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Preemption and Regulatory Failure

David C. Vladeck*

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I. INTRODUCTION

When the *Titanic* sailed on its maiden and final voyage on April 10, 1912, it carried 2,227 passengers and crew; 1,523 perished after it hit an iceberg and sank in the frigid waters of the North Atlantic shortly after

* Associate Professor of Law and Director, Institute for Public Representation, Georgetown University Law Center, and Scholar, Center for Progressive Reform. In the interests of full disclosure, my views about preemption were formed before I joined the Georgetown faculty. Before then, I spent twenty-five years as a staff attorney and then as director of Public Citizen Litigation Group, a public interest law firm in Washington, D.C. During my tenure there, Public Citizen Litigation Group was actively engaged in preemption litigation, arguing in favor of preserving state law damage remedies. A number of the cases discussed in this article, including the Supreme Court’s pivotal ruling in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), and the Third Circuit’s recent ruling in *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004), were handled by my Litigation Group colleagues. I and many Litigation Group colleagues filed amicus briefs or otherwise participated in several of the major Supreme Court cases involving preemption issues, including those discussed below. I would like to thank Brian Wolfman, the Litigation Group’s current director, Allison Zieve, a senior lawyer at the Litigation Group, and Professors Lisa Heinzerling, Thomas McGarity, Douglas Kysar, and John Mikhail for their thoughts on this article.

midnight on April 15, 1912.¹ The *Titanic* carried sixteen lifeboats with a maximum capacity of 980 people, thus satisfying, and in fact exceeding, the then-current maritime safety regulations set by the British Board of Trade.² The Board of Trade's standard had been set in 1884, when the largest vessel afloat was approximately one-quarter of the size of the *Titanic* and other new "super liners," such as the *Lusitania* and the *Mauretania*, which carried far more passengers than their predecessors.³ The Board of Trade was not unmindful of this development. In fact, a Board advisory committee met in 1911 to consider upgrading the Board's lifeboat requirements, but took no action.⁴ A year later, over 1,500 died.

Now fast-forward ninety-three years to March 2005. Joshua Oukrop, a twenty-one-year-old college student, is on a spring break trip to Moab, Utah, with his girlfriend.⁵ They go for a bike ride, but Joshua soon complains of fatigue, falls to the ground, and dies of cardiac arrest.⁶ Why? Because a defibrillator implanted in Joshua's chest — a Ventak Prizm 2 Model 1861 manufactured by the Guidant Corporation — had a defect that caused it to short-circuit and malfunction.⁷ Joshua was born with a relatively common genetic disease, hypertrophic cardiomyopathy, which causes erratic heartbeats and, if untreated, can trigger abrupt cardiac arrest.⁸ But Joshua was able to lead a normal life because the defibrillator ensured that his heart beat regularly, that is, until it short-circuited and failed.⁹ Nearly thirty thousand of these units were sold by Guidant, many *after* Guidant had learned of the design flaw and had developed a newer and safer defibrillator.¹⁰ The Food and Drug Administration ("FDA") had approved this defibrillator for use in patients with hypertrophic cardiomyopathy, but was unaware of the defect at the time the device was approved or indeed, at the time of Joshua's death.¹¹ Ultimately, three years after learning of the defect, after dozens of other failures (including at least one other death and several heart attacks), and prodding from the FDA, Guidant reluctantly decided to "recall" the product.¹²

1. See JOHN P. EATON & CHARLES A. HAAS, *TITANIC: DESTINATION DISASTER THE LEGENDS AND THE REALITY* 148 (1987); JOHN DUDMAN, *GREAT DISASTERS: THE SINKING OF THE TITANIC* 12-13, 20 (1988).

2. EATON & HAAS, *supra* note 1, at 113.

3. *Id.*

4. *Id.*

5. Barry Meier, *Maker of Heart Device Kept Flaw From Doctors*, N.Y. TIMES, May 24, 2005, at A1; see also Barry Meier, *Repeated Defect in Heart Device Exposes a History of Problems*, N.Y. TIMES, Oct. 20, 2005, at A1.

6. *Id.*

7. *Id.*

8. *Id.*

9. *Id.*

10. Barry Meier, *Citing Flaws, Maker Recalls Heart Devices*, N.Y. TIMES, June 18, 2005, at A1.

11. *Id.*

12. *Id.* "Recalling" a defibrillator implanted in the chest of a patient is different from recalling other consumer products, such as toys or cars. For many cardiac patients, the risks of additional surgery to explant a defective defibrillator, pacemaker, or heart valve outweigh the risks posed by even a defective product. See, e.g., Barry Meier, *Maker of Heart Device Kept Flaw From Doctors*, N.Y. TIMES, May 24, 2005, at A1. As a result, many patients rationally may decide not to undergo

Often a page of history speaks volumes. The tragic deaths of Joshua Oukrop and the over 1,500 who perished on the star-crossed *Titanic* offer a cautionary tale of the hazards of relying on regulatory standards alone to define an appropriate level of public safety. Indeed, there are sound reasons why regulatory and tort systems have historically operated in tandem to place separate, albeit reinforcing, disciplines on the market. When functioning well, a regulatory system prevents injury and rewards innovation. But too often there are regulatory gaps that jeopardize public safety. Since the founding of our Republic, tort liability has filled those gaps by providing compensation to those who are injured and by deterring unwarranted risk-taking. But the safety net of tort liability is under assault by aggressive, and often successful, assertions of federal preemption. That same battle is likely to be fought over the death of Joshua Oukrop, since it is a virtual certainty that Guidant will claim that any action brought against it by Joshua's family is preempted by federal law.

This symposium was convened to address the growing and seemingly conflicting jurisprudence governing federal preemption of state damage actions. One way to evaluate the evolution of preemption law is to examine it through the lens of litigation under the preemption provision of the 1976 Medical Device Amendments ("MDA") to the federal Food, Drug, and Cosmetic Act¹³ — a provision that in many respects is typical of express preemption provisions in regulatory statutes and has spawned a high volume of litigation. The question raised in cases under the MDA is whether the Act's preemption provision nullifies state damage actions based on personal injuries caused by medical devices that are defective, poorly designed, or promoted in ways that do not alert patients (and physicians) to the risks that attend their use.¹⁴ The answer to that question depends on how one reads the MDA preemption provision. It provides, in pertinent part, that

no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any

replacement surgery, but then endure the risk of life-threatening product failure. *See, e.g., id.* A young and otherwise healthy patient like Joshua Oukrop would have likely opted to have replacement surgery. This problem is a recurring one. *See* Letter from J. Kermit Smith, Chairman, Supervisory Panel of Trustees for the Bowling-Pfizer Heart Valve Settlement Funds (Jan. 1998), available at <http://www.fda.gov/medwatch/SAFETY/1998/bjork.htm> (reporting recommendations of an expert panel working under the FDA's auspices on the criteria that should be employed to determine whether patients with defective Bjork-Shiley heart valves should endure risk of surgery to obtain a replacement valve); *see also* Barry Meier, *Faulty Heart Devices Force Some Scary Decisions*, N.Y. TIMES, June 20, 2005, at A1; Ben Harder, *Heart Device Recall: For Patients With Suspect Models, Tough Choices*, WASH. POST, June 18, 2005, at H1.

13. 21 U.S.C. § 360k (1999).

14. *See, e.g., Medtronic, Inc. v. Lohr*, 518 U.S. 470, 474 (1996) ("The question presented is whether [the MDA] pre-empts a state common-law negligence action against the manufacturer of an allegedly defective medical device.").

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 or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.¹⁵

Note at the outset that nothing in this statute says, in so many words, that Congress is seeking to nullify existing state damage claims, which traditionally provide compensation to those injured through the fault of others. There are federal statutes that do, in fact, explicitly nullify state-law damage claims, but they do so in unmistakable terms, and generally provide a federal remedy in lieu of the displaced state remedies.¹⁶ The MDA is not one of these rare statutes. It provides the FDA regulatory authority over medical devices, and seeks to displace inconsistent state regulation to avoid saddling medical device manufacturers with state-imposed regulatory burdens that conflict with or differ from those imposed by the FDA.

Despite the MDA's focus on regulation and not liability, courts have entertained claims from medical device manufacturers that the MDA broadly preempts state damages claims.¹⁷ As the courts see it, the crucial interpretative question is what does the word "requirement" mean?¹⁸ The Act preempts only state law "requirement[s]" that are "different from, or in addition to, any requirement" imposed by the Act relating to the "safety or effectiveness of the device."¹⁹ The word "requirement" could plausibly be read to encompass only positive state law — that is, commands imposed by state statutes or duly promulgated state regulations that carry the force of law. Under that reading, the MDA preemption provision would bar only state law or regulations that imposed requirements different from or in addition to those imposed by federal law regarding the device in question. Or the word "requirement" could be read more broadly to include state tort and damages law, which, through serial jury verdicts, could also be said to impose "requirement[s]." Courts have struggled with this question and have reached differing conclusions.

The Supreme Court had an opportunity to resolve the question in *Medtronic, Inc. v. Lohr*,²⁰ a personal injury action brought by a woman who

15. 21 U.S.C. § 360k(a).

16. See, e.g., 42 U.S.C. § 2210 (2000) (provision of the Price-Anderson Act federalizing all claims for personal injury and property damage arising from significant accidents at nuclear power plants); 42 U.S.C. §§ 300aa-1 to 300aa-34 (2000) (National Childhood Vaccine Injury Act of 1986, federalizing all claims arising from personal injuries relating to the administration of vaccines); 49 U.S.C. § 40101 (Supp. 2004) (Air Transportation Safety and System Stabilization Act of 2001, also known as the September 11th Victim Compensation Fund, which substitutes a federal remedy for the tort claims 9/11 victims and their families could have asserted against the airlines whose planes were hijacked); 29 U.S.C. § 1144 (1999) (provision of the Employee Retirement Income Security Act of 1974 federalizing disputes over certain employment related benefits).

17. See, e.g., *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 488-89 (1996).

18. *Id.*

19. 21 U.S.C. § 360k(a).

20. 518 U.S. 470 (1996).

sustained serious injuries when her pacemaker failed.²¹ Medtronic Corporation, the device's manufacturer, argued that the MDA entirely preempted her claims and left her without any remedy.²² In rejecting Medtronic's preemption defenses, the Court noted that, although the FDA had generally approved the marketing of similar pacemakers, the FDA had not specifically approved the design of the Medtronic pacemaker.²³ Had the FDA done so, the Court observed, that might present a more difficult case.²⁴ But the Court did not reach that question. Although agreeing with the majority's holdings, Justice Breyer filed a concurring opinion, concluding that the preemption provision's reference to "requirements" encompasses not just state positive law, but, relying on *Cipollone v. Liggett Group, Inc.*, also state common law tort actions that, when enforced through jury awards, impose duties on device manufacturers.²⁵ Justice Breyer also disagreed with the observation in the plurality opinion, written by Justice Stevens, that preemption under the MDA would be "rare."²⁶

The contours of the Court's ruling in *Medtronic* are unclear and hotly disputed, and there has been a flood of conflicting lower court cases in *Medtronic*'s aftermath attempting to draw a line between those claims preempted by the MDA and those claims that are not preempted. This article explores the repercussions of *Medtronic*, not just for medical device litigation, but more broadly for preemption cases where the defendant claims that federal law ousts state law damage actions. It makes four points:

First, the Court took a wrong turn in *Cipollone*, and it should not repeat that error elsewhere.²⁷ Congress' use of words like "requirements" in regulatory statutes should be seen as references to positive state law only, and should not be read, unless there is an explicit command by Congress to the contrary, to subsume state law damage actions.²⁸ In the context of regulatory statutes, words like "requirement" should be read in context to include only specific state statutory or regulatory commands. Indeed, it

21. *Id.* at 480-81.

22. *Id.* at 481.

23. *Id.* at 493.

24. *Id.* at 493-94.

25. *Id.* at 504 (Breyer, J., concurring) (citing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992)).

26. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 508 (1996) (Breyer, J., concurring).

27. *Cipollone*, which is discussed in greater detail below, *see infra* notes 64-76 and accompanying text, held that certain state damage claims for injuries alleged to have been caused by cigarette smoking were preempted by the Federal Cigarette Labeling and Advertising Act because common law duties constituted "requirements." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992).

28. This is not a novel idea. *See* Betsy J. Grey, *Make Congress Speak Clearly: Federal Preemption of State Tort Remedies*, 77 B.U. L. REV. 559, 559-60 (1997) (taking the same position and observing that "there is no better illustration of the Court's schizophrenia than in the area of federal preemption of state tort remedies.").

appears that the Court is trying to put the *Cipollone* genie back in the bottle. In *Bates v. Dow Agrosiences LLC*,²⁹ the Court noted that, although common law rules may qualify as “requirements,” that does not necessarily mean that tort actions based on common law rules are preempted.³⁰ Courts must determine whether the common law duties imposed by state law are sufficiently direct and prescriptive to constitute “requirements.” And courts must determine whether there was a history of product liability litigation over the regulated products prior to the enactment of federal law.³¹ If there was, as there was in *Bates*, then the Court thought that if Congress intended to deprive injured parties of pre-existing compensatory remedies, it would do so with unmistakable clarity.³²

Second, lower courts have too often failed to follow faithfully the *Medtronic* preemption rule. That failure, however, may be a byproduct of the confusion sown by the complexity of the opinion itself. Fairly read, the rule of preemption developed in *Medtronic* is a narrow one, requiring that for state law to be ousted there must be *specific* and *conflicting* requirements for a device imposed by *both* state and federal law.³³ General tort duties do not suffice, since they do not impose requirements specific to a given device. Regrettably, some lower courts have found preemption based solely on specific requirements imposed by federal law, even though the counterpart state requirements are general background tort and product liability principles that do not impose device-specific duties on manufacturers. At some point, the Supreme Court will have to clarify this issue, which continues to bedevil the lower courts.

Third, courts should be wary of Executive Branch attempts to engage in “tort reform” efforts in private litigation. The current Bush Administration has taken unprecedented steps to persuade courts to adopt its pro-preemption position. In so doing, the Administration has broken a longstanding Executive Branch tradition of ordinarily providing its views to courts only when asked and has accomplished an about-face concerning the preemptive reach of the MDA preemption provision. Worse, by working hand-in-glove with industry to change the law on preemption, the Administration has given the public legitimate reason to question whether the FDA is serving the interests of the public or the industry it regulates. The Supreme Court has rejected the Bush Administration’s effort to re-write the government’s position on preemption under a different statute;³⁴ the courts should do the same under the MDA.

29. 125 S. Ct. 1788 (2005).

30. *Id.* at 1791; *see, e.g.*, *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002) (holding that the Federal Boat Safety Act does not preempt common law tort claims arising out of a failure to install propeller guards on motorboats).

31. *See Bates*, 125 S. Ct. at 1801-02.

32. *Id.*

33. The Court in *Bates* adopted this reading of *Medtronic*. *See id.* at 1800-01.

34. *See id.* at 1801 (noting agency’s change of views and giving no weight to agency amicus brief). It bears noting that the Clinton Administration also submitted an amicus brief reversing the Federal Highway Administration’s view of the preemptive scope of its statute governing railroad

Fourth, make no mistake about preemption defenses; they are efforts by industry to shed an important source of market discipline — the threat of liability for visiting unjustifiable harm on others — a discipline that regulation cannot itself provide, and preemption claims must be evaluated on those terms. It is no surprise that industry seeks to avoid liability. What is important here is that judges reviewing preemption claims take into account the overall regulatory and liability context in evaluating industry's claim that Congress intended to remove the discipline imposed by the tort system.

Medical devices are a perfect illustration of the inadequacy of relying on regulation alone. The MDA was passed in 1976 in the wake of several notorious failures of medical devices, especially the Dalkon Shield. These failures had been brought to light through product liability litigation, and litigation provided the only compensation to the thousands who were injured. Since the MDA became law, the medical device industry has been extensively regulated by the FDA. The FDA is perhaps the most capable federal safety agency, but it cannot exert sufficient discipline on the marketplace to ensure an adequate margin of safety for the devices on the market, a fact that the agency, at least until recently, itself acknowledged.³⁵ Although the FDA in the current Administration now argues for broad preemption of product liability for manufacturers, the FDA's ability to single-handedly regulate the market does not match its rhetoric. Daily front-page stories about harmful medical devices on the market such as defective Guidant defibrillators, Medtronic and Baxter infusion pumps, and Johnson &

crossing gates, and the Court similarly gave no weight to the agency amicus brief in that case. See *Norfolk S. Ry. Co. v. Shanklin*, 529 U.S. 344, 356 (2000).

35. See Margaret Jane Porter, *The Lohr Decision: FDA Perspective and Position*, 52 *Food & Drug L. J.* 7, 11 (1997). Ms. Porter, then FDA's Chief Counsel, observed:

FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection. FDA regulation of a device cannot anticipate and protect against all safety risks to individual consumers. Even the most thorough regulation of a product such as a critical medical device may fail to identify potential problems presented by the product. Regulation cannot protect against all possible injuries that might result from use of a device over time. Preemption of all such claims would result in the loss of a significant layer of consumer protection, leaving consumers without a remedy for injuries caused by defective medical devices.

Id. The Institute of Medicine has recently voiced concern over the shortcomings of FDA regulation of medical devices and has called on Congress to strengthen the FDA's authority in this area. INSTITUTE OF MEDICINE, *SAFE MEDICAL DEVICES FOR CHILDREN* (Marilyn J. Field & Hugh Tilson eds., Nat'l Academies Press, forthcoming 2006), available at <http://www.nap.edu/books/0309096316/html/> [hereinafter INST. OF MED.]. The Institute had been asked by Congress in 2002 to study the FDA's regulation of medical devices intended for children, but the Institute's team found so little information on the subject that it decided to expand its review to all medical devices. The Institute's report notes "shortfalls in FDA performance" regulating medical devices that "are not specific to children." *Id.* at 5; see generally Marc Kaufman, *Cardiac Devices May Need Replacing: Guidant Confirms Defects in up to 28,000 Pacemakers*, WASH. POST, July 19, 2005, at D1; Barry Meier, *Repeated Defect in Heart Device Exposes a History of Problems*, N.Y. TIMES, Oct. 20, 2005, at A1.

Johnson and Boston Scientific heart stents, raise serious questions about the ability of the FDA approval process to provide adequate assurance of safety by itself.

A. Background

Under federal law, the term “medical device” includes a vast array of products, such as tongue depressors, band-aids, bone screws, hip replacements, artificial heart valves, in vitro diagnostics and MRI machines that might be used to support or enhance human health.³⁶ The FDA estimates that there are over 80,000 medical devices on the market.³⁷ Medical devices are categorized into three classes based on the potential risk of harm posed.³⁸ Class I devices, like tongue depressors, are subject to only “general controls” that provide a reasonable assurance of safety.³⁹ Class II devices, such as hearing aids, are subject to somewhat stricter FDA regulation.⁴⁰ Class III devices – like pacemakers and artificial heart valves – are used to sustain human life or pose potentially unreasonable risks to patients.⁴¹ Before marketing a Class III device a manufacturer must submit a pre-market approval (PMA) application to the FDA requesting permission to market the device for uses identified in the application.⁴² There are two exceptions to this requirement. First, any device marketed prior to the MDA – a “grandfathered” device – is not subject to the PMA requirement.⁴³ Second, a device first marketed after 1976 may bypass the PMA requirement if the manufacturer can show that it is “substantially equivalent” to either a grandfathered device or a Class I or II device.⁴⁴ Before granting a PMA, the FDA must make a determination that there is a “reasonable assurance” that the device is safe and effective for its intended use.⁴⁵

Prior to the MDA, medical devices were largely unregulated by the FDA.⁴⁶ Although the FDA had and exercised the authority to seize adulterated and misbranded products once they were on the market, it lacked the authority to require medical devices to be screened by the agency before entering the market, even though it had possessed that authority with respect to drugs for decades.⁴⁷

36. See 21 U.S.C. § 321(h) (2000).

37. INST. OF MED., *supra* note 35, at 63 (“According to FDA, approximately 20,000 American and foreign firms produce about 80,000 brands and models of medical devices for the U.S. market. Before they can be marketed in the United States, roughly 55 to 60 percent of medical devices require FDA clearance or approval.”) (citation omitted).

38. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996).

39. See *id.* at 476-77 (citing 21 U.S.C. § 360c(a)(1)(A) (2000)).

40. See *id.* at 477 (citing 21 U.S.C. § 360c(a)(1)(B)).

41. See *id.* (citing 21 U.S.C. § 360(a)(1)(C)).

42. See *id.* (citing 21 U.S.C. § 360e(d)(2)).

43. See *id.* at 477-78 (citing 21 U.S.C. § 360e(b)(1)(A)).

44. See *id.* at 478 (citing 21 U.S.C. § 360e(b)(1)(B)).

45. See *id.* at 477 (citing 21 U.S.C. § 360e(d)(2)).

46. See *id.* at 475-76.

47. See *id.*

By the mid-1970s, the perils of this regulatory gap had been driven home to Congress in a series of highly-publicized and widespread public health hazards caused by dangerous medical devices.⁴⁸ Perhaps the most notorious example is that of the defectively-designed Dalkon Shield intrauterine device, which had been introduced and widely marketed by the A.H. Robins Company without FDA approval.⁴⁹ Before it was withdrawn from the market, the Dalkon Shield had caused numerous deaths and thousands of serious injuries to otherwise healthy women.⁵⁰ To fill this regulatory gap, Senator Ted Kennedy proposed the MDA, which he said was “written so that the benefit of the doubt is always given to the consumer. After all it is the consumer who pays with his health and his life for medical device malfunctions.”⁵¹ Prior to the enactment of the MDA, individuals could and did seek redress for injuries caused by medical devices through state law damage actions. Indeed, it was the cumulative weight of such state law damage actions that forced the A.H. Robins Company into bankruptcy.⁵²

There is not a hint in the legislative history of the MDA that Congress intended that the amendments would restrict the right of injured persons to bring state law damage actions for compensation.⁵³ To the contrary, the MDA was enacted to *strengthen* consumer protection in light of public health tragedies like that triggered by the Dalkon Shield.⁵⁴ Surely Congress’

48. *See id.*

49. *See id.* at 476.

50. For riveting accounts of the legal implications of the Dalkon Shield debacle, see RICHARD B. SOBOL, *BENDING THE LAW: THE STORY OF THE DALKON SHIELD BANKRUPTCY* (U. Chi. Press 1991) and MORTON MINTZ, *AT ANY COST: CORPORATE GREED, WOMEN, AND THE DALKON SHIELD* (Pantheon Press 1985).

51. 121 CONG. REC. 10688 (daily ed. Apr. 17, 1975) (statement of Sen. Kennedy).

52. SOBOL, *supra* note 50. The Dalkon Shield story also underscores the shortcomings of tort litigation. Women who sued Robins were subjected to hostile questions by Robins’ counsel. *See id.* at 13. Robins

would interrogate plaintiffs about their sexual and hygienic habits. Robins took the position that multiple sex partners, with the accompanying increased risk of contracting sexually transmitted diseases, were a more likely cause of uterine infections than was the Dalkon Shield. Attorneys for the company would ask the plaintiff to identify her sex partners so that these men could be subpoenaed and asked about their medical histories. Women were also asked to describe their sexual practices

Id. Sobol notes that although “[t]he courts divided on whether to require answers to these questions,” the fact that they were raised “dissuaded many women from pressing forward with their claims (or from making claims at all) and induced others to accept cheap settlements offered by Robins.” *Id.* Not only was the litigation process forbidding, it also fell short of its promise of full compensation to those injured. Once Robins filed for bankruptcy, most claimants were left with little or nothing. *Id.* at 313 (listing post-bankruptcy settlement values of claims, with proposed payouts of \$5,500 for women rendered sterile to \$1,000 for women who had suffered spontaneous abortion).

53. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 490-91 & nn.12 & 13 (1996).

54. *See* Mark E. Gelsing, *Medtronic, Inc. v. Lohr: Is Federal Pre-emption a Heartbeat away from Death under the Medical Device Amendments?*, 25 PEPP. L. REV. 647, 653, 653 n.53 (1998) (stating that with the MDA “Congress desired to protect consumers from ‘increasingly complex

concern with the harm caused by defective medical devices did not impel it to cut-back or indeed erase the remedies available to people injured by such devices.⁵⁵ Congress was well aware of the role that state damage actions played in bringing the Dalkon Shield problem to light, in forcing a recalcitrant company to remove a dangerous product from the market, and in compensating the thousands of women severely injured by the device.⁵⁶ Congress would surely not, in the same Act, have removed all means of judicial recourse for the victims of future tragedies caused by defective medical devices, without saying so in the most unequivocal of terms.⁵⁷ And indeed, for the first decade or more the Act was on the books, preemption defenses were rarely asserted by manufacturers and even more rarely accepted by courts – reflecting the understanding that Congress did not intend the MDA preemption provision to be a defense to state law damage actions.⁵⁸

So why, then, is there an express preemption provision in the MDA? The answer is straightforward. Prior to the enactment of the MDA, state legislatures had tried to fill the vacuum created by the absence of federal regulation. For example, in an effort to prevent recurrences of the Dalkon Shield tragedy, California had passed legislation requiring State pre-marketing approval for intrauterine devices.⁵⁹ Other states regulated hearing aides.⁶⁰ Concluding that state pre-marketing scrutiny was better than none, Congress crafted a preemption provision that permitted state regulatory programs to remain in place until the FDA implemented specific counterpart

devices which pose[d] serious risk if inadequately tested or improperly designed or used'" (quoting S. REP. NO. 94-33, at 5 (1975) (Conf. Rep.) (alteration in original)).

55. *Id.*

56. *Id.*

57. *Id.*

58. See generally James P. Walsh, *Niehoff v. Surgidev Corp: No Preemption of Kentucky Tort Law Claims by the Federal Medical Device Amendments*, 25 N. KY. L. REV. 615, 624 (1998) (noting that "[f]or many years, the Supreme Court was reluctant to find that federal public safety statutes preempted state law tort actions to recover damages," and citing *Silkwood v. Kerr-McGee Corp.*, 484 U.S. 238 (1984)).

59. See generally Exemptions from Federal Preemption of State and Local Medical Device Requirements, 21 C.F.R. § 808 (2005) (laying out procedures by which states may obtain exemptions from preemption under the MDA and identifying state laws not subject to preemption). See also Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 MO. L. REV. 895, 924-25, 924 n.131 (1994) (quoting the House Report on the MDA as stating that, at the time the MDA was enacted, "[t]he most comprehensive State regulation . . . is that of California . . . [The Sherman Food, Drug, and Cosmetic Law, CAL. HEALTH & SAFETY CODE §§ 26000-26851 (Deering 1988)] requires premarket approval of all new medical devices, requires compliance of device manufacturers with good manufacturing practices and authorizes inspection of establishments which manufacture devices.") (quoting H.R. Rep. No. 853, 94th Cong., 2d Sess. 45 (1976)).

60. See, e.g., *New Jersey Guild of Hearing Aid Dispensers v. Long*, 384 A.2d 795, 806 (N.J. 1978) (describing the objectives of the Hearing Aid Dispensers Act of New Jersey and its "pre-sale testing requirement").

regulations.⁶¹ Thereafter, of course, FDA regulations would preempt conflicting state or local regulatory measures.⁶²

B. *Medtronic, Inc. v. Lohr*

As noted, MDA preemption defenses to state-law damage actions were not frequently asserted until the early 1990s.⁶³ That all changed with the Supreme Court's ruling in *Cipollone v. Liggett Group, Inc.*⁶⁴ In *Cipollone*, the son of a long-time smoker who had died from lung cancer sued several tobacco companies, claiming that they were responsible for his mother's death.⁶⁵ His complaint asserted a number of claims, including design defect, failure to warn, negligence, breach of express warranty, fraudulent misrepresentation, and conspiracy to defraud consumers by denying the public scientific information showing the perils of smoking.⁶⁶ The defendants argued that all of Cipollone's claims were preempted by the Public Health Cigarette Acts of 1965 and 1969,⁶⁷ which spelled out warnings for cigarette labels, packaging and advertising and preempted additional regulation of cigarette advertising by state and local governments.⁶⁸ The Court first rejected the companies' claim that the 1965 Act preempted Cipollone's claim.⁶⁹ That Act's preemption provision said that "[n]o statement relating to smoking and health shall be required in the advertising of [properly labeled] cigarettes."⁷⁰ This language, the Court held, "only pre-empted state and federal rulemaking bodies from mandating particular cautionary statements and did not pre-empt state-law damages actions."⁷¹

But the Court reached a different conclusion with respect to the 1969 Act.⁷² The language in that statute was, in the Court's view, "much

61. See Michael K. Carrier, *Federal Preemption of Common Law Tort Awards by the Federal Food, Drug, and Cosmetic Act*, 51 FOOD & DRUG L.J. 509, 552-53 (1996) (describing the construction and implication of the preemption provision).

62. Congress also authorized the FDA to grant state and local governments exemptions from preemption; the FDA's regulations implementing that provision apply only to positive law – statutes, rules, regulations or ordinances. 21 C.F.R. § 808.20(c)(1).

63. See Adler & Mann, *supra* note 59, at 897-98 (citing *Cipollone v. Liggett Group*, 505 U.S. 504 (1992) and saying it prompted courts to "reject injured consumers' claims against device manufacturers on the basis that the claims are preempted" by the 1976 MDA to the Federal Food, Drug and Cosmetic Act).

64. 505 U.S. 504 (1992).

65. *Id.* at 508.

66. *Id.* at 509-10.

67. 15 U.S.C. §§ 1331-1340 (2000).

68. See *Cipollone*, 505 U.S. at 510.

69. *Id.* at 519-20.

70. *Id.* at 518 (quoting § 5(b) of the 1965 Act).

71. *Id.* at 519-20.

72. *Id.* at 520.

broader” in two respects.⁷³ First, the “statement[s]” language was replaced by the term “‘requirement[s] or prohibition[s] . . . imposed under State law,’” and second, the 1969 Act extended beyond “advertising to obligations ‘with respect to the advertising or promotion’ of cigarettes.”⁷⁴ The Court then held that the “phrase ‘[n]o requirement or prohibition’ sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules.”⁷⁵ In light of that conclusion, the Court held that some of the plaintiff’s failure to warn claims — those that were based on representations that the companies made in conformity with the 1969 Act — were preempted, but that other claims, going to the tobacco industries’ fraud and misrepresentation, were not.⁷⁶

Cipollone unleashed a torrent of preemption litigation, including the ongoing litigation over medical devices.⁷⁷ Prior to *Cipollone*, preemption defenses were a rarity; post-*Cipollone*, they were routine. As the petition for certiorari in *Medtronic* made clear, by the time the Eleventh Circuit issued its ruling in the case, most circuits, and many district courts, had weighed in on the question of the preemptive scope of the MDA, and thus the preemption question in *Medtronic* was ripe for decision.⁷⁸

The facts of *Medtronic, Inc. v. Lohr*⁷⁹ are typical of these cases. Lora Lohr was in her late twenties when a heart defect necessitated the use of a pacemaker.⁸⁰ In 1987, Ms. Lohr received a Medtronic pacemaker that used a Medtronic Model 4011 lead, the wire carrying the electrical current from the pacemaker to Ms. Lohr’s heart.⁸¹ The FDA had never approved this

73. *Id.*

74. *Id.* (quoting § 5(b) of the 1969 Act).

75. *Id.* at 521. This passage appears in Part V of the opinion, which was written by Justice Stevens and joined in by Chief Justice Rehnquist and Justices White and O’Connor. It nonetheless constitutes the holding of the Court on this question. Justice Scalia, in a separate opinion in which Justice Thomas joined, largely agreed with Justice Stevens’ statutory analysis and said that

“the language of the [1969] Act plainly reaches beyond [positive] enactments;” that the general tort-law duties petitioner invokes against the cigarette companies can, as a general matter, impose “requirement[s] or prohibition[s]” within the meaning of § 5(b) of the 1969 Act; and that the phrase “State law” as used in that provision embraces state common law.

Id. at 548-49 (citations omitted). Justice Blackmun, joined by Justices Kennedy and Souter, dissented on this aspect of the Court’s ruling. *Id.* at 534-44 (concluding that general tort law duties do not impose “requirements” within the meaning of the 1969 Act).

76. *Id.* at 524-31 (plurality opinion).

77. *Cf. Bates v. Dow Agrosciences LLC*, 125 S. Ct. 1788, 1796-97 (2005) (pointing out that in the aftermath of *Cipollone* there was a “groundswell of federal and state decisions” holding that tort claims against pesticide manufacturers were preempted under the Federal Insecticide, Fungicide and Rodenticide Act).

78. See Petition for a Writ of Certiorari in *Medtronic, Inc. v. Lohr*, No. 95-754, at *11-*14 (filed on Nov. 13, 1995), available at 1995 WL 17013697, citing, *inter alia*, *English v. Mentor Corp.*, 67 F.3d 477 (3d Cir. 1995); *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392 (4th Cir. 1995); *Feldt v. Mentor Corp.*, 61 F.3d 431 (5th Cir. 1995); *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 510 U.S. 824 (1993); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. denied*, 506 U.S. 917 (1992).

79. 518 U.S. 470 (1996).

80. *Id.* at 480.

81. *Id.*

lead.⁸² Although the FDA had classified pacemaker leads as Class III devices, it had never issued a regulation calling for PMA applications for such devices.⁸³ The Medtronic lead had been found “substantially equivalent” to a pre-MDA device and was permitted on the market for that reason.⁸⁴ Four years after the pacemaker was implanted, Ms. Lohr’s device failed, resulting in a “complete heart block,” which required Ms. Lohr to undergo emergency surgery to replace the pacemaker.⁸⁵ Her treating physician traced the pacemaker’s failure to a defect in the lead.⁸⁶

Ms. Lohr and her husband brought a state law damage action in state court raising claims based on defective design, defective manufacture, and failure to warn.⁸⁷ After Medtronic removed the case to federal court, it moved to dismiss the case in its entirety, arguing that the MDA’s preemption provision gives device manufacturers a blanket immunity from tort liability.⁸⁸ The district court granted summary judgment to Medtronic.⁸⁹ The Eleventh Circuit reversed in part, finding that some of the Lohrs’ claims were preempted, but that others were not.⁹⁰ The Supreme Court granted review and issued what remains the controlling decision on the scope of MDA preemption.⁹¹ Unfortunately, the Court’s opinion is fractured and stating the Court’s holding therefore requires careful attention to the votes cast by each Justice on each issue. Part III of the majority opinion sets forth three holdings that commanded the votes of all Justices. *First*, the MDA does not broadly preempt all state-law damage actions against medical device manufacturers.⁹² *Second*, the Lohrs’ design-defect claim was not preempted because the FDA had not issued any design-specific requirements for the device.⁹³ *Third*, a damage claim premised on state-law duties “equal to, or substantially identical to” requirements under the MDA or FDA implementing regulations is not preempted.⁹⁴

In addition, the Court held in Part V of the majority opinion, by a 5-4 margin, that the Lohrs’ manufacturing defect and failure to warn claims were not preempted – even if they were based on state law duties that went

82. *Id.* at 493.

83. *Id.* at 493-94.

84. *Id.* at 493.

85. *Id.* at 480-81.

86. *Id.* at 481.

87. *Id.*

88. *Id.*

89. *Id.* at 483.

90. *Id.* at 483-84.

91. *Id.* at 484.

92. *Id.* at 494, 497, 502 (majority); *id.* at 513 (O’Connor, J., concurring in part and dissenting in part).

93. *Id.* at 493-94 (majority); *id.* at 513 (O’Connor, J., concurring in part and dissenting in part).

94. *Id.* at 497 (majority); *id.* at 513 (O’Connor, J., concurring in part and dissenting in part).

beyond duties imposed by federal requirements for manufacturing and labeling.⁹⁵ The Court looked to the language of the MDA preemption provision and noted the “overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest.”⁹⁶ The Court also was guided by the overriding purpose of the MDA, which was to provide for the safety and effectiveness of medical devices intended for human use.⁹⁷ In *Medtronic*, the generality of the FDA’s regulations applicable to pacemakers “reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements.”⁹⁸ The Court also found the Lohrs’ common-law claims not preempted because they were based on general state-law duties that do not specifically address medical devices.⁹⁹ General duties to use care in manufacturing and to warn users of possible risks are not the type of requirements that Congress or the FDA feared would impede the FDA’s ability to enforce specific federal law.¹⁰⁰

Speaking for a four-Justice plurality, the lead opinion also relied on the MDA’s language and history to conclude in Part IV that the MDA preemption provision was not intended to preempt most, and perhaps all, damage actions.¹⁰¹ The plurality did not decide definitively the scope of MDA preemption because under the majority’s analysis, none of the Lohrs’ claims were preempted.¹⁰²

Justice Breyer filed a pivotal concurring opinion addressing his concerns with Parts VI and VI of the plurality opinion.¹⁰³ In his view, the preemption provision’s reference to “requirements” encompasses not just state positive law, but, relying on *Cipollone v. Liggett Group, Inc.*,¹⁰⁴ also state law damage actions.¹⁰⁵ He therefore did not join Part VI of the plurality opinion because he was not convinced that MDA preemption of common law claims would be “rare.”¹⁰⁶ He joined fully in the holdings set forth above, including Part V of the majority opinion, which demands specificity on both the federal *and* state side of the preemption analysis.¹⁰⁷ In Justice Breyer’s view, the text of the MDA preemption provision reflected basic principles of conflict preemption, which ordinarily require a high degree of specificity,

95. *Id.* at 501.

96. *Id.* at 500.

97. *See supra* note 54 and accompanying text.

98. *Medtronic*, 518 U.S. at 501.

99. *Id.*

100. *Id.* at 502.

101. *Id.* at 488-91.

102. *Id.* at 502.

103. *Id.* at 503 (Breyer, J., concurring).

104. 505 U.S. 504, 519 (1992).

105. *Medtronic*, 518 U.S. at 508.

106. *Id.*

107. *Id.* at 500.

and he found no conflict between any federal requirement and any of the Lohrs' claims.¹⁰⁸

Justice O'Connor filed an opinion dissenting in part and concurring in part, which was joined by Chief Justice Rehnquist and Justices Scalia and Thomas.¹⁰⁹ As did Justice Breyer, Justice O'Connor took the view that common law claims can constitute "requirements" under the preemption provision.¹¹⁰ Although she agreed that the Lohrs' design-defect claim was not preempted, she would have held that the manufacturing defect and failure to warn claims were preempted to the extent that they sought to impose requirements different from those imposed by the FDA's manufacturing and labeling rules.¹¹¹ She agreed with the majority, however, that the Lohrs' state law manufacturing defect and failure to warn claims were not preempted to the extent that they were based on alleged violations of federal law.¹¹²

Post-*Medtronic*, courts remain divided on the question that the Court did not reach; namely, whether the MDA preempts tort cases for PMA devices where the FDA in fact approved the specific device at issue. Some courts, like the Tenth Circuit in *Oja v. Howmedica, Inc.*¹¹³ and Eleventh Circuit in *Goodlin v. Medtronic, Inc.*,¹¹⁴ apply the analysis laid out in *Medtronic*. They require that a manufacturer show specific and conflicting federal *and* state law requirements applicable to the particular device in order to establish preemption.¹¹⁵ Other courts follow the approach typified by the Third Circuit's recent ruling in *Horn v. Thoratec Corporation*,¹¹⁶ which held that FDA approval of a PMA constitutes sufficient FDA oversight to trigger the preemption provision of the MDA.¹¹⁷ According to the *Horn* court, "any finding" based on "general claims of negligence or defective design and

108. *Id.* at 508.

109. *Id.* at 509-14 (O'Connor, J., dissenting in part and concurring in part).

110. *Id.* at 513.

111. *Id.* at 513-14.

112. *Id.* at 514. The Supreme Court has addressed the preemptive reach of the MDA only once since *Medtronic*. In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), plaintiffs injured by surgical screws (Class III devices) brought actions against a consulting firm that had assisted the manufacturer in obtaining FDA approval on a number of theories, including the theory that the consultant had made fraudulent representations to the FDA. *Id.* at 343. The Supreme Court held that the plaintiffs' fraud-on-the-FDA claims were preempted, not by virtue of the MDA's express preemption provision, but under an implied conflict preemption theory that rested on the observation that "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration," and that the balance achieved by the MDA "can be skewed by allowing fraud-on-the-FDA claims under state tort law." *Id.* at 348.

113. 111 F.3d 782, 789 (10th Cir. 1997).

114. 167 F.3d 1367 (11th Cir. 1999).

115. See, e.g., *State ex rel. Miller v. New Womyn, Inc.*, 679 N.W.2d 593, 596 (Iowa 2004); *Niehoff v. Surgidev Corp.*, 950 S.W.2d 816, 822 (Ky. 1997).

116. 376 F.3d 163 (3d Cir. 2004).

117. *Id.* at 173.

manufacture — be it by a jury or a court — would necessarily amount to a state substantive requirement ‘different from, or in addition to, the federal requirements imposed by the FDA.’”¹¹⁸ At some point, the Supreme Court will have to step in to resolve this ongoing conflict. The following observations should guide the Court’s analysis.

II. ABSENT A CLEAR CONGRESSIONAL COMMAND, WORDS LIKE “REQUIREMENTS” IN REGULATORY STATUTES SHOULD NOT PREEMPT STATE DAMAGE CLAIMS

The first and most important step the Supreme Court should take to restore coherence to its preemption jurisprudence is to acknowledge the error it made in *Cipollone*.¹¹⁹ The Court should confine *Cipollone* to its facts and declare that Congress’ use of words like “requirement” in regulatory statutes is a reference to positive state law only, and should not be read, unless there is clear-cut evidence to the contrary, to subsume state law damage actions.¹²⁰

The Court took a wrong turn in *Cipollone* in holding that the reference to “requirement[s] or prohibition[s]” in the preemption provision of the Federal Cigarette Labeling and Advertising Act (FCLAA) reaches common law tort actions. There is not a hint in either the language of the FCLAA or its legislative history that Congress understood that the preemption provision would nullify *any* state common law claims – even failure to warn claims that might arguably be in tension with the Act’s dictates. To the contrary, the provision was included in the Act to “avoid the chaos created by a multiplicity of conflicting [state and local] regulations,” not to deprive injured smokers of their state damages action remedies.¹²¹

118. *Id.* at 179. See also *Martin v. Medtronic, Inc.*, 254 F.3d 573, 585 (5th Cir. 2001); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997).

119. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992).

120. By “regulatory statutes” I mean enactments that allocate regulatory responsibility between federal and state governments and assign regulatory responsibilities to federal agencies. Such enactments include, for example, the Medical Device Amendments, 21 U.S.C. § 360k (2000), which assign regulatory responsibility over medical devices to the FDA; the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. § 136 (2000), which assigns regulatory authority over certain agricultural chemicals to the EPA; or the National Traffic and Motor Vehicle Safety Act of 1996, 49 U.S.C. §§ 30101-30169 (2000), which assigns responsibility for regulating the safety features of motor vehicles to the National Highway Traffic Safety Administration. I use this term to distinguish regulatory statutes from statutes that are specifically designed to supplant state liability regimes with federal ones, like the Price-Anderson Act, discussed *supra* note 16 and accompanying text.

121. S. REP. NO. 91-566 (1969) reprinted in 1970 U.S.S.C.A.N. 2652, 2663; see also H. R. REP. NO. 91-289, at 9 (1969) (stating that the legislation “will prevent a chaotic situation from developing as different Federal, State, and local agencies strive to exercise overlapping and conflicting jurisdiction in this regard”). The language of the Act supports this reading. The Act states that its purpose is to ensure that “commerce and the national economy . . . not [be] impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.” 15 U.S.C. § 1331(2) (2000). Justice Blackmun argued in his *Cipollone* dissent that “there is absolutely no suggestion in the legislative history that Congress intended to leave plaintiffs who were injured as a result of cigarette manufacturers’ unlawful conduct without any alternative remedies; yet that is the regrettable effect of the ruling today that many state common-law damages claims are pre-empted.” *Cipollone v. Liggett Group Inc.*, 505 U.S. 504, 531,

Nor, as a textual matter, is it at all clear that general common law duties constitute “requirements.” Had Congress intended to broadly displace state damage actions, the choice of the word “requirements” is “singularly odd,” particularly since far more precise words, like “remedies,” are available.¹²² Words like “requirement” reflect an understanding that the state is imposing specific rather than general duties on the manufacturer. This was one point stressed by Justice Blackmun in his dissent in *Cipollone*,¹²³ which Justices Souter and Kennedy joined. Justice Blackmun argued that, “[i]n light of the recognized distinction in this Court’s jurisprudence between direct state regulation and the indirect regulatory effects of common-law damages actions, it cannot be said that damages claims are clearly or unambiguously ‘requirements’ or ‘prohibitions’ imposed under state law.”¹²⁴ Tort liability necessarily exerts only an “indirect” effect on a manufacturer’s behavior because,

[a]lthough an award of damages by its very nature attaches additional consequences to the manufacturer’s continued unlawful conduct, no particular course of action (*e.g.*, the adoption of a new warning label) is required. A manufacturer found liable on, for example, a failure-to-warn claim may respond in a number of ways.¹²⁵

It could adopt a new warning label, “dispens[e] warnings through a variety of alternative mechanisms, such as package inserts, public service advertisements, or general educational programs,” or even decide to make no changes and “accept damages awards as a cost of doing business.”¹²⁶ “The level of choice that a defendant retains in shaping its own behavior

541 (1992) (Blackmun, J., concurring in part and dissenting in part). The 1965 Act was far more limited than its successor; it required warning labels on cigarette packaging, but prohibited further regulation of cigarette advertising by any governmental body. Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 79 Stat. 282 (1965). The 1969 Act banned cigarette advertisements on television and radio, gave the Federal Trade Commission (“FTC”) the authority to impose warning-label requirements on print advertisements, and stiffened the warnings on packaging. Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 (1970). In light of the broad regulatory authority conferred on the FTC over cigarette advertising and promotion by the 1969 Act, a preemption provision barring state and local regulation of cigarette advertising and promotion made sense. *See generally* Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 543-46 (2001) (explaining that under the 1969 Act, the “FTC sought a complete ban on radio and television advertising, a requirement that broadcasters devote time for health hazard announcements concerning smoking, and increased funding for public education and research about smoking.”). The *Lorillard* Court found a Massachusetts regulation that broadly restricted the outdoor advertising of cigarettes preempted by the FCLAA. *Id.* at 544, 546-51.

122. *See* Medtronic, Inc. v. Lohr, 518 U.S. 470, 487 (1996) (plurality opinion).

123. 505 U.S. at 531, 535 (Blackmun, J., concurring in part and dissenting in part).

124. *Id.* at 538.

125. *Id.* at 536.

126. *Id.*

distinguishes the indirect regulatory effect of the common law from positive enactments such as statutes and administrative regulations.”¹²⁷

To be sure, given the purpose of the FCLAA — to comprehensively regulate the warnings appearing on cigarette packaging and advertising¹²⁸ — one can see why the Court might have perceived a tension between the Act’s requirements and a common law claim for failure to warn. But nothing in the FCLAA prevented the companies from providing additional warnings.¹²⁹ Tobacco companies could have made general public service announcements, underwritten educational programs, or engaged in other forms of advertising to warn consumers about the risks of smoking, all without running afoul of the Act. Thus, there would have been no conflict between the federal goals articulated in the FCLAA and jury verdicts finding that the companies had failed to meet their state law duties to warn consumers about the hazards of tobacco use. In the absence of a clear direction by Congress to abrogate state law damages claims, the Court in *Cipollone* was wrong to hold that FCLAA preempted any state-imposed duties other than conflicting positive state law.¹³⁰ Indeed, until *Cipollone*, it does not appear that the Court had ever invoked preemption to nullify a state damage action where the effect of doing so was to leave injured parties without any remedy.¹³¹

The *Medtronic* Court compounded the error in *Cipollone* by importing uncritically the rule of *Cipollone* into the MDA.¹³² The error in *Medtronic* is hard to fathom. At the outset of the Court’s opinion, it acknowledges that Medtronic’s sweeping preemption argument was “not only unpersuasive, it is implausible,” precisely because it would “have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation in order ‘to provide for the safety and effectiveness of medical devices intended for human use.’”¹³³ The Court found it “difficult to believe that Congress would, without comment, remove all means of judicial recourse for those

127. *Id.*

128. *Id.*

129. *Id.*

130. Other factors may have played a role in the Court’s disposition in *Cipollone*. For one thing, because the Court’s ruling only found failure to warn claims preempted from 1969 forward, its ruling did not nullify *Cipollone*’s claims based on pre-1969 conduct by the industry. *See id.* at 524. Moreover, the Court in *Cipollone* preserved claims based on “express warranty, intentional fraud and misrepresentation, or conspiracy,” leaving the heart of the case intact. *Id.* at 530-31. Thus, in contrast with many preemption cases where a preemption finding leaves the victim without any remedy, the impact of the Court’s ruling in *Cipollone* was more modest. The plurality opinion in *Medtronic* makes this point as well. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 487-89 (1996).

131. The only case cited in Justice Stevens’ plurality opinion for the proposition that state regulation can be as effectively asserted through damages actions as positive law is *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 247 (1959). *Garmon* held that the National Labor Relations Act (“NLRA”) preempted state law regulating labor-management relations. *Id.* But critical to the *Garmon* Court’s reasoning was the Court’s observation that the NLRA was “a complex and interrelated federal scheme of law, remedy, and administration.” *Id.* at 243. Parties injured by labor strife have recourse to the National Labor Relations Board, which has substantial remedial authority. *See id.* at 245-46.

132. *Medtronic*, 518 U.S. at 484-85.

133. *Medtronic*, 518 U.S. at 487 (plurality opinion) (quoting 90 Stat. 539 (preamble to the MDA)).

injured by illegal conduct,” and said that it would “take language much plainer” than that in the MDA preemption provision “to convince us that Congress intended that result.”¹³⁴ Nonetheless, the *Medtronic* Court left open the possibility that the MDA could “remove all means of judicial recourse for those injured by illegal conduct” where PMA devices are approved by the FDA.¹³⁵

It appears, however, that the Court is moving away from *Cipollone*. The path to put the *Cipollone* genie back in the bottle was marked, perhaps ironically, in *Medtronic*. There, Justice Stevens, the author of the plurality opinions in both *Cipollone* and *Medtronic*, was quite careful to confine *Cipollone* to its facts and to give the narrowest possible reading to its holding.¹³⁶

The Court’s next opportunity to address whether common law duties qualify as regulatory requirements came in *Sprietsma v. Mercury Marine*.¹³⁷ In *Sprietsma*, Justice Stevens, this time writing for a unanimous Court, addressed broad preemption claims made by a boat manufacturer, who contended that the Federal Boat Safety Act (“FBSA”)¹³⁸ nullified all state law design defect damage actions.¹³⁹ The action was brought by the family of a woman killed when she fell overboard from the family’s motorboat and was struck by the boat’s propellers, which were not shielded by propeller guards.¹⁴⁰ The FBSA gives the Coast Guard broad authority to prescribe safety and performance standards for boats to be used for recreational purposes.¹⁴¹ The Coast Guard had imposed a wide-range of requirements, but had not required motor-boat manufacturers to install propeller guards, although it was considering doing so.¹⁴² The boat manufacturer argued, among other things, that the family’s claims were preempted in their entirety

134. *Id.* (quoting *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984)).

135. *Id.*

136. *Id.* at 487-89 (distinguishing *Cipollone* on a number of grounds).

137. 537 U.S. 51 (2002). There was one intervening preemption decision that addressed the same essential question, but it was resolved on implied, not express, preemption grounds. *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000). In *Geier*, the Court found a tort claim based on the lack of an air-bag in an automobile involved in a crash preempted. *Id.* at 866-68. The Court rejected Honda’s argument that the express preemption provision in the National Highway Traffic Safety Act preempted the claim, since the provision applies only to a “safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not identical to the Federal standard.” *Id.* at 866-68 (quoting 15 U.S.C. § 1392(d) (1988) (current version at 49 U.S.C. § 30103(b) (2000))). Nonetheless, the Court ruled 5-4 that the claim was impliedly preempted because permitting a tort claim to go forward would conflict with the Department of Transportation’s decision to provide for a phase-in of air-bags. *Id.* at 876-81.

138. 46 U.S.C. §§ 4301-4311 (2000).

139. *Sprietsma v. Mercury Marine*, 537 U.S. 51, 55-56 (2002).

140. *Id.* at 54-55.

141. *Id.* at 57 & n.6 (citing 46 U.S.C. § 4302).

142. *Id.* at 59-62.

by the FBSA's preemption provision, which is similar to that in the MDA.¹⁴³ It provides that "a State or political subdivision of a State may not establish, continue in effect, or enforce a law or regulation establishing a recreational vessel or associated equipment performance or other safety standard or imposing a requirement for associated equipment . . . that is not identical to a regulation prescribed under" the Act.¹⁴⁴

Writing for the Court, Justice Stevens quickly disposed of the boat manufacturer's express preemption defense.¹⁴⁵ Observing that the FBSA's preemption provision applies to state or local "law or regulation," he concluded that the language of the provision "is most naturally read as not encompassing common-law claims" because the terms used together "indicate that Congress pre-empted only positive enactments."¹⁴⁶ He also emphasized that this reading of the FBSA "does not produce anomalous results. It would have been perfectly rational for Congress not to pre-empt common-law claims, which — unlike most administrative and legislative regulations — necessarily perform an important remedial role in compensating accident victims."¹⁴⁷

The Court took its most significant step away from *Cipollone* in its recent ruling in *Bates v. Dow Agrosciences LLC*.¹⁴⁸ *Bates* was an action brought by Texas peanut farmers against Dow, which sold a weedkiller called "Strongarm," which the farmers alleged severely damaged their peanut crops in 2000.¹⁴⁹ Dow had registered Strongarm with the Environmental Protection Agency ("EPA") in 2000 with a label that stated, "Use of Strongarm is recommended in all areas where peanuts are grown."¹⁵⁰ The farmers alleged that Dow knew or should have known at the time that Strongarm stunted the growth of peanuts in soil with a pH of 7.0 or greater.¹⁵¹ When Dow registered Strongarm for 2001, it sought EPA approval for a supplemental label to be used in states where farmers experienced crop damage which set forth the following warning: "Do not apply Strongarm to soils with a pH of 7.2 or greater."¹⁵²

Under the Federal Fungicide, Insecticide and Rodenticide Act ("FIFRA"),¹⁵³ the EPA has comprehensive regulatory authority over pesticides, and pesticides may not be lawfully sold in the United States

143. *Id.* at 56.

144. 46 U.S.C. § 4306.

145. *Sprietsma*, 537 U.S. at 62-63.

146. *Id.* at 63.

147. *Id.* at 63-64 (citation omitted). Tellingly, the Court does not mention *Cipollone* in addressing the manufacturer's express preemption claim and *Cipollone* is nowhere discussed in the opinion. It is cited only once as part of the Court's discussion of the manufacturer's implied preemption claims, which the Court also rejected. *Id.* at 69.

148. 125 S. Ct. 1788 (2005).

149. *Id.* at 1792-93.

150. *Id.* at 1793.

151. *Id.*

152. *Id.*

153. 7 U.S.C. §§ 136-136y (2000).

unless they have been registered with the EPA.¹⁵⁴ The EPA will register a pesticide if it determines that it will not cause “unreasonable adverse effects on humans and the environment, and that its label complies with [FIFRA’s] prohibition on misbranding.”¹⁵⁵ A pesticide is misbranded if its label contains a statement that is “false or misleading in any particular,” or if it fails to contain adequate instructions for its use.¹⁵⁶ FIFRA also contains a preemption provision, 7 U.S.C. § 136v(b), which provides that “[a] State shall not impose or continue in effect any requirements for labeling or packing in addition to or different from those required under this subchapter.”¹⁵⁷ Dow argued, and the lower courts agreed, that the farmers’ strict liability, negligence, fraud, and breach of warranty claims were preempted in their entirety.¹⁵⁸

In rejecting Dow’s preemption defense, the Court began by noting that FIFRA’s preemption provision applies only to “requirements” and that under *Cipollone*, the term “reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties.”¹⁵⁹ Despite this nod to *Cipollone*, the Court then distanced itself from, if not repudiated, this core aspect of *Cipollone*. The lower court in *Bates* had concluded that the farmers’ claims were preempted because a finding of liability “would induce Dow to alter [its] label.”¹⁶⁰ The Court rejected this reasoning because an “effects-based test” finds no support in FIFRA’s preemption provision, “which speaks only of ‘requirements.’”¹⁶¹ In language that echoes Justice Blackmun’s dissent in *Cipollone* and cannot be squared with *Cipollone*’s holding, the *Bates* Court then explained that “[a] requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement.”¹⁶²

154. *Bates v. Dow Agrosciences LLC*, 125 S. Ct. 1788, 1795 (2005).

155. *Id.* at 1795 (citations omitted). Prior to 1978, the EPA also determined whether the pesticide was efficacious for its intended use. *Id.* at 1796. Congress amended the Act to authorize the EPA to waive data requirements pertaining to efficacy, thus permitting the EPA to register pesticides without confirming the efficacy claims made on the pesticide’s label. *Id.* (citing 7 U.S.C. § 136a(c)(5)). In 1979, the EPA invoked this authority to issue a general waiver of efficacy review, with only limited qualifications not applicable in *Bates*. *Id.* (citing 44 Fed. Reg. 27932 (1979); 40 C.F.R. § 158.640(b)).

156. *Id.* at 1795.

157. 7 U.S.C. § 136(v)(b). The Court had previously ruled that the Act’s reference to a “State” did not foreclose local regulation of pesticide use. *See Wis. Pub. Intervenor v. Mortier*, 501 U.S. 597 (1991).

158. *Bates*, 125 S. Ct. at 1793-94.

159. *Id.* at 1798.

160. *Id.* at 1799.

161. *Id.*

162. *Id.*; *see also id.* at 1798 (“An occurrence that merely motivates an optional decision does not qualify as a requirement.”).

To drive this point home, the *Bates* Court added that the fact that FIFRA “might pre-empt judge-made rules” says “nothing about the *scope* of that pre-emption.”¹⁶³ Under FIFRA, for a state rule to be preempted, two conditions must be met. First, the state rule “must be a requirement ‘for labeling or packaging’; rules governing the design of a product, for example, are not pre-empted.”¹⁶⁴ And second, the state rule “must impose a labeling or packaging requirement that is ‘*in addition to or different from* those required under this subchapter.”¹⁶⁵

The Court then held that the farmers’ “claims for defective design, defective manufacture, negligent testing, and breach of express warranty [were] not preempted.”¹⁶⁶ “Rules that require manufacturers to design reasonably safe products, to use due care in conducting appropriate testing of their products, to market products free of manufacturing defects, and to honor their express warranties or other contractual commitments plainly do not qualify as requirements” because “[n]one of these common-law rules requires that manufacturers label or package their products in any particular way.”¹⁶⁷ With respect to Dow’s express warranty, the Court added that although the warranty was on Strongarm’s label, the “common-law rule does not require the manufacturer to make an express warranty, or in the event that the manufacturer elects to do so, to say anything in particular in that warranty.”¹⁶⁸

With respect to the farmers’ fraud and failure to warn claims, the Court did find that adverse jury determinations on such claims could qualify as “requirements” if they actually imposed a substantive standard for a product’s labeling.¹⁶⁹ But even here, the Court immediately made clear that the *Cipollone* analysis would not govern because of the “rather obvious textual differences” between the two preemption provisions.¹⁷⁰ FIFRA, the Court noted, prohibits only state law restrictions that are “*in addition to or different from*” those imposed by FIFRA, and for that reason, a state law requirement is not preempted if it is equivalent to, and fully consistent with, FIFRA’s requirements.¹⁷¹ Federal and state laws that impose parallel requirements do not give rise to preemption. This analysis, the Court said, “finds strong support in *Medtronic*,” which addressed “a similarly worded preemption provision.”¹⁷² Invoking Justice O’Connor’s separate opinion in *Medtronic*, the Court noted that “a state cause of action that seeks to enforce a federal requirement ‘does not impose a requirement that is “different from,

163. *Id.* at 1798 (emphasis in original).

164. *Id.*

165. *Id.* (emphasis in original).

166. *Id.*

167. *Id.*

168. *Id.* at 1798-99.

169. *Id.* at 1800.

170. *Id.*

171. *Id.*

172. *Id.*

or in addition to,” requirements under federal law.”¹⁷³ Moreover, the Court noted, FIFRA “does not preclude States from imposing different or additional *remedies*, but only different or additional *requirements*,” and thus the fact that a damage remedy might give companies an additional reason to comply with the law is no defense to the application of consistent state law.¹⁷⁴

So far, *Bates* simply builds on pre-existing preemption law. But *Bates*’ significance becomes apparent in its concluding paragraphs, which defend its non-preemption ruling on two grounds never before given prominence in the Court’s preemption decisions. First, the Court found that the “long history of tort litigation against manufacturers of poisonous substances” buttressed its conclusion that the farmers’ claims were not preempted.¹⁷⁵ The Court cited many reasons why this history was so significant. For one thing, the Court reasoned that had Congress intended “to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly.”¹⁷⁶ For another, the history of tort litigation “emphasizes the importance of providing an incentive to manufacturers to use the utmost care in the business of distributing inherently dangerous items.”¹⁷⁷ And the Court found it implausible that Congress considered a “relatively obscure” provision of FIFRA to “give pesticide manufacturers virtual immunity from certain forms of tort liability.”¹⁷⁸

Second, the Court laid bare and grappled with Dow’s policy arguments, joined in by the United States as amicus, that tort liability going forward, coupled with EPA regulation, would lead to over-deterrence. The Court acknowledged that “[o]ver-enforcement of FIFRA’s misbranding prohibition creates a risk of imposing unnecessary financial burdens on manufacturers.”¹⁷⁹ But that risk was outweighed, said the Court, because “under-enforcement creates not only financial risks for consumers, but risks that affect their safety and the environment as well.”¹⁸⁰ The Court added that “[p]rivate remedies that enforce federal misbranding requirements

173. *Id.* (quoting *Medtronic*, 518 U.S. at 513 (O’Connor, J., concurring in part and dissenting in part)).

174. *Id.* (emphasis in original). Later in the opinion the Court adds a measure of clarity to the inquiry on equivalence in a way that tilts the scales in favor of preserving state law. “To survive pre-emption, the state-law requirement need not be phrased in the *identical* language as its corresponding FIFRA requirement; indeed, it would be surprising if a common-law requirement used the same phraseology as FIFRA.” *Id.* at 1804.

175. *Id.* at 1801.

176. *Id.*

177. *Id.* at 1802.

178. *Id.*

179. *Id.*

180. *Id.*

would seem to aid, rather than hinder, the functioning of FIFRA.”¹⁸¹ State tort actions “may aid in the exposure of new dangers associated with pesticides,” may prompt EPA to “decide that revised labels are required in light of the new information that has been brought to its attention,” and may “provide manufacturers with added dynamic incentives to continue to keep abreast of all possible injuries stemming from use of their product so as to forestall such actions through product improvement.”¹⁸²

These arguments, which carried considerable weight in *Bates*, apply with even greater force to the MDA. After all, the MDA was enacted in response to a massive regulatory failure brought to light by tort litigation, and there is no hint in the text or legislative history of the MDA that Congress intended “to deprive injured parties of a long available form of compensation.”¹⁸³ Nonetheless, the courts remain fractured on whether the MDA preempts state damages actions in cases involving products specifically approved by the FDA. Since no MDA preemption case has been decided post-*Bates*, it is too soon to tell whether courts will take their cue from *Bates*. In the meantime, however, it is clear that lower courts have not faithfully followed *Medtronic*, creating disarray in the interpretation of the MDA.

III. LOWER COURTS SHOULD APPLY *MEDTRONIC*'S PARALLEL REQUIREMENTS TEST

Medtronic establishes a narrow rule of preemption. As the plurality opinion put it, “given the critical importance of device specificity in our (and the FDA’s) construction of § 360k [the MDA preemption provision], it is apparent that few, if any, common-law duties have been pre-empted by this statute.”¹⁸⁴ The MDA preempts state law when, but only when, (1) there are specific requirements for a device (2) that are imposed by *both* federal and state law, and (3) that are in conflict.¹⁸⁵ Generality on either side of the equation defeats preemption, as do federal and state requirements that impose parallel and consistent obligations.¹⁸⁶ To illustrate this point, Justice

181. *Id.*

182. *Id.* (quoting *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1541-42 (D.C. Cir. 1984)). One might question why a history of litigation bears on the preemption question and how specific that litigation has to be in order to count against preemption. The Court in *Bates* addresses these concerns. As to the basic question why litigation history matters, the Court’s answer in *Bates* dovetails with the general proposition that when Congress “intend[s] to deprive injured parties of a long available form of compensation,” it “express[es] that intent more clearly.” *Id.* at 1801; *see also* *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984). The history of litigation goes to whether a preemption ruling would upset settled expectations and deprive injured parties of tort remedies that had long been available. As to the specificity of this litigation, the *Bates* Court was careful to suggest that litigation in the same general area, and not over the specific product, would suffice. *Bates*, 125 S. Ct. at 1801. After all, the relevant yardstick in *Bates* was *not* specific litigation against pesticide manufacturers for crop damage, but was instead the more general “history of tort litigation against the manufacturers of poisonous substances.” *Id.*

183. *Bates*, 125 S. Ct. at 1792.

184. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 502 (1996) (plurality opinion).

185. *See id.* at 506-07.

186. *See id.* at 502, 507.

Breyer offered the example of a federal requirement that hearing aid wires be two inches in length, preempting a common-law claim based on a *specific* state requirement for a one-inch wire.¹⁸⁷ Under those circumstances, compliance with both federal and state requirements would be impossible and thus preemption makes sense. The existence of conflicting requirements is the essence of the preemption holding in *Medtronic*, as Justice Breyer's illustration makes plain. Regrettably, some lower courts have failed to adhere to this rule.¹⁸⁸

Typical of the decisions that have strayed from *Medtronic* is the Third Circuit's ruling in *Horn v. Thoratec Corporation*.¹⁸⁹ *Horn* involved the failure of a device called the HeartMate, which "is a pump that assists the blood flow between the heart's ventricle and the aorta in patients with cardiac conditions."¹⁹⁰ Barbara Horn's husband, Daniel Horn, suffered a heart attack and his doctors determined that he needed a heart transplant.¹⁹¹ While waiting for a suitable donor heart to become available, Mr. Horn's condition deteriorated and a HeartMate was implanted in him to provide circulatory support.¹⁹² He "began to bleed from the spot where the HeartMate" had been implanted and underwent exploratory surgery that revealed that the pump had become disconnected.¹⁹³ The disconnection had allowed an air embolus to travel to Mr. Horn's brain, causing a fatal brain hemorrhage.¹⁹⁴

Ms. Horn alleged that the HeartMate was defectively designed and manufactured, and that the company had failed to warn patients and physicians of the defects.¹⁹⁵ The district court dismissed the action in its entirety on preemption grounds, and the Third Circuit, in a two-to-one ruling, affirmed.¹⁹⁶

The majority first found that the pre-marketing approval (PMA) process, in which the FDA approves the design of Class III medical devices, culminated in the imposition of federal "requirements."¹⁹⁷ This ruling was

187. *Id.* at 504 (Breyer, J., concurring).

188. *Compare, e.g.,* *Oja v. Howmedica, Inc.*, 111 F.3d 782, 789 (10th Cir. 1997), and *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) (conducting the *Medtronic* preemption inquiry and finding no preemption), with *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004), *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001), and *Mitchell v. Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997) (looking only at the specificity of the federal requirements and finding preemption notwithstanding the generality of the state requirements at issue).

189. 376 F.3d 163 (3d Cir. 2004).

190. *Id.* at 164.

191. *Id.* at 165.

192. *Id.*

193. *Id.*

194. *Id.*

195. *Id.*

196. *Id.* at 164.

197. *Id.* at 171.

in error. Obtaining a license to sell a product — even through a process as rigorous as FDA PMA review — does not result in the imposition of a federal “requirement.”¹⁹⁸ Unless the FDA has set out specific regulations specifying the design standards for a particular device (which is almost invariably not the case) the manufacturer may select the design, manufacturing, fabrication and labeling features that will satisfy the minimum and general standards set forth in the MDA and its implementing regulations.¹⁹⁹ The FDA’s job is to ensure that there is a “reasonable assurance” that the resulting product is safe and effective for its intended use.²⁰⁰ The FDA plays no initiating role in the design of medical devices or how they are manufactured or labeled.²⁰¹ Nor does the FDA have the authority to determine whether the design is optimal from a public health standpoint, or even whether there are safer and more effective devices already on the market.²⁰² So long as a device meets the statutory standards, the FDA has no choice but to approve it. This point is critical, but it is generally overlooked.²⁰³

Not only was the *Horn* court wrong to find “requirements” on the federal side of the equation, it compounded its error by concluding that state common law duties are sufficiently specific to the HeartMate to trigger preemption.²⁰⁴ As the *Horn* court saw it, although the *Medtronic*

plurality opinion did not inform us of when common law requirements may become substantive requirements, we are satisfied that Horn’s general state law claims would impose substantive requirements on [the manufacturer] that would conflict with, or add to, the requirements imposed by the FDA involved in the design, manufacturing, fabrication and labeling of the HeartMate.²⁰⁵

Key to the court’s conclusion was its assumption that a design defect liability finding against the company “unquestionably would require” it to redesign its product along the line advocated by Horn’s experts.²⁰⁶ But that assumption confuses the imposition of a device-specific requirement that comes through positive state enactments and the indirect effect of tort

198. See 21 C.F.R. § 812.2 (2005) (discussing the applicability of the FDA requirements).

199. See generally 21 C.F.R. §§ 812, 814 (2005) (laying out the federal regulations and procedure for medical devices).

200. 21 U.S.C. § 360e(d)(2)(A)-(B) (2000).

201. See 21 U.S.C. § 360e(d).

202. *Id.*

203. *Id.* These limitations on its authority place the FDA in a vastly different position than, for instance, the Defense Department when it contracts for the production of military equipment. See, e.g., *Boyle v. United Techs. Corp.*, 487 U.S. 500 (1988) (creating federal common law immunity from tort liability for contractor who produced, according to government specifications, a helicopter for the United States Marine Corps).

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

205. *Id.* at 176.

206. *Id.*

judgments.²⁰⁷ An adverse jury ruling in *Horn* would not have *required* the device's manufacturer to do anything at all, other than to pay money damages. Of course, a manufacturer might decide to take measures to avoid a recurrence of the device's failure that lead to Mr. Horn's death or to better inform physicians and patients of the risks associated with the device. But the manufacturer could also decide to do nothing, reasoning that the likelihood of recurrence is too remote to justify any change in the product's design, manufacture, or labeling.

Horn cannot be squared with the Court's more recent preemption jurisprudence, which makes clear that jury verdicts are generally not sufficiently prescriptive to impose "requirements" for preemption purposes. This point was pivotal in both *Sprietsma* and *Bates*. In *Sprietsma*, the Court rejected the manufacturer's argument that a jury award based on the finding that motor-boats lacking propeller guards were defectively designed would force it to install guards, notwithstanding the Coast Guard's failure to require them.²⁰⁸ And in *Bates* the Court rejected Dow's contention that a finding that Stongarm was negligently designed and marketed in areas with soil with pH levels of above 7.2 would necessarily force it to modify labels the EPA had approved.²⁰⁹ As *Bates* drives home, "an event, such as a jury verdict, that merely motivates an optional decision is not a requirement."²¹⁰

It may be that lower courts will begin to interpret *Medtronic* through the lens provided by *Bates* and *Sprietsma* and become more discerning in reviewing preemption claims. But there is reason to think that they will not. As part of his "tort reform" campaign, President George W. Bush has pressed Executive Branch agencies to push for broad interpretations of preemption provisions in regulatory statutes.²¹¹ The FDA has been on the

207. *Id.* at 184 (Fuentes, J., dissenting) (noting that "[i]t is true that Horn's cause of action may have the indirect consequence of holding the HeartMate to a higher standard than does the FDA, but this consequence is sanctioned by Part V of the [*Medtronic v.*] *Lohr* opinion and not expressly barred by Justice Breyer's concurrence.").

208. *Sprietsma v. Mercury Marine*, 537 U.S. 51, 65-67 (2002).

209. *Bates v. Dow Agrosciences, LLC*, 125 S. Ct. 1788, 1799 (2005).

210. *Id.*

211. See Margaret H. Clune, *Stealth Tort Reform: How the Bush Administration's Aggressive Use of the Preemption Doctrine Hurts Consumers*, Center for Progressive Regulation White Paper 403 (Oct. 2004) at 7-9, available at <http://www.progressiveregulation.org/articles/preemption.pdf> (arguing that the Bush Administration has pursued tort reform through legal means largely hidden from public view rather than through asking Congress to change the laws). As a Scholar with the Center, I assisted Ms. Clune in the preparation of that White Paper.

It bears noting that the Administration's pro-preemption campaign is not limited to the FDA. Two illustrations should suffice. First, the Office of the Comptroller of the Currency has been roundly criticized for issuing a regulation that broadly preempts state consumer-protection laws enacted to curb an epidemic of predatory lending. Nicholas Bagley, Note, *The Unwarranted Regulatory Preemption of Predatory Lending Laws*, 79 N.Y.U. L. Rev. 2274, 2275 (2004) (arguing that the agency, in promulgating its regulation, 12 C.F.R. § 34.4(a)(2004), "overstepped its congressionally delegated authority" and urging courts "to strike it down in order to leave space for

front line of this campaign, both reversing its longstanding view that the MDA preemption provision applies only in exceptional circumstances, and aggressively presenting its new pro-preemption views in court.²¹² In *Horn*, for instance, the FDA filed an amicus brief strongly supporting the manufacturer's position, and the court relied heavily on the FDA's views in holding Ms. Horn's claims preempted.²¹³ Just as the Supreme Court rejected the Bush Administration's effort to reverse the long-held government position on the preemptive scope of FIFRA, so too should lower courts be skeptical of the FDA's new pro-preemption campaign.

IV. COURTS SHOULD REJECT THE FDA'S PRO-PREEMPTION PUSH

Like most federal agencies, the FDA has historically resisted becoming enmeshed in private products liability litigation.²¹⁴ Although the FDA has on occasion provided the courts with its view on the meaning of the statutes it enforces and the regulations it has promulgated, it rarely sought to inject itself into private litigation, that is, until the administration of President George W. Bush.²¹⁵ Since then, the FDA has accomplished a complete transformation of its position on the preemptive scope of the MDA and has actively solicited guidance from pharmaceutical and medical device firms about pending lawsuits in which the FDA could participate to press its pro-preemption position.²¹⁶ At last count, the FDA has asked for leave to participate as an amicus in at least four cases, and in each case, it has urged the court to find the plaintiffs' state law damage claims preempted.²¹⁷

state legislatures and Congress to develop and test novel responses to the growing problem of abusive lending"). Second, the National Highway Traffic Safety Administration, taking its cue from *Geier*, see *supra* note 137, has argued that the auto safety regulations it is developing should broadly preempt state damage actions. See, e.g., Federal Motor Vehicle Safety Standards; Roof Crush Resistance, 70 Fed. Reg. 49223, 49245 (Aug. 23, 2005) (to be codified at 49 C.F.R. pt. 571) (proposing regulation to upgrade the agency's safety standard on roof crush resistance and suggesting the new standard, if adopted, will preempt state damage actions); Federal Motor Vehicle Safety Standards; Designated Seating Positions and Seat Belt Assembly Anchorages, 70 Fed. Reg. 36,094, 36,094, 36,102 (June 22, 2005) (to be codified at 49 C.F.R. pt. 571.3) (proposing regulation to amend the definition of "designated seating position," to revise requirements for anchoring seat belts, "to establish a new procedure for determining the number of designated seating positions on bench and split bench seats;" suggesting that the new standard, if adopted, will preempt state damage actions).

212. See *Horn*, 376 F.3d at 177-80.

213. *Id.*

214. See Clune, *supra* note 211, at 1-3.

215. See generally Clune, *supra* note 211.

216. In an FDA publication, the FDA's Chief Counsel, Daniel E. Troy, announced that the FDA would "participate in product liability lawsuits brought under state law as necessary to safeguard [the agency's] considerable expertise in regulating the content of drug labeling and advertising." Daniel E. Troy, *FDA Involvement in Product Liability Lawsuits*, UPDATE, Jan.-Feb. 2003, at 7-8. Mr. Troy repeated that comment to an audience of several hundred lawyers representing the drug and medical device industries, where he urged the attendees to suggest lawsuits in which the agency might intervene. Mr. Troy apparently cautioned the attendees that the FDA "can't afford to get involved in every case," so interested attorneys should, in their dealings with the FDA, "make it sound like a Hollywood pitch." See Affidavit of Jessica R. Dart, ¶ 5, *Dusek v. Pfizer*, No. H-02-3559, 2004 WL 2191804 (S.D. Tex. Feb. 20, 2004).

217. *Motus v. Pfizer, Inc.*, 358 F.3d 659, 660 (9th Cir. 2004); *Dowhal v. SmithKline Beecham Consumer Healthcare*, 88 P.3d 1 (Cal. 2004); *In re Paxil Litigation*, 2002 WL 31375497 (C.D. Cal.

There is no dispute that the FDA's new position on the scope of the MDA preemption provision represents a 180-degree shift of position for the agency. In *Medtronic* itself, the FDA took the position that the scope of the MDA preemption provision was quite narrow and was not intended to displace state tort law remedies.²¹⁸ More significant, however, is an FDA amicus brief filed by the Solicitor General in *Smith Industries Medical Systems, Inc. v. Kernats*, in response to a request from the Supreme Court.²¹⁹ In *Kernats*, the Solicitor General rejected the suggestion that the pre-market approval process preempts remedies for injuries caused by a defective medical device, arguing that neither federal nor state law impose requirements specific to the medical device at issue.²²⁰ On the federal side, preemption occurs only when "the FDA determines that precise design, manufacturing, or labeling specifications are necessary [and it] . . . impose[s] such requirements through the promulgation of specific regulations. . . . We have been informed by the FDA that it imposes such specific requirements on Class III devices only in extraordinary situations," that were not present in the case.²²¹ On the state side of the ledger, the MDA preemption provision is "inapplicable in the circumstances of this case because [the manufacturer] has not shown that common law imposes a substantive requirement specifically with respect to the medical device at issue here."²²² Those observations would have applied precisely to the circumstances in *Horn*, and indeed universally in the MDA preemption cases decided post-*Medtronic*.²²³

2002); *Murphee v. Pacesetter, et. al.*, No. 005429-00-3 (Tenn. Ct. App. Dec. 12, 2003), as Ex. A in *Mem. in Supp. of Mot. Summ. J.*, *Downes v. Medtronic, Inc.*, No. 05-80746, at 3 (D. Fla. 2005). Although the FDA did not initiate its participation in *Horn v. Thoratec*, the Third Circuit requested that it submit a brief after the *Horn* defendant submitted the FDA's briefs in *Murphee* and urged the Third Circuit to defer to the pro-preemption position outlined in the *Murphee* briefs. *Horn*, 376 F.3d at 171 & n.13. In *Motus* and *Dowhal*, the FDA argued for broad preemption of failure to warn claims with respect to pharmaceutical products, even though the drug provisions of the Food, Drug and Cosmetic Act (FDCA) do not contain an express preemption provision, and even though the courts had not previously entertained such claims. See Brief of Public Citizen as Amicus Curiae Supporting Cross-Appellee at 13, *Motus v. Pfizer*, 358 F.3d 659 (9th Cir. 2004) (Nos. 02-55372, 02-55498), 2003 WL 22716063, at *13 (arguing that "since enactment of the FDCA 65 years ago, no reported decision has held that the Act preempts common-law damages actions with respect to drugs."). The Court in *Motus* did not reach the preemption question. *Motus*, 358 F.3d at 660.

218. See Brief for the United States as Amicus Curiae Supporting Respondents/Cross-Petitioner, *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (Nos. 95-754, 95-886), 1996 WL 118035 (arguing for a narrow reading of the MDA preemption provision).

219. Brief for the United States as Amicus Curiae, *Smith Indus. Med. Sys. v. Kernats*, 669 N.E.2d 1300 (Ill. App. 1996) (No. 96-1405) [hereinafter Brief for the United States, *Kernats*]. The lower court opinion is set forth at 669 N.E.2d 1300 (Ill. App. 1996).

220. *Id.*

221. Brief for the United States, *Kernats*, *supra* note 219, at 15.

222. *Id.* at 17.

223. Shortly after the Court handed down its decision in *Medtronic*, FDA Chief Counsel Margaret Porter noted that the Court's non-preemption ruling in *Medtronic* was consistent with the FDA's

Notwithstanding the clarity of the FDA's position in *Kernats* and the absence of any change in the law — statutory, regulatory, or decisional — that might explain a reversal of field, the FDA now takes the diametrically opposite position. Relying principally on policy arguments, the agency claims that the MDA broadly preempts state-law damage claims not “only in extraordinary situations,” but indeed in every instance where the device has received pre-market approval by the FDA.²²⁴ The fact that the FDA's position would leave injured consumers without a remedy is apparently not a matter of concern. According to the FDA, “[s]tate common law tort actions threaten the statutory framework for the regulation of medical devices,” because tort relief in the form of damage awards could pressure manufacturers to alter the device's design or to add warnings the FDA had not approved.²²⁵ The FDA also warned that “individualized redetermination of the benefits and risks of a product” in tort cases could harm the public health by “resulting in scientifically unsubstantiated warnings and underutilization of beneficial treatments.”²²⁶ These are the arguments that the FDA made in *Horn*, and they were endorsed by the panel majority.²²⁷

Courts should be leery of the FDA's pro-preemption campaign for three reasons. First, simply as a matter of administrative law, courts owe no deference to the agency's current view of the law, especially when it contradicts an interpretation the agency has held for more than twenty years and is reflected in a substantive agency regulation.²²⁸ Indeed, the Supreme Court recently rejected a similar effort by the Bush Administration to reverse field on a preemption issue but nonetheless claim that its new position is entitled to deference.²²⁹ In *Bates*, the Court noted that the Administration

“longstanding . . . presumption against preemption.” Margaret Jane Porter, *The Lohr Decision: FDA Perspective and Position*, 52 FOOD & DRUG L. J. 7, at 7, 10 (1997). Ms. Porter added

[g]iven the harsh implications of foreclosing all judicial recourse for consumers injured by defective medical devices, FDA does not believe that Congress intended to effect so sweeping change without even a comment. Rather, the agency believes that Congress intended to restrict preemption to positive enactments (for example, legislation or regulations) that apply to the marketing of medical devices within a state, and did not intend to preempt state tort remedies for injury to individual consumers.

Id. at 9.

224. Brief for the United States, *Kernats*, *supra* note 219, at 15.

225. *Horn*, 376 F.3d at 177-78 (quoting Letter Brief of Amicus Curiae United States, at 25-26, 2004 WL 1143720).

226. *Id.*

227. *Id.* at 177-80.

228. See, e.g., *United States v. Mead Corp.*, 533 U.S. 218, 228-32 (2001). *Mead* gives new weight to the rule that courts owe substantial deference to an agency's interpretation of a statute set forth in a regulation promulgated after notice and comment rulemaking. In contrast, *Mead* cautioned courts against giving deference to agency interpretations arrived at through less formal means. *Id.* at 234-35. Post-*Mead*, a court confronted with the FDA's current position on preemption would be bound to defer to the agency's regulation, which remains on the books, and may be modified or rescinded only through a formal rulemaking that addresses the comments submitted by interested parties. See generally 5 U.S.C. § 551(5) (2000) (defining “rulemaking” as the “agency process for formulating, amending, or repealing a rule”).

229. *Bates v. Dow Agrosiences LLC*, 125 S. Ct. 1788 (2005).

had changed its position on the preemptive scope of FIFRA, and gave no weight to the pro-preemption arguments in the agency's brief.²³⁰

Second, and more fundamentally, the FDA's new position cannot be squared with its long-standing preemption regulation, which the agency has not amended. The FDA's existing regulation states that preemption is limited to instances in which the FDA "has established specific counterpart regulations or there are other specific requirements applicable to a particular device" or class of devices.²³¹ The regulation also provides that the MDA "does not preempt State or local requirements of general applicability where the purpose of the requirements relates either to other products in addition to devices . . . or to unfair trade practices in which the requirements are not limited to devices."²³² The FDA has never questioned the continued validity of this regulation, but it has also never explained how its views can be reconciled with it. Perhaps for good reason. The thrust of the regulation, as the Court recognized in *Medtronic* and as the Solicitor General explained in *Kernats*, is to ensure that preemption occurs only when there are inconsistent, device-specific requirements imposed by both the FDA and the state — an occurrence that is an exception, not the rule, as the FDA now claims.²³³

Third, there is a serious cost to the FDA's pro-preemption campaign that should be considered as well. The press has covered the FDA's campaign extensively, questioning whether an agency that takes extraordinary measures to insulate from liability the industry it is supposed to regulate best serves the public's interest.²³⁴ From this perspective, the FDA's campaign

230. *Id.* at 1794 n.7, 1801.

231. 21 C.F.R. § 808.1(d).

232. *Id.* at § 808.1(d)(1).

233. The only effort the FDA makes to defend its pro-preemption provision in light of its regulation is to claim that pre-market approval constitutes a specific federal requirement because once approved, the device's "attributes are fixed in place, as they can be materially changed only with FDA approval." See Brief for United States as Amicus Curiae at 19-17, *Horn v. Thoratec, Inc.*, 376 F.3d 163 (3d Cir. 2004) (No. 02-4597), 2004 WL 1143720. But this argument is a non-starter. The same was true of the grandfathered device in *Medtronic*, and indeed all Class III medical devices; once approved by the FDA, a manufacturer may not alter a device's design without FDA approval. 21 C.F.R. §§ 807.81(a)(3)(I), 814.39(a) (2005).

234. The FDA's campaign to intervene in product liability litigation on behalf of medical device and pharmaceutical manufacturers has been widely covered in the press. For a representative sampling of articles, see, for example, Clune, *supra* note 211, at 1 n.1 (citing Robert Pear, *In a Shift, Bush Moves to Block Medical Suits*, N.Y. TIMES, July 25, 2004, at A1; Robert Cohen, *FDA Stepping Into Liability Lawsuits on Side of Drug Makers it Regulates*, THE SEATTLE TIMES, May 11, 2004, at A1; Patrick McGann, *FDA's Chief Lawyer Stands Up for the Big Guys*, LEWISTON MORNING TRIBUNE, July 31, 2004, at 10A; Anne C. Mulkern, *Watchdogs or Lapdogs? When Advocates Become Regulators President Bush Has Installed More Than 100 Top Officials Who Were Once Lobbyists, Attorneys or Spokespeople for the Industries They Oversee*, THE DENVER POST, May 23, 2004, at A1; Gary Young, *FDA Strategy Would Pre-empt Tort Suits: Does it Close Off Vital Drug Data?*, NAT. L.J., Mar. 1, 2004). Members of Congress were also troubled by the FDA's efforts to support industry in preemption cases. Representative Maurice Hinchey (D - NY) introduced

was not well-timed. In the past few years, the FDA has experienced perhaps its worst period of regulatory failure with medical devices. The irony is palpable. The FDA's pro-preemption story is that the FDA is perfectly capable of ensuring, single-handedly, safe and effective medical devices. Imposing tort liability on medical device manufacturers, the FDA argues, interferes with the agency's ability to protect the public health because the FDA alone should define the duties that device manufacturers must live up to. But the agency's shift in position has coincided with a stream of highly publicized recalls of defective medical devices, including stents, pacemakers, defibrillators, and infusion pumps.²³⁵ These defective products have exacted a serious toll on public health, and the publicity attending their removal from the market has undermined public confidence in the agency. This experience has shown that the FDA's rhetoric does not match its record. Regulation alone is far from an adequate guarantee of safety, which is why Congress did not intend to nullify state damages law when it enacted the MDA.

V. PREEMPTION IN A TIME OF REGULATORY FAILURE

In the debate over MDA preemption, the medical device industry is fighting to shed a discipline that state tort law imposes on its conduct and to avoid financial accountability for its mistakes.²³⁶ Tort liability serves two

legislation to cut \$500,000 from the budget of the FDA's Chief Counsel's office; the amount Rep. Hinchey estimated the FDA spent supporting industry in preemption litigation. 150 CONG. REC. H5598 (daily ed. July 13, 2004) (remarks of Rep. Hinchey).

235. See, e.g., Reed Abelson, *Boston Scientific Expands Recall of Troubled Stent*, N.Y. TIMES, Aug. 6, 2004, at C5 (recall of over 100,000 of Boston Scientific stents); Barnaby J. Feder, *J. & J. Recalls 300 Heart Stents After Defects Are Found in 6*, N.Y. TIMES, Jan. 14, 2005, at C5 (recall of over 300 Johnson & Johnson stents); Ben Harder, *Heart Device Recall; For Patients With Suspect Models, Tough Choices*, WASH. POST, June 28, 2005, at F1 (reporting effects of recall of nearly 50,000 Guidant defibrillators and over 100,000 Medtronic defibrillators); Ashley M. Heher, *Guidant Recalls Heart Devices; Defibrillator Supplier Cites Malfunction Risk*, WASH. POST, June 18, 2005, at D1 (reporting same recall of Guidant Defibrillator); Barry Meier, *Pacemakers by Guidant Have Flaw*, N.Y. TIMES, July 19, 2005, at C1 (recall of nine other models of Guidant defibrillators); *Company Recalls Blood Vessel Devices*, N.Y. TIMES, June 28, 2005, at C1 (recall of Boston Scientific vascular grafts); Associated Press, *Guidant Issues Second Defibrillator Warning*, L.A. TIMES C3, (June 25, 2005) (Guidant recall of defibrillators); Reuters, *FDA Classifies Recall by Guidant as Serious*, L.A. TIMES, July 23, 2005, at C3 (Guidant's defibrillator recall classified as most dangerous type by FDA); Gardiner Harris, *F.D.A. Orders Recall of Intravenous Pumps*, N.Y. TIMES, July 22, 2005, at A12 (Baxter Healthcare recall of all of its Colleague Volumetric Infusion Pumps because they may shut down unexpectedly); *Class I Recall Issued For Baxter Infusion Pumps*, 2 FDAnews Device Daily Bulletin (No. 144, July 22, 2005); *Medtronic Recalls Faulty Drug Infusion Pumps in UK*, 31 Devices & Diagnostics Letter (No. 24, June 14, 2004) (Medtronic infusion pumps recalled due to possible software problems); *Recalls Continue to Plague Guidant's CRM Line*, 32 Devices & Diagnostics Letter (No. 30, Aug. 1, 2005) (Guidant recalled twenty models of defibrillators and pacemakers).

236. See Robert J. Katerberg, *Patching the "Crazy Quilt" of Cipollone: A Divided Court Rethinks Federal Preemption of Products Liability in Medtronic, Inc. v. Lohr*, 75 N.C. L. REV. 1440, 1495 & n.343 (1997) (noting that "[t]he medical products industry has unsuccessfully lobbied Congress for legislation that would directly immunize manufacturers who complied with federal standards from products liability lawsuits."); see also Valerie Watnick, *Federal Preemption of Tort Claims Under FIFRA: The Erosion of A Defense*, 36 MICH. J.L. REFORM 419, 441 (2003) (explaining that "one of the congressional purposes of the MDA had been to reign in an industry in need of more, not less,

important and related functions unserved by regulation: tort liability compensates those injured by products found to impose an unjustified risk and, in so doing, it deters excessive risk-taking by forcing the risk-taker to absorb the costs that come with marketing a product that imposes an unjustifiable risk of harm. Because the functions served by tort law are a complement to, but not a substitute for, the functions served by regulation, the burden on proponents of preemption to demonstrate that Congress intended to remove the discipline of the tort system imposes should be high. For garden-variety regulatory statutes like the MDA, which assign regulatory primacy to federal agencies but do not address liability, that burden should be virtually insurmountable.

Once again, the MDA is a paradigmatic case. The idea that Congress, when it enacted the MDA, intended to displace tort law altogether is hard to reconcile with a number of considerations that are too often overlooked in MDA preemption litigation:

First, nothing in the MDA says that Congress intended to deprive consumers injured by defective medical products compensation. Unlike statutes like the Price-Anderson Act, the Vaccine Act, or the 9/11 Compensation Fund, the MDA provides neither a federal right of action nor a system of compensating injured parties.²³⁷ A finding of preemption simultaneously immunizes industry for its errors and deprives injured consumers of compensation that historically has been available.

Second, there is no preemption of state damage claims under the drug provisions of the Food, Drug and Cosmetic Act, to which the MDA is an amendment.²³⁸ Had Congress wanted to make such a dramatic change to existing law, it would have said so.²³⁹

Third, although it is generally referred to as a public health statute, the MDA is not designed to optimize public health. It is a licensing statute that trades off public health imperatives for the benefit of medical device manufacturers, as is illustrated by the following examples:

* The MDA does not instruct the FDA to approve only the “best” medical devices, or to determine whether there are better or more effective devices available.²⁴⁰ To the contrary, if a device meets the statutory tests of

oversight, and that a broad interpretation of the MDA’s preemptive scope would not further this legislative goal.”).

237. See 42 U.S.C. § 2210 (2000) (Price-Anderson Act); 42 U.S.C. §§ 300aa-1 to 300aa-34 (2000) (National Childhood Vaccine Injury Act of 1986); 49 U.S.C. § 40101 (Supp. 2004) (Air Transportation Safety and System Stabilization Act of 2001).

238. See Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-399 (2000).

239. See generally *Jones v. United States*, 526 U.S. 227, 228 (1999) (“Congress is unlikely to intend any radical departures from past practice without making a point of saying so.”).

240. Like many regulatory statutes, the MDA sets *performance* standards and does not impose *design* standards. This choice reflects a growing preference for non-prescriptive regulation that leaves the decision of how best to achieve statutory or regulation goals to the regulated entity. See

safety and efficacy, the FDA must approve it, even if there are better and safer products on the market, and even if the FDA knows that the device's design is not optimal. As the examples of recently-recalled products show, faulty devices are approved by the FDA in spite of the rigorous pre-market approval process.²⁴¹

* Devices are not "term limited." Devices are approved indefinitely. Once they are on the market they are not subject to periodic review, and they are not subject to withdrawal even if they are superseded by superior products. The MDA presumes that the market, and not FDA regulation, will weed out devices rendered obsolete by newer, safer, and more effective ones.

* The MDA does not require adequate reporting of problems with medical devices to the FDA; device manufacturers ordinarily file reports annually and those reports are not made available to physicians or the public.²⁴²

* The MDA gives the FDA only limited authority to deal with defective devices, and the FDA has invoked this authority sparingly. To order any kind of relief, the agency must determine that the device is not simply defective, but that it "presents an unreasonable risk of substantial harm to

generally Thomas O. McGarity, *Media-Quality, Technology, and Cost-Benefit Balancing Strategies for Health and Environmental Regulation*, L. & Contemp. Prob., Summer 1983, at 159, 162-64. For this reason, the presumption against preemption should be at its zenith when an agency's organic statute directs the imposition of performance standards. In those instances, by definition, the regulated entity retains a high degree of freedom in determining how best to meet the demands of regulation, and thus it is unlikely that tort liability will interfere with, much less conflict with, federal regulatory goals.

241. See, e.g., Abelson, *supra* note 235, at C5; Harder, *supra* note 235, at F1.

242. The MDA gives the FDA discretion to mandate reporting on medical devices. 21 U.S.C. § 360i (2000); see also *id.* § 360l (post-marketing surveillance authority). The FDA reporting requirements are set forth in 21 C.F.R. Part 803, and recently were strengthened by the FDA, effective July 2005. See Medical Device Reporting, 70 Fed. Reg. 9516 (Feb. 28, 2005) (to be codified at 21 C.F.R. pt. 803). Under these requirements, manufacturers have thirty days to report a defect that may be life threatening, and five days to report a defect that "necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health." *Id.* at 9520. "Baseline" reports that describe the number of devices sold and the performance of the devices are filed annually, and most of those reports are withheld because they are considered confidential business information. *Id.* at 9522; see Barry Meier, *F.D.A. Will Not Release Some Data on Heart Devices*, N.Y. TIMES, Aug. 6, 2005, at C3 (reporting that the FDA rejected a request under the Freedom of Information Act to obtain medical device reports); Barry Meier, *A Choice for the Heart; It's Easier to Get Data on a Car Than on a Medical Device*, N.Y. TIMES, June 23, 2005, at C1 (noting complaints by physicians that, in contrast to pharmaceutical products, there is no comparative data available on the safety, effectiveness, or reliability of medical devices). Manufacturers are required to report device malfunctions that, if they recur, could lead to serious injury or death. Records and Reports on Devices, 21 U.S.C. § 360i(a)(1)(B); Medical Device Reporting, 21 C.F.R. § 803.50(a)(2) (2005) (requiring manufacturers to file a report within thirty days when a device it has manufactured "malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur"). Manufacturers must also report, within five working days, events that suggest a "trend" requiring remedial action to protect public health. Medical Device Reporting, 21 C.F.R. § 803.53(a) (2005). And manufacturers are required to report "promptly" any "correction" of a medical device undertaken by the manufacturer to "reduce a risk to health posed by the device . . ." 21 U.S.C. § 360i(f)(1)(A); 21 C.F.R. § 806.10(a)(1).

public health.”²⁴³ As best as I could determine, the FDA has never exercised its power to recall a defective medical device, although it has used the threat of a recall to force device manufacturers to withdraw defective devices from the market.

The point of this list is not to critique the MDA. Rather, it is to show that the regulatory screen erected by the MDA is far from airtight. Devices that do more harm than good will continue to reach consumers. Even a well-intentioned and diligent FDA cannot prevent dangerous and defective devices from entering the marketplace and doing serious harm to consumers. Furthermore, once the FDA approval process has unleashed a dangerous device into the market, the FDA’s authority to address that situation is far from comprehensive.²⁴⁴ All of this was known to Congress when it enacted the MDA, and these limitations strongly support the proposition that Congress intended the MDA to operate against the backdrop of existing tort law, which provides an independent and important discipline on the market.

The same critique could be applied with equal force to any of the regulatory statutes that are now preemption battlegrounds. Indeed, if

243. 21 U.S.C. § 360h. Once the FDA determines that a device “presents an unreasonable risk of substantial harm to the public health,” it may require device manufacturers to notify health care providers and device recipients of the defect. *Id.* § 360h(a). In non-implanted devices, the agency can also order the company to repair, replace, or provide a refund. *Id.* § 360h(b). The agency also has authority, added to the MDA in 1992, to order a recall of defective devices after (1) finding that “there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death,” and (2) “providing [the device manufacturer] an opportunity for an informal hearing.” *Id.* § 360h(e)(1), (2). Insofar as I can determine, the FDA has never exercised its authority under this provision of the Act, although it has apparently threatened to invoke this provision to press manufacturers to undertake “voluntary” recalls. But the FDA generally relies on market forces to prompt the recall of dangerous, defective devices. Typical is the tragic case of Bjork-Shiley heart valves. Between 1979 and 1986, Shiley, Inc., a wholly-owned subsidiary of Pfizer, Inc., manufactured a human-implant heart valve known as the Bjork-Shiley convexo/concave heart valve (“valve”). See *Bowling v. Pfizer, Inc.*, 143 F.R.D. 141, 147 (S.D. Ohio 1992). “Somewhere between 50,000 and 100,000 of the valves were implanted in patients . . .” *Id.* By 1992, approximately 450 of these valves had fractured resulting in approximately 300 deaths. *Id.* The valves were continuing to fracture at a rate considerably higher than comparable valves, due to a serious design defect. *Id.* As a result, hundreds of heart patients had to undergo risky surgery to explant the defective valve and replace it with a safer one. *Id.* The Shiley valves were withdrawn by the company only after years of litigation, which culminated in a massive class action settlement. *Id.* at 147-48.

244. These concerns put aside perennial problems that all federal safety agencies have with underfunding and under-staffing. The FDA, which regulates one-quarter of the American economy, employs only around 9,000 people nationwide. Food and Drug Administration, <http://www.fda.gov/oc/opacom/fda101/sld015.html> (last visited Aug. 11, 2005). In addition to medical devices, these employees are responsible, among other things, for reviewing new drug applications, monitoring the safety of drugs on the market, inspecting drug manufacturing facilities, inspecting virtually all of the non-meat food products sold in this country (including imports), inspecting food processing facilities, regulating dietary supplements, overseeing the safety of the blood supply, and regulating biological and radiological products, as well as veterinary medicines and cosmetics. *Id.*

anything, the protections built into FIFRA,²⁴⁵ the National Traffic and Motor Vehicle Safety Act,²⁴⁶ and the Federal Boat Safety Act²⁴⁷ are less comprehensive than those in the MDA. All of these statutes embody trade-offs between public health concerns and the need to ensure a competitive marketplace that rewards innovation and quality. None of these statutes, standing alone, imposes a discipline on the marketplace sufficient to ensure a reasonable margin of safety, and nowhere in those statutes or their legislative histories does Congress suggest otherwise. These factors suggest that Congress enacted these statutes with the understanding that the background discipline of tort law would remain undisturbed.

VI. CONCLUSION

One way to bring the debate over preemption into sharp focus is to return for a moment to the tragic and premature death of Joshua Oukrop.²⁴⁸ Assuming that the FDA's approach prevails, Joshua's family has no recourse at all; his death will be a tragedy marked only by the personal loss to his family and friends. Any claim his family might want to bring against the device's manufacturer will be preempted. The manufacturer will escape financial responsibility to Joshua's family. And because the FDA rarely imposes financial sanctions against device manufacturers, it is likely that the manufacturer will incur no financial loss for the defect in the device that caused Joshua's death.²⁴⁹ Under the FDA's approach, the company has only weak financial incentives to withdraw a defective device from the market, little incentive to make changes to improve the device's safety, and almost no incentive to warn patients and physicians of possible defects. To be sure, new and better devices will, over time, supersede older and less efficient ones; but that is a consequence of market forces and not regulation. Nor do regulatory consequences necessarily flow from marketing a defective device. As noted above, the manufacturer had a duty to report Joshua's death to the FDA,²⁵⁰ a duty it apparently discharged.²⁵¹ Yet according to press reports,

245. Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y (2000).

246. National Traffic and Motor Vehicle Safety Act of 1966, 49 U.S.C. §§ 30101-30169 (2000).

247. Federal Boat Safety Act of 1971, 46 U.S.C. §§ 1451-1484 (2000).

248. See *supra* notes 5-6 and accompanying text.

249. The FDA does have criminal and civil sanctions available to punish manufacturers who fail to submit timely reports or otherwise fail to meet their regulatory obligations. The Food, Drug, and Cosmetic Act contains a provision governing "penalties," which permits the imposition of criminal and civil sanctions, including monetary penalties, for engaging in what the Act characterizes as "prohibited acts." See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331 (2000) (setting forth "prohibited acts"); Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 333 (setting forth penalties for committing prohibited acts). Recent press reports suggest that the FDA may have launched a criminal investigation to determine whether Guidant violated any law in the way it discharged its reporting duties with regard to this defibrillator. See Barry Meier, *Guidant Case May Involve Crime Inquiry*, N.Y. TIMES, Sept. 29, 2005, at C1.

250. 21 U.S.C. § 360i(a)(1)(A) (2000).

251. It is unclear whether the manufacturer reported earlier-detected failures with this device and whether it brought the severity of the risk of the failures to the FDA's attention. According to one press account, the manufacturer did submit reports of the device's malfunction to the FDA. But the company nonetheless continued to sell this model even after it had developed an improved model

although Guidant knew of the possible defect for three years prior to Joshua's death, it did not alert doctors and patients until Joshua died.²⁵² In the meantime, nearly 25,000 of these devices were implanted in other patients.²⁵³ And why not? Without the looming threat of tort liability, the company had little incentive — economic or regulatory — to do otherwise.²⁵⁴

Now assume that the FDA's preemption position is rejected, and that state damage claims are available to Joshua's family.²⁵⁵ They will likely sue, and if they prevail, the manufacturer will bear financial responsibility to the family. Moreover, the manufacturer will have powerful incentives to monitor the performance of its devices and make improvements to respond to possible imperfections and to keep pace with innovation. This dynamic is not a product of regulation. It is a product of the tort system. As the Court emphasized in *Bates*, private remedies that reinforce and strengthen federal standards enhance, rather than hinder, the functioning of federal regulation.²⁵⁶ State damages actions "may aid in the exposure of new

that did not pose a risk of short-circuiting. Barry Meier, *F.D.A. Will Not Release Some Data on Heart Devices*, N.Y. TIMES, Aug. 6, 2005, at B3. Nothing in the FDA's regulations appears to forbid this conduct by the manufacturer. Cf. 21 C.F.R. § 806.10 (2005) (requiring manufacturers to promptly report "corrections" made to medical devices, but not to remove uncorrected devices from the marketplace or to discontinue their sale).

252. See, e.g., Barry Meier, *New Report of Problems at Guidant*, N.Y. TIMES, July 30, 2005, at B1; Barry Meier, *Maker of Heart Device Kept Flaw From Doctors*, N.Y. TIMES, May 24, 2005, at A1.

253. Barry Meier, *Maker of Heart Device Kept Flaw From Doctors*, N.Y. TIMES, May 24, 2005, at A1.

254. To be fair to the company, it claims that the failure rate with this model defibrillator is on par with, or lower than, the failure rates of comparable devices. Barry Meier, *Maker of Heart Device Kept Flaw From Doctors*, N.Y. TIMES, May 24, 2005, at A1. But the company's eventual recall of the device, coupled with the announcement that it will pay for replacement surgery, suggests that the company may be worried about a higher incidence of failures in the future. Barry Meier, *New Report of Problems at Guidant*, N.Y. TIMES, July 30, 2005, at B13; Barry Meier, *Citing Flaws, Maker Recalls Heart Devices*, N.Y. TIMES, June 18, 2005, at A1. Moreover, the company's willingness to pay for replacement surgery suggests that the company may not be confident that courts will find personal injury claims by patients preempted. Barry Meier, *Guidant Agrees to Pay for Defibrillator Replacements*, N.Y. TIMES, June 17, 2005, at C2.

255. It is not far-fetched to suggest that with a robust tort system in place, Joshua might not have died. Recall that Guidant waited several years before notifying patients and physicians that this device contained a possible defect. Barry Meier, *F.D.A. Refuses to Release Some Data on Heart Devices*, N.Y. TIMES, Aug. 6, 2005, at B3. By that time, Guidant had produced a newer, defect-free, defibrillator. *Id.* Given that Joshua was an otherwise young and healthy patient, Joshua and his physician might well have decided that the risk of the device's failure outweighed the risk of additional surgery to replace the Guidant defibrillator with a safer model. The right of patients and physicians to make informed judgments about such matters would form the core of a failure to warn case brought by Joshua's parents. But under a pro-preemption approach to the MDA, even though a common-law failure to warn theory would likely parallel the FDA's reporting and notification regulations, it would be preempted. One consequence of such an approach, of course, is that manufacturers like Guidant have little economic incentive to notify patients and physicians of a possible defect.

256. *Bates v. Dow Agrosiences, LLC*, 125 S. Ct. 1788, 1802 (2005).

dangers associated” with devices, may prompt manufacturers of the FDA to decide that modifications are “required in light of the new information that has been brought” to their attention by litigation, and may “provide manufacturers with added dynamic incentives to continue to keep abreast of all possible injuries stemming from use of their product so as to forestall such actions through product improvement.”²⁵⁷

As the Guidant defibrillator recall demonstrates, there are sound reasons why the tort and regulatory systems operate in tandem and place separate, albeit reinforcing, disciplines on the market. When functioning well, a regulatory system prevents injury and ensures products on the market have a favorable risk-reward profile. But the tort system is vital because far too often there are gaps that our regulatory agencies — even those as effective as the FDA — cannot fill. Perhaps in a perfect world one could expect the FDA to have immediate access to data enabling it to pinpoint and solve problems like a wiring flaw in a defibrillator, a defective lead in a pacemaker, or faulty welds in heart valves (the defect with the Shiley valve).²⁵⁸ But that would be a world where the FDA never lacks the information, personnel, technical data and other resources needed to deal immediately with emerging safety hazards; where the agency acts as soon as it identifies a problem requiring a regulatory solution; where rules are updated swiftly to reflect needed design changes, technological advances or scientific knowledge; where companies quickly and candidly inform the FDA about the problems they identify; and where regulatory decisions are made free from political considerations — without pressure from regulated industry, congressional committees and the White House and the Office of Management and Budget. That is perhaps the world that some see, but it is not the world observed by those who regularly work with regulatory agencies.²⁵⁹ Nor is it the world that existed when Joshua Oukrop fell off his bicycle and died because his defibrillator malfunctioned.

257. *Id.* (quoting *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1541-42 (D.C. Cir. 1984)).

258. *See supra* notes 12, 243 and accompanying text (discussing the recall of defective Shiley heart valves).

259. For an extended discussion of this point, see David C. Vladeck, *Defending Courts: A Brief Rejoinder to Professors Fried and Rosenberg*, 31 SETON HALL L. REV. 631, 640 (2002).