEN, *Democratic Chief Counsel and Staff Director*

CONTENTS

STATEMENTS OF COMMITTEE MEMBERS

	Page
Kohl, Hon. Herbert, a U.S. Senator from the State of Wisconsin	2
Leahy, Hon. Patrick J., a U.S. Senator from the State of Vermont, prepared statement	130
Sessions, Hon. Jeff, a U.S. Senator from the State of Alabama	20
Specter, Hon. Arlen, a U.S. Senator from the State of Pennsylvania	1

WITNESSES

Engler, John, Former Governor of Michigan, and President, National Association of Manufacturers, Washington, D.C.	9
Maron, Barry J., M.D., Director, Hypertrophic Cardiomyopathy Center, Mineapolis Heart Institute Foundation, Minneapolis, Minnesota	4
Mays, Donald L., Senior Director, Product Safety and Consumer Sciences, Consumers Union, Yonkers, New York	15
Panish, Brian J., Panish, Shea and Boyle, LLP, Los Angeles, California	7
Schwartz, Victor E., Shook, Hardy and Bacon, LLP, Washington, D.C.	13
Steinbuch, Rob, Professor, University of Arkansas at Little Rock, William H. Bowen School of Law, Little Roxk, Arkansas	12
Vandall, Frank, Professor, Emory School of Law, Atlanta, Georgia	11

QUESTIONS AND ANSWERS

Responses of John Engler to questions submitted by Senator Specter	32
Responses of Barry J. Maron to questions submitted by Senator Specter	39
Responses of Donald L. Mays to questions submitted by Senators Specter and Leahy	44
Responses of Brian J. Panish to questions submitted by Senators Specter and Leahy	53
Responses of Victor E. Schwartz to questions submitted by Senators Specter and Leahy	61
Responses of Rob Steinbuch to questions submitted by Senators Specter and Leahy	76
Responses of Frank Vandall to questions submitted by Senators Specter and Leahy	81

SUBMISSIONS FOR THE RECORD

Center for Corporate Policy, Charlie Cray, Director, Washington, D.C, prepared statement	89
Claybrook, Joan, President, Public Citizen, Laura MacCleery, Deputy Director, Auto Safety Group, Public Citizen, and Rachel Weintraub, Director of Product Safety & Senior Counsel, Consumer Federation of America, Washington, D.C., joint prepared statement	102
Engler, John, former Governor of Michigan, and President, National Association of Manufacturers, Washington, D.C., prepared statement	114
Hester, Theordore M., King & Spalding, LLP, Washington, D.C., on behalf of Guidant Corporation, letter	128
Maron, Barry J., M.D., Director, Hypertrophic Cardiomyopathy Center, Mineapolis Heart Institute Foundation, Minneapolis, Minnesota, prepared statement	132
Mays, Donald L., Senior Director, Product Safety and Consumer Sciences, Consumers Union, Yonkers, New York, prepared statement and oral testimony	137

Page

New York Times, Stephen Labaton, March 10, 2006, article 149
Panish, Brian J., Panish, Shea and Boyle, LLP, Los Angeles, California, prepared statement 152
Schwartz, Victor E., Shook, Hardy and Bacon, LLP, Washington, D.C., prepared statement and attachment 179
Steinbuch, Rob, Professor, University of Arkansas at Little Rock, William H. Bowen School of Law, Little Roxk, Arkansas, prepared statement 202
Terwilliger, George J., III, White & Case LLP, Washington, D.C., prepared statement and attachment 213
Vandall, Frank, Professor, Emory School of Law, Atlanta, Georgia, prepared statement and attachement 246

DEFECTIVE PRODUCTS: WILL CRIMINAL PENALTIES ENSURE CORPORATE ACCOUNTABILITY?

FRIDAY, MARCH 10, 2006

UNITED STATES SENATE,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Committee met, pursuant to notice, at 9:30 a.m., in room SD–226, Dirksen Senate Office Building, Hon. Arlen Specter, Chairman of the Committee, presiding.

Present: Senators Specter, Sessions and Kohl.

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

Chairman SPECTER. Good morning, ladies and gentlemen. The Senate Judiciary Committee will now proceed with our hearing on the subject of defective products, with a focus on whether the imposition in certain extraordinary circumstances of criminal penalties would promote individual and corporate accountability.

The essential issue is that when an individual knowingly, maliciously, intentionally engages in reckless conduct which results in the death of another person, such conduct constitutes malice at common law and supports prosecution for murder in the second degree. The issue which the Committee will be exploring is whether that would be, as a matter of public policy, appropriate for legislation at the Federal level.

I would have preferred to have held this hearing last Tuesday when it was originally scheduled, but the Judiciary Committee has had a very, very heavy workload and we were occupied with the immigration reform legislation, so we had to put it off. And the question was whether we put it off for several weeks or try to move ahead, and many witnesses were lined up and we thought we would do it on Friday, since we had an open date.

Friday is not a very good day to hold hearings from the point of view of having Senators present, but it is a good day to hold hearings from the point of view of being uninterrupted because the Senate is not in session today, so there will not be votes, which frequently occur which delay the hearings.

Senators characteristically return to their home States as soon as the Senate is not in session to take care of business in their home States. As a matter of fact, later today I will be back in Pennsylvania myself. We have heard that at least one other Senator plans

to attend, and we will see what develops and there may be others who come in.

The issue at hand came into very sharp focus many years ago with the Pinto case, where there were corporate documents which showed that the gas tank was placed in a dangerous position because it was cheaper to put the gas tank in that locale and to pay damages for injuries and deaths, that it would be a matter of corporate profitability.

That case made a fair size impact on me personally. I was district attorney of Philadelphia at the time. There ultimately was a prosecution in that case by a local prosecutor in Indiana, I believe, and there was an acquittal. From all indications, the case was not handled as well as it might have been, certainly not as well as a Federal prosecution would be.

Welcome, Senator Kohl.

The problems continue at the present time with story just last week in the New York Times concerning the Guidant Corporation, where there was knowledge for 3 years that its heart defibrillator might short-circuit and fail after being implanted. The publication in the New York Times suggested that a number of patients might have died there, and the problem is as current as the Guidant case and we will hear some testimony on that today.

In selecting the matters to be presented in the hearing, we necessarily have gone to some cases which are old cases, and they have been selected because they make the point. To the extent that this conduct continues at the present time is something which we will endeavor to determine.

It is not our intent to create any further problems for any companies which are having tough times in a tough market. I think it not inappropriate to note that foreign manufacturers illustratively of automobiles would have liability. Even though the cars were manufactured out of the United States, where they are sold in the United States and injuries occur in the United States, that would be within the jurisdiction of Federal legislation. So as a competitive matter, it would balance out.

Let me yield at this time to my distinguished colleague, Senator Kohl, of Wisconsin.

STATEMENT OF HON. HERB KOHL, A U.S. SENATOR FROM THE STATE OF WISCONSIN

Senator KOHL. Thank you very much, Senator Specter. I appreciate very much your calling this hearing today. It is an unfortunate truth that from time to time consumers are injured by products they purchase. Your bill tries to minimize the frequency of these injuries by punishing anyone who would knowingly sell unsafe items. That is an admirable and a serious approach to the issue, but not the only one.

Another way to protect consumers is to let them know when the products they buy have done harm to others. This is the goal of a bill that I have supported for many years called the Sunshine in Litigation Act. This bill would curb the ongoing abuse of secret settlement agreements in Federal courts. The result of this abuse is to keep important health and safety information from the public.

The problem is not hard to understand. Typically, an individual sues a manufacturer for an injury resulting from a product defect. The injured person has limited resources and faces a corporation that can spend an unlimited amount of money to delay and defend the case. Facing a formidable opponent, plaintiffs often seek to settle the litigation. In exchange for the award that they sought, the victim agrees to keep secret information disclosed during the litigation. While the plaintiff gets a respectable settlement, the defendant keeps secret the information about the defective product. Others eventually pay the price, as the public remains unaware of critical public health and safety information that could potentially save lives.

The most famous case of abuse involved Bridgestone-Firestone tires. From 1992 to 2000, tread separations of various tires were causing accidents across the country, many resulting in serious injuries and even fatalities. Instead of acting responsibly, Bridgestone-Firestone quietly settled dozens of lawsuits, most of which included secrecy agreements. It wasn't until 1999 when a Houston public television station broke the story that the company acknowledged its wrongdoing and recalled 6.5 million tries. But by then, it was too late to prevent many unnecessary injuries and deaths which occurred.

The case of General Motors fuel tanks also demonstrates the problem. An internal memo showed that GM was aware of the risks from crashes of trucks with side-saddle fuel tanks which eventually led to an estimated 750 fatalities. When victims sued, GM disclosed documents only under protective orders and settled these cases on the condition that the information remain secret. GM used this type of fuel tank for 15 years before it was discontinued.

There are no records kept of the number of confidentiality orders accepted by the State or Federal courts. However, anecdotal evidence suggests that court secrecy and confidential settlements are prevalent. Beyond General Motors and Bridgestone-Firestone, secrecy agreements had real-life consequences by allowing Dalkon Shield, Bork-Shiley heart valves, Con Edison cable covers and numerous other dangerous products to remain on the market.

The Sunshine in Litigation Act is a modest proposal that would require Federal judges to perform a simple balancing test to compare the defendant's interest in secrecy against the public's interest in health and safety information. Specifically, prior to making any portion of a case confidential or sealed, a judge would have to determine by making a particularized finding of fact that doing so would not restrict the disclosure of information relevant to public health and safety.

Moreover, all courts, both Federal and State, would be prohibited from issuing protective orders that prevent disclosure to relevant regulatory agencies. Of course, important trade secret information could still be kept private. This legislation does not prohibit secrecy agreements across the board. It does not place an undue burden on judges or our courts. It simply states that where the public interest in disclosure outweighs legitimate interests in secrecy, then courts should not shield important health and safety information from the public.

Mr. Chairman, letting sunshine in on these secret settlements would complement your legislation on defective products, and I hope that we can work together on this issue to protect consumers.

Thank you, Mr. Chairman.

Chairman SPECTER. Thank you very much, Senator Kohl.

Senator Leahy, the Ranking Member of this Committee, could not be here today. When the hearing was rescheduled, he could not make it. He had other business in his State to attend to. But without objection, we will make his statement a part of the record. The first paragraph I think it appropriate to read briefly.

Senator Leahy in his statement writes, quote, "Today, we convene to discuss the merits of legislation that would provide Federal criminal penalties for the introduction of dangerously defective products into the stream of interstate commerce. This is important legislation that could protect millions of Americans and its potential is something we should carefully explore. Today's hearing is a good start, and I commend Chairman Specter for his efforts here."

Our first witness this morning is Dr. Barry Maron, Director of the Hypertrophic Cardiomyopathy Center at Minneapolis Heart Institution Foundation, and was active in disclosures on the Guidant defibrillator case. Dr. Maron received his undergraduate degree from Occidental College, in Los Angeles, and his M.D. from Tulane University in New Orleans.

By way of brief additional introduction, the New York Times just yesterday published a story accounting for certain events in this matter, and one worth noting specifically was a memorandum submitted by a consultant, Dr. Richard Fogus, who told the company that their decision to withhold data about device defects was a breach of ethical duty and has subjected patients to the risk of serious bodily harm or, beyond that, fatalities.

Dr. Maron, thank you for joining us. The rule of our Committee is that there be 5-minute opening statements, and before you testify I would like to have all the witnesses stand and have the oath administered, which is the Committee's practice.

Do each of you solemnly swear that the testimony you will give this Senate Judiciary Committee will be the truth, the whole truth and nothing but the truth, so help you God?

May the record show that all have answered in the affirmative.

Dr. Maron, the floor is yours.

STATEMENT OF BARRY J. MARON, M.D., DIRECTOR, HYPERTROPHIC CARDIOMYOPATHY CENTER, MINNEAPOLIS HEART INSTITUTE FOUNDATION, MINNEAPOLIS, MINNESOTA

Dr. MARON. Thank you, Chairman Specter, Senator Kohl. As you mentioned, my name is Dr. Barry Maron. I am a cardiologist, in Minneapolis, at the Minneapolis Heart Institute.

Hypertrophic cardiomyopathy, also known as HCM, is a genetic form of heart disease and the most common cause of sudden cardiac death in young people, including athletes. Since 2000, I have promoted the implantable defibrillator as a preventive therapy for sudden death in hypertrophic cardiomyopathy, and with good reason, for we have demonstrated repeatedly that the defibrillator is life-saving by virtue of recognizing and automatically terminating lethal disturbances of heart rhythm.

In 1999, I and my colleague, Robert Hauser, treated a 21-year-old student, Joshua Oukrop. He had a severe form of this disease and was at high risk for sudden and unpredictable death. We recommended that a defibrillator be implanted as a prophylactic measure in late 2001. The model is Guidant Prizm 2DR 1861.

Three-and-a-half years after receiving his defibrillator, Joshua Oukrop died unexpectedly while on vacation in Utah. Analysis of the defibrillator by Guidant found that a short-circuiting defect caused the device to become electrically inoperative and to fail. When the defibrillator tried to issue a life-saving shock, electrical energy short-circuited and dissipated, and therefore did not enter Joshua's heart as it should have and he was unprotected and he died.

Shortly thereafter, in a meeting with four Guidant executives, I learned that this precise problem had been known by the company for over 3 years, but only to Guidant and to any physicians or patients. It was obvious that Guidant believed that it was correct, and even prudent, to conceal all information related to such defibrillator defects. I was asked for my opinion on this strategy and I said I think this is going to be the biggest mistake you will ever make. They said they did not agree.

Mr. Oukrop's reaction, the father: "I told Joshua that the defibrillator was his best chance, that it would allow him to survive and live his life, and you are telling me that they knew all along?" In fact, at that time Guidant did know. They had already documented 25 other similar short-circuited defibrillators and had already made adjustments in 2002 to newly manufactured defibrillators to correct the problem. Still, Guidant had not informed physicians, patients or the Government. Furthermore, and perhaps most disturbing, the company continued to sell old defibrillators known to be defective.

Therefore, this death was not due to an unforeseen, random component failure, as the company once suggested, but, in fact, was a systematic, repetitive, and to some extent predictable problem that cannot be anticipated or monitored. In effect, Guidant had taken over the primary medical management of thousands of high-risk defibrillator patients without their permission. It was the executives who were practicing medicine in this situation and not the physicians.

Only because the facts of this unfortunate situation were documented in a series of New York Times articles by Barry Meier have these problems in the defibrillator industry become evident to all. In fact, these circumstances ultimately led to the largest recall of defibrillators and pacemakers in the 25-year history of this industry.

The Guidant affair is about patients and their physicians, and the overwhelming importance of informed consent and full disclosure to patients through their physicians. Patients have the right to know any information that could potentially impact their risk for injury or death. It simply is not ethical to withhold such information. Patients must have this autonomy, the opportunity to make important medical decisions in conjunction with their fully informed physicians.

It is also important to establish what the Guidant affair is not. It is not a statistical issue. It is not about percentages and probabilities, because patients are not numbers. They are individuals with a reasonable expectation that industry will communicate openly and accurately with their physician. I think most observers agree that that did not happen here. One of our patients told a Guidant executive, quote, "It is just not your call to make," unquote. Most of the cardiovascular community, I think, would agree with that.

It is time for greater oversight, greater transparency and communication between industry and the physician community in order to restore the trust of patients in powerful medical devices such as the implantable defibrillator. To make it criminal to knowingly sell defective defibrillators would, I think, have the desired effect on the willingness of companies to make full disclosure. However, such a bill would have to be drawn narrowly enough to avoid a potentially chilling effect on law-abiding companies whose products could, in fact, have occasional random defects.

Thank you for the opportunity to tell this story to the Committee.

Chairman SPECTER. Thank you, Dr. Maron.

We had extended an invitation to Guidant to come in and participate in the hearing so that they would have an opportunity to respond to what Dr. Maron has testified to. Ordinarily, we await the conclusion of the entire panel before Senators question and we will follow that as a generalization here today, but in an effort to get Guidant's point on the record contemporaneously with your testimony, Dr. Maron, I note that your statement says that Guidant executives believed that it was correct, and even prudent, to conceal all information related to such defibrillator defects.

To state their position to the extent you can, when you say that they believed it was correct and even prudent, what factors would lead Guidant to that conclusion?

Dr. MARON. Yes. That argument includes the idea that they did not want to frighten the general public, and part of that would have been that—and this is their position, obviously, not mine—patients would have their devices removed, these potentially defective devices, and replaced with other devices, and that would place these patients at undue risk.

The risk I think they are talking about there is the small risk of infection which is treatable. It is less than 1 percent, and every patient who has a defibrillator must have their device removed and replaced every 5 years, on the average, anyway. So the argument is a little bit weak in the sense that they are suggesting a danger by replacing defibrillators that would have to be replaced anyway as a course of the standard management of their disease and the defibrillator.

Chairman SPECTER. Thank you, Dr. Maron.

[The prepared statement of Dr. Maron appears as a submission for the record.]

Chairman SPECTER. Our next witness is Mr. Brian Panish, lead plaintiff's counsel in the products liability case against General Motors involving a defective 1979 Chevrolet Malibu fuel tank that caused serious bodily injury to several people. Mr. Panish received

his undergraduate degree from California State University and his law degree from Southwestern University Law School.

Mr. Panish, you are going to be testifying about a case which is admittedly an old case, and I think that ought to be plain on the record so that those who are listening to it understand that these events happened a long while ago and do not necessarily mean that General Motors is engaging in the same conduct at the present time. But the case did receive considerable public attention because of the underlying facts and it was decided that this is a case which had value for a public understanding of the nature of the problem.

Thank you for joining us and we look forward to your testimony.

STATEMENT OF BRIAN J. PANISH, PANISH, SHEA AND BOYLE, LLP, LOS ANGELES, CALIFORNIA

Mr. PANISH. Well, thank you. Good morning, and I thank the members of the Committee for inviting me to speak here today. This issue is an issue extremely important to the health and safety of all Americans, and I am pleased that the Senate Judiciary Committee is taking the time to examine it in detail.

I am also encouraged by your willingness, Senator Specter, to consider additional legislative steps that would complement the civil justice system in helping to deter corporations from selling products that they know are dangerous. I look forward to working with the Committee on this issue.

I have seen firsthand the devastating impacts that corporate deceit can have on a family. I represented Patricia Anderson and her four children in a case against General Motors that went to trial in 1999.

Chairman SPECTER. That went to trial in 1999?

Mr. PANISH. Was the trial, yes, sir.

Patricia and her children suffered horrendous and disfiguring burn injuries by General Motors because General Motors put a car on the market, the Malibu, that it knew contained dangerous defects related to the placement of the fuel system. If the tank had been designed differently, the vehicle would not have exploded when it was rear-ended and the children would have suffered only minor injuries and walked away.

On Christmas Eve, Patricia and her children were returning from church in their 1979 Malibu. As they approached an intersection, their vehicle was rear-ended and the gas tank, due to its close location to the bumper, was punctured, resulting in leakage of fuel and a huge explosion. Patricia saw smoke and flames and heard her children asking Jesus to help them. Her 8-year-old daughter Kiontra tried to shield her younger brother and sister from the flames with her body. As a result, she received horrific burn injuries.

Several witnesses immediately rushed to the vehicle trying to free the passengers, but the door knobs were too hot to open the doors. So they used a shopping cart to smash the window to remove the passengers. As a result of the fire, Patricia and her children suffered third-degree burns over large portions of their bodies and underwent numerous skin-grafting surgeries which involved taking healthy skin from other parts of their bodies and grafting it to the unhealthy skin that had been burned. The burns resulted in loss

of limb, severe scarring and significant deformities. The scarring resulted in serious pain to the children as they grew, causing future surgeries, loss of range of motion and serious psychological damage.

General Motors knew what was going to happen. What makes this horrible story more outrageous is that the injuries were preventable. Before General Motors sold the gas tank in the Malibu, they knew that the placement was dangerous. The evidence revealed that they knew a safer location of the fuel tank existed, that they had performed cost/benefit analysis comparing the cost of human life in a dollar amount versus the cost of redesigning the fuel system. They knew that its testing was woefully inadequate and they made a conscious decision to sell a product they knew was dangerous and could cause death or serious injury.

At trial, we established and the evidence proved that General Motors knew for several decades that a safer design existed. As far back as 1961, Ed Cole, a design engineer who later became president of General Motors, had patented an over-the-axle tank that had been proposed that GM had designed prototype vehicles for and had tested. GM again had engineers perform cost/benefit analysis evaluating the location of the fuel system, and in this case less than 11 inches from the rear bumper, in a memo which later became known as the Ivey memo, and I have provided copies.

Mr. Ivey determined that about 500 deaths per year were caused by fuel-fed fires and they, General Motors, would spend an average of $200,000 per fatality. Mr. Ivey further concluded that based on the number of vehicles on the roadway, General Motors would spend approximately $2.40 per vehicle to prevent fuel system-fed fires. The amount to redesign and place the gas tank in the alternative location cost $8.59. At trial, the chief design engineer of fuel systems testified that performing cost/benefit analysis of human life was despicable. Finally, in 1983, this memo came to light and Mr. Ivey was interviewed by General Motors lawyers and admitted that, in fact, he had performed this memo for his superiors, that he was directed to perform it, and the jury was able to hear the cold, calculated decisions that General Motors made.

Patricia Anderson and her children's lives will never be the same. Perhaps your attention to this issue will avoid similar outcomes for other families. This case illustrates the vital role the civil justice system plays in both revealing facts that are important to the public's health and safety and attaining some measure of justice for those families injured or killed due to the deliberate actions of others.

Sadly, this is not the only example of corporate executives choosing to risk the lives and futures of families like the Andersons for a few extra dollars of profit. Not too long ago, we faced the Ford-Firestone crisis. I encourage any additional steps this Committee can take to see that only safe products are put on the market and that if a product well on the market is determined unsafe that the manufacturers do the right thing and remove it from the market. The threat of criminal sanctions could help corporate execs make better and safer choices.

I thank you for your time and welcome any questions you may have. Thank you.

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

Chairman SPECTER. Thank you very much, Mr. Panish.

Our next witness is the former Governor of the State of Michigan, Mr. John Engler, now the President of the National Association of Manufacturers—three-term Governor, actually, from Michigan, with extensive experience as majority leader of the Michigan State Senate before that. He has his undergraduate degree from Michigan State and his law degree from Thomas Cooley Law School.

We welcome you back to the Judiciary Committee, Governor Engler. You were here to testify about the asbestos crisis, which has caused serious injuries to tens of thousands of people and resulted in 77 bankruptcies and an enormous drain on the economy. I mention that because it is relevant as to your contribution and help to the Senate, and also to say that we are still working on asbestos. So you may be recalled at a later time.

But today you are here representing the National Association of Manufacturers and we welcome you to give another perspective on this issue.

STATEMENT OF JOHN ENGLER, FORMER GOVERNOR OF MICHIGAN, AND PRESIDENT, NATIONAL ASSOCIATION OF MANUFACTURERS, WASHINGTON, D.C.

Governor ENGLER. Thank you very much, Mr. Chairman. I am delighted to be back, and I also want to compliment you on the work that you have been doing this week on immigration, also a very important topic. We are grateful for you and the Committee.

Mr. Chairman, the National Association of Manufacturers is the Nation's largest industrial trade association, representing small and large manufacturers in every industrial sector in all 50 States, including Senator Kohl's State of Wisconsin. Through our direct membership and our affiliated organizations, the Council of Manufacturing Associations, the Employer Association Group and State Associations Group, we represent more than 100,000 manufacturers. We are grateful for the invitation and the opportunity to testify on this very important question: Would it be wise to make the act of knowingly allowing a defective to be introduced into the stream of interstate commerce a criminal offense?

While this proposal may be well-intentioned, the NAM believes it is fraught with many unforeseen and potentially counterproductive consequences. The National Association of Manufacturers does not defend any manufacturing employee who would intentionally introduce a defective product into the marketplace. However, we are here today because of our concern about the real-world and practical difficulties of criminalizing what often are subjective judgments.

There already are criminal statutes at the disposal of a U.S. Attorney to address this kind of behavior. This relatively new idea of criminalizing product liability has been explored by Congress at least twice in the recent past, in 2000—this has been mentioned already—when the Transportation Recall Enhancement, Accountability and Documentation Act was passed. That was the Firestone-Ford matter.

More recently, a criminal penalties provision for maritime products actually showed up in the Senate-passed Coast Guard Authorization Act of 2004. That language didn't have the chance to come before this Committee, was not publicly debated, ended up being modified in conference and ultimately tied to objective criteria.

In both cases, the NAM felt that the committees with jurisdiction over criminal penalties—and that would be the respective Judiciary Committees of the Senate and House—needed to explore the issue more carefully. Here is why. Thousands of decisions are made in a manufacturing company everyday by the R and D staff, by the engineers, product and quality personnel, assembly line and factory floor workers.

Defining "product defect" is one of the most complex and varied aspects of product liability, as evidenced by the numerous variations of product defect standards among the States. At the same time, the legal concept of what constitutes a criminal act is sort of being whittled away by the courts.

Imagine the dilemma faced by a manufacturer who keeps very precise records about products that are returned. What if one or more proved to be defective? Even if the defect rate is extremely low, would the manufacturer knowingly be placing a defective product into the stream of interstate commerce simply because the product line is not one hundred-percent defect-free? Are we seeking to hold a manufacturer criminally liable for the one-in-a-million problem? By the same token, would criminal intent be established if there was a warning label and that warning label was not clear enough for every single consumer user of the product to understand?

Every product can cause injury under some circumstances. Justice Breyer wrote, "Using this vivid example, over the next 13 years we could expect more than a dozen deaths from ingested toothpicks," end quote. If product liability violations were criminalized, actual victims also might find themselves forced to wait out the criminal justice system.

Mr. Panish's example of a trial that took place in 1999—that would be a long wait, almost as long as some of those asbestos cases, Senator. But no judge presiding over civil litigation is certainly going to force an individual involved to forswear his or her right to Fifth Amendment protections. The criminalization of product liability law could impede safety, as companies delay improving products for fear it will be seen as an admission that their products are dangerous.

Poorly conceived legislation could end up forestalling fact-finding, including how and why the problem occurred. It could also worsen the U.S.'s comparative advantage, or in this case disadvantage, in legal costs which, expressed in GDP terms, are twice as high as in other industrial nations that we compete everyday with.

As you consider this matter, I hope that this Committee will remember the genesis of punitive damages in the common law is that they were to serve as a substitute punishment and deterrent for acts that would be difficult to criminalize. We are pleased that the Judiciary Committee is studying the issue. We hope the Committee will carefully weigh the arguments and conclude that the proposal to criminalize product liability as prepared today is not a good idea.

We are happy to answer questions, Mr. Chairman.

[The prepared statement of Governor Engler appears as a submission for the record.]

Chairman SPECTER. Thank you very much, Governor Engler.

Our next witness is Professor Frank Vandall, a professor at the Emory School of Law. He has written extensively on torts, product liability and design defects of consumer products. He received his undergraduate degree from Washington and Jefferson College, near Pittsburgh, and his law degree from Vanderbilt University.

Thank you for coming to Washington today, Professor Vandall, and we look forward to your testimony.

STATEMENT OF FRANK VANDALL, PROFESSOR, EMORY SCHOOL OF LAW, ATLANTA, GEORGIA

Mr. VANDALL. Mr. Chairman, Senator Sessions, it is my pleasure to be here. I would like to discuss with you two concepts—preemption and non-enforcement of the law.

Preemption is a recent development and holds that Federal statutes or regulations may preempt a State statute, regulation or the common law. Preemption emanates from the Supremacy Clause of the Constitution, Article VI, section 2. My reading of the key cases—*Cipollone* v. *Liggett*, *Geir* v. *American Honda* and *Medtronics* v. *Lohr*—is that the Federal courts can decide to preempt State law at will. The goal in a preemption case is to discern the intent of Congress. Therefore, it is on a case-by-case basis and there is no black letter law of preemption. The bill as drafted leaves open the risk that it may be interpreted to preempt State products liability law.

Non-enforcement refers to the issue of whether or not a particular written law will be enforced. Because of insufficient funds and a shortage of personnel in the investigative and prosecutorial levels, there is a real risk that the Act will not be enforced. People respond to the level of enforcement, not the written law. This can be shown by driving on the interstate in Atlanta, Georgia. The speed limit is 70 miles an hour. The people travel at 80 miles an hour, until they see a police car. Then they slow down to 70 or 65.

My concern is the interplay between preemption and non-enforcement. Once the bill is passed, it is likely that the courts will hold that it preempts State products liability law because it occupies the field. This would be a tragedy because civil products liability law is the cheap and effective method of deterring defective products.

Further, because of the high cost of prosecuting corporate executives and social realities—that is that the judges and the CEOs come from the same class, have similar educations and perhaps are golfing buddies—the Act will not likely be enforced. The reality is that corporate executives and employees will not likely be prosecuted. The result will be that although the Act will not be enforced, it will be interpreted to preempt State products liability law. The solution is easy, and that is that the bill should clearly state that Congress does not intend to preempt State statutes, regulations or the common law with this Act.

In conclusion, I am in favor of the bill if the phrase "Congress does not intend to preempt State law" is inserted. I am opposed to the bill if it could be interpreted to preempt State products liability

law. I am concerned that the Act will not be fully enforced. In my opinion, a better solution than the bill would be to shore up and support the civil products liability system. The product system police, the litigation attorneys, are trained and ready.

Thank you.

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

Chairman SPECTER. Thank you very much, Professor Vandall.

We now turn to Professor Robert Steinbuch, from the University of Arkansas School of Law, formerly counsel to Senator Michael DeWine, a distinguished member of this Committee, and Professor Steinbuch was special counsel to the Justice Department at one time. He received his undergraduate and master's degrees from the University of Pennsylvania, and a law degree from Columbia.

The floor is yours, Professor.

STATEMENT OF ROB STEINBUCH, PROFESSOR, UNIVERSITY OF ARKANSAS AT LITTLE ROCK, WILLIAM H. BOWEN SCHOOL OF LAW, LITTLE ROCK, ARKANSAS

Mr. STEINBUCH. Thank you, Mr. Chairman, Senator Sessions. It is an honor to be back before this Committee.

Currently, only corporations are exposed to civil liability for risky corporate behavior. Corporate executives do not face a comparable liability. Corporate actors, however, receive the benefits of risk-taking by corporations. These corporate actors externalize the costs of risky behavior, but internalize those benefits. The result is excessively dangerous behavior and unsafe outcomes.

Your legislation, Senator, will correct this. Your legislation will correct the incentive asymmetry that is created by this dual system of liability. It places non-transferrable costs directly on corporate actors. Your legislation will create appropriate incentives for data collection and investigation, and appropriate incentives for disclosure. A core premise underlying the efficient market theory is that adequate information is disseminated to the public. Your legislation will pursue this goal.

Senator, if Sarbanes-Oxley can impose criminal penalties on corporate actors for financial wrongs, surely we can have the same standard for acts that kill. There have been several criticisms levied against your legislation. First is that it is hard to define a defect or an excessively dangerous product. Let's be clear about what we are talking.

There are many products on the market today that are dangerous, but not excessively dangerous. There are many products on the market today that are dangerous, but have no defects. More Americans die in car accidents over 2 years than died in the whole Vietnam war, but cars are not inherently defective. They have an inherent danger. That is acceptable.

A defect is defined in several ways; as Mr. Panish described, one refers to the introduction of a risk that is beyond what is already in the marketplace. That is unacceptable. There are several examples of this, some discussed already here. You mentioned the Ford Pinto case, a well-known case; the Dalkon Shield case, where the company allowed women to be subjected to defective products that injure or kill for years before it was disclosed.

Also, Senator, I am involved with the Chest Pain Society, and through this work I have come to learn a little bit about heart attacks. If you are having a heart attack, you go to a hospital. You go because you want an angioplasty. You want that blocked blood vessel to be opened. Well, there are many hospitals that don't have this capability, but they want your business, and so they advertise the ability to treat chest pain patients.

Mather Memorial Hospital in New York is one such hospital. They put out this flyer which is entitled "Community News." It looks like a news report. It contains articles looking like news reports. It is not a news report. It is an advertisement. In that advertisement, they say patients are seen and evaluated within moments of their arrival for chest pain and appropriate treatment is begun immediately.

The problem with this advertising, Senator, is that they can't do angioplasty. What is the appropriate treatment? The American Heart Association and the American College of Cardiology says it is angioplasty, but this hospital advertises for your business. That is misleading. That causes death.

Another concern raised about your bill, Senator, is that there may be rogue prosecutors and law enforcement pursuing these cases for their own personal interest. Well, I guess that is a possibility. I do know, Senator, that you as well as Senator Sessions were both prosecutors, and I trust in the public service of people like you to do the right thing.

There is also the suggestion that criminal prosecution would delay civil recovery. That is simply wrong. Civil cases run parallel to criminal cases. Indeed, any plaintiff's attorney worth his salt wants the criminal case; it helps his case.

Senator, I thank you for listening to my remarks and I am open to any questions.

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

Chairman SPECTER. Thank you very much, Professor Steinbuch.

We now turn to Mr. Victor Schwartz, who chairs the Public Policy Group at Shook, Hardy and Bacon, and has been co-author of the most widely used tort case book in the United States. He has an undergraduate degree from Boston and a law degree from Columbia. Mr. Schwartz has appeared before Congressional committees with some frequency over the past couple of decades, to my knowledge, and he is very, very experienced in this field.

We welcome you back, Mr. Schwartz.

STATEMENT OF VICTOR E. SCHWARTZ, SHOOK, HARDY AND BACON, LLP, WASHINGTON, D.C.

Mr. SCHWARTZ. Thank you, Senator, and good morning to you, Senator, and to Senator Sessions. I have been pleased to be invited here today. The U.S. Chamber Institute for Legal Reform, thousands of members, and the American Tort Reform Association asked me to be here on their behalf. But they have heard me before, so they said they are not responsible for anything I say.

I do want to address something in this proposed bill because it it relates to a topic that I have learned from the people who taught me law, Bill Prosser, and for 30 years Dean Wade, my coauthor.

They first attempted to define "defect" in *Restatement of Torts* (Second), where they said a defective product was unreasonably dangerous to the user or consumer. That is what they said.

This definition of defect spawned more case law than any other words in the history of torts, conflicting all over the place. What is a design defect? What is a warning defect? Case books, law books, thousands of pages. Can such a word be used to describe a crime? You can know something, and a knowing standard is a very important standard, but if what you know is a non-descriptive word, it really isn't fair to somebody because they have no notice of what the crime is.

Senator Sessions, you pointed that out in the TREAD Act when that was going through and helped modify it so there wasn't a non-descriptive word used for a crime like "defect."

From 1992 to 1998, I worked with the brightest law professors in America. I learned then what I saw today: you can have two law professors and four opinions. But I also learned that the trouble of defining "defect" persists. We tried to define "defect." It is in *Restatement of Torts* (Third). We did a better job, I think, because of the 30 years of experience that we had, but it is still an opaque concept.

Just take the recent Vioxx cases. In the first case, Vioxx manufacturers lost a $253 million judgment under "defect." In the second case, in Atlantic City, a jurisdiction that is friendly to plaintiffs, Merck won. In the third case, which was in Texas, there was a hung jury. In the next case, which was the same case moved over to Louisiana, there was a defense verdict. I don't think we want the criminal law to depend on standards like that, a roulette wheel of that type.

The bill also tries to talk about comparative safety, and that is an important concept, but any product that is made today has a degree of safety and you usually can find a product that is safer and less safe. The bill suggests that the one on the bottom of the food chain is going to be criminally viable. But if they are, then you go up one more. How many safety features are on a product may depend on the price of the product. If you buy a toaster oven for $100, it is going to have more features than one for $20. But this would, apart from searching for something that I think is very hard to find, and that is a defective product, cause manufacturers to shun less expensive products that do the job, but really are not dangerous at the level that deserves punishment. And let me mention punishment.

We have punitive damages. If anything, there is over-heating in the system now. Just as Sandra Day O'Connor said, punitive damages have run wild in this country and people don't know when they are going to be punished or how they are going to be punished or where. It is over-heated at this point, and that is why constitutional constraints have been put on punitive damages. It is really not a wise thing right now to add yet another vague alternative and make it criminal.

I did want to add to the record an article by Professor Wheeler, who tried the Pinto criminal law case. I didn't append it to my testimony because I didn't want a lot of paper sent up here, but I think you would find it informative.

In a nutshell, this is an idea that really does sound good. We don't want manufacturers to be killing people, but to put a crime based on the topic of defect is putting a crime based on a fog. And we don't want our Department of Justice to be there where instead of doing their job, you have good friends, like one who testified earlier, kind of waiting outside to see if there is going to be an indictment, because even if there was the slightest hint of an indictment, I assure you there would be a product liability pinata lawsuit following that that no one has ever seen before.

I thank you for your time. I look forward to your questions.

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

Chairman SPECTER. Thank you very much, Mr. Schwartz.

Our final witness is Mr. Donald Mays, Senior Director for Product Safety and Consumer Services at Consumer Reports. He received his undergraduate and master's degrees from Manhattan College.

Thank you for joining us today, Mr. Mays, and we look forward to your testimony.

STATEMENT OF DONALD L. MAYS, SENIOR DIRECTOR, PRODUCT SAFETY AND CONSUMER SCIENCES, CONSUMERS UNION, YONKERS, NEW YORK

Mr. MAYS. Good morning, Chairman Specter and Senator Sessions. I am Donald Mays, Senior Director of Product Safety and Consumer Sciences for Consumers Union, publisher of "Consumer Reports." Thank you for providing me the opportunity to come before you today to discuss ways to improve the quality and safety of the consumer marketplace and support all efforts to achieve this important goal.

The ultimate question before the Committee today is whether or not criminal penalties will ensure corporate accountability. Will the threat of jail time serve as an effective deterrent in preventing dangerous products from reaching the hands of consumers? Will it force manufacturers to think twice? Would such legislation have prevented Ford-Firestone?

Before we answer those questions, I believe that it is critical to look at why legislation targeting marketplace accountability is necessary for the consumer interest, which, based on my experience, I believe to be very much the case.

My career has focused on product safety and performance testing for manufacturers and retailers, as well as for consumers. I believe I bring to the floor a unique perspective of someone who understands the competitive pressures of getting new products to the marketplace as quickly and as economically as possible. And from a consumer perspective, I understand the need to trust that all the products in the marketplace are produced with a high degree of integrity and safety.

My breadth of experience includes work in laboratories and factories both here and abroad. It has exposed me to countless examples of suppliers that failed to diligently build safety into their products. What is more disturbing are cases that I have seen where manufacturers and retailers have continued to sell unsafe products,

despite the emergence of a clear hazard pattern that results in serious injury.

My product safety work and expertise have led me to six overall conclusions that I would like to share with the Committee. No. 1, many injuries are avoidable if adequate pre-market safety testing is conducted. Two, manufacturers do not always react responsibly when informed that their products could potentially cause a repeated pattern of death or injury.

Three, due to changes in the global marketplace, consumers face increased risk from defective products. Four, there is a lack of compliance with voluntary safety standards. Five, there is inadequate enforcement authority, resources and activity by Federal agencies. And, six, civil penalties may not be an effective deterrent in preventing unsafe products from being in the marketplace. An example: a $750,000 civil penalty levied against Wal-Mart in 2003 for failing to report safety hazards with fitness machines cost the company an equivalent of their sales rung up in only 1 minute and 33 seconds.

So, clearly, Consumers Union strongly believes that the consumer marketplace does, in fact, need greater accountability. Consumers Union supports the introduction of legislation clearly designed to deter company employees with decisionmaking authority from knowingly jeopardizing consumer safety. And on this point, please let me be clear. We understand that any company can make a mistake, but it is what companies do after they have taken the time to do their due diligence and establish that they have a defect that could likely cause bodily injury or death that should be the focus of this bill. If companies don't go public and they continue to sell their defective products, then the individuals responsible should be punished to the fullest extent possible.

We believe the language of any legislation should be targeted so that responsibility cannot be avoided by company representatives who have the power to ensure that unsafe products are not marketed. In addition, knowledgeable employees who fail to pass along this information to appropriate government agencies should be held criminally responsible. Without this important information, government watchdog agencies are ineffective.

Furthermore, we believe the scope of any bill should be broad enough to underlie the entire marketplace and include not only traditionally manufactured products, but also vehicles, foods and drugs. A company representative that knowingly allows the introduction of tainted meats or hazardous pharmaceuticals to the market should be just as culpable as manufacturers that produce unsafe vehicles. We believe that the triggers for determining when a product is defective must be clearly defined and that an appropriate definition of "defective" is when a product could potentially cause a repeated serious injury or death.

Finally, this legislation should be expanded and address head-on how a company whose employees are prosecuted under the law must deal with removing their defective product from the marketplace. While it sends a strong message to make corporate officials responsible for their misdeeds, it is also important to take timely and effective measures to inform and assist consumers who still have the unreasonably dangerous product in their home. To pre-

vent future death and injury, the product itself should also be placed behind bars so that it cannot cause anymore harm.

Therefore, we urge you to consider expanding corporate duties to include an intensive effort on the part of the manufacturer to get the defective products off the market. Companies should at least be required to spend advertising dollars to inform consumers about their defective products with as much splash and sophistication as they spend on marketing it in the first place. Effective legislation to ensure responsible corporate behavior must focus on appropriate liability in a court of law and accountability in the court of public expectations.

I thank the Chairman and other members of the Committee for the opportunity to testify and I look forward to answering questions. Thank you.

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

Chairman SPECTER. Thank you very much, Mr. Mays.

We will now proceed with 10-minute rounds of questions by the Senators on the panel, Senator Sessions and myself.

Beginning with you, Mr. Mays, you made reference to a case involving Wal-Mart. What are the facts of that case?

Mr. MAYS. Wal-Mart continued to sell some exercise devices in their stores even after they knew that they were causing injury to customers who were actually trying the equipment out in their stores. Their failure to report that information to the Consumer Products Safety Commission, as required by Section 15(b), resulted in a civil penalty of only $750,000.

Chairman SPECTER. Are there many similar matters called to the attention of the Commission?

Mr. MAYS. There are many similar matters. Failure to report incident data to the Commission is probably the most common cause of civil penalties.

Chairman SPECTER. Mr. Schwartz, do you think that the possibility of a criminal sanction would have any effect at all on judgments of corporate officials in evaluating safety precautions which are expensive, contrasted with the evaluation of what their damages would be if the safety precautions are not undertaken?

Mr. SCHWARTZ. That is a good question and it does call for speculation, but I don't think so. I think that right now they can lose their jobs and they can lose their market share completely on a product once it is branded in the product liability system as being bad. It takes some time, and that threat, potentially millions and billions of dollars, is sufficient.

I think if there are additional penalties in the CPSC, that may be needed. That is a different question as to whether you introduce something that is very vague, very hard to understand, and illusory to kind of grab onto. So I don't think it will. Specific penalties, sir, that would be very clear and easy to understand might be needed in some areas, and they may help proper decisionmaking.

Chairman SPECTER. In what areas?

Mr. SCHWARTZ. Well, let's take the CPSC. If there isn't proper reporting of defective products to the CPSC, current penalties may be insufficient. People have a reason to know when they are supposed to report to the CPSC.

Chairman SPECTER. Those penalties go against the company, not the individuals.

Mr. SCHWARTZ. That is right. The separation of individuals and the companies is nothing that I have seen in my practice in 30 years. They are the company.

Chairman SPECTER. You think there would be no difference between an impact of a decisionmaker, say a chief executive officer, if he or she faced criminal sanctions, contrasted with the punitive damages in a civil case which would be awarded against the company and a cost really to the shareholders?

Mr. SCHWARTZ. As the appendix to my testimony shows, there are criminal sanctions for very serious acts by individual executives, and State attorneys general have power, which you would know, to go after people personally if they have the evidence that they have done something criminally wrong.

Chairman SPECTER. On defects in products?

Mr. SCHWARTZ. Well, not on defects in the products, and that is, I guess, the core of my testimony. "Defect" is one of those words that we think we know what it means, but not when it gets down to actually defining it, it is hard enough to define it in tort law. It is one of those words that we think, ah, I know what that means, like we may think we know what a reasonable person is in tort law.

Chairman SPECTER. I take it your answer is no.

Mr. SCHWARTZ. Well, I began with "no," but then you wanted to get me to "yes," so I went back to "no."

Chairman SPECTER. I didn't hear a "no." If I had heard a "no," I would have moved on to the next question. The question isn't whether there are some penalties scattered through the State law books. The question is whether there is any real program which deals with defects. And I will use that word; I think we can define it. I think there are many terms that are difficult to define. You started to move on to the definition of "reasonable." There are tens of thousands, hundreds of thousands of cases written on it, but on individual cases we deal with it.

That is why, Mr. Schwartz, I come back to the question as to whether the existing laws which you refer to involve products, and your answer to that was no.

Mr. SCHWARTZ. Well, the product liability laws are amazingly strong, over-strong, in my view, and this separation of somehow an executive, because he may not feel personally that he is going to go to jail, needs additional deterrence I have answered. I think when people are working in the companies—I work with them every single day of my life—they are thinking carefully about what decisions they are making, what warnings are to be on products. I have spent hundreds of hours on this and I don't see the need for any additional criminal deterrence to get to the right decision. That is just based on my experience.

Chairman SPECTER. Well, summarize for us again what are existing criminal deterrents.

Mr. SCHWARTZ. Well, there are existing criminal laws on manslaughter, negligent homicide and other provisions, and they are spelled out more carefully in the appendix to my statement. But I think that the power of——

Chairman SPECTER. But those don't refer specifically to products.

Mr. SCHWARTZ. No, they don't, but they can capture somebody who has knowingly and willfully tried to intentionally kill another person. I mean, those words we understand. We know what those words mean. We have always been kind to one another and we just happen to differ here, but the tort law classes—I was thinking of Fleming James, who may have been your teacher back at Yale.

Chairman SPECTER. He was.

Mr. SCHWARTZ. In tort law classes, they will say, "Well, what about this? What about that?" It is all vague. You step over into the criminal law and then there are very precise rules that govern conduct, and I think the two worlds shouldn't be put together.

Chairman SPECTER. When you describe the sequence of events, including manslaughter, those are not available to the Federal prosecutor.

Mr. SCHWARTZ. Well, there are State prosecutors and State tort laws. I don't see a need for Federal intervention and the Department of Justice getting into the area of defective products.

Chairman SPECTER. I take it your answer then to my question is they do not apply for Federal prosecutions.

Mr. SCHWARTZ. That is right.

Chairman SPECTER. OK, we got there.

Dr. Maron, tell us a little bit about the defibrillator. How does it work? What is its structure? What are the functions?

Dr. MARON. Well, it is a sophisticated device that has been in the marketplace for 25 years that is intended to——

Chairman SPECTER. And what happened to your patient?

Dr. MARON. Well, what happened was the device short-circuited, literally, and therefore the electrical energy that was intended to go into the heart to defibrillate, to restore normal rhythm, did not. It was dissipated. As a consequence, it was a non-functioning device at the precise moment that it was intended to function and was implanted for that reason.

Chairman SPECTER. And did Guidant, the manufacturer, know about that kind of a defect?

Dr. MARON. Yes. At the time of the death, they had 25 other examples, including 4 near-deaths, with precisely the same defect, the short-circuiting.

Chairman SPECTER. How do you know that Guidant knew that?

Dr. MARON. They told us. It is a matter of record. There is no dispute.

Chairman SPECTER. Professor Steinbuch, you mentioned the Dalkon Shield case. In passing, could you amplify what the facts were in the Dalkon Shield matter?

Mr. STEINBUCH. Senator, I am not an expert on that case, but I can tell you that the company put out a product for women to use, an IUD, that turned out to be severely flawed. It made women much more prone to infection, and then the company discovered this defect and did not disclose it to the public. And many women were injured, and I believe some women died as a result of this product.

Chairman SPECTER. And what were the facts, as you understand them, with respect to the knowledge on the part of the A.H. Robins Company which manufactured the Dalkon Shield IUD?

Mr. STEINBUCH. Well, I think it is the same issue that Dr. Maron just spoke about, and this is the same issue that pervades product defect cases. Companies discover that there is a defect. They have complaints and the complaints are processed and they are analyzed and they are evaluated. And they don't share this information with the public. They don't allow the public to make these choices. Today, we live in a complex world where a strict application of the concept of *caveat emptor* is no longer appropriate.

Chairman SPECTER. My time is almost up, so I want to come to a core question. Do you think the response from corporate executives would be different in notifying in the public, as you put it, if a potential criminal sanction was present?

Mr. STEINBUCH. Absolutely, Senator. Corporate tenure has been on the decline. People move from company to company, and the response of civil liability often comes after corporate actors leave individual corporations. Putting the responsibility on them criminally will carry along with them wherever they are and their actions will reflect that.

Chairman SPECTER. Thank you very much, Professor, and I will turn now to my distinguished colleague, Senator Sessions. By way of a brief introduction, you might be interested to know that yesterday at this time we had the tables arranged differently and we had a dozen Senators in this room going over a 300-page statute on immigration reform. And one of our most active participants was Senator Sessions, who had an array of amendments, and we went through them one by one.

We did our best to focus on an issue and, when we had a Committee consensus, to move on so that we could have some prospect at some time of finishing that bill. One of the most interesting moments that Senator Sessions and I were both involved in was a complex amendment offered by Senator Feingold which no one understood. I won't say Senator Feingold didn't. You would have to examine the transcript.

But the way we function is we have papers and we have assistants behind us and when we come to a question that we don't know the answer to—and I know this will be hard for you to believe that there are some questions we don't know the answers to—we turn to our assistants. And the communication is not very good on these complex questions, and we had gone around for about 30 minutes on an issue and we were getting nowhere. And as Chairman, I set the question aside until we could find out what we were talking about. We were analogizing it to Charlie McCarthy and Edgar Bergen, with the staff assistants trying to tell us what was happening here. But it just wasn't working, so we moved on. That is what you call a 1-minute digression.

Senator Sessions.

STATEMENT OF HON. JEFF SESSIONS, A U.S. SENATOR FROM THE STATE OF ALABAMA

Senator SESSIONS. Thank you, Mr. Chairman, and you have done a good job with immigration. It is a very difficult, difficult issue and people have some various views about it and it is important. You have also moved the asbestos bill, which is also hugely impor-

tant. Some of these witnesses are aware of that or have even testified with regard to that.

We have had the PATRIOT Act, a Supreme Court Justice, and what else this year?

Chairman SPECTER. Class action.

Senator SESSIONS. Class action.

Chairman SPECTER. Bankruptcy.

Senator SESSIONS. Bankruptcy.

Chairman SPECTER. Chief Justice Roberts, Justice Alito. I could go on and on.

Senator SESSIONS. I don't think there has been a Committee that has been this busy—and then he had the gall to tell us yesterday that if we didn't want to show up at the hearing, we ought not to be on the Committee. I was glad I was there, so I knew you weren't talking about me.

Chairman SPECTER. Well, that kind of talk is very seldom engaged in in the Senate. But you can't transact business—you need a quorum—unless Senators are present. It is a high-visibility Committee, a very popular Committee, and as Chairman I want the members present if they want to be on the Committee.

Senator SESSIONS. Well, it was a correct comment.

Mr. Chairman, I would just——

Chairman SPECTER. Would you begin Senator Sessions's time again at 10 minutes? Thank you.

Senator SESSIONS. I would just note that as a person who spent the better part of my political or governmental career as a prosecutor, almost all of that as a Federal prosecutor, and 2 years as attorney general, I have become somewhat uneasy about the vague criminal laws that we are passing. I think that is a legitimate criticism of what Congress and State legislatures are doing.

You remember the old burglary statute, you know, breaking and entering. You had to break in the door, then you enter with intent to commit a felony therein. Robbery was the taking by force and violence of a thing of value from a person. These were the elements, and you knew what the elements were and you knew what you had to prove. And this is where you are talking about a person's liberty, where you are going to put them in the slammer and send them off to the big house.

Now, we have not been quite so scrupulous about taking people's money, you know. You need less proof to take people's money, and Mr. Panish has probably done that more than once. I have tried to a few times, but probably haven't been as successful as he has been in suing people for money. It is a different deal, so I just want to point that out.

I would note that the bill itself uses the words "knowing and reckless introduction of a defective product." My understanding of current law in most States—and I missed most of the colloquy you had over manslaughter or other type things—most States do have laws that deal with reckless misconduct. But if you read the legislation that has been introduced, "reckless" is in the description of the bill, but not in the words of the statute. In fact, it just says any person who introduces into commerce a product known by that person to be defective and capable of causing death shall be fined. So it is getting pretty scary here a little bit.

And you mentioned corporate executives come and go. You come in and you are president of a corporation and somebody sends you a memo, and then the next thing you know, you have been indicted by a Federal prosecutor under this new law. So I do think we have a responsibility to draw the statute clearly before we put somebody in jail, particularly in light of the fact that they can be sued for punitive damages today.

Mr. Vandall, I think you raised a very valid point about the likelihood or the ability to prosecute. I think we can have a very, very uneven, aberrational type of prosecution depending on the mood of their prosecutor or their predilection almost entirely. It is hard to have a basic standard, it seems to me, with regard to these cases.

I got a note from George Terwilliger that you had invited him, former Deputy Attorney General of the United States and a longtime prosecutor, who was going to be a witness on this panel and couldn't come for personal reasons. I got his statement during the hearing, so I haven't read it, but I think he expressed some of those same concerns, in general.

With regard to a civil case, Mr. Panish, what do you have to have before you can file that complaint and ethically maintain a cause of action? What are your standards there?

Mr. PANISH. Well, Senator, you need to have some evidence that support the various elements. As you mentioned in your criminal example, you need to have evidence that supports your elements that you need to prove for your case.

Senator SESSIONS. You are not totally free to sue somebody.

Mr. PANISH. No, sir.

Senator SESSIONS. I mean, you, as a lawyer, can be sued if you over-reach. What is the basic standard for a plaintiff lawyer in a defective suit, preponderance of the evidence?

Mr. PANISH. In a court of law, depending on the various elements, preponderance is one standard. In California, the standard——

Senator SESSIONS. You can file a suit for less than preponderance of the evidence, can't you?

Mr. PANISH. Anyone can file any lawsuit they want, but in a product liability case, when you are a lawyer taking on a case like that against the manufacturer, you better have your ducks lined up if you think you are going to be successful for your client. The manufacturers are not going to roll over. It is going to be a——

Senator SESSIONS. Well, I know that, but I guess I would just make the obvious point that you can file and commence an action, a civil action, easier than a prosecutor can commence a criminal action, assuming there is a responsible prosecutor.

Second, with regard to obtaining information, when you file a suit, Professor Schwartz, you can take the deposition of the person and compel them to testify and provide evidence, can you not?

Mr. SCHWARTZ. Yes, you can, extensively.

Senator SESSIONS. And in a criminal case, of course, you can't. If the defendant is a target of the grand jury, they are able to refuse to answer and refuse to produce any documents in their personal control. But if you are suing someone civilly, you can obtain all kinds of documents from them in an easier fashion, isn't that correct?

Mr. SCHWARTZ. Sure, warehouses full.

Senator SESSIONS. Warehouses full. And it is out of this that good plaintiff lawyers have found the Ivey memo, have found the memo in asbestos that proved that asbestos companies knew that this was a dangerous product and people shouldn't be exposed to it. Yet, they took no action. This was 50 years ago. I think you have a lot less of it today than you used to have. But 50 years ago, they had this information and they didn't tell people and people died as a result of it. So we kind of know how that all plays out.

But it is a much easier thing to pursue a civil suit and we have set it up that way. When it goes to the jury, the question is do you believe by a preponderance of the evidence that they violated the standards of care that are called for, and therefore how much damages do you want to give them, an award. That is how it works.

In a criminal case, you have got to take a case before a grand jury. You can't get as much evidence and you have to prove the case beyond a reasonable doubt, and the leeway for a prosecutor to try a case at trial is much more difficult. So I say that, as a practical matter, if you are going to take out after a corporation who you may have some reason to believe through the Vioxx deal is doing something wrong, you are committing yourself to a very long period of time with many more roadblocks than a good civil lawyer would have in pursuing the same case. So I don't think you are going to have a whole lot of them.

Now, Professor Schwartz, you are the author of the most widely used torts textbook in America today. Is the descendent of *Prosser on Torts* that I had, I guess. You may have been on the book then, I think—perhaps you were—when I was in school.

So I guess I would ask you about your Vioxx example. That was curious to me that you had such aberrational verdicts. It is one thing to have aberrational verdicts when a person might have to pay some money out of his pocket. It is another to have aberrational verdicts when it comes down to putting somebody in jail for 15 years.

Would you agree?

Mr. SCHWARTZ. Absolutely. That is at the core of my testimony. You don't want to import the tort casino over to criminal law. The risks of being wrong are too great. Somebody is going to prison, or even an indictment where there is no real good basis for it.

I mean, Mr. Panish knows, and we all know who practice that if there were an indictment against a particular product, that company would probably not be around very long because it would be followed by product liability suits because of the publicity that would be on television. People watch, oh, "x" company is being indicted for selling a product. I wouldn't want to have to defend a case, frankly, on behalf of a company after that flashed over all three networks.

So it is not even the conviction. It is the weapon, and the weapon has many effects. And as you have said—I am restating—tort law in a way has a right to be wrong. The Vioxx cases still are playing out, but that is not unusual to have a case won, a case lost, a case won, a case lost. And sometimes they go away and sometimes they don't, but it takes years to sort out whether or not the product really was defective. And in part that is because people at a higher

level than I am—Bill Prosser thought he knew what "defect" was. Dean Wade thought that it was less likely that he knew, and as the low person on the totem pole I find it even vaguer than they did.

Senator SESSIONS. Well, that would be a concern to me, Mr. Chairman, whether we would be carrying over into the criminal justice system an area that is awfully disputable about whether an indictment should ever be brought, whether a verdict should be rendered, whether a person should be sent to jail. The more you get into these complex areas, the more potential for abuse I think we can see.

Thank you.

Chairman SPECTER. Thank you very much, Senator Sessions. Your introductory comments about being as precise as we can on tightening the language, I think, is very, very valid. That is something that at markup we really work that over, and we have a lot of experienced people. Senator Sessions was a U.S. Attorney and an attorney general, and Senator Leahy was a district attorney in Vermont and I was district attorney in Philadelphia.

One of the grave, difficult problems in evaluating this issue is to what extent this is a prevalent problem, to what extent it exists, how much of it there is. I am going to ask Governor Engler and Mr. Panish and others on the panel, but I will start with Governor Engler and Mr. Panish on this issue as to whether cases we have examined are anecdotal, just random occurrences, or whether there is really a prevalent problem in the commercial world.

There have been a number of references made to the Firestone-Ford situation. There were some 271 deaths and more than 700 injuries on the defective tires that were put on the Ford from Firestone, and concealed. Finally, we legislated on it and it was my amendment which imposed criminal liability there, so that we do have precedent for criminal liability where there are defects which were known to both the manufacturer and the automobile company which put the tires on the cars.

We have a situation with Zylon bullet-proof vests where the company knew as early as 1997 that the material had failed to comply with quality tests and deteriorated. And the company made a decision, and these are documented in internal memoranda, that they would continue to operate as though nothing was wrong until one of their customers was killed or some agency disclosed the defect publicly, but the company decided not to. Then in June of 2003, a police officer was shot to death wearing one of these so-called bullet-proof vests which had, in fact, deteriorated.

There are the famous cases involving Oraflex anti-arthritis drug where Eli Lilly failed to tell the FDA that it knew of over 25 deaths in different countries that were linked to the drug. Then there were the Playtex and Tambrands cases where there was a substance known as polyacrylate which caused toxic shock syndrome. And here again it was well-known to the company and more than one hundred women died from the exposure there.

Then we had the Ford Mustang case, where again it was a design defect and it was a cost/benefit analysis. And it wasn't really brought to light or it wasn't emphasized until there was a taped conversation between President Nixon and the president of Ford

which disclosed that Ford had saved almost $20 million over 3 years by delaying the safety modifications to the Mustang.

Governor Engler, you are the head of the National Association of Manufacturers, and I would say a very effective president in articulating the views, and it is a judgment call. You don't know what goes on in all the corporate board rooms, all the research and development, so it is a matter of an evaluation.

Are we dealing here with an issue which comes up now and then, or do we have a problem which really is serious enough to call for Congressional action?

Governor ENGLER. Mr. Chairman, I think it is a very good question. You know, being here under oath, the obvious answer is I don't know. The speculation is a little bit like with Sarbanes-Oxley. I mean, we had a few companies that through their behavior resulted in a sweeping law being passed which many would say, particularly the smaller and medium-sized manufacturers, has been overkill.

When it comes to defective products or allegations of defects in products, you have got the collision of innovation trying to bring especially in the pharmaceutical example some of the supplies that we would like to see into commerce. I mean, I think you push the envelope to try to bring those out, and you try to understand what it takes to make them better.

The examples you use, I think, are small in number, but any time there is a single death that one can point to, one can say, well, was that avoidable? It is impossible, I think, to de-risk our society. There are in all of these cases, I think, pretty heavy penalties that have been paid by these companies. Some of these companies that were involved have changed dramatically. In some cases, management has lost their jobs and their careers. In other cases, the publicity has led to dramatic reforms.

But, again, the question here is, you know, given all of what may have happened in the past, do we have a cure? Would anything be different in the future? I think there is some question about is this the solution. I think that we probably as a Nation spend more on safety and more on prevention and trying to get it right than anyplace in the world. I think we do a pretty good job of that.

Would this bill in some way help us do a better job? Would it focus the attention of an executive, or in this case all the way down the line, because I assume a middle management employee touching a product who is part of that production might herself or himself have to ask do I let this go forward?

So the ambiguity is very difficult to deal with. There are certainly challenges, and you will hear a different perspective in just a moment, but I think that by and large the record of safety is commendable in this country and that what is a focus on every company's mind today is how do we make the products we make better and can we afford to take new ideas to the market with whatever risk that might present to consumers.

Chairman SPECTER. Well, thank you for that answer. What we are looking toward is the situation where there is solid proof and the kinds of cases we have cited here where there are internal documents which show a cost analysis that it would cost $8 to make

a change in the location of the gas tank, as opposed to $2.40, where they calculate the payment on tort claims.

A criminal penalty requires proof beyond a reasonable doubt, so there would have to be very specific proof that the corporate executive knew what was going on and had made the decision, participated in the decision, to reach that standard.

I think you are right. There are enormous efforts at product safety, but we do have these cases come up where they have known about it for a long time, documented, and not disclosed in the interest of corporate profits, and many injuries and many deaths.

Mr. Panish, how would you evaluate the question as to whether this is anecdotal, happens from time to time, or a real, major problem in our stream of commerce?

Mr. PANISH. Well, Mr. Chairman, once again I would say that the problem does exist. It is the civil justice system that allows the attorneys that are able to uncover these memos and documents and knowledge of the corporate executives.

Chairman SPECTER. Well, is that sufficient, a lot of able lawyers like you who are doing the job? You are motivated. Sometimes, you even get a good fee.

Mr. PANISH. Well, we are motivated about helping our clients, No. 1, and our clients have been seriously injured by these defective products.

Chairman SPECTER. I am not suggesting that it was a mercenary motive. It is a part of your work.

Mr. PANISH. I understand, but the problem does exist. Safety is paramount in this country and all manufacturers know that. These situations of putting profits over safety do occur. It is not an isolated incident. You have just brought up five or more examples of specifics, from your bullet-proof vests to the Ford Pinto, all the way down the line.

And in a way, personal accountability and having somebody on the line knowing that when they are making these decisions that they could be held personally accountable—they are going to think twice before they try to up the bottom line. That can act in and of itself as a deterrent. Both yourself and Senator Sessions being prosecutors know if you are prosecuting a case like this, you are not going to be filing every case. You are going to want to have a solid evidentiary case, you are going to want to have witnesses, and you are going to know the higher standard of proof that you have to meet to convict somebody in a criminal case.

I don't think the courts are going to be flooded with cases like this, but it is important for personal accountability for people to know that if they make the wrong choice, not to try to put out a more creative product or innovative product, but if they know that there is a problem and they do put profits over safety that they can be personally held accountable. I believe that that would act as a deterrent effect to corporate executives who, as the professor said, move from company to company and by the time this surfaces they are no longer with the company.

It also penalizes the companies that are doing the right thing, that are spending the extra money for safety. And to allow these other companies that aren't doing that to profit by that would be unfair to the companies that are actually doing the right thing.

Chairman SPECTER. Senator Sessions.

Senator SESSIONS. Well, you are correct about the challenge and responsibility of corporations to make their products safe, and there is no doubt about that.

We are willing to take some risk in civil actions to get justice based on a preponderance of the evidence. I am thinking of the example of brakes, Professor Schwartz. Let's say somewhere in the development of a new form of brakes for a vehicle an engineer does a memo that under certain circumstances there might be a problem and he sends that through the system. And the brakes go fine for 5 years, and they are even maybe better than other brakes in most instances. But this very thing occurs and something happens and somebody gets killed. Then this document appears. Ah-hah, you knew this could happen; you go to jail 15 years.

How does that strike you? You have been studying these cases and all the complexities of proof and defect that are so critical to American tort law. How would you evaluate it?

Mr. SCHWARTZ. Well, your question goes to the two sides of the coin here. If that executive knew that he might be subject to a criminal penalty, he might not have written the memo and we wouldn't have it. That is why this is not an easy area.

In the TREAD Act which the Chairman referred to, in the beginning for a while there was a provision about defective products and there was debate about that. But ultimately when the bill passed, they eliminated that and they went to making false or misleading statements. Well, I can understand what that is, but as you go into this area one little change is like a child's kaleidoscope. It may change the picture, but I don't think anybody on the panel under oath can swear to what that new picture would be.

And again we take that employee who has now the courage to write the memo, but if he says, boy, if I write something like this I could get in trouble—or he could write more memos if he knew about it. It is just not that easy in the context of the real world, it isn't.

Senator SESSIONS. On the question of recklessness, which is not in the statute but is only in the preamble or the heading, I do believe that most States have a standard for reckless disregard. The classic case is driving through a neighborhood where children are playing at high rates of speed in reckless disregard of the consequences. A person can be held criminally liable for that. I don't see any prosecutors at the table here.

Could not a person who introduces a product into the highway of life not be held to that reckless disregard standard? Would that standard not be available in criminal court for products liability cases? Does anybody want to comment on that?

I mean, what normally happens is that they are sued and if they are actually in reckless disregard, then you are entitled to punitive damages, aren't you, Mr. Panish?

Mr. PANISH. In our State, California, there is a higher burden of proof for punitive damages. California requires a clear and convincing standard to be proved. It is conscious disregard for the rights and safety of others, and it is pretty narrowly drawn.

Senator SESSIONS. Clear and convincing evidence, but it is a conscious disregard?

Mr. PANISH. A conscious disregard for the rights and safety of others. And there are other provisions; there are three different prongs under which it can be awarded.

Senator SESSIONS. So I guess my concern would be, or my point would be that there are ways now to prosecute criminally under the reckless disregard standard that we have classically had in criminal law for really egregious actions that were knowingly and deliberately done or done with reckless disregard.

If you knowingly and deliberately drive into a crowd of people, then you are going to be held liable for first-degree murder, whether you actually intended anybody to be murdered or not. If you do it with reckless disregard, it may be second-degree murder, depending on the State law. But there are ways to do that under current law.

I am concerned about the standards here and that we create now a Federal criminal action based on more vague standards that look more like civil lawsuit standards.

Mr. SCHWARTZ. It does look like civil standards. That is the line between tort and crime, and law schools package this stuff separately. You know, you go to torts class and then you go over to criminal class, and they never have the two people together. I used to try. I used to bring the criminal law professor in and we would discuss the very things that are being discussed in this Committee today about the difference between tort and crime, the difference between standards.

And there are criminal standards, just like what happened ultimately with the TREAD Act where a criminal standard which was easy to understand was incorporated. And there are criminal statutes about reckless disregard for life. Whether that is going to be used in the context of product liability, I don't know. If the Chairman would ask me has it ever been used, I do think that they tried in Indiana, as the Chairman averted to, in the Pinto case, but the case fell apart. The article I submitted tells why. But there is a difference in drawing lines and how you express things in criminal law versus tort law, and there are good reasons for the differences.

Senator SESSIONS. Professor Steinbuch, on your advertisement there, I am concerned about these advertisements. Some of them look like newspaper articles, No. 1. I don't like that. No. 2, they make statements that I know are not true. So you could do that through giving some regulatory agency administrative authority to gain an injunction to shut down the advertisement, which I think we have done pretty aggressively, sue for damages, and/or you could put the person in jail. I am not against either one. I mean, I think all three are appropriate, depending on the clarity of the proof and the clarity of the standard.

Would you agree that in a product production thing, whether the head man at Merck—did they do Vioxx, did you say, Professor?

Mr. SCHWARTZ. Yes.

Senator SESSIONS. Merck knew everything there was in every report that ever existed about—he might have been hired because of his financial expertise, and whoever gets held liable for something is in a more uncertain area.

Mr. STEINBUCH. Well, I think, Senator, you raise an interesting point and a good point, and that is that on criminal law we must

be confident of who we are prosecuting. But I think we may be paying too much attention to the marginal cases and are less concerned about the clear cases that you have heard about on this panel.

It reminds me of a parable that my father once taught me, which was we can tell the difference between night and day easily even though the exact point that one changes to other is often not clear. Everybody knows that 11 p.m., is night. Everybody knows that 11 a.m. is daytime. 5:48 a.m.—I don't know if that is day or night; I don't know exactly. But, we can still easily tell the difference between night and day.

And so, yes, there will be marginal cases, but with limited resources and good prosecutors such as yourself and such as Chairman Specter, I am confident that a properly tailored statute would achieve the goals that the Chairman has sought.

Senator SESSIONS. Professor Vandall?

Mr. VANDALL. Yes. I would like to try to put some of the questions and comments into context, if I could, and responding back to the Chairman's question of anecdotal and Professor Schwartz's comment in regard to the Pinto prosecution.

The Pinto prosecution failed because it was underfunded. This was a county D.A. He had $20,000 for the whole year. He spent $20,000 of his own money, so $40,000 total. When you read the book, and it is an excellent book on the Pinto case, it shows that Ford just blew him out of the water.

Mr. Schwartz commented that the product liability system is over-heated. I think that is short of the problem. If it was over-heated, we wouldn't be here today. If it was over-heated, we wouldn't have Guidant having the interest, the ability to do and say what they did. Punitive damages are thrown around here——

Chairman SPECTER. You can be tougher than "interest" and "ability," Professor Vandall, when you talk about Guidant. It is pretty blatant and it is pretty current.

Mr. VANDALL. Exactly.

Chairman SPECTER. No, wait a minute. You haven't been tough enough.

Senator SESSIONS. Do you want to advise him of the libel rules of the Senate?

Chairman SPECTER. Don't lead the witness, Senator Sessions.

Go ahead, Professor Vandall.

Senator SESSIONS. No. I mean in the sense that we can say it and not be sued. I don't know about you. I was going to ask the Chairman.

Chairman SPECTER. I didn't want to interrupt you unduly, but when you talk about Guidant, you can be a little tougher than "interest."

Mr. VANDALL. Thank you. I will keep that in mind.

In regard to punitives, the word has been thrown around. Professor Schwartz implies that we have a lively system of punitive damages. And as you all know, there have been several recent Supreme Court cases that have gutted the concept of punitive damages, and it is entirely unclear where punitive damages are going to go for personal injury.

If these cases were superseded by the Senate, I don't think we would be having the discussion today; that is, the corporations are all about profit, are all about making money, which is what they should be. I am not challenging that, but we know how to get their attention and that is with substantial, aggressive and appropriate punitive damages.

Just to get back to Professor Schwartz's comment and something that we have been talking about all day, and that is corporations deal with risk in everything they do. They deal with it in terms of marketing, they deal with it in regard to products. Products have a degree of risk for just about every product. Let's talk about motorcycles at one end of the spectrum and white flour at the other end. We know motorcycles are dangerous. We all know someone who has been killed on a motorcycle. That doesn't make them defective. Let's put cars and drugs in the middle of the spectrum. Those are tough cases.

So what are corporations about? They are about figuring out what the niche is, figuring out the cost of the product. The reason the Pinto was poorly designed was because it had to come in at $2,000. Honda had just introduced its wonderful car, the Civic. The Vega, the worst car ever designed by GM, was there at about $2,300. So Ford said we have got to make it priced in the showroom at not a penny over $2,000. That is why it was a cheap car.

Now, we are talking about Federal prosecution. Let's remember who the father of the Pinto was. The father of the Pinto was Lee Iacocca. How do you feel about going after him and locking him up? I think the Governor from Michigan might have something to say about that because Lee Iacocca single-handedly became president of Chrysler and appealed to Congress and brought Chrysler out of the depths that they were in with their unfortunate automobile line. So I do not think we want to talk about Lee Iacocca as the kind of person that we should be thinking about locking up. He was responsible; he signed off on the Pinto.

Thank you.

Chairman SPECTER. Professor Vandall, we impeach presidents of larger entities than motor companies. No one is immune, no one is exempt.

Senator SESSIONS. I agree with that. In the course of these things, there oftentimes have to be many documents and statements filed. That is what we did on Sarbanes-Oxley, I guess, was say when you file a document, you have got to take some effort to make sure it is correct. You can't just say, well, I didn't have time to look at it.

There are some legitimate problems out here. I thank the Chairman for raising them and I just think we need to be cautious and not over-reach.

Mr. SCHWARTZ. I do find intriguing something that Professor Vandall said. Thank you for mentioning my name a few times; that is always good—but you suggested that the application of the Constitution of the United States gutted punitive damages. The application of the Constitution to criminal law occurred in *Miranda*. Did that gut criminal law? In punitive damages, they applied the Due Process Clause. It was more than a majority. The mixture of the Justices, Mr. Chairman, were not your usual conservative versus

liberal. There was overkill in the punitive system under the Constitution of the United States, and the application of punitive damages has continued to ferret out wrongdoers.

Mr. VANDALL. Could I respond to that?

Chairman SPECTER. Of course, Professor Vandall.

Mr. VANDALL. Justice Scalia wrote a dissent in that case and he said there is no constitutional issue. So I think it is a debatable question as to whether the restricting of punitive damages rests on constitutional principles.

Chairman SPECTER. Well, that is a complex issue which we won't be able to really explore here today.

We are going to leave the record open for 1 week, which is our custom, and we very much appreciate your coming in. We have had a fair amount of response. One caller representing a big company said we have caught the attention of the American corporate community.

Are you nodding in the affirmative, Mr. Schwartz?

Mr. SCHWARTZ. Yes. You did catch their attention.

Chairman SPECTER. I have caught their attention.

The final question I have, but we are running a little late as it is, would be whether having a hearing, whether introducing a bill—the readership of the Congressional Record is not too heavy. Not too many people read the Congressional Record, so you put a bill in. There is a question whether anybody notices it. You have a hearing and you get a little more attention. I don't know that anybody watches C–SPAN except for me when I get home. Our Judiciary Committee hearings have a favorite spot at about 3 a.m. We have a tremendous following among insomniacs in America.

Do you think a hearing like this helps to catch attention and might have some deterrent effect, Mr. Schwartz? Last question, yes or no.

Mr. SCHWARTZ. Yes, I do.

Chairman SPECTER. Thank you all very much.

[Whereupon, at 11:21 a.m., the Committee was adjourned.]

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

[Additional material is be retained in the Committee files.]

QUESTIONS AND ANSWERS

John Engler
President and CEO

April 28, 2006

The Honorable Arlen Specter
Chairman
Committee on the Judiciary
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

It was a pleasure to testify before the Committee on the Judiciary during its March 10 hearing on "Defective Products: Will Criminal Penalties Ensure Corporate Accountability?" Please find enclosed a copy my answers on behalf of the National Association of Manufacturers (NAM) to the follow-up written questions.

Thank you, again, for allowing me to offer the views of the NAM on the very important issue of criminalizing product liability actions. Please let me know if you and the committee have any additional questions or if the NAM can be of any further assistance.

Sincerely,

John Engler

JE/laf

Manufacturing Makes America Strong
1331 Pennsylvania Avenue, NW • Washington, DC 20004-1790 • (202) 637-3106 • Fax (202) 637-3460 • www.nam.org

SENATOR SPECTER
QUESTIONS FOR GOV. JOHN ENGLER

1. Governor Engler, you state in your written testimony that the "[m]ost important" reason that NAM opposes a crime for defective products is that such a crime would delay justice in the civil tort system for the victims. Your written testimony states that the reasons such a delay would ensue are, among others, that key witnesses would assert the Fifth Amendment until the conclusion of criminal proceedings, delaying the resolution of civil claims; and that the company generally would respond in a defensive posture, rather than constructively.

We have a long history with white-collar crime in this country—under the securities laws, the antitrust laws, and others—and I think it is useful to test whether your predictions have been borne out in those contexts.

Let me take the most prominent example of white-collar crime in this decade: Enron. As everyone knows, the criminal investigation of Enron has not concluded—indeed, former CEO's Kenneth Lay and Jeffrey Skilling are on trial as we speak. But notwithstanding the ongoing criminal probe, as of last month, Enron's shareholders had already landed more than $7 billion in settlements connected with the case. That total represents the largest recovery in any securities class action lawsuit in U.S. history.

I cite Enron only because it is so well-known, but there are many other examples in the history of white-collar crime where the criminal track and the civil track have proceeded in tandem. Don't you agree, Governor Engler, that the examples of Enron, WorldCom, and numerous other companies severely undermine your prediction that criminalizing defective products would so significantly delay civil recovery as to make such a crime counterproductive?

A. First, we will never know for certain whether the civil justice actions in the question could have occurred in a more expeditious or efficient manner absent the criminal probes and prosecutions. We also don't know how many civil cases are still awaiting the outcome of the criminal proceedings in Enron before they get resolved. Several Enron figures

accused in both civil and criminal court were let out of the civil cases while the criminal cases proceeded. Prosecutors also asked that civil Securities and Exchange Commission cases against Enron criminal defendants be frozen until the criminal cases are complete. Sometimes civil defendants will settle a case that threatens to drag on through expensive discovery and pretrial activities for years simply to eliminate litigation risk and get the case behind them.

But often civil cases are not cut-and-dried. Plaintiffs and their attorneys may not have, nor want to spend, the resources needed to undertake extensive discovery. Rather, they will wait for the criminal prosecutors to do that work for them. It is much easier to prove civil liability under a preponderance-of-the-evidence standard after criminal liability has been adjudicated using a beyond-a-reasonable-doubt standard. So while there may be civil suits that proceed concurrently with criminal proceedings, it can be a much more complicated, expensive and difficult process.

If there is a product malfunction, especially one involving deaths or serious injuries, the many employees who took part in product development, testing, assembly, etc., are not likely to know until late in the process whether they have a need to fear criminal prosecution. In nearly all of the types of actions it appears the proposal would criminalize, it is highly unlikely that the individuals involved set out intending to maim or kill anybody. Thus, it would be prudent for nearly every employee in the manufacturing process to seek outside counsel and it could likely be malpractice for a criminal attorney not to advise them to keep their personal papers and notes to themselves and not to speak to anyone (even internal investigators) without the presence of their own individual attorney. (In those rare instances where there was clear intent to allow or to cause harm, criminal charges are available without creating new ones out of whole cloth.)

Because of this concern, and the need for the public to know what, if anything, they need to fear, agencies such as the National Highway Traffic Safety Administration have traditionally opposed the broad application of criminal prosecutions. For this reason, the Tire Recall Enhancement, Accountability, and Documentation Act allows the Secretary of Transportation to waive criminal penalties for individuals cooperating with investigations under that law.

It should be noted that the examples of Enron and WorldCom (where the former CEO received 25 years imprisonment) show that the system is working (and these prosecutions are under pre-Sarbanes-Oxley laws). But they also show that the tort system serves a completely different function than the criminal laws. Tort laws deal primarily with subjective judgments and are designed to compensate individuals for a harm that they suffered whether or not the defendant set out to cause the harm. Criminal laws, by contrast, are designed to punish individuals who purposefully and knowingly — and, beyond a reasonable doubt — commit wrongful acts.

2. Governor, you comment in your written testimony that punitive damages are a "substitute" punishment and deterrent for acts that are difficult to criminalize. You argue that punitive damages "loom large" in the minds of executives making decisions about products—so much so that "[l]ittle good" would come from adding a new crime for defective products. In other words, punitive damages provide such strong deterrence that little additional value would be achieved by imposing criminal penalties on top of them.

However, punitive damages ultimately come out of the pockets of shareholders, whereas criminal penalties would target the corporate executives and employees who actually make the key decisions about introducing defective products. Is it NAM's position that a business executive who would <u>personally</u> face a penalty for an action would process risk in a virtually identical way as a business executive who knows that, at worst, thousands of <u>other people</u> will face such a penalty? If punitive damages loom so large in the minds of executives making decisions, why is it that we continue to see defective product after defective product after defective product—even in those industries where companies have been liable for sizeable punitive damages judgments?

A. First, I take exception to the characterization that there are a slew of defective products. The executives I speak with tell me about their commitment to quality and their company's efforts to minimize product defects. They take great care to recall products when accidents occur and take great strides to correct design or other flaws. It is similar to airline

accidents: there seem to be far more than there are statistically because they are so well publicized.

I'd also like to clear up any confusion that may exist implying that punitive damages in and of themselves act as a deterrent. I know of no research, for example, to indicate that products are less safe in jurisdictions that do not have punitive damages. To the contrary, a recent study has concluded that caps on non-economic damages, caps on punitive damages, a higher evidence standard for punitive damages, product liability reform and prejudgment interest reform led to fewer accidental deaths.[1] The point in the NAM's testimony is that since punitive damages were created as a substitute for actions of a subjective nature (where it would not be appropriate to provide for criminal penalties) then the committee should consider eliminating punitive damages where they exist if it were to move forward on directly criminalizing product liability actions.

As to your first question, a business executive who would personally face a criminal penalty for an action would *not* process risk in a virtually identical way as a business executive whose company could face punitive or other civil damages. In fact, he or she would become far more cautious, perhaps overly so. Just as the fear of litigation has led doctors to order tests that are medically questionable but that might be entered as "Exhibit A" if they had not been done, manufacturing executives would tend to make sure that additional product testing (though duplicative or otherwise unnecessary) has been performed. This might or might not be beneficial but it will drive up costs. Corporate legal expenses would also rise as executives seek advice from an internal law department or, if the company lacks one or does not have the resources, outside counsel. In addition, the fear of criminal penalties (perhaps on the advice of counsel) could also inhibit innovation. Even now, the U.S. is already at a competitive disadvantage due to the costs of our tort system.

As it is, an executive who is responsible for actions leading to a huge punitive damages award is likely to be punished by the shareholders if not her own management if there was intentional disregard for placing the company at undue risk for liability. This is especially true if, as the question

---

[1] P. Rubin & J. Shepherd, "Tort Reform and Accidental Deaths," at www.aei.org/docLib/20051012_RubinAccidentalDeathPaper.pdf.

intimates, the same executive needlessly and gratuitously places the company at risk over and over.

3. Governor, your written statement also provides that the "primary danger" of introducing criminal liability into the defective products area "is that you would criminalize a subjective judgment" – namely, what constitutes a defective product.

Let me articulate a counterargument to that analysis and suggest that there are a number of federal crimes on the books already that arguably fall into the category that you describe. The venerable Rule 10b-5, promulgated under the Securities Exchange Act of 1934, provides criminal penalties when an individual makes an untrue statement of a "material fact" in connection with the purchase or sale of any security. The Sherman Antitrust Act has, for more than a century, provided criminal penalties for a "contract, combination . . . or conspiracy, in restraint of trade." And there are, one could suggest, numerous other longstanding examples of federal crimes containing phrases that lend themselves to judgments far more subjective than the phrase "defective products."

Please comment on this analysis. Is the phrase "defective product" really so much more subjective than the phrase "material fact"?

A. Criminal law serves a different purpose than tort law. Because the defendant could ultimately pay for his alleged crimes through loss of liberty, agencies and courts have taken steps to provide as much clarity as they can to "material fact" and other vague, nebulous terms. If history is any guide, there is little reason to expect that either a responsible agency or the courts will be able to provide guidance as to what makes a product defective. Forty years after tort law began to use the word "defect" in product liability litigation, there is still a debate about its meaning. The Reporter's Notes to the Third Restatement of Torts (Product Liability) show just a part of the muted rainbow of definitions of defect.[2]

---

[2] Restatement of the Law, Third: Products Liability s 2, at 14-111 (1998) (examining various definitions of defect and general considerations in determining whether a product is defective).

The antitrust agencies have issued guidelines in various areas to make up for the subjectivity of the Sherman Act. And, over the years, the courts have been forced to step in to help clarify various terms and actions and how they should be analyzed (*per se* versus rule of reason, for example) for the Sherman Act and other statutes with vague, nebulous terms. In addition, the market itself serves as a good indicator of what is or is not a material fact and the stock exchanges list examples of what is deemed to be material.

The NAM hopes that the Committee on the Judiciary would not want to grant the courts or the Consumer Product Safety Commission — or some other agency to be created — the power to provide similar clarity for the term "product defect." As the NAM discusses in its testimony, tort statutes and case law vary widely among the states that deal in this area. Such imprecision may be an acceptable trade-off for civil liability but the NAM believes that it is not acceptable if the penalty is to brand an individual a criminal for the rest of his life and to deprive him of liberty during the time served in prison.

As you know, criminal laws must be precisely tailored and clearly stated to provide constitutionally valid notice to those who are bound by them. The courts have been struggling for years to define product defect, and there is much ambiguity throughout the case law. Reasonable people can differ over whether a product that may cause an injury is defective, just as reasonable people can differ over whether a low incidence rate of such events is a material fact. Drawing such a line in a criminal statute, whether it be related to securities, antitrust or product design and manufacture, is extremely difficult. Just because the securities and antitrust laws include vague and ambiguous terms does not justify a similar abdication of legislative responsibility relating to products. Our economy and standard of living depend on fair and reasonable government behavior to create an environment where manufacturers can design, make and sell reasonably safe products without the threat of criminal liability.

SENATOR SPECTER
QUESTIONS FOR DR. BARRY MARON

1. **I was interested to see the article in yesterday's New York Times about the latest revelations in the Guidant controversy. As you no doubt know, the article described two lengthy memos that a consultant wrote Guidant executives in May 2005, days before the defects in the defibrillators exploded onto the front pages of the nation's newspapers. According to the Times account, the consultant advised Guidant that by refusing to inform doctors of the defect, the company had committed an ethical breach, violating a "sacred obligation" to doctors by substituting its medical judgment for theirs. The memo also noted that any company has an "obvious" conflict of interest that would naturally lead it to disclose product defects only when "absolutely necessary," according to the Times account.**

   You as a doctor, and I as a lawyer, both understand the nature of professional obligations. As someone who works in a field where your treatment can literally mean life or death for a patient, are you comfortable relying upon ethical obligations, no matter how "sacred," in conjunction with lawsuits in order to motivate companies to make the necessary disclosures?

2. **According to your written testimony, the most egregious aspect of the Guidant matter was Guidant's decision not to inform physicians, patients or the government that the defibrillators on which thousands of patients relied demonstrated defects linked to dozens of deaths. You noted the importance of allowing patients and their physicians to make informed decisions, saying that Guidant's failure to disclose known defects amounted to Guidant "tak[ing] over the medical management of thousands of high risk defibrillator patients.**

   How would doctors and hospitals handle information about potential defects in a product that might be used by their patients? Do you believe that companies that make the medical devices on which you rely are more likely to disclose potential defects, or simply to take their products off the market to avoid criminal liability?

3. **In considering legislation that would impose criminal penalties on medical device makers when they sell products that they know to be dangerous, I want to tread very carefully so as not to inappropriately stifle important medical innovation. In your written testimony, you note the importance of narrowly crafting legislation to avoid "a potentially disastrous, chilling effect on law-abiding companies whose products may have occasional random defects."**

   As a doctor, and in your capacity as a director at a major heart center, do you know of examples of other devices that have been subject to what you call "occasional random defects?" How might our decisions regarding the scope of potential legislation be informed by examples of "occasional random defects" that you argue should absolutely not be the basis of criminal liability.

4. **Dr. Maron, on the basis of your experience in the Guidant matter, is there any doubt in your mind that imposing a criminal penalty for the introduction of defective products into the stream of commerce would have made Guidant <u>significantly</u> more likely to have removed the defective defibrillators years before your patient died?**

QUESTIONS AND ANSWERS

Responses of Barry Maron to questions submitted by Senator Specter

April 24, 2006

Senator Arlen Specter
Chairman, U.S. Senate Committee
on the Judiciary
Washington DC 20610-6275

Dear Senator Specter:

In a March 20, 2006 letter you have proposed several additional questions related to the Guidant Affair and the previous Committee hearing on "Defective Products: Will Criminal Penalties Ensure Corporate Accountability?" (March 10, 2006). It is my pleasure to provide answers to these questions as follows:

1. *"...are you relying upon ethical obligations (no matter how "sacred") in conjunction with lawsuits in order to motivate companies to make the necessary disclosures?"*

   This question raises the consideration, in matters such as the Guidant Affair, whether ethical responsibility is ever enough to restrain such companies...or alternatively are potential criminal penalties truly necessary to ensure that corporate executives will do the right thing?

   My short answer...is that not only would the restrictions which necessarily accompany a criminal statute be useful in these situations...they would in fact be virtually *necessary* to prevent another Guidant-type fiasco. I reached this conclusion based on my recent experiences and with the aid of the important and independent Myerburg Panel report – commissioned by Guidant – which has dissected the entire situation in detail. That document can be downloaded at www.guidant.com.

   In brief, the information and decisions made by Guidant regarding defibrillator reliability and defects came almost solely from the statistical input of engineers while the company executives were largely disconnected from and ignorant of the relevant considerations. Furthermore, there was virtually no medical input within the company from the standpoint of patient safety. Indeed, the sole physician theoretically connected to patient-related issues within Guidant, Dr. Joseph Smith (medical director), has testified that as far as he was concerned his job description was completely *unrelated* to patient safety and only involved interactions with physician-client-customers...i.e., he did not view the ethical obligations as a physician to be restraining in his role as a Guidant executive.

   Certainly, this point is substantiated by the Fogoros memo (written by a Guidant consultant to the company) which emphasizes the priority that should be attached to full patient disclosure...which, in fact, was rejected in principal by the medical director (Dr. Smith). In other words, Guidant was the second largest medical device company, selling

thousands of life-saving defibrillators, in which executives were making decisions independent of any medical oversight regarding patient safety. With these considerations in mind it is obvious to me that the threat of criminal penalties for individual executives would have had (and would have in the future) a "chilling" effect so that it would no longer be so easy to ignore their obligation for full disclosure to patients. Executives making these decisions for the company could not simply follow the lead of engineers and would be personally responsible for all implications of their business decisions. This would also promote a greater role and influence for medically-trained executives in device and pharmaceutical companies to ensure that the rights of patients receiving these products would be honored.

2. *"...are [companies] more likely to disclose potential defects or simply to take their products off the market to avoid criminal liability?"*

This is an unlikely strategy for the companies. To remove defective products from the marketplace (presumably without explanation) would be obvious to all - - i.e., "why have they done this?" - - and would only compound their problem with even greater exposure to potential (criminal) liability.

3. *How might our decisions regarding the scope of potential legislation be informed by examples of "occasional random defects" that you argue should absolutely not be the basis of criminal liability?"*

The issue of "random defects" (also called "random component failure") must be defined and resolved for the proposed Bill. Guidant (and to some extent, the defibrillator/ pacemaker industry in general) has developed and has often applied this nebulous term incorrectly in the past. Remarkably, in the Guidant Affair the company conveniently used the term "random" to cover virtually *any* defect, no matter how frequent or repetitive. Specifically, with regard to the defective Guidant Prizm DR short-circuiting defibrillator (which triggered the entire scenario), their knowledge of *26* fatal and nonfatal events related to that problem was consistently regarded as "random." The former CEO, Fred McCoy, testified that "everyone" in his company had a different definition of "random component failure." The reality is that this is really an imprecise engineering term, based on virtually no evidence, which has been generally adopted (and adapted) to mean what the industry wanted it to mean.

A "random component failure" for the purpose of legislation should be: a failure which is not repetitive...and therefore occurs only once...presumably due to a human manufacturing flaw (although, of note, defibrillators are now largely manufactured and assembled by machine) and does not appear to be due to a systematic cause. This, of course, raises the challenge as to the threshold number of similarly defective devices that

should trigger an official recall or advisory to the physician community…or alternatively a potential criminal penalty if not disclosed to patients or physicians in a timely fashion. The answer is probably…any small number (> 1) of defective defibrillators that a reasonable and knowledgeable person would judge likely to occur again with adverse clinical consequences, and necessitating action to be taken.

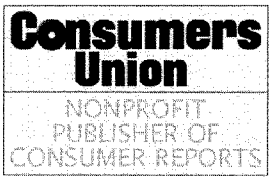
4. *Is there any doubt in your mind that imposing a criminal penalty…would have made Guidant significantly more likely to have removed the defective defibrillators years before your patient died?"*

Based on my personal knowledge of this situation, substantial interaction with my colleagues, and the findings of the Myerburg panel report…I have absolutely no reservation in stating that if potential criminal penalties holding individual executives responsible for their decisions had been operative 4-5 years ago, the sequence of events constituting the Guidant Affair would *not* have occurred. Company executives would have been obligated to follow an ethical and moral compass, and place patient concerns above corporate profits.

I hope these comments are helpful. I would, of course, be willing and highly motivated to participate in this project in the future should you request my input.

Sincerely,

BARRY J. MARON, M.D.
Director, Hypertrophic Cardiomyopathy Center
BJM/tmh



May 5, 2006

Honorable Senator Specter
Chairman
U.S. Senate Judiciary Committee
Dirksen Senate Office Building
Washington, D.C. 20510

Re: SENATOR SPECTER QUESTIONS FOR DONALD MAYS

Dear Mr. Chairman:

Thank you for your follow-up questions regarding my testimony during the Senate Judiciary Committee hearing regarding "Defective Products: Will Criminal Penalties Ensure Corporate Accountability?" Below are my responses to your questions on behalf of myself and Consumers Union, publisher of *Consumer Reports*.

1. In your testimony, you cite numerous cases where companies (Graco child products, Fisher-Price) fail to report – as required under law – to the Consumer Product Safety Commission hundreds of injuries resulting from dangerous and defective products. In the Fisher-Price case, Fisher-Price failed to report 116 fires and resulting injuries from a Power Wheel toy. Fisher-Price paid a small fine and continued business as usual. You state in your testimony that the existing cap "is too small to be an effective deterrent for large corporations." At what point do you believe a company may step over the line into possible criminal conduct for the failure to report?

Response: The Federal requirements for companies to report serious product safety issues to Government agencies is essential to ensure that those agencies have necessary information required to protect the public. Corporate officials who intentionally withhold critical safety information from the Government or the public, and make a conscious decision to continue to sell an unreasonably unsafe product, should be held criminally accountable. Reckless disregard for pubic safety crosses the line, in our opinion, from justice served through civil penalties to conduct that warrants criminal punishment. The transfer of responsibility from one of corporate financial responsibility to individual accountability will be a much greater deterrent to reckless disregard for public safety. Consumers Union sees a critical need for legislation clearly designed to deter individuals within corporations from knowingly jeopardizing consumer safety.

2. You explain in your testimony one success story concerning a child safety seat made by Combi, and how after you conducted independent testing and brought a serious defect to their attention, the manufacturer recalled the product and replaced defective parts within several weeks. In your experience, is this a rare occurrence? Or, do manufacturers welcome

independent analysis and typically make changes within a reasonable period of time? Can you cite examples where corporations refused to comply with a specific defect when confronted with corroborative supporting evidence?

Response: The situation where Combi recalled their child safety seat -- shortly after our report disclosed a serious defect with this product -- was a refreshing act of corporate responsibility. Although manufacturers sometimes react in a similar fashion when our testing uncovers safety defects, all too often this has not been the case. When Consumers Union tested child safety seats in 1995, we rated three models Not Acceptable. Two manufacturers, Kolcraft and Evenflo, recalled their seats and fixed the problems within a several months of our report. Century, on the other hand, continued to deny that there were safety problems with their popular model 590 infant seat despite evidence to the contrary. They continued to sell the seat for more than a year after our report was published.

Manufacturers' reactions to our independent evaluations seem to vary according to amount of economic damage product recalls could impose. In our experience, companies are quick to recall products that have little household penetration. However, once defects are found with popular, widely-sold models, manufacturers are often reluctant to admit fault, and shirk responsibility for recalling unsafe and defective products from consumers' homes.

3. As Senior Director of Product Safety for Consumers Union, you have experience leading product safety initiatives involving a number of products with the goal of reducing unsafe products in the marketplace. Given your unique experience having worked in both consumer and manufacturing environments, you understand both sides of the story. Are consumer products becoming more dangerous? If so, can you attribute this to inadequate testing and pre-manufacturing analysis, or due to simple cost-benefit analysis (i.e., it would be too expensive to make the product safer)?

Response: I have no statistics to prove that products are generally becoming more dangerous. However, the landscape for product safety is significantly different today that it was 10 years ago. I have identified three factors that threaten the safety of products in the U.S. marketplace.

First, the transference of manufacturing operations from the U.S. to overseas factories has increased the risk of production of unsafe products. Unfamiliarity with U.S. safety standards, regulations, and good manufacturing and quality assurance practices can often result in substandard products. Hazardous materials such as lead and cadmium rarely, if ever, used in U.S. consumer product manufacturing regularly are used in Asian countries. A lack of understanding of U.S. consumer behavior also can lead to unpredicted consequences. In recent years, the subjects of product recalls are more often foreign made goods than U.S. made goods.

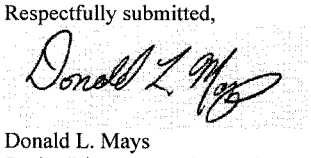
Second, the "speed-to-market" mantra that has now dominated consumer product manufacturing practices can treat product safety and quality assurance as a low priority. Safety testing practices have had to follow the same speed-to-market practices. This often results in corners being cut in order to meet shipping date schedules. For example, the safety testing and certification that UL (Underwriters Laboratories) once conducted in their own laboratories are now commonly conducted in Chinese factories where the goods are produced, in many cases by the factory's own personnel -- not UL engineers. This practice, in our opinion, compromises the independent safety evaluation process.

Third, the power for setting the standards for product safety and quality has shifted from the manufacturer to the retailer. Major retailers have grown larger and more powerful.

Companies such as Wal-Mart, Home Depot, and Costco squeeze suppliers to deeply cut margins on the goods they provide while demanding fast delivery of new products. These large retailers have now begun to write their own product specifications, including safety and quality standards, taking the power away from manufacturers who have far more experience in developing product specifications. Both poor quality and unsafe products can result when a quest for low-cost goods compromises the need for safety. One example is with the inexpensive furniture market – low-cost furniture sold at major discount retailers. Consumers Union's recent tests have proven that much of this furniture is unsafe and fails to meet even the weakest industry safety standards for tip-over resistance. This has resulted in an increasing number of fatalities and injuries to children who are crushed by falling furniture.

I commend you on your proposal, and I thank you for the opportunity to comment on this critically important consumer safety issue.

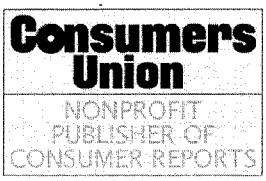
Respectfully submitted,



Donald L. Mays
Senior Director, Product Safety
Consumers Union

ASTM F15 Executive Committee Member
ASTM 000150714

cc: Kathie Morgan – ASTM
John Blaire - Dupont



May 5, 2006

Honorable Patrick Leahy
Senate Judiciary Committee
Dirksen Senate Office Building
Washington, D.C. 20510

Re: Post-Hearing Questions Submitted by Senator Patrick Leahy
On March 10, 2006 Hearing, "Defective Products: Will Criminal Penalties Ensure Corporate Accountability?"

Dear Senator Leahy:

Thank you for your follow-up questions regarding my testimony during the Senate Judiciary Committee hearing on "Defective Products: Will Criminal Penalties Ensure Corporate Accountability?" Below are my responses, on behalf of myself and Consumers Union, publisher of *Consumer Reports*.

I. The morning of our Judiciary Committee hearing the New York Times published an article entitled "Silent Tort Reform Is Overriding States' Powers." The writer, Stephen Labaton, referred to a number of Bush Administration initiatives to preempt state safety and products liability laws through administrative rule changes. Federal agencies, led by the White House, are eliminating important state-level checks on corporate behavior.

The Times article noted that "[a]t the urging of industry groups, the federal agencies have inserted clauses in new rules that block trial lawyers and state attorneys general from applying both higher standards in state laws and those in state court precedents." Industries covered by recent rule changes include automakers, pharmaceutical companies, and the lending industry. The Chairman and I wrote a letter a few months ago regarding one of the issues discussed in this timely article – safety standards for car roofs. In this letter we both expressed concerns that congressional intent in this context was *not* to preempt state standards. Examples of these rule changes are included in my statement and I have also included the article with these questions for the official hearing record.

a. **If a company's product is affected by a federal agency rule change such that both applicable state regulations and state product liability laws are preempted, and the company is granted full immunity if its product meets minimum federal standards, what legal recourse would a consumer have who was injured or killed as the result of a defective product that nonetheless met the minimum federal standards? What is your opinion of the Bush Administration's actions discussed in the attached New York Times article?**

Response: *When looking at the impact of a legislative or regulatory proposal that seeks to preempt state statutory or common law, we have taken a case-by-case approach. Whether or not we support or oppose the proposal depends upon the current state of consumer protections on the state level. As a rule, we do not want to see a weak law apply nationally – especially where strong state remedies will be preempted. In the alternative, where consumers are not adequately protected under current state laws, we are likely to support a strong new federal standard designed to improve consumer protections for most consumers.*

We are very concerned about the recent attempts to foreclose consumers' remedies under state statutory and common law. These recent attempts generally fall into the first category above, i.e., weak proposed federal standards intended to preempt state protections. For example:

Auto Manufacturers: *In the National Highway Traffic Safety Administration's (NHTSA's) Notice of Proposed Rulemaking to upgrade the agency's safety standard on roof crush resistance,*[1] *NHTSA inserted Section F, "Civil Justice Reform," stated to preempt "all differing state statutes and regulations."*[2] *NHTSA tentatively concluded that "if the proposal were adopted as a final rule, it would "preempt all conflicting state common law requirements, including rules of tort law."*[3]

Without providing evidence in support of its concerns, NHTSA concluded that "either a broad State performance requirement for greater levels of roof crush resistance or a narrower requirement mandating that increased roof strength be achieved by a particular specified means, would frustrate the agency's objectives by upsetting the balance between efforts to increase roof strength and reduce rollover propensity."[4] *The agency continued, that it "believe[d] that any effort to impose either more stringent requirements or specific methods of compliance would frustrate [its] balanced approach to preventing rollovers from occurring as well as the deaths and injuries that result when rollovers nevertheless occur."*[5] *CU strongly objected to this view. In our comments to NHTSA, we stated that:*

> *[T]ort law establishes a duty of care that protects citizens when the Government is too slow to act, when federal minimum standards are grossly insufficient or outdated or when standards are not well enforced. The agency's preemption position, if accepted by the courts, would reduce or eliminate manufacturer incentives to exceed this inadequate minimum standard. Any preemption of state common and statutory law in this case would remove incentives for car makers to make safer cars – by shielding them from findings that their vehicle, despite meeting a weak federal standard, was nonetheless unreasonably unsafe, causing harm or death.*[6]

---

[1] "Federal Motor Vehicle Safety Standards; Roof Crush Resistance," 70 Fed. Reg. 49223 (August 23, 2005).
[2] Id. at 49,245.
[3] Id. at 49,246.
[4] Id. at 49,245.
[5] Id.
[6] Id. at 49,245. See Comments of Consumers Union of U.S., Inc., in response to the National Highway Traffic Safety Administration's (NHTSA) Notice of Proposed Rulemaking to upgrade the agency's safety standard on roof crush resistance, NHTSA Docket No. 2005-22143, 70 Fed. Reg. 49223 (August 23, 2005), "Federal Motor Vehicle Safety Standards; Roof Crush Resistance," November 21, 2005, at 6.

Banking: *Consumers Union strongly opposed a proposal by the U.S. Office of the Comptroller of the Currency ("OCC") issued in August of 2003.*[7] *The scope of the proposed preemption was broad, impacting nearly all state consumer protection laws, and many other state laws. CU stated that, if adopted and upheld by the courts, it would exempt nationally chartered banks from nearly all state consumer protection statutes.*[8] *Large and small national banks would escape state laws concerning real estate lending, other lending, deposit taking, and many other types of state laws. CU expressed concern that the loss of these state protections would harm U.S. consumers, make it likely that abuses against consumers in which banks participate would have to spread nationwide before such abuses could be outlawed, place national banks at an unfair advantage as compared to their non-bank competitors, and reduce innovation in consumer protection at the state level. Despite this fact, the OCC finalized this rule – incorporating this damaging preemption language.*[9]

We therefore believe that, rather than trying to restrict the constitutional rights of citizens to a trial by jury, or curtail states' efforts to protect their residents, the Government should, instead, seek to reduce the number of lawsuits in a far more ethical way – by instituting meaningful and effective incentives for responsible individual and corporate behavior.

b. **In your opinion, and preemption arguments aside, do state tort laws and regulations help to ensure product safety?**

Response: *Yes, state tort laws and regulations help to ensure product safety. Tort law establishes a duty of care that protects citizens when the Government is too slow to act, when federal minimum standards are grossly insufficient, outdated, or when standards are not well enforced.*

As I stated in my written testimony, many hazards associated with products are avoidable though the use of proactive steps. As a result, many harms resulting from product use cannot be termed "mere accidents." Many dangerous products are hazardous due to the lack of manufacturer compliance with voluntary standards, or inadequate premarket testing. As state-of-the art methods for preventing harms and identifying hazards is constantly improved, state legislatures often are better at protecting consumers from new and emerging dangers than the Federal legislative and regulatory process.

c. **In your opinion, does the draft legislation examined at the hearing make it clear that these criminal penalties are not an attempt to preempt state law? If so, how could this important issue be clarified?**

Response: *As drafted, the proposed legislation does not clearly state that the criminal penalties are not intended to preempt state law. I strongly urge that the language is amended to add a "savings clause" that clearly evidences an intent that these criminal penalties are*

---

[7] Notice of Proposed Rulemaking, "Bank Activities and Operations; Real Estate Lending and Appraisals," 68 Fed. Reg. 46119 (August 5, 2003). See http://www.occ.treas.gov/fr/fedregister/68fr46119.pdf

[8] Consumers Union letter, "Opposition to Proposed Rule on Preemption, Docket No. 03-16," October 1, 2004. See http://www.consumersunion.org/pub/core_financial_services/000770.html

[9] Final Rule, "Bank Activities and Operations; Real Estate Lending and Appraisals," 69 Fed. Reg. 1904 (January 13, 2004). See http://www.occ.treas.gov/fr/fedregister/69fr1904.pdf

intended to supplement and not to supplant any state statutory or common law consumer protections.

II. Mr. Panish testified about the startling evidence revealed through litigation about the Chevy Malibu, where corporate actors made a conscious decision that lawsuits and the potential harm resulting from the defective product were preferable to fixing a deadly defect. Professor Schwartz testified that this legislative proposal might have the effect of preventing individuals in a corporation from ever writing a memo like the Ivey memo, which was discovered in the Chevy Malibu case. That is certainly not our intent. Corporations must investigate the relative risks and benefits of their products and it is in the best interest of all parties to make sure the decision-maker has all the relevant information about a product's safety.

a. **What language would you recommend to ensure that corporations continue to engage in frank and honest risk assessments?**

Response: *In our view, this legislation does not pose a credible risk of preventing corporations from developing unbiased product risk assessments internally, or from using independent, third party testing laboratories. Instead, it is designed to ensure responsible behavior after an unreasonably dangerous defect is discovered. We strongly support the passage of legislation that also would require manufacturers to conduct premarket testing on products and prototypes of products for use by and with children. Such products should be evaluated for safety under all reasonable foreseeable use conditions. Any serious hazards uncovered through testing that could imperil users should be addressed through redesign or the application of appropriates safety warnings.*

b. **What improvements would you recommend to clarify the role of whistleblowers in preventing or deterring harmful products from entering our marketplace?**

Response: *I recommend that this legislation also include penalties for a company and/or individuals that retaliate against employees that, reasonably believing that a company product is defective and unreasonably dangerous, alerts Government authorities.*

III. When a corporation takes risks by introducing a defective product, the risks are only realized at the corporate level. When the company is rewarded as a result of those risks, the rewards are felt at both the corporate and individual level. For example, an executive responsible for a defect who leaves the company prior to the defect manifesting itself in an injury or death is not even subject to the effects of a punitive damage award against a company. This situation is exacerbated by the fact that federal agencies such as the CSPC are understaffed and underfunded, and do not have the ability to impose adequately deterrent fines for the failure to report defects.

a. **Do you agree that criminal penalties will serve, as Professor Steinbuch noted, as deterrent "non-transferable costs" to corporate executives? Why or why not?**

Response: *Our review of recent monetary fines assessed against companies reveals that they are a grossly inadequate incentive for companies to report product safety hazards to the responsible Government agencies. I therefore strongly agree that criminal penalties that can be assessed*

against individuals within a company serve as a deterrent, "non-transferable" cost to corporate executives.

The preventable loss of a loved one is a very personal experience. Similarly, legislation to improve manufacturer, distributor and retailer reporting must place responsibility on real people. Any weaker provision that puts responsibility civil or criminal liability on corporations only, and insulates the individuals responsible for the foreseeable deaths and injuries of consumers fails to ensure adequate incentives to prevent defective products from entering, or being eliminated from, the marketplace. Although corporate officials may weigh the costs of compliance against the likelihood of having their product exposed as defective, and the costs saved by keeping silent, employees are less likely to gamble with their personal freedom, or risk a criminal conviction.

b. **Can you suggest alternatives to criminal sanctions to discourage the cover-up of defective products?**

Response: *I believe that criminal sanctions must be part of any proposal aimed at reducing the number of unreasonably dangerous defective products on the market. I therefore would suggest that, in addition to criminal sanctions, companies be required to take affirmative and effective steps to remove unreasonably dangerous and defective products from consumers' possession. Current recalls conducted in conjunction with the CPSC often are ineffective. Companies should be required to spend funds to alert (such as through advertising) consumers to the dangers involved and to create a way for consumers to easily return dangerous products.*

IV. The laudable purpose of the Chairman's legislative proposal is to alter corporate conduct to save consumers from serious injury and death. We must provide new incentives within corporations to make it less desirable to introduce defective products. Some witnesses testified that new incentives were not needed because we currently have punitive damages available in our civil liability system.

a. **In your opinion, if a corporate executive is convicted for knowingly introducing a defective product into the stream of interstate commerce, should punitive damages be foreclosed against the company that is responsible for the defective product? What would be the consequences to consumers if punitive damages were precluded from defective products cases in civil actions?**

Response: *Public policy makes it necessary that both individuals and corporations have incentives to ensure that unreasonably dangerous defective products are not introduced into the stream of commerce. This double layer of protection can better ensure responsible action on the part of all corporate actors. As individuals within a company are faced with a decision about how to proceed in the face of evidence that their product is defective, and unreasonably dangerous, the existence of possible punitive corporate damages can influence a decision to disclose by making the withholding of this information potentially unprofitable. Precluding punitive damages would increase the risk that companies would conclude that it makes more financial sense to withhold information about unreasonably unsafe products.*

b. **Do punitive damages against a company and criminal penalties against an individual serve the same ends such that they are interchangeable?**

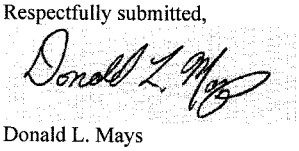
Response: *Punitive damages against a corporate entity alone are not an adequate deterrent. Penalizing a company monetarily cannot serve as a substitute for holding the individual decision-makers in companies accountable for the failure keep unreasonably dangerous products out of the hands of consumers. In any individual case in which a responsible person within a company realizes that a product they manufacture or distribute is unreasonably dangerous, that person -- often along with their colleagues -- has a decision to make. As seen in the examples discussed during the hearing, it is imperative that the calculation hinge on more than a potential monetary loss. It is a very different discussion if the potential penalties involved include jail-time.*

c. **Can you identify any societal benefit or deterrent effect that would result from immunizing a company from punitive damages if one of its employees is convicted based on an injury or death caused by the defective product?**

Response: *Yes. Decreasing harm caused by unreasonably dangerous products has enormous potential societal benefit. Currently, I would expect to a societal benefit from a system in which individual actors within a company realize that their actions – such as allowing the continued sale or distribution of an unreasonably dangerous defective product – would not be supported or protected by their company. A corporate executive tempted to protect the company's bottom line by failing to remove an unreasonably dangerous defective product from the market would know that, should someone suffer harm – or should this failure be discovered – the company would be likely to protect itself at the expense of culpable individuals. The incentives for both individuals and corporate entities together should ensure safer products.*

Thank you for the opportunity to comment on this critically important consumer safety issue.

Respectfully submitted,



Donald L. Mays
Senior Director, Product Safety
Consumers Union

ASTM F15 Executive Committee Member
ASTM 000150714

PANISH
SHEA &
BOYLE
LLP

April 28, 2006

VIA E-MAIL
Huefner, Barr (Judiciary) [Barr_Huefner@judiciary-rep.senate.gov]

Arlen Specter, Chairman
UNITED STATES SENATE
Committee on the Judiciary
Washington, D.C. 20510

Dear Chairman Specter:

In response to your letter of March 20, 2006, enclosed please find my written responses to questions from Committee members.

Thank you for inviting me to participate in the hearing regarding "Defective Products: Will Criminal Penalties Ensure Corporate Accountability?" on March 10, 2006.

Sincerely

Brian J. Panish

BJP/cd

Enclosure

BJP - ARLEN SPECTER 042806.wpd

11111 Santa Monica Boulevard, Suite 700 • Los Angeles, CA 90025 • 310.477.1700 phone • 310.477.1699 fax • www.PSandB.com

SENATOR SPECTER
QUESTIONS FOR BRIAN PANISH, ESQ.

1. You have considerable litigation experience against major corporations in product defect cases and have been successful in obtaining large verdicts and settlements, including the then largest punitive damage award, $4.9 billion in the Malibu case. Punitive damages, as you know, are designed not to compensate the victim, but to deter and punish the defendant's conduct that attributed to the damage to the victim. Have you noticed a change in the conduct or actions of corporations after obtaining punitive damage awards? If so, in what ways have corporations changed their policies or actions? Can you estimate the length of time it took for a corporation to change their policies from the time you either obtained a settlement/verdict or filed your initial complaint?

If you have not noticed a change in overall corporate conduct, why do you suspect they have not changed their ways? Are punitive damages enough of a deterrent to cause corporations to change?

2. Many personal injury attorneys litigate their cases as if they were prosecutors in criminal cases. However, unlike plaintiff attorneys, criminal prosecutors enjoy the benefit of vast resources from state, local, and federal law enforcement, and often more lenient evidentiary and procedural rules. Criminal prosecutors also enjoy the investigative benefits of a secret grand jury. Do these differences impair or enhance your ability to explore corporate misconduct in?

3. In your experience in litigating cases against major corporations, have you identified evidence or conduct that would generally be defined as reckless or having malice on the part of individual officers, either in the actual evidence itself, or in the subsequent litigation with counsel in their defense of the evidence? Please describe the conduct that you have encountered.

Response to Questions:

Questions from Senator Specter:

1) Punitive damages serve the extremely important function of deterring corporations from engaging in conduct that would pose a danger to the public's health and safety. For most large corporations, the amount of money necessary to cover a victim's medical and other expenses amounts to nothing more than a small business expense. But punitive damage awards, when calculated as a potential cost of putting a dangerous product on the market, can force corporations to think twice before engaging in conduct that may kill people. Punitive damages awards also send the message to other corporations that deliberate corporate conduct that puts lives at risk will not be tolerated.

2) I would not agree that criminal prosecutors enjoy the benefit of "vast resources" and "more lenient evidentiary standards" as opposed to civil attorneys. In fact, the differences between the two systems enable civil attorneys to be in a better position to hold a corporation accountable. Many times corporate prosecutions are not undertaken due to the lack of resources at the county and state level. A good example of this is the Ford/Firestone case. Ford, with its vast resources, was able to bury the district attorney in paper, experts, and motions. Because the district attorney had very limited time and resources with which to prosecute the case, Ford executives were allowed to go without criminal sanctions despite the fact that their deliberate actions caused the deaths of numerous Americans.

In a criminal proceeding, numerous constitutional protections and additional procedures apply and there are much tougher evidentiary and procedural hurdles a prosecutor must overcome before evidence can be admitted or a conviction can be obtained. As a result, a civil attorney may be more able to hold a corporation responsible for its conduct and better able to reveal to the public the bad corporate conduct that put the public's safety in jeopardy. It is for exactly these reasons that, should the Committee decide to propose criminal sanctions for corporate defendants, the Committee must ensure that the civil justice system also remains a strong tool to address corporate wrongdoing.

3) In addition to my extensive testimony on the GM Chevy Malibu, I represented the family of Mr. Mendoza who was killed because of a defective transmission in a Ford pick-up truck. There were hundreds of prior cases where the same problem occurred and people died as a result. Despite the fact that Ford knew about these accidents, they failed to take immediate action.

I also represented numerous victims of the Phen-fen diet drug. These individuals suffered severe heart problems because they were not warned by the manufacturers about the cardiovascular risks that were known to the company prior to marketing.

Post-Hearing Questions Submitted by Senator Patrick Leahy for Donald Mays, Brian Panish, and Professors Vandall, Schwartz, and Steinbuch "Defective Products: Will Criminal Penalties Ensure Corporate Accountability?" March 16, 2006

I. The morning of our Judiciary Committee hearing the New York Times published an article entitled "Silent Tort Reform Is Overriding States' Powers." The writer, Stephen Labaton, referred to a number of Bush Administration initiatives to preempt state safety and products liability laws through administrative rule changes. Federal agencies, led by the White House, are eliminating important state-level checks on corporate behavior.

The Times article noted that "[a]t the urging of industry groups, the federal agencies have inserted clauses in new rules that block trial lawyers and state attorneys general from applying both higher standards in state laws and those in state court precedents." Industries covered by recent rule changes include automakers, pharmaceutical companies, and the lending industry. The Chairman and I wrote a letter a few months ago regarding one of the issues discussed in this timely article – safety standards for car roofs. In this letter we both expressed concerns that congressional intent in this context was *not* to preempt state standards. Examples of these rule changes are included in my statement and I have also included the article with these questions for the official hearing record.

a. **If a company's product is affected by a federal agency rule change such that both applicable state regulations and state product liability laws are preempted, and the company is granted full immunity if its product meets minimum federal standards, what legal recourse would a consumer have who was injured or killed as the result of a defective product that nonetheless met the minimum federal standards? What is your opinion of the Bush Administration's actions discussed in the attached New York Times article?**

b. **In your opinion, and preemption arguments aside, do state tort laws and regulations help to ensure product safety?**

c. **In your opinion, does the draft legislation examined at the hearing make it clear that these criminal penalties are not an attempt to preempt state law? If so, how could this important issue be clarified?**

II. Mr. Panish testified about the startling evidence revealed through litigation about the Chevy Malibu, where corporate actors made a conscious decision that lawsuits and the potential harm resulting from the defective product were preferable to fixing a deadly defect. Professor Schwartz testified that this legislative proposal might have the effect of preventing individuals in a corporation from ever writing a memo like the Ivey memo, which was discovered in the Chevy Malibu case. That is certainly not our intent. Corporations must investigate the relative risks and benefits of their products and it is in the best interest of all parties to make sure the decision-maker has all the relevant information about a product's safety.

a. **What language would you recommend to ensure that corporations continue to engage in frank and honest risk assessments?**

b. **What improvements would you recommend to clarify the role of whistleblowers in preventing or deterring harmful products from entering our marketplace?**

III. When a corporation takes risks by introducing a defective product, the risks are only realized at the corporate level. When the company is rewarded as a result of those risks, the rewards are felt at both the corporate and individual level. For example, an executive responsible for a defect who leaves the company prior to the defect manifesting itself in an injury or death is not even subject to the effects of a punitive damage award against a company. This situation is exacerbated by the fact that federal agencies such as the CSPC are understaffed and underfunded, and do not have the ability to impose adequately deterrent fines for the failure to report defects.

a. **Do you agree that criminal penalties will serve, as Professor Steinbuch noted, as deterrent "non-transferable costs" to corporate executives? Why or why not?**

b. **Can you suggest alternatives to criminal sanctions to discourage the cover-up of defective products?**

IV. The laudable purpose of the Chairman's legislative proposal is to alter corporate conduct to save consumers from serious injury and death. We must provide new incentives within corporations to make it less desirable to introduce defective products. Some witnesses testified that new incentives were not needed because we currently have punitive damages available in our civil liability system.

a. **In your opinion, if a corporate executive is convicted for knowingly introducing a defective product into the stream of interstate commerce, should punitive damages be foreclosed against the company that is responsible for the defective product? What would be the consequences to consumers if punitive damages were precluded from defective products cases in civil actions?**

b. **Do punitive damages against a company and criminal penalties against an individual serve the same ends such that they are interchangeable?**

c. **Can you identify any societal benefit or deterrent effect that would result from immunizing a company from punitive damages if one of its employees is convicted based on an injury or death caused by the defective product?**

Questions from Senator Leahy:

I. (a) If courts find that the recent agency statements on preemption should be interpreted as controlling and grant a company immunity as long as it can prove it met minimum federal standards, a consumer would have no legal recourse for any harm suffered. State regulations and state product liability law hold corporations to a reasonable standard of safety and allow individuals harmed by corporations the right to seek redress in a court of law. If preemption is allowed, American consumers would be left with nothing but an inadequate federal standard that won't protect them from harm or allow them any remedy if injured.

President Bush's recent actions indicate that the Administration is more interested in protecting corporate interests than the health and safety of the American people. This is evident based on the fact that these recent regulations that attempt to extinguish state laws and state standards that make people safer, in favor of industry-friendly federal regulations, have no chance of actually protecting the public.

President Bush's recent actions also appear to be pushing regulatory agencies to legislate on matters without Congress's authority or approval. Wiping out entire areas of state regulations is a matter for Congress and the courts to decide, not a group of unelected federal agencies, many of whom held previous jobs in the industries they are now charged with regulating. It appears as though the Administration is unconstitutionally attempting to accomplish through regulatory agencies what it has largely been unable to accomplish through appropriate legislative means.

I. (b) State tort laws and regulations most definitely help to ensure product safety. Because federal standards are typically behind the times in terms of product safety improvements, state standards and state tort law hold corporations to a current, reasonable standard of safety. Federal standards are the minimum standards corporations must meet in order to put their products into the stream of commerce, but state tort law ensures that corporations are held responsible if they put a dangerously defective product on the market, despite the fact that the product met the minimum federal standard.

I. (c) The draft legislation examined at the March 16th hearing *does not* make clear that the criminal penalties imposed by the legislation are not intended to preempt state law. However, there is no reason that criminal penalties imposed at the federal level cannot be complementary to state regulations and state tort law; the two systems could easily work in a parallel manner to ensure corporate accountability. Therefore, a simple solution would be to add language to the end of the bill stating that nothing in the Act shall preempt state law or state tort liability.

II. (a) Language that would ensure corporations continue to engage in frank and honest risk assessments should make clear that failure to perform an "honest" analysis can be used as evidence against the corporation in any subsequent criminal proceedings. The language should clarify that any corporation that engages in the destruction of documents

relating to a risk assessment shall subject the corporation to civil and/or criminal sanctions.

II. (b) Whistleblowers serve an important function in ensuring corporate accountability and public access to essential safety information. An employee willing to reveal information regarding his or her employer's wrongdoing helps to ensure that important safety information reaches the public. Any legislation that imposes criminal sanctions on corporate executives for knowingly putting a dangerous product into the marketplace could also contain language clarifying that any whistleblower that comes forward with information relating to a defective product shall not be subject to any retaliatory action by his or her employer for the act of coming forward.

III. (a) I do agree that criminal penalties assessed against an individual corporate executive who was responsible for making the deliberate decision to endanger the lives of the American public will serve as deterrent "non-transferable costs." If a corporate executive knows that he or she could be held personally financially responsible (as opposed to the corporation and regardless of whether that executive remains an employee of that company) that executive may take more responsible care in the oversight of major design and production decisions related to a product.

III.(b) Criminal sanctions will undoubtedly serve as an important mechanism to help ensure that dangerously defective products are never put on the market. However, the civil justice system must also remain strong and accessible to all Americans. Even with corporate sanctions, state civil justice systems remain the only way that an individual citizen can bring a claim against a powerful corporation and hold it accountable for causing harm. A government prosecutor must elect to institute criminal proceedings whereas an individual can bring a claim in civil court directly after he or she has suffered a legal wrong. Similarly, criminal sanctions are generally paid to a governmental entity, but civil remedies serve to compensate the person or the family who has suffered a loss.

IV. (a) Criminal sanctions against a corporate executive and punitive damages assessed against a corporation are entirely different and the availability of one should not foreclose availability of the other. Both are ways to hold corporations accountable for intentionally harming people and both may deter future bad conduct. However, even if a corporate executive is convicted for knowingly introducing a defective product into the stream of interstate commerce, a company should still be subject to punitive damages.

Without the civil justice system and punitive damages, a corporation's deliberately dangerous conduct might never be revealed and the corporation never be held financially accountable. Also, because of the differences in the civil and criminal systems, as described above, the civil justice system may be more likely to succeed in holding corporations accountable.

IV. (b) Punitive damages against a company and criminal penalties against an individual are not the same and are not interchangeable. Criminal penalties could certainly complement the civil justice system in achieving the shared objectives of accountability

and deterrence, but because of the differences between the criminal and civil systems, as described above, they are not interchangeable.

IV. (c) There would be no societal benefits or deterrent effects gained from immunizing a company from punitive damages. In fact, granting immunity from punitive damages would have the opposite effect. It would remove a huge deterrent companies now have from engaging in conduct that poses a danger to the health and safety of the American public. It would allow companies to operate without the threat of financial punishment if they engage in conduct that threatens public health and safety.

My case involving the Chevy Malibu is a perfect example. In that case, executives performed a cost-benefit analysis and determined it would be more cost effective to keep the car in its dangerously defective condition than to fix the car and save lives. However, factoring in a large punitive damage award may have made the cost of making the car safe more financially advantageous. Because punitive damages can be difficult to predict because they require a higher standard of proof, companies may be unable to calculate how much they would be responsible for paying, should they maliciously injure or kill someone. However, knowing that the threat of punitive damages exist, may lead companies to make safer calculations.

Punitive damages also send a strong signal to other companies that engaging in similar conduct will subject them to similar financial punishment.

Shook, Hardy & Bacon L.L.P.
www.shb.com

Victor E. Schwartz

Hamilton Square
600 14th Street, N.W., Suite 800
Washington
D.C. 20005-2004
202.783.8400
202.662.4886 DD
202.783.4211 Fax
vschwartz@shb.com

April 18, 2006

Mr. Barr Huefner
Clerk, Senate Judiciary Committee
224 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Barr:

This is in response to your letter of March 20, 2006, enclosing written questions from Committee Members with respect to the March 10 Senate Judiciary Committee hearing about "Defective Products: Will Criminal Penalties Ensure Corporate Accountability?" My answers to those questions are enclosed.

I would be pleased to assist you and the Senator if there is to be further action on this issue. I would value knowing if there will be further action, or whether the hearing will complete your work on this important matter.

With appreciation and kind regards, I am,

Sincerely,

Victor E. Schwartz
Enclosure

Geneva
Houston
Kansas City
London
Miami
Orange County
Overland Park
San Francisco
Tampa
Washington, D.C.

SENATOR SPECTER
QUESTIONS FOR PROFESSOR VICTOR SCHWARTZ

1. **In your testimony, you mention there has been no showing of a need in our legal system to deter the manufacture of defective products. What is distinguishable, however, from the typical products liability case to which you cite, is that those cases do not include documented knowledge and a failure to remedy the defective situation by corporate executives. Do you believe a corporate executive should not be held criminally accountable in cases where a corporate executive knows – perhaps for several years – about a defective product, refuses to repair it, and engages in lengthy analysis about the negative impact change would have on profits?**

VES: Your question asks whether I believe that "a corporate executive should not be held accountable in cases where a corporate executive knows – perhaps for years – about a defective product, refuses to repair it, and engages in lengthy analysis about the negative impact change would have on profits?"

This question assumes that there is either a consistent or an objective definition of a product "defect." In the real world of products liability litigation, this is not what I have experienced. For example, a company may launch a new drug and learn that it has had some adverse risk reactions. On the other hand, the company has also learned that it has provided good therapy to tens of thousands of people. Is the product defective?

Our legal system can give a multiplicity of answers to that question, but from the executive's perspective, it is reasonable for him/her to focus on the good that the product has done as well as its risks. All drugs create risks, some substantial.

The same type of analysis is true with most other products. An executive may learn that an all-terrain automobile has rolled over when hitting a curb at a very high rate of speed. The executive is also told that if the all-terrain vehicle is provided with a wider wheelbase, and a narrow center of gravity rollovers would be reduced, but it would not be able to function as well in off-road activities. This is the general trade-off for high occupancy vehicles that go off-road. Is the product defective? Again, in my experience, the hypothetical in the question does not correspond with the real world. There occasionally may be situations where an executive knows that there is poison in food he/she sells or that there is broken glass inside a sealed container. If that executive knowingly sells such a product to a consumer, then there are state laws to punish the executive. In my judgment, that is not the same as the amorphous "defect." There are laws covering those specific situations.

2. **In the Zylon vest case, the Second Chance Body Armor Company publicly acknowledged its Zylon bulletproof vests deteriorated rapidly, decreasing their effectiveness. Internal memoranda demonstrate the company knew as early as 1997 that the Zylon material failed company quality tests. The company board even documented a possible solution as follows: "We continue to operate as though nothing is wrong until one of our customers is killed or wounded or Germany, Japan, Dupont or some other entity exposes the Zylon problem." This case, as you may know, ended with an officer having been killed in the line of duty. Is there any legal standard – however high – you feel would be appropriate to criminalize the conduct of the bulletproof vest company?**

VES: As you know from your days as a prosecutor, taking just one sentence or a memorandum out of context is not a basis for criminalizing behavior. If a specific individual in a company knowingly and willfully put a consumer's life in imminent danger, there are already adequate

remedies at law to prosecute that executive. Broad standards "criminalizing" product liability law would encompass conduct that might be both benign and wrongful. Tort concepts simply do not work in the field of criminal law.

3. **The Supreme Court has acknowledged its general concern over excessive and unpredictable punitive damage awards over the years. As a result, do you believe the true reason why juries award such exorbitant awards is to send a message to corporations that something else needs to be done to stop this conduct?**

VES: There are multiple reasons why juries reach and make exorbitant awards for punitive damages. In my experience, especially studying plaintiff lawyer closing arguments, most of these exorbitant awards are the result of a court allowing a plaintiff's lawyer to engage in improper argument, sometimes based on evidence that should not have been admitted, resulting in a verdict based on bias and passion. For example, in a Mississippi case, the plaintiffs' lawyers asked the jury to "send a message to people in the company back East." The jury sent a message, but the Supreme Court of Mississippi wisely threw out an exorbitant verdict because of bias and prejudice.[1] A careful study of the basis of a "message" -- namely, a billion-dollar punitive damages award -- in Texas against Wyeth indicates that the plaintiff's lawyer continually referred to a Wyeth subsidiary that manufactured Fen-Phen® as a "French" company.[2] The word was used over and over, to try to catch the bias of jurors who lived all their lives in Southwest Texas and had no use for the French. In

---

1 *Janssen Pharmaceutica, Inc. v. Bailey*, 878 So.2d 31 (Miss. 2004).

2 *See Coffey v. Wyeth*, No. E-167334 (Jefferson Co., Texas, Dist. Ct. 2004).

another New York case involving asbestos and a mesothelioma death, the jurors decided to award $18 million because $18 million represented the eighteenth letter of the Hebrew alphabet, and that letter "Chai" represented life; the jury wanted to give life back to the plaintiff.[3] In sum, jurors sometimes believe they are sending a message, but they have been motivated into doing so through elements other than the specific facts of the case. When jurors are not misled by bias and prejudice, but focus on the specifics of a case, their punitive damages awards may be temperate and meet and measure the behavior that has been alleged as wrongful. Nevertheless, the very loose standards and guidelines involved in whether to award punitive damages and the amount thereof, and the resulting instructions make this situation unusual. This is the reason the Supreme Court of the United States has placed due process guidelines on both procedural aspects of punitive damages awards and their amount.[4]

Post-Hearing Questions Submitted by Senator Patrick Leahy for Donald Mays, Brian Panish, and Professors Vandall, Schwartz, and Steinbuch "Defective Products: Will Criminal Penalties Ensure Corporate Accountability?" March 16, 2006

I. The morning of our Judiciary Committee hearing the *New York Times* published an article entitled "Silent Tort Reform Is Overriding States' Powers." The writer, Stephen Labaton, referred to a number of Bush Administration initiatives to preempt state safety and

---

3 Wade Lambert, *Jurors Calculate Punitive Damages in Unusual Manner – Big Award in Asbestos Case was Based on Number 18, Meaning Life in Hebrew*, WALL ST. J., Apr. 14, 1994.

4 *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003); *see also Honda v. Oberg*, 512 US 415 (1994) (substantive) and *Cooper Industries v. Leatherman Tool Grp.*, 532 US 424 (2001) (procedural).

products liability laws through administrative rule changes. Federal agencies, led by the White House, are eliminating important state-level checks on corporate behavior.

The Times article noted that "[a]t the urging of industry groups, the federal agencies have inserted clauses in new rules that block trial lawyers and state attorneys general from applying both higher standards in state laws and those in state court precedents." Industries covered by recent rule changes include automakers, pharmaceutical companies, and the lending industry. The Chairman and I wrote a letter a few months ago regarding one of the issues discussed in this timely article – safety standards for car roofs. In this letter we both expressed concerns that congressional intent in this context was *not* to preempt state standards. Examples of these rule changes are included in my statement and I have also included the article with these questions for the official hearing record.

a. **If a company's product is affected by a federal agency rule change such that both applicable state regulations and state product liability laws are preempted, and the company is granted full immunity if its product meets minimum federal standards, what legal recourse would a consumer have who was injured or killed as the result of a defective product that nonetheless met the minimum federal standards? What is your opinion of the Bush Administration's actions discussed in the attached New York Times article?**

VES: As a torts scholar, I respectfully question the premise of your inquiry, that preemption creates "full immunity." It does not. For example, under the *Cippilone* decision,[5] the Supreme Court ruled that the Federal Cigarette Labeling Act "preempted" duty to warn claims against tobacco companies after 1969, when labels thereafter made clear that cigarettes were dangerous to people's health and caused cancer. Nevertheless, *Cippilone* did not give tobacco companies full immunity; plaintiffs have brought cases and still could bring cases based on fraud, misrepresentation, defective design and violation of express warranty. With respect to the recent Food & Drug Administration (FDA) proposal to preempt certain product warnings, claims still could be brought that are based on other theories of liability, including defective design, fraud and misrepresentation.

I found the *New York Times* article of interest, but know of no evidence that there was somehow a White House or "Bush Administration" initiative to create

---

5 *Cipillone v. Liggett Group, Inc.*, 505 U.S. 504, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992).

preemption in different agencies. In point of fact, each agency's action on preemption was independent and based upon separate factual considerations. For example, with the National Highway Traffic Safety Administration (NHTSA) proposed preemption of state laws, the proposal was confined to design standards on automobile roofs, not the entire vehicle or any other part of it. NHTSA believed that its new, stronger roof strength rule should be uniform in application and that juries around the country should not create new and different design rules for roofs. NHTSA understood that different and varying rules for roof strength could affect other safety elements of the car, including braking and steering. The agency believed that the need for uniformity overcame the risk that some tort claims might be precluded by its approach. The FDA proposal came about through a totally different means. This was not a proposal, but accompanied a new rule that would work to simplify warnings and make them easier to understand. The FDA appreciated that if a drug company simplified warnings and eliminated discussion of certain risks, and those risks arose later, the company would be ripe fodder for a product liability case. The FDA would have helped create that case because the FDA mandated that the warnings be kept simple and easy to comprehend. They did so because of the view of some commentators, who have worked to find more effective warnings – that over-warning tends to cause those who read them to "blur out" and not pay attention to anything.[6] In sum, the need for preemption in risk areas – drug warnings – was totally and completely different from the situation that arose with

---

[6] *See* Victor E. Schwartz & Russell Driver, *Duty to Warn: The Need for a Synthesis of Law and Communication Theory*, 52 CINC. L. REV. 38 (1983)

NHTSA. That is true in other circumstances, and one can find no concert of action among these agencies to take these specific steps.

Finally, there is nothing "wrong" with properly applied preemption. In many situations, the public need for a coherent, policy (*e.g.*, what should a warning state on a drug) far outweighs the risk that one aspect of individual product liability will be preempted.[7]

b. **In your opinion, and preemption arguments aside, do state tort laws and regulations help to ensure product safety?**

VES: It is very difficult to generalize as to whether state tort laws and regulations help ensure product safety. Some regulations, such as those dealing with seatbelts and airbags at the federal level, have clearly helped bring about safety and reduced serious harms in some instances. The airbags also created risks. State product liability law has at times resulted in corrective behavior by corporations and led to the safer design of products. On the other hand, product liability "overkill," which does exist, has resulted in removing good, needed and effective products from the market (*e.g.*, the morning sickness drug, Bendectin®). Liability overkill has chilled the manufacture of products that society needs; for example, it has driven some smaller drug companies out of spending capital to produce an AIDS vaccine. Product liability law has been very imprecise, and people on both

---

7 Victor E. Schwartz & Cary Silverman, *Punitive Damages and Compliance with Regulatory Standards: Should a Manufacturer or Service Provider be Punished When it Follows the Law?*, WHITEPAPER, VOL. 12, NO. 1 (NAT'L LEGAL CTR. FOR THE PUB. INTEREST, SEPT. 2005).

sides of the aisle can give you examples of where it may have done some good, and where it failed society.

c. **In your opinion, does the draft legislation examined at the hearing make it clear that these criminal penalties are not an attempt to preempt state law? If so, how could this important issue be clarified?**

VES: I do not read the draft bill as an attempt to preempt state tort law. I appreciate that Professor Vandall had problems in this area, but courts are reluctant to find preemption, and there is no indication in the draft bill itself that preemption is intended.

II. Mr. Panish testified about the startling evidence revealed through litigation about the Chevy Malibu, where corporate actors made a conscious decision that lawsuits and the potential harm resulting from the defective product were preferable to fixing a deadly defect. Professor Schwartz testified that this legislative proposal might have the effect of preventing individuals in a corporation from ever writing a memo like the Ivey memo, which was discovered in the Chevy Malibu case. That is certainly not our intent. Corporations must investigate the relative risks and benefits of their products and it is in the best interest of all parties to make sure the decision-maker has all the relevant information about a product's safety.

a. **What language would you recommend to ensure that corporations continue to engage in frank and honest risk assessments?**

VES: If product liability law is criminalized under standards similar to the draft bill, I know of no language that would ensure that employees at corporations continue to engage in frank and honest risk assessments. A person who writes a memorandum suggesting that there is a problem with a product could, by definition be deemed to "know about the risk." Placed in a larger context of the product, the author of the memorandum may be incorrect. Nevertheless, when he/she writes the memorandum, he/she is demonstrating knowledge of a potential issue with a product, in effect, has been criminalized by the federal law. If he/she simply writes the memorandum and does not go directly to the

police, he/she sets himself/herself up for possible prosecution in the future. I do not know of language that would preclude that result.

b. **What improvements would you recommend to clarify the role of whistleblowers in preventing or deterring harmful products from entering our marketplace?**

VES: I do not know of a showing that the current whistleblower laws are inadequate in preventing persons from alerting law enforcement officials that serious wrongful conduct is occurring in their company (*e.g.*, consciously producing the food product that they know could cause serious illness). To the best of my knowledge, current whistleblower laws are adequate to meet this protection.

III. When a corporation takes risks by introducing a defective product, the risks are only realized at the corporate level. When the company is rewarded as a result of those risks, the rewards are felt at both the corporate and individual level. For example, an executive responsible for a defect who leaves the company prior to the defect manifesting itself in an injury or death is not even subject to the effects of a punitive damage award against a company. This situation is exacerbated by the fact that federal agencies such as the CSPC are understaffed and underfunded, and do not have the ability to impose adequately deterrent fines for the failure to report defects.

a. **Do you agree that criminal penalties will serve, as Professor Steinbuch noted, as deterrent "non-transferable costs" to corporate executives? Why or why not?**

ANS: With due respect to Professor Steinbuch, I am not sure what is meant by "non-transferable costs." I do know what costs substantial product liability can bring, when there is a clear, consistent pattern that a product has been defective. This occurred in the A.H. Robbins' Dalcon Shield® case. The company went into bankruptcy, and ultimately another company absorbed it. To the best of my knowledge, those who were involved in the decisions that created this fiasco all lost their jobs.

b. **Can you suggest alternatives to criminal sanctions to discourage the cover-up of defective products?**

ANS: Careful scrutiny of criminal law sanctions are required, especially at the state level. It was the belief of a number of witnesses and Senator Sessions that

alternatives to criminal sanctions are not needed because current state criminal sanctions do their job. As I indicated in prior answers, there is a great deal of difficulty in using the phrase "defective products" as a criminal standard. The premise of the question about the cover-up of "defective products" would appear to fail. There has been an ongoing effort in product liability law over forty years to describe the word "defective." The latest major attempt is located in Restatement (Third), Torts: Products Liability, which breaks the word "defect" down into three separate components. First, manufacturing defects, which are easy to understand: a product that hurt a consumer, and is not made in accordance with the manufacturer's own standards.[8] Second, it deals with defective design and states that such a defect can arise where a harm could be avoided by "the adoption of a reasonable alternative design by the seller. . . and the omission of the alternative design renders the product not reasonably safe." Note that the definition contains numerous non-descriptive words, such as "reasonable" and "not reasonably safe."[9] These are not terms that are or should be part of the criminal law. Third, the *Restatement* states that a product can be defective if "inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller . . . and the omission of the instructions or warnings renders the product not reasonably safe."[10] A careful review of this definition also reveals a broad, ambiguous and uncertain terminology. Therefore, we are chasing a fog in suggesting

---

8 *Id.* at §2(a).
9 *Id.* at §2(b).
10 *Id.* at §2(c).

alternatives to criminal sanctions to discourage the cover-up of "defective products."

IV. The laudable purpose of the Chairman's legislative proposal is to alter corporate conduct to save consumers from serious injury and death. We must provide new incentives within corporations to make it less desirable to introduce defective products. Some witnesses testified that new incentives were not needed because we currently have punitive damages available in our civil liability system.

a. In your opinion, if a corporate executive is convicted for knowingly introducing a defective product into the stream of interstate commerce, should punitive damages be foreclosed against the company that is responsible for the defective product? What would be the consequences to consumers if punitive damages were precluded from defective products cases in civil actions?

ANS: First, I do not believe there is a need for criminal law that would convict a person of "knowingly introducing a defective product in the stream of interstate commerce." I have stated my reasons why. Due to its broad ambiguities, the term "defective product" is not a phrase that should be placed in criminal law. If an executive was fined because of his/her specific conduct in which he/she engaged (e.g., misrepresenting key aspects of the safety of a product), I do not believe that such a fine should, in turn, create a shield for punitive damages for an entire company.

b. Do punitive damages against a company and criminal penalties against an individual serve the same ends such that they are interchangeable?

ANS: Criminal penalties against individuals are aimed to deter specific conduct by that individual. Criminal penalties should only be framed in specific language that is familiar to the criminal law, not tort terms such as "defective product." The threat of punitive damages can serve to deter wrongful conduct by corporations. Nevertheless, as Justice O'Connor has observed, the problem is

that "punitive damages have run wild in this country."[11] Through the good efforts of the Supreme Court of the United States and specific tort reforms adopted in some states, punitive damages law may become more effective because it may become clearer in that an executive would know when he/she is engaging his/her corporation in activities that could lead to punitive damages. With good punitive damages reform, a corporate official would know to a reasonable degree of certainty, when punitive damages might be applied, as well as a reasonable estimate of the amount of punitive damages. After all, punitive damages are a form of punishment and a close cousin to a criminal law sanction. Under well-drafted criminal law, the "crime" is spelled out with precision and the amount of the penalty is not left to speculation.

c. Can you identify any societal benefit or deterrent effect that would result from immunizing a company from punitive damages if one of its employees is convicted based on an injury or death caused by the defective product?

ANS: As long as punitive damages are encapsulated in uncertain words as to when they will be awarded and how much, they may create deterrence or over-deterrence. Over-deterrence deprives society of new and useful products or causing existing, good products to be removed from the marketplace. Both of these events have occurred.

March 10, 2006
Legal Beat

'Silent Tort Reform' Is Overriding States' Powers

By STEPHEN LABATON

WASHINGTON

---

11 *TXO Production Corp. v. Alliance Resources Corp.*, 509 U.S. 443, 475 (1993) (O'Connor, J., joined by White and Souter, JJ., dissenting in part) (quoting *Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1, 18 (1991)).

SUPPORTERS and detractors call it the "silent tort reform" movement, and it has quietly and quickly been gaining ground.

Across Washington, federal agencies that supervise everything from auto safety to medicine labeling have waged a powerful counterattack against active state prosecutors and trial lawyers. In the last three decades, the state courts and legislatures have been vital avenues for critics of Washington deregulation. Federal policy makers, having caught onto the game, are now striking back.

Using a variety of largely unheralded regulations, officials appointed by President Bush have moved in recent months to neuter the states. At the urging of industry groups, the federal agencies have inserted clauses in new rules that block trial lawyers and state attorneys general from applying both higher standards in state laws and those in state court precedents.

The efforts by the federal regulators may wind up doing more than Congress to change state tort laws.

Last month, for instance, the bedding industry persuaded the Consumer Product Safety Commission to adopt a rule over the objections of safety groups that would limit the ability of consumers to win damages under state laws for mattresses that catch fire. The move was the first instance in the agency's 33-year history of the commission's voting to limit the ability of consumers to bring cases in state courts.

In January, the Food and Drug Administration approved a drug label rule that pre-empts state laws. The rule will make it easier for pharmaceutical makers to prevail in consumer lawsuits that could have been brought under state laws more favorable to victims.

Pending before the National Highway Traffic Safety Administration are proposals announced last year by the agency that would pre-empt state laws on the safety standards for car roofs and seat positions. A third rule proposed by the traffic safety agency would preclude states from adopting more stringent fuel emission standards for light trucks and sport utility vehicles.

This week, the Office of Thrift Supervision, a unit of the Treasury Department, successfully challenged a law recently adopted in Montgomery County, Md., a suburb of Washington, that was intended to reduce discriminatory lending practices.

Congress has occasionally encouraged the effort. On Wednesday the House of Representatives, at the urging of the White House and the food industry, adopted a food safety measure that would prevent the states from imposing higher standards than those set by the F.D.A. The bill, which faces an uncertain future in the Senate, was strongly opposed by the states. They say it would undermine scores of stringent state laws and regulations.

The moves in recent months magnify the more limited action taken earlier in the Bush administration to pre-empt the states in consumer cases. The Comptroller of the Currency, another unit of the Treasury Department, has repeatedly moved at the urging of large banks to block enforcement of tougher lending laws in New York, California and elsewhere.

The trend alarms consumer and victims' rights groups and some legal scholars. They say it is not only unfair to victims and gives short shrift to thoughtful state lawmakers and judges, but it also eliminates an important check on inept federal regulators.

"It's very troubling," said Professor Thomas O. McGarity, an expert on regulation and tort law at the University of Texas School of Law. "There is a certain hubris on the part of the regulatory

agencies to make the assumption that they are doing their jobs perfectly and should not be second-guessed, especially in light of repeated history of agencies being misled by industries."

State prosecutors and state lawmakers have also lodged objections. Attorneys general in 16 states, including New York, California and Massachusetts, recently sent a letter to the National Highway Traffic Safety Administration about the effort to preempt roof safety rules.

"The state common law court system serves as a vital check on government-imposed safety standards," the state prosecutors said. They said the proposal "is likely to erode manufacturer incentives to assure that vehicles are as safe as possible for their intended use."

Administration officials, industry representatives and their scholarly supporters disagree. They say that overzealous state regulators and vexatious lawsuits require a federal response that sets uniform national standards.

"What has been happening is largely reactive and responsive to industry demands that arise because the industries are confronting similar problems—private liability lawsuits and state attorneys general," said Michael S. Greve, the John G. Searle scholar at the American Enterprise Institute and director of the research organization's Federalism Project. "What Professor McGarity thinks as insufficiently demanding standards, too many people think of as outrageously demanding. Many people think that too high standards imposed by the states hamper research and innovation."

"I just don't see how enforcement by Eliot Spitzer or trial lawyers in Beaumont, Tex., will yield better results," he added.

The new regulations are likely to face court scrutiny in the coming years. But the regulatory agencies have engineered the new rules in a way that they hope will make them less vulnerable to immediate challenge. By putting the pre-emption language in the preambles of the new rules, the agencies make it difficult for some consumer and lawyer groups to challenge them.

The official White House view has been that the federal government knows better than the states.

"The Supreme Court has frequently recognized that federal agencies, rather than courts, are often in the best position to make this determination about what best protects public safety," said Alex Conant, a spokesman at the Office of Management and Budget, part of the White House. "State courts and juries often lack the information, expertise and staff that the federal agencies rely upon in performing their scientific, risk-based calculations."

Mr. Conant said that "having a single federal standard can be the best way to guarantee safety and protect consumers."

Officials said that the White House had not formally orchestrated the efforts by the agencies, some of which are supposed to be independent from the executive branch. Still, others said that the administration's message had been loud and clear, and that no formal directive would be necessary.

"If somebody at the White House had said, Stop it, then it would stop," Mr. Greve said.

SENATOR SPECTER
QUESTIONS FOR PROFESSOR ROB STEINBUCH

1. **In your written testimony, you suggest that companies should be under a positive duty to investigate and ensure the safety of their products, saying "we should expect manufacturers to study the comparative safety of their products to ensure that they are not inherently more dangerous than what prevails." Your testimony also notes that "liability should coincide with a duty of reasonable investigation and data collection."**

   While you suggest that using criminal laws to impose a duty to investigate product safety would encourage companies to internalize the costs of consumer harm, the egregious corporate conduct in the now infamous Dalkon Shield and Ford Pinto cases involve the failure of companies to impose a much more basic duty than a duty to investigate. A. H. Robins failed to simply disclose the known danger of abortion and death from the use of their internal contraceptive device, the Dalkon Shield. Ford tallied up the number of dollars that it would cost to save a human life, and then decided that saving lives was not worth the $10 dollars per vehicle it would cost to install a much safer fuel tank.

   As we are considering what standard we might want to include in legislation on this issue, do you think that imposing a positive investigatory duty on companies will provide the proper incentives? Might a lower standard, such as a standard requiring disclosure of known defective products, or requiring a company to pull products off the market if they are known to cause death or serious bodily injury through a defect be equally effective?

   I believe that we need both. That is, we need a positive investigatory duty to disclose, coupled with a standard that requires (1) disclosure of known defective products or services and (2) companies to pull defective products or services from the market if they are known to cause death or serious bodily injury. Absent the former, producers and service providers would avoid obtaining the very knowledge that would require these companies to disclose and pull products and services from the market. As such, the latter without the former creates a negative incentive to be informed. Equally, if we impose a positive investigatory duty on companies but do not require disclosure and recall, then companies might obtain the requisite knowledge, but might not act on that information.

2. **You indicate in your written statement that you are currently conducting research on an article that seeks to prevent under-equipped medical facilities from causing the death of patients with coronary problems. In your research, you state that evidence from the legal community demonstrates great efforts are taken by**

hospitals in false advertising cases to ensure confidentiality. Can you comment on the evidence that would sustain the charge that the identity of medical facilities remain secret?

I cite caselaw in my forthcoming article PREVENTING UNDER-EQUIPPED MEDICAL FACILITIES FROM KILLING HEART-ATTACK PATIENTS: CORRECTING INEFFICIENCIES IN THE CURRENT REGULATORY PARADIGM FOR PROVIDING CRITICAL HEALTH-CARE SERVICES TO PATIENTS WITH ACUTE CORONARY SYNDROME©, *to be published this winter in Case Western Health Matrix: Journal of Law and Medicine, that discusses the efforts to ensure the confidentiality of settlement agreements. I have attached a copy of the article.*

3. **If the current tort system provides insufficient incentives to prevent fraudulent corporate actors from knowingly injuring people, what factual scenario do you envision would describe an appropriate and reasonable criminal prosecution? In other words, where is the line drawn between civil products liability litigation and criminal conduct involving a known defect that is kept secret in order to sustain profit margins? Based on your research, what legal standard do you feel should be required under any proposed legislation to criminalize this activity?**
The facts as described by Dr. Maron at the hearing seem appropriate for criminal sanction. In that case, the corporate actors continued to sell their defective product after they knew of the deadly defect, while all along failing to inform consumers of the product's deadly potential (which was ultimately realized). Equally, when self-designated "chest-pain emergency rooms" that do not have angioplasty facilities actively advertise for heart-attack patients in communities with fully equipped catheterization laboratories, those medical professionals intentionally directing critical patients to sub-optimal facilities purely out of profit motives should be subject to prosecution. If a medical facility is demonstrably less well equipped to handle a particular injury or illness than a nearby institution, the former should not be permitted to actively solicit patients with those illnesses or injuries. Hospitals should be more concerned about patient health than their own parochial profit-making.

While the legal standard could be defined in various ways, for the facts in the above cases, conviction could be had simply by proving beyond a reasonable doubt that the corporate actors knowingly sold defective products or advertised defective services that caused death.

Post-Hearing Questions Submitted by Senator Patrick Leahy
for Donald Mays, Brian Panish, and Professors Vandall, Schwartz, and Steinbuch
"Defective Products: Will Criminal Penalties Ensure Corporate Accountability?"
March 16, 2006

I. The morning of our Judiciary Committee hearing the New York Times published an article entitled "Silent Tort Reform Is Overriding States' Powers." The writer, Stephen Labaton, referred to a number of Bush Administration initiatives to preempt state safety and products liability laws through administrative rule changes. Federal agencies, led by the White House, are eliminating important state-level checks on corporate behavior.

The Times article noted that "[a]t the urging of industry groups, the federal agencies have inserted clauses in new rules that block trial lawyers and state attorneys general from applying both higher standards in state laws and those in state court precedents." Industries covered by recent rule changes include automakers, pharmaceutical companies, and the lending industry. The Chairman and I wrote a letter a few months ago regarding one of the issues discussed in this timely article – safety standards for car roofs. In this letter we both expressed concerns that congressional intent in this context was *not* to preempt state standards. Examples of these rule changes are included in my statement and I have also included the article with these questions for the official hearing record.

a. **If a company's product is affected by a federal agency rule change such that both applicable state regulations and state product liability laws are preempted, and the company is granted full immunity if its product meets minimum federal standards, what legal recourse would a consumer have who was injured or killed as the result of a defective product that nonetheless met the minimum federal standards? What is your opinion of the Bush Administration's actions discussed in the attached New York Times article?**
I don't believe that civil causes of actions should be preempted by agency rulemaking.

b. **In your opinion, and preemption arguments aside, do state tort laws and regulations help to ensure product safety?**
Tort law, when used appropriately, creates positive incentives for safety.

c. **In your opinion, does the draft legislation examined at the hearing make it clear that these criminal penalties are not an attempt to preempt state law? If so, how could this important issue be clarified?**
Professor Vandall spoke on this issue during the hearing. I have not analyzed this issue.

II. Mr. Panish testified about the startling evidence revealed through litigation about the Chevy Malibu, where corporate actors made a conscious decision that lawsuits and the potential harm resulting from the defective product were preferable to fixing a deadly defect. Professor Schwartz testified that this legislative proposal might have the effect of preventing individuals in a corporation from ever writing a memo like the Ivey memo,

which was discovered in the Chevy Malibu case. That is certainly not our intent. Corporations must investigate the relative risks and benefits of their products and it is in the best interest of all parties to make sure the decision-maker has all the relevant information about a product's safety.

a. **What language would you recommend to ensure that corporations continue to engage in frank and honest risk assessments?**
I would examine legislation such as Sarbanes-Oxley and the standards used in civil products-liability cases to ensure the proper incentive to conduct research and report risks exists.

b. **What improvements would you recommend to clarify the role of whistleblowers in preventing or deterring harmful products from entering our marketplace?**
Whistleblower protection is a feature common in law today, and I would recommend its use in the legislation under consideration here.

III. When a corporation takes risks by introducing a defective product, the risks are only realized at the corporate level. When the company is rewarded as a result of those risks, the rewards are felt at both the corporate and individual level. For example, an executive responsible for a defect who leaves the company prior to the defect manifesting itself in an injury or death is not even subject to the effects of a punitive damage award against a company. This situation is exacerbated by the fact that federal agencies such as the CSPC are understaffed and underfunded, and do not have the ability to impose adequately deterrent fines for the failure to report defects.

a. **Do you agree that criminal penalties will serve, as Professor Steinbuch noted, as deterrent "non-transferable costs" to corporate executives? Why or why not?**
Yes, because criminal penalties are internatilized.

b. **Can you suggest alternatives to criminal sanctions to discourage the cover-up of defective products?**
Theoretically, Congress could enact civil penalties applicable to individual actors and prohibit the transfer of these costs, although it's not clear how one would actually implement such a system.

IV. The laudable purpose of the Chairman's legislative proposal is to alter corporate conduct to save consumers from serious injury and death. We must provide new incentives within corporations to make it less desirable to introduce defective products. Some witnesses testified that new incentives were not needed because we currently have punitive damages available in our civil liability system.

a. **In your opinion, if a corporate executive is convicted for knowingly introducing a defective product into the stream of interstate commerce, should punitive damages be foreclosed against the company that is**

responsible for the defective product? What would be the consequences to consumers if punitive damages were precluded from defective products cases in civil actions?
Criminal liability for corporate actors and punitive damages are designed to achieve similar ends. As such, having both in any one case, may result in an inefficient allocation of resources -- assuming that each sanction individually is set at the proper level to create the optimal outcome. On the other hand, removing punitive damages in such cases could lead to rent seeking and other inefficient behavior by would-be plaintiffs hoping to maintain their civil causes of action.

b. **Do punitive damages against a company and criminal penalties against an individual serve the same ends such that they are interchangeable?**
They typically serve similar ends of incentivizing proper behavior. They go about achieving those ends in different fashions, and so they are not "interchangeable."

c. **Can you identify any societal benefit or deterrent effect that would result from immunizing a company from punitive damages if one of its employees is convicted based on an injury or death caused by the defective product?**
Such immunity would be beneficial if the criminal sanction fully incentivized corporate actors. In such a situation, the additional punitive damage would be inefficient.

SCHOOL OF
LAW

EMORY

Frank J. Vandall
Professor of Law
Email: fvandall@law.emory.edu
Tel: 404-727-6510
Fax: 404-727-6820

April 18, 2006

Arlen Specter, Chair
U.S. Senate Committee
on the Judiciary
224 Dirksen Senate Office Building
Washington, D.C. 20510

Attention: Ben Huefner

Dear Mr. Chairman:

Please find enclosed my answers to your questions and to Senator Leahy's questions that followed the hearing on "Defective Products [and] Criminal Penalties," March 10, 2006.

Also please find a copy of the hearing transcript with my changes noted in red ink.

I was pleased to participate in the hearing as a witness, do not hesitate to contact me if I can be of further assistance.

Yours very truly,

Frank J. Vandall
Professor of Law

Emory University
Gambrell Hall
1301 Clifton Road
Atlanta, Georgia 30322-2770
An equal opportunity, affirmative action university

Tel 404.727.6816
Fax 404.727.6820

SCHOOL OF
LAW

EMORY

Frank J. Vandall
Professor of Law
Email: fvandall@law.emory.edu
Tel: 404-727-6510
Fax: 404-727-6820

April 18, 2006

Arlen Specter, Chair
U.S. Senate Committee
on the Judiciary
224 Dirksen Senate Office Building
Washington, D.C. 20510

Attention: Ben Huefner

Dear Mr. Chairman:

The following are my answers to the questions presented by Senator Patrick Leahy in regard to the hearing on Criminal Penalties:

I. a. ***If a company is granted full immunity if its product meets minimum federal standards, what legal recourse would a consumer have who was injured or killed as the result of the defective product?***

The victim would have no legal recourse. She could recover from insurance if she had any, of course. (40% of the population lack health care insurance).

For those 40% who lack healthcare insurance, they would be forced to rely on the state, city or county for care and assistance. Therefore, the manufacturer or seller would have shifted their losses onto the state. The incentive to make a safe product would be lost.

Emory University
Gambrell Hall
1301 Clifton Road
Atlanta, Georgia 30322-2770
An equal opportunity, affirmative action university

Tel 404.727.6816
Fax 404.727.6820

What is your opinion of the Bush administrations' actions discussed in the attached New York Times article, 'Silent Tort Reform'?

In about 1980, corporate America realized that they could increase profits by reducing the number and the success of law suits. They proposed and had passed numerous "tort reforms." Some of these "tort reforms" are obvious, such as caps on damages, statute of repose, and reduction in punitive damages, *see F. Vandall,* "Constricting Products Liability: Reforms in Theory and Procedure," 48 *Villanova L. Rev.* 843 (2003).

Other "tort reforms" are less apparent as presented in "'Silent Tort Reform' Is Overriding States' Powers." The impact of all tort reform is the same: increase the cost of suits, reduce the damages recoverable, close the courthouse doors to victims and thereby increase corporate profitability.

My opinion is that Bush's "tort reforms" have further injured the victims of defective products and helped the manufacturers and sellers, because often the victim has no where to turn for assistance.

I. b. ***Do state tort laws and regulations help to ensure product safety?***

Yes. Most products liability cases begin in the state courts based on violation of state common law. Often, however, they are transferred to the federal courts. The federal courts generally apply state law under the *Erie* doctrine, however.

There is a cost to a law suit. The defendant pays the judgment and then raises the price of the product (the defendant may be insured or absorb the loss, also). In the market, the consumer hunts for the lowest priced product. Therefore, she rejects the higher priced (defective) product. By this method, basic economics brings pressure on the seller of defective products to produce safe products. Tort reform and immunizing product manufacturers (guns) prevents the system of economics from functioning. *See, F. Vandall,* "Our Products Liability System: An Efficient Solution to a Complex Problem, "64 *Denver L. Rev.* 703 (1988).

I. c. ***Does the draft legislation make it clear that these criminal penalties are not an attempt to preempt state law?***

No. As I testified in my oral presentation there is no "black letter" law of preemption. The question of preemption is an attempt to find the intent of Congress and is therefore vague and undefined. There is a real risk that a court will find that the criminal penalties in the act are intended to preempt state law. There may be a solution, however. The solution is to put language in the Bill that provides: "The statute is not intended to preempt state statutes, regulations, nor state common law."

There is a risk however, that a court will ignore such a "savings clause" and still find that the state law is preempted. This was the result in *Grier v. Honda*, 529 U.S. 861(2000).

II. a. ***What language would you recommend to ensure that corporations continue to engage in frank and honest risk assessment [of their products]?***

The goal of corporations is to make a profit. The greatest profit is produced by "frank and honest" risk assessment. Therefore I think that people employed by corporations, at all levels, are driven by profits to speak openly. Enron and Guidant are exceptions, of course.

Therefore, I do not think that specific statutory language would be helpful to encourage "frank and honest" risk assessment. Perhaps severe penalties for document destruction (in anticipation of prosecution) would be helpful.

II. b. ***What improvement would you recommend to clarify the role of whistleblowers?***

Perhaps it would be helpful for the Bill to provide that: "A person who has provided helpful information in regard to the prosecution of persons who manufacture or sell defective products and is fired, within three years of providing the information, shall be presumed to have been fired because of providing such information and shall be rehired at triple the lost salary, plus her attorney's fees."

III. a. ***Do you agree that criminal penalties will serve as deterrent "non-transferable cost" to corporate executives?***

Yes, criminal penalties will serve as a deterrent and they are personal to the defendant and are therefore non-transferable.

III. b. ***Can you suggest alternatives to criminal sanctions to discourage cover-ups of defective products?***

Yes, because of the expansion of tort reform, it is very difficult to find an attorney who will take a defective products' case worth less than $100,000. *See, Vandall,* "Constricting Products Liability," *infra.*

A court of claims or a Superfund is needed for these "small" cases. *Id.* Many of the "tort reforms" should be superceded by Congress.

IV. a. ***Should punitive damages be foreclosed against the company that is responsible for the introduction of a defective product into the stream of interstate commerce?***

No. Punitive damages are rarely awarded and when awarded, they are small. *See D. Owen* "Punitive Damages in Products Liability Litigation," 74 *Mich L. Rev.* 1257 (1976).

We talk about punitive damages because they appear on the front page and attract corporate attention. That is appropriate. The purpose of punitive damages is the same as criminal prosecution: get the attention of the corporation. Punitive damages are a good thing and Congress should supersede *BMW v. Gore,* 517 U.S. 559 (1996).

Punitive damages are subject to precise tuning ($10,000, $100,000 or $100,000,000) as compared to criminal sanctions (five years in jail).

IV. b. ***What would be the consequences to consumers if punitive damages were precluded from defective products cases in civil actions?***

If the damages are not compensable (a 92 year old unemployed person or a stay-at- home-mother is killed), the attorney might bring the case to recover punitive damages if the corporate act was willful. Absent punitive damages, the suit would not be brought.

IV. c. ***Do punitive damages against the company and criminal penalties against an individual serve the same ends such that they are interchangeable?***

No, I don't think so. Punitive damages have been in existence for perhaps 100 years or more. *See, Scott v. Donald,* 165 U.S. 58(1896), cited in Prosser On Torts 9 (4th ed.). Attorneys and courts have developed a tradition for dealing with them. Although juries may award large amount ($100 million in the Pinto case), they are usually later reduced ($3 million in the Pinto case). Large punitive awards grab the headlines and attract the attention of the corporations in product cases, but they are probably not of much importance to the corporate bottom line.

In contrast, criminal penalties against individuals are new and untested. If very large, they would attract media attention. I doubt they would overcome the economic pressures to make profits that exist for all products such as SUV's, small cars and implantable defibrillators. Of great importance, putting corporate employees in jail does nothing to assist the injured victim. Therefore, punitive damages and criminal penalties are not interchangeable.

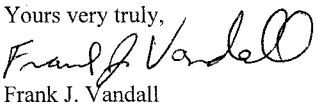
IV. d. ***Can you identify a benefit that would flow from immunizing a company from punitive damages if one of its employees is convicted?***

No. If the corporation is immunized from punitive damages, it means that the injured person has recovered less. It is false to consider punitive damages a windfall. The victim rarely recovers full compensation because her attorney takes his compensation from the amount recovered. If there are only compensatory damages and the attorney gets one third, then the victim is short one third. Punitives, therefore, help the victim to recover her full damages.

I think both can work in parallel. The jury in the civil case could weigh the criminal punishment levied in the prosecution. Also, the jury in the criminal case could weigh the amount of punitive in the civil case.

Punitive damages are an excellent deterrent. I doubt that corporate executives will ever be criminally prosecuted, under the proposed act, in the same magnitude that they are sued civilly for manufacturing and selling defective products.

Yours very truly,



Frank J. Vandall
Professor of Law

SUBMISSIONS FOR THE RECORD

Testimony submitted to the Senate Judiciary Committee

In re: "Defective Products: Will Criminal Penalties Ensure Corporate Accountability?"

Submitted by
Charlie Cray
Director
Center for Corporate Policy
Washington, DC

Mr. Chairman and Members of the Committee:

The Center for Corporate Policy is a project of Essential Information, a tax-exempt non-profit public interest group.

We wish to commend the Chairman and the Senate Judiciary Committee for considering the merits of legislation that would provide for Federal criminal penalties for the introduction of dangerously defective products into interstate commerce.

The absence of such penalties has left a significant gap in the array of federal laws deterring corporate crime. We support the proposal to introduce legislation carefully designed to close that gap without preempting states' abilities to enforce their own laws, since it would have the potential to protect millions of Americans from preventable harms.

It is difficult to estimate precisely how many Americans are harmed each year by the deliberate introduction or continued marketing of products known to cause death or serious injury. As the Department of Justice explains, "precise financial losses resulting from White Collar Crime (WCC) for consumers, government, and business are unknown since no systematic data collection exists."*1* According to The U.S. Consumer Product Safety Commission (CPSC), "despite significant reductions over the years, there remains on average about 25,900 deaths and 33.2 million injuries each year related to consumer products under CPSC's jurisdiction…deaths, injuries and property damage associated with consumer products cost the nation over $700 billion annually."2

These figures do not include deaths associated with products outside the CPSC's jurisdiction, or the thousands of annual deaths caused by cancer and other diseases indirectly linked to corporate pollution, defective products, tainted food and addictive substances such as tobacco, and other causes. Using conservative estimates put forth by those who dismiss environmental causes of cancer as negligible (i.e. 2 percent of the total incidence of 553,400 cancer deaths estimated by the National Institutes of Cancer in 2001) 3, author, scientist and cancer survivor Sandra Steingraber calculates that at least 11,098 such individuals would have died from cancers traceable solely to environmental causes (i.e. industrial pollution).4

There is little doubt that potential criminal sanctions would save lives by forcing a significant shift in corporate decision-making culture. While the victims of this kind of corporate crime may be anonymous to the perpetrator(s), and the effects removed in time and location from the actions that ultimately cause such harms, the evidence is clear that death from defective products knowingly introduced into commerce is no less egregious than other forms of crime. After the epidemic of corporate fraud witnessed in the past several years, Congress sought fit to establish a clear criminal sanction for financial fraud in the Sarbanes-Oxley Accounting Reform Act of 2002 – surely corporate actions leading to preventable death and grave injury is just as serious and equally deserving of strong criminal sanctions.

It might be objected that this kind of corporate crime is unintentional -- motivated less by the greed of individual executives than bureaucratic exigencies designed to maximize corporate profits or minimize corporate overhead. But a child choking on a hazardous toy, or a car needlessly rolling over into a ditch because of predictable tire tread separation the crime is no less appalling a crime if a corporation or its executives are aware of or should have known of the potential hazard.

Many academic scholars have written that the influence of jury verdicts is vastly disproportionate to their number, and that there is no need for criminal sanctions, so long as juries are willing to demonstrate that certain types of conduct will not be tolerated in the community. Indeed, a comprehensive survey by the Center for Justice and Democracy found that verdicts and settlements in a number of civil cases have pushed innumerable unsafe products off the market, forced improvements in health care and led to the elimination of unsafe practices.5 Yet the same thing can be said for the threat of tougher criminal sanctions for unsafe products that the Conference Board said in 1987 of the risk of civil liability: "Where product liability has had a notable impact – where it has most significantly affected management decision-making – has been in the quality of the products

themselves. Managers say products have become safer, manufacturing procedures have been improved, and labels and use instructions have become more explicit."6

The need for criminal sanctions may becomes even greater as the push for deregulation infects regulations designed to protect consumers, workers, public health and the environment. Business lobbyists have made tremendous strides in weakening safety laws and regulations in recent years.7

Without tougher sanctions, modest criminal fines and administrative penalties can be anticipated by corporations conducting cost-benefit analysis related to the manufacture and marketing of defective products as merely the "cost of doing business." A number of well-known examples make it abundantly clear that even where strict civil liability exists, it has not been enough to deter companies from continuing to market products known to be dangerously defective.

Merck-Vioxx

In November, 2004, one of the Food and Drug Administration's top drug safety experts testified before the Senate Finance Committee that the number of Americans who had suffered heart attacks or stroke as a result of taking the arthritis drug Vioxx was somewhere between 88,000 and 139,000. As many as 40 percent of these people, or about 35,000-55,000, died as a result, he said.8

After publishing a meta-analysis of available studies, the prestigious British medical journal The Lancet concluded in December 2004 that "the unacceptable cardiovascular risks of Vioxx (rofecoxib) were evident to the company and the FDA as early as 2000" – i.e. a full four years before the drug was finally withdrawn from the market.9

In February 2006, the New England Journal of Medicine reaffirmed earlier concerns about a Vioxx-related study the journal published in 2000, which "did not accurately represent the safety data available to the authors when the article was being reviewed for publication."10

The Wall Street Journal, citing an unreleased study of side effects by government regulators, reported that Vioxx was responsible for more than 27,000 heart attacks and sudden cardiac deaths before Merck decided to recall the drug. The Journal reported that internal emails and correspondence showed that Merck executives clearly knew about the risk of heart attack and stroke.11

Two million Americans were taking Vioxx when it was finally pulled off the market on September 2004.

Ford and Firestone

The two companies knew of at least 35 deaths and 130 injuries that resulted from the failure of 15-inch tires on Ford's Explorer SUV, before the National Highway Traffic and Safety Administration launched a probe in 2000. The companies knew about these cases because they were being sued by the families of the victims, and as a condition for settlement, Ford and Firestone were demanding that lawyers who brought the cases not speak to anyone about what they learned during discovery.12

Ford internal documents discovered through litigation reveal that company engineers recommended changes to the Explorer's vehicular design after it rolled over in company tests prior to introduction, but other than a few minor changes, the suspension and track width were not changed. Instead, Ford, which sets the specifications for the manufacture of its tires, decided to lower the recommended tire pressure to 26 psi. (The Firestone-recommended psi molded into the tire for maximum load is 35 psi.)13

As documented by Public Citizen, within a year after the vehicle was introduced to the market, lawsuits against Ford and Firestone were filed for tire failures that resulted in crashes and rollovers. At least five cases were filed by 1993, and numerous others followed in the early 1990s. Almost all were settled with gag orders prohibiting the attorneys and the families of the victims from disclosing information about the cases or their documentation to either the public or federal regulators.14

"When lawsuits are filed against a company about a safety defect, the company organizes an internal investigation to assemble information and analysis about the allegations," Public Citizen's Joan Claybrook explained. "Top company officials are kept informed about all lawsuits against the company, particularly when they accumulate concerning one problem. There is no question the companies knew they had a problem. But they kept it secret."15

By 1996, state agencies in Arizona were reporting problems with Firestone tires on Explorers. By 1998, Ford and Firestone had entered into discussions over tire failures with authorities in Middle Eastern, Asian and South American countries. "Ford eventually decided to conduct its own recall without Firestone and replace the tires in the various countries in 1999 and 2000," Claybrook noted.16

Nevertheless, the companies failed to act to remedy the problem in the United States until 2001, when the National Highway Traffic and Safety Administration began investigating the problem.

Sara Lee: Ball Park Franks

Despite the fact that taxpayers invest more than a billion dollars each year in federal food safety inspection programs, unsafe food causes an estimated 76 million illnesses and 5,000 deaths each year.17 Of those, an estimated 2,000 persons become seriously ill, and 500 die, from consuming food contaminated with Listeria monocytogenes bacteria.18

Between July 1, 1998 and April 1, 1999 meat produced and packaged by a division of Sara Lee Corporation was contaminated with listeria bacteria. An unknown number of people bought the products, which included Ball Park Frank Hot Dogs, before Sara Lee was compelled to issue a recall.19

In June 2001, Sara Lee pled guilty to two misdemeanor counts in connection with a listeriosis outbreak that led to the deaths of at least 21 consumers who ate Ball Park Franks hot dogs and other meat products. One hundred people were seriously injured. The company paid just $200,000 in fines and $1.2 million to settle a related lawsuit for selling meat to the Pentagon, in addition to pledging $3 million for food safety research at Michigan State University.20

Although U.S. attorney Phillip J. Green said the company was not charged with a felony because investigators found no evidence that the company produced or distributed unadulterated meats, reports later surfaced that employees had told USDA investigators that they knew with 'virtual certainty' that meats were contaminated.21

Point Blank: Defective Body Armor

When supplied to government law enforcement and/or military personnel, defective products cannot only be fatal, but can also undermine national and community security.

Point Blank, a division of DHB Industries, supplied bulletproof vests to various police departments, as well as Marines serving in Iraq.22 As early as 2002, employees of the company submitted sworn affidavits alleging that Point Blank routinely cut corners when making the vests to boost profits.23

In April 2005 the Southern States Benevolent Association settled a lawsuit with Point Blank after the company agreed to replace an estimated 2,609 potentially defective pieces of body armor. Then, on August 24, 2005 the National Institute of Justice, the federal agency that enforces standards for body armor, issued a study that found that nine of 12 vests manufactured by Point Blank Body Armor failed to meet safety requirements. 24

Army Times reported in May 2005 that the Marine Corps and Point Blank rejected the advice of a Marine Corps ballistics expert responsible for ensuring that Marine vests were up to specification, who wrote in a related memo that "based on the ballistic data and previously identified quality assurance failures I do not recommend acceptance of these lots and do not recommend acceptance of any future lots until this issue is resolved." A Marine program manager responsible for ordering the tests issued a waiver, despite the fact that the Defense Contract Management Agency backed the ballistics expert's recommendation. Although it is unclear whether any casualties resulted from the decision to use the vests, in May 2005 the Marines recalled 5,277 Interceptor vests manufactured by Point Blank. 25

DHB's CEO David Brooks earned $70 million in 2004, and cashed out an additional $184 million by selling his company's stock.26

Dow and Dursban

In June 2000, EPA announced an agreement with Dow and other manufacturers of Dursban (chlorpyrifos) to eliminate its use around homes, schools and other places children could be exposed. EPA administrator Carol Browner stated that the scientific evidence of unacceptable risk was clear, noting that poison control centers had received 800 calls a year for related incidents.27

Less than three years later, New York Attorney General Eliot Spitzer announced his intent to sue Dow for violating an agreement the company had made regarding Dursban-related advertising. Dow was supposed to stop making claims that Dursban was "safe," but had continued to make the claim, despite the fact that it had been linked to severe health problems.28

An investigation by Spitzer's office in the 1990s found that Dow engaged in false and misleading advertising that violated both state and federal law. In exchange for avoiding a fine, Dow had agreed to reform its advertising and marketing practices. Nevertheless, Dow AgroSciences continued to claim

that Dursban had no "long term (health) effects" in advertisements. In mid-December 2003, Dow Agro-Sciences agreed to pay a $2 million penalty to resolve the dispute with New York. Perhaps the threat of an additional federal sanction might have caused Dow to pause before issuing its misleading safety claims. "By misleading consumers about the potential dangers associated with their use of their products, Dow's ads may have endangered human health and the environment by encouraging people to use their products without proper care," Spitzer said.29

Corporate Recidivism and the Need for Tough Criminal Sanctions

The record of chemical companies like Dow Chemical suggests a pattern of reckless disregard for public health and safety. There has been little in the way of fundamental change in corporate culture or decision-making policies after each product-related scandal. Corporate historian Jack Doyle has documented how Dow continued to market defective products over a period of decades – including Agent Orange, dioxin-contaminated herbicides and lawn-chemicals, DBCP (a worm-killing pesticide known to cause sterility in workers), Perchloroethylene (industrial solvent and dry cleaning fluid), silicone implants (along with Dow Corning), and other products -- in some cases even after company officials had received knowledge of existing complaints or the potential for significant harm to human health or the environment.30

It would be unfair to single out Dow as the only chemical company responsible for a pattern of harmful behavior. Indeed, companies like DuPont (ozone-depleting chemicals and, more recently, perfluorochemicals) and Monsanto (PCBs) have equally egregious records when it comes to marketing defective products for years after the evidence of significant threats to workers, consumers or the environment. Two public health researchers familiar with the industry concluded in 2002 that certain sectors of the chemical industry – including sectors manufacturing lead, vinyl chloride, asbestos and other products -- have evinced "a pattern of responding to potent evidence of the danger of their products by hiding information, controlling research, continuing to market their products as safe when they were known to be dangerous, enlisting industrywide groups to participate in denying that there was a problem, and attempting to influence the political process in order to avoid regulation."31

This conclusion is bolstered by additional evidence of widespread harm caused by the chemical industry and other industries, including a recent EPA estimate that after decades of cleanup, a total of 235,000 to 355,000 toxic waste sites will still need to be cleaned up, at a total cost to the nation of $170-250 billion.32

Nor is the deliberate diffusion of life-threatening products limited to the chemical industry alone. Other industries – including tobacco, pharmaceuticals, oil, weapons manufacturers, and motor vehicle manufacturers – have all evinced an appalling track record in that regard.33

Getting at the Source of the Problem

What is to be concluded from learning that these problems are so widespread?

Most criminologists would view the marketing of defective products not as a deliberate crime, but as the result of rational choices made within a corporate bureaucracy that "incentivizes" certain risk-making decisions, with little regard for the consequences.34 This may be especially true of certain industries where pressures exist to capture increasing market share, especially when it involves the introduction of cutting-edge technologies – e.g. pharmaceuticals, chemicals, biotechnology, etc.

Some industry analysts suggest that decision-makers should develop a means of incorporating the Precautionary Principle, whose mandate is to take preventive action in the face of uncertainty to prevent harm.35 While government treaty negotiators and regulatory bodies have begun to take up the challenge, others are slow to adopt the Precautionary Principle. Indeed, it may be virtually impossible to do so as long as key decisions about the selection, use and distribution of life-threatening technologies are left to largely to corporate decision-makers operating under market pressures. Without strong federal criminal penalties for the knowing introduction or continued distribution of harmful products, it is difficult to imagine individual executives erring on the side of caution, let alone such a fundamental shift in the broader corporate decision-making system.

The reasons for that may have much to do with the nature of the corporation, and the context in which it operates. For many corporate decision-makers, pressures to compete – both internally among different corporate divisions and externally within specific industrial sectors – as well as pressures to deliver value to the company's shareholders have created a complex system of self-reinforcing incentives and corporate culture that is inherently biased against the requirements of public health or consumer protection. Indeed, experts on corporate crime believe that certain companies or even entire industrial sectors may be inherently criminogenic due to industry norms and conditions.36

An even broader conclusion is drawn by Dr. Robert Hare, a psychologist and internationally renowned expert on psychopathy who, when asked to compare the nature of corporate organizational behavior to

the clinical characteristics of psychopathic individuals, suggested that not only can the attitudes people adopt and the actions they execute when acting as corporate operatives be characterized as psychopathic, but corporations themselves "act" as if they are "singularly self-interested and unable to feel genuine concern for others in any context." The lack of empathy and asocial tendencies are key characteristics of the corporation, says Hare – "their behavior indicates they don't really concern themselves with their victims"; and corporations often refuse to accept responsibility for their own actions and are unable to feel remorse.37

If we want individuals working within an organizational context that provides no inherent incentive to think twice before taking an action that might lead to the introduction of a defective product, then we will need to balance the above-mentioned pressures to cut corners in the name of profit with the deterrent threat of stiff criminal penalties. Until such penalties are in place, it is unlikely that rates of corporate recidivism will decline.

As Justice Berger once noted, "the requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous but they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them."38

Part of the problem the committee wishes to address is simply a gap in the law. Although existing Federal law penalizes some forms of life-threatening activity – e.g. explosives and fireworks – there are many actions involving defective products that escape criminal sanction. The CPSC has successfully completed less than 20 criminal actions against corporate defendants for product-related violations in the past decade.39 By creating a general offense for life-threatening activities, many such gaps in the law related to product safety could be closed.

Sanctioning the Corporation

Such legislation should include sanctions both for the organization as well as any individuals within the firm that acts in a way that could reasonably be expected to either kill or cause serious injury. In cases where there may not be enough evidence to pin the blame on any single individual, the firm itself should bear responsibility for the crime. Knowing the stakes, corporate executives are certain to protect themselves by conveying to employees the understanding that they do not wish to be told of information, which may subject the corporation to liability.40

Although the federal government does not maintain a comprehensive record or analysis of corporate violations, the studies that exist suggest that strong sanctions are rarely provided for corporations convicted of any crimes, and that the sanctions for consumer product-related crimes are even more lenient than those for antitrust, fraud, and other categories of corporate crime. In Marshall Clinard's 1979 study of 582 corporations, for example, over 85 percent of all sanctions imposed were administrative in nature (e.g. warnings, recalls), 9.2 percent were civil, and 2.7 percent criminal. In only 0.9 percent of all enforcement actions was a corporate official criminally sanctioned – probation, fine, suspended sentence, or jail; in all, just five officials (out of 1,553 actions) went to prison. Almost forty percent of the 1,446 primary sanctions imposed on manufacturing corporations were for actions that directly harmed consumers in terms of the quality or safety of the product.41 U.S. Sentencing Commission data for the three most recent years for which data is publicly available (2001-2003) indicate a consistent rate of about 7 percent of all major organizational offenses are related to food, drug, agricultural and consumer products.42

Clearly any criminal fines should go beyond the "cost of doing business," so that any rational cost-benefit calculation by the corporation will be protective of consumers and public health. In addition, since the sanction of imprisonment is unavailable for the corporation itself, the use of creative penalties -- including structural changes within the company that address the source of lawbreaking (with a court-appointed overseer), equity fines and superadded liability for corporate directors and executives who hold a privileged class of stock, should be explored.43

We believe any legislation drafted to address this issue should require that any victim or victims be publicly notified in a manner consistent with the market strategies used to advertise the product in the first place -- thus providing the additional the deterrent threat of significant stigmatization. When judged appropriate, direct restitution should also be provided, not only to take the profit out of such crimes, but also to directly compensate those who are victimized, and their families.

Serious corporate crimes should result in the use of serious additional sanctions, including suspension and debarment from government contracts, license revocation, and even the "corporate death penalty" (i.e. charter revocation and dismantlement), as suggested by the Department of Justice in its most comprehensive report on corporate crime.44

The same Justice Department report found that actions affecting consumer product quality were "responded to with the least severe sanctions."45 Though the report was completed in 1979, there is

little reason to believe the situation has changed much since, while the reckless recidivism of certain companies drives home the need for strongly designed legislation, with tougher criminal penalties.

Conclusion

The Center for Corporate Policy believes that the enactment of strong criminal sanctions for knowing introduction of products proven to cause serious injury or death will have a strong deterrent effect. The intensity of objection to such a proposal within the corporate community is a testament to the effect such legislation would have. Voluntary standards have not worked. Administrative penalties have become a cost of doing business. The establishment of effective compliance programs, a culture of compliance, with the ability of whistleblowers to report problems up the corporate ladder and, if necessary, to federal prosecutors is necessary to create a real shift in corporate culture.

In addition to the above-mentioned tough criminal sanctions for the introduction of defective products into interstate commerce, the Senate Judiciary Committee should bolster its efforts against corporate crime in the following ways.

1) Unseal the civil court records. When disputes are resolved without a public record, wrongdoers can prolong misconduct and suppress information about dangerous products and practices for years. Courts can perform a simple balancing test to determine what portions of the documents discovered in civil or criminal cases should be made available to the public in order to prevent the perpetuation of harm. As we have seen in the early Ford/Firestone cases, civil actions can reveal the extent of a company's knowledge of the harm its products are causing; yet the facts may end up concealed as a condition of the terms of settlement of the case. For plaintiffs such a deal can be a bitter pill that must be swallowed in order to obtain restitution, but without a public airing of the facts, or a requirement that all remaining products be recalled, the corporation will continue to place others at risk.

2) Direct the Department of Justice to develop a strategy for better coordination, funding and direction to address the massive and complex challenge of corporate crime. For instance, the Bureau of Justice Statistics should be strongly encouraged to compile a comprehensive annual report on corporate crime, as it does each year for street crime, providing the law enforcement

community, the media and shareholders with an increasingly accurate picture of the depth and variety of organizational crimes committed by corporations each year.

---

1 U.S. Department of Justice, Strategic Plan 2001-2006. Available at www.usdoj.gov The FBI compiles only certain white-collar crime statistics in its Uniform Crime Report, including the most prevalent economic crime offenses, fraud arrests, sentences imposed, recidivism rate and fines and restitution ordered.

2 U.S. Consumer Product Safety Commission 2006 Budget Request and Performance Plan Budget Request 2007, page iii, available at http://www.cpsc.gov/cpscpub/pubs/reports/2007plan.pdf.

3 See J. NCI:93:10, 'Stat Bite" May 6, 2001.

4 Living Downstream: An Ecologist Looks at Cancer and the Environment, New York: Addison-Wesley, 1997, pp. 268-9.

5 Meghan Mulligan and Emily Gottlieb, "Lifesavers: CJ&D's Guide to Lawsuits That Protect Us All," (updated), Center for Justice and Democracy, 2002.

6 Nathan Weber, "Product Liability: The Corporate Response," Research Report #893, The Conference Board (1987).

7 Citizens for Sensible Safeguards, "Special Interest Takeover," (2005) available at http://www.sensiblesafeguards.org/sit.phtml

8 Testimony of Dr. David Graham, MPH, Associate Director for Science, Office of Drug Safety, Center for Drug Evaluation and Research, U.S. Department of Health and Human Services, Food and Drug Administration, Washington, DC, available at: http://www.senate.gov/~finance/sitepages/hearing111804.htm

9 R. Horton Vioxx, the implosion of Merck, and aftershocks at the FDA (editorial). The Lancet, Volume 364, Issue 9450, Pages 1995-1996, December 4, 2004.

10 Gregory Curfman et al., "Expression of Concern Reaffirmed," NEJM online editorial, February 22, 2006. http://content.nejm.org/cgi/content/short/NEJMe068054

11 Matthew AW, Martinez B. "E-mails suggest Merck knew Vioxx's dangers at early state." Wall Street Journal, Nov. 1, 2004: A1.

12 Statement of Joan Claybrook on Firestone Tire Defect and Ford Explorer Rollovers
United States Senate Committee on Commerce, Science and Transportation, Washington, D.C.
September 12, 2000

13 Statement of Joan Claybrook on Firestone Tire Defect and Ford Explorer Rollovers
United States Senate Committee on Commerce, Science and Transportation, Washington, D.C.
September 12, 2000

14 Statement of Joan Claybrook on Firestone Tire Defect and Ford Explorer Rollovers
United States Senate Committee on Commerce, Science and Transportation, Washington, D.C.
September 12, 2000

15 Statement of Joan Claybrook on Firestone Tire Defect and Ford Explorer Rollovers, U.S. Senate Committee on Commerce, Science and Transportation, Washington, D.C., September 12, 2000.

16 Statement of Joan Claybrook on Firestone Tire Defect and Ford Explorer Rollovers
United States Senate Committee on Commerce, Science and Transportation, Washington, D.C.
September 12, 2000

17 Michael Jacobson et al., Center for Science in the Public Interest, letter to George W. Bush, March 14, 2002. Available at http://www.cspinet.org/new/bushletter_031402.html.

18 Russell Mokhiber and Robert Weissman, "Corporations Behaving Badly: The Ten Worst Corporations of 2001," Multinational monitor, December 2001. Jon Bigness, "Warning labels may be sought on hot dog and deli meats: USDA under fire on Sara Lee recall," Chicago Tribune, Feb. 6, 1999.

19 Jon Bigness, "Warning labels may be sought on hot dog and deli meats: USDA under fire on Sara Lee recall," Chicago Tribune, Feb. 6, 1999.

20 David Barboza, Sara Lee Corp. Pleads Guilty in Meat Case, New York Times, June 23, 2001.

21 Ameet Sachdev and Susan Chanler, "Listeria affliction still pains Sara Lee; Report alleges managers knew meat tainted," Chicago Tribune, August 31, 2001.

22 Trevor Aaronson, "Vested Interests: War has been good for Pompano Beach's Point Blank Body Armor," Broward-Palm Beach New Times, September 29, 2005, available at http://www.newtimesbpb.com/issues/2005-09-29/news/feature_1.html.

23 Trevor Aaronson, "Vested Interests: War has been good for Pompano Beach's Point Blank Body Armor," Broward-Palm Beach New Times, September 29, 2005, available at http://www.newtimesbpb.com/issues/2005-09-29/news/feature_1.html.

24 See https://www.pddocs.com/PointBlank2/.

25 Christian Lowe, "The Marines' flawed body armor: Corps recalls more than 5,000 vests that experts rejected -- but some remain in the field," May 9, 2005.

26 See United for a Fair Economy/Institute for Policy Studies, "Executive Excess 2005: More Bucks for the Bang," available at http://www.faireconomy.org/press/2005/EE2005_pr.html

27 Andrew C. Revkin, "EPA, citing Risks to Children, Signs Accord to Limit Insecticide," New York Times, June 9, 2000, p. A-1.

28 Eric Durr, "Dow AgroSciences Agrees to Pay $2 M to State Over Pesticide Ads," Albany Biz Journal, December 15, 2003.

29 Eric Durr, "Dow AgroSciences Agrees to Pay $2 M to State Over Pesticide Ads," Albany Biz Journal, December 15, 2003.

30 See Jack Doyle, Trespass Against Us: Dow Chemical and the Toxic Century, Common Courage Press 2004. http://www.trespassagainstus.com.

31 Gerald Markowitz and David Rosner, Deceit and Denial: The Deadly Politics of Industrial Pollution, U. of California Press, 2002.

32 U.S. EPA, Cleaning Up the Nation's Waste Sites: Markets and Technology Trends, 2004 Edition, EPA 542-R-04-015, September, 2004, at www.epa.gov/tioclu-in.org/marketstudy

33 See Marshall B. Clinard and Peter C. Yeager, Corporate Crime, 2006 (reprint from 1980 with new introduction).

34 For an extensive discussion see David O). Friedrichs, Trusted Criminals: White Collar Crime in Contemporary Society, as well as Clinard and Yeager, Corporate Crime, 1980.

35 See interview with Carolyn Raffensperger, Science and Environmental Health Network, Multinational Monitor, September 2004. http://www.multinationalmonitor.org/mm2004/09012004/september04interviewraffen.html

36 Marshall B. Clinard and Peter C. Yeager, Corporate Crime, 2006 (reprint from 1980 with new introduction).

37 Joel Bakin, The Corporation. New York, Free Press, 2004, page 57.

38 U.S. v Park (421 U.S. 658, 1975, C.J. Burger).

39 CPSC, criminal penalties by fiscal year, http://www.cpsc.gov/cgi-bin/recalldb/crify.asp.

40 See "Corporate Crime: Regulating Cor4porate Behavior through Criminal Sanctions" (note), Harvard Law Review, April 1979, at 1254.

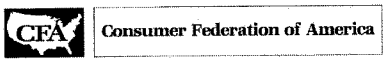
41 Clinard and Yeager, Corporate Crime (1980).

42 U.S. Sentencing Commission, "Organizational Sentencing Practices" (Excerpts from annual reports – see Table 51), FY 2001, FY 2002, and FY 2003. See http://www.ussc.gov/corp/organizsp.htm.

43 Equity fines would require convicted corporations to issue equity securities (special shares) and place them in a victim's compensation fund. Such fines allow for a more powerful deterrent effect because they threaten future earnings and limit harm mainly to corporate owners, sparing consumers and other wholly innocent parties. See Prof. John Coffee, " 'No soul to damn; no body to kick,': An unscandalized inquiry into the problem of corporate punishment." Michigan Law Review 79: 386-459. For a discussion of public directors see Christopher Stone, Where the Law Ends (1972), as well as Marshall Clinard et al., "Illegal Corporate Behavior," U.S. Department of Justice, National Law Enforcement Administration, October 1979.

44 Marshall Clinard et al., "Illegal Corporate Behavior," U.S. Department of Justice, National Law Enforcement Administration, October 1979.

45 "Illegal Corporate Behavior," U.S. Department of Justice, Law Enforcement Assistance Administration, National Institute of Law Enforcement and Criminal Justice, October 1979.



Written Testimony of
Joan Claybrook, President, Public Citizen,
Laura MacCleery, Deputy Director, Auto Safety Group, Public Citizen,
and
Rachel Weintraub, Director of Product Safety & Senior Counsel,
Consumer Federation of America,
before the
Senate Judiciary Committee, United States Congress,
Submitted March 17, 2006

Thank you for providing this opportunity to submit testimony to the written record for the hearing on March 10, 2006, on the criminalization of acts which endanger human life due to identified hazards in products. Both Public Citizen and the Consumer Federation of America strongly support the addition of criminal penalties for these acts, which claim human life and cause suffering equal to acts long viewed as criminal under law.

We would like to take this opportunity to address the objections to such a provision that were raised at the hearing and to supplement the record on key areas of interest to our organizations. We believe that there are strong affirmative arguments for criminal penalties and that these are a much-needed compliment to existing protections in regulation and product liability common law. We also support a Sunshine in Litigation Act for federal courts, to reduce the use of settlement orders that require concealment of dangerous defects, on the condition that the Act not override laws currently available in some state courts to accomplish a similar result.

Our testimony raises the following points:

1. The committee should add a "savings clause" to any proposed legislation on this subject to ensure that there is no preemptive effect from the bill on remedies available under state law;
2. As a general matter, criminal penalty provisions are both morally warranted and economically efficient. Furthermore, they would enhance rather than hamper manufacturing competitiveness;
3. The TREAD Act criminal provision on false statements falls far short of the mark and is in fact no substitute for a general criminal provision on product liability;

4. A criminal penalty for the knowing introduction of defective or hazardous products a logical next step in the evolution of safeguards to protect society from needless harm;
5. Regulatory protections, such as those available from the Consumer Product Safety Commission (CPSC) and the National Highway Traffic Safety Administration (NHTSA) are often undermined and are insufficient to protect consumers.

As a threshold issue, some commentators raised objections to the notion of a criminal penalty provision on the grounds that it was "vague" or "subjective," rather than "objective." We agree that elements of a crime should be as specific as possible, although we note that the inconsistency of verdicts under a jury system for murder, for example, has never been cited as a cause to abandon its prosecution.

In development of the most enforceable and clear statute, however, we would recommend that the committee consider enactment of a "duty to correct" statute. This would provide that criminal penalties attach when a person receives information that serious bodily injury or death may occur as a result of a product introduced into interstate commerce and fails to take corrective action, including warning consumers and regulators and recalling the product. Possible language for such a crime could be as follows:

> Any person who learns that a defect in a product introduced into interstate commerce is likely to cause death or serious bodily injury to a person because of that defect and who knowingly or recklessly fails to act to correct the harm by warning both the public and federal regulators in a manner likely to inform virtually all persons at risk from that harm and taking all feasible steps to reduce the risk of harm, including but not limited to, a product recall or other remediation, shall be fined under this title, imprisoned for a term of up to 15 years, or both.

Many, if not most, of the cases considered by the committee contained these elements. In those cases, not only did company executives learn of the potential for serious or deadly harm; most reprehensibly, even after such information was available, they failed to warn the public or take steps to prevent the harm from occurring.

We also observe that efforts should be made to clearly define "defect" for the purposes of the statute to minimize confusion, and express our confidence that a clear definition of terms will avoid much of the difficulty described in detail by hearing witnesses opposed to enactment of criminal penalties. The definition of "defect" should specify that it is capable of repetition and that a defect may exist in a product regardless of its recognition by federal regulation or its conformance to existing standards for product safety.

The argument that federal regulators' failure to determine whether a defect exists was crucial, for example, in the exoneration of executives in the notorious case involving the Ford Pinto. While evidence that a product conforms to applicable safety standards may certainly be relevant to a jury's determination of whether a defect exists, it should

not be viewed as determinative. Federal regulators have many competing demands upon their time, and federal standards may be utterly obsolete. Many minimum vehicle safety standards have not been updated since they were first issued over thirty years ago, and mere compliance with those standards does little to assure consumers that a product is not defective. Compliance standards are the minimum safety assurances that allow a product to be sold, and are no substitute for the informed engineering judgment of company executives regarding whether a product is actually safe.

Such a provision would reward prompt action to alert the public of hazards in products while punishing to those who evince a clear disregard for human life by knowingly or recklessly covering up known hazards. It would be likely that legislation embodying this language would drastically reduce the number of "cover-ups" of defective products and dramatically alter the calculus of executives who, like those at Guidant, replace the informed consent of the public with their own judgments about risk and the likely harm to the economic interests of the corporation.

The Bill Should Include a Clear Statement that It Does Not Preempt State Law

As members of the hearing panel observed, the legislation should include an unambiguous statement that the bill does not undermine or threaten to undermine remedies available to consumers under state tort law. There would be little sense in enhancing federal enforcement in one area of the law at the cost of further limitations on state civil justice access for individuals who have been personally harmed.

A Criminal Penalty Is Both Morally Warranted and Economically Efficient

Criminal sanctions are an essential code of conduct for desired action within a society and both express and enact a shared set of moral values. It is difficult, if not impossible, to derive any principle which would distinguish between actions which are normally described as second-degree murder and the act of an executive who is made aware that a product may cause death to an unidentified individual and who chooses not to disclose the risks or prevent the death. Indeed, criminal law has historically been deemed an appropriate sanction to address harm to individuals – even individuals unidentified at the time of the crime, such as when a person fires indiscriminately into a crowd.

Criminal penalties are distinct from civil penalties not only in their seriousness for individuals but because they are not compensatory in function and are intended instead to make clear that some actions are reprehensible to society. Enactment of such a penalty provision would also address the class bias which pervades our categories and recognition of criminal acts, in which crime which occurs in suites is treated as less significant than crime which occurs on the street.

Moreover, a criminal sanction would provide a uniquely strong deterrent that cannot easily be accommodated into corporate balance sheets that monetize the risk imposed on others. History shows that fines and monetary penalty for corporations or

executives will merely be input for cost-benefit calculations. Yet harm to individuals is personal, physical, visceral and ongoing.

Criminal sanctions would enhance justice by addressing the distributional inequities between risk decision makers and those unable to give informed consent to risks imposed upon them by others. As one observer has noted, "[t]here is an ethical difference between falling and being pushed — even if the risks and benefits are the same."[1] To the extent that the public's unwitting and unwilling exposure to unreasonably risky products is a function of an information disparity between the industry and consumers, a duty to correct provision may help restore public autonomy and the public's right to informed consent.

While the moral argument is strong, criminal penalties, as a supplement to the civil liability system, are also economically efficient and empirically justified. First, they would yield economic efficiencies by encouraging harm prevention. The incentive to prevent harm should be most acute for those with the knowledge and authority to prevent it because it is far cheaper and more moral to prevent harm than to remedy consequences after the fact. Strong incentives to correct a defect before it harms anyone are therefore highly efficient.

Second, criminal sanctions would reduce externalization of costs by corporations and produce a more accurate social accounting of harm to individuals. Numerous examples, from the Ivey memo to the recent Guidant debacle, show that corporate decision making does not in fact consider social costs (that is, the total cost of likely harm to the public) but merely calculates the likely costs to the corporate entity (cost of liability exposure and compensation to identified victims), weighing those against the cost of the fix.

Yet costs to the corporate entity are far smaller than – likely only a fraction of – the total social costs of harm. Most injured victims do not litigate to recover damages, and most recoveries, when litigation occurs, compensate victims for only part of the costs of injury, meaning that victims will go without needed care or will depend on the government for care-related expenses.[2] There is therefore a fundamental asymmetry in cost-benefit calculations done by corporate entities, an asymmetry which externalizes a majority of the actual social costs of preventable harm and can only be addressed with the strong deterrence of a criminal sanction.

Third, incentives to do the right thing to remedy a defect have likely been even further diminished by the increasing mobility of corporate decision-makers and the fluidity of corporate structures, conditions which demand a form of personal

---

[1] Mark Sagoff, The Economy of the Earth 46 (1988).

[2] Factors that affect whether compensation is available include: whether the risk and manufacturer is identifiable; whether the plaintiff will be interested in litigation and persist in such intention; whether they will prevail; whether the verdict will be appealed and be maintained on appeal, and many other factors. *See* Malcolm E. Wheeler, "The Use of Criminal Statutes to Regulate Product Safety," *The Journal of Legal Studies*, Vol. 13, No. 3 (1984), at 605.

accountability that will follow individuals over time. Indeed, corporate penalties are likely to be far more efficient as a deterrent in the context of corporate crime than in the case of the more typical common law offense because corporate executives, with their access to risk assessment resources, are the consummate "rational actors." In their case, a direct and informed response to any specific deterrence regime creating a new statutory duty to inform the public and regulators of incipient defects is virtually assured.

Fourth, criminal penalties would avoid, insofar as is reasonable, harm to others within the corporate structure and encourages disclosure. Civil liability, even for corporate officers, can be insured against, the costs of which are nearly uniformly paid by the company (and its shareholders), rather than the individual. Similarly, both civil and criminal fines are levied against the corporation, which in turn penalizes shareholders. A criminal investigation of conduct by individuals, on the other hand, would be more likely to reveal whether a single individual or set of bad actors within the company are responsible for the harm, thus enabling actual accountability for decisions and encouraging disclosure by others within the corporate structure to avoid sharing in criminal culpability.

While hearing witnesses suggested that criminal indictments would be devastating for companies, it seems far more likely that it would only be the case if a large number of indictments were filed against a single company. In that case, a company's poor reputation might be well deserved. Yet any indictment, given the higher burden of proof in criminal investigations and the need to find accountable individuals against whom to bring charges, is far more likely to focus narrowly on the few decision-makers who committed the criminal acts. If it is a case of a few "bad apples," a criminal process is far more likely to assure that they do not ruin the whole bushel because it points the finger at individuals, rather than at the corporation as a whole.

Hearing witnesses also raised several objections of a more practical or procedural nature, all of which were meritless. As several witnesses pointed out, the likelihood for abuse of a criminal provision is significantly reduced by the higher evidentiary burden of "beyond a reasonable doubt."

Moreover, we find claims that industry will cease to analyze product risks or produce engineering analyses under the threat of criminal sanctions dubious at best. First, it is a core function of company engineers to test, analyze and monitor product use, quality and other similar issues and they have not stopped doing this job even in contexts in which there are criminal and civil penalties currently on the books. It seems far more likely that corporations would generate more data and be more diligent in documenting safety testing, leading to the introduction of safer products. By this argument, any law to enhance corporate oversight on virtually any topic would merely create additional incentives for manufacturers to cover up wrongdoing rather taking more pains to avoid the culpable act.

Arguments that criminal prosecution would endanger the civil recovery of injured victims or hamper the discovery of defects by creating an oppositional process are

similarly unavailing. The criminal process is far faster, generally speaking, than the civil caseload in the courts and is attended by speedy trial and other protections which assure this outcome.

Discovery processes for federal prosecutors are also far more efficient and are limited only by the Fourth Amendment rather than by the complex and burdensome discovery rules that apply among parties to a civil claim. While some indicted individuals may refuse to self-incriminate, as is their right, others may cooperate far more fully than in the civil context due to the strong leverage of a reduction in their sentence. While some witnesses suggested that information would also be less available to prosecutors than to plaintiffs due to resort to a subpoena, federal prosecutors are far more likely, once a valid case is before them, to pursue any means necessary to collect evidence. Collection of documents and other materials, of course, regardless of ownership, is not barred by the Fifth Amendment, which applies only to speech.

Due to the higher burden of proof, evidence assembled in the service of a criminal trial would be an invaluable and efficient predicate to a speedy civil recovery for damages. It would likely spur settlements and avoid the years-long wait most plaintiffs now experience who go through a trial and even, perhaps, one or more appeals. As just one timely example, a criminal sentence in the trial of Jack Abramoff could be decided in one case in a Florida court as early as the end of this month.

Hearing witnesses also suggested that manufacturing competitiveness would be negatively impacted by new criminal sanctions. This pessimism about the state of executive decision making appears to us to be unwarranted. In fact, most of the evidence on environmental and safety protections points in the opposite direction. Just as pollution wastes resources, unchecked harm to society is a squandered opportunity to prevent injury or save lives. We all pay, in terms of higher insurance and medical costs, in lost worker productivity and illness, and even in traffic delays. As just one example, the annual cost of all traffic crashes in the U.S., which take more than 42,000 lives and inflict more than 3 million injuries every year, is more than $230 billion in 2000 dollars, or $800 for every man, woman and child in the U.S.[3]

A criminal penalty would likely enhance competitiveness by encouraging beneficial innovation, stimulating product evolution, and enhancing accountability. Innovation from enhanced government oversight results in cleaner, higher quality products with more consumer appeal and export value, and creates new industries and jobs (*i.e.*, in recycling, manufacturing pollution abatement technologies, antilock brakes, or air bags). Rules that internalize the real costs of activities connect cause with effect, focus attention on mitigation at the source, and generate useful information about inefficiencies. While in theory this brings the price of goods closer to the actual resource costs, in practice it often does even better by stimulating greater efficiencies – both improving quality and reducing harm. They also prevent damage to company reputations and save the cost of later recalls or other consumer remedies.

---

[3] L. Blincoe *et al.*, "The Economic Impact of Motor Vehicle Crashes 2000," NHTSA Report No. DOT HS 809 446, May 2002.

In fact, stimulating investment in safer practices is a core government function that also benefits industry. According to the "Porter hypothesis," a theory authored by Michael Porter of Harvard's Kennedy School of Government which posits that well-crafted regulations lead to economic growth, the stimulation effect is far greater when regulations are more rather than less stringent. This is because growth from such "innovation offsets" can encourage true progress: extraordinarily creative measures which leap-frog industrial practices to new levels of quality, utility, environmental responsibility and societal well-being.[4]

Criminal Penalties in the TREAD Act Are No Substitute for the Proposed Criminal Sanctions

Although much was made of them at the hearing, even the National Highway Traffic Safety Administration (NHTSA) is on record as stating that the TREAD Act's criminal penalty provisions are ineffective and will likely rarely, if ever, be invoked. As NHTSA noted in its interim final rule on the provision, little use, if any, is expected to be made of the provision, which is already a virtual dead-letter:

> We believe that there will be very few criminal prosecutions under section 30170, given its elements. Accordingly, it is not likely to be a substantial motivating force for a submission of a proper report.[5]

Under the law, TREAD-related penalties would apply only to persons who violate section 1001 of Title 18, an existing criminal statute, and they apply to only a very small class of actions. To prosecute under the TREAD provision, the state must prove that someone: 1) violated 18 U.S.C. 1001 (meaning that the lie or cover-up to the government was both knowing *and* willful); 2) violated 18 U.S.C. 1001 in reporting as required by the early warning rule; 3) had "the specific intention of misleading the Secretary" about a motor vehicle or motor vehicle equipment safety defect (not noncompliance with a safety standard or recall directive); and 4) the defect *had already* caused death or grievous bodily harm to someone at the time of the false report or failure to report. In addition, the

---

[4] The leading article in this line of study is the justly famous Michael E. Porter & Claas van der Linde, *Toward a New Conception of the Environment-Competitiveness Relationship*, 9 J. Econ. Perspectives 97 (1995). Other important studies include the following: Ebru Alpay, Steven Buccola & Joe Kervilet, *Productivity Growth and Environmental Regulation in Mexican and U.S. Food Manufacturing*, 84 Amer. J. Agr. Econ. 887 (2002) (finding that Mexican food manufacturers developed improved efficiencies in operations as a result of increasing stringency of environmental regulation); Eli Berman & Linda T.M. Bui, *Environmental Regulation and Productivity: Evidence from Oil Refineries*, 83 Rev. Econ. & Stats. 498 (2001) (finding that L.A. Air Basin oil refineries achieved improved operations directly because of heightened environmental standards); Eban Goodstein, *Polluted Data*, Amer. Prospect, Nov.-Dec. 1997, at 64 (charting many cases in which regulations resulted in innovations that significantly offset the initial cost of compliance); Stephen Meyer, *Environmentalism and Economic Prosperity: An Update* (MIT, Feb. 1993) (finding that states with stronger environmental protections tended to have higher GDP growth than states with laxer regulation); Office of Tech. Assessment, U.S. Cong., Gauging Control Technology and Regulatory Impacts in Occupational Safety and Health: An Appraisal of OSHA's Analytical Approach (Rep. No. OTA-ENV-635, Sept. 1995), *available at* <http://www.wws.princeton.edu/~ota/disk1/1995/9531_n.html>.

[5] *See* "Motor Vehicle Safety: Criminal Penalty Safe Harbor Provision." 65 F.R. 81417, Dec. 26, 2000.

law created a huge safe harbor, providing that no penalties will apply if the perpetrator "corrects any improper reports or failure to report within a reasonable time."[6]

In short, while the section increases the rarely-applied maximum penalty for a violation of federal law concerning reports made to the government, at the same time it completely undercuts this new authority by prohibiting application of criminal penalties if the person who lied eventually recants. Because prosecutors always retain the ability to grant immunity, and to place case-specific limits on that immunity for witnesses or participants to secure testimony, the broad language of the "safe harbor" provision creates a much larger window for illegal activity than previously existed under the law. In addition, this law requires a request from the DOT to the Justice Department prior to prosecution, a highly unusual potential pitfall for enforcement of any criminal liability.

This provision now in law was written into the House bill. It is no substitute in practice for the Senate version of the TREAD Act's very workable approach to a new criminal penalty authority for NHTSA. That provision was far superior because there was no additional form of immunity, and would have been a real deterrent to the failure to remove dangerous products from the market by penalizing the cover-up of dangerous defects. In contrast, the language in the TREAD Act, as NHTSA makes clear, accomplishes very little, if anything.

Criminal Penalties Are a Logical Evolution in the Development of Safeguards

To effectively prevent consumers from being harmed by unsafe products the existence and enforcement of adequate legal tools must be available. These legal tools are created by the symbiotic relationship of civil and criminal law. However, history has shown that civil and criminal laws alone have not adequately protected consumers from hazards posed by products. In fact, beginning in the early 1970's an evolutionary process began to better protect consumers from product hazards. This evolutionary process must continue to develop.

The creation of the U.S. Consumer Product Safety Commission provides an illustrative example of the existence of an evolutionary process to better protect consumers from risks associated with product hazards. In 1967 the National Commission on Product Safety (NCPS) was created by an Act of Congress to study the existing measures employed to protect consumers from the risks associated by "household" products.[7] The NCPSC completed its final report in 1970[8] and its recommendations led to the eventual passage of the Consumer Product Safety Act,[9] which created the U.S. Consumer Product Safety Commission.

The final report found that "federal law to curb hazardous products was virtually nonexistent, and state and local laws were an unenforceable "hodgepodge of tragedy-

---

[6] *See* 49 CFR 578.7.
[7] Pub. L. 90-146, (1967), 81 Stat. 466.
[8] *Final Report of the National Commission on Product Safety,* Library of Congress Card No 76-606753 (June 1970).
[9] Consumer Product Safety Act, Pub L No 92-573, 86 Stat 1207, 15 USC §§ 2051-2082.

inspired responses . . . . The common law (product liability) was unreliable in restraining product hazards. Rather it was concerned primarily with providing consumers post-injury remedies."[10] Thus, the creation of the U.S. Consumer Product Safety Commission was based upon the failure of the existing civil and criminal legal systems to adequately protect consumers from unsafe products.

Congress gave two tools to CPSC to enforce its laws: civil and criminal penalties. Section 20(a) of the CPSC provides CPSC with the ability to assess civil penalties against any person who knowingly violates provisions of CPSC's statutes of jurisdiction.

However, the current cap on civil penalties is woefully inadequate. The current civil penalty is capped at $7,000 for each violation up to $1.65 million. A "knowing violation" occurs when the manufacturer, distributor or retailer has actual knowledge or is presumed to have knowledge deemed to be possessed by a reasonable person who acts in the circumstances, including knowledge obtainable upon the exercise of due care to ascertain the truth of representations. Knowing violations often involve a company's awareness of serious injury or death associated with their product. There is a dire need to eliminate this cap as elimination would encourage manufactures to recall products faster and comply with CPSC's statutes in a more aggressive way. Importantly, the elimination of the cap will act as a deterrent to non-compliance with CPSC's regulations.

The Senate actually passed an increase on the cap on civil damages from $1.65 million to $20 million in 2003, but the House filed to act and the current cap remains the legal limit. These limitations are laughable in terms of the value of the companies that product products under CPSC's jurisdiction and fail to create a meaningful deterrent for violation of product safety laws and the introduction of unsafe products into the market place.

Section 21 of the CPSA sets forth the criminal penalties that CPSC can assess against any person who knowingly and willfully violates CPSC statutes. However, this provision can only be assessed after the person received notice of noncompliance from the CPSC. Thus, an entity can be in knowing violation of CPSC statutes dozens of times but unless notice was received by that entity from the Commission alerting that entity of non-compliance, no entity can be assessed. Given its complexity, this provision has been rarely utilized by the Commission. For example, according to CPSC's Web site, CPSC has assessed criminal penalties or jail time 21 times since 1993 and no records are indicated for years before 1993.

A number of examples of CPSC penalties show how inadequate they are in preventing the infiltration of unsafe products into the market place. CPSC fined Cosco, a Canadian company, the largest children's product manufacturer and distributor in the United States, $725,000 in September 1996 for failing to report 96 known toddler bed and guardrail entrapments and one death associated with its toddler beds. In 2001, CPSC again fined Cosco and Safety 1st a record fine of $1.75 million after failing to report two

[10] Lemov, Michael R., *Consumer Product Safety Commission, Regulatory Manual Series*, Shepard's/McGraw- Hill, Colorado Springs, CO, February 1983, p 1-12 (*citing the NCPS Report).*

deaths and 303 injuries to CPSC. However, these companies never admitted wrongdoing and obviously the penalty did not deter non-compliance with the reporting requirements.

In March of 2005, CPSC levied a record $4 million civil penalty against Graco Children's Products Inc., of Exton, Pa., now owned by Newell Rubbermaid, for failing to inform the government in a timely manner about more than 12 million products that posed a danger to young children nationwide. From 1991 through 2002, Graco and Century, now Graco, failed to report defects in juvenile products that the Commission said could create substantial product hazards or unreasonable risks of injury or death to young children.

According to the CPSC, the company failed to report hundreds of incidents and injuries involving 16 different products. The products, all used by young children, include infant carriers, high chairs, infant swings, strollers and toddler beds. The injuries ranged from contusions and fractures to strangulation and included fatalities.[11] The products for which Graco filed to report were previously subject to at least seven recalls. While this civil penalty was the largest levied by CPSC in its history, it did not come close to the cap which would have allowed an assessment of $26.4 million. Graco was previously subject to a civil penalty of $100,000 in 1991 for failure to report defects and injuries associated with a children's stroller.[12]

The statutory limits on civil penalties, the size of the companies that CPSC regulates, the notice provision required before an assessment of criminal penalties, and a limited and shrinking CPSC budget, show that a need for the further evolution of product safety law.

Regulatory Safeguards Are Insufficient to Protect Consumers

Due to the disparate power of industry forces and consumers, decisions by regulators do not always reflect the balance of social costs and risks inherent in a defective product. A recent example is provided by NHTSA's response to a mandate enacted in the wake of the Ford/Firestone tragedy as part of the Transportation, Recall Enhancement, Accountability and Documentation (TREAD) Act.

The TREAD Act's new authority for NHTSA to collect "early warning" safety defect information was the result of a clear determination by Congress to make the automotive industry publicly accountable for past decisions not to recall dangerous and defective vehicles by mandating disclosure of potential safety defects to both the agency and public.

The law followed shocking media and Congressional revelations of secret company memoranda and actions, including communications to dealers in foreign

---

[11] U.S. CPSC Press Release, "Record Civil Penalty Levied Against Graco Children's Products Inc. *CPSC, Graco announce new recall of 1.2 million toddler beds*," March 22, 2005, available on the Web at http://www.cpsc.gov/cpscpub/prerel/prhtml05/05138.html

[12] U.S. CPSC Press Release, "Graco Pays $100,000 To Settle Alleged Reporting Violations," February 6, 1991, available on the Web at http://www.cpsc.gov/cpscpub/prerel/prhtml91/91036.html.

companies and foreign recalls that should have been given to U.S. regulators. Congress also called in the NHTSA Administrator for hard questions, upset that the federal auto safety watchdog was asleep on the beat. A State Farm investigator had given the agency more than 20 fatal cases from Ford/Firestone rollovers in 1998, but the agency had done nothing to investigate. Nearly 300 people died and 700 people were badly injured from the defects in the U.S. alone.

The public availability of information in that case would have saved lives and prevented a catastrophic loss of faith in both the industry in general and the reputation of Ford and Firestone specifically. The solution in the TREAD Act was to require automakers to submit information as it develops to a new NHTSA early warning database showing the industry knowledge of, and the consumer's experience with, vehicle safety. Like adverse drug reaction information collected by the Food and Drug Administration, the information was intended to be available to the public.

While the bill was pending in the House of Representatives, Rep. Markey (D.-Mass.) conducted a colloquy on the subject with Rep. Billy Tauzin (R-LA) on the floor of the House during debate on the bill. In that colloquy, Rep. Tauzin affirmed Rep. Markey's statement that the "special disclosure provision for new early stage information is not intended to protect [information] from disclosure that is currently disclosed under existing law."[13] In addition, when signing the law on November 1, 2000, the President stated that he was directing NHTSA "to implement the information disclosure requirements of the [TREAD] Act in a manner that assures maximum public availability of information."

The agency's advance notice of proposed rulemaking (ANPRM) contained a brief section on the disclosure provision under TREAD, in which the agency noted that "we believe that section 30166(m)(4)(C) will have almost no impact." Although the early warning rule expanded the universe of information available to NHTSA, principles governing its disclosure would be similar to those applying to information already collected in the course of defect investigations, which is routinely disclosed by NHTSA.

The agency's notice of proposed rulemaking (NPRM) on early warning also unequivocally supported the public disclosure of early warning information:

> Historically, these types of information generally have not been considered by the agency to be entitled to confidential treatment, unless the disclosure of the information would reveal other proprietary business information, such as confidential production figures, product plans, designs, specifications, or costs.

The agency continued "[a]ccordingly, the agency does not expect to receive many requests for confidential treatment for submissions under the early warning requirements of the TREAD Act."

---

[13] *See* 146 Cong. Rec. H9629 (Oct. 10, 2000).

Perhaps because the early warning docket was rife with statements upholding disclosure, the agency pulled a bait and switch. Without any notice in the early warning docket, and prior to issuing the final rule on early warning, on April 30, 2002, NHTSA published a notice in the federal register concerning the agency's *sua sponte* plans to amend the procedures that it uses to process confidentiality requests under 49 CFR Part 512.

At first glance, this arcane rulemaking notice barely appeared to affect the early warning rulemaking, as the discussion of the rule was virtually non-existent. Yet the manufacturers seized upon this opening as an opportunity to argue that the information collected as a part of the early warning rule should be kept from the public. And in marked contrast to its notice, NHTSA's final confidentiality rule focused almost entirely on the secrecy of the early warning database, and announced the agency's policy that all the information – with the exception of deaths and injuries – will remain secret and be withheld from the public even after a specific request under the Freedom of Information Act (FOIA).

Members of Congress who authored portions of the TREAD Act, including Rep. Henry Waxman (D.- Calif.), have indicated that the agency's decision to maintain this information in secret gravely undermines the law. This novel use of FOIA to undermine information about public health and product safety is the subject of a petition for reconsideration by consumer groups, which was recently denied by NHTSA, and is now the focus of a lawsuit currently pending in federal court and brought by Public Citizen.

While the lawsuit has been pending for the past several years, not even the death and injury information that was to be released according to the terms of the final rule has been made available. The outcome? The Congressional mandate in TREAD for an early warning database has resulted in little or no new information being released publicly to assist consumers in identifying dangerous defects in vehicles.

Ever since the Ford Pinto case in the late 1970s highlighted the deeply cynical nature of the industry in measuring costs against saving lives, the public has been all too well aware of the practice of bean-counting by manufacturers. Indeed, consumers have been injured, maimed and killed by repeated incidents in which the cost of the fix, rather than the seriousness of the safety defect and the risk it poses to human life, determines the industry's decisions on dangerous defects and remedies. Providing strong incentives for disclosure of risk, such as criminal penalties, would greatly supplement the all-too-predictable failure of regulators to act in the public interest by bringing information about risks quickly to light.

Testimony

of John Engler
President

on behalf of the National Association of Manufacturers

before the United States Senate Committee on the Judiciary

on Defective Products: Will Criminal Penalties Ensure Corporate Accountability?

March 10, 2006

Executive Summary

The National Association of Manufacturers (NAM) appreciates that the proposal to make knowingly placing a defective product into the stream of interstate commerce a criminal offense is well intentioned. While the NAM neither condones nor would support someone intentionally releasing a defective product onto an unsuspecting public, we are strongly opposed to the proposal since it will have numerous negative consequences.

Most importantly, it will delay justice for the victims. Civil litigation will have to wait until the criminal process is concluded. This is especially true if the individuals involved invoke their Fifth Amendment right against self incrimination.

The Constitution's Fifth Amendment protections will also postpone discovering what happened and why. Every lawyer with knowledge in this field that the NAM has spoken with has said that the first advice of a criminal lawyer will be to not talk to the employer nor any federal, state or local agencies involved. If the individuals involved do otherwise, they will have waived their right to Fifth Amendment protections at a very early stage. Thus, the public will be denied vital information about the incident and what to do about it.

Moreover, while subjective judgments are appropriate for civil litigation, the increased severity (most especially including jail time) of criminal penalties demands objective criteria. Manufacturing a product that will eventually be placed into interstate commerce requires innumerable decisions at many turns. Having employees concerned about whether they need to talk to a lawyer while weighing these decisions would be a major disruption to productivity.

In addition, punitive damages were created as a heavy-deterrent civil substitute for actions that would be difficult to make criminal. If product liability were criminalized, punitive damages should be eliminated as there would no longer be a need for the civil substitute.

The proposal also raises other, more technical problems including the *mens rea* (criminal intent) requirement, defining what a defective product is and is not, the delay or non-research into making current products safer, how to engage in best practices for quality production without establishing a basis for "knowing" about defective products, and international implications.

TESTIMONY OF

JOHN ENGLER
PRESIDENT

NATIONAL ASSOCIATION OF MANUFACTURERS

BEFORE THE

COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

MARCH 10, 2006

Mr. Chairman, members of the committee, my name is John Engler and I serve as president and CEO of the National Association of Manufacturers (NAM). I appreciate your asking me to testify on the very important issue of making the act of knowingly allowing a defective product to be introduced into the stream of interstate commerce a criminal offense. This proposal may be well-intended, but is fraught with many counter-productive consequences.

The NAM is the nation's largest industrial trade association representing small and large manufacturers in every industrial sector and in all 50 states. Through our direct membership and our affiliate organizations — the Council of Manufacturing Associations, the Employer Association Group and the State Associations Group — we represent more than one hundred thousand manufacturers.

It is important at the outset to understand that although the NAM has strong concerns about the idea of making it a criminal offense to knowingly place a defective product into the stream of interstate commerce, we certainly would not condone nor

defend a manufacturing employee, including — and perhaps especially — a high-level executive, who intentionally committed such a horrendous act. Our concerns center on the real-world and practical difficulties of criminalizing what is, at its core, a subjective judgment concerning how safe a product must be to be reasonably safe, judgments that are routinely made by people acting in good faith with no true intent to do harm. Further, to the extent that an individual engages in plainly unlawful conduct with the intention of inflicting injuries on purchasers of a product, there are other criminal statutes based on objective criteria such as murder, manslaughter, reckless endangerment or even terrorism at the disposal of a U.S. attorney.

The issue of criminalizing product liability has been explored by Congress twice in the recent past: first, in the immediate aftermath of the Ford-Firestone incidents in 2000 that resulted in enactment of the Transportation Recall Enhancement, Accountability, and Documentation (TREAD) Act; more recently, a criminal penalties provision for maritime products somehow made its way into the Coast Guard Authorization Act of 2004.

In both cases, the NAM unsuccessfully made the argument that the committees with jurisdiction over criminal penalties — the respective Committees on the Judiciary — needed to explore the issue more carefully. In the case of the TREAD Act, time was running out before adjournment and in the case of the Coast Guard Authorization Act the criminal provision was removed in conference. Thus, the NAM is at least pleased that the issue is being considered by the appropriate committee of jurisdiction.

We will be concerned, however, with all of the unintended consequences that criminalization would put in place if the committee were to make a favorable

recommendation to the full Senate. Nevertheless, we are hopeful that the members of this committee will carefully weigh the arguments and conclude that however well-intended the proposal to criminalize a product liability action may be that it is not a good idea. This would send a signal to the other committees that they should not be so quick to adopt a similar provision on an authorization or other bill in the future.

To set the stage for what this discussion really is about, let me quote from an article penned by Marion Blakey, who served as National Highway Traffic Safety Administrator during the Administration of the first President Bush. The article appeared in the September 26, 2000, edition of *The Wall Street Journal*. Ms. Blakey wrote the article during consideration of the TREAD Act and framed the arguments rather succinctly:

> [With civil penalties a] jury need not find the company guilty beyond a reasonable doubt, but can penalize a company if it concludes that it is more likely than not that the company's product is responsible for death or injury. . . .The criminal process, by contrast, is based on conflict and coercion, not cooperation and openness.

For the record, I note that the False Statements Act, which covers making statements to federal agencies that are not true, already contains criminal penalties. Unless superseded by another statute, this law applies to all agencies and for an individual imposes a fine of up to $250,000 and up to a five-year federal prison sentence. Corporate fines can run as high as $500,000. In the case of the TREAD Act, the False Statements Act penalties were incorporated into the National Highway Traffic Safety Act and trebled; in the case of the Coast Guard Authorization Act of 2004, criminal penalties were imposed of not more than $10,000, or imprisonment for not more than one year, or both. Importantly, both provide for a safe harbor if the persons involved are cooperative

and make a good-faith effort to rectify the situation. They also rely on objective criteria, such as failure to file a truthful report, rather than subjective criteria such as a "product defect."

The primary danger of turning a product liability matter from a civil issue to a criminal issue is that you would criminalize a subjective judgment. Thousands of decisions are made in a manufacturing company every day by the R&D staff, the engineers, product quality personnel, and assembly line and factory floor workers. In her *Wall Street Journal* article, Ms. Blakey noted that "no statute or regulation clearly defines a safety-related defect." Defining "product defect" is one of the most complex and varied aspects of product liability law as evidenced by the many variations of product defect standards among the states. Think of what would happen to productivity if each of the people involved in the manufacturing process decided that they needed to talk to a lawyer before allowing a product to be placed into interstate commerce.

The definition of what constitutes a "defective product" is extremely important for constitutional reasons. Criminal laws are unconstitutional if they do not provide defendants with adequate notice about what an offense entails. As noted above, determining what is and is not a "product defect" is complex and open to interpretation, as witnessed in the many conflicting jury decisions regarding even the same product when used in an identical or nearly identical manner. As Professor David Owen, one of today's leading experts on product liability law, has observed, "The very notion of how much design safety is enough . . . involves a morass of conceptual, political, and practical issues on which juries, courts, commentators, and legislatures strongly disagree. . . . . For [design defects], there probably cannot in the nature of things be a bright line

separating good products from bad to guide the engineer or the judicial forum reviewing his work years hence." David G. Owen, Problems In Assessing Punitive Damages Against Manufacturers Of Defective Products, 49 U. Chi. L. Rev. 1, 37-38 (1982).

Beyond that, the legal concept of what constitutes *mens rea* — dealing with the intent of one who commits a criminal act — is being whittled away by the courts. In just one example of this trend, the NAM filed an *amicus* brief urging the Supreme Court to hear the appeal in *McNab v. United States*. Seafood importers in this case are serving time in federal prison (two for eight years) for convictions of violating the Lacey Act, which makes it a U.S. crime to import seafood or wildlife in violation of foreign law even though the government of Honduras said in court briefs that the Honduran regulation in question was not even valid. In addition, and perhaps more egregious, they were also convicted of money laundering based on the simple fact that they sold the lobsters to seafood wholesalers in the normal course of business, and were also charged with smuggling simply because the lobster tails were packed in clear transparent plastic bags instead of cardboard boxes as allegedly required by the invalid Honduran regulation.

The *mens rea* requirement would become highly important, for example, in the case of a manufacturer that keeps very good records about the percentage of products that are returned because they turned out to be defective. Even if the rate is extremely low such as one or two percent, would the manufacturer "knowingly" be placing a defective product into the stream of interstate commerce? His real goal is to try to get the percentage down to as close to zero as possible so as not to inflict harm on anyone. Would the *mens rea* requirement of a new law to criminalize product liability provide for

a certain percentage of products to "knowingly" be defective? If so, what is acceptable in order to differentiate a criminal from a law-abiding manufacturer?

Currently, if someone is harmed by the defective one or two percent that make their way into the marketplace, he or she will have grounds for a civil lawsuit. The company could try to avoid future lawsuits by using the statistics about product quality by motivating front-line workers and managers to do a better job to spot the defects before they hit the market. But if corporate executives and other employees could find themselves facing jail time because these very statistics "proved" that they "knew" a certain percentage (albeit small) of a product was being placed into interstate commerce, they would have a motivation to stop collecting the data.

Similarly, would warning labels demonstrate criminal intent if the label stated that the product was harmful if used in a certain way but was not clear enough for a certain segment of the population to comprehend? Indeed, every product is capable of causing injury under some circumstances; as Justice Breyer has recognized, "over the next 13 years, we can expect more than a dozen deaths from ingested *toothpicks.*" Stephen Breyer, *Breaking the Vicious Circle* at 14 (Harvard University Press 1993), quoting *Corrosion Proof Fittings v. E.P.A.,* 947 F.2d 1201, 1223 n. 23 (5th Cir. 1991). Will toothpick manufacturers be subject to prosecution because they intentionally distributed a product knowing that deaths could occur?

That is why it is a very important consideration that agencies such as the Consumer Product Safety Commission (CPSC), the Occupational Safety and Health Administration (OSHA) and the Environmental Protection Agency (EPA) all have objective criteria in their statutes before criminal penalties can be assessed. Section 19 of

the Consumer Product Safety Act, for example, requires a violation of a set standard, the manufacture or sale of a banned product or not complying with established reporting requirements. This is a far cry even from "knowingly" placing a "defective product" into the stream of interstate commerce. In addition, before the CPSC can prosecute someone criminally, the full commission must vote to do so. This acts as a check on a rogue prosecutor out to make a name for himself or herself following the failure of a well-known product to perform properly and/or safely.

This is not to say, however, that simply ensuring that the criteria that could be placed in a statute are objective would be sufficient. Consider the case of Jim Knott, president and CEO of Riverdale Mills Corporation in Northbridge, Massachusetts, who serves on the NAM Board of Directors. Nine years ago, an EPA SWAT team (yes, they have one) of 21 armed men swooped in on his plant offices. They hauled out boxes of files seven feet deep, plunging Mr. Knott into a legal odyssey of seven years costing hundreds of thousands of dollars. Three years into it, "60 Minutes" exposed the EPA for what it had done: created incriminating evidence by forging Riverdale Mills documents to indicate that the company had discharged criminal levels of wastewater. Mr. Knott won his case and is now suing the EPA for its fraudulent enforcement.

What does Mr. Knott's story tell us? That perhaps criminalization raises the stakes for the agencies and agency employees so that they could be willing to alter documents simply to make it appear as if the agency involved was not in the wrong even when it was.

I want to clarify that the NAM understands that the EPA action in Mr. Knott's case may be an aberration, although he has spoken to numerous others who have similar

experiences. Nonetheless, it is something that has happened, is not a hypothetical and that should be kept in mind as you explore this issue. And, in the end, we appreciate that at least the standards of EPA criminal enforcement are objective, and are not based on subjective decisions. Nevertheless, the actions of the EPA SWAT team members in Mr. Knott's case should cause pause in any rush to judgment that criminalization is a panacea.

Beyond the problem of criminalizing a subjective decision, you quickly get into the quagmire of what happens following an incident. Agencies — and, any company that is protective of its reputation — will want to conduct an immediate investigation into how the problem arose, who was involved and how best to rectify the situation.

Every knowledgeable attorney with whom the NAM has consulted has agreed that the first advice that would be given to employees with knowledge of the situation would be to not talk to either the agency or even their employer. It would be paramount for those employees to not waive their Fifth Amendment rights under the Constitution and, as we all know from "Dragnet," anything that they say to either the investigating agency or their employer "can and will be used against [them] in a court of law."

Certainly, in employment-at-will situations, the employee could be discharged by his or her employer. But to what purpose? This will not force the employee to waive his or her constitutional right against self-incrimination. The agency will still be left in the dark. And the company is no closer to determining how its product became defective and, if it knew that, how it entered the stream of interstate commerce.

Would it not, therefore, be better to free the employee from facing jail time so that he or she would be willing to talk and to share his or her engineer's notebooks or other

documents? One could argue that the documents and other work product belong to the employer. But if a new criminal penalty possibly protected by the Fifth Amendment is imposed, how long would it take for the courts to sort this out? Would it not be better to not find out?

The Fifth Amendment issue also brings up consideration for victims involved. While the NAM has decried the problems in the U.S. civil litigation system, we have always maintained that civil litigation, when not abused or misused, serves an appropriate function. But what would happen if product liability violations were criminalized? The actual victims would be forced to wait out the criminal system. Thus, to the extent that the Fifth Amendment right — which is appropriate for any United States citizen to use when confronted with jail time — is invoked, civil litigants will have to wait until the criminal proceedings are concluded. No judge presiding over civil litigation would force an individual involved to foreswear his or her right to Fifth Amendment protections as this could be a ruling subject to appeal. (And one where the judge would be likely to lose.)

In addition to the Fifth Amendment problems that a criminalization proposal would raise, there is also the issue of subpoena authority. Let the record note that, in the case of the Ford-Firestone incident in 2000, the companies cooperated and did not require a subpoena. If either the company or individuals within the companies involved in a future incident are facing criminal charges, either or both are likely to require a subpoena, which is likely to be challenged. How long would it take to adjudicate this?

Moreover, criminalization of product liability law could actually serve as a deterrent to making products safer. To begin with, companies might delay the "new and

improved" version of a product currently on the market due to an overabundance of caution that they have covered all bases. Or, the company may decide that even researching how to make the product safer, including the consideration of after-market devices, could be seen as an admission that executives "know" that the current product is inherently dangerous even when it is completely safe. In the meantime, users of the current, less-safe version could get harmed or worse. In addition, safer often means more expensive and some useful products may either be withheld from the market because the potential sales are not outweighed by the risk of prosecution or they will be priced out of the reach of less affluent customers.

You further have the problem even now of trial attorneys who are quite content for taxpayer-paid prosecutors to do most of the hard work of discovery and framing of the issues. The potential awards are high, as are the fees, and all with little work. This is with prosecutions based on objective criteria, and will only get worse if a rogue prosecutor were allowed to start using his or her power based on subjective judgments. If the prosecution succeeds, a rush to the courthouse by the trial bar is a foregone conclusion.

Thus, a law purporting to help victims by criminalizing the act of introducing a defective product into the stream of interstate commerce would only serve to delay true justice to the very victims who were actually hurt or traumatized. It would also forestall finding facts, including how and why the problem occurred. In addition, it would only worsen the U.S. comparative disadvantage in legal costs, which currently are twice as high as a percentage of GDP as other industrialized countries.

International considerations bring up several other concerns. What would happen, for example, if a manufacturing firm based overseas decided to put a product on the market in spite of known dangerous defects, but U.S. management and other employees were never told about the situation? First and foremost, there likely would be problems in serving the arrest warrants and then extradition. Would you then go after the U.S.-based management if there were clues and the advantage of hindsight allowed a U.S. attorney to allege that they should have known? Would the presence of this law make it more difficult to recruit highly trained employees to work in the United States?

As you consider this matter, please remember that the genesis of punitive damages in the common law is that they were to serve as a substitute punishment and deterrent for acts that would be difficult to criminalize. As it is, they loom large in the minds of company executives in making decisions about products. Little good and much harm would come out of adding the prospect of jail time in addition to the possibility of punitive damages. On the other hand, if the reason for creating punitive damages in the first place were overridden with a new law that would criminalize product liability actions, would it not therefore make sense to eliminate punitive damages entirely?

The NAM does not question the sincerity of anybody who wants to increase the safety of the American public. Nor do we wish to defend an individual or company that is interested solely in potential profit without any care to known public risks. We do, however, want to be sure that the issue of criminalization of product liability law raises serious concerns not to be pondered lightly. We are pleased that at least — and finally — the appropriate committee is investigating this issue.

In the case of the TREAD Act, for example, we did not support the bipartisan compromise reached in the House of Representatives, although we did not think it was nearly as threatening as the Senate version. We were concerned that the criminal penalties that the TREAD Act imposed could be extended to other industries. Indeed, the NAM's prophecy came true during consideration of the Coast Guard Authorization Act in 2004 (which originally sought to use subjective standards). Now it appears that some would want to extend criminal penalties to all industries.

The NAM hopes that the thoughtful, legal-oriented minds on this committee will consider ALL of the legal ramifications that the proposal to make a criminal offense out of introducing a defective product into the stream of interstate commerce would entail. First, we want you to keep in mind that NOT criminalizing a product liability action is in the best interest of true victims and society at large. We also hope that you remember that the False Statements Act already applies to all agencies. We further encourage you to not forget that current criminal laws can be applied where appropriate and that the Consumer Product Safety Act already contains criminal penalties, albeit limiting the ability of a self-promoting prosecutor to take advantage of a situation due to the oversight of the Consumer Product Safety commissioners exercising the application of objective standards. Finally, we hope that the committee will offer guidance regarding the full, unintended consequences of criminalization to other authorizing committees for their consideration should they decide, once again, to try to appease the media or other constituencies in their quest to quell whatever crisis is at hand.

Thank you, Mr. Chairman. I will be pleased to take whatever questions the committee has.

KING & SPALDING LLP

1700 Pennsylvania Avenue, N.W.
Washington, DC 20006-4706
www.kslaw.com

Theodore M. Hester
Direct Dial: (202) 626-2901
Direct Fax: (202) 626-3737
thester@kslaw.com

March 17, 2006

The Honorable Arlen Specter
United States Senate
Chairman, Senate Committee on the Judiciary
Washington, D.C. 20510

Re: Hearing Before the Senate Judiciary Committee on "Defective Products: Will Criminal Penalties Ensure Corporate Accountability"

Dear Chairman Specter:

On behalf of Guidant Corporation, I hereby respectfully request that the following additions and clarifications be made to the record of the Hearing Before the Senate Judiciary Committee on "Defective Products: Will Criminal Penalties Ensure Corporate Accountability" held on March 10, 2006.

In particular, Guidant has become aware of the written statement of Dr. Barry Maron submitted at the Hearing in which Dr. Maron discusses the unfortunate death of Joshua Oukrop, a 21 year old individual who suffered from a severe form of hypertrophic cardiomyopathy. There was an issue raised by Dr. Maron in his testimony on which Guidant offers the following comments.

As Dr. Maron notes, Mr. Oukrop was a patient who had received an implantable Guidant Prizm 2 DR defibrillator in October 2001. Nearly three and one half years later, Mr. Oukrop collapsed and died while mountain biking during a vacation trip in Utah. Dr. Maron's written testimony states that a post-mortem analysis of Mr. Oukrop's defibrillator revealed an electrical problem that Guidant and only Guidant had known about for over three years. Dr. Maron states that Guidant "believed it was correct and even prudent to conceal all information related to such defibrillator defects." (Dr. Maron's Statement at 3).

Contrary to Dr. Maron's testimony, Guidant had advised the FDA of such issues by submitting Medical Device Reports ("MDRs"), which are publicly available, for each of the "25 other similar short-circuited defibrillators" referenced in Dr. Maron's statement. In addition, in most cases, Guidant shared the results of its analysis into the failure of a device with the physician who returned the affected device. Further, Guidant offered to work with Dr. Maron on a case report Dr. Maron indicated he was working on for possible publication that would have described the failure mechanism that was associated with Mr. Oukrop's device.

There currently are no prescribed guidelines for medical device manufacturers to follow concerning when and how they should broadly communicate to physicians and/or patients any problems with devices of which they might become aware. Guidant, however, is doing its best to ensure that physicians and patients have the product information they need to make informed decisions about therapy. To that end, Guidant's 2005 Product Performance Report now leads the industry in disclosure of product quality and performance information to physicians, patients, public, regulatory bodies, and industry. In addition, Guidant convened an independent panel to make recommendations about communicating to physicians and the public regarding issues of the type presented by the device that had been prescribed for Mr. Oukrop. The panel is chaired by Dr. Robert J. Myerburg, Professor of Medicine and Physiology at the University of Miami, and includes 11 other distinguished experts covering a broad range of disciplines. The report of the panel is expected to be made public shortly.

Guidant has continued to work diligently to investigate and correct any problem that might arise with respect to any of its devices, including the short-circuiting problems referenced by Dr. Maron, to ensure that its products can be relied upon to successfully deliver the innovative, lifesaving therapies that have been developed by the company.

Sincerely,

Theodore M. Hester

Statement of Senator Patrick Leahy
Hearing Before the Senate Judiciary Committee
"Defective Products: Will Criminal Penalties Ensure Corporate Accountability?"
March 10, 2006

Today we convene to discuss the merits of legislation that would provide federal criminal penalties for the introduction of dangerously defective products into the stream of interstate commerce. This is important legislation that could protect millions of Americans, and its potential is something we should carefully explore. Today's hearing is a good start, and I commend Chairman Specter for his efforts.

Even with strict liability and enhanced whistleblower protections, some continue to manufacture and introduce dangerously defective products into interstate commerce. Corporate actors that do this sometimes ignore known risks, putting profits over responsibility. The recent Vioxx situation is an example. Before that the public was victimized by unsafe tires and unsafe cars. While individual cases and class actions can provide some accountability, Congress must change the incentives to discourage this particularly harmful aspect of corporate behavior. The Chairman's proposal would go a long way toward achieving this.

For those corporations that complain about increased litigation, the remedy is within their control. They must disclose any potentially dangerous defect and let consumers decide if the risks are acceptable. Just look at the asbestos situation we currently face in this country. Were it not for years and years of the continued manufacture and distribution of asbestos during a purposeful cover up of its dangers, we would not be watching people suffer and die, while the companies that made them sick retreat into bankruptcy. Perhaps if a law like this had been in place then, asbestos company executives would have thought twice about engaging in such actions.

I hope that we will also consider the effect this legislation will have on state law. I do not intend for us to preempt state law, and I look forward to the witnesses today providing us with their insight and suggestions about how best to fashion this legislation so that we avoid any unintended consequences. I have seen too many federal legislative schemes that merely serve to slam the courthouse door in the faces of those who are injured. The victims are not to blame. At the very least, companies that make dangerous products owe a commitment to American consumers to ensure full disclosure of known risks, to hide nothing, and to make the safest products possible. When there are potential or known defects that are outweighed by a product's usefulness, such that its introduction is warranted, those defects should still be disclosed. This legislation should be to ensure that this responsibility is fulfilled.

This legislation is especially important given the Bush-Cheney Administration's anti-consumer policies. For example, in 2003 the Bush-Cheney Administration sought to "reinterpret" the Federal Insecticide, Fungicide and Rodenticide Act to foreclose state suits for damages based on defective pesticide products that destroy crops, cause environmental damage, or illness. Thankfully, the Supreme Court rejected this interpretation in 2005 in *Bates v. Dow Agrosciences*. In 2004, the Bush-Cheney Administration sought to weaken organic food standards through legally binding USDA "guidances," which would relax these hard-won and relied-upon standards to the detriment of consumers who make conscious choices to buy organics, and producers who conscientiously strive to meet these exacting requirements. In 2005, buried in proposed guidelines to strengthen automobile roofs, the NHTSA inserted a provision that would shield automakers from liability through preemption if the automobile met minimum federal safety standards. In January of 2006, the FDA finalized a rule regarding labels on pharmaceuticals that will preempt state products liability laws and will insulate drug makers from products liability lawsuits.

In addition to the serious substantive objections to these Bush-Cheney Administration actions is the fact that these policy changes were subject to no congressional scrutiny whatsoever. These are back door, unilateral rule changes at the expense of consumers.

Finally, in 2005, the Bush-Cheney Administration filed an amicus brief in the Supreme Court in *Garcetti v. Ceballos* arguing that individuals who blow the whistle on governmental corruption should not be allowed to sue for subsequent retaliation by their supervisors. Not only is this Administration's position contrary to governmental accountability and the role of whistleblowers, but it is contrary to the spirit of the First Amendment.

I do not see the Bush-Cheney Administration encouraging accountability and corporate responsibility. I have not seen much of that in the Republican Congress. Rather, what I see is the self-proclaimed "small government" party supporting big government efforts to preempt state consumer protection laws that present an economic inconvenience to big business. Just this week the House passed a bill that would weaken consumer protections by preempting state laws that require stricter standards for food safety and labeling. The proposal we discuss today is an exception and I commend Chairman Specter for his initiative.

As we consider this bill, I would like to see language providing whistleblower protection for individuals who disclose a dangerous product defect. It is important that we provide an incentive for individuals who have knowledge of a defective product to come forward.

At the very least, adding a criminal penalty for defective products will help encourage responsible actions within corporations, and may even serve to encourage employees to blow the whistle when human safety is at stake.

One of the witnesses with us is a whistleblower, Dr. Barry Marron, and I greatly appreciate his willingness to provide a first-hand account of his experiences relevant to today's hearing. I also thank the Consumers Union for being with us today.

Testimony

United States Senate Committee on the Judiciary

Need for Reform in the Medical Device (Implantable Defibrillator) Industry

March 10, 2006

Testimony

Barry J. Maron, MD

Director, Hypertrophic Cardiomyopathy Center

Minneapolis Heart Institute

Minneapolis, MN

Chairman Specter, Senator Leahy and distinguished members of the Judiciary Committee. Thank you for the opportunity to share with you today my experiences and views on the recent medical device controversy (largely involving implantable defibrillators). My name is Dr. Barry Maron and I am a Minneapolis cardiologist and Director of the Hypertrophic Cardiomyopathy Center at the Minneapolis Heart Institute. Hypertrophic cardiomyopathy (also known by the acronym, HCM) is a common form of genetic heart disease and the most common cause of sudden cardiac death in young people, including competitive athletes. The Hypertrophic Cardiomyopathy Center at the Minneapolis Heart Institute is one of the few in the U.S. dedicated to the diagnosis and treatment of this important heart condition.

Since year 2000, I and my colleagues have promoted the implantable defibrillator as a preventive therapy for sudden death in hypertrophic cardiomyopathy---and with good reason---for we have been able to demonstrate in peer reviewed data analyses that the implanted defibrillator is frequently life-saving…by virtue of its power to recognize and automatically terminate potentially lethal disturbances of heart rhythm in patients with this and other profound cardiac diseases.

In this role, I and my colleague, Dr. Robert Hauser, came to diagnose and treat a young, 21-year-old, college student, Joshua Oukrop, in 1999. Mr. Oukrop was judged to have a severe form of hypertrophic cardiomyopathy and to be at high risk for sudden, unexpected and unpredictable…death.

Therefore, we recommended to Joshua and his father that a defibrillator be implanted as a prophylactic measure on October 4, 2001…and they readily agreed. The defibrillator model is known as Guidant Prizm 2DR 1861. Over the next 3 years, Joshua returned for 12 device maintenance checks every 3 months, as routinely advised, without any evidence of problems.

Indeed, on March 14, 2005, 3 ½ years after receiving his defibrillator, Joshua Oukrop died suddenly and unexpectedly while on vacation in Utah. Detailed post-mortem analysis of the Oukrop defibrillator by representatives of Guidant found a short-circuiting defect that had caused the device to become electrically inoperative and to fail. In other words, when the defibrillator tried to issue a life-saving shock, the electrical energy short-circuited and was dissipated… and did not enter Joshua's heart as it should have. Due to this defect, he was unprotected…and died.

Shortly thereafter, in a meeting with 4 Guidant executives, I learned that this precise defect and problem had been known by the company for over 3 years…but only to Guidant…and not to any physicians or to any patients. During that meeting it was obvious from the Guidant executives that they believed it was correct and even prudent to conceal all information related to such defibrillator defects. I was asked directly for my opinion about that particular corporate strategy: I said…I think this is going to be the biggest mistake you could ever make. They said they didn't agree. Some would say that subsequent events have made my comment prophetic.

It then fell upon me to inform Joshua's father (who also has a defibrillator for hypertrophic cardiomyopathy) of developments. I have…as obviously any cardiologist has…often been the bearer of bad news. But I cannot forget Mr. Oukrop's reaction when told that Guidant had for several years known that his son's defibrillator was potentially defective and could not save him. Although he was controlled…it was as if his last breath had left his body. He said: "I told Joshua that the defibrillator was his shot…that it would allow him to survive and live his life… and you are saying that they knew all along."

In fact, at that time Guidant had already documented 25 other similar short-circuited defibrillators…and had already made manufacturing adjustments on two occasions in April and then again in November of 2002 to new defibrillators of the same model to correct the defects

that were known and had been defined in detail. Still…Guidant had not informed physicians, patients or the government. Furthermore, and perhaps most disturbing, it has been documented that Guidant continued to sell defibrillators they knew to be defective. That is defibrillators that were manufactured before the changes in April and November of 2002.

Therefore, Joshua Oukrop's death was not due to an unforeseen "random" defibrillator failure, as suggested by Guidant to physicians…but in fact was a systematic, repetitive and to some extent predictable defect…and no one else knew. In effect, Guidant had by themselves taken over the medical management of thousands of high-risk defibrillator patients.

Probably only because the facts of this unfortunate scenario were documented in a series of *New York Times* articles by Barry Meier beginning in May of 2005, have these problems in this sector of the defibrillator industry---in what has come to be known as the Guidant Affair---now become evident to all. In fact, these circumstances have led to the largest recall/advisory of defibrillators and pacemakers in the 25 year history of this important industry, involving almost 200,000 devices, including combination defibrillator and pacemaker models implanted for coronary heart disease and heart failure---which have also been associated with several deaths.

It is important to focus on what this scenario and debate is really about. The Guidant Affair is about patients (and their physicians)…and the overwhelming importance of informed consent and full disclosure to patients through their physicians. Patients have a right to know…any information that could potentially impact their risks for injury or death. It is simply not ethical to withhold such information. Patients must have the opportunity to interact with and make such medically important decisions in conjunction with advice from their fully informed physician.

It is also important to establish what the Guidant Affair is not. It is not a statistical issue. It is not about percentages and likely probabilities. Patients are not numbers…they are individuals with the reasonable expectation that industry---in this case defibrillator manufacturers---will communicate openly and accurately with their physician…and in their best interest. Most observers agree that did not happen here. As one of our moms with 3 sons having both hypertrophic cardiomyopathy and defibrillators told a Guidant executive, "Shame on you. It just was not your call to make." I agree…and I believe that vast majority of the cardiovascular community does as well. It is about trust. It is time for change and greater oversight, transparency and communication between industry and the physician community to restore the trust of patients in sophisticated and powerful medical devices such as the implantable defibrillator.

To make it a crime to knowingly sell defective defibrillators to be implanted into high risk patients would I believe have the desired effect on the willingness of companies to make full disclosure. However, such a bill would have to be drawn narrowly so as to not have a potentially disastrous, chilling effect on law-abiding companies whose products may have occasional random defects. Thank you for the opportunity to tell this important story to the Committee.

TESTIMONY OF DONALD L. MAYS

SENIOR DIRECTOR, PRODUCT SAFETY & CONSUMER SCIENCES

CONSUMERS UNION

On

"Defective Products: Will Criminal Penalties Ensure Corporate Accountability?"

Before the

SENATE JUDICIARY COMMITTEE

March 10, 2006

Good morning, Chairman Specter, and other members of the Committee. I am Donald Mays, Senior Director of Product Safety and Consumer Sciences for Consumers Union, publisher of *Consumer Reports®* magazine.[1] Thank you for providing me the chance to come before you today to discuss ways to improve the quality and safety of the consumer marketplace and support all efforts that will help achieve this important goal.

The ultimate question before the Committee today is whether or not criminal penalties will ensure corporate accountability. Will the threat of jail time serve as an effective deterrent in preventing dangerous products from reaching the hands of consumers? Will it force manufacturers to think twice? Would such legislation have prevented Ford/Firestone?

Based on my experiences, I believe that legislation targeted at marketplace accountability is critically important. Individuals in companies who knowingly allow dangerously defective (*i.e.* likely to cause death or serious bodily injury) products to be introduced into interstate commerce should be held accountable. In addition, knowledgeable employees who fail to pass along this information to responsible government agencies should be held criminally responsible.

My 29-year career has focused on product safety and performance testing for manufacturers and retailers as well as for consumers. I believe I bring a unique perspective of someone who understands the competitive pressures of getting new products to the market as quickly and as economically as possible. And from a consumer perspective, I understand the need to trust that all the products in the marketplace are produced with a high degree of integrity and safety.

My breadth of experience includes work in laboratories and factories both here and abroad. It has exposed me to countless examples of suppliers that fail to diligently

[1] Consumers Union is a nonprofit membership organization chartered in 1936 under the laws of the State of New York to provide consumers with information, education and counsel about goods, services, health, and personal finance. Consumers Union's income is solely derived from the sale of *Consumer Reports*, its other publications and from noncommercial contributions, grants and fees. In addition to reports on Consumers Union's own product testing, *Consumer Reports* and *ConsumerReports.org* with more than 6.2 million paid circulation, regularly carries articles on health, product safety, marketplace economics and legislative, judicial and regulatory actions that affect consumer welfare. Consumers Union's publications carry no advertising and receive no commercial support.

build safety into their products. What's more disturbing are the cases I have seen where manufacturers and retailers have continued to sell unsafe products despite the emergence of a clear hazard pattern that results in serious bodily injury.

For four years, I served as the Technical Director of the Good Housekeeping Institute, where I managed testing programs and administered the Good Housekeeping Seal. In this position, I oversaw testing for investigative reports on product performance and safety, and to substantiate claims made for products advertised in the magazine. During my tenure at Good Housekeeping, our projects uncovered many unsafe products, including substandard bicycle helmets and flammable Halloween costumes. Where we found unsafe products, we collaborated with the U.S. Consumer Product Safety Commission (CPSC) to spur recalls of the products we found to be dangerous.

As a former Vice President of Intertek Group, an international testing and safety certification organization, I was responsible for creating a business unit that worked with global retailers and manufacturers. In this role, I assisted clients in developing safety testing and quality assurance programs both domestically and abroad. I focused a lot of my resources in Chinese laboratories and factories that supply products to the American market. I educated manufacturers and retailers about voluntary and mandatory product performance and safety standards. In addition, I taught manufacturers how to take product safety to the next level by analyzing how a consumer is likely to use a product (known as a "human factors analysis"), and determining how foreseeable use could impact product safety. Because a consumer's use of a product often is determined by product design, and the clarity of the instructions, these elements are a part of any safety analysis.

Finally, I also serve on the Board of Directors of the International Consumer Products Health and Safety Organization, and I am an active member of the Executive Committee on Consumer Products for the ASTM-International, a leading standards-setting organization. I work collaboratively with manufacturers, retailers, testing labs, and consumers who write and approve industry safety standards.

Many Hazards are Avoidable

Many hazards associated with products are avoidable through the use of proactive steps, and as a result, many harms resulting from product use cannot be termed "mere accidents." Manufacturers have a choice. Those manufacturers that care the most about safety can subject product prototypes to premarket testing – especially products for use by and with children. During testing, products can be evaluated by experts that will take into account likely real-word use of a product by consumers. Individual product testing can enable manufacturers to exceed voluntary standards when they are found to fall short. At minimum, where a voluntary safety standard exists, manufacturers should comply with these minimum safeguards.

Consumers Union Product Safety Initiative

For the past 70 years, Consumers Union has been testing and reporting on products and services in order to arm consumers with the information they need to protect themselves in the marketplace. Our mission is to work for a fair, just and safe marketplace for all consumers. In my current role at Consumers Union, I oversee the organization's product safety initiative. The goal of this project is to reduce the number of unsafe products in the marketplace. The research and testing programs I direct are designed to identify and decrease product defects – either inherent in a product's design, or due to defects that occur during the manufacturing process. Understanding product defects and consumer behavior is critical because it allows us to work proactively to anticipate and to help prevent injuries and fatalities. Our independent testing often uncovers deficiencies in product designs that, in some cases, may imperil the user. When we find products that we deem unsafe, we rate those products "Not Acceptable," our lowest and most serious product rating. We contact the manufacturers of products we rate "Not Acceptable" to alert them of our findings and to urge them to take swift and immediate action to remove their dangerous product from the market. Reactions from manufacturers have been mixed, ranging from a quick recall of a defective product to ignoring the safety problems that we brought to their attention.[2]

[2] One example of a success story is that of the Combi Avatar child safety seat. Last Spring, we rated this seat "Not Acceptable" because it catastrophically failed in our crash tests. Within a few weeks of

Consumers Face Increased Risks from Defective Products

We are very concerned that current trends may increase the risk that unsafe products will make their way to the marketplace -- and remain on the market even after safety hazards are uncovered. As the world's large, powerful retailers squeeze manufacturers to reduce prices, we have seen evidence that quality and safety can also be reduced. Today, more than ever, pressure from major retailers has created a "speed to market" mantra that can leave little time and few resources for the product safety testing and quality assurance process. Off-shore design and manufacturing is too often conducted by companies who have inadequate knowledge of American voluntary and mandatory safety standards. In addition, sometimes foreign manufacturers lack an understanding of how consumers will use the products they produce because use of the product is not prevalent in the country. For example, the manufacture of gas grills is moving rapidly from the U.S. to China where the concept of grilling food on a gas heated cooking grid is unfamiliar. We believe that a recent result is the manufacture of substandard and sometimes dangerous gas grills; since 2004, there have been one dozen product safety recalls on gas grills -- in all cases the defective products or components were made outside of the U.S. Over a similar two-year period just 10 years ago, when most gas grills were U.S. made, there were no recalls.

The CPSC itself has identified a disturbing trend, and has documented that from 1991 to 2002, the number of older adults (75 and older) treated in US hospital emergency rooms for products-related injuries increased 73%. This increase is almost three times the group's increase in population. Many of the injuries were related to common household products such as yard and garden equipment, ladders, step stools, and personal use items. As the population ages, it is even more important that manufacturers work to reverse this recent trend with products that are not defective and unreasonably dangerous when used by the elderly.

---

discussing our findings with the manufacturer, Combi instituted a recall of the seats and replaced the defective parts.

Lack of Compliance with Voluntary Safety Standards

The March 2006 issue of *Consumer Reports* features an article on furniture tipover, a problem that results in 8,000 to 10,000 serious injuries each year, mostly to young children. Although ASTM-International publishes a safety standard to prevent furniture tipover injuries, many of the products CU tested do not comply. In fact, since the CPSC requested that ASTM develop an industry safety standard, the numbers of annual fatalities associated with falling furniture have actually increased by 50 percent. In today's highly competitive marketplace, there is often little incentive for manufacturers to meet voluntary safety standards.

Inadequate Enforcement Authority and Activity by Federal Agencies

CU is concerned that the Government agencies responsible for keeping unsafe products off the market are underfunded and understaffed. For example, the staffing level of the CPSC has been steadily dwindling. The budget for fiscal 2007 culminates a two-year reduction of full-time positions from 471 to 420 -- a total loss of 51 employees. Limited resources and funding will force scaling back of the CPSC's work on important programs such as residential fire prevention and child drowning prevention. Under-budgeting and staffing cutbacks will clearly result in reduced enforcement of safety statutes. Without adequate policing, unsafe products could easily infiltrate the marketplace.

Inadequacy of Civil Penalties

The use of civil penalties to penalize suppliers for selling or failing to report unsafe products is often an ineffective deterrent. The $750,000 civil penalty levied against Wal-Mart in 2003 for failing to report safety hazards with fitness machines cost the company an equivalent of the sales rung up in only 1 minute and 33 seconds. For large retailers and manufacturers, paying civil fines are a small cost of doing business.

The Consumer Product Safety Act's Section 15 (b) requires that manufactures, distributors, and retailers who learn that their product either: (1) fails to comply with an applicable consumer product safety rule or with a voluntary consumer product safety standard; (2) or contains a defect that could create an unreasonable risk of serious

injury or death (i.e., a "substantial product hazard") must immediately notify the CPSC – unless the company knows the CPSC has already been informed. See 15 U.S.C. § 2064(b).

The history, however, of manufacturers' failure to report in a timely manner under this section is all too well known. Especially of concern are manufacturers' failures to report children's products known by them to have caused injury or death. Included among companies failing to report are Wal-Mart and General Electric (GE) -- two of the wealthiest corporations in America. We believe the cap on the fines CPSC can levy for failure to report known hazards weakens the power of the reporting statute. Current total fines may not exceed $1,850,000 for any related series of violations. This amount is too small to be an effective deterrent for large corporations.

Below are details of fines the CPSC has imposed for failure to report under Section 15 (b):

- In 1991, Graco, a children's products manufacturer, paid a $100,000 civil penalty for failing to report stroller injuries to CPSC in a timely fashion. In 1989, the Philadelphia Inquirer estimated Graco's revenues at $150 million.
- Again in 2005, Graco, which is now owned by Newell Rubbermaid, was fined for the same violation – failure to report safety issues including deaths and serious injuries associated with 16 juvenile products sold under the Graco and Century brands. From 1991 through 2002, the company engaged in "systematic violations" of the law. This time, the fine was largest civil penalty ever levied by the CPSC -- $4 million. Yet, this was less than one-tenth of one percent of Newell Rubbermaid's annual sales.
- In April of 2001, Cosco/Safety 1st agreed to pay CPSC a total $1.75 million in civil penalties—the largest fine CPSC has ever levied—for failing over a four year period to report to CPSC defects in cribs, strollers and a toy walker that caused the deaths of two babies and countless other injuries. Both companies had previously been fined for failing to report under 15 (b); in 1996 Cosco paid a $725,000 civil penalty and in 1998 Safety 1st paid a $175,000 penalty. Both companies have also had an inexcusable number of recalls or products used by children. By the time this fine was levied in 2001, Cosco had 12 recalls of

children's products and Safety 1st had five recalls. Dorel Industries, which owns Cosco and Safety 1st, reported $421million in sales from juvenile products in 2002. Does a $1.75 million fine deter a firm of this size from failing to report?

- In June of 2001, CPSC fined Fisher-Price $1.1 million for failing to report injuries from a dangerous and defective toy. The company had not reported 116 fires from Power Wheels toy. Fisher-Price, a wholly owned subsidiary of Mattel, boasts sales of $1.2 billion in its most recent annual report and notes that its sales are up 8% worldwide.
- In November 2001, CPSC fined Icon Health and Fitness $500,000 for failure to report serious safety hazards with home exercise equipment.
- In August of 2002, GE paid the CPSC a $1 million penalty for failing to report defects in dishwashers that it first became aware of 10 years earlier. GE is one of the largest companies in the history of the United States, with 2002 revenues of $131.7 billion.
- In March 2001, West Bend Co. paid CPSC a $225,000 fine for failing to report fire hazards caused by a defect in its water distillers it had learned about three years earlier.
- In 2002, the CPSC won a case in court imposing a $300,000 fine on a juice extractor company that had failed to inform CPSC about injuries 22 customers had complained of when using their juicers.
- In 2002, Honeywell paid $800,000 for failing to report under 15 (b). In 2003 to date, Weed Wizard had paid $885,000, while Wal-Mart has paid $750,000.

Are these fines acting as an adequate incentive for companies to report product safety hazards? The record suggests they are not. We believe these companies are well-represented, and well aware of the CPSA's reporting requirements—these requirements have been on the books for more than 30 years. It seems clear that the caps on these fines limit their deterrence effect to the equivalent of a $2 ticket for parking violations in downtown New York City.

Need for Legislation Criminalizing Knowing or Reckless Failures to Inform That Leads to Injury

Consumer Union supports the introduction of legislation designed to deter company employees with decision-making authority from knowingly jeopardizing consumer safety. And on this point, please let me be clear. Perhaps any company can make a mistake. However it is what individuals within a company do after they have completed their due diligence and are aware that they have an unreasonably dangerous or potentially fatal defect in one of their products that should be the focus of this bill. If companies fail to disclose this information, or continue to sell a product then they should be held criminally responsible.

We believe the language of any legislation should be targeted so that responsibility cannot be avoided by company representatives who have the power to ensure that unsafe products are not marketed. Furthermore, we believe the scope of any bill should be broad enough to underlie the entire product system and include not only traditionally manufactured products, but also vehicles, foods and drugs. A company representative that knowingly allows the introduction of tainted meats or hazardous pharmaceuticals to the market should be just as culpable as manufacturers that produce unsafe vehicles.

We believe that the triggers for determining when a product is defective must be clearly defined, and that an appropriate definition of defective is when it is likely to cause serious bodily injury or death.

Manufacturers' responsibilities to make products that are not unreasonably unsafe should not be defined by either mandatory or voluntary safety standards. In many cases, safety standards fail to account for reasonably foreseeable use. Warning labels and instructions must not be used by manufacturers as a shield against concerns that a product is defective if it reasonably could cause unnecessary harm. Many products that meet applicable standards are still unreasonably unsafe. For example, a dresser sold by Sears that we tested recently tips over too easily, yet meets the voluntary industry safety standard.

Need for Broad Authority for Criminal Penalties

Manufacturers have failed to inform the CPSC of the dangers related to their product despite mounting evidence and increasing numbers of injured consumers. It is clear from this record that mere fines failed to deter corporate employees from failing to report substantial product hazards to the CPSC. The preventable loss of a loved one is a very personal experience. Similarly, legislation to improve manufacturer, distributor and retailer reporting must place responsibility on real people. Any weaker provision that puts responsibility civil or criminal liability on corporations only, and insulates the individuals responsible for the foreseeable deaths and injuries of consumers would fail to ensure adequate incentives to prevent defective products from entering, or being eliminated from, the marketplace. Although corporate officials may weigh the costs of compliance against the likelihood of having their product exposed as defective, and the costs saved by keeping silent, employees are less likely to gamble with their personal freedom, or risk a criminal conviction.

Individuals in companies who knowingly allow dangerously defective (*i.e.* likely to cause death or serious bodily injury) products to be introduced into interstate commerce should be held accountable. In addition, knowledgeable employees who fail to pass along this information to responsible government agencies should be held criminally responsible. Without this important information, government watchdog agencies are ineffective.

Other areas of the law include criminal penalties for parties who put the public at risk of harm. Under the Consumer Product Safety Act, criminal penalties (fines and imprisonment) can be levied against any person who knowingly and willfully violates the prohibited act section of the CPSA (Section 19) after having received notice of noncompliance from the CPSC. See 15 U.S.C. § 2070 (a). In addition:

> any individual director, officer, or agent of a corporation who knowingly and willfully authorizes, orders, or performs any of the acts or practices constituting in whole or in part a violation of section 19, and who has knowledge of notice of noncompliance received by the corporation from the Commission, shall be subject to penalties under this section without regard to any penalties to which that corporation may be subject under subsection (a). 15 U.S.C. § 2070(b).

Under Section 303 of the Federal Food, Drug, and Cosmetic Act (FDCA), individuals can be held criminally liable for violations of Section 301 (21 U.S.C. § 321), the prohibited acts section of the FDCA "shall be imprisoned for not more than one year or fined not more than $1,000, or both." 21 U.S.C. § 333(a)(1) However, the commission of such a violation after a conviction, or with the intent to defraud or mislead "shall be imprisoned for not more than three years or fined not more than $10,000 or both." 21 U.S.C. § 333(a)(2). Other criminal violation such as the knowing distribution of drugs Finally, the government has reserved the right to impose criminal penalties for violations involving someone who knowingly and willfully falsifies, conceals a material fact; makes materially false, fictitious, or fraudulent statements; or makes or uses a false writing to the government can be fined or imprisoned up to 5 years, or both. See 18 U.S.C. § 1001.

We strongly urge Congress to create criminal penalties for an individual who knowing the likely harm, introduces a product into commerce known to be defective and capable of serious bodily injury or death; or has the requisite level of responsibility or authority over a product and fails to notify the appropriate agency of a known product defect that is capable of causing death or serious bodily injury. We believe that this authority is appropriate and necessary to supplement existing criminal penalties.

Need for "Savings Clause" and to Prevent Preemption of State Criminal and Tort Law

We recommend that any legislation contain a "savings clause" to ensure that states will still be able to hold manufacturers criminally responsible for the allowing the knowing or reckless introduction of defective products into interstate commerce. If this "savings clause" is not included in the legislation, we strongly recommend that if this bill should go forward any attempt to either preempt states from pursuing criminal charges against individuals, or to limit the ability of consumers to seek redress through state tort systems should be rejected. Tort law establishes a duty of care that protects citizens when the Government is too slow to act, when federal minimum standards are grossly insufficient or outdated or when standards are not well enforced. Preemption, if accepted by the courts, would reduce or eliminate manufacturer incentives to exceed this inadequate minimum standard. Any preemption of state common or statutory law in

this case would remove incentives for manufacturers to make safer products – by shielding them from findings that their product was unreasonably unsafe, causing serious bodily injury or death.

Finally, this legislation should address head-on how a company whose employees are prosecuted under this law must deal with removing their defective product from the marketplace. While it sends a strong message to make corporate officials responsible for their misdeeds, it is also important to take timely and effective measures to inform and assist consumers who still have the unreasonably dangerous product in their home.

To prevent future deaths and serious injuries, the defective products themselves should also be placed "behind bars" so that they cannot pose unreasonable risks of harm. Therefore, we urge you to consider expanding corporate duties to include an intensive effort on the part of the manufacturer to get the defective product off the market. Companies should at least be required to spend advertising dollars to inform consumers about their defective products with as much splash and sophistication as they spent on marketing it in the first place. Effective legislation to ensure responsible corporate behavior must focus on appropriate liability in a court of law and accountability in the court of public expectations.

* * *

I thank the Chairman and other members of the Committee for the opportunity to testify, and I look forward to answering any questions you have.

March 10, 2006
Legal Beat

'Silent Tort Reform' Is Overriding States' Powers

By STEPHEN LABATON

WASHINGTON

SUPPORTERS and detractors call it the "silent tort reform" movement, and it has quietly and quickly been gaining ground.

Across Washington, federal agencies that supervise everything from auto safety to medicine labeling have waged a powerful counterattack against active state prosecutors and trial lawyers. In the last three decades, the state courts and legislatures have been vital avenues for critics of Washington deregulation. Federal policy makers, having caught onto the game, are now striking back.

Using a variety of largely unheralded regulations, officials appointed by President Bush have moved in recent months to neuter the states. At the urging of industry groups, the federal agencies have inserted clauses in new rules that block trial lawyers and state attorneys general from applying both higher standards in state laws and those in state court precedents.

The efforts by the federal regulators may wind up doing more than Congress to change state tort laws.

Last month, for instance, the bedding industry persuaded the Consumer Product Safety Commission to adopt a rule over the objections of safety groups that would limit the ability of consumers to win damages under state laws for mattresses that catch fire. The move was the first instance in the agency's 33-year history of the commission's voting to limit the ability of consumers to bring cases in state courts.

In January, the Food and Drug Administration approved a drug label rule that pre-empts state laws. The rule will make it easier for pharmaceutical makers to prevail in consumer lawsuits that could have been brought under state laws more favorable to victims.

Pending before the National Highway Traffic Safety Administration are proposals announced last year by the agency that would pre-empt state laws on the safety standards for car roofs and seat positions. A third rule proposed by the traffic safety agency would preclude states from adopting more stringent fuel emission standards for light trucks and sport utility vehicles.

This week, the Office of Thrift Supervision, a unit of the Treasury Department, successfully challenged a law recently adopted in Montgomery County, Md., a suburb of Washington, that was intended to reduce discriminatory lending practices.

Congress has occasionally encouraged the effort. On Wednesday the House of Representatives, at the urging of the White House and the food industry, adopted a food safety measure that would prevent the states from imposing higher standards than those set by the F.D.A. The bill, which faces an uncertain future in the Senate, was strongly opposed by the states. They say it would undermine scores of stringent state laws and regulations.

The moves in recent months magnify the more limited action taken earlier in the Bush administration to pre-empt the states in consumer cases. The Comptroller of the Currency, another unit of the Treasury Department, has repeatedly moved at the urging of large banks to block enforcement of tougher lending laws in New York, California and elsewhere.

The trend alarms consumer and victims' rights groups and some legal scholars. They say it is not only unfair to victims and gives short shrift to thoughtful state lawmakers and judges, but it also eliminates an important check on inept federal regulators.

"It's very troubling," said Professor Thomas O. McGarity, an expert on regulation and tort law at the University of Texas School of Law. "There is a certain hubris on the part of the regulatory agencies to make the assumption that they are doing their jobs perfectly and should not be second-guessed, especially in light of repeated history of agencies being misled by industries."

State prosecutors and state lawmakers have also lodged objections. Attorneys general in 16 states, including New York, California and Massachusetts, recently sent a letter to the National Highway Traffic Safety Administration about the effort to preempt roof safety rules.

"The state common law court system serves as a vital check on government-imposed safety standards," the state prosecutors said. They said the proposal "is likely to erode manufacturer incentives to assure that vehicles are as safe as possible for their intended use."

Administration officials, industry representatives and their scholarly supporters disagree. They say that overzealous state regulators and vexatious lawsuits require a federal response that sets uniform national standards.

"What has been happening is largely reactive and responsive to industry demands that arise because the industries are confronting similar problems—private liability lawsuits and state attorneys general," said Michael S. Greve, the John G. Searle scholar at the American Enterprise Institute and director of the research organization's Federalism Project. "What Professor McGarity thinks as insufficiently demanding standards, too many people think of as outrageously demanding. Many people think that too high standards imposed by the states hamper research and innovation."

"I just don't see how enforcement by Eliot Spitzer or trial lawyers in Beaumont, Tex., will yield better results," he added.

The new regulations are likely to face court scrutiny in the coming years. But the regulatory agencies have engineered the new rules in a way that they hope will make them less vulnerable to immediate challenge. By putting the pre-emption language in the preambles of the new rules, the agencies make it difficult for some consumer and lawyer groups to challenge them.

The official White House view has been that the federal government knows better than the states.

"The Supreme Court has frequently recognized that federal agencies, rather than courts, are often in the best position to make this determination about what best protects public safety," said Alex Conant, a spokesman at the Office of Management and Budget, part of the White House. "State courts and juries often lack the information, expertise and staff that the federal agencies rely upon in performing their scientific, risk-based calculations."

Mr. Conant said that "having a single federal standard can be the best way to guarantee safety and protect consumers."

Officials said that the White House had not formally orchestrated the efforts by the agencies, some of which are supposed to be independent from the executive branch. Still, others said that the administration's message had been loud and clear, and that no formal directive would be necessary.

"If somebody at the White House had said, Stop it, then it would stop," Mr. Greve said.

STATEMENT OF BRIAN J. PANISH
Senate Judiciary Committee Hearing: "Defective Products: Will Criminal Penalties Ensure Corporate Accountability?"
March 10, 2006

I thank the Chairman and Members of the Committee for inviting me to speak today. This issue is extremely important to the health and safety of all Americans and I am pleased that the Senate Judiciary Committee is taking the time to examine it in detail. I am also extremely encouraged by your willingness, Chairman Specter, to consider additional legislative steps that would compliment the civil justice system in helping to deter corporations from selling a product they know is dangerous. I look forward to working with the committee on this issue.

I have seen first-hand the devastating impacts that corporate deceit can have on a family. I represented Patricia Anderson and her four children in a case against General Motors (GM) in 1999. Ms. Anderson and her children suffered horrendous and debilitating burns because General Motors put a car on the market, the Malibu, it knew contained dangerous defects related to the placement and design of the fuel tank. If the fuel tank system had been designed differently, Ms. Anderson's car would not have exploded and the Andersons would have suffered only minor injuries. But because GM placed profits over safety when designing and marketing the Malibu, my client and her children sustained life-altering injuries.

The Anderson Case

On Christmas Eve, 1993, Patricia Anderson and her four children left their home in Los Angeles, California in their 1979 Malibu to attend holiday services at their community church. After the services were over, Ms. Anderson and her children got in their car and headed towards home. On the way, Ms. Anderson saw a neighbor, 40 year-old Jo Tigner, and offered her a ride home. They stopped briefly at the neighborhood store to get some candy. As Ms. Anderson was pulling up to a red light, going 10 miles per hour, she was rear-ended by another car driven by a man named Daniel Moreno. Mr. Moreno's car hit Ms. Anderson's car in such a way that the front of his car went partially underneath her rear bumper and punctured her fuel tank in several places. Fuel leaked out, and the car exploded into flames with the force of 108 sticks of dynamite.

Ms. Anderson saw smoke and flames, and heard her children "asking Jesus to help them." In the back seat, eight year-old Kiontra tried to cover up her little brother and sister with her own body to keep the flames off of them. In doing so she suffered horrific burns to her back.

Ms. Tigner, burning in the front passenger seat, grabbed at the door handle to get the car door open, but could not hold on because it was unbearably hot. Several people who had witnessed the accident immediately rushed over to help get Ms. Anderson, Ms. Tigner, and the children get out of the car. Because the door handles were too hot to touch, they used a shopping cart to smash the car's windows. The rescuers pulled the children out of the car and doused them and the inside of the car with buckets of water. Kiontra ran from the car crying because her back and legs were burning. She then ran back to the car to help get her sister out of the car. In doing so, she suffered severe burns to her hands.

As a result of the explosion, Ms. Anderson and all of her children suffered third-degree burns over large portions of their bodies. They all had to undergo numerous skin grafting surgeries which involved taking healthy skin from other parts of the body to put over the burned areas. The burns also resulted in severe scarring which caused significant deformation. The scarring will especially affect the children because as they grow, the scars can be painful and require future surgeries. The scarring also resulted in the loss of range of motion and major psychological problems.

What makes this horribly tragic story even more outrageous is that the injuries suffered by these four children and their mother were preventable. This is because GM knew years prior to Ms. Anderson's accident that there were major defects in the car. It knew that the placement of the fuel tank in the Malibu made the car unreasonably dangerous and at risk for exploding in the event of a rear collision *before* they sold it to families like the Andersons. The case against GM revealed the following:

1. GM knew there was a much safer design for the fuel tank placement before they ever put the cars on the market;
2. GM had studies performed that did a cost-benefit analysis, comparing the cost of human life, in a dollar amount, to the cost of redesigning the fuel tank system;
3. GM testing of the car was woefully inadequate; and
4. GM made a conscious decision to market a product they knew would kill people.

The Evidence against General Motors

GM knew for several decades that there was a safer design for the fuel tank system. It knew that instead of placing the fuel system underneath the car, close to the rear bumper, it could put the fuel tank over the rear axle. It knew the safer design was the so-called "over axle" fuel tank design as opposed the less-safe "under floor" fuel tank design. It also knew that there were ways to build the fuel tank so it was less likely to be punctured during a rear bumper collision. This would decrease the chance of a fuel leak and a resulting explosion.

As far back as 1961, GM employee Edward Cole, who later became its President, acquired a patent for the Corvair fuel tank system which had its fuel tank inboard and over the rear axle. Then, in 1964, GM designed a prototype vehicle, for manufacture in the 1970's, with a tank over the axle.

In 1966, GM had a corporate policy that required engineers to pay careful attention to eliminating or shielding the fuel tank from punctures. This directive constituted GM's internal standards and even though these standards existed, GM violated its own policy with the Malibu and failed to protect the fuel tank from punctures in the design.

GM also knew in 1966 that the space between the fuel tank and rear bumper should be at least 17 inches. GM's expert, Mr. Cichowski, acknowledged that the reason for increasing space between the bumper and the fuel tank was to increase the crashworthiness of the vehicle's fuel tank. The closer the fuel tank is to the rear bumper, the more exposed the tank is to danger.

In August of 1970, the government issued a new proposed standard for car crashworthiness. In response, on November 17, 1970, GM's Safety Review Board (composed of GM's chairman of the board, the president, and GM's top chief engineers) issued a "Safety Review Board Action" directing that all future designs starting with the 1973 models would have the over axle fuel tank design instead of the under floor design, in order to comply with the new proposed federal standard. GM even cancelled its order of parts for the "under floor" design. But this decision to design cars with the safer fuel tank option would not last long.

GM soon realized that the over axle design would cost $8.59 per car more than the under floor location. Because of that added cost, GM began a campaign against the government's proposed standard. GM filed its objections to the government's new proposed standard and began looking for ways to comply with the government standard while still keeping the fuel tank system in the under floor location.

In December of 1971, GM engineers were directed to perform cost-benefit evaluations while it awaited the government's actions on their objections to the new proposed federal standard.

On June 6, 1973, Mr. Mutty, a GM engineer, was directed to determine the cost of putting the fuel tank over the axle. Mr. Mutty began working with another GM engineer, Mr.Ivey, on the fuel tank location. Thereafter, the two had frequent meetings and discussions about fuel tank designs. As part of their analysis, they considered whether to locate the fuel tank under floor or over the axle. The team concluded that the over axle tank offered the best protection in accidents above 30 miles-per-hour.

GM also asked Mr. Ivey to do a cost-benefit analysis of the under floor placement of the fuel tank. This cost-benefit analysis became known as "the Ivey memo." The memo reflects that Mr. Ivey found that the estimated 500 fatalities per year caused by fuel fires would cost the company on average, $200,000 per fatality. He further concluded that, based on the number of such anticipated fatalities divided by the number of GM automobiles on the road, that "fatalities related to accidents with fuel fed fires are costing General Motors $2.40 per automobile in current operation." This amount is much less than the $8.59 it would cost to use the safer over axle design. This memo proves that not only did GM know that the under floor placement of the fuel system was *likely* to kill people, it also proves that it sold these cars in a defective condition, choosing profits over American lives. GM's witnesses at trial, Mr. Mutty and Mr. Cichowski, admitted that Mr. Ivey's cost-benefit analysis, and all other such studies weighing the cost of human life against the cost of production, is "despicable."

Mr. Ivey's study was not the only cost-benefit study commissioned by GM. On March 28, 1974 another GM engineer, Mr. Fisher, performed a cost-benefit study eerily similar to Mr. Ivey's. Mr. Fisher, similar to Mr. Ivey, estimated 600 deaths would be caused by car fires each year. He also assumed the cost of each fatality would be $200,000. Mr. Fisher calculated that fuel-fed fire-related deaths would cost GM $2.00 per car. He also concluded that the $2.00 per car would be used up in extra fuel for the additional weight required to modify the fuel tank to make it safe.

Significantly, the approaches used by Mr. Ivey and Mr. Fisher were consistent with GM's general policy to use cost-benefit studies to evaluate the cost of human life compared to the cost of production. As early as July 1970, one of GM's engineers, Mr. Terry, authored a report entitled "Estimating the Benefit in Automotive Safety Cost/Benefit Analysis." The report praised the value of weighing the severity of the injury, including fatality, in order to evaluate the "payoff" of a proposed safety design.

Within one year of Mr. Ivey's cost-benefit study and shortly after the federal government's new proposed standard was squashed, Mr. Mutty recommended to upper GM management that the fuel tank be located under the floor. Mr. Mutty also told the Safety Review Board that he was convinced he could design a fuel tank in either the over axle location or the under floor location which could pass a 50 miles-per-hour car-to-car test, as required by other existing government standards.

In 1972 and 1973, the highest levels of management at GM were well aware that of the importance of designing a fuel system that would not catch fire in an impact collision where the occupants of the car survived the crash. In fact, in a May 1972 presentation to GM, one of GM's own engineers, Ron Elwell, recommended that fuel system integrity be "premised on the concept that occupants involved in collisions which produce occupant impact forces below the threshold level of fatality should be free from the hazard of post-collision fuel fires." Mr. Elwell noted in his presentation that the improvement of fuel system safety would result in decreased cost to GM in the form of reduced lawsuits and reduced adverse publicity.

In 1977, GM became aware of additional problems with the under floor fuel system safety performance. Testing revealed the fuel tank leaked on rear-end impact. Even in a 30 miles-per-hour rear-moving barrier test, their station wagons leaked fuel about 50 percent of the time. Despite this testing data, GM continued with the under floor design.

On August 17, 1977, GM certified to the National Highway Transportation Safety Administration that the Malibu met government standards and was ready for production. However, after that, the car failed or leaked during twenty-one crash tests.

GM also had to ensure that the Malibu met the government's Motor Vehicle Safety Standard (MVSS) 301 before putting the cars on the market. On August 23, 1977, GM engineers reported that test cars were barely passing the MVSS 301's 30 miles-per-hour moving barrier test. Moreover, the engineers bluntly told the fuel system coordination committee in March of 1978 that GM's "test procedures for MVSS 301 do not provide an objective measure of compliance margin." This is clear evidence that GM was knew that just because a car passed MVSS 301, it did not mean that the car was safe. In Mr. Mutty's words, "it takes a lot more to develop a satisfactory fuel system than just passing MVSS 301." In fact, a car could pass 301 and still be unreasonably dangerous.

In 1978, only three months before Ms. Anderson's car was released for sale, Mr. Aldrich, a GM fuel system engineer, recommended three areas where the fuel system could be improved and the leakage problems could be fixed. Those areas included preventing inward buckling of the left rear frame side rail, interaction between the muffler and the right front corner of the

fuel tank, and separation of the rear fuel tank strapped underbody attachment. Mr. Aldrich proposed fixes for all three problems. However, on April 6, 1979, when Ms. Anderson's Malibu was put on the market, none of Mr. Aldrich's proposed fixes were present in the Malibu.

In 1981, the Ivey memo appeared along with other GM documents. They surfaced for the first time in a brown-paper wrapper on Mr. Elwell's desk. The memo consisted of three pages, the first being a cover sheet bearing the names of persons to whom the memo was distributed. The cover page subsequently disappeared. Mr. Elwell was the first person to testify he saw the memo in 1981. Mr. Elwell took the memo and gave it to a lawyer for GM, Mr. Graves. Mr. Elwell also showed it to fellow GM employee, Mr. Cichowski.

Mr. Ivey was soon interviewed by Mr. Howard, another GM lawyer. In the interview, Mr. Ivey stated that he recalled performing his cost-benefit analysis, including an analysis of societal loss. His report was written "for Mutty specifically" and "at Mutty's request." The analysis he performed was "trying to figure out how much Olds could spend on fuel systems." He also stated somewhat reluctantly, "that he had assigned a value to human life in the study," and he obtained the "human life value" from a previous GM cost-benefit report. He also admitted that GM was "very cautious with distribution of the copies due to the nature of the subject."

In 1983, a court, in other litigation against GM (Swanic v. GM), ordered the company to produce all cost-benefit studies, including the Ivey memo. On September 20, 1983, another GM lawyer, Mr. Kemp, interviewed Mr. Ivey. Mr. Ivey confirmed to Mr. Kemp that his superiors had requested the report to determine how much per car it would cost GM to prevent fuel-fed fire-related deaths.

In August of 1984, before Mr. Ivey gave his first deposition in a case involving GM, Mr. Cichowski held the first of what would amount to approximately 100 meetings with Mr. Ivey concerning his memo. Following those meetings, Mr. Ivey was deposed and took the position that he simply did the report, stuck it in "the file," and that was the end of the matter.

At trial, GM tried desperately to distance itself from Mr. Ivey. Mr. Mutty claimed that Mr. Ivey's report was authored only days before he transferred out of the fuel tank design division. Mr. Mutty also claimed he "knew" that Mr. Ivey's last day of work with the fuel system engineering group was July 1, 1973 (two days after Mr. Ivey wrote his cost-benefit memo). However, Mr. Ivey's official personnel records showed this to be a lie. Mr. Ivey did not transfer out until August 1, 1973.

This case is just one example of how a corporation put American lives at risk for the sake of their bottom line. I hope this case illustrates the vital role the civil justice plays in both revealing facts that are important to the public's health and safety and in attaining some measure of justice for those families injured or killed because of the deliberate actions of others. I encourage any additional steps this Committee can take to see that only safe products are put on the market. I thank for your time today and welcome any questions you may have.

PRESENTATION TO SENATE COMMITTEE ON THE JUDICIARY

Defective Products: Will Criminal Penalties Ensure Corporate Accountability?

Anderson vs. General Motors

Brian Panish
Panish, Shea & Boyle, LLP
11111 Santa Monica Blvd, Suite 700
Los Angeles, CA 90025
www.psandb.com
(panish@psandb.com)

Summary of Accident Facts

- Date of Accident: 12/24/93
- Returning from Church when rear-ended

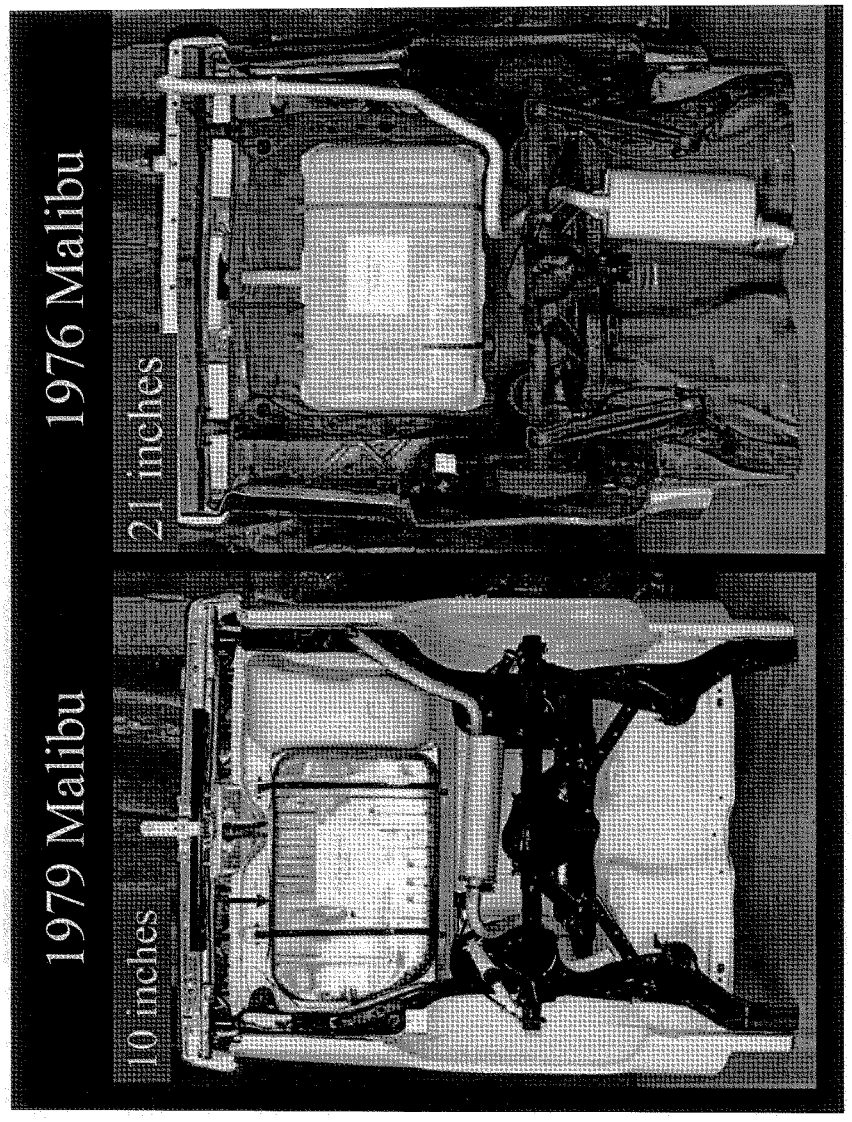
- 6 Passengers with severe burn injuries
- 2 Adults
- 4 Children
- 2 Broken legs - Fully Recovered

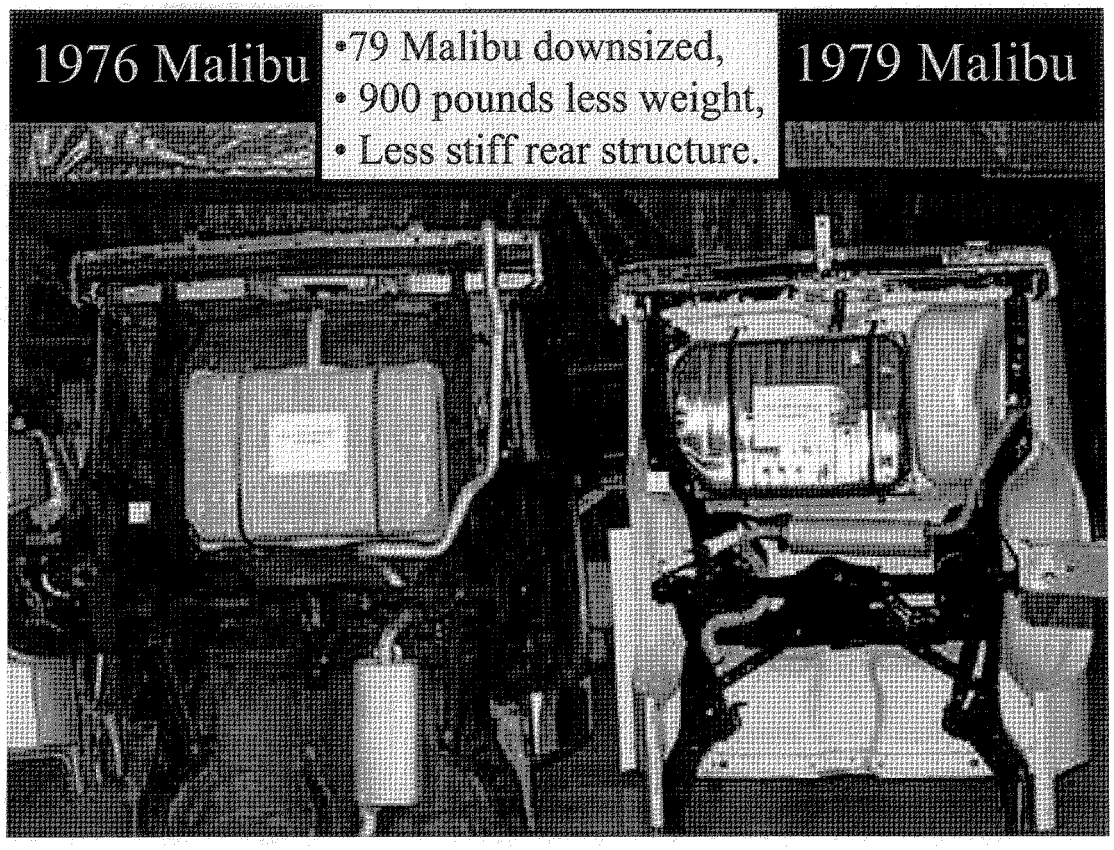
Theories of Liability

- Design defect -- fuel system
- Location of tank in crush zone
- Failure to shield or guard tank
- Profits over safety -- corporate wide policy set by highest officers of company

Malibu Downsized and Fuel System In Dangerous Location

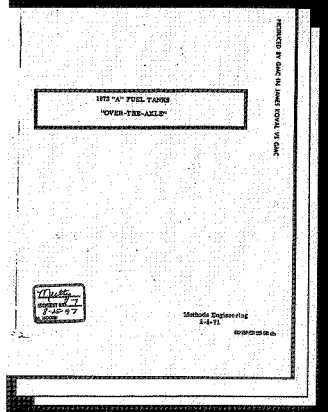
- 76 Malibu tank 21 inches from bumper.
- 79 Malibu tank 10 inches from bumper.
- 79 Malibu downsized, 900 lbs. less weight, less stiff rear structure. Yet fuel tank in crush zone and closer to bumper than previous model.
- Exemplars tell the whole story


1979 Malibu
10 inches
1976 Malibu
21 inches


1976 Malibu
•79 Malibu downsized,
• 900 pounds less weight,
• Less stiff rear structure.
1979 Malibu

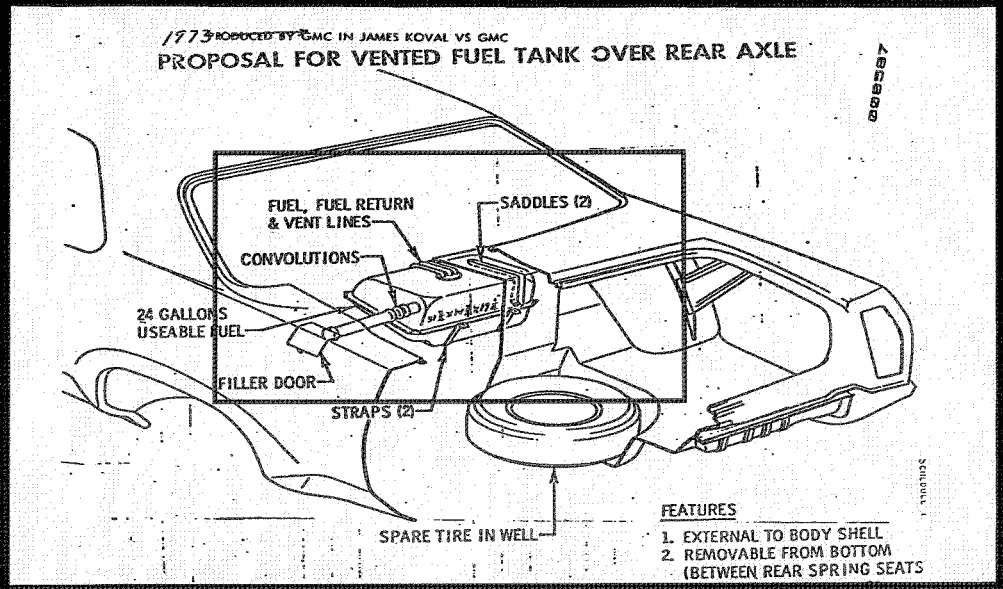
01-05-71

GM Proposal for Location of Fuel Tank



1973 "A" Fuel Tanks
"OVER-THE-AXLE"

Safe Design Available
01-05-71
GM Proposed Location for 1979 "A" Car



- GM did cost benefit analysis with human life to determine if money ($$$) should be spent on safety.
- That is the reason fuel tank not relocated.
- Had design been changed the victims would not have had serious burns.

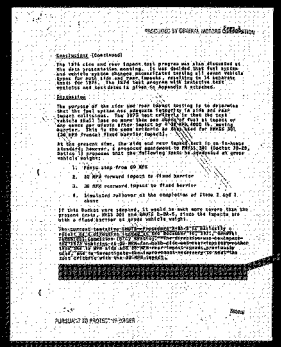
Cost to Make safer fuel system

- Relocation of tank = $8.59 per car
- Shield = $10 to $12 per car

GM Cost Benefit – Internal Policy

March 29, 1973: GTC -- Requests Cost-Benefit for 301 Changes

Chief engineers' directive



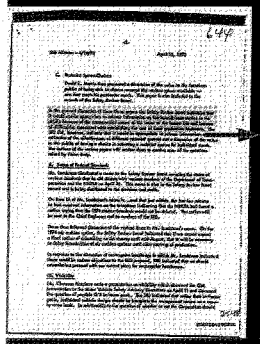
Ex.. 589

"The **directive** also stated that the **cost/safety benefit ratio was to be evaluated** before releasing components required to meet this performance objective which exceeds current MVSS requirements."

GM Cost Benefit

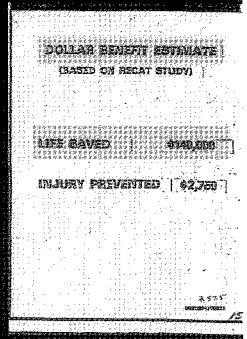
April 23, 1973: Safety Review board (CEO, President, 2 chief engineers, highest level of management)

-- $140,000 per fatality "Not Make Public"



Ex.. 711

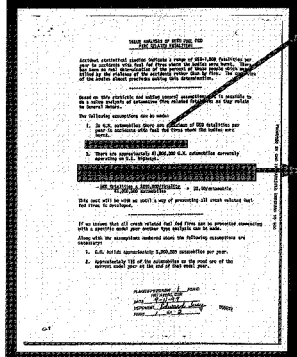
"In the general discussion of these three papers the Safety Board indicated that it would **not be appropriate to release information on the benefit/cost studies to the public because of the controversial nature of the value of the human life** and because of difficulties associated with establishing the cost of final production hardware."



GM Cost Benefit for Location of Fuel system

June 29, 1973: Ivey Memo

"2. Each **fatality** has a **value** of **$200,000.**"

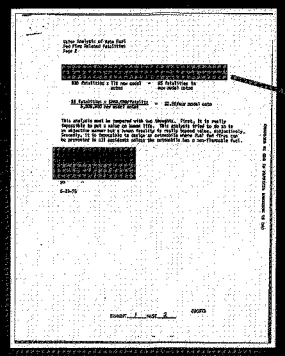


Ex.. 120, p. 1

"Analyzing these figures indicates that fatalities related to **accidents with fuel fed fires are costing General Motors $2.40 per automobile** in current operation."

GM Cost Benefit for Location of Fuel system

June 29, 1973: Ivey Memo



Ex.. 120, p. 2

"This analysis indicates that for G.M., it would be **worth approximately $2.20 per new model auto** to prevent a fuel fed fire in *all* accidents."

GM Engages in Corporate wide Cover-up Regarding Ivey Memo

Ivey testifies and has lack of recollection of **purpose of memo** *16 times* under oath.

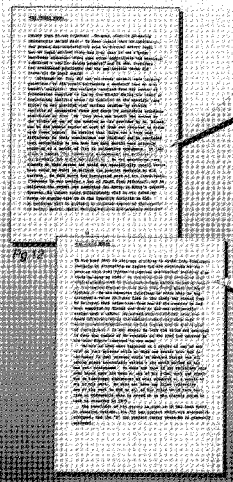
Attys. interview engineer
Ivey, author of memo

November 3, 1981

Interview of Edward C. Ivey

Interview of Edward C. Ivey

By: Don Howard, Esq. (Strasburger & Price)
Re: The Value Analysis of Auto Fuel Fed Fire Related Fatalities
November 3, 1981



He then wrote a report "for Oldsmobile management" and believes it was probably for Mutty specifically.

* * *

He believes that he probably circulated copies of the report to Mutty, Benner, Ball, Perkins, Wallace and possibly Ridenour

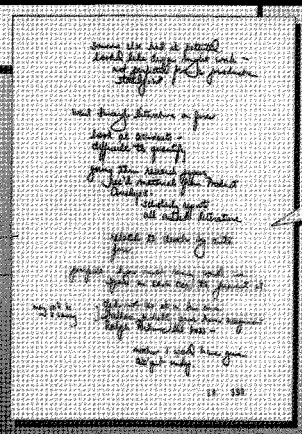
He characterizes the nature of his analysis submitted to Mutty and others as one to assist them in "trying to figure out how much Olds could spend on fuel systems."

* * *

He agreed that he did not like the sound of such a study and admitted that they were very cautious with distribution of the copies due to the nature of the subject.

Interview of Edward C. Ivey

November 1983



. . . related to deaths by auto fire.

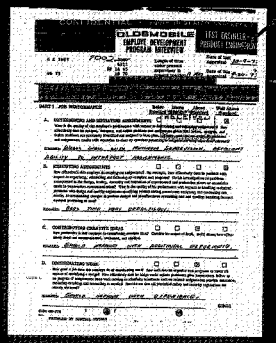
purpose: how much money could we spend on each car to prevent it

did not do it on his own
Wallace probably gave him assignment

Purpose of Memo

July 31, 1973: Ivey Employment Records at time memo written

"*COMPLETED AS OF **7-31-73**"



"Summary of Employe's Current Responsibilities

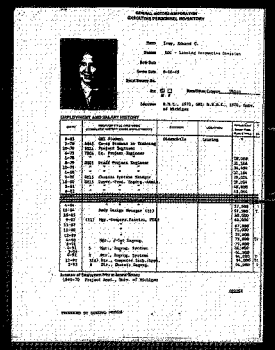
Follow advance design projects **as assigned**

Mathematically analyze designs as required, report results."

Time of First Deposition

Iveygate: "The Cover-up"

March, 1983: Ivey gets 22.5% Raise

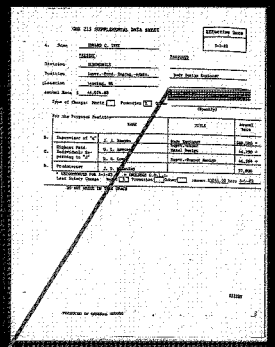


Average raise up to 3/83 = 4%

"8-82 . . . 44,075

3-83 . . . 54,000"

3/83 Swanic order



" 54,000 % Increase 22.5"

Failure to Recall
Crash Test Failures After Release of Car

1978 – 1981 "A" CAR
REAR MOVING BARRIER CRASH TEST FAILURES and INCIPIENT FAILURES

DATE	CRASH TEST #	RESULT
~~Aug 17, 1977~~	~~4235~~	~~Chevrolet Malibu passes 301~~
Sep 13	4269	***FAILED*** *(Trailer Hitch)*
Sep 13	4270	*Fuel tank contact with muffler and hitch cross member*
Oct 17	4310	***FAILED*** *(Trailer Hitch)*
Nov 15	4319	*Fuel tank dropped off car*
Dec 13	4349	*Spillage after impact from puncture of left front tank by frame rail*
Dec 22	4353	*Spillage after impact, tank cut by strap*
Dec 22	4355	*Spillage from right front fuel tank due to muffler contact*
Jan 17, 1978	4358	***FAILED***
Jan 31	4385	***FAILED***
May 25	4491	***FAILED***
May 30	4494	***FAILED***
Jun 9	4495	***FAILED***
Jun 22	4520	***FAILED***
~~Sep 1~~	~~4590~~	~~Fuel tank with plastic "bathtub"~~
Sep 22	4624	***FAILED***
Oct 3	4600	***FAILED***
Oct 19	4636	***FAILED***
Oct 27	4641	***FAILED***
Dec 18	4681	***FAILED***
~~Apr 6, 1979 – Anderson 1979 Chevrolet Malibu manufactured~~		
May 30, 1980	5035	***FAILED*** *(Trailer Hitch)*

16 Failures or Incipient Failures *AFTER* Self Certification

TESTIMONY BY

VICTOR E. SCHWARTZ
SHOOK, HARDY & BACON LLP
WASHINGTON, D.C.

"CRIMINALIZING PRODUCT LIABILITY: A ROAD TO UNINTENDED CONSEQUENCES"

ON BEHALF

OF

THE U.S. CHAMBER INSTITUTE FOR LEGAL REFORM

&

THE AMERICAN TORT REFORM ASSOCIATION

BEFORE

THE SENATE JUDICIARY COMMITTEE
UNITED STATES CONGRESS

ON

MARCH 10, 2006

PENALIZING PRODUCT LIABILITY: A ROAD TO UNINTENDED CONSEQUENCES

Good morning, Chairman Specter, and Members of the Committee. Thank you for your kind invitation to testify today about the merits of criminalizing product liability law. I am testifying today on behalf of the United States Chamber of Commerce's Institute for Legal Reform and the American Tort Reform Association. The views stated today are my own, based on my experience in the product liability field.

In that regard, since 1976, I have co-authored PROSSER, WADE & SCHWARTZ'S TORTS (11th ed. 2005), the most widely used torts casebook in the United States. I served as dean of Cincinnati Law School, and worked with other counsel on behalf of injured persons for more than fourteen years. I am a life member of the American Law Institute, and one of the only defense lawyers to serve on the Advisory Committees of the three most recent RESTATEMENTS OF TORTS, the most important of which for today's hearing being PRODUCTS LIABILITY.

For more than twenty-five years, I have worked on public policy issues, including jury service reform, addressing problems related to baseless

claims, and other civil justice issues, many of which have been considered by this honorable Committee.

I have counseled clients regarding warnings on their products, design and other issues that are directly involved in the proposal to criminalize product liability.

Tort and Crime – Basic Differences

When I taught tort law, I often would invite as a guest teacher the professor who taught criminal law. In a couple of hours, we would address some of the differences between a tort and a crime. Key differences arise in the proposed bill that attempts to criminalize product liability law.

All definitions of the word "defect" are filled with some ambiguities, and that is part of tort law, not criminal law. Tort law has room for error. That is why there are defense verdicts, plaintiff verdicts, high verdicts and low verdicts in many product liability cases, all with respect to the same product.

Just look at what is happening with Vioxx™. The first verdict in a Texas court (in a local jurisdiction particularly friendly to plaintiffs) was for the plaintiff in the amount of $253 million. In the second trial in Atlantic City, where many legal rulings favored the plaintiff, there was a verdict for the

defendant. In the third trial in a Texas Federal District Court, again the same product and virtually the same evidence, there was a hung jury. When the exact same case was tried again in a New Orleans Federal District Court, there was a verdict for the defendant.

The lack of predictability of standards in tort law, especially involving the word "defect," has been a continuing problem. The RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY (1998) attempted to provide more definition to what is "defective." It is useful and more precise than earlier incarnations, but it is still filled with ambiguities. Nevertheless, in tort law, there is room for self-correction. A second or third case can correct the first.

There is no such room in criminal law. If a person were fined or imprisoned, there is no room for a second case to come along and restore a person's freedom. Even if the defendant prevails, the product's name value would be devastated. This fact is well documented in an article describing the only well-known product liability criminal trial that took place in the last fifty years.[1]

A Long Thirty-Year March

The reason the RESTATEMENT (THIRD) was drafted was based, in part, on the fact that the famous (or infamous) RESTATEMENT (SECOND) OF TORTS § 402A that introduced so-called "strict product liability" to the world had ambiguities. It stated that a product was "defective" if a product was "unreasonably dangerous to the user or consumer" (attached). My casebook and other books are replete with various attempts to define design flaws or failure to warn under Section 402A.

Section 402A spawned a torrent of conflicting cases about the meaning of defect in design and warnings cases. This occurred over a thirty-year period. The definition in this bill also discusses "defect" with respect to "instructions." As was true with "design" defects, hundreds of products liability cases have created battlegrounds over whether instructions were "flawed," or whether instructions failed to be "reasonable" or "adequate." Again, while the cost of product liability cases has almost bankrupted companies (and in some cases, it has) and removed useful products, such as Bendectin™, from the marketplace, at least there were no prison sentences or criminal fines against those who produced the products.

---

[1] MALCOLM E. WHEELER, "PRODUCT LIABILITY, CIVIL OR CRIMINAL – THE PINTO LITIGATION, 13 A.B.A. FORUM 250

Some have suggested that ambiguities with respect to punitive damages should be abolished, and that all punishments for defective products should be imposed under criminal law. The proposed bill does not follow that path; it adds ambiguous criminal sanction to existing, ambiguous tort law. In point of fact, there has really been no showing that punitive damages, with their "ambiguous" power, are needed to assure product safety.

About a decade ago, then Senator Slade Gorton of Washington asked a variety of consumer groups if they could demonstrate that there were more harmful products in his state, Washington (which has no punitive damages), than there were in California (which had such damages). There was absolutely no showing that was the case.

Similarly, there has been no showing that there is a need for additional power in our legal system to deter the manufacture and distribution of dangerous products. In point of fact, the Supreme Court of the United States has stated that punitive damages have been so extreme and unpredictable that the Due Process Clause of the Constitution must contain them.[2] As Justice Sandra Day O'Connor has recognized, "[T]ime and

---

(1981).

[2] *BMW of N. America v. Gore*, 517 U.S. 553 (1999); *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

again, this Court and its Members have expressed concern about punitive damages awards 'run wild,' inexplicable on any basis but caprice or passion."[3] If such reining in of punishment has occurred in civil tort law, there should be a steel gate against applying criminal law sanctions with ambiguous standards, and the threat of imprisonment or fine.

The proposed bill refers to a product "known by the person to be defective" that would be introduced into interstate commerce. This "knowledge" standard, while seemingly fair, does not solve the problem, because at the core of the alleged "knowledge" is still "defect." Since that term is highly ambiguous, it creates a contradiction in terms that one would "know" that a product is "defective" when that key word is vague. One knows when someone steals something; one knows it is a crime when someone sets fire to a house; and we know it is a crime when someone burglarizes an apartment. One cannot meaningfully "know" when a product is "defective," as defined in the proposed bill, or the panoply of definitions that have been used to define "defect" in two RESTATEMENTS OF LAW and case law over the past thirty to forty years.

---

[3] *TXO Production Corp. v. Alliance Resources Corp.*, 509 U.S. 443, 475 (1993) (O'Connor, J., joined by White and Souter, JJ., dissenting in part) (quoting *Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1, 18 (1991)).

Congress's Past Experience with Vague Criminal Sanctions and "Defective" Products

In the midst of the Bridgestone Firestone tire recall, the 106th Congress considered legislation to improve automobile safety with criminal penalties similar to the bill now before this Committee. The Motor Vehicle and Motor Vehicle Equipment Defect Notification Improvement Act, S. 3059, was introduced by then Commerce Committee Chairman John McCain with the best of intentions. It would have subjected a director, officer, or agent of a motor vehicle or motor vehicle equipment manufacturer who introduces a vehicle or equipment knowing that a defect or noncompliance with safety standards "created an imminent or serious danger of death or grievous bodily harm" to criminal sanctions. Similar to this bill, S. 3059 would have jailed executives for up to five years if the product caused grievous bodily harm, and up to fifteen years if the product caused a death if a jury, in hindsight, found that he or she knew of a defect.

The McCain bill was moved quickly through the Senate Commerce Committee, receiving a favorable report in less than two weeks of introduction. Soon thereafter, the problem with authorizing vague criminal penalties of this nature became apparent. As Senator Jeff Sessions (R-AL)

recognized, for example, "We are really blurring the line between criminal liability and civil liability, and that's a dangerous trend."[4] Marion C. Blakely, a former administrator of the National Highway Transportation Safety Administration (NHTSA), suggested that such criminal penalties would "actually lead to less safety, not more" because they would create a disincentive for companies to investigate potential safety hazards, as they might avoid the possibility of "knowing" anything that could place them at risk of committing a felony.[5]

Due to concern among Members of the Senate over criminalizing product liability, S. 3059 was put on hold. As an alternative, the Transportation Recall Enhancement, Accountability, and Documentation (TREAD) Act moved forward in the House and was ultimately signed into law. In enacting the TREAD Act, Congress, wisely, did not criminalize product liability law. Instead, it included criminal penalties against auto executives who make false or misleading statements to the Secretary of Transportation with the intent to mislead the government with respect to a

---

4 Steven A. Holmes, *Transportation Spending Bill is Approved*, N.Y. Times, Oct. 7, 2000, at C14.

5 Marion C. Blakey, *Criminalizing Auto Defects is Unsafe*, The Phoenician (Scottsdale, Ariz.), Sept. 26, 2000.

potential defect, an area where an individual's and corporation's responsibility is much more clearly defined and understood.

Current Proposals to Criminalize Products Liability Law

At the core of the current proposal to criminalize the introduction of defective products into the stream of interstate commerce is the definition of the term "defective." Curiously, it follows a pattern that is different from that set forth in an appendix to my testimony, which was included in RESTATEMENT THIRD, TORTS: PRODUCTS LIABILITY § 2. The RESTATEMENT spells out liability in separate rules for design, warnings and mismanufacture (attached).

It is instructive that the tripartite definition in the RESTATEMENT, which took hundreds of hours and more than five years to produce, is very different from the definition in the proposed bill. There are many definitions of "defective," and each one has its own ambiguities.

For example, in the core of the proposal, the definition discusses defective meaning a "flaw in design." Perhaps most courts regard product "flaw in design" as one where there is a "reasonably feasible alternative design." Other courts consider a "flaw in design" as "unreasonably dangerous from the perspective of the user or consumer." Many lawyers view the word

"flaw" as a reference to a "manufacturing defect," which is a failure in quality control, where a product is produced that does not follow the manufacturer's own standards; for example, a foreign object in a soda pop bottle. The proposed bill's definition suggests that a crime would occur because the product would be "dangerous to human life and limb beyond the reasonable and accepted risks associated with such or similar products lacking such a flaw." (emphasis added)

With respect to any product, there are usually similar products with various degrees of safety. Some have excellent safety records; some are not as good. The proposed bill's definition could be interpreted to mean that the one on the bottom of the safety list could result in a criminal penalty for someone who made it, designed it, or wrote instructions that accompanied the product. If such a person were convicted, then the bottom of the list would change, and the next product would come along and that would be deemed a product that could expose employees of a company to criminal sanctions if similar products up the safety chain lacked such a "flaw."

Whether it is automobiles, lawnmowers, or even toaster ovens, there are various degrees of safety in products. This scale of safety occurs with virtually any mass product. Often, products with more expensive costs

have more built-in safety features. This does not mean that products lacking those safety features should be subject to tort law sanctions and certainly should not be subject to punishment under the criminal law.

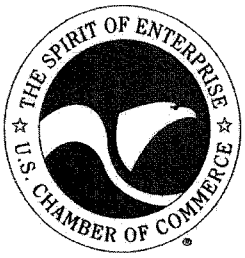
Conclusion

While there may be specific, wrongful acts of conduct that should be subject to sanction, the ambiguities of product liability placed into criminal law do not achieve that goal. When Congress considered the TREAD Act just a few years ago, this very problem was pointed out to Congress and it was corrected. Early bills created ambiguous sanctions; the later bills were highly specific with respect to what was deemed "wrongful conduct."

Over the past four decades, on both sides of the aisle, I have brought and defended product liability cases. There are problems with the current product liability system, but under-deterrence is not one of them. To the contrary, over-deterrence, as recognized by the Supreme Court, has infiltrated the system. Criminalizing this area of law will not cure that problem; it will exacerbate it. The risks of further deterring the conduct, judgment and innovation will outweigh any benefits such an effort to criminalize product liability law would produce.

I commend the Chairman for highlighting this important issue. It is one that does need to be discussed. Tort law, with all of its flaws, should be left to deal with product liability. Criminal law should address specific crimes and punish them appropriately.

I would be pleased to answer any questions you may have.



Statement
of the
U.S. Chamber
of Commerce

ON: **Criminalization of Product Liability Law**

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

DATE: **March 10, 2006**

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

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

More than 96 percent of the Chamber's members are small businesses with 100 or fewer employees, 71 percent of which have 10 or fewer employees. Yet, virtually all of the nation's largest companies are also active members. We are particularly cognizant of the problems of smaller businesses, as well as issues facing the business community at large.

Besides representing a cross-section of the American business community in terms of number of employees, the Chamber represents a wide management spectrum by type of business and location. Chamber membership in each major classification of American business – manufacturing, retailing, services, construction, wholesaling, and finance – numbers more than 10,000 members. Also, the Chamber has substantial membership in all 50 states.

The Chamber's international reach is substantial as well. We believe that global interdependence provides an opportunity, not a threat. In addition to the U.S. Chamber of Commerce's 101 American Chambers of Commerce abroad, an increasing number of members are engaged in the export and import of both goods and services and have ongoing investment activities. The Chamber favors strengthened international competitiveness and opposes artificial U.S. and foreign barriers to international business.

Positions on national issues are developed by a cross-section of Chamber members serving on committees, subcommittees, and task forces. Currently, some 1,800 business people participate in this process.

Additional Views
on
Criminalization of Product Liability Law
Hearing before the
SENATE COMMITTEE ON THE JUDCIARY
On behalf of the
U.S. CHAMBER OF COMMERCE
March 10, 2006

Introduction

The U.S. Chamber of Commerce appreciates the opportunity to address the important question posed by this hearing and the possibility of legislation that would impose criminal liability on companies that manufacture products which are deemed defective.

Everyone can agree that the overarching goal of today's hearing – preventing consumers from being harmed by defective products – is certainly a noble one. The problem, however, is that legislation that would very broadly criminalize the sale of any products with potential defect challenges would not achieve that goal. Instead, it would have a profound, deleterious effect on U.S. commerce with no corresponding benefit to U.S. consumers.

There are already numerous regulatory mechanisms in place for preventing the dissemination of defective products into U.S. markets, and there is already a host of legal sanctions, both state and federal, that hold corporations and individuals responsible if they knowingly, recklessly, or negligently create or distribute products that harm consumers. Indeed, a number of studies have concluded that current law over-deters American manufacturers by dissuading them from creating new, innovative products for fear of tort suits. Broad criminal statutes addressing defective products would exacerbate that problem, chilling innovation by American corporations at a

time when preserving and increasing the competitiveness of American business is critical. It would also tax already-overburdened law enforcement officials. In short, despite its good intentions, this bill would have very negative effects.

Legislation Seeks To Fill A Non-Existent Void

As an initial matter, it is not clear what problem any proposed legislation on defective product criminalization is attempting to solve. By definition, such legislation would be premised on the idea that American business presently is not sufficiently deterred from manufacturing and distributing defective products. But that premise has no basis in fact – rather, current law contains multiple layers of legal sanctions designed to deter corporations and individuals from creating and selling defective products.

First, many of the products covered by this proposed legislation are already subject to existing federal regulatory regimes that monitor and regulate such products for defects. Indeed, federal agencies such as the Consumer Product Safety Commission, the FDA, and NHTSA currently possess the power to investigate claims of defect, compel information from corporations about their products, order product recalls, and to levy fines against a corporation if they determine that a product is defective. In addition, the False Statements Act regulates disclosures to federal agencies and ensures that corporations and individuals will face criminal fines if they do not disclose accurate information to federal regulators.[1]

Second, most states give their attorney general the authority to bring suits to protect the health and well-being of the state's citizenry. Thus, if a state attorney general believes that a particular product is defective and poses a risk to his or her state's consumers, he or she can bring suit against the

[1] 18 U.S.C. § 1001.

manufacturer or distributor. And state attorneys general make ample use of this authority; in fact, most state attorneys general have a consumer protection division within their offices that specifically focuses on these sorts of issues.

Third, all products are subject to state consumer fraud and tort laws. Every state permits consumers to come into court and sue to recover damages for personal injury and property damage, including pain and suffering damages. Indeed, every state offers a bevy of common law and statutory remedies to consumers, ranging from state consumer protection acts to common law causes of actions such as strict liability and negligence.

Finally, corporations that manufacture or sell defective products are subject to state criminal and quasi-criminal sanctions for particularly egregious misconduct. Most states provide for some form of punitive damages in the product liability arena which, as the Supreme Court has recognized, are quasi-criminal penalties in nature. In cases involving gross misconduct by a defendant and particularly serious harm to consumers, corporate defendants often face judgments in the tens to hundreds of millions of dollars. In addition, corporations or individuals who intentionally manufacture or distribute extremely hazardous defective products can, in certain instances, face state criminal liability under state wrongful death or other criminal statutes.

Thus, as a practical matter, there are ample legal mechanisms already in place that hold individuals and corporations who knowingly introduce defective products into interstate commerce responsible for their actions. Under present law, if a corporation becomes aware that it is producing a defective product that has the potential to kill or seriously injure consumers, and nevertheless continues to manufacture and sell that product in marketplace, that corporation will likely face: numerous investigations by federal regulators; product recalls; multiple actions by state attorneys general; mountains of civil litigation; and

punitive damage awards numbering in the hundreds of millions or even billions of dollars. In short, the notion that American business is not sufficiently deterred from knowingly producing and distributing defective products is simply without foundation.

The Real Concern Under The Current Tort System Is Over-Deterrence – Not Under-Deterrence

Far from being under-deterred from manufacturing potentially harmful products, American business is currently over-deterred and often refrains from creating products that would be beneficial to American society. This phenomenon is well-documented. In hearings held by the Senate Commerce Committee in connection with the Product Liability Reform Act in the late 1990s, numerous witnesses testified that the current product liability system is stifling innovation in American industry, keeping beneficial products off the market, and harming the competitiveness of American business.[2] For example, the American Medical Association stated at that time that the current product liability law is having a "profoundly negative impact on the development of new medical technologies."[3] Similarly, former Secretary of Commerce Robert Mosbacher testified that, as a result of the current legal regime, universities have refused to license patents to small manufacturers out of fear of potential liability – thereby allowing valuable intellectual capital to go to waste.[4] Other reports have reached similar conclusions. Studies performed by the RAND Institute have found that current product liability law has significantly hindered innovation efforts in the areas of vaccines, contraceptives, orphan drugs, and

---

2 S. Rep. 105-32, at 8-13.

3 *Id.* at 9.

4 *Id.*; *see also* Deborah J. La Fetra, *Freedom, Responsibility, and Risk: Fundamental Principles Supporting Tort Reform*, 36 Ind. L. Rev. 645, 656-57 (2003).

biotechnology.[5] And a report prepared by Pace University law professor M. Stuart Madden in the 1990s indicated that the current product liability regime has caused 36% of American manufacturers to withdraw products from the world market, 47% of American manufacturers to withdraw products from the domestic market, 39% of American manufacturers to not introduce new products, and 25% of American manufacturers to discontinue new product research.[6]

The most significant effect that criminalizing the law of product liability will have is that it will make executives and corporations extremely reluctant to develop or distribute new products, thereby exacerbating the "chilling effect" on U.S. innovation of current tort law. Legal scholars have long observed that criminal sanctions tend to deter some socially valuable conduct as individuals not only avoid engaging in criminal activity, but also avoid engaging in activity that even has the potential of causing them to be charged with a crime.[7] That is a particular problem with regard to the development of new products. As any attorney who practices in the field of product liability is well aware, there is no such thing as perfectly safe product. All products have some capacity to harm consumers in some form of use or misuse. When such harm occurs, individuals often sue the manufacturer or distributor – even if no rational person could deem the manufacturer or distributor to be at fault under any theory of liability. Indeed, it is an unfortunate – but an all too common – occurrence in the present legal system for a corporation to face massive legal exposure from lawsuits that are wholly lacking in merit.

---

5 Steven J. Garber, Rand Inst. for Civil Justice, Product Liability and the Economics of Pharmaceuticals and Medical Devices 144 (1993).

6 H.R. Rep. 104-63, at 9.

7 *See, e.g.*, Geraldine Szott Moohr, *Defining Overcriminalization Through Cost-Benefit Analysis: The Example of Criminal Copyright Laws*, 54 Amer. L. Rev. 783, 801 (2005) ("More specifically, criminal enforcement . . . may also deter socially valuable conduct that is not unlawful. Such overdeterrence occurs when people refrain from lawful conduct because they fear involvement with the criminal justice system.").

Accordingly, when corporations presently determine whether to introduce a new product, the possibility of civil litigation weighs heavily in their calculus. If the possibility seems too high, then – regardless of the benefits of the product and whether any of the potential civil liability is warranted – the corporation will decline to engage in new product development. And, as previously noted, that is precisely what has been happening in this country over the past couple of decades. The multi-layered nature of the current civil justice system combined with expansive government regulation and an aggressive plaintiffs' bar has created the threat of massive legal exposure unconnected to any actual culpability, and that threat is deterring American corporations from new product development to a significant extent.

Coupling this problem with criminal penalties would make a bad situation far worse. Adding criminal sanctions to the present mix of civil remedies dramatically increases the potential risk posed by new product development. As the Arthur Anderson litigation illustrated, an indictment of a corporation – even an improper indictment – can effectively destroy a business in short order. In addition, the possibility of personally going to prison for alleged corporate misconduct is far more terrifying to executives and employees than the possibility that the corporation for which they work will incur general civil liability. Accordingly, if criminalization occurs, every new product would carry with it some risk of criminal indictment – just like every new product currently contains some risk, however miniscule, of civil liability. And unsurprisingly, given the higher stakes, those will be risks that even fewer individuals and corporations will be willing to take. As Professor Michael Krauss has observed, the imposition of criminal liability in the product liability context "will necessarily lead manufacturers to reduce innovation and new

product design and introduction, for fear that a misstep will lead not only to civil liability (as it does now) but to prison for executives."[8]

Thus, it is no argument to suggest, as some proponents of this approach might, that the only corporations and executives whose conduct will be affected by criminalization are those who make or conceal manufacture of defective products. The reality of American business is that criminalizing product liability law will chill innovation and deter new product design across the board. There is simply no guarantee – nor can there be one – that every indictment of a corporation or corporate executive will be proper. Yet the unfortunate truth is that an indictment alone, whatever its merit, is in many cases sufficient to end a career or destroy a business. In other words, the damage done by an improper indictment, just like the damage done by a spurious lawsuit, will often be impossible to repair after the fact. American corporations therefore will have no choice but to consider the possibility of unwarranted criminal sanctions in conducting their business if this legislation passes. And that in turn will make them even more reluctant to innovate and even less competitive on the global stage than they already are.

Legislation Would Further Strain Prosecutorial Resources

Criminalizing the law of product liability raises another societal concern as well – placing yet another set of criminal responsibilities on the plate of overburdened federal prosecutors. Federal prosecutors are already responsible for more areas of the law than ever before. As a 1998 ABA Task Force noted, more than 40% of the federal criminal statutes currently on the books have

---

[8] Remarks of Professor Michael I. Krauss to the Federalist Society for Law and Public Policy Studies, Oct. 6, 2000, available at http://www.fed-soc.org/Publications/practicegroupnewsletters/PG%20Links/krause.htm.

been enacted since 1970,[9] and a 2004 Federalist Society Report found that there are more than 4,000 offenses that currently carry a federal criminal penalty.[10] Despite the vast nature of their existing responsibility, proponents of criminalization nevertheless would require federal prosecutors to spend time policing an area of law which is already subject to substantial regulation from federal administrative agencies and robust state civil and criminal legal regimes. Under the circumstances, such diversion of scarce prosecutorial resources is simply wasteful.

Conclusion

Protecting consumers and deterring the manufacture and distribution of defective products are always important goals, but legislation that criminalizes product liability law does not advance either of them. All that criminalizing the law of product liability will do is waste federal prosecutorial resources in unnecessary prosecutions and cause American manufacturers to refrain from lawful innovation at a time when we as a country cannot afford to lose our competitive edge. There are already enough problems with the product liability system in this country. We respectfully urge Congress to work to resolve the existing problems – rather than create new ones.

---

[9] James Strazella et al., Task Force on the Federalization of Criminal Law, Am. Bar Ass'n Criminal Justice Section, The Federalization of Criminal Law 7 (1998)

[10] John S. Baker, Jr., Federalist Soc'y for Law & Pub. Pol'y, Measuring the Explosive Growth of Federal Crime Legislation 12 (2004).

Professor Robert Steinbuch
University of Arkansas at Little Rock
William H. Bowen School of Law
1201 McMath Ave.
Little Rock, AR 72202
(501) 324-9963
resteinbuch@ualr.edu

Professor Steinbuch has held numerous positions in government, academia and the private sector prior to joining Arkansas's faculty, including: Counsel to the United States Senate Judiciary Committee, Subcommittee on Antitrust, Competition Policy and Consumer Rights; Deputy Senior Counsel to the Commissioner of the Internal Revenue Service; Trial Attorney for the United States Department of Justice, Commercial Litigation Branch; and, Special Counsel to United States Department of Justice, Webster Commission on F.B.I. Security.

Professor Steinbuch clerked on the United States Court of Appeals for the Eleventh Circuit and was an Olin Law and Economics Fellow at Columbia University School of Law – where he earned his Juris Doctor. Prior thereto, he received a Masters in Political Theory and a Bachelors in Political Science from the University of Pennsylvania.

Currently, Professor Steinbuch serves on the Board of Trustees of the Society of Chest Pain Centers and is as the only Board Member in the history of the organization who is not a medical-care professional. The Society is a non-profit international organization focused upon improving care for patients with acute coronary syndromes and other maladies, and is the only organization entitled to certify medical facilities as Accredited Chest Pain Centers.

Professor Steinbuch teaches Law & Economics and Business Associations and has published on commercial law and related topics.

Mr. Chairman, I support the ideals behind imposing some criminal liability on corporate actors who knowingly, or with reckless disregard for life, introduce excessively risky products or services into the stream of commerce. The existing system of assigning liability for such acts solely to the corporate entity is inefficient as a consequence of the externalization of the cost of harm. That is, corporate actors rationally interested in maximizing personal remuneration will necessarily undervalue the costs on society of risky corporate behavior because those costs either remain externalized to society or, to the extent that they are internalized by the corporation through a liability rule, they rest exclusively at the corporate level. In contrast, however, the benefits of risky behavior are shared by both the corporate entity and the corporate actors themselves. Thus, corporate actors enjoy some benefit without bearing any cost of corporate risk taking. This disincentive/incentive asymmetry rationally leads corporate actors to pursue riskier than optimal activities. The proposed legislation is designed to improve upon the existing incentive scheme in order to optimize the production and provision of beneficial products and services and minimize the production and provision of excessively dangerous products and services.

Specifically, corporate actors receiving the typical compensation package of stock options and salary will seek to maximize relatively short-term profits by exploiting the higher return associated with risk-taking and will not discount this return by the expected cost of liability for that risky behavior. Since corporate actors fully realize the gains of salary and executed stock options, but do not bear the potential liability costs, they have no incentive to limit the latter if doing so will negatively impact the former. Indeed, for various reasons, many not implicating strategic departure, corporate CEO

tenure has been on the decline. Regardless of the cause, however, the cyclical nature of executive tenure fosters an environment in which they overvalue short-term return and undervalue long-term costs. The direct imposition of liability on corporate actors across time will increase their internalization of the long-term corporate costs of risk taking in such an environment.

While corporate law traditionally has sought to protect corporate actors from personal liability, the legal landscape has always resisted a dogmatic application of such a policy in an attempt, albeit inconsistent, to balance equities. As a preliminary matter, we should examine the two apparent exceptions to the limitation on personal liability in the corporate context before considering new rules to avoid the corporate shield.

First, the doctrine of piercing the corporate veil theoretically allows personal liability to be imposed directly upon corporate actors. The application of the doctrine to large publicly-held corporations, however, is highly limited; and, when viewed with the goal of achieving personal liability of corporate actors – rather than parent corporations – it is all but a theoretical curiosity.

Second, corporate actors may be exposed to personal liability in actions brought directly against them rather than against the corporations. Director and officers liability insurance ("D&O insurance"), and, to a lesser extent, indemnification and advancement-of-expenses clauses and post-*VanGorkon* statutes, such as Del. GCL § 102(b)(7), have virtually eliminated any significant likelihood of personal liability for corporate actors by allowing these actors to shift these costs back to the corporation. Indeed, given the diffuse nature of shareholders, resistance to corporations' assumption of director and officer liability or the costs of D&O insurance is insignificant. As such, neither of these

devices to assign personal liability to corporate actors ultimately is relevant here, and we are left with an incentive scheme that allows corporate actors to insufficiently account for societal costs.

Criminal penalties, in contrast, are unique in two ways that prevent corporate actors from shifting the costs of personal liability back to the corporation. First, criminal penalties, regardless of their form or nature, carry a social stigma of moral condemnation. As such, even if the penalty is de minimus and does not infringe personal freedom, the sanction has a significant non-transferable cost to corporate actors. Given their relative risk adversity, corporate actors are particularly sensitive to this sanction. Second, these non-pecuniary costs typically translate to direct financial costs by limiting corporate actors' future access to the executive labor market.

Mr. Chairman, as the Committee pursues this important issue, I believe that we can take many lessons from the success of recent legislation to craft a statute that achieves the goals discussed above, while limiting the negative consequences. Indeed, the recent enactment of Sarbanes-Oxley provides us with significant guidance: Sarbanes-Oxley requires the Chief Executive and Chief Financial Officer of covered corporations to personally certify that SEC reports comply with regulatory standards. The failure to do so personally exposes these senior executives to criminal sanctions, ensuring that corporate actors cannot shift responsibility to unwitting or powerless subordinates. As such, this statute applies criminal penalties directly to corporate actors and, at the very same time, prevents them from asserting the ignorance defense adopted by Ken Lay and others. The legislation under consideration today should mirror these requirements by incentivizing businesses to elicit and maintain organized data on serious injuries and

deaths sustained as a result of their products and services, with senior executives being required to review this information.

Further, the legislation under consideration should seek to protect whistle-blowing activity. By offering security to whistleblowers and imposing criminal liability on corporate executives who knowingly and intentionally retaliate against them, we encourage the efficient communication of critical information. Again, such provisions are found in Sarbanes-Oxley. Similarly, the Standards Development Organization Advancement Act of 2004 ("SDOA") put into place a criminal-prosecution amnesty program for disclosures of criminal-antitrust-law violations. Under SDOA, if a corporate conspirator self-reports its illegal antitrust activity to the Department of Justice and meets certain conditions, *e.g.*, it is the first conspirator to confess, it is not the ringleader of the conspiracy, and it agrees to cooperate fully with the investigation, this corporate conspirator may both obtain amnesty from criminal liability and avoid the exposure to treble civil damages in private actions. These devices encourage the distribution of relevant information to law enforcement and the consumer market.

These requirements can be applied without undue cost to the health of corporate America. Indeed, notwithstanding the sizeable criminal penalties of Sarbanes-Oxley, we have not seen the mass exodus of corporate executives predicted by some during the statute's enactment. I believe that comparable prognostications offered about the current proposal ultimately will be relegated to a similar position of obscurity. That is not to say, however, that legislation of this type will not have negative consequences. It may indeed. But, as with any policy decision, the costs must be balanced against the benefits. If the imposition of such significant personal responsibility on corporate actors can, and indeed

has, been adopted for financial wrongdoing with the adoption of Sarbanes-Oxley, the same approach certainly should be available for wrongs that directly result in physical injury or death.

Mr. Chairman, there are myriad areas in which the current tort system provides insufficient incentives to prevent disreputable corporate actors from knowingly injuring and killing people. In fact, I discuss some of these issues in my forthcoming article: *Preventing Under-Equipped Medical Facilities from Killing Heart-Attack Patients: Correcting Inefficiencies in the Current Regulatory Paradigm for Providing Critical Health-Care Services to Patients with Acute Coronary Syndrome.* In this Article, I describe how individuals in the midst of heart attacks are deceptively and intentionally lured into sub-standard medical facilities to enhance these institutions' revenue at the expense of patients' lives.

Heart Attacks are the number one killer in the United States. Each year about 1.2 million Americans suffer from heart attacks and approximately 500,000 die as a result. When a patient suffers from a blockage-caused heart attack, doctors have a very limited time to open the obstructed artery. The "gold standard" method to do so is through angioplasty -- that is, by threading a balloon-tipped catheter through an artery of the patient's leg, and crushing the blockage against the wall of the artery.

Since, (1) half of the treatable heart-attack patients are brought to the hospital by friends, relatives or drive themselves, and (2) chest pain is the number two reason for all emergency room visits, small hospitals in need of revenue seek to attract these customers by self designating and advertising as "Chest Pain Centers" or the like, without any angioplasty facilities whatsoever. These under-equipped community hospitals knowingly

exploit patient ignorance for their own profit. For example, one hospital, Mather Memorial Hospital in New York, sends flyers to all households in the community advertising its "Chest Pain Emergency Room" and the ability to "stop a heart attack in progress."[1] Mather, however, has no angioplasty capability. In this advertising, Mather boasts the following "upgrades" to assist in the care of heart-attack and other patients: a cellular-phone system and a "state-of-the-art" blood pressure monitor.[2]

Such advertising might be acceptable if angioplasty facilities were a rare occurrence, so that under-equipped facilities' "modest" care was the only available treatment. But, eighty percent of Americans live within one hour's drive of a facility that performs angioplasty, and that is well within the timeframe to perform this procedure. For example, Mather Memorial Hospital is only a few minutes from a fully-equipped angioplasty center at a state university hospital. Mather executives know this, but still advertise for heart-attack patients. Indeed, these executives are apparently aware enough of the importance of angioplasty-capability that they are now seeking to obtain such technology. Interestingly, however, they have long been advertising as having a chest-pain emergency room.

Experts recognize that most heart-attack patients end up in under-equipped community hospitals instead of nearby angioplasty centers and "the real reason has more to do with economics [than anything else]. 'There is no incentive to change. . . . The

---

[1] JOHN T. MATHER MEMORIAL HOSPITAL, HELP IN A HURRY, FROM TRIAGE TO TREATMENT, COUNT ON MATHER'S EXPERTS IN EMERGENCY CARE (2005) (self-published advertising flyer entitled "Community News").

[2] *Id.*

small hospitals don't want to divert patients to larger hospitals, because that is lost revenue.'"[3]

Such modeling is supported by evidence that the existing regulatory scheme predictably leads to rent seeking by sub-optimal facilities desirous of maintaining their inefficient market share. As Dr. Joseph Carrozza, Chief of Interventional Cardiology at Boston's Beth Israel Deaconess Medical Center, said: "[t]here are a lot of strong community hospitals that aren't offering primary angioplasty and would line up all their politicians against an effort to have heart attacks taken away from their hospitals."[4]

While institutions are civilly liable for the fraudulent claims that they make, this liability – to date -- has not dissuaded this behavior. Non-mass tort or class actions often do not efficiently distribute market-correcting information in large measure because most cases settle, and these settlements routinely require confidentiality. Evidence from the legal community demonstrates that great efforts are taken by hospitals in false advertising cases to ensure their confidentiality upon settlement. So, executives at these ill-equipped facilities continue to put sub-standard service on the market and present it as a state-of-the-art technology. This intentional deceptions leads to preventable deaths every day, and we need appropriate incentives to avoid this result.

Mr. Chairman, you have been a leader on these issues of consumer welfare. Indeed, you and six of your colleagues wrote a bipartisan letter to leading heart-health

---

[3] CNN.com, *The Best Treatment Most Heart Victims Aren't Getting: Drugs More Likely to Be Used Over Angioplasty Procedure*, Oct. 10, 2003, http://www.cnn.com/2003/HEALTH/conditions/10/10/heart.attacks.ap/. *See also* Sharon Salyer, *Heart Attack Strategy Changes*, Washington Herald, HERALD.NET, Oct. 13, 2003, http://www.heraldnet.com/Stories/03/10/13/17605065.cfm ("most patients end up at hospitals that cannot perform them and are never transferred to hospitals that can").

[4] CNN.com, *supra* note 3.

organizations last year, questioning, *inter alia*, the practice of under-equipped medical facilities self designating as "Chest Pain Centers."[5]

In addition, as a leading expert on the health-care regulatory environment, Senator DeWine has introduced the Heart Attack Safety Act ("HASA")[6] to require hospitals to meet specific requirements set by the Secretary of H.H.S. in order to advertise as having a "Chest Pain Center" or otherwise solicit heart-attack patients away from nearby facilities. This is an excellent start. And, I recommend a unified approach, where HASA is combined with your current proposal to create an integrated bill to address these important issues, much like Senator Hatch did with the many outstanding bills that contributed to the Justice for All Act.

Indeed, there are many other areas of corporate behavior that could be improved through your important proposal. For example, as we know, the automotive industry sells products with inherent risks. We must analyze the relative level of risk imposed by individual product lines in this industry and the efforts taken to maintain the safety of the public. Thus, while we acknowledge that the industry cannot ensure that no injuries or deaths result from the use of their products, we should expect manufacturers to study the comparative safety of their products to ensure that they are not inherently more dangerous than what prevails.

---

[5] Letter from United States Senators Arlen Specter (R-PA) (Chairman of the Senate Judiciary Committee), John McCain (R-AZ) (Chairman of the Senate Commerce Committee), Sam Brownback (R-KS), Herb Kohl (D-WI) (Member of the Special Committee on the Aging), Mike DeWine (R-OH) (Chairman of the Retirement, Security, and Aging Subcommittee of the Committee of Health, Education, Labor and Pensions), Mary Landrieu (D-LA) (Member of the Congressional Heart & Stroke Caucus), Orin Hatch (R-UT) (Member of the Congressional Heart & Stroke Caucus, Former Chairman, and current member of, Committee of Health, Education, Labor and Pensions, Ranking Republican on the Finance, Judiciary, and Intelligence Committees) to the American Heart Ass'n ("AHA") and American College of Cardiology ("ACC") (May 31, 2005), http://www.scpcp.org/media/files/senators.PDF.

[6] S. 1277, 109th Cong. (2005).

There have been numerous occasions in which automobile companies have been accused of falling short of this modest standard. The now classic case of the Ford Pinto demonstrates just one example of this phenomenon. Similar accusations have been levied against General Motors regarding their pick-up trucks produced in the 1970s and 1980s, the 1975 Ford Mustang, and the 1979 Chevy Malibu. The resulting inquiry, indeed, is two-fold: what did these manufacturers know and when did they know it? Thus, as discussed, liability should coincide with a duty of reasonable investigation and data collection, on the one hand, and disclosure safe-harbors, on the other. This positive and negative incentive scheme will cause corporate actors to seek out and disseminate information on the safety of their products and services – allowing consumers to make rational decisions that were otherwise made unwittingly on their behalf by corporate actors.

Recent events cause us to ask the very same questions about the corporate decisions made at Firestone and Ford: what did corporate executives know about the dangers of the Firestone tires used in conjunction with Ford Explorers and when did they know it? Why did it take so long for the information to become publicly available? What efforts did executives take to gather, analyze, and disseminate such critical information? Were individuals injured or killed as a result of delays in communicating such information after it was discovered? While we do not know the answers to all of these questions, what seems clear is that the current incentive scheme encourages ignorance, secrecy, and denial at the expense of openness and safety. This model needs to be changed.

Mr. Chairman, your proposal, if appropriately tailored, will allow us to optimize the benefits of an ever-advancing technological environment, while minimizing unreasonable risks to the safety of the public. Thank you for considering my remarks.

WHITE & CASE

White & Case LLP
701 Thirteenth Street, NW
Washington, DC 20005

Tel + 1 202 626 3600
Fax + 1 202 639 9355
www.whitecase.com

Direct Dial + 1 202 626 3628 gterwilliger@whitecase.com

March 8, 2006

The Honorable Arlen Specter
Chairman
Committee on the Judiciary
United States Senate
Washington, DC 20510

Re: "Defective Products: Will Criminal Penalties Ensure Corporate Accountability?"

Dear Mr. Chairman:

Thank you for the invitation to testify before the Committee on the Judiciary on "Defective Products: Will Criminal Penalties Ensure Corporate Accountability."

As your staff may have informed you, I was prepared to attend the hearing when it was tentatively scheduled for Tuesday, March 7, 2006. Regretfully, previous commitments outside Washington will prevent me from appearing on Friday, March 10, 2006, the currently scheduled hearing date. I am, however, offering for the Committee's consideration the attached statement which was prepared in connection with the hearing.

Thank you again for inviting me to testify. Please do hesitate to contact me if I can be of assistance to the Committee with regard to this or other matters.

Sincerely yours,

George J. Terwilliger III

cc: The Honorable Patrick J. Leahy

STATEMENT OF

GEORGE J. TERWILLIGER III

Before

COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

WASHINGTON, D.C.
MARCH 10, 2006

Mr. Chairman, Senator Leahy and Members of the Committee:

Thank you for the opportunity to provide this statement concerning the Committee's consideration of legislation which would criminalize product liability. While I appreciate and understand the concerns which provoke consideration of this legislation, I urge the Committee to carefully assess the bill in light of the unfortunate trend to overextend the criminal law in the realm of commercial affairs—using criminal sanctions to regulate legitimate commercial activity. In addition, it would be remiss not to note the potential adverse impact of this legislation both on the cost of products, a cost which will ultimately be borne by individual consumers, and—more broadly—on the entrepreneurial innovation that has fueled our economic expansion.

I am especially grateful for the opportunity to address this bill as it would have the undesirable effect of furthering the ill-advised trend to criminalize business regulation. Traditionally, federal criminal law in the commercial context was utilized to protect the means and instrumentalities of commerce. Today, federal criminal law is used to regulate commerce itself. This development should evoke fundamental consideration of the proper role of government and the tools that it should use in regulating commercial activity. Such consideration, of course, is one aspect of respecting the broader value in generally limiting the role of government in the affairs of citizens, including in the commercial arena. Just as our abiding values require restraint in the government's intrusions on personal liberties and free expression, it is no less important to limit government intrusions which might unnecessarily starve the engine of commerce of the fuel of entrepreneurial spirit.

As I offer constructive criticisms of the trend to extend the reach of criminal law farther and farther into the affairs of business, touching legitimate activity with the mighty weapon of criminal prosecution, I would respectfully request that the Committee please bear in mind my abiding support for vigorous enforcement of law. I carry no brief, nor am I an apologist, for those who abuse the competitive, commercial arena for personal gain, to commit fraudulent acts, or otherwise to lie, cheat and steal in contravention to the requirements of traditional criminal laws and fair dealing in business affairs. I am a strong believer in the value, indeed the absolute necessity, of a free, open and honest marketplace. A dishonest market is not a free market. One need look no further than certain emerging market economies in other parts of the world to see the corrosive and inhibiting influence of corruption on the development of a robust free market system. In addition, in my own professional experience with our clients, U.S. and international companies are often placed at a competitive disadvantage because they work assiduously to conform their business behavior to the requirements of U.S. and other nation's anti-bribery laws, while many of their competitors do not.

The distinguishing feature of criminal violations in Anglo-American jurisprudence has been the formation of what the law recognizes as an evil intent—the traditional "mens rea." Corporations are prosecuted for criminal violations in the United States even though they obviously are legal fictions that cannot form any intent, let alone an evil one, but rather can only act through the conduct and intent of the human beings that run them. The Supreme Court's 1916 decision in *New York Central & Hudson River Railroad v. United States* [212 U.S. 481 (1909)] held for the first time that corporations could be criminally prosecuted. It is a decision remarkably short of any meaningful analysis considering the ramifications the decision has today for corporations, their stockholders and leadership. The Court simply reasoned that if a

corporation could bind its shareholders to a contract, it should be held responsible for conduct on the corporation's behalf that is determined to be a crime. Further, the Court appeared to suggest that if corporations could not be held criminally liable, there would be wrongs that could not be remedied or deterred. At least in today's world, that is simply not the case, as the scope of civil remedies available to address corporate wrongs is more than adequate. Many companies, as this Committee knows so well, have suffered the commercial equivalent of capital punishment carried out through bankruptcy as a result of huge civil liabilities. Moreover, the keystone criminal remedy—loss of liberty—cannot, of course, be applied to corporations. Nonetheless, corporations today are held to strict criminal standards, with draconian penalties attached. Regardless of whether corporations themselves should be subject to criminal enforcement, at least let us consider carefully what conduct should subject corporations to criminal prosecution.

Reviewing the historical development of our law demonstrates that the common use of criminal sanctions in a commercial context was to protect the means and instrumentalities of commerce, not to prosecute otherwise legitimate activity that ran afoul of regulatory standards. Examples of criminal statutes that protected the means and instrumentalities of commerce include:

- protection against the use of the mail system to perpetrate frauds,
- protection of the telegraph, the seminal communications technology,
- protection of the railroads, the first means of large-scale interstate transportation of goods,
- protection of the process by which the government procured war material and other goods.

In the Twentieth Century, the federal government moved to protect those vital engines of commerce, the banks. Indeed, if one examines our criminal code today it is apparent

that the criminal statutes protecting banks and other financial institutions rival in scope and severity of punishment those used to protect the functions of government itself. These measures represent a wise course and necessary policy because protecting the integrity of the means and instrumentalities of commerce is a function of government that is necessary to secure the benefits of wealth to our citizens. Alexander Hamilton recognized, in remarks at the Constitutional Convention, that the core functions of the central government included "commerce, revenue, [and] agriculture" as well as ensuring domestic tranquility and establishing national strength and stability. In the last century, the federal government also took steps, consistent with this core federal function, to protect the integrity of the financial markets themselves, promoting investor and creditor confidence in the commercial processes used to raise the capital necessary to run the engine of commerce. Congress also saw fit to protect the marketplace from the predatory practices of cartels and other instrumentalities that might artificially distort competitive market forces.

In the 1970s and beyond, however, the use of criminal law underwent a sea change, one that I would respectfully submit separated the federal criminal law from its constitutional and common law moorings and turned it, ill advisedly, into a tool of regulation of legitimate commercial activity. This change occurred almost imperceptibly. Political consensus coalesced around a number of initiatives to extend the reach of federal programs involving commerce and to regulate, at the federal level, various aspects of business behavior. These initiatives tracked an increase in the scope of the federal establishment generally and were focused on what we now recognize as highly regulated industries, such as banking and finance, energy, and healthcare, as well as on overarching objectives, such as—earlier—environmental protection and—later—financial reporting , that regulate a vast array of legitimate businesses

activity. The net result was a fundamental change in the use of criminal law from protecting the means and instrumentalities of commerce, to its use as a means to regulate commerce itself with the most draconian of penalties, a criminal prosecution.

Let us look at one example of using criminal law to regulate legitimate commercial activity. When the extensive regime of environmental regulations was enacted, criminal penalties were included. The fundamental objective of these statutes was to curb "pollution," that is, the introduction of foreign or harmful substances into the environment. Pollution, however, was not outlawed. Indeed, the government gives permits to pollute. What is a crime, however, is polluting too much—that is, in excess of the amount allowed by a permit. This is determined by science, where the difference between what is permitted and what is not is measured in parts per million and can be the basis for conflicting views of highly specialized experts. Such conduct has little nexus to the traditional basis for imposing criminal liability—that is, an evil intent. It is this same battle over standards that is often implicated today in other kinds of criminal cases involving various regulatory requirements, not the least of which are accounting and financial reporting standards. These standards, under Sarbanes-Oxley, likewise can give rise to criminal violations based on standards about which experts can reasonably disagree.

I respectfully submit that the legislation under consideration would further accelerate and exacerbate the trend to extend criminal enforcement in the regulation of otherwise legitimate commercial activity. Consideration of this bill is an opportunity to reconsider this trend. To put it plainly, applying the blunt tool of criminal law and criminal sanctions to "defective" products is akin to declaring these products, legitimately made and manufactured, as contraband. I would respectfully submit that they are not, in fact, contraband, and treating them

as if they were is not a wise public policy choice. There is simply no need, in order to secure legitimate governmental, or even societal, interests, to push this trend further and deeper into day to day legitimate business activity.

There are perfectly adequate, comprehensive and effective alternatives to criminally sanctioning the knowing production or distribution of defective products. As you know, the basic purpose of the civil justice system is to provide compensation for injury caused by another through an act the law recognizes as a civil wrong. In addition, where conduct is intentional and so antisocial that it deserves separate sanction, significant punitive damages can be imposed for the specific purpose of punishing such conduct above and beyond whatever the appropriate recompense for the injury caused may be. These are more than adequate safeguards and prophylactic devices to prohibit and inhibit the purposeful introduction of defective products into the stream of commerce.

An additional defect of the legislation from the standpoint of the criminal law is that it is hopelessly, and likely unconstitutionally, vague. As the Supreme Court has repeatedly held, a criminal statute must provide such notice of what conduct it prohibits or requires that a person of ordinary intelligence can discern its standards. At least in concept, the contemplated legislation defines "defective" as "having a flaw in design, manufacture, or assembly that renders the product dangerous to human life and limb beyond the reasonable and accepted risks associated with such or similar products lacking such a flaw." What is a "flaw"? What is "a reasonable and accepted risk"? How are manufacturers (and, later, courts and juries) to interpret such standards? Is it a standard at all if scores of prosecutors each interpret it differently, or district courts do likewise? Is selling products with flawed instructions for assembly or use a crime? Anyone who has tried to assemble almost anything, such as a backyard grill, may have a

case to refer to federal prosecutors. All products may be said to be more or less "dangerous." Will every lawnmower have to be constantly modified with the latest safety gizmo, designed to protect the careless few among the careful many who exercise commonsense precaution when operating things that whirl, cut and mulch? In short, whether there is a "flaw" that renders a product defective is a vague standard on which to premise the invocation of criminal sanctions, and likely creates a constitutional infirmity in the legislation.

Further, the difficulty of determining what is "defective" is highlighted by the enormous amount of research and testing already conducted by industry and independent labs, as well as by federal regulators such as NHTSA and even state regulators. Each year, thousands of products are put to tests designed to ferret out problems that might develop under normal conditions of use and even under severe misuse. This process is not only very expensive; it is also time-consuming. For example, the FDA takes an average of a year or more to approve a new drug. A vast bureaucracy designed to effectuate the regulation of commercial activity in various fields is in place. These bureaucracies are staffed by experts. Whatever the merits of having created this bureaucracy, one thing we should not do at this point is undermine the effectiveness and fairness of the process by which it makes determinations within the expertise of its field. Criminalizing behavior that runs afoul of the regulations these bureaucracies administer does exactly that by using the brutal, blunt force of a criminal prosecution, founded exclusively on the discretion of an individual prosecutor, to decide what regulatory transgression merits a jail sentence or a huge corporate fine. In essence, the prosecutors become the bureaucratic overseer, capable of overriding the determinations of agencies and their experts in these various fields of expertise. They do so simply by deciding that some knowing regulatory violation merits a criminal prosecution. That decision is virtually unreviewable by any court,

irreversible by Congress and, if at odds with the application of agency standards, corrosive to the effective functioning of that agency's mission.

Statutes specifically making commerce in defective products a crime also carry their own unique set of challenges to the already difficult exercise of prosecutorial discretion. Not the least of these is the likely pressure from multiple sources to bring cases where the facts show tragic consequences but the cause of such consequences is subject to considerable debate, even among experts. The danger is that otherwise non-meritorious cases arousing public or political outrage will be indicted, because it is easier for the prosecutor to charge and lose, rather than to decline and explain restraint.

The criminal penalties in the legislation are also likely to be counterproductive to its own overall goals. The threat of criminal penalties virtually guarantees that some corporations will be less forthcoming concerning product defects. A business manager faced with the decision between "disclose and maybe go to jail" versus "don't disclose and maybe avoid punishment" may well choose non-disclosure. The threat of criminal fines or imprisonment would also necessarily result in individuals consulting counsel, who no doubt frequently would advise clients who could be prosecuted not to disclose information or to cooperate with product defect inquiries or studies because their statements could be used against them.

Even if this bill was not defective on the philosophic, legal policy and the other grounds outlined above, it is especially ill-advised given the further interplay it will occasion between a well organized, well funded and powerful bar of plaintiffs' lawyers and prosecutors charged with the evenhanded administration of the criminal law. In my fifteen years in the

Justice Department, which included twelve years as a field prosecutor, I encountered plaintiffs' lawyers who came either to our offices or those of our sister investigating agencies, seeking the initiation of a criminal investigation in order to further their own interests regarding a particular civil claim or potential class action. I, like most prosecutors past and present, I believe, cast an extremely wary eye on such sources of potential criminal charges. It was quite evident to me, and many colleagues with whom I discussed these issues at the time, that those seeking criminal investigations had little interest in seeing the interests of the government vindicated through a prosecution, but rather saw the initiation of a criminal investigation and the potential of a prosecution as tremendous leverage in their claims seeking private gain. If prosecutors were to be put in the position of making decisions about initiating product liability criminal prosecutions, the exercise of their discretion could have incredible distorting effects on related civil cases and the outcome of their decision could spell a difference of millions of dollars in the disposition of those cases, especially for the attorneys who bring them. Such should not, I would respectfully submit, be the business of federal prosecutors.

For all of these reasons, I urge members of the Committee to consider most carefully whether this legislation is needed or well advised.

Included for the Committee's consideration and for the record, if the Committee deems it appropriate, is a paper I recently presented at a General Counsel Forum hosted by the Delaware Valley Corporate Counsel Association.

Thank you.

CORPORATIONS, COMMERCE AND FEDERAL CRIMINAL LAW:

Addressing the Criminalization of Commercial Regulation

AN UPDATE

George J. Terwilliger III

DELAWARE VALLEY CORPORATE COUNSEL ASSOCIATION
FOURTH ANNUAL GENERAL COUNSEL FORUM
SEPTEMBER 14, 2005
PHILADELPHIA, PENNSYLVANIA

I. Introduction

Federal criminal law is a critical tool for maintenance of an honest and free marketplace. But, like any powerful tool, it can be used to the point of abuse. The current state of federal criminal law with respect to corporations is the result of a twenty-five year trend of increased resort to criminal law and other punitive enforcement mechanisms for the purpose of regulating business activity. The trend to regulate corporate behavior through criminal prosecution has caused federal criminal law to stray from its core purpose of protecting the means and instrumentalities of commerce.

Today, in the enforcement priorities of federal authorities, we see the result of yet another cycle of overreaction to what by any measure was a certain amount of real corporate criminality. Fraud in corporate financial reporting is a crime that victimizes both individual investors and the great engine of commerce fueled in our securities markets. But in reacting to reporting abuses, Congress has again unnecessarily extended the reach of federal criminal law by applying its powerful tools, in essence, to enforce accounting and financial reporting standards. This continues a trend, now nearly a century in the making, that began with the Supreme Court in a 1909 holding that a corporation can be criminally prosecuted. As a result of legislation further reflecting this trend, prosecutors and securities enforcement authorities today are also aggressively pursuing violations of the Foreign Corrupt Practices Act (1977) which sanctions severely U.S. companies and their wholly owned foreign subsidiaries for making payments to foreign officials to obtain business from overseas governments. Stamping out business bribery in foreign lands is a laudable goal, but is the use of criminal law and stringent securities enforcement mechanisms against international corporate entities consistent with the fundamental character of a criminal violation, marked by intent to do bad acts? Should criminal sanctions be imposed, as they now can be, where a company spends millions to see that it complies with the

law, but where employees in distant lands disregard its policies and foolishly reflect in their work local practices more corrupt than U.S. law allows?[1]

II. The Trend to Criminalize Business Regulation

Overuse of the federal criminal law as a regulatory tool is ill-advised for a number of reasons. It is inconsistent with the fundamental reach of criminal law in our constitutional system, it abandons the core purpose of business-related criminal prohibition – protecting the means and instrumentalities of commerce – and moreover, it can chill entrepreneurial risk-taking by basing criminal violations on vague and unintelligible regulatory standards.

Rather than being used to protect the means and instrumentalities of commerce, government regulation of business has become a tool for pursuing social goals. While many of these goals are laudatory and enjoy widespread support, that is not sufficient justification to prosecute as crimes legitimate behavior that happens to run afoul of a regulatory standard. Yet government increasingly resorts to criminal sanctions as a means of ensuring compliance with regulatory norms. The result has been what a Federalist Society report characterized as "the explosive growth of federal crime legislation." According to this report, "[t]here are over 4,000 offenses that carry criminal penalties in the United States Code. This is a record number, and reflects a one-third increase since 1980."[2]

To question the use of criminal sanctions to enforce regulatory norms is not to suggest that fraud or dishonesty in the marketplace should be condoned. Far from it – a dishonest market

[1] It should be noted that commercial and official bribery is today outlawed in many foreign lands, including some where it was previously condoned. The trend overseas is toward more aggressive enforcement of anti-bribery standards.

[2] John S. Barker, Jr., *Measuring the Explosive Growth of Federal Crime Legislation*, The Federalist Society for Law and Public Policy Studies (2004).

is not a free market. But there is value in recognizing that a core function of the federal government, and therefore the core purpose of federal criminal law in the business context, is to promote commerce by protecting its means and instrumentalities. When federal criminal law is used as a tool of social engineering, it pushes past this core purpose and criminalizes behavior that is not characterized by intentional bad acts.

The federal government and federal law enforcement have a critical role to play in policing the marketplace for fraud and corruption. This role stems from the necessity of establishing and enforcing standards that promote investor confidence in capital markets and providing transparency in credit transactions. Even though such measures present difficulties and expense for businesses, one does not have to look far for examples of how dishonesty, deceit, and corruption can cripple a nation's economy and its commercial system. Indeed, businesses themselves have a vital interest in a level—that is, an honest—commercial playing field.

But much of the criminal law that applies to business today has strayed far from promoting these core values and instead punishes criminally what are, in essence, regulatory offenses. In the 20th century, Congress pursued many regulatory initiatives that set the stage for this new use of criminal enforcement authority. Most of these were enacted as part of a continued expansion of federal regulations and programs in general. These initiatives were the catalyst for an accelerated pace in the regulation of business activities by punitive mechanisms.

Examples of this trend abound. Environmental laws, for instance, incorporate steep civil and criminal enforcement penalties for failing to meet regulatory standards in conducting what is otherwise legitimate and innocent commercial behavior. Polluting is legal in the United States; the government issues permits for it. Polluting too much, however, is a felony. The line between the two is razor thin, often expressed in parts per million, and the stuff of great debate

between experts and scientists. Similarly, billing government health programs for medical services is obviously legitimate commercial activity. Unbundling of charges or otherwise sending a bill to the government that does not conform to the requirements of a sheaf of federal regulatory dictates, however, can be felonious conduct. Again, experts can and do disagree about minute aspects of coding medical services for reimbursement by public or private insurers, yet payees can be held to answer for a criminal violation if they run afoul of such regulatory minutia. As a final example, pumping oil and gas from federal lands is, of course, legitimate commercial activity. Yet failing to abide by complex government regulations when valuing crude oil or raw gas at the well for royalty purposes may not only lead to treble damages claims under the False Claims Act, but federal grand jury attention as well.

III. The Evolution of Federal Criminal Law

Understanding how the relationship between federal authority and commercial activity has evolved is an essential part of any discussion concerning the core federal function of promoting commerce. Article I, section 8 of the Constitution gives Congress the power to "regulate" commerce, both with foreign nations and among the states.[3] It also expressly gave Congress the power to "punish" treason, counterfeiting, piracies, felonies committed on the high seas and offenses against the law of nations. These provisions seem to have been intended by the Founders to serve one common and fundamental purpose: to protect the country and its government and to empower it, in turn, to protect the channels and instrumentalities of commerce, as they were then known. The notion that federal criminal statutes could be used

[3] Const., Art. I, § 8. As the Supreme Court has twice held in recent years, however, this power does not confer on Congress a general power to pass criminal laws. *See United States v. Lopez*, 514 U.S. 549, 567 (1995); *United States v. Morrison*, 529 U.S. 598, 617 (2000).

directly to "regulate" commerce was simply not part of the Founders' vision. As Alexander Hamilton wrote in The Federalist, "[t]here is one transcendent advantage belonging to the province of the State government which alone suffices to place the matter in a clear and satisfactory light. I mean the ordinary administration of criminal and civil justice."[4]

Early on, Congress followed the philosophical lead of the Founders. The first Congress enacted laws punishing treason,[5] misprision of treason,[6] murder and robbery on federal property or on the high seas,[7] perjury in federal court,[8] bribery of federal judges,[9] forgery of federal certificates and securities,[10] and customs offenses.[11] These and other statutes tracked the narrow grant of powers conferred on the federal government by the Constitution, serving largely to protect the government (and indeed the country itself), and to protect the channels and instrumentalities of commerce.

This pattern of lawmaking, by which the sanction of criminal laws safeguarded commerce and cleansed it of corruption, persisted beyond the founding. The Civil War brought the False Claims Act,[12] which, though enacted to prevent fraud, also operated to ensure fair

---

[4] Federalist No. 17, at 107 (Alexander Hamilton) (Jacob E. Cooke ed., 1961).

[5] Act for the Punishment of Certain Crimes Against the United States, § 1, 2 Stat. 112, 112.

[6] *Id.* at §§ 3, 16, 8.

[7] *Id.* at § 18.

[8] *Id.* at § 21.

[9] *Id.* at § 14.

[10] Act to Provide More Effectually for the Collection of Duties Imposed by Law on Goods, Wares and Merchandise Imported Into the United States, and on the Tonnage of Ships or Vessels, § 27, 2 Stat. 145, 163 (1790), *repealed by* Act of March 12, 1799.

[11] Id. at § 18.

[12] 31 U.S.C. § 3279.

dealing in connection with government contracts and contractors. Similarly, the mail fraud statute was enacted to protect the mails, another important instrumentality of commerce.

The practice of enacting criminal statues to protect the means and instrumentalities of commerce continued through much of the 20th century. Banks were recognized as obviously critical instrumentalities of commerce. Thus, first through the federal bank robbery statutes and later via a broad panoply of criminal prohibitions, banks became as well fortified by protection of criminal statutes as was the government itself. The Interstate Commerce Act and the Sherman Antitrust Act[13] sought to provide similar protection to the free market by aiming to free interstate commerce from unnatural, anticompetitive impediments. New Deal securities acts and financial reporting laws were designed to preserve the integrity of commerce and increase investor and consumer confidence in publicly traded markets and the financial system generally.[14] Years later, the Racketeer Influenced Organizations Act ("RICO")[15] was enacted to respond to the risk posed to legitimate commerce by the infiltration of organized crime.

IV. A New Paradigm: Using Federal Criminal Law to Regulate Corporate Behavior

When the Supreme Court decided in a 1909 watershed decision that corporations could be prosecuted for crimes, it is doubtful that it foresaw the minefield of regulatory offenses that the modern corporation would need to traverse on a daily basis. In *New York Central & Hudson*

[13] 15 U.S.C. §§ 1–7.

[14] *See, e.g.*, Securities Act of 1933, 15 U.S.C. § 77a; Securities Exchange Act of 1934, 15 U.S.C. § 78a.

[15] Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §§ 1961–1968.

River Railroad v. United States,[16] the Court reasoned that if a corporation could bind its shareholders to a contract, it should be held responsible for conduct on the corporation's behalf that is determined to be a crime.[17] In reaching this result, the Court also moved, rather casually, from the premise that corporations could be held liable for injuries to the conclusion that they also could be held accountable for crimes. The Court seemed to base its reasoning on the theory that, if corporations could not be prosecuted, there were wrongs that could not be remedied and deterred. This notion seems odd today, since the scope of civil remedies available to right corporate wrongs seems more than adequate, and the keystone criminal remedy—loss of liberty—is not applicable to corporations. Nonetheless, the notion that corporations should be prosecuted criminally for their "wrongs" has proven to be a common refrain as the federal government has migrated away from its core purpose of fostering commerce by protecting the means and instrumentalities necessary to it.

The lengths to which the government sometimes will go to turn a regulatory infraction into a criminal case would be humorous if it were not for the consequences to the corporate defendant. In 1982, in *United States v. Hartley*,[18] the Eleventh Circuit upheld the conviction of a corporation and two of its employees for selling the military breaded shrimp that failed to meet certain specifications, including the amount of breading on each piece of shrimp.[19] To be sure, the defendants in that case also had committed serious criminal acts. They deceived the government by altering inspection standards and changing the weights used to determine how

[16] 212 U.S. 481 (1909).

[17] *Id.* at 493-96.

[18] 678 F.2d 961 (11th Cir. 1982).

[19] *Id.* at 966.

much shrimp the government bought. The latter action deserved criminal treatment because they involved the type of deception and dishonesty that characterize criminal intent. But one must question whether the under-breading of shrimp, the fundamental aspect of the case, justified 33 counts of conspiracy, mail fraud, violations of the National Stolen Property Act, and RICO.

The government appears to have maintained its interest in shellfish. In *United States v. McNab*,[20] the National Marine Fisheries Service seized a shipment of Honduran lobster tails as they were coming into the United States. Honduran law requires that exported lobster tails be 5½ inches long, that they be processed prior to shipment, and that they be shipped in cardboard boxes. Inspection of the shipment at issue showed that 2.5% of 70,000 pounds of lobster tails were less than 5½ inches long, that they were not processed prior to shipment, and that the lobster tails were shipped in clear plastic bags. Based on these facts, in September of 2000, a grand jury returned a 47-count indictment alleging conspiracy, smuggling, money laundering, and violations of the Lacey Act prohibiting the importation of "fish or wildlife taken, possessed, transported, or sold in violation of … any foreign law."[21] Following prosecution, the principal defendants were found guilty and sentenced to prison terms of 97 months. Had they pled guilty, the punishment would have been fines and probation.

The result in *McNab* yields two valuable lessons about dealing with the federal government. First, it puts corporations on notice that the government apparently will base a federal prosecution on a violation of even foreign regulatory law. In making out such a case, prosecutors will call upon their foreign counterparts to give testimony concerning the validity of the foreign law serving as the predicate for the criminal charges. Second, the government can be

[20] 331 F.3d 1228 (11th Cir. 2003).

[21] *Id.* at 1236.

expected to dissuade defendants from going to trial and testing the case against them by offering extremely generous terms in exchange for guilty pleas. As the *McNab* individual defendants learned, the price for passing up such a deal and forcing the government to prove its case can be substantial prison time.

It should go without saying that corporations have a responsibility to abide by duly promulgated federal regulations. But enforcing those regulations through criminal prosecutions seems far from the traditional purpose of federal criminal law applied in the commercial setting. This is not to say that an 18th century view of the relationship between commercial activity and criminal law could be appropriately applied in today's world. Traditionally, however, commercial crimes were characterized by dishonest conduct in which the *mens rea* that delineates a criminal act was obviously present. Federal criminal law, as currently applied to commerce, seems to have lost that limitation. The potential result is an environment with too little entrepreneurial risk-taking and business decisions governed more by fear of oppressive federal inquiries into conduct controlled by the minutia of arcane federal regulations than by traditional economic calculus.

Congress is at least partially to blame for the use of federal criminal law as a regulatory tool because it continues to allow regulatory agencies to define federal crimes. Typically, Congress enacts a statute with broad regulatory objectives, empowers an agency to promulgate regulations to accomplish those objectives, and provides criminal penalties as part of the statute's general enforcement mechanisms. As a result, agency bureaucrats writing regulations establish the substantive elements of such crimes.

Though a familiar pattern in purely regulatory matters, delegating the substantive definitions of crimes to unelected regulators presents particular concerns. Individuals and corporations must wade through a morass of regulations to determine what constitutes a crime.

Further, federal criminal law is imbued with an amorphous character that can transform business decisions into criminal acts. In addition, these regulations usually require regulated entities to provide information to the government, both formally and informally. Such reporting often involves data that is something other than merely objective compilations of quantifiable information. As a result, reports and certification of compliance with regulatory requirements become fodder for prosecutors considering whether to prosecute a corporation for making false statements or concealing material information from the government.

A 1995 decision of the United States Court of Appeals for the District of Columbia Circuit provides a good example of the perils of depending too heavily on regulatory agencies to flesh out substantive elements left ambiguous by legislators. In *General Electric Co. v. EPA*,[22] the EPA had fined General Electric ("GE") $25,000 for processing polychlorinated biphenyls in a manner not authorized under the EPA's interpretation of its own regulations. GE petitioned for review of the EPA's order.

The court noted that the regulation in question was part of a "comprehensive and technically complex" regulatory scheme, and that agencies' interpretations of their regulations are given deference. Accordingly, the court concluded, the EPA's interpretation was reasonable.[23] Yet because GE had suffered the punishment of a fine, the court determined that it was also required to assess whether GE had received fair notice of the proscribed activity. If, "by reviewing the regulations and other public statements issued by the agency … [the company] acting in good faith would be able to identify with 'ascertainable certainty' the standards with which the agency expects the parties to conform, then the agency has fairly notified [the

[22] 53 F.3d 1324 (D.C. Cir. 1995).

[23] *Id.* at 1328.

company] of the agency's interpretation," the court held.[24] The EPA's highly technical and opaque regulations failed to meet that standard, and the court vacated the EPA's finding of liability.

V. Use of Federal Criminal Law for Regulation: A Continuing Trend

Three factors suggest that the trend toward increased use of the federal criminal law to regulate business activity will continue. The first is the January 20, 2003, Memorandum from Deputy Attorney General Larry D. Thompson concerning "Principles of Federal Prosecution of Business Organizations" ("Thompson Memo"). The Thompson Memo is essentially geared toward achieving two ends. It is designed to ensure that "corporate governance mechanisms" are "truly effective rather than mere paper programs."[25] It also emphasizes the importance of "authentic[]" corporate cooperation and voluntary disclosure.[26] Where an entity has effective corporate governance programs, cooperates with the government, and makes voluntary disclosure, the Thompson Memo states that prosecution is less warranted than in a situation where such action has not been taken.

By linking the evaluation of corporate governance mechanisms to "Federal Prosecution of Business Organizations," the Thompson Memo outlines an approach that plainly involves using the criminal law to regulate corporate conduct, even to the point of dictating corporate management. Indeed, the Thompson Memo directly links the exercise of prosecutorial discretion

---

[24] *Id.* at 1329.

[25] Memorandum from Larry D. Thompson, Deputy Attorney General, to Heads of Department Components, U.S. Attorneys (Jan. 20, 2003).

[26] *Id.*

to an evaluation of whether the organization is properly monitoring its activities – an endeavor more typically considered to be within the regulatory province.

The Thompson Memo also encourages prosecutors who are considering charging a corporation to evaluate cooperation by looking to the corporation's willingness "to disclose the complete results of its internal investigation[,] and to waive attorney client and work product protection" that would otherwise obtain with respect to relevant communications, reports, or other information.[27] As a result, corporations are being pressured to provide otherwise privileged reports, memoranda, and records of advice from counsel as the price of avoiding prosecution or mitigating penalties. Where parallel civil proceedings lurk on the horizon of a criminal investigation, any waiver could be construed as a subject-matter waiver, possibly resulting in discovery in parallel civil matters of all attorney-client communications or work product related to the subject of the government's investigation. The link between the Thompson Memo and civil discovery is *de facto* regulation through the threat of prosecution because the specter of civil lawsuits often shapes corporate behavior.

This scenario occurred in a recent California case, *McKesson v. Superior Court*,[28] where the target of a government investigation retained outside counsel to perform an internal investigation concerning violations of various securities laws. During the course of the investigation, outside counsel informed the United States Attorney and the Securities and Exchange Commission ("SEC") that McKesson was willing to disclose the results of the internal investigation to the government. Disclosure occurred "subject to agreements designed to

---

[27] *Id.*

[28] 115 Cal. App. 4th 1229 (Cal. Ct. App. Feb. 20, 2004).

preserve the confidentiality of any materials given to the government."[29] However, "the agreements did provide for disclosure under certain circumstances, including the prosecution of McKesson."[30] The California Court of Appeals held that McKesson "waived the attorney-client privilege and work product protection for documents shared with the government."[31] As a result, these documents were discoverable in related civil litigation and may have aided the plaintiff's case.

The threat to the attorney-client and attorney work product privileges became more pronounced in an amendment to the United States Sentencing Guidelines, which took effect on November 1, 2004. This amendment to the Commentary to Section 8C2.5 essentially provided the government with another instrument to use to coerce companies into waiving their attorney-client privilege in order to demonstrate "thorough" cooperation with the government. The relevant portion of the Commentary now reads: "Waiver of attorney-client privilege and of work product protections is not a prerequisite to a reduction in culpability score under subdivisions (1) and (2) of subsection (g) *unless such a waiver is necessary in order to provide timely and thorough disclosure of all pertinent information known to the organization.*"[32]

This exception, however, threatens to devour the rule. Is it likely that the government would take the position, in a given investigation, that an attorney-client privilege waiver is unnecessary and would not aid its investigation? Thus, a corporation that refuses the government's request to waive its attorney-client privilege faces the prospect of not only being

---

[29] *Id.* at 1233.

[30] *Id.* at 1234.

[31] *Id.* at 1241.

[32] U.S. Sentencing Guidelines Manual § 8C2.5, Commentary Note 12 (2004) (emphasis added).

labeled "uncooperative" by the government, with the immediate detrimental effects to its public image, stock price, and credit worthiness, but also failing to obtaining a crucial reduction in its Culpability Score under the Sentencing Guidelines (and thereby qualify for a more lenient sentence), despite the fact that it may have otherwise cooperated thoroughly with the government.

This amendment erodes and weakens the attorney-client privilege between companies and their lawyers, and indeed has the opposite effect than that intended. Rather than strengthening compliance with the law, it undermines compliance in three serious ways. First, it discourages company employees from consulting with the company's attorneys, thus impeding the attorneys' ability to effectively represent and counsel their clients regarding compliance with the law. Second, it makes a company's early detection of wrongdoing more difficult by undermining the effectiveness of its internal investigations, which depend on candid and confidential conversations and interviews between its employees and attorneys. Finally, it encourages excessive subsequent civil litigation by making privileged material accessible to civil attorneys on the same subject matter of the government's investigation, which in some cases can lead to a far greater financial risk.

Fortunately, barely a year after this amendment came into effect, the United States Sentencing Commission included this amendment on its list of tentative priorities for the upcoming amendment cycle. In a letter to the Commission, several high-level former Justice Department officials, including myself, urged the Commission to retain this issue on its list of priorities and remedy the problem as soon as possible. In particular, we recommended revising the amendment to affirmatively state that "waiver of attorney-client and work product

protections should not be a factor in determining whether a sentencing reduction is warranted for cooperation with the government during an investigation."[33]

While the Supreme Court recently reduced the influence of the U.S. Sentencing Guidelines by holding that they are advisory, rather than binding,[34] another amendment to the Sentencing Guidelines for organizational defendants is a second factor suggesting increased regulation of organizations through federal criminal law. This amendment seeks to deter organizational misconduct by reinforcing the importance of maintaining an "effective compliance and ethics program." This goal is accomplished in two ways. First, an amendment adding § 8B2.1 establishes a specific and workable framework for an "effective compliance and ethics program."[35] In this way, the Sentencing Guidelines essentially tell organizations how they should structure their compliance and ethics programs. Second, Sentencing Guidelines § 8C2.5(f) reduces an organization's culpability score if an "effective compliance and ethics program" was in place at the time of the offense. Consequently, an organization would be foolish not to institute the kind of program prescribed by the government.[36]

The third factor suggesting a continuation of the trend toward regulation through prosecution can be called simply "Enron" and its progeny. Enron epitomized a phenomenon that began some time ago regarding concern with false or misleading corporate financial statements. This issue had been bubbling up for several years, attracting the interest of both securities enforcers and the Justice Department and, of course, private plaintiffs' counsel. Sustained

---

[33] August 15, 2005 Letter to The Honorable Ricardo H. Hinojosa, at 3.

[34] *United States v. Booker*, 125 S. Ct. 738 (2005).

[35] U.S. Sentencing Guidelines Manual § 8B2.1 (2004).

[36] *Id.* § 8C2.5.

pressure from the public to "do something," along with the passage of laws like the Sarbanes-Oxley Act, strongly suggest that the use of federal criminal law as a regulatory device will continue. The reversal of the Arthur Andersen conviction does not signal an abatement of this trend. It may, however, signal a helpful midcourse correction toward more responsible evaluation of the necessity of prosecuting business entities to secure legitimate goals.

VI. Fixing the Problem

What approaches are available to alter the reliance on federal criminal law to enforce regulatory norms? There are three elements to an effective response to this growing trend to regulate commercial activity by application of criminal law. First, this issue should be addressed at the policy level in both the legislative and executive branches, by beating the drum regularly to remind policymakers of the core purposes of federal criminal law as applied to commerce. Second, we must press both the policy and the legal issues at the pre-indictment stage[37] in all cases where prosecutors, and particularly responsible supervisory officials, might be persuaded that core considerations of federalism, among others, militate against criminal prosecutions based on purported transgressions of regulatory standards. Third, where the opportunity presents itself, corporations should be prepared to litigate the underlying policy issue by challenging prosecutions premised on unclear and ambiguous regulatory standards, particularly those subject to legitimate dispute by experts such as accountants, engineers, and other specialized professionals.

[37] As is discussed below, an appeal to a prosecutor's sense of restraint may not be the only option available to a corporation in this situation.

The policy argument is obvious: focus on using federal criminal provisions to secure the core federal interest of promoting and protecting the means and instrumentalities of commerce. A good first move would be to scrap the Thompson Memo's insistence on insuring that "corporate governance mechanisms" are "truly effective" and its focus on "authentic" corporate cooperation and voluntary disclosure that results in waiver of the attorney-client and work product protections. Rethinking these aspects of the Thompson Memo is a good vehicle to move to a more well-reasoned and sound policy on corporate prosecutions because it will decrease the regulation that occurs through prosecution or the threat of prosecution. Another obvious policy option is to seek other means to achieve regulatory goals. Choices include the use of other financial incentives for meeting regulatory objectives, real rewards for self-policing, and, as necessary, civil damages and consent agreements to deter and change corporate behavior.

The second and third elements can be achieved if those subjected to prosecutorial scrutiny are bold enough to argue and, if necessary, litigate some of the issues raised by egregious use of federal criminal law to regulate commercial activity. The Eleventh Circuit, in *United States v. Whiteside*,[38] rejected the overbroad application of a general criminal statute to ordinary commercial conduct. The principle underlying the court's opinion, combined with a well-established principle of due process, can be used to craft persuasive arguments to establish limits on the untoward use of criminal enforcement mechanisms in the commercial context.

The well-established principle of due process springs from the Supreme Court, which has repeatedly held that "a penal statute must define a criminal offense with sufficient definiteness that ordinary people can understand what conduct is prohibited and in a manner that does not

[38] 285 F.3d 1345 (11th Cir. 2002).

encourage arbitrary and discriminatory enforcement."[39] The value of this principle becomes apparent if one wades through the Medicare cost reimbursement rules and asks if the notice they provide is sufficient to justify the use of criminal sanctions when there is a lapse in compliance.

In fact, that is precisely what the Eleventh Circuit did in March 2002, and the conclusion it reached is well worth considering. In *Whiteside*, the court reversed the convictions of two hospital officials who had been prosecuted for knowingly and willfully filing false statements in federal health program reports required to be submitted to the government. The case turned on whether the defendants knowingly and willfully made a false statement when they filed a single report classifying debt interest in terms of "how the debt was being used at the time of the filing of the cost report rather than how the funds were used at the time of a loan origination."[40] The court of appeals found no legal authority clearly supporting the government's interpretation of the regulation upon which the prosecution charged criminal offenses. Experts had disagreed as to whether the government's position was correct. The court concluded that "competing interpretations of the applicable law are far too reasonable to justify these convictions."[41]

These points and arguments have currency in litigation, and can be used aggressively and effectively during the pre-indictment stages of a case to persuade prosecutors that alternative means to accomplish governmental objectives may be a far better policy choice than criminal prosecution. This is particularly so when the matter is presented to prosecutorial officials who have the responsibility to set policy in the exercise of prosecutorial discretion.

---

[39] *Kolender v. Lawson*, 461 U.S. 352, 357 (1983).

[40] *Whiteside*, 285 F.3d at 1351.

[41] *Id.* at 1353.

It may also be possible to raise a challenge to a tenuous prosecution using these principles before trial. In *United States v. Levin,*[42] the Sixth Circuit upheld a district court's dismissal of a 560-count indictment charging the defendants with Medicare fraud and related charges. The defendants were charged with violating Medicare regulations when they received free surgical supplies with each purchase of a specific medical device, the cost of which was reimbursed by Medicare. The provision of free surgical supplies as a promotional measure had been approved, however, by the Health Care Financing Administration, a part of the Department of Health and Human Services, and this approval was naturally circulated throughout the targeted professional medical community.[43]

On a motion pursuant to Federal Rule of Criminal Procedure 12(b), the district court ruled that under the undisputed evidence in the case, the government simply could not demonstrate the requisite criminal intent, and accordingly the indictment would be dismissed. On appeal, the Sixth Circuit affirmed, holding that due process does not permit the government to mislead individuals through assurances that certain conduct is legal, then later initiate prosecution for engaging in that conduct. Quoting the Supreme Court, the court of appeals noted that "[a] state may not issue commands to its citizens, under criminal sanctions, in language so vague and undefined as to afford no fair warning of what conduct might transgress them."[44] Noting that under Rule 12 the district court was not limited to the face of the indictment in

[42] 973 F.2d 463 (6th Cir. 1992).

[43] *Id.* at 465.

[44] *Id.* at 466.

determining whether to dismiss it, the court rejected the dissent's contention that the district court had engaged in impermissible pretrial weighing of the evidence.[45]

These cases, as well as others such as the previously mentioned 1995 D.C. Circuit decision in the *GE* case, are examples which suggest a potential line of defense that is grounded in due process and that can be utilized to restrain the unrestricted use of criminal sanctions and severe civil penalties to enforce regulatory-type norms in business conduct.

VII. Conclusion

Quite rightly, the Department of Justice and the Federal Bureau of Investigation have continued to identify white collar crime as a priority. It is clear that the demands on federal law enforcement today are greater than ever before, and it is apparent that enforcement authorities cannot be everywhere at once. This is an opportunity to address and further consider the issue of regulating corporate behavior through the application of federal criminal law and to refocus federal law enforcement on core federal functions. This means putting the emphasis back on protecting the means and instrumentalities of commerce rather than using criminal law to punish and control ordinary commercial activity governed by regulation. In mounting a defense to this trend, certain concepts are worth repeating. Corporations are not inherently evil. Wealth can serve good purposes. Commerce carries blessings to people far beyond the buyer and seller in a particular transaction.

---

[45] In a more recent decision by the district court in the Eastern District of Pennsylvania, now on appeal, a court concluded that principles of due process prohibited the government from returning an indictment against a company that had entered into an amnesty agreement with the government, absent a judicial finding that the company had breached that agreement. *Stolt-Nielsen S.A. v. United States,* 352 F. Supp. 2d 553 (E.D. Pa. 2005). In the interest of full disclosure, I should note that my firm was counsel for Stolt-Nielsen in this case and I participated in the trial proceedings.

Business leaders, including counsel, can contribute much by reminding our political leaders of these fundamental principles. The adventurous, risk-taking endeavors that lie at the heart of American commerce will thrive only so long as they are nourished in a hospitable environment. The trend toward regulation through criminalization poses a threat to that environment. It would be a mistake for us not to consider these issues and take such corrective actions as consensus might allow.

Testimony before the Senate Judiciary Committee:

Title 18, chapter 28 Sec. 561:

INTRODUCING DEFECTIVE PRODUCTS INTO INTERSTATE COMMERCE

Friday, March 10, 2006

Prof. Frank Vandall

Emory University School of Law

fvandall@law.emory.edu

I. Preemption?

As written, sec. 561, Introducing defective products into interstate commerce, may be interpreted to preempt state law. The three most important cases on preemption involve tobacco, Cipollone v. Liggett Group, 505 U.S. 504 (1992) air bags, Geir v. Am. Honda, 529 U.S. 861 (2000) and pacemakers, Medtronics v. Lohr, 518 U.S. 470 (1996).

The point of these three cases is that preemption is a new defense. The concept of preemption is vague and undefined, like proximate cause in torts. Taking the three cases together, it appears that the federal courts use preemption to decide (at will) whether to allow the state suit or to forbid it (preempt).

To avoid preempting state law: the bill should clearly state: "It is not the intent of Congress to preempt state statues, regulations or common law with this act (Sec. 561)."

II. A Trojan Horse is Pulled up the Potomic.

The worst possible result would be for the statute to be passed and not enforced, but nevertheless courts would hold that the intent of Congress is to preempt state law, including punitive damages.

There are numerous reasons why the act would not be enforced. Because prosecutors are under funded - and undermanned, they must be selective in their enforcement. Prosecuting corporate executives will be complex, expensive, and time consuming, therefore there would be a strong likelihood that these criminal suits would not be brought. Or, low level employees, would be prosecuted, but

not high ranking C.E.O's, and the corporation would see this minor expense as merely a cost of doing business.

Regardless of whether the Act is enforced, the courts might hold that the intent of Congress, in passing the Act, was to preempt all state law.

The Trojan horse analogy is suggested because many safety advocates will likely embrace the theory of the Bill, but only later realize that it has taken all of what they hold dear: state statutes and common law products liability cases (including punitive damages).

To avoid this unintended result, the Bill must clearly state that it is not intended to preempt state statutes, regulations, state common law nor the theory of punitive damages.

III. In order to reduce the sale of defective products, is this bill aimed at the appropriate "persons"?

The term "person" is defined as the employees of any corporation, company, association, firm, partnership, or other business entity or a sole proprietor. Later "person" is expanded to include person who has authority to introduce a product into interstate commerce, withdraw or recall a product from interstate commerce, or has the authority over the manufacturer, assembly, importing or sale of a product.

This definition of "person" is sufficiently broad to catch all those who know the product is defective and capable of causing death or serious bodily injury. The persons ensnared by this net would include: engineers, designers, team

leaders, line workers, sales staff, presidents, vice-presidents, and corporate C.E.O's.

This broad definition of "person" will encourage whistle-blowers to step forward and speak to the press or the appropriate agency. Examples that come to mind are Jeffrey Wigand in the tobacco litigation and Professor Roger Tuttle in the Dalkon Shield case.

Example: What if the drug causes vaginal cancer in the daughter of the consumer? Cancer can lead to death. In the DES cases the manufacturers were held liable for the resulting cancer under the strict liability cause of action. It is not clear that the pharmaceutical executives "knew" at the time of sale that cancer would result in third parties, and therefore the executives would not be subject to prosecution under the Bill.

In the cases of MER-29 and Oraflex, however, the executives knew of the risk of serious bodily injury (MER-29) and death (Oraflex) and would have been subject to prosecution under this Bill. See appendix.

IV. The introduction to the Bill says "knowing and reckless", but the remainder of the Bill only uses "knowing". Is "knowing" the proper standard for Mens Rea?

The use of these two terms seems appropriate. Professor Wayne La Fave concludes in his criminal law text: "the word 'intent' in the substantive criminal law has traditionally not been limited to the narrow dictionary definition of purpose, aim or design, but instead has often been viewed as encompassing much

of what would ordinarily be described as knowledge". (La Fave, Criminal Law, 4th ed. at 246.)

Clearly, knowledge is a higher standard (and more narrow) than reckless. La Fave presents the following example:

> We have seen that crimes defined so as to require that the defendant intentionally cause a forbidden bad result are usually interpreted to cover one who knows that his conduct is *substantially certain* to cause the result, whether or not he desires the result to occur. "Recklessness" in causing a result *exists* when one is aware that his conduct *might* cause the result, though it is not substantially certain to happen. One may act recklessly if he drives fast through a thickly settled district though his chances of hitting anyone are far less than 90%, or even 50%. Indeed, if there is no social utility in doing what he is doing, one might be reckless though the chances of harm are something less than 1%. Thus, while "knowledge" require[s] a consciousness of almost-certainty, recklessness requires a consciousness of something far less than certain or even probability. (La Fave, Criminal Law, 4th ed. at 269)

More people will be brought into the net if the term "reckless" is used. The Committee needs to decide whether they only want to prosecute those who know death is a substantial certainty, or want to also include those who know death might result (reckless).

The standards of negligence (reasonable care), and strict liability (liable without knowledge or negligence), are not mentioned in the draft and are not in issue here.

The Model Penal Code defines "knowingly" as follows:

A person acts knowingly with respect to a material element of an offense when:

> (i) if the element involves the nature of his conduct or the attendant circumstances, he is aware that his conduct is of that nature or that such circumstances exist; and
>
> (ii) if the element involves a result of his conduct, he is aware that it is practically certain that his conduct will cause such a result. [Model Penal Code (2002) ed., at pg. 304]

V. Could a whistle-blower be subject to punishment under the Bill?

The whistle-blower fits within the definition of a person who knows the defective product could cause death or serious bodily injury and therefore appears to be subject to prosecution. This is good because it will encourage employees with such knowledge to come forward and complain to the media or to the appropriate agency. However, the whistle-blower will not be prosecuted because she is protected by federal legislation, Whistle-blowers Act of 2002, 5 U.S.C. Sec. 2301 (Public Law Number 107-1744). See for example, Pearson v. Dodd, 410 F.2d 701 (1969).

VI. Bad Results, Under the Bill

A serious problem with the Bill is that it could create a whistle-blower culture. Large numbers of employees could be found complaining to the press or agencies for all manner of "trivial" problems with products. This could lead to substantial expense for the corporation as it sifts through the stack of complaints. It could strain employer-employee relations.

On the other side, the Bill could save lives by preventing the manufacture and sale of dangerous and defective products. Because of the threat of criminal prosecution, products would be designed more safely.

VII. The Size of the Fine is Important.

The Bill mentions a "fine" at several points, but does not set an amount. The size of the fine is important, if the fine is small, the corporation will disregard it or perhaps even pay the fine for some of its executives. Therefore, high ranking executives in major corporations will have to be fined large amounts to get their attention.

If the word "person" is interpreted to include the corporation, then the fine must be truly substantial to avoid being ignored. When death results, I suggest that 1% of the firm's profits for the year would be a starting point (see appendix). In the Pinto case the fine would have been 16 million dollars in 1981. But clearly the victims must also have a parallel civil suit to compensate them for their losses. Jail-time or a fine does nothing for the survivors of the crime.

VIII. Technical Problems with the draft of the Bill

A. "Reckless" is used in the introduction but not later in the Bill. To avoid confusion, "reckless" should be deleted from the Bill.

B. Does the Bill apply to all "products".

As drafted all produces are covered. Clearly it would apply to SUV's televisions, airplanes and tires. Seemingly prescription drugs such as Vioxx and Oraflex would be covered.

Does the Committee intend that tobacco products would be within the Bill? Clearly tobacco kills, but there is substantial debate as to whether tobacco is "defective."

What about handguns? Do you want handgun CEO's and sales people, who know that handguns are sold beyond the saturation point -in the South- to "strawmen", who sell them on the black market in New York City and Chicago, to be prosecuted under the Act? Handguns kill and some are defective, but handgun manufacturers were recently immunized by Congress. Should this immunity be replicated in the Bill?

Above ground swimming pools - They kill several people each year. Are they defective? The same can be said for four wheel ATV's.

IX. Problems created by specific language in the draft.

In (a)(1), line 6. The term "instruction" is used. This word should be replaced with "warnings." A product can be found to be defective if it has a flawed warning; it fails to explain how to use the product safely.

The word "accepted" in (a)(1) line 8 is confusing and should therefore be deleted. A person may know of a risk or be aware of a risk, but that does not mean it is "accepted".

(a)(3), line 14. Should "person" include the corporation itself? Often the employee will be unable to pay a hefty fine, but the corporation will have the needed funds. The corporation may encourage a culture of ignoring serious risks to the consumer and it should therefore be prosecuted and fined.

(a)(3), line 24. Does impairment of mental faculty include emotional distress? Is emotional distress intended to be a recoverable damage under the Bill?

(b)(2) line 7. What does "recall" mean? Does that refer to the power to recall the product, or merely send out a "recall" letter. The two may be different.

(b)(2) lines 5-15. A person who fails to disclose the defective product to "the appropriate agency". There may be no agency designated to receive the complaint.

When the Ford Explorer/Firestone tire litigation began, the chair of DOT said, I did not know of the rollover problem. The American public learned that Ford had no duty to inform DOT of the problem. Worse, Ford said they did not keep statistics on Explorer roll-overs and did not know of the number of roll-overs.

The Bill should be clear in stating that a "person" can complain to the media, as well as an agency, and there is no intent to quell free speech. The agency may collect the complaints and do nothing more. Therefore, the employee must be encouraged to inform the media.

(2)(2), line 15. Reporting serious defects to an "agency" is a fine idea, but perhaps Congress should identify the "appropriate agency" to receive the complaints.

X. Conclusion

The Bill fills an important need that exists because of two legal developments: first the explosion of tort reform; second the erection of procedural and substantive hurdles to products litigation (see, F. Vandall, "Constricting Products Liability": Reforms in Theory and Procedure," 48 Vill. L.R. 843 (2003).

A serious flaw in the proposed Bill, however, is that once enacted the statute may not be enforced. Nineteen years ago I was able to argue that courts will not lock-up corporate executives (see, F. Vandall, "Criminal Prosecution of Corporation for Defective Products," 12 International Legal Practitioners 66 (Sept. 1987), Reprinted in J Abell & E. Sheehy, Criminal Law and Procedure 91 (1995, 1998, and 2004). Reprinted in 14 Verdict 9 (April, 1989). [Attached as an appendix]

But perhaps that view needs to be revisited since Health South, Enron, Martha Stewart, and similar recent cases involving executive prosecution and imprisonment.