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COMMENT

LICENSE TO MAIM: FEDERAL PRE-EMPTION AND THE MEDICAL DEVICE AMENDMENTS OF 1976

*Michael E. Petrella**

I. INTRODUCTION

SUPPOSE YOU LOOKED IN THE MIRROR tomorrow and noticed a few ugly wrinkles around your eyes. Dis-mayed, you turn to your family physician for help. "No problem," the doctor tells you. He recommends a few injections with a product known as Zyderm, an FDA-approved medical device more generically referred to as collagen. Elated, you respond in the affirmative. A few days after treatment, however, you experience a high fever, sweats, and extreme muscle pain. "What is going on?" you ask your doctor. As it turns out, you have developed dermatomyositis/polymyositis (DM/PM), an autoimmune disease, as a result of the injections. After several months of discomfort and costly medical attention, you find that not only have your wrinkles not disappeared, but your face is permanently scarred.

Infuriated, you now head straight for the family attorney. "The product must be defective and negligently manufactured," your faithful servant of justice informs you. "Let's sue." Armed with a complaint bearing nineteen counts of products liability allegations, beaming with anticipation, you and your attorney dash for the courthouse. Prior to trial, Zyderm's manufacturer moves for summary judgment. "Granted!" the judge

* J.D., Case Western Reserve University School of Law (1994).

scowls. Overcome with disbelief, you ask your attorney why you can not bring your lawsuit. "Federal pre-emption," shrugs the lawyer. He sheepishly turns his back on you, your medical bills, and your hideously deformed countenance. Stalin's Russia? Castro's Cuba? No. Such is the current state of American tort law under the Medical Device Amendments of 1976.

II. BACKGROUND

A. The Medical Device Amendments of 1976

1. The MDA Classification System

Federal regulation of medical devices was initiated by Congress in 1976 with the passage of the Medical Device Amendments (MDA)¹ to the Food, Drug and Cosmetic Act (FDCA).² The legislation sought to classify the broad range of medical devices according to three general categories.³

a. Class I & Class II Medical Devices

Class I medical devices include relatively benign instruments such as tongue depressors.⁴ A device achieves Class I status if a "reasonable assurance of the safety and effectiveness of the device"⁵ can be provided pursuant to an enumerated list of general controls established by the FDCA.⁶ Even if insufficient information exists to permit a conclusion that these "general controls"⁷ are capable of affording an acceptable guarantee of safety and effectiveness, a device will be classified as

1. 21 U.S.C. § 360c-1 (1994).

2. 21 U.S.C. §§ 301-394 (1994).

3. All classification decisions under the MDA are issued by authority of the Secretary of the Department of Health and Human Services (HHS). *Id.* § 360c(b)(1); § 321(d). General procedures and requirements regarding the MDA classification process are advanced at 21 U.S.C. §§ 360c(b)-(g).

4. *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1418 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993).

5. 21 U.S.C. § 360c(a)(1)(A)(i) (1994).

6. These "general controls" pertain to adulterated devices, *id.* § 351, misbranded devices, *id.* § 352, device registration, *id.* § 360, banned devices, *id.* § 360f, notification requirements and remedies, *id.* § 360h, device records and reports, *id.* § 360i, and other general provisions, *id.* § 360j.

7. *See* 21 C.F.R. § 860.3(c)(1) (1992) (referring to certain FDCA provisions collectively as "general controls").

Class I where it "is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,"⁸ and "does not present a potential unreasonable risk of illness or injury."⁹ Medical devices falling within the ambit of this latter category are thus ultimately regulated by the aforementioned FDCA general controls.¹⁰

Class II medical devices include items such as tampons and oxygen masks.¹¹ Such devices cannot be categorized in Class I because "the general controls themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device,"¹² and, besides, "there is sufficient information to establish special controls to provide such assurance"¹³

b. Class III Medical Devices and Premarket Approval (PMA)

Class III medical devices include, among other things, hip prostheses, intraocular lenses, and heart valves.¹⁴ These devices cannot be placed in either the Class I or the Class II category because inadequate information exists to support a determination that general¹⁵ and special¹⁶ controls would be sufficient to provide a reasonable assurance of safety and effectiveness.¹⁷ Moreover, Class III devices present "a potential unreasonable risk of illness or injury"¹⁸ or are offered for uses which support human life, sustain human life, or "prevent the impairment of human health."¹⁹ Consequently, Class III medi-

8. 21 U.S.C. § 360c(a)(1)(A)(ii)(I) (1994).

9. *Id.* § 360c(a)(1)(A)(ii)(II).

10. *Id.*; see also *supra* note 6.

11. *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1418 (5th Cir.), cert. denied, 114 S. Ct. 86 (1993).

12. 21 U.S.C. § 360c(a)(1)(B) (1994).

13. *Id.* "Special controls" include performance standards set by the FDA. *Id.* General procedures and requirements for the development of Class II medical device performance standards are advanced at 21 U.S.C. §§ 360d(a)-(b).

14. Susan A. Allinger, *Federal Pre-emption of Products Liability Actions Against Medical Device Manufacturers*, 29 TEX. TRIAL LAW. F. 1 (1993).

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

16. See *supra* note 13 and accompanying text.

17. 21 U.S.C. § 360c(a)(1)(C) (1994).

18. *Id.* § 360c(a)(1)(C)(ii)(II).

19. *Id.* § 360c(a)(1)(C)(ii)(I).

cal devices alone are subject to premarket approval, the most stringent regulatory procedure established under the MDA.²⁰ However, manufacturers of two types of Class III devices are able to avoid the formal premarket approval process. Devices which are "introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976"²¹ or "substantially equivalent"²² to such a device may be marketed without premarket approval (PMA),²³ subject to certain notification requirements.²⁴

All other applicants seeking to market a Class III device must submit an application for premarket approval to the Secretary of Health & Human Services (HHS).²⁵ Applications must include, among other things, testing data, samples, proposed labelling, and descriptions of manufacturing methods and materials.²⁶ The FDA then generally refers each application to a panel of qualified experts.²⁷ The panel reviews the PMA and prepares a report and recommendation concerning approval.²⁸ Based on the findings of the panel, the Secretary either approves or disapproves the device for marketing.²⁹ Denial of a PMA application requires the HHS Secretary to inform the manufacturer of the measures which must be taken in order to complete an acceptable application.³⁰ Such remedial steps may include additional research in conjunction with FDA protocols.³¹ Ratified Class III devices remain subject to FDA review, and the Secretary may revoke or suspend approval upon a finding that a given device has proved inadequate in terms of safety or labelling requirements.³² The Secretary is authorized to promulgate recording and reporting regulations in order to evaluate the continued safety and effectiveness of Class III

20. See generally *id.* § 360e.

21. *Id.* § 360e(b)(1)(A).

22. *Id.* § 360e(b)(1)(B); see also § 360c(i).

23. See *id.* § 360e(b).

24. See *id.* § 360(k).

25. See *id.* § 360e(c).

26. *Id.* § 360e(c)(1).

27. *Id.* § 360e(c)(2).

28. *Id.*

29. *Id.* § 360e(d)(1)(A).

30. *Id.* § 360e(d)(2).

31. *Id.*; see also *id.* § 360e(f).

32. *Id.* § 360e(e).

medical devices.³³

c. Effect on State and Local Requirements

Much of the dispute currently surrounding the Medical Device Amendments of 1976 stems from a provision which attempts, albeit with a considerable lack of clarity, to define the relationship between the federal legislation and other state and local laws. In this regard, the MDA states:

[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety and effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.³⁴

This rather brief Congressional mandate has touched off a sea of litigation, dividing state and federal courts on its proper interpretation.³⁵ The principal point of controversy in many cases has centered squarely upon the question of whether section 360k of the MDA³⁶ pre-empts state tort and product liability suits brought by consumers injured by FDA-approved Class III medical devices which have endured the rigors of the PMA process.³⁷

33. See *id.* § 360i.

34. *Id.* § 360k(a).

35. See *infra* note 80 and accompanying text.

36. See *supra* text accompanying note 34.

37. An issue which is beginning to receive increased judicial attention concerns whether manufacturers of Class III medical devices which pass through the MDA's less stringent, "substantially equivalent" regulatory route, see *supra* notes 21-24 and accompanying text, can enjoy the same blanket pre-emptive effect of § 360k, see *supra* text accompanying note 34, as that experienced in the PMA context. Of course, the issue still turns upon whether the plaintiff's asserted claims would "establish or continue in effect [a state] requirement . . . different from, or in addition to," 21 U.S.C. § 360k(a) (1994), the federal MDA regulatory scheme "which relates to the safety or effectiveness of the device . . ." *Id.* Nevertheless, the courts appear to be severely divided on the proper interpretation of this language in situations involving "substantially equivalent" medical devices. See *Mendes v. Medtronic, Inc.*, 18 F.3d 13 (1st Cir. 1994) (pre-empting plaintiffs state law claims because they related to the safety and effectiveness of a "substantially equivalent" device and would conflict with specific MDA regulations, but refusing to reach the issue of whether the "substantial equivalence" route constitutes a "requirement" for the purposes of section 360k(a) of the MDA); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1423 n.6 (5th Cir.) (suggesting in dicta that some products liability actions based on injuries incurred from "substantially equivalent" Class III medical devices might not be pre-empted by § 360k), *cert. denied*, 114 S. Ct. 86 (1993); *English v. Mentor Corp.*, No. 93-2725, 1994 U.S. Dist. LEXIS 7941, (E.D. Pa. June 10, 1994) (holding that "the MDA's substantial equivalence process is, like the PMA process, a 'requirement' within the meaning of § 360k(a) that pre-empts state requirements,

B. Recent Federal Appellate Decisions

1. *King v. Collagen Corporation*

On September 11, 1992, the United States Court of Appeals for the First Circuit heard *King v. Collagen Corporation*.³⁸ The defendant, Collagen Corporation (Collagen), manufactured and distributed Zyderm, a Class III medical device consisting of processed cow tissue.³⁹ Zyderm was injected into the skin in order to alleviate a variety of conditions, including wrinkles.⁴⁰ In 1987, appellant Jane King received a test injection of Zyderm prior to full treatment.⁴¹ As of the date of the test dose, Collagen had obtained FDA approval for the device via the PMA process.⁴² Shortly after exposure, Mrs. King began to experience a variety of symptoms, including joint and muscular pains.⁴³ Subsequent tests by Mrs. King's physician revealed that the patient had acquired DM/PM, an autoimmune disease wherein the body's immune system identifies and at-

including common law causes of action, relating to the safety or effectiveness of a device"); *LaMontagne v. E.I. DuPont de Nemours, Inc.*, 834 F. Supp. 576, 583 (D. Conn. 1993) (regarding a patient injured by unclassified "substantially equivalent" jaw implant. State negligence, inadequate warning, and warranty claims were not pre-empted under the MDA because no specific regulations had been issued by FDA for the device); *Cameron v. Howmedica, Inc.*, 820 F. Supp. 317, 321 (E.D. Mich. 1993) (pre-empting state design defect claims due to the existence of a federal regulation addressing the design of the specific "substantially equivalent" device at issue); *Larsen v. Pacesetter Sys., Inc.*, 837 P.2d 1273, 1282 (Haw. 1992) (holding that a patient's claims related to the safety and effectiveness of a "substantially equivalent" Class III pacemaker were not pre-empted by the MDA because FDA finding of "substantial equivalence" did not amount to approval of device's design).

Those courts which have been reluctant to afford the "substantial equivalence" marketing route equal standing with the PMA process for the purposes of the pre-emption issue have generally based their reasoning on the following language in the Federal Regulations accompanying the MDA: "Although a determination of substantial equivalence involves a review by the FDA of what is known of the safety and effectiveness of the devices, and may even include some additional clinical testing, it is not equivalent to an approval by the FDA of the device's safety and effectiveness." 21 C.F.R. § 807.97 (1992). *Stamps*, 984 F.2d at 1423 n.6; *Larsen*, 837 P.2d at 1282. At least two commentators have attempted to evaluate the significance of this statement as it relates to the pre-emption issue. See Brian J. Donato & Mary Beth Neraas, *Federal Pre-emption of Product Liability Claims Involving Drugs and Medical Devices Regulated Under the Federal Food, Drug and Cosmetic Act*, 48 FOOD & DRUG L.J. 305, 314-16 (1993).

38. 983 F.2d 1130 (1st Cir.), cert. denied, 114 S. Ct. 84 (1993).

39. *Id.* at 1131.

40. *Id.*

41. *Id.* at 1132.

42. *Id.*

43. *Id.*

tacks natural skin and muscle tissue.⁴⁴ Mrs. King brought suit alleging strict liability, breach of implied warranty of merchantability, negligence, misbranding and mislabeling, misrepresentation, failure to warn, and fraudulent inducement of FDA approval for Zyderm by Collagen.⁴⁵ The district court had granted Collagen's motion for summary judgment, finding that the MDA pre-empted each of Mrs. King's products liability claims.⁴⁶

Filing a separate opinion, Judge Torruella briefly reviewed the doctrines of express and implied pre-emption and,⁴⁷ relying on *Cipollone v. Liggett Group, Inc.*,⁴⁸ concluded that section 360k(a) of the MDA⁴⁹ constituted express pre-emption of Mrs. King's causes of action.⁵⁰ Judge Torruella felt that it was "clear that the FDA ha[d] imposed requirements on Zyderm related to labeling, design, manufacturing and other aspects of the device pursuant to the MDA scheme."⁵¹ Consequently, he reasoned, since a state requirement could "emanate from any requirement established by a state including statutes, regulations, *court decision* or ordinances,"⁵² the state products liability counts advanced by Mrs. King fell within the pre-emptive sweep of section 360k(a).⁵³ Judge Torruella then proceeded to find that each of King's first six causes of action⁵⁴ would "impose additional or different [state] requirements"⁵⁵

44. *Id.*

45. *Id.*

46. *Id.*

47. For explanation and commentary regarding the doctrines of federal express and implied pre-emption, see generally Barbara L. Atwell, *Products Liability and Pre-emption: A Judicial Framework*, 39 BUFF. L. REV. 181 (1991); Richard C. Ausness, *Federal Pre-emption of State Products Liability Doctrines*, 44 S.C. L. REV. 187 (1993); Philip H. Corboy & Todd A. Smith, *Federal Pre-emption of Product Liability Law: Federalism and the Theory of Implied Pre-emption*, 15 AM. J. TRIAL ADVOC. 435 (1992); Donato & Neraas, *supra* note 37; Marilyn P. Westerfield, Comment, *Federal Pre-emption and the FDA: What Does Congress Want?*, 58 U. CIN. L. REV. 263 (1989).

48. 112 S. Ct. 2608 (1992).

49. See *supra* text accompanying note 34.

50. *King v. Collagen Corp.*, 983 F.2d 1130, 1134 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993).

51. *Id.*

52. *Id.* (quoting 21 C.F.R. § 808.1(b)) (emphasis added).

53. *King*, 983 F.2d at 1135-36.

54. See *supra* text accompanying note 45.

55. *King v. Collagen Corp.*, 983 F.2d 1130, 1135 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993).

on Zyderm so as to conflict with the MDA's federal regulatory plan.⁵⁶ As a result, each count was deemed to be in direct contravention of section 360k(a). With respect to King's final allegation that Collagen had fraudulently obtained FDA approval for Zyderm, Judge Torruella found that appellant's lack of privity with Collagen was fatal and, alternatively, that the charge was pre-empted as being essentially equivalent to a "failure to warn" claim.⁵⁷

The other two members of the three-judge panel agreed with the result of Judge Torruella's analysis, but founded their holding on a different approach. The *King* majority discerned two overriding purposes for the MDA as evidenced in the legislative history accompanying the legislation. First, the court conceded that the primary emphasis of the statute focused on "protection of the individual user."⁵⁸ Nevertheless, the court insisted, the Senate had implicitly recognized that "[p]erfection is impossible and a few individuals may be denied full protection at the cost of benefitting the rest."⁵⁹ Consistent with this interpretation, the majority opined, was the second MDA objective to be culled from the corpus of the available legislative history — to encourage the research, development, and rapid dissemination of new and improved medical devices.⁶⁰ Next, citing what it perceived to be the extensive regulatory requirements of the MDA,⁶¹ the *King* majority found that section 360k(a)⁶² afforded "maximum protection and express pre-emption, leaving no need to seek implications."⁶³ And thus it was held: "[a]s all but one of plaintiff's sustainable claims are premised on a failure to warn, pre-emption here is unavoidable" ⁶⁴ Mrs. King's fraud claim was similarly dismissed.⁶⁵

56. *Id.* at 1135-36.

57. *Id.* at 1136.

58. *Id.* at 1138.

59. *Id.*

60. *See id.*

61. *See id.* at 1138-39.

62. *See supra* text accompanying note 34.

63. *King v. Collagen Corp.*, 983 F.2d 1130, 1139 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993).

64. *Id.*

65. *Id.* at 1139-40.

2. *Stamps v. Collagen Corp.*

Just over a month following the *King* decision, the United States Court of Appeals for the Fifth Circuit entertained its first opportunity to address the pre-emption issue within the context of Class III medical devices approved by the FDA through the PMA procedure. In *Stamps v. Collagen Co., Inc.*,⁶⁶ Collagen Corporation again found itself the subject of a lawsuit brought by a woman who had developed DM/PM.⁶⁷ However, the allegedly defective devices now included not only Zyderm, but also another Collagen product known as Zyplast.⁶⁸ In addition, Mrs. Stamps advanced only three state tort law theories: defective design, inadequate warnings, and negligent failure to warn.⁶⁹

Writing for a unanimous majority, Judge Smith found that section 360k(a) of the MDA amounted to a Congressional declaration of express state law pre-emption.⁷⁰ Furthermore, the *Stamps* court rejected appellant's argument that the provision was not intended to affect state tort law in particular. Citing *Cipollone*,⁷¹ the court found that section 360k(a) of the MDA, like the applicable statute in that case, "sweeps broadly and suggests no distinction between positive enactments and common law"⁷² The court then turned to the question of whether appellant's specific claims were pre-empted. In this regard, *Stamps* relied to a considerable extent upon another Fifth Circuit opinion, *Moore v. Kimberly-Clark Corporation*.⁷³

In *Moore*, the plaintiff sustained injuries as a result of the use of tampons, a Class II medical device.⁷⁴ While *Moore's* labeling and "failure to warn" state tort claims were held to be pre-empted by section 360k(a), her defective construction and design counts, also based on state law, were allowed to

66. 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993).

67. *Id.* at 1419; *see supra* text accompanying note 44.

68. *Stamps v. Collagen Corp.*, 984 F.2d at 1419.

69. *Id.* at 1418.

70. *Id.* at 1420.

71. 112 S. Ct. 2608 (1992).

72. *Stamps*, 984 F.2d at 1421 (quoting *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608, 2620 (1992)).

73. 867 F.2d 243 (5th Cir. 1989).

74. *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 245 (5th Cir. 1989).

stand.⁷⁵ The latter causes of action survived because, unlike warning and labeling features, the MDA did not endeavor to regulate design and construction aspects of Class II devices.⁷⁶ As a result of *Moore*, the *Stamps* court held, appellant's "inadequate warning" and "negligent failure to warn" claims were pre-empted.⁷⁷ Next, extending the *Moore* rationale and affirming the trial court's analysis, the *Stamps* court concluded the appellant's defective design claim also was pre-empted under section 360k(a) because the more pervasive scope of MDA regulation in the Class III context (relative to the Class II context) encompassed oversight of this area,⁷⁸ and hence rendered the theory a "requirement either different from, or in addition to, a [federal] requirement — the Class III PMA process — that the MDA has made applicable to Zyderm and Zyplast."⁷⁹

III. SHOULD INJURED CLASS III MEDICAL DEVICE CONSUMERS BE DENIED ACCESS TO STATE PRODUCTS LIABILITY REMEDIES?

As the preceding sections suggest, most of the current legal battles being fought over medical device tort suits center around the pre-emption issue.⁸⁰ Indeed, many persuasive argu-

75. *Id.* at 247.

76. *Id.* at 246.

77. *Id.* at 247.

78. *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1422 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993).

79. *Id.* at 1421.

80. *See Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989) (stating where plaintiff sustained injuries from the use of tampons, a Class II medical device, state law claims based on inadequate labeling and warning pre-empted by MDA, but claims alleging defective design, composition, and construction not pre-empted); *Ministry of Health v. Shiley, Inc.*, 858 F.Supp. 1426 (C.D. Cal. 1994) (following *King* with regard to negligence, misbranding, failure to warn, and strict liability claims, but refusing to follow *King* as to breach of warranty, fraud, and misrepresentation claims); *Parenteau v. Johnson & Johnson Orthopedics, Inc.*, 856 F.Supp. 61 (D.N.H. 1994) (stating strict liability, negligence, implied warranty, and loss of consortium claims based on injury caused by Class II knee prosthesis survive pre-emption due to absence of specific FDA regulations pertaining to the device); *Brown v. Medtronic, Inc.*, 852 F.Supp. 717 (S.D. Ind. 1994) (pre-empting all claims arising from use of dorsal column stimulator except for those involving Class II lead wire portion); *Mulligan v. Pfizer, Inc.*, 850 F.Supp. 633 (S.D. Ohio 1994) (denying that section 360k(a) of the MDA was intended to pre-empt state tort claims arising from the use of medical devices); *Tucker v. Collagen Corp.*, No.93 C2375, 1994 U.S. Dist. LEXIS 3101 (N.D. Ill. Mar. 14, 1994) (following *Stamps* and *King*); *Michael v. Shiley, Inc.*, No. 93-1729, 1994 U.S. Dist. LEXIS 1973 (E.D. Pa. Feb. 25, 1994) (pre-empting plaintiff's state negligence, intentional infliction of emotional distress, strict liability, warranty, and fraud claims regarding

ments can be formulated which might seemingly justify a reversal of the *Stamps* and *King* adjudications.⁸¹ However, the

Bjork-Shiley heart valve prosthesis, a PMA-sanctioned Class III medical device); *Bravman v. Baxter Healthcare Corp.*, 842 F.Supp. 747 (S.D.N.Y. 1994) (state products liability counts brought against manufacturer of Class III heart valve which had received premarket approval pre-empted under MDA); *Griffin v. Medtronic, Inc.*, 840 F. Supp. 396 (D. Md. 1994) (state tort claims based on allegedly defective pacemaker pre-empted, including count sounding in fraud); *Elbert v. Howmedica, Inc.*, 841 F.Supp. 327 (D. Haw. 1993) (where Class II knee prosthesis caused injury, plaintiff's state negligence, warranty, and strict liability claims not pre-empted because device was not subject to rigorous PMA process and only existing MDA regulations applicable to prosthesis related merely to identification); *Gondeau v. Mentor Corp.*, No. 1:92CV2149, 1993 U.S. Dist. LEXIS 20157 (N.D. Ohio Dec. 14, 1993) (strict products liability claim based on Class III prosthesis pre-empted by MDA); *Murray v. Medtronic, Inc.*, No. 93-1196, 1993 U.S. Dist. LEXIS 17476 (E.D. La. Dec. 2, 1993) (state products liability counts pre-empted under MDA as to Class III medical device components of dorsal column stimulator, but not pre-empted as to Class II constituents); *Kemp v. Pfizer, Inc.*, 835 F. Supp. 1015 (E.D. Mich. 1993) (MDA pre-empts eleven state tort claims advanced by widow of patient who died after treatment with a prosthetic heart valve, a premarket-approved Class III device); *Schubert v. Medtronic, Inc.*, No. 92-2967, 1993 U.S. Dist. LEXIS 13700 (E.D. La. Sept. 29, 1993) (pre-empting all claims arising from use of Class III dorsal column stimulator except for those involving Class II lead wire portion); *Sloman v. Tambrands, Inc.*, 841 F.Supp. 699 (D.Md. 1993) (MDA pre-empts negligence, failure to warn and punitive damages claims arising from the use of tampons, a Class II device); *Reiter v. Zimmer, Inc.*, 830 F. Supp. 199 (S.D.N.Y. 1993) (FDA's premarket approval of bone cement, a Class III medical device, pre-empts plaintiff's strict liability claim, but not a claim that defendant had not complied with its own FDA-approved manufacturing process); *Northrip v. International Playtex, Inc.*, 750 F. Supp. 402 (W.D. Mo. 1989) (where plaintiff sustained injuries from the use of tampons, a Class II medical device, state law claims based on inadequate labeling and warning pre-empted by MDA, but claims alleging defective design, composition, and construction not pre-empted); *Bejarano v. International Playtex, Inc.*, 750 F. Supp. 443 (D. Idaho 1989) (same); *Lindquist v. Tambrands, Inc.*, 721 F. Supp. 1058 (D. Minn. 1989) (MDA pre-empts state "inadequate warning" claim brought by plaintiff who had developed toxic shock syndrome from use of tampons); *Desmarais v. Dow Corning Corp.*, 712 F. Supp. 13 (D. Conn. 1989) ("failure to warn" claim advanced by patient injured due to leaking silicone breast implants not expressly pre-empted, but only because plaintiff received implants before effective date of MDA); *Cornelison v. Tambrands, Inc.*, 710 F. Supp. 706 (D. Minn. 1989) (MDA pre-empts state "inadequate warning" claim brought by plaintiff who had developed toxic shock syndrome from use of tampons); *Callan v. G.D. Searle & Co.*, 709 F. Supp. 662 (D. Md. 1989) (holding that products liability claims were not pre-empted because MDA did not apply to IUDs, which were regulated by FDA as prescription drugs in 1989, and that even if MDA did apply, the statute did not intend to pre-empt state tort law); *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293 (D. Minn. 1988) (same). See generally Beverly L. Jacklin, Annotation, *Federal Pre-Emption of State Common-Law Products Liability Claims Pertaining to Drugs, Medical Devices, and Other Health-Related Items*, 98 A.L.R. FED. 124 (1992).

81. See generally Brief for Appellant, *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.) (No. 92-2084), cert. denied, 114 S. Ct. 86 (1993) [hereinafter *Stamps* Brief]. Many of the courts which have followed the *Stamps* and *King* readings of the pre-emption issue appear to have overlooked some critical language in the federal regulations accompanying section 360k(a) of the MDA. The regulations state: "[Section 360k(a)] does not pre-empt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., . . . general electric codes and the Uniform Commercial Code . . .), or to unfair trade practices in which the requirements are not limited to devices." 21 C.F.R. § 808.1(d)(1) (1992).

Moreover, the actual text of the MDA appears explicitly to recognize the continued

author eschews a jaunt into this well-trodden territory in favor of a different approach.

The legislative history which accompanies the Medical Device Amendments of 1976 reveals a Congressional intent to further two principal goals: 1) the protection of the medical device consumer⁸² and 2) the encouragement of the rapid development and availability of new and beneficial medical devices.⁸³ Based on these asserted ends, this Note now seeks to assess the wisdom of perpetuating the effect of an MDA which denies access to state tort law for plaintiffs who have incurred injuries from the use of Class III medical devices⁸⁴ approved by the FDA via the PMA process. We will also explore the question of whether this approach in practice serves to strike the proper, congressionally intended balance between the two goals. Should the lack of state tort remedies prove incongruous to the attainment and reconciliation of the identifiable MDA legislative objectives,⁸⁵ a more direct tack is required which will circumvent the judicial pre-emption quagmire and restore the full panoply of products liability remedies to aggrieved medical consumers.⁸⁶

validity of state tort causes of action based on injuries sustained by consumers as the result of the use of medical devices. See *Mulligan v. Pfizer, Inc.*, 850 F.Supp. 633 (S.D. Ohio 1994) (advancing a persuasive argument against MDA pre-emption of state products liability claims based on § 360h of the act); see also 21 U.S.C. § 360h (1994) (especially section 360h(d) which states: "Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law").

82. See *King v. Collagen Corp.*, 983 F.2d 1130, 1138 (1st Cir.) ("Concededly, the [legislative history of the] Medical Device Amendments of 1976, shows the principal emphasis to be on the protection of the individual user"), *cert. denied*, 114 S. Ct. 84 (1993); S. REP. NO. 33, 94th Cong., 2d Sess. 2 (1975), reprinted in 1976 U.S.C.A.N. 1070, 1071 ("Medical device legislation is intended to assure that medical devices . . . meet the requirements of safety and effectiveness before they are put in wide-spread use throughout the United States") [hereinafter MDA Legislative History].

83. See MDA Legislative History, *supra* note 82, at 1071 ("[A]n increasing number of sophisticated, critically important medical devices are being developed and used in the United States. These devices hold the promise of improving the health and longevity of the American people. The Committee wants to encourage their research and development").

84. Our discussions here deal exclusively with the pre-emption issue in the context of Class III medical devices. For the sake of clarity and brevity, Class II devices will not be considered. However, the reader should bear in mind that many of the arguments advanced here may be equally applicable to the pre-emption of state products liability actions based on injuries sustained from the use of Class II devices.

85. See *supra* text accompanying notes 82-83.

86. The structure of our analysis can be analogized to one commentator's perception of how courts should resolve the pre-emption issue: "[T]he proper approach is to determine whether the continued existence of the state law is consistent with the general purpose of the federal statute

A. An Evaluation: Is Pre-emption Consistent with the Attainment of MDA Legislative Goals?

1. Consumer Protection

a. The Safety Incentives Created by Products Liability Law

Congress presumably envisioned that the MDA would advance the goal of consumer protection in the Class III medical device context through the comprehensive and rigorous regulatory system established by the PMA process.⁸⁷ However, one encounters difficulty in attempting to refute the observation that state tort law tends to serve a similar purpose. Indeed, many courts and commentators have recognized that the threat of products liability invariably encourages manufacturer self-monitoring and serves a deterrent function, hence creating an incentive for manufacturers to market safer products.⁸⁸

Thus, absent the looming spectre of legally compelled

by seeking to define the evil Congress sought to remedy and the method chosen to effectuate its cure." Lester J. Mazor, Note, *Pre-Emption As A Preferential Ground: A New Canon of Construction*, 12 STAN. L. REV. 208, 210 (1959).

87. See 21 U.S.C. § 360e (1994); *supra* note 82.

88. See *Bravman v. Baxter Healthcare Corp.*, No. 89 Civ. 3444 (RWS), 1994 U.S. Dist. LEXIS 546, (S.D.N.Y. Jan. 24, 1994) ("[T]he state tort law system currently acts as an incentive for manufacturers to continue to improve their products as well as to disclose developments in products safety and their side effects . . . It must be recognized that state tort actions . . . remain a powerful incentive for improving product safety"); *MacGillivray v. Lederle Lab.*, 667 F. Supp. 743, 745 (D.N.M. 1987) (recognizing that tort actions could induce drug manufacturers to develop and market safer products); *Graham v. Wyeth Lab.*, 666 F. Supp. 1483, 1493 (D. Kan. 1987) (noting that state tort suits against vaccine manufacturers are consistent with the goal of maximum national health); *Atwell, supra* note 47, at 207, 226 ("Permitting tort claims . . . clearly furthers the goal of keeping the public informed by giving manufacturers an incentive to be as direct and forthright in their warnings as possible . . . Products liability laws . . . also . . . protect public safety. They provide manufacturers with incentives to make their products as safe as possible"); *Ausness, supra* note 47, at 251 ("[M]anufacturers would have little incentive to spend money on product safety if the costs of product-related injuries were borne entirely by accident victims. A strict liability rule forces manufacturers to choose between paying damages . . . or spending money to prevent them from occurring in the first place"); *Robert D. Cooter, Economic Analysis of Punitive Damages*, 56 S. CAL. L. REV. 79, 137 (1982) ("[T]here is now a rich body of academic literature supporting the view that a primary purpose of tort liability rules is to discourage inappropriate behavior on the part of accident causers"); *Corboy & Smith, supra* note 47, at 455 ("Tort law is unquestionably intended to foster socially desirable conduct"); *Clarence Morris, Punitive Damages in Tort Cases*, 44 HARV. L. REV. 1173, 1177 (1931) (recognizing that both compensatory and punitive damages awards serve an "admonitory" function); *John W. Wade, On the Nature of Strict Tort Liability for Products*, 44 MISS. L.J. 825, 826 (1973) (products liability can prevent excessively dangerous products from reaching the market); *Westerfield, supra* note 47, at 282 ("A tort judgment against a manufacturer could work to provide an incentive to develop improved, safer [products]").

remuneration for injured consumers of defective Class III medical devices, manufacturer incentives shift drastically toward the blind and uninhibited pursuit of economic gain. With the "nuisance" of state products liability actions permanently abated, what motive can a Class III medical device producer harbor other than to secure FDA approval for a device as quickly and as inexpensively as possible? But let us temper this argument. While many manufacturers undoubtedly regard product safety as a paramount consideration, the potential nevertheless exists for unscrupulous companies to exploit the "free rein"⁸⁹ afforded by decisions like *Stamps* and *King* in order to achieve maximum revenues before the inevitable consumer complaints begin to mount.⁹⁰ The temptation intensifies as these corporations realize that negative public reaction can be largely deflected with the badge of legitimacy provided by pre-marketing FDA approval.⁹¹ Allowing such a system of perverse incentives to continue unchecked is akin to playing "Russian Roulette" with the health of patients who have placed full trust in the competency of their physician and the FDA.

Moreover, the circumstances become more ominous when we note that the accuracy of the FDA's PMA process is largely, if not exclusively, dependent upon testing and safety data provided solely by the manufacturer-applicant.⁹² Limited FDA

89. Many courts and commentators have likened the federal pre-emption of state products liability law to the effective immunization of manufacturers from responsibility for the safety of their products. *See, e.g.,* *Wack v. Lederle Lab.*, 666 F. Supp. 123, 128 (N.D. Ohio 1987) (supporting denial of state tort claims will serve to grant defendants immunity from liability for allegedly negligent conduct).

90. *See supra* notes 38-79 and accompanying text.

91. *See* 21 U.S.C. § 360e (1994).

92. *See Hurlley v. Lederle Lab.*, 851 F.2d 1536, 1542 (5th Cir.) (characterizing the FDA as a "passive" agency which must rely substantially upon product information provided by manufacturer-applicants), *superseded by* 863 F.2d 1173 (5th Cir. 1988). A 1992 House Report clearly expressed the nature of FDA reliance upon device manufacturers:

It is unfortunate that FDA advisory committee meetings . . . continue to rely almost exclusively on information provided by the company whose product is under review, or their paid consultants. Other researchers are rarely invited to participate As a result, important research results and clinical findings that are not supportive of the application may be excluded from review by FDA staff or the advisory committee.

This is a serious flaw in the current approval system, which makes it especially difficult for the FDA to make unbiased decisions.

HOUSE COMM. ON GOV'T OPERATIONS, IS THE FDA PROTECTING CONSUMERS FROM DANGEROUS OFF-LABEL USES OF MEDICAL DRUGS AND DEVICES?, H. REP. NO. 1064, 102d Cong., 2d Sess. 41 (1992) (additional views of Hon. Donald Payne) [hereinafter OPERATIONS

financial resources and staffing translate into a PMA regulatory system in which economically motivated profiteers are empowered to skew the approval decision in their favor before the process even begins.⁹³ In short, the FDA has essentially entrusted the fox with responsibility for guarding the proverbial henhouse. Is it beyond the realm of possibility that some applicants might exploit this situation by "simplifying" testing, recording, and reporting procedures?⁹⁴ Worse still, might not the FDA eventually become a pawn of medical device manufacturer interests?⁹⁵ Thus, given the glaring disparity between the relative capacities of manufacturers and consumers to protect their respective interests throughout the PMA process, it is easy to conclude that the "safety net" of state products liability law is necessary to counteract the disproportionate influence exerted by Class III medical device producers.

b. The Complaisance of the FDA

A critic might dismiss the arguments advanced in the preceding section as unfounded and alarmist. He would likely maintain that the PMA system after *Stamps* and *King* provides adequate protection to the general public,⁹⁶ and insist that the process necessarily sacrifices the protection of the "idiosyncratic few"⁹⁷ in order to ensure a regulatory scheme which serves

REPORT]. Moreover, the information provided by device labels "is limited by data that the manufacturer provides to the FDA, and by pressure from the manufacturer to make the warnings less frightening to doctors and their patients." *Id.* at 31; see also *Stamps* Brief, *supra* note 81, at 4-5 ("The FDA does not do independent research on the information provided by the manufacturer; the agency merely reviews the papers which the device's proponent submits").

93. See, e.g., Ausness, *supra* note 47, at 276 ("[T]he FDA has experienced budget cutbacks and staff reductions over the past decade. This lack of resources limits the FDA's ability to obtain information about . . . risks from independent sources and forces the agency to rely heavily on information provided by . . . manufacturers"); Bruce A. Silverglade, *Pre-emption: The Consumer Viewpoint*, 45 FOOD DRUG COSM. L.J. 143, 144 (1990) (noting that FDA budget restraints have led to the loss of approximately 2000 FDA employees since 1980).

94. See *infra* notes 107-14, 124 and accompanying text.

95. See *infra* notes 114-24 and accompanying text.

96. Cf. Pennington P. Landen, *Federal Pre-emption and the Drug Industry: Can Courts Co-Regulate?*, 43 FOOD DRUG COSM. L.J. 85, 112 (1988) (arguing that the FDA is a potent federal agency); Charles J. Walsh & Marc S. Klein, *The Conflicting Objectives of Federal and State Tort Law Drug Regulation*, 41 FOOD DRUG COSM. L.J. 171, 193 (1986) (defending FDA standards both comprehensive and rigorous).

97. *King v. Collagen Corp.*, 983 F.2d 1130, 1138 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993).

the greater good. He would steadfastly argue that the FDA is an expert, disinterested entity capable of deterring undesirable marketing practices through the imposition of fines and penalties upon transgressors.⁹⁸ Our critic would be wrong. In fact, the FDA has drawn considerable fire in recent years for acting as a reliable "rubber stamp" for medical device manufacturers rather than as an objective and zealous protectorate of public safety.⁹⁹

In 1992, Thomas Dorney, Special Assistant to the Oversight Subcommittee of the House Energy and Commerce Committee, raised "allegations that medical device reviewers at the FDA are unofficially required to maintain a ninety-eight percent approval rate of medical devices, irrespective of whether the devices actually deserve approval."¹⁰⁰ Dorney's charges were based on an extensive study which included interviews with FDA staffers, the examination of a wide range of medical device applications, and the survey of confidential questionnaires completed by Office of Device Evaluation (ODE) reviewers.¹⁰¹ The investigation concluded that device evaluators who exceeded the expected two percent disapproval limit were subjected to a myriad of sanctions in order to bring them back into compliance.¹⁰² FDA staff members also were charged with pandering to the medical device industry and seeking to facilitate the approval of unworthy PMA applications over the objections of "recalcitrant" medical device reviewers.¹⁰³ One anonymous FDA official reportedly acknowledged that "many

98. See Landen, *supra* note 96, at 119 (asserting that the FDA is a neutral entity, unlikely to be susceptible to various "special interest" pressures).

99. See Dingell *Continues FDA Device Probe*, Predicasts, June 10, 1992, available in LEXIS, News Library ("FDA officials are pressuring rank and file inspectors to rubber-stamp approval of medical devices, say investigators . . . [S]urveys and interviews . . . reveal a 'review process geared solely toward approval' in which managers use 'coercive tactics' to keep up with a heavy workload").

100. Robin E. Margolis, *Is FDA's Medical Device Evaluation Process Overly Complaisant to Industry?*, HEALTHSPAN, July/Aug. 1992, at 19, available in WESTLAW, File No. 270 (Prentice Hall Law and Business).

101. *Id.*

102. *Id.* Sanctions were alleged to include: "[G]iving disapproved applications to other reviewers; labeling uncooperative reviewers as 'nitpicker[s]' and 'not a 'team player''; holding back those reviewers' promotions and bonuses; withdrawing those reviewers' training opportunities, permissions to publish, and credit for their scientific contributions; and continuously hounding, challenging, or browbeating those reviewers"). *Id.*

103. *Id.*

companies will try and get away with providing the least amount of information possible . . . ,”¹⁰⁴ and hence confirmed concerns raised in the previous section which hypothesized that medical device manufacturers left unbounded by the strictures of state tort law might conceivably cut FDA-established corners.¹⁰⁵ More alarmingly, “[m]edical device reviewers also allegedly told the investigators that medical device documentation is sometimes taken from files or destroyed, never placed in files, or altered.”¹⁰⁶

Similar and more serious allegations received a substantial additional dose of validity through a 1992 House Report approved and adopted by the Committee on Government Operations. The Report verified that Class III medical device producers do in fact seek to deceive the FDA regarding the negative health effects associated with the use of their products.¹⁰⁷ Citing a Texas Department of Health investigation, the Report stated that:

Texas officials concluded that Collagen Corp. had provided inaccurate data on the safety of their product. They claim the company failed to report hundreds of adverse reactions to the FDA’s MDR (Medical Device Reporting) system. For example, Dr. Richard Beauchamp, an epidemiologist at the Texas Department of Health, testified that Collagen Corp. reported only fifty-four adverse reactions from the more than 6,000 consumer complaints received. The Texas Department of Health concluded that more than 800 systemic reactions, as well as other serious problems, were not reported to the FDA’s MDR system.¹⁰⁸

Subsequent to the Texas study, the Report continued, the FDA reviewed 508 patient files and ultimately determined that, of the one-third of the cases which were deemed serious enough to require FDA notification, Collagen Corporation had failed to submit a single report.¹⁰⁹ An additional thirty-nine percent of the files were found to be so fundamentally flawed that it became “impossible to determine whether or not reports should

104. *Id.*

105. *See supra* text accompanying note 94.

106. Margolis, *supra* note 100.

107. *See supra* text accompanying notes 92-95.

108. OPERATIONS REPORT, *supra* note 92, at 25.

109. *Id.*

have been filed.”¹¹⁰ In response, FDA provided Collagen with six examples of the type of cases which should have been reported. These anomalies included lupus, abscesses, arthritis, and scarring.¹¹¹ Nevertheless, the company defended its non-disclosure decisions on the grounds that such maladies were either not sufficiently serious to warrant mention, or not attributable to the use of collagen.¹¹² In a refreshing display of candor, the 1992 House Report characterized the scenario as a “classic Catch-22 situation: the company has informed physicians that collagen does not cause autoimmune disorders, and it is therefore not surprising that the physicians do not report that a case of lupus was caused by the injections.”¹¹³ The Report further capitulated that the phenomenon of inadequate reporting procedures among device manufacturers was widespread, and by no means unique to the FDA’s experience with Collagen Corporation.¹¹⁴

Moreover, the Report found that the FDA had served as more than a mere passive party to Collagen’s MDA reporting violations. In fact, the administrative agency was criticized for negotiating “a new definition of adverse reactions with Collagen officials.”¹¹⁵ As a result of this concession, the company had agreed to report autoimmune disorders only where the doctor failed to state specifically that collagen probably did not give rise to the adverse reaction observed.¹¹⁶ In addition, reporting requirements were waived for incidences of scarring which lasted less than six months or did not yet constitute “permanent damage.”¹¹⁷ With respect to the FDA “compromise,” the House Report declared that:

110. *Id.*

111. *Id.*

112. *Id.*

113. *Id.* Other salient findings contained in the Report indicated that the injuries sustained by the plaintiffs in the *Stamps* and *King* cases might have been avoided had Collagen Corp. fully complied with MDA reporting requirements. *See id.* at 26 (“Texas Department of Health officials criticized Collagen Corp. for misleading the FDA and the public about the safety of their product, whether for approved or off-label uses. They focused on growing evidence that collagen injections might cause or trigger autoimmune diseases, particularly . . . [PM/DM]”).

114. *Id.* at 30 (“Collagen is but one of many cases where the subcommittee has found tremendous shortcomings in the adverse reaction reporting system”).

115. *Id.* at 26.

116. *Id.*

117. *Id.*

By acquiescing to company pressure to eliminate many negative side effects from the MDR reporting requirements, the FDA has undermined the ability of patients and potential patients to learn about the problems experienced by other consumers. It also makes it more difficult for the FDA to determine the potential risks. Since informed consent depends on accurate information about risks as well as benefits, the FDA has undermined that process by allowing the company to ignore valuable information about adverse reactions.¹¹⁸

Nor did the FDA take any steps to enforce available criminal sanctions against Collagen after it had become apparent that the corporation was violating MDA reporting regulations. The Committee chastised the agency, recognizing that

[E]ven when . . . information was provided, the FDA was reluctant to pursue criminal prosecution of the company for their failure to obey the law. If the FDA is not willing to enforce the law, it will not be surprising if companies do not take those reporting requirements seriously. Enforcement would have an important deterrent effect that would also benefit consumers.¹¹⁹

Finally, FDA performance was found to be deficient in a number of other critical areas. General testing and review procedures,¹²⁰ labelling regulation,¹²¹ and the policing of off-label uses¹²² all were identified as spheres of FDA in-

118. *Id.*

119. *Id.* at 30-31.

120. The Report noted that, despite clear evidence regarding the health risks involved in the cosmetic use of silicone, FDA sanctioned a "thoroughly unscientific" human study of the product in the mid-1960s. *Id.* at 18. The subcommittee concluded: "The FDA should have responded to these major shortcomings by refusing to approve Dow Corning's proposed study in 1965; however, the FDA approved the study proposal, and the study was conducted for the next 10 years." *Id.* In addition, "just as the FDA did not carefully monitor the use of silicone injections by 'investigators' participating in the Dow Corning studies, the FDA also failed to respond to the increasingly widespread use of silicone injections by other physicians." *Id.* at 19. More specifically, "the FDA did virtually nothing . . . to protect consumers or to criticize clinicians or manufacturers. Despite their inaction, FDA officials were concerned about the dangers of silicone injections and knew that the agency was responsible for regulating the product." *Id.*

121. *See id.* at 31 (noting that on many occasions, the FDA had "succumbed to pressure from the manufacturer to back down on decisions it had made regarding the labeling for collagen injections. Although manufacturers deserve the opportunity to defend their product, it is equally important that patients' right to informed consent be considered").

122. Off-label uses are defined as "those [uses] that the FDA has not determined to be safe or effective, either because the manufacturer did not submit an application requesting approval for such uses, or because the FDA did not approve an application that was submitted in support for

fluence which had been egregiously neglected. Truly, the overall tenor of the House Report was sufficiently dismal to lead one committee member to note bluntly that: "This report presents very troubling findings about FDA's failure to protect consumers from products whose risks may far outweigh their benefits."¹²³ The agency's medical device review process garnered additional criticism in 1993 and 1994.¹²⁴

such uses." *Id.* at 2. Off-label uses are illegal. *See* 21 U.S.C. § 352 (1994). Dr. Lawrence Solomon, head of the dermatology department at the University of Illinois Medical School, has noted that "sanctions against the illegal promotion of [drugs and devices] for an off-label use are viewed simply as one of the costs of doing business for some companies, because the benefits of this practice far outweigh the penalties, and the penalties are rarely enforced by the FDA." OPERATIONS REPORT, *supra* note 92, at 29.

123. OPERATIONS REPORT, *supra* note 92, at 41 (additional views of Hon. Donald M. Payne).

124. In 1993, a 246-page House Report declared that: "A series of subcommittee hearings and investigations have documented a number of instances in which the FDA approved devices that proved unsafe in use. In every case that the subcommittee examined, personnel within the FDA were aware of problems with the device at the time of approval." HOUSE SUBCOMM. ON OVERSIGHT AND INVESTIGATIONS, 103D CONG., 1ST SESS., LESS THAN THE SUM OF ITS PARTS 1 (Comm. Print 1993). Since the FDA had failed to implement various MDA provisions punctually, the Report noted, "the assurances of safety intended by the 1976 Amendments have not been realized." *Id.* at 8. The Report further cited a 1991 hearing which focused on "the FDA's apparent inability to evaluate the merits of an application for approval to market a medical device under a . . . PMA." *Id.* at 15. In addition, "[t]wo subcommittee hearings in 1992 noted that the FDA continues to regulate devices inadequately due to serious problems in its device monitoring and approval structures, which hinder FDA's efforts to preclude or minimize the occurrence of device failures or chronic problems." *Id.* at 17. The 1993 Report also pointed to an earlier investigation which concluded that "the FDA was regulating pacemakers as if they were no riskier than tongue depressors and that the Agency's failure to implement reporting requirements had resulted in a lack of knowledge about the risks associated with certain devices." *Id.* at 10. Referring to a previous case study involving heart valves manufactured by Shiley, Inc., the Subcommittee noted that "Shiley kept the FDA uninformed of the problems by failing to report incidences of strut fracture and by withholding information regarding manufacturing and design issues." *Id.* at 12. Thus, it had become "apparent that the environment of voluntary compliance in which the FDA and medical device manufacturers operated was ineffective . . . and that the FDA was incapable of wielding regulatory authority against uncooperative medical device manufacturers." *Id.* As a result, "[t]he FDA failed to respond to the high numbers of deaths and injuries associated with the catastrophic failure of the . . . heart valves . . ." *Id.* A series of case studies detailed in the 1993 Report "revealed that the FDA could not, or would not implement the procedures needed to meet the objectives of the [MDA]." *Id.* at 21.

In a more general indictment of the FDA's device review system, it was acknowledged that "[t]he PMA process for critical (Class III) devices has rested on the integrity of data submitted by the medical device manufacturer seeking approval." *Id.* at 57. Although the FDA was found to have established a method for evaluating the accuracy of such information, inspector efforts were found to be "usually confined to procedural audits, which check to see only if the research protocols are being followed, and generally do not seek to determine whether the data generated by the clinical trials will demonstrate that the device is safe and effective." *Id.* With respect to enforcement, the subcommittee recognized that, despite recent efforts, serious institutional deficiencies still existed within the FDA, including an "historically weak and ineffective management information system, which includes an adverse reaction device reporting

Thus, it should now be apparent that FDA oversight alone is wholly insufficient to protect the health and safety of Class III medical device consumers. While the PMA system was undoubtedly originally intended as a comprehensive federal means to ensure patient well-being,¹²⁵ this vision has just as surely been relegated to little more than an empty promise. It is important to recall at this point that Class III medical devices are classified as such because they are deemed to be either highly intrusive and implicative of human health or capable of presenting "a potential unreasonable risk of illness or injury."¹²⁶ Nevertheless, we have already seen that FDA scrutiny of these items does not even begin to approximate the necessary rigidity which the above definition clearly requires. The inherent reliance upon information supplied by manufacturers throughout the PMA process,¹²⁷ the demonstrated willingness of device producers to mislead the FDA,¹²⁸ the susceptibility of the FDA to industry pressures,¹²⁹ and the reluctance of the agency to enforce MDA regulations¹³⁰ all combine to create a predicament in which uninformed patients are virtually helpless in attempting to guard against imprudent and untested medical treatments. As the federal circuits inexorably follow the lead of recent court decisions which pre-empt state products liability

system that the FDA itself acknowledged to be useless" *Id.* at 66. Such difficulties were viewed as being "compounded by the lack of adequate inspector training." *Id.* at 69. Not surprisingly, the Subcommittee's report bluntly concluded that "the FDA has been unable to carry out its statutory requirements adequately." *Id.* at 19. The list of FDA shortcomings continues throughout the comprehensive report, and is far too lengthy to be addressed fully here.

Moreover, on February 2, 1994, Bruce A. Finzen informed the House Subcommittee on Commerce, Consumer Protection and Competitiveness that "FDA approval of a medical device or pharmaceutical product is no guarantee of safety and effectiveness of that product, much less any guarantee that the manufacturers of the product have been free from punitive conduct in the design, testing or manufacture of the product." *Prepared Testimony of Bruce A. Finzen, Esquire, Partner, Robins, Kaplan, Miller & Ciresi, Minneapolis, Minnesota; H.R. 1910 — Fairness In Product Liability Act of 1993; The U.S. House of Representatives, Comm. on Energy and Commerce, Subcomm. on Commerce, Consumer Protection and Competitiveness, Federal News Service, Feb. 2, 1994, available in LEXIS, News Library, Script File.* In addition, Finzen stated that "industry's perception of the FDA's inability to effectively perform its duties of conducting both pre-and post-market surveillance of the safety and efficacy of products dramatically lowers the quality of those products." *Id.*

125. See *supra* note 82 and accompanying text.

126. 21 U.S.C. § 360c(a)(1)(C)(ii)(II)(1994).

127. See *supra* note 92 and accompanying text.

128. See *supra* notes 100-24 and accompanying text.

129. See *supra* notes 115-19, 124 and accompanying text.

130. See *supra* text accompanying note 119.

law under MDA auspices, citizens like Jennifer Stamps and Jane King will be shorn of their last line of defense against the hegemony consistently exhibited by Class III medical device manufacturers.¹³¹ As a result, individuals injured by any given "PMA-approved" device are more likely to prove the commonplace victims of shoddy design, premature marketing, or woefully inadequate testing rather than the unfortunate members of the discrete class so tactfully monikered by the King court as the "idiosyncratic few."¹³²

In light of the foregoing then, the tendency of state tort law to encourage product safety must be viewed as wholly consistent with the Congressionally enunciated objective of safeguarding consumer health through the MDA.¹³³ More importantly, the arguments advanced above indicate that, given the current state of FDA review procedures, the failure to permit state products liability actions based on injuries sustained through the use of Class III medical devices actually is antithetical to the attainment of that goal.

131. Indeed, the pre-emption of state products liability law leaves injured Class III medical device consumers with virtually no legal recourse against a manufacturer. *See, e.g., Stamps v. Collagen Corp.*, 984 F.2d 1416, 1425 (5th Cir.) ("[W]e acknowledge that our reading of the MDA effectively denies Stamps access to state law damages actions as a remedy for her injuries."), *cert. denied*, 114 S. Ct. 86 (1993); *Reiter v. Zimmer, Inc.*, 830 F. Supp. 199, 204 (S.D.N.Y. 1993) (characterizing state products liability law pre-emption under the MDA as a "harsh outcome"). The plaintiff's predicament remains the same even where the producer has allegedly deceived or misled the FDA during the PMA process. *See King v. Collagen Corp.*, 983 F.2d 1130, 1140 (1st Cir.) (responding to plaintiff's allegation that defendant had fraudulently obtained FDA approval of collagen, the court found pre-emption under the MDA not only ran "afoul of the general principle against implying personal causes of action . . . plaintiff would be breaching the federal dike in the absence of its keeper"), *cert. denied*, 114 S. Ct. 84 (1993); *Michael v. Shiley, Inc.*, No. 93-1729, 1994 U.S. Dist. LEXIS 1973, *29-*30 (E.D. Pa. Feb. 25, 1994) ("Ms. Michael also alleges fraud was committed on the FDA, and therefore seeks in effect to act as a private attorney general on the agency's behalf. We find no warrant for allowing Ms. Michael to serve as the FDA's champion"); *Hamilton v. Surgidev Corp.*, No. 92-3466, 1993 U.S. Dist. LEXIS 17858, (E.D. La. Dec. 9, 1993) (pre-empting under the MDA plaintiff's claim that defendant had fraudulently misrepresented and concealed the defective nature of the medical device at issue); *Kemp v. Pfizer, Inc.*, 835 F. Supp. 1015, 1018 (E.D. Mich. 1993) ("Plaintiff has alleged that defendants engaged in a campaign of disinformation against the public and the FDA. Even if true, plaintiff's state law claims are still pre-empted. This court will not imply a personal cause of action based on violations of the MDA . . .").

132. *King v. Collagen Corp.*, 983 F.2d at 1138.

133. *See Atwell, supra* note 47, at 226 ("Since the objectives of both products liability laws and Congress are to enhance public awareness and safety, the goals are compatible. Thus, permitting common law tort claims to be considered on the merits furthers Congressional objectives. It does not stand as an obstacle to accomplishing them"); *supra* note 82.

2. Encouragement of Medical Device Development & Marketing

a. Reconsidering the ends

As noted previously, the second major Congressional goal apparent from the legislative history of the MDA involves encouraging the expeditious development and availability of new and improved Class III medical devices.¹³⁴ Recent courts, most notably the *King* tribunal,¹³⁵ have cited this objective in order to bolster their findings of state products liability law pre-emption under the MDA.¹³⁶ The reasoning is quite simple: medical device manufacturers will be much more inclined to research, develop, and market new products absent the threat of numerous and costly suits for monetary damages initiated by injured consumers.¹³⁷ In the Class III device context, the task of patient protection, under this theory, is of course, left to the comprehensive and infallible FDA oversight authorized and established by the MDA's PMA process.¹³⁸

However, the mere Congressional assertion of an intent to facilitate the invention of new devices and consumer access thereto does not alone tell the entire story. We must carry the ideas conveyed by this base policy assertion to their logical conclusion. Indeed, closer analysis indicates that the simple existence of new Class III devices and a coincident potential availability to patients cannot have been the ultimate outcome desired when Congress enacted the MDA. Consider the following statement contained within the legislative history of the MDA: "The purpose of this authority is to permit new or improved devices to be marketed without delay *so that the public may have such beneficial devices available to them as soon as possible.*"¹³⁹ Implicit in the legislature's announced aim lies a more critical purpose, a purpose perhaps too obvious to war-

134. See *supra* note 83 and accompanying text.

135. See *supra* notes 38-65 and accompanying text.

136. See, e.g., *Kemp v. Pfizer, Inc.*, 835 F.Supp. 1015, 1018 (E.D. Mich. 1993) ("The MDA allows and encourages manufacturers to produce new medical devices without the threat of tort litigation").

137. See *supra* notes 59-60, 84 and accompanying text.

138. See 21 U.S.C. § 360e (1994).

139. MDA Legislative History, *supra* note 82, at 1083 (emphasis added).

rant specific mention. Nevertheless, since the First Circuit was unwilling to elucidate, the author will gladly oblige. The pertinent point is this: surely Congress would have viewed the rapid development and accessibility of Class III medical devices as worthless *sans* the willingness of patients actually to submit to treatment with such instrumentalities. Truly, a device can only be termed "beneficial" if the persons whom it is intended to benefit are amenable to its use; a mechanism which sits on the shelf gathering dust may have the potential to do immense good, but it has yet to produce any tangible societal advantage. Thus, the relevant Congressional goal must not be viewed as the prompt development and availability of new Class III devices, but rather the speedy utilization of such products. Evaluated from this perspective, as we shall see, the role of state products liability law becomes essential to the realization of legislative ends.

b. The impact of publicity

A modicum of additional analysis is required. Each year, U.S. courts hand down a staggering volume of opinions which arouse little public interest. While obscure tax and bankruptcy decisions may activate the salivary glands of the occasional attorney or legal academic, such adjudications are likely to elicit from the average citizen nothing more enthusiastic than a prolonged yawn. In fact, these cases more often than not pass by the layman entirely unnoticed. However, the situation becomes quite different when matters of public health reach the courts. People are understandably fascinated by the judicial resolution of issues which could potentially effect their personal, physical well-being at some point in the future. Ever perceptive, the mainstream media inevitably caters to these interests. For example, many widely circulated newspapers ran stories about both the federal district and circuit court dispositions of the *Stamps* and *King* cases, each detailing the sad plight of the plaintiffs who had been denied the opportunity to seek compensation for their injuries.¹⁴⁰ These articles general-

140. See Lee Berton & Edward Felsenthal, *FDA Approval Shields Firms in Injury Suits*, WALL ST. J., Jan. 21, 1993, at B1 (reporting that the *King* court had ruled that FDA approval of

ly conveyed the important message that certain medical devices approved by the FDA can give rise to injuries which patients "can't do anything about"¹⁴¹ in terms of legal recourse.

Consequently, the considerable publicity surrounding cases like *Stamps* and *King*, publicity which laments the loss of civil remedies for plaintiffs in the Class III medical device context, necessarily must lead the average citizen to become more wary of new, FDA-approved devices.¹⁴² Indeed, Collagen Corporation has recently recognized that negative media reports such as those discussed above have led to a decline in consumer receptivity to their products.¹⁴³ However, one can convincingly argue that the revenue losses experienced by Collagen should be at least partially attributed to that aspect of media coverage which portrays the company's devices as unsafe, as opposed to information regarding the lack of judicial recourse associated with the products. Concededly, it is probably impossible to determine with any degree of certainty the magnitude

medical devices bars state law damage claims); *Briefly: Health*, L.A. TIMES, Jan. 8, 1992, at D2 (reporting that the U.S. district court disposition of the *Stamps* case held that the plaintiff's "claims regarding the company's allegedly defective manufacturing, labeling and warning were pre-empted by Medical Device Amendments to the Food, Drug and Cosmetic Act"); Alan Derringer, *Collagen Conflict: Lawsuits Prompt New Look At Cosmetic Injections*, CHI. TRIB., Nov. 8, 1992, at Womanews 12 ("In the past year, federal judges in two instances ruled that patients had no right to sue because the injections had been approved by the FDA"); Judy Foreman, *Collagen Case Called Ill Omen for Consumers: Judge: FDA Approval Precludes Liability Suit*, BOSTON GLOBE, Mar. 17, 1992, at 61 ("Several lawyers who specialize in product liability law said the rulings threaten not just the rights of patients who have been given collagen injections, but also those of anyone claiming injury from a Class III medical device, the designation for the potentially most dangerous medical devices"); Judy Foreman, *Rulings May Jeopardize the Right of Patients to Sue Manufacturers*, SEATTLE TIMES, Mar. 20, 1992, at A1 ("The judges ruled that because FDA approval means, in theory, that if an approved product is manufactured, packaged and labeled in accordance with strict guidelines, then suits against the manufacturers are 'pre-empted,' in that federal regulations take precedence in state and federal courts"); *Judge Dismisses Suit that Claimed Collagen Cause of Disease*, HOUSTON CHRON., Oct. 26, 1991, at A38, Feb. 23, 1993, at A18 (correction) (discussing the pre-emption of state products liability suits against Collagen Corporation); *Ruling Shields Medical-Device Manufacturers: FDA Approval of Some Products Bars Liability Lawsuits, Court Says*, SAN JOSE MERCURY NEWS, Jan. 22, 1993, at 1G ("In the [*King*] decision, the 1st U.S. Circuit Court of Appeals in Boston ruled that federal regulatory approval of some medical devices largely shields the products' makers from lawsuits seeking damages for injuries to users").

141. Foreman, *supra* note 140, at 61.

142. See Allinger, *supra* note 14, at 6 ("The average consumer, aware that manufacturers are now insulated from liability, will be less willing to try new medical products").

143. *Annual Report to Shareholders*, Collagen Corporation, Sept. 27, 1993, at 20 ("The Company believes the lack of growth in demand in North America in fiscal 1993 was primarily due to the lingering effects of the recession and adverse publicity, which resulted from continuing negative reports from the media concerning cosmetic procedures").

of the respective roles played by each of these factors in depressing sales of Zyderm and Zyplast. Nevertheless, it logically follows that horror stories regarding the unavailability of products liability remedies attendant to newly approved Class III medical devices conceivably could create an adverse effect upon consumer willingness to subject themselves to innovative treatments.¹⁴⁴ This state of affairs might prove desirable with respect to products of questionable validity such as Zyderm and Zyplast, but what of other genuinely worthy devices? What rational individual would not hesitate in acquiescing to a physician-recommended treatment with any new, FDA-sanctioned medical device after reading about the legal "dead end" confronted by others similarly situated?¹⁴⁵

To illustrate, imagine for a moment a hypothetical, new, PMA-approved Class III medical device claimed to be useful in alleviating a particular ailment. Further suppose that the manufacturers of this device have provided the FDA with complete and accurate information regarding testing and safety data.¹⁴⁶ Now, stretch the imagination to its limits and entertain the ludicrous proposition that the FDA has diligently and impartially reviewed the potential efficacy of the product through the PMA process.¹⁴⁷ Finally, assume the investigation ultimately yields legitimate FDA approval; all available signs indicate that the new device will work an astounding benefit to society. Shortly thereafter, Patient X is diagnosed as having fallen victim to the particular illness for which our device is helpful. Patient X's physician informs him that the FDA has just approved a brand new medical device which holds great promise for his full recovery. However, Patient X has recently read an article which related the woeful sagas of Jennifer Stamps and Jane King, two fellow patients who had been injured by FDA-sanctioned medical devices, but were nevertheless denied the opportunity to sue for damages.¹⁴⁸ As a result, Patient X opts for the other alternative suggested by his physi-

144. See *supra* note 140.

145. *Id.*

146. But see *supra* notes 110-14, 124 and accompanying text.

147. But see *supra* notes 100-06, 124 and accompanying text.

148. See *supra* note 140.

cian: treatment with a relatively outdated device which, although boasting an impressive and well-established safety record, is generally agreed to be substantially and empirically less effective than the new device.

Let us change the scenario slightly. Assume that the fictitious device discussed above is swiftly marketed after rigorous FDA scrutiny and, after one year, a considerable number of patients derive substantial benefit from its use. However, one individual, Patient Y, immediately sustains serious injuries from use of the device. The cause of the harmful effects are largely unknown, but a preliminary study indicates that the number of patients who could be expected to experience similar difficulties is relatively small. Patient Y brings a products liability suit against the manufacturer of the device in state court. The case is eventually dismissed by a federal appellate court which holds that section 360k of the MDA¹⁴⁹ pre-empts the action. A number of prominent newspapers report the details of Patient Y's misfortune. Several months later, Patient Z is identified as a candidate for treatment with the new device. Patient Z is told by his physician of the product's remarkable success story, but is warned about the sketchy medical details surrounding the Patient Y mishap. However, Patient Z is more worried about the legal details. He has already read articles concerning the insurmountable medical bills Patient Y faced after a federal court denied him the chance to sue for damages. Thus, Patient Z becomes daunted by his uncertainty and refuses to be treated with the new device.

The first example attempts to demonstrate the possibility that widely publicized tales of pre-emption related to any single device, whether truly unsafe or not, could lead to a "chilling effect" on patient eagerness to try *other* new and objectively beneficial Class III medical devices. Perhaps more importantly, the second example endeavors to illustrate that the mere existence of injuries caused by a device does not conclusively establish defective design, negligent failure to warn, or any other charge of manufacturer wrongdoing.¹⁵⁰ In short, a

149. See *supra* text accompanying note 34.

150. Professor Madden has thus expressed the point:

[I]n a products liability action it is not enough to show only that an injury was caused

device which causes physical harm in a few isolated instances may nevertheless still pass muster under the standards of reasonableness erected by state products liability law, and work an overall benefit to society. Admittedly, a few well-documented accounts of anomalous injuries alone could have an adverse effect on patient perceptions of a device which is, on balance, otherwise largely beneficial. Notwithstanding, as the second hypothetical suggests,¹⁵¹ consumer incentive to forego useful new technologies intensifies when consumers learn that not only are injuries possible, but also that they will be denied the chance to prove manufacturer error if harm does occur. In this regard, it is important to recognize that a patient's decision regarding whether to submit to treatment with any newly approved Class III medical device usually will be, at its base, the product of an informal weighing of benefits and burdens.¹⁵² Therefore, even if conversations with physicians indicate that the ratio of total users of a given Class III device to injured users is relatively minute,¹⁵³ the informed patient also will consider the reality that legal redress will not be an option should he or she eventually prove to be among the unfortunate minority. Physicians, presumably better-versed than the average

by a product. Plaintiff is required to prove that the injury was caused by a defect in the product, and this is true whether the plaintiff proceeds on a theory of negligence, warranty, or strict tort liability. In misrepresentations, liability may be imposed for harm caused by a nondefective product, but in a products liability action, it is the defectiveness of the product that gives rise to liability. Thus knives may cut, steam may burn, automobiles may crash, and injury may result without liability on the part of the manufacturer or seller, if such injury was not caused by a defect in the product.

M. STUART MADDEN, PRODUCTS LIABILITY § 1.1 (2d Ed. 1988). Even strict liability generally may not be imposed on a seller unless a given product has been sold "in a defective condition unreasonably dangerous to the consumer . . ." RESTATEMENT (SECOND) OF TORTS § 402A (1965). The Official Comments accompanying § 402A state that the burden of proof that "the product was in a defective condition at the time that it left the hands of the particular seller is upon the injured plaintiff; and unless evidence can be produced which will support the conclusion that it was then defective, the burden is not sustained." *Id.* at cmt. g. Moreover, "[t]he article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." *Id.* at cmt. i.

151. See *supra* text accompanying notes 148-50.

152. See *infra* note 178.

153. Note that, since the current PMA system features incentives for device manufacturers to withhold important product safety information from the FDA, see *supra* text accompanying notes 107-14, 124, physician attempts adequately to inform patients of the relative risks and benefits of a given treatment, see *infra* note 178, may be frustrated. See *infra* text accompanying notes 174-93.

citizen in recent legal and medical developments in their field, also may be reluctant to recommend the use of new Class III medical devices after learning of the current judicial trend toward pre-emption of state products liability claims.¹⁵⁴ As suggested previously, such calculations often may tend to tip the mental balance of both patients and care-givers away from the use of truly salutary devices.¹⁵⁵

Furthermore, recall that our hypotheticals presuppose a responsible pattern of FDA regulatory oversight.¹⁵⁶ As we have seen, however, the reality of the situation is quite to the contrary. If the PMA process continues to be characterized by the blatant disregard for patient safety exhibited in recent years,¹⁵⁷ we can only expect that sub-standard quality controls will cause damaging stories of medical device-related injuries, along with coincident tales of judicial pre-emption,¹⁵⁸ to mount. As a result, the level of popular reticence toward new devices steadily will rise; introduction to the market of truly safe, new medical devices will become increasingly rare, and any hope for the public to embrace these exemplary products may be eliminated by frequent reports of pre-empted lawsuits and uncompensated injuries.¹⁵⁹

Conversely, the availability of state products liability remedies may in many cases reassure patients and their physicians that, in the event of injury, the individual at least will be afforded an attempt to prove that the device at issue is unreasonably unsafe. Secure in the knowledge that the potential for pecuniary recompense is not absolutely foreclosed, the analyti-

154. Such hesitancy on the part of physicians might be magnified when health care professionals realize that pre-empted suits against device manufacturers generally leave the aggrieved individual with one possible outlet for recovery: a medical malpractice claim. *Cf. Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1334 (7th Cir. 1992) (noting that pre-emption "does not affect cases charging negligence [by the physician or] failure to obtain the patient's informed consent to the procedure"); *Corrigan v. Davne*, 853 F. Supp. 832 (E.D. Pa. 1994) (although plaintiff was injured by a medical device subject to the MDA, that statute does not pre-empt common law claims alleging malpractice, failure to obtain informed consent, civil conspiracy, or failure to properly diagnose and treat).

155. *See supra* text accompanying notes 145-50.

156. *See supra* text accompanying notes 145-47.

157. *See supra* text accompanying notes 100-24.

158. *See supra* note 140.

159. Indeed, even a partial list of recent MDA pre-emption decisions is quite lengthy. *See supra* note 80.

cal scales shift, and patients may be more willing to accept a degree of risk attendant to treatment. In this way, medical device consumers might eventually come to realize fully the benefits of new Class III medical devices in a manner consistent with the intent of the 94th Congress.¹⁶⁰ Therefore, given the potential impact of the publicity surrounding cases like *Stamps* and *King*, the loss of state products liability remedies for injured Class III device consumers must be viewed as inconsistent with the attainment of the legislatively announced "immediate access" objective.

B. Assessing the Damage and Restoring the Balance

Before we proceed with our analysis, let us engage in a brief recapitulation in an attempt to gain a more meaningful focus on the development and current state of the MDA. If we believe the recent avalanche of federal case law, Congress expressly intended that section 360k of the legislation pre-empt state products liability laws in order to encourage the rapid development and marketing of new Class III medical devices.¹⁶¹ On paper, the goal of protecting public health was to be simultaneously achieved through the exhaustive statutory provisions which together comprised the PMA process.¹⁶² However, *Congress did not fail to prioritize between these two potentially conflicting legislative objectives; the pursuit of consumer safety was avowedly the more critical purpose to be served by the MDA.*¹⁶³ Alas, as we have seen, the delicate balance of the theoretical model envisioned by Congress has subsequently encountered two unforeseen, but unsettling obstacles in practice. Indeed, the drafters of the MDA certainly did not antici-

160. See *supra* text accompanying notes 82-83.

161. See *supra* note 80.

162. See *supra* note 82 and accompanying text.

163. See, e.g., *King v. Collagen Corp.*, 983 F. 2d 1130, 1138 (1st Cir.) ("Concededly, the [legislative history of the] . . . Medical Device Amendments of 1976, shows the principal emphasis to be on the protection of the individual user"), *cert. denied*, 114 S. Ct. 84 (1993); *Desmarais v. Dow Corning Corp.*, 712 F.Supp. 13, 16 (D.Conn. 1989) ("[T]he sole purpose of the [MDA] is to protect and preserve public health"); MDA Legislative History, *supra* note 82, at 1071 ("Medical device legislation is intended to assure that medical devices . . . meet the requirements of safety and effectiveness *before they are put in wide-spread use throughout the United States*") (emphasis added).

pate the flagrant incidents of industry misdealing and FDA complaisance which have recently served to undermine the ability of the PMA system to safeguard the health of new Class III medical device consumers. Concurrent with these developments, moreover, the lower federal courts have steadfastly affirmed the existence of pre-emption as a legislative means to work aggressively towards the subservient "immediate access" objective. To make matters worse, the continued vitality of the pre-emption approach in the PMA context has threatened to operate as a drag upon valuable manufacturer safety incentives. The ultimate result is a regulatory program which is clearly positioned, albeit unintentionally, to favor the attainment of a secondary legislative goal ("immediate consumer access") almost to the exclusion of a primary Congressional end (patient safety).¹⁶⁴

The sections which follow seek to illustrate specifically how the incentives created by the present, malfunctioning MDA system¹⁶⁵ might translate into the premature marketing of new Class III medical devices under circumstances which unduly jeopardize the various health and safety interests of patients in a variety of contexts. In this regard, the gravity of a given patient's affliction will be weighed against the risk inherent in the potential outcome. Our discussion will conclude that it is necessary, through the abolition of state products liability law pre-emption under the MDA, to sacrifice a degree of "immediate access" in order to augment the legislation's current capacity to ensure public health. Only by affording due deference to the well-documented ability of tort actions to encourage product safety and deter deceptive manufacturer conduct can the proper prioritization of MDA legislative objectives be restored.¹⁶⁶

164. The insight of one commentator affords a telling analogy, highly germane to our analysis. Addressing the pre-emption issue in the context of the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. §§ 1331-1341 (1994), Professor Atwell notes: "A . . . criticism of the courts that pre-empt is that they treat the goals of protecting the economy and informing the public of health hazards as equal goals. If they examined the . . . legislative history . . . these courts would learn that . . . [p]rotecting the economy is clearly secondary to that of protecting public health . . ." Atwell, *supra* note 47, at 207.

165. See *supra* notes 88-124 and accompanying text.

166. See *supra* note 163 and accompanying text.

1. Cosmetic Devices

First, a patient's interest, to say nothing of the national interest, in the swift marketing of new Class III medical devices decidedly diminishes in the context of purely cosmetic treatments. As the *Stamps* and *King* cases so cogently illustrate, many consumers have experienced significant problems with medical devices approved in some form by the FDA which are generally useful only in the cure of dermatological or aesthetic problems.¹⁶⁷ These devices include Retin A, silicone, and collagen.¹⁶⁸ Although various skin conditions certainly can be classified as an annoyance, one can probably safely wager that Jennifer Stamps and Jane King would readily exchange their current autoimmune difficulties for the wrinkles which led to their initial treatment with Collagen Corporation's products.¹⁶⁹ If the loss of state tort law and its attendant safety incentives is the price consumers must pay for mere access to a dangerous and uncertain chance at a clear complexion, that price is simply too onerous to bear.

Surely an individual's interest in physical well-being should not yield any appreciable ground to potentially countermanding interests involving wrinkle-free skin or more attractive breasts. As the Honorable Donald M. Payne so succinctly stated the point, "[w]hen a patient buys a product or treatment that is supposed to make them look better, they should not be risking permanent disfigurement or potentially fatal illnesses."¹⁷⁰ Thus, to the extent that the applicability of state products liability law would encourage safe products and interfere with the ability of Class III medical device manufacturers to develop and market their cosmetic wares swiftly in cooperation with an overly accommodating FDA,¹⁷¹ these minor inconveniences should be tolerated, given the dismal alternative.

167. See generally OPERATIONS REPORT, *supra* note 92.

168. *Id.* at 3-9.

169. See *supra* text accompanying notes 38-79.

170. OPERATIONS REPORT, *supra* note 92, at 41 (additional views of Hon. Donald M. Payne).

171. See *supra* notes 100-06, 124 and accompanying text.

2. Non-Cosmetic Devices

This is not to suggest, however, that the aim of immediate access to newly developed Class III medical devices should supersede the goal of public health where these devices are claimed to be helpful in treating highly debilitating diseases. Again, it is absolutely critical to remember that Class III medical devices are subject to the most extensive federal regulation, at least in theory, because they are considered to be of such a nature that any lesser degree of scrutiny unnecessarily could jeopardize the health or life of a patient.¹⁷² Therefore, while it would be unreasonable for citizens to expect that every new, FDA-approved device without exception will eliminate, or even improve the serious illness for which it has been employed, consumers should at least be entitled to presume that such devices have not been marketed with undue haste and without regard to product safety in the name of instant consumer accessibility. In light of recent developments,¹⁷³ pre-emption affords no such guarantee.

Nevertheless, in some cases patients are confronted with terminal illnesses for which no reasonably effective treatments exist. Faced with this scenario, one might argue that the goal of rapid consumer access to new Class III medical devices outweighs the public interest in health and welfare. After all, physicians can be told of known product risks and side-effects following the PMA process and then may pass this information along to patients, thus allowing informed consent.¹⁷⁴ Since the patient's prognosis is so dim, the argument goes, is not any new treatment not preferable to none at all? Not necessarily. The most significant risk in this area is that industry misdealing coupled with apathetic FDA regulation will lead to the instant marketing of new Class III medical devices which deceptively offer a promise for beneficial results substantially greater than that which would have been suggested by a more deliberate evaluation.¹⁷⁵ In addition, concealed safety data and inadequate testing might fail to apprise physicians of product

172. See 21 U.S.C. § 360c(a)(1)(C) (1994).

173. See *supra* notes 99-124 and accompanying text.

174. See *infra* note 178.

175. See *supra* notes 99-124 and accompanying text.

defects which could render the patient's last days fewer and more painful than would have been the case had the patient simply chosen to live out the rest of his or her life in relative comfort and serenity with the aid of traditional palliative drugs and analgesics.¹⁷⁶ In this regard, the final weeks of a dying individual's life are obviously a time of great stress for both patient and family. This brief period may provide the opportunity for cathartic good-byes, shape memories of the deceased, and create lasting impressions regarding the peacefulness and dignity with which death occurred.¹⁷⁷ Every minute may be precious. Thus, the terminal patient has a strong interest in being able to weigh *reliable* medical information concerning the chance for prolonged life or recovery afforded by a new medical device against the personal need to orchestrate the end of his or her life.¹⁷⁸ By removing manufacturer incentives to en-

176. At least one physician has explained the intricate nature of patient decision making when confronted with terminal or often terminal illnesses:

[The patient] remained very clear about her wish not to undergo chemotherapy and to live whatever time she had left outside the hospital [S]he was convinced she would die during the period of treatment and would suffer unspeakably in the process (from hospitalization, from lack of control over her body, from the side effects of chemotherapy, and from pain and anguish) [T]here was no way I could say any of this would not occur I know how to use pain medicines to keep patients comfortable and lessen suffering. I explained the philosophy of comfort care, which I strongly believe in.

Timothy E. Quill, *Death and Dignity: A Case of Individualized Decision Making*, 324 *NEW ENG. J. MED.* 691, 692-93 (1991). Although cancer is not a disease for which *no* possible treatment is available (as evidenced by the existence of chemotherapy), the analogy rings true in the present discussion if we liken chemotherapy to the type of new, risky Class III medical device which might become available for an illness which had no cure prior to its introduction.

177. The experiences of Dr. Quill also lend support to this assertion:

[I] . . . felt strongly that I was setting her free to get the most out of the time she had left, and to maintain dignity and control on her own terms until her death Her son stayed home from college, and they were able to be with one another and say much that had not been said earlier. Her husband did his work at home She spent time with her closest friends [S]he illustrated in a most profound and personal way the importance of informed decision making, the right to refuse treatment, and the extraordinarily personal effects of illness and interaction with the medical system.

Id. at 693.

178. Ultimately, the choice of whether to accept treatment with a given Class III medical device rests with the individual patient. The doctrine of informed consent imposes a legal duty on physicians to provide patients with a "reasonable disclosure of the choices with respect to proposed therapy and the dangers inherently and potentially involved." *Canterbury v. Spence*, 464 F.2d 772, 782 (D.C. Cir.), *cert. denied*, 93 S. Ct. 560 (1972). The scope of this disclosure generally must include "the inherent and potential hazards of the proposed treatment, the alternatives to that treatment, if any, and the results likely if the patient remains untreated. The factors contributing significance to the dangerousness of a medical technique are, of course, the incidence of injury and the degree of harm threatened." *Id.* at 787-88.

gage in rigorous and candid product evaluation, pre-emption effectively reduces patient decision making in this context to the level of dangerous guesswork. Sadly, the FDA has proved unwilling to intervene on the public's behalf.¹⁷⁹

In other cases, the patient's status will be so grave that any available treatment will present the risk of accelerated illness or death.¹⁸⁰ Because the patient will probably die absent any treatment, he or she in essence risks the loss of a few extra months of life in exchange for a slight chance at temporary improvement or recovery. Here again, however, the potential use of a new, allegedly more effective Class III medical device should not elevate the pursuit of rapid consumer access above the goal of public health. As long as pre-emption persists and the FDA can be viewed as remiss in the exercise of its regulatory authority,¹⁸¹ and hence to have abdicated its statutory role as public protector, dishonest industry practices will continue unhindered and physicians will not be able to provide patients with an accurate indication of the likely risks and side-effects associated with a nascent device.¹⁸² Similarly, doctors will be ineffective in determining the overall merits of an instrument in relation to existing modes of treatment.¹⁸³

Thus, suppose that Patient A is diagnosed with an illness generally considered to be terminal. The best existing measures applicable to this particular ailment reliably offer a five percent chance of full recovery, a five percent chance of two additional years of life, and a ninety percent chance of severe side-effects resulting in a death more rapid than that which would be expected if all curative attempts were refused. Before Patient A makes his decision, industry-censored figures serve as the basis

179. See *supra* notes 99-124 and accompanying text.

180. For example, patients who have developed acute myelomonocytic leukemia currently may choose to undergo induction chemotherapy. This procedure involves three weeks of hospitalization, prolonged neutropenia, probable complications involving infection, and likely hair loss. Quill, *supra* note 176, at 692. Twenty-five percent will die. *Id.* The survivors must endure consolidation chemotherapy, which entails similar side effects. *Id.* Another 25% likely will die at this stage. *Id.* The remaining 50% of the original group must then submit to bone marrow transplantation, which promises two months of hospitalization, whole-body irradiation, and potential infectious complications and graft-versus-host disease. *Id.* Fifty percent of the patients will die at this stage. *Id.*

181. See *supra* notes 100-06, 124 and accompanying text.

182. See *supra* notes 173-79 and accompanying text; *supra* note 178.

183. See *supra* note 178.

for a "rubber stamp" FDA approval of a new, Class III medical device claimed to be useful for A's disease. These sugar-coated numbers boast a ten percent chance of full recovery, a ten percent chance of two additional years of life, and an eighty percent chance of premature death. Patient A unwittingly chooses the new device, although an honest and accurate review would have revealed an actual success rate for the new device slightly lower than that of the older treatment. Patient A dies having lost the benefit of a few percentage points which could have meant the difference between life and death. A great deal of time, money, and familial anguish is on the line when a patient decides to risk his or her mortality on the glimmer of hope provided by an unpredictable, last-ditch effort at preserving life.¹⁸⁴ The law has an obligation to ensure that these assets are not squandered on an illusory prospect engendered solely by the siren song of "immediate access" and promulgated without consideration of public safety. However, the denial of products liability remedies to Class III device consumers reduces the probability that patients and physicians will receive credible information regarding new products.

In still other instances, the patient's condition is highly debilitating, but not life-threatening. Here the consumer may be faced with a choice between older, somewhat imperfect treatments and a newer medical device which promises a chance at a more complete return to health. Such cases can be likened to the factual situation apparent in a 1992 federal appellate decision, *Slater v. Optical Radiation Corporation*.¹⁸⁵ In *Slater*, the plaintiff sought eye treatment following cataract surgery.¹⁸⁶ Since this operation destroys the natural lens, normal vision must be restored with special glasses or contact lenses.¹⁸⁷ However, in 1984, Mr. Slater's physician presented him with a third option, an intraocular lens.¹⁸⁸ This device is installed directly into the eye in the space between the cornea and the iris.¹⁸⁹ Slater elected to receive treatment with the intraocular

184. See *supra* notes 176-78 and accompanying text.

185. 961 F.2d 1330 (7th Cir. 1992).

186. *Id.* at 1332.

187. *Id.*

188. *Id.*

189. *Id.*

lens. Shortly thereafter, he experienced pain, infection, and the deterioration of vision in his left eye.¹⁹⁰ Ultimately, Mr. Slater sustained permanent injury to the eye above and beyond the damage done by the cataract.¹⁹¹

The *Slater* case provides an example of the type of problems which can occur when new medical devices are unceremoniously introduced to the public. Although corrective glasses or contact lenses would have been inconvenient and perhaps less effective than the intraocular lens had the device performed as expected, these marginal benefits surely were not worth the risk of permanent near-blindness. Our now-familiar mantra still applies: evidence of poor product performance can be lost in a PMA system capable only of assuring instant product marketing, and the use of a new Class III device may present an unreasonable health risk where patients suffer from serious, but non-fatal conditions and where reasonable, more established alternative treatments are available.

The arguments advanced above become all the more convincing when we note that the Medical Device Amendments already provide a regulatory "shortcut" through which new medical devices can be made available immediately to patients facing serious, fatal, or unique diseases. These "fast tracks" to marketing are entitled the Investigational Device Exemption (IDE)¹⁹² and the Humanitarian Device Exemption (HDE).¹⁹³

190. *Id.*

191. *Id.*

192. 21 U.S.C. § 360j(g) (1994). The IDE statutory provisions declare that: "It is the purpose of this subsection to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and . . . freedom for scientific investigators in their pursuit of that purpose." *Id.* § 360j(g)(1). Thus, an approved IDE application "permits a device that otherwise would be required to comply with a performance standard or to have premarket approval to be shipped lawfully for the purpose of conducting investigations of that device." 21 C.F.R. § 812.1(a) (1992). FDA approval of an IDE application exempts the device at issue from regular MDA requirements with respect to misbranding, registration, listing, premarket notification, banned devices, recording and reporting, restricted devices, good manufacturing practices, and color additives. 21 U.S.C. § 360j(g)(2)(A) (1994); 21 C.F.R. § 812.1(a) (1992). Certain "grandfathered" investigations and investigations involving devices other than "significant risk devices" are considered to have approved IDE applications, subject to various "abbreviated requirements." *Id.* § 812.2(b). In addition, devices requiring IDE approval can be made available fairly rapidly given that "[a]n application . . . for an exemption for a device . . . shall be deemed approved on the thirtieth day after the submission of the application [unless disapproved] . . ." 21 U.S.C. § 360j(g)(4)(A).

However, the IDE process is by no means wholly unregulated. The Federal Regulations

The relevant provisions quite correctly recognize that in some cases, the primary goal of public health must temporarily yield to rapid public access, and hence exempt "promising experimental devices from the usual requirement of establishing the safety and efficacy of a medical device before it can be sold."¹⁹⁴ Through its neglect, however, the FDA has essentially evaluated all new Class III medical devices, even devices requiring full PMA scrutiny, under the less stringent standards intended only for the IDE and HDE programs.¹⁹⁵ The distinction is important because the MDA demands that manufacturers assure the FDA that all patients treated with devices marketed under schemes like the IDE receive full informed consent.¹⁹⁶ In this way, patients know treatment risks ahead of time, or are at least well-aware that the device to be employed has been subjected to relatively little formal testing. Armed with this information, a patient cannot later be heard to complain if the "experiment" goes awry. Indeed, the plaintiff in the *Slater* case, discussed above, was rightly denied the opportunity to sue for his injuries precisely because he had expressly agreed to participate in an intraocular lens clinical investigation under IDE auspices.¹⁹⁷ In contrast, when pre-emption encour-

accompanying § 360j(g) establish special requirements for IDE devices and their clinical usage pertaining to labeling, 21 C.F.R. § 812.5, application procedures (if required), *id.* § 812.20, investigational plans, *id.* § 812.25, reporting of prior investigations, *id.* § 812.27, FDA approval, *id.* § 812.30, supplemental applications, *id.* § 812.35, monitoring, *id.* § 812.46, significant risk device determinations, *id.* § 812.66, recording, *id.* § 812.140, inspections, *id.* § 812.145, and reporting, *id.* § 812.150.

193. 21 U.S.C. § 360j(m) (1994). The HDE provisions have the stated purpose of encouraging "the discovery and use of devices intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect fewer than 4000 individuals in the United States." *Id.* § 360j(m)(1). HDEs may not be granted unless the Secretary of the Department of Health and Human Services (HHS) determines that "the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health . . . outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment." *Id.* § 360j(m)(2)(C). As of March, 1994, the Secretary of HHS had not yet issued the federal regulations to guide the HDE process.

194. *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1331-32 (7th Cir.), *cert. denied*, 113 S. Ct. 321 (1992).

195. *See supra* notes 192-94 and accompanying text.

196. *See, e.g.*, 21 U.S.C. § 360j(g)(3)(D) (1994) ("[A person applying for an IDE shall] assure that informed consent will be obtained from each human subject (or his representative) of proposed clinical testing involving such device . . .").

197. Judge Richard Posner explained:

The consent form that Mr. Slater signed informed him that he had a choice of treatments, one of which was experimental; he chose the experimental [treatment]. The

ages industry deception and a concomitant FDA ambivalence,¹⁹⁸ thus creating a covert, de facto reduced regulatory standard, physicians are not prepared to warn patients that "anything can happen." In these circumstances, the treating physician is able to warn the patient of only those product risks which the manufacturer and the FDA have seen fit to disclose and evaluate.¹⁹⁹ Any extraneous drawbacks which arise after treatment will be wholly unexpected by the doctor, and will have been completely unconsidered by the patient during his delicate and critical decision making calculus.²⁰⁰

IV. CONCLUSION: A PROPOSED SOLUTION

It should be clear that while Congress unambiguously intended that the MDA serve the end of public health first and foremost,²⁰¹ device manufacturer misdealing,²⁰² undeterred by complaisant FDA practices,²⁰³ has left the PMA process largely incapable of achieving this objective. Little remains of the statutory scheme save an incentive doggedly to pursue the very real, but unquestionably subordinate "immediate access" goal. As a result, we have recognized the catastrophic uncertainty for both patients and physicians which this misguided

experimental procedure was riskier because, by definition, there was limited experience with it. Provided that the risks, including any loss of state tort remedies, were adequately explained to Slater, he cannot complain that the risks materialized.

Slater, 961 F.2d, at 1333-34. For other cases pre-empting state tort claims brought against manufacturers by patients injured due to IDE medical devices, see *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.), *cert denied*, 513 U.S. 965 (1994); *Duncan v. Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994); *Covey v. Surgidev Corp.*, 815 F.Supp. 1089 (N.D. Ohio 1993); *Hunsaker v. Surgidev Corp.*, 818 F. Supp. 744 (M.D. Pa. 1992). However, in five consolidated cases, a federal district court recently held that claims alleging failure to obtain informed consent with respect to IDE devices were *not* pre-empted under the MDA. See *Angelle v. Intermedics Intraocular, Inc.*, No. 93-0403, 1993 U.S. Dist. LEXIS 17805 (E.D. La. Dec. 9, 1993); *Bordenave v. Intermedics Intraocular, Inc.*, No. 93-0407, 1993 U.S. Dist. LEXIS 17807 (E.D. La. Dec. 9, 1993); *Caronia v. Intermedics Intraocular, Inc.*, No. 93-0405, 1993 U.S. Dist. LEXIS 17809 (E.D. La. Dec. 9, 1993); *Ferrara v. Intermedics Intraocular, Inc.*, No. 93-0404, 1993 U.S. Dist. LEXIS 17811 (E.D. La. Dec. 9, 1993); *Lewis v. Intermedics Intraocular, Inc.*, No. 93-0007, 1993 U.S. Dist. LEXIS 17808 (E.D. La. Dec. 9, 1993).

198. See *supra* notes 96-124.

199. See *supra* notes 107-17, 124 and accompanying text.

200. See *supra* note 178.

201. See *supra* note 82 and accompanying text.

202. See *supra* notes 107-14, 124 and accompanying text.

203. See *supra* notes 99-106, 124 and accompanying text.

approach could create. Although one might simplistically assert that the solution is merely to insist that the FDA "clean up its act," preservation of state products liability actions for injured Class III medical device consumers stands as the only pragmatic means to enhance product safety incentives,²⁰⁴ and hence implement some semblance of the proper balance between the two laudable legislative objectives.²⁰⁵ The threat of lower profit margins, not governmental agencies, is the way to ensure quality. Therefore, Congress should amend the MDA to provide explicitly for the preservation of state products liability remedies for injured consumers of Class III medical devices.

If this sound advice is heeded, new Class III devices will tend to be marketed only so expeditiously as the public's legitimate interest in health and welfare will allow. Device producers who opt negligently to breeze past the "paper tiger" of the FDA may at last slam into the brick wall of products liability. Industry officials may come to realize that comprehensive testing and disclosure during the PMA process is infinitely more cost-effective than being forced to clean up the mess afterwards. Truly exigent circumstances will continue to be addressed, without fear of liability,²⁰⁶ through IDE and HDE procedures.²⁰⁷ Manufacturers who continue to ignore statutory

204. See *supra* notes 87-96 and accompanying text.

205. Many commentators have suggested additional, more generic justifications for the continued availability of state products liability remedies. See, e.g., GUIDO CALABRESI, *THE COST OF ACCIDENTS: A LEGAL AND ECONOMIC ANALYSIS* 68-129 (1970) (explaining that products liability laws encourage allocative efficiency and ensure that the market price of a product reflects its true costs); James A. Henderson, *Coping With the Time Dimension in Products Liability*, 69 CAL. L. REV. 919, 931-39 (1981) (asserting that strict liability potentially satisfies goals related to fairness, encouraging investment in product safety, discouraging consumption of hazardous products, reducing transaction costs, and promoting loss spreading); David G. Owen, *The Moral Foundations of Products Liability Law: Toward First Principles*, 68 NOTRE DAME L. REV. 427, 506 (1993) (arguing that products liability laws should serve and be guided by moral values such as "freedom, including truth and equality, and community, including community and sharing"); Robert A. Prentice & Mark E. Roszkowski, "Tort Reform" and the Liability "Revolution": *Defending Strict Liability in Tort for Defective Products*, 27 GONZ. L. REV. 251 (1991-92) (noting that products liability laws tend to spread risk and cure disparities between consumers and manufacturers in terms of bargaining power, knowledge, risk appreciation, and transaction costs); Kathryn D. Sowle, *Toward A Synthesis of Product Liability Principles: Schwartz's Model and the Cost-Minimization Alternative*, 46 U. MIAMI L. REV. 1, 88 (1991) (recognizing that compensation, risk spreading, manufacturer's probable negligence, and minimization of accident costs are all at least partial justifications for the imposition of products liability).

206. See *supra* note 197.

207. See *supra* notes 191-94 and accompanying text.

priorities will finally find themselves taken to task for their willful disregard, caught in the "safety net" long provided by state tort theories.²⁰⁸

208. There are, of course, competing arguments available to those who would continue the current trend toward pre-emption under the MDA. For example, one might suggest that the MDA should be permitted to afford a uniform scheme of federal regulation in the medical device arena. However, several courts have rejected this notion. *See, e.g., Desmarais v. Dow Corning Corp.*, 712 F. Supp. 13, 16 (D.Conn. 1989) ("[T]he [MDA] is not concerned with promoting uniform national standards (other than minimum standards); the sole purpose of the Act is to protect and preserve public health"); *Graham v. Wyeth Labs.*, 666 F. Supp. 1483, 1493 (D. Kan. 1987) ("Uniformity is a goal to be achieved in the interest of more fully protecting citizens from unsafe products — it is not to be achieved by sacrificing public health").

Another potential argument would insist that product manufacturers should be able to rely on compliance with federal standards as fulfilling their legal responsibilities to the consumer. *Cf. Landen, supra* note 96, at 115 ("[W]here the federal government has already addressed the issue of appropriate drug labelling and design, individual states should not be permitted to formulate their own requirements"). Nevertheless, the amendment process would function to serve advance notice to manufacturers that mere adherence to FDA regulations does not end their legal duties. Moreover, it is far from clear that most medical device manufacturers have actually "earned" immunity from liability through strict fidelity to MDA testing and reporting requirements. *See supra* notes 107-14, 124 and accompanying text.

Although the pre-emption debate continues to rage in the courts and law journals, sparking intricate arguments regarding federalism concerns and technical explications regarding whether state products liability law actually constitutes a "requirement" under 21 U.S.C. § 360k, the power to change the law ultimately lies with Congress. If courts like *Stamps* and *King* have misread Congressional intent as expressed in § 360k with respect to the pre-emption issue, our analysis should demonstrate the need for remedial legislative action. If, however, the modern judicial trend has properly interpreted § 360k as the vehicle through which Congress intended to achieve the important ends of the MDA, our purpose has been to re-assess the wisdom of that decision in light of public policy and pragmatic experience. The ultimate question, then, is not whether there are arguments to be made for and against pre-emption under the MDA. Rather, Congress must decide which position best serves, on balance, the legislative goals established for the MDA. Based on our analysis, the answer should be clear.

