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**PUNITIVE DAMAGES AND COMPLIANCE WITH
REGULATORY STANDARDS:
SHOULD A MANUFACTURER OR
SERVICE PROVIDER BE PUNISHED WHEN
IT FOLLOWS THE LAW?**

VICTOR E. SCHWARTZ
CARY SILVERMAN

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**NATIONAL LEGAL CENTER
FOR THE PUBLIC INTEREST**

1600 K Street, N.W., Suite 800

Washington, D.C. 20006

Tel: (202) 466-9360

Fax: (202) 466-9366

E-mail: info@nlcpi.org

Please visit our Web site at: www.nlcpi.org

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PREFACE

Congress and state legislatures have charged government agencies with ensuring that products are safe for public use and that services are provided in a manner that adequately protects consumers. Government regulations provide standards for the design of automobiles, airplanes, construction equipment, bicycle helmets, swimming pools, lawn mowers, automatic garage doors, ladders and scaffolding, workplace protection, pacifiers and rattles, and even matchbooks. The Food and Drug Administration (FDA) specifically approves each prescription drug and medical device as safe and effective before patients can benefit from what can be life-saving treatments. Insurers, public utilities, financial services, and other industries are subject to extensive government oversight. Nevertheless, injuries can occur and lawsuits challenging the design of products as “unreasonably dangerous” or the provision of services as unfair or deceptive may result.

How should courts weigh a product or service’s compliance with government safety regulations or its approval by an agency in deciding negligence, product liability, and consumer protection claims? Currently, many states treat government requirements as mere minimum standards, just another factor that juries are free to consider or disregard. Several states provide greater deference to the authority and expertise of government agencies and provide a rebuttable presumption that a product is not defective if it meets safety requirements. Other states, in the context of products approved by the FDA, do not permit courts to inflict quasi-criminal punishment on a manufacturer, through a punitive damage award, when it has followed the law in designing or gaining and maintaining approval of its product.

The authors of this monograph address the important tort law and public policy issues at play when products and services that meet government safety standards are challenged in court. They point out that government standards are arrived at only after broad consideration of risks and benefits, public participation, data collection, and expert analysis. They suggest that courts, which do not have similar information, expertise, or staff at its disposal, should provide greater deference to government agencies. The authors examine the history and purpose of punitive damages and conclude that, as a matter of fairness and public policy, businesses should not be punished when they fulfill the standards required of them.

Like all other publications of the National Legal Center, this monograph is presented to encourage a greater understanding of the law and its processes. The views expressed in the monograph are those of the authors and do not necessarily reflect the opinions of the advisors, officers, or directors of the Center.

Richard A. Hauser
President
National Legal Center

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**PUNITIVE DAMAGES AND COMPLIANCE WITH
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CARY SILVERMAN

INTRODUCTION

It is a clear sunny day. Dan is driving 60 miles an hour in a 65 mile per hour speed zone. He is wearing his required prescription glasses. All of his headlights, taillights, and blinkers are functioning. His seat belt is securely fastened. Dan's license and registration are valid, his car recently passed state inspection, and he carries more than state-mandated level of insurance. He has no out-standing tickets, and he even recently updated his address at the Department of Motor Vehicles. Dan had a beer with lunch, but is not near the legal definition of "under the influence." He is trying to drive carefully, but nevertheless gets into an accident. The facts indicate that Dan might have avoided the accident if he had driven more slowly and worn sunglasses. In our legal system, Dan may be subject to civil liability and he may be responsible for paying the medical expenses and property damage resulting from the accident. But should the state treat Dan as a criminal? Most people would answer, "no." After all, Dan was following the law.

In the situation described above, each government requirement was reached after a balancing of public policy considerations. For instance, while the state could have set the speed limit at 55 miles per hour, it was the view of Congress that states should be permitted to allow drivers to drive faster. In Dan's state, public officials found that the convenience of allowing drivers to drive as fast as 65 miles per hour exceeded the risk of more accidents. In addition, regulatory agencies charged with protecting transportation safety in Dan's state could have required that

drivers wear sunglasses on bright sunny days or that vehicle windshields include tinted glass, but chose not to do so. Likewise, Dan's state has said it is legal to drive with a blood alcohol content level of less than .07. The state could have set a zero tolerance policy, but that might result in problems for people using prescription drugs, or it could result in people ignoring the law or lack of enforcement. A lower threshold also might result in more drunk driving as irresponsible drivers consider that they are subject to punishment no matter how little, or how much, alcohol they consume. Should an accident or series of accidents require a rethinking of a government standard, a state legislature or agency can and should change the law.

A similar scenario occurs in the civil justice system, where punitive damages are the clear equivalent of state-imposed criminal sanctions. After reviewing the history and purpose of punitive damages, this monograph considers whether it is appropriate to impose punitive damages when a business has complied with all government rules, regulations, and standards, but, nevertheless, an injury results. This situation is placed in the public spotlight most often in lawsuits involving Food and Drug Administration (FDA)-approved prescription drugs and medical devices. Manufacturers of a wide range of products as well as service providers, however, can be subject to punitive damages even when they meet all government requirements. This white paper suggests that courts and legislators follow sound public policy and not allow state-imposed quasi-criminal punishment upon businesses and individuals who follow the law.

OVERVIEW OF PUNITIVE DAMAGES

The Purpose of Punitive Damages

Ordinary civil or tort law damages generally fall into two categories, compensatory and punitive. Compensatory damages provide reimbursement for economic losses, such as lost wages, medical expenses, and other measurable out-of-pocket expenses resulting from an injury. Compensatory damages also can provide payment for non-economic injuries, such as pain and suffering, that are not easy to quantify.

Punitive damages developed and continue to serve a very different, but important function. They were an auxiliary to the criminal law to help ensure that persons who committed wrongful criminal acts paid a price for their bad conduct, even if the government did not have the time or resources to prosecute these acts. Punitive damages are not awarded to compensate for a harm.¹ Rather, they are “private fines levied by civil juries to punish reprehensible conduct and to deter its future occurrence.”² Thus, the purpose of punitive damages is “to further the aims of the criminal law.”³ They are awarded to teach the defendant not to “do it again.”⁴

Although punitive damages are awarded in civil cases between private parties, punitive damages are, in fact, punishment by the state. State means are used to enforce punitive damages, the same way state means are used to enforce the criminal law or government action and civil fines. The sting is the same, sometimes it is more so, because punitive damages—especially when they are large—generate a great deal of adverse publicity for a defendant. Although state power is used to enforce punitive damage awards, most constitutional rights that protect criminal defendants, such as the right to have a claim proven beyond a reasonable doubt or the privilege against self incrimination, do not apply to defendants who are subject to punitive damages. These are basic reasons why both state courts and legislatures should work to ensure the punitive damage system is fair.

A Brief History of Punitive Damages

Punitive damages were first recognized by the English common law in the mid-eighteenth century in two cases involving illegal searches and seizures by

officers of the Crown, *Huckle v. Money*⁵ and *Wilkes v. Wood*.⁶ It was in these cases that English courts expressed for the first time that a “jury shall have it in their power to give damages for more than the injury received . . . as punishment to the guilty, to deter from any such proceeding in the future, and as proof of the detestation of the jury to the action itself.”⁷

Historically, in England and then America, punitive damages were available only in a small class of lawsuits, “the traditional intentional torts,” designed to punish an individual’s purposeful bad act against another.⁸ Punitive damages were confined solely to purposeful, wrongful acts, such as assault, battery, malicious prosecution, and false imprisonment.⁹ Punitive damages were imposed once on a defendant. They also were never larger than compensatory awards, and usually less.

In the late 1960s, American courts radically expanded the availability of punitive damages beyond the traditional intentional torts.¹⁰ Lesser misconduct now could result in punishment. “Reckless disregard” became a popular standard for punitive damages liability;¹¹ even “gross negligence” became enough to support a punitive damages award in some states.¹² A number of states instituted the “triple trigger” approach of “willful, wanton, or gross misconduct,” providing plaintiffs with three separate paths to obtain punitive damages.¹³ In addition, the advent of “mass tort” litigation resulted in an increase of punitive damages claims against manufacturers,¹⁴ including the possibility of repeated imposition of punitive damages for an alleged risk in a *single* product line or a *single* decision.¹⁵

Changes in punitive damages law and practice have impacted both the incidence and size of punitive damages verdicts. As United States Supreme Court Justice Sandra Day O’Connor recognized in 1993, “As little as 30 years ago, punitive damages were ‘rarely assessed’ and usually ‘small in amount.’”¹⁶ Until 1976, for example, there were only three reported appellate court decisions upholding awards of punitive damages in product liability cases, and the punitive damages award in each case was modest in proportion to the compensatory damages awarded.¹⁷ By the late 1970s and early 1980s, “unprecedented numbers of punitive awards in product liability and other mass tort situations began to surface,”¹⁸ and the size of punitive damage awards

THE CROSSROADS OF REGULATORY STANDARDS, LIABILITY, AND PUNITIVE DAMAGES

“increased dramatically.”¹⁹ These trends have led the United States Supreme Court to express concern that punitive damages in this country are “sky-rocketing”²⁰ and have “run wild.”²¹

State Reforms Are Rooted in the Quasi-Criminal Nature of Punitive Damages

In recent years, states have responded by enacting various punitive damages reform laws.²² Each of these reforms is rooted in the origin of punitive damages as a quasi-criminal penalty and the principles of fairness understood in that context.

For example, most states, either by court decision or legislation, have chosen to require plaintiffs to establish proof of punitive damages liability by “clear and convincing evidence.”²³ This middle-ground standard falls between the ordinary civil law “preponderance of the evidence” standard and the criminal law standard of “beyond a reasonable doubt.” The District of Columbia and Maryland restrict punitive damages awards to cases in which the defendant acted with “actual malice,”²⁴ reflecting the intentional tort origins of punitive damages.

Other states have addressed the problem of runaway punitive damages by limiting the amount that can be imposed. This method reflects the importance of proportionality in consideration of the validity of criminal punishment.²⁵ These statutory limits vary from Colorado, where punitive damages may not exceed compensatory damages, to Kansas, where punitive damages are limited to the lesser of \$5 million or the defendant’s annual gross income.²⁶ The most common approach is to limit punitive damage awards to the greater of (1) a ratio of the plaintiff’s compensatory damages award (e.g., two times compensatory damages or three times compensatory damages) or (2) a dollar amount set by law (e.g., \$250,000).²⁷

Finally, some states have adopted a procedural reform called “bifurcation” to prevent evidence that is highly prejudicial and relevant only to the issue of punishment from being heard by jurors and improperly considered when they are determining basic liability.²⁸

Federal and state regulatory agencies are charged with overseeing various aspects of public safety ranging from automobile and aircraft design, to the marketing of prescription drugs and medical devices, to workplace practices. Agencies issue safety regulations that often are the result of extensive public notice and comment, industry participation, and consideration by experts.

Government regulators are charged with protecting the public interest by approving practices and setting standards in a variety of industries. For example, state insurance departments license insurance agents and brokers, regulate rates, and approve policy provisions as reasonable, fair, and understandable. The FDA approves and monitors prescription drugs and medical devices as safe and effective. State and federal agencies closely regulate rates and terms provided by public utility companies. The National Highway Traffic Safety Administration (NHTSA) has closely researched and developed Federal Motor Vehicle Safety Standards that require vehicles to meet crash-worthiness standards. These regulations require seat belts, airbags, windshields, headlights and signals, door beams, roofs, steering columns, tires, and door locks, latches, and hinges to meet certain safety performance standards.²⁹ In each of these areas, government policy makers consult with experts, evaluate data, engage in a risk-benefit analysis, and consider public comment in their decision making.

Nearly any product or service can be made safer in some respect. Often, measuring “safety” is a complex judgment. A product made safer for some situations, may become more dangerous in others. For instance, an enclosed forklift may protect its operator from falling out, but the Occupational Health and Safety Administration (OSHA) recommends an open design because the ability to exit quickly in the case of an emergency is more important to the operator’s safety.³⁰ Even when incorporation of a safety device would increase overall safety, in some cases, adding the extra device may not be financially practical or desirable for the consumer. For example, if the addition of a safety device will significantly increase

the cost of the product, consumers might be unable to afford to purchase it or feel that the nominal reduction in the risk of injury does not warrant the higher price. These consumers might be drawn to purchase a less-safe product of a competitor. Likewise, if additional disclosures to consumers in credit or insurance agreements are likely to detract the purchaser from more important information or discourage reading the fine print at all, then they may be counterproductive. This is the type of balancing for which government agencies are in the best position to accomplish when they set regulatory standards.

Current Treatment of Regulatory Standards and Approvals

Regardless of whether a manufacturer meets the design requirements of a government agency and even when a product is used in a manner that is in compliance with federal or state safety regulations, a manufacturer can be sued in a negligence or a strict product liability action. Such lawsuits claim that a reasonably prudent manufacturer would have done more to protect product users or that the product was “unreasonably dangerous” because of its design or failure to warn of a known risk. Plaintiffs also may seek punitive damages by claiming that the manufacturer recklessly released the product for public use when it knew of a risk of injury. Likewise, insurers and other service providers can face punishment even when its practices were approved by regulators charged with protecting the public interest.³¹

In absence of a statute instructing courts how to weigh compliance with a government safety standard or product or service approval, states vary on how they consider such evidence. Most courts find that compliance with government standards is just one of many factors to be considered by the jury in determining whether or not a product is unreasonably dangerous.³² These courts reason that government regulations provide only “minimum standards,” and, therefore, are not dispositive.³³ On the other hand, most jurisdictions consider violation of a safety regulation as evidence that a product is defective as a matter of law, but do not accord evidence of compliance with government regulations similarly deferential treatment.³⁴

In some cases, courts have accorded weight to government safety standards and approvals, even if it finds compliance is not conclusive of liability.³⁵ Courts occasionally find that meeting a safety standard set by government regulations precludes tort liability.³⁶ For example, the Court of Appeals of Maryland has recognized that “where no special circumstances require extra caution, a court may find that conformity to the statutory standard amounts to due care as a matter of law.”³⁷ The RESTATEMENT (THIRD) recognizes that courts frequently cite compliance with safety regulations is a factor used to justify a directed verdict for a defendant.³⁸

Liability v. Punitive Damages

Some scholars argue that when a product complies with government safety standards or is licensed or otherwise approved by a state or federal agency, the manufacturer should not be subject to any liability.³⁹ This monograph does not address that issue, but argues in support of a modest reform, eliminating punitive damages for products and services that have been approved by regulators.⁴⁰

For example, in 1991, the American Law Institute, a well-respected organization composed of judges, lawyers, and law professors, published a study recommending that compliance with regulatory requirements imposed by a government agency preclude tort liability in certain situations. Under the ALI’s recommendation, tort liability would be precluded when (1) a legislature has placed the risk at issue under the authority of a specialized administrative agency; (2) that agency has established and periodically revises regulatory safety controls; (3) the manufacturer or other entity complied with the relevant regulatory standards; and (4) the manufacturer or other entity disclosed to the agency any material information in its possession or of which it has reason to be aware concerning the products’ risks and means of controlling them.⁴¹

The RESTATEMENT (THIRD) incorporates a similar approach. It suggests that a product should not be considered defective as a matter of law “when the safety standard or regulation was promulgated recently, thus supplying currency to the standard therein established; when the specific standard addresses the very issue of product design or warning

presented in the case before the court; and when the court is confident that the deliberative process by which the safety standard was established was full, fair, and thorough and reflected substantial expertise.”⁴² Conversely, the RESTATEMENT (THIRD) acknowledges that this liability protection would not apply “when the deliberative process that led to the safety standard . . . was tainted by the supplying of false information to, or the withholding of necessary and valid information from, the agency that promulgated the standard or certified or approved the product.”⁴³

Those who view regulatory standards as simply setting the floor for a minimum level of safety object to providing full liability protection to a manufacturer that meets government standards, even when limiting the protection to those that meet the above criteria. Opponents of limiting tort liability might argue that a reasonable manufacturer or service provider that knows of a risk should do more to address it than required by law, even if a government agency charged with protecting the public knows of the risk and determined such measures.

There are legitimate arguments on both sides with respect to liability for compensatory damages when a product or service is in compliance with government standards, particularly in situations when consumer protection regulations are not precise. Those favoring and opposing the potential for liability should be able to agree that, as a matter of public policy, it is unfair to impose the equivalent of *criminal punishment* on a business whose product or service complied with government regulations, but nonetheless resulted in an injury.

SEVERAL STATES GIVE WEIGHT TO COMPLIANCE WITH SAFETY STANDARDS

Several state legislatures addressed this public policy issue by adopting statutes that respect the decision making of federal and state regulatory agencies charged with protecting public safety in tort lawsuits. There are generally two types of laws, which vary in their scope.

The first category of laws are those with broad applicability to any product governed by government safety regulations. These types of statutes have been invoked in cases involving a wide range of products,

including ladders,⁴⁴ nail guns,⁴⁵ cleaning products,⁴⁶ clothing,⁴⁷ airplanes,⁴⁸ and automobiles.⁴⁹ These laws generally provide a presumption that a product is not unreasonably dangerous if it meets safety requirements, thus reducing the potential for a finding of liability. The second category of laws are those that specifically address products approved by the FDA, such as prescription drugs and medical devices, where government review is particularly thorough and demanding. Most of these laws limit the availability of punitive damages when a manufacturer has met all FDA requirements.

State Laws Providing a Rebuttable Presumption of Nondefectiveness

Six states provide that compliance with federal or state government safety regulations creates a rebuttable presumption that a product is not defective. For example, since 1977, Colorado law has provided:

(1) In any product liability action, it shall be rebuttably presumed that the product which caused the injury, death, or property damage was not defective and that the manufacturer or seller thereof was not negligent if the product . . . [c]omplied with, at the time of sale by the manufacturer, any applicable code, standard, or regulation adopted or promulgated by the United States or of this state.⁵⁰

Kansas, Kentucky, Michigan, Tennessee, and Utah have chosen similar routes.⁵¹

There are several variations of “rebuttable presumption” laws. In Colorado and Kentucky, a rebuttable presumption of nonliability may arise in other situations, such as when the product conforms to the “state of the art.” Several states provide a contrary presumption of liability when a product fails to conform to government safety standards. Finally, some state laws provide similar or greater protection where a product’s design was in compliance with a specific government contract.

At least two additional states, Arkansas and Washington, specifically provide by statute that parties may introduce evidence of regulatory compliance to show that a product is not defective or

that its warnings are not inadequate.⁵² These statutes do not assign any particular evidentiary weight to compliance with safety standards.

These laws help ensure that courts allow juries to hear and appropriately consider a product's compliance with government standards when they consider whether the product is defective. It also gives the jury a broader understanding of whether the manufacturer's conduct reaches a level justifying punishment. Those that provide for a rebuttable presumption ensure that the jury will receive a specific instruction emphasizing the importance of considering the manufacturer's compliance with government safety standards in determining whether a product was unreasonably dangerous.

While regulatory compliance statutes do not specifically address punitive damages, they can be influential when a court or a jury makes an assessment as to whether punitive damages are warranted. For example, in a case decided under Kansas law, the question at issue was whether the seat-belt system in the front seat of the Mazda Protégé was defective.⁵³ The basis of the claim was that Mazda should have known that some drivers do not use manual lap belts, that it had actual knowledge that use of a shoulder harness alone increased risk of injury, and it nevertheless "willfully and wantonly" failed to warn consumers about the increased risk. The plaintiff sought compensatory and punitive damages. The court found that Mazda demonstrated that the vehicle satisfied Federal Motor Vehicle Safety Standards for occupant crash protection. In granting the manufacturer's motion for summary judgment, the court found that "a reasonable jury could not find the defendants to have acted in reckless disregard of consumer safety," required for an award of punitive damages.⁵⁴ In reaching its decision, the court emphasized the occupant protection system's compliance with various federal safety requirements.

Even after a state legislature enacts a regulatory compliance presumption, the judiciary must faithfully apply the law in a manner that respects the regulatory body charged with protecting the safety of consumers or workers. This is not always the case. For example, Tennessee courts construe the state's regulatory compliance statute to provide a rebuttable presumption instruction to the jury only when the regulation at issue is directed specifically at the

manufacturer.⁵⁵ For this reason, Tennessee courts have found that a product's compliance with OSHA regulations may not give rise to a rebuttable presumption when the regulation focuses on the conduct of the employer or employee, rather than the manufacturer.

Consider, for instance, this application of the law. It is well known that when a tire is improperly inflated and assembled to the rim, there is a risk of a tire explosion that can seriously harm or kill a worker. Understanding this risk and seeking to help those who assemble its products to avoid accidents, Firestone and other rim manufacturers had petitioned OSHA for an industrywide standard for servicing rims and worked closely with OSHA to develop the regulations. OSHA then adopted regulations requiring inflating the tires in an inflation cage and staying out of the trajectory of the wheel to the extent possible. Firestone also worked with OSHA to develop a wall chart on the procedures required by the regulations to be disseminated to employees. In a case in which a tire exploded and the employee claimed the tire was defective in that it has a proclivity to separate from the rim, the trial court instructed the jury that "compliance with OSHA regulations creates a presumption that the FL wheel was not unreasonably dangerous as to those standards only, which presumption may be overcome by competent evidence."⁵⁶ This guidance was provided after the court also instructed the jury that the statute "does not mean the FL wheels were not defective" and "testimony about the regulations is merely evidence of a minimum standard established by the federal government."⁵⁷ The jury found for the manufacturer.

Despite the trial court's very limited instruction to give some deference to the federal safety standard relevant to the case, Tennessee's highest court reversed and required a new trial, finding that the instruction was improperly given. The court found that the OSHA regulations regulated employers, not manufacturers, and thus a manufacturer could not obtain the benefit of the presumption.⁵⁸ The court reached this outcome even though the regulations involved the safe assembly of the manufacturer's product and required the manufacturer to distribute warnings by developing rim manuals for OSHA to distribute to employers.⁵⁹ The court also ruled that, despite the safety standard, the trial court erred in

providing a directed verdict in Firestone's favor on the plaintiffs' punitive damage claim, finding that reasonable minds could differ as to whether the manufacturer acted in a reckless or fraudulent manner in manufacturing the rim despite its knowledge of the risk of injury during assembly.⁶⁰ As one justice protested in dissent, it is difficult to understand how these circumstances present "the most egregious of cases" warranting punitive damages or include any clear and convincing evidence of any "intentional, fraudulent, malicious or reckless conduct by the Defendant."⁶¹

State Laws Eliminating Punitive Damages When a Manufacturer Fulfills FDA Requirements

The second type of statutes address products specifically approved for safety and effectiveness by the FDA. Special considerations come into play when lawsuits charge that a prescription drug or medical device is unreasonably dangerous when the FDA approved the product at issue after a rigorous review that can span thousands of hours over more than a decade.⁶² Six states have enacted statutes addressing liability for FDA-approved products.

Regulation of prescription drugs provides a compelling example of where punitive damages are unwarranted if a manufacturer has complied with all pre- and post-marketing regulatory requirements.⁶³ Scholars argue that the overlap in federal regulation and tort liability stems research and development of new and effective drugs, increases the public's wait time to benefit from new treatments, results in the withdrawal of beneficial products from the market, and can result in product shortages and unnecessary and duplicative administrative costs.⁶⁴ They also point out that the FDA's judgment is based on expertise and science, and thus is more reliable than a lay jury and reflects the societal benefits and risks of a drug, rather than the injury in a specific case.⁶⁵

The prescription drug market is closely controlled by federal regulations. First, every prescription drug, for some class of patients, could be considered a "miracle cure." It saves their lives, enhances their well-being, or provides hope where hope was lacking. Second, every prescription drug has potential side effects and unavoidable negative reactions in a limited number of patients. Those risks

can be very serious. Where a system is fraught with winners and losers, fashioning the right balance between regulation and liability for governing it can involve complicated legal, medical, and moral issues. Through its New Drug Application (NDA) approval process, the FDA carefully balances the risks and benefits of each prescription drug to ensure that each is safe and effective for public use.⁶⁶ As one commentator has recognized, "In fulfilling its mission to monitor and control the safety and efficacy of drugs, the Agency continually walks a razor's edge between two opposing risks—premature approval of dangerous drugs and undue delay in making safe, effective, and medically useful drugs available to the public."⁶⁷

The NDA process includes study by the pharmaceutical manufacturer, early laboratory and animal testing, and then clinical testing using human subjects.⁶⁸ An NDA often spans more than 100,000 pages and describes the impact of the drug in several hundred to several thousand patients.⁶⁹ It generally includes detailed information on the chemistry, manufacturing, and control of the drug; samples; clinical data and patient information; its use in children; reports of adverse reactions; proposed packaging and labeling; and other pertinent materials.⁷⁰

The FDA's Center for Drug Evaluation and Research (CDER) employs more than 1700 medical doctors, toxicologists, pharmacologists, epidemiologists, chemists, and statisticians to ensure that safe and effective drugs are available to the American public.⁷¹ Through the NDA process, the FDA finds that a prescription drug is "safe and effective."⁷² Specifically, the regulations provide that the FDA will exercise its scientific judgment to approve an application "after it determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling."⁷³ The FDA also examines whether the proposed labeling meets the specific requirements of federal regulations.⁷⁴ Manufacturers must meet these extensive and detailed standards before marketing a prescription drug to the public. From start to finish, the process of bringing a drug to a patient's bedside takes well over a decade and costs an average of \$800 million.⁷⁵

Five states have enacted statutes that provide immunity from punitive damage liability to drug manufacturers whose products are approved or licensed by the FDA. Although these state laws are similar, they vary from state to state in the products to which they apply and the circumstances under which punitive damages remain available.

New Jersey, Oregon, and Ohio appear to be the first states to adopt such laws in 1987. The New Jersey law prohibits punitive damages when a drug, device, food, or food additive was approved or licensed by the FDA or is generally recognized as safe and effective under FDA regulations.⁷⁶ The New Jersey law also applies to claims that labeling was insufficient when the packaging or labeling was in compliance with the FDA's approval. Punitive damages remain available if it is shown that a manufacturer "knowingly withheld or misrepresented information" required to be submitted to the FDA, and that information was "material and relevant" to the injury in the case.

Oregon law differs from New Jersey law in three respects.⁷⁷ First, it applies only to FDA-approved drugs, and does not extend to medical devices, food, and food additives. Second, it provides an additional ground by which punitive damages remain available: when a manufacturer intentionally fails to conduct a recall ordered by a state or federal agency. Finally, the Oregon law provides that the plaintiff must show the manufacturer's misconduct in violating FDA regulations by clear and convincing evidence, as required for an award of punitive damages generally.

As first enacted in 1987, Ohio law contained similar protections and exemptions.⁷⁸ In 2005, the Ohio legislature expanded coverage of the statute to include medical devices and over-the-counter drugs in addition to prescription drugs.⁷⁹ Ohio law also provides other procedural protections for the availability of punitive damages in product liability cases, such as requiring the conduct of the manufacturer to be in "flagrant disregard of the safety of persons who might be harmed by the product" and having the court decide the amount of punitive damages upon a jury verdict finding punitive damages appropriate.⁸⁰ Ohio, unlike Oregon, specifically provides that a plaintiff may meet his or her burden to show the manufacturer's misconduct in failing to

provide information to the FDA by the lower preponderance-of-the-evidence standard.

Arizona and Utah followed New Jersey, Oregon, and Ohio when they passed laws addressing punitive damages in cases involving FDA-approved or licensed products in 1989.⁸¹ Both laws limit protection from punitive damages to FDA-approved drugs, including its packaging and labeling. In addition, both allow plaintiffs to obtain punitive damages only if they show by clear and convincing evidence that the manufacturer withheld from or misrepresented to the FDA information relevant to the plaintiff's injury.

In Michigan, a state that does not recognize punitive damages, state law limits a manufacturer's liability for compensatory damages in product liability actions involving FDA-approved drugs. Michigan law provides a rebuttable presumption that a drug, including its labeling and packaging, is not defective or unreasonably dangerous if the drug is approved for safety and efficacy by the FDA.⁸² Under Michigan law, this presumption would not apply if the drug was sold after an FDA product recall or withdrawal of approval, the defendant intentionally withheld or misrepresented information to the FDA, or the defendant bribed a public official.

It is inaccurate to call this an "FDA-approval" defense in the sense that it would not completely eliminate liability (except in Michigan), nor would its elimination of punitive damages be simply based on the stamp of an FDA approval. FDA approval of a prescription drug would be insufficient to merit such treatment, as the agency relies on the manufacturer to complete and submit all of the extensive testing required by its regulations, and the FDA's approval is based primarily on this data. In addition, FDA regulations require submission of certain information after approval of the drug, such as adverse reaction reports, which allow it to determine whether its approval should be withdrawn and the product recalled. The protection from punitive damages would only apply when the manufacturer has met all of these requirements. Thus, these laws encourage pharmaceutical companies to fully disclose all pre- and post-marketing data and meet and exceed the agency's requirements in order to qualify for protection from extensive punitive damages should it

later be found that the risks of the drug outweighed its therapeutic benefits.

**THE PUBLIC POLICY PURPOSE OF
PRECLUDING PUNITIVE DAMAGES WHEN A
PRODUCT OR SERVICE MEETS
GOVERNMENT STANDARDS**

As this monograph shows, it is unfair and unsound public policy to impose the equivalent of criminal punishment on a business when it provides a product or service that is approved by regulators and meets the standards set by the government.

Government standards should be given strong deference in tort litigation in consideration of institutional expertise and competence in making decisions about very complex issues. In developing product safety and consumer protection regulations, government agencies evaluate scientific literature, test results, and the state of technological development. FDA takes a holistic approach to product safety, ensuring that a device that increases safety in one situation does not make the product substantially more dangerous in another. It examines proposed services to ensure that they are broadly in the public interest. The government agency considers public comment from stake-holders, including consumer groups, businesses, and the general public. It then adopts safety standards and approves products and services based on its expert evaluation of the universe of information available and may need to make sensitive balancing decisions as to the appropriate level of safety and consumer protection requirements. Government regulations provide clear expectations to manufacturers and employers in the design and use of products, and to service providers in their practices.

The tort system does not have comparable resources when it determines liability. The court is generally limited to considering the particular issue raised by the litigants before it. It does not consider the wider impact of its decision, such as the risk-benefit and risk-risk trade-offs carefully evaluated by regulatory agencies. The tort system does not include the broad participation from which the regulatory process benefits, nor do lay judges and juries have the expertise or the staff of an administrative agency. Its decisions are imposed retroactively on a case-by-case

basis, leaving the potential for conflicting rulings from different courts, and creating confusion and unpredictability for manufacturers, service providers, and employers.⁸³

Furthermore, imposing such liability creates tension and conflict between the judiciary and the public policy goals of the legislative branch. This occurs when a government agency finds that a product is safe for the public if it meets certain standards, yet a court finds that the same product meeting those requirements is “unreasonabl[y] dangerous.” When punitive damages are at issue, the court disrespects the government agency further by considering whether placing a product deemed safe by the agency in the market constitutes such malicious conduct to warrant quasi-criminal punishment. The same can occur in service industries, where, for example, regulators find that a particular practice is in the public interest, but a local court disagrees and imposes punitive damages on a provider for that very conduct.⁸⁴

In addition to these reasons of fairness and respect for regulatory expertise, there are practical reasons to preclude punitive damages in such cases. Government standards currently provide a “stick,” but often full compliance comes without a corresponding “carrot.” For instance, a failure to comply with government standards is usually considered sufficient to impose liability if there is a causal relationship between the breach and the plaintiff’s injury. On the other hand, a manufacturer that complies with a regulatory safety standard often is considered as simply providing a minimal floor-level of safety, and the evidence of this compliance may either not be admissible in court or not accorded the same degree of respect as its compliance.

Eliminating the potential for punitive damages provides a useful carrot. As with any law or regulation, there are gray areas as to the definition of full compliance. Assuring businesses and individuals that compliance with government regulations comes with protection from what can amount to unlimited liability encourages them to take the extra steps to meet and go beyond government standards. That may be one reason why no state that limits punitive or even compensatory damages when a product complies with FDA standards has ever repealed any part of it.

It contravenes the fundamentals of our system of “equal justice under law” when state courts through the mechanism of punitive damages punish lawful conduct. Punitive damages do not provide compensation for any injury and come into play only after a jury has awarded damages for medical expenses, pain and suffering, or other financial losses. When punitive damages no longer serve to reprimand or deter bad conduct, they provide nothing more than a windfall to plaintiffs and their attorneys. An employer hit with a punitive damage verdict after doing all the law requires may be deterred only in the sense of selling what may be a beneficial product or service, or it may consider withdrawing from the industry or U.S. market entirely. In addition, unwarranted punitive damages increase the costs, which are passed on to consumers in the form of higher prices, insurance premiums, and rates. For example, liability imposed on vaccine manufacturers that disregard the FDA’s risk-benefit analysis caused many manufacturers to leave the market.⁸⁵ Beneficial drugs have been removed from the market because fear of liability and litigation costs.⁸⁶

Even prominent members of the personal injury bar agree with this concept. For example, advertisements placed along a highway by the Texas Trial Lawyers Association, which is composed of some of the toughest, most effective personal injury lawyers in America, stated: “Punitive damages are needed to punish corporate criminals.” This may be true because law enforcement mechanisms are sometimes overwhelmed with more serious cases and do not have time to punish wrongful, criminal corporate acts. If a corporation has complied with the law and manufactures a product or provides a service that meets the government’s standards, it is difficult, as a matter of public policy, to see why it should be punished. No matter how emotional the arguments might be, it is not sound public policy to punish a company that has complied with the legal rules.

Finally, the government should maintain some level of accountability. If safety standards and regulatory approvals are truly insufficient to protect the public, then the legislature or the administrative

agency should intervene to increase the level of protection. Likewise, if an agency approval of a specific product or service for the public does not mean what it says, then the government should increase the level of scrutiny in the review process or expand its monitoring of the market.

COURTS AND LEGISLATURES SHOULD ACT

This white paper supports two principles. First, courts should provide greater weight to actions taken by federal and state regulatory bodies acting in the public interest when deciding tort lawsuits involving products or services under that agency’s jurisdiction. Legislatures can encourage courts to provide this due deference by enacting statutes that provide a rebuttable presumption that products that fulfill government safety requirements are not defective. Likewise, service providers should be entitled to a similar presumption in private consumer protection litigation when regulators have approved the practice at issue in the lawsuit as serving the public interest. This is not an absolute defense to liability, but helps ensure that courts give the consideration they deserve to standards and approvals reached by experts and policy makers after extensive public participation and evaluation of scientific data, risk, and benefits.

Second, when a business follows the law, it should not be subject to quasi-criminal punishment. Punitive damages should be reserved for the most egregious of circumstances. They should not be available in a case against a manufacturer where its product meets the safety standards provided by a government agency or where a service provider’s practices were subject to close regulatory oversight. Courts should find that punitive damages are not available as a matter of law in such cases because the facts cannot possibly rise to the level of wrongful conduct justifying this harsh sanction. Punitive damages in these situations do not advance public policy goals, namely, they lack any deterrent value. Legislatures can add fairness, predictability, and consistency to the law by adopting legislation precluding punitive damages in such circumstances.

¹Shepherd Components, Inc. v. Brice Petrides-Donohue & Assocs., Inc., 473 N.W.2d 612, 619 (Iowa 1991) (“punitive damages are not intended to be compensatory and . . . a plaintiff is a fortuitous beneficiary of a punitive damage award simply because there is no one else to receive it”) (citing Berenger v. Hatt, 314 N.W.2d 388, 391 (Iowa 1982)).

²Gertz v. Robert Welch, Inc., 418 U.S. 323, 350 (1974).

³Browning-Ferris Indus. v. Kelco Disposal, 492 U.S. 257, 297 (1989) (O’Connor, J., concurring in part and dissenting in part) (quoting Banker’s Life & Cas. Co. v. Crenshaw, 486 U.S. 71, 87 (1988) (Brennan, J., dissenting)).

⁴W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 2, at 9 (5th ed. 1984).

⁵95 Eng. Rep. 768 (C.P. 1763).

⁶98 Eng. Rep. 489 (C.P. 1763).

⁷Wilkes, 98 Eng. Rep. at 498-99 (emphasis added).

⁸See Victor E. Schwartz et al., *Reining in Punitive Damages “Run Wild”: Proposals for Punitive Damages Reform By Courts and Legislatures*, 65 BROOK. L. REV. 1003, 1006-07 (1999).

⁹*Id.* at 1007 (citations omitted).

¹⁰In 1967, a California Court of Appeal held for the first time that punitive damages were recoverable in a strict product liability action. *See Toole v. Richardson-Merrell, Inc.*, 251 Cal. App. 2d 689, 60 Cal. Rptr. 398 (1967).

¹¹*See, e.g.*, UTAH CODE ANN. § 78-18-1(1)(a) (2002) (“willful and malicious or intentionally fraudulent conduct, or conduct that manifests a knowing and reckless indifference toward, and a disregard of, the rights of others”).

¹²*See, e.g.*, Wisker v. Hart, 766 P.2d 168 (Kan. 1988) (“gross negligence”).

¹³*See* FLA. STAT. § 768.73(1)(a) (2002); *see also* MISS. CODE ANN. § 11-1-65(1)(a) (2002) (authorizing punitive damages for “gross negligence which evidences a willful, wanton or reckless disregard for the safety of others”).

¹⁴“Mass tort” litigation began in the late 1960s with cases involving the sale of the anticholesterol drug MER/29. *See* Paul D. Rheingold, *The MER/29 Story - An Instance of Successful Mass Disaster Litigation*, 56 CAL. L. REV. 116 (1968); Roginsky v. Richardson-Merrell, Inc., 378 F.2d 832 (2d Cir. 1967).

¹⁵Schwartz et al., *supra* note 8, at 1029-34. *See generally* Mark A. Behrens & Barry M. Parsons, *Responsible Public Policy Demands an End to the Hemorrhaging Effect of Punitive Damages in Asbestos Cases*, 6 TEX. REV. L. & POL. 137 (2001).

¹⁶TXO Prod. Corp. v. Alliance Res. Corp., 509 U.S. 443, 500-01 (1993) (O’Connor, J., dissenting) (citations omitted).

¹⁷*See* Gillham v. Admiral Corp., 523 F.2d 102 (6th Cir. 1975) (\$125,000 compensatory damages, \$50,000 attorneys’ fees, \$100,000 punitive damages); *Toole v. Richardson-Merrell, Inc.*, 251 Cal. App. 2d 689 (1967) (\$175,000 compensatory, \$250,000 punitive damages); *Moore v. Jewel Tea Co.*, 253 N.E.2d 636 (Ill. App. 1969) (\$920,000 compensatory damages, \$10,000 punitive damages), *aff’d*, 263 N.E.2d 103 (Ill. 1970).

¹⁸John Calvin Jeffries, Jr., *A Comment on the Constitutionality of Punitive Damages*, 72 VA. L. REV. 139, 142 (1986); *see also* Philip Borowsky & Lee K. Nicolaisen, *Punitive Damages in California: The Integrity of Jury Verdicts*, 17 U.S.F. L. REV. 147, 150 (1983) (noting trend of “juries . . . award[ing] substantial punitive damages with increasing frequency”).

¹⁹George L. Priest, *Punitive Damages and Enterprise Liability*, 56 S. CAL. L. REV. 123, 123 (1982).

²⁰*Browning Ferris*, 492 U.S. at 280 (O’Connor, J., concurring in part and dissenting in part).

²¹*Pac. Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1, 18 (1991).

²²*See* Schwartz et al., *supra* note 8, at 1003. Louisiana, Massachusetts, Michigan, Nebraska, New Hampshire, and Washington do not recognize punitive damages. *See* PRODUCT LIABILITY DESK REFERENCE - A FIFTY STATE COMPENDIUM (Morton Daller ed., 2001).

²³*See* Schwartz et al., *supra* note 8, at 1015. Colorado requires proof “beyond a reasonable doubt” to support an award of punitive damages. *See* COLO. REV. STAT. § 13-25-127(2) (2004).

²⁴*See* Jonathan Woodner, Co. v. Breeden, 665 A.2d 929 (D.C. 1995); *Owens-Ill. v. Zenobia*, 601 A.2d 633 (Md. 1992).

²⁵*See* Solem v. Helm, 463 U.S. 277, 284 (1983) (“The principle that a punishment should be proportionate to the crime is deeply rooted and frequently repeated in common-law jurisprudence.”); *Weems v. United States*, 217 U.S. 349, 366-67 (1910) (it is “a precept of the fundamental law” as well as “a precept of justice that punishment should be graduated and proportioned to the offense”).

²⁶COLO. REV. STAT. § 13-21-102(1)(A)(2004); KAN. STAT. ANN. § 60-3701(e)-(f) (2004).

²⁷*See, e.g.*, FLA. STAT. ANN. § 768.73 (2005); IND. CODE ANN. §§ 34-51-3-2, 34-51-3-4; (2005) NEV. REV. STAT. ANN. § 42.005 (2004); N.C. GEN. STAT. § 1D-25(B) (2004).

²⁸*See, e.g.*, CAL. CIV. CODE § 3295(d) (West 2005); MINN. STAT. ANN. § 549.20 (2005); MISS. CODE ANN. § 11-1-65(1) (2005); *see also* *Transp. Ins. Co. v. Moriel*, 879 S.W.2d 10 (Tex. 1994); *Hodges v. S.C. Toof & Co.*, 833 S.W.2d 896 (Tenn. 1992).

²⁹*See* 49 C.F.R. pt. 571; *see also* National Highway Traffic Safety Admin., <<http://www.nhtsa.gov/>>.

³⁰*See* 29 C.F.R. § 1910.178 (adopting by reference the American National Standards Institute’s Powered Industrial Truck for design and construction of forklifts, which recommends against operator enclosures because “rapid and unobstructed ingress or egress for the operator is considered more desirable”).

³¹For example, *Avery v. State Farm* challenged an insurer’s practice of using nonoriginal equipment manufacturer (non-OEM) parts to repair damaged vehicles. This practice was permitted in all jurisdictions at issue. In fact, some states required the availability of generic auto parts to keep costs down. Nevertheless, the nationwide class action lawsuit resulted in a \$1.2 billion award, including

\$600 million in punitive damages. This decision was made over the objections of the National Association of Insurance Commissioners, numerous state attorneys general, and the Center for Auto Safety and Public Citizen. The award is currently on appeal. *See* Victor E. Schwartz & Leah Lorber, *State Farm v. Avery: tate Court Regulation Through Litigation Has Gone Too Far*, 33 CONN. L. REV. 1215 (2001).

³²*See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 Rpt., Note, cmt. (d) (1998) [hereinafter RESTATEMENT (THIRD)].

³³*See* Richard C. Ausness, *The Case for a Strong Regulatory Compliance Defense*, 55 MD. L. REV. 1210, 1241-47 (1996) (providing examples of cases in which courts gave little weight to federal safety regulations spanning a variety of areas, such as flammability standards for clothing, pesticide warnings, automobile design, prescription drug warnings, aircraft design, and workplace safety standards).

³⁴*See id.*

³⁵*See, e.g.*, *Sims v. Washex Mach. Corp.*, 932 S.W.2d 559 (Tex. App. 1995) (“Compliance with government regulations is strong evidence, although not conclusive, that a machine was not defectively designed.”).

³⁶*See, e.g.*, *Lorenz v. Celotex Corp.*, 896 F.2d 148 (5th Cir. 1990) (compliance with safety regulation is strong and substantial evidence of lack of defect); *Ramirez v. Plough, Inc.*, 863 P.2d 167, 176 (Cal. 1993) (concluding that “the prudent course is to adopt for tort purposes the existing legislative and administrative standard of care”); *Dentson v. Eddins & Lee Bus Sales, Inc.*, 491 So. 2d 942, 944 (Ala. 1986) (ruling that a school bus that is not equipped with seat belts is not defective when the legislature has not required seat belts).

³⁷*Beatty v. Trailmaster Prods., Inc.*, 625 A.2d 1005, 1014 (Md. 1993).

³⁸*See* RESTATEMENT (THIRD), *supra* note 32, at § 7 cmt. e (citing *Hawkins v. Evans Cooperage Co.*, 766 F.2d 904, 909 (5th Cir. 1985)).

³⁹*See, e.g.*, Ausness, *supra* note 33, at 1253-57 (arguing “a regulatory compliance defense must fully protect manufacturers from liability when their products [are] meeting applicable federal design, testing, or labeling requirements”).

⁴⁰*See* Mike France et al., *How to Fix the Tort System*, BUSINESSWEEK ONLINE, Mar. 4, 2005, available at <http://www.businessweek.com/magazine/content/05_11/b3924601.htm> (last visited Mar. 9, 2005) (“The long and involved process of winning over the FDA or NHTSA should, at a minimum, insulate managers from claims that they deserve huge financial penalties for wantonly disregarding the public good (unless executives lied to bureaucrats.)”).

⁴¹*See* 2 AM. LAW INST., REPORTER’S STUDY, ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY 96-97 (1991); *see also* Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual Track System*, 88 GEO. L.J. 2167, 2168-70 (2000).

⁴²*See* RESTATEMENT (THIRD), *supra* note 32, at § 4 cmt. e.

⁴³*See id.*

⁴⁴*See* *States v. R.D. Werner Co.*, 799 P.2d 427 (Colo. Ct. App. 1990) (ruling that the trial court did not err by admitting expert testimony on a ladder’s compliance with federal regulations).

⁴⁵*See* *Slisze v. Stanley-Bostitch*, 979 P.2d 317 (Utah 1999) (ruling that federal OSHA standards regulating the design of a pneumatic nailer were admissible as government standards and established a rebuttable presumption of non-defectiveness as they provided “a legitimate source for determining the standard of reasonable care”).

⁴⁶*See* *Uptain v. Huntington Lab, Inc.*, 685 P.2d 218 (Colo. Ct. App. 1984) (finding that manufacturer of a cleaning compound was entitled to presumption of nondefectiveness where an expert testified that the product label’s warnings complied with federal and local laws and was approved by the Environmental Protection Agency).

⁴⁷*See* *Alvarado v. J.C. Penney Co.*, 735 F. Supp. 371 (D. Kan. 1990) (in a case involving a nightgown and robe that were ignited by a open flame gas heater, ruling that the regulatory compliance provision of the Kansas Products Liability Act did not create a conclusive presumption and thus a constitutional challenge by plaintiffs was moot).

⁴⁸*See* *Champlain Enterprises, Inc. v. United States*, 957 F. Supp. 26 (N.D.N.Y. 1997) (ruling that regulatory compliance provision of the Kansas Products Liability Act would provide airplane manufacturer with a defense against liability if it established that the aircraft complied with government safety standards unless the plaintiff shows that “a reasonably prudent product seller could and would have taken additional precautions”).

⁴⁹*See* *Brand v. Mazda Motor Corp.*, 978 F. Supp. 1382, 1387-88, 1391-93 (D. Kan. 1997) (ruling that automobile manufacturer’s compliance with federal regulatory standards was not dispositive of liability or punitive damages absent clear and convincing evidence that the manufacturer acted with reckless indifference to consumer safety).

⁵⁰COLO. REV. STAT. ANN. § 13-21-403(1) (West 2004).

⁵¹KAN. STAT. ANN. § 60-3304(a) (2004); KY. REV. STAT. ANN. § 411.310(2) (Banks-Baldwin 2004); MICH. COMP. LAWS § 600.2946(4) (2004); TENN. CODE ANN. § 29-28-104 (2004); UTAH CODE ANN. § 78-15-6(3) (2004).

⁵²*See* ARK. CODE ANN. § 16-116-105(a) (West 2004); WASH. REV. CODE ANN. § 7.72.050(1) (West 2004).

⁵³*Brand*, 978 F. Supp. at 1385.

⁵⁴*Id.* at 1394.

⁵⁵*See* *Hughes v. Lumbermens Mut. Casualty Co.*, 2 S.W.3d 218 (Tenn. 1999).

⁵⁶*Id.* at 223.

⁵⁷*Id.*

⁵⁸See *id.* at 223-25.

⁵⁹The Court of Appeals of Tennessee issued a similar ruling in *Tuggle v. Raymond Corp.*, 868 S.W.2d 621 (Tenn. 1992), where a plaintiff thrown from a forklift sued the manufacturer. The plaintiff claimed the forklift was unreasonably dangerous because it included an open back rather than an enclosure for the operator. The court of appeals upheld the trial court's refusal to instruct the jury that forklift complied with OSHA design standards. See *id.* at 625. Those standards recommended against operator enclosures because unobstructed ingress and egress is considered vital to operator safety. See *id.* at 624. As in the case of the tire inflation procedures, the court found that OSHA regulations applied only to employers, not manufacturers. See *id.* at 625.

⁶⁰See *id.* at 227.

⁶¹*Id.* at 227-28 (Goddard, J., concurring in part and dissenting in part).

⁶²See Henry I. Miller, *Failed FDA Reform*, 21 REG. 24 (1998) (attributing an increase in cost for new drug development and approval from \$359 million to \$500 million—in pretax 1990 dollars—between 1990 and 1993, and an increase in the time for approval from 8.1 years to 15.2 years since the 1960s to the “FDA’s regulatory zeal”).

⁶³Medical devices are subject to a similarly rigorous review.

⁶⁴See Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REFORM 461, 466-67 (1997).

⁶⁵See *id.* at 467-68.

⁶⁶See generally 21 C.F.R. pt. 314 (2004).

⁶⁷Steven R. Salbu, *The FDA and Public Access to New Drugs: Appropriate Levels of Scrutiny in the Wake of HIV, AIDS, and the Diet Drug Debacle*, 79 B.U. L. REV. 93, 96 (1999).

⁶⁸FDA, CENTER FOR DRUG EVALUATION AND RESEARCH, THE CDER HANDBOOK 5 (1998), available at <<http://www.fda.gov/cder/handbook/>> (last visited Mar. 1, 2005) [hereinafter CDER HANDBOOK].

⁶⁹See *Grundberg v. Upjohn Co.*, 813 P.2d 89, 96 (Utah 1991).

⁷⁰21 U.S.C. § 355(b); 21 C.F.R. §§ 314.50 (providing the required content and format of an NDA), 314.55 (requiring assessment of safety and effectiveness in pediatric subpopulations); see also CDER HANDBOOK, *supra* note 68, at 21.

⁷¹See Daniel Carpenter & A. Mark Fendrick, *Accelerating Approval Times for New Drugs in the U.S.*, 15 REG. AFFAIRS J. 411 (2004), available at <<http://people.hmdc.harvard.edu/~dcarpent/acceleration-raj.pdf>> (last visited Mar. 1, 2005). CDER staff has increased by more than 50% between 1980 and 2000, from approximately 1100 to 1700 employees. See *id.*

⁷²21 C.F.R. § 314.2.

⁷³21 C.F.R. § 314.105(c).

⁷⁴See generally 21 C.F.R. pt. 201 (2004).

⁷⁵U.S. Food & Drug Admin., *Strategic Action Plan, Protecting and Advancing America’s Health: Responding to New Challenges and Opportunities*, Aug. 2003, available at <<http://www.fda.gov/oc/mcclellan/strategic.html>> (last visited Mar. 1, 2005). The price of bringing a new drug to market has increased rapidly over the past decade. See *id.* (noting that the cost more than doubled over the past decade).

⁷⁶N.J. STAT. ANN. § 2A:58C-5c (West 2004).

⁷⁷OR. REV. STAT. § 0.927 (2004).

⁷⁸OHIO REV. CODE ANN. § 2307.80(C) (Anderson 2004).

⁷⁹OHIO LAWS FILE 144 (Am. Sub. S.B. 80) (2005) (amending OHIO REV. CODE ANN. § 2307.80) (effective Apr. 7, 2005).

⁸⁰OHIO REV. CODE ANN. § 2307.80(A), (B).

⁸¹ARIZ. REV. STAT. ANN. § 12-701(A) (West 2004); UTAH CODE ANN. § 78-18-2(1) (2004).

⁸²See MICH. COMP. LAWS § 600.2946(5) (2004).

⁸³For a more comprehensive discussion of the benefits of government regulation over tort liability, see Ausness, *supra* note 33, at 1210, 1217-24.

⁸⁴See generally PETER A. BISBECOS & VICTOR E. SCHWARTZ, THE DAMAGING EFFECT OF REGULATION OF INSURANCE BY THE COURTS (NAMIC 2003), available at <http://www.namic.org/pdf/CJR_22JULY2003.pdf>; see also Schwartz & Lorber, *supra* note 31, at 1217-18.

⁸⁵See Stewart, *supra* note 41, at 2167, 2172.

⁸⁶See *id.* at 2171 (discussing the withdrawal from the market of Bendectin, an antinausea morning sickness pill because of litigation costs despite the lack of evidence linking the drug to limb defects); see also Editorial, *Drug Twilight Zone*, WALL. ST. J., Mar. 2, 2005, at A16 (commenting on the withdrawal of the multiple sclerosis drug Tysabri from the U.S. market following two reported side effects because of fear of liability, despite FDA experts’ position that the agency “continues to believe Tysabri offers great hope to MS patients”).