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# Federal Preemption of State Products Liability Actions

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## FEDERAL PREEMPTION OF STATE PRODUCTS LIABILITY ACTIONS

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## I. INTRODUCTION

Few legal doctrines have had greater impact upon product liability litigation during the last decade than the federal preemption defense. In essence, Congress and federal administrative agencies have immunized manufacturers of a wide assortment of federally-regulated products, including pesticides, medical devices, adhesives and solvents intended for consumer use, animal vaccines, lawn mowers and many others, against many forms of tort liability imposed under state law. Where the preemption defense lies, extensive pretrial discovery, expensive expert witnesses, and judges and jurors sympathetic to the local accident victim and hostile to the unfeeling corporate behemoth seldom make an appearance. Even the most grievously injured plaintiff may find himself deprived of any legal remedy for his injuries due to declarations of exclusivity of federal law issued by Congress and federal agencies.

Not surprisingly, advocates and opponents of federal preemption of state tort claims have waged pitched battles within all three branches of government. What may be somewhat surprising, however, is the degree of disharmony among federal and state courts, Congress, and federal agencies on the issue. Without seeming rhyme or reason, state tort claims involving some products, but not others, may be preempted; some federal agencies favor limiting state tort remedies, while others do not; and, even Congress can be torn by notions of federalism and states' rights on the one hand, and the growing trend toward national (as well as global) uniformity. As a result, the current state of the law regarding federal preemption of state law product liability actions is confusing and chaotic.

This article focuses upon the evolution of the federal preemption defense in product liability actions and, thereafter, upon specific instances where Congress or federal agencies have declared state tort law to be totally or partially preempted and the courts' treatment of those declarations. We offer our views on the factors which have caused the courts to arrive at such disparate results in these cases. Finally, we offer a brief, but hopefully informed, look as to what the future might hold for the preemption defense.

## II. FEDERAL PREEMPTION GENERALLY

The Supremacy Clause of the United States Constitution<sup>1</sup> declares "the Laws of the United States" to be "the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." From the Supremacy Clause springs the concept of federal preemption, *i.e.*, the invalidity of those state laws which conflict with federal law.<sup>2</sup>

Federal preemption comes in three different "flavors"<sup>3</sup> – "express," "implied," or "conflict" preemption.<sup>4</sup> These differ from one another primarily in the manner by which the preemptive effect of federal law is determined.

Express preemption—far and away the most significant flavor of preemption in state product liability actions—arises either where Congress has explicitly declared federal legislation to have preemptive effect,<sup>5</sup> or where a federal agency, acting within the scope of authority conferred upon it by Congress, has expressly declared an intent to preempt state law.<sup>6</sup> Where Congress has acted to expressly preempt state law, identification of "the domain expressly preempted" is central to the task of determining the scope of preemption.<sup>7</sup> Both the plain language of the allegedly preempting statute and an understanding of the congressional purpose supporting the statute are vital to a preemption inquiry.<sup>8</sup> Put another way, as the Supreme Court has repeatedly observed, "[t]he purpose of Congress is the ultimate touchstone" in express preemption cases.<sup>9</sup>

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

2. *McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316, 427 (1819). *See also* *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 654 (1995) (recognizing the Supremacy Clause may entail pre-emption of state law).

3. *Kinley Corp. v. Iowa Util. Bd.*, 999 F.2d 354, 358 n.3 (8th Cir. 1993).

4. *Travelers Ins. Co.*, 514 U.S. at 650 (discussing the three forms of federal preemption).

5. *E.g.*, *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516-17 (1992).

6. *E.g.*, *City of New York v. FCC*, 486 U.S. 57, 65 (1988); *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 698-99 (1984); *Fidelity Federal Savings & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 149-50 (1982).

7. *Cipollone*, 505 U.S. at 517.

8. *E.g.*, *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 484 (1996); *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 111 (1992).

9. *Retail Clerks Int'l Ass'n, Local 1625, AFL-CIO v. Schermerhorn*, 375 U.S.

Where a federal agency has acted to expressly preempt state law, the inquiry is somewhat different. Unlike Congress, federal agencies can address a subject through various means, including regulations, preambles to regulations, interpretive statements, and responses to comments. Each of these types of pronouncements may have preemptive effect, so long as two conditions are met: (1) the agency must have intended to displace state law, and (2) the agency acted within the scope of its congressionally-delegated authority.<sup>10</sup> Importantly, however, an express congressional declaration of preemptive intent is not required.<sup>11</sup> So long as a federal agency's decision to preempt state law "represents a reasonable accommodation of conflicting policies that were committed to the agency's care by statute, [a reviewing court] should not disturb it unless it appears from the statute or its legislative history that the accommodation is not one that Congress would have sanctioned."<sup>12</sup>

Principles of implied and direct conflict preemption may also impact state product liability actions.<sup>13</sup> Implied preemption arises where neither Congress nor a federal agency has expressly declared an intent to preempt state law, but nonetheless "federal law so thoroughly occupies a legislative field 'as to make reasonable the inference that Congress left no room for the States to supplement it.'"<sup>14</sup> Thus, federal legislation acts implicitly as a barrier to state regulation.<sup>15</sup> Conflict preemption arises, again absent an express or implied declaration of Congress' or an agency's intent, when "compliance with both federal and state regulations is a physical impossibility,"<sup>16</sup> or when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."<sup>17</sup>

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96, 103 (1963). *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978); *Cipollone*, 505 U.S. at 516; *Medtronic*, 518 U.S. at 485.

10. *Hillsborough County, Florida v. Automated Med. Lab., Inc.*, 471 U.S. 707, 718 (1985); *de la Cuesta*, 458 U.S. at 153-54; *FCC*, 486 U.S. at 64.

11. *de la Cuesta*, 458 U.S. at 154; *FCC*, 486 U.S. at 64.

12. *United States v. Shimer*, 367 U.S. 374, 383 (1961); *City of New York v. FCC*, 486 U.S. 57, 64 (1988).

13. See, e.g., *Geier v. Am. Honda Motor Co., Inc.*, \_\_\_ U.S. \_\_\_, 120 S. Ct. 1913 (2000), discussed in greater detail *infra* note 20 and accompanying text.

14. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

15. E.g., *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85 (1983).

16. *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963).

17. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

Particularly in the context of matters of public health and safety, federal preemption of state law runs headlong against the states' traditional prominence in protecting the health, safety and property of their citizens.<sup>18</sup> The tension between federal preemption and the exercise of historic state police powers is reconciled, at least in part, by a presumption against federal preemption.<sup>19</sup> Though most often invoked in actions involving implied or conflict preemption,<sup>20</sup> the presumption against preemption also attaches to express preemption cases.<sup>21</sup>

### III. EXPRESS FEDERAL PREEMPTION OF STATE PRODUCT LIABILITY LIABILITY ACTIONS GENERALLY

Prior to 1992, federal preemption of product liability actions brought under state statutes or common law was essentially non-existent. In an oft-cited case, for instance, the District of Columbia Circuit held that a federal statute which prevents states from imposing "requirements" different from or in addition to those imposed by federal law upon a given product did not reach common-law tort claims.<sup>22</sup> Moreover, in an action involving personal injury allegedly caused by exposure to nuclear radiation, the United States Supreme Court held that Congress' grant of federal exclusivity over matters of nuclear safety did not preclude states from indirectly regulating nuclear safety through tort liability.<sup>23</sup>

The early 90's saw a significant change in preemption. In 1992, in the Supreme Court held that certain state law failure-to-warn claims arising out of the sale of cigarettes were preempted by

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18. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 484 (1996).

19. *Rice*, 331 U.S. at 230; *Medtronic*, 518 U.S. at 484. By contrast, the Supreme Court has recently observed that the presumption against preemption "is not triggered when the State regulates in an area where there has been a history of significant federal presence." *United States v. Locke*, \_\_ U.S. \_\_, 120 S.Ct. 1135, 1147 (2000).

20. *E.g.*, *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984). However, the Supreme Court's recent decision and opinion in *Geier v. Am. Honda Motor Co., Inc.*, \_\_ U.S. \_\_, 120 S. Ct. 1913 (2000) casts some doubt on the continuing validity of the presumption against preemption in conflict preemption cases.

21. *Hillsborough County, Florida v. Automated Med. Lab., Inc.*, 471 U.S. 707, 715-16 (1985); *Medtronic*, 518 U.S. at 484.

22. *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529 (D.C. Cir. 1984) (construing the Federal Insecticide, Fungicide and Rodenticide Act's preemption clause, 7 U.S.C. § 136v(b)).

23. *Silkwood*, 464 U.S. at 238.

federal law.<sup>24</sup> *Cipollone* was an action for wrongful death allegedly caused by cigarette smoking. Plaintiff sought damages from cigarette manufacturers pursuant to New Jersey product liability statutes and common-law doctrines, including failure to warn, breach of express warranty, fraudulent misrepresentation, and conspiracy.<sup>25</sup> Defendants argued that plaintiff's claims were preempted by section 5(b) of the Federal Cigarette Labeling and Advertising Act of 1965, as amended by the Public Health Cigarette Smoking Act of 1969.<sup>26</sup> The 1965 version of the statute prohibited states from requiring "[any] statement relating to smoking and health . . . in the advertising of any cigarettes which packages are labeled in conformity with the provisions of this chapter."<sup>27</sup> Four years later, Congress amended § 5(b) to bar states from imposing via state law "[any] requirement or prohibition based upon smoking and health...with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter."<sup>28</sup>

The initial question confronted by the Supreme Court was whether either statute was broad enough to preempt not just state regulation of cigarette labeling, but also state common-law damages actions. Construing both statutes in light of the presumption against preemption, the Supreme Court determined that the 1965 act, barring states merely from requiring "statements" relating to smoking and health, did not preempt any damages claims arising out of cigarette smoking; however, the 1969 act, which prevented states from imposing any "requirement or prohibition" relating to smoking, was held to preempt state common-law damages actions as well as state regulation of cigarette labeling.<sup>29</sup>

Given the Supreme Court's holding that the "no requirement or prohibition" language in the 1969 act extended to requirements and prohibitions imposed by New Jersey common law, the remaining question was whether the 1969 act blocked all, or only a portion, of the plaintiff's claims. The "central inquiry," according to the Supreme Court, was "whether the legal duty that is the predi-

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24. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 530-31 (1992).

25. *Id.* at 508.

26. *Id.* at 510; 15 U.S.C. § 1334(b) (2000).

27. 15 U.S.C. § 1334(b).

28. *Id.*

29. *Cipollone*, 505 U.S. at 518-20 (1965 act), 520-23 (1969 act).

cate of the common-law damages action constitutes a 'requirement or prohibition based on smoking and health...imposed under State law with respect to...advertising or promotion,' giving that clause a fair but narrow reading."<sup>30</sup> The Supreme Court determined that plaintiff's failure-to-warn and fraudulent misrepresentation claims, to the extent they would have imposed upon cigarette manufacturers the obligation to include warnings on their packaging beyond those approved by the federal government, fell within the scope of § 5(b) of the 1969 act and were therefore preempted.<sup>31</sup> However, claims unrelated to the "advertising or promotion" of cigarettes, including ones premised upon defendants' testing of and research into the health effects of cigarette smoking, were held not to be preempted,<sup>32</sup> as were claims which did not rest upon a specific duty imposed by state law, for example, plaintiff's claims for breach of express warranties which the Supreme Court interpreted as duties voluntarily assumed by the defendants.<sup>33</sup>

Four years later, the Supreme Court addressed the question of federal preemption of state common-law damages actions arising out of use of federally-regulated medical devices.<sup>34</sup> Plaintiff contended she was injured by defendant's allegedly defective pacemaker, which was approved for marketing by the Food and Drug Administration pursuant to section 510(k) of the Federal Food, Drug and Cosmetic Act.<sup>35</sup> A preemption clause inserted by Congress into the act in 1976 prohibited states from "establish[ing] or continu[ing] in effect...any requirement - (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device...."<sup>36</sup> A majority of justices held that the term "requirement" contained within the preemption statute encompassed not just state positive enactments, but also legal requirements arising from the application of state common law.<sup>37</sup> How-

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30. *Id.* at 523-24.

31. *Id.* at 524.

32. *Id.* at 524-25.

33. *Id.* at 525-27.

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

35. *Id.* at 480-81; 21 U.S.C. § 360e(b)(1)(A) (2000) (referring to class III devices).

36. 21 U.S.C. § 360k(a) (2000).

37. *Medtronic*, 518 U.S. at 508-09 (O'Connor, J., joined by Rehnquist, C.J. and Scalia and Thomas, JJ.) and at 504 (Breyer, J.).



ever, the Supreme Court, upon a variety of other grounds, ultimately held that none of the plaintiff's claims were preempted by the federal statute.<sup>38</sup>

Most recently, the Supreme Court addressed the degree to which federal motor vehicle safety law may preempt state product liability actions based upon defective automobile design.<sup>39</sup> Plaintiff was injured while driving a 1987 automobile which did not have a driver's side airbag and sued the vehicle's manufacturer for her injuries, claiming that the absence of an airbag rendered the vehicle defective and unreasonably dangerous. Under regulations promulgated in 1984 by the Department of Transportation pursuant to the National Traffic and Motor Vehicle Safety Act of 1966,<sup>40</sup> vehicle manufacturers were required to equip a minimum of 10% of their 1987 model year cars with passive restraint devices – either airbags or automatic seatbelts.<sup>41</sup> Where a federally-promulgated motor vehicle safety standard is in effect, the Act preempts state establishment or enforcement of "any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not identical to the Federal standard."<sup>42</sup> However, a separate "savings clause" in the Act provides that "[c]ompliance with any Federal motor vehicle safety standard issued under this subchapter does not exempt any person from any liability under common law."<sup>43</sup>

Relying heavily upon the savings clause, the Supreme Court in *Geier* held that the preemption clause in the act did not expressly bar plaintiff's defective design claims. According to the Court, the presence of the savings clause indicated that Congress did not intend the preemption clause to broadly bar state common-law product liability actions; otherwise, there would be little if any "liability at common law" to save in the first place.<sup>44</sup> However, the Court de-

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38. *Medtronic* *infra* pp. 22-25 in connection with preemption under the Medical Device Amendments of 1976.

39. *Geier v. Am. Honda Motor Co., Inc.*, \_\_ U.S. \_\_, 120 S. Ct. 1913 (2000).

40. 15 U.S.C. § 1381, recodified without substantive change at 49 U.S.C. § 30301.

41. 49 C.F.R. § 571.208; *see also* the discussion *infra* note 75 and accompanying text.

42. 15 U.S.C. § 1392(d), recodified without substantive change at 49 U.S.C. § 30103(b)(1).

43. 15 U.S.C. § 1397(k), recodified without substantive change at 49 U.S.C. § 30103(e).

44. The majority declined to reach the question of whether "safety stan-

terminated that the savings clause does *not* foreclose or limit the operation of other preemption principles, particularly implied and conflict preemption.<sup>45</sup> Applying principles of conflict preemption, the Court found that plaintiff's "no airbag" claim did directly conflict with the Department of Transportation's 1984 safety standard and was therefore preempted on that basis.<sup>46</sup>

Taken together, *Cipollone*, *Medtronic* and *Geier* establish a reasonably clear framework for evaluating whether state law product liability actions will be deemed to be expressly preempted, in whole or in part, by federal law. First, in most cases a federal statute or an authorized regulation or other declaration from a federal agency, setting forth Congress' or the agency's express preemptive intent, must exist. Although *Geier* illustrates that implied or conflict preemption of state law product liability actions is possible, *Geier* remains the exception, not the rule.<sup>47</sup> Second, the specific preempting language must be broad enough to encompass both state positive enactments and duties imposed by state common-law damages actions. The focus must be upon the specific statutory or regulatory language used by Congress or the agency, and legislative or administrative history illustrating the scope of Congress' or the agency's preemptive intent. Third, in light of *Geier*, the act must, in all likelihood, be devoid of a savings clause preserving common-law remedies. Finally, the subject-matter of the state law claim must fairly fall within the scope of the federal enactment. Where each of these conditions is satisfied, preemption of state law product liability claims arising from harm caused by an allegedly defective prod-

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dards," viewed without regard to the savings clause, is sufficiently broad to encompass state tort claims. *Cf. Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 530-31 (1992) (holding that "requirements" is sufficiently broad). *Geier*, 120 S. Ct. at 1918. By contrast, the dissent concluded that the phrase "safety standard" "refers to an objective rule prescribed by a legislature or an administrative agency and does not encompass case-specific decisions by judges and juries that resolve common-law claims." *Id.* at 1933 (Stevens, J., dissenting).

45. *Id.* at 1919.

46. *Id.* at 1922.

47. *Geier* notwithstanding, neither "implied" nor "conflict" preemption ordinarily prohibits states from imposing upon a product manufacturer requirements more stringent than those which may be required by federal law, absent a situation where the plaintiff alleges that state common law obligated a product manufacturer to design or manufacture a product in a manner expressly prohibited by applicable federal regulations. *Id.* at 1931 n.6 (2000) (Stevens, J., dissenting). Such cases are extremely few and far between.

uct may lie. Absent enactment of master federal legislation applicable to all state products actions, however,<sup>48</sup> *Cipollone* and *Medtronic* illustrate that the preemption question can only be addressed on a product-by-product, statute-by-statute basis.

#### IV. SPECIFIC EXAMPLES OF PREMPTION OF STATE PRODUCT LIABILITY CLAIMS

In a variety of categories of allegedly defective products, defendants have urged that federal law expressly preempts state law product liability claims. The most significant statutory and regulatory schemes, and the courts' treatment of the preemption issue in each, are recounted below.

##### A. *Pesticides*

Pesticides (including insecticides, fungicides, herbicides and rodenticides) are regulated by the Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA").<sup>49</sup> Among other things, FIFRA mandates that all pesticides sold in the United States must be registered for use by the EPA, and that the content of all product labels and inserts must be supported by test data and specifically approved by EPA before the product may be sold.<sup>50</sup> An express preemption clause in FIFRA prohibits states from "impos[ing] or continu[ing] in effect any requirements for labeling or packaging in addition to or different from those required [by the EPA under FIFRA]."<sup>51</sup>

The several United States Courts of Appeals which have addressed the question have uniformly held that FIFRA's express preemption clause bars state tort failure-to-warn claims, whether sounding in strict liability or negligence, which would in net effect impose labeling requirements "different from or in addition to" the

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48. In recent years, several bills have been introduced in Congress which would have generally federalized most product liability law by preempting most forms of state statutory and common law pertaining to product liability actions. *E.g.*, H.R. 1910, 103rd Cong., 1st Sess., § 2; H.R. 956, 104th Cong., 2nd Sess., § 102; S. 2236, 105th Cong., 2nd Sess., § 102. None of these bills was ever enacted into law.

49. 7 U.S.C. §§ 136a, 136v(b) (1999).

50. *Id.* § 136a.

51. *Id.* § 136v(b).

content of a pesticide's EPA-approved label.<sup>52</sup> In addition, most courts have applied FIFRA's preemption clause to bar claims based upon breach of express warranty, breach of implied warranty, or misrepresentation where the claim is in essence a challenge to the EPA-approved label.<sup>53</sup> However, the courts have uniformly held that claims premised upon design or manufacturing defect, or upon negligence in the design or manufacture of a pesticide, are not preempted insofar as those claims do not implicate requirements for "labeling or packaging" of pesticides.<sup>54</sup> State courts have reached essentially similar results.<sup>55</sup>

### B. Medical Devices

Medical devices, including such diverse items as pacemakers, orthopedic implants, tampons and heart catheters, are subject to regulation by the Food and Drug Administration under the Medical Device Amendments of 1976 ("MDA") to the Federal Food, Drug and Cosmetic Act.<sup>56</sup> The MDA obligates the FDA, through a pre-market review and approval process, to evaluate and approve the safety and efficacy of all medical devices.<sup>57</sup> The degree of pre-market review given by the FDA to medical devices is dependent primarily upon the degree of potential risk to human health presented by the device; those devices presenting the greatest risk un-

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52. *Grenier v. Vermont Log Bldgs., Inc.*, 96 F.3d 559, 563 (1st Cir. 1996); *Welchert v. Am. Cyanamid, Inc.*, 59 F.3d 69, 71 (8th Cir. 1995); *Taylor AG Indus. v. Pure-Gro*, 54 F.3d 555, 560-61 (9th Cir. 1995); *Bice v. Leslie's Poolmart, Inc.*, 39 F.3d 887, 888 (8th Cir. 1994); *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1025 (5th Cir. 1994); *Worm v. Am. Cyanamid Co.*, 5 F.3d 744, 748 (4th Cir. 1993); *King v. E.I. Du Pont De Nemours & Co.*, 996 F.2d 1346, 1349 (1st Cir. 1993); *Shaw v. Dow Brands, Inc.*, 994 F.2d 364, 371 (7th Cir. 1993); *Papas v. Upjohn Co.*, 985 F.2d 516, 520 (11th Cir. 1993); *Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc.*, 981 F.2d 1177, 1179 (10th Cir. 1993).

53. *Grenier*, 96 F.3d at 563; *Taylor AG Indus.*, 54 F.3d at 560-61; *Papas*, 985 F.2d at 520; *Lescs v. Dow Chem. Co.*, 976 F.Supp. 393, 397-98 (W.D. Va.).

54. *Papas*, 985 F.2d at 520.

55. See, e.g., *Etcheverry v. Tri-Ag Service, Inc.*, 993 P.2d 366, 366-67 (Cal. 2000); *Ackerman v. Am. Cyanamid Co.*, 586 N.W.2d 208, 215-16 (Iowa 1998); *Ackles v. Luttrell*, 561 N.W.2d 573, 576-79 (Neb. 1997); *Lewis v. Am. Cyanamid Co.*, 715 A.2d 967, 972-75 (N.J. 1998); *Tyler v. Dow Chemical Co., Inc.*, 683 N.Y.S.2d 619, 620-21 (N.Y. App. Div. 1998); *Didier v. Drexel Chem. Co.*, 938 P.2d 364, 365-70 (Wash. Ct. App. 1997). Cf. *Kawamata Farms, Inc. v. United Agric. Products*, 948 P.2d 1055, 1074-81 (Haw. 1997); *Brown v. Chas. H. Lilly Co.*, 985 P.2d 846, 848-53 (Or. Ct. App. 1999).

56. 21 U.S.C. § 360k (1999).

57. *Id.* § 360e(d)(2).

dergo the greatest pre-market scrutiny.<sup>58</sup> However, medical devices deemed to be "substantially equivalent" to devices already on the market in 1976<sup>59</sup> are subject to a far less stringent standard of FDA review; such devices are commonly referred to as "[section] 510(k)" devices.<sup>60</sup> The MDA also provides that "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device...."<sup>61</sup>

Prior to the Supreme Court's 1996 decision in *Medtronic*, most courts addressing the issue held that the MDA's preemption clause barred state tort actions seeking, in net effect, the imposition of duties "different from or in addition to" those imposed by the FDA upon a medical device, regardless of whether the device underwent full pre-market review and approval or was approved through the § 510(k) process.<sup>62</sup> In *Medtronic*, however, an action involving an allegedly defective pacemaker approved by the FDA via § 510(k), the Supreme Court held that state tort claims for defective design and manufacture, failure-to-warn, and noncompliance with federal standards were not preempted. As to the design defect claims, all nine justices agreed that, as a section 510(k)-marketed device, the pacemaker was not subjected to *any* FDA design review, but was merely found by the FDA to be "substantially equivalent" to unreviewed devices on the market in 1976. Hence, for the purposes of the MDA's preemption clause, no "requirement" as to the pacemaker's design had been established by the FDA, and the plaintiff therefore could not seek a requirement "different from or in addi-

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58. *Id.* § 360c(a)(1)(A)-(C).

59. A "grandfather" clause in the MDA allows medical devices already in existence when the MDA was enacted to remain on the market without FDA approval until the FDA initiates and completes the pre-market approval process for such devices. *Id.* § 360e(b)(1)(A).

60. The designation refers to the section of the MDA establishing the "substantially equivalent" means of regulatory approval. *Id.* § 360e(b)(1)(B).

61. *Id.* § 360k(a).

62. *Mitchell v. Collagen Corp.*, 67 F.3d 1268, 1275 (7th Cir. 1995); *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392, 398 (4th Cir. 1995); *Martello v. Ciba Vision Corp.*, 42 F.3d 1167, 1168 (8th Cir. 1994); *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 542 (3rd Cir. 1994); *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 16 (1st Cir. 1994). *But cf. Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1457 (9th Cir. 1995) (holding that MDA does not preempt common law tort claims).

tion to" a requirement which did not exist.<sup>63</sup> A unanimous Court also agreed that tort claims for noncompliance with federal standards were not preempted; to the extent plaintiff merely sought to enforce federal law, she did not seek to impose requirements "different from or in addition to" those imposed by the FDA.<sup>64</sup> Finally, as to the plaintiff's manufacturing and labeling defect claims, a majority of Justices relied upon an FDA interpretive regulation providing in pertinent part that the MDA preempts state law "only when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the [MDA]," and that "State or local requirements of general applicability" were not preempted.<sup>65</sup> According to the majority, the plaintiff's common-law tort theories were not developed "with respect to" medical devices but were "requirements of general applicability" to all products, not just medical devices, and therefore were not preempted.<sup>66</sup>

Post-*Medtronic* decisions interpreting the scope of preemption under the MDA reach generally inconsistent results. About the only consistency shown among the courts is that, where the allegedly defective product is a section 510(k) device, state common-law tort theories are not preempted.<sup>67</sup> Some courts have held that product liability claims involving so-called "IDE" devices,<sup>68</sup> which undergo a greater level of agency scrutiny than section 510(k) devices, are preempted under the MDA, *Medtronic* notwithstanding.<sup>69</sup> The Ninth Circuit has held that, where FDA standards specify the content for a warning label, state failure-to-warn claims, though arguably of "general applicability," are nonetheless preempted.<sup>70</sup> Conversely, the Tenth Circuit has held that common-law failure-to-

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63. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 492, 513 (1996).

64. *Id.* at 507.

65. 21 C.F.R. § 808.1(d) (2000).

66. *Medtronic*, 518 U.S. at 500 (Stevens, J.). The dissent declined to give deference to the FDA's interpretive regulation and concluded that the plain language of the MDA barred plaintiff's manufacturing and labeling defect claims. *Id.* at 513 (O'Connor, J. concurring).

67. *Reeves v. Acromed Corp.*, 103 F.3d 442, 445 (5th Cir. 1997).

68. "IDE" refers to an exemption to the full pre-market review and approval process for "investigational devices" permitted under the MDA, 21 U.S.C. § 360j(g).

69. *Oja v. Howmedica, Inc.*, 111 F.3d 782, 785 (10th Cir. 1997); *Chambers v. Osteonics Corp.*, 109 F.3d 1243, 1248 (7th Cir. 1997); *Martin v. Teletronics Pacing Sys., Inc.*, 105 F.3d 1090, 1093 (6th Cir. 1997).

70. *Papike v. Tambrands, Inc.*, 107 F.3d 737, 740 (9th Cir. 1997).

warn claims are not developed "with respect to" the device at issue and are therefore not preempted.<sup>71</sup> Finally, the Eleventh Circuit recently ruled that no preemption exists whatsoever for tort claims involving a pacemaker undergoing full pre-market review and approval because the premarket approval process did not amount to a "specific federal requirement" within the meaning of the FDA's interpretive regulation;<sup>72</sup> however, the Seventh Circuit reached the opposite conclusion.<sup>73</sup> To suggest that post-*Medtronic* case law regarding MDA preemption is muddled is an understatement.<sup>74</sup>

### C. Motor Vehicles

Much product liability litigation involving this act has focused on Safety Standard 208, the regulation at issue in *Geier*. As promulgated in 1984, Standard 208 required automobile manufacturers to install passive restraints – driver-side airbags or automatic seat belts – in some, but not all, automobiles made between 1986 and 1989.<sup>75</sup> Manufacturers faced with design defect claims brought by injured drivers or occupants of such vehicles, based generally upon the lack of airbag protection, have contended that such claims are preempted under the act as ones which would impose requirements "not identical to" Standard 208.

Prior to the Supreme Court's decision in *Geier*, the courts were badly fractured on the subject. Several federal appeals courts concluded that such claims are either expressly or implicitly preempted;<sup>76</sup> however, state appellate courts, relying upon the act's sav-

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71. *Oja v. Howmedica, Inc.*, 111 F.3d 782, 785, 793 (10th Cir. 1997).

72. *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1376 (11th Cir. 1999).

73. *Mitchell v. Collagen Corp.*, 126 F.3d 902, 904 (7th Cir. 1997).

74. In light of the conflicting results reached by courts applying *Medtronic* to cases involving IDE and full pre-market approval devices, on December 12, 1997, the FDA issued a proposed rule for the purpose of "clarify[ing] and codify[ing] the agency's longstanding position that available legal remedies, including State common law tort claims, generally are not preempted under the Federal Food, Drug, and Cosmetic Act" for any medical device. 62 Fed. Reg. 65384 (1997). The FDA subsequently withdrew the proposed rule on July 24, 1998. 63 Fed. Reg. 39789 (1998).

75. The rule required manufacturers to incorporate passive restraint devices in 10% of their 1987 model year cars, 25% of their 1988 models, and 40% of their 1989 models. 49 C.F.R. § 571.208. All passenger cars manufactured after September 1, 1989 were required to incorporate passive restraints; those manufactured after September 1, 1997 must provide specific airbag protection for the driver and right front passenger. *Id.*

76. *Geier v. Am. Honda Motor Co., Inc.*, 166 F.3d 1236, 1237 (D.C. Cir.

ings clause, generally reached the opposite conclusion.<sup>77</sup> That split has now been resolved by *Geier*, as discussed previously.

In one other notable decision involving preemption under the National Traffic and Motor Vehicle Safety Act, the United States Supreme Court held that a safety standard regarding stopping distances for tractor-trailers promulgated by the National Highway Traffic Safety Administration, but subsequently suspended by a federal appeals court, did not preempt state common-law claims for design defect arising out of the absence of antilock brakes.<sup>78</sup> In the absence of an enforceable federal standard, according to the Supreme Court, the act's preemption clause did not apply.<sup>79</sup>

#### D. *Watercraft*

The Federal Boat Safety Act<sup>80</sup> authorizes the United States Coast Guard to establish safety standards for recreational boats.<sup>81</sup> A broad preemption clause in the act prohibits states from "establish[ing], continu[ing] in effect, or enforc[ing] a law or regulation establishing a recreational vessel or associated equipment performance or other safety standard or imposing a requirement for associated equipment...that is not identical to a regulation prescribed [by the Coast Guard under the act]."<sup>82</sup> However, the act also contains a savings clause which provides that compliance with federal standards does not relieve anyone from liability at common law or under State law.<sup>83</sup>

During 1990, the Coast Guard considered, but ultimately rejected, proposed regulations which would have required marine manufacturers to incorporate propeller guards on their boats.<sup>84</sup> In

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1999); *Irving v. Mazda Motor Corp.*, 136 F.3d 764, 766 (11th Cir. 1998); *Harris v. Ford Motor Co.*, 110 F.3d 1410, 1415 (9th Cir. 1997); *Montag v. Honda Motor Co., Ltd.*, 75 F.3d 1414, 1417 (10th Cir. 1996); *Pokorny v. Ford Motor Co.*, 902 F.2d 1116, 1118 (3rd Cir. 1990); *Kitts v. General Motors Corp.*, 875 F.2d 787, 789 (10th Cir. 1989); *Wood v. Gen. Motors Corp.*, 865 F.2d 395, 401 (1st Cir. 1988).

77. See, e.g., *Munroe v. Galati*, 938 P.2d 1114 (Ariz. 1997); *Tebbetts v. Ford Motor Co.*, 665 A.2d 345 (N.H. 1995); *Drattel v. Toyota Motor Corp.*, 699 N.E.2d 376 (N.Y. 1998).

78. *Freightliner Corp. v. Myrick*, 514 U.S. 280, 283, 289 (1995).

79. *Id.* at 286.

80. 46 U.S.C. §§ 4301, 4302, 4311 (2000).

81. *Id.* § 4302(a)(1).

82. *Id.* § 4306.

83. *Id.* § 4311(g).

84. *Carstenson v. Brunswick Corp.*, 49 F.3d 430, 431 (8th Cir. 1995).



design defect cases involving claims for personal injury due to the absence of such a guard, manufacturers have sought refuge within the act's preemption clause. Once again, the courts have reached inconsistent results. Federal courts have generally concluded that such claims are preempted.<sup>85</sup> While some state courts have also ruled in favor of preemption,<sup>86</sup> others have held that such claims are not preempted.<sup>87</sup>

### *E. Animal Vaccines*

Unlike the preceding examples, preemption of state product liability actions involving animal vaccines is a product of agency, not congressional, action. In the Virus-Serum-Toxin Act,<sup>88</sup> Congress gave broad authority to the Department of Agriculture to regulate the design, manufacture, testing, and distribution of animal vaccines to ensure their safety, efficacy, potency and purity.<sup>89</sup> Congress amended the act in 1985 to confer even more discretionary authority upon the agency and declared that federal control was "necessary to prevent and eliminate burdens on commerce and to effectively regulate such commerce."<sup>90</sup> The legislative history of the 1985 amendments reflects Congress' intent to establish "uniform national standards" for all animal vaccines marketed in the United States.<sup>91</sup> However, Congress did not insert a preemption clause into the act.

In 1992, the Animal and Plant Health Inspection Service ("APHIS"), the arm of the Department of Agriculture charged with

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85. *Lewis v. Brunswick Corp.*, 107 F.3d 1494 (11th Cir. 1997); *Carstensen*, 49 F.2d at 431-32; *Davis v. Brunswick Corp.*, 854 F. Supp. 1574, 1580 (N.D. Ga. 1993); *Shield v. Bayliner Marine Corp.*, 822 F.Supp. 81, 84 (D. Conn. 1993); *Shields v. Outboard Marine Corp.*, Div. of Brunswick Corp., 776 F.Supp. 1579, 1581 (M.D. Ga. 1991); *Mowery v. Mercury Marine*, 773 F. Supp. 1012, 1014-15 (N.D. Ohio 1991). All of these decisions, of course, were rendered before *Geier*; whether *Geier* alters the analysis remains to be seen.

86. *Farner v. Brunswick Corp.*, 607 N.E.2d 562, 567 (Ill. App. Ct. 1992).

87. *Rubin v. Brutus Corp.*, 487 So.2d 360, 363 (Fla. Dist. Ct. App. 1986); *Moore v. Brunswick Bowling and Billiards Corp.*, 889 S.W.2d 246, 249-50 (Tex. 1994); *Ramsey v. Lucky Stores, Inc.*, 853 S.W.2d 623, 637-38 (Tex. App. 1993); *Mulhern v. Outboard Marine Corp.*, 432 N.W.2d 130, 134-36 (Wis. Ct. App. 1988).

88. 21 U.S.C. §§ 151-159 (1999).

89. *Id.* § 154; *See also* *Symens v. SmithKline Beecham Corp.*, 152 F.3d 1050, 1053-54 (8th Cir. 1998).

90. 21 U.S.C. § 159 (1999).

91. S. Rep. No. 99-145, at 338-39 (1985); *Lynnbrook Farms v. SmithKline Beecham Corp.*, 79 F.3d 620, 625 (7th Cir. 1996).

regulating animal vaccines, promulgated a final rule delineating the extent to which states may regulate animal vaccines within their boundaries.<sup>92</sup> The rule, as well, contains no express preemption clause. In its preamble to the final rule, however, APHIS disagreed with comments suggesting that states should have the authority to add to federal standards and declared that "States are not free to impose requirements which are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency or purity of [an animal vaccine]."<sup>93</sup> APHIS further announced in the preamble that "where safety, efficacy, purity, and potency of biological products are concerned, it is the agency's intent to occupy the field."<sup>94</sup>

In reliance upon these agency pronouncements, both federal and state courts have consistently held that state product liability claims for harm to animals caused by allegedly defective animal vaccines are preempted insofar as those claims would effectively impose upon the manufacturer requirements "different from or in addition to" those imposed by APHIS.<sup>95</sup> However, tort claims based upon noncompliance with federal requirements have been found not to be preempted.<sup>96</sup> Tort claims for human injury purportedly caused by accidental exposure to animal vaccines have also been held not to be preempted on the grounds that APHIS' congressionally-delegated authority to preempt extended only to claims involving animal harm.<sup>97</sup>

#### *F. Hazardous Substances Intended For Consumer Use*

In the Federal Hazardous Substances Act, Congress authorized the Consumer Products Safety Commission to establish mandatory

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92. 9 C.F.R. § 102.5 (2000).

93. Viruses, Serums and Toxins and Analogous Products: Restrictions on Distribution and Use, 57 Fed. Reg. 38758, 38759 (1992).

94. *Id.*

95. *Symens v. SmithKline Beecham Corp.*, 152 F.3d 1050, 1053 (8th Cir. 1998); *Lynnbrook Farms*, 79 F.3d at 623; *Gresham v. Boehringer Ingelheim Animal Health, Inc.*, No.CIV.1:95-CV-3376-ODE, 1996 WL 751126, at \*2 (N.D. Ga. Aug. 7, 1996); *Murphy v. SmithKline Beecham Animal Health Group*, 898 F.Supp. 811, 816 (D. Kan. 1995); *Brandt v. Marshall Animal Clinic*, 540 N.W.2d 870, 876 (Minn. Ct. App. 1995).

96. *Gresham*, 1996 WL 751126, at \*3; *Silvey v. Mallinckrodt, Inc.*, 976 S.W.2d 497, 500 (Mo. Ct. App. 1998).

97. *Garrelts v. SmithKline Beecham Corp.*, 943 F.Supp. 1023, 1063 (N.D. Iowa 1996).

labeling requirements for certain hazardous substances intended for consumer use.<sup>98</sup> Where a labeling requirement for a product has been established by the agency, the act prohibits states from establishing or continuing in effect any requirement not "identical to" the federal labeling requirement.<sup>99</sup> Both federal and state courts have consistently held that, where the labeling on a product subject to the act complies with federal requirements, all failure-to-warn claims relating to the content or sufficiency of the label are preempted.<sup>100</sup> However, claims for product defect (including design and manufacture claims) which are not label-based are not preempted, as are failure-to-warn claims charging non-compliance with the applicable federal requirements.<sup>101</sup>

### *G. Hazardous Substances Used In The Workplace*

Under the Occupational Safety and Health Act, Congress delegated to the Occupational Safety and Health Administration the authority to establish federal health and safety standards for the protection of employees in their workplaces.<sup>102</sup> The act contains general provisions establishing the primacy of federal occupational safety and health standards and the necessity of federal approval of state plans<sup>103</sup> and a specific savings clause declaring that "common law or statutory rights, duties, or liabilities of employers and employees . . . with respect to injuries, diseases, or death of employees arising out of, or in the course of, employment" are unaffected by the act.<sup>104</sup> The act does not, however, contain a specific preemption clause similar to many of those described above.

Injured employees' product liability claims against manufacturers or suppliers of allegedly defective products used in the workplace have been held not to be preempted by the act itself.<sup>105</sup>

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98. Hazardous Substance Act, 15 U.S.C. § 1262 (2000).

99. *Id.* § 1261, note (b).

100. *Comeaux v. National Tea Co.*, 81 F.3d 42, 42 (5th Cir. 1996); *Moss v. Parks Corp.*, 985 F.2d 736, 740 (4th Cir. 1993); *Lee v. Boyle-Midway Household Prod. Inc.*, 792 F.Supp. 1001, 1009 (W.D. Pa. 1992); *Busch v. Graphic Color Corp.*, 662 N.E.2d 397, 408-09 (Ill. 1996); *Canty v. Ever-Last Supply Co.*, 685 A.2d 1365, 1374 (N.J. Super. Ct. Law Div. 1996); *Jenkins v. James B. Day & Co.*, 634 N.E.2d 998, 1004 (Ohio 1994).

101. *Canty*, 685 A.2d at 1379.

102. 29 U.S.C. § 651 (b)(3) (2000).

103. *Id.* § 667 (b).

104. *Id.* § 653(b)(4).

105. *See, e.g., Pedraza v. Shell Oil Co.*, 942 F.2d 48, 53-54 (1st Cir. 1991); *York v.*

However, in a comprehensive federal standard governing the evaluation and communication of hazards arising out of workplace chemical use,<sup>106</sup> OSHA stated its intent to "preempt any legal requirements of a state...pertaining to [evaluation and communication of chemical hazards to employees]."<sup>107</sup> OSHA further prohibited states from adopting or enforcing "any requirement" relating to chemical safety addressed by the OSHA standard, "except pursuant to a Federally-approved state plan."<sup>108</sup> The language of the act itself, however, remained unchanged.

At least one federal circuit has held that the OSHA rule preempts failure-to-warn claims against the manufacturer of an alleged injury-causing workplace chemical, so long as the labeling on the chemical's container satisfied OSHA requirements.<sup>109</sup> Another federal court, without deciding the broader issue, held that product liability claims alleging the chemical manufacturer's non-compliance with the OSHA standard are not preempted.<sup>110</sup>

#### *H. Flammable Fabrics*

In the Flammable Fabrics Act, Congress authorized the Consumer Products Safety Commission to research and develop testing standards for the flammability of materials and fabrics.<sup>111</sup> As amended in 1976, the act also bars states from establishing or continuing in effect any "flammability standard or other regulation" which is not "identical to" a federally-established flammability standard or regulation for the fabric or material at issue.<sup>112</sup>

Generally speaking, both federal and state courts have declined to preempt state product liability claims arising from flammable fabrics. Interpreting a prior version of the act's preemption clause, the First Circuit held that the act did not bar states, through

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Union Carbide Corp., 586 N.E.2d 861, 866 (Ind. Ct. App. 1992).

106. 29 C.F.R. § 1910.1200 (a)(1)-(2) (2000).

107. *Id.* § 1910.1200(a)(2).

108. *Id.*

109. *Torres-Rios v. LPS Lab., Inc.*, 152 F.3d 11, 16 (1st Cir. 1998). Notably, nowhere in its opinion did the First Circuit mention its prior opinion in *Pedraza* which was based in part upon the act's savings clause. The continued vitality of *Pedraza* and the possible impact of *Geier* upon this decision, are both unclear at best.

110. *Wickham v. Am. Tokyo Kasei, Inc.*, 927 F.Supp. 293, 295 (N.D. Ill. 1996).

111. 15 U.S.C. § 1201 (b)(1)-(4) (1997).

112. *Id.* § 1203 (a).

the course of common-law tort actions, from enacting more stringent standards than those set by federal law for fabric flammability.<sup>113</sup> In a subsequent ruling construing the act's current language, the First Circuit again declined to preempt state tort claims on the grounds that the phrase "flammability standard or other regulation" does not reach state common-law tort actions.<sup>114</sup> State courts have reached similar results.<sup>115</sup>

### *I. Miscellaneous Consumer Products*

Finally, manufacturers of certain products falling within the purview of the Consumer Product Safety Act<sup>116</sup> (hereinafter "CPSC") have also sought the benefit of the preemption defense in product liability actions. The act prohibits states from establishing or continuing in effect "any provision of a safety standard or regulation which prescribes any requirements as to the performance, composition, contents, design, finish, construction, packaging, or labeling of such 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."<sup>117</sup> However, the act also contains a savings clause providing that "[c]ompliance 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."<sup>118</sup>

Lawnmowers are both subject to a variety of CPSC requirements<sup>119</sup> and a frequent subject of product liability litigation. In one such action, failure-to-warn claims relating to a mower label's warning of injuries to the fingers from the mower blade were held to be expressly preempted, inasmuch as a specific federal safety standard prescribed the content for the label and the label con-

113. *Raymond v. Riegel Textile Corp.*, 484 F.2d 1025, 1028 (1st Cir. 1973).

114. *Wilson v. Bradlees of New England, Inc.*, 96 F.3d 552, 553 (1st Cir. 1996).

115. *O'Donnell v. Big Yank, Inc.*, 696 A.2d 846, 853 (Pa. Super. Ct. 1997).

116. *See generally* 15 U.S.C. § 2051 (1997) (describing the purpose of the Act).

117. *Id.* § 2075(a).

118. *Id.* § 2074(a).

119. For example, each mower must have a blade control system that permits the blade to rotate only if the operator presses on a special control on the handle. 16 C.F.R. § 1205.5(a)(1)(i) (2000). Each mower must also pass a "foot probe" test, which effectively mandates that a protective shield be installed extending from the blade housing. *Id.* § 1205.5(a)(iv)(B).

formed to that standard; however, defective design claims, in the absence of a federal standard regulating lawnmower design, were allowed to proceed to trial.<sup>120</sup> In another case, where the CPSC proposed but then withdrew a safety standard which would have required the use of "no-mow-in-reverse" devices on lawn mowers, design defect claims based upon the absence of such a device were allowed to stand.<sup>121</sup>

## V. HARMONIZING DISPARATE PREEMPTION RESULTS

Given that all federal preemption springs from a single clause in the United States Constitution, at one level the variability and inconsistency of the courts' application of the preemption defense in product liability actions are remarkable. As illustrated above, some products are covered by a federal preemption defense; others are not. In some settings, federal and state courts have construed the same express preemption scheme completely oppositely from one another; in others, such as cases involving medical devices after *Medtronic*, the federal courts appear to be confused and divided among themselves. The term "standards," when used in the context of boat safety, encompasses duties imposed by state tort law; when used in the context of flammable fabrics, "standards" does not reach state product liability claims; and, exactly what "safety standards" means for purposes of motor vehicle safety is anyone's guess. Standards considered but *not* implemented by the federal government for boat propeller guards may still be entitled to preemptive effect; unadopted or invalid "standards" for tractor-trailer braking systems or lawnmowers do not preempt state tort claims. Even four members of the Supreme Court apparently believe that the term "requirements," when used in different preemption statutes governing different products, can carry different meanings in each.<sup>122</sup>

There is no single, or simple, explanation to these inconsistencies. However, notions of federalism, uniformity of standards, access to the courts, and politics aid in understanding why such

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120. *Moe v. MTD Prod., Inc.*, 73 F.3d 179, 182 (8th Cir. 1995) (citing 15 U.S.C. § 2075(a); 16 C.F.R. § 1205.5(a)).

121. *Johnston v. Deere & Co.*, 967 F.Supp. 574, 574 (D. Me. 1997).

122. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 487-90 (1996). Justice Stevens' plurality opinion discusses the term "requirements" as contained in both the Medical Device Amendments and the Public Health Cigarette Smoking Act of 1969. *Id.*

clearly disparate results have arisen and are likely to pervade product liability law for the foreseeable future.

That state courts have tended to be less preemption-friendly than federal courts should come as no surprise. Most if not all state constitutions assure, at least in theory, the right of individuals allegedly aggrieved by another to seek redress in the courts.<sup>123</sup> Particularly where federal and not state law preempts otherwise-applicable state remedies, state judges are often reluctant to divest aggrieved plaintiffs of their day in court.<sup>124</sup> By contrast, because federal courts are of limited jurisdiction and are more experienced in adjudicating questions of federal supremacy, federal courts may be less concerned than state courts about the practical implications of the preemption defense.<sup>125</sup>

Also inherent in preemption of product liability claims is a fundamental tension between federalism and uniformity. The United States Constitution expressly reserves to the states all powers not expressly delegated to the federal government.<sup>126</sup> Compensating persons injured in their persons or property by defective products has long been viewed as a local, not federal, concern reserved to the states under their police powers.<sup>127</sup> Conversely, particularly as many product manufacturers' markets for their goods expand from local to national (and even global) in nature, Congress has increasingly recognized a need for uniform national standards,<sup>128</sup> and industries worldwide have adopted voluntary global standards for the design, manufacture and distribution of certain goods.<sup>129</sup>

123. *E.g.*, MINN. CONST. art. 1, § 8.

124. As the Minnesota Court of Appeals observed in *Brandt v. Marshall Animal Clinic*, 540 N.W.2d 870, 878 (Minn. Ct. App. 1995) "[i]t is worthy of note that . . . the trial court below expressed concern and regret for the remedies lost by preemption. . . . We are mindful of these concerns."

125. This is not to say that federal judges are unsympathetic to the same concerns. *E.g.*, *Murphy v. SmithKline Beecham Animal Health Group*, 898 F.Supp. 811, 818 (D. Kans. 1995) (stating "[t]he court regrets the fact that its decision leaves the plaintiff without a remedy at law"); *Lynnbrook Farms v. SmithKline Beecham Corp.*, 887 F.Supp. 1100, 1106 (C.D. Ill.), *aff'd* 79 F.3d 620 (7th Cir. 1996) (stating "[a]ll this being said, the Court is troubled by the absence of a federal remedy").

126. U. S. CONST. amend. X.

127. *Hillsborough County, Florida v. Automated Med. Lab., Inc.*, 471 U.S. 707, 719 (1985); *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985).

128. *E.g.*, *supra* note 91 and accompanying text.

129. *E.g.*, International Organization for Standardization, International Standard (ISO) 9000.

The tension between these competing considerations was vividly illustrated in 1999, when legislation designed to limit the ability of both Congress and federal agencies to preempt state and local laws and regulations was introduced in both houses of Congress.<sup>130</sup> The legislation was sponsored by an unusual alliance between conservative Republican advocates of states' rights and liberal Democrats interested in enhancing environmental protection through more stringent state laws. However, business groups were opposed to the legislation, claiming that it would subject businesses of all types to a patchwork of differing state standards for their goods and services.<sup>131</sup> Ultimately, the business point of view prevailed and the proposed legislation was dropped—at least for the time being.<sup>132</sup>

The Executive Branch has also recently weighed in on the preemption issue. As the proposed legislation described above was winding its way through Congress, President Clinton issued an Executive Order which, under the guise of federalism promotion, generally precludes federal agencies from preempting state and local law except when Congress has manifested some specific preemptive intent.<sup>133</sup> Because the Executive Order contains language expressly disavowing any intent "to create any right or benefit, substantive or procedural, enforceable at law by a party against . . . any person,"<sup>134</sup> it would appear to offer no protection to product liability plaintiffs seeking to avoid the impact of express agency preemption.<sup>135</sup>

Finally, even where Congress has spoken to the question of preemption, federal agencies are free to, and often do, offer their interpretation of the proper scope of preemption of state tort claims involving the products they regulate. Those positions, and

130. S. Rep. No. 106-159, at 1 (1999).

131. Cindy Skrzycki, *The Chamber Reached A Sticking Point*, WASHINGTON POST, September 17, 1999, at E1.

132. *Id.*

133. Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (1999). The Order essentially restates an earlier proclamation on the same subject by President Reagan. Exec. Order No. 12,612, 52 Fed. Reg. 41,685 (1987).

134. Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (1999).

135. *Murphy v. SmithKline Beecham Animal Health Group*, 898 F. Supp. 811, 815 (D. Kan. 1995). *But cf. Geier v. Am. Honda Motor Co., Inc.*, \_\_ U.S. \_\_, 120 S. Ct. 1913, 1940 (2000) (Stevens, J., dissenting) (observing the general existence of Executive Orders 12,612 and 13,132 and their impact upon agencies intending to preempt state law, but making no mention of the "no private right" language in those Orders).



the courts' treatment of them, can vary widely among different agencies. For example, the FDA has repeatedly expressed its intent that preemption of state tort actions seeking damages for defective medical devices and other products under its regulatory control should, at most, occur in very limited situations.<sup>136</sup> In *Medtronic*, as noted previously, the Supreme Court placed controlling weight upon the FDA's interpretation of the preemption clause in the Medical Device Amendments, as opposed to the literal language of the statute itself.<sup>137</sup> Similarly, after years of silence following the Supreme Court's decision in *Cipollone* and the holdings of numerous federal and state courts upholding preemption of product labeling-related claims under FIFRA, in 1999 the Environmental Protection Agency submitted *amicus* briefs in two cases urging the courts to find that FIFRA's preemption clause does not preempt state tort law, or at a minimum state failure-to-warn claims relating to product efficacy.<sup>138</sup> In neither case, however, did the court accept EPA's position.<sup>139</sup> Conversely, in *Geier*, the Department of Transportation expressed its position through an *amicus* brief that the plaintiff's "no airbag" defective design claim stood "as an obstacle to the accomplishment and execution" of the objectives underlying Standard 208 and should be preempted via conflict; the Supreme Court placed considerable weight upon the agency's views on preemption.<sup>140</sup> And on no less than two separate occasions, APHIS has formally announced that, in construing its declaration of preemption to bar most state tort claims for harm caused by allegedly-defective animal vaccines, the courts' determination of the scope of APHIS' preemptive intent was correct.<sup>141</sup>

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136. *Bansemer v. Smith Laboratories, Inc.*, No. CIV.A. 86-C-1313, 1990 WL 132579, at \*3 (E.D. Wis. Sept. 12, 1988) (discussing FDA's intent that failure-to-warn claims arising out of pharmaceutical labeling should not be preempted).

137. *Id.*

138. *Hart v. Bayer Corp.*, 199 F.3d 239, 244 (5th Cir. 2000); *Etcheverry v. Tri-Ag Serv.*, 993 P.2d 366, 375 (Cal. 2000).

139. In *Etcheverry*, the California Supreme Court flatly rejected the position offered by EPA as *amicus*. In *Hart*, by contrast, the Fifth Circuit did not reach the merits of EPA's position but instead decided the appeal on jurisdictional grounds.

140. *Geier*, 120 S.Ct. at 1926.

141. *Symens v. SmithKline Beecham Corp.*, 152 F.3d 1050, 1055 n.2 (8th Cir. 1998); *Lynnbrook Farms v. SmithKline Beecham Corp.*, 79 F.3d 620, 629-30 (7th Cir. 1996). Notably, these affirmations came in the face of significant political pressure upon APHIS, brought by a United States Senator, to declare the opposite – that the courts' decisions did not correctly reflect agency intent. *Garrelts v. SmithKline Beecham Corp.*, 943 F.Supp. 1023, 1031-32 (N.D. Iowa 1996).

## VI. WHERE IS THE PREEMPTION DEFENSE HEADED?

In light of the foregoing, what does the future hold in store for federal preemption of product liability actions? Allow us to offer a few semi-informed prognostications.

First, in the absence of either (1) national product liability legislation supplanting all federal preemption schemes or (2) the Supreme Court's overruling of *Cipollone*, federal preemption of state product liability actions will continue to yield inconsistent and in many cases inexplicable results. As the statutory language, agency intent, degree of federal regulation and other factors vary from product to product, so, too, will the outcomes reached by the courts. Uniformity and consistency will largely be absent.

Second, the trend toward uniform national, indeed uniform global, standards governing the conduct of American product manufacturers (not to mention providers of financial services and other industries) will continue if not accelerate. Many businesses already require their suppliers to conform to international standards of product design, manufacture, labeling and testing; those numbers will likely grow. In addition, regional or global trade agreements can have the effect of displacing state or local regulation determined to unfairly affect trading partners.<sup>142</sup> The growing pressure towards national and global uniformity will likely cause an increase in calls for protection from state and local requirements that detract from uniformity.

Third, the preemption defense is almost certain to remain highly politicized. Product manufacturers, desirous of greater protection from tort litigation, can be expected to lobby both Congress and federal agencies in the hope of securing (or at least preserving) federal preemption; those representing victims of allegedly defective products will likely lobby Congress and federal agencies for abolition (or at least limitation) of express preemption clauses. These battles will likely be fought on a product-by-product, statute-by-statute basis. In addition, the federalism bills introduced in the House and Senate in 1999 will likely be resurrected by federalism

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142. For example, the World Trade Organization has ruled that a federal ban on the importation of shrimp and shrimp products from nations not certified as harvesting shrimp via techniques protective of sea turtles violates GATT. Pub. L. No. 101-162, 103 Stat. 988, 16 U.S.C. § 1537 note (2000).

advocates in future years and, depending upon which party then controls Congress, may well meet with more success. Similarly, state and local governments have largely sat on the sidelines as Congress and federal agencies have whittled away at their traditional police powers; their strong support for the 1999 federalism bills suggests that state and local governments may more aggressively resist future federal attempts to displace state authority via federal preemption.

Finally, look for federal agencies to play a greater role in the preemption debate. While tort litigation may enhance product safety and efficacy, it can also limit the availability of products in certain markets and sharply increase the price consumers must pay for them. Expert federal agencies, intimately familiar with the products and industries they regulate, are arguably far better suited than Congress to balance these conflicts and to ascertain the degree of federal uniformity necessary to assure safety, efficacy *and* availability at a reasonable cost. Where Congress has not foreclosed federal agencies from resorting to preemption as a regulatory tool, one should not be surprised to see agencies wield that tool with increasing frequency as circumstances dictate the need for federal exclusivity and uniformity in appropriate areas. And as both *Medtronic* and *Geier* illustrate, even where Congress has spoken to the question of preemption, the Supreme Court will still place considerable emphasis upon an agency's interpretation of Congress' language and its "fair and considered judgment" as to whether preemption should lie.<sup>143</sup> The door is wide open for federal agencies to exert far greater influence on the preemption question.

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143. *Auer v. Robbins*, 519 U.S. 452, 461-62 (1997), *quoted in* *Geier v. Am. Honda Motor Co., Inc.*, \_\_\_ U.S. \_\_\_, 120 S. Ct. 1913, 1927 (2000).