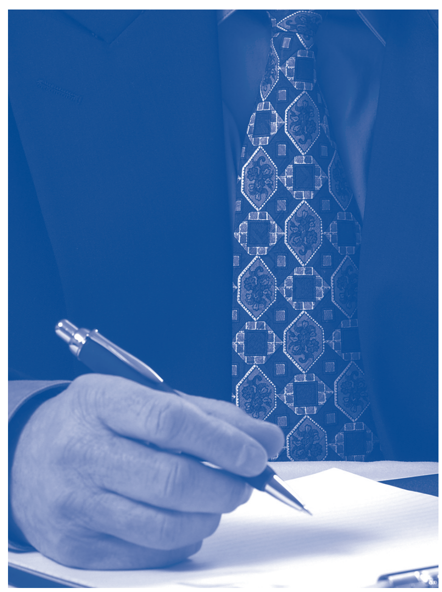
Criminalizing Product Liability Law:
Putting to Rest a Bad Idea



By Victor E. Schwartz and Cary Silverman

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By Victor E. Schwartz and Cary Silverman
Shook, Hardy & Bacon, L.L.P.

EXECUTIVE SUMMARY

Over the years, well-intentioned policymakers and consumer advocates have suggested that it should be a crime to manufacture or sell a defective product. Such proposals may arise from a tragedy in which it is alleged that a flaw in a certain product resulted in serious injuries or deaths. It is indeed important to encourage companies to produce safe products and to punish those who intentionally place profit over safety. But criminalizing product liability law is fraught with problems. It threatens managers and their employees with unpredictable and uncertain criminal penalties, potentially including jail time, for acts that they would not have known were wrong. Moreover, the effectiveness of such an approach is questionable at best and the process may result in less safe products.

Manufacturers make thousands of choices when developing new products. Increasing the safety of one aspect of a product, such as the roof strength of a car, can adversely affect another aspect, such as its propensity to roll over. Warning about an uncommon side effect of a drug can distract from more important warnings and lead some who would benefit from the drug not to use the product at all. With the exception of certain manufacturing defects, such as a foreign object in a bottle of soda, the existence of a product defect is not a black or white decision, like robbery, kidnapping, or homicide.

The introduction of a "defective product" into the marketplace is too vague a standard for criminal sanctions. The legal concept of a "defective product" is rooted in civil, not criminal, law. Determinations about the existence of a "defect" are decided after a fact-intensive inquiry by a jury in individual cases based on many subjective factors. Identification of a defect varies from state to state and from jury to jury. As evidenced by the recent series of Vioxx decisions, juries can reach wildly varying results as to whether the same product is or is not "defective." Future verdicts or developments in science can show whether earlier decisions about defects were right or wrong. For example,

several juries in the mid-1980s found that the morning sickness drug Bendectin caused birth defects, but these verdicts were later shown to be contrary to overwhelming scientific evidence.[1] Likewise, early cases involving silicone breast implants forced Dow Corning to file Chapter 11 bankruptcy in 1995, but when scientists carefully examined the issue, no link was found between implants and autoimmune disorders, cancer or any other serious disease.[2] Criminal law provides no such room to correct past mistakes and misjudgments.

Aside from being unfair and perhaps unconstitutionally vague, criminalizing product liability is likely to have many unforeseen adverse consequences. It may actually lead to less safe products because the potential for criminal penalties could encourage corporate executives and their employees to turn a blind eye to product risks – if they do not "know" of the risk, then they cannot be prosecuted. Moreover, many believe, and evidence shows, that America's product liability laws, and the risk of extraordinary punitive damages, already result in over, not under, deterrence. Criminalizing product liability would further slow innovation efforts and delay introduction of safer products, as those who are designing and manufacturing products may feel they need to talk with a lawyer while weighing their options. Recovery for those harmed by defective products could become more difficult to achieve as corporate executives, concerned about unfair prosecution, invoke their Fifth Amendment right against self incrimination in both civil lawsuits and government investigations.

These are just some of the reasons why past proposals to criminalize product liability have repeatedly failed to gain momentum and have been rejected by Congress. While on the surface criminalizing product liability is an attractive concept with strong rhetorical and emotional appeal, determining product defects should be left to tort law and the civil justice system. There are well-defined criminal laws already on the books that provide prosecutors with the ability to go after corporate executives who knowingly disregard a substantial, unjustifiable risk of harm to the public from a product, or who conceal or misrepresent information to government regulators.

INTRODUCTION

In March 2006, Senate Judiciary Committee Chairman Arlen Specter (R-PA) asked why a corporate executive should not be held accountable in cases where he or she knowingly introduces a "defective" product into the marketplace. As the Chairman may have appreciated as the hearing unfolded, this question assumes that there is either a consistent or an objective definition of a product "defect." In the real world of product liability litigation, this is not the case.

For example, a company launches a new drug and learns that it has had some adverse reactions. On the other hand, the company has also learned that the drug has provided better therapy than anticipated 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 or her to focus on the good that the product has done as well as its risks. All helpful 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 he or she is informed that the vehicle 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? There occasionally may be situations where an executive knows that food sold by his or her business is tainted or that there is broken glass inside a sealed container. If that executive knowingly sells such a product to a consumer, then there are adequate state laws to punish the executive. That is not the same as the amorphous "defect" addressing a product's design or warnings.

TORT AND CRIME – BASIC DIFFERENCES

Tort and criminal law serve two distinct and very different societal goals. Tort, or personal injury, law provides a means for an injured person to obtain compensation from a party who violates a duty to the plaintiff by committing an act or omission that is a substantial cause of the person's harm. The standard for violation of a tort duty varies; sometimes it is based on intent, other times negligence, and in a few situations it may be based on strict liability.

In such situations, the goal of tort law is to make a person "whole" by paying for his or her medical expenses, lost wages, and other intangible losses, such as pain and suffering. The goals of criminal law, on the other hand, are to punish people for conduct that is harmful to society and to deter others from similar conduct in the future. It can apply to a serious threat to society (driving a truck with explosive material through a tunnel) even when no one is injured.[3] Tort law requires an actual injury and may require a defendant to pay a substantial monetary award. A criminal penalty does not. It takes away an individual's freedom and places a stigma upon a person that can persist for the rest of his or her life.

Given their different functions and consequences, product liability and criminal law are subject to varying standards of precision in defining what conduct is prohibited as well as in the required burdens of proof that must be met at trial. For example, whether a product is "defective" or, in other words, unreasonably dangerous to consumers; whether a defendant has acted with due care; or whether a product is "defective," can be determined only after an examination of the specific facts of the case based on a "preponderance of evidence" (more likely than not) standard.

Criminal law has vastly different consequences than civil law and, for that reason, crimes are more precisely defined than torts. A homicide, for example, is the intentional killing of another. A burglary is the unlawful entry into a structure with the intent of committing a theft or felony. A robbery is the taking of anything of value from the care, custody, or control of a person by force, or threat of force or violence, that places the victim in fear of death or bodily harm. In such cases, the jury is charged with determining whether the state has, beyond a reasonable doubt, shown that the defendant committed the precise crime for which he or she is charged. Moreover, the level of proof required is much higher: beyond a reasonable doubt. In criminal law, there are generally no gray areas for deliberation, such as whether the attributes of a product render it defective. The jury is given a clear legal standard and comes back with a finding of guilty or not guilty. This is unlike the fluctuating and unpredictable judgments that can occur in the civil justice system. Moreover, criminal law requires what is known as *mens rea*, an intent to engage in the criminal conduct, a standard that is higher than that required in most civil proceedings.

When a law providing for a criminal penalty is drafted in a manner that would not provide a person of ordinary intelligence with fair notice that his or her contemplated conduct is forbidden, or the law would encourage arbitrary and erratic arrests and convictions, courts will strike it down as "unconstitutionally vague." For example, the U.S. Supreme Court has struck down vagrancy laws that permitted officers to require people to demonstrate that they had good reason to be where they were and that they were engaged in appropriate conduct.[4] These vague vagrancy laws provided police officers with too much discretion regarding whom to stop and what standards to apply before making an arrest. While unconstitutionally vague, these vagrancy laws had more precision than the elusive standard of whether a product is "defective."

Tort law has room for error and for self-correction. 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. A second or third case can effectively correct the first. In addition, monetary judgments can be appealed and, during the course of appeal in most states, a civil defendant needs only to put up a bond securing the amount of the judgment. There is no such room for trial and error in criminal law. While a convicted criminal may appeal his or her sentence, he or she may remain imprisoned during that long process. Even if the defendant prevails at trial or on appeal, his or her reputation, the product's name, and the company's value could be irreparably devastated.

The vagueness of the concept of defect is demonstrated by the recent litigation involving Vioxx™, a painkiller commonly used for arthritis that was pulled from the market by its manufacturer, Merck, after the company found it could lead to an increased risk of heart attack in some patients after months of continuous use. In August 2005, the first verdict in a Texas court (in a local jurisdiction with a reputation for being particularly friendly to plaintiffs) was for the plaintiff in the amount of $253 million, which was subsequently reduced to $26 million.[5] In November 2005, in the second trial in Atlantic City, New Jersey, where many legal rulings favored the plaintiff, there was a verdict for the defendant,[6] which was later set aside by the judge.[7] The next month, jurors heard the third Vioxx trial in a federal court in Texas; they could not reach a decision.[8] When the exact same case was retried three months later in a New Orleans federal court, there was a verdict for the defendant.[9] In an April 2006 New Jersey case involving two plaintiffs, one won and the other lost.[10] Later that month, across the country in Starr County, Texas, a jurisdiction with a plaintiff-friendly reputation, a jury by a 10-2 verdict awarded $32 million to the family of a 72-year-old man who only very briefly took the drug and died of a heart attack.[11] In a New Jersey case in July 2006, the defendant won.[12] In an August 2006 trial in East Los Angeles, an area known as a "Judicial Hellhole" for its unfair treatment of civil defendants, the defendants won yet again.[13] In

August 2006, in the same the federal court in Louisiana that had found the product not defective less than six months earlier, a new jury found the product defective and awarded $50 million in compensatory damages and $1 million in punitive damages.[14] Soon after, the trial court judge threw out the entire award and ordered a retrial on damages, finding the award "excessive under any conceivable substantive standard of excessiveness."[15]

This is the modern roulette system of product liability. Policy makers should focus on correcting the roulette wheel nature of product liability law, not on expanding its erratic and unpredictable qualities into criminal law.

TOO SUBJECTIVE FOR CRIMINAL LIABILITY

The U.S. Supreme Court has recognized that "[a] law is void for vagueness if it fails to give a person of ordinary intelligence fair notice that his contemplated conduct is forbidden by the statute."[16] No statute or regulation clearly defines a product "defect." There are many definitions of "defective"; each has its own ambiguities. That is why the concept of "defect" is part of tort law, not criminal law. In fact, the lack of predictability of standards, especially involving the word "defect," has been a problem in tort law for decades.

The Restatement (Second) Approach

The term "defect" first became prominent in tort law when the American Law Institute, a group of prominent judges, lawyers, and law professors, published Section 402A of the *Restatement (Second) of Torts* (1965). It stated that a product was "defective" if a product was "unreasonably dangerous to the user or consumer." Section 402A spawned a torrent of conflicting cases about the meaning of defect in design and warnings cases over a thirty-year period.

The Restatement Third Sought to Relieve Some Ambiguity

One of the motivating factors behind the drafting of the *Restatement Third of Torts: Products Liability* (1998) was to reduce the level of ambiguity of the term "defect" spawned by the Restatement (Second). The *Restatement Third* attempted to provide more definition to the term "defective." It is useful and more precise than the earlier attempt, but it is still filled with ambiguities. The *Restatement Third* breaks the word "defect" down into three separate components.[17] First, "manufacturing defects," which are easy to understand:

this is a flawed product that was not made in accordance with the manufacturer's own standards.[18] Second, "design defects" occur when 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."[19] The definition of design defect contains numerous "non-descriptive," ambiguous words such as "reasonable" and "not reasonably safe." These are not terms that were intended to be part of criminal law. The same is true of the third type of defect, "failure to warn." Defects in instructions or warnings may occur "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."[20] In sum, while bringing more precision to tort law, the *Restatement Third* tripartite analysis of defects would still create imprecise and inappropriate standards for criminal law.

Neither the Second nor the Third Restatement definitions of defect have gained anything approaching universal support in state courts. The defect lottery continues. Some states follow the *Restatement (Second)* definition of defect by looking at whether a product is unreasonably dangerous. Some courts look to the "reasonable expectations of consumers" in making such determination. Other states follow the *Restatement Third* approach and weigh the risks and benefits of the product's design. Still others suggest combinations of the two standards. Some states determine defectiveness based on their own approaches and policies.[21]

The CPSC Standard for Reporting Defects Does Not Provide a Standard for Criminal Law

The federal Consumer Product Safety Commission's (CPSC) product defect reporting requirements further demonstrate the subjectivity and open-endedness of whether a product is defective. In fact, the CPSC is considering changes to the way it defines a defect for the purpose of triggering a reporting obligation on the part of a manufacturer.[22] Currently, the Commission and its staff consider: (1) the utility of the product involved; (2) the nature of the risk of injury which the product presents; (3) the population exposed to the product and the risk of injury; (4) the Commission's own experience and expertise; (5) the case law interpreting federal and state public health and safety standards; (6) the case law in the area of products liability; and (7) other factors relevant to the determination.[23] The proposed revision would add consideration of four new factors, including the obviousness of the risk, the adequacy of the warning and instructions to mitigate such risk, the role of consumer misuse of the product, and the foreseeability of such misuse.[24] The many subjective factors that the CPSC uses to determine whether a product is defective demonstrate why it is unsound public policy to impose criminal penalties related to such a vague concept as a "defective product."

Legislative Proposals Adopt Their Own, Unique Definitions

Most legislative proposals incorporate very different definitions from those used in the Restatements or by the CPSC. For example, legislative proposals have defined a defect as meaning a "flaw in design." Given the varying definitions in Restatements and its adoption in the states, some 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." In addition, courts may 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.

Proposals to criminalize product liability often refer to a product "known by that person to be defective" that would be introduced into interstate commerce.[25] This "knowledge" standard, while seemingly fair, does not solve the ambiguity problem, because at the core of the alleged "knowledge" is still the ambiguous term, "defect." The proposed criminal law standard creates a contradiction in terms that one would "know" that a product is "defective." One knows when someone steals something; one knows it is a crime when someone sets fire to a house; and one knows it is a crime to burglarize an apartment. Given the panoply of definitions that have been used to define "defect" in two Restatements of Law and case law over the past forty years, one cannot meaningfully "know" when a product is "defective."

Legislative proposals have also discussed "defects" with respect to instructions or warnings.[26] As was true with "design" defects, hundreds of product liability cases have created battlegrounds over whether instructions or warnings were "flawed," or whether instructions failed to be "reasonable" or "adequate." The cost of product liability cases has bankrupted or nearly bankrupted many companies and has removed useful products, such as Bendectin™, from the marketplace. Prison sentences or criminal fines would not have provided any benefit in such cases.

Legislative proposals have also suggested that a crime occurs when a product is "dangerous to human life and limb beyond the reasonable and accepted risks associated with such or similar products lacking such a flaw." But with respect to any product, there are usually similar products with various degrees of safety. For example, whether it is automobiles, lawnmowers, or even toaster ovens, some have excellent safety records; some are not as good. This scale of safety occurs with virtually any mass product. As former Attorney General Dick Thornburgh has pointed out, car manufacturers could create a much safer vehicle than is currently on the road, "but it would be more like a tank and cost millions of dollars."[27] Defining "product defect" based on the availability of similar safer products 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." Moreover, more expensive products often 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.

Finally, these proposals are unclear as to who is subject to criminal prosecution. One might assume these laws target corporate executives who are the primary decision makers in producing such products. But the language of these proposals refers only to a "person."[28] This language could result in criminal charges against everyone involved in manufacturing or selling a product from the assembly line worker, to the engineer, to the mid-level manager, to the truck driver so long as they have some knowledge of a danger posed by the product. While prosecutorial discretion may provide a gatekeeper role, one can foresee the potential for a large number of criminal trials given the expansive application of the law and the lack of any clear definition of a defective product. The potential for uncertainty in prosecutions is magnified by the fact that almost any product can malfunction, be misused, or otherwise cause harm.

Product liability law and the definition of what constitutes a defective product are primarily developed by judges in state courts. While some states may apply similar legal principles, each state has its own product liability law with varying standards and conduct required before a product liability claim is upheld. A federal criminal law incorporating this patchwork would be a virtual disaster. It would add to the confusion among manufacturers as to the definition of "defect."

ISN'T THAT THE POINT OF PUNITIVE DAMAGES?

Companies that introduce defective products knowing that there is a strong likelihood that people will be seriously injured and fail to warn of such risks can be subject to punitive damage awards. In the civil justice system, punitive damages provide a means for punishing and deterring outrageous conduct. Imposition of these damages does not depend on the word "defect." They focus on conscious, flagrant disregard of safety.

Punitive damages, at their genesis, were available in a narrow category of torts involving conscious and intentional harm inflicted by one person on another. These cases, "the traditional intentional torts," were designed to punish an individual's purposeful bad act against another. The causes of action included assault and battery, libel and slander, malicious prosecution, false imprisonment, and intentional interferences with property such as trespass and conversion, malicious attachment or destruction of property, private nuisance, and other conduct amounting to reckless endangerment. Punitive damages were allowed in these cases as an auxiliary, or "helper," to the criminal law system. Over the years, the availability of punitive damages has vastly expanded to allow their imposition for reckless, willful and wanton misconduct, or even gross negligence in a wide range of tort lawsuits.[29]

Punitive damages law attempts to strike the appropriate balance between the standards of civil and criminal law. For example, most states require "clear and convincing" evidence of bad conduct for such an award, a standard falling in between the civil "preponderance of the evidence" standard and proof "beyond a reasonable doubt" required for a criminal conviction.

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. In fact, there has really been no showing that even 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, which has no punitive damages, than there were in California, which had such damages. There was absolutely no evidence that was the case.

Similarly, no objective evidence shows 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. As Justice Sandra Day O'Connor has recognized, "[T]ime and again, this Court and its Members have expressed concern about punitive damages awards 'run wild,' inexplicable on any basis but caprice or passion."[30] If such reining in of punishment has occurred in civil tort law, then there should be a steel gate against applying criminal law sanctions with ambiguous standards, and the threat of imprisonment or fine.

Through the good efforts of the Supreme Court to recognize constitutional limits on both the substantive and procedural aspects of punitive damages,[31] as well as efforts by some state judges and state legislators to apply limits and clarify standards, punitive damages law may become more effective. 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 potential amount of punitive damages. After all, punitive damages are a form of punishment and a close cousin to a criminal law sanction, but even with the best of attempts, the standards for imposition of punitive damages also have serious ambiguities that would be unacceptable in criminal law.

ADVERSE CONSEQUENCES & QUESTIONABLE EFFECTIVENESS

Making it a crime to "knowingly" introduce a defective product into the market may have a number of unintended adverse consequences, resulting in less safe products, creating a barrier to compensation in tort claims, and posing an obstacle in government investigations. Moreover, the complexity of such cases would make them unlikely to be enforced.

Less Safe Products

Criminalization of product liability may have precisely the opposite of its intended effect and lead to more dangerous products. During Congressional consideration of a proposal to criminalize product liability law in 2000, Marion

C. Blakely, who served as National Highway Safety Administrator during the Administration of President George H. W. Bush, understood this adverse effect. In an article published in the *Wall Street Journal*, Ms. Blakely wrote that such proposals "will actually lead to less safety, not more."[32]

While proponents of such an approach believe it will make corporate executives think twice about introducing a risky product, Ms. Blakely recognized that the threat of criminal liability may encourage high-level executives to avoid "knowing" anything about the risks of a product. This could discourage the investigation of potential safety hazards and encourage placing safety-related decisions in the hands of less experienced lower-level workers.[33]

In addition, 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." The author of the memorandum may ultimately be incorrect. Nevertheless, when the employee writes the memorandum, he or she demonstrates knowledge of a potential danger associated with a product, an act that has, in effect, been criminalized by the federal law and the employee may be subject to prosecution in the future. The shadow effect of an ambiguous criminal law may signal: Do not write this memo!

Criminalizing product liability could also have the unintended effect of delaying introduction of safer products. This could occur because a manufacturer might decline to produce a "new and improved" version of a product out of an overabundance of caution. Or, the company may be concerned that introducing a safer product could be viewed as an admission in a criminal prosecution that they knew that the earlier version of the product was dangerous and that it could have taken corrective action earlier.

An Obstacle to Compensation and Civil Investigations

Placing individuals who manufacture products at risk of criminal liability may delay justice for plaintiffs in personal injury cases. Cautious lawyers could advise corporate executives and employees to decline to testify in civil product liability lawsuits if their statements can be used against them in a later criminal case.[34] Ironically, the constitution's right against self incrimination could further slow down our civil justice system.

The potential for criminal liability may also impede government investigations of product-related injuries. As former Attorney General Thornburgh recognized, "with so much at stake, voluntary cooperation would likely grind to a halt, and the industry would probably stop exchanging information with government regulators."[35] Criminal lawyers will promptly advise their clients not talk to the employer or to the government because if they do, they may waive their Fifth Amendment protections. In addition, it has been noted that criminalizing product liability law could present a major disruption to productivity, as those who are designing and manufacturing products may be concerned that they need to talk with a lawyer while weighing their options.[36]

Questionable Effectiveness

Even those who theoretically support criminalizing product liability law question the effectiveness of doing so. For example, Emory University School of Law Professor Frank Vandall testified before the Senate Judiciary Committee that such criminal prosecutions would be rare due to the complexity and expense of such cases, or because low-level employees might be prosecuted but not corporate executives. Professor Vandall also expressed concern that such a law might create a "whistle-blower culture," in which large numbers of employees would complain to the press or government agencies for all manner of trivial problems with products to avoid any criminal liability. This situation could strain employer-employee relations and create a heavy expense for those in the corporation and in the government who need to sort through the complaints to determine if they express legitimate safety concerns.[37]

CONGRESS'S PAST EXPERIENCE WITH VAGUE CRIMINAL SANCTIONS AND "DEFECTIVE" PRODUCTS

Congress has explored the issue of criminalizing product liability three times in recent years. These attempts often come about in response to controversy surrounding a particular product or to gain political points by rallying for corporate accountability. In each case, however, once the unsoundness of the public policy behind such proposals was understood, Congress either rejected or decided not to pursue this course.

The TREAD Act Experience

In 2000, after a number of serious accidents resulting from the separation of the tread from certain Bridgestone/Firestone tires, Congress considered legislation called The Motor Vehicle and Motor Vehicle Equipment Defect Notification Improvement Act that sought to improve automobile safety through criminal penalties.[38] As introduced, the Act would have subjected a director, officer, or agent of a motor vehicle or motor vehicle equipment manufacturer who introduced 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 other proposals to criminalize product liability law, the legislation 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 found, in hindsight, that the executive knew of a "defect."

The bill moved quickly through the Senate Commerce Committee, receiving a favorable report in less than two weeks of introduction.[39] Soon thereafter, the problem with authorizing vague criminal penalties of this nature became apparent. Senator Jeff Sessions (R-AL), a former state attorney general, recognized from his experience as a law enforcement officer, "We are really blurring the line between criminal liability and civil liability, and that's a dangerous trend."[40]

Due to concern among Members of the Senate over criminalizing product liability, the Motor Vehicle and Motor Vehicle Equipment Defect Notification Improvement Act 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.[41] In enacting the TREAD Act, Congress, wisely, did not criminalize product liability law. Instead, it created criminal penalties for auto executives who knowingly or willfully make false or misleading statements to the Secretary of Transportation with the intent of misleading the government with respect to a potential defect; an area where an individual's and corporation's responsibility is much more clearly and objectively defined and understood.[42] It also shielded a company executive or employee from criminal penalties if he or she corrects any improper reports or failures to report within a reasonable time.[43]

The Coast Guard Authorization Act of 2004

The Coast Guard Authorization Act provides another example where Congress considered imposing criminal penalties for production of defective products—in this case recreational vessels—but instead approved legislation with much greater specificity as to the prohibited conduct. In that case, the Senate approved a fine of up to $10,000 and up to one year imprisonment for any person, director, officer, or executive employee of a corporation, who knowingly and willfully manufactured or sold a defective recreational vessel.[44] The criminal provision was amended in conference to add substantially more precision. In contrast to the original proposal, the enacted law included such penalties, but applied them only when an individual knowingly and willfully orders or authorizes the manufacture or sale of a recreational vessel with a specific defect for which it was put on notice by the government.[45] Individuals are not subject to such penalties if they can show that their action was based on a reasonable decision that the nonconformity would not cause a substantial risk of personal injury to the public and the individual advised the government in writing of his or her action.[46]

The Senate Judiciary Committee's 2006 Hearing on "Will Criminal Penalties Ensure Corporate Accountability"

The most recent Congressional foray into criminalizing product liability occurred on March 10, 2006 at a hearing of the Senate Judiciary Committee on the topic of "Defective Products: Will Criminal Penalties Ensure Corporate Accountability?"[47] Concurrently with the hearing, Chairman Arlen Specter (R-PA) circulated a draft bill "to penalize the knowing and reckless introduction of a defective product into interstate commerce."

The draft bill would have criminalized the introduction of products "known by the person to be defective" into the stream of interstate commerce. Those who do so would be subject to imprisonment of up to five years if the product causes serious bodily injury and up to fifteen years if it results in a death, in addition to monetary fines. It defined "defective" as "having a flaw 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." This definition of "defect" is very different from accepted definitions, whether under either the Second or Third Restatement of Torts or the CPSC standard. Most significantly, it provides no degree of certainty as to whether a product is defective. It is inappropriate as a criminal standard.

Senator Specter has not formally introduced the bill or revealed an intention to move it forward. Senator Specter and his colleagues used the hearing process to learn more about the relationship between criminal law and product liability. It is our hope they will reach a conclusion that the two do not mix.

IS THERE A PLACE FOR CRIMINAL LAW WITH RESPECT TO DEFECTIVE PRODUCTS?

There are already well-drafted state and federal criminal laws on the books that address some of the concerns prompting proposals to more broadly criminalize product liability. It was the belief of Senator Sessions and a number of witnesses at the most recent Senate Judiciary Committee hearing that alternatives to criminal sanctions are not needed because current state and federal criminal sanctions do their job.

State Laws

In our system of government, criminal law is largely within the purview of the states. The American Law Institute's Model Penal Code, which influenced the adoption of criminal laws of many states, provides that those who consciously disregard human life may face a felony conviction. Criminally negligent homicide, according to the Model Penal Code, occurs when a person *should* be aware of a substantial and unjustifiable risk that a person will be killed by his or her conduct.[48] The risk must be of a nature and degree that the person's failure to perceive it involves a "gross deviation from the standard of care that a reasonable person would observe in the actor's situation" and when it is practically certain that death will result.[49] In the most extreme cases, an executive or employee can be prosecuted for manslaughter, which is characterized by criminal "recklessness."[50] A person who "consciously disregards a substantial and unjustifiable risk" that it is practically certain a person will be killed by a dangerous product would be subject to a substantial criminal sentence.[51] The difference between criminal negligence and manslaughter, therefore, is whether the person should have been aware of the risk of death or whether he or she was actually aware of the risk, yet disregarded it.

Criminal negligence or recklessness requires a higher degree of culpability than in the civil context.[52] It requires more than carelessness. It requires knowledge of the danger and a conscious disregard for human life or the consequences. Moreover, the Model Penal Code provides authority for the prosecution of both individuals who engage in criminal acts on behalf of a corporation and the corporations themselves where the Board of Directors or a high managerial agent of the corporation authorized or recklessly tolerated the illegal act.[53] Most states have adopted criminal laws with respect to negligent homicide, manslaughter, and corporate responsibility that are very similar or identical to the Model Penal Code.[54]

Federal Law

Federal law provides for criminal sanctions for certain, specific acts, such as introducing an adulterated or misbranded product, making a false statement to the government, or violating established reporting requirements.

For example, the federal False Statements Act, which is generally applicable to information submitted to all government agencies, subjects a company or individual that makes statements that are not true to substantial criminal penalties.[55] Individuals who make false statements risk a fine of up to $250,000 and up to five years in prison. Corporate fines can run as high as $500,000.[56] In the case of the TREAD Act, discussed earlier, the False Statements Act's fines were incorporated into the National Highway Traffic Safety Act and its potential term of imprisonment was tripled.[57]

Corporate executives at companies that produce food or drugs are subject to criminal liability for specific violations of federal law. Section 301 of the Federal Food, Drug, and Cosmetic Act makes the introduction of an adulterated or misbranded FDA-regulated product into interstate commerce a crime, as well as a manufacturer's failure to fulfill various reporting and recordkeeping requirements.[58] Violators are subject to one year in prison and a $1,000 fine, with higher penalties for repeat offenders.[59] Rulings by the U.S. Supreme Court recognize that senior corporate officials may be at risk of criminal penalties if a subordinate violates the law with or without their knowledge. A corporate executive can be convicted of a crime even if he or she did not intentionally commit the prohibited act and even when he or she did not personally participate in the act, so long as the official had authority to prevent or correct the prohibited condition, but failed to exercise such authority.[60]

These laws, like other criminal penalties found in federal law with respect to the Consumer Product Safety Commission,[61] the Occupational Safety and Health

Administration (OSHA),[62] and the Environmental Protection Agency (EPA),[63] all prohibit well-defined conduct. Each statute has objective criteria specifying precisely when criminal penalties may be imposed. For example, the Consumer Product Safety Act requires a violation of a set standard, the manufacture or sale of a banned product, or non-compliance with established reporting requirements.[64] There is no ambiguity in such laws, which place manufacturers on notice that if they engage in certain conduct, they may go to jail. The precision of these laws is a sharp contrast to the vague standard of "knowingly" placing a "defective product" into the stream of commerce.

Some may suggest that there have not been a sufficient number of prosecutions under these laws. If these laws are not properly enforced, then the remedy is not to pass another law, but for the public to demand that government prosecutors enforce existing laws.

RESPONDING TO PROPONENTS OF CRIMINALIZATION

Well-intentioned proponents of criminalizing the knowing introduction of a defective product argue that such a law is needed for various reasons.

For example, Dr. Barry J. Maron of the Minneapolis Heart Institute testified before the Senate Judiciary Committee that he believes that such a law would encourage manufacturers of implantable heart defibrillators and other medical devices to fully disclose the risks of their products to patients, doctors, and federal regulators. Dr. Maron also wisely recognized in his own testimony that "such a bill would have to be drawn narrowly so as to not have potentially disastrous, chilling effect on law-abiding companies whose products may have occasional random defects."[65] Such criminal laws already exist in the form of state negligent homicide and manslaughter statutes, and federal laws prohibiting false reporting. Placing criminal sanctions on the vague concept of a product defect, however, is likely to deter development of and access to life-saving medical devices, which are placed in people with poor health and inherently have some failure rate.

Plaintiffs' lawyer Brian Panish also supports criminalization of product liability law.[66] In 1999, Panish obtained a then-record $4.9 billion verdict for a family that was seriously injured in a tragic accident. Panish argued that the Chevy Malibu the plaintiffs were driving was defective because it was overly susceptible to explode in rear-end collisions. Nevertheless, before jumping to the conclusion that the case supports the need for criminalizing product liability law, it should be noted that the jury was not permitted to hear that the plaintiffs had been rear-ended by a drunk driver at 70 miles per hour. Nor was the defendant, General Motors, allowed to call high-ranking public officials to rebut the plaintiffs' claim that the automaker had lobbied to limit regulations on fuel-tank safety. One might believe that the Los Angeles jury's initial award, which, at the time, surpassed the combined gross domestic product of many small countries, would have the desired effect of making companies closely consider their design decisions to promote safety. In fact, the judge thought it did so excessively and reduced the award to a "mere" $1.2 billion (the case was later settled on undisclosed terms). Again, if the evidence demonstrates that there was a conscious disregard of a known risk to human life, as Panish claims, negligent homicide and manslaughter laws exist precisely for such circumstances. There is no need for a vague and redundant federal criminal law.

Others, such as Professor Rob Steinbuch of the William H. Bowen School of Law, believe that a criminal law is necessary because civil liability reaches only the corporation itself.[67] It does not punish the corporate executive who was responsible for the company's decision making. When there is a true case of wrongdoing, it is likely that the Board of Directors or Chief Executive Officer of the corporation will take action against those responsible, particularly when their conduct hurt the company and its reputation. Again, in the case that a corporate executive knew that a product's design was nearly certain to cause death, yet the executive consciously ignored the risk to human life, existing criminal laws are available to prosecute such individuals.

CONCLUSION

While there may be specific, wrongful acts that are related to product safety, or lack thereof, that should be subject to criminal sanctions, the ambiguities of terms such as "defect" that permeate product liability law should not be placed into criminal law. When Congress considered the TREAD Act just a few years ago, this very problem was pointed out and corrected. Early bills created ambiguous sanctions; the later bills were highly specific with respect to what was deemed "wrongful conduct."

There are problems with the current product liability tort 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 conduct, judgment and innovation will outweigh any benefits such an effort to criminalize product liability law would produce.

Tort law, with all of its flaws, should be left to address product liability. Existing criminal law can, and where appropriate should, address specific crimes and punish them accordingly.

ABOUT THE AUTHORS

Victor E. Schwartz, a former Dean of the University of Cincinnati College of Law, chairs the Public Policy Group in the Washington, D.C., office of Shook, Hardy & Bacon L.L.P. He co-authors the most widely used torts casebook in the United States, *Prosser, Wade and Schwartz's Torts* (11th ed. 2005). He has served on the Advisory Committees of the American Law Institute's *Restatement of the Law of Torts: Products Liability*, *Apportionment of Liability*, and *General Principles* projects. Mr. Schwartz received his B.A. summa cum laude from Boston University and his J.D. magna cum laude from Columbia University.
Mr. Schwartz testified before the United States Senate Committee on the Judiciary on behalf of the Institute for Legal Reform in a 2006 hearing examining "Will Criminal Penalties Ensure Corporate Accountability?" The *National Law Journal* has named Mr. Schwartz one of the 100 most influential attorneys in the country.

Cary Silverman is a senior associate in the Public Policy Group. He received his B.S. in Management Science from the State University of New York College at Geneseo, and his M.P.A. and J.D. with honors from The George Washington University.

ENDNOTES

[1] *See* Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual Track System*, 88 Geo. L.J. 2167, 2071-72 (2000) (discussing Benedictin litigation); E Joseph Sanders, *From Science to Evidence: The Testimony on Causation in the Benedectin Cases*, 46 Stan. L. Rev. 1, 85 (1993) (concluding that trial verdicts and damage awards bore little relation to the weight of scientific opinion in the Bendectin cases); *see also* Peter W. Huber, Galileo's Revenge: Junk Science in the Courtroom (1991).

[2] *See* Marcia Angell, Science on Trial: The Clash of Medical Evidence and the Law in the Breast Implant Case 90-110 (1996) (authored by the executive editor of the *New England Journal of Medicine*).

[3] *See, e.g.*, *Boyce Motor Lines v. United States*, 342 U.S. 337 (1952); Stewart, *supra*

[4] *Papachristou v. Jacksonville*, 405 U.S. 156 (1972).

[5] *Ernst v. Merck & Co.*, Cause No. 19961*BH02 (Dist. Ct. of Brazoria County, Tex., plaintiff verdict issued Aug. 19, 2005).

[6] *Humeston v. Merck & Co.*, Docket No. ATL-L-2272-03 (N.J. Super. Ct., Atlantic County, defense verdict issued Nov. 4, 2006).

[7] *Humeston v. Merck & Co.,* Docket No. ATL-L-2272-03 (N.J. Super. Ct., Atlantic County, defense verdict set aside Aug. 2006).

[8] *Plunkett v. Merck & Co.*, No. 05-4046 (E.D. La., mistrial declared Dec. 12, 2006) (the Louisiana court conducted the trial in Texas due to damage from Hurricane Katrina).

[9] *Plunkett v. Merck & Co.*, Docket No. 05-4046 (E.D. La., defense verdict Feb. 17, 2006).

[10] *Cona v. Merck & Co.*, Docket No. ATL-L-3553-05 (N.J. Super. Ct., Atlantic County, defense verdict issued Apr. 6, 2006); *McDarby v. Merck & Co.*, Docket No. ATL-L-1296-05 (N.J. Super. Ct., Atlantic County, plaintiff verdict issued Apr. 6, 2006).

[11] *Garza v. Merck & Co.*, Cause No. 7:05-cv-00017 (Dist. Ct., Starr County, Tex., plaintiff verdict issued Apr. 24, 2006) (the verdict was reduced to $7.75 million after applying the state's limit on punitive damages). *See* Alex Berenson, *Jury Award Is Big Disappointment for Merck*, N.Y. Times, Apr. 21, 2006 (reporting that the plaintiff's heart attack was caused by his no more than 25-day use of the drug was also questionable given that he had a previous quadruple bypass, and he was a smoker, overweight, and had high blood pressure).

[12] *Doherty v. Merck & Co.*, Docket No. ATL-L-0638-05 (N.J. Super. Ct., Atlantic County, verdict issued July 13, 2006).

[13] *Grossberg v. Merck & Co.*, Docket No. BC 327729, (Cal. Super. Ct., Los Angeles County, verdict issued Aug. 2, 2006).

[14] *Barnett v. Merck & Co.*, No. 06-485 (E.D. La., plaintiff verdict issued Aug. 17, 2006).

[15] Order & Reasons, *In re Vioxx Prods. Liab. Litig.*, MDL No. 1657, *relating to Barnett v. Merck & Co.*, No. 06-485 (E.D. La. Aug. 30, 2006).

[16] *Papachristou*, 405 U.S. at 162.

[17] *See* Restatement Third, Torts: Products Liability § 2 (1998).

[18] *Id.* § 2(a).

[19] *Id.* § 2(b).

[20] *Id.* § 2(c).

[21] *See id.* § 2 cmt. d (providing a summary of the many tests and factor considered in determining defect design adopted in the states).

[22] Consumer Product Safety Commission, *Substantial Product Hazard Reports, Proposed Revision to Interpretive Rule*, 71 Fed. Reg. 30350 (daily ed. May 26, 2006).

[23] 16 C.F.R § 1115.4.

[24] 71 Fed. Reg. at 30351.

[25] *See, e.g.*, Draft Bill, 109th Cong, 1st Sess., § 1 (2006) (presented for purposes of discussion by Senator Arlen Specter at the Judiciary Committee hearing on Mar. 10, 2006).

[26] *See, e.g.*, *id.*

[27] Dick Thornburgh, *Sue, But Don't Prosecute*, N.Y. Times, Sept. 20, 2000.

[28] *See, e.g.*, Draft Bill, *supra*, § 1.

[29] Victor E. Schwartz, Mark A. Behrens & Joseph P. Mastrosimone, *Reining in Punitive Damages "Run Wild": Proposals for Reform By Courts and Legislatures*, 65 Brooklyn L. Rev. 1003, 1007 (2000).

[30] *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)).

[31] *See State Farm Mut. Auto. Ins. Co v. Campbell*, 38 U.S. 408 (2003); *Cooper Industries, Inc., v. Leatherman Tool Group Inc.*, 532 U.S. 424, 433 (2001); *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996); *TXO Production Corp. v. Alliance Resources Corp.*, 509 U.S. 443 (1993); *Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991).

[32] Marion C. Blakely, *Criminalizing Auto Defects is Unsafe*, Wall St. J., Sept. 26, 2000.

[33] *See id.*

[34] Testimony of John Engler, President, National Association of Manufacturers, Defective Products: Will Criminal Penalties Ensure Corporate Accountability?, Before the Committee on the Judiciary, U.S. Senate, Mar. 10, 2006, at 9-10.

[35] Thornburgh, *supra*.

[36] *Supra* note 34.

[37] Testimony of Frank Vandall, Professor, Emory School of Law, Defective Products: Will Criminal Penalties Ensure Corporate Accountability?, Before the U.S. Senate Committee on the Judiciary, Mar. 10, 2006.

[38] S. 3059, 105th Cong., 2d Sess. (2000).

[39] *See* Motor Vehicle and Motor Vehicle Equipment Defect Notification Improvement Act, Report of the Committee on Commerce, Science, and Transportation on S. 3059, S. Rep. No. 106-423 (2000).

[40] Steven A. Holmes, *Transportation Spending Bill is Approved*, N.Y. Times, Oct. 7, 2000, at C14 (quoting Senator Jeff Sessions).

[41] Pub. L. No. 106-414.

[42] *See* Transportation Recall Enhancement, Accountability, and Documentation (TREAD) Act, Report of the Committee on Commerce to accompany H.R. 5164, H. Rep. No. 106-954, at 14-15(2000); 49 U.S.C. § 30170.

[43] 49 U.S.C. § 30170(a)(2).

[44] Coast Guard Authorization Act of 2004, H.R.2443, § 310, 108th Cong., 2d Sess. (2004) (engrossed amendment as agreed to by Senate).

[45] Coast Guard and Maritime Transportation Act of 2004, Pub. L. No. 108-293, § 406 (codified at 46 U.S.C. § 4311(b)).

[46] *Id.*

[47] Hearing agenda and testimony available online at http://judiciary.senate.gov/hearing.cfm?id=1792.

[48] Model Penal Code §§ 2.02(2)(d), 210.4

[49] *Id.* § 2.02(d).

[50] *Id.* § 210.3(1)(a).

[51] *Id.* § 2.02(2)(c).

[52] *See generally* Laura Dietz, et al., 40 Am. Jur.2d Homicide § 85 (2006) ("Degree of negligence required.); C.T. Foster, *Test of Criterion of Term "Culpable Negligence," "Criminal Negligence," or "Gross Negligence," Appearing in Statute Defining or Governing Manslaughter*, 161 A.L.R. 10 (1946 & Supp.).

[53] Model Penal Code § 2.07.

[54] *See, e.g.*, Ark. Stat. §§ 5-2-202, 5-2-502, 5-2-503, 5-10-105; Colo. Stat. §§ 18-1-501, 18-3-104, 18-3-105; Ky. Rev. Stat. §§ 501.020, 502.050, 502.060, 507.040, 507.050; Mo. Rev. Stat. §§ 562.016, 562.056, 562.061, 565.024; Pa. Consol. Stat. tit. 18, §§ 302, 2504; Tenn. Code §§ 39-11-302, 39-11-404, 39-11-405, 39-13-212, 39-13-215.

[55] 18 U.S.C. § 1001.

[56] 18 U.S.C. § 3571.

[57] *See* 49 U.S.C. § 30170.

[58] 21 U.S.C. § 301.

[59] 21 U.S.C. § 303.

[60] *See United States v. Park*, 421 U.S. 658, 670 (1975) (affirming conviction of president of a large national food chain charged with violating the Federal, Food, Drug and Cosmetic Act because food warehouses were contaminated by rodents and the conditions had not been remedied after warning, where defendant was aware of the incident and had been informed that one of the corporate vice presidents was investigating and correcting the problem); *United States v. Dotterweich*, 320 U.S. 277, 280-86 (1943) (affirming conviction of the president of a corporate pharmaceutical distributor charged with misbranding and adulterating drugs under the Federal Food, Drug and Cosmetic Act as an aider and abettor where there was no proof offered to suggest that the president knew that the drugs had been adulterated or mislabeled and no evidence that he had participated in any criminal conduct).

[61] *See* 15 U.S.C. §§ 2068, 2070.

[62] *See* 29 U.S.C. § 666(e) (providing that any employer who willfully violates certain OSHA standards, rules, or orders, and that violation causes death to any employee, is subject to a fine of up to $10,000 or imprisonment for not more than six months, or by both; and doubles the fine and term of imprisonment for repeat violators).

[63] *See, e.g.*, Clean Water Act, 33 U.S.C. § 1319(c) (providing criminal penalties for discharging pollutants without a permit or in violation of a permit, providing enhanced penalties for violations involving "knowing endangerment," and providing criminal penalties for making false statements in government reports and filings); Resource Conservation and Recovery Act (RCRA), 42 U.S.C. § 6928(d) (providing criminal penalties for knowingly transporting hazardous waste to a facility that does not have a permit, knowingly treating, storing, or disposing of hazardous waste without having a permit, or knowingly disposing of hazardous waste in violation of a permit, condition, or applicable regulation, and for knowingly filing documents containing materially false statements, knowingly destroying, altering, or concealing required reports, knowingly transporting hazardous waste without a manifest, or knowingly treating, storing, or disposing of used oil without having obtained a permit or in violation of a permit or applicable regulation); Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), 42 U.S.C. § 9603(b) (providing criminal penalties for failing to notify the government of the releases of hazardous substances above a certain threshold levels).

[64] 15 U.S.C. §§ 2068, 2070.

[65] Testimony of Barry J. Maron, MD, Director, Hypertrophic Cadriomyopathy Center, Minneapolis Heart Institute, Need for Reform in the Medical Device (Implantable Defibrillator) Industry, Before the U.S. Senate Committee on the Judiciary, Mar. 10, 2006.

[66] Testimony of Brian J. Panish, Partner, Shea & Boyle LLP, Defective Products: Will Criminal Penalties Ensure Corporate Accountability?, Before the U.S. Senate Committee on the Judiciary, Mar. 10, 2006.

[67] Testimony of Rob Steinbuch, Professor, William H. Bowen School of Law, Defective Products: Will Criminal Penalties Ensure Corporate Accountability?, Before the U.S. Senate Committee on the Judiciary, Mar. 10, 2006. There are good reasons why the civil liability of corporations is not imposed individually on its officers and employees. Indeed, one of the public policy purposes of corporations, distinct entities that are legally recognized by the state, is to protect the managers and directors who run them from personal liability for their decisions. If this were not the case, then many experienced individuals would be extremely hesitant to take leadership in corporations (for-profit or non-profit, for that matter) because their life savings and those of their family would be put at risk, in addition to the corporate bank account, for the corporation's business contractual obligations and tort liability. The same is true should criminal liability extend to executives who make decisions in reliance on the recommendations and data supplied by numerous actors engaging in risk-benefit and risk-risk analyses when designing products.

U.S. Chamber Institute for Legal Reform
1615 H Street, N.W.
Washington, DC 20062-2000
Tel: 202-463-5724 | Fax: 202-463-5302
www.instituteforlegalreform.org