The Preemption Pentad: Federal Preemption of Products Liability Claims after Medtronic [v. Lohr]

Robert B Leflar
Robert S. Adler

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ROBERT B LEFLAR* AND ROBERT S. ADLER**

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* Professor, University of Arkansas School of Law.
** Professor, Kenan-Flagler School of Business, University of North Carolina.
I. INTRODUCTION

In Medtronic, Inc. v. Lohr,\(^1\) the Supreme Court severely constrained the scope of the federal preemption defense in products liability actions for injuries caused by defective medical devices. The Court’s decision is likely to narrow the extent to which other federal health and safety laws can plausibly be said to bar state-law damage actions.

Preemption analysis, prior to Medtronic, stood in serious need of clarification. Most federal courts of appeals, for example, misinterpreted the medical device law’s preemption rules,\(^2\) and courts’ views of the preemptive effect of other regulatory laws has varied widely.\(^3\) Congress has taken no action, and is considering none, to address the general issue.\(^4\) Justice


The Ninth Circuit’s result in Kennedy v. Collagen Corp., 67 F.3d 1453 (9th Cir. 1995), cert. denied, 116 S. Ct. 2579 (1996), was compatible with Medtronic, but its reasoning differed. The Fifth and Eleventh Circuits’ reasoning, with respect to design defect claims only, corresponded roughly to that of the Supreme Court in Medtronic. See Feld v. Mentor Corp., 61 F.3d 431, 436-38 (5th Cir. 1995), vacated, 116 S. Ct. 2575, on remand, 95 F.3d 4 (5th Cir. 1996); Lohr v. Medtronic, Inc., 56 F.3d 1335 (11th Cir. 1995), aff’d in part and rev’d in part, 116 S. Ct. 2240 (1996).

3. See infra Part V.
4. Proponents of federal products liability bills in recent years have shied away from proposing sweeping, categorical preemption rules of the sort adopted by the federal courts of appeals listed supra in note 2. See infra notes 47-49 and accompanying text.

The proposed Product Liability Reform Act of 1997, S. 5, 105th Cong. (1997), for example, contains provisions that would preempt state law in several significant ways but would leave the core of state-law civil remedies for product-related injuries more or less intact. See id. § 102(b); H.R. 956, 104th Cong. § 102(b) (1996) (discussed in Cynthia C. Lebow, Federalism and Federal Product Liability Reform: A Warning Not Needed, 64 Tenn. L. Rev. 663 (1997)). By contrast, preemption rulings such as those listed supra note 2, had
Stevens’s opinion in *Medronic* illuminates the field as his prior effort in *Cipollone v. Liggett Group* did not.  

In this Article, we analyze the holding and reasoning of the *Medronic* case and propose a five-step approach, premised upon Justice Stevens’s method and consistent with Justice Breyer’s philosophy of statutory construction, that should simplify consideration of federal preemption issues in products liability cases. We illustrate this “preemption pentad” by suggesting how it would apply to products regulated under the drug and medical device laws, the motor vehicle safety law, the Consumer Product Safety Act and the Federal Hazardous Substances Act. The five steps are as follows:

1. **Express preemption:** If Congress has explicitly determined that the specific state-law claim is preempted, that determination governs.

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the Supreme Court endorsed them in *Medronic*, would have had the effect of attacking the core itself, by completely foreclosing many types of claims for entire categories of regulated products—potentially a far more drastic change in the law.

Accordingly, rather than analyzing the substantive and procedural preemptive consequences of proposed federal legislation, a project capably handled in the preceding article by Lebow, in this article we take the laws as they stand after *Medronic*, and offer a method of analyzing the preemption issues that in fact are likely to arise in future products cases.

5. Justice Stevens wrote for a unanimous Court with respect to some claims, and for a five-justice majority as to the others. See infra note 55 and accompanying text. However, only three other Justices joined Justice Stevens’s opinion in its entirety. Justice Breyer disagreed with part of it for reasons unnecessary to his conclusion, as discussed infra at notes 88-95 and accompanying text. No fully articulated approach to preemption now commands a majority of the Court.

7. See infra notes 28-33 and accompanying text.
9. See infra notes 88-95 and accompanying text.
10. See infra notes 126-37 and accompanying text.
11. See infra notes 138-208 and accompanying text.
12. See infra notes 209-42 and accompanying text.
13. See infra notes 248-67 and accompanying text.
14. See infra notes 268-80 and accompanying text. Another area in which preemption defenses have become common is state-law damage actions alleging injury from pesticides. The Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136a-136y (1994) ("FIFRA"), is said to have preemptive effect on many of these claims. FIFRA preemption is outside the scope of this Article.
Congressional intent is to be assessed using standard tools of statutory interpretation.

(2) Express non-preemption: Likewise, if Congress has explicitly determined, for example by a savings provision, that the specific state-law claim is not precluded, preemption shall not apply. Absent an express preemption or non-preemption determination, go to (3).

(3) Dictate preemption: If Congress, or a regulatory agency validly exercising delegated authority, in effect tells the product seller: "You must make or market your product in this particular fashion and no other, or we will ban your product, jail you or fine you," state-law claims alleging injury arising from a product feature complying with the federal dictate are precluded. If no such dictate exists, go to (4).

(4) Federal acquiescence: If Congress or the regulatory agency in effect tells the product seller: "You may make and market your product if it meets these minimum federal criteria or obtains our stamp of approval," state-law claims alleging injury arising from a product legally made and marketed under this standard of acquiescence may go forward if state law allows. (The typical state-law rule is that compliance with statutory or regulatory safety standards is non-conclusive evidence of due care or nondefectiveness, but conclusive effect is occasionally given to compliance with certain federal standards.)

(5) Violation of federal law: State-law claims alleging injury arising from a violation of a federal rule or standard, whether general or particular, are never preempted, and the fact of the violation is given the evidentiary weight that state law allows.

II. PRE-MEDTRONIC PRODUCTS LIABILITY PREEMPTION: THE MANTRA, CIPOLOONE, AND THE AFTERMATH

A. The Mantra

Every court addressing a preemption issue recites, like a mantra, a formulaic incantation of black-letter law. The mantra is not much help in deciding cases—witness the disarray among the pre-Medtronic device


17. Some states hold that violation of a safety statute or regulation constitutes negligence or defectiveness per se. Other jurisdictions consider a violation to raise a presumption of negligence or defectiveness; still others find a violation to be mere evidence of negligence or defectiveness. See generally KEETON ET AL., supra note 15, § 36.
decisions—but its sacred quality requires its repetition at the outset of any treatment of the subject. The following from Cipollone is typical:

Article VI of the Constitution provides that the laws of the United States "shall be the supreme Law of the Land; ... any Thing in the Constitution or Laws of any state of the Contrary notwithstanding." ... Consideration of issues arising under the Supremacy Clause "starts with the assumption that the historic police powers of the States [are] not to be superseded by ... Federal Act unless that [is] the clear and manifest purpose of Congress." Accordingly, "[t]he purpose of Congress is the ultimate touchstone" of pre-emption analysis.

Congress’ intent may be "explicitly stated in the statute’s language or implicitly contained in its structure and purpose." In the absence of an express congressional command, state law is pre-empted if that law actually conflicts with federal law, ... or if federal law so thoroughly occupies a legislative field "as to make reasonable the inference that Congress left no room for the States to supplement it."

The second paragraph of the mantra is taken by courts and commentators to divide all preemption into three parts: "express" preemption and two kinds of "implied" preemption, "conflict" preemption and "field" preemption. Products liability law, growing out of the common law of tort and contract, has such an anchor in state law that with rare exceptions, it is difficult to argue plausibly that Congress has in any instance inferentially occupied the entire field. Therefore, in the products context, the argument in each case typically reduces to whether either "express" or "conflict" preemption applies.

B. Cipollone v. Liggett Group

Prior to the mid- to late 1980s, few courts held that federal preemption barred any product liability claims. Then in 1984 in Silkwood v. Kerr

18. Cipollone, 505 U.S. at 516 (citations omitted) (quoting various Supreme Court cases).


McGee Corp.,22 the Supreme Court rejected preemption as a basis for overturning a punitive damage judgment.23 Ironically, Silkwood had the effect of calling manufacturers’ attention to the possibility that preemption could serve as a defense to tort claims. The theory met with some success, beginning in the mid-1980s, in several cases in which plaintiffs challenged an aspect of a product that complied with an explicit federal rule. These claims chiefly involved cigarette24 and pesticide labeling25 and vehicle crashworthiness.26 Courts began holding medical device claims to be preempted shortly thereafter.27

The Supreme Court’s 1992 decision in Cipollone attempted, but failed, to clarify the application of the preemption defense. The Court’s judgment distinguished between the federal cigarette labeling act enacted in 196528

(noting courts’ early lack of sympathy to preemption claims in product liability cases, “particularly those that would broadly invalidate state common law product liability laws”).

A rare early example of a court’s holding a products liability claim to be federally preempted was City of Chicago v. GMC, 467 F.2d 1262 (7th Cir. 1972) (Clean Air Act emission standards preempted common-law design defect theory on tamper-proof emission control devices).


23. Rejecting the contention that the federal nuclear safety laws preempted a state punitive damage award, the Court stated: “It may be that the award of damages based on the state law of negligence or strict liability is regulatory in the sense that a nuclear plant will be threatened with damages liability if it does not conform to state standards, but that regulatory consequence was something that Congress was quite willing to accept.” Id. at 256.


and that enacted in 1969, finding the later law to preempt some state-law damages actions but the earlier one to have no preemptive effect whatsoever.  

The rationale for the distinction between the two laws was less than clear. Both laws prescribed a specific warning label for cigarette packages. Both contained an express preemption provision banning further state-law warning requirements for labeling and advertising complying with the congressional prescription. The 1969 law's preemption provision stated, "No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." Justice Stevens, writing for a plurality of four, concluded that the phrase "requirement or prohibition . . . imposed under State law" could refer not only to positive enactments by legislatures and agencies but also to common-law damage actions. By contrast, the same plurality took the preemption provision of the 1965 Labeling Act—"No statement relating to smoking and health, other than the statement required by § 4 of this Act, shall be required on any cigarette package"—to refer exclusively to "positive enactments by legislatures or administrative agencies that mandate particular warning labels," not to damage actions. The judgment of Cipollone, then, necessarily means that the congressional interdict against states "requiring" a non-standard warning label sometimes encompasses only state laws and regulations, and sometimes extends to tort

31. 1965 Smoking Act, supra note 29, at § 5(b) (emphasis added).
32. Cipollone, 505 U.S. at 522. Justice Scalia, joined by Justice Thomas, concluded that both the 1965 and the 1969 acts had preemptive effect. Id. at 544-56 (Scalia, J., concurring in the judgment in part and dissenting in part). Their votes tipped the scale to preempt the post-1969 claims, so that a majority of the court concluded that the word "requirements" as used in the 1969 law applied to common-law claims.
Justice Stevens's opinion acknowledged that the 1969 Smoking Act's legislative history "suggest[ed] that Congress was primarily concerned with positive enactments by States and localities." Id. at 521; see id. at 539-42 (Blackmun, J., concurring and dissenting) (no suggestion in legislative history that Congress intended to eliminate judicial recourse for those injured by tortfeasors). This is not surprising, because no court to our knowledge had held any common law products liability claim federally preempted prior to 1969. The idea, at the time, would have been entirely hypothetical.
33. 1965 Labeling Act, supra note 28, at § 5(a) (emphasis added). Section 5(b) contained similar language relating to requirements for cigarette advertising. See id. § 5(b).
34. Cipollone, 505 U.S. at 518-20. The votes of Justices Blackmun, Kennedy and Souter against preemption any claims provided the deciding votes with regard to the 1965 Labeling Act claims.
judgments as well. However, Cipollone failed to make clear how courts are to tell when Congress has done the one and when the other.

Justice Stevens’s plurality opinion reasoned that the 1969 law’s terms preempted some types of state-law claims but not others. (Failure to warn claims and advertising-based misrepresentation claims were preempted; breach of express warranty, general misrepresentation, manufacturing and design defect, and conspiracy claims were not.)35 Lacking clear guidance on the proper method of applying preemption principles, many courts addressing preemption defenses under other regulatory statutes strayed far afield.

C. Cipollone’s Aftermath

The Cipollone Court’s interpretation of the word “requirement” in the 1969 Smoking Act’s preemption provision as encompassing some state-law damage claims provided a springboard for subsequent courts to hold injured consumers’ claims preempted under other statutes.36 (Curiously, these courts generally ignored Cipollone’s contrary treatment of the word “required” in the 1965 Labeling Act.) In many cases, the courts adopted aggressive interpretations of the statutory preemption provisions that dismissed all claims filed by injured consumers, leaving them without judicial remedies.37 Under the medical device law alone, courts barred claims in dozens of cases,38 including allegations of injuries from product risks that the FDA had never considered,39 false manufacturer submissions

35. Id. at 523-30. No rationale for this partition of valid and invalid claims gained the support of a majority.

36. See ALLEE, supra note 21, § 8.09(3), at 8-69 to 8-75 (listing cases under various health and safety laws in which the courts barred tort claims based on the laws’ preemption clauses).

37. See Robert S. Adler & Richard A. Mann, Preemption and Medical Devices: The Courts Run Amok, 59 Mo. L. Rev. 895, 919-921 (discussing the broad nature of the post-Cipollone preemption rulings); Mary J. Davis, The Supreme Court and Our Culture of Irresponsibility, 31 Wake Forest L. Rev. 1075, 1130 (1996) (characterizing these rulings as a “knee-jerk reaction to the ambiguity of Cipollone’s analysis and result”).

38. According to the Executive Vice-President of the Health Industry Manufacturers Association, in a period of roughly four years, medical device manufacturers successfully invoked preemption “in more than 70 formal judicial decisions . . . and to secure any number of favorable settlements.” Ted Mannen, 18 MEDICAL DEV. AND DIAG. IND. 30, 32 (Oct. 1996).

39. See, e.g., Cameron v. Howmedica, 820 F. Supp. 317, 321 (E.D. Mich. 1993); Bravman v. Baxter Healthcare Corp., 794 F. Supp. 96 (S.D.N.Y. 1992). In Bravman, the court found preemption of state common law tort claims regarding excessive noise associated with defendant’s heart valve even though there was a lack of any FDA regulation or FDA consideration of noise when the agency reviewed the device. Bravman, 794 F. Supp. at 101-04. In Cameron, the court preempted state-law claims relating to an allegedly defective
to the government,\textsuperscript{40} and even injuries resulting from the defendant's criminal fraud.\textsuperscript{41} Similar rulings barred claims regarding products regulated under the motor vehicle safety law\textsuperscript{42} and the laws enforced by the Consumer Product Safety Commission.\textsuperscript{43}

Had these courts' expansive readings of \textit{Cipollone} been upheld in \textit{Medtronic}, the case would have marked a dramatic departure from prior law. Interpreting preemption clauses in federal health and safety laws as barring common law tort claims not only would have required abandoning the general presumption against preemption,\textsuperscript{44} but also would have elevated federal safety standards to a loftier position than the courts historically have been willing to recognize. Traditionally, the courts have treated federal safety standards as \textit{minimum} requirements for companies, but not as dispositive of all safety concerns.\textsuperscript{45} That is, safety standards have general-


\textsuperscript{40} See, e.g., \textit{Reeves v. AcroMed Corp.}, 44 F.3d 303 (5th Cir.), \textit{cert. denied}, 115 S. Ct. 2251 (1995); \textit{Klein v. Biscup}, 673 N.E.2d 225 (Ohio Ct. App.), \textit{appeal disallowed}, 667 N.E.2d 987 (Ohio 1996). The defendant manufacturer in both cases was the maker of a metal spinal implant. Having twice been rebuffed by FDA in its attempts to have the product cleared for marketing as a spinal implant, the defendant then removed from the proposed product labeling all language indicating that the device was intended for use on the spine. Once FDA allowed the device on the market for a different use, defendant then sold the product as a spinal implant. The Reeves court held that, despite allegations of the defendant's withholding of material information from the agency, the medical device law's preemption clause barred plaintiff's failure-to-warn claim. \textit{Reeves}, 44 F.3d at 306-07; the \textit{Klein} court held all plaintiff's claims were preempted. \textit{Klein}, 673 N.E.2d at 229-30.

\textsuperscript{41} See, e.g., \textit{Talbot v. C.R. Bard, Inc.}, 865 F. Supp. 37 (D. Mass. 1994), \textit{aff'd}, 63 F.3d 25 (1st Cir. 1995), \textit{petition for cert. dismissed}, 116 S. Ct. 1892 (1996). In that case, notwithstanding that the defendant manufacturer had earlier pleaded guilty to 391 felony charges involving the testing, production, and distribution of its angioplasty catheters, the court determined that the medical device law preempted an injured consumer's tort claims against the manufacturer. \textit{Id.} at 52-53. The court did so despite the submission of an amicus curiae brief from FDA arguing that preemption should not apply in such a case.

\textsuperscript{42} See \textit{infra} note 218 and accompanying text.

\textsuperscript{43} See \textit{infra} note 257 and accompanying text.

\textsuperscript{44} See \textit{supra} text accompanying note 18 (quoting \textit{Cipollone}, 505 U.S. at 516); see also \textit{Hillsborough County v. Automated Med. Labs.}, 471 U.S. 707, 715 (1985).

\textsuperscript{45} The classic view of federal safety standards has always been that they constitute some evidence of due care, but do not necessarily preclude all claims. See \textit{RESTATEMENT (SECOND) OF TORTS} § 288C (1965) ("Compliance with a legislative enactment or an administrative regulation does not prevent a finding of negligence where a reasonable man would take additional precautions."); \textit{ALDER, supra} note 21, § 8.09(1), at 8-62 to 8-65 (citing cases). In fact, compliance with a federal standard has not stopped courts from imposing even punitive damages in compelling cases. See, e.g., \textit{Dorsey v. Honda Motor Co.}, 655 F.2d 650 (5th Cir. 1981), \textit{modified}, 670 F.2d 21, \textit{cert. denied}, 459 U.S. 880 (1982); \textit{Gryc v.}}
ly been viewed as "stung swords" for plaintiffs, but "weak shields" for defendant-manufacturers.46

Moreover, an aggressive interpretation of Cipollone would have constituted the de facto imposition on the states of a "government standards" defense,47 despite numerous unsuccessful efforts in recent years to enact federal product liability legislation with such a provision.48 In other words, it would have accomplished "tort reform" of vast proportions without legislative action.49

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48. Beginning in the early 1970s, members of Congress have introduced legislation that would establish a "government standards" defense. None of these legislative initiatives has passed. In recent years, proponents of a government standard defense have scaled back their proposals at the federal level simply to bar punitive damages for products having premarket approval from the FDA or the FAA. See *Hearings on S. 1400 Before the Subcomm. on the Consumer of the Senate Comm. on Commerce, Science, and Transportation*, 101st Cong. 315 (1990). None of these proposals passed the Congress.

Neither of the major product liability bills introduced in this Congress or the last contained even a watered-down version of the "government standards" defense. No doubt this fact reflects the lack of congressional support for such a controversial approach. See *Product Liability Reform Act of 1997*, S. 5, 105th Cong. (1997); *Common Sense Product Liability Legal Reform Act of 1996*, H.R. 956, 104th Cong. (1996).

49. Jeff Kimbell, Executive Director of the Medical Device Manufacturers Association, said shortly before Medtronic was decided: "If the Supreme Court affirms the preemption, it could go a long way toward achieving tort reform without a single vote from this Congress or the next Congress." *Brief for Respondents at 41*, Medtronic v. Lohr, 116 S. Ct. 2240 (1996) (Nos. 95-754, 95-886) (quoting Jeff Kimbell); see *Manns*, supra note 38, at 32 (noting that preemption under the Medical Device Amendments "was a unique and powerful legal tool—a bullet that, for many device companies, packed far more magic than the widely heralded but politically untenable liability reforms introduced in the 104th Congress").
III. THE MEDTRONIC DECISION

Lora Lohr’s cardiac pacemaker failed in 1990, resulting in a “complete heart block” and requiring her to undergo multiple subsequent surgeries.\(^5\) The Lohrs’ action against the manufacturer, Medtronic, claimed that the pacemaker and its lead—the wire connected to the pacemaker that delivers an electrical impulse to the heart to steady the heart’s rhythm—were defective in design, materials, and assembly.\(^5\) They also claimed that Medtronic had failed to warn her or her physicians of the product’s tendency to fail in life-threatening fashion, despite knowledge of prior product failures.\(^5\) On appeal of a defense summary judgment\(^5\) to the Eleventh Circuit, that court held the Lohrs’ manufacturing defect and failure-to-warn claims to be preempted, but allowed the design defect claim to proceed.\(^5\) The Supreme Court, per Justice Stevens, concluded that none of the Lohrs’ claims was preempted. Justice Stevens’s specific analysis of the medical device law’s preemption provision, with which we agree, was joined by three other justices.\(^5\) No fully articulated reading of the preemption provision gained the support of a majority of the Court.

Pacemakers and leads are regulated by FDA as “Class III devices”\(^5\) under the Medical Device Amendments of 1976.\(^5\) Class III devices are the most risk-laden of the vast array of products regulated under this law.\(^5\)

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51. Id.
54. Medtronic, 56 F.3d at 1352.
55. Justices Kennedy, Souter, and Ginsburg joined Stevens’s opinion. Justice Breyer, whose vote gave the Lohrs their majority with regard to some claims, concurred in part and in the judgment, Medtronic, 116 S. Ct. at 2259-62 (Breyer, J., concurring in part and concurring in judgment). Justice O’Connor, writing for the rest of the Court, agreed that the claims of defective design and violation of federal requirements were not preempted, but argued that some of the manufacturing defect and failure-to-warn claims should be barred. Id. at 2262-64 (O’Connor, J., concurring in part and dissenting in part); see infra notes 85-88 and accompanying text.
58. Among the three statutory classes of medical devices, class III devices are those which “support[] or sustain[] human life or . . . prevent[] impairment of human health, or present[] a potential unreasonable risk of illness or injury.” 21 U.S.C. § 360c(b)(1)(C) (1994).
New Class III devices, in theory, must obtain premarket approval from the FDA upon submission of data satisfying the agency that there is a "reasonable assurance of . . . safety and effectiveness," a process modeled after FDA's approval process for new drugs. However, an expansive grandfather clause in the medical device law permits most Class III devices to be sold without going through the premarket approval process. New-model devices may be marketed simply by notifying FDA of intent to market at least 90 days prior to marketing, and by demonstrating to the agency the new product's "substantial equivalence" to a "predicate device"—one that was already on the market when the law was passed in 1976, or that has itself received a "substantial equivalence" determination. Most Class III devices on the market today, as well as the pacemaker at issue in Medtronic, reached the market through this quicker, less rigorous regulatory procedure.

The medical device law contains ambiguous preemption language susceptible to the same varying interpretations as the language the Court wrestled with in Cipollone. However, close attention to the provision's wording and to the context in which it was enacted demonstrates that Justice Stevens was correct in refusing to regard it as preempting state-law damage actions. The law provides:

Except as provided in subsection (b) of this section, no State or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement—
(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

Subsection (b) authorizes the FDA to grant states and political subdivisions, upon application to the agency, exemptions from subsection (a)'s preemptive

59. Id.
61. This premarket notification process is known as the "§ 510(k) process" after the section in the original law which authorized it. 21 U.S.C. § 360k (1994). For a description of the workings of the § 510(k) premarket notification process, see Leflar, supra note 60, at 27-34, 46-58. The process was given explicit statutory authorization in the Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4515 (1990).
62. Medtronic, 116 S. Ct. at 2247-48, and authorities cited therein. Although the Medtronic decision addressed a device marketed on the basis of a "substantial equivalence" determination, the decision has important implications for products marketed under other regulatory tests as well. See infra Part V.
effect, if the state or local government requirement is more stringent than the federal or is required by compelling local conditions.64

The preemption section as a whole was Congress's response to the situation prevailing in the mid-1970s, when public concerns about quality problems with then-unregulated medical devices such as the Dalkon Shield, intraocular lenses, and cardiac pacemakers led some states to begin enacting laws to afford the consumer protection that FDA was then legally unempowered to provide.65 At the time of the enactment of the medical device law, at least 13 states had laws and regulations providing for varying degrees of control over devices.66 Congress was aware of these laws, the most comprehensive of which was California's Sherman Law,67 and viewed

64. Section 360k(b) reads:
Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—
(1) the requirement is more stringent than a requirement under this Act which would be applicable to the device if an exemption were not in effect under this subsection; or
(2) the requirement—
(A) is required by compelling local conditions, and
(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this Act.


We are taking seriously here the principle of statutory interpretation that "the text be read in its contemporary context." See Stevens, supra note 8, at 1379.

FDA preemption decisions on these laws, and on state laws enacted after the Medical Device Amendments became effective, are set out at 21 C.F.R. §§ 808.53-808.101 (1996).
them as useful in some circumstances; but Congress also recognized the possibility that these laws' differing requirements might burden interstate commerce. Congress therefore set up a clearance system by which states with laws at least as strict as federal law could continue to enforce them with FDA's permission, while other state laws would be preempted. The framework for that clearance system was set out in subsection (b) of the preemption provision.

In contrast to the specific attention Congress gave to the need for a degree of uniformity in the face of varying state laws regulating devices, the legislative history of the Medical Device Amendments is devoid of any mention of varying state-law civil damage judgments as a basis for preemption. This fact is unsurprising: as noted above, at the time of the device law's enactment, the near-universal rule was that compliance with government standards was mere evidence of due care or nondefectiveness in tort actions. Judgments against manufacturers of various FDA-approved products were by no means rare, and no one suggested that they be barred. As Justice Stevens correctly observed: if Congress intended to preempt traditional common-law remedies, "its failure even to hint at it [in the legislative history] is spectacularly odd."

We emphasize the setting in which the preemption provision was enacted because of its importance in interpreting the key term "requirement." The word appears three times in subsection (a) of the preemption section, six times in subsection (b), and 80 times in the Medical Device Amendments of 1976 as a whole. The conclusion that "requirement" in


69. 21 U.S.C. § 360k(b) (1994), quoted in supra note 64.
71. Surely a furor would have been aroused by the very suggestion that Class III medical devices should receive an exemption from products liability litigation while new drugs, subject to similar regulatory scrutiny from the same agency, should remain under the standard tort law regime.
72. Medtronic, 116 S. Ct. at 2253 & n.13. Justice Stevens's Shakespeare Canon essay noted that skepticism is justified when a proposed reading of a statute "appears to make a major change in the law when the legislative history reveals a deafening silence about any such intent." Stevens, supra note 8, at 1382. As Sherlock Holmes reasoned in solving the mystery of a stolen racehorse, sometimes it is the absence of the commonplace that provides the telling clue. Id. at 1381-82 & n.41.
73. See supra note 64.
74. In addition to the nine instances above, the words "requirement" or "requirements" appear in the following provisions of the 1976 law, invariably with reference solely
this law includes state tort judgments hinges on the implausible postulate that at its first occurrence in subsection (a), the word carries a different meaning than in any of its other occurrences, 75 a meaning contradicted by the nature of the problem upon which Congress was focusing when it enacted the law.

In subsections (a)(1) and (a)(2) "requirement" clearly refers only to legislative and administrative directives—"requirements applicable under this chapter," i.e. the law itself and FDA-promulgated implementing regulations—and not to state tort judgments. In subsection (b), "requirement" must likewise refer only to legislative or administrative directives. The mechanism mandated by Congress for obtaining FDA approval of state requirements varying from federal ones—formal application by a state or locality—is a mechanism that reasonably can be invoked only with regard to legislative measures, or to administrative rulemaking of a legislative nature. It is irrational to suppose that a governor, state attorney general, mayor, or county executive must apply to the Commissioner of Food and Drugs for approval of a jury verdict or other personal injury judgment. 76 "Requirements" in the medical device law, considered in context, cannot reasonably be thought to include state-law damage judgments.

75. As the Court had just noted in Commissioner v. Lundy, 116 S. Ct. 647 (1996), "the interrelationship and close proximity of these provisions . . . present a classic case for application of the normal rule of statutory construction that identical words used in different parts of the same act are intended to have the same meaning." Id. at 655 (quoting Sullivan v. Sraap, 496 U.S. 478, 484 (1990) (citations omitted)); see Adler & Mann, supra note 37, at 926 ("That Congress would adopt two separate meanings of a word within one section strikes us as highly improbable."); Stevens, supra note 8, at 1376 ("The second canon of statutory construction . . .: 'Read the entire statute.'") (emphasis in original).


Every FDA regulation granting or denying an exemption from § 521 preemption has addressed the effect of either state legislation affecting devices, see 21 C.F.R. §§ 808.51-808.101 (1996); 62 Fed. Reg. 7390, 7394-95 (Feb. 19, 1997) (proposing 21 C.F.R. §§ 808.51, 808.52, 808.54), or state administrative regulations affecting devices, see 21 C.F.R. §§ 808.80(b), 808.82(a)(2), (b)(2) (1996). No FDA preemption regulation has addressed state-law damage actions.
The medical device law also contains a limited savings clause, further indicating that preemption of state law actions was not part of the congressional design. The law authorizes FDA to issue orders requiring manufacturers and distributors to notify doctors and patients about medical devices presenting an unreasonable risk of harm, and to repair, replace, or refund the price of defective devices. The same section continues: “Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law.” Though this savings clause is circumscribed in its practical impact—FDA has issued few orders under the provision in question—its existence lends additional support to the conclusion that Congress assumed device firms would remain civilly liable for device-related defects.

FDA, interpreting the statute, has likewise taken a restrictive view of the scope of its preemption provision. Concluding that state and local requirements of general applicability are not preempted, the agency holds that only a state’s “substantive requirement for a specific device” might be preempted, and then only if FDA has established “specific counterpart regulations or . . . other specific requirements applicable to a particular device.” The agency’s position, as recently reiterated by FDA Chief

77. 21 U.S.C. § 360h(a), (b) (1994).
78. Id. § 360h(d).
79. For example, a firm’s compliance with an FDA order to notify doctors and patients about a dangerous characteristic of the firm’s device would not necessarily preclude an injured patient’s failure-to-warn claim, if the firm failed to communicate the risk with reasonable promptness or emphasis.

Some lower courts have been confused by an FDA regulation, 21 C.F.R. § 808.1(b) (1996), providing that a state “court decision” might be subject to preemption under the Medical Device Amendments. See, e.g., Slater v. Optical Radiation Corp., 961 F.2d 1330, 1331 (7th Cir.) (Posner, J.), cert. denied, 506 U.S. 917 (1992). Read in context, it is evident that the term “court decision” refers to judicial decrees enforcing or interpreting state legislative or administrative rules, not state-law damage actions. As FDA explained in the preamble to the proposed regulation, when considering requests for exemption from preemption, the agency “must know whether the statute, rule, or regulation has been subject to judicial or administrative interpretations that give it legal meanings in the State or political subdivision that are not readily apparent from the face of the document.” 42 Fed. Reg. 30,383, 30,385 (1977) (emphasis added); accord 43 Fed. Reg. 18,661, 18,663 (1978); see Medtronic, Inc. v. Commissioner, 116 S. Ct. at 2258-59 (plurality opinion); Kennedy v. Collagen Corp., 87 F.3d 1453, 1461-62 (9th Cir. 1996) (Reinhart, J., concurring); Adler & Mann, supra note 37, at 938-93 & nn. 177-78.
Counsel Margaret Porter, is that Congress "did not intend to preempt state
tort remedies for injury to individual consumers."\textsuperscript{82} FDA regulation and
state tort liability, in the agency’s view, "usually operate independently, each
providing a significant, yet distinct, layer of consumer protection."\textsuperscript{83} As
five justices agreed in Medronic, FDA’s interpretation of the statute it
enforces is properly given substantial weight due to the agency’s “special
understanding of the likely impact of both state and federal requirements,
as well as an understanding of whether (or the extent to which) state
requirements may interfere with federal objectives."\textsuperscript{84}

Contrary to the reading of “requirements” implacably compelled by the
statute’s express language in the context of the law’s structure, legislative
history, and interpretation by the agency charged with its enforcement,
Justice O’Connor (writing for four justices) concluded that “state common-
law damages actions do impose ‘requirements’ and are therefore preempted
where such requirements would differ from those imposed by the [medical
device law].”\textsuperscript{85} Drawing on Justice Stevens’s interpretation of the 1969
Smoking Act’s phrase “no requirement or prohibition” in his plurality
opinion in Cipollone,\textsuperscript{86} Justice O’Connor argued that “the general under-
standing of common-law damages actions” is that they “operate to require
manufacturers to comply with common-law duties.”\textsuperscript{87} Justice Breyer, in
a short discussion unnecessary to his conclusion regarding the outcome of
the case, said he “basically agree[d].”\textsuperscript{88} Neither O’Connor nor Breyer, in
their respective discussions of this issue, once addressed the medical device
law’s textual structure or legislative history, or the law’s relationship to
then-existing legal doctrine unquestionably permitting state-law tort claims
against sellers of defective FDA-approved products.

These Justices’ failure to employ standard techniques of statutory
interpretation is highly significant because it evidences a result-oriented
jurisprudence—a willingness (to use the standard pejorative) to “legislate
from the bench.”\textsuperscript{89} Justice O’Connor’s “general understanding of common-

\textsuperscript{82} Porter, supra note 80, at 9.
\textsuperscript{83} Id. at 11.
\textsuperscript{84} Medronic, 116 S. Ct. at 2260 (Breyer, J., concurring in part and concurring in
judgment); id. at 2255-57 (Stevens, J., opinion of the Court).
\textsuperscript{85} Id. at 2262 (O’Connor, J., concurring in part and dissenting in part). Chief
Justice Rehnquist and Justices Scalia and Thomas joined her opinion.
\textsuperscript{86} See supra note 32 and accompanying text.
\textsuperscript{87} Medronic, 116 S. Ct. at 2262-63. Justice O’Connor made no mention of Justice
Stevens’s contrary interpretation of the word “required” in the 1965 Labeling Act. See supra
note 33 and accompanying text.
\textsuperscript{88} Medronic, 116 S. Ct. at 2259 (Breyer, J., concurring in part and concurring in
the judgment).
\textsuperscript{89} See ROBERT S. BORK, THE TEMPTING OF AMERICA 11 (1990) (criticizing activist
judges for their tendency to “legislate policy from the bench”); The Presidential Debate:
Transcript of the Second Debate Between Bush and Dukakis, N.Y. TIMES, Oct. 14, 1988, at
law damages actions [as] requiring manufacturers to comply with common-law duties is a recent one, post-dating Silkwood and certainly post-dating the enactment of the Medical Device Amendments. In ascribing to Congress a fictive purpose to preempt state-law damage actions, Justice O'Connor paid disingenuous homage to the principle of primacy of congressional intent, while in fact attempting to advance a tort reform program of her own. Had Justice O'Connor's view prevailed, the result would have been the undercutting of decades of accepted tort jurisprudence that sellers of injury-causing medical products meeting minimal or general federal standards are not immunized from responsibility for their wrongful acts.

Since Justice Breyer provided the fifth vote to uphold several of the Lohrs' claims, but did not join Justice Stevens's analysis of the meaning of

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A14 (quoting then-Vice President Bush as pledging to "appoint people to the Federal bench that will not legislate from the bench").

90. See supra notes 22-23 and accompanying text.

Cases subsequent to Silkwood likewise recognized state-law damage awards as lacking in coercive effect sufficient to warrant preemption. In Goodyear Atomic Corp. v. Miller, 486 U.S. 174 (1988), for example, the Court distinguished between "direct state regulation" of safety matters and "the incidental regulatory pressure" of damages awarded under a state workers' compensation law. Id. at 185. The state-law money judgment, premised on the federally regulated employer's violation of a state safety rule, was held an insufficient basis for preemption: "Appellant may choose to disregard Ohio safety regulations and simply pay an additional workers' compensation award." Id.; see English v. General Elec. Co., 496 U.S. 72, 85-86 (1990) (state common-law claims for emotional distress damages not preempted by federal nuclear energy law, since the effect of damage awards would be "neither direct nor substantial enough" to warrant preemption).

In effect, an adverse jury verdict confronts a product manufacturer with a business decision, much as would a widely publicized speech by the FDA Commissioner or a state consumer protection official criticizing the firm's product and cutting into its sales. Both the verdict and the speech are official actions that cost the firm money and raise the prospect of future losses, but neither is a "requirement." The firm in each case must decide whether to withdraw the product from the market, modify it, or continue marketing it as before, but the firm is free to choose any of those courses of action. The official action—damage award or high-level jawboning—is different in kind from a regulatory measure, such as an FDA rule whose violation makes the sale of the violative product illegal, the seller subject to federal enforcement actions, and the product itself subject to immediate seizure. See 21 U.S.C. §§ 331-334 (1994).

91. Justice O'Connor did reject Medronic's position that the medical device law preempts all state-law damage claims. She viewed the FDA's § 510(k) substantial equivalence determinations, see supra note 61 and accompanying text, as not constituting "requirements," so that design defect claims against devices reaching the market by that route would not be preempted. Nor did she view state-law claims as preempted if they allege damages resulting from violation of federal "requirements." Medronic, 116 S. Ct. at 2263-64 (O'Connor, J., concurring in part and dissenting part). The Court was unanimous in its conclusion that these two types of claims are not barred.
the word "requirement" in the preemption provision, his views will be of
importance in any medical device preemption cases that come before the
Court in the future. We believe that Justice Breyer's philosophy of statutory
interpretation is consistent with our suggested analysis.

Justice Breyer has been a strong advocate of the discriminating use of
legislative history in the construction of ambiguous statutory language. He
has set out "examples of five circumstances in which courts reasonably use
legislative history to help reach correct results in difficult cases" to avoid
an absurd result, to correct drafting errors, to ascertain specialized meanings
of statutory terminology, to identify a "reasonable purpose" for the
provision, and to choose among reasonable interpretations of a politically
controversial statute. He has not hesitated, in an appropriate case, to
"examin[e] the statute's language, background, and structure," as well as its
legislative history as a way of ascertaining its meaning.

The methods employed above, focusing on the medical device law's
language, background, structure, and legislative history to demonstrate that
the state "requirements" subject to preemption are legislative and administra-
tive in nature rather than state-law damage awards, fit comfortably within
Justice Breyer's repertory of preferred principles of statutory construction.
Breyer did not find it necessary to explore legislative history to reach his
conclusion in *Medtronic*. But the facts that FDA's own statutory analysis
proceeds along lines similar to those employed here and that Breyer paid
deference to the agency interpretation in *Medtronic* suggest that should a
proper case come before the Court, he might well be amenable to
reconsidering his nonessential alignment with Justice O'Connor on the
meaning of the word "requirement."

92. Id. at 2259-60 (Breyer, J., concurring in part and concurring in the judgment).
Justice Breyer agreed that none of the Lohrs' claims were preempted because he found "no
actual conflict between any federal requirement and any of the liability-creating premises of
the plaintiffs' state law tort suit," and no field preemption. Id. at 2261 (Breyer, J.,
concurring in part and concurring in the judgment). Breyer hypothesized that FDA rules
could preempt state-law damage actions in some circumstances, but not in the case of the
claims presented in *Medtronic*.

93. Steven Breyer, *On the Uses of Legislative History in Interpreting Statutes*, 65 S.
94. Id. at 849-61.
96. See Porter, *supra* note 80.
97. *Medtronic*, 116 S. Ct. at 2260-61 (Breyer, J., concurring in part and concurring in
the judgment).
98. Id. at 2259 (Breyer, J., concurring in part and concurring in the judgment).

Justice Breyer, we think, is correct in concluding that in some cases a state law tort
action should properly be preempted by a federal regulation. Those cases are addressed in
the "dictate preemption" segment of our pentad. See infra Part IV-B. Justice Breyer's
example of a federal regulation requiring a two-inch wire in a hearing aid, *Medtronic*, 116
Since Medtronic was decided, the courts have narrowed their treatment of preemption under the medical device law, but in varying and still inconsistent ways. As discussed below, courts addressing claims involving products, like Medtronic’s pacemaker, that reached the market through a "substantial equivalence" determination have allowed those claims to proceed. However, courts have differed on whether claims involving investigational devices and devices cleared through FDA’s premarket approval process are now preempted. Our five-step approach to preemption after Medtronic offers a straightforward method of resolving the difficulty.

IV. THE PREEMPTION PENTAD

A. Express Preemption and Non-Preemption

The first two elements in our preemption pentad proposal simply restate settled law: If Congress explicitly determines that a specific state-law damage claim is either (1) preempted or (2) still available, that determination governs. Whether a specific claim is covered by preemptive or savings language is to be ascertained through standard tools of statutory interpretation, taking into account the traditional presumption against preemption in matters traditionally within the prerogative of the states.

These first two steps are irrefragably compelled by Medtronic and its predecessors. No Justice disagrees with the principle of primacy of congressional intent (though its application may differ); no Justice disagrees that the statutory language must be read in light of the particular nature of the state-law claim at issue vis-à-vis the particular regulatory structure. The benefit of including Step Two in the pentad

99. See infra notes 142-44 and accompanying text.
100. See Medtronic, 116 S. Ct. at 2250 (opinion of the Court) (reiterating traditional presumption against preemption); see also infra notes 110-17 and accompanying text.
101. Medtronic, 116 S. Ct. at 2250-51 (opinion of the Court); id. at 2260 (Breyer, J., concurring in part and concurring in the judgment); id. at 2263 (O’Connor, J., concurring in part and dissenting in part) ("If the statute contains an express pre-emption clause, the task of statutory construction must be in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress’s pre-emptive intent.").
102. Even Justice O’Connor’s opinion in Medtronic accepted that design defect claims could proceed, at least in the case of products marketed on the basis of a “substantial equivalence” determination, and that claims premised on regulatory violations are likewise unaffected by the medical device law’s preemption provision. Id. at 2263-64 (O’Connor, J.,
is that it focuses attention on the effect of savings clauses such as those in the motor vehicle safety law and the Consumer Product Safety Act. As the Court’s fragmented opinions in Cipollone and Medtronic indicate, and the disarray among the lower courts proves, however, determining the scope and meaning of statutory preemption and savings language is fraught with uncertainty. Further guidance is required. Moreover, even supposing a state-law claim is outside the scope of an express preemption clause, it is still possible that the claim might be precluded on the basis of what has been called “conflict preemption.”

Steps Three to Five of the pentad address these questions.

B. Dictate Preemption, Federal Acquiescence, and Violations of Federal Law

The third step of our analysis is an inquiry into the existence of a federal dictate concerning the state-law claim at issue. This step gives specific definition to the category of products liability claims, recognized as a matter of theory by a unanimous Court in Freightliner v. Myrick, in which “[i]n the absence of an express congressional command, state law is pre-empted if that law actually conflicts with federal law.” Such conflict can occur, according to the standard litany, either if “compliance with both federal and state regulations is a physical impossibility,” or if state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”

In products liability cases, we submit, this class of preempted claims should be drawn narrowly for several reasons. First, as the Court has long recognized, a strong presumption exists against preemption of state law in general. This presumption, derived from a decentralist vision of the integral role of the states in our federal system, has particular force when “Congress has ‘legislated . . . in a field which the States have traditionally occupied,’” such as products liability. Second, the federal

concuring in part and dissenting in part).

103. 49 U.S.C. § 30103(6)(2) (1994); see infra notes 211-14 and accompanying text.
104. 15 U.S.C. § 2074 (1994); see infra notes 250-51 and accompanying text.
112. Medtronic, 116 S. Ct. at 2250 (opinion of the Court) (quoting Rice v. Santa Fe
product safety laws with which we are concerned are consumer protection statutes, enacted principally because of the need for controls over risks imposed on the public by sellers of potentially hazardous products.\textsuperscript{113} It would be an unusual logic that would readily interpret laws aimed at enhancing safety simultaneously to withdraw a chief incentive for achieving it.\textsuperscript{114}

Third, the federal regulatory enterprise by its nature suffers from a limited attention span. Typically, an agency will focus on specific parameters of a product—aspects of labeling, design, or performance, for example—at a particular juncture, when a regulatory decision about the product has to be made. Information developed subsequent to that time, for instance about newly discovered product-related risks, or prior to that time, for instance about alternative design or safety features not adopted, may never come within the agency’s ken.\textsuperscript{115} If the information does reach the agency’s notice, it may become lost in a bureaucratic maze or may be shunted aside in favor of other, more compelling agency priorities.\textsuperscript{116} Put another way, the tort-law factfinding process, focusing as it does on a product-specific basis on the development of risk and benefit information over time, is for many types of questions far better adapted to assessing the reasonableness of manufacturers’ product-related judgments than are the regulatory agencies.\textsuperscript{117}

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\textsuperscript{113} See infra Part V. To be sure, other concerns, such as the promotion of product innovation and the avoidance of conflicting federal and state rules, are also reflected in these laws.

\textsuperscript{114} See, e.g., Haudrich v. Howmedica, Inc., 642 N.E.2d 206, 211 (Ill. App. Ct. 1994) ("If safety was Congress’ [sic] primary purpose, it would be strange for Congress to eliminate the safety aspects inherent in tort litigation by destroying tort litigation in the entire country with the same statute it passed to promote safety.").

\textsuperscript{115} For example, during the eight years after the enactment of the Medical Device Amendments, the FDA had no mandatory reporting system in place for device-related injuries and product failures. Instead, the agency relied on a voluntary reporting system which was characterized as inadequate by the General Accounting Office. See U.S. GEN. ACCOUNTING OFFICE, MEDICAL DEVICES: EARLY WARNING OF PROBLEMS IS HAMPERED BY SEVERE UNDERREPORTING (1986); Leflar, supra note 60, at 38-41.

\textsuperscript{116} See, e.g., Policy on Priorities, 16 C.F.R. § 1009.8 (1996) (Consumer Product Safety Commission policy recognizing that, because of limited resources, the agency cannot address all significant hazards.).

\textsuperscript{117} For example, prior to the enactment of the Medical Device Amendments, FDA had power selectively to regulate medical devices as "new drugs." United States v. Bacto-Unidisk, 394 U.S. 784 (1969). However, the agency neither sought nor discovered the facts regarding A.H. Robins Company’s refusal to conduct adequate testing of the Dalkon Shield, dishonesty about the product’s efficacy, ignoring of adverse reaction reports from physicians, and suppression and spoliation of damning evidence. Rather, in 1974 the agency negotiated a voluntary suspension of sales with the company, and turned its attention elsewhere. It took ten years of products liability litigation to bring this evidence out and force A.H. Robins to
In keeping with this need for a restrained view of preemption doctrine's encroachment on state sovereignty and the tort system, we offer the principle of dictate preemption to define the situations in which state-law products liability claims must be preempted by conflicting federal rules even absent express preemption. If Congress, or a regulatory agency validly exercising delegated authority, dictates that a product must be made, labelled, or marketed in a particular fashion and no other, state-law damage claims alleging injury arising from a product feature complying with that federal dictate must be disallowed.

The dictate preemption principle is responsive to the teaching of Supreme Court caselaw over the last half century that preemption is warranted if state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."\textsuperscript{118} A federal dictate in our sense necessarily carries with it the implication that the aspect of the product to which the dictate refers is in compliance with the law, and that any variance is not to be tolerated. A contrary state-law jury finding would be incompatible with the Supremacy Clause.\textsuperscript{119}

Conversely, under the restrained view of implied preemption adopted here, mere federal acquiescence in a manufacturer's adoption of a particular product feature or in the marketing of a product with such a feature should not require preclusion, as a matter of federal law, of a state-law claim attacking the reasonableness of that feature.\textsuperscript{120} This is, in part, the

alert at-risk women in whom the devices were still implanted of the need to remove them. See RICHARD B. SOBOL, BENDING THE LAW: THE STORY OF THE DALKON SHIELD BANKRUPTCY S-22 (1991); Adler & Mann, supra note 37, at 943-45.

\textsuperscript{118} See, e.g., Medtronic, 116 S. Ct. at 2259 (Stevens, J., opinion of the Court); id. at 2261 (Breyer, J., concurring in part and concurring in judgment); Freightliner, 115 S. Ct. at 1488 (recognizing continued vitality of "conflict" preemption); Hines v. Davidowitz, 312 U.S. 52, 67 (1941).

\textsuperscript{119} We acknowledge that under the dictate preemption principle, Cipollone should have been decided, in part, differently. Even though failure-to-warn claims based on the alleged inadequacy of the Surgeon General's warning were not expressly preempted under the 1965 Labeling Act, see supra notes 33-34, the congressional labeling dictate should have foreclosed those claims.

We agree with the Cipollone Court that failure-to-warn claims premised on labeling or advertising complying with the 1969 Smoking Act were properly preempted. However, the better reasoning would have been that, as under the 1965 Labeling Act, the federal dictate precluded these claims. Here, we fear, Justice Stevens may have strayed from his own principles of statutory construction, expressed contemporaneously with his decision in Cipollone. Reading the text "in its contemporary context," Stevens, supra note 8, at 1379, there was no express preemption, since the statutory language "requirement or prohibition" must have referred at the time to legislative or administrative directives, not to state-law damage actions. See supra note 32.

\textsuperscript{120} Put another way, the concepts of a federal dictate and federal acquiescence are two sides of a single coin. If express statutory language does not resolve the preemption
message of Medtronic: FDA’s acquiescence in the marketing of the cardiac pacemaker at issue, with its particular design, on the basis of the agency’s “substantial equivalence” determination did not insulate the manufacturer from liability for design defects. Compliance with the agency’s requirement that Medtronic submit information demonstrating substantial equivalence to a predicate device before being permitted to market the pacemaker in no way conflicted with any state-law rules that damages are to be paid for injuries caused by an unreasonably dangerous design. No federal dictates covered the product features at issue in the Lohrs’ state-law claims, and mere federal acquiescence in those product features is insufficient for preemption.

Consistent with the preservation of state autonomy over tort rules, we recognize that states may validly choose to give presumptive weight, or even claim-preclusive effect, to manufacturers’ compliance with federal requirements. Such decisions are properly left to the states as laboratories of legal innovation.

The final element of our analysis is the easiest. Unlike the first four steps, the fifth addresses state-law claims involving product features

issue, a state-law claim is either preempted because it would conflict with a federal dictate, or not preempted because the regulatory agency is merely acquiescing in the distribution of the product under criteria adequate for federal purposes.

We have separated the description of this aspect of our approach into two parts to clarify and emphasize the distinction between the type of federal action that should invariably preclude state-law damage claims as a matter of federal law, and the type that should not.


Justice O’Connor was incorrect in stating that the premarket notification process under § 510(k) “places no ‘requirements’ on a device.” Medtronic, 116 S. Ct. at 2264 (O’Connor, J., concurring in part and dissenting in part). FDA requires the manufacturer to submit sufficient information to establish the product’s “substantial equivalence” or the product is considered adulterated or misbranded and cannot be marketed. Failure to submit the required information itself a statutory violation. 21 U.S.C. § 331(p) (1994); see Establishment and Premarket Notification Procedures, 42 Fed. Reg. 42,520, 42,524 (1977); Lefflar, supra note 60, at 29. Courts routinely uphold the agency in enforcement proceedings against violators of these requirements. E.g., United States v. Universal Management Servs., Med. Device Rep. (CCH) ¶ 15,340 (N.D. Ohio Jan. 22, 1997).

As Justice O’Connor recognized, however, nothing in the premarket notification rules requires a particular design, see Medtronic, 116 S. Ct. at 2263-64 (O’Connor concurring in part and dissenting in part), so she was correct in her conclusion that design defect claims are not preempted.

122 E.g., 735 ILL. COMP. STAT. ANN. § 5/2-2103 (1996); N.D. CENT. CODE § 28-01.4-02 (1995).

123 See, e.g., MICH. STAT. ANN. § 27A.2946(5) (Law. Co-op. 1996) (broad government standards defense for FDA-approved drugs); Carlin v. Superior Court, 920 P.2d 1347, 1352-53 & n.4 (Cal. 1996) (drug manufacturer may not be held liable for failure to provide warning it has been expressly precluded by FDA from giving) (emphasis in original).
violating federal rules. These claims, a fortiori, are not preempted. Such was the unanimous holding of the Medtronic Court,\textsuperscript{124} rejecting perplexing contrary cases from two courts of appeals.\textsuperscript{125} Again, the proper weight to be given to evidence of the violation—negligence per se, or evidence (presumptive or otherwise) of fault—is a matter to be left to state law.

To illustrate how our analysis would be applied, we now turn to examples of damage claims that have arisen or are likely to arise under several of the chief federal product safety statutes: those regulating drugs, medical devices, motor vehicles, and hazardous consumer products.

V. THE PENTAD APPLIED: PREEMPTION ANALYSIS UNDER THE PRODUCT SAFETY STATUTES

A. Drugs

In keeping with the traditional stance of the common law, courts applying state law have frequently allowed damage awards to plaintiffs claiming injuries caused by drugs alleged to be defective in some respect despite compliance with applicable FDA rules.\textsuperscript{126} States’ deference to FDA conclusions about the acceptability of product features has varied. Cases subjecting drug companies to liability for deficient labeling, warning, marketing and manufacturing practices are legion.\textsuperscript{127} Cases holding drugs’ designs to be defective, in the face of an FDA determination of safety and efficacy, are relatively rare.\textsuperscript{128} At least one state (Michigan) recognizes

\textsuperscript{124} See Medtronic, 116 S. Ct. at 2255-56 (opinion of the Court); \textit{id.} at 2260-61 (Breyer, J., concurring in part and in the judgment); \textit{id.} at 2264 (O'Connor, J., concurring and dissenting).


\textsuperscript{127} For examples of failure-to-warn cases, see \textit{supra} note 126; see also, e.g., Sterling Drug, Inc. v. Yarrow, 408 F.2d 978 (8th Cir. 1969) (negligence in marketing); Merck & Co. v. Kidd, 242 F.2d 592 (6th Cir.), \textit{cert. denied}, 355 U.S. 814 (1957) (manufacturing defect).

\textsuperscript{128} Many cases recognize at least the theoretical availability of design defect claims. See, e.g., Brochu v. Ortho Pharm. Corp., 642 F.2d 652, 656 (1st Cir. 1981) (oral contraceptive: available alternative design would have provided the same benefits with far less risk); Kociemba v. G.D. Searle & Co., 695 F. Supp. 433 (D. Minn. 1988) (IUD regulated as drug: balancing test for reasonableness determines design defect liability); West v. G.D. Searle &
a sweeping government standards defense to virtually all claims against sellers of FDA-approved drugs.129

The drug regulation provisions of the Federal Food, Drug, and Cosmetic Act contain neither preemption nor savings language. Accordingly, our preemption analysis first requires an inquiry into whether a federal dictate affirmatively requires the contested aspect of the drug to take a particular form.

The typical prescription drug failure-to-warn claim involves an assertion that the risk of the kind of harm the plaintiff suffered—an unusual adverse reaction not mentioned or emphasized in the drug’s professional labeling, for example—should have been both known to the manufacturer and called to the attention of the plaintiff’s physician. Such claims often arise in the wake of new information about a drug’s significant hazards that become evident after mass marketing, but were undiscovered or seemed minor based on the relatively small studies the manufacturer conducted and presented to FDA in order to obtain marketing approval.

FDA’s approval of proposed labeling based on data available at the time of approval does not constitute a “dictate.” The agency permits, indeed requires, manufacturers to take the initiative to revise the labeling and warnings “as soon as there is reasonable evidence of an association of a serious hazard with a drug.”130 State-law claims that the post-approval inadequacy of such labeling rendered the drug unreasonably dangerous typically are not precluded under federal law by dictate preemption, because FDA’s approval of the labeling merely represents the agency’s acquiescence in the marketing of the product under the label conditions.131

By contrast, when FDA requires a drug manufacturer to include a specific boxed warning on the label, or a specific warning concerning a non-indicated use,132 that particularized requirement is a strong indication of

Co., 836 S.W.2d 608, 611-13 (Ark. 1991) (manufacturer may defend against design defect case by demonstrating through risk-utility analysis that product was unavoidably unsafe); see generally RESTATEMENT OF TORTS: PRODUCTS LIABILITY 183-87 (Proposed Final Draft, April 1, 1997) (listing cases).

One reason for the relative paucity of design defect claims as opposed to failure-to-warn claims in drug products liability cases may be that the former are far more expensive for plaintiffs to mount as a matter of proof.

129. MICH. STAT. ANN. § 27A.2946(5) (Law. Co-op. 1996). Damage actions against drugs in compliance with FDA approval conditions may proceed only if the drug company has intentionally withheld or misrepresented information to the FDA, or bribed FDA official.


132. FDA regulations provide that:
a federal dictate, and state-law claims contesting the specific warning’s adequacy and based on the same evidence reviewed by FDA should presumptively be barred.\textsuperscript{133} Likewise, if the FDA is aware of the full evidence concerning the alleged risk affecting the plaintiff and has determined, after review, that because of the data’s speculative nature, that alleged risk may not be included in the drug’s labeling, dictate preemption precludes state-law claims to the contrary based on the same evidence reviewed by FDA.\textsuperscript{134}

With regard to design defect claims, FDA licensing of a particular chemical formulation for indications listed in the labeling constitutes federal acquiescence in the product’s marketing under the label conditions, not any kind of dictate. Some jurisdictions allow prescription drug design defect claims to go forward under state law;\textsuperscript{135} others do not.\textsuperscript{136} Resolution of the issue is to be left to state law.

Claims involving violations of federal drug regulations—relating for example to labeling, production quality control, product promotion, or reporting of adverse reactions—\textsuperscript{137} are never preempted, under Step Five of the pentad.

\textit{B. Medical Devices}

Before \textit{Medtronic}, device manufacturers had persuaded some lower courts that state-law claims were preempted by an FDA determination of a

\footnotesize{A specific warning relating to a use not provided for under the “Indications and Usage” section may be required by the [FDA] if the drug is commonly prescribed for a disease or condition, and there is lack of substantial evidence of effectiveness for that disease or condition, and such usage is associated with serious risk or hazard. Special problems, particularly those that may lead to death or serious injury, may be required by the [FDA] to be placed in a prominently displayed box.}

\textsuperscript{21} C.F.R. § 201.57(e) (1996).

\textsuperscript{133} Conceivably, scientifically valid new information not considered by the agency, or a manufacturer’s concealment or spoliation of evidence, might cast doubt on the adequacy even of the specific FDA-required warning. We would not preclude a state-law claim from going forward under such exceptional circumstances. Also, if the agency in requiring a particularized warning states that it does not intend the warning to have preemptive effect, state-law claims should not be precluded.

\textsuperscript{134} See Carlin v. Superior Court, 920 P.2d 1347, 1353 & n.4 (Cal. 1996) (adopting this position as a matter of California law).

\textsuperscript{135} See supra note 128.


\textsuperscript{137} See, e.g., Stanton v. Astra Pharm. Prods., 718 F.2d 553, 558-65 (3d Cir. 1983) (failure to report adverse reactions).}
device's "substantial equivalence" to a predicate device itself lacking FDA recognition of safety and effectiveness. *Medtronic* laid that theory to rest. Nevertheless, the Court's decision did not directly address preemption of claims involving devices regulated under other provisions of the law—in particular, investigational devices and devices that have received premarket approval. Those claims now confront the state and federal courts.

The preemption pendal's analysis of device claims is similar to that of drugs. The similarity is to be expected, because the structure of device regulation is rooted in the FDA's regulatory program for drugs. (In fact, before obtaining general regulatory authority over devices in 1976, FDA regulated several devices of particular concern as "new drugs."))

Unlike the drug law, the medical device law does have an express preemption provision; but as we have demonstrated, the provision refers only to state legislative and administrative directives, not to state-law damage claims. Therefore, as with the drug law analysis, we inquire as to each state-law claim whether a specific federal dictate precludes the claim.

The complexity of the regulatory scheme for devices makes the dictate preemption analysis slightly more complicated than for drugs. Devices are divided into various regulatory categories, and federal requirements for the different categories are of varying stringency. The matrix in Figure 1, infra, sets out the chief regulatory categories and the types of claims typically brought against device manufacturers. The application of preemption analysis to this myriad of possibilities, which at first glance might seem a daunting task, is simplified by Steps Three through Five of our pendal.

1. Devices Marketed on the Basis of Substantial Equivalence Determinations

The Supreme Court held in *Medtronic* that none of the Lohrs' claims were federally preempted. The holding was unanimous as to claims

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139. 21 U.S.C. § 360k (1994). *See* *supra* text accompanying notes 63-64 for the text of this statute.

140. *See* *supra* notes 63-91 and accompanying text.

141. *See* *Medtronic*, 116 S. Ct. at 2246-48 (setting out regulatory structure for medical devices); *see generally* Leflar, *supra* note 60, at 7-24 (explaining in detail regulatory controls for Class I and Class III devices).
<table>
<thead>
<tr>
<th>Regulatory category of device</th>
<th>Premarket Notification (§ 510(k))</th>
<th>General or Special Controls (Class I or II)</th>
<th>Investigational Device Exemption (IDE)</th>
<th>Premarket Approval Application (Class III PMA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturing defect/GMP violation</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Design defect</td>
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<tr>
<td>Failure to warn or instruct</td>
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<tr>
<td>Other marketing defect: promotion, failure to recall &amp;c</td>
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<td></td>
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<tr>
<td>Misrepresentation to FDA</td>
<td></td>
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</tbody>
</table>

Figure 1: Medical Device Regulatory Categories and Types of Claims
involving design defects and claims premised on violations of FDA regulations, such as misrepresentations to the agency and failure to follow Good Manufacturing Practice ("GMP") regulations. A majority of five upheld the remaining claims. This holding of no preemption necessarily applies to corresponding state-law claims regarding other devices marketed through the same § 510(k) premarket notification process on the basis that they are substantially equivalent to a predicate device lacking FDA certification of safety and effectiveness. The substantial equivalence determination constitutes no kind of dictate, but rather is merely federal acquiescence in the marketing of the product. As of this writing, post-Medtronic courts addressing products liability cases involving devices in this regulatory category had unanimously rejected preemption claims.

142 Justice O’Connor’s treatment of manufacturing defect claims was somewhat perplexing. In two successive paragraphs, she stated that claims of violation of federal requirements were not preempted, but that “the Lohrs’ common-law claims regarding manufacture would, if successful, impose state requirements ‘different from, or in addition to’ the [supposedly comprehensive] GMP requirements, and are therefore preempted.” Medtronic, 116 S. Ct. at 2264 (O’Connor, J., concurring in part and dissenting in part). However, common-law manufacturing defect claims may well contain or be premised on allegations of violation of GMPs. See 21 C.F.R. § 820 (1996). It is unclear whether the Lohrs specifically pleaded such violations.

In any case, a firm in compliance with GMP regulations may still distribute products with injury-causing manufacturing defects. To the extent that Justice O’Connor may have intended to preclude liability for product defects if production quality controls are reasonable, she came within one vote of an extraordinary accomplishment: national repeal sub silentio of strict liability for medical devices with manufacturing defects.

Subsequent to the Medtronic decision, FDA rejected Justice O’Connor’s position on this point, announcing that the agency’s new quality system regulation (covering good manufacturing practices) does not preempt state law remedies. 21 C.F.R. § 808.1(d)(10) (promulgated at 61 Fed. Reg. 52,654 (1996)); see also 61 Fed. Reg. 52,602, 52,603 (preamble).

143. In the Safe Medical Devices Act of 1990, Congress for the first time required that device manufacturers filing § 510(k) premarket notifications make available “an adequate summary of any information respecting safety and effectiveness,” and set a statutory standard for FDA substantial equivalence determinations. 21 U.S.C. § 360(e)(1), (3) (1994). It cannot be thought that this fleshing out of the agency’s existing premarket notification process has any significance for preemption analysis. The standard for substantial equivalence is that the new device “is as safe and effective as a legally marketed device, and . . . does not raise different questions of safety and efficacy than the predicate device,” id. § 360(i)(l)(A)(ii). But the predicate device still has never been approved by FDA as safe and effective, and the new device may present problems similar to those of the predicate. The Medtronic Court’s analysis holding that FDA regulation does not preempt state-law damage actions for pre-1990 substantially equivalent products, Medtronic, 116 S. Ct. at 2254-58, applies equally to such products marketed after the effective date of the 1990 law.

144. E.g., Reeves v. AcroMed Corp., 103 F.3d 442 (5th Cir. 1997) (metal bone
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2. Devices Subject Only to General Controls

The vast majority of medical devices are in Class I or Class II, the least risk-laden categories.145 These devices are typically subject only to general controls such as good manufacturing practice, labeling, and adverse experience reporting regulations.146 Nevertheless, quality difficulties with these less-risky devices are frequent and can cause significant health problems.147

The holding of Medtronic with respect to Class III devices marketed on the basis of substantial equivalence determinations applies a fortiori to these less-closely-regulated categories of device. With rare exceptions of federal dictates discussed below,148 FDA rules for manufacturers of these devices simply set the general, minimal parameters for legal production and marketing of the products. They do not preempt state-law claims of any sort.149

3. Investigational Devices


145. New-model devices within Class I or Class II device types may be marketed on the basis of determinations of substantial equivalence to previously marketed devices within those device types. 21 U.S.C. § 360(h)(1)(A) (1994).

146. Class II devices may be subject to "special controls," such as performance standards, postmarket surveillance, patient registries, and the like. 21 U.S.C. § 360(c)(1)(B) (1994). However, such special controls have seldom been implemented since enactment of the device law. See Med. Device Rep. (CCH) ¶ 5519.


148. FDA Enforcement Reports listing manufacturer- and FDA-initiated device recalls, including recalls of Class II devices potentially posing serious risks to life or health, are compiled in Med. Device Rep. (CCH) ¶¶ 14,505-14,850 and the corresponding Developments Transfer Binders from 1976-77 through 1993-94.

indication, the manufacturer must obtain permission to do so from the FDA and from a review board at the institution at which the testing is to be performed.\textsuperscript{150} FDA's permission to conduct the testing is styled an "Investigational Device Exemption" ("IDE") from otherwise applicable provisions of the medical device law, such as that requiring a reasonable assurance of the device's safety and effectiveness.\textsuperscript{151} To obtain an IDE, an applicant must submit to FDA various information about the device and the investigational protocol, or how the experiment is to be conducted. The agency makes its approval determination chiefly or entirely on the basis of that submission. FDA is under a 30-day statutory deadline to respond, or the IDE application is considered automatically approved.\textsuperscript{152}

Although IDEs are supposed to be granted for the purpose of gathering data and advancing scientific knowledge, they have sometimes served as a vehicle for the mass marketing of new devices for profit, despite the lack of proof of the devices' safety and effectiveness. The most notorious example of this phenomenon is the intraocular lens. Under IDEs granted from 1976 onward, more than a million investigational lenses were implanted in the eyes of cataract patients.\textsuperscript{153} Makers of other products such as cancer

\begin{itemize}
\item \textsuperscript{150} 21 U.S.C. § 360(g) (1994).
\item \textsuperscript{151} Id. § 360(g)(2)(A).
\item \textsuperscript{152} Id. § 360(g)(4)(A).
\item \textsuperscript{153} As a historical note, the marketing of intraocular lenses under IDEs was in part the result of a statutory provision unique to intraocular lenses. On April 6, 1976, FDA concluded that intraocular lenses "are not generally recognized by qualified experts as safe and effective for their intended use" and brought them under regulatory control by categorizing them as "new drugs." 41 Fed. Reg. 14,570, 14,573 (1976). At that time, the Senate and the House of Representatives had each passed differing versions of the Medical Device Amendments, neither referring specifically to intraocular lenses, and a joint House-Senate Conference Committee was about to meet to resolve the differences. In reaction to the FDA decision, the Conference Committee inserted a provision applicable only to the lenses into the legislation. The provision gave FDA a specified period to determine whether to designate the lenses as "investigational devices" under 21 U.S.C. § 360(j). If FDA made this designation, permitting various regulatory controls, it had to do so "in such a manner that the device shall be made reasonably available to physicians meeting appropriate qualifications" prescribed by the agency. Id. § 360(j)(3)(D)(iii) (emphasis added); Medical Device Amendments of 1976, H.R. CONG. REP. NO. 94-1090, at 63-64 (1976), \textit{reprinted in} 1976 U.S.C.C.A.N. 1070, 1115-16.
\item Interpreting this congressional edict, FDA’s regulation restricting the lenses to investigational use, 21 C.F.R. § 813 (1996) (promulgated at 42 Fed. Reg. 58,874 (1977)), did not require the small, carefully controlled clinical trials usual with studies of new medical products. Instead, FDA allowed lens makers to conduct so-called "adjunct studies" with unlimited patient enrollment. The lens manufacturers took advantage of FDA’s lax regulatory attitude to prolong their "adjunct studies" without submitting full-fledged premarket approval applications to the FDA, thereby in effect mass marketing lenses that had not received an FDA finding of a reasonable assurance of safety and effectiveness. The National Institutes of Health reported in 1979 that about 100,000 lenses were being implanted annually by some
\end{itemize}
detection tests\textsuperscript{154} and liquid injectable silicone\textsuperscript{155} have also engaged in commercialization of investigational devices.\textsuperscript{156}

Just as with its "substantial equivalence" determinations on § 510(k) premarket notifications, FDA approval of an IDE application does not involve an agency finding that a manufacturer has made reasonable decisions about the design, labeling, or production of the product to be investigated.\textsuperscript{157} Still less does the agency's often sporadic monitoring of IDEs permit any conclusion about whether a particular experiment is being conducted with due care. For example, as part of its brief review of an IDE application, FDA examines the manufacturer's informed consent materials\textsuperscript{158} and may reject the application if they are inadequate.\textsuperscript{159} However, as FDA regulations state: "The informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed for informed

4,000 eye surgeons. \textsc{National Institutes of Health, 2 NIH Consensus Development Summary: Intraocular Lens Implantation} (1979). The rate of lens implantation increased in subsequent years.


155. \textit{Id.} at 99 & n.80 (FDA warning letter to physicians and consent decrees).

156. FDA prohibits firms from "[c]ommercializing an investigational device by charging the subjects or investigators for a device a price larger than that necessary to recover costs of manufacture, research, development, and handling," and from "[u]nduly prolong[ing] an investigation." 21 C.F.R. § 812.7(b), (c) (1996). However, since the agency is primarily concerned with health issues, it seldom if ever spares scarce personnel to audit regulated firms' accounting practices, so these prohibitions go largely unenforced.

157. Grounds for disapproval of an IDE include, \textit{inter alia}, that

[i]t is reason to believe that the device as used is ineffective.

\textit{Id.} § 812.30(b)(4). The "reason to believe" and "importance of the knowledge to be gained" standards may or may not correspond to those determinative of state-law issues. An FDA approval decision based chiefly or entirely on information submitted by the IDE applicant may well carry some weight in the state law damage action, but should not necessarily be determinative.

Moreover, the law allows a manufacturer to proceed with a device study if the FDA has delayed beyond the 30-day statutory period for responding to an IDE application. 21 U.S.C. § 360(j)(g)(4)(A). In such circumstances the application is "deemed approved," even though FDA has made no judgment at all on any issues that might be relevant to the state-law damage action.


consent to be legally effective. An IDE approval cannot be considered a federal dictate of the sort that would preempt every state law action challenging an injury-causing aspect of a product being tested on human subjects.

In addition, it would be illogical, under Medtronic, to provide immunity for a product marketed under a § 510(k) premarket notification, simply because it was also sold or otherwise distributed under an approved IDE for the same use. Such immunity claims are especially likely to be raised by makers of Class III devices as to which FDA requires submission by a time certain of data demonstrating the device’s safety and effectiveness. The implausibility of such claims is evident upon consideration of the shifting liability rule that would be imposed on similarly situated injured patients over time, were the immunity argument accepted. Prior to the FDA determination requiring data submission, state-law claims against a device marketed under a § 510(k) notification could proceed under Medtronic. After the determination, when concerns about the product’s safety hazards or ineffectiveness are known to the world, under this flawed reasoning the manufacturer could magically gain immunity simply by obtaining an IDE for the use for which the device is already marketed.

160. Id. § 50.25(c); see also id. § 50.20, last sentence (evidently assuming that “the sponsor” of the investigation remains civilly liable for its negligence). The sponsor of a clinical study of a device is typically its manufacturer or importer.

161. Products commercially marketed under substantial equivalence determinations are generally exempt from the IDE requirement, unless the investigation concerns the use of the product for a new indication. Id. § 812.2(c)(1), (2); see 45 Fed. Reg. 3732, 3736-38 (1980) (comment 21: statement concerning this exemption in preamble to final rule). However, there is nothing to prevent a manufacturer from filing for and obtaining an IDE for a study of an existing indication, to attempt to use as a shield against products liability actions. The practice of distributing a product simultaneously under both an IDE and a substantial equivalence determination is not uncommon. See, e.g., Feldi v. Mentor Corp., 61 F.3d 431, 434 n.3 (5th Cir. 1995); see also Martin v. Teletronics Pacing Sys., 105 F.3d 1090, 1097-98 (6th Cir. 1997) (system components marketed under § 510(k) determination; system as a whole under IDE).

162. 21 U.S.C. § 360e(b) (1994). The IDE exemption in 21 C.F.R. § 812.2(c)(1), (2) (for studies of existing uses of products marketed under a substantial equivalence determination, see supra note 161) is inapplicable to Class III products for which FDA has issued a regulation requiring submission of safety and effectiveness data. See, e.g., 61 Fed. Reg. 50,704, 50,705 (1996) (final rule requiring premarket approval applications for 41 Class III devices).

At least two courts ruling on preemption arguments involving investigational devices since Medtronic was decided have properly rejected the defense. In the more closely reasoned of these two decisions, a unanimous Missouri Supreme Court held that the existence of an approved IDE for the intraocular lens at issue did not create any conflict with the plaintiffs' specific claims of negligent design or manufacture, failure to warn of unreasonably high complication rates, fraud and misrepresentation, and failure to assure adequate informed consent as required by federal regulation. As to the latter claim, the court drew support from FDA's conclusion that the regulatory informed consent requirements have no preemptive effect.

The post-Medtronic courts are not uniform on the issue, however. The Sixth Circuit, for example, in Martin v. Telectronics Pacing Systems, held all claims against the manufacturer of a defibrillator/pacemaker to be preempted. The device in question contained some components that had reached the market via a "substantial equivalence" determination, while other components and the product system as a whole were under an IDE.

The Sixth Circuit's reasoning in Martin is flawed in several respects. First, the court held manufacturing defect claims to be preempted because

[t]o allow a cause of action for a manufacturing defect under state law where the FDA has specifically exempted an investigational device from Good Manufacturing regulations would thwart the goals of the IDE exemption "to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use."
But nothing about a defectively manufactured product is "consistent with the protection of public health and safety." The granting of an IDE merely imposes on the sponsor, with respect to production quality, various procedural recordkeeping, reporting, and information submission requirements. The IDE says nothing about the substantive standards of quality control that a manufacturer must meet, which are the concern of state tort law. FDA explicitly recognized, in a final rule promulgated more than three months before the Sixth Circuit's decision, that its general quality system regulation "does not preempt [state tort and common law] remedies"; the same conclusion should apply ipso facto to quality control rules for investigational devices. 173

Second, the Martin court held the design defect claims preempted "because under the federal requirement the FDA has determined that the benefits of the device outweigh the risks and, under the state requirement, a jury in a state court action could conclude that the risks outweigh the benefits, [so] the state requirement is different from the federal requirement." However, as demonstrated above, a state-law damage action is not a "requirement" for purposes of the medical device law. 174 Moreover, the issues the FDA reviewer of an IDE application addresses are not necessarily the same as those determinative of a state law damage action. 175 The reviewer's decision is based chiefly or entirely on information submitted by the manufacturer, which may not convey the full picture of the experiment's hazards. More fundamentally, the IDE approval does not constitute a federal dictate that any particular design be used. 176


173. In fact, an IDE sponsor's exemption from GMP rules is conditioned on the sponsor's making available to FDA information about manufacturing quality controls similar (or, at the sponsor's option, equivalent) to that required for other marketed devices. See 21 C.F.R. §§ 812.20(b)(3), 812.140(b)(v) (1996); see also 45 Fed. Reg. 3732, 3743 (1980) (comments 66 & 67: preamble to promulgation of final rule).

174. Martin, 105 F.3d at 1099.

175. See supra notes 63-84 and accompanying text.

176. See supra note 157 and accompanying text.

177. In Slater v. Optical Radiation Corp., 961 F.2d 1330 (7th Cir.), cert. denied, 506 U.S. 917 (1992), Judge Posner rejected a design defect claim in an intraocular lens IDE case on the ground that

[i]n the experimental phase the appropriate regulations of safety and effectiveness are procedural rather than substantive ones. They do not specify the safe and effective design; they specify the procedures for determining whether the experimental design is safe and effective. These are requirements relating to safety and effectiveness and they can therefore have preemptive effect.

Id. at 1333. Judge Posner's reasoning, carefully limited to design as opposed to manufacturing defect claims, in effect invokes field preemption rather than conflict preemption: his view is that although there is no direct conflict between a state-law jury conclusion that an
Third, the Sixth Circuit held the Martins’ failure-to-warn claims preempted on the basis of federal requirements to submit informed consent and labeling materials to FDA with a sponsor’s IDE application. However, the court failed to recognize what the Missouri Supreme Court correctly observed: that FDA regards such informed consent materials merely as meeting minimum standards, and that state informed consent law may impose more stringent standards. Martin, in sum, goes counter to the language and structure of the device law and the teaching of the experimental lens was negligently designed and any specific federal lens design prescription, FDA’s essentially procedural rules concerning device investigations occupy the field and break no state law interference.

While theoretically intriguing, Judge Posner’s analysis cannot withstand close scrutiny. There is no indication in the language or legislative history of the medical device law that state-law damage actions challenging experimental designs are to be precluded. Nor has FDA indicated that preemption is appropriate in the IDE context. To the contrary, as Chief Counsel Porter recently observed: FDA’s position is that Congress “did not intend to preempt state tort remedies for injury to individual consumers.” Porter, supra note 80, at 9; see 21 C.F.R. § 50.25(c) (1996) (FDA regulations on informed consent in drug and device investigations do not preempt state-law informed consent claims).

Moreover, certain factual underpinnings of Judge Posner’s rationale are flawed. His postulate that “[t]he lens was not marketed to the public” and so the informed consent process alone sufficiently protects patients’ interests, Slater, 961 F.2d at 1334, is incorrect. See supra note 153 (history of mass marketing of investigational lenses to the public). His assumption that “the risks, including any loss of tort remedies, were adequately explained” to the plaintiff, Slater, 961 F.2d at 1334 (emphasis added), is unwarranted in light of FDA’s explicit prohibition against exculpatory language in consent forms for device investigations. 21 C.F.R. § 50.20 (1996).

One suspects that the fundamental point underlying Judge Posner’s stated “concern for economic substance rather than legal formality,” Slater, 961 F.2d at 1333, is his observation that “if experimental procedures are subject to hindsight evaluation by juries, so that failed experiments threaten to impose enormous tort liability on the experimenter, there will be fewer experimental treatments, and patients will suffer.” Id. at 1334. His concern is legitimate, but his conclusion is by no means self-evident. Congress did not address the issue, and FDA takes the position that state tort law constitutes a necessary separate “layer of consumer protection.” Porter, supra note 80, at 11. If the duty of due care in the design of products to be tested on human beings is to be abolished, it ought to be done by people with more medical expertise and democratic accountability than federal judges.

178. Martin, 105 F.3d at 1099-1100.
179. Connelly v. Isah Corp., 927 S.W.2d 848, 854-55 (Mo. 1996); see supra note 106 and accompanying text. The Sixth Circuit cited Connelly, 105 F.3d at 1098 n.6, but chose to ignore it.
180. 21 C.F.R. § 50.25(c) (1996) (quoted in supra text accompanying note 154); see id. § 50.20 (“No informed consent . . . may include any exculpatory language [which] . . . releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.”) (emphasis added). The sponsor is typically the product manufacturer.
4. Devices Formally Approved for Marketing

Class III devices with approved premarket approval applications have been determined by FDA to have a "reasonable assurance" of safety and effectiveness. Such devices are in a regulatory status analogous to that of new drugs that FDA has approved for marketing. As noted above, the device law, like the drug law, contains no language expressly preempting state-law damage claims. Therefore, under the preemption analysis advanced here, the inquiry proceeds to whether a specific federal dictate precludes contrary holdings in state-law damage actions.

The analysis for devices approved for marketing parallels that for drugs outlined above. Regarding failure-to-warn and other defective marketing claims, FDA approval of the manufacturer’s proposed labeling is not a dictate. As in the case of drug regulation, a device manufacturer on its own initiative may change the labeling after marketing approval, without prior FDA permission, to provide additional assurance of safety. The determination by a court applying state tort law that a manufacturer was negligent in failing to warn of a hazard not listed in the approved product labeling would therefore not conflict with federal law. As Justice Stevens wrote for a majority of the Court in Medtronic,

the predicate for the failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use. These general obligations are no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a workforce. These state requirements therefore escape

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181. The Martin court held the IDE rules also preempted express warranty and general supplier liability claims. Martin, 105 F.3d at 1100-01. The court’s reasoning as to those claims is subject to the same objections as those developed in the previous paragraphs.


183. See supra notes 138-40 and accompanying text.

184. See supra notes 126-36 and accompanying text.

185. The manufacturer may "add or strengthen a contraindication, warning, precaution, or information about an adverse reaction"; "add or strengthen an instruction that is intended to enhance the safe use of the device"; or "delete misleading, false, or unsupported indications." 21 C.F.R. § 814.39(d)(2) (1996). The Medtronic decision cited this regulation in support of its conclusion that state failure-to-warn claims are not preempted. Medtronic, 116 S. Ct. at 2256 n.16 (opinion of the Court).

186. See generally John Agar, Labeling of Prescription Devices for the Food and Drug Administration and Product Liability: A Primer—Part II, 45 Food & Drug L.J. 569, 572-76 (1990) (explaining "courts' unwillingness to accept compliance with federal law as conclusive evidence of adequate labeling").
pre-emption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be “with respect to” specific devices such as pacemakers. As a result, none of the Lohrs’ claims based on allegedly defective . . . labeling are preempted . . .

State-law manufacturing defect claims, likewise, remain viable against devices formally approved for marketing just as they do against devices receiving a “substantial equivalence” determination. As the FDA has recognized, the rationale of the Medtronic Court, as to manufacturing defects as well as failure to warn claims, is generally applicable and cannot be confined to the regulatory category (products marketed through the § 510(k) process) involved in that case. The agency’s quality control regulations do not constitute specific dictates that would have preemptive effect.

Design defect claims, for devices as for drugs, may proceed despite FDA’s premarket approval decision if state law allows. As the agency has explicitly stated, FDA approval does not amount to a dictate that the product be designed in a particular way; it merely acquiesces in the marketing of the product so designed. The Solicitor General’s position on the question in his amicus brief in Medtronic is compelling:

Neither the [medical device law] nor the FDA’s regulations prescribe criteria for the design of devices. The design of a device originates with its manufacturer. . . . [Design] specifications are applicable to a device as a result of a voluntary decision of a private party, the manufacturer, to introduce the device into the market with a design of the manufacturer’s choosing. That federal law attaches a consequence to such private decisions does not convert them into federal “requirements.”

187. Medtronic, 116 S. Ct. at 2238. Justice Breyer joined in this part of Justice Stevens’s opinion. Id. at 2261-62 (Breyer, J., concurring in part and concurring in the judgment).


189. FDA described its “design control” regulation, 21 C.F.R. § 820.30 (promulgated at 61 Fed. Reg. 52,657 (1996)), in this way:

The regulation . . . provides a framework that manufacturers must use in developing and implementing design controls but does not prescribe the practices that must be used. Rather, it allows manufacturers the flexibility to develop controls that both comply with the regulation and are most appropriate for individual manufacturers’ design and development process.


Moreover, just as the “generality” of state-law duties regarding reasonable care in manufacturing and risk warnings takes those duties outside the scope of conflict preemption, so the state-law duty to design products with reasonable care is insufficiently specific to create a collision with any particular federal dictate.

Claims involving violations of FDA regulations regarding submission of truthful information, labeling, adverse reaction reporting, product promotion, and the like are not preempted, for this regulatory category or for any other. This tenet is likely to prove of considerable practical benefit to plaintiffs, who will no doubt routinely plead violations of the general prohibitions against adulterated and misbranded devices and of corresponding FDA regulations as an adjunct to their state-law manufacturing defect, design defect, failure to warn, negligent promotion, and misrepresentation claims.

Most courts addressing claims after Medtronic against manufacturers of devices with premarket approvals have held that none of the claims were preempted. At this writing, the only exception is the curious Pennsylvania case of Green v. Dolsky. The Green court, atypically employing “field” preemption rather than express or conflict preemption analysis, in

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191. Medtronic, 116 S. Ct. at 2258 (opinion of the Court).
192. See id. at 2255-56 (opinion of the Court).
195. See, e.g., id. § 820.30.
198. See, e.g., 21 U.S.C. §§ 331(e), (q), 352(r) (1994).
Cipollone-like fashion divided the plaintiff's claims against the manufacturer, preempting some but not others, and held as a matter of state law that the malpractice claims against the implanting physician were "circumscribed" by the availability of federally approved informational materials.\footnote{201}

5. Device Dictates

We have canvassed the chief regulatory categories for medical devices\footnote{202} and have determined that the vast majority of FDA actions concerning those devices do not constitute "federal dictates" and have no preemptive effect over state-law damage claims. However, some federal requirements for devices, as for drugs, are sufficiently precise and particularized that contrary state-law claims should be preempted.

Examples of such particularized requirements are the regulations requiring specific labeling on specific types of devices. For example, menstrual tampons must contain labeling information concerning tampon absorbency and the risk of toxic shock syndrome; FDA has by regulation specified in detail the required contents of the label.\footnote{203} Similarly, the agency has specified detailed labeling for hearing aids\footnote{204} and intrauterine contraceptive devices.\footnote{205} State-law challenges to labeling complying with these particularized federal dictates should presumptively be barred—absent an FDA statement that it does not intend the labeling requirement to have preemptive effect, or new, valid scientific evidence casting doubt on the required labeling's adequacy.\footnote{206}

\footnote{201} The court found that plaintiff's negligent product development, failure to warn, improper labeling, breach of warranty, and strict liability claims against the manufacturer were preempted. Green, 685 A.2d at 117-18. Various claims involving the manufacturer's failure to provide FDA with accurate information required by the agency and failure to withdraw the product from the market were allowed to proceed. Id. The court apparently held that under Pennsylvania law, a physician fulfills the duty to provide informed consent by "[making] known to the patient the risks which were stated in the FDA materials." Id. at 118.

Since the dismissal of at least the failure to warn claim is contrary to the explicit language of the Medtronic decision, perhaps the Green case is best understood as stating Pennsylvania law on the effect on tort claims of an FDA marketing approval decision, rather than as interpreting federal law on the subject.


\footnote{203} Id. § 801.430.

\footnote{204} Id. § 801.420.

\footnote{205} Id. § 801.427.

\footnote{206} FDA regulations specifically allow manufacturers to change product labeling to enhance the safety of the device or of its use, without prior FDA permission. See, e.g., id § 814.39(d)(1), (2); see also id. § 860.7(c) (requirement that a device's safety and
Courts addressing state-law failure-to-warn actions involving tampon labeling have in effect adopted this perspective. They have held that whereas claims of design defect, manufacturing defect, and violation of FDA regulations may proceed, failure-to-warn claims attacking labeling in compliance with the detailed regulatory requirements are preempts. This sensible approach gives specific content to Justice Stevens’s suggestion in Medtronic that in the medical device context, a claim might be preempted under conflict preemption analysis.

We turn now to an exploration of the implications of Medtronic and the preemption potent for products liability claims involving products regulated by the National Highway Traffic Safety Administration and the Consumer Product Safety Commission.

effectiveness be established by valid scientific evidence, as defined.


A case in which the court upheld a large compensatory and punitive damage verdict against a tampon manufacturer, O’Givvie v. International Playtex, Inc., 821 F.2d 1438 (10th Cir. 1987), cert. denied, 486 U.S. 1032 (1988), does not necessarily contradict these cases. Preemption was not raised as a defense in O’Givvie. More fundamentally, the court indicated that the adequacy of the product warning, which complied with the FDA regulation, was offset by the manufacturer’s advertising of the product’s effectiveness despite knowledge of its high risk of toxic shock syndrome. Id. at 1446.

The O’Givvie decision, considered in the light of Medtronic and Cipollone, suggests that even if a failure-to-warn claim premised on negligent labeling is barred by a federal regulation dictating a particular label warning, other marketing defect claims (such as negligent promotion of a hazardous product, or failure to warn by non-label means) would not be precluded. See Medtronic, 116 S. Ct. at 2258 n.19 (opinion of the Court); Cipollone, 505 U.S. at 527-29.

208. Medtronic, 116 S. Ct. at 2259 (opinion of the Court) (citing Freightliner, 115 S. Ct. at 1488).

A further (though hypothetical) example of a federal dictate might be an aspect of a performance standard promulgated under 21 C.F.R. § 861 (1996). FDA is authorized to address, for example, "the design, construction, components, ingredients, and properties of the device, and its compatibility with power systems and connections to such systems.” Id. § 861.7(b). If an aspect of such a standard was framed in prescriptive terms, and had not become outdated by technological improvements subsequent to the standard’s promulgation, state-law tort actions challenging a product feature complying with that aspect of the standard might be barred by the dictate.
THE PREEMPTION PENTAD

C. Motor Vehicles

Preemption analysis under the federal motor vehicle safety law begins with an inquiry into the scope of both the express preemption clause and a savings clause.

Section 30103(b) of the National Traffic and Motor Vehicle Safety Act\(^{209}\) details the preemptive effect that federal motor vehicle safety standards have on state and local safety standards. In relevant part, it states:

When a motor vehicle safety standard is in effect under this chapter, a State or a political subdivision of a State may prescribe or continue in effect a standard applicable to the same aspect of performance of a motor vehicle or motor vehicle equipment only if the standard is identical to the standard prescribed under this chapter.\(^{210}\)

The savings clause, entitled “Continuation of Common Law Liability,” states: “Compliance with any Federal motor vehicle safety standard issued under this title does not exempt any person from liability under common law.”\(^{211}\)

The Traffic Safety Act presents one of the strongest cases of “express non-preemption” of state-law damage actions—part two of our pentad—of any of the federal health and safety laws. The savings clause language is pellucid. Moreover, the legislative history of the Act explicitly states that tort claims should not be affected by regulatory actions of the National Highway Traffic Safety Administration (“NHTSA”), the federal agency established by the Traffic Safety Act.\(^{212}\) For example, the Senate Report to the Traffic Safety Act directs:

Federal minimum safety standards need not be interpreted as restricting State common law standards of care. Compliance with such standards would thus not necessarily shield any person from product liability at common law.\(^{213}\)


\(^{211}\) Id. § 30103(e)(2).


In addition, the House committee report states:

\textit{Common law liability}. Section 108(c) of the report bill provides that compliance with any Federal motor vehicle safety standard does not exempt a person from any liability under common law. It is intended, and this subsection specifically establishes, that compliance with safety standards is not to be a defense or otherwise to affect the rights of parties under common law particularly those relating to warranty, contract, and tort liability.\footnote{H.R. REP. NO. 89-1776, at 24 (1966) (emphasis added).}

Moreover, § 30103(b) preempts only state “standards” that are nonidentical to federal “standards.”\footnote{49 U.S.C. § 30103(b) (1994). Under the Traffic Safety Act, \textit{federal} “motor vehicle safety standards” refer only to regulations promulgated by the Secretary of Transportation. Nowhere does the act mention state law tort claims or other civil damage actions, except in the context of the savings provision of § 30103(e). That the Traffic Safety Act would use the term “standard” narrowly with respect to federal action and broadly with respect to state action seems highly unlikely. The courts have long indicated that a term appearing at several places in statutory text is generally read the same way each time it appears. See, e.g., Ratzlaff v. United States, 114 S. Ct. 655, 660 (1994); State v. Besa, 864 P.2d 854, 858 (Or. 1993).}

This suggests that Congress intended to preempt only positive enactments of a directive nature such as statutes, regulations and ordinances, not state-law personal injury verdicts.\footnote{The Supreme Court reserved judgment on this point in \textit{Freightliner}, 115 S. Ct. at 1487 n.3.}

Every indication in the Traffic Safety Act and its legislative history points to the conclusion that Congress intended for NHTSA regulations to be “minimum” standards\footnote{49 U.S.C. § 30102 (1996) (defining “motor vehicle safety standards” as “minimum” standards for motor vehicle or motor vehicle equipment performance); S. REP. NO. 89-1301 (1966), reprinted in 1966 U.S.C.C.A.N. 2709, 2720 (noting that “[f]ederal minimum safety standards need not be interpreted as restricting State common law standards of care”); see also Nader & Page, supra note 212, at 421 (arguing that “minimum” standards} that, even if met, would not preclude state-law
damage actions. Above all, Congress's principal purpose in enacting the Traffic Safety Act was to promote consumer safety. Barring civil suits by injured consumers whenever federal standards exist, however minimal or inadequate they might be (often because of industry opposition to regulation), effectively undermines rather than promotes safety.

constitute a "floor above which common law courts could erect higher standards in product liability suits ").


The Traffic Safety Act's legislative history, however, makes clear that the chief purpose of the Act is safety. Its goal is "to "provide for a coordinated national safety program and establishment of safety standards for motor vehicles in interstate commerce to reduce traffic accidents and the deaths, injuries, and property damage which occur in such accidents . . . ." S. Rep. No. 89-1301, at 1 (1966), reprinted in 1966 U.S.C.C.A.N. 2709. The courts that have relied on the language in the Senate Report mentioning the need for uniformity ignore critical language in the next paragraph of the Senate report:

The States are . . . permitted to set more stringent requirements for purposes of their own procurement. Moreover, the Federal minimum standards need not be interpreted as restricting State common law standards of care. Compliance with such standards would thus not necessarily shield any person from product liability at common law.


220. Given that the auto industry "waged the regulatory equivalent of war against the
This analysis of the preemption and savings clauses of the Traffic Safety Act in light of the statute's background, structure, and legislative history and the traditional presumption against preemption—the first two steps of the pentad—leads to the conclusion that Congress intended the preemption clause to be read as applying only to state legislative and administrative directives, consistent with its approach in other consumer protection laws of the same era such as the drug and medical device laws. Indeed, for the first twenty years or so after the Traffic Safety Act's passage, the courts unanimously rejected arguments that state law damage actions could be preempted by NHTSA safety standards. In recent years, however, a number of courts have invoked the Act's preemption provisions in various ways to bar damage claims filed by injured consumers, most often in cases involving claims that auto manufacturers should have adopted safety measures above and beyond those required in NHTSA's "passive restraint" regulations. The courts that did so generally adopted a conflict preemp-

airbag," Motor Vehicle Mfrs. Ass'n v. State Farm Auto Ins. Co., 463 U.S. 29, 49 (1983), it should come as no surprise that NHTSA's passive restraint rules have mandated airbags in a slow, incremental manner having little to do with optimizing safety. See Kurt Chadwell, Automobile Passive Restraint Claims Post-Cipollone: An End to the Federal Preemption Defense, 46 BAYLOR L. REV. 141, 150 (1994) (describing the "auto industry's dilatory tactics, which successfully postponed implementation of mandatory passive restraint systems for over 20 years" resulting in the loss of many lives that otherwise might have been saved).

221. The Traffic Safety Act was enacted to add to the degree of safety available to the public, not to substitute government regulation for tort claims. Regrettably, government safety standards do not always provide substantial improvements in safety. That is why, on occasion, the courts will uphold even punitive damage awards against companies whose products comply with applicable government safety standards. See, e.g., Dorsey v. Honda Motor Co., 655 F.2d 650 (5th Cir. 1981), modified, 670 F.2d 21, cert. denied, 459 U.S. 880 (1982); Gryn v. Dayton-Hudson Corp., 297 N.W. 727 (Minn.), cert. denied sub nom. Riegel Textile Corp. v. Gryn, 449 U.S. 921 (1980).

222. See, e.g., Shipp v. General Motors Corp., 750 F.2d 418 (5th Cir. 1985); Souris v. General Motors Corp., 717 F.2d 1511 (6th Cir. 1983); Schwartz v. American Honda Motor Co., 710 F.2d 378 (7th Cir. 1983); Dorsey v. Honda Motor Co., 655 F.2d 650 (5th Cir. 1981), cert. denied, 459 U.S. 880 (1982); Dawson v. Chrysler Corp., 630 F.2d 990 (3d Cir. 1980), cert. denied, 450 U.S. 959 (1981); Stonehocker v. General Motors Corp., 630 F.2d 950 (4th Cir. 1978); Fox v. Ford Motor Co., 575 F.2d 774 (10th Cir. 1978); Volkswagen of Am. v. Young, 321 A.2d 737 (Md. Ct. Spec. App. 1974); H.P. Hood & Sons, Inc. v. Ford Motor Co., 345 N.E.2d 683 (Mass. 1976); Arbet v. Gussaron, 225 N.W.2d 431 (Wis. 1976); see also Nader & Page, supra note 212, at 427 (noting that "Until the mid-1980s, defendants requesting the judiciary to defer to the Congress or NHTSA on the matter of auto-design liability consistently met with rejection").

223. Most of the rulings came subsequent to the Supreme Court's decision in Cipollone. See supra notes 28-35 and accompanying text.

tion analysis\textsuperscript{225} that, notwithstanding the explicit language of the Traffic Safety Act’s savings clause,\textsuperscript{226} the clause could not be interpreted to permit state-law damage actions to undermine the Act’s regulatory scheme.\textsuperscript{227} In evaluating whether the cases preempting state-law attacks on passive restraint systems are good law in the light of Medtronic, we turn to Steps Three and Four of the pentad to determine whether, with regard to each type of state-law claim, the defendant was bound by a federal dictate or was marketing the product under a regime of federal acquiescence.

Where plaintiffs challenge an aspect of motor vehicle equipment as to which NHTSA regulations do not specify a particularized requirement, no
federal dictate exists and the claim is not preempted.\(^{228}\) For example, an airbag may meet the performance criteria addressed in the relevant NHTSA regulation, but a different aspect of the airbag design may have caused the plaintiff’s injury.\(^{229}\) The reasonableness of the manufacturer’s design choice, under traditional products liability law, is a matter for the determination of the factfinder, subject to whatever weight state law gives to compliance with the federal standard;\(^{230}\) but as a matter of federal law, the NHTSA regulation would not preclude the claim.

Somewhat more difficult is the analysis of a claim that the auto manufacturer’s choice of a passive restraint system permitted by NHTSA regulation was an unreasonable choice. NHTSA’s Federal Motor Vehicle Safety Standard ("FMVSS") 208,\(^{231}\) for example, permitted manufacturers to use any of several alternative passive restraint systems, e.g., airbags or automatic belts with or without lap belts, that provided crash protection.\(^{232}\) Manufacturers’ design choices have been challenged on grounds that, under principles of state tort law, the companies should have taken steps beyond NHTSA’s “minimum” safety standards.\(^{233}\) Auto companies and some courts have taken the position that, even absent express preemption, under \textit{Freightliner}\(^{234}\) such theories set up an implied conflict between the federal regime and state law.\(^{235}\)

\(^{228}\) See \textit{Freightliner}, 115 S. Ct. at 1488 (holding no preemption where the standard invoked by defendant “imposes no requirements either requiring or prohibiting” the safety feature at issue).


\(^{230}\) See, e.g., Doyle v. Volkswagen Aktiengesellschaft, 481 S.E.2d 518 (Ga. 1997) (holding, in response to certified question from the Eleventh Circuit, that compliance with federal vehicle safety standards or regulations does not bar design defect liability as a matter of Georgia law).

\(^{231}\) 49 C.F.R. § 571.208 (1996).

\(^{232}\) The nature of permitted restraint systems shifted over time, with airbags required in a greater proportion of each manufacturer’s fleet in later years. See id.

\(^{233}\) See, e.g., Hernandez-Gomez v. Leonardo, 917 P.2d 238 (Ariz. 1996) (alleging that the Volkswagen car company should have provided a lap belt in addition to the motorized shoulder belt, knee bolster, and “anti-submarine” seat design); Minton v. Honda of Am., No. 14949, 1996 WL 402070 (Ohio Ct. App.), \textit{review granted}, 670 N.E.2d 1007 (Ohio 1996) (asserting that Honda should have installed airbags in addition to its motorized shoulder belt and manual lap belt); Nelson v. Ford Motor Co., 670 N.E.2d 307 (Ohio Ct. App.), \textit{review denied}, 666 N.E.2d 565 (Ohio 1996) (arguing that defendant should have installed passenger side air bags in addition to its shoulder belt and lap belt).

\(^{234}\) \textit{Freightliner Corp. v. Myrick}, 514 U.S. 280 (1995); see \textit{supra} notes 106-09 and accompanying text.

Attention to the permissive nature of the NHTSA regulation compels the conclusion that auto manufacturers have been operating under a regime of federal acquiescence in their design choices, and that state-law claims challenging those choices are not precluded as a matter of federal law. *Medronic*, we submit, buttresses this conclusion, for three primary reasons. First, the Court reaffirmed its recognition of the presumption against preemption in areas, such as products liability, traditionally subject to state law. Second, the Court’s decision focused on the fact that the federal agency did not require the product in question to incorporate any particular design. In this respect, the FDA’s regulatory posture is similar to that of NHTSA in enforcing FMVSS 208: any product meeting the minimum federal criteria may be marketed.

Finally, the *Medronic* Court affirmed the importance of administrative determinations in assessing the extent of preemption under most statutes. In this regard, we note that the National Highway Traffic Safety Administration has generally taken a “no-preemption” position for many years. That is, NHTSA maintains that a motor vehicle’s compliance with an auto safety standard neither preempts state law damage actions nor


236. *Medronic*, 116 S. Ct. at 2250 (opinion of the Court); *see supra* notes 110-17 and accompanying text.

237. *Medronic*, 116 S. Ct. at 2254-58 (opinion of the Court with respect to design, manufacturing, and labeling claims); *id.* at 2261 (Breyer, J., concurring in part and concurring in the judgment) (applicable FDA requirements, if any, not “specific” enough to have preemptive effect); *id.* at 2263-64 (O’Connor, J., concurring in part and dissenting in part) (FDA process “places no requirements on a device, so plaintiffs’ defective design claim is not preempted.”).

238. In deferring to FDA’s interpretation of the Medical Device Amendments’ preemption section, the *Medronic* majority used language directly relevant to NHTSA, the agency that enforces the Traffic Safety Act:

Unlike the statute construed in *Cipollone*, for instance, pre-emption under the MDA does not arise directly as a result of the enactment of the statute; rather, in most cases a state law will be pre-empted only to the extent that the FDA has promulgated a relevant federal “requirement.” Because the FDA is the federal agency to which Congress has delegated its authority to implement the provisions of the Act, the agency is uniquely qualified to determine whether a particular form of state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,” and, therefore, whether it should be pre-empted.

116 S. Ct. at 2255 (opinion of the Court) (citation omitted); *see also* *id.* at 2260-61 (Breyer, J., concurring in part and concurring in the judgment).

239. *See*, e.g., Letter from Paul Jackson Rice, Chief Counsel, National Highway Traffic Safety Administration, to Arthur H. Bryant, Executive Director, Trial Lawyers for Public Justice (Dec. 26, 1990) [hereinafter Letter from Paul Jackson Rice] (noting that NHTSA has, “for many years, interpreted the Act to allow [state law tort] actions to proceed”) (on file with the author).
provides a complete defense to such claims.\textsuperscript{240} To the limited extent that NHTSA asserts that preemption of state law claims may occur, it insists that preemption will take place only

in those relatively rare cases where the common law duty sought to be imposed on an auto manufacturer would create an actual conflict with a NHTSA safety standard, either because it would be impossible to comply with both state and federal requirements or because the judgment would "stand as an obstacle to" or "frustrate the purpose of" federal law.\textsuperscript{241}

NHTSA's view is consistent with our principle of dictate preemption. The clear wording of the Act's "savings clause" indicates that the Traffic Safety Act should rarely, if ever, preempt state-law damage actions. The only instance in which the Traffic Safety Act might preempt a state-law claim would be where plaintiff's specific theory would require a court to impose damages on a manufacturer for a product feature expressly required under a NHTSA safety standard.\textsuperscript{242} In short, we see little opportunity under this law for barring state law damage claims filed by injured consumers.

\textbf{D. Products Regulated by the Consumer Product Safety Commission}

The U.S. Consumer Product Safety Commission ("CPSC") enforces four health and safety acts that contain preemption clauses roughly similar to those in the medical device and traffic safety laws: the Consumer Product Safety Act\textsuperscript{243} ("CPSA"), the Federal Hazardous Substances Act\textsuperscript{244} ("FHSA"), the Flammable Fabrics Act\textsuperscript{245} ("FFA"), and the Poison Prevention Packaging Act\textsuperscript{246} ("PPPA"). In this section, we examine two of these laws, one with a "savings clause" and one without.\textsuperscript{247}

\begin{itemize}
  \item \textsuperscript{240} Id.
  \item \textsuperscript{241} Id. (restating standard conflict preemption principle).
  \item \textsuperscript{242} If, for example, NHTSA specified that a certain warning label, and no other, be used by auto manufacturers, dictate preemption might apply.
  \item \textsuperscript{244} Id. §§ 1261-1276 (1994).
  \item \textsuperscript{245} Id. §§ 1191-1204 (1994).
  \item \textsuperscript{246} Id. §§ 1471-1474 (1994).
  \item \textsuperscript{247} Although we do not examine preemption issues in the Poison Prevention Packaging Act and the Flammable Fabrics Act, we reach the same conclusion about them that we do for the CPSA and the FHSA, namely that these consumer protection statutes rarely, if ever, preempt state law damage claims. As the First Circuit noted in a post-	extit{Medtronic} case, Wilson v. Bradlees of New England, 96 F.3d 552 (1st Cir. 1996), the preemption provision of the Flammable Fabrics Act was amended in 1976 to include a state exemption mechanism like that of the CPSA and FHSA, discussed infra. "But there is no indication that Congress in 1976 knew that 'requirements' would later be read to encompass common law
1. The Consumer Product Safety Act

Like the Traffic Safety Act enacted in the same period, the Consumer Product Safety Act contains both a preemption provision and savings language. The CPSA's preemption provision prohibits states from establishing "requirements . . . which are designed to deal with the same risk of injury associated with [a] consumer product" for which the Commission has promulgated a safety standard. Coupled with the preemption provision are two "savings clauses" which expressly preserve state common-law and statutory remedies. As detailed in the Act's legislative history, Congress specifically intended that the savings clauses preclude the preemption of state-law damage claims.

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doctrine," the court observed. Id. at 556. The court concluded: "[W]e do not think that Congress, if squarely asked to address the issue, would say that such a standard should extinguish a common-law claim of design defect." Id. at 557; see Askren v. Hymil Mfg. Co., 648 N.Y.S.2d 895 (Sup. Ct. 1996) (no preemption of burn victim's state law tort claims by Flammable Fabrics Act).


249. Section 26 of the Consumer Product Safety Act reads in part:

(a) Whenever a consumer product safety standard under this Chapter is in effect and applies to a risk of injury associated with a consumer product, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a safety standard or regulation which prescribes any requirements as to the performance, composition, contents, design, finish, construction, packaging, or labeling of such consumer product, unless such requirements are identical to the requirements of the Federal standard.


250. Section 2074(a) of the CPSA states: "Compliance with consumer product safety rules or other rules or orders under this Act shall not relieve any person from liability at common law or under State statutory law to any other person." Id. § 2074(a). Additionally, § 2072, which provides a private statutory remedy for persons injured by knowing or willful violations of consumer product safety rules, states: "The remedies provided for in this section shall be in addition to and not in lieu of any other remedies provided by common law or under Federal or State law." Id. § 2072(c).

251. For example, the Senate Commerce Committee Report on § 2074 states in relevant part: "[The definition of 'consumer product safety standard' in § 2056 of the CPSA] read in conjunction with [§ 2074] establishes Federal Government action as 'minimum' action which is not necessarily the optimum level of safety and therefore not conclusive evidence of 'due care' in product liability litigation." See, e.g., H.R. CONF. REP. NO. 92-1593 (1972) reprinted in 1972 U.S.C.C.A.N. 4596, 4650 (compliance with consumer product safety rules "not to release any person from liability at common law to any other person"). This point is reiterated in a later section of the Senate Commerce Committee Report: "[Section 2074] reaffirms the fact that product safety standards promulgated in accordance with this bill are
The clarity of the CPSA's savings clauses makes it evident that the preemption provision was addressed only to state legislative and administrative directives, as was the case with the preemption provisions in the roughly contemporary medical device and motor vehicle safety laws.252 The Commission has explicitly endorsed this position, stating that "the statutory preemption provisions were intended to address the legislative type of standard or regulation" and rejecting the contention that the term "State or local requirement" includes state common or statutory law.253 The agency's conclusion is entitled to deference under Medtronic.254 Steps One and Two of the pentad, then, lead ineluctably to the conclusion that express preemption under the CPSA is improper.

252. Like the medical device law, see supra notes 64, 69, 74 and accompanying text, the CPSA sets up a mechanism by which states and their political subdivisions can petition the federal agency for exemptions from preemption—a mechanism that was evidently designed to be invoked only with respect to directives of a legislative or administrative character. 15 U.S.C. § 2075(c) (1994); see generally James L. Winokur & Jennifer Robbins, Consumer Product Safety: Preemption, the Commerce Clause, and State Regulatory Authority, 25 Vill. L. Rev. 232, 242-54 (1979-80) (history of CPSA preemption provisions demonstrates congressional concern with nonuniform state legislative and administrative standards).

CPSA regulations implementing the preemption exemption provision indicate the agency's understanding that it is state legislation and administrative regulation, not civil damage judgments, that is the subject matter potentially preempted by CPSA standards. "State or local requirements" subject to preemption are defined as "any statute, standard, regulation, ordinance, or other requirement that applies to a product regulated by the Commission, that is issued by a State or local government, and that is intended to have the force of law when in effect." 16 C.F.R. § 1061.2(f) (1996). Applications for exemption of such requirements from CPSA preemption are to contain, for example, "copies of any legislative history or background materials used in issuing the requirement, including hearing reports or studies concerning the development or consideration of the requirement," id. § 1061.7(a); "a detailed explanation of the State or local test method and its rationale," id. § 1061.8(d); and "information on the effect on interstate commerce a granting of the requested exemption would be expected to cause." Id. § 1061.9. None of these items of information is plausibly available if the hypothetical "requirement" in question is a jury verdict.

253. Application for Exemption from Preemption, 56 Fed. Reg. 3414, 3415 (1991) (preamble to 16 C.F.R. § 1061) (emphasis added); see supra note 252 (describing § 1061). As the preamble explained: "The Commission does not believe that 'standards' applied by courts [in civil damage actions] should be included in the definition of 'State or local requirement.' Generally, courts do not establish prospective standards or regulations applicable to a category of persons, but instead deal with the specific parties before them." 56 Fed. Reg. 3414, 3415 (1991).

254. Medtronic, 116 S. Ct. at 2255 (opinion of the Court); see id. at 2260-61 (Breyer, J., concurring in part and concurring in the judgment).
Medtronic and Freightliner indicate in dicta that the fact that a statute does not expressly preempt a state-law civil remedy does not necessarily preclude the possibility of conflict preemption. The breadth of the CPSA's savings clauses, coupled with the general presumption against preemption, counsels the utmost hesitancy in finding that a federal dictate exists barring state-law actions by injured consumers. Nevertheless, in rare cases, highly particularized CPSC standards may have the effect of preempting certain directly contradictory state-law claims.

Few cases raising preemption under the CPSA as a defense to state-law damage actions have arisen in the years since the Act became law. Whether this is due to the clear language of the CPSA's "savings clauses" or to the fact that the Consumer Product Safety Commission has promulgated few standards under the CPSA that could form the basis of a preemption defense is unclear.

Two courts have held failure-to-warn claims, but not design defect claims, to be preempted by CPSC's lawn mower safety standard. In Moe v. MTD Products, the court concluded that a mandatory warning label contained in the CPSC standard preempted the plaintiff's claim that the defendant mower manufacturer should have included a warning about the likelihood that a cable could fray and cripple a safety feature that stopped the mower blade. Since the mandatory warning label addressed the risk of injury from touching the mower blade, the court concluded that any other warning label should be preempted. The court reasoned that the savings clause "should not be interpreted to subvert the preemption provision and should be read to save those claims that are not expressly

255. 116 S. Ct. at 2259.
256. 115 S. Ct. at 1468; see supra notes 106-09 and accompanying text.
257. Moe v. MTD Prods., 73 F.3d 179 (8th Cir. 1995), and Cortez v. MTD Prods., 927 F. Supp. 386 (N.D. Cal. 1996), are exceptional cases upholding preemption defenses.
258. The CPSC has promulgated a relatively small number of consumer product safety standards for a variety of reasons: The CPSA imposes onerous procedural requirements that make it difficult to promulgate standards with ease; the CPSC favors other approaches, e.g., product recalls, over safety standards to achieve its safety goals; and the agency lacks the financial resources to undertake aggressive rulemaking approaches. See generally Robert Adler, From "Model Agency" to Basket Case—Can the Consumer Product Safety Commission Be Redeemed?, 41 ADMIN. L. REV. 61 (1989).
259. 16 C.F.R. § 1205 (1996); see Moe v. MTD Prods., 73 F.3d 179 (8th Cir. 1995); Cortez v. MTD Prods., 927 F. Supp. 386 (N.D. Cal. 1996).
260. 73 F.3d 179 (8th Cir. 1995).
261. 16 C.F.R. § 1205.6(1996) (setting forth the mandatory warning label for reel-type and rotary power mowers). The required label specifically cautioned against the type of behavior that caused plaintiff's injury. See id. § 1205.6(h).
262. Moe, 73 F.3d at 183.
263. Moe, 73 F.3d at 183.
By contrast, the court rejected the manufacturer’s assertion that the mandatory standard also preempted plaintiff’s claim that the safety device required by the standard was defectively designed.

Although the court’s conclusion that the mower standard’s mandatory warning label should have precluded plaintiff’s failure-to-warn claim is defensible in that the required label (which is specifically pictured in the CPSC regulation) could be regarded as a federal dictate, the court’s express preemption analysis was mistaken. Nothing in the CPSA or in the mower standard expressly preempts state law damage claims. In the vast majority of state-law damage actions involving products subject to CPSC regulation, the agency merely acquiesces in the products’ marketing. Only in the rare case in which a plaintiff’s claim is premised on a contradiction of a specific CPSC dictate—as the failure-to-warn claim but not the defective design claim in Moe arguably was—is preemption ever justified under the Consumer Product Safety Act.

2. The Federal Hazardous Substances Act

The Federal Hazardous Substances Act (FSHA) has been enforced by the Consumer Product Safety Commission since passage of the Consumer Product Safety Act in 1972. Originally established purely as a labeling act, the FSHA currently empowers the CPSC to impose design and performance requirements as well as to require warning labels.

The FSHA contains preemption language that addresses warning labels and performance and design requirements. Like the Consum-

264. Id. 265. According to the court: A successful tort action based on the defective design of an installed [safety device to stop the mower’s blade movement within a very short time] would not create a different standard for mower safety or impose additional requirements on the manufacturer. Instead, it would create an incentive for manufacturers to install [a safety device] that works and is properly designed, and thus ensure that the federal standard has meaning.

Id. 266. 16 C.F.R. § 1205 (1996) 267. See supra notes 249-54 and accompanying text. 268. When first passed, the Act was known as the Federal Hazardous Substances Labeling Act.


270. Section 18(b)(1)(A) of the FSHA states: [If a hazardous substance or its packaging is subject to a cautionary labeling requirement under section 2(p) [15 U.S.C. § 1261(p)] or 3(b) [15 U.S.C. § 1262(b)]]
er Product Safety Act and the Medical Device Amendments, the FHSA provides a procedure by which state and local governments can petition the agency for exemption from the preemption rules. The structure and purpose of the FHSA and the CPSA are so similar that the Commission applies the same preemption regulation to both laws, and interprets both laws' references to preemptable state "requirements" to refer only to state legislative and administrative directives. Just as under the CPSA, our analysis of the FHSA thus leads to the conclusion that express preemption of state-law civil remedies is improper.

The analysis of preemption under FHSA regulations is likewise similar to the CPSA analysis. It requires attention both to the exact nature of the plaintiff's claim and to the specifics of the allegedly preemptive regulation, in order to determine if an irreconcilable conflict exists between the two:

Most of the litigation concerning preemption and state law damage actions under the FHSA has arisen with respect to warning labels. As with the other consumer protection statutes treated here, courts in the years following the law's enactment refused to countenance preemption claims. In recent years, however, a number of courts, applying an unreasonably expansive interpretation of the Supreme Court's Cipollone

designed to protect against a risk of illness or injury associated with the substance, no State or political subdivision may establish or continue in effect a cautionary labeling requirement applicable to such substance or packaging and designed to protect against the same risk of illness or injury unless such cautionary labeling is identical to the labeling requirement applicable under section 2(p) or 3(b).

271. Section 18(b)(1)(B) of the FHSA states:
   ... if under regulations of the Commission promulgated under or for the enforcement of section 2(q) [15 U.S.C. § 1261(q)] a requirement is established to protect against a risk of illness or injury associated with a hazardous substance, no State or political subdivision of a State may establish or continue in effect a requirement applicable to such substance and designed to protect against the same risk of illness or injury unless such requirement is identical to the requirement established under such regulations.


decision, have upheld preemption defenses against plaintiffs in hazardous substance product liability cases.275

In the wake of Medtronic, few of these rulings can withstand challenge. Unlike the statutes at issue in Cipollone, the FHSA does not specify the precise wording to be used on package labels. Instead, the FHSA specifies certain critical terms, e.g., “DANGER,” “CAUTION,” or “WARNING,” but leaves the specific wording of labels to manufacturers.276 With the exception of a few regulations setting out specific labeling requirements,277 the Commission typically acquiesces in the marketing of hazardous products meeting the minimum statutory labeling criteria. This leaves the manufacturer considerable discretion, and invites challenge by injured consumers who claim that a reasonable manufacturer would have provided a more effective warning.278

Finally, some state-law damage claims involving hazardous consumer products are to be analyzed under the fifth prong of our pentad, as claims involving violations of federal law or regulation.279 For example, failure-to-warn claims concerning products intended for use by children might allege violation of the FHSA’s requirement that such products be accompanied by “adequate directions for the protection of children from the hazard.”280

E. Conclusion

The consumer protection laws of the 1960s and the 1970s regulating drugs, medical devices, motor vehicles, and consumer products were all

277. See, e.g., 16 C.F.R. § 1511.7(a) (1996) (specifying warning about pacifier strangulation hazard).
278. As the Ohio Supreme Court, in a pre-Medtronic ruling, presciently observed: Given that a manufacturer selects its own language to convey the information, to comply with the FHSA a manufacturer must supply a label which provides a reasonably adequate warning to inform a user of the risks involved, and the action to take to avoid those risks. Because this is essentially the same requirement [plaintiff] attempts to impose on [defendant], . . . it is “identical to the labeling requirement under section 2(p) [15 U.S.C. § 1261(p)]” for purposes of the FHSA’s preemption clause, and [plaintiff’s] claim is not preempted.
279. As noted, the Medtronic Court unanimously held that such claims are not preempted. See Medtronic, 116 S. Ct. at 2255-56 (opinion of the Court); id. at 2260-61 (Breyer, J., concurring in part and in the judgment); id. at 2264 (O’Connor, J., concurring in part and dissenting in part).
enacted against a backdrop of the imposition of serious hazards on the consuming public by manufacturers of defective products. Products liability law was coming into its own—the American Law Institute had adopted Dean Prosser’s strict liability concept,\(^\text{281}\) which was gaining acceptance in every jurisdiction—but Congress concluded that the discipline of the marketplace, backed by state-law civil remedies, was inadequate to protect the public sufficiently. Therefore Congress erected various regulatory structures to supplement private law, typically writing into the laws savings provisions of one sort or another preserving existing civil remedies.

In the absence of effective federal regulation, various states had enacted regulatory programs of their own, creating patchworks of often inconsistent legislative and administrative directives. Cognizant of the need for national uniformity, Congress added preemption language to the federal consumer protection laws of the period, displacing inconsistent state-law directives. Congress typically mitigated these preemption provisions with mechanisms allowing state governments to enforce, upon application to the appropriate federal agency for permission, rules more stringent than the federal. Congress never contemplated that this preemption language might some day be employed to subvert the civil remedies that the consumer protection laws had explicitly or implicitly preserved.

Yet beginning in early 1990s, that was exactly what happened. Taking the language of the federal consumer protection laws out of its proper historical context and inattentive to those laws’ original purposes, judges dissatisfied with the expansion of state products liability law\(^\text{282}\) seized on the Cipollone plurality’s injudicious gloss on the word “requirement” in a cigarette labeling law,\(^\text{283}\) and began reading the preemption provisions of other statutes to bar claims that the states would otherwise hold viable. The ludicrous extreme was reached a medical device case precluding even claims of injured consumers premised on manufacturers’ multiple criminal violations of the regulatory laws.\(^\text{284}\)

In Medtronic, the Supreme Court wisely reined in the more temerarious of these judges from their rampage through the precincts of the common law. But the Court has not yet laid down a definitive approach to preemption issues that will arise in contexts other than the regulatory category addressed in that case.

\(^{281}\) Restatement (Second) of Torts § 402A (1965).


\(^{283}\) See supra notes 28-34 and accompanying text.

\(^{284}\) See Talbot v. C.R. Bard, Inc., 63 F.3d 25 (1st Cir. 1995), petition for cert. dismissed, 116 S. Ct. 1892 (1996); see also supra notes 39-41 and accompanying text.
This Article has offered what we call a "preemption pentad" — a five-point method of analyzing federal preemption defenses. The pentad focuses in turn on (1) the construction of express preemption clauses; (2) the construction of express non-preemption or savings clauses; (3) whether the federal rule in question constitutes a preemptive dictate or (4) whether it operates as part of a regime of federal acquiescence in the marketing of products meeting minimum standards; and (5) whether the plaintiff's claim rests on an alleged violation of federal law. We have illustrated how the pentad would operate with respect to preemption defenses under the drug, medical device, motor vehicle safety, consumer product safety, and federal hazardous substances laws. We submit that this method of analysis is consistent with standard preemption doctrine, will simplify consideration of these difficult issues, and will aid courts to remain true to congressional intent in enacting the federal consumer protection laws.