

DYNAMIC INCENTIVES: IMPROVING THE SAFETY,
EFFECTIVITY, AND AVAILABILITY OF MEDICAL
PRODUCTS THROUGH PROGRESSIVELY INCREASING
DAMAGE CAPS FOR MANUFACTURERS

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To increase the availability, safety, and effectiveness of medical products and, thus, promote public health, medical product manufacturers must invest in the research and development of medical products. Unfortunately, the threat of tort liability discourages medical product manufacturers from doing so. This note attempts to resolve this dilemma. The author begins by briefly providing some background on the relevant medical and pharmaceutical approval processes. After examining the liability protections currently available—preemption of state tort claims, the regulatory compliance defense, and damage caps—the author concludes that these protections are, on the whole, beneficial. However, the author also acknowledges a critical shortcoming associated with the implementation of these tort liability protections—reduced manufacturer incentive to perform adequate post-approval surveillance and testing. To address this shortcoming, the author proposes federal legislation combining preemption, the regulatory compliance defense, and a nontraditional variation of damage cap to encourage investment in research and development while simultaneously maintaining manufacturers’ incentives to perform adequate post-approval surveillance and testing.

I. INTRODUCTION

Lederle Laboratories (Lederle), concerned about the possibility that one of its antibiotics could cause tooth discoloration in developing children, contacted the U. S. Food and Drug Administration (FDA) and proposed an additional warning for the product label.¹ Despite harboring a similar concern, the FDA nonetheless advised against distributing the warning, pending further study.² Lederle followed the FDA recommendation, and was later sued for failure to warn consumers about the

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1. Feldman v. Lederle Labs., 479 A.2d 374, 378–79 (N.J. 1984).

2. *Id.* at 379.

potential for tooth discoloration.³ Reinstating a jury verdict against Lederle, the New Jersey Supreme Court asserted that Lederle's reliance on the FDA recommendation did not guard against liability for failure to warn consumers about the potential for tooth discoloration.⁴ This case raises two important questions. First, why would the FDA recommend against additional warnings on medical products? Second, should Lederle have added the warning in spite of the FDA's advice?

As *Feldman v. Lederle Laboratories* demonstrates, the threat of product liability can place medical product manufacturers in an untenable situation. The very nature of many medical products precludes any attempt to design them in a manner considered "safe" by traditional product liability standards.⁵ Defibrillators send electrical pulses through the heart, coronary stents are in constant contact with surrounding arterial tissues, and pharmaceuticals react chemically with the body. Considering the risks inherent in such products, a medical product manufacturer's reliance on an FDA determination that the benefits of a particular product outweigh the risks seems warranted. However, FDA product approval and post-approval compliance with FDA recommendations do not provide reliable protection against liability.⁶ Lacking an adequate safe zone in which to operate, medical product manufacturers must compensate for a market in which massive tort liability is only one ad hoc jury decision away.

"Directed by Congress to promote and protect the public health, [the] FDA is responsible for ensuring that *safe and effective* medical innovations are *available* to patients."⁷ In the Food and Drug Administration Modernization Act of 1997,⁸ Congress issued two directives defining the FDA's mission.⁹ On one hand, Congress encouraged the FDA to streamline approval requirements to reduce the review time required to bring new products to the market, thereby improving availability and promoting public health.¹⁰ On the other hand, Congress insisted the

3. *Id.* at 379–81.

4. *Id.* at 390–91.

5. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 (1998) ("The issue of foreseeability of risk of harm is more complex in the case of products such as prescription drugs [or] medical devices.").

6. See Jeffrey N. Gibbs & Bruce F. Mackler, *Food and Drug Administration Regulation and Products Liability: Strong Sword, Weak Shield*, 22 TORT & INS. L.J. 194, 243 (1987) ("Under current law, compliance with the FDA requirements affords only modest protection against the successful lawsuit. Indeed, in some situations products liability doctrine attaches far too little significance to adherence with FDA requirements.").

7. FDA, INNOVATION OR STAGNATION: CHALLENGE AND OPPORTUNITY ON THE CRITICAL PATH TO NEW MEDICAL PRODUCTS, at iii (2004) (emphasis added), available at <http://www.fda.gov/oc/initiatives/criticalpath/whitepaper.pdf>.

8. Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 1997 Stat. 830 (1997).

9. TASK FORCE ON RISK MGMT., FDA, MANAGING THE RISKS FROM MEDICAL PRODUCT USE—CREATING A RISK MANAGEMENT FRAMEWORK 16 (1999) [hereinafter FDA, RISK MGMT.] (referencing section 406 of the U.S. Food and Drug Administration Modernization Act of 1997).

10. *Id.* at 16–17.

FDA maintain sufficient requirements to ensure safety and effectivity.¹¹ However, Congress never delineated an appropriate balance between the two goals, and instead delegated that task to the FDA.¹² Lacking a clear congressional directive, the FDA has created stringent regulatory systems intended to balance safety, effectivity, and availability of pharmaceuticals and medical devices.¹³ Despite these stringent regulatory systems, FDA approval does not always absolve medical product manufacturers of liability.¹⁴ In the end, manufacturers' inability to gauge potential liability for unforeseeable risks stifles research and development, thereby reducing availability.¹⁵

Although the aforementioned initiatives—improving safety and effectivity, and ensuring availability—are not necessarily mutually exclusive, progress in the pursuit of one may come at the expense of the other. Improving safety and effectivity requires manufacturers to spend more time designing, testing, and determining appropriate labeling, which slows a product's entry into the market.

The FDA has the means to control safety and effectivity and to restrict availability; however, the FDA's ability to *promote* availability is severely limited. The FDA controls the safety and effectivity of medical products by reviewing and approving product design, performance test data, and manufacturing processes.¹⁶ The FDA may also restrict availability by denying product approval, withdrawing product approval,¹⁷ or requiring more extensive product testing pending approval.¹⁸ However, the FDA cannot force manufacturers to introduce new products to the market or to keep existing products on the market. Therefore, the FDA has little control over the promotion of availability. Although the FDA

11. *Id.* at 16.

12. Jeffrey E. Shuren, Essay, *The Modern Regulatory Administrative State: A Response to Changing Circumstances*, 38 HARV. J. ON LEGIS. 291, 301 (2001).

13. FDA, *supra* note 7, at 11–16.

14. Andrew E. Costa, *Negligence Per Se Theories in Pharmaceutical & Medical Device Litigation*, 57 ME. L. REV. 51, 72 n.151 (2005).

15. James A. Henderson, Jr., *Restatement Third, Torts: Products Liability: What Hath the ALL Wrought?*, 64 DEF. COUNS. J. 501, 518 (1997).

One might argue that liability protection alone provides medical product manufacturers with insufficient incentive to invest more money into research and development. However, the answer to such a question would require an analysis applying law and economics in light of corporate strategy, somewhat beyond the scope of this note. For the sake of simplicity, this note assumes that the liability protections sought by industry and tort reformers will, at least to some extent, spur additional investment in research and development.

16. Brief for the United States as Amicus Curiae Supporting Respondent 16, *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004) (No. 02-4597), 2004 WL 1143720 [hereinafter Brief for the United States].

17. 21 U.S.C. § 360h(e)(1)–(2) (2000) (regarding the FDA's recall authority); Melissa Marie Bean, Comment & Note, *Fatal Flaws in the Food and Drug Administration's Drug-Approval Formula*, 2003 UTAH L. REV. 881, 886 (2003) (“[T]he FDA has the power to withdraw approval of a drug if any new research shows the drug to be unsafe or ineffective.”).

18. James A. Henderson & Aaron D. Twerski, Essay, *Drug Designs Are Different*, 111 YALE L.J. 151, 165 (2001) (referencing the FDA's power to require additional testing during the phases of new drug approval).

may indirectly promote availability by relaxing the costs and delays associated with product approval,¹⁹ it has no way to directly affect one important factor in the promotion of availability: research and development.²⁰ Product development requires manufacturer investment,²¹ and the potential for profit controls the incentive to invest money in research and development.²² Therefore, improving manufacturers' profitability potential encourages investment in research and development and promotes the availability of medical products.

Medical product manufacturers currently utilize three potential forms of protection from state tort liability: federal preemption of state tort claims, the regulatory compliance defense, and statutorily imposed caps on awarded damages. The legal rationale and amount of protection against liability varies for each.

Federal preemption of state tort claims provides absolute protection from liability based on the Constitution's Supremacy Clause,²³ which precludes certain state claims that subvert federal regulation. Whether state tort claims are preempted depends on the court in which they are made, the type of medical product at issue, and the process used to approve the product. The courts are currently split as to whether state tort liability claims are preempted by FDA approval of a medical device through the most stringent approval process.²⁴ Recent adjudications indicate a trend toward preemption of claims against medical device manufacturers.²⁵ However, pharmaceutical manufacturers have yet to receive this level of protection in the lower courts.²⁶

Courts only consider preemption of claims relating to medical products approved under the most stringent FDA approval processes for medical devices and pharmaceuticals—the Premarket Approval (PMA)²⁷

19. Press Release, FDA, FDA Launches Initiative to Improve the Development and Availability of Innovative Medical Products, <http://www.fda.gov/bbs/topics/NEWS/2003/NEW00867.html> (last visited Feb. 5, 2007).

20. See Nina J. Crimm, *A Tax Proposal to Promote Pharmacologic Research, to Encourage Conventional Prescription Drug Innovation and Improvement, and to Reduce Product Liability Claims*, 29 WAKE FOREST L. REV. 1007, 1015–16 (1994) (“Assuming that the products liability system has, in fact, inhibited investment in R&D by the pharmaceutical industry, it follows that there has been an adverse effect on the amount and type of new drug discovery and innovation. Additionally, the riskier a new research area or drug project may be, the less likely it is that the research or project will be undertaken.” (footnotes omitted)).

21. *Id.*

22. Timothy J. McCoy, *Biomedical Process Patents: Should They Be Restricted by Ethical Limitations?*, 13 J. LEGAL MED. 501, 512 (1992) (stating that the profitability associated with an economic monopoly “drives innovation and capital investment in research and development in a market-based economy”).

23. U.S. CONST. art. VI, cl. 2.

24. Catherine T. Struve, *The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation*, 5 YALE J. HEALTH POL'Y L. & ETHICS 587, 610 (2005).

25. *Id.*

26. *Id.* at 610–11.

27. CTR. FOR DEVICES & RADIOLOGICAL HEALTH, FDA, DEVICE ADVICE, <http://www.fda.gov/cdrh/devadvice/pma> (last visited Feb. 5, 2007) [hereinafter DEVICE ADVICE].

and New Drug Application (NDA), respectively.²⁸ FDA approval of an NDA requires a clinical demonstration of safety and “substantial evidence” of effectivity.²⁹ The PMA process requires “a reasonable assurance of safety and effectiveness,”³⁰ a slightly lower standard.³¹ Although manufacturers must perform substantial testing to meet FDA standards, products necessarily are released after testing is performed on a limited number of people under a limited number of conditions.³² Given the inherent limitations of any approval process, questions arise regarding liability for defects or unforeseen adverse consequences that escape testing.

If a state tort claim is not preempted, a court that chooses to defer to the FDA’s proficiency for assessing safety and efficacy may still recognize a regulatory compliance defense.³³ Regulatory compliance defenses are probably the least significant source of current protection, because state courts rarely defer to FDA assessments,³⁴ and those that do provide varying degrees of immunity.³⁵ In stark contrast to preemption, the regulatory compliance defense is available mainly to approved pharmaceuticals, but does not afford protection to medical devices.³⁶

Lastly, in the event a state court imposes liability on a manufacturer, statutorily imposed caps on awarded damages may limit such liability.³⁷ Certain states already maintain statutorily imposed caps on awarded damages,³⁸ and proposals for federal caps have been considered by Congress.³⁹ The state caps can take a variety of forms, limiting damages based on their classification as either noneconomic⁴⁰ or punitive.⁴¹

28. John F. Del Giorno, Comment, *Federal Preemption of Prescription Drug Labeling: Antidote for Pharmaceutical Industry Overdosing on State Court Jury Decisions in Products Liability Cases*, 22 J. MARSHALL L. REV. 629, 645 (1989).

29. 21 U.S.C. § 355(d) (2000).

30. *Id.* § 360e(d)(1)(B)(iii).

31. Peter Barron Hutt et al., *The Standard of Evidence Required for Premarket Approval Under the Medical Device Amendments of 1976*, 47 FOOD & DRUG L.J. 605, 607–08 (1992).

32. FDA, RISK MGMT., *supra* note 9, at 8–9.

33. Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2054 (2000).

34. Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 GEO. L.J. 2147, 2157 (2000).

35. Michael D. Green & William B. Schultz, *Tort Law Deference to FDA Regulation of Medical Devices*, 88 GEO. L.J. 2119, 2125 (2000).

36. *Id.*

37. CONG. BUDGET OFFICE, CONG. OF THE U.S., THE EFFECTS OF TORT REFORM: EVIDENCE FROM THE STATES vii (2004), available at <http://www.cbo.gov/ftpdocs/55xx/doc5549/Report.pdf> [hereinafter CBO REPORT].

38. *Id.* at 5 fig.1 (illustrating the states that implemented tort reform measures between 1986 and 2004 and the type of reform implemented).

39. Help Efficient, Accessible, Low-Cost, Timely Healthcare (HEALTH) Act of 2005, H.R. 534, 109th Cong. (2005); Healthy America Act of 2005, S. 1503, 109th Cong. (2005).

40. Noneconomic damages are awarded for “items other than monetary losses, such as pain and suffering. The term technically includes punitive damages, but those are typically discussed separately.” Conversely, economic damages cover such things as medical bills and lost income related to the injury. CBO REPORT, *supra* note 37, at 2.

41. Punitive damages are “awarded in addition to compensatory (economic and noneconomic) damages to punish a defendant for willful and wanton conduct.” *Id.*

At the federal level, Republicans have presented bills to Congress that would create federal limitations on the recovery of noneconomic and punitive damages from medical product manufacturers.⁴² Proponents argue cost reduction will facilitate the goal of increased accessibility to healthcare.⁴³ Proponents also contend that placing a check on potential damages will facilitate the disclosure and dissemination of information related to adverse events, resulting in better, safer medical products.⁴⁴ So far, attempts to enact reform bills incorporating liability caps have failed because staunch resistance by Senate Democrats has kept the bills from a vote.⁴⁵ Despite such Senate roadblocks, however, Republicans in the House and Senate have not given up on these reform bills and continue to reintroduce them for consideration year after year.⁴⁶

Although many similar policy initiatives drive the arguments behind preemption of state tort claims, the regulatory compliance defense, and damage caps, the issues are often dissected independently and are rarely considered in light of one another. Rather than discuss any one of these issues microscopically, this note takes a high-altitude look at some of the prevalent arguments for and against each, and ultimately proposes a compromise based on a combination of these three types of liability protection. Admittedly, the administrative costs associated with the proposed compromise would be substantial. However, the resulting system has the potential to incentivize manufacturer investment in research and development, while simultaneously encouraging improved postmarketing surveillance and testing.

In order to take a high-altitude snapshot of the arguments relating to each issue, this note generalizes certain positions specifically related to either medical devices or pharmaceuticals to the larger class of medical products. Although the risks and requisite tests differ for drugs and devices, the flexibility of the system proposed in the recommendation addresses these differences. Moreover, although the scope of this note is broad in the sense that it generalizes medical devices and pharmaceuticals as medical products, the scope of the analysis and recommendation is limited to those products that receive approval based on the most stringent testing processes for pharmaceuticals and medical devices—the NDA and PMA processes. Part II provides a brief overview of these approval processes and details the current state of affairs with regard to preemption of state tort claims, the regulatory compliance defense, and liability caps. Part III dissects the arguments for and against preemption of state tort claims, the regulatory compliance defense, and damage caps

42. Help Efficient, Accessible, Low-Cost, Timely Healthcare (HEALTH) Act of 2005, H.R. 534, 109th Cong. (2005); Healthy America Act of 2005, S. 1503, 109th Cong. §§ 104, 107 (2005).

43. See H.R. 534 § 2(a)(1).

44. See *id.*

45. See Melissa C. Gregory, Note, *Capping Noneconomic Damages in Medical Malpractice Suits Is Not the Panacea of the "Medical Liability Crisis,"* 31 WM. MITCHELL L. REV. 1031, 1040–41 (2005).

46. *Id.*

in light of the goals of consumers and the medical products industry. Part IV advocates a system in which state tort claims are preempted in favor of statutorily created federal causes of action subject to progressively increasing damage caps. This proposal aims to promote the availability of medical products by incentivizing investment in research and development while addressing certain consumer safety concerns by improving postmarketing surveillance and testing.

II. BACKGROUND

A medical product manufacturer's liability for claims related to defective design and failure to adequately warn of known risks may be limited or precluded by preemption of state tort claims, the regulatory compliance defense, and damage caps. This note's discussion of these available liability protections focuses first on preemption, separating the discussion of medical devices from pharmaceuticals based on the different preemption theories relied upon by each. Next, the discussion turns to the regulatory compliance defense. Finally, this note discusses damage caps, beginning with those already implemented by state legislatures and ending with the proposals to implement caps at the federal level.

However, before discussing the liability protections available to medical product manufacturers, a brief overview of the FDA's processes for market release of medical products provides some insight into the thoroughness of these processes. The discussion of relevant approval processes is broken up by product type; approval of medical devices is discussed first, followed by approval of pharmaceuticals.

A. *The Medical Device Approval Process*

Per the Medical Device Amendments of 1976,⁴⁷ medical devices are divided into three categories for purposes of regulation.⁴⁸ This note addresses only Class III medical devices, the riskiest and most heavily regulated,⁴⁹ as they are the only medical devices that arguably undergo sufficient scrutiny to warrant preemption of state tort claims or consideration of a regulatory compliance defense.⁵⁰ Class III devices, such as coronary stents and most defibrillators,⁵¹ are those devices about which:

insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and ef-

47. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976).

48. Gregory J. Scandaglia & Therese L. Tully, *Express Preemption and Premarket Approval Under the Medical Device Amendments*, 59 FOOD & DRUG L.J. 245, 247 (2005).

49. *Id.*

50. *See id.* (referencing the fact that only class III devices are subject to PMA approval).

51. Ctr. for Devices & Radiological Health, FDA, Search Classification Database, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm> (enter "defibrillator" or "stent" to see the classification) (last visited Feb. 5, 2007).

fectiveness or that application of special controls . . . would provide such assurance and if, in addition, the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury.⁵²

The FDA's most stringent approval process for Class III devices is the PMA process,⁵³ to which the scope of this note is further limited. The PMA process requires the manufacturer to demonstrate "reasonable assurance of the safety and effectiveness of a device"⁵⁴ based on the users for whom "the device is represented or intended," the "conditions of use prescribed, recommended, or suggested in the labeling of the device," and the "probable benefit to health" weighed against the "probable risk of injury or illness."⁵⁵ A PMA application requires the manufacturer to submit extensive information about the device including, but not limited to, the particular use, the scientific principles upon which the device operates, the performance characteristics, and the technical data available from clinical and nonclinical studies.⁵⁶ Based on the information submitted by the device manufacturer, the FDA weighs the benefits and risks, utilizing its extensive knowledge and expertise, and ultimately decides whether the device is worth placing on the market.⁵⁷ The FDA spends an average of 1200 hours reviewing a typical PMA submission,⁵⁸ underscoring the "thorough and extensive" scrutiny a device must withstand to receive approval.⁵⁹

B. *The Pharmaceutical Approval Process*

Under 21 U.S.C. § 355(a), a new drug must receive FDA approval prior to entering interstate commerce.⁶⁰ FDA approval is contingent upon the manufacturer's submission of clinical data establishing "substantial evidence" of the new drug's safety and effectiveness.⁶¹

The first step in the pharmaceutical approval process involves pre-clinical studies of the drug on laboratory animals, which allow the manufacturer to make initial assessments about the effectivity, dosage levels, and potential side effects.⁶² If results of the preclinical studies appear positive, the manufacturer will file an Investigational New Drug (IND)

52. 21 C.F.R. § 860.3(c)(3) (2006).

53. DEVICE ADVICE, *supra* note 27.

54. 21 U.S.C. § 360c(a)(1)(C) (2000).

55. *Id.* § 360c(a)(2).

56. Scandaglia & Tully, *supra* note 48, at 249–50. For a more detailed description of the vast amount of data that must be submitted with a PMA application, see *id.*

57. *See id.* at 253.

58. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996).

59. Scandaglia & Tully, *supra* note 48, at 253.

60. 21 U.S.C. § 355(a) (2000).

61. *Id.* § 355(d).

62. Michael P. VanHuysen, Note, *Reform of the New Drug Approval Process*, 49 ADMIN. L. REV. 477, 484 (1997).

application, which “notifies the FDA of the manufacturer’s intent to perform clinical studies on human beings.”⁶³ FDA approval of the IND application authorizes the requisite clinical testing for submission with the New Drug Application (NDA).⁶⁴

Manufacturers must perform at least two large-scale clinical trials to meet the “substantial evidence” of safety and effectiveness for NDA approval.⁶⁵ Each clinical trial consists of three phases.⁶⁶ Phase one focuses on the safety of the drug, “determin[ing] metabolism and pharmacologic actions . . . in humans,” as well as “side effects associated with increasing doses.”⁶⁷ The number of subjects utilized for phase one testing ranges from twenty to eighty.⁶⁸ Phase two measures the effectiveness of the drug on diseased patients in clinical studies and gathers information on “short term side effects and risks.”⁶⁹ Phase two utilizes a maximum of several hundred subjects.⁷⁰ Finally, phase three evaluates the potential drug for both safety and effectiveness in “expanded controlled and uncontrolled trials” on “several hundred to several thousand subjects.”⁷¹ Completion of the final phase of clinical testing alone requires an average of three years.⁷²

Upon completion of clinical testing and satisfaction with the results, the manufacturer may submit the NDA for FDA approval.⁷³ The NDA application is a mountain of paperwork, including almost all of the data gathered that relates to the new drug.⁷⁴ Upon the FDA’s assessment that the drug is effective and approval of the manufacturer’s proposed product labeling, the drug may be shipped to the market.⁷⁵

Even brief overviews of the PMA and NDA processes reveal the extensive amount of time, labor, and resources required to obtain FDA approval. Having reviewed the approval processes for medical devices and pharmaceuticals, this note will detail the current status of liability protections available to medical product manufacturers.

63. *Id.*

64. Mitchell Oates, Note, *Facilitating Informed Medical Treatment Through Production and Disclosure of Research into Off-Label Uses of Pharmaceuticals*, 80 N.Y.U. L. REV. 1272, 1278 (2005) (referencing 21 C.F.R. § 312.21 (2005)).

65. Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1771 (1996).

66. See 21 C.F.R. § 312.21 (2006).

67. Therese M. Keeley, *Drugs and Medical Devices: Claims and Defenses*, SK072 ALI-ABA 169, 191 (2005).

68. *Id.*

69. *Id.*

70. *Id.*

71. *Id.* at 192.

72. Oates, *supra* note 64, at 1278 (referencing Charles J. Walsh & Alissa Pyrich, *Rationalizing the Regulation of Prescription Drugs and Medical Devices: Perspectives on Private Certification and Tort Reform*, 48 RUTGERS L. REV. 883, 907 (1996)).

73. VanHuysen, *supra* note 62, at 485 (referencing 21 C.F.R. § 314.50 (1996)).

74. Oates, *supra* note 64, at 1279.

75. See Margaret Gilhooley, *When Drugs Are Safe for Some but Not Others: The FDA Experience and Alternatives for Products Liability*, 36 Hous. L. REV. 927, 938–39 (1999).

C. *The Current Status of Federal Preemption of State Tort Claims*

The Supremacy Clause of the U.S. Constitution provides for preemption of state law when such state law conflicts with federal law.⁷⁶ In keeping with the federalist nature of the United States, courts presume that preemption has not occurred in the absence of one of the following particular circumstances:

- (a) an express preemption provision in a federal regulation or statute;
- (b) comprehensive federal regulation or statute in a particular field;
- (c) “dominant federal interest in a particular . . . field”;⁷⁷ or
- (d) “direct conflict between state and federal law.”⁷⁸

Medical device manufacturers base their preemption arguments on the first circumstance.⁷⁹ Pharmaceutical manufacturers rely on the remaining three.⁸⁰

1. *Preemption of State Tort Claims Against Medical Device Manufacturers*

Section 360k(a) of the 1976 Medical Device Amendments (MDA) to the Food, Drug and Cosmetic Act of 1938 provides the basis for preempting certain state common law products liability claims against medical device manufacturers.⁸¹ The language of the statute provides: “no State . . . may establish . . . any *requirement* . . . which is different from, or in addition to, any *requirement* applicable . . . to the device, and . . . which relates to the safety or effectiveness of the device or to any other matter included in a *requirement* applicable to the device.”⁸²

Although the express declaration in § 360k(a) appears to meet the first circumstance indicating preemption listed above, courts disagree about whether a standard imposed by a state common law tort claim should be considered a “requirement . . . which is different from, or in addition to, any requirement applicable . . . to the device” per the stat-

76. Scandaglia & Tully, *supra* note 48, at 253.

77. *Id.* at 254.

78. *Id.*

79. See, e.g., Brian J. Donato & Mary Beth Neraas, *Federal Preemption of Product Liability Claims Involving Drugs and Medical Devices Regulated Under the Federal Food, Drug, and Cosmetic Act*, 48 FOOD & DRUG L.J. 305, 306 (1993).

80. See, e.g., William Green, *Consumer-Directed Advertising of Contraceptive Drugs: The FDA, Depo-Provera, and Product Liability*, 50 FOOD & DRUG L.J. 553, 562 (1995).

81. *Horn v. Thoratec Corp.*, 376 F.3d 163, 177 (3d Cir. 2004).

82. Medical Device Amendments of 1976, Pub. L. No. 94-295, § 521(a)(1), 90 Stat. 539, 574 (codified at 21 U.S.C. § 360k(a) (2000)) (emphasis added).

ute.⁸³ Courts also disagree about whether the requisites for FDA approval qualify as federal “requirement[s] applicable . . . to the device” which would preclude further state regulation.⁸⁴ To further complicate the matter, a Supreme Court plurality decided that federal regulation must be device-specific or be a counterpart to the particular state regulation to preclude state tort claims.⁸⁵ Therefore, courts must interpret device-specificity at both state law and federal regulatory levels before reaching the question of preemption.⁸⁶

The majority of courts interpret § 360k in such a way that “state law claims that impose additional or inconsistent requirements where the device receives PMA clearance” are preempted.⁸⁷ Courts in the majority frequently support their reasoning using two rationales: (1) state tort liability imposes different or additional device-specific requirements; and (2) PMA approval creates device-specific federal requirements.⁸⁸

The minority of courts interpret the statute such that PMA approval is insufficient to preempt state tort claims.⁸⁹ Most courts holding the minority view rest on the argument that PMA approval does not create device-specific substantive requirements to which state tort claims might be compared.⁹⁰

2. *Preemption of State Tort Claims Against Pharmaceutical Manufacturers*

While § 360k provides express preemption of certain medical device claims, no such provision exists for pharmaceuticals.⁹¹ Instead, pharmaceutical manufacturers must rely on field preemption and conflict preemption to protect them from state tort liability.⁹² Field preemption is implied when Congress overregulates a particular field (the second and third particular interests above).⁹³ Conflict preemption occurs when “it is impossible to comply with both the state and federal requirements”⁹⁴ (the fourth particular interest above). Thus far, most courts have failed to preempt state tort claims against pharmaceutical manufacturers.⁹⁵ How-

83. *Id.*; Rachel Mervis, Note, *Furthering Consumer Safety of Medical Devices: The Necessity of a Device-Specific State Law as Required for Express Preemption Under the MDA*, 27 *CARDOZO L. REV.* 387, 396 (2005).

84. 21 U.S.C. § 360k(a); Scandaglia & Tully, *supra* note 48, at 258.

85. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 500 (1996).

86. Mervis, *supra* note 83, at 394–95.

87. Scandaglia & Tully, *supra* note 48, at 256.

88. *Id.* at 257.

89. *Id.* at 258.

90. *Id.*

91. Sasha B. Rieders, Note, *State Tort Claims and the FDA: Proposing a Consumer-Oriented Prescription in Medical Device Cases*, 25 *CARDOZO L. REV.* 1159, 1175 (2004).

92. *Id.*

93. *Id.*

94. *Id.*

95. Wilfred P. Coronato & Stephen Lanza, *The Fracture That Will Not Heal: The Landscape of Federal Preemption in the Fields of Medical Devices, Prescription and Over-the-Counter Drugs Ten*

ever, a recent FDA push to extend preemptive protection to pharmaceutical claims may provide manufacturers with a degree of hope.⁹⁶ In *Dusek v. Pfizer*,⁹⁷ the court determined that state failure-to-warn claims against a pharmaceutical manufacturer were preempted because they conflicted with federal law. In *Dusek*, the plaintiff contended that the manufacturer of Zoloft failed to include specific language linking use of the drug to suicide.⁹⁸ The court based its decision to preempt the claims upon the FDA's disapproval of such language.⁹⁹ Although the court specifically stated that FDA approval of a pharmaceutical was not itself sufficient to preempt a state tort claim, it refused to judicially impose "what the FDA has expressly disallowed."¹⁰⁰

D. *The Current Status of the Regulatory Compliance Defense*

In contrast to the federal preemption of claims, the regulatory compliance defense does not rely on the interpretation of any federal statute or regulation. Instead, certain state courts judicially limit liability when a medical product is compliant with FDA regulations.¹⁰¹ "The regulatory compliance defense is grounded in the American Law Institute's *Restatement (Third) of Torts: Products Liability* Section 6."¹⁰² Under the Restatement, a medical product manufacturer may be held liable if a plaintiff can demonstrate the product was not reasonably safe based on the foreseeable risks and whether the manufacturer used reasonable care to ascertain those risks.¹⁰³ States recognizing the regulatory compliance defense presume a compliant product is reasonably safe because "the FDA establishes the duty of care for reasonable research, instructions, and warnings."¹⁰⁴

The acceptance and scope of a regulatory compliance defense varies from state to state and often depends on whether the product at issue is a pharmaceutical or device, with pharmaceutical approvals receiving greater deference than device approvals.¹⁰⁵ Most state courts reject the regulatory compliance defense, offering little or no weight to regulatory

Years After Medtronic, Inc. v. Lohr, in PRODUCTS LIABILITY: PHARMACEUTICAL AND MEDICAL DEVICE ISSUES 365, 384-89 (American Law Institute—American Bar Association Continuing Legal Education) (Aug. 18-19, 2005), available at SL038 ALI-ABA 365.

96. *Id.* at 385-86.

97. *Dusek v. Pfizer Inc.*, No. Civ. A. H-02-3559, 2004 WL 2191804 (S.D. Tex. Feb. 20, 2004).

98. *Id.* at *9.

99. *Id.* at *10.

100. *Id.*

101. William G. Childs, *The Implementation of FDA Determinations in Litigation: Why Do We Defer to the PTO but Not to the FDA?*, 5 MINN. INTELL. PROP. REV. 155, 175 (2004).

102. Linda A. Willett, *Litigation as an Alternative to Regulation: Problems Created by Follow-On Lawsuits with Multiple Outcomes*, 18 GEO. J. LEGAL ETHICS 1477, 1489 (2005) (specifically referencing the liability of pharmaceutical manufacturers). However, the Restatement is also applicable to medical device manufacturers. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(b)-(e) (1998).

103. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(a), (b)(2), (b)(3), (c), (d), (e)(2) (1998).

104. Willett, *supra* note 102, at 1489.

105. Struve, *supra* note 24, at 608-10.

compliance.¹⁰⁶ States that do recognize a regulatory compliance defense premise its availability on the belief that FDA approval is not based on minimum standards, but rather standards calibrated to optimize public health.¹⁰⁷ Certain states, such as Ohio, bar punitive damages if a manufacturer has complied with FDA regulatory requirements.¹⁰⁸ Other states, such as New Jersey, have created a rebuttable presumption of adequacy based on FDA approval.¹⁰⁹ These particular statutes further vary in that the New Jersey statute limits protection to failure-to-warn claims,¹¹⁰ whereas the Ohio statute has no such limitation.¹¹¹ Both of these statutes currently extend protection to both pharmaceutical and medical device manufacturers.¹¹²

Although limitation of the regulatory compliance defense to pharmaceuticals has thus far been the norm,¹¹³ certain courts have determined that particular categories, such as implantable medical devices, should receive similar treatment.¹¹⁴ These courts base such decisions on the rationale that, like pharmaceuticals, these categories of devices are “unavoidably unsafe,” and therefore, the FDA’s favorable risk/benefit assessment should preclude design defect claims.¹¹⁵

E. The Current Status of State Damage Caps for Medical Product Manufacturers

In response to concerns that “too many tort claims are filed and that court awards . . . for punitive damages . . . and pain and suffering tend to be excessive,” many states have enacted tort reform statutes.¹¹⁶ Between 1986 and 2003, twenty-three states imposed caps on noneconomic damages ranging from \$250,000 to \$750,000.¹¹⁷ In the same time period, thirty-four states established either set caps on punitive damages ranging from \$250,000 to \$10,000,000 or flexible caps based on a multiple of the compensatory award.¹¹⁸ Some of these state statutes incorporate limits on the liability of medical providers, eliminating or reducing windfall recoveries and, theoretically, making the pursuit of marginal cases less at-

106. Green & Schultz, *supra* note 35, at 2125.

107. Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REFORM 461, 468–69 (1997); Green & Schultz, *supra* note 35, at 2120.

108. OHIO REV. CODE ANN. § 2307.80(C)(1)(a) (LexisNexis 2005).

109. N.J. STAT. ANN. § 2A:58C-4 (West 2000).

110. *Id.*

111. OHIO REV. CODE ANN. § 2307.80(C)(1)(a).

112. *Id.*; N.J. STAT. ANN. § 2A:58C-4 (West 2000).

113. Green & Schultz, *supra* note 35, at 2125.

114. Struve, *supra* note 24, at 609 & n.103.

115. *Id.* at 609–10.

116. CBO REPORT, *supra* note 37, at vii.

117. *Id.* at ix (citing Am. Tort Reform Ass’n, *Tort Reform Record 2–3* (Dec. 31, 2003), http://www.atra.org/files.cgi/7668_Record12-03.pdf).

118. *Id.*

tractive.¹¹⁹ However, state statutes limiting liability have been attacked as unconstitutional and ineffective.

Thus far, the constitutionality of tort reform statutes has been challenged in at least twenty-five states.¹²⁰ Although most of these challenges “have been based on state rather than federal constitutional provisions,” constitutional uncertainty may initially make manufacturers skittish about relying on federal damage caps to protect them against large awards.¹²¹ Most challenges to the constitutionality of statutes limiting noneconomic damages have been unsuccessful.¹²² Rather than perform a thorough analysis of the arguments for and against the constitutionality of liability caps, this note assumes that such liability caps are constitutional under the federal Commerce Clause.¹²³

Although researchers have conducted numerous studies on the effectiveness of tort reform statutes, it is difficult to isolate the impact of liability caps because each statute varies dramatically.¹²⁴ Certain tort reform statutes are general in nature, limiting a variety of tort claims, whereas others concentrate on medical malpractice claims.¹²⁵ Many statutes incorporate damage caps in conjunction with certain other measures,¹²⁶ such as restriction or elimination of joint-and-several liability,¹²⁷ subtraction of third-party payments from damage awards, or introduction of such payments into evidence.¹²⁸ Beyond these already substantial differences, the liability limits themselves vary from state to state. Some states have fixed caps on punitive damages, ranging from \$250,000 to \$10,000,000.¹²⁹ Other states have damage caps that fluctuate based on the value of other awards, for example, compensatory damages.¹³⁰

Perhaps the greatest difficulty in predicting the effectiveness of state damage caps on medical product manufacturers is the fact that the vast majority of studies focus on the effects of such caps on general medical malpractice insurance premiums and insurer profitability. Medical product manufacturing is but a niche in the overall malpractice landscape. Therefore, isolating the effects of damage caps on manufacturers based on the observed effects on insurance for managed care organizations,

119. *Id.* at vii.

120. Carly N. Kelly & Michelle M. Mello, *Are Medical Malpractice Damages Caps Constitutional? An Overview of State Litigation*, 33 J.L. MED. & ETHICS 515, 518 (2005).

121. *Id.* (referencing the possibility that medical liability insurance companies might be unwilling to make immediate reductions in premiums based on tort reform legislation).

122. *Id.* at 525.

123. *Id.* at 526 (“A federal cap . . . could be challenged as an impermissible exercise of the national government’s commerce-clause authority, though such a challenge would be unlikely to succeed.”).

124. CBO REPORT, *supra* note 37, at vii–viii.

125. *Id.* at vii.

126. *Id.*

127. *Id.* at viii.

128. *Id.* at xii.

129. *Id.* at vii.

130. *Id.*

physicians, manufacturers, and so forth does not appear to be possible at present.

F. Federal Proposals to Cap Damages Against Medical Product Manufacturers

As of 2003, the American Medical Association (AMA) determined that forty-four states either were in a healthcare crisis or were symptomatic of such a crisis.¹³¹ In an attempt to curtail the ever-increasing liability associated with these crises, Republican leaders introduced counterpart bills into the House and Senate: the Help Efficient, Accessible, Low-cost, Timely, Healthcare (HEALTH) Act of 2002¹³² and the Patients First Act of 2003.¹³³ Both bills would eliminate the possibility of recovering punitive damages for injuries inflicted by medical products, unless the plaintiff can demonstrate by clear and convincing evidence that the manufacturer violated an FDA requirement.¹³⁴ The bills would also cap noneconomic damages at \$250,000.¹³⁵ By limiting the liability, and presumably the inherent uncertainty, related to malpractice lawsuits, proponents of the HEALTH Act and Patients First Act hope to improve the availability and reduce the cost of healthcare.¹³⁶ Thus far, the originals and subsequent versions of both bills have been blocked by the Senate.¹³⁷

III. ANALYSIS

In order to formulate an effective scheme to protect the public health, this note considers whether protection from state tort liability might better balance the safety and effectiveness of medical products with availability. A proper balance should protect medical products consumers while encouraging innovation by safeguarding the interests of manufacturers. Such a balance requires probing the various statutory interpretation and policy arguments related to preemption, the regulatory compliance defense, and damage caps. This note begins by examining the statutory interpretation arguments advocating preemption of state tort claims and responses to associated criticisms. Currently, statutory

131. Bryan A. Liang & LiLan Ren, *Medical Liability Insurance and Damage Caps: Getting Beyond Band Aids to Substantive Systems Treatment to Improve Quality and Safety in Healthcare*, 30 AM. J.L. & MED. 501, 504 (2004).

132. Help Efficient, Low-Cost, Timely Health Care (HEALTH) Act of 2002, H.R. 4600, 107th Cong. (2002).

133. Patients First Act of 2003, S. 11, 108th Cong. (2003).

134. Help Efficient, Low-Cost, Timely Health Care (HEALTH) Act of 2005, H.R. 5, 109th Cong. § 7(a) & (c) (2005); Patients First Act of 2005, S. 4, 109th Cong. § 107(a) & (c) (2005); Struve, *supra* note 24, at 611.

135. Help Efficient, Low-Cost, Timely Health Care (HEALTH) Act of 2005, H.R. 5, 109th Cong. § 4(c) (2005); Patients First Act of 2005, S. 4, 109th Cong. § 104(c) (2005).

136. Help Efficient, Low-Cost, Timely Health Care (HEALTH) Act of 2005, H.R. 5, 109th Cong. § 2(b)(1)–(2).

137. Gregory, *supra* note 45, at 1041–42.

preemption is available only to medical device manufacturers;¹³⁸ therefore, the initial statutory interpretation arguments and responses are similarly limited. Although statutory preemption is not available to pharmaceutical manufacturers, this note briefly advocates extending conflict preemption to pharmaceutical manufacturers under a broadened *Dusek* rationale. This note next assesses the competing policy arguments for and against preemption and the regulatory compliance defense. The policy arguments are considered together, despite the fact that federal preemption and the regulatory compliance defense are premised on two different sources of authority,¹³⁹ because the arguments are largely overlapping.¹⁴⁰ Finally, this note takes a brief look at empirical studies relating to existing state damage caps and the policy arguments for and against proposed federal damage caps.

A. *Statutory Preemption of State Tort Claims Against Medical Device Manufacturers*

As noted earlier, preemption of state tort claims against medical product manufacturers is premised on section 521(a)(1) of the MDA, which prohibits states from establishing requirements “different from, or in addition to,” federal requirements.¹⁴¹ Advocates of preemption contend (1) the requisites for FDA approval are federal requirements that preclude further state regulation¹⁴² and (2) state common law tort liability imposes prohibited additional requirements.¹⁴³

1. *FDA Regulations Are Federal “Requirements” for Medical Devices, Precluding Further State Regulation*

Medical devices have received favorable treatment under the theory that the requisites for FDA approval are federal “requirements” that preempt concurrent state regulation through tort claims.¹⁴⁴ Most courts supporting this interpretation of § 360k(a) of the MDA follow logic similar to that of *Horn v. Thoratec Corp.*¹⁴⁵ In *Horn*, the Third Circuit stated

138. Donato & Neraas, *supra* note 79, 319–20.

139. Federal preemption relies on the Constitution’s Supremacy Clause. See text accompanying note 76. The regulatory compliance defense is premised on an individual state’s assessment that the FDA’s regulatory expertise deserves deference when assessing the adequacy of a design or product labeling. See text accompanying note 101.

140. See Rabin, *supra* note 33, at 2053; Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual-Track System*, 88 GEO. L.J. 2167, 2167 n.2 (2000).

141. Medical Device Amendments of 1976, Pub. L. No. 94-295, § 521(a)(1), 90 Stat. 539, 574 (codified at 21 U.S.C. § 360k(a) (2000)).

142. See text accompanying notes 144–48.

143. See text accompanying notes 157–62.

144. See generally Mark C. Levy & Gregory J. Wartman, *Amicus Curiae Efforts to Reform Products Liability at the Food and Drug Administration: FDA’s Influence on Federal Preemption of Class III Medical Devices and Pharmaceuticals*, 60 FOOD & DRUG L.J. 495, 501 (2005).

145. 376 F.3d 163, 179–80 (3d Cir. 2004).

that PMA approval imposed the type of device-specific federal requirements that the Supreme Court in *Lohr* “intimated would give rise to preemption.”¹⁴⁶ The *Horn* court supported this assertion with an overview of the extensive PMA approval process, which lasted nearly twenty years in the case of the device in question, including “ten years of live animal and human cadaver studies,” “seven years [of] clinical trials,” and three years of interactive questioning by the FDA.¹⁴⁷ The court further emphasized that PMA approval requirements are not transitory, but impose ongoing standards for production and marketing.¹⁴⁸

2. *Response to Contentions That FDA Regulation Does Not Impose Federal “Requirements” for Medical Devices*

Critics of federal preemption of state tort claims question the *Horn* decision, arguing that PMA approval does not impose federal “requirements.”¹⁴⁹ This criticism relies on the contention that, absent specific “regulations specifying the design standards for a particular device,” the FDA’s regulation is nothing more than a minimum or general standard.¹⁵⁰ However, this argument does not appreciate the thoroughness of the FDA approval process. It also fails to consider the fact that developing device-specific design requirements would have a number of detrimental effects.

Critics who argue that FDA regulations are minimum standards because the regulations lack specific design requirements assume the FDA does not adequately weigh the design of the device when deciding whether to approve. In actuality, the “FDA considers in great depth and detail the performance and design specifications” of each new device, as well as the “methods of manufacture, labeling, and indications for use of a proposed medical device.”¹⁵¹ In holding that PMA approval imposed federal requirements sufficient to warrant preemption, the *Horn* court quoted the FDA:

Although the PMA approval order does not itself expressly reiterate all of the specific features the device’s design, labeling, and manufacturing processes must have, *it specifically approves as a matter of law those features set forth in the application and binds the manufacturer to produce and market the product in compliance with the specifications as approved by FDA.*¹⁵²

Other explanations exist for the absence of more device-specific design requirements. First, the creation of device-specific design regula-

146. *Id.* at 169.

147. *Id.* at 169–70.

148. *Id.* at 172.

149. David C. Vladeck, *Preemption and Regulatory Failure*, 33 PEPP. L. REV. 95, 120 (2005).

150. *Id.*

151. Brief for the United States, *supra* note 16, at 16 (referencing 21 C.F.R. § 814.20).

152. *Horn*, 376 F.3d at 171–72 (quoting the FDA amicus brief) (emphasis added by the court).

tions for existing products would be an enormous task, resulting in the inefficient consumption of FDA resources. Over half of the nearly eighty thousand varieties of medical devices marketed in the United States require FDA scrutiny in some form.¹⁵³ Attempting to draft design-specific requirements for such a high volume of existing technologies would be futile.

Second, as medical devices evolve over time, product lines necessarily diverge as new features are added and the need for different combinations of features arises. Eventually, products can evolve to the point where the resultant product is so different from the original that the term “device specific” loses meaning.¹⁵⁴

Third, device-specific design regulations limit the creation of new designs as well as the evolution of existing designs. Device-specific design requirements constrain manufacturers’ ability to develop creative solutions to existing problems and similarly limit efforts to develop more cost-effective methods of production.¹⁵⁵ The FDA recognizes the inherent inefficiency related to development of such device-specific design regulation, and thus, evaluates designs for safety and effectivity on an individual basis.¹⁵⁶

153. Vladeck, *supra* note 149, at 102 n.37.

154. Device specificity is a difficult term to pin down. At what point does a requirement become “device specific”? The statute and regulations do little to answer this question. One might answer that a device-specific regulation is one which applies to medical devices of a given “type,” such as catheters, bone plates, and defibrillators. However, due to the increasingly divergent attributes associated with the evolution of medical devices, a regulation might not apply exclusively to any “type” of medical device. In the absence of a federal guideline segregating medical devices into “types,” one could always argue that a regulation applying to more than one device is a “general” regulation. The following example is illustrative of the point. Imagine three defibrillators—*A*, *B*, and *C*. Defibrillator *A* is a monophasic external defibrillator. Defibrillator *B* is a biphasic external defibrillator. Defibrillator *C* is a biphasic internal defibrillator. Regulation *X* applies to defibrillators in general. Regulation *Y* applies to all monophasic defibrillators. Regulation *Z* applies to all internal defibrillators. What attributes of the device must one control to be “device-specific”? Regulation *X* could control anything about the highly diversified class of devices; regulation *Y* controls the waveform of the shock pulse; regulation *Z* controls the physical or material design for radically different applications. When further evolution of defibrillators occurs, will these “device-specific” regulations remain so?

Definitions:

“Monophasic” and “biphasic” are terms which describe the waveform of the electrical pulse used to defibrillate a patient. Monophasic defibrillators are an older technology in which a waveform of a single polarity is used to reset the electrical signal within the heart. Biphasic defibrillators are an evolutionary byproduct of monophasic defibrillators in which the electrical pulse reverses polarity at some point during defibrillation, which reduces the current that must be passed through the patient’s body to achieve a similar result.

“External” defibrillators are the ones that laypeople will recognize from medically oriented television shows where paddles are placed on the patient’s chest and a shock is delivered through the torso to the heart. “Internal” defibrillators are those in which electrodes implanted in the heart muscle deliver the shock.

155. Scandaglia & Tully, *supra* note 48, at 260.

156. *Id.*

3. *State Tort Liability Imposes Prohibited “Requirements” on Medical Devices*

Other statutory interpretation arguments advocating federal preemption of medical devices are premised on the contention that general state tort liability imposes “requirements” proscribed by § 360k(a) of the MDA.¹⁵⁷ Again, the court’s analysis in *Horn* provides an excellent explanation for not allowing such liability. The *Horn* court concluded that a successful negligent design or failure-to-warn claim would force the defendant to alter its FDA-approved design and/or accompanying documentation,¹⁵⁸ thereby imposing additional or conflicting requirements.¹⁵⁹ The court noted that FDA rejection of the court-mandated alterations could place the manufacturer in the “untenable and unenviable position of having to comply with conflicting state and federal requirements” because FDA regulations require approval of any such alteration.¹⁶⁰ Section 360k(a) of the MDA specifically prohibits additional or conflicting state requirements¹⁶¹ in an attempt to avoid such a scenario.¹⁶²

4. *Response to Criticism That State Tort Liability Does Not Impose Prohibited “Requirements” on Medical Devices*

An alternate statutory interpretation argument against federal preemption relies on the assumption that state tort judgments do not impose “requirements.” Critics contend that “jury verdicts are not sufficiently prescriptive to impose ‘requirements’ for preemption purposes.”¹⁶³ These critics insist that jury verdicts simply motivate optional decisions, rather than impose requirements on defendants.¹⁶⁴ But insisting that jury verdicts do not impose requirements ignores the fact that, in the end, jury verdicts, federal statutes, and agency regulations all use essentially the same tool to motivate manufacturers—economic incentives. If a product does not comply with a federal statute or agency regulation, the manufacturer cannot market the noncompliant product. The manufacturer must then decide whether it is more economically advantageous to bring the product into compliance and continue sales or to withdraw the product from the market and forfeit the money invested in product development. Although the decision involves a degree of speculation, the manufacturer can decide based on relatively predictable factors: the cost of bringing the product into compliance, the cost of maintaining compli-

157. Brief for the United States, *supra* note 16, at 18.

158. “Documentation” includes instructions and warnings.

159. *Horn v. Thoratec Corp.*, 376 F.3d 163, 176 (3d Cir. 2004).

160. *Id.* at 177 n.21 (citing 21 C.F.R. §814.80, which prohibits manufacturing and labeling inconsistent with approval order, and 21 C.F.R. §814.3a(d), which mandates FDA approval of alterations).

161. 21 U.S.C. § 360k(a)(1) (2000).

162. *Horn*, 376 F.3d at 177 n.21.

163. Vladeck, *supra* note 149, at 121.

164. *Id.*

ance, and the expected continued profitability. Ultimately, the economic incentives are decisive. If the expected continued profitability justifies the compliance costs, the manufacturer will likely bring the product into compliance and remain in the market.

However, if a state jury creates a new standard and decides a product is noncompliant, a manufacturer may be forced to make a significantly more complicated economic decision. Because no framework exists to unify state jury verdicts, the newly created standard set by the jury may conflict with federal standards or standards set by other states. The manufacturer is no longer faced with the simple question of whether the expected return outweighs the compliance costs. Rather, the manufacturer must decide which of the conflicting standards to violate based on the projected liability associated with each violation. Given the unpredictability of jury verdicts,¹⁶⁵ especially using predictive fact scenarios, manufacturers may simply decide that prospective violation of any standard is too much to risk and forego potential future liability by withdrawing the product from the market. Such a withdrawal constitutes the ultimate adverse effect on accessibility.

B. Rationale for Broadening the Scope of Dusek to Preempt Claims Against Pharmaceutical Manufacturers

Pharmaceutical manufacturers, lacking a statutory equivalent of § 360k(a) of the MDA, have not received the same favorable treatment as medical device manufacturers with regard to preemption of state tort claims.¹⁶⁶ However, as noted earlier in *Dusek*, certain jurisdictions may preempt state claims against a pharmaceutical manufacturer if the manufacturer has complied with a directive issued by the FDA on a specific issue.¹⁶⁷ Citing the FDA's assertions that additional, unsubstantiated warnings could limit the accessibility of a "beneficial, possibly lifesaving treatment" and make valid warnings less effective,¹⁶⁸ the *Dusek* court preempted a plaintiff's failure-to-warn claim. However, the *Dusek* court expressly stated the ruling was narrow in scope, refusing to "authoriz[e] judicially what the FDA already has expressly disallowed."¹⁶⁹

Although the *Dusek* court properly realized the impossibility of complying with two sets of conflicting regulations, limiting the applicability of the ruling to previous FDA determinations creates an undesirable

165. Joni Hersh & W. Kip Viscusi, *Punitive Damages: How Judges and Juries Perform*, 33 J. LEGAL STUD. 1, 1 (2004).

166. Coronato & Lanza, *supra* note 95, at 389.

167. *Dusek v. Pfizer Inc.*, No. H-02-3559, 2004 WL 2191804 (S.D. Tex. Feb. 20, 2004); *Needleman v. Pfizer, Inc.*, No. 3:03-CV-3074-N, 2004 WL 1773697, at *5 (N.D. Tex. Aug. 6, 2004).

168. Coronato & Lanza, *supra* note 95, at 385 (citing the FDA's arguments from its amicus brief submitted on behalf of Pfizer in *Motus v. Pfizer*, later submitted in *Dusek v. Pfizer* and *Needleman v. Pfizer*). This reasoning provides the answer to the first question posed in this note's introductory paragraph.

169. *Dusek*, 2004 WL 2191804, at *10.

dependence on the temporal relationship between an FDA determination and the filing of a state tort claim. To demonstrate why such a limitation is undesirable, consider the scenario where a state court finds a manufacturer liable for failure to adequately warn of known risks *before* a subsequent FDA determination. The FDA must consider the effect of such a warning on the overall public health rather than the facts of a single case. Consequently, the FDA might determine the warning is counterproductive, contradicting the state court decision. The state claim cannot be preempted after the fact based on the conflicting FDA determination. Therefore, future compliance with the FDA determination requires the manufacturer to ignore the state court precedent, exposing the manufacturer to further claims that the state court may or may not decide to preempt. As a result, the manufacturer becomes trapped by state regulation that is in “direct, actual conflict with federal law”—exactly the predicament that the *Dusek* court was attempting to avoid.¹⁷⁰

C. Policy Arguments Advocating Preemption of State Tort Claims and the Regulatory Compliance Defense

The policy arguments for preemption of state tort claims and the regulatory compliance defense focus mainly on the wisdom of implementing such rules in light of the institutional competence of the FDA and the social effects of implementation. Advocates of these measures cite the FDA’s superior competence to define optimal regulation¹⁷¹ and the unreasonable burden that overlapping regulation places on medical product manufacturers.¹⁷²

1. The FDA Is Better Suited to Define Regulation than Common Law Juries

Few would argue that a common law jury is better suited to make regulatory decisions about designs than the experts in the FDA.¹⁷³ The Bendectin litigation is one of the most striking examples of indirect regulation of a medical product manufacturer by common law juries ill-suited to the task.¹⁷⁴ Bendectin was an anti-nausea medication prescribed to some pregnant women to control feelings of sickness associated with pregnancy.¹⁷⁵ Several plaintiffs subsequently brought suit against the manufacturer, Merrell Dow Pharmaceuticals, alleging that Bendectin

170. *Id.*

171. Green, *supra* note 107, at 475 (commenting specifically on the FDA’s superior competence for balancing risk/benefit in the pharmaceutical industry).

172. Margaret Gilhooley, *Innovative Drugs, Products Liability, Regulatory Compliance, and Patient Choice*, 24 SETON HALL L. REV. 1481, 1484 (1994) (citing an A.L.I. study).

173. Green, *supra* note 107, at 477.

174. *Id.*

175. Joseph Sanders, *From Science to Evidence: The Testimony on Causation in the Bendectin Cases*, 46 STAN. L. REV. 1, 2 (1993).

taken during the plaintiffs' pregnancies resulted in birth defects.¹⁷⁶ "Despite a strong consensus in the medical, scientific, and FDA communities that Bendectin" was not causally related to the birth defects, Merrell Dow Pharmaceuticals lost nearly forty percent of the jury trials over a period of fifteen years.¹⁷⁷ The litigation alone cost the manufacturer an estimated \$100 million¹⁷⁸ and, rather than fight an ongoing battle, Merrell Dow pulled Bendectin from the market.¹⁷⁹ To this day, the FDA stands by the safety and effectivity of Bendectin.¹⁸⁰

The Bendectin litigation demonstrates why we should leave safety assessments and policy decisions that affect a medical product's availability to the FDA. Lay juries are simply not equipped to properly consider the effects of their decisions beyond the courtroom. In this instance, "withdrawal of this drug . . . left an unmet therapeutic need for pregnant women suffering from severe nausea, which could result in weight loss and dehydration that sometimes necessitated hospitalization."¹⁸¹ No one would question that the juries in the Bendectin trials were made up of well-meaning individuals, attempting to ease the suffering of families that were victims of bad luck. However, these sympathetic juries made judgments lacking a scientific basis and forced Bendectin from the market, inadvertently putting many pregnant women at risk by denying them access to a safe and effective remedy for severe nausea.¹⁸²

2. *Concurrent Federal and State Regulation Places an Undue Burden on Medical Product Manufacturers*

One of the most pronounced reasons for accepting preemption, and to a lesser extent, a regulatory compliance defense, is the unreasonable burden placed on medical product manufacturers when they are forced to comply with FDA standards as well as the standards set by multiple states.¹⁸³ "[T]he prospect of hundreds of individual juries determining the propriety of particular device approvals, or the appropriate standards to apply to those approvals, is the antithesis of the orderly scheme Congress put in place and charged the FDA with implementing."¹⁸⁴ "The overlap of regulation and tort law results in overdeterrence," prompting

176. *Id.* at 4.

177. Green, *supra* note 107, at 477.

178. *Id.* at 468.

179. Rochelle Chodock et al., "Insuring" the Continued Solvency of Pharmaceutical Companies in the Face of Product Liability Class Actions, 40 TORT TRIAL & INS. PRAC. L.J. 997, 999 (2005).

180. Lars Noah, *Triage in the Nation's Medicine Cabinet: The Puzzling Scarcity of Vaccines and Other Drugs*, 54 S.C.L. REV. 741, 760 (2003).

181. *Id.* at 760-61.

182. *Id.* at 760.

183. Gilhooly, *supra* note 172, at 1484.

184. Horn v. Thoratec Corp., 376 F.3d 163, 178 (3d Cir. 2004) (citing the FDA's views from an amicus brief in another case).

manufacturers to forego research and development, delay product release, and withdraw products from the market.¹⁸⁵

D. Responses to Criticisms of Preemption of State Tort Claims and the Regulatory Compliance Defense

Critics assert numerous arguments against federal preemption and regulatory compliance defenses, citing (1) standards based on minimum safety and efficacy goals, (2) lack of FDA accountability for its decisions, (3) administration “capture” by the regulated industry, (4) the need to expose industry cover-ups through state tort claims, and (5) inadequate FDA oversight to guarantee consumer safety. However, careful scrutiny reveals the weaknesses of these arguments.

1. Response to Criticism That FDA Standards Are Minimum Goals

Some courts have rationalized state tort claims by adhering to the notion that the FDA imposes only “minimum” standards, which may be augmented and improved upon by jury verdicts.¹⁸⁶ FDA approvals, however, are not based upon meeting minimum standards, but rather upon a carefully reasoned analysis that the benefits outweigh the risks, sufficient testing has been performed to identify risks, and the proper information relating to identified risks is provided.¹⁸⁷ The FDA itself disputes that approval standards are minimal and asserts that its central role is “the balancing of benefits and risks of a specific device.”¹⁸⁸ The FDA also cautions that allowing lay judges and juries to second-guess its determinations “can harm the public health by retarding research and development . . . [disseminating] scientifically unsubstantiated warnings[,] and [causing] underutilization of beneficial treatments.”¹⁸⁹

Critics also levy a specific extension of the above argument against medical devices in particular, claiming the FDA lacks authority to require “optimal” designs, even if safer and more effective designs exist.¹⁹⁰ However, this argument places too much emphasis on safety and ignores the aspect of availability. Congress likely refused to require optimal designs because it recognized the economic realities of providing medical care. Although safety must be of paramount importance, optimal public health requires a careful balance between safety/effectivity and availability. When a manufacturer develops a medical device, especially a novel device, an exorbitant amount of time and expense would likely be re-

185. Green, *supra* note 107, at 466–67.

186. See, e.g., *Plenger v. Alza Corp.*, 13 Cal. Rptr. 2d 811, 819 n.7 (Ct. App. 1992); *Savina v. Sterling Drug, Inc.*, 795 P.2d 915, 931 (Kan. 1990).

187. Green, *supra* note 107, at 474.

188. Brief for the United States, *supra* note 16, at 25.

189. *Id.* at 26.

190. Vladeck, *supra* note 149, at 120 (referencing 21 U.S.C. § 360e(d)).

quired to develop and test what would be considered an “optimal” design from the standpoint of safety and effectivity. The end result would often be the safest and most effective product that few could afford to buy.¹⁹¹ In the event that individuals could afford such a product, the extensive testing required would delay market release, denying relief to many who might be helped by such a product.¹⁹² In the end, diminished availability could substantially reduce the overall social benefit of such a device.

2. *Response to Criticism That the FDA Lacks Accountability for Decisions*

Critics of preemption and a regulatory compliance defense argue that the FDA is not accountable for inaction related to postmarket evaluation; therefore, any defense relying on agency regulation and compliance with that regulation leaves no one accountable for risks and defects discovered after product approval.¹⁹³ But despite the FDA’s limited liability for improper approval of medical products, intense media and congressional scrutiny of the FDA sufficiently encourages the FDA to make the most informed decision possible.¹⁹⁴ For example, in light of Merck’s voluntary withdrawal of Vioxx from the market, the FDA has been heavily criticized for failure to remove another Cox-2 inhibitor, Celebrex, after a clinical study indicated potentially similar cardiovascular risks.¹⁹⁵ Some might argue that harsh scrutiny is an insufficient incentive if the FDA is not held accountable for its decisions. However, anyone advocating enhanced accountability for liability and policy decisions can hardly justify taking decisions affecting product availability out of the hands of the highly scrutinized FDA and turning them over to “a group of jurors whose obligations end at the close of the case.”¹⁹⁶ Jurors are not

191. Scandaglia & Tully, *supra* note 48, at 262 (“A regulatory environment that creates extraordinarily safe products, which are unaffordable and unable to be produced profitably, will benefit no one.”).

192. Stewart, *supra* note 140, at 2174.

193. Gilhooly, *supra* note 172, at 1490 (“An FDA medical officer’s decision finding no need to add a warning to the labeling with regard to these post-approval risks is a low visibility decision that does not involve a public explanation. Because the agency decision not to require an additional warning is inaction, the non-decision would ordinarily be a matter committed to agency discretion and not subject to judicial review.”).

194. Green, *supra* note 107, at 478–80 (“[A]ny pro-industry bias or influence that may exist with regard to the new drug approval process in the FDA has been outweighed by countervailing risk aversion born of concern about public and congressional calumny in the event of the approval of a new drug that turns out to be a successor to thalidomide.”).

195. Richard A. Epstein, *Regulatory Paternalism in the Market for Drugs: Lessons from Vioxx and Celebrex*, 5 *YALE J. HEALTH POL’Y L. & ETHICS* 741, 743–44 (2005).

196. Scandaglia & Tully, *supra* note 48, at 263; *see also* Noah, *supra* note 34, at 2155–56 (advocating the position that consumer interest organizations, having failed to influence legislators and regulators should not be allowed to use “jurors accountable to no one for decisions that have undoubted regulatory effects” as an alternate means to pursue their agendas); Stewart, *supra* note 140, at 2174–75 (“Juries in individual tort cases deal only with a single accident and may focus disproportionately on the injury suffered by a specific plaintiff in an individual case. As a result, juries may impose liability

only unqualified to make important decisions affecting medical product availability, but lack any accountability for the ultimate societal effects of these decisions.

3. *Response to Concerns Regarding FDA Vulnerability to “Capture” by the Regulated Industry*

Other critics contend the FDA is vulnerable to “capture” by the industry it regulates.¹⁹⁷ These critics fear that politicians use regulatory agencies like the FDA as political fundraising tools by exchanging lenient regulation for industry campaign contributions.¹⁹⁸ Other concerns have also been advanced, such as the potential for improper industry influence through collaborative policymaking efforts with the FDA¹⁹⁹ and the perceived unwillingness of the FDA to sufficiently pressure the regulated industry.²⁰⁰ However, critics offer “little more than anecdote and suspicion” to support the agency capture theory.²⁰¹ Also, critics who fear agency capture need to consider the comparably ominous spectres that may arise in the absence of preemption or a regulatory compliance defense—state government capture by factions²⁰² and “regulation by litigation.”²⁰³

If a political interest group is unsuccessful in its attempts to implement policy at the federal level, it may still impose its will upon product manufacturers by implementing policies in states more receptive to its agenda.²⁰⁴ Although such state legislatures are undoubtedly well meaning²⁰⁵ and have traditionally held the power to legislate to protect the health and safety of citizens,²⁰⁶ states should not have the authority to “govern the design and manufacture of federally licensed, completely standardized goods shipped everywhere in the United States in interstate commerce.”²⁰⁷ Conceding this authority to the states is tantamount to sanctioning states regulating beyond their own borders, because medical products are distributed nationally and therefore must comply with the laws of all jurisdictions in which they are used or sold.

on grounds of product defect, even in cases where liability has the effect of deterring the manufacture of socially beneficial products, and thereby increasing the overall level of environmental, health, or safety risk.”).

197. Thomas O. McGarity, *Beyond Buckman: Wrongful Manipulation of the Regulatory Process in the Law of Torts*, 41 WASHBURN L.J. 549, 564 (2002).

198. *Id.*

199. *Id.* at 565–67.

200. *Id.* at 565–66.

201. Noah, *supra* note 34, at 2154.

202. Robert R. Gasaway, *The Problem of Federal Preemption: Reformulating the Black Letter Rules*, 33 PEPP. L. REV. 25, 29 (2005).

203. Edward T. Schroeder, Note, *A Tort by Any Other Name? In Search of the Distinction Between Regulation Through Litigation and Conventional Tort Law*, 83 TEX. L. REV. 897, 897–98 (2005).

204. Gasaway, *supra* note 202, at 29–30.

205. *Id.* at 29.

206. *See id.* at 35.

207. *Id.*

Failing again at the state legislative level, a political interest group has yet another alternative—“regulation by litigation.”²⁰⁸ By obtaining favorable judgments on state tort claims, a faction may essentially bypass the legislative and administrative processes and establish policy via standards created at common law.²⁰⁹ Separation of powers in our system of government allocates policymaking decisions to the legislative branch, not the judiciary. Therefore, failure to convince legislators and regulators that a particular agenda has merit should preclude subsequent attempts to seek more favorable treatment in the courts.²¹⁰ Preemption and the regulatory compliance defense preclude such attempts.

4. *Response to Criticism That Inhibition of State Tort Claims Will Negatively Impact Exposure of Industry Cover-Ups*

Critics also argue the tort system serves a positive function by bringing to light corporate misconduct involving undisclosed safety risks and manufacturer cover-ups.²¹¹ Critics cite the lack of FDA involvement with the actual compliance testing and the potential for fraud on the agency as potential dangers that might remain unexposed in the absence of concurrent tort regulation.²¹² However, allowing preemption or a regulatory compliance defense should not discourage information gathering by plaintiffs, but rather should have the opposite effect. The requirement that manufacturers comply with regulatory standards to assert either protection should give plaintiffs an added incentive to investigate “noncompliance, nondisclosure, or fraud.”²¹³

5. *Response to Criticism That the FDA Fails to Provide Adequate Oversight to Guarantee Consumer Safety*

One prominent critic argues that in light of “its worst period of regulatory failure” highlighted by “a stream of highly publicized recalls of medical devices,” the FDA cannot effectively provide a “guarantee of safety” through regulation.²¹⁴ Again, this argument seems to overemphasize safety at the expense of accessibility. To illustrate the argument, the critic references the death of a young man whose implanted defibrillator failed.²¹⁵ The critic further notes that dozens of subsequent failures and at least one other death occurred prior to the recall of the device.²¹⁶ The

208. Schroeder, *supra* note 203, at 897–98.

209. *Id.* (citing critics’ contention that “lawsuits constitute ‘end runs around the democratic process’”).

210. Noah, *supra* note 34, at 2155.

211. Rabin, *supra* note 33, at 2068–69.

212. *Id.* at 2069.

213. Noah, *supra* note 34, at 2162.

214. Vladeck, *supra* note 149, at 126.

215. *Id.* at 96.

216. *Id.*

critic also asserts that approximately twenty-five thousand of the defibrillators at issue were implanted in patients in the years between this particular incident and the recall.²¹⁷ Certainly the effects on individuals harmed or killed by the failure of the device at issue were tragic; however, one has to consider the net benefit to society before making any decisions regarding whether FDA regulation is sufficient. This anecdotal criticism fails to address a key question. If nearly twenty-five thousand devices were implanted and there were only two recorded deaths, how many lives were saved by those devices in the intervening years? Perhaps the ease with which we can quantify the harm and death caused by a particular medical product diminishes our willingness to weigh such negatives against the considerably less quantifiable benefits—saved lives and improved quality of life.

Further arguments relating to the adequacy of regulatory oversight assail the FDA's ability to incentivize post-approval compliance with regulations.²¹⁸ However, post-approval compliance with regulations is a natural prerequisite to asserting a regulatory compliance defense or preemption.²¹⁹ A manufacturer's reliance on either preemption or a regulatory compliance defense to limit the extent of liability should create at least a marginal incentive to improve compliance with regulations.²²⁰

E. Valid Criticisms of Preemption of State Tort Claims and the Regulatory Compliance Defense

Critics also contend (1) the availability of preemption and the regulatory compliance defense removes manufacturers' incentives to perform adequate postmarket surveillance and testing²²¹ and (2) a regulatory compliance defense would not deter litigation, but merely shift the focus of litigation from design defects and failure to warn, to regulatory compliance.²²² Although these concerns seem more valid than those previously discussed, they might effectively be addressed through means other than the state tort system.

217. *Id.* at 131.

218. Green & Schultz, *supra* note 35, at 2123.

219. Green, *supra* note 107, at 481; Green & Schultz, *supra* note 35, at 2122–23. Although both references only assert that regulatory compliance should be a prerequisite of a regulatory compliance defense, the same should hold true for preemption. It would be counterintuitive to allow a defendant to assert that the extensive regulations established for approval and continued marketing of medical products should defeat a state tort claim if the defendant has failed to comply with those regulations.

220. Michael D. Green, *Safety as an Element of Pharmaceutical Quality: The Respective Roles of Regulation and Tort Law*, 42 ST. LOUIS U. L.J. 163, 183 (1998) (referencing manufacturers' additional incentive to comply with regulations given an available tort defense, subject to certain additional factors such as market competition, significance of post-approval risks on the market, and significance of profitability).

221. *Id.* at 185.

222. Green, *supra* note 107, at 508.

1. *Manufacturers Lack Incentive to Perform Postmarketing Surveillance and Testing in the Absence of State Tort Claims*

Perhaps one of the most convincing arguments against preemption and a regulatory compliance defense relates to postmarketing surveillance of medical products. The ongoing threat of tort claims ensures that medical product manufacturers must continually monitor their products and disclose known risks to mitigate their tort liability.²²³ Critics of preemption and a regulatory compliance defense argue that removing the threat of tort liability may create economic incentives to forego post-approval surveillance and testing.²²⁴ In the absence of later-discovered risks or defects, FDA approval would provide manufacturers with immunity from liability, making ignorance bliss.²²⁵ Manufacturers would also have a financial incentive to avoid costly investigations related to the discovery of potential risks.²²⁶ To avoid discovering potential risks, manufacturers might be less likely to solicit information about adverse events from doctors and users of their products.

Given the above argument, critics could also derive a corollary: preemption or a regulatory compliance defense eliminates incentives for manufacturers to perform internal postmarket testing on their products. Postmarket testing could serve to uncover only those risks not discovered during the approval process,²²⁷ and knowledge of these latent risks would trigger a manufacturer's responsibility to disclose and address them.²²⁸ Therefore, manufacturers would have financial justification to perform the minimum testing required to obtain approval, then cease all further testing.

2. *A Regulatory Compliance Defense Might Not Deter Litigation, but Merely Shift the Focus*

Another shortcoming of the regulatory compliance defense is that implementation of such a defense may not deter litigation, but merely shift the focus of litigation from design defects to failure to comply with regulations.²²⁹ Because the main arguments for a regulatory compliance defense center on the superior nature of FDA regulatory standards when compared to standards set by a common law jury, noncompliance with

223. *Id.* at 502.

224. Green, *supra* note 220, at 184 (referencing manufacturers' lack of incentive to comply with post-marketing communication of adverse drug reactions given the availability of a regulatory compliance defense); Green, *supra* note 107, at 502 ("With a regulatory compliance defense available, manufacturers would no longer have an incentive to seek labeling changes that would disclose additional risks discovered in the post-marketing period.").

225. Green, *supra* note 107, at 502.

226. *Id.*

227. Struve, *supra* note 24, at 602.

228. Green, *supra* note 107, at 502 n.153.

229. *Id.* at 508.

FDA standards would preclude manufacturers from asserting such a defense.²³⁰ Critics contend that a regulatory compliance defense will not reduce the volume of litigation because plaintiffs will redirect resources, previously expended to demonstrate design flaws and failure to warn, toward proving noncompliance.²³¹ Manufacturers might actually end up spending more on litigation because the depth and complexity of FDA regulations could make a determination of compliance even more confusing to jurors than determination of whether a product was adequately designed.²³²

F. Summary of Policy Arguments for and Against Preemption and the Regulatory Compliance Defense

Although the policy arguments collectively seem to favor preemption and the regulatory compliance defense, neither provides proper incentive for post-approval surveillance and testing. Also, the regulatory compliance defense may not effectively reduce the volume of litigation. This note moves on to discuss another means by which states currently limit tort liability and by which the federal government proposes to do so—damage caps.

G. Empirical Studies Relating to Existing State Statutory Damage Caps Reveal Little

As noted above, analyzing empirical data from states that have enacted liability caps provides limited insight because isolating the effect of damage caps from the effects of other tort reform measures is nearly impossible.²³³ Even if one were capable of estimating the effects of damage caps alone, interpolating the existing data to further pinpoint the effects on medical product manufacturers presents an additional difficulty. However, despite researchers' inability to isolate the effects of liability caps, "[a]s of April 2005, more than half the states had passed legislation imposing some kind of limit on noneconomic damages awards."²³⁴ Such a statistic seems to indicate that state governments, frustrated with the ever-increasing costs associated with medical care, are willing to give damage caps a try.

Drawing conclusions about the effects that federal damage caps would have on medical product manufacturers based on existing studies of state damage caps on medical malpractice insurers requires too many assumptions to be of any practical value. It is sufficient to note that, despite their superficial relevance, several studies seem to indicate that

230. Green & Schultz, *supra* note 35, at 2122–23.

231. Green, *supra* note 107, at 508.

232. *Id.*

233. CBO REPORT, *supra* note 37, at vii–viii.

234. Kelly & Mello, *supra* note 120, at 516.

damage caps have positive effects on medical malpractice insurers,²³⁵ whereas others seem to indicate that damage caps do not produce their intended effects.²³⁶

H. Policy Arguments Relating to Federal Statutory Liability Caps

The major question surrounding the imposition of federal statutory limits on damages remains: do such caps benefit the overall health of society? Although some argue that rising healthcare costs are the result of overly cautious medical liability insurers, the U.S. General Accounting Office has stated the primary contributor is escalating losses on claims.²³⁷ This note briefly examines manufacturers' complaints regarding the unpredictability of state tort liability, then responds to the criticisms that damage caps set an arbitrary maximum recovery and will fail to adequately reduce the volume of litigation.

1. The Unpredictability of State Tort Liability Stifles Investment in Research and Development

Proponents of liability caps contend research and development has been stifled by "the unpredictability of litigation and unreasonable transaction costs" associated with the high volume of litigation.²³⁸ Proponents seek federal limits on certain types of damages based on the same rationale used by many state legislatures—damage caps have the potential to reduce this unpredictability and deter claims that are unlikely to be suc-

235. One study performed by the Department of Health and Human Services found that, over a two-year period, the average highest premium increase in states that enacted liability caps of \$350,000 or less was 18%, as opposed to 45% for states that failed to enact such caps. OFFICE OF THE ASSISTANT SEC'Y FOR PLANNING & EVALUATION, U.S. DEP'T OF HEALTH & HUMAN SERVS., ADDRESSING THE NEW HEALTH CARE CRISIS: REFORMING THE MEDICAL LITIGATION SYSTEM TO IMPROVE THE QUALITY OF HEATH CARE (2003), <http://www.aspe.hhs.gov/daltcp/reports/mediab.pdf> (limiting study to OB/GYNs, Internists, and General Surgeons and selected states).

Another study of state reforms enacted in the 1980s appeared to indicate that limits on noneconomic damages resulted in a "[l]arge decline in losses for both general and medical malpractice insurance." CBO REPORT, *supra* note 37, at 12 tbl.2 (referencing findings from W. Kip Viscusi et al., *The Effect of 1980s Tort Reform Legislation on General Liability and Medical Malpractice Insurance*, 6 J. RISK & UNCERTAINTY 165 (1993)).

A third study indicated such noneconomic damage caps "[l]ed to increased profitability for insurers and a decrease in premiums." *Id.* (referencing findings from Patricia H. Born & W. Kip Viscusi, *The Distribution of the Insurance Market Effects of Tort Liability Reforms*, BROOKINGS PAPERS ON ECON. ACTIVITY: MICROECONOMICS 55 (1998)).

236. See, e.g., Adam D. Glassman, *The Imposition of Federal Caps in Medical Malpractice Liability Actions: Will They Cure the Current Crisis in Health Care?*, 37 AKRON L. REV. 417, 460 (2004); Kathryn Zeiler, *Turning from Damage Caps to Information Disclosure: An Alternative to Tort Reform*, 5 YALE J. HEALTH POL'Y L. & ETHICS 385, 386 (2005).

237. David J. Palmisano, *Health Care in Crisis: The Need for Medical Liability Reform*, 5 YALE J. HEALTH POL'Y L. & ETHICS 371, 376-77 (2005) (quoting U.S. GEN. ACCOUNTING OFFICE, MED. MALPRACTICE INSURANCE: MULTIPLE FACTORS HAVE CONTRIBUTED TO INCREASED PREMIUM RATES 15 (2003), available at <http://www.gao.gov/new.items/d03702.pdf>).

238. Chodock et al., *supra* note 179, at 998.

cessful, but proceed due to their potential to produce inflated jury awards.²³⁹

Proponents of damage caps also cite the fact that jury awards for medical malpractice have begun to soar out of control.²⁴⁰ Proponents point to California's Medical Injury Compensation Reform Act (MICRA)²⁴¹ as a model illustrating the ability of damage caps to reduce cost and improve access to healthcare.²⁴² "[T]he single most important provision of MICRA" is perceived to be the "\$250,000 cap on non-economic damages," which improved insurers' ability to calculate potential future damages, stabilizing California's insurance market.²⁴³

2. *Response to Criticism That Damage Caps Set an Arbitrary Maximum Recovery*

Critics of damage caps dismiss rigid caps assigned by legislators because the values are set without the benefit of a specific fact scenario or judicial guidance, creating an arbitrary maximum recovery for pain and suffering.²⁴⁴ These critics contend that caps unfairly try to remedy the maladies of the insurance industry at the expense of those few severely injured individuals "who are most in need of the larger damage awards for pain and suffering."²⁴⁵ But this argument is essentially an admission supporting the contention that damage caps have the potential to reduce uncertainty at the expense of a relatively small, albeit unfortunate, number of individuals.²⁴⁶ This argument also ignores the tendency of juries to overcompensate individuals suing "deep-pocket" manufacturers.²⁴⁷ Moreover, although limits on recovery may seem arbitrary when viewed on a case-by-case basis, those limits appear less arbitrary when considered collectively in light of the public policy goal of maximizing the availability of medical products.

239. CBO REPORT, *supra* note 37, at vii.

240. Richard E. Anderson, *Effective Legal Reform and the Malpractice Insurance Crisis*, 5 YALE J. HEALTH POL'Y L. & ETHICS 343, 347 (2005).

241. Medical Injury Compensation Reform Act (MICRA) of 1975, chs. 1–2, 1975 Cal. Stat. 2d Ex. Sess. 3949.

242. Anderson, *supra* note 240, at 349–51.

243. *Id.* at 350.

244. Elizabeth Stewart Poisson, Comment, *Addressing the Impropriety of Statutory Caps on Pain and Suffering Awards in the Medical Liability System*, 82 N.C. L. REV. 759, 779–80 (2004).

245. Edward C. Martin, *Limiting Damages for Pain and Suffering: Arguments Pro and Con*, 10 AM. J. TRIAL ADVOC. 317, 337 (1986).

246. A similar argument is advanced by proponents of preemption. Because most medical devices are approved via the FDA's substantial equivalence, or 510(k) process, and courts do not preempt claims related to injuries caused by such devices, preemption affects relatively few claims. Scandaglia & Tully, *supra* note 48, at 263.

247. Note, *A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals*, 103 HARV. L. REV. 773, 781 n.44 (1990).

3. *Response to Criticism That Damage Caps Will Not Adequately Reduce the Volume of Litigation*

Critics also argue that damage caps do not substantially reduce the costs associated with litigation²⁴⁸ because the majority of claims generated seek damages below the limit of the caps.²⁴⁹ Yet medical product manufacturers may actually be more willing to settle many of these smaller claims if they can better estimate future costs. Manufacturers of a particular pharmaceutical or device must always consider that any settlement favorable to a plaintiff will likely encourage other consumers to file claims alleging similar injuries.²⁵⁰ Reducing uncertain monetary losses related to an “admission” of liability by settlement might make recovery for many plaintiffs substantially less costly.

I. *Analysis Summary*

Despite the barrage of arguments decrying preemption, the regulatory compliance defense, and damage caps, all three protections from liability seem superior to the current practice, which gives lay juries excessive discretion to assess tort liability and damages. Simply put, lay juries lack the big-picture perspective necessary to make policy decisions affecting medical device manufacturers. Ill-informed decisions may ultimately upset the careful risk/benefit assessments of the agency to which Congress delegated such policy decisions—the FDA. Along the same lines, the passage of damage caps in most states appears to indicate a popular belief that limiting medical liability will have an overall positive effect on the availability of healthcare. However, the current liability protections of preemption, the regulatory compliance defense, and rigid damage caps do nothing to improve safety and effectivity because they fail to adequately incentivize post-approval surveillance and testing. Part IV proposes a means by which the preemption and regulatory compliance defense could be combined with a nontraditional variation of damage cap to encourage development and manufacture of medical products while simultaneously providing manufacturers with adequate incentive to continuously improve safety and effectivity.

IV. RECOMMENDATION

Although preemption of state tort claims and availability of a regulatory compliance defense might be beneficial to the overall public

248. Christopher J. Marchand, *Arbitration and Long-Term Health Care*, 38 MD. B.J. 32 (2005).

249. Ronen Avraham, *Putting a Price on Pain-and-Suffering Damages: A Critique of the Current Approaches and a Preliminary Proposal for Change*, 100 NW. U. L. REV. 87, 98 (2006); Martin, *supra* note 245, at 337.

250. Patrick Lysaught, *Forces Shaping Mass Tort Litigation: Strategies for Defense Counsel*, 67 DEF. COUNS. J. 165, 168 (2000). See generally Ken Brownlee, *Insurers, Litigation Management, and the Tripartite Relationship*, BRIEF, Spring 2004, at 56, 57.

health, they each have flaws that should be addressed. First, neither provides manufacturers with adequate incentives to improve postmarketing surveillance of their products. Similarly, neither encourages further active investigation or testing beyond that required for approval. With regard to these concerns, the common law tort system currently appears to be the only way to “provide manufacturers with added *dynamic incentives* to continue to keep abreast of all possible injuries stemming from use of their product so as to forestall such actions through product improvement.”²⁵¹ However, well-crafted legislation might provide an alternate means by which to sustain dynamic incentives while simultaneously giving manufacturers increased incentive to invest in research and development.

A. *Moving Claims to Federal Courts and Creating Dynamic Incentives Using Progressively Increasing Damage Caps*

This note proposes legislation that would explicitly preempt state tort claims against medical product manufacturers. However, this legislation would supplant the protection currently afforded by state tort claims with federal causes of action for claims relating to defective design and failure to adequately warn of known risks. FDA determinations relating to the adequacy of design and warnings would be given special deference. The legislation would contain an explicit provision requiring all such claims to be brought in federal court. A rebuttable presumption of regulatory compliance would bar awards of punitive damages and entitle a manufacturer to a progressively increasing cap on noneconomic damages. To overcome the presumption of regulatory compliance, a plaintiff would carry the burden of establishing failure to comply by clear and convincing evidence. The limit on noneconomic damages would begin as a set amount on the date of product approval, then increase over time subject to a “curve” defined by the FDA during the product-approval stage. Eventually, the limit would reach a maximum value set substantially higher than the limits suggested by current federal proposals.

The following Sections illustrate how the dynamic incentives created by this proposal combine the benefits of preemption and the regulatory compliance defense, while addressing the identified pitfalls.

251. *Bates v. Dow Agrosiences LLC*, 544 U.S. 431, 451 (2005) (quoting *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1541–42 (D.C. 1984)) (emphasis added). This quote is referenced by Professor David C. Vladeck in his symposium article, *Preemption and Regulatory Failure*. Vladeck, *supra* note 149, at 131–32. Although *Bates* involved EPA regulation, rather than FDA regulation, Professor Vladeck referenced the case to illustrate the Supreme Court’s recognition of the function of tort liability in a regulated environment. *Id.* at 110, 114.

B. Redistributing Initial Risk Encourages Investment in Research and Development During a Manufacturer's Most Vulnerable Period

The proposal essentially redistributes a portion of the initial risk inherent in all new medical products. Consumers would bear more initial risk, but much of that risk would shift back to the manufacturers over time. One may assume that manufacturers are most vulnerable to losses just after the initial release of a new medical product because they have just made a large, and thus far unrecouped, investment into product development, and have little or no field data about adverse events or reactions beyond the limited testing performed for approval. If unforeseen side effects appear soon after market release, the manufacturer stands to lose not only the investment in research and development, but incalculable damages from resultant tort claims. The proposal limits a manufacturer's loss to the investment in research and development and capped damages, allowing the manufacturer to calculate the loss risk. By shifting some of the risk to consumers during this vulnerable period, manufacturers will have something of a "safe zone" in which to develop new treatments and technologies.

C. Improved Outcome Predictability Should Reduce the Volume of Litigation and Manufacturers' Perceived Need to Pad Prices

Litigation in federal courts under the proposal should improve the predictability of decisions at two layers. First, although juries will still be the ultimate decision makers, they will reach decisions based on more consistent judicial instructions. If decisions do lead to circuit splits, manufacturers may petition the Supreme Court in an attempt to achieve regulatory unity. Second, the instructions themselves will dictate special deference to FDA determinations, theoretically leading to more predictable decisions.

The improved predictability should reduce the volume of litigation because manufacturers will be in a better position to accurately assess which claims should be contested and which should be settled. Requiring plaintiffs to overcome the presumption of regulatory compliance with clear and convincing evidence is necessary to ensure that any reduction in litigation over design defects and failure-to-warn claims is not offset by claims for failure to comply with regulations.

The improved economic predictability resulting from capped damages and reduced litigation volume should also reduce a manufacturer's perceived need to pad pricing in an attempt to self-insure against large future losses.²⁵²

252. Scandaglia & Tully, *supra* note 48, at 263 ("When faced with the possibility of huge verdicts, despite having complied with FDA's requirements, manufacturers likely will pass on to consumers the cost of any estimated liability exposure and may well raise prices to compensate for these possible

D. Progressively Increasing Damage Caps Address Consumer Concerns About Postmarketing Surveillance and Testing

Increasing damage caps also address the failure of preemption and a regulatory compliance defense to adequately incentivize diligent post-marketing surveillance and post-approval testing. Because the damage cap associated with the particular product will increase over time, manufacturers will be inclined to identify, disclose, and, if possible, eliminate risks associated with their products as their protection against liability diminishes. For the proposal to be effective, the FDA would have to tailor the increasing damage cap to adequately incentivize a manufacturer's postmarketing surveillance and post-approval testing. A final cap, set significantly higher than the caps associated with the current federal proposals, would likely be necessary to create an adequate incentive. Manufacturers who fail to actively eliminate risks at a rate that offsets their increasing potential liability will risk a reduction in profitability over the long run.

E. Factors to Consider When Setting the Parameters of Progressively Increasing Damage Caps

In order to set the cap parameters (initial cap, final cap, and "curve"),²⁵³ the FDA would need to create a special committee to weigh a variety of factors. Initially, the committee would need to establish the parameters on a case-by-case basis, given the variety of medical products and varying rates of use. The process for setting the initial curve parameters would necessarily consume more FDA resources and create intra-agency debate. However, the adjustable parameters also provide a means to tailor protection based on the different risks and requisite testing associated with pharmaceuticals and medical devices. In addition, the process should consume fewer resources once the committee establishes a body of parameter-setting "precedent." To address any critical concerns about agency capture and industry manipulation to obtain favorable cap parameters, the committee's decision process would need to be absolutely transparent. All information conveyed to the committee and relied upon in the determination of the final cap parameters would need to be a matter of public record.

The most prominent factor in setting the cap parameters likely would be whether the product at issue is a medical device or pharmaceutical. Critics of preemption and the regulatory compliance defense assert that medical devices are less worthy of protection against state tort claims because device studies are not as stringent as pharmaceutical stud-

losses. Thus, the risk of large jury verdicts may yield no safety benefit whatsoever and, instead, may result in higher prices that will deprive less affluent consumers of the possible benefit of the affected devices.").

253. "Curve" refers to the change in value of the damage cap over time.

ies.²⁵⁴ However, “[t]he more rigorous testing of drugs may be justified because of the greater difficulty in understanding the physiology of drug action as opposed to the physical processes of devices.”²⁵⁵ The committee setting the cap parameters would need to address these arguments openly when making decisions and adjust the parameters accordingly.

The existing data related to similar drugs and devices would be another key factor when determining cap parameters. If a great deal of information is available about similar products, a manufacturer should be able to assess risks and potential losses more accurately. If a manufacturer can make more accurate predictions about risks, the need to incentivize investment by extending comprehensive liability protection is reduced. Therefore, the degree of liability protection afforded to any given product should be inversely proportional to the amount of readily available information about similar products.

Likewise, the rate at which information can be gathered about a product is significant in determining the curve for an increasing damage cap. If a product’s expected usage rate is high, the manufacturer should be able to gather more information about the potentially adverse effects of the product in a shorter period of time. Therefore, the curve should increase more steeply for more frequently used products, taking into account the reality that many adverse effects of pharmaceuticals emerge over time.²⁵⁶ Also, the relative rates of inpatient and outpatient usage, which could affect how quickly field data can be collected, might need to be taken into account.²⁵⁷

Given the curve set by the FDA, the court would then be responsible for determining the date from which the damage cap would be measured. To define the damage cap related to a given lawsuit, the court must ascertain the time of the injury, perhaps using a standard similar to the time of “manifestation of injury” laid out in the Healthy American Act of 2005.²⁵⁸

F. Response to Potential Criticisms of Progressively Increasing Damage Caps

Critics of this plan might argue that allocating a portion of the initial post-release risk to consumers will discourage the use of recently released medical products. This may actually serve a positive purpose. Doctors and patients will be more likely to carefully weigh the potential

254. Green & Schultz, *supra* note 35, at 2136.

255. *Id.* at 2140.

256. Gilhooley, *supra* note 172, at 1492–93.

257. As an example, it would be much easier to gather adverse incident data for a product used in a hospital setting than it would be to obtain similar data for a product used outside the observation of medical personnel. Data can also be gathered more quickly if the product is used frequently, rather than infrequently.

258. Healthy America Act of 2005, S. 1503, 109th Cong. § 103 (2005).

benefits and drawbacks of using a newly released drug or medical device in light of existing, time-tested treatments. As noted earlier, the amount of testing performed on medical products prior to market release is necessarily limited. Therefore, it may be prudent to put new medical products into use more gradually. Placing more risk on consumers naturally encourages gradual introduction because the consumer must acknowledge and assume more of the unknown risk inherent in a new drug or technology.

Critics may also argue that manufacturers might be tempted to place questionable products on the market based on the protection afforded by increasing liability caps, only to pull these products once the damage cap associated with the product has increased to a level the manufacturer deems too risky. The key to avoiding such a scenario would rest in the FDA's setting the increase in the curve gradually enough that such a crossover point would be unlikely to occur.

Some might ask why we should protect medical product manufacturers more than we protect manufacturers of general consumer products. The answer to this question lies in the public policy underlying Congress's directive to the FDA—promoting and protecting the public health.²⁵⁹ We want to encourage medical product manufacturers to develop new medical products because these innovations have the potential to improve social health. Although medical product manufacturers and general product manufacturers have similar profit motives, medical product manufacturers provide a public service by assuming the unavoidably enhanced risks that accompany the interaction between chemistry, technology, and human physiology. The liability doctrines that apply to general product manufacturers inevitably suppress medical products innovation in light of these greater risks. Therefore, mitigating some of the manufacturer's risk may be an effective way to encourage innovation and availability of medical products.

V. CONCLUSION

Establishing an appropriate balance between the availability of medical products and their safety and effectivity promotes and protects the public health. The current overlapping systems of regulation and tort liability suppress innovation by discouraging medical product manufacturers from investing in research and development, thus adversely affecting availability. Although preemption and the regulatory compliance defense incentivize investment in research and development, each fails to provide adequate motivation for a manufacturer to seek out and discover latent defects in a product once the product has been approved. Progressively increasing damage caps incentivize investment in research and de-

259. FDA, *supra* note 7, at iii.

velopment by enhancing predictability and reducing the volume of litigation. At the same time, progressively increasing damage caps incentivize postmarket investigation, disclosure, and correction of risks by gradually eliminating a manufacturer's protection against liability. Because dynamic incentives encourage the availability, safety, and effectivity of medical products, Congress should consider such a proposal as a means to improve public health.