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Peter L. Kahn

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REGULATION AND SIMPLE ARITHMETIC: SHIFTING THE PERSPECTIVE ON TORT REFORM

PETER L. KAHN*

In this Article, Professor Peter Kahn questions the common assumption that removal or limitation of health and safety regulation would result in significant savings to society or to regulated industries. The presence of modern products liability law, he argues, considerably offsets the potential benefits of deregulation and largely offsets the impact of health and safety regulation on the economy. Furthermore, Professor Kahn asserts that the interaction of products liability law with health and safety regulation has led to the overstatement of the cost of governmental involvement in promoting product safety.

According to Professor Kahn, this interaction has for the most part been ignored in prior analyses of both regulation and tort law. He argues that empirical studies of the cost of regulation have not taken the role of liability law into account, and for that reason, have significantly overstated the true cost of regulation.

Because the cost of health and safety regulation is largely or entirely offset by the presence of tort law, Professor Kahn suggests there are previously unexplored opportunities for reform of governmental efforts to ensure product safety. He argues that health and safety regulation imposes little cost on the American economy, yet could improve the rationality and lower the cost of the tort system. Professor Kahn posits that proposals to reduce the role of tort law, for example through the proposed regulatory compliance defense or through an enhanced scope for preemption, risk rendering product safety law ineffective. On the other hand, Professor Kahn concludes that efforts to improve the tort system by enhancing regulatory efforts avoid this risk, impose little cost, and provide the possibility of a significantly improved tort system.

* Assistant Professor of Law, Columbus School of Law, Catholic University of America, Washington, D.C. I would like to thank Linz Audain, Harold McDougall, Shira Perlmutter, and Martin White for their suggestions and insights. I also owe a debt of thanks to Kathryn Kelly sharing with me her time, her energy, and for her encyclopedic knowledge of the law of torts. All remaining errors are very much my own.

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The number of workplace deaths and injuries [is] down in both absolute terms and as a population-adjusted rate. How much of this decline can be attributed to the deterrent effects of the tort system, how much to government regulation, how much to the regime of worker's compensation, and how much to changes in managerial or technological culture and practices is interesting and important to know. Something is causing it. Knowledge of what causes desirable changes would be a valuable guide to do-

ing even better through law reform. Without such knowledge, reforms are shots in the dark.¹

I. INTRODUCTION

Despite the massive attention once focused on the high costs of social regulation² and the decade-long ascendancy of a presidential administration committed to removing or limiting it,³ the political wars of the 1980s left largely untouched direct federal regulation of health and safety.⁴ Indeed, such regulation is no longer the subject of widespread political controversy. Attention has shifted from regulation to the tort system, and to efforts to limit its reach and stringency.⁵ There is a simple reason for this shift of focus: given the existence of the tort system in its present form, health and safety regulation imposes little or no cost on the American economy.

The Consumer Product Safety Commission (CPSC), the Food and Drug Administration (FDA), the National Highway Traffic Safety Administration (NHTSA), and a variety of other federal agencies,⁶ for all their efforts, have seen many of their safety rules overtaken, amplified, and extended by modern products liability law.⁷ Issues peripheral to but not directly addressed by regulatory mandates have themselves been the subject

1. Michael J. Saks, *Do We Really Know Anything About the Behavior of the Tort Litigation System—And Why Not?*, 140 U. PA. L. REV. 1147, 1178 (1992).

2. See, e.g., ROBERT W. CRANDALL, *CONTROLLING INDUSTRIAL POLLUTION* 32-57 (1983).

3. See, e.g., Christopher DeMuth, *Regulation, Productivity, and the Reagan Administration's Regulatory Program*, in *REGULATORY REFORM RECONSIDERED* 21 (Gregory A. Daneke & David J. Lemak eds., 1985); Christopher C. DeMuth & Douglas H. Ginsburg, *White House Review of Agency Rulemaking*, 99 HARV. L. REV. 1075, 1075-76 (1986); Thomas O. McGarity, *Regulatory Reform in the Reagan Era*, 45 MD. L. REV. 253, 254 (1986).

4. See IAN AYRES & JOHN BRAITHWAITE, *RESPONSIVE REGULATION: TRANSCENDING THE DEREGULATION DEBATE* 7-11 (1992); Robert W. Crandall, *Whatever Happened to Deregulation?*, in *ASSESSING THE REAGAN YEARS* 271 (David Boaz ed., 1988).

5. See, e.g., David Frum, *Sanity Is Back in Style*, FORBES, Aug. 2, 1993, at 62, 62 (discussing tort reform during 1993); Gary Lee, *Corporate Lobby Tries to Create 'Big Mo' on Product Liability Bill*, WASH. POST, July 29, 1991, at A9 (discussing tort reform at the federal level and citing increase in congressional support for limitations on products liability); *The Tort Movement's Progress Across the Nation*, NAT'L L.J., Nov. 9, 1992, at 35, 35 (discussing the accomplishments of the tort reform movement as of 1992).

6. The federal agencies concerned with issues of health and safety also include the Environmental Protection Agency, the Federal Trade Commission, the Federal Aviation Administration, the Food Safety and Inspection Service of the United States Department of Agriculture, the Mine Safety and Health Administration of the United States Department of Labor, and the Nuclear Regulatory Commission. The Environmental Protection Agency administers the Federal Insecticide, Fungicide and Rodenticide Act, which can give rise to private liability in tort. See, e.g., *Riden v. ICI Americas, Inc.*, 763 F. Supp. 1500, 1503-06 (W.D. Mo. 1991); *Cox v. Velsicol Chem. Corp.*, 704 F. Supp. 85, 86-87 (E.D. Pa. 1989); *Roberts v. Dow Chem. Co.*, 702 F. Supp. 195, 197-99 (N.D. Ill. 1988); *Little v. Dow Chem. Co.*, 559 N.Y.S.2d 788, 788 (Sup. Ct. 1990).

7. To take just one example, courts have held that virtually all of the National Highway Traffic Safety Administration's Federal Motor Vehicle Safety Standards (FMVSS) pertaining to crash protection and passenger survivability are no more demanding, and in most cases less de-

of products liability litigation.⁸ Although workplace safety issues regulated by the Occupational Safety and Health Administration (OSHA) are insulated from the tort system by state workers' compensation systems, the threat of third-party litigation against equipment suppliers imposes a considerable measure of tort control over the workplace environment.⁹ In general, the safety precautions required of regulated parties to limit potential tort liability are often as great or greater than those required by the express regulatory mandates which they face. In addition, the potential damage awards resulting from tort actions are considerably greater in most cases than the civil penalties wielded by the regulatory agencies.

In many cases, therefore, the regulatory system imposes little incremental cost. With or without federal mandates, most regulatory requirements would be met anyway because of private efforts to limit tort liability. Indeed, the tort reform movement's expressed interest in establishing a regulatory-compliance defense¹⁰ and the newfound willingness of the federal courts to find that federal regulatory legislation preempts state tort actions¹¹ suggest that regulation is less costly than tort law—certainly less costly to the regulated parties.

Empirical studies of the cost of regulation largely ignored the relationship between tort law and federal regulation.¹² For that reason, these studies overstated the costs of regulation, and possibly its benefits as well. As this Article demonstrates, a correct understanding of regulatory costs—indeed, the understanding of costs otherwise generally used in cost-benefit,

manding, than the standards applied in products liability actions against automobile manufacturers. See *infra* note 152.

8. See, e.g., *Perry v. Mercedes-Benz of N. Am.*, 957 F.2d 1257, 1259-62 (5th Cir. 1992) (alleging the impact trigger of airbag to be a design defect).

9. Although workplace safety problems are most directly handled through the workers' compensation system rather than through the tort system, they can nevertheless give rise to tort litigation against equipment manufacturers. See, e.g., *Wagner v. Firestone Tire & Rubber Co.*, 890 F.2d 652, 653 (3d Cir. 1989); *Hale v. Firestone Tire & Rubber Co.*, 820 F.2d 928, 931 (8th Cir. 1987); *Baughman v. General Motors Corp.*, 627 F. Supp. 871, 872 (D.S.C. 1985); *Spencer v. Ford Motor Co.*, 367 N.W.2d 393, 395 (Mich. App. 1984); *Wolf v. Goodyear Tire & Rubber Co.*, 808 S.W.2d 868, 869-70 (Mo. 1991).

10. See James A. Henderson, Jr., *Judicial Review of Manufacturers' Conscious Design Choices: The Limits of Adjudication*, 73 COLUM. L. REV. 1531, 1555, 1574-75 (1973); Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 283-85 (1985); Timothy Wilton & Richard P. Campbell, *Effect of Federal Safety Regulations on Crashworthiness Litigation*, 22 TORT & INS. L.J. 554, 558 (1987).

11. For a discussion of "the current spate of cases finding preemption" and the federal courts' recent "questionable eagerness to find preemption," see Paul Sherman, *Uses of Federal Statutes in State Negligence Per Se Actions*, 13 WHITTIER L. REV. 831, 860, 906 (1992).

12. See, e.g., 1 THE AMERICAN LAW INSTITUTE, COMPENSATION AND LIABILITY FOR PRODUCT AND PROCESS INJURIES 289 (Proposed Final Report Council Draft No. 1, 1990) [hereinafter COMPENSATION AND LIABILITY].

analysis—compels accounting for the tort environment in empirical measurements of the effects of regulation.

The studies of regulatory costs on which regulatory policy has been based for a decade implicitly assumed that the institutional environment was otherwise unchanged as social regulation was imposed during the late 1960s and 1970s. In fact, of course, the institutional environment was undergoing a not-so-quiet revolution¹³ in the form of a burgeoning products liability system, which imposed costly demands on private parties. These massive changes in tort law occurred generally contemporaneously with the inception of modern social regulation. The methodology of these studies, which depended on coincidences in time between the imposition of regulation and changes in industry behavior, swept both sets of changes into a single moment, measured together as one event. Thus, the measured cost of regulations, imposed at the same time the tort environment changed, includes the cost of *both* the new regulations and the changes in tort law. These measured costs are an overestimate, perhaps of considerable magnitude, of the actual costs imposed by the regulations alone.

One implication of this failure to account for tort law is that the anticipated benefits of deregulation were considerably greater than the benefits that could actually be achieved. Because tort law became more activist at the same time social regulation was imposed, efforts to measure the cost of the regulation often captured the combined effect of both sets of institutional developments. Yet deregulation largely focused on reversing only one. Given the new, more activist tort environment, a loosening of regulatory requirements would have had little impact on the behavior of regulated private parties. Indeed, if tort law had led private parties to take *all* the precautions demanded by health and safety regulation, a loosening of formal regulation would have resulted in *no* reduction in the costs of compliance with those requirements. Yet because of empirical studies that suggested vast costs for regulation alone, equally vast benefits were anticipated from deregulation. The inability to achieve those benefits through early deregulatory efforts suggests one possible explanation for the apparent abandonment of health and safety deregulation as a political goal.¹⁴

13. For a description of the development of modern products liability law in rather revolutionary terms, see PETER W. HUBER, *LIABILITY: THE LEGAL REVOLUTION AND ITS CONSEQUENCES* 19-32 (1988).

14. For a somewhat similar explanation of the failure to achieve deregulation, see Robert E. McCormick et al., *The Disinterest in Deregulation*, 74 *AM. ECON. REV.* 1075 (1984), which suggests that deregulation offers the possibility of recapturing only the efficiency losses attributable to regulation but not the original rent-seeking expenditures that were instrumental in creating the regulation in the first place. The authors suggest that rent-seeking expenditures constitute most of the costs of the regulation, and thus "there is little political support from any quarter to return to the status quo ante." *Id.* at 1075.

The unintended inclusion of the costs of the developing products liability regime in estimates of the costs of health and safety regulation has led to excessive pessimism about the costs of public intervention in consumer markets for the purpose of enhancing consumer safety. Although estimates of regulatory cost have included the costs of products liability law,¹⁵ more recent estimates of regulatory cost of the tort system have not been compensated by offsetting adjustments.¹⁶ Thus, we have implicitly double-counted the costs of the tort system: they are accounted for both in cost estimates of the tort system itself *and* in cost estimates of regulation. As a result, society has an excessively negative view of public intervention as a whole, and in particular, an excessively negative view of health and safety regulation.¹⁷

The result has been a reduced willingness to take advantage of the potential benefits offered by health and safety regulation. If additional health and safety regulation has little incremental cost because it simply duplicates the demands tort law places on private parties, we simply have achieved the products-safety equivalent of concurrent life sentences: the second one has little additional effect on behavior.

Though regulation has in part been superceded by tort law, however, does not mean it is without benefit. Regulation may reduce the administrative cost of achieving safer products. By reducing injuries without relying on the relatively costly mechanism of tort law, health and safety regulation can yield significant savings. By lending clarity to the definition of rules

15. For a discussion of the sources on which this assertion is based, see *infra* Part III.

16. See, e.g., JAMES S. KAKALIK & NICHOLAS M. PACE, COSTS AND COMPENSATION PAID IN TORT LITIGATION (RAND Institute for Civil Justice No. R-3391-ICJ, 1986); J. S. KAKALIK & R. L. ROSS, COSTS OF THE CIVIL JUSTICE SYSTEM: COURT EXPENDITURES FOR VARIOUS TYPES OF CIVIL CASES (RAND Institute for Civil Justice No. R-2985-ICJ, 1983); JAMES S. KAKALIK ET AL., VARIATION IN ASBESTOS LITIGATION COMPENSATION AND EXPENSES, (RAND Institute for Civil Justice No. R-3132-ICJ, 1984); ANDREW SCHOTTER & JANUSZ ORDOVER, THE COST OF THE TORT SYSTEM, 8-11 (C.V. Starr Center for Applied Economics, N.Y.U. Dep't Econ., Econ. Pol. Paper # PP-42, 1986); David M. Trubek et al., *The Costs of Ordinary Litigation*, 31 UCLA L. REV. 72, 74-76 (1983).

17. In principle the same problem applies to estimates of regulatory benefits. However, estimates of the benefits of products liability are virtually non-existent and extremely tentative. See COMPENSATION AND LIABILITY, *supra* note 12, at 428-87 (noting that the United States evidence in this context is fragmentary and inconclusive).

Similarly, estimates of regulatory benefits are notoriously scarce and unreliable. See ROBERT E. LITAN & WILLIAM D. NORDHAUS, REFORMING FEDERAL REGULATION 9-18 (1983) ("The precise magnitudes of these benefits . . . are subject to a wide range of uncertainty. . . . The valuation problem is especially severe when human life and limb are involved."); Howard K. Gruenspecht & Lester B. Lave, *The Economics of Health, Safety, and Environmental Regulation*, in 2 HANDBOOK OF INDUSTRIAL ORGANIZATION, 1534-37 (Richard Schmalensee & Robert D. Willig eds., 1989); see also ALLEN V. KNEESE, MEASURING THE BENEFITS OF CLEAN AIR AND WATER 125-26 (1984) (concluding that both actual behavior and hypothetical behavior based on methodologies have limitations and "[t]otal accuracy in benefits estimation is an impossible dream").

Obviously, it is extremely difficult to double-count something that has scarcely been counted at all.

and by reducing reliance on relatively inexpert juries in overseeing complex design decisions, regulation can reduce the litigation costs and inefficiency generated by the tort system.

Yet regulation cannot simply replace tort law, as some have urged.¹⁸ The scope of tort concerns, the level of tort remedies, and the willingness of tort law to enforce behavioral standards when the benefits of standards outweigh their costs provide a level of protection that federal regulation has been unable to provide. The analysis here suggests that we should not abandon the tort system in attempting to reap benefits from regulatory expertise.¹⁹

Part II of this Article argues that the actual costs of regulating health and safety in the American economy are small, perhaps even nonexistent, because interaction with the tort system negates most of its regulatory effect. Similarly, deregulation in today's economy can yield only minor benefits. Part III demonstrates that the estimated costs of most federal health and safety regulations exceed their true cost, because the typical estimation method wrongly and unintentionally includes the costs of the products liability regime that developed simultaneously. Finally, the last section of the Article argues that federal regulation has benefits that have not been counted. Regulation reduces overall administrative costs in a system in which regulation and tort law act together to achieve governmental assurance of health and safety.

II. THE MARGINAL COST OF REGULATION

If there were no formal administrative regulation of health and safety, the tort system would nevertheless provide some control over health and safety decisions by private parties such as product manufacturers or service providers. The cost of a regulatory program should be measured by its opportunity cost—the additional resources expended because we have it—against the baseline of an otherwise identical society that is free of the regulation in question.²⁰ Likewise, the benefits from removing regulations

18. See, e.g., *supra* note 10.

19. For a persuasive description of the disadvantages of reliance solely on regulatory standard-setting and enforcement, without the additional remedies provided by an independent tort system, see Teresa Moran Schwartz, *The Role of Federal Safety Regulations in Products Liability Actions*, 41 VAND. L. REV. 1121, 1128-29 (1988). For a compelling example of the risks of sole reliance on the agency regulatory process, see Bruce Ingersoll & Rose Gutfeld, *Implants in Jaw Joint Fail, Leaving Patients in Pain and Disfigured*, WALL ST. J., Aug. 31, 1993, at A-1 (describing federal Food and Drug Administration approval process for temporomandibular jaw implants).

20. See, e.g., EDGAR K. BROWNING & JACQUELENE M. BROWNING, MICROECONOMIC THEORY AND APPLICATIONS 185-86 (1983) (explaining the concept of opportunity cost).

should be measured by what we gain in freed-up resources by deregulating.²¹

Policymakers have long believed that regulation imposes significant net costs on the economy, and that deregulation would therefore generate significant benefits. The perceived high costs of regulation played a significant role in justifying the deregulatory initiatives of the Reagan Administration²² and continue to be a target of criticism.²³ What this critical view does not take into account, however, is that the tort system, and in particular the products liability regime, which most closely duplicates the concerns of federal health and safety regulation, today offsets much of the impact of federal health and safety regulation. By guaranteeing standards at least as demanding as those required by regulation, state products liability law has rendered essentially unavailable the benefits from removing or limiting administrative regulation of health and safety.²⁴

Federal regulation does not act as a straightforward addition to the mandates imposed on private parties by the courts. If it did, there would be

21. Virtually all of the cost-benefit studies of various regulatory programs have relied on the principle of incremental cost (that is, the additional resources absorbed because of the presence of the regulation) as the appropriate cost concept, as opposed to the simple expenditure concept used in the federal budget. See LITAN & NORDHAUS, *supra* note 17, at 21. As the Office of Management and Budget has pointed out in describing the method of measuring the costs and benefits of a proposed regulatory initiative: "Ordinarily the RIA [Regulatory Impact Analysis] should identify several regulatory options. One option, the status quo, normally serves as the base from which increments in benefits and costs are calculated for the other alternatives." OFFICE OF MANAGEMENT AND BUDGET, *REGULATORY PROGRAM OF THE UNITED STATES GOVERNMENT*, APRIL 1, 1988-MARCH 31, 1989, at 33 (1988).

As Lester Lave, a Brookings Institution economist, has explained, in performing cost-benefit analysis: "[A]nalysis must be incremental, constantly asking about the additional benefit to be gained from additional resources (and similarly asking about the magnitude of benefit to be lost from taking away some resources)." LESTER B. LAVE, *THE STRATEGY OF SOCIAL REGULATION: DECISION FRAMEWORKS FOR POLICY* 30 (1981).

For example, assume it costs the tort system \$1,000 to deal with an accident, including the costs of preventative efforts, the injury itself, and litigation. If, in the absence of tort, regulations with total measured costs of \$3,000 would be used with the goal of preventing that accident, then the net addition to social costs by relying on regulation instead of tort is obviously \$2,000, and only that amount should be counted as costs attributable to the regulation. Raising the cost of the tort approach from \$1,000 to \$1,250 would lower the incremental costs attributable to the regulation to \$1,750.

22. See, e.g., *REGULATORY PROGRAM OF THE UNITED STATES GOVERNMENT*, *supra* note 21, at 5 (noting that the institution of regulatory review process is justified because "the long-term additive costs and structural dislocations have not been readily apparent at the time of promulgation. . . . [T]he cumulative effect of some regulatory programs has become excessively burdensome and counterproductive.").

23. See, e.g., Kevin G. Salwen, *Gore Task Force Considers Plan to Let Firms Do Their Own Safety Inspections*, WALL ST. J., Sept. 2, 1993, at A3.

24. The consumerist spirit of the late 1960s and early 1970s led to the simultaneous development of federal health and safety regulation and products liability law. See, e.g., Teresa Moran Schwartz, *The Consumer Product Safety Commission: A Flawed Product of the Consumer Decade*, 51 GEO. WASH. L. REV. 32, 32-36 (1982).

a clear and simple meaning to the "cost" of regulation: the cost would be the additional resources needed to comply with those additional requirements and could be counted by looking exclusively to the regulation itself and the expenditures mandated by it. Likewise, the benefit of deregulation would arise from freeing those same resources for other uses.

In fact, federal regulation is usually a simple addition to the mandates imposed by tort law. Several possible interactive relationships may exist between tort law and federal regulation, and each brings subtle complexities to the concept of "cost" applicable to regulation.

Federal regulation, for example, may preempt the state tort baseline. When it does, deregulation simply allows the reassertion of state tort law, yielding little net reduction in health and safety precautions mandated by government. If preemption occurs, the additional resources consumed because regulation exists, as compared to the resources needed to comply with state tort mandates in the absence of the regulatory mandate, may be small or even negative. In the absence of regulation, the demands of tort law would spring back to fill the void left by regulation, imposing their own costs. If preemptive regulation imposes behavioral requirements less costly than the tort law that would fill the vacuum left by deregulation,²⁵ regulation reduces the total costs to the regulated parties.²⁶

Alternatively, federal regulation may simply duplicate the mandates imposed by tort law. The standard rule that regulatory compliance is not a defense to a tort action²⁷ permits this result. Defendants may comply with the more demanding tort standards of behavior.²⁸ Furthermore, tort damages often have considerably greater bite in ensuring compliance than do regulatory sanctions.²⁹ If actual compliance with tort law imposes higher

25. Of course, regulation may continue to impose costs associated with reporting and other requirements not immediately related to the implementation of safety standards.

26. See, e.g., *Cipollone v. Liggett Group Inc.*, 112 S. Ct. 2608, 2611 (1992). Allowing state lawsuits to proceed against cigarette manufacturers might well involve significant monetary damages awarded to many millions of potential plaintiffs, which could render the entire line of business financially disastrous. The federal labeling requirements imposed a small cost per package and some highly speculative reduction in demand for cigarettes.

27. See *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1543 (D.C. Cir.) (stating that "federal legislation has traditionally occupied a limited role as the floor of safe conduct"), cert. denied, 469 U.S. 1062 (1984); *Wilson v. Piper Aircraft Corp.*, 577 P.2d 1322, 1324-25 (Or. 1978) (holding that FAA approval of an aircraft design is not a defense to a tort claim based on defective design).

28. The demands of tort law are almost always greater than the demands imposed by regulation. One reason that tort actions are frequently allowed despite defendants' compliance with the formal regulatory standards is that tort remedies function much more effectively as incentives to compliance than do the sanctions imposed by the regulatory authority. Another is the belief that it is important to ensure that injured plaintiffs are compensated. See, e.g., *Piper Aircraft Corp.*, 577 P.2d at 1332-33 (Linde, J., concurring).

29. In the notorious MER/29 case, for example, a drug manufacturer deliberately withheld adverse research results from the FDA. When this came to light, the FDA imposed a fine of \$80,000, the maximum allowed by law. Civil suits against the manufacturer, however, posed a

total costs than does compliance with complementary regulations, the regulation simply has no effect on private behavior and results in no additional compliance costs. Deregulation in this instance generates no cost savings because the regulations have little or no effect on behavior.

Regulation may also lower the administrative costs of the tort system through the prior reduction of injuries, the reduction of evidentiary burdens, or the de facto specification of minimum standards of care.³⁰ If so, deregulation may raise the administrative costs of the tort system, partly or fully offsetting whatever administrative or compliance cost savings the termination of the administrative agency would yield. Calculating the value of these offsets requires attention both to the costs of litigating individual cases and to the overall amount of litigation potentially avoided. As the marginal propensity to litigate increases in response to greater damages awards, lower procedural barriers, and more hospitable substantive rules, every injury stands a greater chance of being litigated, and thus every injury prevented by regulation avoids potential litigation costs. If regulation prevents some injuries, as the empirical evidence suggests,³¹ and if the increasingly stringent tort system implies either an increase in the likelihood that an injury will be litigated or an increase in the cost of litigating, or both, then regulation generates increasing benefits in litigation avoided.³²

On the other hand, some interactions between the litigation system and federal regulation may raise the costs fairly attributable to regulation. This will occur, for example, if (1) federal causes of action are express or implied in the federal regulatory statute, so that the regulatory statute gives rise to litigation that would not exist otherwise; (2) federal regulatory statutes stimulate litigation over statutory interpretation or administrative procedure; or (3) regulatory standards applied through negligence per se or

considerably greater deterrent to similar future behavior: the manufacturer's tort liability ultimately came to between \$45 and \$55 million. STEVEN FREDMAN & ROBERT E. BURGER, *FORBIDDEN CURES* 17 (1976). In general, the tort system "encourage[s] manufacturers to continue research, reveal research results honestly, monitor scientific literature, and request or issue appropriate warnings." Howard A. Denemark, *Improving Litigation Against Drug Manufacturers for Failure to Warn Against Possible Side Effects: Keeping Dubious Lawsuits From Driving Good Drugs Off the Market*, 40 CASE W. RES. L. REV. 413, 431 (1989-90). It is not clear that the FDA could adequately perform these tasks at current staffing and budget levels.

30. This argument is developed more fully in Part IV, *infra*.

31. See ROBERT W. CRANDALL ET AL., *REGULATING THE AUTOMOBILE* 45-74 (1986); Kathleen D. Zick et al., *Does the U.S. Consumer Product Safety Commission Make a Difference? An Assessment of Its First Decade*, 9 J. CONSUMER POL. 25, 26 (1986).

32. Furthermore, a regulation may increase tort compliance because it may subject the violator to punitive damages. See Michael Rustad, *In Defense of Punitive Damages in Products Liability: Testing Tort Anecdotes with Empirical Data*, 78 IOWA L. REV. 1, 85-88 (1992).

related doctrine³³ increase the stringency and cost of the tort system by giving rise to liability when it might not otherwise be present.

Yet these are all relatively rare. Private rights of action under federal regulatory statutes are uncommon.³⁴ Challenges to statutory meaning or the administrative procedure under which a regulation is adopted are probably of tiny cost relative to the economic impact of the regulations themselves.³⁵ The impact of negligence per se, the doctrine by which a plaintiff uses the violation of a statute or regulation³⁶ to prove a breach of the standard of care, is difficult to assess. Courts view some safety statutes or administrative regulations as inappropriate for use under the negligence per se doctrine.³⁷ Furthermore, negligence per se demonstrates violation of the standard of care as a matter of law in only about half of the United States jurisdictions; in other jurisdictions, the statutory violation merely serves as evidence of breach of the reasonable person standard or creates a rebuttable presumption that the standard was breached.³⁸ In addition, the appropriate-

33. For example, the statutory standard may be applied as evidence of the tort standard of care or it may create a rebuttable presumption of that standard, or a statutory standard may be used to define a product defect for purposes of strict products liability.

34. Generally, the federal courts in recent years have been reluctant to imply the creation of a federal cause of action by the statutes which regulate product safety. Thus, FIFRA, the FDA Act, the MVSA, the FTC Act and the Federal Hazardous Substances Act have all been found not to create federal liability. Only the CPSA has been the source of any dispute, but even here the federal courts have appeared to conclude that no cause of action exists unless within the express terms of the federal statute. Sherman, *supra* note 11, at 866.

35. For example, the U.S. Judicial Conference reports that some 869 civil cases were brought in 1988 in United States district courts under the Food, Drug, and Cosmetic Act, and that 29 such cases were brought in 1988 under the Occupational Safety and Health Act. ANNUAL REPORT OF THE DIRECTOR OF THE ADMINISTRATIVE OFFICE OF THE UNITED STATES COURTS 185 (1988).

36. See, e.g., Brooks *ex rel.* Stanton v. Astra Pharmaceutical Prods., Inc., 718 F.2d 553, 563-65 (3d Cir. 1983) (holding that under Pennsylvania law, violation of FDA adverse-reaction reporting requirement designed to protect drug users is negligence per se).

37. See, e.g., Distad v. Cubin, 633 P.2d 167, 178 (Wyo. 1981) (noting that regulation was "overbroad and inflexible"). Violation may be excused for a variety of reasons. W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS 227-28 (5th ed. 1984) (footnote omitted) (quoting St. Louis, Iron Mountain & So. Ry. Co. v. Taylor, 210 U.S. 281 (1907)). Furthermore, the injury must be one that the statute is intended to prevent, and the plaintiff must be a person the statute was intended to protect. Kelly v. Koppers Co., Inc., 293 So. 2d 763, 764 (Fla. Dist. Ct. App. 1974) (per curiam); RESTATEMENT (SECOND) OF TORTS § 286 (1965).

38. KEETON ET AL., *supra* note 37, at 230. There is further reason to be skeptical of the importance of negligence per se. Courts are typically less willing to treat violations of administrative regulations as determinative of negligence than they are with statutes. *Id.* Federal courts have no federal question jurisdiction over state tort claims when the only "federal question" is the application of the federal statute for establishing the state law claim. Merrell Dow Pharmaceuticals, Inc. v. Thompson, 478 U.S. 804, 817 (1986). Some courts have held that the absence of an express or implied private cause of action under the federal statute precludes the use of that statute as the basis for a state claim of negligence per se. See, e.g., R.B.J. Apartments, Inc. v. Gate City Sav. & Loan Ass'n, 315 N.W.2d 284, 285 (N.D. 1982). This approach has not been followed in most state courts, however. See Sherman, *supra* note 11, at 899.

ness of so using federal regulations in conjunction with the negligence per se doctrine has not often been examined by state courts.³⁹

On balance, the growth in importance of the tort system probably has reduced the potential impact of health and safety regulatory requirements on private parties. Whether regulation independently imposes costs on private parties depends in large part on the magnitude of these interactive effects. This Article concludes that preemption and duplication have significantly reduced incremental regulatory costs.

A. *Preemption of State Tort Actions*

Assessing the incremental cost of federal regulation is made more difficult when preemption occurs⁴⁰ because federal regulation eliminates or diminishes the need for compliance with state tort law; instead, federal law substitutes an alternative set of requirements.⁴¹ These substitute require-

39. The Prosser casebook notes, "Surprisingly, there has been very little consideration" of whether violation of a federal statute should be the basis for finding negligence per se in state courts. WILLIAM PROSSER ET AL., *CASES AND MATERIALS ON TORTS* 214 (8th ed. 1988); see also *Sanchez v. Galey*, 733 P.2d 1234, 1244 (Idaho 1986) (finding that violation of federal Occupational Health and Safety Administration regulations constituted negligence per se as a matter of state law). *Sanchez* was a case of first impression and has to date been followed in few other jurisdictions. *Id.* Federal courts have assumed in some diversity cases that the state courts whose law they were applying would apply negligence per se to a federal statute. See, e.g., *Gober v. Revlon, Inc.* 317 F.2d 47, 51 (4th Cir. 1963) (finding violation of Federal Food, Drug and Cosmetic Act as evidence of negligence per se under California law); *Orthopedic Equip. Co. v. Eutsler*, 276 F. 2d 455, 460-61 (4th Cir. 1960) (holding similarly under Virginia law).

40. The Supreme Court has held repeatedly that federal statutes or regulations may preempt state laws. See, e.g., *Hillsborough County v. Automated Medical Labs. Inc.*, 471 U.S. 707, 713 (1985).

41. The Supreme Court has recognized three categories of preemption.

First, in enacting the federal law, Congress may explicitly define the extent to which it intends to pre-empt state law. Second, even in the absence of express pre-emptive language, Congress may indicate an intent to occupy an entire field of regulation, in which case the States must leave all regulatory activity in that area to the Federal Government. Finally, if Congress has not displaced state regulation entirely, it may nonetheless pre-empt state law to the extent that the state law actually conflicts with federal law.

Michigan Canners & Freezers Ass'n v. Agricultural Mktg. & Bargaining Bd., 467 U.S. 461, 469 (1984) (citations omitted). The first of these categories, often described as "express preemption," LAURENCE H. TRIBE, *AMERICAN CONSTITUTIONAL LAW* §§ 6-25 & 6-26, at 479-81 (2d ed. 1988), occurs when Congress explicitly declares its intent to preclude state intervention. The second, known as "implied" preemption, *id.* at 497-501, is found when a

"scheme of federal regulation . . . is so pervasive as to make reasonable the inference that Congress left no room [for the States] to supplement it," because "the Act of Congress may touch a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject," or because "the object sought to be obtained by the federal law and the character of [the] obligations imposed by it may reveal the same purpose."

Pacific Gas & Elec. Co. v. State Energy Resources Conservation & Dev. Comm'n, 461 U.S. 190, 204 (1983) (quoting *Fidelity Fed. Sav. & Loan Ass'n v. De la Cuesta*, 458 U.S. 141, 153 (1983); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Conflict preemption, the third type,

ments may be more or less stringent than the state tort requirements they supplant. Furthermore, the incentives for compliance, in terms of the seriousness and probability of potential penalties, may be greater or smaller than the comparable penalties of tort law.⁴²

As a result, the total costs faced by the regulated parties may be higher or lower than the costs they face in the absence of regulation. If it is less costly to comply with the regulation than with the tort law that it preempts, the regulation is actually a cost-saving measure that reduces the total costs the regulated parties bear in complying with governmentally imposed requirements.

The potential cost savings associated with deregulation in such instances is significantly less than the savings anticipated by the empirical work on the cost of regulation, which largely ignored the impact of tort law.⁴³ Furthermore, because the tort system has become considerably more activist since these studies were conducted,⁴⁴ the net cost savings from deregulation has almost surely diminished.

One important example of this relationship between tort law and preemptive federal regulation involves passenger restraint systems in automobiles. The National Highway Traffic and Motor Vehicle Safety Act of 1966⁴⁵ explicitly preempts any state automobile safety standard that concerns "the same aspect of performance" as a Federal Motor Vehicle Safety Standard (FMVSS) but which is "not identical" to the federal standard.⁴⁶ In spite of this language, most automobile design decisions remain the subject of state tort suits even when a related federal standard exists.⁴⁷ Many

occurs when the state law conflicts or is otherwise impermissibly inconsistent with the federal statute, which can occur when "compliance with both state and federal law is impossible, or when the state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Michigan Cannery & Freezers Ass'n*, 467 U.S. at 469 (citations omitted).

42. Even when Congress preempts common-law actions incompatible with the federal standard, regulation often continues to rely on the compliance incentives posed by tort remedies by allowing tort lawsuits to enforce the federal standards. See, e.g., *Pedraza v. Shell Oil Co.*, 942 F.2d 48, 49 (1st Cir. 1991), cert. denied, 112 S. Ct. 993 (1992); *Wood v. General Motors Corp.*, 865 F.2d 395, 396 (1st Cir. 1988), cert. denied, 494 U.S. 1065 (1990).

43. See *infra* Part III.

44. For a history of the changes in tort and products liability law since the middle 1960s, see George L. Priest, *The Invention of Enterprise Liability: A Critical History of the Intellectual Foundations of Modern Tort Law*, 14 J. LEGAL STUD. 461, 511-27 (1985).

45. National Traffic and Motor Vehicle Safety Act of 1966, Pub. L. No. 89-563, 80 Stat. 718 (1966) (codified at 15 U.S.C. §§ 1381-1431 (1988)) [hereinafter Safety Act].

46. 15 U.S.C. § 1392(d) (1988).

47. The reason is the so-called "savings clause," which provides that persons otherwise liable under state common law are not exempted from liability by virtue of compliance with a safety standard issued under the Act. See 15 U.S.C. § 1397(c) (1988). Most courts, in interpreting the interaction between § 1392(d) and § 1397(c) have concluded that express preemption is not intended. Instead, the Safety Act is "intended to be supplementary of and in addition to the common

courts have held, however, that FMVSS 208, the federal safety standard mandating that automobile producers equip their cars either with certain types of seatbelts or with airbags, preempts state tort actions premised on the manufacturer's failure to provide airbags.⁴⁸

Courts are divided as to whether the respective states would, in the absence of FMVSS 208's preemptive effect, recognize a cause of action for failure to install airbags. Recent caselaw suggests that at least some jurisdictions would impose liability on this basis.⁴⁹ Because of federal preemption, however, courts have not allowed suits against manufacturers to proceed to the determination of whether a failure to include an airbag in an automobile in fact constitutes a design defect. Absent the preemptive effect of the federal safety standard, automobile manufacturers might face significant liability for failing to equip vehicles with airbags. Had they faced such liability, as several courts have noted, they might have been effectively compelled to include airbags because of the potentially enormous financial

law of negligence and product liability." *Larsen v. General Motors Corp.*, 391 F.2d 495, 506 (1968). See generally Ellen L. Theroff, Note, *Preemption of Airbag Litigation: Just a Lot of Hot Air?*, 76 VA. L. REV. 577, 577-626 (1990) (analyzing arguments for and against preemption of common-law airbag suits).

48. This ambiguous statutory scheme has not resulted in preemption of most Federal Motor Vehicle Safety Standards (FMVSSs), because those standards have typically been phrased as simple minimum requirements. Thus, state tort requirements that exceed the FMVSS in stringency have not been regarded as in conflict with the federal standard. FMVSS 208, 49 C.F.R. § 571.208 (1989), which mandates passenger restraint systems in automobiles, specifically allows automobile manufacturers to choose between airbags and seatbelts. *Id.* Many federal courts, therefore, have interpreted this standard as impliedly preempting design defect claims against automobile manufacturers premised on a common-law duty to include airbags. See, e.g., *Pokorny v. Ford Motor Co.*, 902 F.2d 1116, 1122 (3d Cir. 1990), *cert. denied*, 498 U.S. 853 (1990); *Kitts v. General Motors Corp.*, 875 F.2d 787, 789 (10th Cir. 1989), *cert. denied*, 494 U.S. 1065; *Taylor v. General Motors Corp.*, 875 F.2d 816, 826 (11th Cir. 1989), *cert. denied*, 494 U.S. 1065 (1990); *Wood v. General Motors Corp.*, 865 F.2d 395, 408 (1st Cir. 1988), *cert. denied*, 494 U.S. 1065 (1990); *Kalbeck v. General Motors Corp.*, 756 F. Supp. 1144, 1150 (S.D. Ind. 1991); *Dallas v. General Motors Corp.*, 725 F. Supp. 902, 905 (W.D. Tex. 1989); *Surles v. Ford Motor Co.*, 709 F. Supp. 732, 734 (N.D. Tex. 1988); *Schick v. Chrysler Corp.*, 675 F. Supp. 1183, 1186 (D.S.D. 1987).

49. Because the preemptive effect of federal regulation has not been definitively resolved, some courts have reached the question of whether state law would recognize such a claim. *Taylor*, 875 F.2d at 818 (holding that an automaker's failure to equip a car with an airbag could serve as basis for tort liability under Florida law); *Staggs v. Chrysler Corp.*, 678 F. Supp. 270, 273 (N.D. Ga. 1987) (same under Georgia law). But see *Wilson v. Ford Motor Co.*, 656 F.2d 960, 960 (4th Cir. 1981) (holding, under North Carolina law, that automobile manufacturer was not liable for defects in design that merely aggravated injury); *Hughes v. Ford Motor Co.*, 677 F. Supp. 76, 85 (D. Conn. 1987) (stating that Connecticut tort law would not recognize a suit against automaker for failure to install airbags); *Vanover v. Ford Motor Co.*, 632 F. Supp. 1095, 1098 (E.D. Mo. 1986) (holding same under Missouri law); *Higgs v. General Motors Corp.*, 655 F. Supp. 22, 26 (E.D. Tenn. 1985), *aff'd sub. nom. Thomas v. Subaru of Am., Inc.*, 815 F.2d 80 (6th Cir. 1987) (holding same under Tennessee statute).

liability from failing to do so.⁵⁰ Because manufacturers resisted voluntarily installing airbags in vehicles and fought vigorously against attempts to make airbags mandatory,⁵¹ it would appear that airbags impose considerably greater costs on manufacturers than the seatbelt alternative also available under FMVSS 208.⁵² Apparently, then, the requirements that state tort law would impose in the absence of federal regulation considerably exceed the federal requirements in terms of stringency and cost.

However, if NHTSA simply chose not to address the issue of airbags—that is, if it simply “deregulated” that decision⁵³—the preemptive effect of that federal standard would vanish, and those states allowing a failure to provide airbags to support a crashworthiness claim could experience a sudden flood of cases.⁵⁴ Removal of the federal regulation, therefore, would leave the states free to impose an airbag requirement via tort law or state administrative regulation. Because of the substantial scale economies of production in automotive manufacturing, adopting an airbag requirement in only a few states could have a nationwide impact. Ironically, then, terminating a federal regulation could ultimately impose considerably more costly obligations on manufacturers.

50. See, e.g., *Schick*, 675 F. Supp. at 1186 (“A single recovery on an air bag claim would send a signal to all automobile manufacturers that they must install air bags to avoid potential liability.”).

51. The long history of the struggle to mandate airbags in automobiles is chronicled in *Motor Vehicles Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 34-38 (1983), in which the automobile manufacturers’ trade association defended the Department of Transportation’s decision to rescind the passive restraint requirement in 1981, see *id.* at 30-34, and in *State Farm Mut. Auto. Ins. Co. v. National Highway Traffic Safety Admin.*, 680 F.2d 206, 208-18 (D.C. Cir. 1982).

52. Cost considerations played a significant role in the resistance to the passive restraint standard. When Secretary of Transportation Andrew Lewis reopened the passive restraint rulemaking proceeding in 1981, 49 C.F.R. § 571.208 (1981), an action that resulted in the standard’s delay, he based his decision in part on “the fact that economic circumstances have changed since the standard was adopted in 1977,” and on “the difficulties of the automobile industry.” *Id.* He cited high unemployment, “very depressed” sales, and significant financial losses by the domestic manufacturers as reasons for reopening the rulemaking proceedings. *Id.*

53. The Department of Transportation, NHTSA’s parent agency, in fact did exactly that in 1981 when it delayed the passive restraint standard altogether. 49 C.F.R. 571.208 (1981); 46 Fed. Reg. 21172 (1981); *id.* at 21205. Its effort did not succeed because it failed to “supply a reasoned analysis” explaining the rationale for its decision. See *State Farm*, 463 U.S. at 57.

54. The preemption of state airbag requirements arises from the peculiar form that FMVSS 208 assumes. Despite the presence of a general preemption provision in the Safety Act, the courts have held that most FMVSSs have no preemptive effect because they are phrased as minimum standards, which state requirements are free to exceed in stringency. FMVSS 208 differs, however, in that it explicitly offers an option to manufacturers *not* to include airbags, and thus the failure to include airbags in autos cannot give rise to state liability without conflicting with the federal regulation. See *Wood v. General Motors Corp.*, 865 F.2d 395, 401-02 (1st Cir. 1988), *cert. denied*, 494 U.S. 1065 (1990).

Some of these airbag cases would almost surely succeed if courts could apply current tort law. The preemptive effect of FMVSS 208 generally has prevented juries from reaching the question of whether the absence of airbags constitutes an automobile design defect. In areas of automobile safety in which preemption has not been an issue, however, acceptable crashworthiness doctrine has become a legal standard of considerable influence since it was accepted in 1968.⁵⁵ Safety concerns that once were treated only by FMVSSs have become the subject of products liability actions that rely on the crashworthiness doctrine to impose liability on manufacturers for defective design.⁵⁶ Removal of the airbags/seatbelts FMVSS would raise the standards imposed on manufacturers in those states in which crashworthiness liability based on an airbag theory is allowed. Removal would have essentially no effect, however, on the standards facing manufacturers in states not permitting airbag litigation.⁵⁷

The trend in the federal courts suggests that preemption is an increasingly available defense to tort defendants. Traditionally, preemption has

55. *Larsen v. General Motors Corp.*, 391 F.2d 495, 498-506 (8th Cir. 1968).

56. State tort law routinely places more stringent demands on automobile manufacturers than do the related federal requirements. *See infra* text accompanying note 170. The proposition applies generally in all areas of products liability. *See, e.g.*, *Bruce v. Martin-Marietta Corp.*, 544 F.2d 442, 446-49 (10th Cir. 1976) (applying Maryland law in an aviation suit); *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1362 (4th Cir. 1975) (applying North Carolina law in a drug manufacturing case); *Raymond v. Riegel Textile Corp.*, 484 F.2d 1025, 1027-28 (1st Cir. 1973) (applying New Hampshire law in a clothing manufacturing case).

Virtually all of the FMVSSs, except FMVSS 208, have been equalled or exceeded by safety standards applied in products liability litigation against automobile manufacturers. *See supra* note 7 and *infra* note 152.

57. The preemptive effect of regulation also protects tobacco manufacturers from potentially costly tort liability. In *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992), the Supreme Court held that Congress preempted causes of action based on the manufacturers' failure to warn by mandating federal warning requirements for cigarette packages. *Id.* at 2625. However, the Court also held that express warranty claims, fraudulent misrepresentation claims premised on "a general duty not to deceive," or conspiracy, were not preempted by the 1969 Act. *Id.* at 2622-25.

In the absence of any preemptive effect of the federal statutes, cigarette manufacturers might well be found liable on claims based on failure to warn, as well as on other common-law theories. The presumed preemptive effect of the federal cigarette labelling requirement has long protected tobacco manufacturers from a potential flood of litigation. *See Kotler v. American Tobacco Co.*, 926 F.2d 1217, 1222 (1st Cir. 1990), *vacated and remanded*, 112 S. Ct. 3019 (1992) (holding that the 1965 Act preempted failure to warn and intentional misrepresentation claims); *Pennington v. Vistrion Corp.*, 876 F.2d 414, 420-21 (5th Cir. 1989) (holding that the 1965 Act preempted failure to warn and improper advertising claims); *Roysdon v. R.J. Reynolds Tobacco Co.*, 849 F.2d 230, 234-35 (6th Cir. 1988) (holding that the 1965 and 1969 Acts preempted failure to warn claim); *Palmer v. Liggett Group, Inc.*, 825 F.2d 620, 626-27 (1st Cir. 1987) (finding that 1965 Act preempted a failure to warn claim and breach of express warranty claim); *Stephen v. American Brands, Inc.*, 825 F.2d 312, 313 (11th Cir. 1987) (*per curiam*) (finding that 1965 Act preempted a failure to warn claim); *Forster v. R.J. Reynolds Tobacco Co.*, 437 N.W.2d 655, 658-60 (Minn. 1989) (finding a failure to warn claim preempted, but strict liability, design defect, misrepresentation, and breach of warranty claims not preempted unless such claims were premised on a specific duty to warn).

had limited power to affect state torts cases because of a longstanding presumption against preemption of state common-law damages actions.⁵⁸ *Cipollone v. Liggett Group, Inc.*, the Supreme Court's most recent pronouncement on the subject of preemption of state tort law, purports to maintain that presumption.⁵⁹ Nevertheless, a growing number of cases in the lower federal courts suggest the rationale of *Cipollone* may expand the preemptive power of federal regulation.

In *Cipollone*, the Court found that tort claims against cigarette manufacturers based on inadequacy of manufacturers' warning labels, advertising, or promotional materials with respect to the dangers of smoking were preempted by the Public Health Cigarette Smoking Act of 1969.⁶⁰ The decision turned on statutory language stating:

No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.⁶¹

A majority of the Court⁶² chose to treat a state law tort rule potentially giving rise to damages as a "requirement or prohibition" within the meaning of section 5(b) and thus was preempted under the federal law.⁶³ In so holding, the Court resolved a controversy over the nature of tort judgments dating back to *San Diego Building Trades v. Gorman*.⁶⁴ In *Gorman*, the Court, in dictum, treated a state damages award as regulatory in nature and thus subject to preemption by the statute at issue.⁶⁵ In other contexts, however, the Court has held that a jury's award of punitive damages does not constitute a form of state regulation.⁶⁶

58. "Consideration of issues arising under the Supremacy Clause start[s] with the assumption that the historic police powers of the States [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress." *Cipollone*, 112 S. Ct. at 2617 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

59. *Id.* at 2618.

60. *Id.* at 2621-22, 2625; Pub. L. No. 91-222, 84 Stat. 87 (1970) (codified as amended at 15 U.S.C. §§ 1331-40 (1988)).

61. *Cipollone*, 112 S. Ct. at 2621-22 (quoting Public Health Cigarette Smoking and Advertising Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 (1970) (codified as amended at 15 U.S.C. § 1334(b) (1988))).

62. Chief Justice Rehnquist and Justices White and O'Connor joined this portion of Justice Stevens's opinion. *Id.* at 2613. In addition, Justices Scalia and Thomas expressly agreed that "the general tort-law duties petitioner invokes against the cigarette companies can, as a general matter, impose 'requirement[s] or prohibition[s]' within the meaning of § 5(b) of the 1969 Act." *Id.* at 2634 (Scalia, J., concurring in part and dissenting in part).

63. *Id.* at 2630.

64. 359 U.S. 236 (1959).

65. *Id.* at 247.

66. See, e.g., *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 186 (1988); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 241 (1984).

The Supreme Court's other major preemption opinion of the 1992 term, *Morales v. Trans World Airlines, Inc.*,⁶⁷ buttresses *Cipollone's* sweeping impact. In *Morales*, the Court interpreted a provision of the Airline Deregulation Act of 1978 that preempted any state law "relating to rates, routes, or services" of any air carrier.⁶⁸ The Court held that the statute preempted state laws which were enacted to ensure that airline advertising fully informed consumers of actual airfare terms by specifying certain physical characteristics of advertisements.⁶⁹ The Court stated that the evident goal of the preemption provision was to ensure that "the States would not undo federal deregulation with regulation of their own."⁷⁰ To find a conflict with this federal purpose, the Court interpreted the phrase "relating to" as having "a broad preemptive purpose"⁷¹ that reached even a state law which had only the most trivial relationship to the setting of airfares. The Court thus made clear that it understood the phrase "relating to" to have a "broad preemptive purpose."⁷²

These decisions have already extended the reach of federal preemption in at least two areas, and have the potential to reach further still.⁷³ The Federal Food, Drug and Cosmetic Act⁷⁴ was amended by the Medical Device Amendments of 1976⁷⁵ (MDA) to require pre-marketing approval from the Food and Drug Administration for medical devices the FDA classified as "present[ing] a potential unreasonable risk of illness or injury."⁷⁶ The MDA also includes a preemption provision, which states in pertinent part:

67. 112 S. Ct. 2031 (1992).

68. 49 U.S.C. app. § 1305(a)(1) (1988).

69. *Morales*, 112 S. Ct. at 2034.

70. *Id.*

71. *Id.* at 2037.

72. *Id.* The Court apparently did not feel compelled to demonstrate any connection between the state consumer protection law and airfares beyond the statute's explicit requirement of full disclosure or airfare terms. Nevertheless, the Court offered a curious economic defense of the relationship between state advertising guidelines and the deregulatory purpose of the Airline Deregulation Act. Noting that "[a]dvertising serves to inform the public of the . . . prices of products and services," *id.* at 2039 (quoting *Bates v. State Bar of Ariz.*, 433 U.S. 350, 364 (1977)), the Court suggested that state efforts to ensure that advertising accurately inform consumers of prices actually hindered this goal. *Id.*

73. Language similar to that interpreted in *Cipollone* and *Morales* appears in 21 U.S.C. § 343-1(a) (Supp. IV 1992) (preempting state law regulating food); 15 U.S.C. § 2617(a)(2)(A) (1988) (providing state requirements for testing of toxic substances); 7 U.S.C. § 228c (1988) (providing requirements that meatpackers post bonds or comply with prompt-payment provisions of state law); 21 U.S.C. § 678 (1988) (providing state requirements for meat inspection facilities); and 49 U.S.C. § 1804(a)(4)(A) (Supp. III 1991) (requiring state control of transportation of hazardous materials).

74. 21 U.S.C. §§ 301-392 (1988).

75. 21 U.S.C. §§ 360c-360k (1988).

76. 21 U.S.C. § 360c(a)(1)(C)(ii)(III) (1988).

No State . . . may establish or continue in effect with respect to a device intended for human use any requirement—

- (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
- (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.⁷⁷

In determining whether Congress intended this provision to preempt state law claims against makers of medical devices, courts have relied on the view that a “requirement” might not include common-law actions.⁷⁸ Combining this possibility with “the assumption that the historic police powers of the states were not to be superseded by federal law unless that was the clear and manifest purpose of Congress,”⁷⁹ courts have concluded that Congress did not intend preemption. Because the Supreme Court suggested in *Silkwood v. Kerr-McGee Corp.*⁸⁰ that the absence of a federal remedy weighs against an inference of a congressional preemptive purpose, the absence of a remedy provision in the MDA heightened the obstacles facing any preemption claim.⁸¹ The presumption of the lower federal courts that the MDA lacked preemptive effect has resulted in substantial settlements in favor of plaintiffs injured by FDA-approved medical devices.⁸²

Cipollone appears to have reversed that interpretation of the MDA. In *King v. Collagen Corp.*,⁸³ the First Circuit Court of Appeals held that the MDA preempted the plaintiff’s strict liability, breach of warranty, negligence, misbranding, failure to warn, and fraud claims because each would enforce a “requirement” against the manufacturer “different from, or in addition to,” requirements enforced by the FDA.⁸⁴ In *Stamps v. Collagen Corp.*,⁸⁵ the Fifth Circuit Court of Appeals also found that the MDA preempted all of the plaintiff’s common-law claims, including inadequate labeling, failure to warn, and defective design and manufacture,⁸⁶ because each “constitute[d] a requirement different from, or in addition to,”⁸⁷ those

77. 21 U.S.C. § 360k(a) (1988).

78. *See, e.g., Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 668 (D. Md. 1989).

79. *Id.* (citing *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1542 (D.C. Cir. 1984)).

80. 464 U.S. 238 (1984).

81. *Id.* at 251 (“[I]t is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.”).

82. *See, e.g., An Invincible Shield for Medical Manufacturers*, Bus. Wk., Aug. 9, 1993, at 73, 73 (discussing 1992 settlement for \$500 million by manufacturer of defective heart valves).

83. 983 F.2d 1130 (1st Cir. 1993).

84. *Id.* at 1134-36.

85. 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993).

86. *Id.* at 1422. The court did not analyze the plaintiff’s fraud claims because, in the court’s view, the complaint inadequately stated the cause of action. *Id.* at 1422 n.5.

87. *Id.* at 1421.

the FDA imposes in the course of its product approval process.⁸⁸ The court concluded, based on *Cipollone*, that, for preemption purposes, there is "no distinction between positive enactments and common law."⁸⁹

Furthermore, the effect of preemption under the MDA is considerably more sweeping than in *Cipollone*. In *Cipollone*, the plaintiff was left with several causes of action to pursue against the defendant cigarette manufacturers because not all of the state-law claims were "with respect to the advertising or promotion" of cigarettes.⁹⁰ In the cases involving the MDA, however, virtually any claim appears to enforce a "requirement," and thus, as these cases have shown, is preempted.⁹¹

As does *Cipollone*, *Morales* presents a very broad interpretation of the statutory preemptive language, and its impact reaches well beyond the statute under examination there. For example, *Morales* speaks directly to the language of the Medical Devices Amendments.⁹² The MDA's preemption provision sweeps within its reach any state requirement that "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."⁹³ Given the "sweeping interpretation"⁹⁴ of the "relating to" language in *Morales* and the decision to treat state common-law damages actions as "requirements" for preemption purposes, it is difficult to imagine any damages claim that could survive preemption. For all practical purposes, there apparently is no longer any remedy under state law (or anywhere else) for persons injured by an FDA-approved medical device. Since the MDA itself contains no remedy provision, persons injured by an FDA-approved device appear to have no legal recourse.

Cipollone and *Morales* have had a similar effect on the preemptive power of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). FIFRA provides that a state "shall not impose or continue in effect any

88. *Id.*

89. *Id.* (quoting *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608, 2620 (1992)). Similarly, in *Reiter v. Zimmer, Inc.*, 830 F. Supp. 199, 201 (S.D.N.Y. 1993), the court adopted the same test for preemption in MDA cases employed by the First and Fifth Circuits, and applied the same rationale based on the test enunciated in *Cipollone*. *Id.* at 203.

90. *Cipollone*, 112 S. Ct. at 2621. The Court held that the 1969 Act preempted failure to warn claims and any claims based on the assertion that advertising or promotion of the cigarettes tended to neutralize the federally mandated warnings. *Id.* at 2621-23. Express warranties, intentional fraud, misrepresentation, and conspiracy claims were not preempted by the 1969 Act. *Id.* at 2622-25.

91. See *King v. Collagen Corp.*, 983 F.2d 1130, 1134-36 (1st Cir. 1993). The "requirements" language in the MDA is not limited in its reach against safety claims by subsequent restrictive language, as is the language in the Public Health Cigarette Smoking Act.

92. See *supra* text accompanying notes 73-91.

93. 21 U.S.C. § 360k(a)(2) (1988) (emphasis added).

94. *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1422 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993).

requirements for labelling . . . in addition to or different from these required" by the EPA, the regulating agency under FIFRA.⁹⁵ Prior to *Cipollone*, courts generally did not regard this provision as preempting state damages actions resting on inadequate labeling or failure-to-warn theories, because a state finding of liability for damages did not constitute a "requirement."⁹⁶ Since *Cipollone*, however, the cases have clearly reached a contrary result. Courts deciding FIFRA cases since *Cipollone* have held that the statute preempts state common-law claims based on the adequacy of EPA-approved labels, because a state tort decision that labels were inadequate would constitute a "requirement . . . in addition to or different from" the federally approved label.⁹⁷

Deregulation almost certainly would end the preemptive effect of these federal statutes. Preemption can occur in one of three ways. First, the language of the federal statute or regulation can expressly mandate preemption of state tort actions.⁹⁸ Second, federal regulation may so occupy a legislative field "as to make reasonable the inference that Congress left no room for the States to supplement it."⁹⁹ Finally, the regulatory scheme may "actually conflict[]" with the state law such that compliance with both is impossible.¹⁰⁰ In any of these situations, it is difficult to see how the regulatory program's preemptive effect could survive the termination of the regulatory program itself or even, in most cases, any serious restriction of the program or limitation of particular regulations promulgated by the regulatory agency.

If preemption were based on express language in the federal statute or regulation, as with the two cigarette labeling acts and FIFRA, then repeal or termination of the federal law would terminate its preemptive effect.

95. 7 U.S.C. § 136v(b) (1988).

96. See *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1541-42 (D.C. Cir. 1984), cert. denied, 469 U.S. 1062 (1984). Although only the D.C. Circuit had ruled on the question in 1984, *id.*, the federal district courts split on the question of the preemptive effect of FIFRA prior to *Cipollone*. Cases finding preemption include: *Hurt v. Dow Chem. Co.*, 759 F. Supp. 556, 558 (E.D. Mo. 1990); *Fisher v. Chevron Chem. Co.*, 716 F. Supp. 1283, 1289 (W.D. Mo. 1989); *Herr v. Carolina Log Bldgs., Inc.*, 771 F. Supp. 958, 961 (S.D. Ind. 1989); and *Kennan v. Dow Chem. Co.*, 717 F. Supp. 799, 807 (M.D. Fla. 1989). Cases in which no preemption was found include: *Evenson v. Osmose Wood Preserving, Inc.*, 760 F. Supp. 1345, 1348 (S.D. Ind. 1990); *Stewart v. Ortho Consumer Prods.*, No. 87-4252, 1990 U.S. Dist. LEXIS 3391, at *16 (E.D. La. Mar. 26, 1990); *Cox v. Velsicol Chem. Corp.*, 704 F. Supp. 85, 87 (E.D. Pa. 1989); and *Wilson v. Chevron Chem. Co.*, No. 83 Div. 762 (S.D.N.Y. Dec. 17, 1986).

97. *Burke v. Dow Chem. Co.*, 797 F. Supp. 1128, 1140 (E.D.N.Y. 1992); *Casper v. E.I. Du Pont de Nemours & Co.*, 806 F. Supp. 903, 907 (E.D. Wash. 1992).

98. *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977).

99. *Fidelity Fed. Sav. & Loan Ass'n v. De la Cuesta*, 458 U.S. 141, 153 (1982) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

100. *Pacific Gas & Elec. Co. v. Energy Resources Conservation & Dev. Comm'n*, 461 U.S. 190, 204 (1983).

Although Congress could retain a preemption provision while terminating a regulatory program, it is unlikely that it would do so.¹⁰¹ Indeed, the case for deregulation has been based on the premise that the common law could more adequately and efficiently control the problem in question, an outcome incompatible with preemption of common-law actions.¹⁰²

The situation appears to be the same with respect to the other bases of federal preemption. If there is no federal statute, there is no basis on which the courts can imply preemption, because implied preemption rests on the existence of a statute.¹⁰³ The courts are generally unwilling to imply federal preemption of state tort activity¹⁰⁴ and would have increasing difficulty finding congressional intent to preempt state law as the reach of federal law diminished. Similarly, federal preemption may be based on a congressional intent that the federal government's activities occupy the field; when Congress removes federal control, it becomes difficult to argue that Congress intended federal activity to occupy the field so extensively that the actions of other authorities would be inappropriate.

If deregulation occurred regarding the MDA, the agency's interpretation of the statute makes clear the impact of that event on the preemptive effect of the MDA. According to the FDA, "The phrase 'or in addition to, any requirement applicable under the Act to the device' means that an FDA

101. Preemptive provisions in regulatory statutes are typically designed to ensure that no state law interferes with the achievement of the federal purpose. Once the federal program is gone, there presumably is no federal program with which to interfere. *See, e.g.*, *Wisconsin Public Intervenor v. Mortier*, 111 S. Ct. 2476, 2482-84 (1991) (expressing reluctance to find implied preemption of local regulation when the federal statute has left the relevant portion of the field "vacant"). Likewise, express preemption obviously requires some explicit statutory language. *See id.* at 544 ("Mere silence . . . cannot suffice to establish a 'clear and manifest purpose' to preempt local authority."). Maintaining the preemptive effect of an abandoned federal regulatory effort would require a congressional decision that an area of private activity once regarded as inadequately controlled by state tort law to the extent that a federal regulatory program was required to supplement it, should now be deregulated not only at the federal level, but also to prevent any control at the state level, even to the extent of preventing the provision of compensation to individuals for injuries caused by the presumably risky activity.

102. *See, e.g.*, RICHARD A. POSNER, *ECONOMIC ANALYSIS OF LAW* 523-24 (4th ed. 1992).

103. *See supra* note 101.

104. *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981); *see also* *California Fed. Sav. & Loan Ass'n v. Guerra*, 479 U.S. 272, 281 (1987) ("[P]reemption is not to be lightly presumed."); *City of Milwaukee v. Illinois*, 451 U.S. 304, 312-13 (1981) ("The enactment of a federal rule in an area of national concern, and the decision whether to displace state law in doing so, is generally made not by the federal judiciary, purposefully insulated from democratic pressures, but by the people through their elected representatives in Congress."); *United States v. Yazell*, 382 U.S. 341, 352 (1966) (stating that state laws "should be overridden by the federal courts only where clear and substantial interests of the National Government, which cannot be served consistently with respect for such state interests, will suffer major damage if the state law is applied"); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (stating that courts should "start with the assumption that the historic police powers of the States [are] not to be superseded by [a] Federal Act unless that was the clear and manifest purpose of Congress").

requirement must exist before preemption can occur.”¹⁰⁵ The agency’s construction of the statute will control “‘unless it is plainly erroneous or inconsistent with the regulation.’”¹⁰⁶ Thus, an agency decision not to impose or to remove “specific counterpart regulations” arguably would terminate any preemptive effect of the statute. To the extent the agency chooses not to enact “specific counterpart regulations,” state tort law would again be available to plaintiffs. Deregulation would offer few benefits to medical device manufacturers, because agency deregulation would simply allow the reassertion of state tort “requirements.”

The small or even negative cost of regulations with preemptive effects should not be surprising. Preemption is highly prized by potential tort defendants because the blessing of federal regulation protects them from the yawning maw of potentially vast tort liability.¹⁰⁷ To regard regulation as having significant costs to defendants in such circumstances is clearly wrong.¹⁰⁸

Deregulation, then, may on balance result in a higher level of compliance costs than the federal regulatory program had imposed. If state law would entail more costly demands than the federal regulation it would replace, regulation may reduce the costs that fall on the regulated private parties. Whether preemptive regulation is socially desirable is, of course, a more complex question; the answer depends in part on whether the incremental requirements of tort law yield benefits in improved health and safety, and in part on whether tort law offers any administrative efficiencies. It is clear, however, that the cost to society of such regulation may be little or none.

105. 43 Fed. Reg. 18,661, 18,662 (1978). Similarly, 21 C.F.R. § 808.1(d) states:

State or local requirements are preempted only when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements. There are other State or local requirements that affect devices that are not preempted by section [360k(a)] . . . because they are not “requirements applicable to a device” within the meaning of section [360k(a)] of the act.

Id.

106. *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1421 n.2 (5th Cir.) (quoting *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945)), *cert. denied*, 114 S. Ct. 86 (1993); *see also Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1543 (D.C. Cir.) (holding that the interpretation of FIFRA as not preempting state law will continue until Congress expresses a clear intent to the contrary), *cert. denied*, 469 U.S. 1062 (1984).

107. *See, e.g.*, Charles F. Preuss, *Federal Pre-Emption of State Tort Actions: When and How*, DEF. COUNS. J., Oct. 1990, at 434, 444 (stating that defense attorneys should raise preemption arguments “as soon and as often as possible”).

108. *See, e.g.*, John F. Morrall III, *A Review of the Record*, REGULATION, Nov./Dec. 1986, at 25, 30 (citing costs of NHTSA passive restraint standard per life saved).

B. Duplication of Mandates

Preemption, however, is still relatively uncommon.¹⁰⁹ Absent preemption, state and federal law work together to regulate a field. In the conventional view, federal deregulation simply terminates one set of controls and reduces the total compliance costs imposed on the regulated activity.

That, however, is true only in a formal sense. The broad reach of the tort system across virtually all aspects of product safety, and its practical role as the regulator of last resort, allows tort liability to reach virtually every aspect of product performance, including those for which formal administrative regulation exists.¹¹⁰ When this system of dual regulation¹¹¹ exists, regulation has little cost, and deregulation yields far fewer benefits than conventionally understood.

When both regulation and tort control the same aspect of an activity, such as product safety, only one can be the binding constraint on private behavior. One source of law will place the greater demands on the regulated parties for virtually any aspect of performance related to product safety; one will more successfully enforce compliance with its demands. The demands of the other are, in effect, a lesser included set of requirements.

When tort liability places the binding constraint on private behavior, regulation has little incremental cost.¹¹² Defendants comply with regulation, so to speak, along the way to limiting their tort liability. When regulation presents the binding rule, the cost of regulation is again only the incremental cost of compliance, over and above that necessitated by tort law, and not the total cost of compliance, though total cost has often implic-

109. The Supreme Court in most areas of regulation has seemed reluctant to find preemption of state action by a federal statute. See *Project: The Role of Preemption in Administrative Law*, 45 ADMIN. L. REV. 107, 124 (1993).

110. This is true except when preemption has limited the role of common-law claims. See *supra* note 11.

111. For a discussion of the concurrent nature of tort and federal regulation in the area of pharmaceuticals, see Gregory C. Jackson, *Pharmaceutical Product Liability May Be Hazardous to Your Health: A No-Fault Alternative to Concurrent Regulation*, 42 AM. U. L. REV. 199, 204-20 (1992); Note, *A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals*, 103 HARV. L. REV. 773, 775-85 (1990).

112. This is not to suggest that the administrative costs of regulation are insignificant. Rather, regulation imposes little incremental cost on private parties, in terms of their costs of complying with regulatory requirements and the resource misallocation resulting from those expenses. Administrative costs have largely been ignored in the analysis of the costs of regulation. As suggested later in this Article, the administrative costs may play a significant role in the decision of whether to use regulatory solutions for health and safety problems.

itly been treated as the appropriate concept.¹¹³ To a surprising degree, the relatively binding constraint today comes from tort law.

1. Substantive Rules of Behavior

All product risks are potentially subject to federal regulation, just as they are subject to tort liability. NHTSA has authority to regulate and control virtually all aspects of automotive design and construction as they affect the safety of the vehicle.¹¹⁴ Under FIFRA,¹¹⁵ EPA regulates pesticides and a wide range of other chemical products.¹¹⁶ The FDA regulates warnings, additives, testing, and quality of food and drug products.¹¹⁷ Among numerous other agencies¹¹⁸ with regulatory authority in the area of product safety, the Consumer Product Safety Commission has the bulk of responsibilities, which cover all consumer product safety issues not explicitly under the authority of other federal agencies.¹¹⁹

Despite their formal authority, the federal agencies have chosen not to act with respect to the vast majority of product risks. Differences between the scope of concerns of the federal agencies and products liability law arise largely from the inevitable selectiveness with which the federal agencies apply their limited budgets. Regulatory agencies typically must act prior to an actual injury; because not all injuries are predictable and because their resources are limited, regulatory agencies typically have restricted their activities to a small subset of potential sources of injury.¹²⁰

113. See *infra* Part IV.

114. Safety Act, 15 U.S.C. §§ 1381-1431 (1988).

115. 7 U.S.C. §§ 136-136gg (1988).

116. *Id.*

117. Federal Food, Drug and Cosmetic Act of 1938, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-394 (1988)).

118. Among other agencies with authority over product safety issues are the Nuclear Regulatory Commission, the Food Safety Inspection Service, the Federal Aviation Administration, the Animal and Plant Health Inspection Service, the Occupational Safety and Health Administration, and the Office of Surface Mining Reclamation and Enforcement.

119. Consumer Product Safety Act, Pub. L. No. 92-573, 86 Stat. 1207 (1972) (codified as amended at 15 U.S.C. §§ 2051-2083 (1988)).

One way to visualize the [Consumer Product Safety Commission]'s authority is to think of the types of products found in a large shopping mall. With the exception of the pharmacy and grocery stores (and even some items there), virtually everything in the mall falls within CPSC jurisdiction. Congress did specifically exempt certain products from CPSC jurisdiction, such as food, drugs (except for child resistant closure requirements), cosmetics, automobiles, tobacco products, aircraft, boats, and pesticides. . . . Most of these products are regulated by other federal agencies.

Robert S. Adler, *From "Model Agency" to Basket Case—Can the Consumer Product Safety Commission Be Redeemed?*, 41 ADMIN. L. REV. 61, 65 n.30 (1989).

120. The agencies . . . have received harsh criticism for failing to set and enforce regulations to prevent every unfortunate event from lung cancer deaths among asbestos workers to pollution episodes. Reacting to criticism that hundreds of carcinogenic and other toxic chemicals in the workplace are unregulated, the Occupational Safety and Health

In contrast, state and federal courts apply tort concepts of negligence and strict liability to virtually any product characteristic that injures a plaintiff. Their concerns sweep broadly across the full range of products, and reach virtually every aspect of product performance.¹²¹ If federal deregulation were to occur, state tort law would continue to exert post-hoc, presumably deterrent, regulatory authority. Wherever a regulatory agency has chosen to act, a parallel body of law covering the product performance characteristic in question almost always exists.¹²²

The development of tort doctrine over the last two decades has brought virtually every aspect of product safety within the reach of tort law.¹²³ The decline of tort privity¹²⁴ and the ability to disclaim implied warranties,¹²⁵ which had long protected manufacturers from consumer suits in tort; the development of the concept of design defect,¹²⁶ which holds manufacturers liable for product imperfections that are not unique to individual cases but are potentially present in every unit of the product; the rise of the doctrine of the product warning defect,¹²⁷ which focuses on the very same consumer

Administration has sought to regulate many more substances; yet redoubling its efforts has not succeeded in increasing the number of new regulations published each year. Similar examples can be given for each regulatory agency, since each finds that promulgating a new regulation requires thousands of professional man-hours and years of calendar time.

LAVE, *supra* note 21, at 3.

121. As George Priest has pointed out:

Where the function of our courts is to internalize costs and to provide insurance, their powers exceed those of any regulatory agency. . . . Our modern civil justice system . . . aspires to internalize costs to all activities in the society, made within every industry, indeed, by every citizen. Through the daily aggregation of civil damage judgments in the thousands of state courts around the country, our courts aspire to provide fine-tuned control of all injury-causing behavior. Our civil courts have become the most powerful regulatory institution in the modern state.

George L. Priest, *The Modern Expansion of Tort Liability: Its Sources, Its Effects, and Its Reform*, 5 J. ECON. PERSP. Summer, 1991, at 31, 39.

122. Statutory or regulatory standards have on occasion been used to create new tort liabilities. In *Lukaszewicz v. Ortho Pharmaceutical Corp.*, 510 F. Supp. 961, 964-65 (E.D. Wis.), *modified*, 532 F. Supp. 211 (E.D. Wis. 1981), for example, the court held that the violation of an FDA regulation requiring patient package inserts for oral contraceptives justified the creation of a new common-law duty for drug manufacturers to provide consumer warnings. *Id.* at 964-65; *see also* Clarence Morris, *The Role of Criminal Statutes in Negligence Actions*, 49 COLUM. L. REV. 21, 23 (1949) (discussing the advantages of the criminal justice system as the primary regulator of civil responsibility). In such cases, the presence of the statute or regulation clearly exceeds the responsibilities independently imposed by the tort system.

123. One barrier as yet unbreached, of course, is preemption.

124. *See, e.g.*, *MacPherson v. Buick Motor Co.*, 111 N.E. 1050, 1054-55 (N.Y. Ct. App. 1916).

125. *See, e.g.*, *Henningsen v. Bloomfield Motors, Inc.*, 161 A.2d 69, 84-96 (N.J. 1960).

126. *See, e.g.*, *Barker v. Lull Eng'g Co.*, 573 P.2d 443, 446 (Cal. 1978); *Cronin v. J.B.E. Olson Corp.*, 501 P.2d 1153, 1162 (Cal. 1972).

127. *See, e.g.*, *Moran v. Faberge*, 332 A.2d 11, 20 (Md. 1975).

information issues that have long concerned regulators; the development of liability that attributes responsibility for injuries to whole industries;¹²⁸ the decline of defenses relating to consumer behavior;¹²⁹ and ultimately, the redesign of tort law as the guarantor in strict liability of product safety;¹³⁰ have all made it possible for virtually any product risk addressed by regulatory agencies simultaneously to be addressed by the tort system. At the same time, the doctrine of negligence per se has meant that failure to comply with any governmental agency's product safety requirements may help prove liability.¹³¹ Furthermore, because tort enforcement is in the hands of injured private individuals, the activity of the tort system can reach virtually any legally cognizable claim.¹³²

The behavioral standards imposed by the tort system are, in the vast majority of cases, no less stringent than those imposed by federal regulation, and are frequently more stringent. This may in part be the result of the combined effect of the doctrine of negligence per se¹³³ and the traditional rule that regulatory compliance is not a defense to an action in tort;¹³⁴ together these imply that "federal legislation has traditionally occupied a limited role as the *floor* of safe conduct."¹³⁵ But there are more fundamental reasons than this. For one, the enforcement efforts of health-and-safety-related agencies have significantly declined in the last decade or so, while the risk of litigation has increased significantly for product manufactur-

128. For a discussion of enterprise liability, see *Sindell v. Abbott Labs.*, 607 P.2d 924, 933-34 (Cal.), *cert. denied*, 449 U.S. 912 (1980).

129. See, e.g., *Micallef v. Miehle Co.*, 348 N.E.2d 571, 577-78 (N.Y. 1976).

130. See, e.g., *Priest*, *supra* note 44, at 462-66.

131. The inference of liability is mandatory in some states but permissive in others. In those states where it is mandatory, negligence per se at best makes it easier to demonstrate that a product characteristic is unreasonably dangerous, a demonstration that may independently be made without the evidentiary simplification afforded by negligence per se. KEETON ET AL., *supra* note 37, § 36, at 220-33.

132. Although only a small minority of actionable injuries actually result in legal action, there is no reason to think that the rate of litigation from the pool of injuries differs among types of cognizable claims. Saks, *supra* note 1, at 1188.

133. See KEETON ET AL., *supra* note 37, § 36, at 229-31.

134. See, e.g., *Raymond v. Riegel Textile Corp.*, 484 F.2d 1025, 1027 (1st Cir. 1973); *Burch v. Amsterdam Corp.*, 366 A.2d 1079, 1085-86 (D.C. 1976); *Maize v. Atlantic Ref. Co.*, 41 A.2d 850, 853 (Pa. 1945); KEETON ET AL., *supra* note 37, § 36, at 233.

135. *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1543 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984).

ers.¹³⁶ In addition, tort damages awards are typically much greater than the penalties imposed by regulatory agencies or regulatory statutes.¹³⁷

Most importantly, however, the basic decision criteria of the alternative systems tend to force this result. Federal agencies must use a cost-benefit test that prevents the implementation of regulatory requirements with costs that outweigh the benefits,¹³⁸ but nothing compels agency action whenever that criterion is met. Common-law courts apply a more aggressive standard. Courts are supposed to find liability, in applying a negligence standard, whenever the benefits of a precaution outweigh its costs coupled with the probability that injury will occur if the precaution is not taken,¹³⁹ similarly, a strict liability standard gives a potential defendant reason to take a precaution whenever its benefits outweigh its costs.¹⁴⁰ In

136. See, e.g., Adler, *supra* note 116, at 77 (noting agency "has been stripped of resources to the point where it constitutes more of a regulatory speck than a meaningful market presence"); Jerry L. Mashaw & David L. Harfst, *Regulation and Legal Culture: The Case of Motor Vehicle Safety*, 4 YALE J. ON REG. 257, 264 (1987) (noting agency has ceased issuing new safety standards and "relaxed, rescinded, or shelved a number of existing and proposed safety standards").

137. As one observer has noted, "The enormous discrepancy between tort liability and statutory fines has been demonstrated repeatedly." Schwartz, *supra*, note 19, at n.68; see, e.g., the discussion of the MER/29 case, *supra* note 29. Similarly, another drug company was fined \$25,000 for a similar violation under the Food, Drug and Cosmetic Act; a later tort suit involving the defect cost the company \$6 million. See Howard M. Metzbaum, *Is Government Protecting Consumers?*, TRIAL, Apr. 1986, at 22, 26. Another company was fined the largest amount ever levied for a violation of the Food, Drug and Cosmetic Act for deceiving the FDA—the amount of which, some two million dollars, is obviously relatively small by products liability damages standards. Martin Mintz, *Careers, Trust at Stake in Beech-Nut Trial*, WASH. POST, Nov. 29, 1987, at H2.

138. Exec. Order No. 12,291 3 C.F.R. 128 (1981), states:

Sec. 2. *General Requirements.* In promulgating new regulations, reviewing existing regulations, and developing legislative proposals concerning regulation, all agencies, to the extent permitted by law, shall adhere to the following requirements:

.....

(b) Regulatory action shall not be undertaken unless the potential benefits to society for the regulation outweigh the potential costs to society.

See also Exec. Order No. 12,498 3 C.F.R. 323 (1985).

139. *United States v. Carroll Towing Co.*, 159 F.2d 169, 173 (2d Cir. 1947).

140. Courts typically determine that a product is unreasonably dangerous by a risk-utility balancing test, a test which is satisfied if a reasonable person would conclude that the danger outweighs the benefits of the product's design. See, e.g., *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076, 1087 (5th Cir. 1973) (stating that product is unreasonably dangerous if, on balance, utility of product does not outweigh magnitude of danger), *cert. denied*, 419 U.S. 869 (1974); *Thibault v. Sears, Roebuck & Co.*, 395 A.2d 843, 846 (N.H. 1978) (weighing product utility against danger; in this balancing process, the court must consider whether risk could have been reduced without significant impact on product effectiveness and manufacturing cost); *Knitz v. Minster Mach. Co.*, 432 N.E.2d 814, 818 (Ohio) (listing as factors to consider in risk utility test the likelihood of injury, gravity of danger, and mechanical and economic feasibility of improved design), *cert. denied*, 459 U.S. 857 (1982); *Turner v. General Motors Corp.*, 584 S.W.2d 844, 847 (Tex. 1979) (considering the "utility of the product and the risks involved in its use").

Dean Keeton has formulated the risk-utility test this way: "A product . . . is unreasonably dangerous if a reasonable person would conclude that the magnitude of the scientifically perceiv-

other words, federal agencies *may* impose a requirement when benefits outweigh costs, while (in principle) courts *must* find liability when benefits outweigh costs. As a result, in the typical case, tort law makes greater formal demands, backed by incentives more likely to compel compliance, than does regulation itself.¹⁴¹

Regulatory or statutory standards normally define only minimum product design or warning standards. Although a court may regard compliance with regulatory or statutory standards as evidence of the adequacy of a product design or warning label, such compliance is not conclusive.¹⁴² On the contrary, courts normally find compliance to indicate only that the manufacturer has undertaken the minimum effort required to comply with the statute,¹⁴³ not necessarily the effort needed to ensure that a product design creates no "unreasonably dangerous"¹⁴⁴ conditions that may injure a consumer.¹⁴⁵ Even when a regulatory rule clearly applies to the defendant's

able danger . . . outweighed the benefits of the way the product was so designed and marketed." W. Page Keeton, *Products Liability and the Meaning of Defect*, 5 ST. MARY'S L.J. 30, 37-38 (1973). This standard is essentially identical to the cost-benefit test applied in negligence law. See WILLIAM M. LANDES & RICHARD A. POSNER, *ECONOMIC ANALYSIS OF TORT LAW* 64 (1987).

141. State tort law routinely places more stringent demands on manufacturers than do the related federal requirements. See *Bruce v. Martin-Marietta Corp.*, 544 F.2d 442, 446 (10th Cir. 1976) ("Compliance with [federal] governmental air-safety regulations is admissible, but not conclusive, evidence in a suit arising out of a plane crash."); *Caiazza v. Volkswagenwerk, A.G.*, 468 F. Supp. 593, 606 (E.D. N.Y. 1979) (finding manufacturer liable for injury caused by defective design of door locks), *aff'd in part, rev'd in part on other grounds*, 647 F.2d 241, 252 (2d Cir. 1981); *Fouche v. Chrysler Motors Corp.*, 646 P.2d 1020, 1025 (Idaho 1982) (requiring manufacturer of alleged defective seat belt and steering column to apportion plaintiff's injuries). Compliance with federal safety standards generally does not constitute a defense to a products liability action, though failure to comply with federal design standards almost certainly would give rise to liability. The proposition applies generally in all areas of products liability. See, e.g., *Bruce*, 544 F.2d at 446 (Maryland law); *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1362 (4th Cir. 1975) (North Carolina law); *Raymond v. Riegel Textile Corp.*, 484 F.2d 1025, 1027-28 (1st Cir. 1973) (New Hampshire law).

142. See, e.g., *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1539 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984); *Olsen v. United States*, 521 F. Supp. 59, 67 (E.D. Pa. 1981); *MacDonald v. Ortho Pharmaceutical Corp.*, 375 N.E.2d 65, 69-70 (Mass.), *cert. denied*, 474 U.S. 920 (1985); *Wilson v. Piper Aircraft Corp.*, 577 P.2d 1322, 1328, *reh'g denied*, 579 P.2d 1287, 1288 (Or. 1978); *RESTATEMENT (SECOND) OF TORTS* § 288C, at 39-40 (1965); *Lubbock Mfg. Co. v. Perez*, 591 S.W.2d 907, 914-15 (Tex. Civ. App. 1979).

143. Noncompliance with federal product safety standards has for that reason frequently been the basis, not only for tort liability, but also for the imposition of punitive damages in products liability cases. See *Rustad*, *supra* note 32, at 69.

144. See *RESTATEMENT (SECOND) OF TORTS* § 402A(1) (1965). The Restatement provides that "[o]ne who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property." *Id.*

145. Comment (a) to § 288C of the Restatement clearly treats statutory standards as representing only the minimum acceptable level of care. It provides that, absent circumstances which call for further precautions, "the minimum standard prescribed by the legislation or regulation may be accepted by the triers of fact, or by the court as a matter of law, as sufficient for the occasion."

behavior in a product safety suit,¹⁴⁶ in most circumstances the standard of behavior demanded by tort law at least equals that demanded by the regulatory rule, and in many cases, tort law exceeds the regulatory standard.¹⁴⁷

Furthermore, although violations of statutory or regulatory standards might, contrary to the general rule, be found not to constitute negligence as a matter of law, a trier of fact might nevertheless find that the violation amounts to negligence.¹⁴⁸ A court could find that the regulatory rule does not cover the "special risks" presented by the product involved in litigation.¹⁴⁹ Or a court could find that the statute has become obsolete and therefore is inadequate as a standard of care.¹⁵⁰ As one observer has noted, in such circumstances "the agency's regulation does not address the underlying conduct that is at the heart of the tort claim."¹⁵¹ For that reason, the

RESTATEMENT (SECOND) OF TORTS § 288C cmt. a (1965). Dean Prosser has stated that statutory standards of behavior should be regarded as acceptable for purposes of tort liability only in "normal situation[s], clearly identical with . . . [t]hose contemplated by the statute or regulation." WILLIAM L. PROSSER, HANDBOOK OF THE LAW OF TORTS 210 (4th ed. 1971). Professor Morris has argued that the "optimum conditions are seldom present in accident cases." Morris, *supra* note 122, at 47.

146. The Restatement requires that before a statutory standard is adopted as a minimum standard of care, two conditions are fulfilled: first, the person seeking protection under the standard must fall within the class of persons the legislature intended to protect; and second, the injury must be of the type the legislature intended to prevent. See RESTATEMENT (SECOND) OF TORTS § 286 (1965).

147. There are some cases in which statutory requirements exceed the standard of care. The Restatement permits statutory violations to be excused in a tort context under some circumstances, including incapacity, inability, or emergency, and the courts have sometimes ignored statutory requirements in such circumstances. RESTATEMENT (SECOND) OF TORTS § 288A; see, e.g., *Zeni v. Anderson*, 243 N.W.2d 270, 276 (Mich. 1976).

However, certain types of statutes, including those most germane here, are commonly interpreted not to allow for an excuse to commit a tort. These include child labor laws, pure food and drug acts, product safety statutes, and workplace safety statutes. See WILLIAM L. PROSSER ET AL., TORTS: CASES AND MATERIALS 246 (7th ed. 1987).

148. See RESTATEMENT (SECOND) OF TORTS § 288C, cmt. a (1965). The Restatement provides: Where there are no . . . special circumstances, the minimum standard prescribed by the legislation or regulation may be accepted by the triers of fact, or by the court as a matter of law, as sufficient for the occasion; but if for any reason a reasonable man would take additional precautions, the provision does not preclude a finding that the actor should do so.

Id.

149. See, e.g., *Burch v. Amsterdam Corp.*, 366 A.2d 1079, 1085 (D.C. 1976). In *Burch*, the court found that the Federal Hazardous Substances Act mandated that general warnings be provided to users of over 300,000 products, many of which presented special dangers requiring "more detailed and specific instructions than the general warnings prescribed by the Act." *Id.* at 1085; see also *O'Gilvie v. International Playtex, Inc.*, 609 F. Supp. 817, 819 (D. Kan. 1985) (finding FDA-approved warning need not be adequate when defendant's tampon posed greater risk of toxic shock syndrome than other tampons), *modified*, 821 F.2d 1438, 1449 (10th Cir. 1987).

150. See, e.g., *Raymond v. Riegel Textile Corp.*, 484 F.2d 1025, 1027 (1st Cir. 1973) (noting that flammability standards had remained unchanged for over a decade, allowing highly flammable textiles to remain on the market).

151. Schwartz, *supra* note 19, at 1144.

court may choose not to apply a regulatory rule as the standard of care, although the rule clearly controls the very aspect of product performance at issue. If so, tort standards will again exceed the regulatory requirement, even though the two are formally identical. In many instances federal regulatory standards are expressly *designed* to serve only as a minimal requirement; the statutes explicitly allow state tort actions to proceed when claims rest on an asserted higher standard of care than that mandated by the statute.

For example, courts have imposed liability on automobile manufacturers for numerous design characteristics, although the manufacturer had fully complied with the applicable NHTSA requirements germane to the alleged cause of the plaintiffs' injuries.¹⁵² The National Traffic and Motor Vehicle Safety Act¹⁵³ provides: "Compliance with any Federal motor vehicle safety standard issued under this subchapter does not exempt any person from any liability under common law."¹⁵⁴ Courts have interpreted this provision as allowing a tort action to proceed even when it would result in a state standard that exceeds the federal standard. Indeed, Congress explicitly contem-

152. See, e.g., *Shekells v. AGV-USA Corp.*, 987 F.2d 1532, 1533 (11th Cir. 1993) (imposing liability in FMVSS 218, motorcycle helmet case); *Perry v. Mercedes-Benz of N. Am.*, 957 F.2d 1257, 1259 (5th Cir. 1992) (imposing liability in FMVSS 208, occupant crash protection case); *Habecker v. Clark Equip. Co.*, 942 F.2d 210, 212 (3d Cir. 1991) (imposing liability in FMVSS 202, head restraints case); *Sexton v. Bell Helmets, Inc.*, 926 F.2d 331, 333 (4th Cir.) (finding compliance with FMVSS 218 requirements for motorcycle helmet was not a defense to product liability action premised on performance of helmet), *cert. denied*, 112 S. Ct. 79 (1991); *Sours v. General Motors Corp.*, 717 F.2d 1511, 1516-17 (6th Cir. 1983) (imposing liability in FMVSS 216, roof crush resistance case); *Dorsey v. Honda Motor Co., Ltd.*, 655 F.2d 650 (5th Cir. 1982) (finding compliance with FMVSS's 207, 209, and 210 did not preclude liability or punitive damages when inadequate performance of affected automobile characteristics contributed to injury); *Seese v. Volkswagenwerk A.G.*, 648 F.2d 833 (3d Cir. 1981) (FMVSS 212, windshield mounting); *Dawson v. Chrysler Corp.*, 630 F.2d 950 (3rd Cir. 1980) (FMVSS 215, exterior protection); *Fox v. Ford Motor Co.*, 575 F.2d 774 (10th Cir. 1978) (FMVSSs 208 and 210, seatbelts and seatbelt anchors); *Hurt v. General Motors Corp.*, 553 F.2d 1181 (8th Cir. 1977) (FMVSS 209, seatbelt assemblies); *Melia v. Ford Motor Co.*, 534 F.2d 795 (8th Cir. 1976); *Larsen v. General Motors Corp.*, 391 F.2d 495 (8th Cir. 1968) (injury due to displacement of steering column, later the subject of FMVSS 204); *Swope v. STI Transit Co.*, 796 F. Supp. 160, 165 (E.D. Pa. 1992) (finding compliance with FMVSS 108 requirements for illumination was not a defense to products liability action, but defendant's summary judgment motion granted because defendant manufacturer had no duty to warn trailer user of inadequate illumination); *Dancer v. Dorsey Trailer, Inc.*, 1992 WL 76981, *1-2 (E.D. Pa. 1992) (finding compliance with FMVSS 108 requirements for illumination was not a defense to products liability action premised on inability to see trailer at night); *Welsh v. Century Products Inc.*, 745 F. Supp. 313 (D. Md. 1990) (FMVSS 213, child seating systems); *Grimshaw v. Ford Motor Co.*, 119 Cal.App.3d 757, 174 Cal. Rptr. 348 (Cal. Ct. App. 1981) (FMVSS 301, fuel system integrity); *Maccuish v. Volkswagenwerk A.G.*, 22 Mass. App. Ct. 380, 494 N.E.2d 390 (1986) (FMVSS 217, bus window retention and release); *Werthman v. General Motors Corp.*, 187 Mich. App. 238, 466 N.W.2d 305 (Mich. Ct. App. 1990) (FMVSS 205, glazing materials); *Chrysler Corp. v. Todorovich*, 580 P.2d 1123 (Wyo. 1978) (FMVSS 207, seating systems).

153. 15 U.S.C. §§ 1381-1431 (1988 & Supp. III 1991).

154. 15 U.S.C. § 1397(k) (1988 & Supp. III. 1991).

plated that the federal safety standards would state only minimum standards and that manufacturers could be held to higher standards under state tort law.¹⁵⁵

Such cases are common. For example, in *Welsh v. Century Products, Inc.*,¹⁵⁶ a child was injured in an automobile accident while seated in a child car seat that both sides agreed¹⁵⁷ complied fully with FMVSS 213, which "specifies requirements for child restraint systems used in motor vehicles."¹⁵⁸ The parents claimed that the injuries were caused by defects in the design of the seat. The manufacturer moved for summary judgment on the basis that the claim was preempted under the Safety Act by § 1392(d). Relying on the "savings clause,"¹⁵⁹ the court ruled that the claim was not preempted, even though the plaintiffs' claims concerned the "same aspect of performance" as the applicable federal safety standard.¹⁶⁰ Thus, when the plaintiffs' claims succeeded, the standard applied by the jury necessarily exceeded the federal standard, because the federal standard was already satisfied.¹⁶¹

155. The Senate Report on the bill stated that "the Federal minimum safety standards need not be interpreted as restricting state common law standards of care. Compliance with such Standards would thus not necessarily shield any person from product liability at common law." S. REP. NO. 1301, 89th Cong., 2d Sess. (1966), *reprinted in* 1966 U.S.C.C.A.N. 2709, 2720. The House Report stated that "this subsection specifically establishes that compliance with safety standards is not to be a defense or otherwise to affect the rights of parties under common law particularly those related to . . . tort liability." H.R. REP. NO. 1776, 89th Cong., 2d Sess. 24 (1966). Accordingly, 15 U.S.C. § 1392(d) (1988) provides in part:

Whenever a Federal motor vehicle safety standard established under this subchapter is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, with respect to any motor vehicle or item of motor vehicle equipment any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is identical to the Federal standard. Nothing in this section shall be construed as preventing any State from enforcing any safety standard which is not identical to a Federal safety standard.

Id.

156. 745 F. Supp. 313 (D. Md. 1990).

157. *Id.* at 315.

158. *Id.* (quoting 49 C.F.R. § 571.213.S1 (1992)).

159. *See supra* note 47.

160. *Welsh*, 745 F. Supp. at 316-18.

161. Although a few courts have held that § 1392(d) expressly preempts state tort actions, *see, e.g., Cox v. Baltimore County*, 646 F. Supp. 761, 763 (D. Md. 1986) (granting motion for summary judgment on the basis of preemption), the far more widely accepted view is that preemption does not occur (except in the airbag context, in which preemption is normally considered implied and not express), and that state tort actions applying more stringent standards than the applicable FMVSS may go forward, *see, e.g., Garrett v. Ford Motor Co.*, 684 F. Supp. 407, 410-11 (D. Md. 1987) (distinguishing *Cox*).

This has been the view since *Larsen v. General Motors Corp.*, 391 F.2d 495 (8th Cir. 1968), in which the Eighth Circuit held that the Safety Act was intended to be an addition to the common law of negligence and product liability and not a replacement for it, and that it therefore did not prevent plaintiff from pursuing his claims. The court in *Larsen* stated:

Further evidence of a coincidence of concerns between tort and regulation is implicit in defendants' claims that federal regulation preempts state tort liability. Preemption claims are necessarily founded on an assertion of compliance with federal standards, because noncompliance would render the preemption claim moot.¹⁶² Many crashworthiness cases, therefore, involve full compliance with all NHTSA standards, and implicitly contain an assertion that state standards impose more stringent demands.

The situation in the pharmaceutical industry is much the same, despite the unusually comprehensive nature of pharmaceutical regulation. The FDA demands extensive testing of every pharmaceutical product that reaches the market,¹⁶³ approves consumer and physician warning labels,¹⁶⁴ and conducts extensive post-marketing surveillance.¹⁶⁵ Nevertheless, tort law routinely imposes higher standards on manufacturers than does the FDA. Pharmaceuticals, like other products, are subject to strict liability in tort based on manufacturing defects and, depending on the jurisdiction, may be subject to strict liability based on design defect or failure to warn.¹⁶⁶ Juries have been allowed to determine, independently of the FDA's evaluation, whether a pharmaceutical product contains design defects and therefore is unreasonably dangerous per se, and have found products previously

We perceive of no sound reason, either in logic or experience, nor any command or precedent, why the manufacturer should not be held to a reasonable duty of care in the design of its vehicle consonant with the state of the art to minimize the effect of accidents. The manufacturers are not insurers, but should be held to a standard of reasonable care in design to provide a reasonably safe vehicle in which to travel. . . .

. . . .

. . . . The common law standard of duty to use reasonable care in light of all the circumstances can at least serve the needs of our society until the legislature imposes higher standards or the courts expand the doctrine of strict liability for tort. The Act is a salutary step in this direction and not an exemption from common law liability.

Id. at 503, 506; *see also* Dawson v. Chrysler Corp., 630 F.2d 950, 958 (3d Cir. 1980) (holding that compliance with federal safety standards is not incompatible with manufacturers' liability for injuries to the consumer), *cert. denied*, 450 U.S. 959 (1981).

162. 15 U.S.C. § 1392(d) (1988) provides in part: "Nothing in this section shall be construed as preventing any State from enforcing any safety standard which is identical to a Federal safety standard."

163. *See* 21 U.S.C. § 355(i) (1988) (requiring approval of Investigational New Drug application); 21 U.S.C. § 355(d) (1988) (requiring "'substantial evidence' . . . consisting of adequate and well-controlled investigations" for approval of New Drug Application); David A. Kessler, *The Regulation of Investigational Drugs*, 320 NEW ENG. J. MED. 281 (1989) (discussing the regulatory process of pre-market FDA screening). The Food and Drug Administration's statutory responsibilities are defined at 21 U.S.C. §§ 301-393 (1988 & Supp. IV 1992).

164. 21 U.S.C. § 355(b)(1)(F) (1988).

165. 21 C.F.R. § 314.80 (1985); *see also* FOOD AND DRUG ADMINISTRATION, DRAFT GUIDELINE FOR POSTMARKETING REPORT OF ADVERSE DRUG REACTIONS, Docket No. 85D-0249 (Aug. 23, 1985).

166. *See, e.g.*, Feldman v. Lederle Labs., 479 A.2d 374, 380 (N.J. 1984) ("[W]e are of the opinion that generally the principle of strict liability is applicable to manufacturers of prescription drugs.").

approved by the FDA to be unsafe.¹⁶⁷ Similarly, juries have found pharmaceutical manufacturers' warnings inadequate, even when the FDA mandated the warning in question.¹⁶⁸ Compliance with FDA regulatory requirements thus does not provide protection against product liability claims.¹⁶⁹

The same appears to be true in many other areas in which federal health and safety regulation exists: tort standards often exceed those formally enunciated by federal regulators. For example, John Morrall offers a list of federal health and safety regulations for which "cost" has been calculated.¹⁷⁰ The standards of almost all listed regulations have been exceeded in products liability cases. Although not every state or federal judicial cir-

167. See, e.g., *Abbott v. American Cyanamid Co.*, 844 F.2d 1108, 1115-16 (4th Cir.) (remanding for a jury determination of a design defect claim), *cert. denied*, 109 S.Ct. 260 (1988); *Hurley v. Lederle Labs.*, 851 F.2d 1536, 1542 (5th Cir. 1988) (same), *modified*, 863 F.2d 1173 (1989); *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 654-57 (1st Cir. 1981) (holding that manufacturer could be liable for design defect in the drug and for failure to warn physicians of risks associated with the drug); *Wells v. Ortho Pharmaceutical Corp.*, 615 F. Supp. 262, 295 (N.D. Ga.) (including factfinder's holding that pharmaceutical caused birth defect despite FDA finding to the contrary), *modified*, 788 F.2d 741 (11th Cir. 1985), *cert. denied*, 479 U.S. 950 (1986).

The Restatement of Torts has taken the view that prescription drugs should be excluded from liability. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965):

[S]ome products . . . are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . The seller of such products . . . is not to be held to strict liability for unfortunate consequences attending their use Opinions differ as to the extent to which the Restatement's position has reduced the litigation of design defect cases.

Id. Compare Note, *supra* note 111, at 777-78 ("Although the *Restatement* . . . suggests that prescription drugs should be excluded from strict liability, pharmaceuticals are commonly subject to strict liability." (footnotes omitted)) with Judith P. Swazey, *Prescription Drug Safety and Product Liability*, in *THE LIABILITY MAZE: THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION* 291-305 (Peter W. Huber & Robert E. Litan eds., 1991) ("But to date there have been relatively few [design defect cases for prescription drugs], given the Comment k view that these are unavoidably unsafe products").

168. See, e.g., *Brochu*, 642 F.2d at 658 (holding that although warnings were drafted by the FDA, they were inadequate); *McEwen v. Ortho Pharmaceutical Corp.*, 528 P.2d 522, 534 (Or. 1974) (finding manufacturer liable for inadequate warning though FDA wrote the warning); see also *Wooderson v. Ortho Pharmaceutical Corp.*, 681 P.2d 1038, 1057 (Kan.) (finding warning inadequate because of failure to disclose a danger, though FDA had ruled out inclusion of the danger on the warning label because of inadequate scientific evidence for it), *cert. denied*, 469 U.S. 965 (1984); *Feldman v. Lederle Labs.*, 479 A.2d 374, 378-79 (N.J. 1984). See generally Charles J. Walsh & Marc S. Klein, *The Conflicting Objectives of Federal and State Tort Law Drug Regulation*, 41 *FOOD DRUG COSM. L.J.*, 171, 185-88 (1986) (discussing conflict between FDA regulation and state law regarding the content of warning labels).

169. *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1362 (4th Cir. 1975) (holding that compliance with federal regulations will not immunize manufacturers from state product liability common law); *Graham v. Wyeth Labs.*, 666 F. Supp. 1483, 1491 (D. Kan. 1987) (holding that compliance with FDA regulations did not preclude liability for dangerous product); *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65, 70-71 (Mass. 1985) (holding that compliance with FDA requirements is not conclusive of negligence issue), *cert. denied*, 474 U.S. 920 (1985).

170. Morrall, *supra* note 108, at 25.

cuit has addressed the precise factual situation contemplated by each regulation, the advantages of nationwide product distribution and the existence of economies of scale in production often force national compliance with a standard imposed on a less-than-national basis.

Regulatory standards have, at times, explicitly adopted the criteria of tort law. For example, the Consumer Product Safety Act authorizes the Consumer Product Safety Commission (CPSC) to recall products that pose a "substantial risk of injury to the public"¹⁷¹ either because they violate an agency rule or because they contain a "defect." Interpreting the word "defect," the CPSC directly imported the parameters of the "defect" concept of modern products liability law, including the concepts of manufacturing mistake, improper design, and inadequate warning,¹⁷² into its regulatory standard.¹⁷³ The incremental impact of regulation in such cases is clearly minimal.

2. Incentives to Comply with the Rules

The mere announcement of standards by courts does not by itself ensure compliance. However, incentives to comply with tort requirements have risen significantly since the middle 1970s, while the enforcement of federal regulation has declined. The amount of litigation has increased, and the monetary consequences of liability also appear to have escalated. As the vitality of the tort reform movement demonstrates,¹⁷⁴ tort liability has become a predominant concern of potential defendants. Regulation may thus largely be superseded in actual impact as well as in formal mandate. At the same time, other trends have lessened the impact of regulation.¹⁷⁵ Easing health and safety regulation is likely to have less impact on the behavior of an industry than the literature has generally suggested, while ad-

171. 15 U.S.C. § 2064 (1988).

172. Despite efforts to expand the reach of the interpretive rule beyond common-law concepts of product liability, the agency has largely retreated from those efforts. The agency recently expanded the list of examples to include concepts not within the parameters of product liability law, but withdrew them in response to industry complaints. *See* Adler, *supra* note 119, at 118-19.

173. 16 C.F.R. § 1115.4 (1988):

A defect, for example, may be the result of a manufacturing or production error. . . . In addition, the design of and the materials used in a consumer product may also result in a defect. . . . With respect to instruction, a consumer product may contain a defect if the instructions for assembly or use could allow the product, otherwise safely designed and manufactured, to present a risk of injury. . . . However, not all products which present a risk of injury are defective . . . [The product] does not contain a defect . . . [when] the risk of injury is outweighed by the usefulness of the product which is made possible by the same aspect which presents the risk of injury.

Id.

174. *See supra* note 5.

175. *See supra* Part III.

ding additional regulation might well have little impact on private behavior or costs.¹⁷⁶

a. Products Liability Case Filings

Product manufacturers are increasingly susceptible to product liability claims. The pattern of overall tort filings recently has been the subject of controversy, with some commentators suggesting that we are in the midst of a "litigation explosion"¹⁷⁷ and others questioning the data on which that conclusion is based.¹⁷⁸ In both state¹⁷⁹ and federal courts,¹⁸⁰ total caseloads appear to have increased. On the other hand, critics of the "litigation explosion" view question whether this increase in filing rates in federal court suggests that anything has gone seriously wrong with the litigation system. For example, Michael Saks notes that tort filings grew less quickly over the 1975-1985 period than did non-tort cases; that the growth rate in filings over that period is exaggerated by the choice of a year with an unusually low level of claims as the starting point for the comparisons; that one-third of all product liability cases in the mid-1980s were asbestos-related and thus grew out of relatively unusual circumstances; and that the only clear growth in tort filings occurred in the federal courts, where only two percent of cases are filed.¹⁸¹ In state courts, the rate of tort filings is harder to calculate because of state-to-state variation in the quality of record keeping and in definitions of categories. Although there is considerable variation among states, Saks notes that in the aggregate "state tort cases grew at a modest annual rate of somewhere between 2.3% and 3.9%. Adjusting for population growth, the figure does not rise above 3%."¹⁸²

However, these figures describe the behavior of the tort system as a whole and are not relevant to product safety issues. The Rand Corporation's Institute for Civil Justice (RAND) suggests that the aggregate tort data just described are a composite of the results of three separate "worlds," each of which behaves differently from the others.¹⁸³ The first "consists of routine personal injury suits, mostly automobile cases with modest stakes and settled law."¹⁸⁴ This class of cases, which because of its relative size

176. See *infra* Part IV.

177. See, e.g., WALTER K. OLSON, *THE LITIGATION EXPLOSION: WHAT HAPPENED WHEN AMERICA UNLEASHED THE LAWSUIT I* (1991).

178. Andrew Blum, *Debate Still Rages on Torts*, NAT'L L. J., Nov. 16, 1992, at 1, 1.

179. See Henry J. Reske, *Record State Caseloads in 1990*, 78 A.B.A. J., Aug. 1992, at 23, 23.

180. The tort portion of the federal courts' caseload increased 62% from 1975 to 1985, from 25,691 to 41,593 cases. Saks, *supra* note 1, at 1201.

181. *Id.* at 1198-1200.

182. *Id.* at 1207.

183. DEBORAH R. HENSLER ET AL., *TRENDS IN TORT LITIGATION: THE STORY BEHIND THE STATISTICS 2-3* (1987).

184. *Id.*; see, e.g., Saks, *supra* note 1, at 1209.

dominates the data for torts cases as a whole, "show[s] a slight increase, which roughly mirrors population growth during this period; in other words, litigation in this area remained basically stable."¹⁸⁵ The second world of torts cases "consists of high stakes cases, notably products liability, medical malpractice, and business torts. Here the litigation itself is newer, the law is still evolving, and the stakes per case are larger and increasingly uncertain."¹⁸⁶ The limited available data seem to indicate rapid growth in the number of such case filings.¹⁸⁷ Finally, there is "the world of mass latent injury cases, such as asbestos litigation, Dalkon Shield cases, and other suits arising from mass exposure to drugs, chemicals, or other toxic substances."¹⁸⁸ This class of cases demonstrates "truly explosive growth," and a rapidly rising burden for defendants. The increase in the latter two categories of cases suggests that potential defendants in products liability cases have an increased incentive to behave in a manner designed to reduce the risk of liability.¹⁸⁹

b. Damage Awards

The amount of money awarded in products liability cases has also increased since the mid-1970s. The possibility of higher damage awards also suggests that potential defendants have an increased incentive to comply with the behavioral standards of products liability law. Again, it is important to distinguish between aggregate tort awards and awards in the more narrowly defined field of products liability and mass exposure torts. According to the RAND studies, median jury awards in tort cases as a whole were quite stable between 1980 and 1987, but the median jury award in products liability and medical malpractice rose "very sharply."¹⁹⁰ This upward trend apparently persists even if the awards data are adjusted for infla-

185. HENSLER ET AL., *supra* note 183, at 7 (citing DEBORAH R. HENSLER, TRENDS IN CALIFORNIA TORT LIABILITY LITIGATION (RAND Institute for Civil Justice No. P-7287-ICJ, 1987)).

186. *Id.* at 3.

187. *Id.* at 8.

188. *Id.* at 3.

189. In an environment in which total injuries are declining, a rising volume of cases means a higher probability of a potential defendant facing suit. U.S. BUREAU OF THE CENSUS, STATISTICAL ABSTRACT OF THE UNITED STATES 121, tbls. 184 & 185 (112th ed. 1992). One would expect this to produce more behavior designed to reduce the risk of causing injury and thus the risk of liability.

A rising ratio of suits to injuries, however, will not necessarily have that effect. For example, automobile manufacturers might increase their safety expenditures per car only if the number of suits per car sold, or the ratio of damage awards to revenue, were to rise. However, the ratio of suits to injuries might rise while these indicators of the degree of incentive fall, if the number of injuries fall sufficiently. Furthermore, their behavior will be affected by their perception of whether suits are coming from the pool of injuries arguably caused by some defect or from the pool of injuries caused by other sources such as operator error.

190. HENSLER ET AL., *supra* note 183, at 16.

tion using not the Consumer Price Index, but, as Saks urges,¹⁹¹ a medical cost deflator that better reflects the inflation of actual components of tort awards.¹⁹²

As RAND points out,¹⁹³ the *expected* jury award—which more directly affects the behavior of potential defendants than the *average* award—has risen, not just because the average award is higher, but because the probability of plaintiff victory also has risen. Average or median awards reflect only the cases actually litigated to judgment and do not adjust for the number of claims made for which no damage award resulted. The *expected* award per suit brought—and hence the incentive to the plaintiff to bring suit and the incentive to the potential defendant to modify behavior in the hopes of avoiding liability—has risen more sharply than actual awards because the plaintiff's probability of victory has also risen between the 1960s and the 1980s. As RAND points out,

For every type of liability case, Cook County plaintiffs were far more successful in the early 1980's than were plaintiffs twenty years earlier. For example, in the 1960's, plaintiffs won about one-fourth of product liability and malpractice cases. In the late 1970's, they won about one-third of such cases. By the 1980's, they were winning almost one-half of them.

The increased probability of winning, coupled with the increase in average awards, results in higher expected awards The expected award for auto cases has risen from about \$25,000 to \$60,000-\$90,000 at the end of the period, but this move is dwarfed by the rocketing awards in product liability cases, which grew 400-900 percent between 1960 and 1984.¹⁹⁴

Product manufacturers' decisions about product designs, manufacturing monitoring, or safety warning labels are likely to be based on anticipated awards and not past awards. Since both observed awards and probability of plaintiff victory have been rising, the deterrent effect and hence the regulatory value of tort law (and product liability in particular) has also been rising.¹⁹⁵

191. Saks, *supra* note 1, at 1246-47.

192. MARK A. PETERSON, COMPENSATION OF INJURIES: CIVIL JURY VERDICTS IN COOK COUNTY 49-50 (1984). Because tort awards reflect other variables besides medical costs (such as plaintiff's earnings and pain and suffering), adjustments using a medical cost deflator, which Saks suggests, probably overstate the appropriate inflation adjustment.

193. HENSLER ET AL., *supra* note 183, at 13, 18-19.

194. *Id.* at 18-19.

195. Discussion of the deterrent effect of tort law depends on an assumption that the system is perceived to be rational in selecting winning cases. In fact, perceptions about the tort system appear considerably to outrun its actual effect. As Saks explains:

[T]he data strongly suggest that our tort system hits infrequently and lightly. Yet, it has nevertheless somehow succeeded in frightening a great many potential defendants, who seem to go to considerable lengths to avoid becoming actual defendants. Somehow

III. EMPIRICAL STUDIES OF THE COST OF REGULATION

Despite the obvious relevance of the tort system to the evaluation of the costs and benefits of health, safety, and environmental regulation, virtually none of the empirical work evaluating such regulation has considered the dramatic changes in the tort system that occurred simultaneously with the imposition of modern social regulation. Instead, by default, researchers have conflated the costs and benefits of regulation with those of the new tort doctrines. As a result, the measured costs and benefits of regulation and the anticipated benefits from deregulation were overstated to include the costs actually associated with tort law. For two decades, federal regulatory policy has been distorted by what econometricians call an omitted variables problem.¹⁹⁶

The effects of this miscalculation are serious. It means that we have little understanding of the relative costs and benefits of alternative approaches to ensuring product safety. Modern products liability law, for example, has been regarded by some¹⁹⁷ as generating minimal benefits in the form of safer products.¹⁹⁸ The regulatory studies leave open the possibility that tort law may have had an unacknowledged impact in improving product safety.¹⁹⁹

The difficulty results from the powerful coincidence in time between the development of products liability law and much of the modern regulatory regime. Modern products liability doctrine, as a matter of recognized law, could be said to have begun with *Henningsen v. Bloomfield Motors, Inc.*²⁰⁰ It developed with increasing momentum after *Greenman v. Yuba Power Products*²⁰¹ and the publication of the *Restatement (Second) of Torts* in 1964, and began to reach its full development only after *Cronin v. J.B.E. Olson Corp.*²⁰² Although some federal health and safety regulation existed

people have come to overestimate vastly the tort system's vigilance and the magnitude of its sanctions. . . . The tort system is a mouse with an otherworldly roar.

Saks, *supra* note 1, at 1286-87 (citations omitted).

196. See DAVID W. BARNES, STATISTICS AS PROOF: FUNDAMENTALS OF QUANTITATIVE EVIDENCE 389-91 (1983).

197. See GEORGE EADS & PETER REUTER, DESIGNING SAFER PRODUCTS: CORPORATE RESPONSES TO PRODUCT LIABILITY AND REGULATION 99-101 (RAND Institute for Civil Justice No. 3022-ICJ, 1983) (noting that products liability law has little benefit because lower-level corporate managers are unable to perceive or respond to tort incentives).

198. See, e.g., Swazey, *supra* note 167, at 291, 293 (noting marginal effect of liability laws and legislation on safety when compared with federal regulation).

199. Empirical studies of the impact of tort and products liability law on product safety generally remain inconclusive. See *supra* notes 15-17 and accompanying text.

200. 161 A.2d 69 (N.J. 1960).

201. 377 P.2d 897 (Cal. 1963).

202. 501 P.2d 1153 (Cal. 1972). For a discussion of the post-*Greenman* development of products liability law, see FRANK VANDALL, STRICT LIABILITY: LEGAL AND ECONOMIC ANALYSIS 9 (1989).

prior to the 1960s, the modern revolution in health and safety regulation essentially began in 1966 with the passage of the National Traffic and Motor Safety Act.²⁰³ The bulk of federal health and safety regulation was also enacted during the few years surrounding 1970. As noted by one commentator, "Of 47 federal consumer protection laws enacted between 1891 and 1972, fewer than half, or 21 statutes, were enacted in the first 75 years; the remaining 26 were enacted in the years from 1966-1972."²⁰⁴ This powerful coincidence between products liability law and social regulation is nowhere more clearly shown than in the area of automobile safety regulation.

A. *A Brief History of Automobile Safety Mandates*

Regulatory and common-law efforts to improve automobile safety developed essentially simultaneously in the early 1970s. Virtually all of the development of the crashworthiness doctrine, for example, occurred during this period. No requirement to design an automobile to protect the safety of occupants from the so-called "second collision" existed prior to the decision in *Larsen v. General Motors Corp.*²⁰⁵ So long as its products contained no defects of materials or workmanship that themselves caused the accident,²⁰⁶ manufacturers had no duty to ensure the safety of their products.²⁰⁷

Thus, at the time the initial FMVSSs were issued in 1967,²⁰⁸ tort law imposed no requirement on automobile manufacturers to design their products in a manner that reduced the chance of injury to passengers in the event of an accident. For example, in *Evans v. General Motors Corp.*,²⁰⁹ decided the same year that Congress passed the National Traffic and Motor Vehicle Safety Act,²¹⁰ the Seventh Circuit held that a plaintiff who had alleged that a car was not crashworthy had failed to state a claim because the manufacturer had no duty to design its cars so as to protect their occupants in the event of an accident. According to the court, the manufacturer's duties were limited to ensuring that its products contained no latent defects that could cause the accident itself.²¹¹ As one federal court recently noted, "[A]s of 1966, no plaintiff had yet prevailed on a claim that an automobile

203. See Safety Act, 15 U.S.C. §§ 1381-1431 (1988).

204. Adler, *supra* note 119, at 61 n.8; see also STEPHEN BREYER, REGULATION AND ITS REFORM 1 (1982) (describing the growth of federal regulation beginning in the mid-1960s).

205. 391 F.2d 495 (8th Cir. 1968).

206. Henningsen v. Bloomfield Motors, Inc., 161 A.2d 69, 79-80 (N.J. 1960).

207. *Evans v. General Motors Corp.*, 359 F.2d 822, 824-25 (7th Cir.), *cert. denied*, 385 U.S. 836 (1966), *overruled by Huff v. White Motor Corp.*, 565 F.2d 104 (7th Cir. 1977).

208. *Huff*, 565 F.2d at 110.

209. *Id.* at 110 app. A.

210. See 23 C.F.R. § 255 (1992).

211. 359 F.2d 822, 824-25 (7th Cir.), *cert. denied*, 385 U.S. 836 (1966), *overruled by Huff v. White Motor Corp.*, 565 F.2d 104 (7th Cir. 1977).

was defectively designed.”²¹² The initial federal regulatory requirements were imposed in an area essentially untouched by tort law. For example, until the promulgation of FMVSS 208, which required manufacturers to install lap and shoulder belts in all new vehicles,²¹³ automakers had never been required by the tort system to meet this type of design standard.²¹⁴ Yet acceptance of the doctrine that manufacturers had a duty in tort to ensure the reasonable safety of their products, when it came, quickly became widespread. Between the 1968 *Larsen* decision and *Huff v. White Motor Corp.*,²¹⁵ decided in 1977, some thirty jurisdictions recognized the crashworthiness doctrine.²¹⁶

The National Highway Traffic Safety Administration, created in 1966,²¹⁷ was initially a highly activist agency that aimed to impose dramatically new safety requirements on automobile manufacturers. Congress apparently intended the Safety Act to advance the technology of automobile safety;²¹⁸ thus, the agency imposed new and difficult requirements on automakers through a policy described as “technology-forcing,”²¹⁹ to require manufacturers to invent and adopt automobile safety technology that was nonexistent or not widely used at the time the regulation was imposed.²²⁰ Although some have questioned the agency’s success in forcing

212. The Safety Act was enacted in 1966.

213. *Evans*, 359 F.2d at 824-25.

214. *Wood v. General Motors Corp.*, 865 F.2d 395, 405 (1st Cir. 1988), *cert. denied*, 494 U.S. 1065 (1990).

215. See 32 Fed. Reg. 2408, 2415-16 (1967) (codified as amended at 49 C.F.R. § 571.208 (1984)). The initial standard requiring simple lap belts has evolved considerably over the years, initially staying well ahead of existing industry standards.

In 1970, the agency revised Standard 208 to include passive protection requirements, 35 Fed. Reg. 16,927 (Nov. 3, 1970), and in 1972, the agency amended the Standard to require full passive protection for all front seat occupants of vehicles manufactured after August 15, 1975. 37 Fed. Reg. 3911 (Feb. 24, 1972). In the interim, vehicles built between August 1973 and August 1975 were to carry either passive restraints or lap and shoulder belts coupled with an “ignition interlock” that would prevent starting the vehicle if the belts were not connected.

Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Ins. Co., 463 U.S. 29, 35 (1983). Today’s version of Standard 208—still gradually being phased in—is essentially unchanged from the initial passive-restraint standard first introduced in 1972. See 49 Fed. Reg. 28,962 (1984) (allowing phase-in of passive restraint requirements for all newly manufactured automobiles); 52 Fed. Reg. 10,096 (1987) (extending time period for full implementation of passive restraint requirement through 1993).

216. Several states enacted legislation in the early 1960s requiring that cars be equipped with lap belts. Joan Claybrook & David Bollier, *The Hidden Benefits of Regulation: Disclosing the Auto Safety Payoff*, 3 YALE J. ON REG. 87, 101 (1985).

217. Safety Act, 15 U.S.C. §§ 1381-1431 (1988).

218. See *infra* note 220.

219. See Mashaw & Harfst, *supra* note 136, at 259 (citing P. LORANG & L. LINDEN, *AUTOMOBILE SAFETY REGULATION: TECHNOLOGICAL CHANGE AND THE REGULATORY PROCESS* 149-54 (1977)).

220. Claybrook & Bollier, *supra* note 216, at 100; Mashaw & Harfst, *supra* note 136, at 259.

the development of new technology,²²¹ much technology mandated by NHTSA in its first decade, not widely employed in 1966, has become commonplace—such as laminated windshields, collapsible steering assemblies, enhanced door locks, interior padding, seat anchorages, and three-point seatbelts.²²²

As a result, NHTSA's impact occurred early in the agency's history, in the very same period that the crashworthiness doctrine became generally accepted in state courts. Since 1976 NHTSA essentially has ceased to engage in rulemaking, and instead has concentrated its efforts largely on the enforcement of existing standards through recalls of motor vehicles with defects related to safety performance.²²³ By 1974, when NHTSA had

221. LORANG & LINDEN, *supra* note 219, at 64-65 (noting that safety technology is "remarkably similar to what it was in 1968, the first year federal rules took effect"); OFFICE OF TECHNOLOGY ASSESSMENT, TECHNOLOGICAL INNOVATION AND HEALTH, SAFETY, AND ENVIRONMENTAL REGULATION, IX-43 (1981) (stating that federal safety standards had only a "slight influence" on automobile industry innovation); Mashaw & Harfst, *supra* note 136, at 259 (citing STAFF OF THE NAT'L COMM'N ON PRODUCT SAFETY, FEDERAL CONSUMER SAFETY LEGISLATION 21 (1970)).

Some have asserted that the standards NHTSA established in its early rulemaking years largely codified existing industry practice.

The first generation of standards took what was good current practice within the industry at the time and made that the required level of performance. Thus the five inches of rearward movement of the steering column of FMVSS 204, the door-latch strength requirements of FMVSS 206, the glass specifications of FMVSS 205, the seat strength requirements of FMVSS 207, and the rest, all were fixed relative to good current practice of the 1960s and early 1970s.

The one exception to this process was the occupant protection standard, FMVSS 208.

.....
The politics of rule-making appear to require short lead times, which inevitably results in a standard of performance that is already attained by some manufacturers.

.....
The conclusion that must be drawn from the rulemaking process is that regulation does not lead to innovation.

Murray Mackay, *Liability, Safety and Innovation in the Automotive Industry*, in THE LIABILITY MAZE: THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION 191, 204-05 (Peter W. Huber & Robert E. Litan eds., 1991).

222. Claybrook & Bollier, *supra* note 216, at 98. NHTSA issued 19 FMVSSs shortly after its establishment under the Safety Act. 32 Fed. Reg. 2408, 2409-10 (1967) (codified as amended at 49 C.F.R. § 571.208 (1992)).

223. Mashaw & Harfst, *supra* note 136, at 263. Out of 50 general safety regulations adopted under the Safety Act, all were adopted prior to 1976, and some 90% were adopted prior to 1974. *Id.* Although the agency has continued to amend existing rules, Mashaw and Harfst have labeled these post-1976 amendments "substantively trivial." *Id.* at 265. The Bureau of Labor Statistics found in 1985 that approximately 90% of price increases attributable to NHTSA's safety rules occurred between 1967 and 1976. BUREAU OF LABOR STATISTICS, REPORT ON QUALITY CHANGES FOR 1986 MODEL PASSENGER YEAR (1985); see also Mackay, *supra* note 221, at 205 ("From 1974 to 1984, little of major significance changed in the field of vehicle safety regulations aside from some upgrading of existing requirements.").

For some hint of the reasons rulemaking has ceased, see *B.F. Goodrich Co. v. United States Dep't of Transp.*, 541 F.2d 1178 (6th Cir. 1976), *cert. denied*, 430 U.S. 930 (1977).

completed ninety percent of its major rulemaking activity,²²⁴ almost all courts that had considered the issue had accepted the doctrine of crashworthiness.²²⁵

B. *Measuring the Effects of Regulation*

The historical period in which product liability law developed and spread throughout the states make it exceptionally difficult to discern the separate influence of regulation and the new tort doctrine. Yet the enormous costs²²⁶ allegedly attributable to social regulation played a major role in the effort to reduce social regulation during the 1980s.²²⁷ This influence was clearly misplaced; because the statistical studies used to attack social regulation failed to separate the independent effects of tort law and social regulation, those studies clearly overstated the benefits that deregulation alone could achieve.

Two statistical techniques were widely used in measuring the costs of regulation. In the first, less sophisticated method, engineering estimates of the "incremental cost" of the regulation were derived by comparing the costs, for example, of building a new factory that met all environmental or worker safety standards to the costs of building an otherwise identical factory that did not meet the regulatory standards.²²⁸ As has been widely recognized,²²⁹ the direct cost approach depends on the specification of the so-called "counterfactual," which calculates what the level of costs would be in the absence of the regulation. None of these studies incorporates the possibility that the safety improvements might actually have been adopted even

224. See Mashaw & Harfst, *supra* note 136.

225. By the time NHTSA completed the last of its significant rulemakings, all 30 jurisdictions that had considered crashworthiness claims accepted the doctrine that manufacturers had an obligation in tort to design products to protect passengers from a "second collision." See *Huff v. White Motor Corp.*, 565 F. 2d 104, 107; see also *id.* at 110 app. A & B.

226. See Robert W. Hahn & John A. Hird, *The Costs and Benefits of Regulation: Review and Synthesis*, 8 YALE J. ON REG. 233, 240 (1991).

227. See MILTON D. FRIEDMAN & ROSE FRIEDMAN, *FREE TO CHOOSE* 207 (1979):

Granted all this, may these costs not be justified by the advantage of keeping dangerous drugs off the market. . . . The most careful empirical study of this question that has been made, by Sam Peltzman, concludes that the evidence is unambiguous: that the harm done has greatly outweighed the good.

Id. Peltzman's analysis of pharmaceutical regulation is discussed *infra* notes 243-53 and accompanying text.

228. For examples of this technique, see ARTHUR ANDERSEN & CO., *COST OF GOVERNMENT REGULATION STUDY FOR THE BUSINESS ROUNDTABLE passim* (1979); CRANDALL ET AL., *supra* note 31, at 32-37; LITAN & NORDHAUS, *supra* note 17, at 18-27; Kit D. Farber & Gary L. Rutledge, *Pollution Abatement and Control Expenditures, 1982-85*, SURV. CURRENT BUS., May 1988, at 22, 22.

229. See, e.g., Hahn & Hird, *supra* note 226, at 240.

without the regulation in question because of the independent impact of tort law.²³⁰

The second technique used to measure the cost of regulation involves looking for changes in price or output that occurred coincident in time with the regulation and using statistical methods (usually multiple regression analysis) to correct for those changes that would have occurred absent the regulation. Again, the results of this technique depend on the specification of what would have happened without the regulation. Although in principle these statistical methods account for all other factors affecting the industry, none of the studies in question attempted to include, or even recognized the relevance of, the massive contemporaneous changes in tort law.

One such statistical method involves a multiple regression analysis²³¹ explaining industry output or prices over time; the analysis includes a dummy variable²³² for the year in which the regulation was imposed. For example, the impact of a regulation on an industry's prices might be measured by a regression analysis that includes, among other things, a variable that assumes a value of zero for observations prior to the date when the regulation became effective and a value of one for observations after that date. Statistical significance for that variable implies a measurable impact of the regulation on the dependent variable such as industry output or price.

The other statistical method by which coincidences in time are taken into account is quite similar. Using multiple regression analysis, the analyst models the behavior of the industry in the years prior to the regulation, then uses that model to predict the behavior of the industry in the years after the regulation. Any difference between predicted and actual behavior can presumably be attributed to the regulation.

Both statistical methods rely on the *ceteris paribus*²³³ assumption that all that is changing between the world pre-regulation and the world post-regulation are the variables specifically included in the model itself. Such an assumption is incorrect, however, when at the same time the explicitly

230. Hahn and Hird give the example of a change in consumer demand that would lead to the adoption of the same measure compelled by the regulation. In principle, the cost of the safety measure should not be included in the calculated cost of the regulation, because it would have been adopted anyway; however, the expenditure/engineering studies do count the cost of that safety measure, because the regulation compels it. *Id.* at 240.

231. *Regression analysis* is a method for examining the relationships among large numbers of variables. . . . [R]egression coefficients describe the relationships between each of the *independent variables*, so-called because their values are independent of each other, and the *dependent variable*, so-called because its value depends on the values of the independent variables.

BARNES, *supra* note 196, at 293.

232. For an explanation of dummy variables, see *id.* at 322.

233. *Ceteris paribus* is roughly translated as "all else being equal," and it is a central assumption in most economic analysis. See BROWNING & BROWNING, *supra* note 20, at 489.

included factors are changing, another force is reshaping the world upon which the model operates. A measurement designed to gauge the impact of regulation would in fact account for more than the regulation alone; it would capture the combined effect of the regulation and the independent force.²³⁴

That is exactly the case here. Analysts studied the effects of federal health and safety regulation extensively during the last two decades. However, virtually none of this work took into account, in its measurement methodology, the fact that the tort system was changing in the background.

C. *Mattress Safety Regulation*

Consider, for example, the mattress industry. In 1973, CPSC promulgated a rule requiring safety modifications to ensure that mattresses would not burn when exposed to lit cigarettes.²³⁵ At the same time, mattress manufacturers were confronting the changing standards of liability that would have led them independently to be concerned about mattress flammability.²³⁶ Indeed, it was estimated that at the time the regulation was imposed, approximately eighty percent of the mattresses produced already satisfied the safety requirements of the regulation.²³⁷

In a study of the cost of the mattress flammability standard, Peter Linneman²³⁸ attempted to capture the effect on mattress price using a multiple regression analysis. The study explained the price of mattresses over time by using a variety of mattress quality indices and included as an independent explanatory variable a dummy variable set equal to zero for the years 1959 to 1973 (prior to the CPSC rule) and equal to one for the years 1974 to 1977.²³⁹ Because the dummy variable's coefficient was positive and statis-

234. See, e.g., BARNES, *supra* note 196, at 389.

Omission of relevant independent variables affects our estimates of the regression coefficients only if the omitted variable is correlated with one of the included variables. If we calculate the correlation between an omitted variable and the included variable, and if we find a statistically significant relationship between changes in the size of one and the size of the other, we know that the regression coefficient on the included variable is measuring not just the effect of the included variable but also some of the effect of the omitted variable. But our purpose in estimating a regression coefficient is to indicate the effect of the independent variable alone on the dependent variable. The existence of an omitted correlated variable means that the estimate includes the effect of both variables, not just the included variable.

Id.

235. 16 C.F.R. § 1632 (1993).

236. See, e.g., *Berry v. Peterson*, 887 F.2d 635, 636 (5th Cir. 1989); *Farmer v. City of Newport*, 748 S.W.2d 162, 163-64 (Ky. Ct. App. 1988).

237. Peter Linneman, *The Effects of Consumer Safety Standards: The 1973 Mattress Flammability Standard*, 23 J.L. & ECON. 461, 462 (1980).

238. *Id.* at 471-72.

239. *Id.*

tically significant, Linneman inferred that the regulation increased mattress prices and based his cost estimate for the regulation on the estimated size of the price increase.²⁴⁰

Of course, from 1959 to 1977 tort law became much more activist, and products liability law changed significantly. Linneman compared two trend lines (one of which includes the beginning of that period but not its end) with another (which includes only the very end of the period), unavoidably capturing whatever effects on output that change in tort doctrine engendered. Designating those effects "the increase in mattress prices attributable to the [CPSC] standard,"²⁴¹ Linneman overstated the true impact of the regulation. The low R-squareds and statistically insignificant F-values Linneman's results achieved enhance the inference that he omitted an important variable.²⁴²

D. Food, Drug, and Cosmetic Regulation

Another example is Sam Peltzman's influential study²⁴³ of the 1962 amendments to the Food, Drug and Cosmetic Act, which required pharmaceutical manufacturers to test new chemical entities (NCEs) for efficacy.²⁴⁴ This was classic consumer-protection legislation designed to prevent consumers from buying useless products; testing for safety had been required long before the 1962 amendments.²⁴⁵ Peltzman's failure to take tort law into account biased his estimates of the impact of this consumer protection legislation.

Peltzman first developed a model to explain the rate of introduction of new drugs using annual data over the period 1948 to 1962.²⁴⁶ He then used the estimated parameters to predict the rate of new drug introductions for the decade following the 1962 amendments.²⁴⁷ Finding that actual introductions after 1962 were lower than the predicted rate, he concluded that "all of the observed difference between pre- and post-1962 New Chemical Entity (NCE) flows can be attributed to the 1962 amendments."²⁴⁸ He based his estimates of the forgone benefits from new drugs made unachiev-

240. Empirical work employing this methodology includes Sam Peltzman, *The Health Effects of Mandatory Prescriptions*, 30 J.L. & ECON. 207, 213-34 (1987); W. Kip Viscusi, *The Impact of Occupational Safety and Health Regulation, 1973-1983*, 17 RAND J. ECON. 567, 569-73 (1986).

241. Linneman, *supra* note 237, at 471.

242. See BARNES, *supra* note 196, at 355-61, 390; Linneman, *supra* note 237, at 466, 468, 473.

243. Sam Peltzman, *An Evaluation of Consumer Protection Legislation: The 1962 Drug Amendments*, 81 J. POL. ECON. 1049, 1051 (1973).

244. Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-392 (1988 & Supp. III 1992).

245. *Id.* § 360d.

246. Peltzman, *supra* note 243, at 1054.

247. *Id.* at 1056.

248. *Id.* at 1055-57.

able by the amendments, and thus the costs of the amendments, on this measured decline in the introduction rate.²⁴⁹

Of course, the potential tort liability of drug manufacturers also rose after 1962. Although drug efficacy may not give rise to tort liability, rising manufacturer concern about liability for drug safety might also have contributed to the decline of drug introductions. Thus, Peltzman's estimates of the cost of efficacy testing may be conflated with the cost of safety testing beyond that mandated by the FDA, which may also have slowed the rate of drug introductions. Moreover, Peltzman did not attempt to estimate the benefits derived from higher levels of safety testing. His cost estimates, which appear to include the effects of both efficacy testing and safety testing, should be compared both to his estimated efficacy benefits and to the enhanced safety benefits that he did not estimate. In light of these shortcomings, Peltzman's view of the 1962 amendments may be unduly negative.²⁵⁰

The omission of a relevant variable from Peltzman's statistical work appears less obvious on its face than is true of Linneman's work. In the Linneman dummy-variable approach discussed above, one piece of evidence that an important explanatory variable had been omitted from Linneman's estimating equation was the low statistical significance of the equation as a whole. In Peltzman's model, the same complaint cannot be made; Peltzman's model estimates in the 1948-62 pre-regulation time period were statistically highly significant.²⁵¹ This suggests, however, one difference between the Peltzman model-prediction methodology and the Linneman dummy-variable methodology. Peltzman's estimates were derived entirely on data prior to the regulation *and prior to the development of products liability doctrine*. If, in fact, products liability concerns do affect new drug introductions, that omitted variable should have had no impact whatever on Peltzman's pre-1962 estimates. Peltzman's pre-1962 estimates look quite strong but in fact were a weak basis for forecasting the post-1962 period because the omitted variable became significant only after 1962.

One piece of evidence suggesting that the omitted variable of products liability law had an important impact on new drug introductions is that Peltzman's forecasts for the post-1962 period increasingly overestimated

249. Empirical work employing a similar methodology includes Sam Peltzman, *The Effects of Automobile Safety Regulation*, 83 J. POL. ECON. 677, 678-97 (1975).

250. There has been little effort to disentangle the effects of drug regulation from those of product liability for drug manufacturers. There is a significant danger of double-counting costs, with the same costs attributed to both federal drug regulation and tort liability. Compare Peltzman, *supra* note 243, at 1052-58, 1089 with HUBER, *supra* note 13, at 155 (contending, respectively, that decline in introduction of new drugs is due to the federal regulation or expansion of tort liability).

251. Peltzman, *supra* note 243, at 1054.

actual NCE introduction during the 1962-1972 period.²⁵² Efficacy testing was required of all NCEs beginning in 1962. Although the requirement might not have had an immediate impact, the static requirement that drug companies provide proof of efficacy for all NCEs after that date, and the possibility of increasing skill in performing that testing suggest that the requirement might have had its greatest impact quickly, and that the impact may have diminished over time as companies acquired greater skill in performing the tests. On the other hand, products liability law developed gradually over the 1962-1971 period and was considerably more vibrant at the end of that period than at the beginning. If safety testing reduced the rate of NCE introductions, and if greater safety testing was performed in response to growing concern about liability, then one would expect exactly what is observed: that the rate of NCE introductions would decline over the 1962-71 period and that the gap between predicted and actual introductions would widen.²⁵³

E. Automobiles Revisited

Peltzman's later analysis of the impact of automobile safety regulation on fatalities²⁵⁴ also seems to ignore the role of torts. Empirical work testing Peltzman's results tends to confirm this hypothesis.²⁵⁵ Peltzman designed a statistical model to explain highway fatalities (both for automobile occupants and for pedestrians and bicyclists) using data from the period 1947-1965. He then used the model and values of his independent variables to predict fatalities over the period 1966-1972.²⁵⁶ Actual fatalities of automobile occupants in the post-1965 period do lie below the values predicted by his model, though by less than the engineering estimates of the NHTSA standards suggest, but Peltzman finds considerable "offsetting behavior"—that is, that individuals drive less carefully given the enhanced safety features of their cars, and thus fatalities among pedestrians and cyclists rise in

252. *Id.* at 1056. Although Peltzman does not provide actual numbers for his predicted new chemical entities series, the pattern apparent in his chart strongly suggests that the gap between predicted and actual NCEs grew over the post-regulation period. *See id.*

253. Recent tort reform literature strongly suggests the possibility that greater products liability risk has slowed the rate of new pharmaceutical development. *See, e.g.,* Louis Lasagna, *The Chilling Effect of Product Liability on New Drug Development*, in *THE LIABILITY MAZE: THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION* 234 (Peter W. Huber & Robert E. Litan eds., 1991).

254. Peltzman, *supra* note 243, *passim*.

255. CRANDALL ET AL., *supra* note 31, at 45-79.

256. Peltzman, *supra* note 243, at 697. Although NHTSA's initial safety standards—including seatbelts, energy-absorbing steering columns, penetration-resistant windshields, dual braking systems, and padded instrument panels—were not formally imposed until 1968, Peltzman argues that de facto adoption of these standards began by 1964. *Id.* at 678.

the post-regulatory period. Peltzman found that the NHTSA standards had no net impact on death rates, despite their considerable cost.

Peltzman clearly ignored, however, the development of automobile crashworthiness litigation that coincided with the initial imposition of regulation. More recent work testing Peltzman's conclusions produced quite different results. Robert Crandall and his colleagues repeated Peltzman's experiment, using a more complete set of independent variables and, significantly, nine additional years of post-regulation results.²⁵⁷ Crandall and his colleagues found:

Had automobiles been as unsafe in 1981 as in 1965, the estimates . . . suggest that total fatalities would have been 18,000 to 22,000 above their actual 1981 level. The estimate of lives saved per year is about 30 percent of the total deaths that would have been predicted without safer automobiles. This estimate seems rather high in light of engineering estimates of the increase in *occupant* safety of 10 to 35 percent and our identification of some offsetting behavior.²⁵⁸

Thus, where Peltzman had found that fatality reductions were slightly *less* than the engineering estimates of the impact of the NHTSA standards would suggest, Crandall found, over a longer post-regulatory period, that fatality reductions actually *exceeded* engineering estimates, even though driver behavior worked against this trend. As Crandall notes, "Why the estimate is so high frankly remains something of a puzzle."²⁵⁹

The obvious culprit in explaining the puzzle, tentatively suggested by Crandall, is the rising impact of products liability law on automobile safety.²⁶⁰ Crandall's results strongly imply that another factor influencing highway safety had developed during the nine additional years included in Crandall's data.²⁶¹ As argued earlier in this Article, the crashworthiness doctrine did not become fully operative until the mid-1970s and had its

257. CRANDALL ET AL., *supra* note 31, at 68-75.

258. *Id.* at 69.

259. *Id.*

260. *Id.* at 72-73.

261. The bulk of NHTSA safety standards were in place by the end of Peltzman's estimation period in 1972; however, crashworthiness doctrine was still in an early state of development. For example, of the 30 states cited in *Huff v. White Motor Corp.*, 565 F.2d 104 (7th Cir. 1977) as following *Larsen* (including the "Erie-educated guesses," *Erie R.R. v. Tompkins*, 304 U.S. 64 (1938), of various federal courts as to how the relevant state courts might decide such cases) all but five were decided after 1972—after the end of Peltzman's data set. Of those five, three were decided in 1971 or before. It is doubtful, therefore, that the crashworthiness doctrine had much impact on the evaluation of automobile safety captured in Peltzman's data.

If products liability law does play a role, not just in defining standards but also in enforcing standards imposed by the regulatory agency, the unexpectedly low impact of regulation found in Peltzman's study might be explained by the failure of tort law to provide an adequate remedial incentive in the early (pre-crashworthiness-doctrine) period.

greatest impact on manufacturer behavior after that time. Crandall and his coauthors suggest that rising products liability risk might have played a role in the apparent improvement in automobile safety (indeed, they offered no other explanation), but they suggest no definitive conclusion on the role of products liability law.²⁶²

F. Worker Safety Regulation

More recent studies of the cost of health and safety regulation continue to ignore the relevance of tort law. Wayne Gray, for example, attempted to measure the impact of OSHA's worker health and safety regulation and EPA's environmental regulation on the trend in total factor productivity in the United States economy.²⁶³ Gray found a "large negative relationship between such regulation and productivity growth."²⁶⁴ His measure of "the productivity slowdown" for each of 450 United States industries was the change in average annual total factor productivity between the period 1959-1969 and the period 1973-1978.²⁶⁵ The 1959-1969 period was chosen to predate the inception of OSHA and EPA; the 1973-1978 period was chosen "to ensure that the measures of levels of regulation in the later period would also measure changes in regulation from the earlier period."²⁶⁶

Gray used as his dependent variable the change in total factor productivity growth between those two periods as his dependent variable. He regressed this on an array of independent variables that included OSHA and EPA expenditures averaged over the post-regulation period. The resulting coefficients on the regulatory variables were intended to "show the connection between the regulation measures and the productivity slowdown."²⁶⁷ Gray concluded that "the regulation measures together account for a slowdown of .44 percentage points, somewhat over 30 percent of the average industry's productivity slowdown."²⁶⁸ Yet Gray included no measure of the impact of increased tort activism between the two periods. Gray too

262. CRANDALL ET AL., *supra* note 31, at 72-73.

263. Wayne B. Gray, *The Cost of Regulation: OSHA, EPA, and the Productivity Slowdown*, 77 AM. ECON. REV. 998 *passim* (1987). "Total factor productivity" expresses the relationship between aggregate output and the sum of all productive inputs; if the growth rate of income is greater than the sum of the growth rates of all inputs weighted by their initial cost shares, then total factor productivity has risen." *Id.* at 999.

264. *Id.* at 998.

265. The 1959-1969 period was chosen to predate the inception of OSHA and EPA; the 1973-1978 period was chosen "to ensure that the measures of levels of regulation in the later period would also measure changes in regulation from the earlier period." *Id.* at 1001.

266. *Id.* at 1001.

267. *Id.* at 1002-03.

268. *Id.* at 1003.

may have conflated the impact of regulation with that of tort law and incorrectly attributed the combined impact to regulation alone.²⁶⁹

IV. THE ADMINISTRATIVE BENEFITS OF REGULATION

There has been considerable disenchantment with the products liability system expressed recently.²⁷⁰ In part, the controversy has focused on the rationality of tort rules.²⁷¹ This discussion appears ultimately to be a controversy over whether tort damages should be understood as a form of manufacturer-provided insurance for consumers²⁷² or as a deterrence mechanism to ensure that manufacturers confront the full costs of risks posed by their products and thereby minimize unreasonable risks.²⁷³ But current disappointment with tort law extends beyond the basic rules of tort law to the rationality of the torts process.

Juries are, in this view, capricious, ignorant, and incompetent to evaluate the complex technological decisions made by manufacturers that result in products liability claims.²⁷⁴ Furthermore, the *ex post* and unpredictable nature of jury decisions is said to interfere with the ability of corporate managers to make reasoned predictions about the possible payoff from investments in new products and research.²⁷⁵

One frequent suggestion engendered by this dissatisfaction with both the substantive and procedural nature of current products liability doctrine is that we rely more heavily on federal regulation of health and safety issues, and correspondingly reduce the role of common-law courts in supervising the product safety decisions of manufacturers.²⁷⁶ Advocates of this position view the regulatory process as an escape from the dangers of tort law, and suggest that compliance with regulatory requirements should serve as a defense to a products liability action, at least when the relevant agency

269. Gray concedes, "[T]here could be some other explanation for the slowdown, not included in the current set of controls, whose omission biases the regulation coefficients." *Id.*

270. See, e.g., *Uniform Federal Product Liability Law: Hearings on S. 640 Before the Senate Comm. on the Judiciary*, 102d Cong., 2d Sess. (1992); PRESIDENT'S COUNCIL ON COMPETITIVENESS, AGENDA FOR CIVIL JUSTICE REFORM IN AMERICA 3-5 (Aug. 1991); Andrew Blum, *Debate Still Rages on Torts*, NAT'L L. J., Nov. 16, 1992, at 1; Charles R. Epp, *Let's Not Kill All the Lawyers*, WALL ST. J., July 9, 1992, at A15; David M. McIntosh, *Without Malpractice Reform, Forget Health-Care Reform*, WALL ST. J., Sept. 2, 1993, at A21.

271. See, e.g., Kenneth Abraham, *Making Sense of the Liability Crisis*, 48 OHIO ST. L.J. 399 (1987);

272. See, e.g., PAUL H. RUBIN, *TORT REFORM BY CONTRACT* 29-48 (1993).

273. LANDES & POSNER, *supra* note 140, at 23-56.

274. See, e.g., COMPENSATION AND LIABILITY, *supra* note 12, at 67-98; HUBER, *supra* note 13, at 213-15; W. Kip Viscusi, *Toward a Diminished Role for Tort Liability: Social Insurance, Government Regulation, and Contemporary Risks to Health and Safety*, 6 YALE J. REG. 65, 66 (1989).

275. EADS & REUTER, *supra* note 197, at 1-4.

276. See *infra* text accompanying note 293.

has actually examined the product safety issue in question.²⁷⁷ The trend toward reading federal regulatory statutes as preemptive, reversing the long-standing presumption against preemptive interpretations, may reflect judicial sympathy with this approach.²⁷⁸ Proposals to restrict the collateral source rule, joint and several liability, damages for pain and suffering, punitive damages, and jury discretion in the calculation of damages,²⁷⁹ similarly reflect a distrust of the jury system and a desire to reduce the incentives to litigate.

The desire to place greater power in the hands of federal regulatory agencies, and to reduce the role of the common-law courts, stands in stark contrast to the widespread distrust of the regulatory system of a decade ago. Sympathy for these proposals within the tort reform movement undoubtedly stems in part from a belief that the total costs to the regulated parties of complying with agency mandates will be less than the costs they now face due to potential or actual tort liability. Despite the understandable attraction of these proposals to the regulated parties themselves, the substitution of regulation for tort which these proposals would accomplish would solve few of the problems caused by tort law, as this Article will show, and would exacerbate the inadequacy of the deterrence offered by the present tort system.²⁸⁰

Another approach seems clearly preferable. That alternative would seek to take advantage of the strengths of both tort and regulation by expanding the current regulatory effort without restricting the current tort liability of manufacturers. An expanded regulatory effort could yield significant benefits by reducing the risk of irrational jury behavior and by reducing the high administrative costs associated with tort actions, yet would pose no risk of reducing the adequacy of the deterrent to unsafe manufacturer behavior. At the same time, expanding the regulatory effort would have little cost because, as this Article has noted, the current activist stance of tort law effectively negates any significant incremental efficiency cost for a less demanding and largely duplicative regulatory regime. In short, if we accept that the tort system suffers from some severe imperfections, we might be well served by seeking ways to improve its operation, rather than by abandoning it in favor of a regulatory system with severe problems of its own.

277. See *infra* text accompanying note 293.

278. Sherman, *supra* note 11, at 860-64 (noting that federal preemption in the products liability field is limited, undertaken on a case-by-case basis).

279. See COMPENSATION AND LIABILITY, *supra* note 12, at 80-96.

280. Teresa M. Schwartz, *Product Liability Reform by Judiciary*, 27 GONZ. L. REV. 303, 314-15 (1992).

A. Regulation as a Substitute for Tort

1. The Reasonableness of Tort Rules

Proposals to adopt a regulatory compliance defense, to allow enhanced scope for preemption, or otherwise to substitute the judgments of regulatory agencies for common-law courts, suffer from an obvious flaw: they accept regulatory standards that are almost inevitably incapable of fully forcing manufacturers to internalize the costs of their product safety decisions. Instead, manufacturers acting under regulatory standards are likely to be able to avoid a significant share of the costs of injuries stemming from their products, while themselves reaping the benefits of those decisions in reduced manufacturing or design costs.

The reason is inherent in the regulatory process itself: though regulatory review ensures against an inefficiently high level of safety mandates, nothing assures that the level of deterrence will be adequate. Regulatory policy contains no incentive for agencies to mandate safety precautions whenever the social benefits of precautions exceed their costs. Yet an efficient level of deterrence requires exactly such a cost-benefit criterion as a guard against agency inaction as well as against excessive regulation.²⁸¹

The nature of regulation ensures that agencies will sometimes fail to act even when action would be cost-justified. The cost-benefit test embodied in Executive Order 12,866²⁸² and in Executive Orders 12,291 and 12,498 in prior administrations, imposes no affirmative duty to regulate, even when an excess of benefits over costs would be the anticipated result.²⁸³ This policy screens out agency actions that are excessively stringent, but there is no comparable institution that prevents inadequate stringency. The systematic hostility to regulation that characterized the last few presidential administrations²⁸⁴ effectively gutted many agencies of resources and sapped their political will.²⁸⁵ Continuing distaste in the political system for regulation²⁸⁶ could resurrect that trend at any time and further disable the regulatory system. The widely recognized inadequacy of regulatory remedies and their implicit reliance on tort damages to ensure compli-

281. Peter L. Kahn, *Politics of Unregulation: Public Choice and Limits on Government*, 75 *CORNELL L. REV.* 280, 287-88 (1990).

282. 58 *Fed. Reg.* 51,735 (1993).

283. See *supra* note 23.

284. See, e.g., SUSAN J. TOLCHIN & MARTIN TOLCHIN, *DISMANTLING AMERICA: THE RUSH TO DEREGULATE* 102-05 (1983); Douglas M. Costle, *Environmental Regulation and Regulatory Reform*, 57 *WASH. L. REV.* 409, 409-10 (1982).

285. Adler, *supra* note 119 at 74-76; Schwartz, *supra* note 19, at 1158-60.

286. See *supra* note 23.

ance²⁸⁷ further suggest that regulation is not an adequate substitute for tort law.

The inherently limited budgets of federal agencies ensures that no such approach could be meaningful in any case. Despite their statutory responsibilities, agencies sometimes fail to act; the vast scope of potential product risks, the constantly changing array of consumer products and the technology which it embodies, and the inherently limited resources available to agencies, virtually assures that agencies will sometimes fail to act even when legitimate product risks fall within their jurisdictions.

The jury implements a different standard. Under either the risk-utility test in strict liability,²⁸⁸ or the traditional negligence test,²⁸⁹ the defendant is in principle liable whenever it has failed to take some measure that is justified by the benefits and that would have prevented the plaintiff's injury. Even an omniscient jury, appropriately and strictly applying a negligence or risk-utility test, could find liability despite the defendant's compliance with all applicable regulations. Juries that hold defendants to higher standards than did some regulatory agency may just as well be rational juries accurately applying traditional tort liability concepts as irrational juries effectively nullifying their instructions out of sympathy with injured plaintiffs. The case for the regulatory compliance defense, to the extent that it assumes that juries unsatisfied by regulatory compliance are simply blinded by prejudice or ignorance, misconceives the role of tort liability.

These tort standards of liability are in principle desirable²⁹⁰ and should be retained. The goal of the negligence standard has long been to encourage optimal precaution-taking.²⁹¹ To adopt the proposed scaling-back of tort law would effectively abandon these goals in favor of lesser regulatory standards, perhaps adopted in response to shifting political preferences but in any case requiring a less-than-optimal level of safety. The real problem, and the only meaningful case for these proposed reforms, is not that tradi-

287. Howard A. Denemark, *Improving Litigation Against Drug Manufacturers for Failure to Warn Against Possible Side Effects: Keeping Dubious Lawsuits From Driving Good Drugs Off the Market*, 40 CASE W. RES. L. REV. 413, 430 (1990).

288. See, e.g., COMPENSATION AND LIABILITY, *supra* note 12, at 67-98; HUBER, *supra* note 13, at 213-15; W. Kip Viscusi, *Toward a Diminished Role for Tort Liability: Social Insurance, Government Regulation, and Contemporary Risks to Health and Safety*, 6 YALE J. ON REG. 65, 66 (1989).

289. See *McCarty v. Pheasant Run, Inc.*, 826 F.2d 1554, 1556-57 (7th Cir. 1987); *United States Fidelity & Guar. Co. v. Jadranska Slobodna Plovidba*, 683 F.2d 1022, 1026 (7th Cir. 1982); *United States v. Carroll Towing Co.*, 159 F.2d 169, 173 (2d Cir. 1947).

290. See LANDES & POSNER, *supra* note 140, at 312 ("We do not contend that all rules of tort law are efficient—only that most are. . . . We argue that the law creates incentives for parties to behave efficiently . . .").

291. *Id.* at 4-9 (discussing historical roots of view that tort law should "deter[] conduct that is not justifiable on utilitarian grounds").

tional concepts of tort are wrong; rather, it is the possibility the jury will disregard, misunderstand, or be unable to apply its instructions, and find liability when it should not.²⁹² In short, the problem of monitoring governmental decisionmakers to ensure compliance with desired norms is a problem whether one is dealing with agencies or juries. Reforms that enhance the role of regulation but reduce the importance of the tort system, ignore that fact.²⁹³

2. A Catalog of Complaints

Other problems with the current tort system that supposedly justify a reduction of the scope or role of tort law are numerous. W. Kip Viscusi,²⁹⁴ among others, suggests that the role of tort be made "subsidiary" to alternative institutions designed to reduce risk and provide compensation because, in his view, tort tends to function comparatively poorly in the products liability context; he suggests, among other things, the adoption of a regulatory compliance defense.²⁹⁵ Yet many of the problems that Viscusi identifies with the tort system are as well or better addressed by expanding the regulatory regime to supplement the existing tort system, rather than contracting the limits of tort law to meet the boundaries of existing regulation. For example:

a. Scope of Risk Coverage

Viscusi argues that, because the tort system poses significant problems for plaintiffs seeking compensation, the tort system "provides compensation for only a subset of all injuries."²⁹⁶ These problems arise, in his view, in satisfying the legal tests for liability, such as demonstrating "negligence," "defect," or "cause."

Yet if the problem is the inadequacy of tort law as a compensatory mechanism, surely further reducing the scope of tort law is inappropriate, unless some alternative compensation system is to be substituted for it; and

292. See MOLLY SELVIN & LARRY PICUS, *DEBATE OVER JURY PERFORMANCE: OBSERVATIONS FROM A RECENT ASBESTOS CASE 52-54* (Rand Institute for Civil Justice No. R-3479-ICJ, 1987) (detailing research suggesting that juries often forget, misunderstand, or fail to follow the judge's instructions).

293. It is possible that juries will ignore the risk-utility test and find liability despite compliance with an adequate regulation. On the other hand, it is also possible that the legislature will fail to formulate an adequate standard, and that a jury appropriately applying a risk-utility test will be justified in finding liability. The problem of inadequate legislative action is an old one, rooted in what could be described as the public-choice-related problems of industry "capture" and failure to act except in cases of significant political attention. See, e.g., Daniel A. Farber & Philip P. Frickey, *The Jurisprudence of Public Choice*, 65 *TEX. L. REV.* 873, 875-78 (1987).

294. Viscusi, *supra* note 240.

295. *Id.* at 105.

296. *Id.* at 69.

unless the compensatory mechanism is taxpayer-funded rather than funded (as tort compensation now is) by contribution from the injurer, similar legal barriers are likely to exist to protect alleged injurers from wrongful claims. These tests are *intended* to deter illegitimate claims. While it is not a perfect solution, an invigorated regulatory regime could significantly mitigate this problem. As a regulatory agency sets higher standards for behavior, more plaintiffs are likely to qualify for compensation because of the doctrine of negligence *per se*. Further, a plaintiff's incentives to overcome existing procedural hurdles rise because of the enhanced possibility of obtaining punitive damages, since a regulatory violation becomes more likely as regulatory standards rise. Enhanced regulatory standards also can reduce the risk of injury and lessen reliance on the tort system without posing greater obstacles to plaintiffs who have been injured.

b. The Problem of Information

Another inadequacy of the tort system that Viscusi identifies similarly works to place burdens on plaintiffs. Tort liability places high burdens on parties to generate information. To make out her case, a plaintiff must have information about the cost of possible safety measures the defendant could have taken and about the information available to the defendant before the accident occurred.²⁹⁷

Again, an enhanced role for regulatory agencies mitigates that problem. Agencies collect significant amounts of information about risks, causation, and remedies in the normal course of their activities. A more vigorous regulatory regime is likely to increase the information publicly available to plaintiffs and courts for this purpose, and make it easier for plaintiffs to rely on a negligence *per se* theory of fault.

c. Risk Reduction Incentives

Viscusi notes that tort damages provide optimal deterrence as long as potential defendants correctly anticipate damage awards,²⁹⁸ but a variety of problems prevent accurate foresight. Damage awards neglect injuries to third parties; furthermore, speculative firms, or firms facing potential bankruptcy, tend to have short time horizons; and damage awards may be inaccurate.²⁹⁹ For these reasons, tort damages may be too low, leading firms to take less than the cost-justified level of care.

Yet, as argued in this Article, regulatory standards are often even less stringent than tort standards. Furthermore, as Viscusi suggests, agencies

297. *Id.* at 71-76.

298. *Id.* at 82.

299. *Id.* at 83.

consistently underenforce their regulations.³⁰⁰ The concerns which result from the fact that the tort system gives insufficient risk-reduction incentives are obviously not addressed by an alternative which provides even less adequate incentives. It seems far more sensible to leave the tort system in place than to rely instead on hortatory efforts to improve the behavior of the regulatory agencies. If both the tort system and regulation each separately provide inadequate incentives, better to allow the two to operate together with the goal of approximating accuracy than to abandon one in the hopes that the other can be improved.

d. Institutional Overlap

Viscusi notes, curiously, that tort liability “creates inefficient incentives because of the manner in which it determines damages,”³⁰¹ and suggests that the problem is one of institutional overlap, in which both tort and regulation affect risk reduction incentives for the same economic activity. Viscusi suggests reducing institutional overlap by allowing expanded defenses to liability, such as expanding the defense of assumption of risk and by allowing a regulatory compliance defense.³⁰² What is curious about this alleged problem is that the “inefficient incentives” to which Viscusi alludes are actually inefficiently *low* incentives for risk reduction in the tort system.³⁰³ Although Viscusi points to instances of excessively stringent regulatory rules as justifying a restriction of tort law, apparently on the grounds that the concurrent sanctions worsen the already excessive stringency imposed by regulation alone,³⁰⁴ he also points to the reality that government enforcement is notoriously too lax.³⁰⁵

e. Adequacy of Compensation

Viscusi rightly notes that tort damages frequently fail to compensate plaintiffs fully for their injuries,³⁰⁶ and he suggests that an entirely different mechanism, such as social insurance which “mimics” workmen’s compensation, be substituted for tort damages as a compensation mechanism.³⁰⁷ Of course, the legislature could instead mandate increased tort damages to ensure adequate compensation. Any compensation mechanism that pays more

300. *Id.* at 91-92.

301. *Id.* at 99.

302. *Id.* at 100.

303. *Id.* at 99, n. 181. The text to which Viscusi refers suggests that tort incentives are inefficiently low.

304. *Id.* at 99

305. *Id.* at 91-92.

306. *Id.* at 97.

307. *Id.* at 98.

generous awards to injured parties should produce a similar increase in claims.

B. Regulation as a Supplement to Tort

Regulation can supplement the tort system in at least two important ways, and by doing so lower the total administrative costs of enforcing a minimum level of product safety while incurring only minor incremental cost. First, the regulatory agency can serve to supplement the jury's technical expertise; and second, regulatory rules can provide a level of clarity and direction to private parties such that injuries can be prevented without reliance on the costly administrative mechanism of the tort system.

1. The Regulatory Agency as a Pool of Technical Expertise

Proposals for tort reform, in essence, attempt to address issues of controlling and overseeing the discretion of the jury, ensuring that the jury has a reasonably well-informed view of the problem and an understanding of why a knowledgeable decisionmaker acting in a cost-benefit context might or might not mandate the particular safety precaution urged by plaintiff. Although courts are capable of overseeing and controlling juries, expert regulatory agencies can offer a different form of assistance to the factfinder.

Agencies can provide information and informed analysis that may or may not lead the agency to regulate, but which can help a jury, applying different decision criteria, decide whether or not it should find liability. Regulatory agencies not only prevent injuries, which reduces the need to litigate cases,³⁰⁸ but also provide information justifying their actions or failure to act, information that can reduce the cost of litigating and reduce the possibility of jury error. By making the agency's decision process available to the jury confronting related issues, regulation can and should play a role in enhancing the rationality of tort outcomes.

The reasoning process of a regulatory agency, if available to a jury, could aid the jury in confronting the "unusually complex, highly technical analysis" with which they reportedly have problems.³⁰⁹ Plaintiffs have incentives to introduce at trial agency decisions to regulate, to the extent the regulation is relevant to liability; reasoned and articulated decisions by the agency not to go further to include the design aspects suggested by plaintiff should be of considerable value to a defendant's case. Because agencies and juries implement different legal standards, however, the agency's deci-

308. See *infra* text accompanying notes 320-58.

309. James A. Henderson, Jr., *Expanding the Negligence Concept: Retreat from the Rule of Law*, 51 IND. L.J. 467, 479 (1976).

sion whether to proceed on the issue in question should not determine the jury's decision.

Documentation suggesting the reasoning process of agencies could be made available to the parties in court. Government reports are normally admissible into evidence under Rule 403³¹⁰ of the Federal Rules of Evidence,³¹¹ so long as the evidence is not excludable as hearsay under Rule 802.³¹² Furthermore, factual findings from government "[r]ecords, reports, statements, or data compilations" are normally admissible under an exception to the hearsay rule,³¹³ so long as the "circumstances" surrounding the material do not "indicate a lack of trustworthiness." Reports produced in the normal course of the business of a regulatory agency are typically admissible under this rule,³¹⁴ and could be relied upon by juries to aid the determination of whether or not conduct was negligent or a product was "unreasonably dangerous,"³¹⁵ so long as the report is of direct relevance to the issues being litigated.³¹⁶

310. FED. R. EVID. 403.

311. See *Melville v. American Home Assurance Co.*, 584 F.2d 1306 (3d Cir. 1978).

312. FED. R. EVID. 802.

313. FED. R. EVID. 803(8)(C).

314. See *Muncie Aviation Corp. v. Party Doll Fleet, Inc.*, 519 F.2d 1178, 1180 (5th Cir. 1975) (admitting Federal Aviation Administration advisory materials as exception to hearsay rule because of indicia of reliability).

315. KEETON ET AL., *supra* note 37, § 103, at 713.

316. *Prashker v. Beech Aircraft Corp.*, 258 F.2d 602, 608-9 (3d Cir.), *cert. denied*, 358 U.S. 910 (1958). The Notes of the Advisory Committee on the proposed Federal Rules of Evidence suggest that the factors which affect "trustworthiness" and hence admissibility include, of most relevance here, any "possible motivation problems suggested by" those presented in *Palmer v. Hoffman*, 318 U.S. 109 (1943). JAMES W. MOORE ET AL., *MOORE'S FEDERAL PRACTICE* § 803.8, at 322 (1987).

In *Palmer*, a railroad was sued in a diversity action for injuries sustained in a grade-crossing accident that the plaintiff alleged was caused by the railroad's negligent failure to provide warning signals. *Id.* at 110. The railroad held an investigation, during which the engineer of the train (who died prior to trial) was interviewed by a railroad superintendent. *Id.* The railroad then sought to introduce into evidence the transcript of the engineer's statement. The Supreme Court held the transcript was not admissible, even though it was the usual practice of the railroad to hold investigations after accidents, because the investigation was not made "in the regular course of any business." *Id.* at 111 n.1. The statutory rule of evidence that the Court applied stated: "[A]ny writing or record . . . made as a memorandum or record of any act . . . shall be admissible as evidence of said act . . . if it shall appear that it was made in the regular course of any business, and that it was the regular course of such business to make such memorandum or record at the time of such act." *Id.* (quoting Act of June 20, 1936, 49 Stat. 1561).

Reports of the investigation were not admissible, the Court ruled, because they were "for use essentially in the court, not in the business. Their primary utility is in litigating, not in the business." *Id.* at 114. Regulatory actions justified in part by their possible value in the litigation process might be said to violate this criterion of trustworthiness.

That, however, is not so. Government regulatory reports are made, not in the process of preparing for any specific litigation, but prior to the event that gives rise to the litigation. The parties to subsequent litigation are not be known at the time the report is issued. The report in *Palmer* was prepared by one of the parties itself, while government reports have a considerably

Giving the parties more regulatory workproduct on which to rely can also promote the predictability of outcomes and thus the deterrent effect of tort law.³¹⁷ Identification of a product safety issue by the agency may help corporate managers reduce exposure to liability. The need to comply with governmental regulatory edicts will clarify risks to corporate managers. The threat of punitive damages associated with the possible violation of regulatory standards provides further reason to clarify the transmission of signals through corporate bureaucracy; liability risks sometimes are not perceived by those responsible for product design decisions.³¹⁸ Furthermore, regulatory violation can be used to establish liability, thereby reducing the need to litigate issues of due care and reducing the administrative cost of the tort system.

2. Using Regulation to Prevent Litigation

One way in which regulation may lower the costs of the tort system is by preventing injuries that would otherwise be litigated. Tort law relies on after-the-fact deterrence, in which the risk of liability encourages the desired behavior.³¹⁹ Regulation, on the other hand, bans undesired behavior directly. If litigation is more costly than the incremental administrative cost

greater aura of impartiality. Such reports, not prepared for any particular case but instead for all cases germane to the subject of the report, cannot have the overtone of bias that the report in *Palmer* obviously carried.

The alternative to relying on a jury, in any case, whatever its problems, is to rely on agencies with their own shortcomings pursuing a different agenda. If an agency is biased in the preparation of a report made for possible use in some future litigation, there is no reason it will not also be biased in its explicitly regulatory decisions. The jury similarly may be inflamed, biased, or unwilling to adhere to the limits of formal tort doctrine in assigning liability; but the evidence suggests that juries are in fact less willing than the appellate courts that review their actions to find liability.

In fact, the evidence from trials suggests that defendants win at trial in products liability cases considerably more frequently than plaintiffs do, and that judgments in favor of plaintiffs are more frequently reversed on appeal. William M. Landes & Richard A. Posner, *New Light on Punitive Damages*, REGULATION, Sept.-Oct. 1986, at 33. According to Landes and Posner, this suggests that, "if products liability law is becoming more expansive and favorable to plaintiffs' claims, this may be due more to changes in the standards of liability applied by appellate courts than to increased jury sympathy for accident victims or other factors affecting products liability trials." *Id.* at 35.

317. Stephen Sugarman suggests that the unpredictability of tort outcomes is one factor which undermines the deterrent effect of tort law. Stephen D. Sugarman, *Doing Away with Personal Injury Law*, in *PERPECTIVES ON TORT LAW* 126, 131-32 (Robert L. Rabin ed., 1990).

318. See EADS & REUTER, *supra* note 197, at 2-4.

319. One theoretical way to create strong incentives to deterrence is to use sufficiently large sanctions. See Gary S. Becker, *Crime and Punishment: An Economic Approach*, 76 J. POL. ECON. 169, 171-73 (1968). Whether juries would be willing to impose extremely high sanctions for this purpose is questionable; whether those sanctions would be constitutional is also open to question. See *TXO Prod. Corp. v. Alliance Resources*, 113 S. Ct. 2711, 2718-20 (1993); *Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1, 9-12, 18 (1991).

of regulating, regulation presents an opportunity to reduce the volume, as well as the cost, of litigating.

How large these savings might be has never, apparently, been estimated. Yet there are no such estimates. Cost-benefit studies of regulation did not consider administrative costs a significant element of the desirability of regulation, since such costs did not normally even enter the analysis,³²⁰ just as these studies did not consider the tort system as interacting with regulation. And estimates of the costs and benefits of regulation—including the benefits in terms of numbers of injuries prevented—have taken no account at all of the role of the existing tort system.

This Part attempts two alternative estimates of the litigation cost that regulation can prevent. These estimates are admittedly crude; their purpose is not to suggest a definitive number, but only to suggest that there may be significant savings available.

The first of these begins with existing estimates of the injuries that automobile safety regulation prevents,³²¹ and asks, *In the absence of that regulation to prevent injuries, how many lawsuits would those injuries generate, and how much would those lawsuits cost?* Put differently, it asks: What would it cost simply to handle through the courts the injuries that automobile safety regulation now prevent? That figure will then be compared to the administrative costs of preventing those accidents by regulation. The figure suggests the cost impact the elimination of regulation might have in raising the total administrative costs of the system.

An alternative estimate will then be attempted. Using estimates of the costs of complying with automobile safety regulatory requirements, and assuming that none of those costs are legitimately attributable to tort deterrence, the Article asks: *How many additional torts cases (in the absence of regulation) would it take to persuade auto manufacturers to increase their safety expenditures to the level of expenditures now mandated by regulation? And what would it cost to litigate those cases?* While the first estimate assumes that safety expenditures fall by the amount mandated by regulation alone and asks what it would cost to litigate the resulting injuries,

320. Typical of this treatment of alternative administrative costs as peripheral to the real issues in evaluating regulation is Linneman's decision simply not to include them:

The direct costs of the mattress flammability standard are composed of CPSC administrative costs and the increase in mattress prices attributable to the standard. In the absence of accurate intra-agency information on administrative costs, this section [entitled "Costs of the Mattress Flammability Standard"] concentrates solely on the latter effect.

Linneman, *supra* note 237, at 471. In light of Linneman's failure to account for the interaction with the tort system in evaluating the CPSC's flammability standard, the failure to include administrative costs becomes reasonable.

321. CRANDALL ET AL., *supra* note 31, at 69.

the second estimate assumes that safety expenditures are to be restored to their initial level through the incentives of the tort system, and asks what it would cost, in terms of additional litigation expense, to induce all the safety expenditures now made in response to regulation. Both estimates implicitly assume that all injuries which Crandall claims NHTSA regulation prevents in fact are prevented by regulation alone, and are not at all attributable to existing tort incentives; in other words, it takes seriously the view implicit in Crandall's study that tort incentives played no part in preventing any of the injuries Crandall claims regulation prevented.

a. Estimate 1: Handling Injuries Prevented by Regulation Through the Courts

In their study of the impact of NHTSA standards, Crandall and his colleagues suggest that "[h]ad automobiles been as unsafe in 1981 as in 1965, the estimates . . . suggest that total fatalities would have been 18,000 to 22,000 above their actual 1981 level."³²² Though Crandall and his coauthors offer these numbers as estimates of the benefits of regulation, they concede that other factors, possibly the tort system, may have contributed to the decline in traffic fatalities.³²³ However, the autonomous effect of changes in consumer demand for safety (and thus changes in the number of fatalities that would be generated independently through the market mechanism) is theoretically embodied in their estimated regression coefficients³²⁴ for wage rates and income.³²⁵

Because it appears that Crandall's estimate of the reduction in fatalities is at least a partial overestimate of the separate impact of regulation, let us assume that half of the estimated reduction in fatalities, or about 10,000 lives saved, is independently attributable to NHTSA regulation alone. This number is consistent with engineering estimates of the benefits of NHTSA safety standards³²⁶ and with NHTSA's own estimates of lives saved through NHTSA standards.³²⁷

The next step is to ask how many of those deaths (had they occurred) would be actionable against automobile or automobile parts manufacturers. Of course, there is no sure way to tell; as Saks notes, "separating accidental injuries into those which are tortious and those whose costs must remain

322. *Id.*

323. *Id.* at 72.

324. *See* BARNES *supra* note 196, at 293-294 (explaining regression coefficients).

325. For a discussion of this point, *see* Sam Peltzman, *The Effects of Automobile Safety Regulation*, 83 J. POL. ECON. 677, 688 (1975), the results of which Crandall et al. try in their own work to test and extend.

326. *See* CRANDALL ET AL., *supra* note 31, at 51-55, 69.

327. NATIONAL HIGHWAY TRAFFIC SAFETY ADMIN., U.S. DEP'T OF TRANSP., *TRAFFIC SAFETY TRENDS AND FORECASTS 1* (Oct. 1981).

with the injury victim is something that is rarely even attempted."³²⁸ Apparently no studies on automobile injuries exist, but such studies do exist for medical malpractice.³²⁹ As a percentage of all hospitalized patients, those suffering negligent iatrogenic³³⁰ injuries, as found by medical investigators, ranged between 0.79% and 2.18%.³³¹ However, as a percentage only of those suffering iatrogenic injuries, those suffering injuries due to negligence is a much higher number; the data provided by the Harvard study³³² suggests the percentage of negligence victims in the population of iatrogenic injury victims is some 27.6%.³³³ In the absence of any alternative numbers, let us assume the proportion of accidents attributable to actionable negligence based on unreasonable design allegations is of the same approximate magnitude.³³⁴ Related evidence suggests the percentage of such injuries in some contexts may be considerably higher.³³⁵ Taking 25% as an estimate of the share of actual injuries attributable to negligence, approximately 2500 of the deaths we have assumed are prevented annually by NHTSA standards might have had actionable claims against automobile manufacturers had those standards not existed.

Of those 2500 potentially actionable claims, how many would actually result in a claim that would in some way enter the products liability system? Evidence here suggests the percentage of actionable claims actually filed is consistently quite low. One study finds that around 10% of negligently injured patients sought compensation³³⁶; another suggests a number of 6%³³⁷;

328. Saks, *supra* note 1, at 1176.

329. HARVARD MEDICAL PRACTICE STUDY, PATIENTS, DOCTORS, AND LAWYERS: MEDICAL INJURY, MALPRACTICE LITIGATION AND PATIENT COMPENSATION IN NEW YORK, THE REPORT OF THE HARVARD MEDICAL PRACTICE STUDY TO THE STATE OF NEW YORK 3 (1990) [hereinafter HARVARD MEDICAL PRACTICE STUDY]; LEON S. POCINCKI ET AL., THE INCIDENCE OF IATROGENIC INJURIES 50, 55 (1973). There is no question that reliance on medical malpractice statistics may give a misleading impression of the behavior of automobile accident victims. In the absence of data pertinent to those cases, however, I will assume for present purposes that their behavior is roughly similar.

330. Iatrogenic injuries are those caused by medical or surgical treatment. Saks, *supra* note 1, at 1178 n.86 (citing STEDMAN'S MEDICAL DICTIONARY 759 (25th ed. 1990)).

331. See *supra* note 328.

332. HARVARD MEDICAL PRACTICE STUDY, *supra* note 329, at 3-4.

333. *Id.* at 3. Saks suggests this may be an underestimate because the Harvard investigators may have been overly cautious in ascribing injuries to practitioner negligence. Saks, *supra* note 1, at 1178 n.85.

334. Crandall's estimates are of injuries prevented by regulation; thus, in principle, they do not include automobile accidents caused by factors other than those regulated by NHTSA. This is largely a matter of automobile design. Thus, I assume the injuries that would occur in the absence of NHTSA regulation are related to design issues rather than to driver negligence.

335. Saks, *supra* note 1, at 1179-80 & n.92.

336. Patricia Danzon notes that this rate rose to around 20% between the mid-1970s and the mid-1980s. Patricia M. Danzon, *The Frequency and Severity of Malpractice Claims: New Evidence*, LAW & CONTEMP. PROBS., Spring 1986, at 57, 68.

337. Saks, *supra* note 1, at 1178-80.

a third suggests that 18.7% of tortious injuries are litigated.³³⁸ Let us pick a middle estimate and assume that about 10% of actionable claims result in legal action. If so, then our 2500 actionable injuries become 250 lawsuits.

What would be the social cost of those lawsuits? James Kakalik and Nicholas Pace³³⁹ suggest that the total costs of tort litigation in state and federal courts in 1985, not inclusive of compensation paid to plaintiffs,³⁴⁰ came to between \$15.5 billion and \$19 billion.³⁴¹ Kakalik and Pace estimate there were some 866,000 torts cases terminated in state and federal courts of general jurisdiction in 1985.³⁴² The average torts case, therefore, had an approximate net cost to society of between \$17,900 and \$22,200 in that year. Multiplying these respective average costs per torts case times the estimated number of automobile fatality cases prevented in 1985 of 250 yields an estimate of litigation costs avoided of between \$4.5 million and \$5.5 million per year in automobile fatality cases alone.

There are no estimates of non-fatal injuries preventable by improved automobile safety comparable to the estimates by Crandall and his coauthors for fatal injuries prevented. NHTSA, however, has estimated the number of motor vehicle-related injuries for 1979-80;³⁴³ the ratio of non-fatal injuries to fatal injuries, based on NHTSA's numbers, is about 77:1. Crandall suggests this ratio may need adjustment because crash-protection regulation tends to reduce the severity of injuries, thus reducing fatalities only at the cost of increasing the number of non-fatal injuries;³⁴⁴ if so, then in the absence of regulation there would be relatively fewer non-fatal injuries, and that ratio would be lower. On the other hand, Saks points out that, in the context of medical malpractice, "[m]oderately to severely injured malpractice victims were between two and three times more likely to file malpractice suits than families of those who died from negligent injuries."³⁴⁵ If this translates to the automobile litigation context, then the ratio of suits in nonfatal cases to suits in fatal cases would be considerably higher

338. *See id.* at 1184.

339. KAKALIK & PACE, *supra* note 16, at 68-69.

340. Compensation awards from defendants or their insurers to plaintiffs are irrelevant to the comparative social cost of regulation and the tort system because the awards are simply a transfer of resources and do not represent a net cost to society.

341. KAKALIK & PACE, *supra* note 16, at 69 tbl. 7.3. These expenditures, after netting out compensation paid to plaintiffs, include "legal fees and related expenses of both plaintiffs and defendants, insurance company claims-processing costs for claims in suit, the value of litigants' time spent, and the costs of operating the court system for these cases." *Id.* at 66.

342. *Id.*

343. NATIONAL HIGHWAY TRAFFIC SAFETY ADMIN., DEP'T OF TRANSP., THE ECONOMIC COST TO SOCIETY OF MOTOR VEHICLE ACCIDENTS II-2-18, DOT HS-806-342 (1983).

344. CRANDALL ET AL., *supra* note 31, at 76.

345. Saks, *supra* note 1, at 1187 (citing CALIFORNIA MEDICAL ASS'N & CALIFORNIA HOSP. ASS'N, REPORT ON THE MEDICAL INSURANCE FEASIBILITY STUDY (Don H. Mills ed. 1977)).

than the ratio of nonfatal injuries to injuries; multiplying the tort-litigation-cost saving in fatal automobile injury cases by 77 would result in a considerable underestimate. Let us assume simply that the proper number lies between 50 and 100. This results in an obviously speculative estimate of annual tort litigation costs saved because of the existence of NHTSA safety regulations of between \$230 million and \$555 million.

As compared to these numbers, there appears to be a clear savings in administrative cost by relying on NHTSA regulation to prevent those injuries. The entire administrative budget of NHTSA in fiscal year 1985 was \$100.4 million,³⁴⁶ or less than half the administrative costs that would have been necessary to handle the resulting volume of cases through the courts had NHTSA's safety standards not existed.

b. Estimate 2: Achieving the Same Safety Expenditures as Regulation

Let us again assume that all of the estimated engineering costs³⁴⁷ associated with NHTSA regulations are attributable to NHTSA alone. If NHTSA's safety requirements disappeared overnight and the industry could costlessly scale up or down its safety expenditures to its profit-maximizing point, none of those safety costs would be required, either by the now-vanished regulatory regime, the unchanged tort regime, nor by market demand (since by assumption those engineering costs were attributable only to NHTSA). Assume industry can avoid tort liability by adopting safety expenditures. Our question then is this: Assuming no change per case in the cost of litigating or in expected damage awards, how many *additional* torts cases would be required to produce the original level of safety expenditure, the expenditures that were made in response to the regulatory regime which has (by hypothesis) disappeared? Once we have an answer to that question, we can ask about the administrative cost of achieving that level of dollar expenditure on automobile safety alternatively by the current regulatory system or by an expanded tort regime.

My method is this. First, let us ask what it currently costs automobile manufacturers to comply with all applicable NHTSA safety requirements. Assuming risk neutrality³⁴⁸ by automobile manufacturers, and assuming that tort substantive behavioral standards are the same as those now mandated by NHTSA, this Article asks how many additional litigated cases are

346. BUDGET OF THE UNITED STATES GOVERNMENT I-Q14 (1986).

347. I mean to include here all of the costs associated with implementing NHTSA safety regulations, not just the expenditures on engineering services.

348. For an explanation of risk neutrality, see CHARLES J. GOETZ, *LAW AND ECONOMICS: CASES AND MATERIALS* 79 (1984).

necessary to produce expected liability costs³⁴⁹ by manufacturers of this same amount. To answer that question, the average cost to defendants of litigating a torts lawsuit including average damages is found, and the total required liability expense is divided by the current average cost per case to defendants to find the number of cases required to produce the necessary total cost to defendants. That number of cases is then multiplied by the cost-to-society per average case (which is net of damages payments but inclusive of costs to courts, plaintiffs, and defendants), to produce the administrative cost of generating by tort enforcement alone the same level of safety expenditures as results from current NHTSA safety regulation.

Crandall and his coauthors have estimated the current engineering costs to manufacturers of complying with all current NHTSA safety regulations.³⁵⁰ To get these estimates, they combine U.S. General Accounting Office (GAO) figures for the years 1966 through 1974 on the engineering cost of new safety standards with annual estimates of the incremental cost of new standards derived by the U.S. Bureau of Labor Statistics.³⁵¹ They then adjust these figures for inflation, and for learning that reduces the annual cost of compliance for pre-existing requirements.³⁵² Based on these adjustments they derive an estimate of total compliance costs of safety regulation in 1984 of \$491 per automobile produced in that year.³⁵³ There were some 7.7 million new passenger cars produced in the United States in 1984,³⁵⁴ for a total compliance cost for automobile production of \$3.78 billion in 1984 dollars.

If NHTSA-mandated safety precautions are indeed entirely separate from what automobile manufacturers are now induced to spend on safety by tort liability, and manufacturers are risk neutral (so that the uncertainty associated with tort litigation does not by itself change the desired level of expenditures), how much would have to be spent in tort litigation costs to achieve that same level of compliance expenditures? Those expenditures are incremental or additional to the safety expenditures manufacturers are now induced to make by the tort system.³⁵⁵ This should be equal to their expected liability costs if they fail to implement the same safety precautions.

349. For an explanation of expected values, see BARNES, *supra* note 196, at 80.

350. CRANDALL ET AL., *supra* note 31, at 37 tbl. 3-4.

351. *Id.* at 33.

352. *Id.* at 36-37.

353. *Id.* at 37 tbl. 3-4.

354. U.S. DEP'T OF COMMERCE, BUREAU OF THE CENSUS, STATISTICAL ABSTRACT OF THE UNITED STATES 608 tbl. 1034 (1991).

355. This is probably unrealistic, since NHTSA standards, as with most government mandates, tend to be floors and not ceilings for tort liability. See *supra* notes 20-194 and accompanying text.

Kakalik and Pace estimate that all tort litigation in 1985 cost defendants a total of between \$28.7 billion and \$35.1 billion, including between \$8.0 billion and \$10.0 billion of litigation costs and between \$20.7 billion and \$25.1 billion of total compensation to plaintiffs.³⁵⁶ Dividing that figure by 866,000 tort lawsuits in that year in both state and federal courts of general jurisdiction,³⁵⁷ each lawsuit costs defendants between \$33,000 and \$41,000. Let us assume this is what each new lawsuit will cost defendants when current regulation is removed.

To achieve additional expected liability cost of an additional \$3.78 billion (the current total regulatory compliance costs for automobile production in the United States), if each suit can be expected to cost defendants between \$33,000 and \$41,000, then between 93,000 and 117,000 new cases will be required to induce the same safety precautions. Multiplying these additional case numbers by RAND's estimated social cost per tort suit (i.e. litigation costs to both sides plus court costs, exclusive of damage awards) of between \$17,000 and \$22,000 yields a range of results between \$1.5 billion and \$2.5 billion in administrative costs to achieve through the tort system the same level of safety as is currently provided by NHTSA.

If regulation in fact has the ability to prevent injuries without depending on the relatively expensive administrative mechanism of tort deterrence, then a potentially significant new element of benefit is added to the cost-benefit equation. The result may well be a more activist regulatory regime, with associated benefits in enhancing the rationality of jury decisions.

V. CONCLUSION

Tort law affects the true costs of health and safety regulation, yet its impact has been obscured. The unaccounted-for interaction between federal regulation and products liability law has led to an overstatement of the cost of regulation, excessive optimism about the potential benefits of deregulation, and devaluation of public-sector remedies for health and safety issues.

Modern health and safety regulation developed coincidentally with the major growth in products liability law between the early 1960s and the late 1970s. In choosing policy, we wrongly relied on estimates of regulatory cost that included not just the cost of regulation but also the cost of the more expansive products liability regime that developed concurrently with it. For that reason, we have an excessively negative view of the total cost of governmental efforts to affect product safety.

Furthermore, we have misunderstood the nature of the benefits provided by the regulatory system. In those cases in which tort rules supersede

356. KAKALIK & PACE, *supra* note 16, at 69, tbl. 7.3.

357. *Id.* at 66.

or offset regulatory mandates, the impact of regulation on the allocation of private resources is probably small. The real benefits of regulation are different: regulation reduces the costs of operating and maintaining the tort system.

Our measurements of regulatory costs and benefits are tainted by the failure to appreciate the historical coincidence that has given us a dual system of regulation. Their interplay will critically determine the effects of changing either tort law or federal health and safety regulation. Until we recognize the true choices we face, we will be unable to make policy choices that mean what we think they mean.