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The Role of Federal Safety Regulations in Products Liability Actions

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The Role of Federal Safety Regulations in Products Liability Actions

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I.	INTRODUCTION	1122
II.	THE PROPOSED REFORMS: A DEPARTURE FROM COMMON-LAW TRADITION	1125
	A. <i>General Overview of the Proposals</i>	1125
	B. <i>Impacts on Products Liability Law</i>	1127
	1. Eliminating Strict Liability	1127
	2. Complicating the Litigation of Product Claims .	1130
	C. <i>Rejecting the Common-Law Treatment of Standards</i>	1135
	1. Adopting Standards to Further the Legislative Purpose	1136
	2. Adopting Standards Consistent with Common-Law Principles	1140
	3. Rejecting the Traditional Approach to Standards	1145
III.	THE PROPOSED REFORMS IN THE MODERN REGULATORY ERA	1146
	A. <i>Industry Influence</i>	1147
	1. Business Control of Vital Information	1147
	2. Industry Resources	1149
	B. <i>Obsolescence</i>	1151
	C. <i>The Regulatory System Under the Reagan Administration</i>	1152
	1. Industry Influence	1153
	a. "Back Door" Influence	1154

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b.	<i>Secrecy</i>	1155
c.	<i>Cost-Benefit Analysis</i>	1156
d.	<i>Budget Cutbacks</i>	1157
e.	<i>Regulatory Inaction</i>	1158
D.	<i>Broad Ramifications on Regulatory and Tort Systems</i>	1160
1.	<i>Impact on the Regulatory Process</i>	1160
2.	<i>Interaction Between Tort and Regulatory Systems</i>	1161
IV.	CONSIDERING THE PROPOSED REFORMS IN LIGHT OF THE PRODUCTS LIABILITY CRISIS	1163
A.	<i>The Insurance "Crisis"</i>	1164
B.	<i>Increases in Products Liability Claims</i>	1165
C.	<i>Increases in the Size of Recoveries</i>	1167
D.	<i>Increases in the Cost of Litigation</i>	1167
V.	CONCLUSION	1168

I. INTRODUCTION

Product safety is the province of both the regulatory and the tort systems. Each system has come under attack in recent years on both the federal and state levels. Through its regulatory policies, appointments, and budget cuts, the Reagan Administration has weakened the federal regulatory system.¹ At the same time, the Administration has severely criticized the tort system.² State legislatures have enacted a myriad of statutes that weaken the tort system by cutting back on the common-law rights of victims,³ and additional measures are pending in Congress⁴ and in state legislatures across the country.⁵

1. See, e.g., S. TOLCHIN & M. TOLCHIN, *DISMANTLING AMERICA; THE RUSH TO DEREGULATE* (1983); COSTLE, *Environmental Regulation and Regulatory Reform*, 57 WASH. L. REV. 409 (1982); MCGARITY, *Regulatory Reform in the Reagan Era*, 45 MD. L. REV. 253 (1986).

2. UNITED STATES ATTORNEY GENERAL, REPORT OF THE TORT POLICY WORKING GROUP ON THE CAUSES, EXTENT AND POLICY IMPLICATIONS OF THE CURRENT CRISIS IN INSURANCE AVAILABILITY AND AFFORDABILITY (1986) [hereinafter ATTORNEY GENERAL'S REPORT] (interagency study, sharply critical of the tort system and its effect on skyrocketing insurance rates, conducted under the auspices of the Attorney General of the United States).

3. From 1986 to 1988, legislatures in 38 states passed measures aimed at limiting liability by narrowing the scope of liability, eliminating joint and several liability, capping damages, and limiting punitive awards. 16 Prod. Safety & Liab. Rep. (BNA) 108 (1988).

4. See, e.g., H.R. 1115, 100th Cong., 2d Sess. (1988); see also *Federal Product Liability Bill Closer to Reality*, Nat'l L.J., Mar. 14, 1988, at 5, col. 1. Federal products liability reform has been before the Congress since 1979. For a history of federal legislative activity in this area, see Twerski, *A Moderate and Restrained Federal Product Liability Bill: Targeting the Crisis Areas for Resolution*, 18 U. MICH. J.L. REF. 575, 575 n.2 (1985).

5. Measures to limit the scope of products liability law are being urged in a number of industrial states, including Illinois, Indiana, Michigan, and Pennsylvania. 16 Prod. Safety & Liab. Rep. (BNA) 108 (1988).

For the most part, proponents of products liability and tort reform have failed to take into account the interaction between the tort and regulatory systems. These activists have failed to consider the federal government's declining role in safety during the Reagan years and have failed to weigh this factor in assessing the merits of reform proposals.

One set of proposed products liability reforms, however, forces an examination of the relationship between the regulatory system and the tort system. These proposals would increase greatly the influence of the federal government over the products liability system by mandating that, under the common law, federally issued product safety standards are conclusive, or at least presumptive, evidence of adequate safety measures. Under this view, a defendant in a products liability action whose product complied with a federal safety standard would be presumed, or found as a matter of law, to have met all requirements of the tort law and would be immune from civil liability.

These proposals would alter dramatically the longstanding judicial treatment of regulatory and statutory standards as generally good measures of the minimum, but not the maximum, standard of care required by the common law. The courts have treated violations of these standards as negligence per se (presumptive negligence), but they have treated regulatory compliance as merely relevant evidence of due care, deserving no special weight.

Proponents of these proposed reforms argue that the traditional judicial treatment of regulatory standards is neither sound, nor affordable. Proponents suggest two arguments in favor of the reforms. First, the proponents claim that modern regulatory standards set safety requirements that are sufficiently high to be presumed adequate for purposes of the tort law.⁶ Proponents argue that unlike criminal statutes,

6. See generally Henderson, *Manufacturers' Liability for Defective Product Design: A Proposed Statutory Reform*, 56 N.C.L. REV. 625 (1978) [hereinafter Henderson, *Proposed Statutory Reform*].

Proponents of these reforms see the agencies as superior to the courts in determining product safety questions. See Henderson, *Judicial Review of Manufacturers' Conscious Design Choices: The Limits of Adjudication*, 73 COLUM. L. REV. 1531, 1555, 1574-75 (1973) [hereinafter Henderson, *Conscious Design Choices*]. Writing in 1973, Professor Henderson predicted that courts increasingly would defer to federal regulatory standards because the agencies had a "tremendous advantage" over the courts in answering the "polycentric question of '[h]ow much design safety is enough?'" *Id.* at 1555; see also Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277 (1985). In the Huber article, the author states:

Regulatory agencies are equipped to make the risk comparisons on which all progressive transformation of the risk environment must be based. The courts are simply not qualified to second-guess such decisions; when they choose to do so they routinely make regressive risk choices. Requiring—or at least strongly encouraging—the courts to respect the comparative risk choices made by competent, expert agencies would inject a first, small measure of rationality into a judicial regulatory system that currently runs quite wild.

Id. at 335.

which can be viewed as setting minimal standards to deter "severely antisocial conduct," federal regulatory standards set a "reasonable standard of conduct for the manufacturer" that can be used to establish suitable measures of safety under the tort law.⁷ Second, proponents claim that the federal regulatory system will provide the kind of concrete, predictable liability standards demanded by a products liability system now so wildly out of control.⁸

This Article challenges these views concerning the adequacy of modern regulatory standards and the current condition of the products liability system. It also considers some of the troubling ramifications connected with the shifting of substantial control over the tort system from the courts to the federal regulatory system—ramifications that the reform proponents generally have ignored.

Part II of the Article describes the proposals: how they would limit existing products liability law and depart from the traditional use of standards to define tort liability. Part III examines whether the historical judicial approach to these standards remains valid in the modern regulatory state and concludes that, at least in some respects, the traditional view is even more compelling today than it was in the past. Part III also explores some of the disturbing, long-term consequences of the proposed reforms, including the prospects of federalizing products liability law and making it increasingly vulnerable to shifts in federal regulatory policies, such as those that have occurred during the Reagan Administration. Part IV then considers, and ultimately rejects, the possibility that, despite the troubling aspects of the proposed reforms, they might be justified by the products liability "crisis." Finding no crisis, the Article concludes in Part V that the proposals must be rejected.

7. Wilton & Campbell, *Effect of Federal Safety Regulations on Crashworthiness Litigation*, 22 TORT & INS. L.J. 554, 558 (1987).

8. See, e.g., Henderson, *Proposed Statutory Reform*, *supra* note 6, at 628-29; see also R. EPSTEIN, *MODERN PRODUCTS LIABILITY LAW* 93-118 (1980). Professor Epstein places special emphasis on the importance of "certainty and predictability" in his proposals for greater judicial deference to administrative safety standards. *Id.* at 192.

A recurring criticism made by tort scholars has been that the courts have failed to articulate clear legal standards under strict products liability, particularly with respect to claims of design defects and claims of inadequate warnings. See Birnbaum, *Unmasking the Test for Design Defect: From Negligence [to Warranty] to Strict Liability to Negligence*, 33 VAND. L. REV. 593, 600-02 (1980); Twerski, Weinstein, Donaher & Piehler, *The Use and Abuse of Warnings in Products Liability—Design Defect Litigation Comes of Age*, 61 CORNELL L. REV. 495, 513-17 (1976).

A good deal of the recent scholarship in the products liability field has been devoted to a search for appropriate standards for design claims. For a list of the leading articles, see Twerski, *Seizing the Middle Ground Between Rules and Standards in Design Defect Litigation: Advancing Directed Verdict Practice in the Law of Torts*, 57 N.Y.U. L. REV. 521, 521 n.1 (1982) [hereinafter Twerski, *Advancing Directed Verdicts*].

II. THE PROPOSED REFORMS: A DEPARTURE FROM COMMON-LAW TRADITION

A. General Overview of the Proposals

Although the proposed reforms vary considerably both in the products they cover and in the weight they would assign to regulatory compliance, all would require greater judicial acceptance of federal regulations as standards of tort liability.

Some of the proposals are very broad in their coverage, applying across the board to all regulated products.⁹ Others are narrow, applying only to particular products; for example, automobiles that comply with motor vehicle safety standards issued by the National Highway Traffic Safety Administration (NHTSA).¹⁰ Other proposed reforms are limited to products that must be approved by the government prior to marketing; for example, pharmaceuticals approved by the Food and Drug Administration (FDA)¹¹ and aircraft approved by the Federal Aviation Administration (FAA).¹²

As mentioned above, the proposals also vary in the weight that they would assign to regulatory compliance. The most radical proposals would require courts to defer completely to the decisions of the agencies, which comprehensively regulate products such as pharmaceuticals, aircraft, medical devices, and pesticides.¹³ In most of the proposals,

9. See H.R. 1115, 100th Cong., 1st Sess. § 206(b)(1), (3) (1987) [hereinafter H.R. 1115]; R. EPSTEIN, *supra* note 8, at 83-84, 111-12, 192; Henderson, *Proposed Statutory Reform*, *supra* note 6, at 632-33.

10. See generally Wilton & Campbell, *supra* note 7; Note, *Judicial Participation in the Establishment of Vehicle Safety Standards: A System in Need of Reform*, 54 TEMP. L.Q. 902 (1981).

11. See Epstein, *Legal Liability for Medical Innovation*, 8 CARDOZO L. REV. 1139, 1151 (1987); Foote, *Coexistence, Conflict, and Cooperation: Public Policies Toward Medical Devices*, 11 J. HEALTH POL. POL'Y & L. 501, 512 (1986); see also Keeton, *Some Observations About the Strict Liability of the Maker of Prescription Drugs: The Aftermath of MER/29*, 56 CALIF. L. REV. 149, 152 (1968). Professor Keeton argues that while courts may treat general safety rules as minimal safety standards for purposes of tort law, they should give greater weight to agency actions that approve of specific products, such as the FDA's premarket approval of prescription drugs. In the latter case, he argues that the agency's determination is directly at issue in the tort action and deserves more deference. *Id.* at 153-54.

12. See H.R. 2238, 100th Cong., 1st Sess. (1987) [hereinafter H.R. 2238].

13. Huber, *supra* note 6, at 329-35. Professor Huber argues that the tort system should not second guess agency determinations regarding these products, which create generalized "public" health and safety risks, *i.e.*, risks that are "centrally or mass-produced, broadly distributed and largely outside the individual risk bearer's direct understanding." *Id.* at 277. In his view, these products, which are "subject to the most searching and complete state and federal safety regulation," should not be subject to evaluation under the tort law. *Id.* at 344.

Professor Keeton recommends giving conclusive weight to FDA approval of pharmaceuticals if victims were entitled to institute proceedings for the withdrawal of drugs from the market. Keeton, *supra* note 11, at 154. With respect to drugs withdrawn from the market, Keeton would impose strict liability in order to induce manufacturers to take greater safety measures prior to marketing their drugs. *Id.* Professor Epstein also would make compliance with FDA-approved warnings con-

however, compliance with the regulatory standard would create only a rebuttable presumption that the requisite common-law standard of care has been met.¹⁴ The effects of the presumption, however, can vary somewhat under these proposals, depending on the burden imposed on plaintiffs to overcome the presumption. One proposal would require the plaintiff to establish that the regulatory standard was inadequate based on "clear and convincing" evidence—a kind of super negligence standard.¹⁵ Another proposal would require the plaintiff to show that the regulatory standard clearly was outdated, or was based on inaccurate information supplied by the parties subject to the regulation.¹⁶ A third proposal would require the plaintiff to establish that the defendant was negligent in failing to take greater precautions than those required by the regulatory standard.¹⁷

Increasingly, state tort reform statutes¹⁸ and proposed federal products liability legislation include these proposals.¹⁹ While the varied nature of these proposed reforms makes it difficult to forecast precisely their effects on products liability law,²⁰ it is possible to foresee some general impacts.

clusive in tort actions. Epstein, *supra* note 11, at 1151.

14. See, e.g., Foote, *supra* note 11, at 512 (stating that compliance with FDA requirements should create a rebuttable presumption of nondefectiveness).

15. See Henderson, *Proposed Statutory Reform*, *supra* note 6, at 632 (stating that defendants should not be liable for product designs that comply with federal standards unless plaintiff proves by "clear and convincing" evidence that the standards were "inadequate to protect the class of persons of which plaintiff is a member from unreasonable risks of injury or damage").

16. R. EPSTEIN, *supra* note 8, at 83-84, 111-12, 192.

17. See H.R. 1115, *supra* note 9, § 206(b)(1), (3)(c)(3) (stating that a plaintiff must show that "a person exercising reasonable care could and would have taken additional precautions" or that the manufacturer or product seller failed to inform the government of dangers material to the claim that were known to them); KAN. STAT. ANN. § 60-3304(a) (1983) (stating that a plaintiff must prove "by a preponderance of evidence that a reasonably prudent product seller could and would have taken additional steps").

18. See, e.g., Act of July 22, 1987, ch. 197, 1987 N.J. Sess. Law Serv. 188-93 (West). The New Jersey statute makes compliance with FDA-approved warnings presumptively adequate and limits the availability of punitive damages when products approved by the FDA are challenged. See states cited *supra* note 5. Other states also have enacted provisions creating a presumption that products in compliance with government standards are reasonably safe and nondefective. See KAN. STAT. ANN. § 60-3304(a), (b) (1983) (discussed *supra* note 17); TENN. CODE ANN. § 29-28-104 (1980); UTAH CODE ANN. § 78-15-6(3) (Supp. 1987).

19. H.R. 2238, *supra* note 12; H.R. 1115, *supra* note 9.

20. In the past, the insurance industry has been reluctant to forecast that a strengthened statutory compliance defense would have any effect on jury verdicts. INTERAGENCY TASK FORCE ON PRODUCTS LIABILITY, U.S. DEPT. OF COMMERCE, PRODUCTS LIABILITY: FINAL REPORT VII—38 (1978) [hereinafter FINAL REPORT ON PRODUCTS LIABILITY].

B. Impacts on Products Liability Law

The proposals that would make regulatory compliance an absolute defense to tort claims would have the most radical effect on the tort system. Under these proposals, the regulatory system, in effect, would preempt the tort system completely. The other proposals, which are the focus here, would have a less radical, but nevertheless significant impact on tort law. All the proposed reforms are intended to shrink the scope of liability under current products liability law. They would accomplish this goal in two ways: First, by eliminating strict liability in regulatory compliance cases; and second, by increasing substantially the plaintiff's evidentiary burden in such cases.

1. Eliminating Strict Liability

By requiring, at the very least, that the plaintiff establish the defendant's negligent conduct in failing to do more than was required by the regulation, the proposed reforms would eliminate strict liability theory in compliance cases. This return to negligence theory would erase some of the major advantages that plaintiffs have gained in the development of products liability law over the last twenty years.

Under the *Restatement (Second) of Torts (Restatement)* view of strict liability in products liability law, product sellers are liable for injuries caused by products that are in a "defective condition unreasonably dangerous" to the user or consumer.²¹ Strict liability theory focuses on the dangerousness of the product rather than the unreasonableness of the seller's conduct, the focus in negligence theory.²²

Courts have identified three ways in which a product can be defective: It can be mismanufactured, defective in design, or defective due to

21. See RESTATEMENT (SECOND) OF TORTS § 402A (1965) [hereinafter RESTATEMENT]. The *Restatement* provides in relevant part 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.*

22. See, e.g., *Barker v. Lull Eng'r Co.*, 20 Cal. 3d 413, 418, 573 P.2d 443, 447, 143 Cal. Rptr. 225, 229 (1978); *Feldman v. Lederle Laboratories*, 97 N.J. 429, 449, 479 A.2d 374, 385 (1984); *Roach v. Kononen*, 269 Or. 457, 465, 525 P.2d 125, 129 (1984); *Davis v. Globe Mach. Mfg. Co.*, 102 Wash. 2d 68, 72, 684 P.2d 692, 696 (1984).

Some scholars have suggested that focusing on the product rather than the seller's conduct is a distinction without a difference. See *Birnbaum*, *supra* note 8, at 601. Professor *Birnbaum* characterized the shift in focus as "semantic gymnastics that confuse juries." *Id.* In her view, the jury inevitably makes an assessment of negligence in these cases: "The jury may be charged to look at the product, but as a common sense matter the jury, in fact, simply weighs the competing factors put in evidence and then reaches a judgment about the judgment (i.e., conduct) of the manufacturer." *Id.* at 609-10. Nevertheless, courts continue to emphasize the importance of focusing on the product, as opposed to the manufacturer's conduct. See, e.g., *Caterpillar Tractor Co. v. Beck*, 593 P.2d 871, 877 (Alaska 1979); *Ortho Pharmaceutical Corp. v. Heath*, 722 P.2d 410, 414 (Colo. 1986).

inadequate warnings.²³ Cases involving regulatory compliance generally will concern the latter two claims of defect. As applied to warning and design claims, strict liability theory overlaps with negligence theory²⁴ in that under both theories liability is based on a risk-utility balancing test.²⁵ The overlap, however, is not total. In many jurisdictions the

23. See, e.g., *Feldman*, 97 N.J. at 449, 479 A.2d at 385.

24. Sorting out the differences between strict liability and negligence, especially in design cases, has been the source of much of the difficulty for the courts in their attempts to fashion a strict liability standard. See, e.g., Birnbaum, *supra* note 8, at 600-02; Wade, *On the Effect in Product Liability of Knowledge Unavailable Prior to Marketing*, 58 N.Y.U. L. Rev. 734, 741-45 (1983).

In warning cases, most courts find little difference between negligence and strict liability. See, e.g., *Feldman*, 97 N.J. at 450, 479 A.2d at 386. They also find, though, that the scope of the warning claim, under either theory, has grown significantly. Claims grounded on the premise that the product provided inadequate warning to the user, which once might have been decided in favor of the defendant as a matter of law, now go to the jury. See *Laaperi v. Sears, Roebuck & Co.*, 787 F.2d 726, 731 (1st Cir. 1986). In *Laaperi* the court ruled that the assessment of the adequacy of warnings is "almost always an issue to be resolved by a jury [because] few questions are 'more appropriately left to a common sense lay judgment than that of whether a written warning gets its message across to an average person.'" *Laaperi*, 787 F.2d at 731 (quoting *MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass. 131, 140, 475 N.E.2d 65, 71 (1985)). Risks that were once thought obvious as a matter of law now pose questions for the jury. See *Laaperi*, 787 F.2d at 730; *Campo v. Firestone Tire & Rubber Co.*, 98 N.J. 198, 207, 485 A.2d 305, 310 (1984) (finding the obviousness of the risk to be just one factor in determining whether a warning was adequate). Courts typically view the imposition of a warning as an inexpensive procedure, so that under a risk-utility assessment the "balancing process will almost always weigh in favor of an obligation to warn." *Moran v. Faberge, Inc.*, 273 Md. 538, 543-44, 332 A.2d 11, 15 (1975).

25. Most courts have adopted a kind of risk-utility test for strict liability design claims that closely resembles the test for negligence. See, e.g., *Kallio v. Ford Motor Co.*, 407 N.W.2d 92, 94-95 (Minn. 1987); *Micallef v. Miehle Co.*, 39 N.Y.2d 376, 386, 348 N.E.2d 571, 577-78, 384 N.Y.S.2d 115, 121 (1976); *Wilson v. Piper Aircraft Co.*, 282 Or. 61, 66, 577 P.2d 1322, 1325-26 (1978).

Many courts use the detailed list of considerations prepared by Dean Wade as the framework for applying the tests, although there are variations on this list. Dean Wade proposed that the following factors be considered by the court in determining whether a design claim should be submitted to the jury:

- (1) the usefulness and desirability of the product—its utility to the user and to the public as a whole;
- (2) the safety aspects of the product—the likelihood that it will cause injury, and the probable seriousness of the injury;
- (3) the availability of a substitute product which would meet the same need and not be as unsafe;
- (4) the manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility;
- (5) the user's ability to avoid danger by the exercise of care in the use of the product;
- (6) the user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions;
- (7) the feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.

Wade, *On the Nature of Strict Tort Liability for Products*, 44 Miss. L.J. 825, 837-38 (1973) (footnote omitted). Other variations on the list also have been proposed. See Keeton, *Manufacturer's Liability: The Meaning of "Defect" in the Manufacturer and Design of Products*, 20 SYRACUSE L. REV. 559, 565-66 (1969) (a four factor test); Montgomery & Owen, *Reflections on the Theory and*

strict liability theory imposes a less onerous burden of proof on plaintiffs than the negligence theory,²⁶ an advantage that would be lost under the proposed reforms.

Under some strict liability tests, for example, the manufacturer's knowledge of its product's dangerous condition is assumed and the jury is asked whether, with such knowledge, it was reasonable to place the product on the market.²⁷ Under negligence theory the plaintiff must establish that the defendant knew or should have known of the risks.²⁸ The proposed reforms would eliminate the defendant's constructive knowledge by requiring, at a minimum, that the plaintiff establish the defendant's negligence in failing to do more than required by the standard.

Plaintiffs asserting strict liability also would lose other advantages under the reforms. The reforms would eliminate the "consumer expect-

Administration of Strict Tort Liability for Defective Products, 27 S.C.L. REV. 803, 818 (1976) (a four factor test); Shapo, *A Representational Theory of Consumer Protection: Doctrine, Function and Legal Liability for Product Disappointment*, 60 VA. L. REV. 1109, 1370-71 (1974) (a thirteen factor test).

26. See, e.g., *Kallio*, 407 N.W.2d at 92 (ruling that plaintiff need not establish as part of his prima facie case in strict liability that there was a practical alternative design under a risk-utility balancing test).

27. See, e.g., *Phillips v. Kimwood Mach. Co.*, 269 Or. 485, 525 P.2d 1033 (1974). The test is one suggested by Dean Wade. See Wade *supra* note 25, at 834-35 (under which approach "scienter [on the part of the manufacturer] is supplied as a matter of law, and there is no need for the plaintiff to provide its existence as a matter of fact").

28. Dean Wade proposes that knowledge be imputed at the time the product was sold. See Wade, *supra* note 24, at 760. With his suggestion that courts which have not yet applied strict liability to design cases should consider treating them under negligence, Dean Wade seems to acknowledge that such an approach cannot be distinguished from negligence. *Id.* at 760. Further, he questions the continued usefulness of the assumed-knowledge test, which "always had overtones of fiction, and, like all fictions, . . . can create difficulties if taken literally." *Id.* at 764.

Another approach, which would impute knowledge as of the time of trial, is a true strict liability test. Under this approach, which was first proposed by Dean Keeton, the "magnitude of the scientifically perceivable danger as it is proved to be at the time of trial" is weighed against the benefits of the design. Keeton, *Product Liability and the Meaning of Defect*, 5 ST. MARY'S L.J. 30, 38 (1973) (emphasis in original); see *Beshada v. Johns-Manville Prod. Corp.*, 90 N.J. 191, 209, 447 A.2d 539, 549 (1982) (rejecting a state-of-the-art defense and adopting a hindsight test in a warning claim against asbestos manufacturers); *Carreter v. Colson Equip.*, 346 Pa. Super. 95, 101, 499 A.2d 326, 330-31 (1985) (rejecting a state-of-the-art defense for warning and design claims); see also *Johnson v. Raybestos-Manhattan, Inc.*, 740 P.2d 548, 549 (Haw. 1987) (rejecting state-of-the-art defense).

Most courts, however, find that the strict liability and negligence theories overlap in warning cases. See, e.g., *Borel v. Fiberboard Paper Prods. Corp.*, 493 F.2d 1076, 1088-89 (5th Cir. 1973), cert. denied, 419 U.S. 869 (1974). But see *Feldman*, 97 N.J. at 455-56, 479 A.2d at 388. *Feldman* held that the burden of proof is on defendant to show that the risks were not knowable at the time of manufacture, saying that "[i]n strict liability warning cases, unlike negligence cases . . . the defendant should properly bear the burden of proving that the information was not reasonably available or obtainable and that it therefore lacked actual or constructive knowledge of the defect." *Id.*

tation" test of liability recognized by the *Restatement*.²⁹ This simple test, applicable to products that fail to perform as intended or expected, relieves plaintiffs of the burden of establishing the elements of the risk-utility test.³⁰ The reforms also would eliminate strict liability tests that shift the burden of establishing that the benefits of a design outweigh the risks to the defendant, who is most knowledgeable about the product.³¹

In sum, while there is overlap in negligence and strict liability theories, strict liability offers clear advantages to plaintiffs, particularly with respect to evidentiary burdens. These advantages would be lost under the proposed reforms.

2. Complicating the Litigation of Product Claims

The proposed reforms would do more than erase strict liability and replace it with negligence. They would introduce into compliance cases difficult issues about the regulatory standard—its exact coverage, its applicability to the case, its adequacy as a measure of due care. Courts traditionally have not examined these issues closely; thus, they could prove difficult for plaintiffs to address. For example, an initial question in most cases would be whether the standard should apply at all, since the agency may not have considered the issue at stake in the litigation. This inquiry is crucial because a principal argument for increased judicial deference to regulatory standards is agency expertise.³² If an agency has not addressed specifically the matter before the court, the argument

29. Comment i to § 402A defines the term "unreasonably dangerous" by providing a test that is commonly referred to as the consumer expectation test. The test provides that "[t]he article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." *RESTATEMENT*, *supra* note 21, § 402A comment i. In applying the consumer expectation test, however, courts often seem to resort to a risk-utility analysis. *See, e.g.*, *Estate of Ryder v. Kelly-Springfield Tire Co.*, 91 Wash. 2d 111, 587 P.2d 160 (1978), *noted in* Birnbaum, *supra* note 8, at 616-18.

30. *See* *Leichtamer v. American Motors Corp.*, 67 Ohio St. 2d 456, 424 N.E.2d 568 (1981).

31. *See, e.g.*, *Caterpillar Tractor Co. v. Beck*, 593 P.2d 871, 885 (Alaska 1979); *Barker v. Lull Eng'r Co.*, 20 Cal. 3d 413, 426-27, 573 P.2d 443, 452, 143 Cal. Rptr. 225, 234 (1978); *Ortho Pharmaceutical Corp. v. Heath*, 722 P.2d 410, 413-14 (Colo. 1986). Scholars disagree on the impact of this approach. Some argue that it makes "[a]ll product related accidents . . . presumptively actionable." Epstein, *Products Liability: The Search for The Middle Ground*, 56 N.C.L. Rev. 643, 651 (1978). Others conclude its effects are "de minimis." Birnbaum, *supra* note 8, at 607. Professor Sheila Birnbaum points out that "[i]n fact, defense attorneys vigorously attempt to prove that a challenged design is not defective regardless of how the burdens of proof are allocated by the court." *Id.* Since plaintiffs must meet this burden of proof, the shift in the burden of persuasion, as a practical matter, may not be "as dramatic a benefit as it might seem at first blush." *Id.* at 606; *see also* *Feldman*, 97 N.J. at 455-56, 479 A.2d at 388 (putting the burden of proof on defendant with respect to whether the product risks were knowable at the time of manufacture).

32. *See supra* note 6 and accompanying text.

for judicial deference fails.³³

Even when an agency has addressed the matter before the court, the scope of administrative regulations, particularly in the modern regulatory system, is often vague.³⁴ Standards may be drafted in broad, general terms to allow the regulated industry some flexibility in meeting its requirements.³⁵ While desirable for a regulatory scheme, such standards may fail to provide the desired clarity as a basis of tort liability and may introduce into tort litigation difficult questions about its applicability to particular issues at stake. In addition, a standard may raise questions as to whether in fact there has been compliance with its terms.³⁶ Issues such as these necessarily complicate litigation.

Another difficulty in assessing the scope of a regulatory standard results from agency silence. Professor Clarence Morris identified this problem many years ago in his seminal article on the use of administrative safety standards in negligence cases.³⁷ He concluded that "courts are likely to confuse administrative inaction with administrative judgment, and then overgeneralize on the lack of value of proof of conformity."³⁸ This conclusion applies equally today.

The problem of agency silence arises in the following hypothetical: A product in compliance with a regulation requiring that its label warn

33. Morris, *The Role of Administrative Safety Measures in Negligence Actions*, 28 TEX. L. REV. 143, 212 (1949) (stating that "of course when the administrator has passed no judgment on the problem before the court, the administrative process can furnish no acceptable criteria of care"); see also *Howard v. Faberge Inc.*, 679 S.W.2d 644, 649 (Tex. App. 1984) (ruling that the lack of federal standards could not be used to prove that the product was reasonably safe).

34. Note, *Aircraft Crashworthiness: Should the Courts Set the Standards?*, 27 WM. & MARY L. REV. 371, 398-99 (1986).

35. *Id.* at 399. An example of a broad standard is the FAA requirement that aircraft manufacturers must design aircraft "to give each occupant every reasonable chance of escaping serious injury in a minor crash landing." 14 C.F.R. § 23.561(b) (1985). Another example is the labeling requirement of the Federal Hazardous Substances Act, which calls for "precautionary measures describing the action to be followed or avoided." See *Burch v. Amsterdam Corp.*, 366 A.2d 1079, 1084 n.14 (D.C. 1976).

36. See *Burch*, 366 A.2d at 1084 n.14 (in which the court assumed compliance with labeling regulations, although generally phrased requirements of the regulation could have been interpreted to require more specific warnings than actually were given).

37. Morris, *supra* note 33, at 162-63.

38. *Id.* at 167. One of Professor Morris' examples was the plaintiff who was injured when his car ran into the base of a railroad crossing signal placed in the middle of the highway:

The public service commission had adopted a general regulation approving center installations and had approved the defendant's plans for erecting this particular signal. Had the plaintiff been injured by collision with a train, the commission's judgment on the adequacy of the signal as a warning would probably be controlling. But did the commission decide that the signal was not an unreasonable traffic hazard? The defendant made no affirmative showing that this problem was considered. The court held that the issue of negligence in the placement of the signal was properly submitted to the jury and affirmed the judgment for the plaintiff.

Id. at 162 (discussing *McGettigan v. New York Cent. R.R.*, 268 N.Y. 66, 196 N.E. 745 (1935)).

of risks X and Y is challenged in a tort action for failing to warn against risk Z. It is unclear why the regulation does not cover risk Z, but there are at least two possibilities. First, the agency may not have considered risk Z at all (perhaps it was unknown at the time the regulation was issued). Alternatively, the agency may have considered risk Z too insignificant to warrant a warning.

It is clear that the product complies with the regulation, but it is less clear that the regulation should govern the tort claim. If the agency did not consider the risk and did not apply its expertise, its silence should be meaningless in resolving the tort action.³⁹ If the agency did consider the risk and found it too minimal to warrant a warning, it has applied its expertise and, according to the proposed reforms, its determination that no warning is required should be presumptively or conclusively adequate for the purposes of tort law.

Too often, however, regulatory silence will be ambiguous and even close scrutiny of the regulatory history may not reveal a clear answer. A recent General Accounting Office study of several health and safety agencies found that the basis for regulatory decisions frequently was unclear.⁴⁰ Because agencies do not intend or expect their regulations to be used to define tort liability,⁴¹ however, it is unsurprising when these regulations are not drafted in a way that assists the courts.⁴²

Traditionally, courts have avoided the issue of agency silence largely by ignoring it.⁴³ They generally have allowed juries to consider

39. See *supra* note 33 and accompanying text.

40. In a study of risk analyses by several federal health and safety agencies, the General Accounting Office found that "the basis for regulatory decisions was unclear." GENERAL ACCOUNTING OFFICE, HEALTH RISK ANALYSIS, TECHNICAL ADEQUACY IN THREE SELECTED CASES 3 (1987). With respect to an FDA rule, the General Accounting Office concluded:

[T]he public is entitled to know the basis on which decisions are made and whether statutory mandates are being followed. No documentation on the decisionmaking phase was available.

Therefore, FDA's steps in reviewing the options and arriving at a decision about the standard are not clear and are not available for public review.

Id. at 35. With respect to the three agencies studied—the FDA, SHA, and the EPA—the report found that the agencies "did not always clearly articulate the factors they considered, how they considered them, or how their consideration of the several factors was integrated in decisionmaking." *Id.* at 88.

41. See *infra* notes 69-70 and accompanying text.

42. See, e.g., *May v. Parke, Davis & Co.*, 142 Mich. App. 404, 370 N.W.2d 371 (1985). The court found that the FDA's rejection of a request for additional warnings could be given "little weight because the FDA did not state its reasons for doing so. Without further evidence, the jury could have improperly speculated on the FDA's reasoning." *Id.* at 422, 370 N.W.2d at 381.

43. A recent case on point is the highly controversial *Dawson v. Chrysler Corp.*, 630 F.2d 950 (3d Cir. 1980), cert. denied, 450 U.S. 959 (1981). *Dawson* was a crashworthiness case involving a claim of defective automobile design. The court disallowed a regulatory compliance defense, indicating that the regulatory standards set only minimum standards. The court, however, failed to consider carefully whether in fact any federal motor vehicle standard applied directly to the design claim at hand. A closer examination of the issue might have revealed that no standard did apply.

regulatory compliance in product cases, even when it seems clear, or at least highly likely, that the agency has not in fact ruled on the matter. An example of this approach is *Buccery v. General Motors Corp.*,⁴⁴ in which the court ruled that a light pickup truck with no head restraint "complied" with a federal motor vehicle standard that required head restraints for passenger vehicles, but the standard did not apply to the type of vehicle in question, a pickup truck.⁴⁵ This approach treats failures to regulate products or risks as though they were agency decisions that such products or risks are reasonably safe without regulation. The reason for failing to regulate, however, may not be based on safety considerations at all, but rather on the agency's determination that it did not have sufficient resources to address the issue or that other matters deserved higher priority.⁴⁶

A broad interpretation of regulatory compliance has serious ramifications for plaintiffs if the proposed reforms are adopted and regulatory compliance is accorded greater weight. In crashworthiness cases, for example, plaintiffs can expect the compliance defense to be raised frequently because of fifty federal motor vehicle safety standards that cover most aspects of a passenger car.⁴⁷ The standards, however, do not

The plaintiff claimed that the automobile was defective in that it had a seventeen-inch gap in the side of the door frame, which made it inadequate to withstand side impacts. Plaintiff argued that a safer design would have included "a full, continuous steel frame extending through the door panels, and a cross-member running through the floor board." *Id.* at 954. Defendant claimed as a defense its compliance with existing federal crashworthy standards, including side door strength. The court did not consider whether the agency had in fact addressed the issue of vehicle frames or intended its crashworthy standards to provide a comprehensive set of standards with respect to all second collision, side-impact situations. Had the court addressed this point, it may have concluded that the standards did not cover the claim at issue. Federal automobile safety standards do not address all aspects of crashworthiness, and "[a]lthough the agency's long-range goals include development of . . . standards that would gauge occupant protection . . . in a variety of crash scenarios, this is merely a goal and does not reflect standard setting at the present time." Note, *The Relationship Between Federal Standards and Litigation in the Control of Automobile Design*, 57 N.Y.U. L. REV. 804, 831 (1982).

For criticism of *Dawson*, see Twerski, *Advancing Directed Verdicts*, *supra* note 8, at 524, which cites *Dawson* as one of several "poorly reasoned, if not outrageous, appellate court decisions that read the role of the jury in design litigation expansively." The point here, however, is not to address the outcome of the case, rather the court's treatment of the compliance defense.

44. 60 Cal. App. 3d 533, 132 Cal. Rptr. 605 (1976).

45. *Id.* at 537-41, 132 Cal. Rptr. at 607-09. The standard for passenger vehicles did not cover multipurpose vehicles or pickup trucks.

46. Claybrook, *Auto Protection: Beyond Federal Standards*, TRIAL, Nov. 1980, at 38. Ms. Claybrook, who was Administrator of the NHTSA during the Carter Administration, pointed out that regulatory agencies must concentrate their resources on "high payoff requirements" and cannot cover all aspects of the products that come within their jurisdiction, even though they may be important and pose serious risks. *Id.* at 40; see also *infra* notes 191-92 and accompanying text (concerning the push for expanding motor vehicle standards to cover minivans and light trucks).

47. *Hearings on H.R. 1115 Before the Subcomm. on Commerce, Consumer Protection & Competitiveness of the House Comm. on Energy and Commerce*, 100th Cong., 1st Sess. 1, 3 (1987)

address every aspect of crashworthiness. For example, the gas tank of the Ford Pinto, which exploded in rear-end collisions at low speeds, "complied" with the federal fuel tank integrity standard. The standard, however, dealt only with front-end collisions.⁴⁸ Under the proposed reforms, a broad application of the compliance defense, as in *Buccery*, would have presumptively immunized the manufacturer from civil liability in this case.

A broad reading of regulations may be appropriate, so long as compliance is given no special weight. Indeed, that compliance presently is not weighed heavily may account for the failure of courts to consider carefully the scope of regulations in such cases. If, however, under the proposed reforms, regulations become a more important determinant of liability, it will be incumbent on the courts to take a much closer look at the issue of a regulation's applicability to the claim at hand. Although some critics of the reforms have assumed that a broad application of standards would continue despite the strengthened compliance defense,⁴⁹ it seems more likely that the issue of a standard's applicability would become hotly contested in many, if not most, compliance cases.

When the scope of regulations is not always clear, however, new complexities are introduced into the litigation, especially for plaintiffs who would be disadvantaged on this issue. Unlike defendants who are likely to be quite knowledgeable about—perhaps having helped to formulate—the federal regulations that govern their products,⁵⁰ plaintiffs, as a general rule, will not have participated in the federal regulatory process and will be unfamiliar with the regulations that become the frequent subject of tort actions.⁵¹

This disadvantage to plaintiffs could be alleviated if the burden of proof to establish the applicability of standards in compliance cases was placed on defendants. This seems appropriate for two reasons: first, regulatory compliance is an affirmative defense and the party asserting it

[hereinafter Ditlow Testimony] (statement of Clarence M. Ditlow III, Director of the Center for Auto Safety) (stating that "[a]n innovative defense lawyer . . . will be able to find [a federal motor vehicle standard] to cover almost any automobile design liability case").

48. *Id.* The standard established a 30 mile per hour frontal crash requirement. The industry lobbied against an agency requirement of 30 mile per hour rear crash protection until Congress finally mandated it for 1977 model cars.

49. One author assumed that the defendant in *Grimshaw v. Ford Motor Co.*, 119 Cal. App. 3d 757, 174 Cal. Rptr. 348 (1981), a case involving an exploding Ford Pinto fuel tank in a rear-end collision, would escape liability under a strengthened regulatory compliance defense, despite the fact that the federal regulation provided only for front-end collision and said nothing about rear-end collisions. Note, *supra* note 43, at 823; see also *supra* note 47 and accompanying text.

50. See *infra* notes 128-30, 152 and accompanying text.

51. See *infra* notes 133-36, 152 and accompanying text.

should establish its applicability;⁵² and second, as mentioned earlier, defendants are more knowledgeable about the regulations and thus are in a better position than plaintiffs to bear the burden of proof on this issue.⁵³ In the end, however, the plaintiff would have to refute the defendant's claim that a regulatory standard applies and thus could not avoid the issue entirely.

This discussion reveals some of the difficulties inherent in trying to mesh the regulatory and tort systems and demonstrates some of the complexities that the proposed reforms would introduce into the litigation of compliance cases. Even the most preliminary inquiry concerning the applicability of a standard would pose difficulties for plaintiffs. In challenging the merits of standards, plaintiffs would face even greater difficulties, particularly given the absence of clear decisionmaking by agencies⁵⁴ and plaintiffs' unfamiliarity with the regulatory process.⁵⁵

Increased complexity in litigation runs completely counter to products liability developments over the past twenty years, which have been aimed at streamlining product claims and relieving plaintiffs of evidentiary burdens that are especially difficult for them to meet. In addition, as shown in the next section of this Article, the proposed reforms also run counter to the traditional common-law treatment of regulatory standards in compliance cases.

C. *Rejecting the Common-Law Treatment of Standards*

For decades courts have used two criteria in determining whether to adopt statutory and regulatory standards as tort liability standards: First, whether adopting a standard would further the purpose of the statute in question; and second, whether adopting a standard would be generally consistent with common-law principles of liability. Applying these criteria, courts seldom have found that these standards should be viewed as setting the maximum standards of care and safety required under the common law.⁵⁶ Instead, they have found these standards to

52. Professor Morris suggests that the defendant has the obligation to show affirmatively that the problem at hand was considered by the agency. Morris, *supra* note 33, at 162; *see also supra* note 38 (quoting a passage from Morris' article indicating that defendant bears the burden of proof).

53. Courts often have justified placing the burden of proof on defendants when they have superior knowledge of the facts. W. PROSSER, *HANDBOOK OF THE LAW OF TORTS* 210 (4th ed. 1971); *see also supra* notes 28, 31 and accompanying text (identifying cases in which courts have shifted the burden of proof on issues to defendants under strict products liability).

54. *See supra* note 40 and accompanying text.

55. *See infra* notes 133-36, 152 and accompanying text.

56. *See* 4 INTERAGENCY TASK FORCE ON PRODUCTS LIABILITY, U.S. DEPT. OF COMMERCE, *PRODUCTS LIABILITY: FINAL REPORT OF THE LEGAL STUDY* 137 (1977) [hereinafter *PRODUCTS LIABILITY LEGAL STUDY*]. The legal study concluded that the "number of cases in which compliance has been accepted as a complete defense is exceedingly small, so that is an overstatement to characterize

be good measures of the minimum standard of care required.⁵⁷ On this basis courts have ruled, in general, that noncompliance with statutory and regulatory standards constitutes negligence per se, or is presumptive of negligence,⁵⁸ while compliance constitutes relevant evidence of due care, but deserves no special weight.⁵⁹

The proposed reforms reject the traditional approach to statutory and regulatory standards—both the criteria that have served as the basis for adopting standards, as well as the judicial reluctance to adopt standards as measures of the maximum care required by the common law. The next section of this Article examines the origins and development of this traditional judicial approach and how it would be changed by the proposed reforms.

1. Adopting Standards to Further the Legislative Purpose

In Dean William Prosser's view, the most satisfactory justification for using regulatory and statutory standards to define tort liability is that their use can further the safety aims of the statutes in question.⁶⁰

this position as even a 'minority rule.' " *Id.*

Only a handful of products liability cases has found statutory or regulatory compliance conclusive on the issue of tort liability. *See, e.g.,* *Hunter v. E.I. Dupont de Nemours & Co.*, 170 F. Supp. 352 (W.D. Mo. 1958); *Lewis v. Baker*, 243 Or. 317, 413 P.2d 400 (1966), *overruled in* *McEwen v. Ortho Pharmaceutical Corp.*, 270 Or. 375, 528 P.2d 522 (1974); *Leibowitz v. Ortho Pharmaceutical Corp.*, 224 Pa. Super. 418, 307 A.2d 449 (1973) (*per curiam*).

57. This was true even of the earliest rulings on statutory compliance. *See* *Smith v. Maine Cent. R.R.*, 87 Me. 339, 32 A. 967 (1895):

But the statutes prescribing these special duties are little more than an affirmation of the rules of the common law. They do not constitute the sole measure of duty. The common law still requires the exercise of care and prudence commensurate with the degree of danger incurred. The statutes represent the minimum degree of care to be observed, and do not release the company from the obligations to take such additional precautions as the peculiar circumstances of the case may demand.

Id. at 348, 32 A. at 970-71.

58. W. KEETON, D. DOBBS, R. KEETON & D. OWEN, *PROSSER AND KEETON ON THE LAW OF TORTS* 230-31 (5th ed. 1984) [hereinafter *PROSSER & KEETON ON TORTS*]. The majority view "probably" is that an unexcused statutory violation should be deemed conclusive evidence of negligence, or negligence per se, although a substantial number of states treat such violations only as evidence of negligence, which the jury may accept or reject in light of all the evidence. *Id.* at 230. California has adopted a middle position, ruling that a violation creates a presumption of negligence which can be rebutted. *Id.* Some courts give less weight to violations of administrative regulations. For example, among those jurisdictions that view statutory violations as negligence per se, some view administrative regulations as only evidence of negligence. *Id.* at 230-31. Although the reason for this different approach is not entirely clear, it appears to reflect some skepticism that administrative standards will be reasonable. It also reflects a desire to give the court more flexibility in using them.

59. *See* cases cited *infra* notes 67, 97-104.

60. W. PROSSER, *supra* note 53, at 191. Dean Prosser rejected as "pure fiction" the presumption adopted by some courts that the legislature intended to create a civil remedy even though the statute provided only a criminal penalty and made no mention of a civil remedy. *Id.* In his view, these statutes created no civil actions, but the courts could use the statutory standards in tort

Indeed, this view has become the principal rationale⁶¹ for "borrowing" standards from regulatory and criminal statutes, even though these statutes themselves create no civil liability and are not intended for use in the tort system.⁶² The *Restatement* adopts this justification,⁶³ and its criteria governing the use of statutory and regulatory standards to define tort liability assure that this purpose is served.⁶⁴

The *Restatement* requires that two general conditions be met before a statutory standard is adopted as a minimum or maximum standard of care: (1) the person seeking protection under the standard must fall within the class of persons that the legislature intended to protect; and (2) the injury suffered must be of the type that the legislature intended to prevent.⁶⁵ These requirements tend to assure that the

actions if by doing so they would further the general safety aims of the statute. *Id.*

61. Other justifications also exist for using statutory or regulatory standards to define tort liability. Courts have recognized that deference to standards may be warranted on the basis of the expertise of the standard setting institution, whether it be the legislature or the administrative agency. They have noted that the legislature, "by reason of its organization and investigating processes," can be superior to the courts in establishing generalized rules of acceptable conduct. *Rudes v. Gottschalk*, 159 Tex. 552, 555, 324 S.W.2d 201, 204 (1959); see also *Morris, The Role of Criminal Statutes in Negligence Actions*, 49 COLUM. L. REV. 21, 47 (1949) [hereinafter *Morris, Criminal Statutes*] (stating that because of their ability to gather facts, hold hearings, and debate the issues, legislatures have "opportunities to arrive at informed value judgments superior to the opportunities of judges and jurors"). With respect to administrative agencies, it is their technical expertise that is valued. *Morris, supra* note 33, at 144 (stating that the use of administrative safety measures "as tests of negligence will . . . harness any technical knowledge that may have gone into their formulation"). Courts and scholars also recognize that the use of statutory and regulatory standards to define common-law liability can add clarity and predictability to the tort system. *Morris, Criminal Statutes, supra*, at 47 (stating that "a criminal proscription operates as a desirable, more exact standard that smooths up civil procedure").

62. The practice of using standards is neither compelled nor even invited by the statutes or regulations in question; it is solely a matter of judicial discretion. As the California Supreme Court stated some forty years ago, "The decision as to what the civil standard should be still rests with the court, and the standard formulated by a legislative body in a police regulation or criminal statute becomes the standard to determine civil liability only because the court accepts it." *Clinkscapes v. Carver*, 22 Cal. 2d 72, 75, 136 P.2d 777, 778 (1943). The *Restatement* is in accord: "Since the legislation has not so provided, the court is under no compulsion to accept it as defining any standard of conduct for purposes of a tort action." *RESTATEMENT, supra* note 21, § 286 comment d.

63. *RESTATEMENT, supra* note 21, § 286 comment d (stating that "[w]hen the court does adopt the legislative standard, it is acting to further the general purpose which it finds in the legislation, and not because it is in any way required to do so").

64. See *id.* § 286.

65. *Id.* Section 286 provides:

The court may adopt as the standard of conduct of a reasonable man the requirements of a legislative enactment or an administrative regulation whose purpose is found to be exclusively or in part

- (a) to protect a class of persons which includes the one whose interest is invaded, and
- (b) to protect the particular interest which is invaded, and
- (c) to protect that interest against the kind of harm which has resulted, and
- (d) to protect that interest against the particular hazard from which the harm results.

Id. For an application of § 286, see *Nazareno v. Urie*, 638 P.2d 671 (Alaska 1981); *Stachniewicz v. Mar-Cam Corp.*, 259 Or. 583, 488 P.2d 436 (1971); see also *RESTATEMENT, supra* note 21, § 288

adoption of the standard will further the purpose of the legislation, and also that the agency or legislature has focused on the same interests that are at stake in the litigation and applied its expertise to protect those interests.⁶⁶

In cases involving violations of safety standards, courts often have tended to read statutory aims broadly, finding the plaintiff within the protected class and the injuries within those sought to be prevented by the statute.⁶⁷ Therefore, the use of a standard to establish the tort liability of the violator would further the aim of the statute by creating an additional incentive to comply with the statute; indeed, the risk of incurring tort liability may provide a far greater incentive for compliance than the risk of incurring a penalty under the statute.⁶⁸

In compliance cases, on the other hand, adopting a regulatory standard may shield the defendant from liability. It is less evident that such use of standards would promote the safety aims of the statute. Courts have examined the legislative purpose of a wide array of consumer

(which is a corollary to § 286 and identifies those statutory or legislative standards that are not intended to protect individuals from harm and thus should not be borrowed under the criteria of § 286); *id.* § 288C comment a (providing that before a statutory standard is adopted as a maximum standard of care in a compliance case, the court should determine that the standard meets the criteria of § 286).

66. It should be noted, however, that these requirements assure only that the same interests are at stake in both fora; they do not assure that the issues are exactly the same. Thus, they do not obviate the problem of determining the standard's applicability to the issue before the court. *See supra* notes 34-42 and accompanying text.

67. *See, e.g.,* *Ney v. Yellow Cab Co.*, 2 Ill. 2d 74, 117 N.E.2d 74 (1954). *Ney* found that leaving the car key in the ignition in violation of a statute was *prima facie* evidence of defendant's negligence in a claim for damages caused by a thief who stole the car and negligently ran into plaintiff's car. The case has been cited as an "extreme" example of a broad statutory interpretation that would include "all risks which would occur to anyone . . . following the violation." PROSSER & KEETON ON TORTS, *supra* note 58, at 227.

68. The enormous discrepancy between tort liability and statutory fines has been demonstrated repeatedly. For example, in *MER/29*, a drug used to reduce cholesterol caused numerous serious side effects. The manufacturer sought to withhold this information from the public. The companies pleaded no contest to criminal fraud charges and were fined \$80,000. J. BRAITHWAITE, *CORPORATE CRIME IN THE PHARMACEUTICAL INDUSTRY* 60-64 (1984). Over 500 products liability suits stemming from the same conduct are believed to have cost the companies \$200 million. *Id.* at 64.

Consider also another recent example in which Eli Lilly & Co. was fined \$25,000 for failing to report overseas deaths associated with the use of its arthritis drug, Oralflex. *See* Metzenbaum, *Is Government Protecting Consumers?*, TRIAL, April 1986, at 22, 26. In a tort claim brought against Eli Lilly & Co. for a death caused by Oralflex, the jury returned a verdict against the defendant for \$6 million. *Borum v. Eli Lilly & Co.*, Wash. Post, Nov. 25, 1983, at D8, col. 1 (D. Ga. Nov. 24, 1983).

The largest fine ever imposed for a violation of the Food, Drug and Cosmetic Act was \$2 million, which was paid by Beech-Nut Nutrition Corp. for selling a bogus fruit drink as apple juice. Wash. Post, Nov. 29, 1987, at H2, col. 1. The fine was "more than six times the largest ever paid under the 1938 food and drug law." *Id.* These examples suggest how great the gap is between statutory fines and tort liability and how relatively weak the deterrent effects of the regulatory system are compared to the products liability system.

safety statutes and found no express or implied aim to set safety standards adequate for purposes of the common law;⁶⁹ some statutes make explicit the contrary aim.⁷⁰

Treating compliance as an adequate defense in tort claims, however, can provide an incentive to comply with statutes, which furthers the statutes' safety aims in the same way that restating violations as negligence per se furthers safety aims.⁷¹ Possible adverse effects, however, may result from treating compliance as an adequate defense in all cases. Making the compliance defense stronger could actually discourage safety by allowing manufacturers to "sit back" and rely on standards that are inadequate.⁷² Manufacturers often resist implementing new safety measures, though they are readily available in the industry, until government standards compel their adoption.⁷³ This resistance

69. 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; before transforming such legislation into a *ceiling* on the ability of states to protect their citizens . . . courts should wait for a clear statement of congressional intent to work such an alteration" (emphasis in original)) *cert. denied*, 469 U.S. 1062 (1984); *Raymond v. Riegel Textile Corp.*, 484 F.2d 1025, 1028 (1st Cir. 1973) (finding that since "the Flammable Fabrics Act did not provide private civil remedies and does not preclude state development of such remedies, the states are not limited to applying the federal . . . standards in civil cases"); see also *Hubbard-Hall Chem. Co. v. Silverman*, 340 F.2d 402 (1st Cir. 1968). The court in *Hubbard-Hall* stated:

The approval of the label given by the Department of Agriculture merely satisfied the conditions laid down by Congress [under the Federal Insecticide Act] for the shipment of the product in interstate commerce. Neither Congress nor the Department explicitly or implicitly provided that the Department's approval of the label carried with it as a corollary the proposition that defendant had met the possibly higher standard of due care imposed by the common law of torts

Id. at 405; see also *Burch v. Amsterdam Corp.*, 366 A.2d 1079, 1085 (D.C. 1976) (finding "nothing in the statute itself [the Federal Hazardous Substances Act] or the legislative history which implies that Congress intended to limit a seller's common law 'duty to warn'"); *Wilson v. Piper Aircraft Corp.*, 282 Or. 61, 64, 577 P.2d 1322, 1324 (1978) (finding nothing in the Federal Aviation Act or its legislative history to indicate congressional intent that FAA approval of an aircraft design should be a complete defense to a tort claim based on defective design).

The agencies also do not expect their regulations to be used as the upper limits of responsibility under the tort law. See, e.g., 43 Fed. Reg. 4214 (1978) (the FDA's statement of basis and purpose in support of a labeling rule for oral contraceptives indicated no intent to preempt state law tort standards).

70. See, e.g., National Traffic and Motor Vehicle Safety Act, § 108(c), 15 U.S.C. § 1397(c) (1982) (providing that "compliance with any Federal motor vehicle safety standard issued under this subchapter does not exempt any person from any liability under common law"). For a similar provision, see the Consumer Product Safety Act, § 25(a), 15 U.S.C. § 2074(a) (1982).

71. It has been argued that the safety interests of consumers would be served generally by allowing a statutory compliance defense because it would provide an additional economic incentive to comply with the standards. FINAL REPORT ON PRODUCTS LIABILITY, *supra* note 20, at VII-38.

72. *Id.* at VII-39 to -40; see *Johnson, Products Liability "Reform": A Hazard to Consumers*, 56 N.C.L. REV. 677, 687-89 (1978); see also *infra* notes 197-207 and accompanying text (regarding the possible negative effects on the standard setting process if courts were to give greater weight to regulatory compliance).

73. In *Gryc v. Dayton-Hudson Corp.*, 297 N.W.2d 727, 740 (Minn.), *cert. denied*, 449 U.S.

could be encouraged by a strengthened compliance defense. In addition, manufacturers would be motivated to increase their already substantial influence on the regulatory process to assure that standards are not upgraded or their requirements made too onerous (a topic developed in Part II). In sum, the reforms could stifle improvements in safety, rather than fulfill the safety aims of the statute.⁷⁴ Furthermore, strengthening the compliance defense is not essential to spur regulatory compliance because the judicial treatment of statutory and regulatory violations provides sufficient incentive to do so.⁷⁵

2. Adopting Standards Consistent with Common-Law Principles

In general, courts borrow regulatory and statutory standards as measures of tort liability only when they reflect common-law standards of liability. Courts avoid using standards that depart from the common law, either by expanding⁷⁶ or contracting it.⁷⁷

To assure consistency with common-law principles, the *Restatement* provides considerable flexibility in the adoption of statutory and regulatory standards as standards of tort liability. In the case of statutory violations, for example, it provides that courts should not adopt standards that are palpably unreasonable.⁷⁸ Few statutory standards set requirements that make compliance unreasonable. Compliance, however, may be unreasonable when the standards become obsolete,⁷⁹ as

921 (1980), the court found that defendant had decided not to use available flame-retardant materials until required by federal law in order to avoid the additional costs. In *Grimshaw v. Ford Motor Co.*, 119 Cal. App. 3d 757, 775, 174 Cal. Rptr. 348, 361 (1981), the evidence showed that Ford was unwilling to enhance the safety of its gas tank despite the requirements of anticipated federal regulations and the fact that inexpensive "fixes" were available. Ford was willing to defer the safety change until the regulation was actually in effect.

74. See, e.g., *Feldman v. Lederle Laboratories*, 97 N.J. 429, 459, 479 A.2d 374, 390 (1984) (finding it would be "anomalous" and would "undercut" the primary safety aims of the Food, Drug and Cosmetic Act to read the Act as requiring drug manufacturers only to stay within existing regulatory requirements and not to provide warnings even though dangers became known).

75. See *supra* note 58.

76. See, e.g., *Zeni v. Anderson*, 397 Mich. 117, 137, 243 N.W.2d 270, 280 (1976) (stating that: "[w]hile some . . . cases seem to speak of negligence per se as a kind of strict liability . . . there are a number of conditions that attempt to create a more reasonable approach than would result from an automatic application of a per se rule").

77. *Morris*, *Criminal Statutes*, *supra* note 61, at 45-46.

78. Comment d to *Restatement* § 286 provides that the court should not treat an "entirely unreasonable" statute as a standard of negligence. It uses as an example of such a statute a six mile per hour speed limit enacted in 1908 and not repealed for six decades. *RESTATEMENT*, *supra* note 21, § 286 comment d.

79. In referring to the six mile per hour speed limit, the *Restatement* notes that it will be "relatively infrequent [that] legislation directed to the safety of persons or property will be so obsolete, or so unreasonable." *Id.* But see *W. Prosser*, *supra* note 53, at 200 (stating that "[a] troublesome problem is presented by the deplorable array of trivial, obsolete, or entirely unreasonable legislation . . . which persist in our statute books").

when the court's adoption of criminal or regulatory standards would impose duties greater than those recognized under the common law—a result the *Restatement* seeks to avoid.

The *Restatement* also identifies a number of circumstances in which statutory violations may be excused under the tort law.⁸⁰ The *Restatement's* list of excuses, which is not exhaustive, recognizes situations in which it would be unreasonable to expect compliance with a statutory standard, such as when a party either is incapacitated or faces an emergency.⁸¹ Again, the adoption of the statutory standard in such circumstances would be inconsistent with the fault-based, common-law system and therefore is inappropriate. A court has the alternative either to adopt the excuses from the *Restatement's* list,⁸² or to interpret the statute as not covering the particular circumstances.⁸³

In some limited situations, however, the *Restatement* does encourage the adoption of standards when the effect is to alter the common law. This result occurs, for example, when criminal and regulatory statutes impose absolute duties on the actor to comply with their provisions.⁸⁴ In these circumstances, the courts may refuse to excuse violations of these standards for civil purposes, in effect using the standards to create strict liability.⁸⁵ Courts followed this approach, for example, in the early suits involving violations of pure food statutes, which made them among the first product cases to apply strict liability.⁸⁶ In these

80. RESTATEMENT, *supra* note 21, § 288A.

81. *Id.* Section 288A of the *Restatement* provides:

(1) An excused violation of a legislative enactment or an administrative regulation is not negligence.

(2) Unless the enactment or regulation is construed not to permit such excuse, its violation is excused when

- (a) the violation is reasonable because of the actor's incapacity;
- (b) he knows nor should know of the occasion for compliance;
- (c) he is unable after reasonable diligence or care to comply;
- (d) he is confronted by an emergency not due to his own misconduct;
- (e) compliance would involve a greater risk of harm to the actor or to others.

Id.

82. *See, e.g.,* *Byrne v. City & County of San Francisco*, 113 Cal. App. 3d 731, 17 Cal. Rptr. 302 (1980).

83. *See, e.g.,* *Satterlee v. Orange Glenn School Dist.*, 29 Cal. 2d 581, 594, 177 P.2d 279, 286 (1947) (Traynor, J., dissenting in part) (stating that "[i]f there is sufficient excuse or justification, there is ordinarily no violation of a statute, and the statutory standard is inapplicable"); *Zeni*, 397 Mich. at 144, 243 N.W.2d at 283 (stating that "the statute itself provides not only a legislative standard of care which may be accepted by the court, but a legislatively mandated excuse as well"); *see also* *Tedla v. Ellman*, 280 N.Y. 124, 19 N.E.2d 987 (1939).

84. *See* RESTATEMENT, *supra* note 21, § 288A; *see also supra* note 81 (setting forth the text of § 288A).

85. *See* W. PROSSER, J. WADE & V. SCHWARTZ, *TORTS: CASES AND MATERIALS* 246 (7th ed. 1982) (listing statutes that courts have interpreted as not permitting excused violations, including child labor acts, pure food acts, and workplace safety statutes).

86. *Meshbesh v. Channellene Oil & Mfg. Co.*, 107 Minn. 104, 119 N.W. 428 (1909); *Doherty*

cases the use of statutory standards to expand the scope of tort liability was justified on the ground that it furthered the statutory purpose.

On other occasions, courts borrow standards to create new tort liabilities.⁸⁷ Sensing the evolutionary nature of the common law,⁸⁸ courts, on rare occasions, have been willing to "transplant" to the tort system regulatory or statutory standards of safety that have yet to be recognized under the common law.⁸⁹ Despite expanding the common law, such use of regulatory standards is not inconsistent with common-law tradition when the standards are not burdensome⁹⁰ and the imposition of liability for their violation creates no unfair surprise.⁹¹

Rather than expanding the common law, compliance cases tend to contract it through the adoption of standards that are inadequate measures of due care and safety. The *Restatement* seeks to avoid this result by encouraging an evaluation of every standard's adequacy in light of

v. S.S. Kresge Co., 227 Wis. 661, 278 N.W. 437 (1938).

87. Most frequently, courts use statutory or regulatory standards as just one factor in recognizing new tort duties. See, e.g., *MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass. 131, 138, 375 N.E.2d 65, 70 (taking the FDA's patient package insert rule into account in ruling that drug manufacturers have a common-law obligation to provide the inserts), *cert. denied*, 474 U.S. 920 (1985); see also *Morris, Criminal Statutes*, *supra* note 61, at 24 (discussing cases in which the court has looked to the criminal law as one of several factors in determining whether to recognize a new common-law duty). *But see infra* note 89 (citing cases in which the statutory standard has been the sole basis for creating a new common-law duty).

88. The willingness to expand common-law duties through the use of statutory standards is consistent, of course, with the general willingness of courts to recognize new duties under the common law in response to changing societal norms. See, e.g., *Sindell v. Abbott Laboratories*, 26 Cal. 3d 588, 607 P.2d 924, 163 Cal. Rptr. 132 (creating a new "market share" theory of liability for manufacturers of generic drugs when plaintiffs cannot identify the makers of the drugs that caused their injuries), *cert. denied*, 449 U.S. 912 (1980); *Dillon v. Legg*, 68 Cal. 2d 728, 441 P.2d 912, 69 Cal. Rptr. 72 (1968) (recognizing a parent's right to recover for her own physical injuries that resulted from observing a traumatic injury to a child); *Kelley v. R. G. Indus., Inc.*, 304 Md. 124, 497 A.2d 1143 (1985) (recognizing for the first time a strict liability claim against a handgun manufacturer for injuries caused by criminal use of the gun).

89. See, e.g., *Lukaszewicz v. Ortho Pharmaceutical Corp.*, 510 F. Supp. 961 (E.D. Wis.) (finding that the violation of an FDA regulation requiring patient package inserts for oral contraceptives created a new common-law duty for prescription drug manufacturers to provide warnings directly to consumers), *modified*, 532 F. Supp. 211 (E.D. Wis. 1981); *Ney v. Yellow Cab Co.*, 2 Ill. 2d 74, 117 N.E.2d 74 (1954) (discussed *supra* note 67).

90. Courts may view regulatory and statutory standards as reflecting an assessment by the legislature that compliance is practicable and would not impose undue costs. Clarence Morris states that "[a] tort court creating novel liabilities runs a risk of demanding impractical or undesirable safeguards. However, [safety] statutes . . . are not likely to interdict conduct which most people cannot forego in everyday affairs." *Morris, Criminal Statutes*, *supra* note 61, at 23.

91. A statutory standard generally is known to those subject to its provisions. Thus, "[a] man held liable in a damage suit for breach of a criminal statute is not likely to be caught innocently off guard." *Id.*

In earlier decades, some courts used statutory standards as a basis for rejecting harsh no-duty or immunity rules under existing common-law principles. *Id.* at 23-24. As Professor Morris noted, "when a no-duty rule would produce an unappealing result, some courts are likely to hold that civil liability follows criminal responsibility into areas of common law immunity." *Id.* at 23.

the particular circumstances of each case.⁹² While recognizing that standards can be found adequate as a matter of law,⁹³ the *Restatement* anticipated that few cases would arise in which courts would find that the circumstances warranted the adoption of a standard as conclusively or presumptively adequate.⁹⁴

Because the circumstances of cases vary, courts often find that the exigencies of a case fall outside the "normal"⁹⁵ or "optimum"⁹⁶ circumstances covered by the statute. In product cases, courts may find that the product poses special risks and that the broad regulation covering many products does not account for those special risks.⁹⁷ Courts also

92. See *RESTATEMENT*, *supra* note 21, § 288C comment a. 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. (emphasis added).

93. *Id.* § 288C. Although § 288C emphasizes that compliance does not constitute due care if circumstances call for further precautions, comment a provides that, absent such 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." *Id.* § 288C comment a.

Early scholarly articles also accepted the view that standards could serve as conclusive measures of due care. See *Morris*, *supra* note 33, at 167 (stating that "when administrative judgment has been passed, proof of conformity should have as much force to protect defendants from liability as does proof of departure to establish negligence"); *Morris*, *Criminal Statutes*, *supra* note 61, at 44 (stating that "in the absence of affirmative reasons for rejection of the criminal proscription, the courts should assume that the proscription will function properly as a standard for judging care"); see also *W. Prosser*, *supra* note 53, at 164 (stating that there will be cases involving "normal situations, clearly identical with those contemplated [by the statute], in which it may be found that the statute defines the actor's duty, and that nothing more is required").

94. *RESTATEMENT*, *supra* note 21, § 288C comment a. The *Restatement* views the standards as minimum standards and therefore adequate only for the "ordinary situations contemplated by the legislation." *Id.* The text of § 288C contains no statement that compliance is per se due care, but rather that compliance "does not prevent a finding of negligence where a reasonable man would take additional precautions." *Id.* § 288C. The thrust of the section and comment is that compliance will rarely be a conclusive defense.

95. See *W. Prosser*, *supra* note 53, at 164 (stating that statutory standards should be applied to "normal situations, clearly identical with those contemplated [by the statute or regulation]"); see also *RESTATEMENT*, *supra* note 21, § 288C comment a (stating that a statute or regulation is normally "applicable to the ordinary situations contemplated by the legislation").

96. See *Morris*, *Criminal Statutes*, *supra* note 61, at 47. As Professor Morris noted, the "optimum conditions are seldom present in accident cases." *Id.*

97. *Burch v. Amsterdam Corp.*, 366 A.2d 1079 (D.C. 1976). The court found the statute in question, the Federal Hazardous Substances Act, covered over 300,000 products, many of which may involve special dangers which would require more detailed and specific instructions than the general warnings prescribed by the Act. In light of the extreme flammability of [the product at issue], we do not agree that there were no special circumstances here which may have required a higher degree of care.

Id. at 1085; see also *O'Gilvie v. International Playtex, Inc.*, 609 F. Supp. 817 (D. Kan. 1985) (jury allowed to find in case of toxic shock syndrome (TSS) that FDA-approved warning was not adequate when defendant's superabsorbent tampon posed greater risks of TSS than all other tampons), *modified*, 821 F.2d 1438 (10th Cir. 1987).

may find that the manufacturer's conduct undermined the effectiveness of the agency's product safety standard; for example, when a manufacturer withholds vital information from the regulatory agency,⁹⁸ or promotes its products in ways that dilute the effects of the government-approved warning.⁹⁹ In these cases the agency's regulation does not address the underlying conduct that is at the heart of the tort claim. To give special weight to regulatory compliance in these cases would run counter to the statute's safety aims.¹⁰⁰

Courts may find that circumstances have changed since the standard was issued and that it has become obsolete. Although it is rare for rules to become too strict as they grow old,¹⁰¹ it is not unusual for them to become too lax as they grow old.¹⁰² Agencies and legislatures are unable to respond rapidly to new information and new technology;¹⁰³ hence their standards quickly can become outdated and poor measures of defendants' duties.¹⁰⁴ In all cases of special circumstances, however, the

98. See, e.g., *Roginsky v. Richardson-Merrell, Inc.*, 378 F.2d 832 (2d Cir. 1967) (in which misrepresentations were made to the FDA to obtain approval for new drug, MER/29, which caused cataracts); *Toole v. Richardson-Merrell, Inc.*, 251 Cal. App. 2d 689, 60 Cal. Rptr. 398 (1967); *Borum v. Eli Lilly & Co.*, No. 83-00-38, slip op. (D. Ga. Nov. 1983) (in which the defendant withheld information about deaths associated with use of Oraflex); see also cases discussed *supra* note 68.

99. For an early case in which the promotion of a product undermined the government-approved warning, see *Maize v. Atlantic Refining Co.*, 352 Pa. 51, 41 A.2d 850 (1945), in which the Surgeon General's approval of a warning on a highly dangerous cleaning fluid was not conclusive when the warning was diluted by promotion of the product under the name "Safety-Kleen." See also *Stevens v. Parke, Davis & Co.*, 9 Cal. App. 3d 51, 507 P.2d 653, 107 Cal. Rptr. 45 (1973) (involving dispute over promotion of antibiotic, Chloromycetin, which diluted FDA-approved warnings); *Love v. Wolf*, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1964), *aff'd*, 249 Cal. App. 2d 822, 58 Cal. Rptr. 42 (1967); *Whitley v. Cubberly*, 24 N.C. App. 204, 210 S.E.2d 289 (1974); *Incollingo v. Ewing*, 444 Pa. 263, 282 A.2d 206 (1971).

100. *Feldman v. Lederle Laboratories*, 97 N.J. 429, 479 A.2d 374 (1984) (*dicta*).

101. See *supra* notes 78-79 and accompanying text.

102. See, e.g., *Raymond v. Riegel Textile Corp.*, 484 F.2d 1025, 1027 (1st Cir. 1973) (in which flammability standards remained unchanged for over fourteen years, allowing flannelette material that could burst into flames within two seconds of contact with electric range to stay on the market).

103. See *infra* notes 138-46 and accompanying text.

104. See *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 658-59 (1st Cir. 1981) (in which manufacturer had information in 1970 about risks of its oral contraceptive that was not available when the FDA regulation was issued in 1968); see also *Feldman*, 97 N.J. at 438, 479 A.2d at 379 (documenting defendant drug manufacturer's early awareness of risks and its requests that the FDA require a warning; defendant, however, failed to issue any warnings until the FDA finally required them, after plaintiff's injury).

Consider also the testimony of Clarence Dilow III, Director of the Center for Auto Safety: "Present motor vehicle safety standards are woefully in need of strengthening and revision. With the delays in revising old standards and promulgating new ones, few significant changes have been made in motor vehicle safety standards in the 1970's." *Nominations—June: Hearings Before the Senate Comm. on Commerce*, 94th Cong., 2d Sess. 80 (1976). This failure to update motor vehicle standards has continued through the 1980s, despite changes in auto designs that call for the strengthening of some standards. See *infra* notes 189-93 and accompanying text.

courts allow the jury to consider the defendant's compliance, despite its questionable merit.

Even when the circumstances of the case are normal and the regulation has not become outdated, however, modern courts still are reluctant to adopt regulatory standards as conclusively or presumptively adequate under the common law.¹⁰⁵ In individual cases, courts may weigh compliance heavily, especially if the plaintiff's case is weak.¹⁰⁶ Even in these cases, however, courts acknowledge the general rule that the standards are not presumptive or conclusive measures of tort obligations.¹⁰⁷ This pervasive judicial attitude reflects a general skepticism about regulatory standards and an uncertainty about their sufficiency as standards of tort liability. The underpinnings for this skepticism will be explored in Part III.

3. Rejecting the Traditional Approach to Standards

The proposed reforms reject both of the general criteria by which courts now determine whether to adopt statutory and regulatory standards as standards of tort liability.¹⁰⁸ The reforms also reject the notion that standards should be used only when consistent with existing common-law principles.¹⁰⁹ The proposed reforms would shrink common-law liability by eliminating strict products liability¹¹⁰ and by increasing

105. See, e.g., *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529 (D.C. Cir.) (finding that, absent federal preemption, a warning prescribed by the Environmental Protection Agency is not necessarily adequate under state tort law because the purposes of the federal statute and state tort law may be quite distinct and the relevant factors may be weighed differently under each law), *cert. denied*, 469 U.S. 1062 (1984); *MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass. 131, 375 N.E.2d 65 (allowing jury to evaluate adequacy of wording of an FDA-approved warning on oral contraceptives), *cert. denied*, 474 U.S. 920 (1985).

106. *Bruce v. Martin-Marietta Corp.*, 544 F.2d 442 (10th Cir. 1976) (summary judgment for defendant when aircraft complied with FAA regulations and plaintiff failed to establish that an alternative design was available at the time of manufacture); *Wilson v. Piper Aircraft Corp.*, 282 Or. 61, 577 P.2d 1322 (1978) (finding that plaintiff failed to make a prima facie case when aircraft complied with FAA regulations and plaintiff failed to establish a feasible alternative design). In both cases, the courts accepted the view that the FAA standards were the minimum requirements, but found plaintiffs' cases inadequate when they failed to establish more stringent standards as an alternative. *Bruce*, 544 F.2d at 446; *Wilson*, 282 Or. at 64, 69-71, 577 P.2d at 1325, 1327-28; see also *Chambers v. G. D. Searle & Co.*, 441 F. Supp. 377, 383-84 (D. Md. 1975) (directed verdict for defendant when defendant complied with oral contraceptive warning prescribed by FDA and plaintiff's case was weak with respect to scientific knowledge of the risk and causation); *Johnson v. American Cyanamid Co.*, 239 Kan. 279, 718 P.2d 1318 (1986) (trial court should have directed a verdict because Sabin oral polio vaccine complied with FDA regulations and also was approved widely by medical and public health communities nationally and internationally). Neither *Chambers* nor *Johnson*, however, adopted the view that compliance with FDA regulations alone was sufficient to bar a tort claim.

107. See *supra* note 106.

108. See *supra* notes 56-59 and accompanying text.

109. See *supra* notes 76-77 and accompanying text.

110. See *supra* notes 26-31 and accompanying text.

plaintiffs' evidentiary burdens in compliance cases.¹¹¹ Further, proposed reforms which reject the view that standards should be used only to further the purpose of the statute fail to account for a regulation issued with neither the intent nor the expectation that it would be used to determine tort liability.

That courts would ignore the statutory or regulatory purpose is one of the most disturbing aspects of the proposals. The proposed reforms would transform regulatory standards already on the books, which have been neglected for decades by courts and agencies alike, into presumptively or conclusively adequate standards of care. Why, one must ask, should the court presume that a standard is sufficient for the tort system if the agency on whose expertise the court is relying has not established that the standard is adequate?

III. THE PROPOSED REFORMS IN THE MODERN REGULATORY ERA

The proposed reforms are based on the premise that federal regulatory agencies set sufficiently high standards of safety for the tort system and that they would continue to do so if the reforms were adopted. Inherent features of the modern regulatory process, however, belie these assumptions. First, the regulatory process presently is influenced heavily by regulated industries, which seek minimal safety standards. If the reforms were enacted, these industries would have even more at stake in the regulatory process and more incentive to influence it. Second, the federal regulatory system is incapable of keeping product safety standards up-to-date. Low agency budgets, rapidly changing technology, and expanding scientific knowledge combine to make this problem even greater in the modern regulatory era than in the past. Since the Reagan Administration began in 1981, some of these weaknesses in the regulatory system, particularly with respect to industry influence and low agency budgets, have become even more pronounced. As a result, some experts question the wisdom of allowing regulatory standards to set the outer limits of manufacturer responsibility under the common law.¹¹²

111. See *supra* notes 32-55 and accompanying text.

112. PRODUCTS LIABILITY LEGAL STUDY, *supra* note 56, at 131. The report urged rejection of a strengthened statutory compliance defense on several grounds: (1) standards can turn out to be "rubber-stamped" versions of existing industry standards; (2) standards "cannot comprehend every circumstance in which the product may be dangerous in normal use;" and (3) standards become "obsolete quickly." *Id.* The report concluded that "[t]hese inherent characteristics present a compelling argument against treating safety standards as anything more than a minimum or floor, below which product-related dangers are intolerable." *Id.* In its final report, the Interagency Task Force on Products Liability noted these arguments and rejected strengthening the statutory compliance defense. See generally FINAL REPORT ON PRODUCTS LIABILITY, *supra* note 20, at VII-37 to -42.

A. Industry Influence

A troubling aspect of strengthening the regulatory compliance defense is the enormous influence that industry has on the regulatory process, compared to the relatively weak influence of public interest groups. The disparity in influence between industry and consumer groups, however, does not affect all standards that courts might adopt. For example, traffic rules, often borrowed as standards for tort cases, are not as likely to raise this concern because they generally are broadly applicable to the entire population and no special interest group is likely to have pressed unduly for a particular outcome.¹¹³ Business influence, however, pervades industry regulation.¹¹⁴ Several factors contribute to business' predominance in the modern regulatory system, including agency dependence on industry data and expertise to carry out regulatory responsibilities, and the unparalleled wealth of resources that business groups can devote to the process.

1. Business Control of Vital Information

Industry often controls indispensable data about the nature and extent of the safety problem that an agency is attempting to address, as well as information about the technology and costs of reducing or eliminating the risk.¹¹⁵ The agencies often must place "substantial reliance" on industry data, which is not submitted under oath or subject to cross-examination in a rulemaking setting.¹¹⁶ Industry often overestimates the costs, yet agencies rely on the data.¹¹⁷ As a result, "agency choices predictably reflect the perspectives of industry interests."¹¹⁸

Even those agencies with the most pervasive regulatory role over industry, such as the Federal Aviation Administration (FAA) and the

113. RESTATEMENT, *supra* note 21, § 288C comment a. The *Restatement* uses only traffic and railroad crossing rules as illustrations. Of course, industry influence should not be discounted. Some traffic rules could be expected to trigger considerable industry influence on the regulatory process; for example, those governing trucking or the transportation of certain hazardous substances.

114. See D. BOLLIER & J. CLAYBROOK, *FREEDOM FROM HARM: THE CIVILIZING INFLUENCE OF HEALTH, SAFETY AND ENVIRONMENTAL REGULATION* 189 (1986) (stating that "by far the most influential force in the regulatory process is the political resistance of the affected industries").

115. *Id.* at 193; see also Cramton, *The Why, Where and How of Broadened Public Participation in the Administrative Process*, 60 GEO. L.J. 525, 529-30 (1972); Tobias, *Of Public Funds and Public Participation: Resolving the Issue of Agency Authority to Reimburse Public Participants in Administrative Proceedings*, 82 COLUM. L. REV. 906, 908 (1982).

116. Claybrook, *Auto Protection: Beyond Federal Standards*, TRIAL, Nov. 1980, at 38, 40.

117. Costle, *supra* note 1, at 415 n.20 (citing examples when both industry and government have overestimated the costs of regulation in the environmental area).

118. Tobias, *Great Expectations and Mismatched Compensation: Government Sponsored Public Participation in Proceedings of the Consumer Product Safety Commission*, 64 WASH. U.L.Q. 1101, 1103 (1986).

Food and Drug Administration (FDA) (two agencies that arguably deserve more judicial deference in tort actions because they regulate so comprehensively),¹¹⁹ must rely heavily on the information and data supplied by the regulated industries. Indeed, when the regulatory scheme is more comprehensive, the regulatory job for the agency is larger and it may have to depend more on industry.¹²⁰ For example, the FAA, in certifying the design, manufacture, and airworthiness of an aircraft, requires the applicant to conduct the tests to assure compliance with FAA airworthiness requirements.¹²¹ In developing new regulations, the FAA often calls upon industry advisory committees, which have substantial influence on the agency.¹²² Similarly, the FDA must rely on the regulated industry for data. In the past few years, the failure of companies to provide crucial data to the FDA for a series of drugs—Merital,¹²³ Oraflex,¹²⁴ Zomax,¹²⁵ and Selacryn¹²⁶—has been disastrous for consum-

119. See *supra* notes 11-13 and accompanying text (describing proposals that would make conclusively or presumptively adequate under the tort law only agency decisions concerning premarket approval of products).

120. See Keeton, *supra* note 11, at 154 (in which Dean Keeton concluded that, with respect to the FDA, because of the development of so many new drugs, "it is unrealistic to rely on a busy administrative agency to assure that proper precautions have been taken").

121. 14 C.F.R. §§ 21.33, 21.35 (1988). Further, with only 400 engineers, the FAA must turn to private individuals appointed to represent the FAA in the certification process. Those individuals appointed are generally employees of aircraft manufacturers. See *General Aviation Accident Liability Standards: Hearing Before the Subcomm. on Aviation of the Senate Comm. on Commerce, Science, and Transportation*, 99th Cong., 2d Sess. 60-62 (1986) (letter from Consumers Union, Consumer Federation of America, Public Citizen Congress Watch, and United States Public Interest Research Group).

122. See *Airline Safety: The Shocking Truth*, DISCOVER, Oct. 1986, at 30, 48 (describing the FAA's reluctance to strengthen crashworthiness standards and its willingness to postpone standard setting procedures in favor of appointing committees, which make only the most modest recommendations after years of consideration); see also Doggett, *Aircraft Post-Crash Fires*, TRIAL, Nov. 1987, at 30, 32 (describing the use of an industry task force on postcrash fire which concluded that preventing such fires was not cost effective).

123. In the case of Merital, an antidepressant, the FDA, despite indications in its own files and in the medical literature of severe allergic reactions, approved the drug without providing a warning of such reactions. Mintz, *Drug Approval Hit*, WASH. POST, July 21, 1987 (Health News), at 6; see also REPORT OF THE HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS SUBCOMM., GOVERNMENT OPERATIONS COMM., FDA'S REGULATION OF THE NEW DRUG MERITAL, H.R. DOC. NO. 206, 100th Cong., 1st Sess. 80 (1987). In addition, the manufacturer withheld information from the FDA about side effects, including thirty fatalities implicated in the drug's use. *Id.* at 80-81. The drug was marketed for about six months in this country before the company voluntarily ended sales worldwide.

124. Similar regulatory failures took place with regard to Oraflex, an arthritis drug connected with kidney and liver damage, which was manufactured by Eli Lilly & Co.. The FDA approved the drug in the first year of the Reagan Administration, when the FDA was boasting of its increased approval of new drugs over past years. See Demkovich, *Critics Fear the FDA is Going Too Far in Cutting Industry's Regulatory Load*, 1982 NAT'L J. 1249, 1250. The FDA approved twenty-seven new chemical entities in 1981, compared to only twelve in 1980. The Agency had refused to approve Oraflex two years before. *Id.* The company failed to report overseas deaths associated with use of the drug and eventually pleaded guilty to statutory violations. *Id.* Eli Lilly & Co. was fined

ers. In addition, a recent study by the General Accounting Office discovered that companies have underreported significantly the numbers of injuries associated with the use of medical devices.¹²⁷

2. Industry Resources

Regulated industries, with so much at stake in the regulatory process, are willing to commit enormous resources and "generate rather intense activity aimed at influencing"¹²⁸ agency decisions. Industries often are represented by trade associations, which lobby both the agencies and the Congress.¹²⁹ The Outdoor Power Equipment Institute (OPEI) directed an example of powerful lobbying with respect to product safety on behalf of industry. After the Consumer Product Safety Commission (CPSC) issued its safety standard for power lawn mowers, the OPEI successfully lobbied Congress to postpone the standard and amend it to eliminate one of its key safety features.¹³⁰

\$25,000 and one medical officer was fined \$15,000. Metzenbaum, *Is Government Protecting Consumers?*, TRIAL, April 1986, at 23, 24; see also *supra* note 68 and accompanying text.

125. The FDA failed to act on the drug Zomax, a painkiller, despite receipt of reports of over 2,000 allergic reactions. Wash. Post, July 21, 1988 (Health News), at 6, col. 4. In hearings before the House Subcommittee on Human Resources and Intergovernmental Relations, the Subcommittee learned that responsible agency officials were unaware of most of the reports. *Hearings on Zomax Before the Subcomm. on Human Resources and Governmental Relations of the House Comm. on Government Operations*, 98th Cong., 1st Sess. (1983).

126. Selacryn, a high blood pressure medication, is another example of an approved drug with adverse side effects. Again, the manufacturer failed to inform the FDA of cases of liver damage caused by the drug's use in France. It took the Justice Department three years after the FDA recommended criminal charges to bring misdemeanor charges against the company and several of its medical officers for failures to report adverse reactions. Nat'l L.J., July 2, 1984, at 3, col. 1. The officials entered nolo contendere pleas and were sentenced to perform two hundred hours of community service. Metzenbaum, *supra* note 124, at 25. The FDA had recommended felony charges, but Justice Department officials decided the case was not strong enough. *Id.*

127. *Medical Devices: Early Warning of Problems Is Hampered by Severe Underreporting: Hearings Before the Subcomm. on Health and the Environment, House Comm. on Energy and Commerce*, 100th Cong., 1st Sess. (1987) (testimony of the General Accounting Office). The General Accounting Office found that less than 1% of the problems with devices were ultimately received by the FDA, and the type of problem reported was more likely not to involve an injury, suggesting "a certain amount of selective reporting." *Id.* at 7. One unreported incident discovered by the General Accounting Office study resulted in the death of a patient. *Id.*

128. P. QUIRK, *INDUSTRY INFLUENCE IN FEDERAL REGULATORY AGENCIES* 13 (1981). The author states that "[r]egulatory decisions . . . often have major effects on the interests of regulated industries Industry perceives that its overall financial position can be significantly affected by regulatory agency decisions, and it can therefore generate rather intense activity aimed at influencing them." *Id.*

129. D. BOLLIER & J. CLAYBROOK, *supra* note 114, at 206-07.

130. Pittle, *Hill Panel Mows Down Safety Rule*, Wash. Star, May 21, 1981, at A19, col. 1 (editorial comment by then CPSC Commissioner R. David Pittle) (stating that "without a hearing, without a record, [and] without cost benefit analysis," Congress fundamentally altered the rule). For a detailed discussion of the power lawn mower standard setting process, see Schwartz, *The Consumer Product Safety Commission: A Flawed Product of the Consumer Decade*, 51 GEO.

Concomitant to industry influence is the lack of consumer influence. Consumers have few formal organizations, such as trade associations or political action committees, to represent their interests in the regulatory system.¹³¹ Organizing consumers is difficult because their stake in the regulatory system seems small, even imperceptible.¹³² Even when agency procedures have provided for substantial consumer participation in the rulemaking process, as under the original Consumer Product Safety Act,¹³³ consumer influence cannot approximate that of an industry with interests at stake.¹³⁴

Consumer organizations lack adequate resources to advance their interests in the regulatory process. Participation in the adoption of regulatory standards is costly.¹³⁵ Consumer groups, "whose annual budgets often equal the amount spent by one corporation for a sixty second television advertisement,"¹³⁶ cannot afford the same level of participation as industry groups. While the agency can serve as a "counterweight" to the industry's point of view,¹³⁷ the agency is often dependent on the industry and is not fully able to fulfill this task.

WASH. L. REV. 32, 77-95 (1982). The controversial provision of the agency's standard, which the industry opposed, required that the mower blades stop when the operator leaves the operating position, and either that the engine not stop or that it have an easy power restart. In short, the agency did not want to permit an engine shut-off with a manual restart that would prove inconvenient to users and encourage them to disable the system. *Id.* at 91. The lobbying effort produced what the industry wanted and had urged throughout the standard setting process—permission to adopt a mechanism that would shut off the engine to stop the blades. *Id.* at 94.

131. D. BOLLIER & J. CLAYBROOK, *supra* note 114, at 204-07.

132. P. QUIRK, *supra* note 128, at 13 (stating that "[e]ven though in the aggregate the decision may be worth a great deal, each individual considers it a matter of minor or no importance and directs his or her attention elsewhere"); see also D. BOLLIER & J. CLAYBROOK, *supra* note 114, at 203; S. TOLCHIN & M. TOLCHIN, *supra* note 1, at 23-24 (stating that "most people are unaware that regulations play any role in their well-being").

133. See 15 U.S.C. § 2056(d)(2) (1982) (providing for an "offeror" process whereby groups outside the agency, including consumer groups, could develop product safety standards). For a description of the process and a study of one standard setting process conducted by Consumers Union, see Schwartz, *supra* note 130.

134. A case study of CPSC's standard setting procedures found that consumer participants were dependent largely on industry for the technical data. Over time the participation of consumers in the lengthy rulemaking process diminished, while industry's participation "picked up as the standard took form and more businesses became aware of its potential economic impact." Schwartz, *supra* note 130, at 82.

135. The estimated costs to industry of two CPSC standards were over \$1 million for the lawn mower standard and \$500,000 for the architectural glass standard. *Id.* at 64 n.225. The costs to consumer groups are similarly steep. See 3 SENATE COMM. ON GOVERNMENTAL AFFAIRS, 95TH CONG., 1ST SESS., STUDY ON FEDERAL REGULATION, PUBLIC PARTICIPATION IN REGULATORY AGENCY PROCEEDINGS, vii, 17-22 (1977).

136. D. BOLLIER & J. CLAYBROOK, *supra* note 114, at 204.

137. *Id.*

B. Obsolescence

The problem of obsolescence is more acute now than in the past. In the past, the typical standards that courts might adopt, such as a traffic ordinance or a railroad crossing rule, did not become outdated quickly. In the modern, high-tech era, however, changes in technology and science occur more rapidly and can cause product safety standards to become outmoded quickly. For example, adverse side effects of drugs may become known to manufacturers well before they become known to the regulatory agency, and certainly well before the agency can act upon them.¹³⁸

While agencies need to respond quickly to the hazards in the marketplace, the delays inherent in the regulatory process make such a response difficult. Some agencies have taken decades to act on certain products. The FDA's massive review of the effectiveness of prescription drugs took twenty-two years, and might have taken longer if a lawsuit, which spurred the agency to complete the job, had not been filed.¹³⁹ In the past eighteen years only two flammable fabric standards have been issued to cover children's sleepwear; and the industry standard for general wearing apparel, enacted into law thirty-five years ago to prevent the return of "torch sweaters," remains on the books unchanged.¹⁴⁰ In aircraft regulation, seat-strength requirements established in the early 1950s have remained unchanged for over three decades despite enormous changes in aircraft design and widespread agreement that the standards are inadequate.¹⁴¹ Even under normal circumstances, regulatory decisions typically require several years at a minimum.¹⁴²

Limited resources also cause standards to become outdated. With

138. See *supra* note 104 and accompanying text.

139. Molotsky, *U.S. Review of Prescription Drugs Ends*, N.Y. Times, Sept. 16, 1984, at 52, col. 1 (city ed.). The review of 3,443 prescription drugs led to the withdrawal of over 1000. An FDA official heading the review charged that the delay was caused partly by drugmakers using delaying tactics, such as challenging even clear findings of ineffectiveness so they could continue to sell their drugs while the process went on. This charge was denied by the Pharmaceutical Manufacturers Association. *Id.* at col. 2.

140. *Hearings on H.R. 1115 Before the Subcomm. on Commerce, Consumer Protection, & Competitiveness of the House Comm. on Energy and Commerce*, 100th Cong., 1st Sess. (1987) (statement of David Pittle, Technical Director, Consumers Union and former Commissioner, CPSC).

141. *Airline Safety*, *supra* note 122, at 46. An FAA study in 1969 found the seat-strength rules, written when the DC-3 was the standard carrier, were inadequate for 87% of airline accidents. The Civil Aeronautics Board recommended stiffer requirements, but no action has been taken. *Id.*

142. Hutt, *Regulatory Reform Promise Has Not Been Fulfilled*, Legal Times, May 17, 1982, at 13, col. 1 (stating that FDA regulations take at least two years); Schwartz, *supra* note 130, at 62-66 (stating that CPSC standards under the unique "offeror" process established by the Act took an average of three years); Stanfield, *Resolving Disputes*, 1986 NAT'L J. 2764, 2765 (noting that EPA rules take a minimum of three years).

limited resources, agencies can address relatively few safety problems at a time. As an agency pursues the most serious problems, many others must go unattended. For example, when the National Highway Traffic Safety Agency (NHTSA) devoted enormous resources to the passive restraint rule in the late 1970s, it could not revise at the same time other motor vehicle standards that had become outdated.¹⁴³ While the FDA reviewed prescription drug effectiveness, review of nonprescription drugs had to be postponed.¹⁴⁴ The FAA has focused its resources on aircraft standards to reduce the risk of crashes, but it has been notoriously slow in dealing with crashworthiness standards that would reduce injuries in the event of a crash.¹⁴⁵ Indeed, the National Transportation Safety Board has concluded that crashworthiness regulations have failed to reflect findings from FAA and industry studies over the last three decades.¹⁴⁶

Although agency priorities may be sound from a regulatory standpoint, they demonstrate that regulatory standards do not function well as standards of liability under the tort system. One jurist has suggested that courts could take into account an agency's priorities in deciding what weight to assign compliance with its regulations.¹⁴⁷ With respect to FAA standards, for example, courts could give greater deference to those regulations that are central to airworthiness, such as engine design, and less deference to those that deal with crashworthiness, such as seat belts and exits.¹⁴⁸ This suggestion, however, has two drawbacks. It would create uncertainties about the effect to be given regulatory compliance, and courts would have to inquire into agency priorities far afield of the issues typically at stake in tort litigation.

C. *The Regulatory System Under the Reagan Administration*

The problems of industry influence and obsolescence, which are inherent in the regulatory system, have been exacerbated greatly during

143. Interview with Joan Claybrook, former Administrator, NHTSA (Jan. 30, 1988); see also Ditlow Testimony, *supra* note 47 (criticizing the lack of standard setting by NHTSA during the Reagan years).

144. Molotsky, *supra* note 139 (stating that both consumer advocates and FDA officials considered prescription drugs to be the top priority for review).

145. See *Airline Safety*, *supra* note 122, at 30. The emphasis at the FAA and among manufacturers has been on avoiding crashes—"The primary thing is not to crash in the first place." *Id.*

146. Dillingham, *Crashworthiness FARs and the Effect of Compliance in Products Liability Actions Involving Airplanes*, 33 FED'N INS. COUNS. Q. 55, 64 (1982).

147. *Wilson v. Piper Aircraft Corp.*, 282 Or. 61, 85, 577 P.2d 1322, 1335 (1978) (en banc) (Linde, J., concurring).

148. *Id.* at 85-86, 577 P.2d at 1335 (Linde, J., concurring). Justice Linde speculated that the defendant would be able to show that the FAA's standard for engines resulted from the same judgment as would be made under tort law, but that the FAA's standards for exits, instrument knobs, and seat belts might very well not result from the same judgments. *Id.*

the Reagan Administration. Industry influence has never been greater, nor consumer input less, than during the 1980s. Furthermore, the Reagan Administration's generally antiregulatory approach to product safety and its cutbacks in agency resources have heightened the risk that existing standards will become outdated.

1. Industry Influence

From the outset, the Reagan Administration promoted a "regulatory relief" agenda and signalled "an intent to regulate less—not necessarily better."¹⁴⁹ Personnel appointments reflected the Administration's business orientation¹⁵⁰ and the politicization of the regulatory process.¹⁵¹ Industry was given a greater role in the regulatory process at the expense of consumer interests.¹⁵²

Upon assuming office, President Reagan issued Executive Order 12,291, which consolidated oversight of executive agency rulemaking in the Office of Management and Budget (OMB) and established a cost-benefit test for all major executive agency rules.¹⁵³ Implementation of

149. Costle, *supra* note 1, at 409.

150. See S. TOLCHIN & M. TOLCHIN, *supra* note 1, at 85-109:

While President Carter selected those who believed in regulation and looked for ways to expand the impact of regulations, President Reagan appointed critics of the regulatory process who had been fighting government regulations long before they arrived in Washington. The Reagan appointees echoed their boss' view that most regulation was burdensome, inflationary, and unneeded.

Id. at 85.

151. For example, the CPSC had become so heavily staffed with noncareer, political positions that Congress, in its appropriations measure for fiscal year 1988, reduced the number of such positions. It was felt that these appointees were contributing to the turmoil in the agencies and interfering with the agency's safety mission. See 16 *Prod. Safety & Liab. Rep.* (BNA) 4 (1988); H. J. Res. 395, 100th Cong., 1st Sess. (1987); H. REP. No. 498, 100th Cong., 1st Sess. (1987).

152. See *infra* notes 156-57 and accompanying text.

153. Exec. Order No. 12,291, 3 C.F.R. 127 (1982), *reprinted in* 5 U.S.C. § 601 app. at 431-43 (1982). While Executive Order No. 12,291 gave the OMB greater control over agency rulemaking than it had possessed in the past, each president since Nixon has increased the OMB's control over the process. See Morrison, *OMB Interference with Agency Rulemaking: The Wrong Way to Write Regulation*, 99 HARV. L. REV. 1059, 1001-62 (1986). The Order requires executive agencies to prepare a "Regulatory Impact Analysis" detailing the costs and benefits of proposed and final "major" rules. Executive Order No. 12,291, § 3(c)(2), *reprinted in* 5 U.S.C. § 601 app. at 432. Major rules are those with an effect on the economy of \$100 million or more, or a significant adverse effect on prices, competition, employment, and productivity. No rule is to be undertaken "unless the potential benefits to society . . . outweigh the potential costs." *Id.* § 2(d), *reprinted in* 5 U.S.C. § 601 app. at 432. In choosing among alternatives, agencies must choose "the alternative involving the least net costs to society." *Id.* Further, the OMB reviews proposed rules before they are published for comment, and after comment and decision by the agency, the OMB again reviews the final rule and may delay its issuance until the agency has responded to the OMB's views. *Id.* § 3(f)(1)-(2), *reprinted in* 5 U.S.C. § 601 app. at 432. A Presidential Task Force on Regulatory Relief may target existing regulations for review.

In 1985 President Reagan issued Executive Order 12,498, which further expands the OMB's control over agency rulemaking by giving the OMB authority to review agencies' early plans to

this Executive Order has been criticized widely¹⁵⁴ for increasing industry influence on the regulatory process. The application of a cost-benefit analysis under the order also has favored greatly industry interests.

a. "Back Door" Influence

The Executive Order has been characterized as a "back door, unpublished, channel of access to the highest levels of political authority in the Administration for industry alone."¹⁵⁵ At the outset of the Administration, businessmen were encouraged to seek assistance from the OMB or the White House if they could not get satisfaction from the agencies in seeking regulatory relief.¹⁵⁶ Meetings with industry representatives occurred often; similar meetings with consumer groups were rare.¹⁵⁷

Industry influence on the OMB has resulted in the revision, delay, or disappearance of proposed rules.¹⁵⁸ For example, aspirin manufacturers sought to avoid the FDA's proposed rule requiring that labels on aspirin products warn of the risks of Reye's Syndrome, a serious illness associated with the use of that product. In 1982 the FDA had proposed the warning on the basis of a number of scientific studies, as well as reports by the Center for Disease Control and the American Academy

undertake rulemaking and to determine whether they may proceed. Exec. Order No. 12,498, 3 C.F.R. 323 (1986), *reprinted in* 5 U.S.C. § 601 app. at 40-41 (Supp. II 1984). Agencies must provide such a detailed justification for proceeding with rulemaking that the development of any basis upon which to proceed is discouraged. Morrison, *supra*, at 1063. This OMB approval process precludes agencies from requesting data or undertaking any research until they have the OMB's permission to do so, which "den[ies] agencies the benefit of public input on a potential problem at precisely the time when it may be most helpful." *Id.* at 1068.

154. See HOUSE COMM. ON GOVERNMENT OPERATIONS, OMB INTERFERENCE WITH OSHA RULEMAKING, H.R. REP. NO. 583, 98th Cong., 1st Sess. (1983) [hereinafter H.R. REP. NO. 583]; S. TOLCHIN & M. TOLCHIN, *supra* note 1, at 59-60; Costle, *supra* note 1; Morrison, *supra* note 153, at 1071 (arguing that Congress should eliminate the OMB's involvement in agency rulemaking).

155. H. REP. NO. 583, *supra* note 154, at 11. As one industry member honestly assessed the advantages of their access to the OMB: "Whenever we disagree with the FDA, it's nice to have another shot at it—not only at HHS but also at OMB." Kosterlitz, *Reagan is Leaving His Mark on the Food and Drug Administration*, 17 NAT'L J. 1568, 1571 (1985) (statement of John T. Walden, senior vice president of the Proprietary Association and former associate FDA commissioner).

156. S. TOLCHIN & M. TOLCHIN, *supra* note 1, at 59-60 (quoting Vice President Bush's assistant, C. Boyden Gray, in a speech to the Chamber of Commerce on April 10, 1981).

157. See H. REP. NO. 583, *supra* note 154, at 11 (documenting instances in which the OMB met with industry representatives but ignored requests for similar meetings with union representatives).

158. With respect to the FDA, the OMB's influence resulted in the staying of a proposal by the FDA to ban certain dyes found by scientists to cause cancer in laboratory animals, the delaying and changing of quality control standards for makers of infant formula, and the holding up of implementation of reporting requirements for medical device makers. Kosterlitz, *supra* note 155, at 1568-70.

of Pediatrics.¹⁵⁹ After pressure from industry members, however, OMB officials asked the FDA to withdraw the proposal for further scientific study.¹⁶⁰ Even after further scientific proof was developed, the FDA proved to be a reluctant regulator.¹⁶¹ Despite strong evidence of an association between Reye's Syndrome and aspirin use, acknowledged by the FDA Commissioner, the FDA delayed rulemaking, seeking more evidence that would "unequivocally establish" the link.¹⁶² The Agency initiated public service announcements about the risk and encouraged voluntary labeling, but was reluctant to mandate a warning.¹⁶³ Finally, however, a regulation was issued.¹⁶⁴ Unlike the tort system, though, the FDA had required that the risk be "unequivocally established."¹⁶⁵

b. *Secrecy*

The full extent of industry influence on the OMB cannot be gauged because most of it occurs behind closed doors. In a study of the OMB's early implementation of Executive Order 12,291, the General Accounting Office was sharply critical of the OMB's secret proceedings and its failure to document its views and communications with the agencies.¹⁶⁶

159. See Novick, *Use of Epidemiological Studies to Prove Legal Causation: Aspirin and Reye's Syndrome, A Case in Point*, 23 *Torr & Ins. L.J.* 536, 544-45 (1987).

160. *Id.* at 545. In September 1982 the Secretary of the Health and Human Services Department (of which the FDA is a component) signed the proposed regulation; in October, the Health and Human Services Department delayed publication pending OMB review; and in November "under intense pressure from the drug industry," the Health and Human Services Department withdrew the regulation and announced another study of the link between aspirin and Reye's Syndrome. *Id.*

161. *Emergency Reye's Syndrome Prevention Act of 1985: Hearings on H.R. 1381 Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 99th Cong., 1st Sess. (1985).

162. *Id.* at 345.

163. *Id.* at 334-35 (testimony of FDA Commissioner Frank E. Young detailing the agency's extensive education efforts and the voluntary labeling program).

164. 21 C.F.R. § 201 (1986). The mandatory warning went into effect on June 5, 1986.

165. See, e.g., *Schenebeck v. Sterling Drug, Inc.*, 423 F.2d 919 (8th Cir. 1970) (a warning should have been given when a scientific study showed a "correlation" between the drug and blindness, even though the cause and effect relationship was not definitively established at the time).

166. GENERAL ACCOUNTING OFFICE, *IMPROVED QUALITY, ADEQUATE RESOURCES, AND CONSISTENT OVERSIGHT NEEDED IF REGULATORY ANALYSIS IS TO HELP CONTROL COSTS OF REGULATIONS 53-54* (1982). The General Accounting Office reported:

The result of [the OMB's] non-documented approach to rulemaking is that the public cannot determine at whose initiative a rule was issued. While the agency formally remains accountable for its rules, the record does not show whether the agency made its decisions primarily on the basis of its interpretation of the evidence available to it or in response to OMB directives.

. . .

Because OMB's influence is potentially great, its apparent openness to *ex parte* communications . . . about pending rules raises similar disclosure concerns. . . . The public cannot determine either who made the regulatory decision, or on what basis it was made.

Id.

Consumer representatives,¹⁶⁷ legislators,¹⁶⁸ and academics also have criticized the secret proceedings.¹⁶⁹ Decisionmaking becomes highly suspect¹⁷⁰ and meaningful judicial review of agency decisions is undermined by such secrecy.¹⁷¹ If the proposed reforms giving regulatory standards greater weight in tort determinations were adopted, this secrecy would hinder greatly a plaintiff's efforts to challenge the adequacy of these standards.

c. Cost-Benefit Analysis

Many commentators acknowledge that cost-benefit analysis may be a useful tool for making regulatory decisions, but they also recognize inherent weaknesses in applying cost-benefit analysis to health and safety regulations.¹⁷² The problem is that the cost-benefit analysis inevitably favors industry over consumer interests and regulation¹⁷³ because benefits to consumers tend to be undervalued¹⁷⁴ while costs to industry tend to be overstated.¹⁷⁵

Under Executive Order 12,241, the inherent bias against regulation in the cost-benefit approach has been increased. Critics argue that the OMB purposefully has used cost-benefit analysis to reach results that

167. *Regulatory Reform Act: Hearings on H.R. 2327 Before the Subcomm. on Administrative Law and Government Relations of the House Comm. on the Judiciary*, 98th Cong., 1st Sess. 107-08 (1983) [hereinafter *Hearings on H.R. 2327*] (testimony of Joan Claybrook, President, Public Citizen); see also Morrison, *supra* note 153, at 1064 (Morrison is Director of the Public Citizen Litigation Group).

168. H.R. REP. NO. 583, *supra* note 154, at 12-13.

169. See McGarity, *Regulatory Analysis and Regulatory Reform*, 65 TEX. L. REV. 1243, 1309 (1987).

170. See Morrison, *supra* note 153, at 1064 (stating that "the entire process operates in an atmosphere of secrecy and insulation from public debate that makes a mockery of the system of open participation embodied in the Administrative Procedure Act").

171. See *id.* at 1072 (arguing that OMB's oral and written communications to agencies should be put on the record to assure adequate judicial review).

172. See S. TOLCHIN & M. TOLCHIN, *supra* note 1, at 141 (stating that "[a]lthough cost-benefit analysis can be useful in determining the most cost-effective alternative among competing regulatory devices, it should be laid to rest as a dominant policy tool—as inadequate, inequitable, and subject to excessive political distortion in its application"). But see D. BOLLIER & J. CLAYBROOK, *supra* note 114, at 202 (arguing that cost-benefit analysis may be appropriate in "financial investment decisionmaking," but not in health and safety regulation).

173. See, e.g., Clark, *Do the Benefits Justify the Costs? Prove It, Says the Administration*, 1981 NAT'L J. 1382.

174. This is especially true when the benefits do not become manifest immediately upon implementation of a rule, but occur in the future after the rule has had time to take effect. See S. TOLCHIN & M. TOLCHIN, *supra* note 1, at 126-28; see also McGarity, *supra* note 169, at 1283.

175. Costle, *supra* note 1, at 415. The costs of regulation are felt almost immediately and are more easily assessed by business. Often the cost estimates are supplied by industry and are inflated. *Id.* at 415 n.20 (citing examples in which both industry and government have overestimated the costs of regulation in the environmental area).

favor the interests of industry.¹⁷⁶ This goal has been evidenced by the uneven manner in which the cost-benefit analysis has been applied; regulations that further the Administration's political agenda, for example, often have been exempt from cost-benefit analysis.¹⁷⁷ Critics also charge that the benefits of regulation are grossly undervalued by the OMB. The OMB has urged agencies to calculate indirect costs of regulation, but not indirect benefits. One critic has pointed out, however, that "[i]t is our collective thinking about regulation's indirect *benefits* that needs stimulation, not the other way around."¹⁷⁸ With respect to health and environmental regulations that create benefits for future generations, the OMB has insisted on discounting the future benefits to their present value, using a high discount rate that renders their present value very low and "likely to be outweighed by even modest costs."¹⁷⁹ The discrepancy between this regulatory approach to long-term risks and benefits and the tort system's approach is substantial.

d. Budget Cutbacks

Reductions in agency budgets may lead to even greater deference to industry groups in the future and to an inability to keep regulatory standards up-to-date.¹⁸⁰ The cutbacks at some agencies, such as the CPSC¹⁸¹ and the FDA,¹⁸² have been substantial and have led to signifi-

176. See *id.* at 417. Mr. Costle concludes that under Executive Order No. 12,291, "cost-benefit analysis has decidedly shifted from using cost-benefit concepts as an analytical tool to make regulation *better* to requiring cost-benefit analysis to justify a particular regulation, and thus to regulate *less*." *Id.* (emphasis in original).

177. See McGarity, *supra* note 169, at 1315-17. The OMB regularly waives cost-benefit analyses for rules that provide regulatory relief, which demonstrates the bias of the process in favor of industry interests. Clearly such rules can be detrimental to human health and safety and if cost-benefit analysis is a neutral analysis it should be applied evenhandedly to both regulatory and deregulatory proposals. *Id.*

178. Costle, *supra* note 1, at 420 (emphasis in original).

179. McGarity, *supra* note 169, at 1296. As Professor McGarity points out, the OMB's use of a 10% discount rate means that "a dollar's worth of benefits 50 years from now is worth slightly less than a penny today." *Id.* at 1296 n.293.

180. Cutbacks at the CPSC will mean less Agency participation in and monitoring of the voluntary standards process because travel expenses will be among the first items to be cut. 16 Prod. Safety & Liab. Rep. (BNA) 104 (1988). The Agency already relies heavily on industries to develop voluntary standards; less Agency monitoring translates into even greater reliance on industries to regulate themselves.

181. The CPSC's appropriation for 1988 was approximately \$32.7 million, a reduction of \$1.5 million made at the Commission's request, necessitating a reduction in senior staff and operating costs across the board. 16 Prod. Safety & Liab. Rep. (BNA) 4 (1988). The 1989 budget mark of \$32.9 million set by the OMB will require further reductions in funding for a number of projects, including ATVs, the bicycle and riding mower projects, and data collection. 16 Prod. Safety & Liab. Rep. (BNA) 75 (1988).

182. Between 1980 and 1986, FDA lost nearly 1,000 employees, or 12% of its workforce. The staff fell from about 8,000 in 1980 to about 7,000 in 1986. Kosterlitz, *supra* note 155, at 1571.

cant reductions in the workforce and the range of product safety initiatives. Some of the most experienced employees have left the FDA.¹⁸³ Lower budgets also mean fewer safety inspections,¹⁸⁴ less regulation, and less timely regulations. At the CPSC, for example, the agency's data collection system is half the size that it was when the agency was created in 1972,¹⁸⁵ and therefore, it takes twice as long to collect information on product-related injuries and to determine whether regulatory action is warranted.¹⁸⁶ Thus, projects designed to update standards are expected to take four years to complete.¹⁸⁷

e. Regulatory Inaction

One result of both the bias toward industry and the budgetary cutbacks has been a reduction in the creation and enforcement of standards by the agencies responsible for consumer product safety. Delays and inaction similar to those in FDA rulemaking have occurred in other product safety agencies.¹⁸⁸ The NHTSA, for example, issued only one safety standard that was not compelled by a court order in the first four years of the Reagan Administration.¹⁸⁹ The Agency focused "nearly exclusively on modifying driver behavior" and "largely ignored the critical technological mandate" granted by statute to set product safety standards.¹⁹⁰ Critics charge that the NHTSA has failed to address a range of issues that would save thousands of lives.¹⁹¹ For example, it has

183. Among those leaving were some of its most experienced scientists. *Id.* Concern also has been expressed about the replacement of those leaving at the higher levels with appointments that are based more on political background than scientific expertise. *See id.* at 1571-72.

184. For example, due to the deregulation of the trucking industry, the number of interstate trucking companies has jumped from 18,000 to over 30,000, and the number of independent truckers has grown to over 200,000. At the same time, the number of safety inspections has been reduced because of a combination of budget cutbacks and the prevailing view of a limited role for government. Corrigan, *Squeeze on Safety*, 1987 NAT'L J. 356, 361.

185. 16 *Prod. Safety & Liab. Rep.* (BNA) 91 (1988).

186. *Id.* The data are needed to support both voluntary and mandatory standards, according to Carl Blechschmidt, CPSC program manager, because industries generally are not convinced that action is needed unless data demonstrate that there is a problem. *Id.*

187. *Id.* at 91-92. One project studying bicycles is aimed at updating a ten year-old standard that the staff believes may be outdated because of new equipment that has come on the market in the interim. Nearly one-half million bicycle injuries occur each year to children and adults. *Id.* at 92.

188. *See supra* notes 158-60 and accompanying text (regarding OMB's interference in FDA rulemaking).

189. *NHTSA Authorization and Oversight: Hearings on H.R. 2248 Before the Subcomm. on Telecommunications, Consumer Protection and Finance of the House Comm. on Energy and Commerce*, 99th Cong., 1st Sess. 31 (1985) [hereinafter *Hearings on H.R. 2248*] (statement of Rep. Wirth, Chairman of the Subcommittee).

190. *Id.*

191. The Agency should pursue standards for "side impact protection, pedestrian safety, light truck and van automatic crash protection, and heavy vehicle braking [which] could save

failed to make a number of its standards applicable to light pickup trucks and minivans, despite evidence showing that the market share of such multipurpose vehicles has nearly doubled in recent years and that families are using them as passenger vehicles.¹⁹² In 1987 the Senate, frustrated by the delays and inaction, sought to put pressure on the NHTSA by passing legislation that directs it to expedite certain rulemaking proceedings and research projects.¹⁹³

The CPSC, an agency racked by dissension and turmoil,¹⁹⁴ also has virtually abandoned setting mandatory standards. It relies on voluntary standards, developed by industry with some Agency staff input, as the primary means for implementing the safety goals of its statute. The voluntary process often has led to unsatisfactory results.¹⁹⁵ As a result of the CPSC's refusal to act, Congress has attempted to pressure it into regulating a number of products that have become hazardous to the public.¹⁹⁶

thousands of additional lives each year." *Id.* at 91 (statement of Joan Claybrook, President, Public Citizen and former Administrator of the NHTSA). The Agency has either rescinded advance notices of these rules or taken no action. *See id.* at 96-98.

192. 15 *Prod. Safety & Liab. Rep. (BNA)* 49 (1987) (stating that the market share went from 15% in 1971 to 29% in 1985). NHTSA exempted minivans and light pickup trucks from safety standards because they constituted a very small part of the market, but they are now a larger segment and more fatalities are occurring in these vehicles—an increase of 15.8% from 1984 to 1985. Corrigan, *supra* note 184, at 359-60. Although the Carter Administration took initial steps to end the exemption for these vehicles, the Reagan Administration did not pursue the issue. *Id.* at 360. More study was needed, but the Agency was slow to undertake it. *Id.* In 1987 the NHTSA issued an advance notice of proposed rulemaking on possible changes in vehicle classification that would strengthen standards for light trucks and vans. 15 *Prod. Safety & Liab. Rep. (BNA)* 773, 801 (1987). The agency projects a proposed rule in 1988. *Id.* at 105. A final standard, no doubt, will take several years.

193. S. 853, 100th Cong., 1st Sess. (1987), *noted in* 16 *Prod. Safety & Liab. Rep. (BNA)* 103 (1988). The statute directs the Agency to act on extending certain passenger car standards to minivans and light trucks, strengthening side impact protection, requiring lap-shoulder belts in rear seats, and contracting for crashworthiness research. The Agency has indicated that some of these items are included in its rulemaking priorities for 1988. 16 *Prod. Safety & Liab. Rep. (BNA)* 105 (1988). The conference report on appropriations for the Agency directs the NHTSA to move swiftly in these areas in fiscal year 1988 and allocates certain sums for these purposes. H.R. REP. No. 498, 100th Cong., 1st Sess. (1987).

194. *See Outlook for Product Safety & Liability in 1987*, 15 *Prod. Safety & Liab. Rep. (BNA)* 47 (1987) (describing the dissension among commissioners that has disrupted Agency decisionmaking and delayed recent proposals to restructure the Agency in order to make it more effective in protecting consumers).

195. In 1985, for example, the CPSC turned to the all-terrain vehicle (ATV) industry to develop a voluntary standard for its vehicles, but two and one-half years later the CPSC Chairman reported that the industry was still "dragging its feet with respect to ATV safety," and had not met to discuss the issue in several months. *Id.* at 815.

196. Senate and House committees have been especially critical of the Agency's failure to address a number of dangerous products. Recent reauthorization bills in both chambers have directed the Agency to address specific products such as lawn darts, cigarette lighters, all-terrain vehicles, adult sleepwear flammability, and choking hazards in small toy parts. *Id.* at 102-03.

Ironically, under the proposed tort reform the widespread failure to regulate could prove beneficial to plaintiffs, for it would reduce the availability of the strengthened regulatory compliance defense. On the other hand, if the reforms are implemented, industry may seek more regulation.

D. Broad Ramifications on Regulatory and Tort Systems

The above discussion of the modern regulatory process and the developments in the Reagan Administration suggests that the effects of the proposed tort reforms on both the regulatory and tort systems could be profound. Business groups may increase their efforts to influence the regulatory process and assure minimum standards. The tort system may become vulnerable to shifts in federal policies, with the tort system weakening when the federal regulatory system is weak, which could reduce significantly incentives for product safety.

1. Impact on the Regulatory Process

One consequence of the proposed reforms could be to encourage product sellers to "sit back" and not take safety measures that would exceed regulatory requirements.¹⁹⁷ Another effect might be to encourage industry to resist updating existing standards and even to seek more rules that could protect them from civil liability. Industries generally seek regulations that are in their business interests,¹⁹⁸ and they often are successful. With protection from civil liability at stake in the regulatory process, business groups most likely will devote even more effort to influencing the regulatory process.

The proposed reforms also may increase the demands on the regulatory process itself. Currently, regulators do not factor into their deliberations the effects of their standards on products liability litigation.¹⁹⁹ Indeed, the courts have given no indication that regulations will define the levels of safety required by the tort system. The proposed reforms, however, would change the role of regulations in the tort system; thus, agencies would have to factor this broader effect into their rulemaking. Agencies also would have to consider whether a particular rule would further the safety mandates of the statutes if used by the courts to

197. See *supra* note 72 and accompanying text.

198. See Schwartz, *supra* note 130, at 55 n.153 (noting that most agency petitioners represent business interests).

199. Interview with Linda Horton, Deputy Chief Counsel for Regulations and Hearings, FDA, in Washington, D.C. (Mar. 23, 1988). According to Ms. Horton, the effects on tort liability are "not routinely part of the deliberative process before a rule is proposed." The Agency may address the issue if it is raised during the comment period, but in that case, it takes a neutral point of view. *Id.*

shield manufacturers from liability.

The rulemaking process would become more complex and costly if the reforms were adopted. All interested parties, concerned about the impact of these reforms, would provide data to the agencies on the subject and anxiously await the agencies' explanations of agency standards, so that their relevance to tort claims could be determined easily.²⁰⁰ For example, potential defendants might want agencies to consider and reject certain matters in order to lay a basis for the compliance defense in future tort actions.

2. Interaction Between Tort and Regulatory Systems

The interaction of the products liability and regulatory systems enhances overall product safety. As noted earlier, judicial treatment of regulatory violations as negligence per se creates incentives for regulatory compliance.²⁰¹ The two systems also interact in other ways. The tort system can provide an incentive, perhaps the key incentive, for manufacturers to recall their dangerous products.²⁰² The tort system also spurs government to act upon discovery of the otherwise undetectable risks associated with products. The risks associated with asbestos and with the Dalkon Shield are two good examples of risks that first became known through the tort system and later were regulated by the government.²⁰³ A more recent example is burn injuries to children from

200. See *supra* notes 34-42 and accompanying text (concerning the difficulty of applying regulatory standards to issues in litigation).

201. See *supra* note 68 and accompanying text.

202. There is a potential for punitive damages for failing to recall a product. See, e.g., *Lewy v. Remington Arms Co.*, 836 F.2d 1104, 1107 (8th Cir. 1988) (pointing to the fact that defendant's product safety subcommittee decided not to recall a rifle after evaluating consumer complaints; the court determined that the defendant acted with "conscious disregard for the safety of others," which warranted imposition of punitive damages under Missouri law); see also Schwartz & Adler, *Product Recalls: A Remedy in Need of Repair*, 34 CASE W. RES. L. REV. 401, 416, 440, 458 (1984). The authors of that article studied the recall programs of the NHTSA, the FDA, and the CPSC and found that concerns about products liability suits and adverse publicity encourage manufacturers to recall their products voluntarily. They also found that, in the case of automobile recalls, these same concerns could discourage voluntary recalls if the manufacturer thought that the publicity actually might increase lawsuits by informing consumers who had had accidents with the recalled cars that they might have a claim. *Id.* at 417.

Because enforcement actions are costly and time consuming, the government must rely on voluntary compliance to a very great extent in recall cases. *Id.* at 415-16, 438-39, 456-57. Indeed, a recall must be prompt to be effective, which makes voluntary compliance essential to effective enforcement of the statute. If automobile recalls are not carried out quickly, for example, the vehicle owners are more difficult to locate. *Id.* at 422. With respect to other consumer products, the age of the recalled product also affects the response rate of consumers. *Id.* at 441-42. In the food and drug area, of course, the recall must occur promptly before the products are consumed.

203. See D. HENSLER, W. FELSTINER, M. SELVIN & P. EBENER, *ASBESTOS IN THE COURTS: THE CHALLENGE OF MASS TOXIC TORTS*, at iii, xxv-xxvi, 10-12 (1985) [hereinafter *ASBESTOS IN THE COURTS*]; M. MINTZ, *AT ANY COST: CORPORATE GREED, WOMEN, AND THE DALCON SHIELD* (1985).

cigarette lighters.²⁰⁴

Finally, the tort system also can be the stimulus for consumer safety legislation in Congress. A recent example is the Childhood Vaccine Injury Compensation Act, which affords compensation for victims of vaccine-related injuries.²⁰⁵ The numerous products liability claims resulting from vaccines spurred manufacturers and the Congress to find a solution to the problem.²⁰⁶ If compliance with FDA regulations had been a strong defense in these suits, as the proposed reforms would allow, no remedy would have existed for the victims of vaccine injuries.

Under the proposed reforms, the tort system would be weakened by the increased deference to federal standards and no longer would serve as a robust spur to federal safety enforcement. During the Reagan Administration, the role of the tort system has been especially important because of the government's reluctance to take strong enforcement actions.²⁰⁷ The Administration has relied extensively on voluntary in-

204. For example, the CPSC, after some forty products liability suits were filed and Congressional pressure was put on the Agency, initiated a rule to make cigarette lighters child resistant. Walsh, *Consumer Safety Panel to Seek Childproof Cigarette Lighters*, Wash. Post, Jan. 12, 1988, at F2, col. 5. In announcing its action, the CPSC said that in a single year, 1985, children playing with lighters had caused 120 deaths, 860 injuries, and \$60.5 million in property damages. *Id.* In the case of ATVs, the CPSC did not act to force the recall of the vehicles until 1988, despite statistics showing nearly 800 deaths and more than 300,000 injuries relating to their use since 1982. Blum, *ATV Attack: State and Federal Legislation, Legal Action May Come Soon*, Nat'l L.J., Dec. 7, 1987, at 8, col. 1; McAllister, *Lawsuit Seeks to Win Refunds for ATV Buyers*, Wash. Post, Jan. 14, 1988, at A4, col. 1.

205. 42 U.S.C. § 300aa-11 (Supp. 1988), provides a no-fault compensation system for vaccine-related injuries that provides for full recovery of economic damages and a cap of \$250,000 for pain and suffering. Plaintiff may pursue a fault-based tort claim, but warnings in compliance with FDA regulations will be presumed adequate.

206. See generally H.R. REP. NO. 908, 99th Cong., 2d Sess. (1986).

207. A recent example was the failure of the government to require the recall of ATVs, which have been linked to nearly 800 deaths and 300,000 injuries since 1982. Nat'l L.J., Jan. 18, 1988, at 9, col. 1. One year after the CPSC asked the Justice Department to bring suit seeking a recall, the government accepted a consent decree that requires neither a recall nor a refund, but only warnings about the hazards associated with the use of ATVs and training on their proper use. See 16 Prod. Safety & Liab. Rep. (BNA) 60 (1988) (for the text of the complaint and the preliminary consent decree). The consent agreement, which has been criticized widely as inadequate, was accepted by the CPSC, in part because the Justice Department planned to charge the Commission an estimated \$9 million (\$3 million a year for three years) if it insisted on pursuing the claim for a recall and refund. *Id.* at 4 (according to Congressman Doug Barnard (D-Ga), chairman of the House Government Operations Committee's Commerce, Consumer, and Monetary Affairs Subcommittee, the Justice Department does not charge other government agencies for representing them in court). For a small agency like the CPSC, with a budget of roughly \$33 million, it would be an intolerable drain on their resources.

In general, enforcement actions, such as recalls, fell off during the Reagan Administration. With respect to the FDA, for example, in 1984 the number of cases brought represented a 52% drop in the average brought each year during the previous administration. Kosterlitz, *supra* note 155, at 1569. The FDA brought 260 actions in 1984, compared to an average of 542 actions between 1977 and 1980. Critics concluded that the drop reflected the willingness of the Agency to allow industry to mend its ways voluntarily, without an enforcement action. *Id.*

dustry compliance, which only can be successful when a real threat of agency enforcement or tort liability exists. Given the Administration's reluctance to take enforcement actions, due either to lack of will or lack of resources, the tort system remains the key incentive for product safety.

The extent to which the federal government protects consumers, through both standard setting and enforcement actions, bears directly on the question of how strong the tort system should be. If the government is a poor watchdog over consumer safety, as it has been throughout the Reagan Administration, the strength of the tort system becomes crucial.

The experience of the Reagan Administration also serves as a warning that federal regulatory policies can shift dramatically, and that under the proposed reforms the tort system would be more vulnerable to those shifts. Under the proposed reforms, if the federal regulatory system became weaker, the tort system would also become weaker, at the very time when a robust tort system would be most needed.

IV. CONSIDERING THE PROPOSED REFORMS IN LIGHT OF THE PRODUCTS LIABILITY CRISIS

Despite the weaknesses of the proposed reforms, they might be justified as a way to limit tort liability; if, as critics of the tort system

In the area of auto recalls, critics charge that the NHTSA has proceeded at a "snail's pace" in investigating defects. *Hearings on H.R. 2248, supra* note 189, at 29 (remarks of Rep. Wirth). Further, there has been a sharp drop in the number of recalls since the beginning of the Reagan Administration. In the decade prior to 1981, the average number of auto recalls per year was 295. *Id.* at 109 (testimony of Clarence M. Ditlow III, Director, Center for Auto Safety). During the first four years of the Reagan Administration, the recalls numbered 196, 175, 182, and 209 respectively. *Id.* Further, there was an 80% cut in public investigations and fifteen instances in which the NHTSA asked for voluntary recalls, but the manufacturer refused and the NHTSA did not pursue. *Id.* One of the Agency's most publicized failures to recall involves the Ford Motor Company, which marketed millions of vehicles with automatic transmissions that occasionally slip out of park into reverse and which have claimed over 200 lives. *Id.* For a discussion of the Ford transmission case, see Schwartz & Adler, *supra* note 202, at 418-20 (noting that Ford did agree to send vehicle owners a warning about the defect to affix to their dashboards, but refused to recall the vehicles in order to correct the defect). Despite continuing injuries and deaths caused by the defect—indicating the ineffectiveness of the dashboard stickers—as well as prodding by the Center for Auto Safety, the NHTSA has refused to reopen the case.

The NHTSA also has been criticized by the President of the Insurance Institute for Highway Safety for not requiring a mandatory recall of the Audi 5000, which was subject to sudden acceleration problems. Corrigan, *supra* note 184, at 360. In 1987 the Center for Auto Safety reported that over the previous eight years, the NHTSA had made requests—which went unheeded by manufacturers—for the recall of one out of every five cars sold. *Id.*

At the CPSC, the smallest of the product safety agencies, the number of recalls also has fallen drastically during the Reagan Administration. Schwartz & Adler, *supra* note 202, at 426. The number of products recalled went from an average of 34.5 million in the previous administration to an average of 2.5 million in the first years of the Reagan Administration. *Id.*

contend, it is wildly out of control.²⁰⁸ The tort system, however, is not in such dire straits, and its greatest weakness, the high transaction costs of the litigation system, would not even be addressed by the proposed reforms.

A. *The Insurance "Crisis"*

The major impetus for much of the reform movement has been the so-called insurance "crisis." During the years 1984-1986, insurance rates rose sharply. Insurance and industry groups portrayed tort and products liability litigation as the culprit.²⁰⁹ The insurance industry undertook a 6.5 million dollar advertising campaign to convince the public that the "lawsuit crisis" had caused the difficulties in insurance availability and affordability.²¹⁰ The Attorney General's Tort Policy Working Group issued a report tying the insurance crisis to the "veritable explosion of tort liability in the United States."²¹¹

As the issue was studied more carefully, however, it became less clear that an insurance crisis existed at all,²¹² and the connection between insurance rates and the tort system became increasingly tenuous. A study by the General Accounting Office found that the profitability of the insurance industry is related to its cyclical nature and pricing policies.²¹³ In the early 1980s, insurance companies charged lower premiums for insurance in order to obtain funds for investment at then prevailing high interest rates.²¹⁴ As long as interest rates remained high, the return on investments offset underwriting losses and the industry remained

208. See generally ATTORNEY GENERAL'S REPORT, *supra* note 2.

209. See, e.g., Wermel, *Courting Disaster: The Costs of Lawsuits, Growing Ever Larger, Disrupts the Economy*, Wall St. J., May 16, 1986, at 1, col. 6; Taylor, *Product Liability: The New Morass*, N.Y. Times, Mar. 10, 1985, at F1, col. 2. But see Olender, *The Great Insurance Fraud of the '80's*, Nat'l L.J., July 21, 1986, at 15, col. 1; Hunter, *The Insurance Industry is to Blame*, Wash. Post, April 13, 1986, at C7, col. 2.

210. *The Manufactured Crisis*, 51 CONSUMER REP. 544, 545 (1986).

211. ATTORNEY GENERAL'S REPORT, *supra* note 2, at 2. See generally *id.* at 16-59 (acknowledging that the industry's pricing practices and general economic conditions have played a role in the insurance crisis; the Report, nevertheless, finds that the tort law has played the central role in the crisis).

212. See generally N. WEBER, *PRODUCT LIABILITY: THE CORPORATE RESPONSE* 21 (1987) (concluding that "[a]t least for major corporations, the so-called twin crisis of liability and insurance have had relatively little impact"); Kindregan & Swartz, *The Assault on the Captive Consumer: Emasculating the Common Law of Torts in the Name of Reform*, 18 ST. MARY'S L.J. 673, 710-11 (1987) (describing the growth in assets and income of the insurance industry in 1984-86).

213. *The Liability Insurance Crisis: Hearings Before the Subcomm. on Economic Stabilization of the House Comm. on Banking, Finance and Urban Affairs*, 99th Cong., 2d Sess. 89-90 (1986) [hereinafter *Insurance Crisis Hearings*] (statement of William Anderson, Director, General Government Division, General Accounting Office).

214. In the early 1980s interest rates went as high as 20%, which allowed insurance companies to slash the price of premiums. *The Manufactured Crisis*, *supra* note 210, at 544.

profitable.²¹⁵ In 1984, however, when interest rates fell, investment income fell, and the industry suffered a loss.²¹⁶ By 1986 the prospects for the industry again looked good.²¹⁷ By 1987 the insurance crisis almost had disappeared as a basis for reforming tort and products liability laws.²¹⁸

That factors other than tort litigation played a major role in skyrocketing insurance rates became even clearer when the insurance "crisis" waned and the income and profits of the insurance industry began to climb, without any marked change in products liability law to account for the reverse in fortune.²¹⁹ Interestingly, a similar insurance "crisis" occurred during the mid-1970s, generating a push for federal products liability reform, which stalled when "in the midst of this legislative activity . . . [p]roduct-liability insurance premiums came down and the '[c]risis' eased."²²⁰

B. Increases in Products Liability Claims

Another basis for products liability reform is the alleged increase in the number of products liability claims being filed. The Attorney General's Tort Policy Working Group pointed to an astounding 758 percent increase in the number of products liability claims filed in federal court between 1974 and 1985.²²¹ The Report speculated that state courts had experienced a similar increase in claims.²²² The federal claims, however, which account for only two percent of all claims filed nationwide,²²³ do not reflect accurately the experience of state courts. A study of state courts revealed about a nine percent increase in tort claims between 1978 and 1984, while the population grew by eight percent.²²⁴ The study

215. In the period from 1981 to 1985, underwriting losses amounted to \$66 billion, but investment gains amounted to \$97 billion, resulting in a net gain of \$31 billion. *Insurance Crisis Hearings*, *supra* note 213, at 86.

216. *Id.* Underwriting losses were \$19.4 billion and investment gains were \$17.9 billion. In 1985 the situation improved and investment gains were again greater than underwriting losses, by \$7.6 billion. *Id.*

217. Salomon Brothers forecasted that industry profits would rise annually at a rate of 25% in the period 1985-1989. *Id.* at 91.

218. *Outlook for Product Safety & Liability in 1987*, 15 *Prod. Safety & Liab. Rep.* (BNA) 47, 51 (1987) ("The insurance industry, which took the lead in promoting [tort and product liability] changes in 1986, will stay behind the scenes this year").

219. Net income in 1986 was roughly \$11.5 billion and insurance costs were leveling. *Id.*

220. Page & Stephens, *The Product Liability Insurance "Crisis": Causes, Nostrums and Cures*, 13 *CAP. U. L. REV.* 387, 388 (1984).

221. ATTORNEY GENERAL'S REPORT, *supra* note 2, at 45. In 1974 only 1,579 claims had been filed; by 1985 the figure had grown to 13,554. *Id.*

222. *Id.* (stating that "[t]here is no reason to believe that the state courts have not witnessed a similar dramatic increase in the number of product liability claims").

223. Galanter, *The Day After the Litigation Explosion*, 46 *MD. L. REV.* 3, 6 (1986).

224. NATIONAL CENTER FOR STATE COURTS, STATE COURT CASELOAD STATISTICS: ANNUAL RE-

concluded that there was "no evidence to support the often cited existence of a national 'litigation explosion' in state trial courts during the 1981-1984 period."²²⁵

Marked increases have occurred in some types of suits, especially those involving mass latent injuries, such as claims involving asbestos and the Dalkon Shield.²²⁶ A high percentage of the growth in federal claims is attributable to asbestos claims,²²⁷ but they may constitute a unique, never-to-be-repeated phenomenon.²²⁸ Thus, while areas of steep growth may call for targeted reforms,²²⁹ overall court statistics do not establish a litigation explosion that warrants general reform of products liability law.

Underlying the claim that too many suits are being filed is the belief that too many claims are frivolous and undeserving of attention by the tort system. The real problem, however, may be quite the opposite, that too few meritorious claims are being filed.²³⁰ Evidence suggests that victims bring suits in only a small percentage of the circumstances in which they would be warranted.²³¹ The high costs of litigation screen

PORT 1984, pt. 2 (Ct. Statistics & Info. Mgmt. Project, 1986) [hereinafter NCSC REPORT], noted in Galanter, *supra* note 224, at 6-7.

225. NCSC REPORT, *supra* note 224, at 173. There were significant increases, however, in the number of filings between 1978 and 1981. Significant increases have occurred in states that have experienced the greatest increases in population. *Id.*

226. D. HENSLER, M. VAIANA, J. KAKALIK, & M. PETERSON, TRENDS IN TORT LITIGATION: THE STORY BEHIND THE STATISTICS 10 (1987) [hereinafter STORY BEHIND STATISTICS]. In 1981 there were an estimated 16,000 asbestos claims and by 1986 there were 30,000; in 1981 there were 7,500 Dalkon Shield claims and by 1986, after A.H. Robins had sought protection under a Chapter 11 Bankruptcy petition, there were 325,000 claims. *Id.*

227. Asbestos claims account for about 30% of the products liability claims in federal courts. Galanter, *supra* note 224, at 24-25.

228. T. WILLGING, TRENDS IN ASBESTOS LITIGATION, at xi-xii (1987). The author identifies several features of the asbestos litigation that make it unique, among them that the substance was used so widely and for such a long period, that manufacturers suppressed evidence about its dangers, and that general causation was clearly established, although specific causation was difficult in individual cases. The author concludes that the "singularity of asbestos litigation extends backwards and forwards: There are no historical analogues and no projected recurrences of similar phenomena." *Id.* at xii.

229. ASBESTOS IN THE COURTS, *supra* note 203, at 117-24 (calling for a high-level commission to propose alternatives to or alterations in the tort system to deal specifically with mass toxic tort claims).

230. See Sugarman, *Serious Tort Law Reform*, 24 SAN DIEGO L. REV. 795, 799 (1987). (stating that "many people are intimidated by the idea of bringing a lawsuit to redress their rights, or do not even realize that they have legal rights to redress" (citing British study of accident victims, D. HARRIS, COMPENSATION AND SUPPORT FOR ILLNESS AND INJURY 45-78 (1984))).

231. See Saks, *If There Be A Crisis, How Shall We Know It?*, 46 MD. L. REV. 63, 69 (1986) (stating that "[w]hile I am aware of no adequate data on the ratio of false positive (invalid claims granted) to false negative errors (valid claims uncompensated), the system does appear to contain a large percentage of false negatives" (citing empirical studies showing that one in twenty-five patients with valid medical malpractice claims recover through the tort system and one-quarter of consumer complaints are never pursued)).

out the lower range of claims that are not economically feasible.²³²

C. *Increases in the Size of Recoveries*

A third basis for reform is the argument that damage awards have grown astronomically and need to be contained. Again, the empirical evidence suggests a more complicated picture than generally has been portrayed.²³³ While jury awards have increased in products liability and medical malpractice cases, the evidence does not necessarily reflect that juries are "out of control."²³⁴ Much of the growth in the size of awards is accounted for by changes in economic and social conditions, not by juries gone wild.²³⁵ Factors that increase awards include inflation, medical costs beyond inflation, long life expectations, and higher incomes.²³⁶ Furthermore, awards often are reduced after trial, with the highest awards being reduced the most.²³⁷

D. *Increases in the Cost of Litigation*

The real crisis in the tort system may well be the delays and increased cost of litigating claims.²³⁸ The period between injury and compensation can span as much as five years.²³⁹ In the largest trial court in the nation, the time between initial filing and final disposition of a case averages four years.²⁴⁰ State court statistics show that only about half the tort cases are resolved in less than two years and about ten percent

232. *Id.* at 71 n.31. The author states that

[B]ecause cases involving complex litigation generally are difficult and expensive to prepare, an unusually large fraction of them probably are screened out by attorneys. It makes no economic sense for an attorney to take such a case unless the value of the injury is well over three times the cost of preparing the case.

Id.

233. See STORY BEHIND STATISTICS, *supra* note 227, at 12-24.

234. *Id.* at 21. The report did find higher awards in products liability, medical malpractice, and workplace injuries than in auto cases; even in cases in which the same degree of injury has occurred. The "premium" in the larger awards could be due to the deep pockets of the defendants or to the juries' determinations that these defendants can be deterred most effectively from their misconduct by higher awards. *Id.* The report concluded that more research is needed to determine why and how juries reach their conclusions. Possible explanations are that the cases are changing and juries are doing a better job of calculating losses. *Id.*

235. M. COOPER, TRENDS IN LIABILITY AWARDS: HAVE JURIES RUN WILD? (1986).

236. *Id.*

237. STORY BEHIND STATISTICS, *supra* note 227, at 22-24.

238. See Civiletti, *Zeroing in on the Real Litigation Crisis: Irrational Justice, Needless Delays, Excessive Costs*, 46 MD. L. REV. 40 (1986).

239. *Product Liability Voluntary Claims and Uniform Standards Act: Hearings on S. 1999 Before the Subcomm. on the Consumer of the Senate Comm. on Commerce, Science, and Transportation*, 99th Cong., 1st Sess. 88 (1986) (testimony of Deborah Chalfie, Legislative Director, HALT, An Organization of Americans for Legal Reform).

240. Civiletti, *supra* note 239, at 45.

require four years or more.²⁴¹

The costs of the system are extremely high. Studies reveal that the litigation costs account for more than half of the total amount spent on a tort suit.²⁴² The net compensation to plaintiffs in nonautomobile tort litigation is forty-three percent of the total expenditures.²⁴³ In more complex cases, plaintiffs recover an even lower percentage of total expenditures.²⁴⁴ Thus, reforms to reduce the transactional costs of the system may be needed desperately.

The reforms considered in this Article, however, do nothing to decrease the costs of litigating product claims. Indeed, as discussed earlier,²⁴⁵ the reforms would increase, perhaps substantially, the complexity and the cost of litigating plaintiffs' claims and would exacerbate the problem of transaction costs. In sum, the proposed reforms, with all their weaknesses, cannot be justified on the basis of a products liability/insurance "crisis."

V. CONCLUSION

This Article has set forth a number of reasons why federal regulatory standards should not be treated as conclusively or presumptively adequate measures of safety under the common law.

First, as a practical matter, regulatory standards do not readily mesh with the issues at stake in tort litigation. Often regulations are drafted in general terms and are ambiguous in scope. To determine their applicability with any precision on a case-by-case basis (as would be necessary if compliance were to be given special weight) would complicate the litigation of compliance cases and disadvantage plaintiffs. Allowing juries to consider regulatory compliance and to weigh it as they find appropriate, as they do currently, is a far more simple and fair approach.

Second, the regulatory system is incapable of keeping standards sufficiently up-to-date for the tort system. The agencies often have neither the resources nor the will to do so. Given the prospects of continuing federal budget deficits and cutbacks in agency resources, this problem is likely to continue well into the next decade. The proposed

241. *Id.* Experiments in some jurisdictions with case management and the use of alternative dispute resolution have shown, however, that such delays can be reduced.

242. STORY BEHIND STATISTICS, *supra* note 227, at 27-29.

243. *Id.* at 27. Defendants' time, legal fees, and expenses constitute 30% of the costs; plaintiffs' time, legal fees, and expenses account for 26% of costs; and court expenditures and claims processing constitute 4% of costs. *Id.*

244. *Id.* at 27-28. In asbestos cases, plaintiffs recover 37% of total costs. *Id.* at 28-29. Defendants' legal fees and expenses increase to 37% of total costs in these cases. *Id.*

245. See *supra* notes 34-42 and accompanying text.

reforms also could make the regulatory process itself more complicated and could encourage more industry lobbying for protective regulatory standards. If so, the regulatory process could become even slower, which would make the problem of obsolescence even greater.

Finally, increasing the role of the federal government over the products liability system and decreasing that of the courts is troubling. It centralizes control of the tort system in a few federal agencies and makes it subject to increased business and political pressure, as has occurred during the Reagan Administration. Indeed, the example of the Reagan Administration should serve as a warning of the risks inherent in making tort standards reflect those of the federal regulatory system. The tort system is hardly perfect, and reforms are clearly needed to reduce the transaction costs of the system, but it continues to serve as an independent incentive for product safety in this country.

