Missouri Law Review

Volume 59
Issue 4 *Fall 1994*

Article 3

Fall 1994

Preemption and Medical Devices: The Courts Run Amok

Robert S. Adler

Richard A. Mann

Preemption and Medical Devices: The Courts Run Amok

Robert S. Adler[*]
Richard A. Mann[**]

I. INTRODUCTION

Attitudes toward regulation and litigation as means of promoting public health and safety constantly evolve in the United States. During the so-called "Consumer Decade,"[1] from the mid-sixties to the mid-seventies, Congress, in reaction to the strong national anti-business sentiment that prevailed during this period,[2] enacted a great number of consumer protection laws, many in the area of health and safety.[3] In parallel, the courts and various state legislatures

---

* Associate Professor of Legal Studies, Kenan-Flagler School of Business, University of North Carolina. A.B., University of Pennsylvania; J.D., University of Michigan.

** Professor of Legal Studies, Kenan-Flagler School of Business, University of North Carolina. B.S., University of North Carolina; J.D., Yale University.

1. Of 47 federal consumer protection laws enacted between 1891 and 1972, "fewer than half, or 21 statutes, were enacted in the first 75 years, and the remaining 26 were enacted [in the years from] 1966-1972." This led some observers to call the latter period the "Consumer Decade." Teresa M. Schwartz, *The Consumer Product Safety Commission: A Flawed Product of the Consumer Decade*, 51 GEO. WASH. L. REV. 32, 34 n.2 (1982).

2. *See* DAVID VOGEL, FLUCTUATING FORTUNES: THE POLITICAL POWER OF BUSINESS IN AMERICA (1989) (noting the dramatic drop in public confidence in business during the consumer decade: "between 1968 and 1977, the percentage of Americans who believed that 'business tries to strike a fair balance between profits and the interests of the public' declined from 70 percent to 15 percent.").

3. *See, e.g.*, National Traffic and Motor Vehicle Safety Act of 1966, Pub. L. No. 89-563, 80 Stat. 731 (codified at 15 U.S.C. §§ 1381-1431) (1988 & Supp. 1991); Consumer Product Safety Act of 1972, 15 U.S.C. §§ 2051-2083 (1988 & Supp. 1991); Occupational Safety and Health Act of 1970, Pub. L. No. 91-596, 84 Stat. 1590 (codified at 29 U.S.C. §§ 651-678) (1976 and Supp. V. 1981); Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended in scattered sections of 21 U.S.C.). *See also* ROBERT N. MAYER, THE CONSUMER MOVEMENT: GUARDIANS OF THE MARKETPLACE (1989) (describing the historical development of consumer groups and documenting their achievements during the 1960s and 1970s); PETER W. HUBER, LIABILITY: THE LEGAL REVOLUTION AND ITS CONSEQUENCES 26 (1988) (describing the "spate of new legislation rivaled only by the New Deal laws in scope and complexity" relating to matters of food, drink, "cars, toys, power plants, pesticides, and consumer products of every description" enacted during

expanded tort doctrines, especially those relating to product liability.[4] In recent years, however, the courts and legislatures, responding to the concerns of business, have retreated from the expansion of health and safety protections for consumers and workers.[5]

Perhaps the most dramatic indication that the courts have shifted attitudes on health and safety matters comes from recent cases relating to medical devices and preemption. Medical devices include a vast array of products from "bedpans to brainscans"[6]—in all, roughly 1,700 different types of medical devices are produced in over 7,000 establishments, which turn out more than 41,000 separate products.[7] A growing number of courts[8] have

---

this period).

4. In particular, the promulgation of § 402A of the Restatement (Second) of Torts led to a rapid expansion of the doctrine of "strict liability." Within a few years, the vast majority of jurisdictions in the United States had adopted some form of strict product liability. *See* W. PAGE KEETON ET AL., PRODUCTS LIABILITY AND SAFETY: CASES AND MATERIALS 195-96 (1980) (noting that the "general adoption of the doctrine [of strict liability] in this country from 1963 to the mid-1970s is one of the most rapid and dramatic doctrinal developments ever to occur in the law of torts").

5. *See* VOGEL, *supra* note 2, at 283 (noting that since the Reagan Administration took office, the trend toward increased government regulation of corporate social conduct "dramatically slowed"). *See also* James A. Henderson, Jr. & Theodore Eisenberg, *The Quiet Revolution in Products Liability: An Empirical Study of Legal Change*, 37 U.C.L.A. L. REV. 479 (1990) (detailing a broad doctrinal change among the courts to favor defendants in product liability cases beginning in the early to mid-1980s); David Strauss, *Whose Confirmation Mess?*, THE AMERICAN PROSPECT 91, 93-94 (Summer 1994) (describing the appointment of more than 550 federal district court judges by the Reagan and Bush Administrations as the "systematic conservative stacking of the lower courts"). Even juries appear to have shifted attitudes: A firm that publishes national jury verdict trends, Jury Verdict Research, has concluded that juries "nationwide have become markedly tougher on people who sue doctors, insurance companies and other deep-pocket defendants, siding less often with plaintiffs. And there is evidence that the size of the awards has leveled off, too." Richard Perez-Peña, *U.S. Juries Grow Tougher on Those Seeking Damages*, N.Y. TIMES, June 17, 1994, at A1.

6. STAFF OF HOUSE SUBCOMM. ON OVERSIGHT AND INVESTIGATIONS OF THE HOUSE COMM. ON ENERGY AND COMMERCE, 98TH CONG., 1ST SESS., REPORT ON MEDICAL DEVICE REGULATION: THE FDA'S NEGLECTED CHILD 1 (Comm. Print 98-F 1983) [hereinafter FDA'S NEGLECTED CHILD].

7. *Id.*

8. *See, e.g.*, Gile v. Optical Radiation Corp., 22 F.3d 540 (3d Cir. 1994) (intraocular lens), *petition for cert. filed* __U.S.L.W. __; Mendes v. Medtronic, Inc., 18 F.3d 13 (1st Cir. 1994) (pacemaker); Hinners v. Optical Radiation Corp., 15 F.3d 1096 (11th Cir. 1994) (per curiam) (intraocular lens); Duncan v. IOLAB Corp., 12 F.3d. 194 (11th Cir. 1994) (intraocular lens); Stamps v. Collagen Corp., 984 F.2d 1416

rejected injured consumers' claims against device manufacturers on the basis that the claims are preempted by the 1976 Medical Device Amendments ("MDA")[9] to the Federal Food, Drug and Cosmetic Act.[10] The courts have become particularly aggressive in doing so since the U.S. Supreme Court's

---

(5th Cir. 1993) (bovine collagen used as anti-wrinkle treatment), *cert. denied*, 114 S. Ct. 86 (1993); King v. Collagen Corp., 983 F.2d 1130 (1st Cir. 1993) (bovine collagen used as anti-wrinkle treatment), *cert. denied*, 114 S. Ct. 84 (1993); Slater v. Optical Radiation Corp., 961 F.2d 1330 (7th Cir. 1992) (intraocular lens), *cert. denied*, 113 S. Ct. 327 (1992); Moore v. Kimberly-Clark Corp., 867 F.2d 243 (5th Cir. 1989) (tampon), *reh'g denied*, 873 F.2d 297 (1989); Michael v. Shiley, Inc., No. 93-1729, 1994 WL 59349 (E.D. Pa. February 25, 1994) (Bjork-Shiley heart valve); Griffin v. Medtronic, Inc., 840 F. Supp. 396 (D. Md. 1994) (pacemaker); Kemp v. Pfizer, Inc., 835 F. Supp. 1015 (E.D. Mich. 1993) (Bjork-Shiley heart valve); Reiter v. Zimmer, Inc., 830 F. Supp. 199 (S.D. N.Y. 1993) (bone cement); Cameron v. Howmedica, Div. of Pfizer Hosp. Products Group, Inc., 820 F. Supp. 317 (E.D. Mich. 1993) (artificial hip); Hunsaker v. Surgidev Corp., 818 F. Supp. 744 (M.D. Pa. 1992) (intraocular lens) *aff'd*, 5 F.3d 1489 (3d Cir. 1993); Covey v. Surgidev Corp., 815 F. Supp. 1089 (N.D. Ohio 1993) (intraocular lens); Bravman v. Baxter Healthcare Corp., 794 F. Supp. 96 (S.D.N.Y. 1992) (heart valve), *aff'd in part and rev'd in part*, 984 F.2d 71 (2d Cir. 1993), *rehearing*, 842 F. Supp. 747 (S.D. N.Y. 1994); Bejarno v. International Playtex, Inc., 750 F. Supp. 443 (D. Idaho 1990) (tampon); Northrip v. International Playtex, Inc., 750 F. Supp. 402 (W.D. Mo. 1989) (tampon); Desmarais v. Dow Corning Corp., 712 F. Supp. 13 (D. Conn. 1989) (breast implant); Rinehart v. International Playtex, Inc., 688 F. Supp. 475 (S.D. Ind. 1988) (tampon); Stewart v. International Playtex, Inc., 672 F. Supp. 907 (D.S.C. 1987) (tampon); Green v. Dolsky, 641 A. 2d. 600 (Pa. Super. Ct. 1994). *But see* National Bank of Commerce v. Kimberly-Clark Corp., 38 F.3d 988 (8th Cir. 1994) (tampon); Oliver v. Johnson & Johnson, Inc., 863 F. Supp. 251 (W.D. Pa. 1994); Ginochio v. Surgikos, Inc., 864 F.Supp. 948 (N.D. Cal. 1994); Mulligan v. Pfizer, 850 F. Supp. 633 (S.D. Ohio 1994) (prosthetic knee); Callan v. G.D. Searle & Co., 709 F. Supp. 662 (D. Md. 1989) (intrauterine device); Kociemba v. G.D. Searle & Co., 680 F. Supp. 1293 (D. Minn. 1988) (intrauterine device); Evarets v. Intermedics Intraocular, Inc., 34 Cal. Rptr. 2d 852 (Cal. Ct. App. 1994); Larsen v. Pacesetter Systems, Inc., 837 P.2d 1273 (Haw. 1992) (pacemaker), *reh'g granted and opinion amended*, 843 P.2d 144 (Haw. 1992); Tetuan v. A.H. Robins Co., 738 P.2d 1210 (Kan. 1987) (intrauterine device).

9. Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended in scattered sections of 21 U.S.C.) [hereinafter "Medical Device Amendments" or "MDA"]. For an overview of the legislative history of the Medical Device Amendments, see AN ANALYTICAL LEGISLATIVE HISTORY OF THE MEDICAL DEVICE AMENDMENTS OF 1976 (Daniel F. O'Keefe, Jr. & Robert A. Spiegel eds., 1976) [hereinafter ANALYTICAL LEGISLATIVE HISTORY].

10. 21 U.S.C. §§ 301-393 (1982).

decision in *Cipollone v. Liggett Group*,[11] which declared that the Public Health Cigarette Smoking Act of 1969[12] preempted certain state tort claims.

In this Article, we review the law relating to preemption, the *Cipollone* decision, the preemption provisions of the MDA, the regulations issued by the Food and Drug Administration ("FDA") relating to preemption, and the impact of *Cipollone* on court interpretations of the MDA. Based on our review of the intended preemptive effect of the MDA, we conclude that it is unlikely that either Congress or the FDA intended for the MDA to preempt state tort claims. Moreover, even if preemption were justified for some tort claims—a proposition we reject—the courts have extended the rationale in *Cipollone* far beyond anything that the Supreme Court intended in its ruling. In short, we maintain that the courts have run amok in their rulings on preemption.

II. FEDERAL PREEMPTION

Federal preemption arises directly from the "Supremacy Clause" of the U.S. Constitution. This clause states:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; . . . shall be the supreme law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws to the Contrary notwithstanding.[13]

The meaning of these words is simple: federal law displaces state laws.[14] Although the Supreme Court has consistently espoused preemption since the Court's ruling in *M'Culloch v. Maryland*,[15] that state law which conflicts with federal law is "without effect,"[16] this doctrine remained hotly debated until its clear resolution by the Civil War.

---

11. 112 S. Ct. 2608 (1992).

12. 15 U.S.C. §§ 1331-1340 (1988).

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

14. For further discussion of federal preemption see Barbara L. Atwell, *Products Liability and Preemption: A Judicial Framework*, 39 BUFF. L. REV. 181 (1991); Richard C. Ausness, *Federal Preemption of State Products Liability Doctrines*, 44. S.C. L. REV. 187 (1993); Jonathan S. Massey, *Federal Preemption of Medical Device Tort Claims: Not What Congress (or the Doctor) Ordered*, 30 TRIAL 58 (June 1994); Marilyn P. Westerfield, *Federal Preemption and the FDA: What Does Congress Want?*, 58 U. CIN. L. REV. 263 (1989); Beverly L. Jacklin, Annotation *Federal Preemption of State Common Law Products Liability Claims Pertaining to Drugs, Medical Devices and Other Health-Related Items*, 98 A.L.R. FED. 124 (1990).

15. 17 U.S. (4 Wheat.) 415, 433 (1819).

16. *See* Cipollone v. Liggett Group, 112 S. Ct. 2608, 2617 (1992); Maryland v. Louisiana, 451 U.S. 725, 746 (1981).

A. Some Difficulties in Applying Preemption

Theoretically, it should be an easy matter to determine whether a state law must give way to federal law: simply look to the wording and, if necessary, the legislative history of a statute to determine whether or not Congress intended to invalidate contrary state law.[17] Unfortunately, this determination has often proved extremely challenging—to the exasperation of courts and commentators.[18] Sometimes, the difficulty arises from the inherent ambiguity of language itself; even the most determined effort to be clear on a point nonetheless may result in cloudiness.[19] At other times, the difficulty arises from the not infrequent legislative resort to intentional ambiguity when precision in language would provoke substantial opposition.[20] Finally, the difficulty arises from the lack of an accepted protocol for legislatively invoking preemption. Despite the enormous quantity of litigation Congress has spawned by its frequent fuzziness on the issue, it never has developed a uniform approach to specifying in legislation its intentions regarding preemption. Accordingly, the courts must search for the extent of preemption in each new legislative pronouncement.

---

17. Courts, of course, also look to whether agencies, acting within the scope of their "congressionally delegated authority," intend their administrative regulations to be preemptive. Louisiana Public Serv. Comm'n v. FCC, 476 U.S. 355, 369 (1986). Obviously, agency action requires a proper congressional delegation of authority.

18. *See, e.g.*, Ausness, *supra* note 14, at 190 (noting that despite numerous product preemption cases in recent years, "federal courts remain hopelessly divided" on the extent of preemption in products liability cases).

19. "There is . . . no infallible guide to good writing [and] no assurance that a person who thinks clearly will be able to write clearly . . . ." WILLIAM STRUNK, JR. & E.B. WHITE, THE ELEMENTS OF STYLE 66 (3d ed. 1979). *See also* Zechariah Chafee, Jr., *The Disorderly Conduct of Words*, 41 COLUM. L. REV. 381 (1941) (discussing the difficulties of using words to convey thoughts).

20. *See* JACK DAVIES, LEGISLATIVE LAW AND PROCESS 191-92 (2d ed. 1986) (A bill's sponsor may choose intentional ambiguity when the sponsor fears that a "tough bill will not pass." In such a case, "vagueness may cause those affected to overlook some hazard in the bill or to decide they are willing to gamble on ultimately winning the finessed decision. The sponsor then faces milder opposition and a simpler legislative battle.").

B. Express Versus Implied Preemption

Although one can classify preemption in a variety of ways,[21] most courts[22] and commentators[23] typically divide the doctrine into two categories: express and implied.

1. Express Preemption

Express preemption occurs when Congress explicitly provides language indicating that it wishes state laws to be displaced.[24] For example, in the Consumer Product Safety Act ("CPSA"),[25] Congress detailed in elaborate fashion the extent to which it wished state laws to be preempted by the CPSA[26] and the extent to which it wished them to remain in force.[27]

The fact that Congress has spoken expressly with respect to preemption, of course, does not mean that it has spoken clearly. Whether Congress has spoken clearly or not, interpreting congressional intent remains the key challenge since the "purpose of Congress is the ultimate touchstone" in determining preemption.[28] The task of determining congressional intent has

---

21. *See, e.g.*, Ausness, *supra* note 14, at 192 (noting that preemption can "occur in a variety of ways;" he divides it into the following categories: (i) express, (ii) implied when a federal regulatory scheme totally occupies the field, (iii) implied when a state regulatory scheme conflicts with federal regulatory objectives).

22. *See, e.g.*, *Cipollone*, 112 S. Ct. at 2617 ("Congress' intent may be 'explicitly stated in the statute's language or implicitly contained in its structure and purpose.'") (citing Jones v. Rath Packing Co., 430 U.S. 519, 525, (1977)).

23. *See, e.g.*, Westerfield, *supra* note 14, at 264-66; Elaine M. Martin, *The Burger Court and Preemption Doctrine: Federalism in the Balance*, 60 NOTRE DAME L. REV. 1233, 1235-36 (1985).

24. *See, e.g.*, Hillsborough County v. Automated Medical Lab., 471 U.S. 707, 713 (1985); Shaw v. Delta Air Lines, Inc., 463 U.S. 85, 106-08 (1983); *Jones*, 430 U.S. at 525; Railway Employes' Dept. v. Hanson, 351 U.S. 225, 232 (1956).

25. Consumer Product Safety Act of 1972, 15 U.S.C. §§ 2051-2083 (1988).

26. *See infra* note 149 (quoting 15 U.S.C. § 2075 (1988) (setting forth the preemptive effect of the Consumer Product Safety Act)).

27. *See* 15 U.S.C. § 2074 (1988) (stating, among other things, that "[c]ompliance with consumer product safety rules or other rules or orders under this Chapter shall not relieve any person from liability at common law or under State statutory law to any other person.") Further, Congress provided a scheme whereby states with regulations providing a "significantly higher degree of protection" than CPSC rules and orders could petition the Consumer Product Safety Commission for an exemption from preemption. *See infra* note 149 (quoting 15 U.S.C. § 2075(c) (1988)).

28. Wisconsin Pub. Intervenor v. Mortier, 501 U.S. 597, 605 (1991); Retail Clerks Int'l Ass'n Local 1625 v. Schermerhorn, 375 U.S. 96, 103 (1963). *See also* Rice v.

assumed even greater importance since *Cipollone* because the Supreme Court stated that where Congress has expressly preempted state law, the courts should refrain from any implied preemption analysis.[29]

2. Implied Preemption

Implied preemption occurs when courts infer from a regulatory scheme that Congress intended to invalidate state laws, even though Congress did not explicitly state that intent. Implied preemption can arise in a variety of ways:[30] when Congress passes legislation that is so comprehensive that it occupies the entire field;[31] when federal law conflicts with state law such that compliance with both is impossible;[32] and when compliance with both is

---

Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947) ("We start with the assumption that the historic police powers of the states were not to be superseded by the federal act unless that was the clear and manifest purpose of Congress.").

29. As stated by the Court:

> When Congress has considered the issue of pre-emption and has included in the enacted legislation a provision explicitly addressing that issue, and when that provision provides a "reliable indicium of congressional intent with respect to state authority," *Malone v. White Motor Corp.*, 435 U.S. at 505, 98 S. Ct., at 1190, "there is no need to infer congressional intent to pre-empt state laws from the substantive provisions" of the legislation. [Citation omitted] Such reasoning is a variant of the familiar principle of *expressio unius est exclusio alterius*: Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted.

Cipollone, 112 S. Ct. at 2618.

30. For a more detailed discussion of implied preemption see Atwell, *supra* note 14, at 186-91; Ausness, *supra* note 14, at 193-200; Westerfield, *supra* note 14, at 264-66.

31. *See, e.g., Cipollone*, 112 S. Ct. at 2617 ("In the absence of an express congressional command, state law is preempted . . . if federal law so thoroughly occupies a legislative field [that no room is left for the states to regulate]."); Fidelity Fed. Sav. & Loan Ass'n v. De la Cuesta, 458 U.S. 141, 153 (1982); City of Milwaukee v. Illinois, 451 U.S. 304, 317 (1981) ("Congress has . . . occupied the field through the establishment of a comprehensive regulatory program supervised by an expert administrative agency"); Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 234 (1947) ("Congress did more than make the Federal Act paramount over state law in the event of conflict. It . . . terminat[ed] the dual system of regulation").

32. *See, e.g.*, Capital Cities Cable, Inc. v. Crisp, 467 U.S. 691, 694 (1984) (state statute barring the broadcast of advertisements for alcoholic beverages preempted by FCC regulation requiring that cable operators broadcast out-of-state commercials in full); *Fidelity Fed. Sav. & Loan Ass'n*, 458 U.S. at 153 (implied preemption occurs when state law actually conflicts with federal law and it would be impossible to

possible, but state law prevents implementation of the objectives of the federal law.[33]

C. *The Judicial Reluctance to Impose Preemption*

Historically, the courts have acted with extreme caution in holding that federal law preempts state law. As the Supreme Court has stated, in order to avoid "unintended encroachment on the authority of the states,"[34] courts should construe federal law with a heavy "presumption against the preemption of state police power regulations."[35] Accordingly, preemption will not lie "unless [it is] the clear and manifest purpose of Congress."[36] Consistent with its reluctance to find preemption absent "clear and manifest" direction from Congress, the Supreme Court has indicated that ambiguous legislative pronouncements by Congress will not support the displacement of state law,[37] particularly in areas where the states have devoted many years to the development of common-law doctrines.[38] This has meant, for example, that the courts have been particularly slow to preempt state laws relating to health

---

comply with both); McDermott v. Wisconsin, 228 U.S. 115, 133-34 (1913) (preempting state statute that required labeling illegal under federal law).

33. *See, e.g.*, Michigan Canners & Freezers Ass'n v. Agricultural Mktg. & Bargaining Bd., 467 U.S. 461 (1984) (Michigan statute that required nonmember farmers of a state-organized bargaining agent for farmers to pay service fees or adhere to contracts negotiated by state bargaining unit was preempted by federal statute that did not require farmers to cooperate with such bargaining agents); Pacific Gas & Elec. Co. v. Energy Resources Conserv. & Dev. Comm'n, 461 U.S. 190, 204 (1983).

34. *See* CSX Transp. v. Easterwood, 113 S. Ct. 1732, 1737 (1993) ("In the interest of avoiding unintended encroachment on the authority of the States, . . . a court interpreting a federal statute pertaining to a subject traditionally governed by state law will be reluctant to find pre-emption.")

35. *Cipollone,* 112 S. Ct. at 2618; New York State Dep't of Social Serv. v. Dublino, 413 U.S. 405, 413 (1973) (quoting Schwartz v. Texas, 344 U.S. 199, 202-03 (1952)).

36. Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947). *See also* Garcia v. San Antonio Metro. Transit Auth., 469 U.S. 528, 546 (1985) (interpreting preemption of the common law without a clear congressional mandate "inevitably invites an unelected federal judiciary to make decisions about which state policies it favors and which it dislikes"). *See generally* CSX Transp. v. Easterwood, 112 S. Ct. 1732 (1993).

37. *See, e.g.*, Maryland v. Louisiana, 451 U.S. 725, 746 (1981).

38. *See, e.g.*, CSX Transp. v. Easterwood, 113 S. Ct. 1732 (1993); *Pacific Gas & Elec. Co.*, 461 U.S. at 206; Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 144 (1963); Medical Soc. v. Cuomo, 976 F.2d 812, 816 (2d Cir. 1992).

and safety matters,[39] especially tort claims,[40] because such matters have historically been the exclusive concern of the states.[41] Similarly, the courts have shown extreme reluctance to find preemption where such a finding will leave injured persons without a judicial remedy.[42]

One vivid example of the Supreme Court's reluctance to preempt state law is *Silkwood v. Kerr-McGee Corp.*[43] In that case, the father of a woman who had been contaminated by plutonium at a federally regulated nuclear facility sought tort damages for her contamination. A jury awarded actual damages of $505,000 and punitive damages in the amount of $10 million. Despite its prior ruling that Congress had intended to occupy the "entire field of nuclear safety concerns, except the limited powers expressly ceded to the states,"[44] the Supreme Court found no basis for barring the state common law tort action. The Court cited two reasons for finding no preemption. First, permitting preemption would effectively remove any means of judicial recourse for victims of illegal conduct by nuclear facilities since Congress provided no federal remedy for such victims.[45] Second, subsequent to the passage of the Atomic Energy Act in 1954, Congress, in 1957, enacted the Price-Anderson Act, which imposed an indemnification scheme with respect to private lawsuits by aggrieved members of the public. Had Congress

---

39. *See, e.g.*, Hillsborough County v. Automated Med. Labs, Inc., 471 U.S. 707, 715 (1985); Abbot by Abbot v. American Cyanamid Co., 844 F.2d 1108, 1112 (4th Cir.), *cert. denied*, 488 U.S. 908 (1988); New Jersey Guild of Hearing Aid Dispensers v. Long, 384 A.2d 795, 811 (N.J. 1978).

40. *See, e.g.*, *Hillsborough County*, 471 U.S. at 715 (noting the presumption against preemption of health and safety laws); *Florida Lime & Avocado Growers, Inc.*, 373 U.S. at 144 (determination of tort remedies "is a subject matter of the kind . . . traditionally regarded as properly within the scope of state superintendence"); Cleveland v. Piper Aircraft Corp., 985 F.2d 1438 (10th Cir. 1993) (Federal Aviation Act did not preempt state common law action for negligent aircraft design); Buzzard v. Roadrunner Trucking, 966 F.2d 777 (3d Cir. 1992).

41. *Hillsborough County*, 471 U.S. at 719.

42. *See* English v. General Elec. Co., 496 U.S. 72, 87-90 (1990); Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 251 (1984); United Constr. Workers v. Laburnum Constr. Corp., 347 U.S. 656, 663-64 (1953).

43. 464 U.S. 238 (1984).

44. *Pacific Gas & Elec. Co.*, 461 U.S. at 212.

45. *Silkwood*, 464 U.S. at 251 ("[T]here is no indication that Congress even seriously considered precluding the use of [state tort law remedies] either when it enacted the Atomic Energy Act in 1954 or when it amended it in 1959. This silence takes on added significance in light of Congress' failure to provide any federal remedy for person injured by such conduct. It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct. [citation omitted].").

intended to bar tort lawsuits in the Atomic Energy Act, there would have been no need for the Price-Anderson Act.[46] In short, despite the awkwardness in permitting state tort damages, the Supreme Court refused to impose preemption.[47] Absent clear direction from Congress that a different result was intended, the Court left matters alone.

III. CIPOLLONE V. LIGGETT: A NEW APPROACH TO PREEMPTION?

Prior to the 1980s, few courts upheld preemption claims that would invalidate state product liability laws.[48] The 1980s, however, brought a general judicial turn against plaintiffs in product liability cases[49] and the courts began increasingly to interpret federal statutes as requiring preemption in such cases.[50]

A number of courts in the 1990s appear to view the 1992 decision of the U.S. Supreme Court in *Cipollone v. Liggett Group*[51] as a green light to find preemption in product liability claims, particularly with respect to medical devices.[52] Whether *Cipollone* supports such an expansive approach to preemption is open to question.

In *Cipollone*, the son of a smoker who had died of lung cancer petitioned the Supreme Court to review a determination by the Third Circuit that various tort claims brought on his mother's and father's behalf against a cigarette

---

46. *See Silkwood*, 464 U.S. at 251.

47. According to the Court:

> 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.

48. *See* JOHN S. ALLEE, PRODUCT LIABILITY § 8.09(3) at 8-67 (1994) (noting that, until the 1980s, "[d]espite the potential for conflicting regulation by a federal agency and by courts and juries in fifty states, courts were initially not sympathetic to preemption claims in product liability cases (particularly those that would broadly invalidate state common law product liability laws . . . ."). *See also id.* (listing cases under the Atomic Energy Act; the Flammable Fabrics Act; the Federal Insecticide, Fungicide, and Rodenticide Act; and the National Traffic and Motor Vehicle Safety Act in which the courts rejected preemption).

49. *See generally* Henderson & Eisenberg, *supra* note 5.

50. *See* ALLEE, *supra* note 48, at 8-68 to 8-70.2 (listing cases upholding preemption claims).

51. 112 S. Ct. 2608 (1992).

52. *See supra* notes 11-12 and accompanying text.

manufacturer were preempted by the Public Health Cigarette Smoking Act of 1969.[53] Section 5(b) of the Act states:

> (b) 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.[54]

In analyzing the preemptive effect of this language, the Supreme Court reiterated the general presumption against preemption[55] and emphasized its view that the courts should resort to implied preemption analysis only when the legislature is silent with respect to preemption.[56] Notwithstanding this cautionary language and the fact that the 1969 Act nowhere mentions the common law,[57] the Court found that the 1969 statute expressly preempted certain state tort claims. This application of preemption contrasts with the Court's assessment of the predecessor statute, the Federal Cigarette Labeling and Advertising Act of 1965.[58] The earlier act, according to the Court, preempted only "positive enactments by legislatures or administrative agencies that mandate particular warning labels"[59] and not state common law tort claims.

---

53. 15 U.S.C. § 1331 (1988).

54. *Id.* § 5(b).

55. *See supra* notes 34-47 and accompanying text.

56. *Cipollone*, 112 S. Ct. at 2618.

57. *Id.* at 2620. The majority conceded that Congress "did not expressly include common law within § 5's preemptive reach," but argued that this omission occurred because Congress did not wish to preempt *all* state common law actions. *Id.* at 2621 n.22. The Court's view is a possible, but not necessarily the most plausible, explanation for this omission. In the 1960s, when Congress enacted these laws, few, if any, tort lawsuits had been filed against tobacco manufacturers. Accordingly, it is likely that Congress did not think about the law's impact on tort claims one way or the other. It is also quite possible that the law's drafters, wishing to avoid controversy, intentionally left the preemption section vague. *See also supra* note 20 and accompanying text.

58. 15 U.S.C. §§ 1331-1340. The relevant sections of this Act read as follows:

> (a) No statement relating to smoking and health, other than the statement required by section 4 of this Act, shall be required on any cigarette package.
>
> (b) No statement relating to smoking and health shall be required in the advertising of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.

Id. at §§ 1334(a), (b).

59. *Cipollone*, 112 S. Ct. at 2618-19.

Why the difference? In large part, the Court focused on the change in several terms from the 1965 Act to the 1969 Act. According to the Court, the earlier Act focused on preempting federal, state and local rulemaking bodies from requiring "any statement" that conflicted with the mandated warning labels.[60] In contrast, the Court observed, the 1969 Act bars "requirement[s] or prohibition[s] . . . imposed under State law."[61] Moreover, the Court indicated that the 1969 Act extends beyond statements in advertising to include obligations "with respect to the advertising or promotion" of cigarettes.[62] These changes convinced the Court that the 1969 Act operated with much broader effect than the 1965 Act.

In reaching its conclusion, the Court brushed aside the plaintiff's arguments that the legislative history of the 1969 Act indicated a congressional intention merely to "clarif[y]" the 1965 Act.[63] To the contrary, according to the Court, the 1969 Act went well beyond the narrow preemptive provisions of the 1965 Act.[64]

The Supreme Court saw an additional reason to consider the words "requirements and prohibitions" significant. According to the Court, because common law damages arise from tort claims, they "are premised on the

---

60. *Id.* at 2619. The Court stated that:

> [A] warning requirement promulgated by the FTC and other requirements under consideration by the States were the catalysts for passage of the 1965 Act. These regulatory actions animated the passage of § 5, which reflected Congress' efforts to prevent "a multiplicity of State and local regulations pertaining to labeling of cigarette packages," H.R.Rep. No. 89-449, 89th Cong., 1st Sess. 4 (1965), and to "preempt [all] Federal, State, and local authorit[ies] from requiring *any statement* . . . relating to smoking and health in the advertising of cigarettes.
>
> For these reasons, we conclude that § 5 of the 1965 Act only preempted state and federal rulemaking bodies from mandating particular cautionary statements and did not preempt state law damages actions.

Id. (citation omitted).

61. *Id.*

62. *Id.*

63. *Id.*

64. The Court stated:

> We reject [this argument] as incompatible with the language and origins of the amendments. As we noted in another context, "[i]nferences from legislative history cannot rest on so slender a reed. . . . The 1969 Act worked substantial changes in the law: rewriting the label warning, banning broadcast advertising, and allowing the FTC to regulate print advertising. In the context of such revisions and in light of the substantial changes in wording, we cannot accept the parties' claim that the 1969 Act did not alter the reach of § 5(b).

Id. at 2619-20.

existence of a legal duty and it is difficult to say that such actions do not impose requirements or prohibitions."[65]

In response to the plaintiffs' insistence that common law damages actions do not impose "requirement[s] or prohibition[s]" of the sort contemplated by the 1969 Act, the Court, with several justices vigorously dissenting,[66] disagreed:

> [S]uch an analysis is at odds both with the plain words of the 1969 Act and with the general understanding of common law damages actions. The phrase "[n]o requirement or prohibition" sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common law rules. As we noted in another context, "[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy."[67]

---

65. *Id.* at 2620. Further, the Court said:

> It is in this way that the 1969 version of § 5(b) differs from its predecessor: Whereas the common law would not normally require a vendor to use any specific *statement* on its packages or in its advertisements, it is the essence of the common law to enforce duties that are either affirmative *requirements* or negative *prohibitions*. We therefore reject petitioner's argument that the phrase "requirement or prohibition" limits the 1969 Act's pre-emptive scope to positive enactments by legislatures and agencies.

Id.

66. Justice Blackmun, with Justices Kennedy and Souter joining, challenged the majority's view that the phrase "no requirement or prohibition" is so clear.

> Although the Court flatly states that the phrase "no requirement or prohibition" "sweeps broadly" and "easily encompass[es] obligations that take the form of common law rules," . . . those words are in reality far from unambiguous and cannot be said clearly to evidence a congressional mandate to pre-empt state common-law damages actions. The dictionary definitions of these terms suggest, if anything, specific actions mandated or disallowed by a formal governing authority. See, *e.g.*, Webster's Third New International Dictionary 1929 (1981) (defining "require" as "to ask for authoritatively or imperatively: claim by right and authority" and "to demand as necessary or essential (as on general principles or in order to comply with or satisfy some regulation)"); Black's Law Dictionary 1212 (6th ed. 1990) (defining "prohibition" as an "[a]ct or law prohibiting something;" an "interdiction").

Id. at 2627 (Blackmun, J., dissenting).

67. *Id.* at 2620 (quoting San Diego Bldg Trades Council v. Garmon, 359 U.S. 236, 247 (1959)).

The Court's heavy reliance on the point that tort damages can play a regulatory function is surprising. Although the prospect of damages may deter tortious conduct, prior to *Cipollone*, the Supreme Court had generally drawn a sharp distinction between the *direct* state regulation of safety matters and the *incidental* regulatory effects of damage awards.[68] The former was typically preempted; the latter generally not. There are good reasons for this: although damage awards do put pressure on companies to avoid behavior that brings tort liability, they provide much more "wiggle" room for a defendant to decide whether to alter its conduct than do regulations.[69] For example, a

---

68. As noted by Justice Blackmun in dissent, the *Cipollone* majority cited *San Diego Building Trades Council* to support its holding that Congress intended to preempt tort claims in the 1969 Act. But, on several other occasions, the Court had found *Garmon's* reasoning unpersuasive:

> Not only has the Court previously distinguished *Garmon*, but it has declined on several recent occasions to find the regulatory effects of state tort law direct or substantial enough to warrant preemption.
>
> In *Goodyear Atomic Corp. v. Miller*, for example, the Court distinguished, for purposes of preemption analysis, "direct state regulation" of safety matters from "the incidental regulatory effects" of damages awarded pursuant to a state workers' compensation law. 486 U.S. at 185, 108 S. Ct. at 1712. Relying in part on its earlier decision in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 256, 104 S. Ct. 615, 625 (1984), the Court stated that "Congress may reasonably determine that incidental regulatory pressure is acceptable whereas direct regulatory authority is not." 486 U.S. at 186. Even more recently, the Court declined in *English v. General Electric Co.*, 496 U.S. at 86 to find state common-law damages claims for emotional distress preempted by federal nuclear energy law. The Court concluded that, although awards to former employees for emotional distress would attach "additional consequences" to retaliatory employer conduct and could lead employers to alter the underlying conditions about which employees were complaining, *ibid*, such an effect would be "neither direct nor substantial enough" to warrant preemption. *Id.*, at 85.

Cipollone, 112 S. Ct. at 2628-29.

69. Justice Blackmun, in dissent, effectively described the choices available to a manufacturer found liable on a tort claims, such as failure-to-warn:

> [The manufacturer] may decide to accept damages awards as a cost of doing business and not alter its behavior in any way. [citation omitted] Or, by contrast, it may choose to avoid future awards by dispensing warnings through a variety of alternative mechanisms, such as package inserts, public service advertisements, or general educational programs. The level of choice that a defendant retains in shaping its own behavior distinguishes the indirect regulatory effect of the common law from positive enactments such as statutes and administrative regulations [citation omitted].

112 S. Ct. at 2628 (Blackmun, J., dissenting).

defendant—perhaps believing that it did nothing wrong and convinced that another court loss is unlikely—may choose to pay a tort judgment, but not change its product. It has the freedom to risk paying future damages rather than adjust its behavior.[70] Thus, not preempting state tort law means that state tort policies are neither automatically overridden by less stringent federal rules nor are they automatically imposed upon companies who insist that their products are safe. Absent some compelling reason, preemption of state tort law seems unnecessary and inflexible.

Moreover, replacing state regulations with federal regulations addressing the same risks is less likely to harm injured consumers than barring tort remedies. The latter approach will prevent consumers from recovering compensation for serious injuries, illness or loss of life due to a defective product.[71]

Having rejected the plaintiffs' contention that the 1969 Act preempted no state tort claims, the Court then specified which claims were preempted and which were not. In doing so, the Court reiterated its view that it must narrowly construe the preemption section in the Act.[72] To explain the basis for its finding of preemption, the majority noted that Congress failed either to mention expressly that common law tort claims were preempted or to include a "savings clause" preserving common law claims. This, according to the majority, made "perfect sense: Congress was neither preempting nor saving common law as a whole—it was simply preempting particular common law claims, while saving others."[73]

We are skeptical that such a congressional approach makes "perfect," or even common, sense. Surely—given the likelihood of confusion and substantial litigation arising from the statute's ambiguous silence—if Congress had intended to preempt some common law claims and not to preempt others, it would have made far greater sense to state precisely which claims were to be displaced and which were to be left alone.[74]

---

70. *See, e.g., Goodyear Atomic Corp.*, 486 U.S. at 185-86.

71. *See* Ferebee v. Chevron Chemical Co., 736 F.2d 1529, 1540, *cert. denied*, 469 U.S. 1062 (1984); Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 255 (1984).

72. *See Cipollone*, 112 S. Ct. at 2621 ("[W]e must fairly but—in light of the strong presumption against pre-emption—narrowly construe the precise language of § 5(b) and we must look to each of petitioner's common law claims to determine whether it is in fact preempted."). This is a particularly unconvincing statement given that nothing in the preemption clause mentions common law actions, let alone lists which are preempted and which are not.

73. *Id.* at 2621 n.22.

74. The Court's construction of a set of preempted and non-preempted tort claims particularly frustrated Justice Blackmun and his dissenting colleagues. In examining the Court's approach, he stated:

Nevertheless, the Court concluded that the 1969 act preempted the following claims: (1) failures to warn, insofar as they rest upon the proposition that the defendants should have included additional, or more clearly stated warnings[75] and (2) fraudulent misrepresentations, insofar as they rest upon the defendants' false advertising to neutralize the effect of the federally mandated warning labels.[76] The Court held that the following claims were not preempted: (1) warranties expressly made by the defendants,[77] (2) fraudulent misrepresentations, insofar as they concealed material facts in violation of a state law duty "to disclose such facts through channels of communication other than advertising or promotion,"[78] or (3) intentional conspiracies to misrepresent or conceal material facts concerning the health hazards of smoking.[79]

IV. AN OVERVIEW OF THE MEDICAL DEVICE AMENDMENTS

Before passage of the MDA, the FDA could not review a medical device—no matter the risk—for safety and effectiveness prior to its being marketed unless the agency could convince a court to treat the device as a

---

> Notwithstanding the Court's ready acknowledgement that "'[t]he purpose of Congress is the ultimate touchstone' of preemption analysis," . . . the Court proceeds to create a crazy quilt of preemption from among the common law claims implicated in this case, and in so doing reaches a result that Congress surely could not have intended.

Id. at 2631 (Blackmun, J., concurring/dissenting) (citation omitted).

75. *Id.* at 2621-22.

76. *Id.* at 2623.

77. The Court stated:

> A manufacturer's liability for breach of an express warranty derives from, and is measured by, the terms of that warranty. Accordingly, the "requirements" imposed by an express warranty claim are not "imposed under State law," but rather imposed *by the warrantor* . . . . While the general duty not to breach warranties arises under state law, the particular "requirement . . . based on smoking and health . . . with respect to the advertising or promotion [of] cigarettes" in an express warranty claim arises from the manufacturer's statements in its advertisements. In short, a common law remedy for a contractual commitment voluntarily undertaken should not be regarded as a "requirement . . . *imposed under State law*" within the meaning of § 5(b).

Id. at 2622 (citations omitted).

78. *Id.* at 2623. "Thus, for example, if state law obliged respondents to disclose material facts about smoking and health to an administrative agency, § 5(b) would not preempt a state law claim. . . ." *Id.*

79. *Id.* at 2624.

drug.[80] In 1976, however, Congress amended the Food, Drug and Cosmetic Act[81] to provide the FDA with jurisdiction over medical devices.[82] The primary purpose of the Amendments was to expand consumer protection against dangerous devices,[83] prompted in large part by the emerging scandal

---

80. *See, e.g.*, U.S. v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784 (1969) (cardboard disc impregnated with various antibiotics used to determine a patient's antibiotic sensitivity); AMP, Inc. v Gardner, 389 F.2d. 825 (2d. Cir. 1968), *cert. denied*, 393 U.S. 825 (1968) (suture product used to stitch blood vessels together during surgery).

81. 21 U.S.C. §§ 301-393 (1982).

82. For a legislative history of the amendments, see ANALYTICAL LEGISLATIVE HISTORY, *supra* note 9. For an overview of the development and implementation of the Medical Device Amendments, see SUSAN BARTLETT FOOTE, MANAGING THE MEDICAL ARMS RACE: INNOVATION AND PUBLIC POLICY IN THE MEDICAL DEVICE INDUSTRY (1992); THE MEDICAL DEVICE INDUSTRY: SCIENCE, TECHNOLOGY, AND REGULATION IN A COMPETITIVE ENVIRONMENT (Norman F. Estrin, ed., 1990); NATIONAL ACADEMY OF ENGINEERING, INSTITUTE OF MEDICINE, NEW MEDICAL DEVICES: INVENTION, DEVELOPMENT AND USE (Karen B. Ekelnam, ed., 1988); Robert B. Leflar, *Public Accountability and Medical Device Regulation*, 2 HARV. J.L. & TECH. 1 (1989).

83. Among the key reports that convinced Congress to enact medical device legislation was one by a blue-ribbon committee of the then Department of Health, Education and Welfare called the Cooper Committee. *See* STUDY GROUP ON MEDICAL DEVICES, DEPARTMENT OF HEALTH, EDUCATION & WELFARE, MEDICAL DEVICES: A LEGISLATIVE PLAN (1970) [hereinafter, COOPER COMMITTEE REPORT]. According to the Cooper Committee, medical devices were involved in 10,000 injuries and 751 deaths during the previous ten years. *See also*, H.R. REP. No. 853, 94th Cong., 2d Sess. 12 (1976) ("Absent clear, statutory authority to regulate medical devices, the FDA cannot safeguard the health of the American public by assuring the safety and effectiveness of [medical devices]."); S. REP. NO. 33, 94th Cong., 2d Sess. 5 (1976) ("Although many lives have been saved or improved by [medical devices], the potential for harm to consumers has been heightened by the critical medical conditions in which sophisticated modern devices are used and by the complicated technology involved in their manufacture and use. . . . Increasing numbers of patients have been exposed to increasingly complex devices which pose serious risks if inadequately tested or improperly designed or used.").

Some courts have suggested that Congress had a dual purpose in enacting the Medical Device Amendments: safety *and* product innovation. *See, e.g.*, King v. Collagen Corp., 983 F.2d 1130, 1138 (1st Cir. 1993), *cert. denied*, 114 S.Ct. 84 (1993). They justify preemption, in part, on the latter purpose. We find such an argument unsupported by the legislative record. *See infra* note 126 and accompanying text.

and substantial litigation concerning the A.H. Robins Company's Dalkon Shield.[84]

A. The MDA Regulatory Scheme

The MDA's regulatory scheme is a complex one, reflecting the wide range of hazards associated with the broad array of products classified as medical devices.[85] Some devices, such as bedpans, present minor and obvious risks and thus require only minimal regulatory scrutiny. Other devices, such as pacemakers, are implanted into consumers' bodies and present enormous risks. These products require extensive evaluation for safety and effectiveness.

In order to provide the FDA with sufficient flexibility and authority to regulate the diversity of devices under its jurisdiction, Congress established a three-tiered scheme. Under this scheme, the agency must place all medical devices into one of three classes.[86]

Class I devices are the most simple and relatively risk-free devices. They may be sold without premarket approval and need not conform to FDA safety standards.[87] They must meet specified "general controls," such as good

---

84. As noted in the House Report on the 1976 Medical Device Amendments:

> An example of a legitimate medical device which was marketed without adequate premarket testing is the Dalkon Shield.... By mid-1975, the Shield had been linked to sixteen deaths and twenty-five miscarriages. Presently, more than 500 lawsuits seeking compensatory and punitive damages totalling more than $400 million are pending against the manufacturer of the Shield ....

H.R. REP. NO. 853, 94th Cong., 2d Sess. 8 (1976).

The Dalkon Shield was cited numerous times during the debates on the MDA in both the House and Senate. 122 CONG. REC. H1719-1731 (daily ed. March 9, 1976); 121 CONG. REC. S6139-6162 (daily ed. April 17, 1975). Liability claims eventually led A.H. Robins to declare bankruptcy, at which time more than 300,000 women filed claims against the company for Dalkon Shield injuries and illness. *See* RICHARD B. SOBOL, BENDING THE LAW: THE STORY OF THE DALKON SHIELD BANKRUPTCY (1991); Stephanie Goldberg, *Manufacturers Take Cover*, 72 A.B.A. J. 52 (July 1986). From 1974-1986, half of all product liability lawsuits filed in federal courts in the United States against pharmaceutical manufacturers were filed against A.H. Robins with respect to injuries or death allegedly caused by the Dalkon Shield. *See* TERENCE DUNGWORTH, PRODUCT LIABILITY AND THE BUSINESS SECTOR: LITIGATION TRENDS IN FEDERAL COURTS 51 (1988) (study for the RAND Corporation).

85. *See FDA's Neglected Child*, *supra* note 6 and accompanying text.

86. 21 U.S.C.§ 360c(a)(1) (1992). Because some courts have imposed preemption according to the degree of regulation under the MDA, it is necessary briefly to review some of the provisions of the Act.

87. 21 U.S.C. § 360c(a)(1)(A) (1992).

manufacturing practices ("GMPs").[88] Among the devices classified in Class I are tongue depressors, elastic bandages, ice bags, and bed pans.

Class II devices present greater risks than Class I devices. As originally enacted, the MDA required the FDA to draft performance standards for all Class II devices because "general controls" under Class I were viewed as insufficient to provide a reasonable assurance of safety and effectiveness.[89] Unfortunately, the administrative complexity of promulgating performance standards rendered this provision of the law unworkable,[90] leading Congress to amend it in the Safe Medical Devices Act of 1990.[91] Under the amended procedures, the FDA may impose "special controls" that include, but are not limited to, performance standards.[92] Performance standards are no longer mandatory and may now be promulgated under simpler notice and comment rulemaking procedures.[93] Examples of Class II devices include syringes, bone plates, hearing aids, resuscitators, condoms, and electrocardiograph electrodes.

Class III devices present the greatest risks and require the greatest regulatory scrutiny: premarket approval ("PMA").[94] This means that no

---

88. 21 U.S.C. § 360c(a)(1)(A)(i) (1992). General controls relate to adulteration, misbranding, registration, premarket notification, good manufacturing practices, and reporting. A device meeting these controls is thought likely to be reasonably safe and effective. *See* Leflar, *supra* note 79, at 7. *See also* Robert S. Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 FOOD DRUG COSM. L.J. 511, 512 (1988); David A. Kessler, et. al., *The Federal Regulation of Medical Devices*, 317 NEW ENG. J. MED. 357, 358 (1987).

89. 21 U.S.C. § 360c(a)(1)(B) (1988). *See also* Boguslaki, *Classification and Performance Standards under the 1976 Medical Device Amendments*, 40 FOOD DRUG COSM. L.J. 421 (1985).

90. *See FDA's Neglected Child*, *supra* note 6, at 12 (describing the highly detailed process of promulgating a performance standard involving as many as five separate *Federal Register* notices spread out over a lengthy period of time); Kessler, et. al., *supra* note 88, at 362 (estimating that it would require 50,000-plus staff years to promulgate all of the devices that FDA had placed in Class II); Adler, *supra* note 88, at 522 (describing § 360d as expensive, time-consuming, and ineffectual).

91. 21 U.S.C. § 360i (1992).

92. 21 U.S.C. § 360c(e) (1992). Special controls include performance standards, post-market surveillance, patient registries, development and dissemination of guidelines, and other appropriate actions as the FDA deems necessary to provide reasonable assurances of safety and effectiveness. *See* Ellen J. Flannery, *The Safe Medical Devices Act of 1990: An Overview*, 46 Food Drug Cosm. L.J. 129, 136 (1991) (describing the changes set forth with respect to Class II devices).

93. *Id.*

94. The requirements for premarket approval are set forth in the MDA at 21 U.S.C. §§ 360c(a)(1)(C), 360e (1992).

device in Class III may be marketed until its manufacturer has submitted extensive data that provide reasonable assurance that the device is safe and effective. Each manufacturer must secure a PMA in order to sell the device.[95] Among the types of devices in Class III are pacemakers, IUDs, intraocular lenses, and replacement heart valves.

At the time the MDA became law, thousands of devices were on the market, all requiring classification and regulation. Had Congress insisted that each device the FDA placed in Class III be withdrawn from the market until it underwent premarket approval, the results would have been devastating since the agency lacked the resources to process such large numbers of PMAs quickly. Instead, Congress permitted currently marketed devices determined by the FDA to belong in Class III to remain on the market while the FDA evaluated them for safety and effectiveness.[96] Permitting these "preenactment" Class III devices to remain on the market, in turn, created difficulties for devices in the same product category that were introduced into the market after 1976. Had the "postenactment" devices been barred from commerce until obtaining premarket approval, they would have faced an unfair competitive disadvantage relative to the preenactment devices. Accordingly, Congress provided a procedure, the so-called "510(k) notification, "that allows a manufacturer to market a device "substantially equivalent" to a preenactment device.[97]

As originally enacted, the 510(k) notification approach became the procedure of choice for companies wishing to market new devices.[98] Alarmed by the large number of Class III devices entering the market without premarket approval, Congress enacted the Safe Medical Devices Act of 1990 to stiffen the requirements for companies seeking 510(k) approval.[99] As

---

95. For an excellent summary of how the premarket approval process operates, see Leflar, *supra* note 82, at 9-22.

96. *See generally* 21 U.S.C. §§ 360c, 360e (1992).

97. 21 U.S.C. § 360(k) (1992). Under this procedure, companies are required to notify FDA ninety days in advance of distributing and selling a device "substantially equivalent" to a device on the market. For a description and discussion of the 1976 MDA procedures, see Jonathan Kahan, *Premarket Approval versus Premarket Notification: Different Routes to the Same Market*, 39 FOOD DRUG COSM. L.J. 510 (1984); Alan H. Kaplan, *Through the Maze of 510(k)s*, 39 FOOD DRUG COSM. L.J. 160 (1984).

98. In 1986, for example, 4,338 devices reached the market through the "510(k)" route while only 72 devices did so through the PMA process. *See Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 100th Cong., 1st Sess. 341 (1987). Included in the "510(k)" notifications were 281 Class III devices, which claimed substantial equivalence to preenactment devices on the market. *Id.*

99. 21 U.S.C. § 360c(i) (1992). *See also* Flannery, *supra* note 92, at 132-33.

amended, section 510(k) requires more extensive disclosure of information regarding safety and efficacy, including clinical data in appropriate cases.[100] In enacting the 1990 Act, Congress nonetheless insisted that the strengthened requirements of 510(k) were "in no way intended to establish the determination of substantial equivalence as an alternative to premarket approval."[101] In other words, the 510(k) notification procedures, although a route to the market, do not constitute premarket approval nor do they constitute, to any significant degree, FDA approval of a device's safety and effectiveness.[102]

B. Preemption Under the MDA

The controversy regarding preemption under the Medical Device Amendments begins with section 360k of the MDA,[103] the Act's preemption clause. In this section, Congress wrote the following language:

> (a) Except as provided in subsection (b), 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 Act 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.[104]

As we shall discuss, we believe that the courts have misinterpreted this section. After this, we shall return to discuss section 360k to provide what we

---

100. Under the new procedures, companies seeking 510(k) approval must submit a summary of the information on safety and efficacy—including clinical data in some instances—on which they have relied in support of their request for a substantial equivalence finding. In the case of Class III devices claiming substantial equivalence to preenactment devices, the submitter of the 510(k) notification must certify to FDA that the submitter has conducted a reasonable search of all information known or otherwise available to it respecting the preenactment device, and has included in the 510(k) notification a summary of and citation to all adverse safety and effectiveness data with respect to the preenactment device and to the device it seeks to market. *Id.*

101. H.R. REP. No. 101-808, 101st Cong. 2d Sess. 25 (1990) *reprinted in* 1990 U.S.C.C.A.N 6318, 6319.

102. This point is critical in the debate regarding preemption with respect to Class III devices that have reached the market through 510(k) procedures rather than through premarket approval. *See infra* notes 120-21 and accompanying text.

103. 21 U.S.C. § 360k(a) (1992).

104. *Id.*

believe is a more comprehensive and accurate analysis of it to demonstrate that it does not bar common law tort claims.

V. THE COURTS' APPLICATION OF CIPOLLONE TO THE MDA

Prior to *Cipollone*, few courts addressed preemption under the MDA, perhaps reflecting the prevailing view that compliance with FDA standards constituted a "strong sword" for plaintiffs, but a "weak shield" for defendants.[105] That is, a manufacturer's failure to comply with an FDA standard generally triggered a finding in court of negligence *per se* against the manufacturer, but the manufacturer's compliance with an FDA standard provided little protection against tort claims of a plaintiff. Of the courts that did rule on preemption under the MDA, the results were mixed; some courts found no preemption under the Amendments,[106] while other courts held that the MDA barred at least certain tort claims.[107] Since *Cipollone*, however,

105. *See* Jeffrey N. Gibbs & Bruce F. Mackler, *Food and Drug Administration Regulation and Products Liability: Strong Sword, Weak Shield*, 22 TORT & INS. L.J. 194, 243 (Winter 1987) (Analysis of product liability law governing drugs and medical devices reveals that "[u]nder current law, compliance with the FDA requirements affords only modest protection against the successful lawsuit. . . . Conversely, evidence of non-compliance can be a highly valuable offensive weapon for the plaintiff, virtually establishing liability."). *See also* Teresa M. Schwartz, *The Role of Federal Safety Regulations in Products Liability Actions*, 41 VAND. L. REV. 1121, 1123 (1988) (criticizing legislative proposals that "would alter dramatically the longstanding judicial treatment of regulatory and statutory standards as generally good measures of the minimum, but not the maximum, standard of care required by the common law"); Frederick H. Fern, *FDA Standards Are Not the Final Word*, 14 THE BRIEF 24 (Spring 1985) (discussing the case of Wooderson v. Ortho Pharmaceutical, Inc., 681 P.2d 1038 (Kan. 1984), *cert. denied*, 105 S. Ct. 365 (1984), in which the Kansas Supreme Court upheld an award of punitive damages against a manufacturer despite its compliance with FDA-approved labeling).

106. *See, e.g.*, Callan v. G.D. Searle & Co., 709 F. Supp. 662 (D. Md. 1989) (intrauterine device) (noting that if CU-7 were a device, no preemption would apply); Kociemba v. G.D. Searle & Co., 680 F. Supp. 1293 (D. Minn. 1988) (intrauterine device) (noting that if CU-7 were a device, no preemption would apply); Larsen v. Pacesetter Systems, Inc., 837 P.2d 1273 (Haw. 1992) (pacemaker), *reh'g granted and opinion amended*, 843 P.2d 144 (Haw. 1992); Tetuan v. A.H. Robins Co., Inc., 738 P.2d 1210 (Kan. 1987) (intrauterine device).

107. *See, e.g.*, Bejarno v. International Playtex, Inc., 750 F. Supp. 443 (D. Idaho 1990) (tampon); Desmarais v. Dow Corning Corp., 712 F. Supp. 13 (D.C. Conn. 1989) (breast implant); Northrip v. International Playtex, Inc., 750 F. Supp. 402 (W.D. Mo. 1989) (tampon); Rinehart v. International Playtex, Inc., 688 F. Supp. 475 (S.D. Ind. 1988) (tampon); Stewart v. International Playtex, Inc., 672 F. Supp. 907 (D.S.C. 1987); Berger v. Personal Products, Inc., 797 P.2d 1148 (Wash. 1990), *cert. denied*,

the courts have been nearly unanimous in finding preemption,[108] in most cases ruling simply that the preemption section in the MDA uses the same word, "requirement," that the Supreme Court found preemptive in *Cipollone*. To say the least, we find such an analysis inadequate and illogical.[109]

A careful reading of *Cipollone* does not justify such an approach. First, the *Cipollone* court did not rest its analysis solely upon the addition of the words "requirements and prohibitions" in the 1969 Act. Had this been the

---

499 U.S. 961 (1991) (tampon).

108. *See, e.g.*, Gile v. Optical Radiation Corp., 22 F.3d 540 (3rd Cir. 1994) (intraocular lens); Mendes v. Medtronic, Inc., 18 F.3d 13 (1st Cir. 1994) (pacemaker); Hinners v. Optical Radiation Corp., 15 F.3d 1096 (11th Cir. 1994) (per curiam) (intraocular lens); Duncan v. IOLAB Corp., 12 F.3d. 194 (11th Cir. 1994) (intraocular lens); Rogers v. Optical Radiation Corp., 12 F.3d 194 (11th Cir. 1994); Stamps v. Collagen Corp., 984 F.2d 1416 (5th Cir. 1993) (bovine collagen used as anti-wrinkle treatment), *cert. denied*, 114 S. Ct. 86 (1993); King v. Collagen Corp., 983 F.2d 1130 (1st Cir. 1993) (bovine collagen used as anti-wrinkle treatment), *cert. denied*, 114 S. Ct. 84 (1993); Slater v. Optical Radiation Corp., 961 F.2d 1330 (7th Cir. 1992) (intraocular lens), *cert. denied*, 113 S. Ct. 327 (1992); Moore v. Kimberly-Clark, 867 F.2d 243 (5th Cir. 1989) (tampon); Michael v. Shiley, Inc., No. 93-1729, 1994 WL 59349 (E.D. Pa. Feb. 25, 1994) (Bjork-Shiley heart valve); Griffin v. Medtronic, Inc., 840 F. Supp. 396 (D. Md. 1994) (pacemaker); Elbert v. Howmedica, 841 F. Supp. 327 (D. Haw. 1993) (artificial knee); Kemp v. Pfizer, Inc. & Shiley, Inc., 835 F. Supp. 1015 (E.D. Mich. 1993) (Bjork-Shiley heart valve); Lamontagne v. E.I. DuPont de Nemours & Co., Inc., 834 F. Supp. 576 (D. Conn. 1993) (dental prosthesis); Reiter v. Zimmer, Inc., 830 F. Supp. 199 (S.D.N.Y. 1993) (bone cement); Covey v. Surgidev Corp., 815 F. Supp. 1089 (N.D. Ohio 1993) (intraocular lens); Hunsaker v. Surgidev Corp., 818 F. Supp. 744 (M.D. Pa. 1992) (intraocular lens); Bravman v. Baxter Healthcare Corp., 794 F. Supp. 96 (S.D.N.Y. 1992) (heart valve), *aff'd in part and rev'd in part*, 984 F.2d 71 (2d Cir. 1993), *reh'g granted*, 842 F. Supp. 747 (S.D.N.Y. 1994). *But see* National Bank of Commerce v. Kimberly-Clark Corp., 38 F.3d 988 (8th Cir. 1994) (no preemption of state tort law where defendants have failed to comply with federal requirements); Oliver v. Johnson & Johnson, Inc., 863 F. Supp. 251 (W.D. Pa. 1994) (MDA preempts state tort law only when FDA has established specific "counterpart" regulations); Ginochio v. Surgikos, Inc., 864 F. Supp. 948 (N.D. Cal. 1994) (MDA does not preempt state tort law); Mulligan v. Pfizer, 850 F. Supp. 633 (S.D. 1994) (tort claims not preempted by Medical Device Amendments); Larsen v. Pacesetter Systems, Inc., 837 P.2d 1273 (Haw. 1992) (finding no preemption of state tort claims by the Medical Device Amendments), *opinion amended in part on grant of reh'g*, 843 P.2d 144 (Haw. 1992); Evarets v. Intermedics Intraocular, Inc., 34 Cal. Rptr. 2d 852 (Cal. Ct. App. 1994) (claims for breach of express warranty, negligence per se, and fraudulent or negligent misrepresentations not preempted by the MDA).

109. *See infra* notes 114-116 and accompanying text.

only change from the 1965 Act, it is at least debatable whether the Court would have extended preemption to state tort claims.[110]

Second, unlike other health and safety legislative pronouncements that the Court must review for preemptive effect, the 1969 Act detailed the specific words of warning that must be used with respect to cigarettes and the arenas in which they would appear.[111] Congress, in the 1969 cigarette act, wanted those warning words required by the statute, all of those words, and nothing but those words in the advertising and promotion of cigarettes. Congress is rarely this prescriptive in other statutes, certainly not in the MDA.[112]

Third, assuming *arguendo* that Congress used the terms "requirements" and "prohibitions" to preempt state tort actions in the 1969 Public Health Cigarette Smoking Act, that does not mean every time one or both of these terms occurs in federal law that state tort law is preempted.[113] Although it would make life simpler if Congress used words consistently from statute to statute, it does not.[114] Interpreting a statute still requires an examination of the words used, the context within which they are used, the purpose of the statute, and its legislative history in order to understand its meaning.

Fourth, it would be particularly illogical to assume that Congress knew in 1976 when it drafted the MDA that the Supreme Court would interpret the word "requirement" in 1992 in *Cipollone* to include common law tort claims. Yet, without such an assumption, virtually the entire argument in support of finding preemption of tort claims under the MDA falls apart.

---

110. In addition to the changes in wording, the Court relied upon other "substantial changes" in the law, for example, "banning broadcast advertising and allowing the FTC to regulate print advertising" to reject the claim that the 1969 Act simply continued the provisions of the 1965 Act. *Cipollone*, 112 S. Ct. at 2619-20.

111. 15 U.S.C. §§ 1331-1340 (1988).

112. Nothing in the Medical Device Amendments prescribes specific wording for medical devices. To the contrary, FDA regulations specifically permit manufacturers, without prior agency approval, to make labeling and other changes that enhance safety with respect to regulated medical devices. *See* 21 C.F.R. § 814.39(d)(1) (1986).

113. *See, e.g., infra* notes 150-61 and accompanying text (arguing that the term "requirement" in the preemption section of the Federal Hazardous Substances Act does not displace state tort law).

114. According to Davies:

> [L]egislatures are fallible institutions. Statutes are not the product of months of work by a single brilliant individual who polishes it by rewriting. Legislative acts emerges [sic] from the hubbub of legislative struggle, from the drafts of beginning lawyers, from the work of lobbyists who are casual about clarity but forceful about policy, from the chaos of adjournment deadlines. . . . Eugene O'Neill dramas confuse; so do statutes. No one should be surprised.

Davies, *supra* note 20, at 304.

What is extremely disturbing about some rulings is the extent to which the courts have expanded preemption beyond the relatively narrow holding in *Cipollone*. In *Cipollone*, the Supreme Court took pains to emphasize the types of tort claims that were,[115] and were not,[116] preempted by the 1969 cigarette act. Notwithstanding this carefully tailored holding, a number of courts have granted summary judgment[117] in cases where plaintiffs have alleged fraud of the type specifically determined not to be preempted in *Cipollone*,[118] express warranty violations,[119] claims involving Class III

---

115. *See supra* notes 75-76 and accompanying text (noting that *failure to warn* claims, insofar as they rest upon the proposition that the defendants should have included additional, or more clearly stated warnings and *fraudulent misrepresentation* claims, insofar as they rest upon defendants' false advertising to neutralize the effect of the federally mandated warning labels, are preempted under the Public Health Cigarette Smoking Act of 1969).

116. *See supra* notes 77-79 and accompanying text (noting that *warranty claims* expressly made by defendants and *fraudulent misrepresentation* claims, insofar as defendants concealed material facts in violation of a state law duty to disclose such facts through channels of communication other than advertising or promotion, are not preempted by the Public Health Cigarette Smoking Act of 1969).

117. In order to dismiss a claim on a motion for summary judgment, a court must find, based on the pleadings, depositions, answers to interrogatories, and admissions on file, that "there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). *See* Silver v. City Univ., 947 F.2d 1021, 1022 (2d Cir. 1991); Rose v. Communications Satellite Corp., 759 F.2d 355, 363 (4th Cir. 1985). All inferences must be drawn, all ambiguities must be resolved, and all doubts must be resolved, in favor of the non-moving party. Celotex v. Catrett, 477 U.S. 317, 331 (1986); Adickes v. S.H. Kress & Co., 398 U.S. 144, 158-59 (1970); United States v. Diebold, Inc., 369 U.S. 654, 655 (1962); Gans v. Mundy, 762 F.2d 338, 340 (3d Cir. 1985), *cert. denied*, 474 U.S. 1010 (1985). As one court put it, "[e]ntry of summary judgment indicates that no reasonable jury could return a verdict for the losing party." Coach Leatherware Co. v. AnnTaylor, Inc., 933 F.2d 162, 167 (2d Cir. 1991). According to another court, even where a trial judge is convinced that the party opposing a motion for summary judgment is unlikely to prevail at trial or lose to a motion for directed verdict, the judge must permit the case to go forward where there is a dispute as to material fact. Hughes v. American Jawa, Ltd., 529 F.2d. 21, 25 (6th Cir. 1976).

Notwithstanding these stringent requirements, the courts that have upheld preemption have dismissed claims against manufacturers on motions for summary judgment.

118. In *Cipollone*, the Supreme Court held that its ruling did not preclude fraud claims "insofar as those claims rely on a state law duty to disclose [material] facts through channels of communication other than advertising or promotion. Thus, for example, if state law required obliged respondents to disclose material facts about smoking and health to an administrative agency, § 5(b) would not preempt a state law claim based on a failure to fulfill that obligation." *Cipollone*, 112 S. Ct. at 2612.

devices that had reached the market through "510(k) notifications" rather than through premarket approval,[120] and tort claims with respect to risks not

---

Notwithstanding this, a number of courts have refused to permit plaintiffs to proceed with such claims under the Medical Device Amendments. *See, e.g., King*, 983 F.2d at 1140 (according to concurring opinion, although plaintiff's fraud claim was "troubling," the claim should be barred since FDA "was authorized to render the expert decision on Collagen's use and labeling it, and not some jury or judge, is best suited to determine the factual issues and what their effect would have been on its original conclusions"); *Kemp*, 835 F. Supp. at 1022 ("Plaintiff has alleged that defendants engaged in a campaign of disinformation against the public and the FDA. Even if true, plaintiff's state law claims are still preempted."); *Griffin*, 840 F. Supp. at 397.

To suggest that Congress would exempt from tort liability a medical device manufacturer who had acted fraudulently with respect to its obligations to the Food and Drug Administration is to offer an approach that Congress has rejected in other contexts, such as the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-11 to 300aa-34 (1988 & Supp. II 1990). In the vaccine act, Congress exempted from punitive damages manufacturers that could demonstrate that they had complied in all respects with requirements under the Food, Drug, and Cosmetic Act, but specifically withheld this exemption from any manufacturer "engaged in . . . fraud or intentional and wrongful withholding of information from the [Food and Drug Administration] during any phase of a proceeding for approval" of the vaccine by FDA. 42 U.S.C. § 300aa-23(d) (1988 & Supp. II 1990).

In addition, to suggest that FDA, by itself, can effectively police risks in the marketplace with respect to medical devices is to ignore the many instances in which the agency has misjudged product hazards or has been unaware of them. *See infra* note 192 and accompanying text.

119. *See, e.g., King*, 983 F.2d at 1135 (holding that plaintiff's express warranty claims are preempted because any express warranties could arise only out of FDA-approved labeling and packaging); *Kemp*, 835 F. Supp. at 1018 (holding without explanation that express warranty claims are preempted); *Michael*, 1994 WL 59349 (holding no breach of express warranty where plaintiff had had her Bjork-Shiley heart valve removed because of numerous reports of deaths associated with the valve, but where her specific valve, upon removal, did not appear to malfunction).

FDA regulations buttress the notion that "requirements of general applicability," such as warranty laws, are not preempted by the Medical Device Amendments:

> Section 521 (a) does not preempt State or local requirements of general applicability where the purpose of the requirement related either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness), or to unfair trade practices in which the requirements are not limited to devices.

21 C.F.R. § 808.1(d)(1) (1993). *A fortiori*, if a warranty of fitness is not preempted, an express warranty, which a manufacturer has complete discretion to provide or not provide, should not be preempted.

120. *See* Griffin v. Medtronic, Inc., 840 F. Supp. 396 (D. Md. 1994) (barring

covered by specific "counterpart" FDA regulations.[121] To be sure, other courts have refused to extend preemption as aggressively,[122] or at all,[123]

---

claims against implantable pacemaker that had reached the market through determination that it was "substantially equivalent" to a pre-1976 device, even though neither device had ever gone through pre-market approval). To say the least, the level of regulatory scrutiny through this approach is minimal. *See* Leflar, *supra* note 82, at 46-58. Moreover, even taking Medtronic's pacemaker through the FDA's more stringent procedures now required under the 1990 Safe Medical Device Act amendments would not have constituted pre-market approval either for it or for the pre-1976 pacemaker to which it claimed "substantial equivalence." *See supra* notes 101-02 and accompanying text.

121. Under FDA's preemption guidelines, "[s]tate or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device different from, or in addition to, the specific Food and Drug Administration requirements." 21 C.F.R. § 808.1(d) (1993). Notwithstanding the need for specific FDA regulations, some post-*Cipollone* courts have found preemption anyway. *See, e.g., Bravman*, 842 F. Supp. at 761 (despite "some reservation" in doing so, court found preemption of claims regarding excessive noise associated with heart valve even though there was a lack of any FDA regulation or FDA consideration of noise when agency reviewed device); Cameron v. Howmedica, Div. of Pfizer Hosp., 820 F. Supp 317, 321 (E.D. Mich. 1993) (FDA regulation which merely identifies artificial hip without establishing any requirements for risks alleged by plaintiff held to be preempted by court). *But see Elbert*, 841 F. Supp. at 331 (finding *Cameron* "unpersuasive, as the plain language of the FDA's regulations reveal").

122. *See, e.g., Elbert*, 841 F. Supp. 327 (holding that an FDA regulation that merely "identifies" an artificial knee as a Class II device does not preempt common law tort claims for negligence, breach of warranty, and strict liability); *Lamontagne*, 834 F. Supp. at 583 (holding that, although material used to make dental implant had been specifically regulated by FDA, the dental implant itself had not been regulated, accordingly no "counterpart" FDA regulation existed and preemption would not apply); *Reiter*, 830 F. Supp. at 204 (plaintiff's negligent manufacturing claim against bone cement producer not preempted).

123. *See* National Bank of Commerce v. Kimberly-Clark Corp., 38 F.3d 988 (8th Cir. 1994) (no preemption of state tort law where defendants have failed to comply with federal requirements); Olver v. Johnson & Johnson, Inc., 863 F. Supp. 251 (W.D. Pa. 1994) (MDA preempts state tort law only when FDA has established specific "counterpart" regulations); Ginochio v. Surgikos, Inc., 864 F. Supp. 948 (N. D. Cal. 1994) (MDA does not preempt state tort law); *Mulligan*, 850 F. Supp. at 635 (similarly finding that, notwithstanding the ruling in *Cipollone*, the Medical Device Amendments do not preempt state tort claims); Larsen v. Pacesetter Systems, Inc., 837 P.2d 1273 (Haw. 1992) (finding that, notwithstanding the ruling in *Cipollone*, the Medical Device Amendments do not preempt state tort claims); and Evartes v. Intermedics Intraocular, Inc. 34 Cal. Rptr. 2d 852 (Cal. Ct. App. 1994) (claims for breach of express warranty, negligence per se, and fraudulent or negligent misrepresentations not preempted by the

but the net impression from the recent decisions is that the courts increasingly are intent on discouraging, if not eliminating, any product liability litigation under the MDA.

Motivating the courts in many instances appears to be a sense that product liability claims must be suppressed because they fundamentally impede technological innovation.[124] Aside from the fact that such a view is highly debatable,[125] virtually nothing in the MDA supports the notion that Congress intended to implement a "protect technology at all costs" policy in the MDA.[126] To the contrary, the MDA represents a congressional policy

---

MDA).

124. *See, e.g., Slater*, 961 F.2d at 1334 (arguing that "if experimental procedures are subject to hindsight evaluation by juries, . . . there will be fewer experimental treatments . . . ."); *Kemp*, 835 F. Supp. at 1023 ("If the preemption protection afforded by the MDA were removed once a faulty device was pulled from the market, then the fear and hesitancy in developing original and ground-breaking medical devices that Congress meant to alleviate would always remain as a bar to the development of needed devices that are potentially dangerous."); *Gile*, 1994 WL 160861 (arguing that "state tort claims run counter to the important public policy, recognized by Congress, of promoting scientific inventions").

125. For example, an industry group, the Conference Board, reported in 1987 that product liability had had a *beneficial* impact on product quality.

> [W]here product liability has had a notable impact—where it has most significantly affected management decision making—has been in the quality of the products themselves. Managers say products have become safer, manufacturing procedures have been improved, and labels and use instructions have become more explicit.

THE CONFERENCE BOARD, PRODUCT LIABILITY: THE CORPORATE RESPONSE 2 (1987). *See also*, Joan Claybrook, *Products Liability: Serving All Americans*, 26 TRIAL 27, 29-30 (1990) (arguing that it is a "spurious allegation" that the product liability system undermines innovation or halts research investment in medical technology); PETER REUTER, THE ECONOMIC CONSEQUENCES OF EXPANDED CORPORATE LIABILITY: AN EXPLORATORY STUDY 40 (1988) (study for the RAND Corporation). In the RAND study by Reuter, documentation that the liability system impeded technological progress proved elusive, if not non-existent.

> Curiously, [our research] yielded few instances in which products available in other nations have not yet been made available here by virtue of liability concerns, and this seemed a reasonable test of whether liability issues have yet had an impact on product variety. . . . [A]part from Bendectin, no one could offer an example of a major product withheld solely from the U.S. market as a result of liability concerns.

Id. at 41.

Moreover, why should medical devices be protected from tort liability any more than other "high-tech" products such as drugs, automobiles, or computers?

126. Any fair reading of the legislative history of the Medical Device Amendments will reveal that, except for a few passing references to the need to avoid

that unfettered and irresponsible device manufacturers must be held accountable for public health and safety.[127]

We reject the narrow approach of the post-*Cipollone* courts. For the most part, they have rested their analysis on the fact that the word "requirement" appears both in *Cipollone* and in the MDA and have concluded that preemption should apply. Such reasoning ignores (1) the textual and contextual differences of the *Cipollone* case itself, (2) the fact that Congress does not use terminology uniformly across all of its enactments, and (3) the limited preemption the Court found in *Cipollone*. To illustrate our concerns, we propose to present a comprehensive analysis of the preemption provisions of the MDA—an analysis that the post-*Cipollone* courts have done only superficially or have failed to do at all.

VI. A PRINCIPLED APPROACH TO MEDICAL DEVICE PREEMPTION

At the outset, we note that there is no absolutely dispositive language in the MDA regarding preemption and the common law. That is, nowhere in the amendments or in the legislative history of the amendments does Congress indicate that state common law tort claims are preempted[128] or are not

---

slowing innovations in medical technology, *see, e.g.*, H.R. REP. NO. 853, 94th Cong., 2d Sess. 12 (1976), the critical, and endlessly repeated, focus of congressional attention was to protect consumers from dangerous devices. *See Larsen*, 837 P.2d at 1281, in which the court, having examined the legislative history of the Medical Device Amendments, stated:

> [The legislative history of the Medical Device Amendments] reveals that Congress was concerned with *increasing* the protection afforded medical device consumers under existing law rather than with *restricting* or reforming the law in existence at the time of the Act. Moreover, in 1990, subsequent to FDA promulgation of § 808.1(d), Congress amended the Medical Device Amendments of 1976. The purpose of the legislation was to "modify the underlying law in ways that will result in *greater* protection of the public health." (emphasis added). The 1990 amendments left § 360k untouched, providing evidence that § 808.1(d) is an accurate reflection of Congressional intent under § 360k.

Id. (quoting H.R. REP. NO. 808, 101st Cong., 2d Sess. 13, *reprinted in* 1990 U.S.C.C.A.N. 6305, 6306).

127. *See supra* notes 83-84 and accompanying text.

128. A careful perusal of the entire legislative history reveals no mention of preempting state common law tort claims. *See* 121 CONG. REC. 10,687-710 (1975); S. REP. NO. 33, 94th Cong., 2d Sess. 3, *reprinted in* 1976 U.S.C.C.A.N. 1070-103; H.R. CONF. REP. NO. 1090, 94th Cong., 2d. Sess. 3, *reprinted in* 1976 U.S.C.C.A.N. 1103-18; H.R. REP. NO. 853, 94th Cong., 2d Sess. (1976). *See also*, Callan v. G.D. Searle & Co., 709 F. Supp. 662, 667 (D. Md. 1989) (finding no preemption of state tort claims under the Medical Device Amendments, in part, because "[t]he plain

preempted.[129] On the other hand, with respect to tort claims under the Food, Drug and Cosmetic Act ("FD&C Act") generally, in 1933, Congress rejected a provision in a draft of the original FD&C Act providing a federal cause of action for damages because "a common law right of action [already] exists."[130] We see nothing to indicate that Congress has changed its mind since then.

The legislative history of section 360k focused entirely on legal difficulties raised by conflicting state laws and regulations.[131] Congress was concerned that several states, including California, had statutorily required

---

language of § 360k indicates that Congress intended to preempt state or local legislation and administrative regulations governing devices.... The common law is never mentioned, and there is no provision of a federal remedy for those wrongfully injured by [unsafe medical] devices.").

As a general rule, one would expect Congress to provide either statutory language or legislative history indicating its intention to wipe out common law tort claims given the significance of such an approach. *See* Gallegos v. Lyng, 891 F.2d 788 (10th Cir. 1989).

129. Congress sometimes, although not always, states specifically that it does not wish to have common law tort claims preempted by federal agency rules. The courts refer to sections that explicitly preserve common law claims as "savings clauses." *E.g., Cipollone*, 112 S. Ct. at 2621 n.22.

130. H.R. 6110, 73d Cong., 1st Sess. Section 25 (1933); S. 1944, 73d Cong., 2d Sess. §24 (1933). *See Hearings Before a Subcommittee of the Committee on Commerce of the United States Senate on S. 1944*, 73d Cong., 2d Sess. 400, 403 (1933).

131. According to the only portion of the legislative history that deals with section 360k:

> The Committee recognizes that if a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened.... In the absence of effective Federal regulation of medical devices, some States have established their own programs. The most comprehensive State regulation of which the Committee is aware is that of California, which in 1970 adopted the Sherman Food, Drug, and Cosmetic Law. This law requires premarket approval of all new medical devices, requires compliance of device manufacturers with good manufacturing practices and authorizes inspection of establishments which manufacture devices. Implementation of the Sherman Law has resulted in the requirement that intrauterine devices are subject to premarket approval in California.
>
> Because there some situations in which regulation of devices by States and localities would constitute a useful supplement to Federal regulation, the reported bill authorizes a State or political subdivision thereof to petition the Secretary for exemptions from the bill's general prohibition on non-Federal regulation.

H.R. REP. NO. 853, 94th Cong., 2d Sess. 45 (1976).

premarket approval by the state of all new medical devices and compliance by device manufacturers with good manufacturing practices.[132] To the extent that Congress mentioned common law tort claims, it was not to criticize them or to suggest that they needed to be barred once a federal regulation was in place. Rather, it was to note how they demonstrated that *additional* protections for consumers were needed.[133]

With no "smoking gun" to resolve the issue, we turn to an examination of the language and legislative history of the MDA for clues regarding Congress' intent with respect to preemption.[134] To do so, we search for the meaning of the words of section 360k alone, the meaning of those words when read together with the rest of the statute, the FDA's interpretation of section 360k, and the meaning of the words when "read against the background of that part of human conduct with which the Act deals."[135]

---

132. *Id.* *See also* Susan Foote, *Loops and Loopholes, Hazardous Device Regulation Under the 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act*, 7 ECOLOGY L.Q. 101, 128-30 (1978) (explaining California regulations).

133. *See, e.g.*, H.R. REP. NO. 853, 94th Cong., 2d. Sess. 8 (1976) (citing "more than 500 lawsuits seeking compensatory and punitive damages" against the Dalkon Shield that might have been prevented had FDA had adequate authority to require premarket testing). *See also supra* notes 83-84 and accompanying text.

134. Absent an immediately clear resolution of the congressional meaning of the statute, one undertakes the task of interpreting the section and statute. Doing so requires resort to principles of interpretation. How this is done is explained by Jack Davies:

> The basic rule of statutory interpretation is that statutes are to be read to further the intent of the legislature. In the governmental scheme of separation of powers, the legislature has the policymaking prerogative. When a legislature has established a public policy, all the rest of the community, including the judiciary, is to follow that policy as it expressed by the words of the statute. But determining legislative intent is often difficult, so formulae, canons of construction, practical guides, and folklore have grown up around it.

Davies, *supra* note 20, at 294. *See also* Carpenters Dist. Council v. Dillard Dep't. Stores, 15 F.3d 1275 (5th Cir. 1994) (if a statute is susceptible of more than one reasonable interpretation, a reviewing court must look beyond language of statute in effort to ascertain intent of legislative body).

135. John Willis, *Statute Interpretation in a Nutshell*, 16 CAN. BAR. REV. 1, 4 (1938), *quoted in* HORACE E. READ ET AL., LEGISLATION: CASES AND OTHER MATERIALS 1091 (1959). *See also* Guertin v. Dixon, 864 P.2d 1072 (Ariz. Ct. App. 1993) (in determining legislative intent of statute, courts must consider context of statute, language used, subject matter, historical background, effects, consequences, spirit, and purpose of law); Buttelo v. S.A. Woods-Yates American Machine Co., 864 P.2d 948 (Wash. Ct. App. 1993) (when meaning of statute cannot be derived from plain meaning of statute, court may use various tools of statutory construction to

A. The Scope of Section 360k

Examining the words in section 360k(a) alone produces no absolute answer to congressional intent since the section provides no definition of the critical word "requirement." We note that the word "requirement" occurs three times in section 360k(a). Only once, however, does the word appear to be ambiguous. In section 360k(a)(1), the phrase "any requirement applicable under this Act to the device" and in section 360k(a)(2), the phrase "a requirement applicable to the device under this Act" can refer only to "positive enactments" (*i.e.*, legislative type rules) by the FDA, and not to common law tort actions, since the FDA has no authority under the MDA to impose requirements through common law tort actions. Whether Congress intended the initial use of the word "requirement" before subsection (a)(1) in section 360k to be more expansive than its two later uses of the term lies at the core of the debate about preemption. That Congress would adopt two separate meanings of a word within one section strikes us as highly improbable.[136]

The next subsection of section 360k provides exemptions from preemption. Because section 360k(b) was drafted at the same time as 360k(a) and also pertains directly to preemption, it should provide more insight into Congress' attitudes towards preemption than almost any other provision in the statute.[137] Section 360k(b) states:

---

interpret its meaning).

136. Such a reading would contradict the Supreme Court's dicta that a term appearing at several places in statutory text is generally read the same way each time it appears. *E.g.*, Ratzlaff v. U.S., 114 S. Ct. 655 (1994). *See also* State v. Bea, 864 P. 2d 854 (Or. 1993) (if the legislature uses the same term throughout the statute, a court should infer the same meaning throughout the statute).

137. *See* United States v. Morton, 467 U.S. 822, 828 (1984) ("We do not . . . construe statutory phrases in isolation; we read statutes as a whole. Thus, the words . . . must be read in light of the immediately following phrase . . . .").

> (b) 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) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this Act.[138]

This subsection is entirely inconsistent with an intent to have the term "requirement" include the common law. How a state petitions the FDA to grant an exemption for common law tort claims presents a mystery incapable of solution. The prospect of a state filing a formal request with the FDA under section 360k(b) to exempt from preemption each and every verdict in tort suits is ludicrous,[139] rendering this provision superfluous and meaningless in such a context.[140] Clearly, Congress intended for this subsection to apply only to legislative type enactments by the states and not

138. 21 U.S.C § 360k(b) (Supp. 1994).

139. As one court put it, "if the term 'requirement' were interpreted so as to include tort law, the exemption procedures would be rendered absurd; is the State supposed to petition the Secretary of Health and Human Services after every verdict in favor of an IUD tort plaintiff?" *Callan*, 709 F. Supp. at 667.

140. The courts generally reject interpretations that would render parts of a statute mere surplusage or meaningless. *See* Greenpeace, Inc. v. Waste Tech. Indus., 9 F.3d 1174 (6th Cir. 1993); Harley-Davidson v. Minstar, Inc., 837 F. Supp. 978 (E.D. Wis. 1993); People v. Hicks, 863 P.2d 714 (Ca. 1993).

to common law tort claims.[141] Given this, it violates established canons of statutory interpretation to read subsection 360k(a) in a different light.

B. Interpreting the Medical Device Amendments As A Whole

Examining the words of the entire MDA provides little or no support for the proposition that common law tort claims are preempted. Whenever the word "requirement" is used elsewhere in the MDA, it seems clear that Congress intended the word to refer only to legislative-type obligations promulgated by the FDA.[142]

---

141. FDA's interpretation of section 360k(b) focuses exclusively on legislative-type rules and appears not to contemplate the possibility of exemptions for tort decisions. Section 808.20 states:

> (a) Any State or political subdivision may apply to the Food and Drug Administration for an exemption from preemption for any requirement that it has *enacted* and that is preempted. An exemption may only be granted for a requirement that has been enacted, promulgated, or issued in final form . . . .
>
> . . . .
>
> (c) For each requirement for which an exemption is sought, the application shall include the following information . . .
>
> > (1) Identification and a current copy of any *statute, rule, regulation, or ordinance* of the State or political subdivision considered by the State or political subdivision to be a requirement which is preempted, with a reference to the date of enactment, promulgation, or issuance in final form. The application shall also include, where available, copies of any *legislative history or background materials pertinent to enactment, promulgation, or issuance of the requirement,* including hearing reports or studies concerning development or consideration of the requirement. If the requirement has been subject to any judicial or administrative interpretations, the State or political subdivision shall furnish copies of such judicial or administrative interpretations.

21 C.F.R. §§ 808.20(a), (c) (1993) (emphasis added).

142. *E.g.*, 21 U.S.C. § 360j(a) (Supp. 1994), which states:

> (a) Any requirement authorized by or under section 351, 352, 360, or 360i . . . applicable to a device intended for human use shall apply to such device until the applicability of the requirement to the device has been changed by action taken under section 360c, 360d, or 360e . . . or under subsection (g) of this section, and any requirement established by or under section 351, 352, 360, or 360i . . . which is inconsistent with a requirement imposed on such device under section 360d or 360e . . . or under subsection (g) of this section shall not apply to such device.

One section of the MDA, Section 360h(d),[143] appears particularly inconsistent with the notion that common law tort actions are preempted by the MDA. This section, which deals with FDA orders requiring producers and distributors to repair, replace or provide refunds with respect to defective devices, states:

> (d) Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy, provided him under such order shall be taken into account.[144]

The section explicitly indicates that a company's compliance with an FDA recall order will not bar tort claims against it.[145] Clearly, compliance with an FDA order and compliance with an FDA rule both involve FDA imposed requirements. Accordingly, it is perplexing to imagine Congress preempting requirements imposed by FDA *rules*, but refusing to do so with respect to FDA *orders*. This would be particularly baffling in situations involving the mandatory recall of Class III products. If Congress intended to preempt tort claims against manufacturers whose products complied with FDA *regulations*, why would it not do the same for manufacturers whose product complied with FDA recall *orders*? The illogic of such an approach strongly suggests that Congress did not intend to preempt common law tort claims with respect to FDA rules.

C. Examining the MDA's Legislative History

Having examined the words of the MDA, we next turn to the Act's legislative history. This involves two separate analyses. First, we consider the legislative history of the MDA by itself. Next, we look to other relevant legislative enactments to help provide a social context within which to understand the policies behind the preemptive provisions in the MDA.

Id. The references here are clearly to regulations promulgated by FDA and not to common law tort actions.

143. Section 360h(d) represents a substantive provision of law related to tort liability that operates in a manner inconsistent with a legislative scheme to preempt state common law tort actions.

144. 21 U.S.C. §360h(d) (1984).

145. Of course, nothing in the MDA bars a manufacturer from offering its compliance with an FDA order as evidence of due care. It would be up to a court to determine whether, under the facts of a given case, a company's prompt response to an FDA order demonstrated due care.

1. The MDA By Itself

With respect to the MDA's legislative history, the most critical aspect to note is the law's emphasis on strengthening protections from dangerous devices for consumers.[146] One court, while conceding that the "principal emphasis [of the MDA is] the protection of the individual user,"[147] nevertheless insisted that a secondary purpose of the Act in promoting research and development demonstrated a congressional intent to make FDA requirements the "total maximum protection afforded the individual user."[148] Contrary to the court's opinion, however, even a casual reading of the legislative history reveals that the quotes lifted by the court carry no hint whatsoever that FDA regulations should preempt common law tort claims.[149]

---

146. *See supra* notes 83-84 and accompanying text.

147. *King*, 983 F.2d at 1138.

148. *Id.* According to the court, "[p]erfection is impossible and a few individuals may be denied full protection at the cost of benefitting the rest." *Id.*

149. The court quoted from three separate portions of the Senate Commerce Committee's Report. To say the least, these quotes are so general and irrelevant to the resolution of the preemption issue that one is tempted to consider the court's invocation of them to be misguided at best and disingenuous at worse. They read as follows:

> As medicine progresses, as research makes new breakthroughs, an increasing number of sophisticated, critically important medical devices are being developed and used in the United States. These devices hold the promise of improving the health and longevity of American people. The Committee wants to encourage their research and development.

S. REP. NO. 33, 94th Cong., 1st Sess. 2 (1976).

> S.2368 recognizes the benefits that medical research and experimentation to develop devices offers to mankind. It recognizes, too, the need for regulation to assure that the public is protected and that health professionals can have more confidence in the performance of devices.

Id. at 6.

> The Committee recognizes the rapidly changing nature of the devices field and therefore feels that provisions must be made to amend standards on the basis of improved technology or new scientific evidence. Such amendments should be made in an expedited fashion so that appropriate changes can be rapidly implemented. The purpose of this authority is to permit new or improved devices to be marketed without delay so that the public may have such beneficial devices available to them as soon as possible.

Id. at 14.

None of these quotes support the court's proposition. The first quote, for example, is quite out of context. Had the court included the very next sentence in the Senate Report, an entirely different meaning would have emerged. The next sentence

2. Clues From the Consumer Product Safety Commission

We next examine the historical and social context of the MDA's preemption provisions. Congress did not draft section 360k in a vacuum. To the contrary, as it did with other provisions in the MDA, Congress borrowed from the preemption provisions that it placed in legislation enforced by the Consumer Product Safety Commission ("CPSC").[150] Specifically, as Congress drafted the MDA in 1976, it was almost simultaneously[151] drafting amendments to the preemption provisions of the four acts enforced by the CPSC.[152] The resulting legislation, the "Consumer Product Safety Commission Improvements Act of 1976,"[153] contained language substantially similar to that used in the MDA,[154] in particular, the language that provided

---

states: "The Committee also wants to be sure that the FDA has the proper authority to regulate that process so that Americans are not put at risk from the use of unsafe and ineffective medical devices." *Id.* at 2.

The second quote does little support the court's point. If anything, it emphasizes the need to regulate devices "to assure that the public is protected." The third quote occurs in a section addressing the standards-setting authority under the MDA and simply addresses the need for quick and efficient amendment procedures for standards.

150. *See, e.g.*, S. REP. NO. 33, 94th Cong., 1st Sess. 13 (1976) (noting that the Senate Committee on Labor and Public Welfare included provisions in the MDA related to stockpiling noncomplying devices prior to the promulgation of a safety standard that are "analogous to provisions of the Consumer Product Safety Act"); *Id.* at 16 (noting that the Committee "has been guided in the development of [§515 of the MDA] by the provisions of [two acts enforced by the Consumer Product Safety Commission], the Federal Hazardous Substances Act and the Consumer Product Safety Act"); H.R. REP. NO. 1090, 94th Cong., 2d Sess. 21 (1976) (noting that the House Committee on Interstate and Foreign Commerce added to the MDA a notification provision that is similar to comparable authority contained in several acts, including the Consumer Product Safety Act).

151. The CPSC amendments were enacted on May 11, 1976. The Medical Device Amendments were enacted on May 28, 1976.

152. The four acts are the Consumer Product Safety Act (CPSA), 15 U.S.C. §§ 2051-2083 (1982); the Federal Hazardous Substances Act (FHSA), 15 U.S.C. §§ 1261-1276 (Supp. 1994); the Flammable Fabrics Act, 15 U.S.C. §§ 1191-1204 (1982); the Poison Prevention Packaging Act, 15 U.S.C. §§ 1471-1474 (1982).

153. Act of May 11, 1976, Pub. L. 94-284, 90 Stat. 503.

154. As amended, § 26 of the Consumer Product Safety Act, 15 U.S.C. § 2075 (1982), now reads:

> (a) State compliance to Federal Standards—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

procedures for states to petition for exemption from preemption.[155] Because

---

requirements as to the performance, composition, contents, design, finish, construction, packaging, or labeling of such product which are designed to deal with the same risk of injury associated with such consumer product, unless such requirements are identical to the requirements of the Federal standard.

(b) Consumer product safety requirements which impose performance standards more stringent than federal standards.

Subsection (a) of this section does not prevent the Federal Government or the government of any State or political subdivision of a State from establishing or continuing in effect a safety requirement applicable to a consumer product for its own use which requirement is designed to protect against a risk of injury associated with the product and which is not identical to the consumer product safety standard applicable to the product under this Chapter if the Federal, State, or political subdivision requirement provides a higher degree of protection from such risk of injury than the standard applicable under this Chapter.

(c) Exemptions

Upon application of a State or political subdivision of a State, the Commission may be rule, after notice and opportunity for oral presentation of views, exempt from the provisions of subsection (a) . . . (under such conditions as it may impose in the rule) any proposed safety standard or regulation which is described in such application and which is designed to protect against a risk of injury associated with a consumer product subject to a consumer product safety standard under this Chapter if the State or political subdivision standard or regulation-

(1) provides a significantly higher degree of protection from such risk of injury than the consumer product safety standard under this Act, and

(2) does not unduly burden interstate commerce.

In determining the burden, if any, of a State or political subdivision standard or regulation on interstate commerce, the Commission shall consider and make appropriate (as determined by the Commission in its discretion) findings on the technological and economic feasibility of complying with such standard or regulation, the cost of complying with such standard or regulation, the geographic distribution of the consumer product to which the standard or regulation would apply, the probability of other States or political subdivisions applying for an exemption under this subsection for a similar standard or regulation, and the need for a national, uniform standard under this Act for such consumer product.

Id. Clauses similar to this were added to the other three acts enforced by the CPSC.

155. As discussed *supra* notes 138-41 and accompanying text, procedures that permit a state to petition a regulatory body for an exemption from preemption make no sense with respect to tort cases, thereby implying that common law tort claims were not envisioned by Congress when it added preemption provisions either to the CPSC

(1) the CPSC acts and the MDA all address protecting the public from dangerous consumer products, (2) the CPSC acts and the MDA were generally written by the same congressional committees,[156] (3) Congress drafted the CPSC acts and the MDA more or less simultaneously, and (4) the CPSC acts and the MDA adopt similar approaches to preemption, established principles of statutory interpretation suggest that these statutes should be read consistently.[157]

Several significant points emerge from the preemption provisions of the laws governing the CPSC. First, Congress never mentioned preemption of common law tort claims as one of its purposes in enacting preemption clauses in the four acts. To the contrary, Congress amended the preemption section in the Consumer Product Safety Act without modifying that act's explicit

---

acts or the Medical Device Amendments.

156. In the House of Representatives, the Committee on Interstate and Foreign Commerce drafted laws for both the CPSC and for the FDA. In the Senate, the Committee on Commerce wrote the CPSC acts while the Committee on Labor and Public Welfare wrote the Medical Device Amendments. The Senate Labor and Public Welfare Committee expressly acknowledged borrowing language from legislation governing the CPSC. *See supra* note 150 and accompanying text.

157. According to Davies, a statutory interpretation doctrine known as *in pari materia* controls when two statutes relate to the same topic:

> When more than one statute relates to a subject, the statutes must be considered together. The reason for this is that the whole body of law must be kept consistent with itself; one act must not be read to undermine or distort another act. One consequence of this bonding of acts is that a word must carry the same meaning from one statute over into another related statute, just as a word should carry one meaning throughout a single enactment. This canon makes the interpretation given a statute in one case relevant in a later case involving a different, but related, statute.

Davies, *supra* note 20, at 310. *See also* Goulder v. Arizona Dep't of Transp., 868 P.2d 997 (Ariz. Ct. App. 1993) (indicating that statutes relating to the same subject matter should be read *in pari materia* to determine legislative intent and to maintain harmony), *aff'd*, 877 P.2d 280 (Ariz. 1994); *In re* Markaus V., 260 Cal. Rptr. 126 (Cal. Ct. App. 1989) (stating that word or phrases in a statutory provision that were used in a prior act or closely related act pertaining to the same subject will usually be construed to be used in the same sense); Richardson v. City of Honolulu, 868 P.2d 1193 (Haw. 1993) (laws *in pari materia* to each other should be construed with reference to each other); AMISUB (Saint Joseph Hosp.) Inc. v. Board of County Comm'rs, 508 N.W. 2d 827 (Neb. 1993) (stating that when a court considers a series or collections of statutes pertaining to a certain subject matter which are *in pari materia*, they may be considered and construed together to determine the intent of the legislature); Transamerica Commercial Fin. Corp. v. Blueville Bank, 438 S.E. 2d 817 (W. Va. 1993) (indicating that statutes that relate to the same subject matter are "in pari materia" and must be construed together).

"savings clause"[158]—clearly indicating that Congress had no intent to preempt common law tort claims. Second, Congress emphasized the need to make the preemption provisions as uniform as possible.[159] Third, Congress, in addressing preemption, used the terms "requirements" and "standards"[160]

---

158. Section 25 of the Consumer Product Safety act states in part: "(a) 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." 15 U.S.C. § 2074(a) (1982).

159. The report of the Senate Commerce Committee, referring to the need to amend acts governing the CPSC, makes this point clearly.

> [T]his legislation addresses the question of the preemptive effect of Federal safety standards. For the first time, it would provide *a uniform Federal preemption clause for the Federal Hazardous Substances Act, the Flammable Fabrics Act, and the Consumer Product Safety Act.* The general rule would be that, if the Consumer Product Safety Commission has in effect a *requirement* for a product established to deal with a risk of illness or injury associated with that product, no State or political subdivision may establish or continue in effect a *requirement* applicable to that product and designed to deal with the same risk of illness unless it is identical to the Federal *requirement.* The exception to this general rule is that a State may maintain such a *requirement* if (a) compliance with the *requirement* would not cause the product to be in violation of the Federal *standard*; and (b) the State or local *requirement* provides a significantly higher degree of protection than the Federal *requirement* and it does not place an undue burden upon the manufacture or distribution of products in interstate commerce.

S. REP. NO. 251, 94th Cong., 1st Sess. 4 (1975) (emphasis added). *See also* the report of the House Committee on Interstate and Foreign Commerce, which states:

> *Uniformity of administration of Federal preemption of State and local requirements* is provided by amendments to existing sections in the Consumer Product Safety Act, the Federal Hazardous Substances Act, the Flammable Fabrics Act, and the Poison Prevention Packaging Act of 1970. . . .

H.R. REP. NO. 325, 94th Cong., 1st Sess. 10 (1975) (emphasis added).

Aside from demonstrating a congressional intent to impose a uniform approach to preemption, these excerpts demonstrate the use of the word "requirement" in a context where Congress clearly intended the term to apply only to positive enactments, or legislative-type rules, and not to common law tort claims. It did so by referring to the Consumer Product Safety Act, which had a "savings clause" expressly preserving common law tort claims. Accordingly, Congress could not have intended to bar tort claims. Moreover, in the Senate Report, they show the interchangeability of the term "requirement" and the word "standard," further undermining the view that the term "requirement" carries a meaning broader than legislative-type enactments.

160. We have seen no suggestion that Congress ever intended that the term "standard" refer to common law tort claims.

interchangeably[161]—again suggesting that it intended only to preempt legislative-type rules, not tort claims.

Given the *Cipollone* Court's focus on the word "requirement," we must determine whether Congress intended it to be interpreted more broadly than the word "standard" or "regulation." With respect to the acts enforced by the CPSC, we conclude that the answer is clearly no. The act enforced by the CPSC that most closely resembles the MDA in using the word "requirement" is the Federal Hazardous Substances Act ("FHSA").[162] We see no evidence that Congress intended for this act to preempt common law tort claims while preserving them under the other acts enforced by the CPSC. This conclusion seems particularly compelling in light of Congress' express intention to make

---

161. *See supra* note 159 and accompanying text. *See also* Conference Report on S. 644, in which the conferees stated with respect to whether a federal requirement preempts state requirements:

> [T]he key factor is whether the State or local *requirement* respecting a product is designed to deal with the same risk of injury or illness associated with the product as the Federal *requirement*. Even though the State or local *requirement* is characterized in different terms than the Federal *requirement* or may have different testing methods for determining compliance, so long as the Federal and State or local *requirements* deal with the same risks of injury associated with a product, the Federal *requirement* preempts a different State *requirement*. For example, a Federal *requirement* with respect to bicycles would preempt a different State *requirement* for bicycles so long as they were both designed to protect against the same risk of injury, even though the State characterized its *requirement* as a "motor vehicle" *standard*. Or a State *standard* designed to protect against the risk of injury from a fabric catching on fire would be preempted by a Federal flammability *standard* covering the same fabric even though the Federal *standard* called for tests using matches and the State *standard* called for tests using cigarettes. When an item is covered by a Federal flammability *standard* . . . a different State or local flammability *requirement* applicable to the same item will be preempted since both are designed to protect against the same risk . . . .

H.R. REP. NO. 1022, 94th Cong., 2d Sess. 29 (1976) (emphasis added).

162. In part, the preemption provision of the FHSA reads:

> (B) Except as provided in paragraphs (2), (3), and (4), if under the regulations of the Commission promulgated under or for the enforcement of [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.

15 U.S.C. § 1261 (note) (Supp. 1994).

the preemption provisions of the CPSC uniform.[163] We suspect that Congress used the word "requirement" in the FHSA for one simple reason: the FHSA contains no standards setting provisions *per se*; it imposes standards by declaring products that fail to meet mandated requirements to be "banned hazardous substances." Rather than use the awkward term "banned hazardous substance" in a preemption section, Congress chose the more generic word, "requirement."

Similar reasons likely explain the use of this word in the MDA. That is, Congress used the term "requirement" generically to cover the concepts of general controls,[164] performance standards,[165] and premarket approval.[166] By so doing, Congress avoided the constant need to list these concepts each time it wished to refer to them. It certainly gave no indication that the term included common law tort claims.

Even if Congress had other, less obvious, motives for choosing to use the term "requirement" in the preemption section of the FHSA, we find no evidence that Congress intended preemption under this act to apply more broadly than in the other CPSC acts.[167] Nothing in the Consumer Product Safety Commission Improvements Act hints this to be the case; to the contrary, Congress emphasized the need to make the acts' preemption provisions operate uniformly.[168]

In short, we conclude that the CPSC acts approach preemption uniformly, that they do not bar common law tort claims,[169] and that they represent a

---

163. *See supra* note 159 and accompanying text.

164. *See* 21 U.S.C. § 360c(a)(1)(A) (Supp. 1994).

165. *See* 21 U.S.C. § 360c(a)(1)(B) (Supp. 1994). The Medical Device Amendments now provide for "special controls" in addition to performance standards. *See supra* note 92 and accompanying text.

166. *See* 21 U.S.C. §§ 360c(a)(1)(C), 360e (Supp. 1994).

167. The FHSA preemption provisions have not been read to displace state law absent a congressional intent to preempt that is "clear and manifest." *See* Toy Mfrs. of America, Inc. v. Blumenthal, 986 F.2d 615, 617 (2d Cir. 1993) (refusing to preempt a Connecticut statute requiring toys marketed for children between the ages of three and seven to bear a warning label that the toys contained small parts hazardous for children under three even though the CPSC had regulations on small parts which it had declined to extend to cover this situation).

168. *See supra* note 159 and accompanying text.

169. Prior to *Cipollone*, most courts that addressed products regulated under the FHSA did not even address the issue of preemption. To the extent that defendants demonstrated compliance with FHSA rules, they argued that such compliance showed a lack of defectiveness with their products, not that it preempted the plaintiff's claims. *See, e.g.*, Ellis v. K-LAN Co., 695 F.2d 157, 162 n.4 (5th Cir. 1983) (noting that neither the FHSA nor any regulation promulgated under it "mandates the use of a specific variety or form of device or warning, to the exclusion of any other or

strong precedent for concluding that the MDA, similarly, does not bar tort claims.

D. FDA's Interpretation of Section 360k

Another step in understanding preemption in the MDA is to examine the FDA's interpretation of section 360k. An agency's interpretation of its own statute has taken on added significance since the Supreme Court's decision in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council.*[170] In that case, the Court established a rule that requires a reviewing court to follow an administrative agency's interpretation of its statute where the statute presents ambiguities and the agency's approach is a reasonable one.[171] Despite the

---

additional devices or warnings for the same purpose, as opposed to merely setting minimum standards or requirements"); Hickman v. Thompson Co., 644 F. Supp. 1531, 1535 (D. Colo. 1986) (stating that compliance with FHSA constitutes a rebuttable presumption that product is not defective).

One case prior to *Cipollone* did find a limited preemption under the FHSA. *See* Lee v. Boyle-Midway Household Products, Inc., 792 F. Supp. 1001, 1008 (W.D. Pa. 1992) (holding that the FHSA impliedly preempts certain common law tort claims). The *Lee* case held that the preemption clause in the FHSA, although expressly preempting state "regulations," did not expressly preempt common law claims. This led the court to rule that the FHSA *impliedly* preempted such claims. *Id.* Had the court followed the Supreme Court's ruling in *Cipollone* that the courts cannot find implied preemption in a case where a statute contains an express preemption clause, it would have clearly reached a contrary result.

Not surprisingly, however, *Cipollone* has crept into at least one FHSA case. *See* Moss v. Parks Corp., 985 F.2d 736, 741 (4th Cir.) (based on *Cipollone*, the court concluded that the FHSA preempts certain state tort labeling claims), *cert. denied*, 113 S. Ct. 2999 (1993). Again, we note the illogic of applying the *Cipollone* court's 1992 interpretation of a term to a preemption clause enacted in 1976.

170. 467 U.S. 837 (1984).

171. *Chevron* is consistent with a number of cases giving weight to an agency's interpretation of its statute. *See, e.g.*, National R.R. Passenger Corp. v Boston & Maine Corp., 112 S. Ct. 1394, 1401 (1992); Youakin v. Miller, 425 U.S. 231, 235 (1976); N.Y. Dep't of Social Services v. Dublino, 413 U.S. 405, 421 (1973); Udall v. Tallman, 380 U.S. 1, 16 (1964); Bowles v. Seminole Rock Co., 325 U.S. 410, 414 (1945).

Court's spotty record in following its own rule,[172] agency interpretations still offer useful insights into how laws function.[173]

Two sections from the FDA's regulation on preemption are particularly pertinent. Section 808.1(b) reads as follows:

> Section [360k(a)] of the act contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.[174]

The phrase "whether established by statute, ordinance, regulation, or *court decision*" in section 808.1 raises an immediate question. Do the words "court decision" extend to common law actions or do they simply cover court decisions interpreting state statutes, ordinances, or regulations? Contrary to several courts'[175] and one commentator's [176] conclusion that these words

---

172. According to Professor Thomas Merrill, during the period 1984-1990, the Supreme Court followed the *Chevron* approach only in about one-third of the cases where it was arguably relevant despite the parties' raising it with great regularity. Thomas W. Merrill, *Judicial Deference to Executive Precedent*, 101 YALE L.J. 969, 980 (1992).

173. *See, e.g.*, Orengo Caraballo v. Reich, 11 F.3d. 186, 192-93 (D.C. Cir. 1993) (agency's decision is approached with due deference to its interpretation of statutes and regulations whose enforcement has been committed to the agency); Chow v. I.N.S., 12 F.3d 34, 37 (5th Cir. 1993) (interpretations of ambiguous law by an executive agency are accorded considerable weight and deference); Atlantic States Legal Foundation, Inc. v. Eastman Kodak Co., 12 F.3d 353, 358 (2d Cir. 1993), *cert. denied*, No. 93-1839, 1994 WL 210037 (1994) (reasonable interpretation by federal agency charged with enforcing statute is entitled to due deferential treatment by a reviewing court); Arkansas AFL-CIO v. FCC, 11 F.3d 1430, 1441 (8th Cir. 1993) (indicating that as long as an agency's interpretation of a statute is reasonable, a reviewing court cannot replace an agency's judgment with its own).

174. 21 C.F.R. § 808.1(b) (1993).

175. *See, e.g.*, *Bravman*, 842 F. Supp. at 755 ("[FDA] regulations parenthetically include court decisions in its definition of state requirements."); *Lamontagne*, 834 F. Supp. at 582 ("The FDA has interpreted Section 360k(a) of the MDA as preempting 'any requirements established by a state including statutes, regulations, court decisions or ordinances.'"); *Reiter*, 830 F. Supp. at 202; *Cameron*, 820 F. Supp. at 319.

176. *See* Ausness, *supra* note 14, at 283 (arguing that "FDA has specifically

include common law tort claims, specific advisory opinions issued by the FDA clarify that the latter approach is all that the FDA intended and demonstrate that FDA has never interpreted the MDA as extending generally to common law remedies[177] or specifically to tort claims.[178]

The second section relevant to assessing the FDA's view of the preemptive effect of the MDA is section 808.1(d)(1). It reads as follows:

> Section [360k(a)] does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other

---

interpreted [section 360k] to preempt state tort law"). Professor Ausness never mentions FDA's specific pronouncements on preemption of product liability laws, *see infra* note 178, suggesting that his opinion of the agency's interpretation of § 360k would change if he had done so.

177. *See* Letter from Joseph P. Hile, Associate Commissioner for Regulatory Affairs, Food and Drug Administration, to Robert E. Manchester, National Women's Health Network, (March 8, 1984). In that letter Associate Commissioner Hile states that the preemption provisions of the Medical Device Amendments do not bar common law remedies, such as injunction, against defective intrauterine devices. According to Associate Commissioner Hile:

> There is no indication in the legislative history of section [360k(a)] that Congress intended that the section preempt State or local requirements respecting general enforcement . . . .

Id. Associate Commissioner Hile's view is consistent with FDA's view that § 360k does not preempt state or local requirements of "general applicability." *See infra* note 179.

178. *See* letter from Joseph Sheehan, Chief, Regulation Staff, Food and Drug Administration to Cindy Whaley, Esquire, (February 2, 1987). In that letter Mr. Sheehan wrote:

> As you can see from these Federal Register documents, it is the Food and Drug Administration's position that [section 360k] of the Food, Drug and Cosmetic Act (21 U.S.C. 360k) preempts only state and local requirements that are specifically related to medical devices. *Therefore, FDA believes that section [360k] does not preempt general product liability requirements.*

Id. (Emphasis added). In a recent development, FDA, on November 23, 1994, submitted an amicus curiae brief in a case, Talbott v. C.R. Bard, Inc., CA 1, No. 94-1951, arguing that the MDA does not preempt state tort claims—particularly where those claims arise with respect to criminal violations of the MDA. *See Federal Law Does Not Pre-Empt Claims Concerning Noncomplying Device, FDA Says*, 22 BNA PRODUCT SAFETY & LIABILITY REP. 1230 (December 2, 1994). *See also* Richard M. Cooper, *Drug Labeling and Products Liability: The Role of the Food and Drug Administration*, 41 FOOD DRUG COSM. L.J. 233 (1986) (article by former General Counsel to FDA arguing that "[t]he FDA has no expertise or authority for managing systems of redress for private injuries. The value judgment necessary for such management—how the scales for plaintiffs and defendants should be set up—are best left to legislatures and courts.").

> products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness), or to unfair trade practices in which the requirements are not limited to devices.[179]

If the MDA does not preempt general bodies of law such as the UCC and state unfair trade practices laws, *a fortiori*, it would not preempt broader, more established bodies of general law such as common law torts.[180]

E. The Congressional Context

A proper analysis of the language of section 360k requires an assessment of the likelihood that Congress in 1976 would take the dramatic step of enacting legislation to preempt common law tort claims without debate, objection, or controversy. Given the explosion in the number of health and safety laws,[181] the dramatic expansion of tort doctrines,[182] the furious filing of tort suits against the Dalkon Shield during the pendency of the MDA,[183] and the general approach of product liability law to recognize tort claims despite a company's compliance with a federal regulatory requirement,[184] it is inconceivable that as Draconian a measure as preempting common law tort claims found its way into the MDA in 1976 without one word from concerned members of Congress. The fact is that heated congressional debates have flared up whenever any attempt to enact broad federal product liability legislation has occurred.[185] Moreover, none

---

179. 21 C.F.R. § 808.1(d)(1) (1993).

180. *See Mulligan*, 850 F. Supp. at 635 (interpreting this section as precluding preemption).

181. *See supra* note 3 and accompanying text.

182. *See supra* note 4 and accompanying text.

183. *See supra* note 84 and accompanying text. Not once during the extensive process of enacting the Medical Device Amendments did a member of Congress hint disapproval of these lawsuits or suggest that the legislature should bar future tort claims.

184. In 1976, most courts held that compliance with a federal safety statute or standard constituted some evidence of due care, but was not dispositive, let alone preemptive. *See, e.g.*, Raymond v. Riegel Textile Corp., 484 F.2d 1025, 1027-28 (1st Cir. 1973); LaGorga v. Kroger Co., 275 F. Supp. 373, 378 (W.D. Pa. 1967) *aff'd* 407 F.2d 671 (3d Cir. 1969); Stevens v. Parke, Davis & Co., 507 P.2d 653, 661 (Cal. 1973); Burch v. Amsterdam Corp., 366 A.2d 1079, 1085-86 (D.C. Ct. App. 1976); Jonescue v. Jewel Home Shopping Service, 306 N.E. 2d 312, 316 (Ill. App. Ct. 1973); Rumsey v. Freeway Manor Minimax, 423 S.W. 2d 387, 394 (Tex. Ct. Civ. App. 1968); *See also*, EDWARD M. SWARTZ, HAZARDOUS PRODUCTS LITIGATION (1973). This view generally prevailed until the Supreme Court's ruling in *Cipollone*.

185. In the early 1970s, product liability insurance rates increased dramatically,

of these attempts has succeeded.[186] With respect to medical devices specifically, congressional supporters of tort reform, having repeatedly tried and failed to bar tort claims against products complying with FDA regulations,[187] have retreated to attempting to prevent the imposition of punitive damages against products that comply with FDA requirements.[188] Even these more modest provisions have failed to pass Congress.[189]

---

prompting Congress to appoint an Interagency Task Force on Product Liability in 1976. The Task force issued a report in 1978 calling for reforms in the product liability system. *See* INTERAGENCY TASK FORCE ON PRODUCT LIABILITY, DEPARTMENT OF COMMERCE, FINAL REPORT VII at 242-57 (1978) (calling for reforms in product liability law). Shortly thereafter, members of Congress began introducing proposals for federal product liability legislation. *See* Sheila I. Birnbaum, *Legislative Reform or Retreat? A Response to the Product Liability Crisis*, 14 FORUM 251, 259 (1978) (noting that approximately 20 product liability bills were introduced in the 95th Congress). In the decades since, numerous such bills have been introduced in Congress. *See, e.g., Hearings on S. 1400, the Product Liability Reform Act, Before the Subcommittee on the Consumer of the Senate Committee on Commerce, Science, and Transportation on S. 1400, the Product Liability Reform Act*, 101st Cong., 2d Sess. 1 (1990) (statement by Senator Richard Bryan, Chairman, that Congress has been grappling with "controversial" product liability issues "for a good many years"). At these hearings, Senator Slade Gorton noted that the issue of product liability "is not new.... The debate heats up when the different factions—business, consumer groups and lawyers—attempt to craft a solution." *Id.* at 5.

186. *See infra* note 189 and accompanying text.

187. Beginning in 1977 with the National Product Liability Insurance Act, S. 403, 95th Cong., 1st Sess. (1977), a bill that would have made compliance with federal laws and regulations a complete defense to product liability claims, members of Congress have sought unsuccessfully to bar tort claims against products in compliance with federal rules. Having failed at that, congressional opponents of the product liability system unsuccessfully sought to enact more modest legislation that would bar claims only against FDA and FAA-premarket approved products. Accordingly, Senator Robert Kasten, the principal congressional proponent of federal product liability legislation, sought an even more modest approach. In 1990, he stated that S. 1400, the bill then pending before Congress, had been modified from bills introduced in previous years to eliminate "[c]ompliance with [FDA] standards defenses for compensatory damages . . . , an issue that we have discussed which was contentious." *See Hearings on S. 1400 Before the Subcommittee on the Consumer of the Senate Committee on Commerce, Science, and Transportation*, 101st Cong., 2d Sess 315 (1990). S. 1400, which would have barred punitive damages for products having premarket approval from the FDA or FAA, also failed to pass—as have all recent similar measures. *See infra* note 189 and accompanying text.

188. *See id.* at 26 (S. 1400 § 303(c)(1)).

189. The most recent Senate bill, S. 687, failed, in June 1994, to pass the Senate. *See Product Liability Legislation Defeated As Senate Fails Twice To Curtail Filibuster*, 22 PRODUCT SAFETY AND LIABILITY REP. 663 (1994). Opponents have prevented a

In short, to suggest that in 1976 Congress had any intention to bar tort claims is to ignore history and reality. If ever there were an instance in which significance should attach to congressional silence ("the dog that didn't bark"), preempting tort claims is it. In view of the profound congressional silence regarding tort claims, it makes no sense to interpret the MDA as preempting such claims.

VII. CONCLUSION

The net effect of the courts' post-*Cipollone* rulings with respect to preemption under the MDA is ominous. Sacrificing consumer health and safety based on a vague sense that medical technology cannot progress in the face of tort claims,[190] and adopting the unsubstantiated view that Congress placed total faith in the FDA's ability to monitor the medical device marketplace for health and safety,[191] the recent preemption rulings refuse to

---

floor vote on similar bills in the House of Representatives. *Id.* at 664.

190. In fact, despite the outcry about the negative impact of government regulation and product liability litigation during the past twenty years, the United States continues to dominate the $36 billion world-wide market in new medical technologies and in exports. *See* Foote, *supra* note 82, at 179; Michael C. Fuchs, *Economics of U.S. Trade in Medical Technology and Export Promotion Activities of the U.S. Department of Commerce* in Estrin, *supra* note 82, at 917 (describing how in 1987 the U.S. share of world-wide production of medical technologies constituted roughly 60 percent). This is similar to the situation with respect to drugs. *See Innovation in Medicines*, WASH. POST, March 14, 1990 (noting that the Pharmaceutical Manufacturers Association reports that the U.S. leads in the discovery of world class drugs with the origin of 25 new drugs marketed by the U.S. out of a total of 60 new drugs worldwide).

191. To the contrary, Congress has repeatedly identified shortcomings in FDA's regulation of medical devices. *See, e.g.*, SUBCOMMITTEE ON OVERSIGHT & INVESTIGATIONS, HOUSE COMMITTEE ON ENERGY & COMMERCE, LESS THAN THE SUM OF ITS PARTS: REFORMS NEEDED IN THE ORGANIZATION, MANAGEMENT, AND RESOURCES OF THE "FDA'S CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, 103d Cong., 1st Sess. (1993); STAFF OF HOUSE COMMITTEE ON ENERGY & COMMERCE, THE BJORK-SHILEY HEART VALVE: "EARN AS YOU LEARN," 101 Cong., 2d Sess. (1990); U.S. GENERAL ACCOUNTING OFFICE, COMPTROLLER GENERAL, MEDICAL DEVICES: EARLY WARNING OF PROBLEMS IS HAMPERED BY SEVERE UNDERREPORTING (1986) (report by congressionally operated watchdog department); *FDA's Neglected Child*, *supra* note 6; U.S. GENERAL ACCOUNTING OFFICE, COMPTROLLER GENERAL, FEDERAL REGULATION OF MEDICAL DEVICES: PROBLEMS STILL TO BE OVERCOME (1993); *Hearings Before Senate Committee on Aging on Pacemakers Revisited: A Saga of Benign Neglect*, 99th Cong., 1st Sess. (1985); *Hearings Before Subcommittee on Oversight & Investigations of the House Committee on Energy & Commerce on Anaesthesia Machine Failures*, 98th Cong., 2d Sess. (1984); *Hearings Before the*

permit severely injured consumers from even entering the courtroom. Thus, consumers are prevented from arguing that their injuries have resulted from poorly designed products, defectively manufactured devices, devices with inadequate warnings, devices approved by the FDA due to manufacturer fraud, and devices that long ago should have been removed from the market.[192] The courts have done so despite a lack of evidence that Congress intended to preempt such claims.

To comprehend the impact of what the courts have done, the reader need only imagine what would happen if A.H. Robins introduced the Dalkon Shield after the enactment of the MDA rather than in 1970. To say the least, the

---

Subcommittee on Oversight & Investigations of the House Committee on Energy and Commerce, 98th Cong., 2d Sess. (1984).

In addition to these negative reports by Congress, other observers have been critical of FDA, among other reasons, for providing loopholes in regulating medical devices, failing properly to review drugs and devices, failing to review adverse experience reports carefully and expeditiously, slowing investigations under political pressure and lacking adequate authority to remove dangerous products. *See* JOINT REPORT BY CONSUMERS UNION, PUBLIC CITIZEN, CITIZEN ACTION, U.S. PUBLIC INTEREST RESEARCH GROUP, AND THE CONSUMER FEDERATION OF AMERICA, S. 687, "THE PRODUCT LIABILITY FAIRNESS ACT" IS UNIFORMLY UNFAIR TO CONSUMERS, A-1 to A-13 (Winter 1994) (report by coalition of consumer groups opposing provisions in pending product liability legislation that would exempt manufacturers in compliance with FDA rules from punitive damages); Daniel W. Sigelman, *Turning the Tables on Drug Companies: Exposing Deficiencies in FDA Regulation* 30 TRIAL 72 ("Implicit in the 'FDA approval defense' is the assumption that agency regulation protects the public from the dangers of marketed drugs. Congressional oversight of FDA's performance, however, challenges the validity of this assumption.").

192. For example, intraocular devices, because of a special provision in the law, have been permitted to conduct so-called "adjunct studies," that permit substantial numbers of lenses to enter the market for commercial purposes. *See* 21 C.F.R. § 813.50 (1993) (exempting intraocular lenses from "no-commercialization" restrictions). Hundreds of thousands of such lenses have been sold over the years without ever being submitted for premarket approval. In fact, many of them have been withdrawn from the market because the manufacturers realized that the IOLs would not meet FDA requirements for safety and effectiveness. At the time FDA issued its final rule regarding IOLs as investigational devices, it specifically stated that "[i]t is not the duty of FDA to protect [IOL manufacturers] or investigators from lawsuits by subjects." 42 Fed. Reg. 58874, 58881 (1977). Injured consumers have filed lawsuits contending that some IOL manufacturers, knowing that their products would never gain FDA approval, nevertheless took advantage of their investigational status to keep them on the market and reap substantial profits. *See, e.g.*, Angelle v. Intermedical Intraocular, Inc., No. 93-0403, 1993 U.S. Dist. LEXIS 17805 at *5 (E.D. La. Dec. 10, 1993) (asserting that defendant IOL manufacturer used its investigational statute for more than six years "as a guise to market its lenses commercially," despite never filing for premarket approval).

results would be catastrophic. First, the device would enter the market through a "510(k) notification" by claiming "substantial equivalence" to one of the many pre-MDA IUDs.[193] Despite the fact that it had never obtained premarket approval for the Dalkon Shield, A.H. Robins would argue for, and likely receive, summary dismissal of cases against it based on preemption.[194] With cases against Robins dismissed by summary judgment, it is unlikely that the extent of the company's iniquity ever would emerge. Robins' dishonesty regarding the efficacy of its device,[195] its refusal to conduct adequate testing of the Dalkon Shield,[196] its ignoring of numerous adverse reports from physicians,[197] its attacks on the personal character of victims in product liability lawsuits,[198] and, ultimately, its suppression and illegal destruction of damning evidence against it[199] were uncovered only after years of product liability litigation, some of which was unsuccessful because of Robins' suppression of critical evidence. In fact, none of this evidence was sought, or discovered, by the FDA. To the contrary, the FDA turned its attention away from the Dalkon Shield after negotiating a "voluntary" suspension of sales in the United States on June 26, 1974.[200] Not until 1984, ten years later, after

193. *See supra* note 107. Even as revised by the Safe Medical Devices Act of 1990, § 510(k) remains the preferred route to market for most medical devices. There is little doubt that an IUD like the Dalkon Shield would have followed this route rather than obtaining premarket approval.

194. The only post-*Cipollone* ruling of which we are aware that rejected preemption for a Class III device that reached the market through "510 notification" is Larsen v. Pacesetter Systems, Inc., 837 P. 2d 1273 (Haw. 1992). On the other hand, cases such as Cameron v. Howmedica, Div. of Pfizer Hosp., 820 F. Supp. 317 (E.D. Mich. 1993) and Griffin v. Medtronic, 840 F. supp. 396 (D. Md. 1994), in which the courts unhesitatingly imposed preemption even in the absence of any counterpart FDA regulation, convince us that the courts have run amok.

195. At the time the Dalkon Shield was marketed, Robins claimed a pregnancy rate of 1.1 percent despite having information in its files showing that the true pregnancy rate was many times that. *See* Sobol, *supra* note 84, at 5.

196. *Id.* at 7.

197. *Id.* at 8-9.

198. *Id.* at 13.

199. *Id.* at 21-22. One of Robins' defense attorneys, Roger Tuttle, eventually suffered regrets and, on July 30, 1984, in a deposition, confessed that he had been ordered to destroy incriminating documents by William Forrest, general counsel to A.H. Robins. Instead of destroying them, he had secreted them away and revealed them during the deposition. *See also* Morton Mintz, *Dalkon Shield Papers Were Burned, Says Ex-Robins Attorney*, WASH. POST, Aug. 1, 1984 at A14; Mary Williams Walsh, *Robins Ex-Official Says He Destroyed Dalkon Shield Data*, WALL ST. J., Aug. 1, 1984 at 19.

200. *See* Sobol, *supra* note 84, at 10. Robins continued selling the Dalkon Shield for months after its voluntary withdrawal in at least forty foreign countries.

being publicly castigated by a federal judge overseeing a group of product liability cases,[201] did Robins finally begin a campaign to convince women to have the IUDs removed.

In short, had preemption been applied to the Dalkon Shield, A.H. Robins would have succeeded in operating incompetently and illegally. More importantly, hundreds of thousands of injured women would have been denied recompense and justice.

We think preemption of product liability claims against medical device manufacturers is misplaced—at least without careful thought and a precise plan for offsetting approaches to protect consumers. Innovation without protection hardly improves the lives of our citizens and, despite its commendable efforts on behalf of the public, the FDA by itself simply cannot provide an adequate source of safety to the public from dangerous medical devices.

We hope that the courts, upon reflection, will reconsider their preemption rulings and stop barring claims filed by injured consumers. In the absence of such a reconsideration, we call upon the Food and Drug Administration to clarify in more forceful terms its view that agency regulations do not support the courts' misguided interpretation that the FDA endorses preemption of tort claims. Ultimately, however, Congress may have to re-enter the picture with definitive language clarifying the exact scope of preemption under the Medical Device Amendments.

---

201. Federal Judge Miles Lord, stated in an emotional appeal, directly to company president E. Claiborne Robins and General Counsel, William Forrest:

> Under your direction, your company has in fact continued to allow women, tens of thousands of them, to wear this device—a deadly depth charge in their wombs ready to explode at any time . . . . The only conceivable reasons you have not recalled this product are that it would hurt your balance sheet and alert women who have already been harmed that you may liable for their injuries . . . .
>
> If this were a case in equity, I would order your company to make an effort to locate each and every woman who still wears this device and recall your product. But this court does not have the power to do so. I must therefore resort to moral persuasion and a personal appeal to each of you. . . . Please, in the name of humanity, lift your eyes above the bottom line . . . . Please, gentlemen, give consideration to tracing down the victims and sparing them the agony that will surely be theirs.

Quoted in id. at 20. *See also* Morton Mintz, *U.S. Judge Assails Officers of Dalkon Shield Maker*, WASH. POST, Mar. 2, 1984 at A4.