Regulatory Standards and Products Liability: Striking the Right Balance Between the Two

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Common law courts have a long tradition of borrowing legislative and regulatory standards to define standards of care under the tort system. Treating such standards as setting minimum levels of care and safety under tort law, the courts uniformly have ruled that violations of standards constitute negligence per se, while compliance is merely evidence of negligence. Although critics of the tort system have urged legislatures and courts to adopt rules giving greater weight to regulatory compliance in products liability cases, the drafters of the Restatement (Third) of Torts: Products Liability have declined to do so. They have adopted instead an approach that largely tracks common law precedent. This Article analyzes the new Restatement's treatment of regulatory and legislative standards, and concludes that the drafters generally have pursued a wise policy, and in a number of respects have improved upon existing common law rules.

INTRODUCTION

Under the common law of negligence and the Restatement (Second) of Torts, courts have a long tradition of borrowing standards of conduct set out in legislation or administrative regulations to define what constitutes reasonable conduct, even where the borrowed legislation or regulation creates no tort liability.1 This judicial borrowing has been discretionary and limited by a set of common law rules aimed at assuring that the borrowed

1 The seminal case is Martin v. Herzog, 126 N.E. 814, 815 (N.Y. 1920) (finding that the absence of buggy lights in violation of state law constituted negligence per se). See also Meshbesher v. Channellene Oil & Mfg. Co., 119 N.W. 428, 429–30 (Minn. 1909) (ruling that violation of pure food statute created strict tort liability); Doherty v. S.S. Kresge Co., 278 N.W. 437, 441 (Wis. 1938) (holding that a defendant can be found liable for injuries caused by unwholesome food if she violates the state's pure food statute "independently of any showing of actual negligence").
standard not only is consistent with tort law doctrine but also furthers the general purposes of the statute or regulation in question.\textsuperscript{2} In general, a borrowed standard is viewed as establishing a minimum, not a maximum, level of safety.\textsuperscript{3} Violations tend to be treated as negligence per se,\textsuperscript{4} while bare compliance is seen merely as evidence of negligence "where a reasonable man would take additional precautions."\textsuperscript{5}

As products liability law took hold in the 1970s and 1980s, courts adapted these negligence-based rules to strict products liability cases, using statutory and regulatory standards as appropriate, to determine whether products were in a "defective

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The Restatement (Second) of Torts adopted the long tradition of borrowing statutory and regulatory standards. 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.

RESTATMENT (SECOND) OF TORTS § 286 (1965).

2. See RESTATMENT (SECOND) OF TORTS § 286 cmt. d (1965) ("When 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."); see, e.g., Stanton v. Astra Pharm. Prods., Inc., 718 F.2d 553, 563–64 (3d Cir. 1983) (finding that violation of a governmental safety regulation constitutes negligence per se where the regulation was intended, in part, to protect individuals similar to the injured plaintiff); Lukaszewicz v. Ortho Pharm. Corp., 510 F. Supp. 961, 964 (E.D. Wis. 1981) (articulating the rule that a statutory standard should be adopted in a tort action only where the statute aims to protect the class of persons and type of harm involved in the tort action); Clinkscales v. Carver, 136 P.2d 777, 778 (Cal. 1943) (noting that "the standard formulated by a legislative body . . . becomes the standard to determine civil liability only because the court accepts it"); Hatch v. Ford Motor Co., 329 P.2d 605, 608 (Cal. Ct. App. 1958) ("Unless the person injured is within the class of persons whom the statute was designed to protect and the hazard is one which the statute was designed to protect against, no liability arises out of its violation."); see also W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 36, at 222 (5th ed. 1984) (arguing that courts use statutory standards only when they further the safety aims of the statutes in question).

3. See RESTATMENT (SECOND) OF TORTS § 288C cmt. a (1965) ("Where a statute, ordinance or regulation is found to define a standard of conduct for the purposes of negligence actions . . . the standard defined is normally a minimum standard, applicable to the ordinary situations contemplated by the legislation.").

4. See id. § 288B(1) ("The unexcused violation of a legislative enactment or an administrative regulation which is adopted by the court as defining the standard of conduct of a reasonable man, is negligence in itself.").

5. Id. § 288C.
condition unreasonably dangerous” to consumers—the liability standard set forth in section 402A of the Restatement (Second).\(^6\)

The new Restatement (Third) of Torts: Products Liability sets out, for the first time, specific rules for borrowing statutory and regulatory standards in products liability cases.\(^7\) It adopts a legal framework that largely follows existing precedent.\(^8\) To the extent there are modifications, they are relatively minor departures from common law rules.\(^9\)

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6. Id. § 402A. Section 402A of the Restatement (Second) of Torts provides:

(1) One 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, if
   (a) the seller is engaged in the business of selling such a product, and
   (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although
   (a) the seller has exercised all possible care in the preparation and sale of his product, and
   (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Id.


7. See RESTATEMENT (TIRD) OF TORTS: PRODUCTS LIABILITY § 7 (Tentative Draft No. 2, 1995) [hereinafter Tentative Draft No. 2]. Section 7 provides:

In connection with a product seller’s or distributor’s liability for defective design or inadequate instructions or warnings:
   (a) a product’s noncompliance with an applicable product safety statute or regulation renders the product defective with respect to the risks sought to be reduced by the statute or regulation; and
   (b) a product’s compliance with an applicable product safety statute or regulation is properly considered in determining whether a product is defective with respect to the risks sought to be reduced by the statute or regulation, but does not necessarily preclude as a matter of law a finding of product defect.

Id.

8. Section 7 of the Restatement (Third) follows the traditional approach that noncompliance with safety regulation renders a product defective per se while compliance with such regulation is relevant but inconclusive evidence of a lack of defect. See id. § 7; infra notes 87, 111, 120 and accompanying text.

9. For example, section 7 eliminates the “excused violation” defense in noncompliance cases recognized under the Restatement (Second). See infra note 98 and accompanying text. Additionally, section 7 of the Restatement (Third), unlike the Restatement (Second), applies only to state and federal laws and regulations, and not to local ordinances.
The key provisions, as set forth in section 7 of the new Restatement (Third), limit judicial borrowing to federal and state statutes and regulations\(^{10}\) that were (1) "in force and applicable" to the product in question at the time of sale,\(^{11}\) and (2) aimed at preventing the risk that caused the harm in the actual case.\(^{12}\) If such standards are appropriate for borrowing, section 7 adopts the same premise adopted historically by the courts that those statutes and regulations should be viewed as establishing minimum levels of safety.\(^{13}\) Thus, products that violate applicable regulatory standards and thereby fail to meet even minimal standards of safety are by definition defective, or defective per se.\(^{14}\) Products that comply with regulatory or statutory standards, however, do not necessarily meet the level of safety required by the liability standards of the Restatement (Third).\(^{15}\) Compliance is relevant but not conclusive evidence of reasonable safety; the weight of the evidence varies with the circumstances of the case and the nature of the standard.\(^{16}\)

10. See Tentative Draft No. 2, supra note 7, § 7. Section 7 applies to "[p]roduct safety statutes or regulations," defined in the comments as those "promulgated by federal and state legislatures and governmental agencies, intended to promote greater safety in the design and marketing of products." Id. § 7 cmt. a. This language departs from the Restatement (Second), which includes local ordinances as well as state and national standards. See Restatement (Second) of Torts § 286 cmt. a (1965). The change reflects that only state and national standards apply to the design and marketing of products; local ordinances, on the other hand, are aimed at how products are used, repaired, installed, etc. See Tentative Draft No. 2, supra note 7, § 7 reporters' notes, at 202.

11. Tentative Draft No. 2, supra note 7, § 7 cmt. b.

12. See id. § 7 cmt. c.

13. See id. § 7 cmt. e, at 198.

Section 7(b) reflects the traditional view that, at least in one important sense, the standards set by most product safety statutes or regulations are minimum standards. Thus, most product safety statutes or regulations establish a floor of safety below which product sellers fall only at their peril, but leave open the question of whether a higher standard of product safety should be applied. This is the general rule, applicable in most cases.

Id. at 198–99.

14. See id. § 7(a). The per se rule does not apply, however, if the statute or regulation is repealed or no longer in effect prior to adjudication, see id. § 7 cmt. b, or where the risk involved in a particular case is not among the risks that the statute or regulation seeks to prevent, see id. § 7 cmt. c.

15. See id. § 7(b). Where a federal law or regulation preempts state tort law, of course, section 7 does not apply. See id. § 7 cmt. e, at 197–98. By its very terms, preemption means that state law is displaced by federal law, and the federal legal standards govern. See id.

16. See id. The drafters leave open the possibility that in some circumstances the court could determine that a product in compliance with a standard is not defective as a matter of law; in other circumstances, however, compliance might be given little or
In taking this traditional approach, the drafters of section 7 rejected many critics’ proposed reforms that would require greater judicial deference to regulatory or statutory compliance. Some critics have argued for a broad rule that would treat compliance as presumptive evidence of non-defectiveness for most regulated products. Others have argued for a narrower version of this approach, limited to closely regulated products that are subject to pre-market approval, such as prescription drugs and devices, and aircraft. The rejection of all such proposals is one of the more significant policy decisions made by the drafters of the new Restatement.

This Article explores that decision, as well as the specific provisions of section 7. Part I begins with an overview of critics’ proposals to require greater judicial deference to government standards in cases of regulatory compliance. It finds these proposals less draconian than many other recent tort reform proposals, and not without some merit, especially with respect to prescription products. Part II then examines the long-standing judicial reluctance to adopt such an approach, even though courts have moved in a pro-defendant direction in other areas. It examines underlying concerns regarding regulatory standards, including the fact that they can become quickly outdated and can be influenced unduly by business interests and the political environment. It concludes that these concerns only

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19. See American Law Inst., supra note 18, at 86–87, 103–05, 109 (proposing a stronger compliance defense for products subject to the greatest regulatory oversight, such as prescription products, pesticides, and aircraft).

20. See sources cited infra note 51 (citing recent studies that show litigation trends favoring defendants).
may grow as cutbacks in government resources impede agency efforts to keep standards up to date and induce even greater government reliance on industry expertise and data in the regulatory process.

Part III examines section 7(a), which provides that noncomplying products are defective per se, and compares this new approach to the per se rule under the Restatement (Second). It finds that section 7(a) strengthens the traditional rule by making it easier for plaintiffs to establish product defectiveness in noncompliance cases. The net effect of the new per se rule may be to give product makers an additional incentive to comply with government standards, thereby promoting broad compliance with the regulatory system and furthering the aims of the statutes in question.

Part IV examines the regulatory compliance provisions in section 7(b). It finds that the drafters have acted wisely in choosing to continue the long-standing common law approach of treating regulatory standards as minimum standards of safety. In addition, it approves of the specific provisions of the section that have been crafted to clarify the standards and provide guidance to the courts on how to apply them. Part IV considers the possible need for a strengthened compliance defense in prescription products cases. It finds that section 8 of the Restatement (Third), which carves out new protective liability standards for all prescription drugs and devices, should obviate any need for additional legal protection, including a strengthened compliance defense, for this category of products.

Finally, the Article concludes that the drafters of the Restatement (Third) have chosen the better rule to govern regulatory compliance and noncompliance. It reflects sound policy and provides an improved formulation of the legal rules in this area of the law.

I. CRITICISMS OF COMMON LAW REGULATORY COMPLIANCE DEFENSE

Critics urging a stronger regulatory compliance defense constitute part of a larger group of critics that in recent years has

22. See Restatement (Second) of Torts § 288B(1) (1965).
attacked the entire products liability system as too costly and erratic, as well as responsible for making insurance less affordable and less available for many products, dramatically increasing prices for some products, deterring innovation, slowing the development and marketing of products, unduly burdening interstate commerce, and reducing American competitiveness in the global marketplace. While these claims have been sharply disputed and the evidence to support them

23. See, e.g., NEWT GINGRICH ET AL., CONTRACT WITH AMERICA 143 (Ed Gillespie & Bob Schellhas eds., 1994) ("Frivolous lawsuits and outlandish damage rewards make a mockery of our civil justice system."); see also AMERICAN LAW INST., supra note 18, at 50 (stating that the tort law system contains "high administrative costs and long delays e 

24. See TORT POLICY WORKING GROUP, supra note 23, at 45–52 (arguing that the incorrect findings of liability, excessive damages, and high transaction costs of the current products liability scheme have created a high burden that decreases the effective availability of insurance).

25. See Brown v. Superior Ct., 751 P.2d 470, 479 (Cal. 1988) (citing the tort system as contributing to sharp increases in the price of Bendectin and DTP vaccine).


27. See Common Sense Product Liability Legal Reform Act of 1996, H.R. 956, 104th Cong. § 2(a)(4) (1996) (vetoed) (noting that because of the liability system's excessive and unpredictable damage awards, "consumers have been adversely affected through the withdrawal of products, producers, services, and service providers from the marketplace"); see also Brown, 751 P.2d at 479 (declining to adopt strict liability for prescription drugs out of concern for, among other things, the adverse effects on pharmaceutical research and development).

28. See H.R. 956, § 2(a)(3) (finding that "excessive, unpredictable, and often arbitrary damage awards and unfair findings of liability have a direct and undesirable effect on interstate commerce by increasing the cost and decreasing the availability of goods and services").


30. See, e.g., Shanks v. Upjohn Co., 835 P.2d 1189, 1195 (Alaska 1992) (finding it "speculative at best" to think that eliminating strict liability in drug cases could enhance "the availability and affordability of prescription drugs"); Judith P. Swazey, Prescription Drug Safety and Product Liability, in THE LIABILITY MAZE: THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION 295–96 (Peter W. Huber & Robert E. Litan eds., 1991) (noting that drug companies, who are in a position to divulge data about the adverse effects of litigation and to document the need for proposed reforms, have been
critics of the current system have pressed, often successfully, for tort and products liability reforms to address their concerns. Proposed reforms have included an array of measures to limit damage awards and to establish legal standards that make claims more difficult to bring or to win. These proposed reforms often include a strengthened regulatory compliance defense as part of their package of reforms.

unwilling to do so); Marc Galanter, News from Nowhere: The Debased Debate on Civil Justice, 71 DENV. U. L. REV. 77, 94–95 (1993) (pointing to a contraction in the number of products liability claims and awards and arguing that “this contraction should induce skepticism about the asserted role of products liability litigation in undermining the competitiveness of American business”); Jerry J. Phillips, Comments on the Reporters’ Study of Enterprise Responsibility for Personal Injury, 30 SAN DIEGO L. REV. 241, 248 (1993) (arguing that “the alleged disincentive to product innovation and development brought about by a strict products liability regime. . . . is not supported empirically, and runs counter to common sense in most respects”).

31. See, e.g., Steven P. Croley & Jon Hansen, What Liability Crisis? An Alternative Explanation for Recent Events in Products Liability, 8 YALE J. ON REG. 1, 89–90 (1991) (finding that only a few products have been seriously affected by increased liability while stating “that for most products the expansion of liability is having only a minor effect on prices”); Michael J. Saks, Do We Really Know Anything About the Behavior of the Tort Litigation System—And Why Not?, 140 U. PA. L. REV. 1147, 1288 (1992) (“In short, our society has been unable to produce research that is even minimally adequate to answer our most basic questions about the behavior of the civil justice system.”); Joseph A. Page, Deforming Tort Reform, 78 GEO. L.J. 649, 689 (1990) (reviewing Peter W. Huber, LIABILITY: THE LEGAL REVOLUTION AND ITS CONSEQUENCES (1988)) (noting that Huber “fails to establish that the harm tort law causes by either removing useful products from the market or failing to discover beneficial products outweighs the benefits”); Colman McCarthy, House Zealots Serve Half-Baked Evidence, WASH. POST, Mar. 21, 1995, at C9 (stating that congressional debates on civil justice reform lacked “hard information” and that in the “debate to reduce the number of lawsuits, no deceits or shards of disinformation about the trial bar were held to be too wild”); Richard B. Schmitt, Truth Is First Casualty of Tort-Reform Debate, WALL ST. J., Mar. 7, 1995, at B1 (opining that “much of the debate [about tort reform] is driven by anecdote, and it doesn’t seem whether detailed facts can be verified”).


33. See Martha Middleton, A Changing Landscape, A.B.A. J., Aug. 1995, at 56, 59 (providing an overview of the past 10 years of state tort law reforms restricting joint and several liability, punitive damages, noneconomic damages, and products liability doctrines); see also Linda Lipsen, The Evolution of Products Liability as a Federal Policy Issue in TORT LAW AND THE PUBLIC INTEREST 262–71 (Peter H. Schuck ed., 1991) (providing detailed information on states that have adopted general tort reform and product liability legislation). In 1995, a spate of bills was introduced in the new Republican Congress to reform the civil justice system, including bills with loser pay provisions that would shift attorney fees to the losing party and provisions to curtail strict liability. See ABA Says No To Litigation “Reforms” in Republican Contract with America, 63 U.S.L.W. 2506, 2506–07 (Feb. 21, 1995).

34. See AMERICAN LAW INST., supra note 18, at 83–110 (urging a regulatory compliance defense for prescription products, pesticides and aircraft); Henderson, supra note 17, at 639 (proposing a rebuttable presumption of nondefectiveness for regulatory
Some of the critics' proposals have been particularly draconian, providing for extreme damage caps on noneconomic losses, and loser-pay provisions to shift attorney fees to the losing party. Many of the proposals to strengthen the compliance defense, on the other hand, have not been as harsh, and have been based on more solid policy grounds.

The proponents of a stronger regulatory compliance defense argue that government agencies are superior to courts in making the technical and policy decisions necessary in product design and warning cases because agencies have greater institutional expertise to determine what constitutes reasonable levels of safety for products within their jurisdiction and because they have the capacity through their rulemaking procedures to gather a broad spectrum of information. In short, these proponents contend that government standards, crafted by experts and developed through a quasi-legislative compliance). A good example of such a proposed reform is the regulatory compliance defense for prescription products that was among the tort reforms on the agenda of the new Republican Congress in 1995. See Product Liability Reform Bill Approved by Wide Margin in House Judiciary Committee, 23 Prod. Safety & Liab. Rep. (BNA) No. 8, at 190–91 (Feb. 24, 1995) [hereinafter Approved by Wide Margin]. This so-called “FDA defense” provision was defeated early in the legislative process. See infra note 50.

35. See, e.g., Tort Policy Working Group, supra note 23, at 68 (limiting noneconomic damages, including punitive damages, to $100,000).


37. See, e.g., Product Liability Fairness Act, S. 640, 102d Cong. § 303(c) (1991) (providing that punitive damages shall not be awarded in products liability cases involving drugs or devices given premarket approval by the Food and Drug Administration (FDA), as long as there is no fraud in obtaining such approval).

38. See Huber, supra note 17, at 333–35 (finding that regulatory agencies' expertise makes them better than courts at assessing the risks posed by new products); Clarence Morris, The Role of Administrative Safety Measures in Negligence Actions, 28 Tex. L. Rev. 143, 144 (1949) (arguing agencies' expertise should be respected and used); Viscusi & Moore, supra note 18, at 125 (arguing that the specialized knowledge possessed by regulatory agencies leaves them better suited than courts for making product safety decisions that implicate greater societal interests); see also Grundberg v. Upjohn Co., 813 P.2d 89, 98–99 (Utah 1991) (finding that prescription drug designs present just the kind of complex “polycentric” problem that courts are poorly suited to address and precisely the kind of problem that the FDA was established to address).

39. See Clarence Morris, The Role of Criminal Statutes in Negligence Actions, 49 Colum. L. Rev. 21, 47 (1949) (pointing to the advantages legislatures have over courts in being able to hold hearings, gather facts, and debate issues when “informed value judgments” need to be made); see also Ramirez v. Plough, Inc., 863 P.2d 167, 176 (Cal. 1993) (deferring to legislative and administrative standards for nonprescription drug labeling on the grounds that the court had neither the resources nor the procedures to undertake the broad review necessary to justify replacing the legislative standard in question).
process, are more likely to be sound and consistent measures of reasonable safety than those set on a case-by-case basis by judges and juries.40

Arguments for a strengthened compliance defense can be more persuasive when limited to prescription products.41 First, the regulatory system for most of these products is more comprehensive than others, requiring extensive scientific review and agency approval before products are allowed on the market. Arguably, this system assures a higher level of product safety and consumer protection.42 Second, prescription products, as a class, are especially valuable to society43 and are perhaps more deserving of a liability rule, such as a strengthened compliance defense, that would narrow the grounds for liability and help reduce any adverse impacts created by the current products liability system.44 Finally, a stronger compliance defense would

40. See Paul Dueffert, Note, The Role of Regulatory Compliance in Tort Actions, 26 HARV. J. ON LEGIS. 175, 208 (1989) (arguing that today's regulatory schemes are more complex and entitled to greater judicial deference than the simple legislative schemes, such as those governing railroad crossings, for which the regulatory compliance rule was first designed); see also Lars Noah, Reconceptualizing Federal Preemption of Tort Claims As the Government Standards Defense, 37 WM. & MARY L. REV. 903, 965 (1996) (noting that "modern regulatory systems more typically represent legislative or administrative efforts to set optimal, not minimal, safety standards").

41. See Noah, supra note 40, at 977 n.285 ("Products regulated by the FDA are the most frequently mentioned as deserving the protections of a government standards defense."). But see Margaret Gilhooley, Innovative Drugs, Products Liability, Regulatory Compliance, and Patient Choice, 24 SETON HALL L. REV. 1481, 1488–93 (1994) (noting situations where a regulatory agency would be unable to review products adequately, and, consequently, a regulatory compliance defense would be inappropriate).


43. Prescription products are unique in that they can save lives, reduce pain, and cure illness. See Brown v. Superior Ct., 751 P.2d 470, 478 (Cal. 1988); see also Grundberg, 813 P.2d at 95 (Utah 1991) (arguing that the "unique nature and value" of prescription drugs, plus FDA's "elaborate regulatory system" overseeing them make strict liability an unsuitable standard to apply). Of course, prescription products also are capable of causing injury on a massive scale, as we have seen with DES and the Dalkon Shield. See Teresa Moran Schwartz, Prescription Products and the Proposed Restatement (Third), 61 TENN. L. REV. 1357, 1359–60 (1994).

44. For criticisms of liability rules and their adverse impact on prescription products, see Huber, supra note 17, at 285–90 (describing how strict liability forced most private companies to stop producing vaccines even though the societal benefit of those vaccines was enormous); Victor Schwartz, Unavoidably Unsafe Products: The Meaning and Policy Behind Comment k, 42 WASH. & LEE L. REV. 1139, 1143 (1985).
clarify and stabilize the liability standards applicable to prescription products, which traditionally have varied among the states and still remain unsettled and unnecessarily confusing.

On the strength of some of these arguments, and without good empirical data about the liability system and its economic impacts, a few states have enacted a stronger regulatory compliance defense in their tort reform packages. This defense, however, has not been one of the more widely adopted tort reforms among the states. Courts have been even less

(assuming that the application of strict liability to drugs marketed in good faith would discourage the release of many potentially beneficial drugs). See also S. Rep. No. 102-215, at 38 (1991) (expressing concern about "overdeterrence of socially desirable products" when they are subject to both regulation and tort liability); Tentative Draft No. 2, supra note 7, § 8 cmt. b, at 212 (referring to the "possible negative effects of judicially imposed liability on the cost and availability of valuable medical technology").

45. One great benefit of borrowing standards is that they establish a "more exact standard that smooths up civil procedure." Morris, supra note 39, at 47.


48. See sources cited supra notes 30-31 (describing the lack of empirical data).

49. See, e.g., Ark. Code Ann. § 16-116-105(a) (Michie 1997) (providing that compliance with statutory or regulatory standards shall be evidence that a “product is not in an unreasonably dangerous condition”); Kan. Stat. Ann. § 60-3304(a)(1994) (providing that if a product complies with administrative or legislative standards, the product is not defective “unless the claimant proves by a preponderance of the evidence that a reasonably prudent product seller could and would have taken additional precautions”); N.D. Cent. Code § 28-01.3-09 (Supp. 1995) (providing a rebuttable presumption of nondefect where a product's plans, designs, warnings, instructions, manufacture, or testing complied with applicable government standards, or where no applicable government standard exists); Ohio Rev. Code Ann. § 2307.76(C) (Anderson 1995) (providing that an “ethical” drug is not defective because of an inadequate warning if the FDA does not require a direct warning to the ultimate user and if the manufacturer provides an adequate warning to the prescriber or dispenser of the drug); Utah Code Ann. § 78-15-6(3) (1992) (providing a rebuttable presumption of nondefect if the design, manufacture, inspection, and testing of the product conform with government standards).

50. See Teresa Moran Schwartz, *Punitive Damages and Regulated Products*, 42 AM. U. L. REV. 1335, 1341 (1993) (“Even with the ‘nationwide burst’ of tort reform statutes adopted throughout the country in the 1980s, this particular reform measure [the strengthened regulatory compliance defense] has not fared well.” (citation omitted)). At the federal level, a limited version of the regulatory compliance defense that appeared in
receptive than legislatures to arguments to increase judicial deference to regulatory and statutory standards. We turn next to consider their concerns.

II. THE JUDICIARY'S CAUTIOUS TREATMENT OF REGULATORY COMPLIANCE

Although courts seem to have been influenced by critics in many areas of tort law,51 they generally have not accepted the critics' argument for a stronger regulatory compliance defense.52 In the absence of legislation,53 courts have continued to adhere to the common law premise that regulatory and statutory standards establish minimum levels of safety and should not substitute across the board for tort standards of safety.54


52. See James A. Henderson, Jr. & Aaron D. Twerski, Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn, 65 N.Y.U. L. Rev. 265, 320 (1990) (observing that "for reasons that we find difficult to understand, courts have not deferred to the determinations of product safety agencies"); see also Dueffert, supra note 40, at 175–77 (discussing the burdensome dual regulation of product safety through statutory requirements and tort law, and the need for a common standard).

53. For examples of recent state legislative provisions adopting some form of strengthened regulatory compliance defense, see supra note 49.

Underlying this judicial approach to regulatory standards may be concerns about the suitability and adequacy of such standards as measures of safety under the tort system. These concerns, discussed more fully below, may stem from a number of factors. For example, (1) regulatory standards are not designed for the tort system and may not be a good fit, (2) government standards can become outdated and therefore too lax as safety standards, (3) agencies and legislatures may be unduly influenced by the regulated industry, and (4) the regulations may be the product of political influence. A number of regulatory failures over the past several decades, resulting in serious injuries to consumers, would seem to confirm the validity of these concerns.

A. Standards Not Designed for Tort Law

By definition, the regulations and statutes that courts are borrowing are not intended to be used to establish standards of

"traditional view" applicable in most cases is that legislative and regulatory standards are minimum standards and "establish a floor of safety below which product sellers fall only at their peril").

55. Even proponents of greater judicial deference to government standards recognize weaknesses in the regulatory system. See, e.g., W. KIP VISCUSI, REFORMING PRODUCTS LIABILITY 118–24, 212 (1991) (acknowledging that reliance on regulation for product safety standards and enforcement is misplaced because regulatory agencies are prone to political pressures, delay, and inefficiency, and often set noncomprehensive or inappropriate standards); see also PAUL J. QUIRK, INDUSTRY INFLUENCE IN FEDERAL REGULATORY AGENCIES 4–14 (1981) (discussing the difficulty of assessing an agency's ability to balance the public interest against the interests of a regulated industry, given the conflicting interests of the two groups and the unquantifiable benefits of regulatory actions); SUSAN J. TOLCHIN & MARTIN TOLCHIN, DISMANTLING AMERICA: THE RUSH TO DEREGULATE 4–9 (1983) (finding that some complaints about government regulation are justified); Teresa Moran Schwartz, The Role of Federal Safety Regulations in Products Liability Actions, 41 VAND. L. REV. 1121, 1147–60 (1988) (discussing problems in the regulatory process, including the strong influence of regulated industries, rapid technological change creating obsolescent regulations, and antiregulatory sentiment among those in power).

56. Failures include medical devices such as the Dalkon Shield, and drugs for which FDA approval was obtained through fraud, such as MER/29, Orflex, and Selacryn. See RUSSELL MOHIBER, CORPORATE CRIME AND VIOLATION: BIG BUSINESS POWER AND THE ABUSE OF THE PUBLIC TRUST 149–62, 289–99, 332–36, 394 (1988); see also Morton Mintz, The Cure That Could Kill You: FDA Reforms Are Bad Medicine, WASH. POST, July 14, 1996, at C1 (listing eight major companies who, over the last 12 years, have failed to report adverse drug reactions within FDA's deadline); John Schwartz, Firm Fined for Selling Faulty Surgical Devices, WASH. POST, Oct. 16, 1993, at A1 (discussing a recent case in which a major manufacturer, C.R. Bard, defrauded the FDA and sold defective medical devices that had not been tested properly or approved by the FDA).
tort liability. Courts therefore exercise considerable care when determining that a standard fits a case. They consider first whether the standard was intended to address the type of injury in the case and second, whether adopting it as the tort standard of safety would advance the aims of the statute in question. Even then, courts cannot assume that legislatures or regulatory agencies have products liability cases in mind when they adopt regulatory standards, or that those bodies would make the same decisions if they took tort law into account. Given these circumstances, courts understandably have taken a cautious approach to adopting regulatory standards.

B. Difficulties of Keeping Regulatory Standards Up to Date

The problem of regulatory lag is of particular concern to courts. Under administrative rulemaking procedures, it can take many years for agencies to set new product safety standards or amend existing ones. As a consequence, government

57. Sometimes statutes specifically provide that regulatory standards are not intended to set standards for tort liability. See, e.g., National Traffic and Motor Vehicle Safety Act, 49 U.S.C. § 30103(e) (1994) ("Compliance with a motor vehicle safety standard . . . does not exempt a person from liability at common law.").

58. Furthering the safety aims of the statute has become the principal rationale for borrowing standards in tort cases. See Schwartz, supra note 55, at 1136–37. For a discussion of how carefully courts have applied the requirement that borrowing standards must further statutory aims, see id. at 1136–40.

59. See id. at 1160 n.199 (according to then Deputy Chief Counsel for Regulation and Hearings at the FDA, the agency does not consider routinely the effects of proposed standards on tort liability during the deliberative process).

60. See, e.g., Hubbard-Hall Chem. Co. v. Silverman, 340 F.2d 402, 405 (1st Cir. 1968) (concluding that neither Congress nor the agency promulgating the standard in question ever intended that it would define the standard of due care imposed by the common law of torts).

61. The FDA's efforts to issue a rule classifying breast implants as a high risk device under the Medical Device Amendments serve as an example. The rule took six years to complete (from 1982 to 1988), and then it took another three years to finalize a rule requiring submission of safety data. See Gayle L. Troutwine, Breast Implants: A Beauty Fraud, TRIAL, Aug. 1993, at 48–50. The FDA's massive review of prescription drugs took more than two decades—from the mid-1960s to the mid-1980s, and led to the withdrawal of more than a thousand drugs from the market. See Schwartz, supra note 55, at 1151 n.139.

Across the federal government, rulemaking and standard setting may become even more time consuming, as congressional interest grows in adding procedural requirements such as cost-benefit analysis, waiting periods for congressional consideration, and expansion of judicial review. See generally Phillip K. Howard, Administrative Procedure
standards frequently become outdated, and are therefore poor measures of safety for the tort system. Indeed, in the modern, high-tech marketplace where new information develops quickly and technological change occurs at a rapid rate, this problem can be expected only to grow.

C. Industry Influence in Standard Setting

In formulating product safety standards, government agencies necessarily rely to a great extent on the industries that will be subject to the regulations, since industry generally has greater technological expertise about product design, knowledge about the costs and benefits of their products, data about risks, and experience in marketing the products. As a result, manufacturers can exert enormous influence on the regulatory outcome. To some extent, the common law rule treating regulatory standards as minimum levels of safety serves to discount that influence.

D. Diminishing Government Resources

The two concerns just discussed—regulatory obsolescence and industry influence on standard setting—grow directly out of the fact that government regulatory resources are so limited. Government must rely on industry data, for example, because


62. See, e.g., Brochu v. Ortho Pharm. Corp., 642 F.2d 652, 658–59 (1st Cir. 1981) (noting that risks became known in 1970 that were not available when FDA’s regulation of oral contraceptives was issued in 1968); Feldman v. Lederle Lab., 479 A.2d 374, 379 (N.J. 1984) (finding that the manufacturer and the FDA had knowledge of risks, but that the FDA failed to act before plaintiff’s injury).

63. See generally ADVISORY COMM. ON THE FOOD AND DRUG ADMIN., U.S. DEP’T OF HEALTH AND HUMAN SERVS., FINAL REPORT (1991) [hereinafter FDA FINAL REPORT] (reporting on the challenges facing the FDA, including insufficient resources and rapidly changing technology).

64. See JOAN CLAYBROOK, RETREAT FROM SAFETY: REAGAN’S ATTACK ON AMERICA’S HEALTH xxiv–xxv (1984) (noting that “the government has far less information than the regulated industry with which to make key regulatory decisions”).

it often lacks sufficient resources to support its own research or to test the reliability of data submitted by others.\textsuperscript{66} Ironically, this problem can be most serious for those agencies whose regulatory responsibilities are the most comprehensive, such as the Food and Drug Administration (FDA) and Federal Aviation Administration (FAA).\textsuperscript{67}

Insufficient funds also cause obsolescence. When Congress expands the jurisdiction of an agency, or when products within the agency's authority proliferate in the marketplace, the agency is seldom given the additional resources needed to support its new responsibilities.\textsuperscript{68} Indeed, a comprehensive FDA study in 1991 found that the agency was “able to monitor a smaller share of the production, distribution, and sale of regulated products than a decade ago.”\textsuperscript{69} With limited resources, of course, agencies have to prioritize their responsibilities, making it necessary to let some regulations grow old and out-of-date.\textsuperscript{70}

Again, this problem is not new. It is, however, almost sure to grow as all levels of government face more and more cutbacks in their resources.\textsuperscript{71} Indeed, with annual budget deficits ahead as far as the eye can see, a smaller role for government seems inevitable well into the next century.\textsuperscript{72}

\textsuperscript{66} Where an agency does rely on industry data, it may lack funds necessary to check the quality of the data. A recent example was the Environmental Protection Agency's inability, due to lack of funds, to check data filed by companies on their release of certain chemicals into the air. See Cindy Skrzycki, \textit{De Facto Deregulation: Changing the Rules of the Game: Slowing the Flow of Federal Rules} (pt. 1), \textit{WASH. POST}, Feb. 18, 1996, at A1.

\textsuperscript{67} See Schwartz, supra note 55, at 1147-49.

\textsuperscript{68} See FDA \textit{FINAL REPORT}, supra note 63, at 15–17, app. C at 2–3. Between 1980 and 1990, the FDA's responsibilities were increased substantially by more than 30 new federal laws and by the enormous growth in the number and complexity of products within the agency's jurisdiction; during this period, however, there was no corresponding increase in its funds or staff to implement those responsibilities. See \textit{id.} at 15–17, app. A at 9–10.

\textsuperscript{69} Id. at 26.

\textsuperscript{70} See David Noland, \textit{Airline Safety: The Shocking Truth}, \textit{DISCOVER}, Oct. 1986, at 30 (finding that the Federal Aviation Administration (FAA) has focused on standards that prevent crashes and has allowed standards that reduce injuries in crashes to grow stale); see also Schwartz, supra note 55, at 1151–52 (reporting that the National Highway Traffic Safety Agency resource-intensive effort to adopt a passive restraint rule for automobiles meant the agency did not have sufficient resources to revise other out-of-date motor vehicle standards).

\textsuperscript{71} See Stephen Barr, \textit{De Facto Deregulation: Changing the Rules of the Games: Cuts Frustrate OSHA Plans to Improve Worker Safety} (pt. 2), \textit{WASH. POST}, Feb. 19, 1996, at A1 (reporting on budget cuts that have forced the Occupational Safety and Health Administration to limit safety inspection, reduce the training of employees, and cut back on the number of safety standards it will issue).

\textsuperscript{72} See infra note 84 and accompanying text.
E. Political Influences

Politics is almost always a factor in the regulatory process. Sometimes it is no more than a general, background influence; other times it is more open and specific. 73 During the 1980s, for example, regulatory relief for business was near the top of the political agenda. 74 In the Reagan administration, the Office of Management and Budget (OMB) played a key role in limiting regulatory activities, 75 and in the Bush administration, the Council on Competitiveness, chaired by Vice President Quayle, played a similar role. 76

Across the board, deregulation was a high priority in this period, with serious consequences for product safety regulation. 77 For example, at the FDA—one of the agencies hardest hit by the Reagan era movement toward deregulation—resources were slashed, enforcement actions fell steeply, 78 and proposed regulatory actions were stopped, slowed, or watered down. 79 Not surprisingly, this “decade of laissez-faire policies” produced a series of notorious scandals at the FDA. 80 To reestablish the

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73. For example, President Reagan made his anti-regulatory agenda very open, promising broad-based regulatory relief, including a package of measures to reduce safety and environmental regulations for the auto industry, described as the industry’s “wish list” of reforms. See Teresa Moran Schwartz, A Product Safety Agenda for the 1990s, 45 WASH. & LEE L. REV. 1355, 1356-57 (1988).

74. See id. at 1362-66.

75. See TOLCHIN & TOLCHIN, supra note 55, at 73-85.


77. See generally CLAYBROOK, supra note 64 (arguing that deregulation by the Reagan administration may result in health and safety regulations that are not based on scientific expertise and, therefore, could impede the development of new product safety designs).

78. See Julie Kosterlitz, Reagan is Leaving His Mark on the Food and Drug Administration, 17 NAT'L J. 1568, 1569-71 (1985) (stating that the average number of annual FDA enforcement actions fell from 542 in the previous administration to 260 under Reagan and that the number of staff fell from roughly 8000 in 1980 to 7000 by 1985).

79. For example, the Secretary of Health and Human Services declined to require warning labels about the risk of Reye’s Syndrome to children using aspirin, despite studies by the Centers for Disease Control establishing the risk; the Office of Management and the Budget delayed regulations involving infant formula and medical devices, and stayed an FDA proposal to ban dyes found by scientists to cause cancer in animals. See id. at 1569-70.

80. Ingersoll, supra note 42, at A1. One major fraud on the FDA in the 1980s—when the FDA, in effect, had “stopped being a regulatory agency”—involved the bribery of FDA staff by generic drug industry members. Michael Specter, Leaderless FDA’s Daunting Task, WASH. POST, Nov. 22, 1989, at A21 (quoting former FDA Commissioner Jere Goyan). Another scandal in this era involved a manufacturer of
credibility of this critically important safety agency, President Bush appointed vigorous new leadership for the agency.

The 1992 and 1994 elections changed the political scene again, once more with implications for the regulatory environment. This time, the combination of declining resources and broad political support for smaller government produced a more subtle but still quite significant "de facto deregulation of American business." Indeed, some view it as "a significant departure from decades of government policy."

Whatever the impact, and however deep and long lasting, one thing is clear: the regulatory environment shifts with the political environment. Such shifts should raise serious concerns for the judiciary about relying on the regulatory system to set the safety standards for the tort system.

_heart catheters who lied to the FDA about the experimental use of its devices, sold devices without FDA approval, and covered up its actions. The FDA ordered a recall of the products by 1990 and then pursued criminal charges. See Philip J. Hilts, Manufacturer Admits Selling Untested Devices for Heart, N.Y. TIMES, Oct. 16, 1993, at A1. The criminal prosecution resulted in a $61 million fine—the largest fine ever imposed in an FDA enforcement case. See Schwartz, _supra_ note 56, at A1. Still another instance of wrongdoing in the 1980s involved Eli Lilly's failure to reveal serious adverse reactions experienced by English users of its drug Oraflex. See CLAYBROOK, _supra_ note 64, at 48–49. The drug was approved, promoted heavily, and caused an estimated 50 deaths before it was withdrawn from the U.S. market. See id. at 48–50._

81. _Cf._ Mintz, _supra_ note 56, at C5 (describing the FDA as "the world's most admired regulatory agency").

82. "This anti-regulatory period came to a halt" with David Kessler's appointment to head the FDA. Schwartz, _supra_ note 43, at 1391.

83. _See De Facto Deregulation: Changing the Rules of the Game_ (pts. 1–4), WASH. POST, Feb. 18–21, 1996, at A1 (four-part series on how the pressures from Congress and the administration, plus budget cuts fundamentally changed the way federal agencies with responsibilities for product safety, the environment, and workplace safety, do their job); _see also_ Mintz, _supra_ note 56, at C5 (describing "FDA reformers emboldened by the Republican takeover of Congress" seeking to change fundamentally the way food and drugs have been regulated since the 1930s by transferring key functions to private contractors).


85. Skrzycki, _supra_ note 66, at A1; _see also_ id. at A10 (describing the myriad actions, including budget cuts, government shutdowns, legislative bans on enforcing specific regulations, proposed regulatory reform legislation, to name but a few, which have had a "significant impact on weakening the resolve and reach of regulators"). In short, a change in "tone and substance" has been created that has accomplished many of the reforms the Republican Congress wanted, but without legislation. _Id._

86. _Id._ at A1.
III. THE PER SE RULE FOR NONCOMPLYING PRODUCTS

Judicial concerns about the adequacy of regulatory standards are at the heart of two key common law rules: (1) that government standards set only minimal levels of safety; and (2) that products in violation of such government safety standards are defective per se. 87

The per se rule, now captured in section 7(a) of the Restatement (Third), 88 has come to play an important role in both the tort and regulatory systems. In the tort system, the rule offers plaintiffs the advantage of relying on government standards to establish the "floor of safety" required under tort law. 89 Like strict liability for flawed products, the per se rule streamlines plaintiffs' cases by eliminating the cost of having to establish independently what constitutes an appropriate standard of safety. 90

The per se rule also furthers the aims of the regulatory system; indeed, this was one of the original justifications for adopting the rule. 91 It furthers those aims by providing companies with an additional incentive for complying with government standards and thereby supports the efforts of regulatory agencies to achieve broad compliance with their standards.

In modern times, the tort system, with its per se rule, creates even greater incentives for regulatory compliance than the regulatory system itself. Noncompliance under tort law is likely to expose a wrongdoer to greater monetary consequences than those imposed by the regulatory system. 92 For example, in cases

88. See Tentative Draft No. 2, supra note 7, § 7(a).
89. Id. § 7 cmt. e, at 198 ("Most [standards] establish a floor of safety below which product sellers fall only at their peril . . . .").
90. Departure from the regulatory standard is treated like departure from the manufacturer's design standards, and strict or per se liability is imposed. See Tentative Draft No. 2, supra note 7, § 2(a) (imposing strict or per se liability when a product "departs from its intended design even though all possible care was exercised").
91. See supra note 58 and accompanying text.
92. Civil and criminal penalties tend to be low even when injuries are high. Consider Selacryn: this drug caused 60 deaths and more than 500 cases of liver damage. Misdemeanor charges, however, resulted in only a $100,000 fine against the company and probation for three executives. See MOKHIBER, supra note 56, at 392–99. In the case of the drug Oraflex, numerous deaths were caused in the United States
where civil or criminal penalties were in the range of $20,000–80,000, tort damages for the same statutory violations amounted to millions, even hundreds of millions of dollars. In addition, unlike civil penalties, tort damages can never be dismissed easily as a cost of doing business. With some exceptions, they carry far more deterrent clout than statutory penalties.

The role for the tort system in assuring regulatory compliance is especially important in these times of limited government. Increasingly, budget cutbacks mean fewer resources for inspections, investigations, and legal actions, and almost certainly greater opportunities for wrongdoers to escape detection and prosecution. In this environment, the products liability system may become the predominant factor in promoting compliance with the regulatory system.

The per se rule of section 7(a) of the new Restatement (Third) preserves tort law’s important role of fostering regulatory compliance. It even strengthens the common law rule in that it rejects rules adopted in a minority of jurisdictions that give less weight to statutory violations and eliminates the “excused

before it was withdrawn from the market; the company “pleaded guilty to 25 misdemeanour counts of failing to notify the FDA of numerous deaths and injuries among overseas users of Oraflex” and paid a fine of only $25,000. Id. at 337.

93. The tort and regulatory systems have imposed widely disparate monetary payments for the same corporate misbehavior. See, e.g., id. (describing how the jury verdict in a wrongful death action involving Oraflex resulted in an award of $6 million while the fine against the company was $25,000); see also JOHN BRAITHWAITE, CORPORATE CRIME IN THE PHARMACEUTICAL INDUSTRY 64 (1984) (recounting that the penalties for fraud in testing and marketing the drug MER 29 were fines against the company of $80,000 and probation for three employees and that the damages awarded in some 1500 civil suits amounted to about $200 million).

94. Where no personal injury results from a statutory violation, civil penalties may be greater than any tort damages. For example, in 1987, Beech-Nut Nutrition Corporation paid a $2 million fine, one of the largest penalties ever imposed for violation of the Food Drug and Cosmetic Act, for selling a bogus fruit drink as apple juice. See United States v. Beech-Nut Nutrition Corp., 677 F. Supp. 117 (E.D.N.Y. 1987), aff’d, 871 F.2d 1181 (2d Cir. 1989); see also Leonard Buder, Beech-Nut is Fined $2 Million for Sale of Fake Apple Juice, N.Y. TIMES, Nov. 14, 1987, at 1.

95. See Skrzynski, supra note 66, at A10. For example, when the government shut down in the fall of 1995, fewer inspectors were available to check imported toys to find those that failed to meet safety standards; the number of toys identified as posing risks fell dramatically in this period. See id. To the extent the government cannot serve to prevent such risky products from entering the marketplace, it is especially important that the tort system serve as an effective deterrent to manufacturers.

96. See Specter, supra note 80, at A21 (describing the bribery of FDA staff by generic drug industry members).

97. See Tentative Draft No. 2, supra note 7, § 7 reporters’ note, at 199–200, 202 (indicating that a minority of jurisdictions hold that regulatory violations create either a rebuttable presumption or merely evidence of negligence or product defectiveness).
Striking the Right Balance

v1.0.8 defense that traditionally has been available.98 Under this defense statutory or regulatory violation can be excused for a number of reasons, including emergency, lack of knowledge, and inability despite due care to comply.99

The drafters of the Restatement (Third) found none of the listed excuses viable in today's products liability context where defendant sellers, as a class, are experts and knowledgeable about the law.100 Although the drafters found that courts "routinely reject" this excuse defense,101 they chose to foreclose all future opportunities to raise it. By strengthening the per se rule in this way, the drafters made it an even more powerful tool for fostering regulatory compliance.102

In the final analysis, the per se rule supports both the tort and regulatory systems.103 In the current environment, however,

98. The seminal case on the per se rule, Martin v. Herzog, 126 N.E. 814 (N.Y. 1920), allowed defendant to argue that the violation should be excused. See also Ramirez v. Plough, Inc., 863 P.2d 167, 172 (Cal. 1993) (finding that proof of a statutory violation creates a presumption of negligence that can be refuted only by showing justification or excuse).

99. See RESTATEMENT (SECOND) OF TORTS § 288A (1965). In listing the excused violations, the Restatement (Second) 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 neither 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.

100. See Tentative Draft No. 2, supra note 7, § 7 reporters' note, at 205.
101. Id.

102. The new rule stands in sharp contrast to the Restatement (Second) approach, which left the door open to the possibility that additional excuses, not in the black letter list, could be available to defendants. See RESTATEMENT (SECOND) OF TORTS § 288A cmt. a (1965).

103. The per se rule is only one way that the products liability and regulatory systems interact to assure product safety for consumers. Concerns about tort liability, for example, may motivate a manufacturer to recall voluntarily a potentially dangerous product under a regulatory statute. See Lewy v. Remington Arms Co., 836 F.2d 1104, 1107 (8th Cir. 1988) (finding punitive damages may be appropriate for a failure to recall a product with known risks); see also Teresa M. Schwartz & Robert S. Adler, Product Recalls: A Remedy in Need of Repair, 34 CASE W. RES. L. REV. 401, 402 (1984) (finding that prompt, voluntary product recalls are especially important if injuries are to be prevented). The tort system also can provide benefits to the regulatory system by uncovering safety risks previously unknown to the government. See DEBORAH R. HENSLER ET AL., ASBESTOS IN THE COURTS: THE CHALLENGE OF MASS TOXIC TORTS at iii, xxv–xxvi, 10–12.
its more important role—and one the new *Restatement (Third)* clearly fosters—may be its support of the regulatory system.

**IV. A LIMITED ROLE FOR REGULATORY COMPLIANCE**

**A. Interaction of Tort and Regulatory Systems in Compliance Cases**

Arguably, the regulatory compliance defense, like the per se rule for noncompliance, also furthers the aims of the regulatory system. This defense provides an additional incentive for compliance by giving companies a safe harbor from tort liability when they comply with statutes and regulations.\(^4\)

It is not clear, however, that a compliance defense is necessary to provide such an incentive because the per se rule alone already provides a powerful incentive.\(^5\) Nor is it clear that a compliance defense that shields defendants from liability actually furthers the safety aims of statutes. In fact, such a defense might have quite the opposite effect and actually undermine consumer safety.\(^6\) Experience shows that product makers already are inclined to “sit back” and wait until regulations are updated and strengthened\(^7\)—an inclination likely to be encouraged by a stronger regulatory compliance defense. A strengthened defense also could serve as an incentive for business to lobby for lower standards during the regulatory

process. These concerns provide more than sufficient grounds for the Restatement drafters' decision not to strengthen the defense, especially given the already mentioned concerns about the adequacy of regulations due to regulatory lag, industry and political influence, and diminishing government resources.

This is not to say, of course, that compliance should not be a consideration in determining whether a product is defective. Indeed, compliance can be relevant, even compelling, evidence of nondefectiveness in individual cases. We turn next to consider the new Restatement's approach to weighing compliance on a case-by-case basis.

**B. Restatement (Third) and Regulatory Compliance**

Consistent with the Restatement (Second) and court rulings, the new Restatement recognizes that in some circumstances courts can find that regulatory standards set optimal levels of safety and that compliance therewith constitutes a complete defense. The Restatement (Third) also goes farther than the Restatement (Second) and most court opinions, however, by providing guidance on how to weigh regulatory compliance in products liability cases. It identifies a number

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108. See Schwartz, supra note 55, at 1160. Not only would it encourage more industry influence during the development of regulatory standards, but it could complicate and prolong the rulemaking process as agencies try to take into account the effects of their rules in defining safety standards for the tort system—something they do not do now. See id.; see also supra notes 59–60 and accompanying text.

109. RESTATEMENT (SECOND) OF TORTS § 288C (1965) (“Compliance with a legislative enactment or an administrative regulation does not prevent a finding of negligence where a reasonable man would take additional precautions.”).

The accompanying comment also recognizes, however, that there can be situations where a “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 cmt. a.


111. See Tentative Draft No. 2, supra note 7, § 7 cmt. e (“After reviewing relevant circumstances . . . a court may properly conclude that a particular product safety standard set by statute or regulation adequately serves the objectives of tort law and therefore that the product that complies with the standard is not defective as a matter of law.”).

112. The Restatement (Second) does supply examples of circumstances where a reasonable person would take additional precautions, such as driving under the speed limit where traffic calls for it, or providing more than the required hand signal where
of circumstances where a regulatory standard might be considered adequate under the tort system: (1) where a standard was "promulgated recently, thus supplying currency";\(^{113}\) (2) where it addresses the "very issue of product design and warning presented in the case";\(^{114}\) and (3) where the standard setting process "was thorough and responsible and reflected substantial expertise."\(^{115}\) The new *Restatement (Third)* also identifies circumstances where compliance should be given "little or no weight," such as where the regulatory process was "tainted" either by false information or by the withholding of necessary and valid information.\(^{116}\)

Not surprisingly, the *Restatement's* guidance addresses many of the concerns discussed earlier about obsolescence, the fairness of the regulatory process, and the proper "fit" of tort and regulatory standards.\(^{117}\) The *Restatement's* approach is also similar to the kind of assessments that courts already are making in compliance cases.\(^{118}\)

Courts, however, do not always articulate fully the grounds for their treatment of standards, and, therefore, critics have suggested that courts may be giving little thought to the issue.\(^{119}\) On some occasions, courts simply apply the general rule there is reason to know that it has not been observed. *See Restatement (Second) of Torts* § 288C cmt. a (1965). Such examples, however, are outdated and offer little guidance in the products liability setting. *See Dueffert, supra* note 40, at 208 (commenting on the fact that the *Restatement (Second)*'s regulatory compliance rules are based upon a time of simpler regulations and simpler accidents). Similarly, judicial opinions often fail to indicate how compliance should be weighed. *See infra* notes 119–20 and accompanying text.

113. Tentative Draft No. 2, *supra* note 7, § 7 cmt. e. The concern here, of course, is the problem of regulatory lag.

114. *Id.* This criterion goes to the issue of whether a regulation fits the case, i.e., whether the expertise of the agency was focused on the same issues now before the court. For a discussion of "fit," *see supra* notes 57-58 and accompanying text.


116. *Id.*

117. *See supra* Part II.A–E.

118. A sampling of cases reveals that courts weigh regulatory compliance in varying degrees, depending on the circumstances of the case. *See infra* notes 120–22 and accompanying text.

119. *See, e.g.*, Stevens v. Parke, Davis & Co., 507 P.2d 653, 661 (Cal. 1973) (stating that "mere compliance" with FDA approved warnings may not be sufficient because those warnings may be "only minimal in nature"); *see also* Henderson & Twerski, *supra* note 52, at 320 ("The [typical court's] analysis usually begins and ends with the statement that agency standards are minimum, not maximum, standards and that courts are therefore free to disregard them."); Noah, *supra* note 40, at 965 (noting that courts dismiss the regulatory compliance defense "out of hand with the oft-repeated and largely unexamined premise that government safety standards are nothing more than minimum requirements").
that standards set minimal levels of safety and then allow the fact finders to give those standards whatever weight they feel they deserve.\textsuperscript{120} On the rare occasions when courts do depart from the general rule and find compliance determinative, however, they offer a fuller explanation.\textsuperscript{121}

In many cases, the courts neither minimize a rule, nor deem it controlling; instead, they acknowledge the general rule for regulatory compliance and then treat compliance as one factor in the analysis. In individual cases, courts often seem to give compliance considerable weight, but no uniform approach to weighing regulatory compliance emerges from these cases.\textsuperscript{122} It is possible, however, that over time the guidance provided by the Restatement (Third) will promote greater uniformity in this area.

\textsuperscript{120} \textit{See}, e.g., Tobin \textit{v.} Astra Pharm. Prods., 993 F.2d 528, 538 (6th Cir. 1993) (opining that "the jury may weigh FDA approval as it sees fit, especially in a case where the plaintiff has presented evidence to support an articulable basis for disregarding an FDA finding"); MacDonald \textit{v.} Ortho Pharm. Corp., 475 N.E.2d 65, 70–71 (Mass. 1985) (treating compliance with an FDA-approved warning on oral contraceptive as a factor to be considered); Jackson \textit{v.} Spagnola, 503 A.2d 944, 948 (Pa. 1986) (arguing that regulatory compliance is "only a piece of the evidentiary puzzle" (quoting Shipp \textit{v.} General Motors Corp., 750 F.2d 418, 421 (5th Cir. 1985))).

\textsuperscript{121} \textit{See}, e.g., Ramirez \textit{v.} Plough, Inc., 863 P.2d 167, 176–78 (Cal. 1993) (explaining the court's rationale for deferring to legislative and administrative standards requiring English-language labels on institutional competence grounds); Grundberg \textit{v.} Upjohn Co., 813 P.2d 89, 96–99 (Utah 1991) (providing a thorough review of the FDA's regulatory process and the value of prescription products in deciding that the court should defer completely to the FDA's risk-benefit analysis in design claims). Perhaps more detailed explanations of decisions to defer to regulatory standards can be explained by the fact that in such circumstances courts are departing from the general rule and therefore need greater justification for their ruling.

\textsuperscript{122} \textit{See}, e.g., Thomas \textit{v.} Hoffman-LaRoche, Inc., 949 F.2d 806, 815–16 (5th Cir. 1992) (finding that an FDA-approved warning was adequate as a matter of law even though the testimony of plaintiff's single expert and the practices of thousands of physicians were contrary to the FDA's view); Lorenz \textit{v.} Celotex Corp., 896 F.2d 148, 152 (5th Cir. 1990) (noting that regulatory compliance constitutes "strong and substantial evidence that a product is not defective"); Bruce \textit{v.} Martin-Marietta Corp., 544 F.2d 442, 448 (10th Cir. 1976) (granting summary judgment where aircraft complied with FAA regulation); Chambers \textit{v.} G.D. Searle & Co., 441 F. Supp. 377, 383–84 (D. Md. 1975) (granting a directed verdict for the defendant involving an FDA-approved oral contraceptive); Johnson \textit{v.} American Cyanamid Co., 718 F.2d 1318, 1325–26 (Kan. 1986) (weighing both compliance with FDA regulations and widespread support for the vaccine in question from the public health community and the medical profession in finding that a directed verdict should have been granted); Beatty \textit{v.} Trailmaster Prods., Inc., 625 A.2d 1005, 1014 (Md. 1993) (ruling that conformity with statutory standards constitutes due care in the absence of special circumstances); McDaniel \textit{v.} McNeil Lab., Inc., 241 N.W.2d 822, 828 (Neb. 1976) (holding that a product in compliance with regulatory standards cannot be challenged simply because the opinions of some experts differ); Wilson \textit{v.} Piper Aircraft Corp., 577 P.2d 1322, 1325–26 (Or. 1978) (finding that compliance with FAA regulations is an important factor in finding that no prima facie case for a design claim had been made).
The impact of the *Restatement (Third)*, of course, is difficult to predict. There is some possibility that it will lead to more frequent treatment of regulatory compliance as determinative of nondefectiveness. Section 7 invites courts to evaluate the regulatory process and the merits of the standard in question, and, if the standard is found sufficient, to adopt it for the products liability system. Additional, in providing a framework for making the regulatory evaluation, it may make it easier for courts to undertake this endeavor.

If, on the other hand, a court wants to adopt a regulatory standard as the tort standard of safety, the new *Restatement* requires that court to explore the regulatory process in greater depth than it has been accustomed to doing. Such an inquiry is complex, time consuming, and one a court may prefer to sidestep, especially if it can achieve the same result by just weighing the compliance heavily and ruling in favor of the defendant on the basis of all the evidence.

In the final analysis, the *Restatement (Third)* may have its greatest impact in the "middle ground" cases where courts weigh compliance but do not find it conclusive. The *Restatement (Third)* offers useful guidance by giving courts criteria for assessing standards. If the courts follow these criteria and explain their decisions, they can produce a body of case law that would help clarify the relationship between products liability and regulatory standards and provide greater uniformity in the treatment of standards.

C. A Special Compliance Defense for Prescription Products?

A final issue deals with whether the drafters of the *Restatement (Third)* should have adopted a stronger compliance defense

123. *See* Tentative Draft No. 2, *supra* note 7, § 7 cmt. e, at 199 ("A conclusion of non-defectiveness may be especially appropriate when the court is confident that the deliberative process by which the safety standard was established was thorough and responsible and reflected substantial expertise." (emphasis added)).

124. *See id.*; cf. *Wilson*, 577 P.2d at 1332-36 (Linde, J., concurring) (discussing the need for courts to examine the scope, purpose, and completeness of a government standard before either adopting or rejecting that standard for a compliance defense).

125. The parties, too, might find this area difficult to explore during tort litigation. Defendants, however, may have a slight advantage as they are more likely to be acquainted with and perhaps even have participated in the standard setting process, whereas plaintiffs are unlikely to be familiar with that process and could find it difficult and costly to challenge. *See Schwartz, supra* note 55, at 1134.
for prescription drugs and devices. As noted above, the support
for this defense has been based on, among other things, the
unique value of these products to society, the role the FDA plays
in assuring their safety, and concerns about the adverse impacts
of tort liability on pharmaceutical research and development.\textsuperscript{126}

In fact, the drafters of the \textit{Restatement (Third)} recognized the
validity of a number of the arguments made in support of such
a defense.\textsuperscript{127} Rather than addressing their concerns with a
special compliance defense, however, they chose another ap-
proach—a set of liability standards specifically tailored for
design and warning claims involving prescription products.
Those standards, which apply both to drugs and devices, are
contained in section 8 of the \textit{Restatement (Third)}.\textsuperscript{128}

\begin{footnotes}
\item[126.] \textit{See supra} notes 41-47 and accompanying text.
\item[127.] \textit{See Tentative Draft No. 2, supra note 7, § 8 cmt. b. Although rejecting
"unqualified deference" to regulatory standards in prescription products cases, the
drafters accepted the notion that the regulatory system is "a legitimate mechanism for
setting the standards for drug design" and that "regulatory agencies adequately review
new prescription drugs and devices, keeping unreasonably dangerous designs off the
market." \textit{Id.}
\item[128.] \textit{Id.} § 8. The second Tentative Draft of the \textit{Restatement (Third)} provides:
\begin{enumerate}
\item A manufacturer of a prescription drug or medical device who commercially
sells or otherwise distributes a defective product is subject to liability for harm
to persons caused by the product defect. A prescription drug or medical device
is one that may be legally sold or otherwise distributed only pursuant to a
health care provider's prescription.
\item For purposes of liability under Subsection (a), a product is defective if at the
time of sale or other distribution:
\begin{enumerate}
\item the drug or medical device contains a manufacturing defect as defined in
§ 2(a); or
\item the drug or medical device is not reasonably safe due to defective design
or because of inadequate instructions or warnings.
\end{enumerate}
\item A prescription drug or medical device is not reasonably safe due to defective
design when the foreseeable risks of harm posed by the drug or medical device
are sufficiently great in relation to its foreseeable therapeutic benefits so that
no reasonable health care provider, knowing of such foreseeable risks and
therapeutic benefits, would prescribe the drug or medical device for any class
of patients.
\item A prescription drug or medical device is not reasonably safe because of
inadequate instructions or warnings when
\begin{enumerate}
\item reasonable instructions or warnings regarding foreseeable risks of harm
posed by the drug or medical device are not provided to prescribing and
other health care providers who are in a position to reduce the risks of harm
in accordance with the instructions or warnings; or
\end{enumerate}
\end{enumerate}
\end{footnotes}
To a significant extent, the new standards for prescription products reflect common law standards applicable in most states.\textsuperscript{129} For example, section 8 retains strict liability for flawed prescription products,\textsuperscript{130} and establishes a negligence-based standard for warning claims, very similar to the standard it adopts for products in general.\textsuperscript{131} On the warning issue most unique to prescription products—the role of the "learned intermediary" health care provider who prescribes the products—section 8 adopts the majority view and provides that warnings need go only to the learned intermediary, not directly to the patient.\textsuperscript{132} Here, as in

\begin{itemize}
\item[(2)] reasonable instructions or warnings regarding foreseeable risks of harm posed by the drug or medical device are not provided directly to the patient when the manufacturer knew or had reason to know that no health care provider would be in a position to reduce the risks of harm in accordance with the instructions or warnings.
\end{itemize}

(e) A retail seller or other distributor of a prescription drug or medical device is subject to liability only if:

\begin{itemize}
\item[(1)] at the time of sale or other nonmanufacturing distribution the drug or medical device contains a manufacturing defect as defined in § 2(a); or
\item[(2)] during the period leading up to the sale or other distribution of the drug or medical device the retail seller or other nonmanufacturing distributor fails to exercise reasonable care and such failure causes harm to persons.
\end{itemize}

\textit{Id.} § 8.


130. The new \textit{Restatement} treats a prescription product containing a "manufacturing defect" like any other product. \textit{Compare} Tentative Draft No. 2, \textit{supra} note 7, § 2(a) (establishing strict liability for manufacturing defects in "products"), \textit{with id.} § 8(b)(1) (applying the same rule to prescription products). This treatment of mismanufactured drugs is based on long standing common law rulings. \textit{See id.} § 8 reporters' note, at 220.

131. \textit{Compare} Tentative Draft No. 2, \textit{supra} note 7, § 2(c) (requiring "reasonable instructions or warnings regarding foreseeable risks of harm" for products in general), \textit{with id.} § 8(d) (making essentially the same requirement applicable to prescription products). Courts have long found no real difference between negligence and strict liability in warning cases. \textit{See, e.g.}, Johnson v. American Cyanamid Co., 718 P.2d 1318, 1324 (Kan. 1986) (finding that negligence principles, not strict liability, apply to warning claims); Feldman v. Lederle Lab., 479 A.2d 374, 386 (N.J. 1984) (finding that negligence and strict liability are "functional equivalents" in warning cases).

132. \textit{See} Tentative Draft No. 2, \textit{supra} note 7, § 8(d)(1). This approach is well grounded in the common law. \textit{See, e.g.}, Polley v. Ciba-Geigy Corp., 658 F. Supp. 420, 422-23 (D. Alaska 1987) (finding that, with the exception of cases involving mass immunizations and oral contraceptives, "Every single court which has considered the
almost every instance, the Restatement (Third) rejects pro-
plaintiff minority rules.\textsuperscript{133}

In contrast, for design claims involving prescription products, the Restatement (Third) departs considerably from common law standards.\textsuperscript{134} It adopts an extremely narrow standard for liability, in effect a kind of "super negligence," requiring plaintiff to establish that the product should not have been marketed at all.\textsuperscript{135} Under this standard, a plaintiff must establish that the risks of the prescription product so outweigh its benefits that no reasonable health care provider, knowing of the risks and benefits, would prescribe the product "for any class of patients."\textsuperscript{136} The acknowledged aim of this new approach is to make design cases, already extremely difficult for plaintiffs to win,\textsuperscript{137} successful only in the most "unusual circumstances."\textsuperscript{138}

In sum, the special rules contained in section 8 of the Restatement (Third) offer considerable protection for prescription products. Perhaps equally important from the industry's standpoint, these rules make it unlikely that courts will further

\textsuperscript{133} See Schwartz, supra note 129, at 401.

The drafters selected as the "better" rules for inclusion in the new Restatement those majority rules that favor defendants, and in almost every case rejected minority rules that favor plaintiffs . . . . While it does not propose draconian measures or a return to an earlier era of harsh "no duty" rules, it does eliminate an array of rules that have made it easier for plaintiffs to pursue their claims.


\textsuperscript{135} See Tentative Draft No. 2, supra note 7, § 8(c).

\textsuperscript{136} Id.

\textsuperscript{137} See generally Viscusi et al., supra note 51 (providing 13 years of statistical data from federal court cases showing that plaintiffs have lower success rates than defendants in product liability claims against pharmaceutical companies).

\textsuperscript{138} Tentative Draft No. 2, supra note 7, § 8 cmt. f.
expand common law liability for these products. In the final analysis, section 8's provisions make any additional legal protection for prescription products unnecessary, including a special regulatory compliance defense.

CONCLUSION

The decision of the drafters of the Restatement (Third) to retain the long-standing common law approach to regulatory compliance and noncompliance was right on both policy and legal grounds. Despite criticisms of the approach, its underlying rationale—that statutory and regulatory standards establish minimum levels of safety for purposes of tort law—remains sound. Indeed, in today's environment of limited government and diminishing resources, there may be more reason to stay with this approach.

The drafters also are to be applauded for the manner in which they have crafted the specific provisions of section 7. They have strengthened the per se rule for non compliance cases in ways that should make it an even more effective tool for fostering regulatory compliance—thereby supporting the regulatory system at a time when government law enforcement resources are shrinking. And the drafters have provided rules and commentary for the regulatory compliance defense that provide useful guidance to the courts and should go a long way toward greater consistency and clarity in this area of the law. In sum, in section 7 of the Restatement (Third), the drafters have accomplished one of the aims of any restatement: they have adopted the "better rule."

139. The greatest impact of the Restatement (Third) may not necessarily come from its specific provisions but rather from "its general policy thrust," i.e., "that liability rules should be less open-ended, the duty of manufacturers more narrowly defined, and courts less innovative." Schwartz, supra note 129, at 413.