

# PUNITIVE DAMAGES AND REGULATED PRODUCTS

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## INTRODUCTION

Measures to limit punitive damage claims were key features of Vice President Quayle's proposed Agenda for Civil Justice Reform.<sup>1</sup> These measures were not entirely new, however. Both the Reagan and the Bush administrations supported proposals, some of which were quite drastic, to limit punitive damages awards. Among the proposals were measures to curtail the availability<sup>2</sup> and size<sup>3</sup> of punitive awards, to make the awards more difficult to obtain,<sup>4</sup> and to eliminate punitive awards almost entirely in cases where the product causing harm complied with federal regulations.<sup>5</sup> It is the last category of proposals involving products subject to regulatory compliance that is the subject of this Article.

Specifically, this Article examines proposals supported by the Bush administration that would ban punitive damages in cases where products are closely regulated and subject to government approval before being marketed. A recent example of such a proposal was Senate bill 640, the Product Liability Fairness Act.<sup>6</sup> The bill

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1. See PRESIDENT'S COUNCIL ON COMPETITIVENESS, AGENDA FOR CIVIL JUSTICE REFORM IN AMERICA 8, 22 (Aug. 1991) [hereinafter AGENDA FOR CIVIL JUSTICE REFORM] (suggesting that punitive damages be awarded in separate proceedings, under clear and convincing standard, and not in excess of compensatory damages award); see also Dan Quayle, *Civil Justice Reform*, 41 AM. U. L. REV. 559, 561-69 (1992) (discussing key items on civil justice reform agenda).

2. See S. 640, 102d Cong., 1st Sess. § 303(a) (1991) (stipulating that "punitive damages may not be awarded in the absence of a compensatory award" except when alleged harm is death or when state law provides for punitive damages only); see also S. 44, 98th Cong., 2d Sess. § 12(a)(2) (1984) (stating that "punitive damages may not be assessed in the absence of liability for compensatory damages").

3. See AGENDA FOR CIVIL JUSTICE REFORM, *supra* note 1, at 22 (limiting punitive damages to amount awarded for compensatory damages); see also U.S. ATTORNEY GEN., REPORT OF THE TORT POLICY WORKING GROUP ON THE CAUSES, EXTENT AND POLICY IMPLICATIONS OF THE CURRENT CRISIS IN INSURANCE AVAILABILITY AND AFFORDABILITY 68 (1986) [hereinafter ATTORNEY GENERAL'S REPORT] (limiting noneconomic damages, including punitive damages, to \$100,000).

4. See, e.g., S. 640, *supra* note 2, § 303(a) (allowing punitive damages to be awarded only to claimants who establish through clear and convincing evidence that injuries resulted from defendants' "conscious, flagrant indifference" to claimants' safety); H.R. 1115, 100th Cong., 2d Sess. § 207(a) (1988) (requiring that claimants show through clear and convincing evidence that defendants' conduct could result in punitive damages claim under applicable state law); AGENDA FOR CIVIL JUSTICE REFORM, *supra* note 1, at 22 (arguing that jury's determination of punitive damages award should only be based on clear and convincing evidence); Quayle, *supra* note 1, at 565 (positing that punitive damages awards be based on standard of proof requiring element of intent and that juries should base awards on clear and convincing evidence). Another proposal gives product manufacturers the right to ask for a separate proceeding to determine whether punitive damages should be awarded and the amount of the award. See S. 640, *supra* note 2, § 303(d) (allowing defendant to request that punitive damages be considered in separate proceeding).

5. See H.R. 1115, *supra* note 4, § 207(d) (exempting certain FDA-approved drugs and devices from purview of punitive damages awards).

6. S. 640, *supra* note 2. The Bush administration expressed strong support for the bill. S. REP. NO. 215, 102d Cong., 1st Sess. 13 (1991). After completion of this Article, a similar product liability reform measure was introduced in the 103rd Congress. S. 687, 103d Cong.,

called for a general ban on punitive damages, absent fraud, for three product categories: *drugs* and *devices* approved by or meeting the standards of the Food and Drug Administration (FDA), and *aircraft* approved by the Federal Aviation Administration (FAA).<sup>7</sup> While Senate bill 640 was not enacted,<sup>8</sup> a handful of states in recent years has adopted similar provisions banning punitive damages for government-approved products.<sup>9</sup>

The proposed reform is not draconian. It provides a regulatory compliance defense for only certain categories of products and does not apply at all to compensatory damages.<sup>10</sup> The suggested reform includes exceptions that permit punitive damages in cases of serious misconduct.<sup>11</sup> Still, the measure is worrisome because it removes an important safety incentive from the manufacturers of products that are among the most high-risk items in the marketplace.

Proponents of the reform counter that there is little need for punitive damages in cases of drugs, devices, and aircraft because the comprehensive regulatory schemes for these products are adequate to ensure their safety.<sup>12</sup> Further, proponents claim that the reform is badly needed in order to limit punitive damages awards that are out of control and "overdetering" the development of these socially useful products.<sup>13</sup>

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1st Sess. (1993). Although its provisions on punitive damages liability are quite similar to those in S. 640, there are some differences, which are noted *infra*, note 11.

7. S. 640, *supra* note 2, § 303(c)(1)-(2) (exempting from punitive damages any drug or device subject to premarket approval by FDA that was subsequently approved, and exempting any aircraft product subject to premarket approval that was subsequently certified by FAA and continues to comply with standards for airworthiness).

8. See *Product Liability Bill Dies in Senate After Supporters Fail To End Filibuster*, 20 Prod. Safety & Liab. Rep. (BNA) 995-96 (Sept. 11, 1992) (noting that bill died on September 10, 1992, when Senate was twice unable to obtain 60 votes needed to end filibuster mounted by opponents to bill).

9. See, e.g., *infra* note 17 and accompanying text (describing various state statutes that prohibit punitive damages awards in cases involving FDA-approved drug or drug that complied with FDA terms, conditions, or regulations).

10. See S. 640, *supra* note 2, § 303 (imposing limitations on punitive damages alone); see also S. 687, *supra* note 6, § 203 (same).

11. See S. 640, *supra* note 2, § 303(c)(1)(B)-(c)(2)(C) (excepting punitive damages limitations when defendant either withheld or misrepresented material and relevant information from Government or when defendant made illegal payment to FDA in attempt to secure agency approval of product); accord S. 687, *supra* note 6, §§ 203(b)(2)(B), (c)(2)(B) (excepting punitive damages for misdeeds identified in S. 640 and including illegal payment to FDA and FAA that had not been covered in S. 640.); S. 687, *supra* note 6, § 203(b)(2)(A) (exempting manufacturers who fail to meet their post-sale obligations to report adverse effects to FDA, which was not specifically provided in S. 640).

12. See *infra* note 67 and accompanying text (noting that proponents often argue that because FDA-regulated products must satisfy agency standards prior to their marketing and sale, agencies provide adequate assurances that products will be safe).

13. See *infra* note 68 and accompanying text (detailing contention that products having great societal value should not be subject to punitive damages because such damages deter product development).

This Article explores these claims. It challenges the idea that government regulation can be relied on to assure product safety and argues that the recent history of government deregulation in the Reagan and Bush administrations clearly refutes that notion. The Article also challenges the widespread notion that punitive damages are excessively high and are awarded routinely without sufficient grounds. The Article concludes that even a limited regulatory compliance defense, as proposed in Senate bill 640, cannot be justified.

## I. MEASURES TO LIMIT PUNITIVE DAMAGES FOR REGULATED PRODUCTS

### A. *Proposed and Enacted Reforms*

Only recently has federal product liability reform legislation included provisions banning punitive damages for specific regulated products. Earlier measures attempted to limit punitive damages<sup>14</sup> and others tried to create strengthened regulatory compliance defenses,<sup>15</sup> but there had not been a provision combining regulatory compliance and punitive damage limits. The Uniform Product Safety Act of 1988 proposed such a provision.<sup>16</sup> Like a handful of state tort reform laws,<sup>17</sup> the bill banned punitive damages in cases of drugs and devices approved by the FDA.<sup>18</sup> The preliminary version

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14. See *supra* notes 3-5 and accompanying text (discussing proposals to limit damages through various methods).

15. See *infra* note 36 and accompanying text (noting Uniform Products Liability Act and Uniform Product Safety Act as two provisions attempting to develop regulatory compliance defense).

16. H.R. 1115, *supra* note 4, § 207(d)(1).

17. A vast majority of the states have enacted tort and product liability reform measures in the past decade. In only a small number of states, however, has the reform legislation included provisions limiting punitive damages in cases of regulated products. Where states have adopted such provisions, they have limited protection to FDA-approved drugs and devices. Five states (Arizona, New Jersey, Ohio, Oregon, and Utah) have limits on punitive damages in cases of FDA-approved drugs. See ARIZ. REV. STAT. ANN. § 12-701 (1992) (prohibiting punitive or exemplary damages when drug is manufactured and labeled according to FDA requirements or is generally recognized as safe and effective by FDA); N.J. STAT. ANN. § 2A:58C-5(c) (West 1987) (precluding punitive damages if food or drug is approved or licensed by FDA or is generally regarded by FDA as safe and effective); OHIO REV. CODE ANN. § 2307.80(c) (Anderson 1991) (prohibiting punitive damages if drug is manufactured according to FDA terms of approval or license absent fraud); OR. REV. STAT. § 30.927 (1991) (proscribing punitive damages if drug is either labeled and manufactured pursuant to FDA terms of approval or license or is generally recognized as safe and effective by FDA); UTAH CODE ANN. § 78-18-2 (1992) (denying claimant punitive damages when drug either received premarket approval or licensing from FDA or is generally regarded as safe and effective by FDA); see also S. REP. NO. 215, *supra* note 6, at 37 n.195 (1991) (listing states that have enacted statutes prohibiting punitive damages in cases involving FDA-approved drugs).

18. See H.R. 1115, *supra* note 4, § 207(d)(1) (precluding awards of punitive damages for harms caused by FDA-approved drugs and devices absent intentional and wrongful withholding or misrepresentation of information required for submission to FDA or relating to safety and efficacy of drug or device or absent violation of Food, Drug, and Cosmetic Act).

of the Act also banned punitive damages in cases of aircraft certified by the FAA.<sup>19</sup>

Several years later, the Product Liability Fairness Act, Senate bill 640, proposed a similar ban on punitive damages for products regulated by the FDA and the FAA.<sup>20</sup> Specifically, the legislation proscribed punitive damages for prescription drugs and devices subject to premarket approval, as well as over-the-counter drugs subject to more general FDA regulation.<sup>21</sup> In addition, Senate bill 640 prohibited punitive damages for aircraft that had been certified by the FAA and were in compliance with postsale airworthiness requirements.<sup>22</sup> The bans on punitive damages in Senate bill 640, however, were not absolute. The legislation recognized two significant exceptions that limited the impact of the bans. First, the bill included a fraud exception that applied to all three groups of products: drugs, devices, and aircraft.<sup>23</sup> Second, the bill included a bribery exception applicable to drug and device manufacturers.<sup>24</sup> The last exception had not appeared in earlier legislation,<sup>25</sup> but was necessitated by a recent highly publicized scandal at the FDA involving generic drug manufacturers.<sup>26</sup> With these exceptions, Senate bill 640 assured that punitive damages would continue to be available in most cases involving egregious misconduct.

### B. *Origins of the Reform Measures*

The provisions of Senate bill 640 borrow features from two different areas of tort reform. They combine a limit on punitive damages,

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19. *Id.* § 208(c)(2). The bill as approved by the House Energy and Commerce Committee, however, did not include the provisions banning punitive damages for aircraft approved by the FAA. *See id.* § 207(d) (banning punitive damages for FDA-approved drugs and devices only).

20. *See S. 640, supra* note 2, § 303(c)(1) (exempting from punitive liability those drugs and devices either subject to premarket approval by FDA and subsequently approved or generally recognized as safe and effective by FDA).

21. *Id.* § 303(c)(1)(A)-(B).

22. *Id.* § 303(c)(2) (precluding punitive awards in cases involving aircraft where aircraft was subject to premarket certification by FAA, was approved, and subsequently complied with FAA standards concerning airworthiness).

23. *See id.* §§ 303(c)(1)(B), (c)(2)(C) (subjecting to punitive damages those defendants who made misrepresentations to or withheld material information from Federal Government about performance of their products).

24. *See id.* § 303(c)(1)(B) (stipulating that defendants who make illegal payments to FDA officials to secure product approval are subject to punitive damages).

25. *See H.R. 1115, supra* note 4, § 207(d)(1) (providing that ban on punitive damages would not apply to manufacturers of drugs and devices if they withheld from or misrepresented to government officials material information about performance of their products).

26. *See* Larry Thompson, *How Safe Are the Drugs You Take? Scandal at FDA Raises New Questions About Generic Medicines*, WASH. POST, Aug. 22, 1989, (Health Magazine) at 12 (describing bribery scandal involving FDA official and crisis it caused for FDA); *see also infra* notes 61-63 and accompanying text (explaining that FDA scandal involved generic drug company that bribed FDA employees to approve drug company's products).

which has been a popular subject of tort reform in the states, with a regulatory compliance defense, which has not generated as much interest.

### 1. *Legislative reforms to limit punitive damages*

The hue and cry over punitive damages during the past decade has resulted in a "dizzying array"<sup>27</sup> of legislation enacted around the country to curb punitive damages.<sup>28</sup> Proposals to limit punitive damages awards also have been part of proposed federal product liability legislation.<sup>29</sup> Senate bill 640, for example, included a number of provisions governing punitive damages claims. The bill defined the conduct required for a punitive damages award<sup>30</sup> and established a uniform standard of proof in such cases.<sup>31</sup> The bill also gave defendants the right to separate proceedings to determine punitive awards<sup>32</sup> and listed factors to be used in calculating the amount of such awards.<sup>33</sup> Thus, the provisions banning punitive damages for FDA- and FAA-approved products were only part of a much broader scheme to limit punitive damages awards.

### 2. *Reforms to strengthen the regulatory compliance defense*

Reforms to strengthen the regulatory compliance defense have not been widely adopted in the states. Although many proponents of product liability reforms have urged a stronger role for regulatory compliance,<sup>34</sup> including making compliance a complete defense

27. JAMES A. HENDERSON, JR. & AARON D. TWERSKI, *PRODUCTS LIABILITY: PROBLEMS AND PROCESS* 302 (2d ed. 1992).

28. *See id.* at 859 (showing that more than half of states enacted some punitive damages measures between 1986 and 1991); *see also* Joseph Sanders & Craig Joyce, "Off to the Races": *The 1980s Tort Crisis and the Law Reform Process*, 27 *HOUS. L. REV.* 207, 220-22 (1990) (listing most frequently enacted state tort reform measures between 1985-1986).

29. *See, e.g.*, Product Liability Act, S. 44, 98th Cong., 2d Sess. § 12 (1983) (attempting to limit availability of punitive damages); H.R. 1115, *supra* note 4, § 207(d)(1) (proscribing availability of punitive damages for FDA-approved drugs and devices); Uniform Product Liability Act (UPLA) § 108(c), 44 *Fed. Reg.* 62,714 (1979) (providing defendants with compliance defense, which could be rebutted by plaintiff by preponderance of evidence that product was defective).

30. *See* S. 640, *supra* note 2, § 303(a) (requiring "conduct manifesting a . . . conscious, flagrant indifference to the safety" of user as standard for assessing punitive damages).

31. *See id.* (requiring clear and convincing evidence showing by plaintiff to obtain punitive damages).

32. *Id.* § 303(d).

33. *See id.* § 303(e) (stipulating that following factors should be considered when determining amount of punitive damages: (1) financial condition of defendant and profitability of challenged conduct; (2) number of products sold; (3) severity of harm to plaintiff; (4) other punitive awards already imposed or that may be imposed for defendant's conduct; and (5) imposition of any criminal penalties or civil fines for conduct).

34. *See, e.g.*, 2 *AMERICAN LAW INST., ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY REPORTER'S STUDY* 83-110 (1991) [hereinafter *ALI, ENTERPRISE RESPONSIBILITY*] (maintaining that "[a]t a minimum, regulatory compliance should preclude the award of any punitive dam-

under certain conditions,<sup>35</sup> recent federal product liability legislation has not incorporated a broad regulatory compliance defense<sup>36</sup> and few states have enacted such reforms.<sup>37</sup> Even with the “nation-wide burst” of tort reform statutes adopted throughout the country in the 1980s,<sup>38</sup> this particular reform measure has not fared well. The question now is whether a narrower version of the compliance defense, as contained in Senate bill 640, will be more palatable to legislators at the state and federal level if it is promoted as a way of limiting the increasingly unpopular punitive damages award.

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ages”); James A. Henderson, Jr., *Manufacturers' Liability for Defective Product Designs: A Proposed Statutory Reform*, 56 N.C. L. REV. 625, 632 (1978) (arguing for regulatory compliance defense in defective design cases if defendant proves by preponderance of evidence that product complied with federal regulatory standards unless plaintiff can show by clear and convincing evidence that such standards were inadequate); Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 329-35 (1985) (arguing that courts should be required to defer to expert decisions of regulatory agencies regarding product design).

35. See ALI, ENTERPRISE LIABILITY, *supra* note 34, at 110 (stating that there is “persuasive case for making regulatory compliance a complete bar to tort liability once certain carefully-defined conditions have been satisfied respecting the regulation”).

36. See Uniform Products Liability Act (UPLA) § 108(a), 44 Fed. Reg. 62,714 (1979) (providing that product complying with government regulation should be deemed nondefective, but allowing plaintiff to show otherwise by preponderance of evidence). UPLA's compliance defense did not alter the plaintiff's burden of proving defectiveness in any significant way. A similar provision was included in the Uniform Product Safety Act. See H.R. 1115, *supra* note 4, § 207(d)(1) (1988) (precluding use of regulatory compliance defense upon showing of intentional withholding or misrepresentation of information or fraud). An early measure in the Senate, the Product Liability Act, S. 2631, 97th Cong., 2d Sess. (1982), contained no regulatory compliance defense. See S. REP. No. 670, 97th Cong., 2d Sess. 13-14 (1982) (stating that committee did not include regulatory compliance defense in bill). In considering the legislation, the Senate Committee on Commerce, Science, and Transportation heard conflicting testimony on the issue and concluded that it needed further study. *Id.* More recent legislation has also not included the broad regulatory compliance defense. See S. 640, *supra* note 2, § 303 (providing regulatory compliance defense for punitive damages only).

37. See, e.g., COLO. REV. STAT. ANN. § 13-21-403 (West 1987) (stating that injurious product is rebuttably presumed not defective and maker not negligent if product conforms to either “state of the art” pursuant to industry standards or any code, standard, or regulation regarding product promulgated by state or federal agency); KAN. STAT. ANN. § 60-3304 (1983 & Supp. 1987) (providing compliance defense for products conforming to legislative or administrative standards unless it is shown by preponderance of evidence that reasonably prudent manufacturer would have taken additional precautions); N.D. CENT. CODE § 28-01.1-05(3) (1991) (stipulating that products in compliance with government standards as to manufacturing, testing, and inspecting are rebuttably presumed not defective); TENN. CODE ANN. § 29-28-104 (1978 & Supp. 1987) (stating that compliance with federal or state statute or regulation raises rebuttable presumption that product is not unreasonably dangerous); UTAH CODE ANN. § 78-15-6(3) (1992) (allowing rebuttable presumption that product is free from defects when product conforms with government standards). These statutes all create presumptions that regulatory compliance constitutes reasonable safety measures.

38. See Sanders & Joyce, *supra* note 28, at 210 n.13 (noting that only two states—Pennsylvania and Vermont—did not enact some kind of tort reform legislation during latter half of 1980s).

## II. THE REGULATORY COMPLIANCE DEFENSE

### A. Arguments for Judicial Deference to Regulatory Standards

Before considering the narrow version of the regulatory compliance defense contained in Senate bill 640, it is helpful to review the pros and cons of the broader defense. Its proponents argue, among other things, that the judicial system should defer to safety standards set by regulatory agencies because the agencies have greater expertise than the courts in assessing risks and in determining what constitutes reasonable product safety.<sup>39</sup> They argue that the current dual system of tort and regulatory standards makes it impossible for manufacturers to know what standards they must meet,<sup>40</sup> and that judicial deference to the regulatory system would create much-needed uniformity in product safety standards.<sup>41</sup> Proponents of the regulatory compliance defense contend that no additional safety incentives from the tort system are needed to supplement the regulatory system.<sup>42</sup>

### B. Judicial Treatment of Regulatory Compliance

Courts reject these arguments almost uniformly and refuse to treat regulatory standards as equivalent to the standards of safety required by tort law.<sup>43</sup> Instead, courts regard regulatory standards

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39. See W. Kip Viscusi & Michael Moore, *Rationalizing the Relationship Between Product Liability and Innovation*, in *TORT LAW AND THE PUBLIC INTEREST* 125 (Peter H. Schuck ed., 1991) (arguing that courts should take advantage of government regulatory agencies' expertise because agencies' wealth of specialized knowledge makes them better suited than courts for making certain society-wide judgments). See generally James A. Henderson, Jr., *Judicial Review of Manufacturers' Conscious Design Choices: The Limits of Adjudication*, 73 *COLUM. L. REV.* 1531, 1555-56 (1973) (stating that complete deference to Government in standard setting is best course for courts); Huber, *supra* note 34, at 332-35 (encouraging deference by courts to agencies because of agencies' unique abilities to balance risks).

40. See, e.g., ALI, *ENTERPRISE RESPONSIBILITY*, *supra* note 34, at 88-89 (arguing that dual system creates "combination of legal constraints, delays, and uncertainties that imposes special burdens on new products and processes and threatens innovation").

41. See ALI, *ENTERPRISE RESPONSIBILITY*, *supra* note 34, at 87-89 (arguing against dual remedial system consisting of both regulation and liability because such system creates danger of overdeterrence).

42. See, e.g., RICHARD EPSTEIN, *MODERN PRODUCT LIABILITY LAW* 110-12 (1980) (noting comprehensive nature of agency review of drugs and arguing that agency standards should be both maximum and minimum requirements); Peter W. Huber & Robert E. Litan, *Overview*, in *THE LIABILITY MAZE: THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION* 1, 13 (Peter W. Huber & Robert E. Litan eds., 1991) (arguing that specific liability verdicts have not produced substantially safer products, but asserting that regulation is "the most important government factor in ensuring safety of pharmaceuticals and aircraft"); John D. Graham, *Product Liability and Motor Vehicle Safety*, in *THE LIABILITY MAZE*, *supra*, at 120, 183 (finding that consumer demands, regulation, and professional responsibility, and not threat of product liability, are all that is necessary to achieve product safety improvements).

43. See 4 *INTERAGENCY TASK FORCE ON PRODUCT LIABILITY*, U.S. DEPT. OF COMMERCE, *ITFPL-77/02, PRODUCT LIABILITY: FINAL REPORT OF THE LEGAL STUDY* 137 (1977) (finding that so few cases treated regulatory compliance as complete defense that it is not even minor-

as *minimum* standards of safety under the tort system that are relevant but not necessarily deserving of special weight in determining liability.<sup>44</sup> There are two primary reasons for this result. First, courts often find that a given regulatory standard definition is a matter of legislative intent<sup>45</sup> with some statutes explicitly precluding the use of tort standards of care as the regulatory safety standard.<sup>46</sup> Whether such intent is explicitly stated or not, courts seldom find the adoption of regulatory standards, which would have the effect of protecting compliant manufacturers from tort liability, to be consistent with the safety aims of these statutes.<sup>47</sup> Second, courts reject regulatory standards in circumstances where their adoption would run counter to common law standards of liability. Examples of this might include situations where regulations are outdated or clearly unsuitable as standards of care,<sup>48</sup> or where inadequacies in the regulatory process or the misconduct of a product manufacturer would make the regulatory compliance defense inappropriate.<sup>49</sup>

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ity rule); Paul Dueffert, *The Role of Regulatory Compliance in Tort Actions*, 26 HARV. J. ON LEGIS. 175, 175-76 (1989) (noting that courts generally admit compliance with government statutes and regulations regarding defendant's exercise of due care, and that courts view such regulations and statutes as merely establishing minimum standards); Teresa M. Schwartz, *The Role of Federal Safety Regulations in Products Liability Actions*, 41 VAND. L. REV. 1121, 1123 (1988) [hereinafter Schwartz, *Federal Safety Regulations*] (finding that courts have always treated compliance with regulatory and statutory standards as measure of minimum, not maximum, tort law standard).

44. See, e.g., *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1543 (D.C. Cir.) (holding that government regulations occupy "the floor of safe conduct . . . [not] a ceiling on the ability of states to protect their citizens"), *cert. denied*, 469 U.S. 1062 (1984); *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65, 70-71 (Mass.) (rejecting contention that FDA warning requirements preempt or define common duty to warn), *cert. denied*, 474 U.S. 920 (1985). But see *Grundberg v. Upjohn Co.*, 813 P.2d 89, 98-99 (Utah 1991) (providing immunity from strict liability based on design defects in FDA-approved prescription drugs because of agency's extensive regulatory system). For a discussion of *Grundberg*, see Teresa M. Schwartz, *Product Liability Reform by the Judiciary*, 27 GONZ. L. REV. 303, 326-27, 332-33 (1991-1992) [hereinafter Schwartz, *Product Liability Reform*].

45. See, e.g., *Raymond v. Riegel Textile Corp.*, 484 F.2d 1025, 1028 (1st Cir. 1973) (finding that Flammable Fabrics Act was not intended to establish standards of flammability for tort liability); *Wilson v. Piper Aircraft Corp.*, 577 P.2d 1322, 1324-25 (Or. 1978) (noting that nothing in Federal Aviation Act or its legislative history indicates intent for FAA standards to bind common law courts in tort actions).

46. See National Traffic and Motor Vehicle Safety Act § 108(c), 15 U.S.C. § 1397(c) (1988) (providing that compliance with auto safety standards "does not exempt any person from any liability under common law").

47. One rationale for adopting a regulatory standard as the appropriate tort standard is to further the safety goals of the statute. WILLIAM PROSSER, *HANDBOOK ON THE LAW OF TORTS* 191 (4th ed. 1971). A regulatory compliance defense, however, constricts common law liability and therefore seldom would further the aims of enhancing safety.

48. See, e.g., *Raymond*, 484 F.2d at 1027 (noting that material that could burst into flames two seconds after contact with heat source complied with federal flammability standards that had not been changed in 14 years).

49. See, e.g., *McDaniel v. McNeil Lab.*, 241 N.W.2d 822, 828 (Neb. 1976) (stipulating that evidence of fraud or nondisclosure to FDA by manufacturer allows FDA determinations concerning drugs to be challenged).

### C. *Flaws in the Regulatory System*

#### 1. *General concerns about the regulatory system*

There are a number of reasons beyond those offered by the courts that explain why regulatory standards should not displace tort standards of safety. One of the reasons is the problem of regulatory "lag" between the time that regulations should be and are issued or updated.<sup>50</sup> Lag results because agencies do not have the necessary resources to assure that all regulations are current,<sup>51</sup> or, because the agencies might not have the political will to act.<sup>52</sup> The influence of industry groups on the regulatory process is also worrisome. Unlike other interested parties such as consumer groups, industry members have considerable resources to devote to influencing the regulatory process,<sup>53</sup> and in addition, they have data that the agencies need to regulate the industries.<sup>54</sup> Given the significant role that industry groups play in the development of regulatory standards, it should come as no surprise that the courts are reluctant to adopt such regulatory standards as the common law rules of conduct for those same industries.

#### 2. *Special concerns about the regulatory system under former Presidents Reagan and Bush*

Concerns about the adequacy of the regulatory system, which have long been reflected in the judicial treatment of regulatory stan-

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50. See ALI, *ENTERPRISE LIABILITY*, *supra* note 34, at 85 (noting that there is often lag between time risks are created by enterprises and time curative regulations are adopted).

51. A recent thorough study of the FDA by an advisory committee chaired by former FDA Commissioner, Dr. Charles Edwards, identified the lack of resources as a recurring theme in the FDA's history. See U.S. DEP'T OF HEALTH & HUMAN SERVS. ADVISORY COMM., *FINAL REPORT ON THE FOOD AND DRUG ADMINISTRATION 39* (1991) [hereinafter *EDWARDS REPORT*] (finding that FDA's "grave" resource limitations impose "staggering burdens" on Agency). According to the report, "[t]he challenge posed by rapidly changing technology is as much a constant for the [FDA] as the chronic shortage of funds." *Id.* at 4. Those associated with the FDA, from former department officials and employees to business and consumer representatives, described the Agency as "overextended, underfunded and shackled by bureaucratic constraints." *Id.* at 5-6. The report concluded that even though the FDA's workload continues to increase, it is unlikely that the Agency will be able to increase its number of employees or be given a commensurate increase in funds. *Id.* at C-13. These same concerns about inadequate resources had appeared in similar advisory committee reports in 1955 and 1962. *Id.* at 3-4.

52. See ALI, *ENTERPRISE RESPONSIBILITY*, *supra* note 34, at 86 (stating that "[r]egulatory agency 'failure' may occur because of inadequate resources or on account of political and bureaucratic pressures").

53. PETER QUIRK, *INDUSTRY INFLUENCE IN FEDERAL REGULATORY AGENCIES* 13 (1981).

54. See JOAN CLAYBROOK, *RETREAT FROM SAFETY: REAGAN'S ATTACK ON AMERICA'S HEALTH* xxiv-xxv (1984) (claiming that regulated industries have information that U.S. Government needs to promulgate appropriate regulations). Cuts in an agency's budget preclude it from independently gathering information, thus forcing the agency to rely on industry data. *Id.* at xxiv. In such cases, the Government "has far less information than the regulated industry with which to make key regulatory decisions." *Id.*

dards, have been heightened in recent years as a result of the deregulatory agendas of both the Reagan and Bush administrations.<sup>55</sup> While commentators generally consider the Reagan administration to have been more antiregulatory than the Bush administration,<sup>56</sup> both administrations in fact adopted procedures that markedly increased the influence of industry in the regulatory process, mostly through secret processes that were outside public view.<sup>57</sup> The behind-the-scenes maneuvering during these two administrations to kill or undercut agency-proposed regulations caused an already slow system to be further delayed, thereby exacerbating problems of regulatory lag.<sup>58</sup> In addition, a moratorium on federal regulations imposed during the Bush administration brought the regulatory process to a virtual halt.<sup>59</sup> Both the Bush and Reagan administrations reduced the role of government by cutting back on agency budgets.<sup>60</sup>

It was perhaps inevitable that in this lax, antiregulatory environ-

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55. See *id.* at 58-70 (describing antiregulatory actions of Reagan administration in product safety area); Teresa M. Schwartz, *A Product Safety Agenda for the 1990s*, 45 WASH. & LEE L. REV. 1355, 1355-68 (1988) [hereinafter Schwartz, *Product Safety Agenda*] (describing Reagan administration's antagonistic approach to regulation and product liability claims).

56. See, e.g., Bob Davis, *January Surprise: Bush Plans To Unveil a 90-Day Moratorium on New Regulations*, WALL ST. J., Jan. 20, 1992, at A1 (describing Bush as "Reregulation President" during his first three years in office until he took "a page out of Reagan's book" and proposed regulatory moratorium as part of plan to address floundering economy).

57. In the Reagan administration, industry members were invited by high-level officials to seek relief from regulations at the Office of Management and Budget (OMB). Relief was sought behind the scenes and without public knowledge or an equal opportunity for the public to have input. See SUSAN J. TOLCHIN & MARTIN TOLCHIN, *DISMANTLING AMERICA: THE RUSH TO DEREGULATE 73-85* (1983) (describing OMB's role in rebuking agency regulatory initiatives). In the Bush administration the President's Council on Competitiveness, chaired by former Vice President Quayle, played a similar role, intervening to curb agency regulations, always behind the scenes without public scrutiny so as to leave "no fingerprints." See Bob Woodward & David S. Broder, *Quayle's Quest: Curb Rules, Leave "No Fingerprints,"* WASH. POST, Jan. 9, 1992, at A1 (stating that Quayle's Council on Competitiveness was "command post for a war against government regulation . . . [that] intervened in dozens of unpublicized controversies" involving important federal regulatory issues).

58. See NANCY WALTZMAN & CHRISTINE TRIANO, *VOODOO ACCOUNTING: THE TOLL OF PRESIDENT BUSH'S REGULATORY MORATORIUM JANUARY-AUGUST 1992* 7-8 (1992) (noting that during Bush administration, Council on Competitiveness delayed implementation of many regulations, including labeling rules under Nutrition Labeling and Education Act of 1990); Schwartz, *Product Safety Agenda*, *supra* note 55, at 1363-64 (detailing OMB's intervention during Reagan administration to stop FDA's proposal to require that labels on aspirin containers warn of Reye's Syndrome risks, causing four-year delay between regulation's proposal and its enactment).

59. See generally WALTZMAN & TRIANO, *supra* note 58, at 2-17 (describing various regulatory concerns that were either eliminated, delayed, or weakened by Bush administration between January-August 1992).

60. See EDWARDS REPORT, *supra* note 51, at 47 (finding that between fiscal years 1991 and 1992, President Bush cut budget request for FDA by more than \$117 million and urged establishment of user fee to make up difference). In the Reagan administration, some of the largest cutbacks occurred in the Consumer Product Safety Commission (CPSC), which suffered budget cuts of 25% and staff cuts of close to 30%. See CLAYBROOK, *supra* note 54, at 60-61 (stating that few agencies have experienced magnitude of CPSC's mid-1980s budget losses).

ment, a scandal would occur like the one that arose at the FDA in the late 1980s. The scandal, which involved the bribery of FDA employees by generic drug company officials to gain governmental approval of their products, was detected and "vigorously pursued"<sup>61</sup> by private sector and federal investigators, not by the FDA.<sup>62</sup> The scandal was certainly a low point in the history of one of the Federal Government's most respected regulatory agencies.<sup>63</sup> While there has been no indication that safety was actually compromised as a result of this scandal,<sup>64</sup> the incident does serve as a dramatic reminder of the flaws that exist in the regulatory system, even with respect to agencies that regulate comprehensively and are required to approve products before marketing.

If there was ever a time when a strengthened compliance defense should *not* have been adopted, it was during the twelve antiregulatory years of the Bush and Reagan administrations. Even in a more pro-consumer era,<sup>65</sup> however, the problems in the regulatory system such as the pervasive role of industry, regulatory lag, and the lack of adequate agency resources will continue to exist. These are inherent characteristics of the regulatory system that cannot be eliminated entirely, and they serve to underscore the importance of a vital tort system as an independent incentive for product safety.

Many of the reasons mentioned previously for opposing a general regulatory compliance defense also apply, perhaps with less force, to the narrowly crafted defense contained in Senate bill 640. In the next Part, the pros and cons of the more limited defense are explored.

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61. EDWARDS REPORT, *supra* note 51, at 1.

62. EDWARDS REPORT, *supra* note 51, at 1.

63. As a result of the scandal, a special advisory committee was established to review all operations of the Agency and a new FDA commissioner was appointed to restore confidence in the Agency. See EDWARDS REPORT, *supra* note 51, at 6 (noting that Dr. David Kessler was selected to head newly formed committee and to serve as commissioner).

64. See EDWARDS REPORT, *supra* note 51, at 6 (finding that public health was not threatened by shortcomings brought to light in report); see also Paul W. Valentine, *More Indictments Expected in Generic Drug Probe*, WASH. POST, Dec. 20, 1990, at A4 (stating that U.S. Attorney indicated that there had been no finding of harm caused by generic drugs despite industry's "reckless disregard for the health and safety of the consuming public").

65. There are some early signs that the Clinton administration will be a pro-consumer era. For example, the President reappointed FDA Commissioner David Kessler, who had aggressively enforced the food and drug laws during his previous two years in the office. David Brown & Boyce Rensberger, *Kessler Asked To Remain as Head of FDA; Healy Announces Resignation at NIH*, WASH. POST, Feb. 27, 1993, at A1. The Clinton-appointed Secretary of Transportation proposed a fiscal 1994 budget increase for the National Highway Traffic Safety Administration of 14%. *Pena Proposes FY 1994 Budget for NHTSA; 14 Percent Increase Means \$30.7 Million*, 21 Prod. Safety & Liab. Rep. (BNA) 353, 353 (Apr. 12, 1993). The Department of Transportation asked General Motors to recall 4.7 million pick-up trucks. *Doron P. Levin, Battle over G.M.'s Pickup Could Take Years To Settle*, N.Y. TIMES, April 12, 1993, at D1.

### D. *A Limited Regulatory Compliance Defense*

#### 1. *Closely regulated products*

Proponents of a narrow compliance defense for FDA- and FAA-regulated products argue that the defense does not contain the weaknesses of an across-the-board regulatory compliance defense<sup>66</sup> and is justified for two reasons. First, concerns about regulatory system adequacy should not exist. The products in question must be approved by a regulatory agency before they can be marketed and therefore are subject to far greater regulatory scrutiny than other products.<sup>67</sup> Second, these products are special because of their value to society. They deserve protection from tort doctrines such as punitive damages that might deter their production and development.<sup>68</sup> In sum, more is at stake with these products and more should be done to safeguard them.

The other side of this argument, of course, is that more is also at stake for the public if these products are not adequately controlled. While admittedly these products are socially useful, they also pose some of the greatest risks to human beings. Consider, for example, the widespread injuries that thousands of women suffered as a consequence of using the Dalkon Shield<sup>69</sup> or DES,<sup>70</sup> to name but two

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66. See S. REP. NO. 215, *supra* note 6, at 60 (commenting that S. 640 was portrayed by its proponents as less "draconian" than earlier product liability bills in terms of effects on consumers); cf. S. 640, *supra* note 2, § 303 (limiting recovery of punitive damages only and providing exceptions where manufacturers withheld or misrepresented information or where they made illegal payments to FDA officials).

67. See S. REP. NO. 215, *supra* note 6, at 38 (asserting that because government expends many resources in conducting reviews of drug and aircraft products' safety and risks, their extensive regulation makes them inappropriate subjects of punitive damages claims).

68. See S. REP. NO. 215, *supra* note 6, at 38 (suggesting that "imposing tort liability on top of safety regulation can result in overdeterrence of socially desirable products and activities").

69. See MICHAEL RUSTAD, THE ROSCOE POUND FOUNDATION, DEMYSTIFYING PUNITIVE DAMAGES IN PRODUCTS LIABILITY CASES: A SURVEY OF A QUARTER CENTURY OF TRIAL VERDICTS 8 (1991) (citing Dalkon Shield as clear example of inadequate testing). The Dalkon Shield, which had not been tested adequately but was aggressively marketed, was implanted in more than two million women. *Id.* From the mid-1970s to the mid-1980s, the Dalkon Shield cases alone accounted for more than 10% of the increase in product liability case filings in federal courts. See Judith P. Swazey, *Prescription Drug Safety and Product Liability*, in THE LIABILITY MAZE, *supra* note 42, at 295 (noting that according to General Accounting Office Dalkon Shield litigation was responsible for 12% of growth in federal product liability filings from 1974-1985).

70. See RUSSELL MOKHIBER, CORPORATE CRIME AND VIOLENCE: BIG BUSINESS POWER AND THE ABUSE OF THE PUBLIC TRUST 179 (1988) (stating that between 1941 and 1971, between 500,000 and 2 million women took DES to prevent miscarriages). Hundreds of lawsuits with thousands of named plaintiffs have been filed around the country against the manufacturers of DES. Sales of the drug were halted by the FDA in 1971 when it was discovered that a rare vaginal cancer was afflicting daughters of mothers who took DES during their pregnancies. See Rorie Sherman, *New DES Front*, NAT'L L.J., Mar. 12, 1990, at 26 (discussing history of DES liability). Subsequently, it was discovered that DES sons also suffered adverse consequences. See J.T. Johnson & Mark Dowie, *Revenge of a DES Son*, MOTHER JONES, Feb./Mar. 1983, at 31 (describing various genital abnormalities suffered by men exposed to DES as fetuses).

prescription products. Indeed, the level of potential risk from such products is one of the reasons they are so closely regulated.<sup>71</sup>

In addition, history does not suggest that the regulatory systems governing these products have been so effective in protecting the public that the tort system, with its punitive damage component, has been rendered unnecessary as an incentive for product safety. The recent bribery scandal at the FDA already has been discussed.<sup>72</sup> Consider also the following examples of drugs and devices that passed muster under the FDA's comprehensive regulatory schemes and were marketed to the public.

1. ORAFLEX, an arthritis drug, was approved by the FDA in the first year of the Reagan administration, even though the agency had refused to approve the drug two years earlier.<sup>73</sup> The drug's manufacturer, Eli Lilly, aggressively promoted Oralflex with a \$12 million marketing campaign.<sup>74</sup> It was later learned that Eli Lilly had knowledge of but failed to report a number of overseas deaths related to the drug.<sup>75</sup> Before Oralflex was withdrawn from the U.S. market, estimates indicated that the drug had caused fifty deaths in this country.<sup>76</sup> Ultimately, Eli Lilly pleaded guilty to statutory violations and was assessed a fine of \$25,000.<sup>77</sup> The company's chief medical officer was fined \$15,000.<sup>78</sup>

2. ORCOLON, a gel used in eye surgery, was approved by the FDA despite misgivings by the lead FDA reviewer and evidence that the product could cause elevated eye pressure.<sup>79</sup> After thirty-three patients had to undergo additional eye surgery to save their eyes be-

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71. See *Speedier Drugs*, ECONOMIST, Dec. 7, 1991, at 16 (discussing fear of deregulation of drugs).

72. See *supra* notes 61-64 and accompanying text (describing FDA scandal involving bribery by generic drug companies in late 1980s).

73. See Schwartz, *Federal Safety Regulations*, *supra* note 43, at 1148-49 n.124 (stating that Oralflex received approval from FDA only two years after being rejected); see also S. REP. NO. 215, *supra* note 6, at 82 (noting FDA's lack of diligence in reviewing information available to it prior to approving Oralflex); CLAYBROOK, *supra* note 54, at 48-50 (describing Oralflex and circumstances surrounding its approval by FDA).

74. See MOKHIBER, *supra* note 70, at 329-30 (describing Eli Lilly's promotional barrage, which included letters to doctors and newspaper, radio, and television advertisements).

75. See MOKHIBER, *supra* note 70, at 329-38 (stating that Eli Lilly had knowledge of numerous fatalities and other adverse reactions that it did not share with enforcement officials; detailing Justice Department report on case wherein prosecutors revealed that Eli Lilly knew of at least 23 deaths and dozens of serious adverse reactions caused by Oralflex early in first two months of 1982 and still began sale of drug in United States in spring of that year).

76. CLAYBROOK, *supra* note 54, at 50.

77. MOKHIBER, *supra* note 70, at 337.

78. MOKHIBER, *supra* note 70, at 337.

79. See Bruce Ingersoll, *Amid Lax Regulation, Medical Devices Flood a Vulnerable Market*, WALL ST. J., Mar. 24, 1992, at A6 (noting that Orcolon was approved despite fact that FDA officials were aware of findings that two people required surgery to prevent total blindness after using Orcolon, and lead reviewer had "deep misgivings about the product").

cause of Orcolon, the product was withdrawn from the market.<sup>80</sup>

3. BREAST IMPLANTS were among the 140 categories of high-risk devices whose safety was supposed to be established by manufacturers under the Medical Device Amendments of 1976.<sup>81</sup> Since 1976, however, the FDA has asked manufacturers of only eight device categories to prove the safety of their products.<sup>82</sup> Not until 1991 did the FDA request test data on silicone breast implants,<sup>83</sup> despite the facts that serious questions regarding their safety had been raised decades earlier<sup>84</sup> and that the FDA had received some 5000 complaints about them since 1983.<sup>85</sup> Recently, a number of successful lawsuits against breast implant manufacturers has resulted in punitive damages awards.<sup>86</sup>

4. ASPIRIN LABELING pertaining to Reye's Syndrome risks was delayed for years by the FDA and the Office of Management and Budget under the Reagan administration.<sup>87</sup> This delay persisted despite widespread agreement in the medical and scientific communities about the serious risks to children who take aspirin.<sup>88</sup>

5. MERITAL, an antidepressant, was approved by the FDA despite information it had in its files about allergic reactions to the drug.<sup>89</sup> The manufacturer also withheld information about some thirty deaths associated with the drug's use.<sup>90</sup>

6. COPPER 7 IUD was approved by the FDA and marketed to women who were first-time mothers, despite the manufacturer's knowl-

80. *Id.* at A1.

81. See 21 U.S.C. § 360c (1988) (providing that manufacturers of high-risk devices introduced before 1976, including breast implants, must prove safety of devices prior to devices' marketing).

82. Ingersoll, *supra* note 79, at A6.

83. Ingersoll, *supra* note 79, at A6.

84. Ingersoll, *supra* note 79, at A6.

85. See Sandy Rovner, *Implant Safety: Who's Right?*, WASH. POST, Nov. 12, 1991, (Healthtalk) at 212 (reporting that FDA had received 5000 complaints concerning silicone breast implants from 1983-1991).

86. See Tamar Lewin, *As Silicone Issue Grows, Women Take Agony and Anger to Court*, N.Y. TIMES, Jan. 19, 1992, at A1, A18 (stating that three multimillion-dollar jury awards have been made in past year to women suffering from breast implant complications).

87. See Schwartz, *Product Safety Agenda*, *supra* note 55, at 1363-64 (describing four-year delay in promulgation of aspirin labeling precipitated by OMB and Reagan administration pressure).

88. See Schwartz, *Product Safety Agenda*, *supra* note 55, at 1363-64 (describing OMB's intervention in promulgation of aspirin labeling).

89. See Schwartz, *Federal Safety Regulations*, *supra* note 43, at 1148 n.123 (describing how FDA ignored medical reports of severe allergic reactions to Merital).

90. Schwartz, *Federal Safety Regulations*, *supra* note 43, at 1148 n.123; see REPORT OF THE HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS SUBCOMM., GOV'T OPERATIONS COMM., FDA'S REGULATION OF THE NEW DRUG MERITAL, H.R. DOC. NO. 206, 100th Cong., 1st Sess. 47 (1987) (revealing that subcommittee investigation found that Merital's manufacturer failed to report to FDA prior to approval that it knew of at least 30 deaths associated with drug).

edge that the IUD posed special risks to this particular category of women.<sup>91</sup> A jury awarded significant compensatory and punitive damages to a woman in this category who had been injured by the Copper 7 IUD.<sup>92</sup>

7. TAMPON LABELING for toxic shock syndrome was delayed some twenty months because the FDA chose to rely first on voluntary standards by the industry (although the standards were not universally adopted) instead of issuing a rule requiring the labeling.<sup>93</sup>

8. SELACRYN, a medication for high blood pressure, was heavily promoted by its manufacturer at the same time the manufacturer withheld information from the FDA about serious adverse effects from the drug.<sup>94</sup> When the information was reported, it was "buried in a massive and routine manuscript" and not immediately discovered by FDA officials.<sup>95</sup> In the eight months the product was on the market, it caused sixty deaths and 513 cases of liver damage.<sup>96</sup> In the end, the FDA recommended that felony charges be brought against the manufacturer, but the Justice Department chose to bring misdemeanor charges.<sup>97</sup> As a result, the company was fined only

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91. See S. REP. No. 215, *supra* note 6, at 83 n.95 (positing that strong evidence existed that Copper 7 IUD's manufacturer had knowledge that device posed dangers for women who had not previously had children); see also *Kociemba v. G.P. Searle & Co.*, 707 F. Supp. 1517, 1537 (D. Minn. 1989) (finding that evidence presented by plaintiff would have led jury to conclude that "defendant knowingly placed millions of American women, especially [women who have not had children], at risk of serious infection, loss of fertility, and surgery for removal of organs").

92. See *Kociemba*, 707 F. Supp. at 1535-38 (denying motion for new trial in case awarding millions in punitive damages). The case was settled without appeal. S. REP. No. 215, *supra* note 6, at 78.

93. See STAFF OF SUBCOMM. ON OVERSIGHT AND INVESTIGATIONS OF THE HOUSE COMM. ON ENERGY AND COMMERCE, 98TH CONG., 1ST SESS., MEDICAL DEVICE REGULATION: THE FDA'S NEGLECTED CHILD 48-50 (Comm. Print 1983) (discussing history of toxic shock syndrome warning requirements for tampon manufacturers). The House Subcommittee on Oversight and Investigations reviewed the voluntary labelings adopted by tampon manufacturers and found them to be unsatisfactory. *Id.* at 49. The subcommittee found that some manufacturers discontinued the warnings over time while others misrepresented facts regarding the incidence of risk. *Id.*

94. See MOKHIBER, *supra* note 70, at 392-99 (discussing history of Selacryn). In April of 1979 the FDA allowed Selacryn's manufacturer, Smithkline, to market the drug. *Id.* at 395. The FDA required Smithkline to include a warning label explaining that adverse reactions had been reported. *Id.* The label, however, also stated that no causal relationship had been established between the drug and the reported adverse reactions. *Id.* Almost immediately after Selacryn's debut, the company received numerous reports of adverse reactions, including at least 12 cases of severe liver damage. *Id.* at 396. Yet, despite being required by law to report known adverse reactions to the FDA within 15 days of notification, the company failed to inform the FDA for more than three months. *Id.*

95. See MOKHIBER, *supra* note 70, at 396 (explaining that while FDA usually handles unexpected side-effect cases expeditiously, fact that reports were buried in 2500-page routine filing further delayed drug-review process).

96. MOKHIBER, *supra* note 70, at 397.

97. See Schwartz, *Federal Safety Regulations*, *supra* note 43, at 1149 n.126 (citing Selacryn as another example of manufacturer's failure to disclose vital information to governmental agency).

\$100,000, and three executives received probation and sentences of community service.<sup>98</sup>

9. OPREN, an arthritis drug, was known by its manufacturer, Eli Lilly, to have been associated with more than seventy deaths in Britain before it was withdrawn from the market in the early 1980s.<sup>99</sup> In addition, Eli Lilly had "grossly understated" problems with the drug by failing to report to the FDA a large number of the adverse reactions caused by the drug and reported to the company by doctors around the country.<sup>100</sup>

10. MER/29, a blood-cholesterol reducing agent, was the subject of perhaps the "most shocking case of fraud" in drug safety testing history.<sup>101</sup> Richardson-Merrell, MER/29's manufacturer, committed innumerable abuses while testing the product by fabricating data and concealing adverse effects that were discovered in animal and human testing of the drug.<sup>102</sup> Eventually, the Government filed criminal charges against Richardson-Merrell that resulted in fines of \$80,000 against four employees, including the company's president.<sup>103</sup> In addition, several individual defendants were sentenced to probation.<sup>104</sup> Subsequently, some 1500 civil suits were filed,<sup>105</sup> resulting in costs to the defendant companies of approximately \$200 million.<sup>106</sup> In one of these cases, the court treated the FDA's approval of the drug as conclusive evidence of adequate safety measures and dismissed the case.<sup>107</sup> Punitive damages were

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98. See MOKHIBER, *supra* note 70, at 398 (discussing disposition of suit after company plead guilty to charges of failure to report drug's side effects in timely manner).

99. See JOHN BRAITHWAITE, *CORPORATE CRIME IN THE PHARMACEUTICAL INDUSTRY* 56 (1984) (discussing cases where dangerous effects of drugs were concealed and misrepresented by drug companies).

100. See *id.* (noting that list of side effects in initial FDA application for Opren was substantially different from list included in final submission).

101. See *id.* at 60 (noting that soon after MER/29 was distributed in marketplace, people began reporting side effects such as "baldness, skin damage, changes in the reproductive organs and blood, and serious eye damage").

102. See *id.* at 60-64 (detailing specific instances of tampering with animal and human laboratory test results).

103. See RUSTAD, *supra* note 69, at 7 (finding that punitive damages are not awarded in absence of "aggravated misconduct;" classifying fraud and misrepresentation that occurred in testing and marketing of MER/29 as "fraudulent-type affirmative misconduct" sufficient to constitute "aggravated misconduct").

104. BRAITHWAITE, *supra* note 99, at 64 (noting that three corporate defendants received six months probation). The market for MER/29 was considered to be worth billions of dollars, and thus the risk of \$80,000 in fines was well worth taking. See *id.* at 64 (noting that MER/29 market was estimated at \$4.25 billion annually).

105. See RUSTAD, *supra* note 69, at 7 (discussing history of MER/29 litigation).

106. See BRAITHWAITE, *supra* note 99, at 64 (noting that most suits regarding MER/29 were settled out of court).

107. See *Lewis v. Baker*, 413 P.2d 400, 404 (Or. 1966) (stating that plaintiff is barred from recovery for breach of warranty against seller in absence of proof that drug contained impurities or that labeling was inadequate), *overruled by* *McEwen v. Ortho Pharmaceutical Corp.*, 528 P.2d 522, 524 (Or. 1974). In expressly overruling the decision in *Lewis*, the court in *McEwen*

awarded to plaintiffs in only three cases, however.<sup>108</sup>

11. DALKON SHIELD, an intrauterine device, was inadequately tested yet aggressively marketed for many years by A.H. Robins.<sup>109</sup> The device was finally recalled, but not before causing hundreds of injuries such as ectopic pregnancies, uterine perforations, and sterility.<sup>110</sup> None of these injuries was reported to the FDA.<sup>111</sup> In the product liability litigation that followed, only about fifty Dalkon Shield cases were tried, with approximately half of the plaintiffs winning and half of those being awarded punitive damages.<sup>112</sup> Few actually received their punitive awards, however, because A.H. Robins subsequently filed for reorganization under chapter 11 of the bankruptcy laws.<sup>113</sup>

## 2. *Exceptions for fraud and bribery under Senate bill 640*

While the above cases certainly raise concerns about any compliance defense for FDA-approved products, it also appears that most of the cases would fall outside the compliance provisions of Senate bill 640. Many of these cases involved misrepresentations to or withholdings of information from the FDA, both of which are conduct that is specifically not protected by Senate bill 640. In addition, products such as tampons, the Dalkon Shield, and breast

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was unconvinced that mere compliance with FDA warning requirements absolved this manufacturer from liability. *McEwen*, 528 P.2d at 534. The court reasoned that where the FDA imposed minimum warning requirements, but the manufacturer knew or had reason to know of "greater dangers not included in the warning," the manufacturer could be liable for breach of the duty to warn. *See id.* (quoting *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 661 (Cal. 1973)).

108. RUSTAD, *supra* note 69, at 7. A famous case that first raised concern about the possibility of multiple punitive damages awards in such circumstances was *Roginsky v. Richardson-Merrell, Inc.*, 378 F.2d 832 (2d Cir. 1967). In *Roginsky*, the plaintiff sought to recover compensatory and punitive damages, claiming that the defendant manufacturer's blood cholesterol-reducing drug, MER/29, caused the plaintiff to develop cataracts. *Roginsky*, 378 F.2d at 834. In denying judgment as to punitive damages, the court held that the plaintiff had not "clearly established" the quality of conduct necessary to warrant punitive damages. *Id.* at 850. The court stated:

It would be hard to think of a situation more appropriate for invoking [the clear and convincing] standard than where the manufacturer of a new drug honestly believed to assist in prolonging human life is faced with claims for penalties by hundreds of plaintiffs running into millions of dollars, in addition to many millions more for damages sustained.

*Id.* at 851.

109. *See* RUSTAD, *supra* note 69, at 8-9 (characterizing Dalkon Shield cases as "inadequate testing" cases and noting that inadequate testing was central in 12% (44) of cases studied).

110. *See* BRAITHWAITE, *supra* note 99, at 258 (discussing Dalkon Shield in context of practice of pharmaceutical dumping in developing countries).

111. BRAITHWAITE, *supra* note 99, at 253. At that time, A.H. Robins, the Dalkon Shield's manufacturer, was not required to report adverse reactions to the FDA. *Id.*

112. *See* RUSTAD, *supra* note 69, at 8-9 (noting that despite seemingly meritorious claims, Dalkon Shield victims were not necessarily awarded punitive damages).

113. RUSTAD, *supra* note 69, at 8-9.

implants would not have been governed by Senate bill 640's regulatory compliance provision because at the time they were marketed, FDA approval was not required.<sup>114</sup> Thus, insofar as the above products and circumstances are concerned, Senate bill 640's compliance defense would not apply and punitive damages would be available. Of course, it should be noted that the mere availability of punitive damages in such cases does not mean they are sought or awarded. Even in the cases of egregious manufacturer conduct described above, few punitive damages awards were ever made or paid under the common law.<sup>115</sup>

Indeed, it is not at all clear that the outcome of any past cases involving drugs, devices, or aircraft would be changed by the compliance provisions of Senate bill 640. The Senate report on the bill identified no cases that would be changed by the new provision.<sup>116</sup> In fact, with one exception, the report identified no punitive damages awards involving drugs, devices, or aircraft that it viewed as *wrongly* decided. The one exception was a Kansas case in which a jury awarded \$8 million in punitive damages against a vaccine manufacturer.<sup>117</sup> The case, however, was reversed on appeal.<sup>118</sup>

In the final analysis, the fraud and bribery exceptions of Senate bill 640 go a long way toward assuring that cases of serious misconduct would remain subject to punitive damages awards. One might ask, then, why the opponents of Senate bill 640 should be concerned about this regulatory compliance provision. The answer, in part, is that there would still be some cases, although not many, where punitive awards now available under the common law would not be allowed under Senate bill 640. In his exhaustive study of punitive damages, Professor Michael Rustad identified several cases that appeared to warrant punitive damages despite regulatory compliance and the absence of fraud on the part of the manufacturer.<sup>119</sup>

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114. See S. REP. NO. 215, *supra* note 6, at 55 n.197 (specifying that Dalkon Shield would not have been protected from punitive damages under Senate bill 640, but failing to mention whether breast implants were subject to provision).

115. See *supra* notes 86, 108, 112 and accompanying text (discussing rarity of punitive damages awards).

116. See S. REP. NO. 215, *supra* note 6, at 33-39 (failing to provide cases demonstrating potential impact of compliance provision).

117. See S. REP. NO. 215, *supra* note 6, at 34, 54 n.174 (questioning lack of judicial deference to agency determinations concerning comprehensively regulated industries).

118. See *Johnson v. American Cyanamid Co.*, 718 P.2d 1318, 1326 (Kan. 1986) (determining that no colorable legal theory existed upon which defendant could be liable). At the trial level, the jury awarded \$2 million in compensatory damages and \$8 million in punitive damages. *Id.* at 1325. On appeal, the Supreme Court of Kansas reversed, finding that the lower court erred in not granting a directed verdict for the defendant vaccine manufacturer. *Id.* at 1326.

119. See RUSTAD, *supra* note 69, at 48 (discussing implications of punitive damages reform). One case involved a defectively designed intraocular lens. *Id.* The manufacturer dis-

Still, if this type of case is rare, as Rustad acknowledges,<sup>120</sup> it might not, alone, be a sufficient basis for rejecting a limited compliance defense.

There are other concerns, however, about limiting the availability of punitive damages in cases of drugs, devices, and aircraft. One concern is that such a limitation would remove an important incentive for product safety. Although it is questioned whether punitive damages act as such an incentive,<sup>121</sup> there should be little dispute that the economic consequences of punitive damages are far more serious to corporations than the consequences of civil, or even criminal, penalties.<sup>122</sup> While on a cost-benefit basis the risk of a civil fine might be well worth taking, the same can seldom be said of the risk of uncertain, albeit remote, punitive damages.

Another concern about limiting the availability of punitive damages in cases of drugs, devices, and aircraft is that such limitations would have an adverse effect on plaintiffs' ability to obtain settlements, which account for ninety percent of all tort case resolutions.<sup>123</sup> This would be especially true in serious injury cases where it is widely acknowledged that plaintiffs are seldom fully compensated for their injuries.<sup>124</sup> The mere availability of punitive dam-

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covered through its own studies that the lenses exposed patients to a risk of sight-threatening injury that was three to five times higher than acceptable levels. *Id.* The FDA knew of these results but failed to order a recall of the lenses. *Id.* A second example involved a V-tail plane that had been approved by the FAA despite its involvement in some 500 deaths with no regulatory response by the Agency. *Id.* at 49 n.11.

120. See RUSTAD, *supra* note 69, at 48 (noting that almost every drug case studied involved elements of fraudulent activity by manufacturer). Professor Rustad notes that, because fraudulent activity is so pervasive in these drug cases, Senate bill 640's safe harbor provisions will have "little impact" on curtailing punitive damages awards. *Id.*

121. See ATTORNEY GENERAL'S REPORT, *supra* note 3, at 69 (asserting that punitive damages are not effective deterrent because punishments are not enforced until years after conduct occurs). The report contends that punitive damages' deterrent effect could be obtained through civil fines. *Id.* at 69 n.16. *But see infra* note 122 and accompanying text (contrasting statutory liability system with tort liability system).

122. Civil or criminal fines seldom come close to the size of typical tort and punitive damages awards. Consider the fine of \$25,000 imposed on Eli Lilly, the manufacturer of Oralflex. See *supra* note 77 and accompanying text (discussing Oralflex case). A wrongful death action involving the drug resulted in a jury verdict of \$6 million. MOKHIBER, *supra* note 70, at 337. Similarly, in the case of MER/29, the criminal fines were less than \$100,000, but the tort suits cost the companies approximately \$200 million. See Schwartz, *Federal Safety Regulations*, *supra* note 43, at 1138 n.68 (noting "enormous discrepancy between tort liability awards and statutory fines" and concluding that deterrent effect of product liability system is much stronger than that of regulatory system).

123. See Patricia M. Danzon, *The Medical Malpractice System: Facts and Reforms*, in *THE EFFECTS OF LITIGATION ON HEALTH CARE COSTS* 28, 30 (Mary Ann Bailly & Warren I. Cikins eds., 1985) (noting high incidence of pretrial settlement in refuting assertion that tort system is "erratic lottery").

124. See Michael J. Saks, *Do We Really Know Anything About the Behavior of the Tort Litigation System—And Why Not?*, 140 U. PA. L. REV. 1147, 1287, 1216-20 (1992) (concluding that while "modest losses are . . . overcompensated . . . the larger the loss suffered, the more pronounced the undercompensation"; further stating that pattern "is so well replicated that it

ages, even if they are unlikely to be awarded, might give plaintiffs additional clout and thereby level the playing field somewhat in negotiating settlements in such cases.<sup>125</sup> Indeed, proponents of this reform are quite concerned about the intangible role of punitive damages in settlements,<sup>126</sup> which suggests that the damages are at least perceived as having some effect on the process. If punitive damages are unavailable from the outset, absent fraud or bribery, as would be the case under Senate bill 640, it certainly would be more difficult for plaintiffs to negotiate favorable settlements in serious injury cases.

Finally, opponents of Senate bill 640 should be concerned about the difficulty of framing a compliance provision narrow enough to exclude all the types of misconduct that should be exempted from its coverage. As noted earlier, the regulatory compliance provisions of Senate bill 640 had to be updated to address a recent example of wrongdoing: bribery at the FDA.<sup>127</sup> While the new version of the compliance defense dealt specifically with the FDA situation, it failed to make any provision for bribery involving aircraft manufacturers or the FAA. Thus, as drafted, Senate bill 640 would seemingly protect from a punitive damages award an aircraft manufacturer that engaged in bribery. Obviously, this is not the intent of the drafters,<sup>128</sup> but it does demonstrate the inherent difficulty in trying to frame a statutory solution that anticipates all the

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qualifies as one of the major empirical phenomenon of tort litigation”); see also S. REP. NO. 215, *supra* note 6, at 5 (noting that minor losses are overcompensated and major losses are undercompensated).

125. See RUSTAD, *supra* note 69, at 6 (discussing responses of plaintiffs’ attorneys to questionnaire and finding that plaintiffs’ attorneys generally view threat of punitive damages as having positive effect on settlement negotiations). Interestingly, not all plaintiffs’ attorneys believe that punitive damages have a significant impact on settlements. See *id.* (noting one plaintiffs’ attorney from Utah who felt that threat of punitive damages played negligible role in settlement negotiations). Generally, however, plaintiffs’ attorneys feel that, although punitive damages are never paid as part of settlements, they can help lawyers negotiate higher settlements for actual damages on behalf of their clients. *Id.* To the extent punitive damages do make a difference in settlement negotiations, plaintiffs’ attorneys seem to believe that only in cases where the manufacturer engaged in serious misconduct is there a genuine likelihood that punitive damages would be awarded if the case went to trial. *Id.*

126. See S. REP. NO. 215, *supra* note 6, at 6 (arguing that uncertainty as to liability standards regarding punitive damages claims inhibits manufacturers’ ability to negotiate effectively). The report seemingly maintained that punitive damages claims actually discourage settlements, but also implied that a different effect obtains if a claim is made in a “‘situation [that] truly calls for punitive damages.’” *Id.* at 34 (quoting Professor Aaron D. Twerski, *A Moderate and Restrained Federal Product Liability Bill: Targeting the Crisis Areas for Resolution*, 18 U. MICH. J.L. REF. 575, 612 (1985)); see also Twerski, *supra*, at 612 (claiming that threat of punitive damages “sabotages” settlement negotiations).

127. See *supra* notes 24-26 and accompanying text (discussing reason for including bribery exception in Senate bill 640’s proposed ban on punitive damages).

128. In S. 687, *supra* note 6, § 203(c)(2)(B), bribery of FAA officials was included in the conduct that was not protected from punitive damage awards.

circumstances under which punitive damages should or should not be allowed.

Another difficulty emerges in interpreting Senate bill 640's fraud exceptions. For example, would the compliance defense exceptions apply to cases like the Selacryn case, where the manufacturer arguably informed the FDA of the problems with its drug but in such a manner that it did not catch the attention of FDA officials?<sup>129</sup> No doubt there would be a myriad of such cases that would need to be decided under the statute's constraints. In the end, these cases are best left to the tort system where a judge or jury can assess the conduct of the defendant in light of all the circumstances of the case.<sup>130</sup>

Having addressed the question of why Senate bill 640 opponents should be concerned about a provision that would have a limited impact on the common law, this Article next considers why Senate bill 640 proponents believe the provision is so important. The answer, at least in part, is found in proponents' deep-seated concerns about punitive damages awards and their desire to find ways of limiting such awards. If, as the proponents claim, punitive damages awards are out of control, then a limited regulatory compliance defense might still be justified. The next Part examines the claims about punitive damages as a justification for the proposed defense.

### III. PUNITIVE DAMAGES LIMITS

#### A. Critics of Punitive Damages

The perception that punitive damages are out of control has been growing in recent years.<sup>131</sup> A Justice Department study produced during the Reagan administration focused on the issue and found there had been an "explosion in damage awards" for noneconomic losses, i.e., pain and suffering and punitive damages.<sup>132</sup> The study

129. See *supra* notes 94-98 and accompanying text (discussing history of Selacryn case).

130. Certainly the record of punitive damages in this country indicates that the judicial system is capable of doing a good job with respect to punitive damages awards. See *infra* notes 149-55 and accompanying text (discussing Professor Rustad's comprehensive study of all product liability cases awarding punitive damages from 1965 to 1990).

131. See ALI, ENTERPRISE RESPONSIBILITY, *supra* note 34, at 232 (discussing public's perception of punitive damages awards). The study states:

The topic [of punitive damages] has surfaced in the public and political arena as people have become aware of occasionally huge jury verdicts—such as the \$125 million award against Ford Motor Company in the Pinto case and the \$3 billion award against Texaco arising out of the Pennzoil litigation.

*Id.* (citations omitted). The American Law Institute posits that news stories have furthered the impression that punitive damages in tort cases are being awarded more often and in greater amounts than in previous years. *Id.*

132. See ATTORNEY GENERAL'S REPORT, *supra* note 3, at 42 (claiming that increase in punitive damages awards during 1980s exceeded inflation rate over same period).

concluded that awards had “soared in the United States without any apparent justification”<sup>133</sup> and recommended a drastic cap on noneconomic damages of \$100,000 per case.<sup>134</sup> More recently, and more colorfully, former Vice President Quayle expressed the views of the Bush administration on punitive damages:

Even a casual observer knows that, in the last several decades, punitive damages have grown dramatically in both frequency and size. What began as a sanction only for the most reprehensible conduct has now become almost routine. . . . And as these awards become more common, so do the instances of their arbitrary, even freakish, application.<sup>135</sup>

Numerous critics of the tort and product liability system have focused on punitive damages as a central problem in the system.<sup>136</sup> Demands for punitive damages are characterized as “routine”<sup>137</sup> and awards are said to be “skyrocketing”<sup>138</sup> and “epidemic.”<sup>139</sup> The open-ended nature of the product liability system as a whole, and by implication its indeterminate punitive damages component,

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133. ATTORNEY GENERAL'S REPORT, *supra* note 3, at 42.

134. See ATTORNEY GENERAL'S REPORT, *supra* note 3, at 68-69 (justifying cap on noneconomic damages by arguing that only small percentage of all tort claims would be affected and tort system would enjoy greater predictability overall). The study actually considered a total ban on punitive damages but rejected such a ban in favor of including punitive damages with a \$100,000 limit on noneconomic damages. See *id.* at 68 (arguing that “punitive damages at best have a tenuous basis in tort law”). The study's suggestion is a radical proposal compared to state tort reform proposals, none of which has included such low limits on punitive damages. See Schwartz, *Product Safety Agenda*, *supra* note 55, at 1370-71 (discussing Reagan administration's critical view of product liability law). Indeed, the lowest state caps on punitive damages are at least twice the amount proposed by the Reagan administration. *Id.* For example, a 1987 survey revealed that 20 states had enacted either an overall or a noneconomic cap on medical malpractice claims. See Thomas W. Farrell, *Virginia's Medical Malpractice Cap and the Doctrine of Substantive Due Process*, 23 TORT & INS. L.J. 684, 688 (1988) (discussing constitutionality of caps). The lowest cap was \$250,000, and most caps exceeded that amount. *Id.*

135. Vice President Dan Quayle, Agenda for Civil Justice Reform in America, Address Before the American Bar Association (Aug. 13, 1991), *reprinted in* N.J. L.J., Aug. 29, 1991, at 15, 25.

136. See, e.g., WALTER K. OLSON, THE LITIGATION EXPLOSION: WHAT HAPPENED WHEN AMERICA UNLEASHED THE LAWSUIT 285 (1991) (describing process of awarding punitive damages as “guesswork on stilts” because jury first guesses whether particular defendant harmed particular plaintiff and then guesses how many similar wrongs have gone undetected).

137. See PETER HUBER, LIABILITY: THE LEGAL REVOLUTION AND ITS CONSEQUENCES 127 (1988) (noting that punitive damages are “routine when the injury is serious and a wealthy institution is numbered among the accused”); see also S. REP. NO. 215, *supra* note 6, at 34 (claiming that plaintiffs in product liability suits “routinely” seek punitive damages and that such awards are generally large).

138. See *Browning-Ferris Indus., Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257, 282 (1989) (O'Connor, J., concurring in part and dissenting in part) (characterizing punitive damages awards as “skyrocketing” and claiming that research and development of new products is severely curtailed by threat of such awards).

139. See Peter Brimelow & Leslie Spencer, *The Plaintiff Attorneys' Great Honey Rush*, FORBES, Oct. 16, 1989, at 197, 199 (claiming that even compliance with governmental regulatory standards does not insulate manufacturers against punitive damages awards).

is blamed for driving manufacturers out of business and depriving society of valuable products.<sup>140</sup> As an example, one commentator charges that punitive damages assessed against A.H. Robins, the manufacturer of the Dalkon Shield, "opened the floodgates for punitive attacks on . . . safer [contraceptive] substitutes"<sup>141</sup> and ultimately caused other IUD manufacturers to withdraw from the market.<sup>142</sup> If such views of the system are correct, then there may indeed be grounds for regulatory compliance provisions to limit punitive damages.

### B. Response to the Critics

Empirical studies, unlike the anecdotes used by reform advocates to show that the civil justice reform system is out of control,<sup>143</sup> simply do not support the conclusion that punitive damages awards are arbitrarily or "freakishly" applied. In his exhaustive review of the empirical studies in this area, Professor Michael Saks concluded that views such as those of former Vice President Quayle, although widely shared, have little basis in fact.<sup>144</sup> Citing studies by the RAND Institute for Civil Justice,<sup>145</sup> Daniels and Martin,<sup>146</sup> and Landes and Posner,<sup>147</sup> Saks found that the cumulative evidence shows that punitive awards are infrequent and not exorbitant, espe-

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140. See OLSON, *supra* note 136, at 283 (noting that companies have regularly been held liable for punitive damages for actions expressly condoned by government regulations); see also HUBER, *supra* note 137, at 155-71 (claiming that tort liability has negative effect on innovation).

141. HUBER, *supra* note 137, at 128 (discussing Dalkon Shield cases' effect on punitive damages awards against other contraceptive manufacturers).

142. See HUBER, *supra* note 137, at 162 (arguing that while Dalkon Shield unquestionably warranted banning, subsequent substitute IUDs did not).

143. See Saks, *supra* note 124, at 1161 (criticizing use of anecdotal evidence in analyzing litigation system). Saks states:

Anecdotes have a power to mislead us into thinking we know things that anecdotes simply cannot teach us. . . . Anecdotes about undeserving plaintiffs are intriguing or outrageous and have been repeated often in the media. Consequently people readily believe that the category of undeserving plaintiffs dominates the system.

*Id.*

144. See Saks, *supra* note 124, at 1254-56 n.401 (claiming that one Justice Department report misread data by including in its analysis punitive damages awards in nontort suits and by using mean values rather than median values in computing average awards).

145. See MARK A. PETERSON & GEORGE L. PRIEST, *THE CIVIL JURY: TRENDS IN TRIALS AND VERDICTS, COOK COUNTY, ILLINOIS, 1960-1979* 33-57 (1982) (comparing mean and median awards in Cook County, Illinois from 1960-1979 and noting that median remained stable during time period).

146. See Stephen Daniels & Joanne Martin, *Myth and Reality in Punitive Damages*, 75 MINN. L. REV. 1, 38 (1990) (analyzing punitive damages awards in selected counties and finding only marginally significant upward trends in recent years).

147. See William M. Landes & Richard A. Posner, *New Light on Punitive Damages*, REG., Sept.-Oct. 1986, at 33, 35 (studying treatment of punitive damages awards on appeal and finding that relatively few survive appeals).

cially when post-trial adjustments are taken into account.<sup>148</sup>

Perhaps the most thorough study ever undertaken of punitive damages was completed recently by Professor Michael Rustad.<sup>149</sup> In his study, Rustad searched for all product liability cases in which punitive damages were awarded during the quarter century from 1965 to 1990 and then studied in depth the 355 cases he uncovered. The small number of cases in itself is noteworthy, given that in the period from 1974 to 1990 there were 161,686 product liability cases filed in the federal system alone,<sup>150</sup> and a vastly larger number in the state system.<sup>151</sup> The punitive damages awards are thus a very small piece of the overall picture.

Another striking characteristic of the 355 awards was that more than half of them were reversed or reduced after trial.<sup>152</sup> The reductions most often occurred as a result of appeals or post-trial settlements.<sup>153</sup> A RAND study of post-trial reductions in awards also showed that the larger the initial award, the greater the reduction after trial.<sup>154</sup> It is interesting to note that while the media typically publicizes initial punitive awards, especially those that are extremely high and seem questionable, it seldom reports on the frequent reductions or eliminations of these awards that occur on appeal.<sup>155</sup>

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148. See Saks, *supra* note 124, at 1254-62 (discussing various studies in supporting conclusion that punitive damages awards are not "skyrocketing" as some tort reform advocates claim).

149. See RUSTAD, *supra* note 69 (studying all product liability cases between 1965 and 1990 where punitive damages were awarded and concluding that empirical facts from study contradict myths concerning punitive damages).

150. Saks, *supra* note 124, at 1259.

151. See Marc Galanter, *The Day After the Litigation Explosion*, 46 MD. L. REV. 3, 6 (1986) (estimating that federal filings account for only about 2% of all civil action claims nationwide).

152. See RUSTAD, *supra* note 69, at 30-31 (stating that appellate reversal of punitive awards was "common" and noting that appellate courts affirmed compensatory damages awards more frequently than punitive damages awards).

153. See RUSTAD, *supra* note 69, at 30-32 (discussing post-trial disposition of cases involved in study).

154. See DEBORAH R. HENSLER ET AL., TRENDS IN TORT LITIGATION: THE STORY BEHIND THE STATISTICS 22-24 (1987) (noting that while reduction in jury awards for cases less than \$100,000 averaged 75%, reduction in jury awards over \$1 million averaged almost 40%). The study noted, however, that product liability suits and cases involving deep-pocket defendants resulted in smaller reductions. *Id.*

155. See RUSTAD, *supra* note 69, at 31 (citing as example media reporting \$75 million punitive award in Bendectin case but failing to report that award was eliminated on appeal); see also ALI, ENTERPRISE RESPONSIBILITY, *supra* note 34, at 232-35 (discussing legitimacy of punitive damages awards). The ALI report notes:

News stories have fueled a general impression that punitive awards are now being rendered in far more tort cases and in far greater amounts. . . .

[M]ore systematic surveys [of punitive damages, however,] provide a helpful perspective on the somewhat distorted perception one gets from reading about only the largest and most questionable punitive awards.

ALI, ENTERPRISE RESPONSIBILITY, *supra* note 34, at 232, 235.

C. *Punitive Awards in Drug, Device, and Aircraft Cases*

To conclude that there is no overall problem with punitive awards, of course, is not to eliminate the possibility that there is a problem in cases involving drugs, devices, and aircraft. As noted earlier, however, the Senate committee reporting on Senate bill 640 identified no cases, except the Kansas vaccine case that was later overturned, in which a punitive award had been improper or excessive.<sup>156</sup>

According to Rustad's study, there have been fifty-three punitive damages awards involving medical products in the last twenty-five years.<sup>157</sup> Many of these cases involved breast implants, the Dalkon Shield, MER/29, and Oraflex.<sup>158</sup> Indeed, probably twenty percent of the medical product cases involved the Dalkon Shield alone.<sup>159</sup> No improper awards among these fifty-three, except in the Kansas case, were identified by the Senate committee, however. While, as noted earlier, one prominent critic of the current tort system criticized punitive damages claims in the Dalkon Shield cases because they encouraged similar claims against other contraceptive makers,<sup>160</sup> the Senate committee avoided any such implication by pointing out that the Dalkon Shield would not have been protected from punitive damages under Senate bill 640.<sup>161</sup> In short, the Senate committee failed to make a case against specific punitive damages awards.

The committee, however, did provide a wide-ranging critique of the entire product liability system and the burdens it places on productivity, innovation, and U.S. competitiveness.<sup>162</sup> The committee

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156. See *supra* notes 116-18 and accompanying text (discussing effect that compliance provisions of Senate bill 640 would have had on past product liability cases had provisions been in operation at time cases were decided).

157. See RUSTAD, *supra* note 69, at 26 (listing number of punitive damages awards in different product categories). The medical products category included drugs, breast implants, hospital equipment, contraceptives, and prosthetic devices. *Id.*

158. See *supra* notes 73-78, 83-86, 101-13 and accompanying text (discussing history of various product liability cases).

159. See RUSTAD, *supra* note 69, at 8 (discussing history of Dalkon Shield cases). Fewer plaintiffs actually received punitive awards in the Dalkon Shield litigations, of course, due to the chapter 11 proceedings initiated by A.H. Robins, the Shield's manufacturer. *Id.* at 8-9.

160. See *supra* notes 141-42 and accompanying text (noting Peter Huber's contention that withdrawal of Dalkon Shield from market led to increase in claims filed against other IUD manufacturers and had residual effect of forcing those manufacturers out of market).

161. S. REP. NO. 215, *supra* note 6, at 55 n.197. The report states:

[The regulatory compliance provision of Senate bill 640] does not apply to medical devices that were never subject [sic] to pre-market approval by the FDA, such as the interuterine device known as the Dalkon Shield, which was taken off the market before FDA pre-market regulation of medical devices began in 1976.

*Id.*

162. See S. REP. NO. 215, *supra* note 6, at 7-10 (claiming that cost of supporting product liability system places tremendous burden on nation's economy).

identified various ways in which the system would adversely affect the three industries that would benefit from the regulatory compliance defense: the pharmaceutical, medical device, and aircraft industries.<sup>163</sup> The committee gave as an example of overdeterrence in the pharmaceutical industry the decision of two of the three diphtheria-tetanus-pertussis (DPT) vaccine manufacturers to stop producing the vaccine because of high product liability costs.<sup>164</sup> While this was a legitimate concern some years ago, it has been recognized and addressed in an equitable manner by the National Childhood Vaccine Injury Compensation Program.<sup>165</sup> Indeed, the adverse effects of the product liability system in this case had the positive effect of motivating industry, consumers, and the medical profession to fashion legislation that would be fair to all interested parties.<sup>166</sup>

With respect to the aircraft industry, the committee pointed to the declining fortunes of the general aviation industry, largely attributing them to the liability system.<sup>167</sup> The fact that the fortunes of the pharmaceutical industry have been soaring,<sup>168</sup> despite the product liability system, was not mentioned by the committee.

The committee did not specifically tie the adverse effects on the industries to punitive damages. Instead, the charges were more generally aimed at the product liability system as a whole. As is often the case in the debate over product liability reform, however, the link between the product liability system and its adverse effects on industry, such as an entire industry's poor economic health, is seldom clearly established. The information needed to assess the linkage is in the hands of industry groups, and they do not want to divulge it for public scrutiny. Even the committee's own source for many of its claims about the system, *The Liability Maze*, acknowledges

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163. See S. REP. NO. 215, *supra* note 6, at 8 (stating that system adversely affects productivity by forcing diversion of resources such as management time away from productivity efforts).

164. See S. REP. NO. 215, *supra* note 6, at 8 (noting that discontinuation of DPT production led to supply shortage of vaccine).

165. See 42 U.S.C. §§ 300aa-10 to -33 (1988). The Act is designed to compensate victims of vaccine-related injuries or deaths. *Id.* Congress passed the law in response to a rise in liability claims against vaccine manufacturers for childhood vaccine injuries. See Schwartz, *Product Liability Reform*, *supra* note 44, at 317 (discussing nature and purpose of Act). The Act's cap on damages and prohibition on punitive awards is an attempt to induce the reentry of manufacturers into the vaccine market and to halt the spiraling costs of vaccines. *Id.*

166. See Schwartz, *Product Liability Reform*, *supra* note 44, at 317 (discussing trends in state and federal tort reform legislation).

167. See S. REP. NO. 215, *supra* note 6, at 8 (noting that between 1979 and 1989, sales in general aviation industry dropped by more than 90% and that in 1985, despite sound industry safety records, "insurance premiums averaged \$70,000 per airplane").

168. See *Wasted Health Care Dollars*, CONSUMER REP., July 1992, at 435, 445 (noting that pharmaceutical industry is one of "nation's most profitable industrial sectors . . . with an average profit margin of 15%"). Over the last decade, investors in pharmaceutical companies have enjoyed an average return each year of 25%. *Id.*

the lack of hard data.<sup>169</sup> According to one contributing author in that volume, the prospects that manufacturers will ever supply better information are dim. The author states, "For prescription drugs and other products, the publicly extant information is fragmentary and inconclusive at best, because of the general unwillingness of companies to document their claims about a product liability crisis by providing data about the actual effects of litigation."<sup>170</sup>

The positive impacts of the product liability system on safety are even less likely to be supplied by industry. As the editors of *The Liability Maze* themselves observe, "Even if liability does encourage safer practices, no obstetrician or car company will wish to spend much time advertising the connection."<sup>171</sup> Thus, other than by use of anecdotal cases,<sup>172</sup> it is almost impossible to verify the adverse effects, such as overdeterrence, that are claimed by the critics of the product liability system. Even the specific cases offered as examples of those effects often reveal other concerns that may have been responsible for deterring the marketing of the product.<sup>173</sup>

The one aspect of the product liability system for which there is very good empirical data is the extent to which punitive damages are awarded and paid.<sup>174</sup> Punitive damages have been shown to be a very small piece of the overall tort system, yet they receive enormous attention<sup>175</sup> and apparently strike great fear in the business community.<sup>176</sup> It is not entirely clear why this is so. Perhaps the fear arises in response to the disproportionate media attention paid

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169. See Swazey, *supra* note 69, at 295-96 (discussing trends in product liability concerning prescription drugs).

170. Swazey, *supra* note 69, at 295-96.

171. See Huber & Litan, *supra* note 42, at 11 ("To concede positive safety effects resulting from liability is to invite more liability.").

172. See Saks, *supra* note 124, at 1159 (criticizing use of anecdotal evidence in analyzing tort litigation system by arguing that "[a]necdotes do not permit one to determine either the frequency of the occurrence of something or its causes or effects"). Saks states:

The use of anecdotal evidence has been unusually popular in discussions about the nature of the litigation system. . . .

Nevertheless, anecdotal evidence is heavily discounted in most fields, and for a perfectly good reason: such evidence permits only the loosest and weakest inferences about matters a field is trying to understand.

*Id.*

173. See S. REP. NO. 215, *supra* note 6, at 77-80 (minority views of Senators Hollings and Gore) (addressing safety problems associated with six different products that proponents of Senate bill 640 claim were "unfairly" forced off market because of product liability system).

174. See *supra* notes 143-55 and accompanying text (discussing empirical studies on punitive damages awards in product liability cases).

175. See *supra* notes 135, 155 and accompanying text (discussing attention paid by Bush administration and media to punitive damages issue).

176. See Saks, *supra* note 124, at 1262 (finding that various studies do not support public's and policymakers' negative perception of punitive damages). Saks posits that "in light of the empirical evidence [about punitive damages], the more interesting question might be how such mistaken beliefs came about and how the level of fear rose to the heights that it has." *Id.*

to large verdicts,<sup>177</sup> or perhaps it derives from the claims of the industry groups themselves.

If the threat of punitive damages is having a deterrent effect that is out of proportion to its real threat and thus "overdetering" manufacturers,<sup>178</sup> should legislation such as the regulatory compliance provision of Senate bill 640 be enacted to dispel it? The answer must be no. A baseless fear, especially one that may be attributable in part to the claims of the business community itself, should not be a basis for legislation. If the fear is not baseless, industry has the burden of proving it is not. Only industry has the data to establish the cause and effect relationship, if any, between the product liability system and the claimed unreasonable hardships on the business community. With respect to regulatory compliance provisions like those contained in Senate bill 640, the industries in question need to establish clearly the connection between the threat of punitive awards and the alleged overdeterrence and economic ruin. At the very least, they should provide examples of cases where excessive or unwarranted punitive damages were awarded and ultimately paid by defendant corporations. To date, they have not done so.

#### CONCLUSION

This Article began by expressing grave reservations about any regulatory compliance defense, even for closely regulated products. It considered the narrowly framed defense in Senate bill 640 to be a modest proposal, however. The Article assessed the impact of the compliance defense on plaintiffs and product safety and found that, while negative, the impact is somewhat limited. After carefully considering whether the compliance defense might be warranted as a means of curbing unreasonable punitive damages claims, one is compelled to conclude that no justification exists for even this limited regulatory compliance defense. No punitive damages crisis has been established, either through empirical studies or through data supplied by industry. Until it is, the proposed compliance defense should not be enacted.

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177. See *supra* notes 135, 155 and accompanying text (discussing enormous attention that punitive damages issue receives).

178. See Saks, *supra* note 124, at 1284 (stating that "[o]ne of the greatest increases in costs associated with litigation may grow not out of lawsuits themselves, but out of irrational fears of lawsuits—irrational in that they respond not to the actual behavior of the tort litigation system but to inaccurate beliefs about that behavior").

