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## The Case for a "Strong" Regulatory Compliance Defense

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## The Case for a "Strong" Regulatory Compliance Defense

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# THE CASE FOR A "STRONG" REGULATORY COMPLIANCE DEFENSE

RICHARD C. AUSNESS\*

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## INTRODUCTION

Federal administrative agencies have established safety standards or licensing procedures for airplanes,<sup>1</sup> motor vehicles,<sup>2</sup> pesticides,<sup>3</sup> drugs,<sup>4</sup> medical devices,<sup>5</sup> and a variety of other products.<sup>6</sup> At the same time, product sellers are subject to tort liability even though their products comply with applicable federal safety standards.<sup>7</sup> Product sellers maintain that compliance with federal safety standards ought to protect them from liability under state tort law and have relied upon several legal principles to support this claim. The first, and

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1. See 49 U.S.C. § 1421 (1988 & Supp. II 1990) (granting the Federal Aviation Administration (FAA) authority to control the design and safety requirements of aircraft).

2. See 49 U.S.C.A. §§ 30101-30162 (West Supp. 1995) (formerly codified at 15 U.S.C. §§ 1381, 1391, 1395, 1396 (1988)) (directing the Secretary of Transportation to promulgate safety standards for motor vehicles).

3. See Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136-136y (1994) (authorizing the Environmental Protection Agency (EPA) to regulate the development, manufacture, sale, and use of pesticides).

4. See Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301, 321, 331-337, 341-353, 355-363, 371-379, 381-383, 391-394 (1994); Public Health Service Act (PHSA), 42 U.S.C. §§ 247b, 262 (1994); Anne N. James, Comment, *Warnings and the Pharmaceutical Companies: Legal Status of the Package Insert*, 16 HOUS. L. REV. 140, 143 (1978) (stating that FDCA and PHSA combine to authorize the FDA to regulate virtually all aspects of the manufacture and marketing of pharmaceutical products).

5. See Medical Device Amendments of 1976 (MDA), Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified in part at 21 U.S.C. §§ 360c-k (1994) (authorizing FDA to approve the manufacture and sale of medical devices).

6. See generally Richard C. Ausness, *Federal Preemption of State Products Liability Doctrines*, 44 S.C. L. REV. 187, 189-90 (1993) (describing various federal product safety statutes).

7. Garey B. Spradley, *Defensive Use of State of the Art Evidence in Strict Products Liability*, 67 MINN. L. REV. 343, 367 (1982) (indicating that compliance with federal safety standards "constitutes some evidence of adequacy of the product's design, but is not conclusive").

most successful, theory is federal preemption.<sup>8</sup> Under this concept, Congress may expressly or impliedly assert the primacy of federal law under the Supremacy Clause of the U.S. Constitution,<sup>9</sup> thereby displacing competing (or even complementary) state regulation.<sup>10</sup> So far, product manufacturers have successfully invoked the doctrine of preemption to defeat damage claims by injured consumers in connection with cigarette labeling, pesticide labeling, motor vehicle design, and medical device labeling and design.<sup>11</sup>

The regulatory compliance defense is another concept that can limit tort liability. In its strong version, the regulatory compliance defense provides that a product is not defective if it meets applicable regulatory standards or requirements. However, very few jurisdictions recognize regulatory compliance as a complete defense to tort liability. Instead, most courts allow juries to take compliance with regulatory standards into account, but steadfastly refuse to treat federal safety standards as anything more than minimum standards.<sup>12</sup>

Many commentators have argued that courts should pay more deference to federal product safety standards.<sup>13</sup> This position is based on the assumption that administrative agencies generally do a good job of regulating product safety.<sup>14</sup> Consequently, manufacturers whose products comply with these standards should not ordinarily be required to comply with additional standards imposed upon them by

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8. See Barbara L. Atwell, *Products Liability and Preemption: A Judicial Framework*, 39 BUFF. L. REV. 181, 181 (1991) (stating that federal preemption is a popular defense in product liability cases because of the predominant role of federal agencies in regulating products).

9. U.S. CONST. art. VI, cl. 2; see *infra* note 101.

10. See Atwell, *supra* note 8, at 183 (discussing the doctrine of federal preemption of state law).

11. See *infra* part III.

12. See *infra* part IV.

13. See, e.g., Richard A. Epstein, *Legal Liability for Medical Innovation*, 8 CARDOZO L. REV. 1139, 1151 (1987) ("What is needed, I believe, is a rule that provides that certain warnings approved by, say, the FDA shall be conclusively regarded as adequate in any subsequent lawsuit."); 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, 321 (1990) ("Courts recognizing the limits of their institutional capabilities should refuse to second-guess the judgments of agencies who possess not only expertise but also a capacity for knowledge and memory which the courts cannot match."); Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 335 (1985) ("Once a determination has been made by an expert licensing agency, the courts should respect it."); John P. Raleigh, *The "State of the Art" in Product Liability: A New Look at an Old "Defense"*, 4 OHIO N.U. L. REV. 249, 261 (1977) ("[W]here government standards have been promulgated, there should be adopted judicially, or adopted by legislative action if necessary, a limitation on product design responsibility to coincide with the 'state of the art' or the level of 'skill in performance' as reflected by the governmental standards.").

14. See *infra* part II.

principles of state tort law.<sup>15</sup> On the other hand, injured consumers should be allowed to challenge federal safety standards that are obsolete or inadequate.<sup>16</sup> Because under the doctrine of federal preemption, federal standards would displace tort liability even when they were inadequate, preemption should be rejected as a comprehensive solution to the problem of dual regulation.<sup>17</sup>

The regulatory compliance defense has more flexibility because it would allow injured parties to challenge unsatisfactory regulatory standards. Unfortunately, the regulatory compliance defense, as it presently exists in most states, provides virtually no protection to manufacturers whose products comply with federal safety standards. However, a stronger regulatory compliance defense, which would immunize manufacturers from tort liability as long as their products satisfied reasonably adequate federal safety standards, may be a more promising solution to the problem of dual regulation.<sup>18</sup>

Part I of this Article provides a brief overview of significant federal product safety legislation. Part II sets forth the argument that administrative agencies can regulate product safety more cheaply and effectively than tort law. The concept of federal preemption is discussed and critiqued in part III. Part IV focuses on the conventional treatment of regulatory compliance in products liability law and proposes a "strong" regulatory compliance defense that will foreclose most damage claims against product manufacturers who comply with federal safety standards. Finally, part V analyzes the effect such a proposal would have on product safety and the compensation of injured consumers. The Article concludes that the administrative cost savings that a strong regulatory compliance defense would achieve should more than offset any negative effects that the defense might have on product safety and victim compensation.

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15. See Raleigh, *supra* note 13, at 261 ("It is patently absurd that the machinery of governmental standard setting should be observed through vigorous procedures, and that designers should be required to meet the mark of that standard, only to have their designs second guessed and their responsibilities expanded case by case . . .").

16. See James A. Henderson, Jr., *Manufacturers' Liability for Defective Product Design: A Proposed Statutory Reform*, 56 N.C. L. REV. 625, 638-40 (1978) (discussing a proposed product liability reform statute that would allow a plaintiff to overcome a presumption that a product was safe, simply because it complied with federal regulations, by producing clear and convincing evidence that the regulation was inadequate).

17. *Id.* at 638-39 ("Not all regulations sufficiently protect against risks to merit being employed as standards in product liability cases. To accept without question all regulations would be to prejudice unfairly the rights of plaintiffs in some cases.")

18. See *infra* part V.

## I. AN OVERVIEW OF FEDERAL PRODUCT SAFETY LEGISLATION

Federal agencies play a major role in the regulation of product safety.<sup>19</sup> For example, the Consumer Product Safety Act of 1972<sup>20</sup> created the Consumer Product Safety Commission (CPSC)<sup>21</sup> to issue safety standards for consumer products.<sup>22</sup> These standards impose requirements for design, construction, packaging, warnings, instructions, and product performance.<sup>23</sup> In addition, the Commission has the power to ban consumer products that cannot be made safe through the enforcement of such standards.<sup>24</sup> The Commission also administers various "transferred acts," such as the Flammable Fabrics Act,<sup>25</sup> the Federal Hazardous Substances Act,<sup>26</sup> the Child Protection and Toy Safety Act of 1969,<sup>27</sup> and the Poison Prevention Packaging Act of 1970.<sup>28</sup>

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)<sup>29</sup> authorizes the Environmental Protection Agency (EPA) to regulate the manufacture, sale, and use of pesticides.<sup>30</sup> All pesticides must be registered with the EPA before they can be sold.<sup>31</sup> The EPA will permit registration of a pesticide only if it can perform its intended function safely and "without unreasonably adverse effect on the environment."<sup>32</sup> The EPA regulates product labeling as part of its registration process.<sup>33</sup> The Agency not only approves particular warning language for a product, but also specifies the type, size, color, and placement of such warnings.<sup>34</sup>

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19. See *supra* notes 1-6 and accompanying text (describing various federal regulatory statutes).

20. 15 U.S.C. §§ 2051-2084 (1994).

21. See *id.* § 2053 (describing the composition and authority of the CPSC).

22. *Id.* § 2056(a)(1)-(2).

23. *Id.* Section 2056 states:

A consumer product safety standard shall consist of one or more of any of the following types of requirements: (1) Requirements expressed in terms of performance requirements. (2) Requirements that a consumer product be marked with or accompanied by clear and adequate warnings or instructions, or requirements respecting the form of warnings or instructions.

*Id.*

24. *Id.* § 2057.

25. *Id.* §§ 1191-1204.

26. *Id.* §§ 1261-1277.

27. *Id.* §§ 1261, 1262, 1274, 1278.

28. *Id.* §§ 1471-1474, 1976.

29. 7 U.S.C. §§ 136-136y (1994).

30. *Id.* §§ 136, 136a, 136w.

31. *Id.* § 136a(a), (c).

32. *Id.* § 136a(c)(5)(C).

33. *Id.* § 136a(c)(5)(B), (c)(6).

34. See 40 C.F.R. § 156.10(a) (1995).

The National Traffic and Motor Vehicle Safety Act of 1966<sup>35</sup> directs the Secretary of Transportation to promulgate safety requirements for automobiles and other motor vehicles.<sup>36</sup> Each safety standard must protect the public against "unreasonable risk of accidents occurring because of the design, construction, or performance of motor vehicles and . . . unreasonable risk of death or injury in an accident."<sup>37</sup> Federal Motor Vehicle Safety Standards currently govern safety glass, door strength and latch design, fuel system integrity, occupant protection, and numerous other aspects of motor vehicle safety.<sup>38</sup>

The Federal Food, Drug, and Cosmetic Act<sup>39</sup> and the Public Health Service Act<sup>40</sup> authorize the Food and Drug Administration (FDA) to regulate the development, production, testing, and labeling of chemical drugs and biological products.<sup>41</sup> The FDA requires manufacturers to produce, package, and store all pharmaceutical products in accordance with prescribed "Good Manufacturing Practice."<sup>42</sup> In addition, the FDA must license new prescription drugs before they can be marketed.<sup>43</sup> This licensing process begins with the submission

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35. See Pub. L. No. 89-563, 80 Stat. 718 (1966). This statute was originally codified at 15 U.S.C. §§ 1381, 1391, 1392, 1395, 1396 (1988). In 1994, the statute was recodified. Pub. L. No. 103-272, 108 Stat. 1379 (1994). The National Traffic and Motor Vehicle Safety Act is now codified as 49 U.S.C.A. §§ 30101-30162 (Supp. 1995).

36. 49 U.S.C.A. § 30111(a) (formerly codified at 15 U.S.C. § 1392).

37. *Id.* § 30102(a)(8) (formerly codified at 15 U.S.C. § 1391(1)). See generally Michael D. Hitt, Comment, *Occupant Protection in Automobiles—Air Bags and Other Passive Restraints: The State of the Art, the Federal Standard, and Beyond*, 27 AM. U. L. REV. 635, 643 (1978) (declaring that the federal standard is one of "reasonable safety").

38. See Stephen J. Werber, *The Products Liability Revolution—Proposals for Continued Legislative Responses in the Automotive Industry*, 18 NEW ENG. L. REV. 1, 46 (1982-83).

39. 21 U.S.C. §§ 301-394 (1994).

40. 42 U.S.C. § 247b (1988 & Supp. II 1990).

41. 41 U.S.C. § 262 (1988 & Supp. II 1990); see also Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301, 343 (1994) (indicating that the FDA, along with the U.S. Department of Agriculture (USDA), also regulates the labeling of food and other products for human consumption); Fair Packaging and Labeling Act, 15 U.S.C. § 1451 (1994) (declaring congressional policy that the packaging and labeling of consumer products should enable the purchaser to obtain accurate information regarding the content and quality of the product); Federal Meat Inspection Act, 21 U.S.C. §§ 601, 611 (1994) (authorizing USDA meat inspection program); Egg Products Inspection Act, 21 U.S.C. §§ 1031, 1036 (1994) (authorizing USDA egg inspection program); Poultry Products Inspection Act, 21 U.S.C. §§ 451, 457 (1994) (authorizing USDA poultry inspection program).

42. See 21 C.F.R. pt. 211 (1995) (drugs); 21 C.F.R. pt. 820 (1995) (medical devices); see also Jeffrey N. Gibbs & Bruce F. Mackler, *Food and Drug Administration Regulation and Products Liability: Strong Sword, Weak Shield*, 22 TORT & INS. L.J. 194, 203-04 (1987) (discussing the new drug approval process).

43. 21 U.S.C. § 355(a) (1988).



of an Investigational New Drug (IND) application,<sup>44</sup> and if the IND application is approved, the manufacturer is then allowed to prepare a formal New Drug Application (NDA).<sup>45</sup> The NDA must contain all information that is known about the drug at the time of the application.<sup>46</sup> Prior to licensing, experts review the data in the NDA and determine that the drug is safe and effective for its intended purpose.<sup>47</sup> Vaccines and other biological products are subject to a similar licensing process.<sup>48</sup>

The Medical Device Amendments of 1976 (MDA)<sup>49</sup> authorize the FDA to approve the manufacture and sale of medical devices.<sup>50</sup> New devices are approved by a Premarket Approval Application (PMA) process that involves clinical testing of the product and review of test results by a panel of outside experts.<sup>51</sup> Medical devices that are "substantially equivalent" to products that were in commercial distribution prior to the passage of the MDA may be licensed under a less rigorous procedure.<sup>52</sup>

The Federal Aviation Administration (FAA), acting under the authority of the Federal Aviation Act of 1958,<sup>53</sup> regulates commercial and private aircraft safety.<sup>54</sup> As a part of this responsibility, the FAA promulgates airworthiness standards, known as Federal Aviation Standards or "FARS."<sup>55</sup> These regulations impose requirements for air-

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44. *Id.* § 355(i). See generally Note, *A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals*, 103 HARV. L. REV. 773, 776 (1990) (describing the contents of an IND application).

45. 21 U.S.C. § 355(b)(1).

46. *Id.*; see also Pennington P. Landen, *Federal Preemption and the Drug Industry: Can Courts Co-Regulate?*, 43 FOOD DRUG COSM. L.J. 85, 100 (1988) (describing the contents of an NDA).

47. 21 U.S.C. § 355(d) (1988); see 21 C.F.R. § 314.125(b)(1)-(16) (1995) (detailing reasons for denying approval of an NDA).

48. See generally Peggy J. Naile, Note, *Tort Liability for DPT Vaccine Injury and the Preemption Doctrine*, 22 IND. L. REV. 655, 688-89 (1989) (discussing FDA regulation of vaccines and biologics).

49. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified in part at 21 U.S.C. §§ 360c-k (1994)).

50. 21 U.S.C. § 360c. See generally Edward M. Basile, *Improving FDA's Product Approval Process for Medical Devices*, 41 FOOD DRUG COSM. L.J. 287, 288-89 (1986) (discussing the time delays associated with obtaining approval by the FDA for new medical devices).

51. 21 U.S.C. §§ 360c(a)-(g), 360e(c); see Gibbs & Mackler, *supra* note 42, at 207-09 (discussing the PMA process).

52. 21 U.S.C. §§ 360c(f)(1)(A)(i)-(ii), 360e(b).

53. 49 U.S.C. §§ 1301-1557 (1988 & Supp. V 1993).

54. *Id.* § 1421 (authorizing the FAA to impose regulations to promote the safety of civil aircraft).

55. See *id.* § 1421(a)(1) (granting the FAA authority to establish minimum safety standards relating to aircraft design, materials, construction, and performance of aircraft engines and systems).

craft performance and flight characteristics, structural integrity, fuel systems, hydraulic systems, electrical systems, engines, instruments, lights, and safety equipment.<sup>56</sup>

Finally, the Occupational Safety and Health Act (OSHA)<sup>57</sup> requires employers to provide a safe workplace for their employees and to comply with all occupational safety and health standards promulgated under the Act.<sup>58</sup> These standards are formulated by the Department of Labor and cover virtually every aspect of worker safety, including safety standards for industrial machinery.<sup>59</sup> In this fashion, the Department exercises considerable, though indirect, control over product safety.

## II. *EX ANTE* REGULATION VERSUS *EX POST* LIABILITY

Products liability is a mixture of state tort law and federal regulation.<sup>60</sup> Although both of these approaches seek to achieve an optimal level of product safety, they operate in very different ways.<sup>61</sup> Federal administrative agencies regulate product safety directly by establishing mandatory requirements that manufacturers must meet in order to sell their products to the public.<sup>62</sup> In contrast, tort liability regulates product safety indirectly by holding manufacturers liable to injured parties for product-related accident costs.<sup>63</sup> A comparison of these

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56. *Id.*; see also 14 C.F.R. pt. 23 (1995) (describing FARS for general aviation); 14 C.F.R. pt. 25 (1995) (describing FARS for transport aircraft).

57. 29 U.S.C. §§ 651-1678 (1994).

58. *Id.* § 654(a). See generally Barbara M.G. Lynn, Comment, *The Occupational Safety and Health Act of 1970: Its Role in Civil Litigation*, 28 Sw. L.J. 999, 999-1003 (1974) (describing the purpose and enforcement procedures of OSHA).

59. 29 U.S.C. § 655(a); 29 C.F.R. § 1910 (1994).

60. See Paul Dueffert, Note, *The Role of Regulatory Compliance in Tort Actions*, 26 HARV. J. ON LEGIS. 175, 177 (1989) (discussing how product manufacturers are subject to a dual system of regulation).

61. See Donald Wittman, *Prior Regulation Versus Post Liability: The Choice Between Input and Output Monitoring*, 6 J. LEGAL STUD. 193, 205-09 (1977) (comparing *ex ante* regulation, which employs standards in order to prevent harm from ever occurring, with *ex post* liability, which imposes liability for harm caused from the violation of standards); Christopher D. Stone, *The Place of Enterprise Liability in the Control of Corporate Conduct*, 90 YALE L.J. 1, 16-19 (1980) (discussing harm-based liability rules, which are triggered upon the occurrence of the harm, and standards-based liability rules, which attempt to prevent harm from ever occurring).

62. See Craig Brown, *Deterrence and Accident Compensation Schemes*, 17 U.W. ONT. L. REV. 111, 112 (1979) ("There is also the regulatory approach to deterrence with some institution in society determining standards of safety for activities and requiring that those standards are met.").

63. See Epstein, *supra* note 13, at 1139 ("Tort remedies tend to operate by indirection: There is no direct supervision over the behavior of the various parties who, it is hoped, are induced to perform properly by the threat of actions for damages.").

approaches suggests that in many ways direct regulation is a superior method of risk control for products.<sup>64</sup>

### A. *Advantages of Ex Ante Regulation*

One advantage of *ex ante* regulation is that its mandates are specific and uniform. In addition, regulatory agencies have the necessary competence to make correct decisions about product safety issues, and also have effective methods of enforcing their safety requirements. Finally, and most importantly, regulation of product safety by federal agencies is relatively inexpensive.

1. *Specificity and Uniformity.*—Regulatory safety standards may be either descriptive or performance oriented. Descriptive or specification standards mandate the use of particular materials, processes, designs, or labeling.<sup>65</sup> Performance standards describe the performance characteristics of a product but do not specify how these characteristics are to be achieved.<sup>66</sup> Performance standards are thought superior to descriptive standards because they allow for flexibility without sacrificing the benefits of specificity.<sup>67</sup> However, both descriptive standards and performance standards are more specific than tort liability rules.<sup>68</sup> Unlike regulatory safety standards, tort liability rules regarding causation and foreseeability are often open-ended and contextual.<sup>69</sup>

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64. The discussion below should not be regarded as an argument for every form of regulation. Federal regulatory programs are often unnecessary, ineffective, wasteful, and oppressive. The point that I am trying to make is that existing federal safety standards on product labeling and design are preferable in most cases to equivalent regulation under tort law.

65. See James A. Brodsky & Marsha N. Cohen, "Uncle Sam," *the Product Safety Man: Consumer Product Safety Standards in the Marketplace and in the Courts*, 2 HOFSTRA L. REV. 619, 624 (1974) (asserting that descriptive standards limit design initiatives).

66. See Susan Rose-Ackerman, *Tort Law in the Regulatory State*, in TORT LAW AND THE PUBLIC INTEREST 80, 95 (Peter H. Schuck ed., 1991) (promoting the superior incentive characteristics of performance standards).

67. See John Braithwaite, *The Limits of Economism in Controlling Harmful Corporate Conduct*, 16 LAW & SOC'Y REV. 481, 483-84 (1981-82) (enumerating the advantages of performance standards over descriptive standards).

68. See Henderson, *supra* note 16, at 638 ("The utility of federal product safety regulations as standards for decision is their specificity.").

69. For example, in failure-to-warn cases, concepts like causation and foreseeability make it difficult to determine what a manufacturer must do to meet its duty. See Henderson & Twerski, *supra* note 13, at 270 ("Concepts such as risk foreseeability, risk-utility balancing, and proximate causation are so devoid of content in the failure-to-warn context that they cannot hope to test the bona fides of the plaintiff's claim."); W. Kip Viscusi et al., *Detering Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 SETON HALL L. REV. 1437, 1468 (1994) [hereinafter Viscusi et al., *Inefficient Pharmaceutical Litigation*] ("In the context of warnings litigation, the absence of

Another advantage of federal regulations is that they apply uniformly throughout the country. Uniform standards allow manufacturers to take advantage of economies of scale because they do not have to employ different product designs and labeling for different markets.<sup>70</sup> Tort liability doctrines, on the other hand, often vary widely from state to state. This lack of uniformity increases production costs without providing any increased safety benefit.

2. *Agency Decision-making.*—Regulatory agencies are generally well-equipped to make objective decisions about risk management and other product safety issues.<sup>71</sup> First of all, agency personnel are likely to be familiar with the technical aspects of the products they regulate and, when necessary, they can commission studies and obtain advice from outside experts.<sup>72</sup> Second, the procedures by which product safety standards are formulated provide the agency with opinions and information from a wide variety of sources. Consequently, agencies can take a diversity of interests into account when they make decisions about product safety.<sup>73</sup>

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meaningful standards is quite troublesome."). In design defect cases, the risk-utility test, which sets forth a number of factors for consideration by the jury, is far too vague to provide clear answers to either manufacturers or juries. See W. Kip Viscusi, *Wading Through the Muddle of Risk-Utility Analysis*, 39 AM. U. L. REV. 573, 575-76 (1990) [hereinafter Viscusi, *Wading Through the Muddle*] (arguing that the risk-utility test in design defects cases is too vague). But see Steven L. Holley, Note, *The Relationship Between Federal Standards and Litigation in the Control of Automotive Design*, 57 N.Y.U. L. REV. 804, 820 (1982) ("The problem of uncertainty is outweighed by the value of preserving independent, decentralized determinations of design deficiency by a politically insulated judiciary.").

70. See Susan B. Foote, *Administrative Preemption: An Experiment in Regulatory Federalism*, 70 VA. L. REV. 1429, 1462-63 (1984) ("If many states have differing design standards, national marketing becomes constrained and economies of scale become impossible."); Mary Lee A. Howarth, Comment, *Preemption and Punitive Damages: The Conflict Continues Under FIFRA*, 136 U. PA. L. REV. 1301, 1324-25 (1988) (discussing product labeling problems that would result if pesticide labeling was regulated by the individual states).

71. See Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 335 (1985) ("Regulatory agencies are equipped to make the risk comparisons on which all progressive transformation of the risk environment must be based."); Naile, *supra* note 48, at 694 (noting that federal agencies have greater ability than laymen to evaluate the safety of products).

72. See Holley, *supra* note 69, at 819 (finding that one advantage of federal regulation over tort liability is the ability of regulatory agencies to research broad safety concerns as opposed to the narrow issues involved in individual cases).

73. See W. KIP VISCUSI, *REFORMING PRODUCTS LIABILITY* 212 (1991) ("[W]e should . . . attempt to shift the task of promoting product safety to those institutions [such as administrative agencies] that are better equipped to handle the necessary societal tradeoffs."); Dix A. Noel, *Products Defective Because of Inadequate Directions or Warnings*, 23 SW. L.J. 256, 258 (1969) ("An administrative agency, after extensive and impartial research, can understand engineering complexities better than a jury, and can better balance against safety the other interests such as economy, style and performance."); Huber, *supra* note 71, at 335 ("Regu-

On the other hand, courts are institutionally incapable of resolving complicated product safety issues.<sup>74</sup> In the first place, both judges and lay juries often have difficulty understanding technical or scientific evidence.<sup>75</sup> Second, access to information is limited because litigants have no incentive to provide courts with information unless it supports their position.<sup>76</sup> Finally, the case-specific nature of the trial process causes courts and juries to focus on narrow issues and prevents them from paying proper attention to broader social or safety concerns.<sup>77</sup>

3. *Enforcement.*—Administrative agencies have a wide assortment of enforcement devices at their disposal.<sup>78</sup> An agency may secure compliance with safety standards by such measures as inspections and licensing procedures. In addition, an agency can respond to potential safety threats by ordering recalls of dangerous products.<sup>79</sup> Finally, when violations occur, federal agencies can enforce civil or criminal penalties against the guilty parties. Although some commentators have criticized federal agencies for lax enforcement of product safety

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latory agencies are equipped to make the risk comparisons on which all progressive transformation of the risk environment must be based.”). *But see* Barry R. Furrow, *Governing Science: Public Risks and Private Remedies*, 131 U. PA. L. REV. 1403, 1437 (1983) (“The relative freedom of the courts from short-term political pressures gives them a unique perspective from which to gauge the long-term risks and implications of major new developments, without the unique problems associated with administrative agencies.”).

74. *See* James A. Henderson, Jr., *Judicial Review of Manufacturers’ Conscious Design Choices: The Limits of Adjudication*, 73 COLUM. L. REV. 1531, 1531 (1973) (“Courts are inherently unsuited to the task of establishing product safety standards in cases involving the liability of manufacturers.”); Huber, *supra* note 71, at 319 (“[T]ort liability is a poor vehicle for choosing risks because judges and juries have little capacity to make risk choices wisely.”).

75. *See* Scott G. Lindvall, Note, *Aircraft Crashworthiness: Should Courts Set the Standards?*, 27 WM. & MARY L. REV. 371, 401 (1986) (discussing the difficulties courts and juries have in understanding aircraft design issues); Peter J. Mooney, Note, *Judicial Participation in the Establishment of Vehicle Safety Standards: A System in Need of Reform*, 54 TEMP. L.Q. 902, 919-20 (1981) (indicating that juries have difficulty discerning between design choices that were selected and those that were rejected by motor vehicle manufacturers).

76. Henderson, *supra* note 74, at 1532-33 (indicating the inability of courts to adequately investigate safety standard decisions by manufacturers).

77. *See* VISCUSI, *supra* note 73, at 8-9 (“[T]he courts are not regulatory agencies and do not have the expertise to set safety levels, especially since they must act within the narrow perspective of a particular case.”); Note, *A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals*, 103 HARV. L. REV. 773, 780 (1990) (“[T]he narrow focus of the trial setting and the tort system’s reliance on lay juries as the final arbiter of complex scientific issues make it difficult for the tort system to internalize scientific data appropriately.”).

78. *See* Dueffert, *supra* note 60, at 177 (describing the various enforcement mechanisms that regulatory agencies employ).

79. *Id.*

standards,<sup>80</sup> agencies generally do a good job of enforcing their existing regulations.<sup>81</sup> In contrast, the tort system relies entirely upon private enforcement. As a result, the judicial response to product safety problems is haphazard at best.<sup>82</sup>

4. *Administrative Costs.*—As a system of risk control, *ex ante* regulation is much cheaper to administer than *ex post* liability systems such as tort law.<sup>83</sup> The administrative costs of government regulation include the general expenses of maintaining an agency staff as well as the cost of formulating and enforcing safety standards. The tort system's administrative costs include the costs to manufacturers of discerning the applicable safety standards under tort law.<sup>84</sup> They also include the legal expenses incurred by plaintiffs, defendants, and liability insurers to adjudicate damage claims.<sup>85</sup> In addition, some of the

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80. See Peter L. Kahn, *Regulation and Simple Arithmetic: Shifting the Perspective on Tort Reform*, 72 N.C. L. REV. 1129, 1182 (1994) ("[T]he vast scope of potential product risks, the constantly changing array of consumer products and the technology which it embodies, and the inherently limited resources available to agencies, virtually assures that agencies will sometimes fail to act even when legitimate product risks fall within their jurisdiction.").

81. See, e.g., Robert S. Adler, *From "Model Agency" to Basket Case—Can the Consumer Product Safety Commission Be Redeemed?*, 41 ADMIN. L. REV. 61, 117 (1989) (noting that CPSC's recall program is considered to be a great success story); Gregory C. Jackson, Comment, *Pharmaceutical Product Liability May Be Hazardous to Your Health: A No-Fault Alternative to Concurrent Regulations*, 42 AM. U. L. REV. 199, 215-16 (1992) ("Though criticized in the past as underfunded, ill-equipped, and incapable of effectively performing its public-protection mandate, the FDA has recently been granted significant funding increases by Congress.").

82. For example, many injured parties fail to sue. See Robert A. Prentice & Mark E. Roszkowski, *"Tort Reform" and the Liability "Revolution": Defending Strict Liability in Tort for Defective Products*, 27 GONZ. L. REV. 251, 259 (1991-92) (finding that only one in ten of those injured each year by defective products brings suit against manufacturers). At the same time, excessive damage claims create an "overdeterrence" problem for some industries. See Charles J. Walsh & Marc S. Klein, *The Conflicting Objectives of Federal and State Tort Law Drug Regulations*, 41 FOOD DRUG COSM. L.J. 171, 177 (1986) (discussing the negative effect of tort liability on development and introduction of new pharmaceutical products).

83. See Viscusi et al., *Inefficient Pharmaceutical Litigation*, *supra* note 69, at 1450 (1994) ("Direct regulation can sometimes achieve the social goal of deterring inefficient accidents more economically and accurately than the indirect incentives provided through tort law.").

84. See Victor E. Schwartz & Liberty Mahshigian, *A Permanent Solution for Product Liability Crises: Uniform Federal Tort Law Standards*, 64 DENV. U. L. REV. 685, 692 (1988) ("Because the rules vary from state to state . . . both manufacturers and claimants spend unnecessary time, effort and resources determining what the applicable legal rules are . . .").

85. See Steven Shavell, *Liability for Harm Versus Regulation of Safety*, 13 J. LEGAL STUD. 357, 363-64 (1984) ("[T]he costs of the tort system must be broadly defined to include the time, effort, and legal expenses borne by private parties in the course of litigation or in coming to settlements . . .").

expense of maintaining the civil courts may be attributed to the tort system.<sup>86</sup>

It is generally agreed that the tort system's administrative costs are enormous.<sup>87</sup> This is because manufacturers or their liability insurers must spend large amounts of money to investigate, defend, and settle product liability claims.<sup>88</sup> Plaintiffs, of course, also incur heavy litigation costs if their claims are contested.<sup>89</sup> A study conducted by the RAND Corporation during the mid-1980s estimated that net annual compensation to plaintiffs under tort law totaled between \$14 billion and \$16 billion, while administrative costs ranged from \$16 billion to \$19 billion.<sup>90</sup> Although more recent cost estimates are not available, if one extrapolates the figures from these earlier studies, it is

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86. One study estimated that the cost to the court system of the average tort case was \$407 per case in a state court and \$1740 per case in a federal court. The overall expenditure was \$425 million. See J.S. KAKALIK & R.L. ROSS, COSTS OF THE CIVIL JUSTICE SYSTEM: COURT EXPENDITURES FOR VARIOUS TYPES OF CIVIL CASES 81-85 (1983); see also JOHN G. FLEMING, THE AMERICAN TORT PROCESS 18-21 (1988) (examining the transaction costs of the tort system).

87. See FLEMING, *supra* note 86, at 18 ("The most negative feature of the tort system is its staggering overhead cost."); Stephen D. Sugarman, *Doing Away with Tort Law*, 73 CAL. L. REV. 558, 596 (1985) ("[T]he tort system is fabulously expensive to operate in comparison to modern compensation systems."); Jackson, *supra* note 81, at 233 ("Strict liability thus creates excessive administrative or transactional costs in the form of litigation expenses . . .").

88. See John G. Fleming, *Is There a Future for Tort?*, 44 LA. L. REV. 1193, 1207 (1984) ("Compensation [under the tort system] is dependent on issues of causation and fault, which require investigation and are frequently contested.").

89. Most plaintiffs hire attorneys on a contingent fee basis. If successful, the attorney typically receives about one-third of the plaintiff's recovery. See Lester Brickman, *Contingent Fees Without Contingencies: Hamlet Without the Prince of Denmark?*, 37 UCLA L. REV. 29, 30 (1989) (describing the one-third rate as "standard"); Christopher F. Edley, Jr. & Paul C. Weiler, *Asbestos: A Multi-Billion-Dollar Crisis*, 30 HARV. J. ON LEGIS. 383, 393 (1993) (noting that the usual range of contingent percentage is 30% to 40%); John F. Vargo, *The American Rule on Attorney Fee Allocation: The Injured Person's Access to Justice*, 42 AM. U. L. REV. 1567, 1617 (1993) (discussing the contingent arrangement as generally a one-third percentage).

90. See JAMES S. KAKALIK & NICHOLAS M. PACE, COSTS AND COMPENSATION PAID IN TORT LITIGATION 69 (1986) ("To deliver this \$14 to \$16 billion in net compensation, the tort litigation system expended \$16 to \$19 billion in transaction costs."). The administrative costs of the tort system are not only high in absolute terms, but they are high in relation to the amount of compensation paid to victims. According to one study, only 47 cents of every dollar spent by manufacturers on product-related claims ultimately reaches the claimant. See Michel A. Coccia, *Uniform Product Liability Legislation: A Proposed Federal Solution*, 51 INS. COUNS. J. 104, 117 (1984) (asserting that under the present system more money goes to attorneys and claims investigators than injured claimants). In contrast, approximately 30% of the cost of the workers' compensation system is attributable to administrative costs. See Robert E. Litan, *The Liability Explosion and American Trade Performance: Myths and Realities*, in TORT LAW AND THE PUBLIC INTEREST, *supra* note 66, at 127, 135 (questioning whether the possible deterrence benefits warrant the high costs of the current system). Administrative costs consume only 15% of the health insurance premium dollar and 1% of the Social Security system dollar. *Id.*

not unreasonable to conclude that the tort system's current administrative costs are probably in the \$20 billion to \$25 billion range.<sup>91</sup>

The administrative costs of direct regulation seem modest by comparison. For example, at the time of the RAND Corporation study, the FDA's budget was \$409 million, the National Highway Traffic Safety Administration's (NHTSA) budget was \$246 million, and CPSC's budget was only \$34 million.<sup>92</sup> Even today, the administrative costs of direct regulation, as indicated by the budgets of various federal agencies, are still quite low in comparison with the administrative costs of the tort system. For example, the proposed fiscal year (FY) 1997 budget for the FDA is \$1.02 billion;<sup>93</sup> a FY 1997 budget of \$352 million was suggested for NHTSA,<sup>94</sup> and CPSC's budget will be \$43 million.<sup>95</sup> These agency budgets add up to more than \$1.5 billion. Even if one includes the costs of product safety activities by such agencies as the OSHA and the FAA, the total budgetary cost of direct regulation for product safety probably does not exceed \$2 billion per year.<sup>96</sup>

In fairness, the administrative costs of direct regulation should also take into account the cost to manufacturers of complying with agency licensing, testing, and recordkeeping requirements.<sup>97</sup> Although there is no way to calculate these costs precisely, it is doubtful that they amount to more than several billion dollars a year. Adding this estimate to the \$2 billion figure for current agency budgets results in approximate administrative costs of government regulation of \$4 billion per year. This total is considerably less than the cost of tort litigation involving defective products.<sup>98</sup>

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91. If we assume a 3% per year increase in administrative costs starting in 1985, the RAND study's lower estimate of \$16 billion would rise to \$21.5 billion by 1995 and the study's higher estimate of \$19 billion would rise to about \$25.5 billion by 1995.

92. See Adler, *supra* note 81, at 61 n.2.

93. See BNA HEALTH CARE DAILY (Mar. 20, 1996).

94. See INSIDE DOT & TRANSP. WEEK (Mar. 21, 1996).

95. See ANALYTICAL PERSPECTIVES, BUDGET OF THE U.S. GOV'T, FISCAL YEAR 1997, at 484 (1996).

96. OSHA's proposed budget for FY 1997 is \$341 million, but most of this will be spent on other regulatory activities. *Id.* at 453-54. Likewise, the FAA's proposed budget for FY 1997 is \$8.25 billion, but most of this will be spent on airport construction and air traffic control. See INSIDE DOT & TRANSP. WEEK (Mar. 21, 1996).

97. The production costs that manufacturers incur in order to comply with additional safety requirements are not considered to be administrative costs. In any event, if safety regulations are economically efficient, marginal savings in liability costs will equal or exceed marginal costs for product safety.

98. See *supra* notes 87-91 and accompanying text. Much of the \$20 to \$25 billion dollar cost of the tort system covers automobile accidents, slip and fall cases, medical malpractice, and other activities that are not directly regulated by federal administrative agencies. To



B. *Upholding the Primacy of Ex Ante Regulation*

The foregoing discussion suggests that *ex ante* regulation is a cheaper and more effective method of risk control than *ex post* liability. At the present time, however, manufacturers must comply with the requirements of both regulatory regimes. Unfortunately, this dual system of regulation often sends conflicting signals to product manufacturers. For example, while the FDA strictly regulates the labeling of pharmaceutical products in order to promote "rational prescribing" by physicians,<sup>99</sup> the tort system frustrates this goal by encouraging manufacturers to place warnings on their products that exaggerate known risks or raise unwarranted concerns about hypothetical or unproven risks.<sup>100</sup>

Clearly, one system of risk control must prevail, while the other system is restricted to a complementary or subordinate role. In view of the inherent superiority of direct regulation over tort liability, it appears that government standards should occupy this position of primacy in the regulation of product safety. However, at the present time, tort liability standards often prevail over government regulations because courts treat the latter as makeweights rather than as authoritative judgments about product safety issues. Such judicial decisions undermine the credibility and authority of agency decisionmaking and impair the regulatory effect of federal safety standards.

Something needs to be done to ensure that federal safety standards are not marginalized by courts when product safety is at issue. Federal preemption and the regulatory compliance defense are two principles that can be used to compel courts to give more weight to federal product safety standards. The remaining portions of this Article will examine these concepts and will propose an approach that emphasizes the strengths of both tort liability and government regulation.

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be fair, one must compare only the relative costs of tort law and federal regulation in the products liability area. However, the cost of litigating product liability claims almost certainly exceeds the cost of federal product safety regulation.

99. See Richard M. Cooper, *Drug Labeling and Products Liability: The Role of the Food and Drug Administration*, 41 FOOD DRUG COSM. L.J. 233, 238 (1986) ("FDA's interest is in rational prescribing."); *Feldman v. Lederle Labs.*, 592 A.2d 1176, 1200 (N.J. 1991) ("[FDA] has an interest in 'rational prescribing,' i.e., ensuring that the risks and benefits of a particular drug be fairly presented so that a physician can compare them with other available therapies."), *cert. denied*, 112 S. Ct. 3027 (1992).

100. See Walsh & Klein, *supra* note 82, at 187-88 (stating that if drug manufacturers are compelled to notify physicians of every potential hazard of each drug, they will have a strong incentive to press the FDA for approval of warnings based on unreliable information).

### III. FEDERAL PREEMPTION OF STATE PRODUCT LIABILITY CLAIMS

#### A. *The Preemption Doctrine*

According to the Supremacy Clause of the U.S. Constitution, federal legislation may preempt state law under certain circumstances.<sup>101</sup> This same principle applies to state common-law doctrines<sup>102</sup> and local ordinances.<sup>103</sup> Moreover, a federal agency, acting within the scope of its authority, may also preempt state and local law.<sup>104</sup>

Courts and commentators traditionally distinguish between various types of preemption.<sup>105</sup> For example, express preemption occurs when a federal statute or administrative regulation specifically excludes state regulation in a particular area.<sup>106</sup> However, federal law may also preempt state regulation when the federal government com-

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101. U.S. CONST. art. VI, cl. 2. Article VI states in pertinent part: "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."

102. See, e.g., *International Paper Co. v. Ouellette*, 479 U.S. 481, 487 (1987) (holding that the Clean Water Act preempts nuisance actions against out-of-state defendants); *Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981) (holding that the interstate Commerce Clause preempts state law tort claim based on abandonment of railway service).

103. See, e.g., *City of Burbank v. Lockheed Air Terminal, Inc.*, 411 U.S. 624, 640 (1973) (holding that FAA regulations preempt a municipal airport curfew ordinance).

104. See, e.g., *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 699-700 (1984) (holding that FCC regulations with respect to television cable operators preempt state law prohibiting advertising of alcoholic beverages); *Ray v. Atlantic Richfield Co.*, 435 U.S. 151, 178 (1978) (holding that Department of Transportation regulations on oil tanker safety preempt state tanker safety law); *Free v. Bland*, 369 U.S. 663, 670 (1962) (holding that Treasury regulations creating right of survivorship for holders of U.S. savings bonds preempt state community property laws).

105. For a general discussion of the various categories of preemption, see Atwell, *supra* note 8, at 183-91. See also Richard C. Ausness, *Cigarette Company Liability: Preemption, Public Policy, and Alternative Compensation Systems*, 39 SYRACUSE L. REV. 897, 913-24 (1988) ("The preemption doctrine is a reflection of the fact that Congress may pass legislation which nullifies inconsistent state statutes."); S. Candice Hoke, *Preemption Pathologies and Civic Republican Values*, 71 B.U. L. REV. 685, 699-701 (1991) (discussing the nature of implied and express preemption claims); Elaine M. Martin, Note, *The Burger Court and Preemption Doctrine: Federalism in the Balance*, 60 NOTRE DAME L. REV. 1233, 1234-37 (1986) ("The Supreme Court has traditionally recognized three types of pre-emption—express, conflict, and occupation of the field."); Louise Weinberg, *The Federal-State Conflict of Laws: "Actual" Conflicts*, 70 TEX. L. REV. 1743, 1796-98 (1992) (rejecting traditional preemption analysis and proposing instead a unified approach to deciding conflicts between state and federal law based on conflict-of-laws principles).

106. See, e.g., *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 108 (1983) (holding that the Employee Retirement Income Security Act (ERISA) preempts state antidiscrimination law requiring employers to pay sick leave benefits to pregnant employees); *Fidelity Fed. Sav. & Loan v. de la Cuesta*, 458 U.S. 141, 170 (holding that federal banking regulations preempt state restrictions on due-on-sale clauses in residential mortgages).

pletely occupies a particular regulatory field.<sup>107</sup> In addition, state law will be preempted when it is impossible to comply with both federal and state law,<sup>108</sup> when state law impairs the exercise of federal rights or benefits, or when state law stands as an obstacle to federal regulatory goals.<sup>109</sup>

### B. *Preemption of State Product Liability Claims*

In recent years, manufacturers have argued that tort claims should be barred by the preemption doctrine when their products comply with applicable federal labeling or design requirements.<sup>110</sup> When a manufacturer invokes the preemption doctrine as a defense to tort liability, the court must determine whether Congress intended to foreclose tort suits by injured consumers. This task is complicated by the fact that no federal product safety statute explicitly mentions whether such tort claims are preempted. Despite this lack of legislative guidance, many courts have concluded that federal product safety statutes preempt such claims.

1. *Federal Cigarette Labeling and Advertising Act.*—Section 1334(b) of this Act declares that if cigarette packages carry the statutorily mandated health warning, no additional requirements or prohibitions relating to smoking and health may be imposed under state law with

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107. See, e.g., *Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293, 310 (1988) (holding that pervasive federal regulation preempts state law regulating financing of natural gas pipelines); *Graham v. Richardson*, 403 U.S. 365, 377-81 (1971) (holding that the dominant federal interest in foreign affairs preempts state welfare eligibility requirements that discriminate against aliens).

108. See, e.g., *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963) (holding that when compliance with both state and federal law is impossible, federal law preempts state law).

109. See, e.g., *International Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987) (holding that a state law is preempted if it interferes with the methods by which a federal statute was designed to achieve a certain goal); *Michigan Canners & Freezers Ass'n, Inc. v. Agricultural Mktg. & Bargaining Bd.*, 467 U.S. 461, 478 (1984) (holding that a state law authorizing producers' associations to engage in conduct that a federal act forbade stood as an obstacle to congressional objectives and was consequently preempted by federal law); *McCarty v. McCarty*, 453 U.S. 210, 235 (1981) (preempting state community property law that reduced the value of federal life insurance contract for military personnel); *Hisquierdo v. Hisquierdo*, 439 U.S. 572, 585 (1979) (holding that federal railroad retirement benefits are not subject to state law claims of divorced spouse); *McDermott v. Wisconsin*, 228 U.S. 115, 137 (1913) (finding preemption of a state labeling law because it would subject syrup producer who complied with federal law to criminal liability for mislabeling).

110. See generally *Ausness*, *supra* note 6, at 200-31 (discussing recent litigation involving preemption of product liability claims); Lars Noah, *Reconceptualizing Federal Preemption of Tort Claims as the Government Standards Defense*, 37 WM. & MARY L. REV. 903, 926-38 (1996) (same).

respect to advertising or promotional activities.<sup>111</sup> This language obviously prohibits states from imposing mandatory labeling requirements by statute or administrative regulation.<sup>112</sup> Until recently, however, it was not clear whether the terms "requirements and prohibitions" included liability imposed under principles of state tort law.<sup>113</sup> This issue was finally settled in 1992, when the Supreme Court in *Cipollone v. Liggett Group, Inc.*<sup>114</sup> held that the duty to warn was a state law requirement with respect to advertising and promotion, and as such, was expressly preempted by the Act.<sup>115</sup> This holding effectively barred failure-to-warn claims based on cigarette package labeling subsequent to 1969.<sup>116</sup>

2. *Consumer Product Safety Act.*—The Consumer Product Safety Act (CPSA) expressly preempts state product safety standards that differ from those promulgated by the Consumer Product Safety Commission.<sup>117</sup> The Commission may exempt a state standard from preemption if it concludes that the proposed standard provides "a significantly higher degree of protection" from the product risk covered by the existing federal standard and that the proposed state standard

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111. 15 U.S.C. § 1334(b) (1994).

112. See Leila B. Boulton, Comment, *Tobacco Under Fire: Developments in Judicial Responses to Cigarette Smoking Injuries*, 36 CATH. U. L. REV. 643, 655 (1987) (declaring that 15 U.S.C. § 1334 bars states from directly regulating cigarette labeling or advertising).

113. Although most courts concluded that the labeling act preempted state failure-to-warn claims, almost all commentators prior to the *Cipollone* decision, see *infra* note 114 and accompanying text, reached the opposite conclusion. See, e.g., Ausness, *supra* note 105, at 924 (arguing that 15 U.S.C. § 1334 does not preempt claims under state tort law); Bruce A. Levin, *The Liability of Tobacco Companies—Should Their Ashes Be Kicked?*, 29 ARIZ. L. REV. 195, 231-36 (1987) (concluding that the labeling act does not preempt state failure-to-warn claims); Boulton, *supra* note 112, at 666 (stating that because of the strong presumption against preemption, plaintiffs should be allowed to bring failure-to-warn claims against cigarette manufacturers); Taylor A. Ewell, Comment, *Preemption of Recovery in Cigarette Litigation: Can Manufacturers Be Sued for Failure to Warn Even Though They Have Complied with Federal Warning Requirements?*, 20 LOY. L.A. L. REV. 867, 919 (1987) (stating that the cigarette labeling act expresses congressional intent not to preempt state failure-to-warn claims).

114. 112 S. Ct. 2608 (1992).

115. *Id.* at 2625. For an analysis of *Cipollone*, see Richard C. Ausness, *The Impact of the Cipollone Case on Federal Preemption Law*, 15 J. PROD. & TOXICS LIAB. 1, 6-18 (1993).

116. The Court concluded that the 1965 Act did not expressly preempt such claims. *Cipollone*, 112 S. Ct. at 2619. At the same time the *Cipollone* Court upheld a variety of other claims, such as breach of express warranty, fraudulent misrepresentation, and conspiracy to misrepresent or conceal health risks associated with smoking. *Id.* at 2622-25.

117. 15 U.S.C. § 2075(a) (1994); see also *National Kerosene Heater Ass'n v. Commissioner*, 653 F. Supp. 1079, 1088 (D. Mass. 1986) (holding that the CPSA would have preempted a state statute regulating unvented kerosene heaters if the CPSC had issued mandatory standards).

will "not unduly burden interstate commerce."<sup>118</sup> At the same time, another provision of the Act declares that compliance with CPSA safety standards will not immunize a manufacturer from civil liability.<sup>119</sup> This suggests that the CPSA will not preempt product liability claims by injured consumers.<sup>120</sup>

A number of decisions also test the preemptive effect of the Federal Hazardous Substances Act (FHSA) and the Flammable Fabrics Act (FFA), both of which are administered by the CPSC.<sup>121</sup> The FHSA has an express preemption provision.<sup>122</sup> This has led several courts to conclude that compliance with the Act's labeling requirements will preempt inadequate warning claims.<sup>123</sup>

Section 1203(a) of the Flammable Fabrics Act expressly preempts nonidentical state flammability standards.<sup>124</sup> States may adopt stricter standards for their own use<sup>125</sup> and they may request the Consumer Product Safety Commission to authorize them to promulgate stricter standards.<sup>126</sup> Despite this preemptive language, the courts generally

118. 15 U.S.C. § 2075(c); *see also* James L. Winokur & Jennifer Robbins, *Consumer Product Safety: Preemption, the Commerce Clause and State Regulatory Authority*, 25 VILL. L. REV. 232, 247-62 (1979-80) (discussing the CPSA's preemption provision).

119. 15 U.S.C. § 2074(a).

120. *See* Paul Sherman, *Use of Federal Statutes in State Negligence Per Se Actions*, 13 WHITTIER L. REV. 831, 859 (1992) ("There are no reported cases in which a claim of federal preemption under the Consumer Product Safety Act has been upheld."). *But see* *Moe v. MTD Prods., Inc.*, 73 F.3d 179, 182 (8th Cir. 1995) (holding that CPSA expressly preempts failure-to-warn claim, but not design defect claim, against manufacturer of lawnmower).

121. *See supra* notes 25-26 and accompanying text.

122. 15 U.S.C. § 1261 note (b)(1)(A) (1994).

123. *See Moss v. Parks Corp.*, 985 F.2d 736, 740-41 (4th Cir.) ("To the extent the Plaintiff seeks warnings that are more elaborate or different from those issued by Congress and promulgated by CPSC, . . . those claims are preempted."), *cert. denied*, 113 S. Ct. 2999 (1993); *Lee v. Boyle-Midway Household Prods., Inc.*, 792 F. Supp. 1001, 1007-09 (W.D. Pa. 1992) (holding that, if Congress intended to occupy the field of labeling drain cleaning products, any state claim that would mandate different requirements would be preempted by federal requirements); *Salazar v. Whink Prods. Co.*, 881 P.2d 431, 434 (Colo. Ct. App. 1994), *cert. denied*, 115 S. Ct. 1315 (1995) (finding that FHSA preempts claim against manufacturer of rust stain remover based on failure to provide adequate warnings on product's label). *But see* *Chemical Specialties Mfrs. Ass'n v. Allenby*, 958 F.2d 941, 949-50 (9th Cir.) (holding that a state statute requiring "point of sale" warnings for products determined to be carcinogenic or reproductively toxic does not conflict with FHSA and, therefore, is not preempted), *cert. denied*, 113 S. Ct. 80 (1992); *Jenkins v. James B. Day & Co.*, 634 N.E.2d 998, 1005 (Ohio 1994) (holding that an inadequate warning claim is not preempted when the product warning allegedly failed to meet FHSA requirements); *Birch v. Amsterdam Corp.*, 366 A.2d 1079, 1085 (D.C. Ct. App. 1976) (holding that FHSA establishes only minimum warning requirements and the Act does not necessarily preclude a finding that an actor was negligent in failing to take additional precautions).

124. 15 U.S.C. § 1203(a) (1994).

125. *Id.* § 1203(b).

126. *Id.* § 1203(c).

have allowed injured parties to sue manufacturers who have complied with FFA flammability standards.<sup>127</sup>

3. *Federal Insecticide, Fungicide, and Rodenticide Act.*—Although FIFRA permits the states to regulate the sale and use of registered pesticides,<sup>128</sup> section 136v(b) declares that no state shall impose “any requirements for labeling or packaging in addition to or different” from those required by the EPA.<sup>129</sup> At the present time, there is a split of authority over the preemptive effect of FIFRA,<sup>130</sup> although

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127. See *Raymond v. Riegel Textile Corp.*, 484 F.2d 1025, 1027-28 (1st Cir. 1973) (holding that a claim against a manufacturer was not preempted even though the children's nightwear product complied with FFA flammability standards); *Gryc v. Dayton-Hudson Corp.*, 297 N.W.2d 727, 734-35 (Minn.) (holding that a manufacturer of children's pajamas was liable for punitive damages despite compliance with federal flammability requirements), *cert. denied*, 449 U.S. 921 (1980); *Feiner v. Calvin Klein, Ltd.*, 549 N.Y.S.2d 692, 693 (App. Div. 1990) (finding that compliance with the FFA may constitute evidence of due care but does not preclude a finding of negligence).

128. 7 U.S.C. § 136v(a) (1994).

129. *Id.* § 136v(b).

130. *Compare* *King v. E.I. Dupont de Nemours & Co.*, 996 F.2d 1346, 1349 (1st Cir. 1993) (holding that, in light of *Cipollone*, FIFRA preempts plaintiff's state law tort claims based on defendant's failure to warn); *Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc.*, 959 F.2d 158, 164 (10th Cir.) (holding that the direct conflict between federal regulation of pesticides and state tort actions based on failure to warn required preemption of state law), *vacated sub nom. Arkansas-Platte & Gulf Partnership v. Dow Chem. Co.*, 113 S. Ct. 314 (1992); *Papas v. Upjohn Co.*, 926 F.2d 1019, 1025 (11th Cir. 1991) (holding that FIFRA has occupied the entire field of pesticide labeling regulation precluding states from supplementing federal law by means of state common-law tort actions), *vacated sub nom. Papas v. Zoecon Corp.*, 112 S. Ct. 3020 (1992); *Young v. American Cyanamid Co.*, 786 F. Supp. 781, 785 (E.D. Ark. 1991) (holding that FIFRA preempts any state tort claims alleging inadequate labeling or failure to warn); *Kennan v. Dow Chemical Co.*, 717 F. Supp. 799, 811 (M.D. Fla. 1989) (holding that Congress has expressly preempted state law tort claims based on inadequate labeling); *Fisher v. Chevron Chem. Co.*, 716 F. Supp. 1283, 1289 (W.D. Mo. 1989) (holding that plaintiff's failure-to-warn claims are preempted because they conflict with the regulatory goals of FIFRA); *Fitzgerald v. Mallinckrodt*, 681 F. Supp. 404, 407 (E.D. Mich. 1987) (holding that any state law tort recovery based on a failure-to-warn theory would abrogate Congress's intent to provide uniform regulations governing the labeling of pesticides) *with* *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1541-43 (D.C. Cir.) (holding that (1) Congress has not explicitly preempted state damage actions; (2) compliance with both state and federal law cannot be said to be impossible; and (3) state damage actions do not interfere with FIFRA objectives), *cert. denied*, 469 U.S. 1062 (1984); *Montana Pole & Treating Plant v. I.F. Laucks & Co.*, 775 F. Supp. 1339, 1344 (D. Mont. 1991) (holding that FIFRA does not preempt failure-to-warn claims on actual conflict grounds); *Cox v. Vesicol Chem. Co.*, 704 F. Supp. 85, 87 (E.D. Pa. 1989) (holding that FIFRA does not preempt plaintiff's claims based on inadequate warnings); *Roberts v. Dow Chem. Co.*, 702 F. Supp. 195, 199 (N.D. Ill. 1988) (holding that FIFRA regulation of pesticides does not preclude state court remedies for a manufacturer's failure to warn).

most courts since the *Cipollone* decision have concluded that section 136v(b) of FIFRA preempts inadequate labeling claims.<sup>131</sup>

4. *National Traffic and Motor Vehicle Safety Act.*—Section 30103(b) of the National Traffic and Motor Vehicle Safety Act (NTMVSA) declares that no state may establish any motor vehicle safety standard that is not identical to an applicable federal standard.<sup>132</sup> At the same time, however, section 30103(e) provides that “[c]ompliance with any Federal Motor Vehicle Safety Standard (FMVSS) issued under this subchapter does not exempt any person from any liability under common law.”<sup>133</sup> This has led many courts to conclude that safety standards issued under NTMVSA do not preempt common-law tort claims.<sup>134</sup>

131. *Cf. MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1024-25 (5th Cir. 1994) (holding that FIFRA preempts tort claims based on alleged inadequacy of EPA-approved pesticide warnings); *Shaw v. Dow Brands, Inc.*, 994 F.2d 364, 369-71 (7th Cir. 1993) (holding that common-law actions for labeling and packaging defects are barred under FIFRA); *Papas v. Upjohn Co.*, 985 F.2d 516, 520 (11th Cir. 1993) (“FIFRA expressly preempts state common-law claims against manufacturers of EPA-registered pesticides to the extent such actions are predicated on claims of inadequate labeling or packaging.”); *Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers*, 981 F.2d 1177, 1179 (10th Cir. 1993) (holding that § 136v(b) expressly preempts state law tort claims based on inadequate warning); *Worm v. American Cyanamid Co.*, 970 F.2d 1301, 1308 (4th Cir. 1992) (holding that the language of § 136v(b) manifestly preempts common-law duty that would impose liability requirements inconsistent with those established by FIFRA); *Kinser v. Ciba-Geigy Corp.*, 837 F. Supp. 217, 219 (W.D. Ky. 1993) (holding that FIFRA preempted state common-law tort claims based on failure to warn); *ISK Biotech Corp. v. Doublerly*, 640 So. 2d 85, 88 (Fla. Dist. Ct. App. 1994) (recognizing that federal courts have generally agreed that FIFRA preempts all state common-law claims based on inadequate labeling); *Hopkins v. Ciba-Geigy Corp.*, 432 S.E.2d 142, 146 (N.C. Ct. App. 1993) (holding that FIFRA preempts state common-law claims based on inadequate labeling); *see also* R. David Allnutt, Comment, *FIFRA Preemption of State Common Law Claims After Cipollone v. Liggett Group, Inc.*, 68 WASH. L. REV. 859, 869-76 (1993); Stephen D. Otero, Note, *The Case Against FIFRA Preemption: Reconciling Cipollone’s Preemption Approach with Both the Supremacy Clause and Basic Notions of Federalism*, 36 WM. & MARY L. REV. 783, 823-33 (1995). *But see* *MacDonald v. Monsanto Co.*, 813 F. Supp. 1258, 1261 (E.D. Tex. 1993) (holding that FIFRA does not preempt failure-to-warn claims against pesticide manufacturers).

132. 49 U.S.C.A. § 30103(b) (West Supp. 1995) (formerly codified at 15 U.S.C. § 1392(d)).

133. *Id.* § 30103(e) (formerly codified at 15 U.S.C. § 1397(k)).

134. *Compare* *Myrick v. Freuhauf Corp.*, 115 S. Ct. 1483, 1488 (1995) (holding that a state common-law tort claim based on the failure to equip a truck with antilock brakes was not preempted by NTMVSA); *Buzzard v. Roadrunner Trucking, Inc.*, 966 F.2d 777, 783-86 (3d Cir. 1992) (holding that even though a state common-law tort claim based on inadequate lighting equipment may have some negative effect on uniformity, it was not preempted by FMVSS 108); *Dawson v. Chrysler Corp.*, 630 F.2d 950, 958 (3d Cir. 1980) (finding that a crashworthiness claim was not preempted despite the company’s compliance with applicable federal safety standards), *cert. denied*, 450 U.S. 959 (1981); *Welsh v. Century Prods., Inc.*, 745 F. Supp. 313, 321 (D. Md. 1990) (holding that a state common-law tort claim based on improper design of child restraint system not preempted by FMVSS

A large number of NTMVSA preemption cases have involved FMVSS 208, which establishes requirements for active and passive restraint systems.<sup>135</sup> FMVSS 208 permits automobile manufacturers to comply by installing airbags in their vehicles or by installing various combinations of lapbelts and shoulder harnesses.<sup>136</sup> Plaintiffs maintain that manufacturers must equip their vehicles with airbags if they are to avoid tort liability, while manufacturers respond that FMVSS 208 preempts such design-defect claims because it allows them to satisfy occupant safety requirements by providing lapbelts and shoulder harnesses.<sup>137</sup> Although plaintiffs occasionally have prevailed on this issue,<sup>138</sup> most courts have held that FMVSS 208 preempts "no airbag" claims.<sup>139</sup>

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213); *Garcia v. Rivera*, 541 N.Y.S.2d 880, 889 (N.Y. Sup. Ct. 1989) (holding that a state common-law tort claim based on the improper height of truck bumpers was not preempted by federal safety standards) *with Myrick v. Fruehauf Corp.*, 795 F. Supp. 1139, 1143 (N.D. Ga. 1992) (holding that FMVSS 121 preempts design-defect claim based on the failure to provide antilock brakes on truck and trailer rig); *Crowe v. Fleming*, 749 F. Supp. 1135, 1140-41 (S.D. Ga. 1990) (holding that a state design-defect claim based on the failure to place reflective tape along the sides of a truck was preempted by FMVSS 108); *Verna v. United States Suzuki Motor Corp.*, 713 F. Supp. 823, 827 (E.D. Pa. 1989) (holding that a state common-law design-defect claim based on the failure to install modulating headlamp on a motorcycle was preempted by FMVSS 108).

135. 49 C.F.R. § 571.208 (1994); *see also* Kurt B. Chadwell, Comment, *Automotive Passive Restraint Claims Post-Cipollone: An End to the Federal Preemption Defense*, 46 BAYLOR L. REV. 141, 143-53 (1994) (discussing the history and objectives of FMVSS 208).

136. 49 C.F.R. § 571.208.S4.1.2.1 to -3.

137. *See* Keith C. Miller, *Deflating the Airbag Pre-Emption Controversy*, 37 EMORY L.J. 897, 911-16 (1988) (discussing the intent of FMVSS 208 and the arguments over which common-law tort claims should be preempted); Timothy Wilton, *Federalism Issues in "No Airbag" Tort Claims: Preemption and Reciprocal Comity*, 61 NOTRE DAME L. REV. 1, 3-7 (1986) (discussing the history of passive restraint regulation and the NHTSA's preference for mandatory seat belt laws over mandatory air bag installation to protect passenger safety).

138. *See* *Garrett v. Ford Motor Co.*, 684 F. Supp. 407, 411-12 (D. Md. 1987) ("The most reasonable way to reconcile the language of the NTMVSA does not preempt plaintiff's common law claims"); *Murphy v. Nissan Motor Co.*, 650 F. Supp. 922, 924 (E.D.N.Y. 1987) (holding that the plaintiff's airbag claim was not preempted because New York common law did not conflict with federal law); *Loulos v. Dick Smith Ford, Inc.*, 882 S.W.2d 149, 152 (Mo. Ct. App. 1994) (holding that the NTMVSA does not preempt "no airbag" claim against automobile manufacturer); *Gingold v. Audi-NSU-Union, A.G.*, 567 A.2d 312, 330 (Pa. Super. Ct. 1989) (holding that NTMVSA does not preempt passive restraint claims, including "no airbag" claims).

139. *See* *Taylor v. General Motors Corp.*, 875 F.2d 816, 827 (11th Cir. 1989) (holding that "no airbag" claims would frustrate the regulatory goals of FMVSS 208 and were, accordingly, preempted); *Kitts v. General Motors Corp.*, 875 F.2d 787, 789 (10th Cir. 1989) (holding that the NTMVSA preempted plaintiff's airbag claim); *Wood v. General Motors Corp.*, 865 F.2d 395, 419 (1st Cir. 1988) (holding that "no airbag" claims were preempted because they are regulatory in nature), *cert. denied*, 494 U.S. 1065 (1990).



5. *Food, Drug, and Cosmetic Act.*—Neither the FDCA, nor the Public Health Services Act (PHSA), contains an express preemption provision.<sup>140</sup> Consequently, if FDA standards are to preempt tort claims, they must do so on the basis of occupation-of-the-field or conflict grounds. In fact, preemption claims have seldom prevailed, at least where chemical drugs<sup>141</sup> or biological products<sup>142</sup> were involved. On the other hand, the courts have been more receptive to preemption arguments in the case of medical devices. Section 360k(a) of the Medical Act Amendments expressly limits the power of state and local governments to impose requirements for medical devices that are licensed by the FDA.<sup>143</sup> Furthermore, the FDA has declared that section 360k(a)'s preemptive language applies to court decisions as well

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140. See Jennie Clarke, Comment, *Federal Preemption: A Vaccine Manufacturer's Defense*, 56 UMKC L. REV. 515, 531 (1988).

141. See *Tobin v. Astra Pharmaceutical Prods., Inc.*, 993 F.2d 528, 537-38 (6th Cir. 1993) (holding that FDA approval of a labor-inhibiting drug did not preempt design defect claim); *Osburn v. Anchor Lab., Inc.*, 825 F.2d 908, 912-13 (5th Cir. 1987) (finding that absent actual conflict between FDA regulations and state tort law, or an intent by Congress to occupy the entire field, defendant's preemption challenge fails), *cert. denied*, 485 U.S. 1009 (1988); *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 658-59 (1st Cir. 1981) (finding that labels drafted by FDA were not conclusory on the adequacy of warnings); *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1362 (4th Cir. 1975) (holding that compliance with federal regulations concerning a drug does not by itself absolve a manufacturer of state tort liability); *Mazur v. Merck & Co.*, 742 F. Supp. 239, 248 (E.D. Pa. 1990) (holding that mere compliance with FDA regulations does not absolve manufacturer of liability); *Ramirez v. Plough, Inc.*, 12 Cal. Rptr. 2d 423, 430-31 (Ct. App. 1992) (finding that aspirin manufacturer's compliance with FDA labeling requirements does not preclude liability for failure to provide warning in Spanish about risk of Reye's Syndrome); *Feldman v. Lederle Labs.*, 592 A.2d 1176, 1192 (N.J. 1991) (holding that FDA labeling standards do not preempt failure-to-warn claim against manufacturer of tetracycline drug), *cert. denied*, 112 S. Ct. 3027 (1992).

142. See *Abbot ex rel. Abbot v. American Cyanamid Co.*, 844 F.2d 1108, 1111-14 (4th Cir.) (holding that compliance with FDA regulations does not preempt failure-to-warn claim against manufacturer of DPT vaccine), *cert. denied*, 488 U.S. 908 (1988); *Jones ex rel. Jones v. Lederle Labs.*, 695 F. Supp. 700, 712 (E.D.N.Y. 1988) (holding that a strict liability claim against a vaccine manufacturer based on defective design was not preempted by federal law); *McMillan ex rel. Foyle v. Lederle Labs.*, 674 F. Supp. 530, 532-34 (E.D.N.C. 1987) (holding that state law claims for injuries caused by DPT vaccine were not preempted by federal law); *Martinkovic ex rel. Martinkovic v. Wyeth Labs., Inc.*, 669 F. Supp. 212, 214 (N.D. Ill. 1987) (holding that FDA regulations did not preempt state tort claims against vaccine manufacturers); *Graham ex rel. Graham v. Wyeth Labs.*, 666 F. Supp. 1483, 1491-93 (D. Kan. 1987) (holding that federal regulations did not preempt state tort law claims against drug manufacturer); *Wack v. Lederle Labs.*, 666 F. Supp. 123, 127 (N.D. Ohio 1987) (holding that FDA approval of "whole cell" DPT vaccine does not preempt design-defect claim against vaccine manufacturer). *But see Hurley v. Lederle Labs.*, 851 F.2d 1536, 1542 (5th Cir.), *superseded by* 863 F.2d 1173 (5th Cir. 1988) (holding that compliance with FDA-approved labeling immunizes drug manufacturers from tort liability if they provide the agency with all appropriate information about product risks before it approves the labeling).

143. 21 U.S.C. § 360k(a) (1994).

as statutory and administrative regulations.<sup>144</sup> Until recently, this led many courts to conclude that section 360k(a) expressly preempted tort claims against manufacturers whose products are licensed under the MDA.<sup>145</sup> However, this interpretation of section 360k(a) has now been called into question by the Supreme Court's decision this summer in *Medtronic, Inc. v. Lohr*.<sup>146</sup> In that case, the Court held that neither manufacturing-defect, design-defect, or failure-to-warn claims

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144. 21 C.F.R. § 808.1(b) (1995).

145. See *Martin v. Teletronics Pacing Sys., Inc.*, 70 F.3d 39, 41-42 (6th Cir. 1995) (holding that MDA expressly preempts claims against manufacturer of cardiac pacemaker); *Mitchell v. Collagen Corp.*, 67 F.3d 1269, 1275-76 (7th Cir. 1995) (holding that MDA preempts claims against manufacturer of intraocular lenses); *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392, 396-98 (4th Cir. 1995) (concluding that MDA preempts certain claims against implant manufacturer); *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 542-45 (3d Cir. 1994) (holding that a state common-law tort claim against a manufacturer of an experimental intraocular lens was preempted by MDA), *cert. denied*, 115 S. Ct. 429 (1994); *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 18 (1st Cir. 1994) (holding that negligence and implied warranty claims against manufacturer of heart pacemaker that were premised on inadequate warnings were preempted by MDA); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1423-24 (5th Cir.) (holding that the MDA preempts failure-to-warn claim against manufacturer of antiwrinkle implants), *cert. denied*, 114 S. Ct. 86 (1993); *King v. Collagen Corp.*, 983 F.2d 1130, 1135-36 (1st Cir.) (holding that the MDA preempts implied warranty claim against manufacturer of antiwrinkle implants), *cert. denied*, 114 S. Ct. 84 (1993); *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989) (holding that a failure-to-warn claim against tampon manufacturer was preempted by MDA); *Kemp v. Pfizer, Inc.*, 851 F. Supp. 269, 273 (E.D. Mich. 1994) (holding that a warranty claim against manufacturer of artificial heart valve was preempted by MDA); *Griffin v. Medtronic, Inc.*, 840 F. Supp. 396, 397 (D. Md. 1994) (holding that a design-defect claim against heart pacemaker was preempted by MDA); *Bravman v. Baxter Healthcare Corp.*, 842 F. Supp. 747, 760-61 (S.D.N.Y. 1994) (holding that a failure-to-warn claim against manufacturer of artificial heart valve was preempted by MDA); *Cameron v. Howmedica, Inc.*, 820 F. Supp. 317, 321 (E.D. Mich. 1993) (holding that a design-defect claim against manufacturer of artificial hip was preempted by MDA); *Lindquist v. Tambrands, Inc.*, 721 F. Supp. 1058, 1063 (D. Minn. 1989) (holding that a failure-to-warn claim against a tampon manufacturer was preempted by MDA). *But see* *Parenteau v. Johnson & Johnson Orthopedics, Inc.*, 856 F. Supp. 61, 64-65 (D.N.H. 1994) (holding that a design-defect claim against manufacturer of knee prosthesis was not preempted because FDA regulation imposed no design standard); *Oja v. Howmedica, Inc.*, 848 F. Supp. 905, 907 (D. Colo. 1994) (holding that MDA does not preempt state law tort claims based on defectively designed artificial hip implant); *Desmarais v. Dow Corning Corp.*, 712 F. Supp. 13, 16 (D. Conn. 1989) (holding that a failure-to-warn claim against manufacturer of silicone breast implants was not preempted when product was implanted prior to enactment of § 360k); *Mitchell v. Iolab Corp.*, 700 F. Supp. 877, 878-79 (E.D. La. 1988) (holding that a claim based on lack of informed consent against manufacturer of experimental intraocular eye lens was not preempted by MDA); *Larsen v. Pacesetter Sys., Inc.*, 837 P.2d 1273, 1282 (Haw. 1992) (holding that a breach of warranty claim against manufacturer of heart pacemaker was not preempted by MDA because FDA had not promulgated regulations at the time of sale); see also *Lars Noah, Amplification of Federal Preemption in Medical Device Cases*, 49 FOOD & DRUG L.J. 183, 199-200 (1994) (discussing recent medical device preemption cases).

146. 116 S. Ct. 2240 (1996).

against the manufacturer of an electronic pacemaker were preempted by the MDA.<sup>147</sup>

6. *Federal Aviation Act.*—Section 1305(a) of the Federal Aviation Act expressly preempts state laws, regulations, or standards that purport to regulate “rates, routes, or services.”<sup>148</sup> However, the Act also contains a savings clause that declares that “[n]othing contained in this chapter shall in any way abridge or alter the remedies now existing at common law or by statute . . . .”<sup>149</sup> This language has persuaded the courts to reject arguments by manufacturers that FAA aircraft safety standards preempt common-law design-defect claims.<sup>150</sup>

7. *Occupational Safety and Health Act.*—Section 667 of the Occupational Safety and Health Act prohibits the states from establishing safety standards in areas where OSHA standards have already been promulgated.<sup>151</sup> However, because OSHA safety standards are aimed at employers, rather than product manufacturers, it has been suggested that the preemptive language of section 667 does not extend to tort actions brought against manufacturers who comply with OSHA standards.<sup>152</sup>

### C. A Critique of Preemption Jurisprudence

Court decisions on preemption are inconsistent and appear to have little predictive value. Thus, manufacturers who believe that federal safety standards preempt tort liability must engage in lengthy and expensive litigation in order to obtain an authoritative decision from

147. *Id.* at 2251-58. It should be noted that the device in question did not undergo conventional premarket approval by the FDA, but was approved under section 510(k) as a “substantially equivalent” device. *Id.* at 2248. In the Court’s view, this greatly weakened the manufacturer’s preemption claim since the primary focus of section 510(k) was equivalence to existing devices rather than safety. *Id.* at 2254.

148. 49 U.S.C. § 1305(a)(1) (1988).

149. *Id.* § 1506.

150. See *Public Health Trust v. Lake Aircraft*, 992 F.2d 291, 295 (11th Cir. 1993) (holding that an airplane seat design-defect claim was not expressly preempted by FAA regulations); *Cleveland v. Piper Aircraft Corp.*, 985 F.2d 1438, 1443-47 (10th Cir.) (holding that a design-defect claim was not preempted by FAA standards), *cert. denied*, 114 S. Ct. 291 (1993); *Holliday v. Bell Helicopters Textron, Inc.*, 747 F. Supp. 1396, 1400 (D. Haw. 1990) (holding that plaintiffs’ crashworthiness claim was not impliedly preempted by FAA regulations); see also Patrick J. Shea, Note, *Solving America’s General Aviation Crisis: The Advantages of Federal Preemption over Tort Reform*, 80 CORNELL L. REV. 747, 779-81 (1995).

151. 29 U.S.C. § 667 (1994). States may seek permission from OSHA to assume regulatory responsibilities that would otherwise be reserved to OSHA. *Id.* § 667(b), (c).

152. See *Independent Sch. Dist. No. 197 v. W.R. Grace & Co.*, 752 F. Supp. 286, 306 (D. Minn. 1990) (holding that because OSHA is aimed primarily at employers, and not manufacturers of products used by employers, asbestos removal is outside the Act’s scope).

the courts on this issue. This failing greatly reduces the value of the preemption doctrine as a "safe harbor" for manufacturers whose products satisfy federal regulatory standards.

The prevailing method of statutory interpretation significantly contributes to the indeterminacy problem. When courts decide preemption cases they often focus on the concept of "regulatory purpose."<sup>153</sup> Unfortunately, this approach is largely circular because the outcome of the case depends on how the court resolves the "purpose" question. Thus, in pesticide labeling cases, for example, courts that conclude that FIFRA's regulatory purpose is to establish uniform labeling requirements usually preempt state tort law on conflict grounds.<sup>154</sup> On the other hand, courts are less likely to preempt tort claims if they determine that FIFRA is only concerned with the establishment of "minimum regulatory standards."<sup>155</sup>

Another problem with preemption analysis is that it requires courts to make critical findings of fact on the basis of inadequate evidence. For example, a key issue in many preemption cases is whether damage awards will obstruct a statute's regulatory purpose. Because reliable information is seldom available, courts are left to speculate about the effects of possible tort liability on manufacturer behavior. Inevitably, different assumptions about such behavior lead to different conclusions about the preemption issue.<sup>156</sup>

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153. See generally Ausness, *supra* note 6, at 212.

154. See, e.g., *Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc.*, 959 F.2d 158, 160-62 (10th Cir.) (holding that state tort actions based on labeling and alleged failure to warn are implicitly preempted by FIFRA), *vacated sub nom. Arkansas-Platte & Gulf Partnership v. Dow Chem. Co.*, 113 S. Ct. 314 (1992); *Papas v. Upjohn Co.*, 926 F.2d 1019, 1025-26 (11th Cir. 1991) (holding that "FIFRA impliedly preempts state common law tort suits against manufacturers of EPA-registered pesticides to the extent that such actions are based on claims of inadequate labeling") (emphasis omitted), *vacated sub nom. Papas v. Zoecon Corp.*, 112 S. Ct. 3020 (1992).

155. See, e.g., *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1541 (D.C. Cir.) (explaining that while FIFRA does not allow states to apply additional labeling requirements, FIFRA does allow states to impose more stringent requirements on the use of EPA-approved pesticides), *cert. denied*, 469 U.S. 1062 (1984); *Riden v. ICI Americas, Inc.*, 763 F. Supp. 1500, 1508 (W.D. Mo. 1991) (stating that FIFRA establishes minimum standards for pesticide labeling); *Cox v. Velsicol Chem. Corp.*, 704 F. Supp. 85, 86-87 (E.D. Pa. 1989) (stating that Congress likely intended FIFRA to set minimum requirements for pesticide labeling).

156. Compare *Ferebee*, 736 F.2d at 1541 (finding for an injured plaintiff after holding that while the EPA may have approved the defendant's label as consistent with FIFRA, this does not preclude a jury from finding that the label is inadequate for state tort law purposes) and *Cox*, 704 F. Supp. at 87 (finding that Congress did not intend "to preempt the entire field of pesticide labeling thus immunizing manufacturers from state tort claims alleging inadequate warnings") with *Wood v. General Motors Corp.*, 865 F.2d 395, 410-12 (1st Cir. 1988) (finding that FMVSS were intended to be national uniform standards and therefore state regulations would expressly be preempted because they could destroy this uniformity), *cert. denied*, 494 U.S. 1065 (1990) and *Kennan v. Dow Chem. Co.*, 717 F. Supp. 799, 807

As long as federal product safety statutes contain ambiguous preemption provisions, courts will continue to decide preemption claims without adequate legislative guidance. This is an unsatisfactory situation for all concerned. Clearly some reform will be necessary before manufacturers whose products comply with applicable federal safety standards can rely on federal preemption to protect them against tort liability.

#### D. Agency Preemption

Of course, Congress and federal agencies could assume more responsibility for determining when damage claims based on state tort law principles are to be preempted. The simplest and most obvious way to resolve preemption questions would be for Congress to state explicitly whether compliance with federal safety standards will affect tort liability for product-related injuries.<sup>157</sup> This action would provide clear guidance to interested parties and would prevent a good deal of unnecessary litigation. Unfortunately, Congress has shown little interest in resolving such issues in the past and is unlikely to do so in the future.

A less desirable, but more realistic, approach would be for each federal agency to issue an interpretation of its statutory authority to determine whether it preempts state tort liability. Although such agency interpretations may not be binding on the courts,<sup>158</sup> they are likely to receive a good deal of deference from the judiciary.<sup>159</sup> The Food and Drug Administration has already taken such a step with respect to section 360k(a) of the Medical Device Amendments.<sup>160</sup> This provision prohibits the states from establishing any "requirements" for medical devices that differ from FDA standards.<sup>161</sup> The FDA has is-

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(M.D. Fla. 1989) (holding that FIFRA expressly preempts state law regulation of pesticide labeling).

157. Congress could also include a savings clause expressly preserving state law damage claims if it wished to limit the preemptive effect of product safety legislation. *See, e.g.*, Comprehensive Smokeless Tobacco Health Education Act of 1986, 15 U.S.C. § 4401 (1994).

158. *See Frank Diehl Farms v. Secretary of Labor*, 696 F.2d 1325, 1329-30 (11th Cir. 1983) ("The weight given the interpretation by the reviewing court 'will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade . . .'" (citations omitted)).

159. *See New Jersey v. United States Dep't of Health and Human Servs.*, 670 F.2d 1262, 1282 (3d Cir. 1981) (stating that great deference should be given to agency interpretations).

160. 21 U.S.C. § 360k(a)(1) (1994).

161. *Id.*

sued a regulation that declares that section 360k(a) preempts state court decisions as well as statutes, ordinances, and administrative regulations.<sup>162</sup> In general, the courts have accepted this interpretation of section 360k(a) as authoritative.<sup>163</sup>

Finally, federal agencies can preempt state tort law on their own initiative. This power, known as administrative preemption, may be exercised by a federal agency when Congress expressly or impliedly authorizes it to preempt state law.<sup>164</sup> Although administrative preemption has been used most often to preempt state statutes and administrative regulations, it can also be invoked to preempt state common-law doctrines.<sup>165</sup> Thus, when administrative preemption is available, a federal agency may expressly preempt state tort law.

### E. Concerns About Agency Preemption

Although express preemption of state tort law by Congress or by federal administrative agencies will provide consistency and clarity, broad use of federal authority to preempt state tort law also will have a number of negative consequences. First of all, any sweeping displacement of state tort law by Congress or federal administrative agencies raises serious federalism concerns. As the Supreme Court has acknowledged, the protection of public health and safety are traditionally matters of state and local responsibility.<sup>166</sup> Because large-scale

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162. 21 C.F.R. § 808.1(b) (1995).

163. See, e.g., *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 247 (5th Cir. 1989) (holding that state law claims based on inadequate labeling and warning statements are preempted by § 360k); *Cornelison v. Tambrands, Inc.*, 710 F. Supp. 706, 709 (D. Minn. 1989) (concluding that § 360k preempts state tort standards that would "impose requirements upon producers of medical devices which are different from, or in addition to, the requirements of the Medical Device Amendments"); *Meyer v. International Playtex, Inc.*, 724 F. Supp. 288, 292 (D.N.J. 1988) (stating that Congress and the FDA excluded states from establishing labeling standards for medical devices through § 360k); *Rinehart v. International Playtex, Inc.*, 688 F. Supp. 475, 477 (S.D. Ind. 1988) (concluding that § 360k set out the standard to be applied to labeling requirements and that neither the court nor the jury may impose additional warning requirements); *Lavetter v. International Playtex, Inc.*, 706 F. Supp. 722, 723 (D. Ariz. 1988) (holding that where defendant's user warning was in compliance with § 360k plaintiff's claims based on state law were preempted); *Edmonson v. International Playtex, Inc.*, 678 F. Supp. 1571, 1572 (N.D. Ga. 1987) (stating that § 360k prohibits any additional labeling requirements by the states).

164. See Hoke, *supra* note 105, at 734; Richard J. Pierce, Jr., *Regulation, Deregulation, Federalism, and Administrative Law: Agency Power to Preempt State Regulation*, 46 U. PITT. L. REV. 607, 636-41 (1985) (discussing federal agency invalidation of state regulatory actions).

165. See *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 159 (1982) (holding that regulation issued by Home Loan Bank Board preempted state court decisions prohibiting "due on sale" clauses in residential mortgages).

166. See, e.g., *Hillsborough County v. Automated Medical Labs., Inc.*, 471 U.S. 707, 719 (1985) (declaring that "regulation of health and safety matters is primarily, and histori-

federal preemption of state tort law would impair a state's power to protect the health and safety of its citizens, it would amount to a serious infringement on state sovereignty. Obviously, such an intrusion into traditional areas of state interest should be avoided if possible.

Second, preemption effectively insulates manufacturers of defective products against tort liability when federal safety standards are inadequate or obsolete. Unfortunately, federal labeling and design requirements are sometimes the product of political compromises,<sup>167</sup> excessive influence within the agency by the regulated industry,<sup>168</sup> or excessive dependence upon industry sources for necessary information.<sup>169</sup> Tort liability offsets these flaws in the regulatory process by encouraging manufacturers to exceed federal safety requirements when it is cost-effective to do so. This incentive will be foreclosed if state tort claims are preempted by agency action.

Finally, federal preemption strips injured parties of their state law remedies. Imposing tort liability on the manufacturers of defective products shifts the costs of accidents from individuals to the manufacturers who can spread liability costs to consumers through the pricing mechanism.<sup>170</sup> This loss-spreading effect of products liability promotes social welfare by reducing "secondary" accident costs.<sup>171</sup> However, these benefits are lost when federal preemption relieves a manufacturer of its duty to compensate accident victims.

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cally, a matter of local concern"); *Head v. New Mexico Bd. of Examiners*, 374 U.S. 424, 428 (1963) (stating that regulations to protect public health and welfare fall within historic powers of the states).

167. See Anita Johnson, *Products Liability "Reform": A Hazard to Consumers*, 56 N.C. L. REV. 677, 687 (1978) ("Manufacturers have enormous power to influence the formation of government standards, with the result that the standards are frequently political compromises at best."); Susan Rose-Ackerman, Comment, *Progressive Law and Economics—And the New Administrative Law*, 98 YALE L.J. 341, 363 (1988) ("Overall, rulemaking priorities seem guided more by political than by cost-effectiveness criteria.").

168. See Clayton P. Gillette & James E. Krier, *Risk, Courts and Agencies*, 138 U. PA. L. REV. 1027, 1065-69 (1990) (describing the phenomenon of industry capture of an agency); Jerry L. Mashaw & David L. Harfst, *Regulation and Legal Culture: The Case of Motor Vehicle Safety*, 4 YALE J. ON REG. 257, 270 (1987) (discussing a beneficial regulatory scheme for an industry maintained by "reelection-oriented legislators").

169. See Teresa M. Schwartz, *The Role of Federal Safety Regulations in Products Liability Actions*, 41 VAND. L. REV. 1121, 1147 (1988) ("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.").

170. See W. Page Keeton, *Products Liability—Liability Without Fault and the Requirement of a Defect*, 41 TEX. L. REV. 855, 856 (1963) (stating that there is wide acceptance of the theory that large corporations should pass on to general users the losses of the few).

171. See Guido Calabresi, *Some Thoughts on Risk Distribution and the Law of Torts*, 70 YALE L.J. 499, 517-18 (1961) (proposing that losses are least harmful if broadly spread).

## IV. REGULATORY COMPLIANCE AS A DEFENSE

The regulatory compliance defense appears to be a promising alternative to preemption. This defense offers manufacturers who comply with product safety standards some protection against tort liability. Unfortunately, in its present form, the regulatory compliance defense is too weak to provide much of a safe harbor to product sellers. At the present time, most courts treat failure to comply with applicable government safety standards as conclusive evidence of negligence; however, they usually regard compliance with such standards as nothing more than evidence of due care.<sup>172</sup> Apparently, these courts do not believe that government safety standards should be the exclusive measure of product quality.<sup>173</sup>

A. *Compliance Versus Noncompliance with Regulatory Standards*

In most jurisdictions, unexcused violations of state statutes are treated as negligence per se.<sup>174</sup> The concept of negligence per se assumes that the legislature has established a mandatory standard of civil conduct when it enacts a criminal or regulatory statute.<sup>175</sup> Therefore, one who violates a statute may justifiably be held liable in tort even though the statute makes no express provision for civil liability.<sup>176</sup> Violations of municipal ordinances also constitute negligence

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172. See Schwartz, *supra* note 169, at 1136 ("[C]ourts have ruled, in general, that non-compliance with statutory and regulatory standards constitutes negligence per se, or is presumptive of negligence, while compliance constitutes relevant evidence of due care, but deserves no special weight.").

173. See Teresa M. Schwartz, *Punitive Damages and Regulated Products*, 42 AM. U. L. REV. 1335, 1342-43 (1993) (stating that courts often consider regulatory standards as minimum standards of safety and therefore not "equivalent to the standards of safety required by tort law").

174. See *Teal v. E.I. Dupont de Nemours & Co.*, 728 F.2d 799, 805 (6th Cir. 1984) (stating that a breach of a duty imposed by OSHA is negligence per se if the plaintiff is a member of the class intended to be protected by the regulation); *Eaton v. Eaton*, 575 A.2d 858, 865-66 (N.J. 1990) (holding that, when a statute prohibited careless driving, "proof of the violation of the statute is proof of negligence itself"); *Gressman v. McClain*, 533 N.E.2d 732, 735 (Ohio 1988) (concluding that selling liquor to an intoxicated person violates a duty imposed by the law and thus constitutes negligence per se); *McIntyre v. Balentine*, 833 S.W.2d 52, 59 (Tenn. 1992) ("[V]iolation of a penal statute is negligence per se . . .").

175. See *Staudinger v. Barrett*, 544 A.2d 164, 167 (Conn. 1988) ("The doctrine of negligence per se serves to superimpose a legislatively prescribed standard of care on the general standard of care."); *Carter v. William Sommerville & Son, Inc.*, 584 S.W.2d 274, 278 (Tex. 1979) ("Negligence per se is a tort concept whereby a legislatively imposed standard of conduct is adopted by the civil courts as defining the conduct of a reasonably prudent person.").

176. See *Nazareno v. Urie*, 638 P.2d 671, 676 (Alaska 1981) (holding that a statute prohibiting the sale of liquor to intoxicated persons subjects violator to civil liability); *Largo Corp. v. Crespin*, 727 P.2d 1098, 1107 (Colo. 1986) (holding that the breach of a



per se,<sup>177</sup> although some jurisdictions merely consider such violations to be evidence of negligence.<sup>178</sup> Violations of administrative regulations are also usually viewed as negligence per se,<sup>179</sup> although some states treat such violations more leniently.<sup>180</sup>

The concept of negligence per se is applicable to products liability. Consequently, a product manufacturer may be held civilly liable as a matter of law for injuries caused by its failure to comply with applicable safety standards.<sup>181</sup> It should be noted, however, that some

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statute prohibiting the sale of alcohol to an intoxicated person may be relied upon to establish the breach of a legally owed duty for a negligence suit).

177. See *Stephens v. Stearns*, 678 P.2d 41, 48-49 (Idaho 1984) (holding that the violation of a building code constituted negligence per se); *Brichacek v. Hiskey*, 401 N.W.2d 44, 46-47 (Iowa 1987) (holding that the violation of a housing code can be used as the basis for a tort action); *Boyles v. Oklahoma Natural Gas Co.*, 619 P.2d 613, 618 (Okla. 1980) (holding that a violation of an ordinance requiring a gas company to check valves before turning on gas was negligence per se); *Nixon v. Mr. Property Management Co.*, 690 S.W.2d 546, 549 (Tex. 1985) (holding that a violation of a requirement to keep premises secure against unauthorized entry, without a valid excuse, is per se negligence).

178. See *Cassibo v. Bodwin*, 386 N.W.2d 559, 561 (Mich. Ct. App. 1986) (stating that a violation of a dog leash ordinance "is only evidence of negligence"); *Keyes v. Amundson*, 391 N.W.2d 602, 608 (N.D. 1986) (finding that a violation of a "no parking" ordinance may be considered evidence of negligence); *Hall v. Warren*, 632 P.2d 848, 850 (Utah 1981) (stating that a violation of a municipal housing code "is prima facie evidence of negligence"); *Crago v. Lurie*, 273 S.E.2d 344, 345-46 (W. Va. 1980) (concluding that a violation of a sidewalk maintenance ordinance "constituted prima facie actionable negligence when it was the proximate cause of any injury").

179. See *Britton v. Wooten*, 817 S.W.2d 443, 447 (Ky. 1991) (stating that a violation of an administrative regulation prohibiting the accumulation of trash near buildings constitutes negligence per se); *Hyatt v. Sellen Constr. Co.*, 700 P.2d 1164, 1167 (Wash. Ct. App. 1985) (stating that a violation of state department of labor worker-safety regulations could constitute negligence per se).

180. See *Amcast Indus. Corp. v. Detrex Corp.*, 779 F. Supp. 1519, 1542 (N.D. Ind. 1991) (stating that a violation of a reporting requirement for toxic chemical spills is only evidence of negligence in Indiana), *aff'd in part and rev'd in part*, 2 F.3d 746 (7th Cir. 1993), *cert. denied*, 114 S. Ct. 691 (1994); *Davis v. Marathon Oil Co.*, 356 N.E.2d 93, 97-98 (Ill. 1976) (finding that a violation of a regulation requiring a competent person to be present during the loading and unloading of gasoline tank trucks should be considered prima facie evidence of negligence); *Haselhorst v. State*, 485 N.W.2d 180, 187 (Neb. 1992) (stating that a violation of the requirements for the placement of foster children is evidence of negligence).

181. See *Orthopedic Equip. Co. v. Eutsler*, 276 F.2d 455, 461 (4th Cir. 1960) (holding that a violation of FDA labeling requirements by a manufacturer of surgical nails is negligence per se); *Lukaszewicz v. Ortho Pharmaceutical Corp.*, 510 F. Supp. 961, 964-65 (E.D. Wis. 1981) (holding that the failure to comply with FDA warning requirements for oral contraceptives could be negligence per se); *Elsworth v. Beech Aircraft Corp.*, 691 P.2d 630, 634 (Cal. 1984) (finding that the plaintiff was entitled to an instruction on negligence per se if the aircraft manufacturer failed to comply with FAA regulations), *cert. denied*, 471 U.S. 1110 (1985); see also *Schwartz*, *supra* note 169, at 1135-36 (stating that courts have generally found regulatory standards to give the minimum standard of care required).

courts conclude that noncompliance merely creates a presumption of negligence.<sup>182</sup>

Courts treat compliance with government safety standards somewhat differently than they treat noncompliance with such standards. Section 288C of the *Restatement (Second) of Torts* provides that compliance with a legislative enactment or an administrative regulation does not preclude a finding of negligence in cases where a reasonable person would take additional precautions.<sup>183</sup> Most states appear to follow the *Restatement's* approach in negligence cases. Thus, compliance with safety regulations is generally considered to be some evidence of due care,<sup>184</sup> but it is seldom conclusive.<sup>185</sup>

### B. *Effect of Compliance with Federal Product Safety Standards*

Ordinarily, regulatory compliance is treated the same in product liability cases as it is in negligence cases. Although there are some exceptions,<sup>186</sup> most courts agree that federal safety regulations are relevant evidence in products liability cases.<sup>187</sup> On the other hand, few courts are willing to give much weight to such statutes. Instead, most

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182. See *Toole v. Richardson-Merrell, Inc.*, 60 Cal. Rptr. 398, 408-09 (Dist. Ct. App. 1967) (holding that the violation of the labeling and marketing provisions of the Food, Drug, and Cosmetic Act creates a presumption of negligence); *Bateast v. Wyeth Labs., Inc.*, 560 N.E.2d 315, 323 (Ill. 1990) (stating that an Aminophylline manufacturer's failure to comply with FDA warning requirements would be prima facie evidence of negligence if the violation was the proximate cause of the plaintiff's injury and the plaintiff was a member of the class intended to be protected by the regulation).

183. RESTATEMENT (SECOND) OF TORTS § 288C (1965).

184. See *Christou v. Arlington Park-Washington Park Race Tracks Corp.*, 432 N.E.2d 920, 924 (Ill. App. Ct. 1982) (holding that defendant's compliance with safety glass requirements was admissible to show lack of negligence).

185. See *Pickering v. State*, 557 P.2d 125, 127 (Haw. 1976) ("[C]ompliance with established statutory and administrative standards are [sic] not necessarily conclusive on the issue of negligence."); *Leonard v. Sav-A-Stop Servs., Inc.*, 424 A.2d 336, 340 (Md. 1981) ("Compliance with a legislative enactment . . . does not prevent a finding of negligence . . . ." (citing RESTATEMENT (SECOND) OF TORTS § 288 (1965))); *Miller v. Warren*, 390 S.E.2d 207, 209 (W. Va. 1990) (holding that a motel's compliance with the fire code, while relevant, is not conclusive evidence of due care).

186. See *McKinnon v. Skil Corp.*, 638 F.2d 270, 275 (1st Cir. 1981) (determining that OSHA regulations requiring circular saws to have blade guards is not admissible because they applied to industrial, not consumer, use); *Sheehan v. Cincinnati Shaper Co.*, 555 A.2d 1352, 1354-55 (Pa. Super. Ct. 1989) (concluding that the trial court did not err in refusing to admit evidence that OSHA standards required employers, not manufacturers, to place safety guards on shearing machines).

187. See *Moehle v. Chrysler Motors Corp.*, 443 N.E.2d 575, 577-78 (Ill. 1982) (finding federal safety standards relating to rear seat anchoring system admissible by manufacturer as evidence that design was not defective); *Rucker v. Norfolk & Western Ry.*, 396 N.E.2d 534, 536-37 (Ill. 1979) (holding that in this design-defect case the defendant was allowed to submit evidence of his compliance with federal standards of construction for railroad tank cars); *Hatfield v. Sandoz-Wander, Inc.*, 464 N.E.2d 1105, 1109 (Ill. App. Ct. 1984) (holding

have concluded that compliance with federal safety standards is merely evidence that a product is not defective, effectively allowing juries to substitute their judgment for that of a regulatory agency.<sup>188</sup>

1. *Flammable Fabric Act.*—A number of courts have held that compliance with the flammability standards of the Flammable Fabric Act does not necessarily protect manufacturers against tort actions by injured consumers.<sup>189</sup> *Raymond v. Riegel Textile Corp.*<sup>190</sup> is illustrative. In *Raymond*, a child was burned when her nightgown came into contact with an electric grill.<sup>191</sup> The trial court, acting without a jury, found in favor of the plaintiff notwithstanding the fact that the manufacturer had complied with applicable flammability standards.<sup>192</sup> On appeal, the federal appeals court agreed that federal safety standards were not conclusive on the issue of defectiveness.<sup>193</sup> The court cited the *Restatement (Second) of Torts*<sup>194</sup> for the proposition that standards

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that a defendant may introduce evidence that the prescription drug, Mellaril, was approved by the FDA to support its claim that its package insert labeling was adequate).

188. See *Shorter v. Champion Home Builders Co.*, 776 F. Supp. 333, 338 (N.D. Ohio 1991) (holding that compliance with the National Manufactured Housing Construction and Safety Standards Act was not conclusive on the issue of whether a mobile home that had formaldehyde in its flooring was defectively designed); *Blasing v. P.R.L. Hardenbergh Co.*, 226 N.W.2d 110, 115 (Minn. 1975) (holding that compliance by a manufacturer of flammable liquid finish remover with federal warning requirements was not conclusive on issue of due care); *Stone v. Sterling Drug, Inc.*, 490 N.Y.S.2d 468, 470 (App. Div. 1985) (stating that compliance with federal labeling standards for industrial strength acid was not conclusive on the issue of due care); see also *Spradley*, *supra* note 7, at 367 (“[C]ompliance with governmental design standards, rules, and regulations constitutes some evidence of the adequacy of the product’s design, but is not conclusive.”).

189. See *Howard v. McCrory Corp.*, 601 F.2d 133, 138 n.9 (4th Cir. 1979) (holding that a manufacturer’s compliance with the Flammable Fabrics Act was relevant in determining whether the bathrobe at issue was “unreasonably dangerous for use as clothing,” but not conclusive on the issue); *Raymond v. Riegel Textile Corp.*, 484 F.2d 1025, 1027-28 (1st Cir. 1973) (holding that compliance with the Flammable Fabrics Act does not bar a strict liability claim against the manufacturer); *Gryc v. Dayton-Hudson Corp.*, 297 N.W.2d 727, 734-35 (Minn.) (concluding that compliance with federal flammability standards by a manufacturer of children’s pajamas does not preclude liability for punitive damages), *cert. denied*, 449 U.S. 921 (1980); *Feiner v. Calvin Klein, Ltd.*, 549 N.Y.S.2d 692, 694 (App. Div. 1990) (holding that compliance with the Flammable Fabric Act may constitute some evidence of due care, but is not conclusive); *Sherman v. M. Lowenstein & Sons, Inc.*, 282 N.Y.S.2d 142, 143-44 (App. Div. 1967) (“While a defendant’s compliance with a statute ‘is some evidence of the exercise of due care’ it does not preclude a conclusion that he was negligent.” (citations omitted)).

190. 484 F.2d 1025 (1st Cir. 1973).

191. *Id.* at 1026.

192. *Id.*

193. *Id.* at 1028.

194. RESTATEMENT (SECOND) OF TORTS § 288C (1965).

established by criminal statutes are not necessarily controlling in civil litigation.<sup>195</sup>

2. *Federal Insecticide, Fungicide, and Rodenticide Act.*—Courts that reject preemption generally conclude that compliance with FIFRA is nothing more than weak evidence that conforming pesticide warnings are adequate.<sup>196</sup> *Ferebee v. Chevron Chemical Co.*<sup>197</sup> is the leading case. In *Ferebee*, an agricultural worker brought suit against an herbicide manufacturer, alleging injury from long-term occupational exposure to paraquat.<sup>198</sup> The plaintiff claimed that the labeling was defective because it failed to warn that long-term exposure to paraquat could cause serious lung disease.<sup>199</sup> Rejecting the manufacturer's preemption argument, the court observed that "mere compliance with [federal or state] regulatory labeling requirements does not preclude a [jury from] finding that additional warnings should have been given."<sup>200</sup>

3. *National Traffic and Motor Vehicle Safety Act.*—A number of courts have concluded that compliance with federal motor vehicle safety standards does not foreclose tort liability.<sup>201</sup> *Dawson v. Chrysler*

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195. *Raymond*, 484 F.2d at 1028.

196. See *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1542 (D.C. Cir.) (holding that the jury could still find the pesticide warnings inadequate, despite compliance with FIFRA), *cert. denied*, 469 U.S. 1062 (1984); *Burke v. Dow Chem. Co.*, 797 F. Supp. 1128, 1142 (E.D.N.Y. 1992) (concluding that compliance with FIFRA does not immunize a manufacturer from state tort liability); *Roberts v. Dow Chem. Co.*, 702 F. Supp. 195, 199 (N.D. Ill. 1988) (concluding that, because "[t]he purposes of FIFRA and state tort law may be quite distinct," a court may find that a pesticide label adequate under FIFRA is not adequate under state tort law).

197. 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984).

198. *Id.* at 1531-32 (explaining that paraquat is an agricultural herbicide sold under extensive regulation).

199. *Id.* at 1532.

200. *Id.* at 1542 (quoting from *Burch v. Amsterdam Corp.*, 366 A.2d 1079, 1086 (D.C. 1976)).

201. See *Sours v. General Motors Corp.*, 717 F.2d 1511, 1517 (6th Cir. 1983) (finding that federal motor vehicle safety standards do not immunize manufacturer from common-law liability); *Dorsey v. Honda Motor Co.*, 655 F.2d 650, 656 (5th Cir. 1981) (concluding that compliance with federal regulations does not exempt a party from liability under common law), *cert. denied*, 459 U.S. 580 (1982); *Dawson v. Chrysler Corp.*, 630 F.2d 950 (3d Cir. 1980) (stating that compliance with motor vehicle safety standards does not relieve a manufacturer of tort liability), *cert. denied*, 450 U.S. 959 (1981); *Murphy v. Nissan Motor Corp.*, 650 F. Supp. 922, 927 (E.D.N.Y. 1987) (finding that Congress has expressly intended to preserve common-law remedies and thus compliance with federal regulations does not cause exemption from common-law liability); *General Motors Corp. v. Edwards*, 482 So. 2d 1176, 1198 (Ala. 1985) (noting that compliance with federal highway safety standards is not conclusive and does not provide a defense to state tort law claims); *Gingold v. Audi-NSU-Auto Union, A.G.*, 567 A.2d 312, 325 (Pa. Super. Ct. 1989) (finding that compliance with

*Corp.*<sup>202</sup> is illustrative. In *Dawson*, the plaintiff alleged that the defendant's automobile was designed defectively because it did not have a continuous steel frame.<sup>203</sup> Chrysler maintained that its design was adequate because it complied with applicable federal safety standards.<sup>204</sup> The court, however, relied upon a provision of the National Traffic and Motor Vehicle Safety Act, which expressly preserved tort claims against automobile manufacturers.<sup>205</sup> In the court's view, this authorized tort liability even though manufacturers complied with motor vehicle safety standards.<sup>206</sup>

*Dorsey v. Honda Motor Co.*<sup>207</sup> involved a claim for punitive damages by the owner of a subcompact automobile who was injured when his vehicle collided with a larger car.<sup>208</sup> The trial court concluded that compliance with federal motor vehicle standards precluded an award of punitive damages because it negated the element of recklessness as a matter of law.<sup>209</sup> The court of appeals observed, however, that the NTMVSA expressly preserved common-law tort claims.<sup>210</sup> The *Dorsey* court also relied on the *Restatement (Second) of Torts* to conclude that "compliance with regulatory standards . . . does not require a jury to find a defendant's conduct reasonable."<sup>211</sup> If compliance with a federal regulatory standard did not automatically cause defendant's conduct to be considered reasonable, the court reasoned that it could be reckless, thereby justifying an award of punitive damages.<sup>212</sup>

4. *Food, Drug, and Cosmetic Act.*—Compliance with FDA standards is seldom conclusive on the issue of defectiveness.<sup>213</sup> In *Mac-*

federal motor vehicle safety standards does not "shield the manufacturer from common law liability"). *But see* *Hurt v. General Motors Corp.*, 553 F.2d 1181, 1184 (8th Cir. 1977) (holding that a lap belt that complied with motor vehicle safety standards was not defective).

202. 630 F.2d 950 (3d Cir. 1980), *cert. denied*, 450 U.S. 959 (1981).

203. *Id.* at 954.

204. *Id.* at 957.

205. *Id.* at 958.

206. *Id.*

207. 655 F.2d 650 (5th Cir. 1981), *cert. denied*, 459 U.S. 880 (1982).

208. *Id.* at 652-53.

209. *Id.* at 656.

210. *Id.*

211. *Id.* (citing RESTATEMENT (SECOND) OF TORTS § 288C (1965)).

212. *Id.*

213. *See* *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 658 (1st Cir. 1981) (finding that FDA approval of the warning on oral contraceptive pills is not conclusive); *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1362 (4th Cir. 1975) (finding that compliance by a manufacturer of chloramphenicol with FDA labeling requirements was not conclusive on the duty-to-warn issue); *Martinkovic ex rel. Martinkovic v. Wyeth Labs., Inc.*, 669 F. Supp. 212, 217 (N.D. Ill. 1987) (concluding that DPT vaccine manufacturer's compliance with

*Donald v. Ortho Pharmaceutical Corp.*,<sup>214</sup> for example, the manufacturer of an oral contraceptive drug issued an FDA-approved booklet in order to warn users about the health risks of taking birth control pills.<sup>215</sup> Among other things, the booklet warned about the risk of blood clots, but failed to use the word "stroke."<sup>216</sup> Concluding that the warning was inadequate, the court declared that "compliance with FDA requirements, though admissible to demonstrate lack of negligence, is not conclusive on this issue, just as violation of FDA requirements is evidence, but not conclusive evidence, of negligence."<sup>217</sup>

A federal district court reached a similar conclusion in *Graham v. Wyeth Laboratories*.<sup>218</sup> In that case, parents whose infant daughter suffered brain damage after being vaccinated with DPT vaccine, brought suit against the manufacturer.<sup>219</sup> The plaintiffs claimed, inter alia, that the manufacturer failed to warn about the risk of a severe reaction from the vaccine.<sup>220</sup> The defendant requested the court to find it "non-negligent per se" because the warning given had been approved

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FDA licensing requirements "is but one factor for the jury to consider in deciding the reasonableness of the manufacturer's conduct"); *Graham v. Wyeth Labs.*, 666 F. Supp. 1483, 1491 (D. Kan. 1987) (stating that FDA certification of DPT vaccine is not conclusive of the drug manufacturer's reasonableness); *Chambers v. G.D. Searle & Co.*, 441 F. Supp. 377, 383 (D. Md. 1975) (stating that compliance with FDA labeling requirements is not necessarily conclusive on the question of the adequacy of other warnings in failure-to-warn suit against manufacturer of oral contraceptives), *aff'd*, 567 F.2d 269 (4th Cir. 1977); *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 661 (Cal. 1973) (stating that compliance with FDA labeling requirements by manufacturer of chloramphenicol is not conclusive on issue of whether the warning was adequate); *Malek v. Lederle Labs.*, 466 N.E.2d 1038, 1039-40 (Ill. 1984) (stating that evidence of compliance with federal regulations is relevant for the consideration of a product's dangerousness but it is not conclusive as to that issue), *judgment reaff'd*, 504 N.E.2d 893 (1987); *Ortho Pharmaceutical Corp. v. Chapman*, 388 N.E.2d 541, 554 (Ind. Ct. App. 1979) (determining that an oral contraceptive manufacturer's compliance with FDA labeling requirements did not make the warning adequate as a matter of law); *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65, 70-71 (Mass.) (determining that compliance with federal regulations does not establish a lack of negligence), *cert. denied*, 474 U.S. 920 (1985); *Feldman v. Lederle Labs.*, 592 A.2d 1176, 1197 (N.J. 1991) (holding that civil tort liability is not precluded because of a conflict with federal law); *McEwen v. Ortho Pharmaceutical Corp.*, 528 P.2d 522, 534-35 (Or. 1974) (holding that a manufacturer's compliance with FDA warning requirements was not conclusive in negligence action); *Bristol-Meyers Co. v. Gonzales*, 561 S.W.2d 801, 804 (Tex. 1978) (holding that a manufacturer of an antibiotic was liable for failure to warn despite compliance with FDA labeling requirements).

214. 475 N.E.2d 65 (Mass. 1985).

215. *Id.* at 66-67.

216. *Id.* at 67.

217. *Id.* at 70-71.

218. 666 F. Supp. 1483 (D. Kan. 1987).

219. *Id.* at 1485.

220. *Id.*

by the FDA.<sup>221</sup> The court, however, declared that FDA standards were nothing more than "minimum standards," which the jury could consider, but which were not dispositive.<sup>222</sup>

5. *Federal Aviation Act.*—In general, the courts have refused to treat compliance with FAA regulations as conclusive evidence that an aircraft is properly designed.<sup>223</sup> *Wilson v. Piper Aircraft Corp.*<sup>224</sup> involved a suit against the manufacturer of a Piper Cherokee by the personal representatives of two passengers who were killed when the airplane crashed.<sup>225</sup> The plaintiffs alleged that the airplane lost power when its carburetors iced up.<sup>226</sup> They claimed, inter alia, that the aircraft was defective because the manufacturer had failed to install a fuel injection system.<sup>227</sup> On appeal from a jury verdict for the plaintiffs,<sup>228</sup> the defendant contended that FAA approval of the airplane's design foreclosed any further inquiry into the safety of its design.<sup>229</sup> The Oregon Supreme Court, however, observed that the Federal Aviation Act itself provided that FAA design standards were "minimum standards only."<sup>230</sup>

6. *Occupational Safety and Health Act.*—Although most courts admit evidence of OSHA standards in product liability cases,<sup>231</sup> compli-

221. *Id.* at 1499.

222. *Id.*

223. See *Bruce v. Martin-Marietta Corp.*, 544 F.2d 442, 446 (10th Cir. 1976) (concluding that "[c]ompliance with governmental air-safety regulations is admissible, but not conclusive" in determining negligence); *Elsworth v. Beech Aircraft Corp.*, 691 P.2d 630, 635-36 (Cal. 1984) (finding that a manufacturer may be found liable for "defective design even if the airplane complies with every regulation"), *cert. denied*, 471 U.S. 1110 (1985); *Wilson v. Piper Aircraft Corp.*, 577 P.2d 1322, 1324-25 (Or. 1978) (finding that FAA approval of an aircraft is not a complete defense to civil liability for faulty design); *Berkebile v. Brantly Helicopter Corp.*, 281 A.2d 707, 710 (Pa. Super. Ct. 1971) (concluding that compliance with FAA regulations does not establish that due care was exercised).

224. 577 P.2d 1322 (Or. 1978).

225. *Id.* at 1324.

226. *Id.*

227. *Id.*

228. *Id.*

229. *Id.*

230. *Id.* at 1324-25 (citing 49 U.S.C. § 1421(a)(1) (1988)).

231. See *Turney v. Ford Motor Co.*, 418 N.E.2d 1079, 1084-85 (Ill. App. Ct. 1981) (holding that the defendant would be allowed to introduce evidence that OSHA regulations did not require the installation of a roll bar on a tractor); *Hansen v. Abrasive Engineering & Mfg., Inc.*, 831 P.2d 693, 697 (Or. Ct. App. 1992) (reversing trial court's exclusion of OSHA standards in an action involving the design of sander), *aff'd in part and rev'd in part*, 856 P.2d 625 (Or. 1993). But see *McKinnon v. Skil Corp.*, 638 F.2d 270, 275 (1st Cir. 1981) (holding that OSHA regulations on circular saws for industrial use are not admissible in a case involving a saw designed for consumer use).

ance with OSHA safety standards has not precluded a jury from finding that a product is defective.<sup>232</sup> *McCullock v. H.B. Fuller Co.*<sup>233</sup> is one of the few cases to address this issue. In *McCullock*, a book bindery employee brought suit against the manufacturer of hot melt glue, arguing that the manufacturer failed to warn her of the risks of exposure to glue fumes in an unventilated area.<sup>234</sup> The manufacturer sought immunity from liability on the grounds that it had complied with applicable OSHA warning requirements.<sup>235</sup> The federal court of appeals, however, concluded that a warning that complied with OSHA safety standards might still be inadequate.<sup>236</sup>

### C. Precedents for a "Strong" Regulatory Compliance Defense

The traditional regulatory compliance defense provides little or no protection to defendants whose products meet applicable federal safety standards. The discussion below examines some of the efforts that have been made in the past to strengthen the legal effect of compliance with regulatory standards.

1. *Model Acts.*—Several uniform or model acts have included a strong regulatory compliance defense. The proposals suggested by Professor James Henderson and the Model Uniform Product Liability Act are especially noteworthy in this regard.

a. *The Henderson Proposal.*—In 1978 Professor James Henderson drafted a proposed federal statute to reform and rationalize design-defect litigation.<sup>237</sup> One section of the Henderson proposal provided that a manufacturer would avoid liability under certain circumstances for design of a product that complied with federal standards.<sup>238</sup> In such cases, the plaintiff was required to prove by clear

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232. See *McCullock v. H.B. Fuller Co.*, 981 F.2d 656, 658 (2d Cir. 1992).

233. *Id.*

234. *Id.* at 656-57.

235. *Id.* at 658.

236. *Id.*

237. See Henderson, *supra* note 16, at 630.

238. *Id.* at 632. This provision declares that:

In any products liability action, a defendant shall not be liable for negligence in the formulation or design of a product if the defendant proves by a preponderance of the evidence that the product formula or design complied with mandatory standards or regulations adopted by the federal government which were applicable to the product at the time of manufacture and which pertained directly to the formula or design-related hazard of which the plaintiff complains, unless the plaintiff proves by clear and convincing evidence, in addition to other facts required to be proved under state or federal law, including other provisions of this Act, that the mandatory federal standards or regulations applicable to the



and convincing evidence that the standards in question were inadequate to protect against unreasonable risks of injury or damage.<sup>239</sup>

*b. The Model Uniform Product Liability Act.*—In 1976 a Federal Interagency Task Force on Products Liability was created to study problems in the liability insurance industry.<sup>240</sup> After consulting with ten federal agencies, the Task Force issued a comprehensive report in 1977.<sup>241</sup> One of the Task Force's recommendations was that compliance with federal standards should give rise to a rebuttable presumption that a product manufacturer acted reasonably.<sup>242</sup> The Task Force study led to the publication of a Model Uniform Product Liability Act (MUPLA) by the Department of Commerce in 1979.<sup>243</sup>

Section 107 of MUPLA permits a defendant to request that the trial court determine whether the product conformed to an administrative or legislative standard that has the following characteristics: (1) the standard reflects the results of a thorough product testing and safety evaluation; (2) the agency considered consumer interests in formulating the standard; (3) the standard is regarded as more than a minimum standard; and (4) the standard reflects the level of technological and scientific knowledge reasonably available at the time the product was manufactured.<sup>244</sup> If the trial court concludes that the product meets such a standard, it must instruct the jury to presume that the product was not defective.<sup>245</sup> This presumption may only be rebutted by clear and convincing evidence that the risks of the product outweighed its utility.<sup>246</sup>

2. *Federal Legislative Proposals.*—Many legislative tort reform proposals have provided for an enhanced regulatory compliance defense.

product were inadequate to protect the class of persons of which the plaintiff is a member from unreasonable risks of injury or damage.

*Id.*

239. *Id.*

240. See Rodman Elfin, *Product Liability Law Reform: A Critique of Proposed Federal Legislation*, 1984 S. ILL. U. L.J. 579, 579.

241. U.S. DEP'T OF COMMERCE, INTERAGENCY TASK FORCE ON PRODUCTS LIABILITY, FINAL REPORT (1977) [hereinafter INTERAGENCY TASK FORCE]. The Task Force identified three areas of concern: the subjective nature of insurance ratemaking practices; unsafe products; and the effect of uncertainties in tort litigation on product liability insurance rates. For a detailed discussion of this report, see Coccia, *supra* note 90, at 105-08.

242. INTERAGENCY TASK FORCE, *supra* note 241, at VIII-40 to VIII-42.

243. MODEL UNIFORM PRODUCT LIABILITY ACT, 44 Fed. Reg. 62,714 (proposed Oct. 31, 1979).

244. *Id.* § 107.

245. *Id.*

246. *Id.*

As early as 1977, a legislative proposal declared that manufacturers who complied with federal product safety standards would have a defense to damage claims from injured consumers.<sup>247</sup> This bill was sent to committee, but no further action was taken.<sup>248</sup> Another bill, introduced in the House of Representatives during that same year, provided for a rebuttable presumption that a product was not negligently or defectively designed if its manufacturer complied with applicable federal or state standards.<sup>249</sup> This bill was not reported out of committee either.<sup>250</sup>

A number of products liability reform proposals were introduced in the 1980s.<sup>251</sup> Senate Bill 1999, introduced by Senator Danforth in 1985,<sup>252</sup> contained a regulatory compliance defense to punitive damages but did not purport to extend this defense to compensatory damage claims.<sup>253</sup> Senator Danforth introduced Senate Bill 2760 in

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247. S. 403, 95th Cong., 1st Sess. § 601 (1977). For a discussion of this proposal, see Sheila I. Birnbaum, *Legislative Reform or Retreat? A Response to the Product Liability Crisis*, 14 FORUM 251, 260-63 (1978) (describing the National Product Liability Insurance Act's aim at providing several defenses to product liability claims that were either "abolished or limited by recent case law" and preserving other existing defenses).

248. Victor E. Schwartz, *Federal Action on Products Liability—What Has Occurred and What May Occur*, 14 FORUM 287, 299 (1978).

249. H.R. 6300, 95th Cong., 1st Sess. § 8(a)(3) (1977); see also Birnbaum, *supra* note 247, at 265-68 (discussing the provisions of H.R. 6300).

250. Coccia, *supra* note 90, at 108 n.21. A similar bill, H.R. 5626, was again introduced in the House in 1979. *Id.* at 108 n.23 (noting H.R. 5626, 96th Cong., 2d Sess. (1979)). H.R. 5626 is reprinted in *Product Liability: Legislative Hearings: Supplemental Hearings on H.R. 5626 and H.R. 7000 Before the Subcomm. on Consumer Protection and Finance of the House Comm. on Interstate and Foreign Commerce*, 96th Cong., 2d Sess. 3-22 (1980). This bill also established government regulations as the appropriate standard of care in design-defect litigation. *Id.* § 5(d). Once again, however, no action was taken in committee. 125 CONG. REC. INDEX 2239 (1979-80).

251. The first of these bills was introduced by Senator Kasten in 1982. See S. 2631, 97th Cong., 2nd Sess. (1981). The Kasten bill attempted to strengthen some of the defenses available to product manufacturers, but did not contain a regulatory compliance defense. See Coccia, *supra* note 90, at 111. The bill was reported out of committee, but was not voted on by the full Senate. Linda Lipsen, *The Evolution of Products Liability as a Federal Policy Issue, in TORT LAW AND THE PUBLIC INTEREST*, *supra* note 66, at 247, 257. Senator Kasten reintroduced the bill in 1983. See S. 44, 98th Cong., 1st Sess. (1983). Extensive hearings were held during 1983 and 1984, but no vote was taken. See Elfin, *supra* note 240, at 581. A similar bill was also introduced in 1985. See S. 100, 99th Cong., 1st Sess. (1985). However, this bill was also rejected in committee. Lipsen, *supra*, at 257. Meanwhile, in October 1982, Representative Shumway introduced a products liability reform bill in the House. See H.R. 7284, 97th Cong., 2d Sess. (1982). Unlike the Kasten bill, the Shumway proposal provided that compliance with government standards would give rise to a rebuttable presumption that the product was safe. *Id.* § 7(a)(2). However, this bill failed to reach the House floor.

252. S. 1999, 99th Cong., 1st Sess. (1985).

253. *Id.* § 306(c); see also Joseph A. Mahoney, Note, *Senate Bill 640: Proposed Federal Product Liability Reform and Its Potential Effect on Pharmaceutical Cases and Punitive Damages Claims*,

1986.<sup>254</sup> This bill retained the provision that allowed drug manufacturers to avoid liability for punitive damages if they complied with FDA regulatory standards.<sup>255</sup> The bill was reported out of committee in 1986, but filibuster threats prevented a vote by the full Senate.<sup>256</sup>

Several years later, Senator Kasten introduced Senate Bill 640, a revised version of a bill he had introduced in 1981.<sup>257</sup> This bill prohibited punitive damage claims against drug manufacturers whose products were licensed by the FDA, as well as punitive damage claims against aircraft manufacturers whose products complied with FAA airworthiness standards.<sup>258</sup> Although the bill reached the Senate floor, in 1992 it fell victim to a filibuster and was not voted upon by the full Senate.<sup>259</sup>

In 1993 Senators Rockefeller, Danforth, and others introduced Senate Bill 687.<sup>260</sup> This bill prohibited punitive damage awards against manufacturers of prescription drugs and medical devices if the drug or device was subject to FDA premarket approval<sup>261</sup> or if it was "generally recognized as safe and effective pursuant to conditions established by the FDA and applicable regulations, including packaging and labeling regulations."<sup>262</sup> In addition, the bill exempted aircraft

36 ST. LOUIS U. L.J. 475, 504 (1992) ("Interestingly, S. 1999 was the first proposal to contain a government standards defense to punitive damage claims.")

254. S. 2760, 99th Cong., 2d Sess. (1986), reprinted in *Product Liability Reform Act: Hearings Before the Senate Comm. on the Judiciary*, 99th Cong., 2d Sess. 3-45 (1986). S. 2760 was a revised version of the Kasten bill. See *supra* note 251 (describing the Kasten bill).

255. S. 2760 § 303(c)(1).

256. Lipsen, *supra* note 251, at 258-59. No significant legislation was introduced in the Senate during the 100th Congress, which met during 1987 and 1988. See S. REP. NO. 356, 101st Cong., 2d Sess. 15 (1990). However, proposed legislation was introduced in the House. *Id.*; see, e.g., H.R. 1115, 100th Cong., 1st Sess. (1987). This bill contained a provision that protected manufacturers who complied with government standards against liability for punitive damages. However, like S. 2760, this legislative proposal was not acted upon. See Mahoney, *supra* note 253, at 505.

257. S. 640, 102d Cong., 1st Sess. (1991), reprinted in 137 CONG. REC. S3256-60 (1991); see also *supra* note 251 (describing the earlier bill). For an analysis of S. 640, see Robert A. Goodman, Note, *Proposed Federal Standards for Product Liability*, 30 HARV. J. ON LEGIS. 253, 305-318 (1993) (discussing the provisions of the bill, policy arguments surrounding tort reform proposals, and concluding that tort reform is better addressed at the state level). See also SENATE COMM. ON COMMERCE, SCIENCE, AND TRANSP., REPORT ON S. 640, S. REP. NO. 215, 102d Cong., 1st Sess. (1991).

258. S. 640, 102d Cong., 1st Sess. § 303(c) (1991). For a discussion of this provision, see Mahoney, *supra* note 253, at 511-14.

259. Goodman, *supra* note 257, at 299.

260. S. 687, 103d Cong., 1st Sess. (1993). A companion bill, H.R. 1910, was introduced in the House by Representative Rowland and others. For a discussion of S. 687, see M. Stuart Madden, *Recent Federal and American Law Institute Products Liability Reform Initiatives*, 29 A.B.A. TORT & INS. L.J. 569, 570-75 (1994).

261. S. 687, 103d Cong., 1st Sess., § 203(b)(1)(A) (1993).

262. *Id.* § 203(b)(1)(B).

manufacturers from liability for punitive damages if they received FAA certification and complied with postapproval reporting requirements.<sup>263</sup> Like its predecessors, Senate Bill 687 was not enacted into law.

Proposed legislation was introduced in the 104th Congress in 1995 as part of the Republican "Contract with America." However, neither House Bill 10,<sup>264</sup> nor its successor, House Bill 956,<sup>265</sup> contained a regulatory compliance provision.

3. *State Legislation.*—Many state statutes now allow or require courts to consider the effect of compliance with government safety standards. However, the procedural consequences of such compliance vary considerably from state to state. For example, statutes enacted in Arkansas,<sup>266</sup> Michigan,<sup>267</sup> and Washington<sup>268</sup> permit parties to introduce evidence of regulatory compliance to show that a product is not defective or that its warnings are not inadequate; however, these statutes do not assign any particular evidentiary weight to compliance with safety standards. Other statutes provide that compliance with government safety regulations creates a rebuttable presumption that a product is not defective. Colorado,<sup>269</sup> Kansas,<sup>270</sup> Kentucky,<sup>271</sup>

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263. *Id.* § 203(c).

264. H.R. 10, 104th Cong., 1st Sess. (1995).

265. H.R. 956, 104th Cong., 1st Sess. (1995).

266. ARK. CODE ANN. § 16-116-105(a) (Michie 1987). This statute provides:

Compliance by a manufacturer or supplier with any federal or state statute or administrative regulation existing at the time a product was manufactured and prescribing standards of design, inspection, testing, manufacture, labeling, warning, or instructions for the use of a product shall be considered as evidence that the product is not in an unreasonably dangerous condition in regard to matters covered by these standards.

*Id.*

267. MICH. COMP. LAWS ANN. § 600.2946(2) (West 1986). This statute declares:

It shall be admissible in evidence in a products liability action that the manufacture, construction, design, formula, development of standards, preparation, processing, assembly, inspection, testing, listing, certifying, warning, instructing, marketing, advertising, packaging, or labeling was done pursuant to the federal and state laws, rules, or regulations in effect at the time the product was sold or delivered by the defendant to the initial purchaser or user.

*Id.*

268. WASH. REV. CODE § 7.72.050(1) (1992). This statute sets forth that "[e]vidence . . . that a product was or was not in compliance with . . . legislative regulatory standards or administrative regulatory standards, whether relating to design, construction or performance of the product or to warnings or instructions as to its use may be considered by the trier of fact." *Id.*

269. COLO. REV. STAT. § 13-21-403(1) (1989). This statute declares that it shall be rebuttably presumed that the product which caused the injury, death, or property damage was not defective and that the manufacturer or seller thereof was not negligent if the product: . . . [c]omplied with, at the time of sale

Tennessee,<sup>272</sup> and Utah<sup>273</sup> have chosen this approach. New Jersey also allows a rebuttable presumption for regulatory compliance, but limits it to warnings approved or prescribed by the FDA for drugs, medical devices, food, or food additives.<sup>274</sup>

Other states have adopted more limited forms of regulatory compliance legislation. For example, five states have enacted statutes that provide immunity from punitive damage liability to drug manufactur-

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by the manufacturer, any applicable code, standard, or regulation adopted or promulgated by the United States or by this state, or by any agency of the United States or of this state.

*Id.*

270. KAN. STAT. ANN. § 60-3304(a) (1994). This statute provides:

When the injury-causing aspect of the product was, at the time of manufacture, in compliance with legislative regulatory standards or administrative regulatory safety standards relating to design or performance, the product shall be deemed not defective by reason of design or performance, or, if the standard addressed warnings or instructions, the product shall be deemed not defective by reason of warnings or instructions, unless the claimant proves by a preponderance of the evidence that a reasonably prudent product seller could and would have taken additional precautions.

*Id.*

271. KY. REV. STAT. ANN. § 411.310(2) (Baldwin Supp. 1995). This statute declares:

In any product liability action, it shall be presumed, until rebutted by a preponderance of the evidence to the contrary, that the product was not defective if the design, methods of manufacture, and testing conformed to the generally recognized and prevailing standards . . . in existence at the time the design was prepared, and the product was manufactured.

*Id.*

272. TENN. CODE ANN. § 29-28-104 (1980). This statute sets forth that

[c]ompliance by a manufacturer or seller with any federal or state statute or administrative regulation existing at the time a product was manufactured and prescribing standards for design, inspection, testing, manufacture, labeling, warning or instructions for use of a product, shall raise a rebuttable presumption that the product is not in an unreasonably dangerous condition in regard to matters covered by these standards.

*Id.*

273. UTAH CODE ANN. § 78-15-6(3) (1992). This statute states:

There is a rebuttable presumption that a product is free from any defect or defective condition where the alleged defect in the plans or designs for the product or the methods and techniques of manufacturing, inspecting and testing the product were in conformity with government standards established for that industry which were in existence at the time the plans or designs for the product or the methods and techniques of manufacturing, inspecting and testing the product were adopted.

*Id.*

274. N.J. STAT. ANN. § 2A:58C-4 (West 1987). According to this statute, "[i]f the warning or instruction given in connection with a drug or device or food or food additive has been approved or prescribed by the federal Food and Drug Administration . . . , a rebuttable presumption shall arise that the warning or instruction is adequate." *Id.*

ers whose products are approved or licensed by the FDA.<sup>275</sup> These statutes declare that the manufacturer or seller of a drug shall not be held liable for punitive damages if the drug that allegedly caused the harm was manufactured and labeled in accordance with the terms of an approval or license issued by the FDA or is generally recognized as safe and effective pursuant to conditions established by the FDA and applicable regulations, including packaging and labeling regulations.<sup>276</sup> These statutes also provide that the regulatory compliance defense will not apply if the plaintiff proves by clear and convincing evidence that the defendant, either before or after making the drug available for public use, knowingly, and in violation of applicable FDA regulations, withheld from or misrepresented information known to be material and relevant to the harm that the plaintiff allegedly suffered.<sup>277</sup>

#### D. A Proposed Regulatory Compliance Defense

Although some of the measures discussed above are useful approaches, they do not go far enough. To be truly effective, a regulatory compliance defense must fully protect manufacturers from liability when their products meet applicable federal design, testing, or labeling requirements. It must also provide immunity to manufacturers whose products have satisfied federal requirements for premarket licensing or approval. With these considerations in mind, I propose that the following statute be enacted for use in federal courts:<sup>278</sup>

(1) No product seller shall be liable for any injury to a claimant allegedly caused by some aspect of the formulation, labeling, or design of a product if the product seller proves by a preponderance of the evidence that the product's formula, labeling, or design complied with mandatory safety standards or regulations adopted and promulgated by an agency of the federal government, which were applicable to the product at the time of manufacture, and which governed the product risk that caused harm, unless the claimant proves by clear and convincing evidence that the mandatory

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275. ARIZ. REV. STAT. ANN. § 12-701(A) (1992); N.J. STAT. ANN. § 2A:58C-5c (West 1987); OHIO REV. CODE ANN. § 2307.80(C) (Anderson 1995); OR. REV. STAT. § 30.927(1) (1988); UTAH CODE ANN. § 78-18-2(1) (1992).

276. See statutes cited *supra* note 275.

277. ARIZ. REV. STAT. ANN. § 12-701(B) (1992); N.J. STAT. ANN. § 2A:58C-5c (West 1987); OHIO REV. CODE ANN. § 2307.80(C) (Anderson 1995); OR. REV. STAT. § 30.927(2) (1988); UTAH CODE ANN. § 78-18-2(2) (1992).

278. The proposed federal statute could also serve as a model for state legislation.

federal safety standards or regulations applicable to the product were grossly inadequate to protect the public from unreasonable risks of injury or damage.

(2)(a) No product seller shall be liable for any injury to a claimant allegedly caused by some aspect of the formulation, labeling, or design of a product if the product seller proves by a preponderance of the evidence that the product was subject to premarket licensing or approval by an agency of the federal government, that the manufacturer complied with all of the agency's procedures and requirements with respect to premarket licensing or approval, and that after full consideration of the product's risks and benefits, the product was approved or licensed for sale by the agency.

(b) The provisions of subsection (a) shall not apply if the claimant proves by clear and convincing evidence that the standards or procedures used in the particular premarket approval or licensing process were grossly inadequate to protect the public from unreasonable risks of injury or damage.

(c) The provisions of subsection (a) shall not apply in any case in which the manufacturer, before or after premarket approval or licensing of the product, withheld from or misrepresented to the agency required information that was material and relevant to the performance of the product and was causally related to the claimant's injury.

(3) The provisions of sections (1) and (2) shall not extend to manufacturing flaws or defects even though the product manufacturer has complied with all quality control and manufacturing practices mandated by the agency.

Section (1) of the proposal is based on section (f) of Professor Henderson's proposed federal statute.<sup>279</sup> However, unlike the Henderson proposal, section (1) extends the regulatory compliance defense to labeling as well as product design.<sup>280</sup> Section (2) is modeled after section 203(b) of Senate Bill 687.<sup>281</sup> The language in this subsection of Senate Bill 687 applies to punitive damage claims against the manufacturers of drugs and medical devices licensed by the FDA.<sup>282</sup> In contrast, the provisions of section (2) in the legislation proposed above apply to claims for compensatory damages and extend to premarket approval or licensing decisions by federal agencies as well as to safety standards embodied in formal regulations. Finally,

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279. See Henderson, *supra* note 16, at 632.

280. See *id.*

281. S. 687, 103d Cong., 1st Sess. § 203(b) (1993).

282. *Id.*; see *supra* notes 260-263 and accompanying text.

section (3), which is original, provides that the regulatory compliance defense will not apply to manufacturing defects even though the manufacturer has complied with federally mandated manufacturing practices.

The proposed regulatory compliance defense is subject to a number of significant exceptions. First of all, the defense will not be available to a manufacturer if there are no federal safety standards applicable to the product risk that has allegedly caused the claimant's injury. In other words, the regulatory compliance defense will not apply to products or safety risks that are not subject to federal regulatory standards. In addition, the regulatory compliance defense will not be applicable if a product has failed to comply with applicable standards or, in the case of licensing, if the manufacturer has withheld or misrepresented test data or other information required for submission as part of the licensing process. Obviously, a regulatory compliance defense should not protect a manufacturer whose products fail to meet applicable standards. The regulatory compliance defense is also inappropriate when a manufacturer has secured premarket approval from an agency through fraud. Furthermore, compliance with federal manufacturing practices or quality control procedures will not protect a product seller from liability when the victim complains of a manufacturing defect. Because state tort law works well in this context, there is no need to displace it.<sup>283</sup> Finally, the regulatory compliance defense will not be available if the claimant proves by clear and convincing evidence that the product safety standards applied by the agency were grossly inadequate to protect the public from harm.

Adoption of a regulatory compliance defense such as the one proposed above will have a number of desirable consequences. First, it will uphold the integrity of agency decision-making on product safety issues and protect it against collateral attack in the courts. Second, it will insulate product manufacturers against wasteful and unnecessary litigation. Third, it will check the tendency toward "overdeterrence" in certain industries.

The proposed regulatory compliance defense ensures that in most cases courts will rely on applicable federal safety standards, rather than tort liability rules, to determine whether a product's labeling or design is defective. This will reduce overhead costs because manufacturers can look to criteria that are consistent, specific, and

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283. See VISCUSI, *supra* note 73, at 85 ("Strict liability would continue to pertain to manufacturing defect cases . . .").



uniform to define their safety responsibilities.<sup>284</sup> At the same time, public safety will be protected because the proposed defense allows consumers to challenge safety standards that do not provide reasonable protection against product-related risks.<sup>285</sup>

In addition, the proposed regulatory compliance defense will secure significant administrative cost savings by reducing litigation costs. At the present time, courts do not give much weight to federal safety standards in product-labeling or design-defect litigation. As a result, manufacturers and victims must spend large amounts of money litigating product safety issues on a case-by-case basis. If the proposed regulatory compliance defense is adopted, both parties will know whether a product is defective, thus avoiding costly litigation.<sup>286</sup>

Finally, the proposed regulatory compliance defense will lessen the effect of overdeterrence in products liability. Overdeterrence occurs when manufacturers become excessively concerned with potential tort liability. For example, fear of damage claims has discouraged manufacturers of pharmaceutical products from introducing new products and has sometimes induced them to remove existing products from the market.<sup>287</sup> Airplane manufacturers also have reacted negatively to potential tort liability by greatly reducing the production of small aircraft.<sup>288</sup> This sort of overdeterrence is undesirable because it either removes useful products from the marketplace or greatly in-

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284. See W. Kip Viscusi, *Toward a Diminished Role for Tort Liability: Social Insurance, Government Regulation, and Contemporary Risks to Health and Safety*, 6 YALE J. ON REG. 65, 72 (1989) ("The great benefit of regulation is that every party covered by the regulation does not incur information costs.").

285. Professor Henderson has suggested that plaintiffs be allowed to challenge product safety standards by showing that the processes by which the standards in question were established, when compared with other government standard-making processes, were inadequate to protect the interests of product users and consumers. See Henderson, *supra* note 16, at 639 ("[I]t might be shown that the processes by which the regulatory standards were established, when compared with other governmental standards processes, were inadequate to protect the interests of the product users and consumers.").

286. See Peter L. Kahn, *Regulation and Simple Arithmetic: Shifting the Perspective on Tort Reform*, 72 N.C. L. REV. 1129, 1134-35 (1994) ("By lending clarity to the definition of rules and by reducing reliance on relatively inexpert juries in overseeing complex design decisions, regulation can reduce the litigation costs and inefficiency generated by the tort system.").

287. See Howard A. Denemark, *Improving Litigation Against Drug Manufacturers for Failure to Warn Against Possible Side Effects: Keeping Dubious Lawsuits from Driving Good Drugs Off the Market*, 40 CASE W. RES. L. REV. 413, 415 (1989-90) ("Potential liability can drive drug companies to withdraw products from the market, and discourage research into new drugs used by individuals likely to sue and receive large damage awards."); Walsh & Klein, *supra* note 82, at 177 (asserting that tort liability is "forcing the withdrawal of drug products from the market and inhibiting their introduction in the first instance").

288. See VISCUSI, *supra* note 73, at 8 (contending that tort liability caused the production of small aircraft to fall from 17,000 in 1979 to 1085 in 1987).

creases their cost to consumers. By providing manufacturers who comply with federal safety standards with a "safe harbor," the proposed regulatory compliance defense will help prevent overdeterrence.

## V. A LOOK AT SOCIAL COSTS

Because *ex ante* regulation appears to be cheaper and more effective than *ex post* liability, I have proposed a regulatory compliance defense that is intended to secure the advantages of direct regulation while allowing accident victims to bring tort claims against product manufacturers when safety standards are clearly inadequate. Although this approach attempts to maximize the benefits of both regulation and tort liability, it necessarily involves trade-offs. First, product safety may be adversely affected to the extent that courts are foreclosed from imposing higher safety standards on product manufacturers. Second, fewer plaintiffs will be compensated for their injuries if a strong regulatory compliance defense is adopted. Although these social costs are not trivial, I do not believe that they are substantial enough to outweigh the benefits that would accrue from a strong regulatory compliance defense.

### A. Product Safety

A common objection to the regulatory compliance defense is that its adoption will increase accident costs.<sup>289</sup> Because manufacturers would be immune from suit as long as their products met federal product safety standards, they would have little incentive to make voluntary improvements in product safety.<sup>290</sup> Consequently, accident costs that would otherwise be deterred by the threat of tort liability would occur once the threat of tort liability was removed.<sup>291</sup>

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289. See generally Johnson, *supra* note 167, at 687 ("[T]his defense would adversely affect safety incentives.").

290. See Schwartz, *supra* note 169, at 1139 ("Making the compliance defense stronger could actually discourage safety by allowing manufacturers to 'sit back' and rely on standards that are inadequate."); Mark DeSimone, Comment, *The State of the Art Defense in Products Liability: "Unreasonably Dangerous" to the Injured Consumer*, 18 DUQ. L. REV. 915, 923 (1980) ("By preventing the courts from determining the standards by which a product is judged, the defense frustrates product improvement since the manufacturer is satisfied merely to comply with minimum government regulations.").

291. The accident costs attributable to such a change can be determined by subtracting existing product-related accident costs from the product-related accident costs that would occur if a strong regulatory compliance defense were adopted. Existing accident costs can be expressed mathematically as  $A=B - (C + D)$ . In this equation, *A* stands for existing accident costs; *B* stands for accident costs that would occur if there were no legal controls over product safety; *C* stands for accident-cost savings attributable to government regulation;

Although the adoption of a strong regulatory compliance defense will no doubt lead to some increase in product-related accident costs, it is not clear what the magnitude of this increase will be. This is important because it would be undesirable to adopt a strong regulatory compliance defense if its projected social costs are too great. Several issues seem to be relevant to the question of accident costs. One is the adequacy of existing federal product safety standards; another is the deterrent effect of tort liability.

The first issue for consideration is the adequacy of existing product safety regulations.<sup>292</sup> Some legal scholars object to a strong regulatory compliance defense because they believe that federal safety standards alone cannot adequately protect consumers against product-related risks.<sup>293</sup> These commentators point out that many federal safety standards are either obsolete<sup>294</sup> or substantively inadequate.<sup>295</sup>

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and  $D$  stands for additional accident-cost savings attributable to tort liability. The shift from the existing legal regime to one that recognized a strong regulatory compliance defense would result in a new level of accident costs, which would be expressed as  $A' = B' - (C' + D')$ .  $B'$ , of course, would remain the same as  $B$ . Furthermore, if existing government regulations were not changed,  $C'$  would remain the same as  $C$ . Consequently,  $A'$  would be a function of  $D'$ , and  $A'$  would go up as  $D'$  went down.

292. Many types of "regulatory failure" exist, although commentators do not always distinguish among them. They include (1) failure of an agency to regulate a particular class of products or product risk, (2) inadequate enforcement by the agency of existing safety standards, (3) deficiencies in the licensing process, and (4) obsolete or substantively inadequate safety standards. Adoption of a strong regulatory compliance defense will not increase accident costs associated with the first three types of regulatory failure. For example, the regulatory compliance defense would have no application to failure to regulate situations because it cannot be invoked as a defense against product-related risks unless they comply with regulatory standards. The regulatory compliance defense is not relevant in the second situation either because a manufacturer can invoke the defense only if a product actually complies with applicable safety standards. The third type of regulatory failure occurs when agencies license excessively dangerous products because applicants have provided incomplete or inaccurate data about potential risks. Once again, a strong regulatory compliance defense does not aggravate this type of problem because it provides no protection to manufacturers who deliberately, or even innocently, mislead licensing agencies.

293. See, e.g., Kahn, *supra* note 80, at 1181 ("Proposals to adopt a regulatory compliance defense . . . suffer from an obvious flaw: they accept regulatory standards that are almost inevitably incapable of fully forcing manufacturers to internalize the costs of their product safety decisions."); Schwartz, *supra* note 173, at 1343 (reasoning that courts must be free to reject regulatory standards "where regulations are outdated or clearly unsuitable as standards of care, or where inadequacies in the regulatory process or the misconduct of a product manufacturer would make the regulatory compliance defense inappropriate").

294. See DeSimone, *supra* note 290, at 923 ("[G]overnment regulations which may have been adequate when originally enacted are often obsolete and fall well below the level of safety needed for products manufactured at a later date.").

295. Safety standards may be substantively inadequate because the agency does not have sufficient resources or expertise to act independently and must rely upon industry sources for essential information about product-related risks and safety technology. See Schwartz,

The implicit assumption behind these observations is that the weaker federal safety standards are, the more tort liability must be relied upon to maintain an adequate level of product safety.<sup>296</sup> Consequently, they argue that because a strong regulatory compliance defense would scale back tort liability, its adoption would be particularly undesirable if existing regulatory standards were low.<sup>297</sup>

Do federal product safety standards really fail to provide sufficient protection to users and consumers? Commentators who question the adequacy of regulatory standards often cite examples of past regulatory failures to prove that regulatory standards are universally weak,<sup>298</sup> or they allege that the regulatory process is subject to sys-

*supra* note 169, at 1147 (discussing an inherently self-serving process in which agencies rely on industry-supplied data to formulate industry regulations). Government safety standards may also be affected by influence exercised over the agency by regulated industries. See Johnson, *supra* note 167, at 687 ("Manufacturers have enormous power to influence the formation of government standards . . .").

296. This can be illustrated by returning to the equation,  $A=B - (C + D)$ . If  $A$  remains constant,  $D$  will increase as  $C$  decreases. Therefore, the less accident-cost reduction or deterrence that direct regulation provides, the more accident-cost reduction or deterrence will be achieved by tort liability, assuming that total accident costs remain the same.

297. See, e.g., Schwartz, *supra* note 169, at 1146 (fearing the situation in which courts would apply outdated standards resulting in an undeservedly easy defense for manufacturers).

It may be recalled that existing product-related accident costs can be expressed by the equation  $A=B - (C + D)$ . See *supra* note 291.  $C$  represents accident-cost savings attributable to direct regulation, and  $D$  represents accident-cost savings attributable to tort liability. Consider two situations: In the first case,  $C$  is low and  $D$  is high, while in the second case,  $C$  is high and  $D$  is low. It is assumed that existing accident costs, represented by  $A$ , are the same.

What would happen in each situation if tort liability were scaled back? This new situation can be represented by the equation  $A'=B' - (C' + D')$ . Accident-cost savings attributable to tort liability, represented by  $D'$ , would decline because the deterrent effect of tort liability would be lessened. On the other hand, accident costs, represented by  $A'$ , would presumably increase, assuming that accident-cost savings attributable to direct regulation, represented by  $C'$ , remained the same.

Will the values in the second equation be affected by the respective values assigned to  $C$  and  $D$  in the original equation? It appears that the extent to which  $D'$  declines (and  $A'$  increases) will depend primarily on how the change affects tort liability rather than on the magnitude of  $C$  or  $D$ . For example, a change in tort liability rules that affects only a small class of regulated products will have a relatively small impact on  $D'$  and  $A'$  even though  $C$  is small and  $D$  is large. On the other hand, if the change affects all regulated products, it may decrease  $C'$  (and increase  $A'$ ) substantially even though  $C$  is relatively high and  $D$  is relatively low. However, once all other variables are eliminated, it would appear that any change in tort liability rules affecting regulated products would have a greater effect if  $C$  is low and  $D$  is high. In other words, if the scope of tort liability is reduced, accident costs are likely to be greater if regulatory standards are low instead of high.

298. See *infra* notes 300-301 and accompanying text.

temic weaknesses that inevitably cause regulatory standards to be inadequate.<sup>299</sup>

This first line of argumentation places a great deal of emphasis on past regulatory failures. Critics of federal regulation mention the former federal fabric flammability standard,<sup>300</sup> the FDA's licensing of dangerous drugs,<sup>301</sup> and other regulatory fiascos to show that federal standards are too low to maintain an acceptable level of product safety. However, examples of past regulatory failures merely demonstrate that problems have occurred from time to time within a particular agency; they do not prove that federal safety regulations are inadequate across the board.

The second line of argument posits the existence of systemic flaws in the regulatory process that ensure that federal regulations can never be wholly successful. For example, agencies are said to be chronically underfunded and, thus, lack the resources necessary to do their job properly.<sup>302</sup> Agencies are also allegedly dependent upon industry sources for essential information about product risks and safety technology.<sup>303</sup> Finally, some commentators maintain that agencies are subject to overwhelming influence and pressure from politicians and from the industries that they regulate.<sup>304</sup> While this regulatory model identifies many of the conditions that *may* result in weak regulatory standards, it does not prove that they necessarily *will* be ineffective. On the contrary, the fact that some agencies appear to do a

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299. See *infra* note 302 and accompanying text.

300. This standard was reputedly so low that fabrics as flammable as ordinary toilet tissue could meet it. See David C. Campbell & John F. Vargo, *The Flammable Fabrics Act and Strict Liability in Tort*, 9 IND. L. REV. 395, 403 (1976) ("The situation is so bizarre that some plaintiff's experts have demonstrated that ordinary toilet tissue will pass . . . the test.").

301. See, e.g., Schwartz, *supra* note 173, at 1347-52 (discussing 11 instances in which the FDA licensed dangerous pharmaceutical products); Daniel W. Sigelman, *Turning the Tables on Drug Companies*, 30 TRIAL, Mar. 1994, at 72, 72 (discussing numerous instances of FDA failure to discover drug-related risks during the licensing process).

302. See Kahn, *supra* note 80, at 1181 ("The systemic hostility to regulation that characterized the last few presidential administrations effectively gutted many agencies of resources and sapped their political will."); Schwartz, *supra* note 169, at 1157-58 (describing the adverse effects of budgetary cutbacks on the regulatory efforts of the FDA and CPSC).

303. See Schwartz, *supra* note 169, at 1147 ("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.").

304. See Johnson, *supra* note 167, at 687 ("Manufacturers have enormous power to influence the formation of government standards, with the result that the standards are frequently political compromises at best."); Spradley, *supra* note 7, at 372 ("Large corporate manufacturers have the organization and financial resources to lobby government agencies and legislative bodies to adopt minimum safety standards.").

better job than others indicates that the regulatory model described above may be unduly pessimistic.

In fact, it is not possible to prove, either empirically or theoretically, that federal product safety standards are universally inadequate.<sup>305</sup> Conditions do exist that may affect the integrity of the regulatory process, and admittedly a number of serious regulatory failures have occurred. However, there is simply not enough evidence to support the conclusion that most safety standards promulgated by regulatory agencies are inadequate or that such standards are less rigorous than those formulated by the courts.

Furthermore, even if existing regulatory standards fail to achieve an acceptable level of product safety, it does not follow that the tort system will do a better job. To be sure, conventional wisdom assumes that tort liability provides significant incentives for manufacturers to make their products safer.<sup>306</sup> These incentives will be weakened if

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305. Of course, there is no general agreement on how to evaluate the adequacy of safety standards. A popular approach is to measure adequacy in terms of economic efficiency. See, e.g., Viscusi, *supra* note 73, at 2 ("The task of a well-functioning social risk management policy is to strike an appropriate balance between safety and the costs incurred to achieve this safety."). According to this criterion, safety standards should be set at a level where marginal accident costs equal the marginal costs of preventing them. A safety standard would be deemed inefficient, and thus inadequate, if it allowed accident costs to occur which exceeded the costs of preventing them. However, safety regulations may reflect other values besides economic efficiency. See Stone, *supra* note 61, at 14 ("There may be a collective aversion to certain events . . . that make us willing to expend more to avert them than we would suffer in damages were they to occur."). In such cases, other criteria must be employed to judge the adequacy of safety regulations.

306. See Prentice & Roszkowski, *supra* note 82, at 274 ("Strict product liability induces manufacturers to make safer products.").

Tort liability operates at two levels to optimize accident costs. On an individual level, tort liability encourages those engaged in risky activities to reduce the risk of injury in order to lower their exposure to damage claims. See Brown, *supra* note 62, at 128 ("[The imposition of tort liability] provides an incentive for those engaged in a particular activity to make it safer, for by doing so, their costs will be lower."). For this reason, a manufacturer will spend money on product safety so long as the marginal cost of additional safety measures is less than the marginal reduction of expected tort liability. See James A. Henderson, Jr., *Product Liability and the Passage of Time: The Imprisonment of Corporate Rationality*, 58 N.Y.U. L. REV. 765, 768 (1983) ("[A] manufacturer will respond to threatened liability by investing in safety up to, but not beyond, the point at which the marginal costs of the investment equal the marginal costs of accidents thereby avoided.").

On an economy-wide level, tort liability promotes economic efficiency by helping to ensure that the prices of goods and services reflect their true social costs. See Richard J. Pierce, Jr., *Encouraging Safety: The Limits of Tort Law and Government Regulation*, 33 VAND. L. REV. 1281, 1289-90 (1980) ("[B]y forcing firms whose products or services are responsible for accident costs to absorb those costs, society [through tort liability] forces the prices of goods and services to reflect all costs required to make them available, including costs of accidents."). It is assumed that goods and services will be allocated more efficiently by the market if their prices include all costs of production. See Calabresi, *supra* note 171, at 501-02 (1960) (describing how prices affect the allocation of goods within the economy). If

product safety standards are determined by regulation alone.<sup>307</sup> Recently, however, a number of legal scholars have questioned whether tort liability actually deters risk-generating conduct to any meaningful degree.<sup>308</sup> They point out that in the real world, various factors mitigate tort liability's deterrent effects. For example, tort law is so vague and open-ended that manufacturers cannot rely on it to determine how safe their products must be to avoid liability.<sup>309</sup> In addition, corporate decision-makers often discount or ignore long-term risks in order to maximize short-term profits for their firm.<sup>310</sup> Moreover, even when they wish to improve product safety, corporate managers have difficulty communicating with those responsible for carrying out their orders.<sup>311</sup> Finally, the availability of liability insurance reduces the incentive to improve product safety because manufacturers can externalize their liability costs to others in the insurance pool.<sup>312</sup>

In the final analysis, it is difficult to tell whether the conditions described above actually diminish the deterrent effect of tort liability. However, the foregoing discussion does suggest that the impact of tort liability on product safety may be overrated. If that is so, then one

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accident costs are fully internalized by manufacturers, prices of dangerous products will rise and consumption will fall as consumers seek less expensive substitutes. See Richard C. Ausness, *Compensation for Smoking-Related Injuries: An Alternative to Strict Liability in Tort*, 36 WAYNE L. REV. 1085, 1107-08 (1990) ("[I]f a manufacturer is forced to raise prices to reflect the cost of product injuries, demand for dangerous products will fall accordingly.").

307. See Kahn, *supra* note 80, at 1185 ("The concerns which result from the fact that the tort system gives insufficient risk-reduction incentives are obviously not addressed by an alternative which provides even less adequate incentives.").

308. See William Powers, Jr., *A Modest Proposal to Abandon Strict Products Liability*, 1991 U. ILL. L. REV. 639, 644 ("It is debatable, both analytically and empirically, whether strict liability increases product safety, much less whether it tends to *optimize* product safety."); Sugarman, *supra* note 87, at 587 ("[T]heorists who defend torts on deterrence grounds have no convincing empirical support for their position."); see also Gary T. Schwartz, *Reality in the Economic Analysis of Tort Law: Does Tort Law Really Deter?*, 42 UCLA L. REV. 377, 405-13 (1994) (discussing a number of recent studies on the deterrent effect of product liability on manufacturers).

309. See Viscusi et al., *Inefficient Pharmaceutical Litigation*, *supra* note 69, at 1468 ("In the context of warnings litigation, the absence of meaningful standards is quite troublesome."); Viscusi, *Wading Through the Muddle*, *supra* note 69, at 575-77 (arguing that the risk-utility standard used in design-defect litigation is too vague to be of much use as an evaluative tool).

310. See Sugarman, *supra* note 87, at 569 ("Managers tend to worry most about their short-run profits . . . rather than the firm's long-term financial health.").

311. See George Eads & Peter Reuter, *Designing Safer Products: Corporate Responses to Product Liability Law and Regulation*, 7 J. PROD. LIAB. 263, 278 (1984) (discussing the inadequacies of corporate-level safety efforts absent involvement at lower levels of a company).

312. See Izhak Englard, *The System Builders: A Critical Appraisal of Modern American Tort Theory*, 9 J. LEGAL STUD. 27, 46 (1980) (stating that liability insurance "constitutes a serious hinderance to market deterrence since it creates . . . 'externalization due to insufficient subcategorization'").

may also conclude that a strong regulatory compliance defense will not affect product safety very much even when it substantially limits tort liability.<sup>313</sup>

### B. *Compensation and Risk Distribution*

The tort system not only attempts to deter manufacturers from subjecting consumers to excessive product-related risks; it also serves a risk-distribution or compensatory function.<sup>314</sup> Adoption of a strong regulatory compliance defense would undoubtedly reduce the chances of compensation for injured parties because it would protect manufacturers whose products comply with applicable federal safety standards from liability.<sup>315</sup>

Risk distribution is concerned with how losses are allocated in a society,<sup>316</sup> while loss-shifting<sup>317</sup> and loss-spreading<sup>318</sup> are two important mechanisms for distributing these losses. Both are aspects of "secondary accident cost avoidance."<sup>319</sup> This principle provides that the secondary consequences of accidents can be reduced or eliminated if those losses are not left to fall entirely on the victim.<sup>320</sup> Loss-shifting involves the shifting of accident losses from the victim to another party, such as an employer or a product manufacturer, with greater economic resources. Loss-spreading, on the other hand, operates on the notion that the secondary effects of a catastrophic loss are lessened if they are spread among members of a large risk pool.<sup>321</sup> Product liability involves both loss-shifting and loss-spreading. First, the economic costs of product-related injuries are shifted from the

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313. To return to the equations,  $A=B - (C + D)$  and  $A'=B' - (C' + D')$ , additional accident costs attributable to a strong regulatory compliance defense,  $A' - A$ , would presumably be smaller if  $D$  and  $D'$  were smaller, as they would be if tort liability had little deterrent effect on product manufacturers. See *supra* notes 291, 296-297.

314. See Jon D. Hanson & Kyle D. Logue, *The First-Party Insurance Externality: An Economic Justification for Enterprise Liability*, 76 CORNELL L. REV. 129, 137-38 (1990) ("A tort regime's ability to allocate the risks of unprevented product accidents may be as important a determinant of that regime's overall efficiency as is its ability to deter product accidents.").

315. See Schwartz, *supra* note 169, at 1127 (predicting that regulatory reforms "would erase some of the major advantages that plaintiffs have gained in the development of products liability law over the last twenty years").

316. Ausness, *supra* note 306, at 1113.

317. See GUIDO CALABRESI, *THE COSTS OF ACCIDENTS* 21 (1970) (defining loss shifting as "the placing of losses on those classes of people or activities who are best able to pay").

318. *Id.* (explaining loss spreading as "the accomplishment of the broadest possible spreading of losses, both over people and time").

319. *Id.*

320. See *id.* at 27-28.

321. See Calabresi, *supra* note 171, at 517-18 ("[S]ocial dislocations, like economic dislocations, will occur more frequently if one person bears a heavy loss than if many people bear lighter ones.").



victim to the manufacturer; then the manufacturer spreads these costs to its customers through the pricing mechanism.<sup>322</sup>

However, not all legal scholars believe that the tort system is an effective mechanism for shifting and spreading product-related accident costs. Some observe that the tort system overcompensates some victims<sup>323</sup> and undercompensates others.<sup>324</sup> They point out that workers' compensation, private insurance plans, and various social welfare programs largely duplicate the risk-distribution function of tort liability.<sup>325</sup> Finally, these commentators maintain that the tort system is far more expensive to administer than either private or public compensation schemes.<sup>326</sup> If other mechanisms do a better job of compensation than the tort system, one can argue that victims should rely on these systems instead of tort liability to distribute the risks of product-related injuries.<sup>327</sup> Because most injured consumers have access to some source of private or public compensation, foreclosing certain

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322. See Keeton, *supra* note 170, at 856 (commenting that manufacturers "are capable, if held responsible [for product liability], of passing on to users generally losses suffered by the few").

323. See Sugarman, *supra* note 87, at 595-96 (arguing that, in comparison with other compensation systems, tort law is overly generous to injured parties).

324. *Id.* at 592-94 (arguing that the consequences of tort law principles often result in uncompensated or undercompensated victims).

325. See George L. Priest, *The Continuing Crisis in Liability*, 1 PROD. LIAB. L.J. 243, 248 (1989) ("[W]orkers filing 60 percent of products liability claims are already covered for disability losses and full medical expenses through workers' compensation. Similarly, the vast majority of the U.S. population possesses medical coverage . . ."). Professor Priest also points out that tort law, when viewed as a form of forced insurance, is extremely regressive because all consumers pay the same "premium" but high-income claimants typically receive larger awards than low-income claimants. See George L. Priest, *Modern Tort Law and Its Reform*, 22 VAL. U. L. REV. 1, 17 (1987) ("[T]ort law's lumping of low-income consumers and high-income consumers into the same insurance pool and charging them a similar premium for insurance, forces low-income consumers to subsidize high-income consumers.").

326. See Litan, *supra* note 90, at 135 ("The tort system is an extremely expensive device for compensating injured parties."). Administrative costs consume more than half of every dollar spent by manufacturers for product-related claims. Deborah R. Hensler, *Trends in Tort Litigation: Findings from the Institute for Civil Justice's Research*, 48 OHIO ST. L.J. 479, 492 (1987) ("Overall, plaintiffs appear to receive, in net compensation, about fifty percent of tort litigation expenditures."). In contrast, administrative costs consume 30% of every dollar spent on workers' compensation, 15% of every dollar spent on health insurance, and 1% of every dollar spent on the social security system. See Litan, *supra* note 90, at 135.

327. I would maintain that accident victims who are fortunate enough to recover in tort actions are often grossly overcompensated. Large damage awards for "pain and suffering" are common even in cases where pecuniary damages are relatively small. There is no justification for multi-million dollar awards for pain and suffering except where the victim suffers serious permanent disfigurement, injuries that require long-term medical care, or injuries that result in permanent disability.

classes of tort claims will not necessarily result in large secondary accident costs.

Another distributional concern is that a strong regulatory compliance defense would benefit large corporations (or their shareholders) at the expense of accident victims. This regressive transfer of wealth from a relatively poor group (victims) to an economically advantaged group (manufacturers) would be socially undesirable. It is true that accident victims as a group will receive less total compensation if a strong regulatory compliance defense is adopted and reductions in tort liability will initially benefit product manufacturers. However, in a competitive market, a large portion of these savings (as well as the resulting administrative-cost savings) ultimately will be transferred to consumers in the form of lower product prices.<sup>328</sup>

### *C. A Final Assessment of Costs and Benefits*

Ordinarily, the best way to determine if a strong regulatory compliance defense should be adopted is to compare costs and benefits. If the benefits of a strong regulatory compliance defense exceed its social costs, the defense should be adopted. If the opposite is true, the regulatory compliance defense should be rejected.

A comparison of costs and benefits requires that both costs and benefits be identified and quantified. It is fairly easy to identify most of the social costs and benefits that would accrue from the adoption of a strong regulatory compliance defense. On the benefit side, a strong regulatory compliance defense will provide manufacturers with specific and uniform standards to follow. This would reduce production costs and allow manufacturers to market their products more cheaply. In addition, manufacturers who met applicable safety standards would not have to worry about tort claims and would be free to develop and market useful but risky products, such as pharmaceuticals. Finally, by restricting tort liability, a strong regulatory compliance defense would generate enormous administrative-cost savings.

On the loss side, the lessening of tort liability would deprive manufacturers of some incentive to invest in product safety. Consequently, products would become more dangerous and product-related accidents would increase accordingly. In addition, by limiting tort lia-

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<sup>328</sup> If this occurred, one might argue that a strong regulatory compliance defense transferred wealth from accident victims to consumers in general. While this may be correct, it cannot be said that such a transfer would be regressive because there is no evidence to suggest that accident victims are less wealthy than ordinary consumers.

bility, a strong regulatory compliance defense would deprive many accident victims of a chance to receive compensation for their injuries.

Having identified the costs and benefits of a strong regulatory compliance defense, the next step is to quantify them. Unfortunately, neither costs nor benefits can be easily monetized. On the cost side, there is no way to calculate the dollar cost of a shift from the present legal regime to one that limits tort liability by means of a strong regulatory compliance defense. Hard economic data is also lacking on the benefits as well. Because neither the costs nor the benefits can be quantified accurately, it is impossible to do a formal cost-benefit analysis on the regulatory compliance defense. Instead, one must rely on an educated guess to determine whether benefits outweigh losses. In my opinion, it is reasonable to conclude that a strong regulatory compliance defense is cost effective. On the benefit side, substantial administrative-cost savings are virtually certain to occur if the defense is adopted. On the other hand, product-related accident costs also will increase if a strong regulatory compliance defense is adopted. My own view is that this increase will not be very great because tort liability does not greatly affect product safety when regulatory standards are reasonably adequate. Accordingly, I believe that a strong regulatory compliance defense should be adopted.

#### CONCLUSION

The present system of product safety regulation is flawed because courts do not give sufficient weight to federal regulations when they evaluate the adequacy of labeling or design in product liability cases. This subjects manufacturers to a wasteful system of dual regulation. One solution to the problem is for Congress or federal administrative agencies to preempt state products liability law explicitly. Preemption, however, involves some significant social costs. For example, it encroaches upon important state interests and it also prevents injured consumers from challenging federal standards when they are inadequate to protect public safety.

A strong regulatory compliance defense, such as the one proposed here, is another option. A strong regulatory compliance defense would not infringe upon state interests to the same extent as preemption. At the same time, if this proposal were adopted, injured parties would be able to challenge federal regulations that were excessively weak. Thus, a strong regulatory compliance defense would provide all of the benefits of preemption without incurring some of its costs.

It has been suggested that the adoption of a strong regulatory compliance defense might have a negative effect on product-safety and risk-distribution goals. While this may be correct, I believe that the benefits of such a defense, particularly in the area of administrative-cost savings, will outweigh these social costs. Accordingly, I recommend that a strong regulatory compliance defense, such as the one proposed in this Article, be adopted at both the state and federal levels.