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## Federal Preemption of Products Liability Claims

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# FEDERAL PREEMPTION OF PRODUCTS LIABILITY CLAIMS

DAVID G. OWEN\*

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\* Carolina Distinguished Professor of Law, University of South Carolina. A later version of this Article will appear in DAVID G. OWEN, *PRODUCTS LIABILITY LAW* (forthcoming 2004). Thanks to Mary Davis and Richard Ausness for commenting on an earlier draft of this Article, and to Trent Kirk, Aaron Dias, and Tod Williams for research, editorial, and technical assistance. Not having seen a draft, Pat Hubbard might not fairly be blamed for much herein.

## I. INTRODUCTION

No issue in modern products liability law is more important, or more inscrutable, than the doctrine of federal preemption. The doctrine is important because the defense of federal preemption in recent years has grown from little more than a blip on the radar screen to one of the most powerful defenses in all of products liability law. The doctrine is inscrutable because it is a formless and elusive creature, based on ephemeral notions of federalism and the oft-obscure intent of Congress, that vacillate according to shifting political sentiments—on federal versus states rights, on Congress versus the courts, and on regulatory versus products liability law.<sup>1</sup> Despite the best efforts of courts and commentators to bring order to the chaos,<sup>2</sup> the law on federal preemption has obstinately refused to set anchor in enduring principles. Instead, it continues to

1. See, e.g., Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 229 (2000) (noting that “the politics of preemption are complicated”); Scott A. Smith & Duana Grage, *Federal Preemption of State Products Liability Actions*, 27 WM. MITCHELL L. REV. 391, 415 (2000) (predicting that “the preemption defense is almost certain to remain highly politicized”); David B. Spence & Paula Murray, *The Law, Economics, and Politics of Federal Preemption Jurisprudence: A Quantitative Analysis*, 87 CAL. L. REV. 1125, 1129 (1999) (stating, “For most judges, whether liberal or conservative, these cases pit one dimension of their ideology, their principles of federalism, against another, their policy preferences or attitudes toward the particular local regulation at issue.”). See generally JOHN E. NOWAK & RONALD D. ROTUNDA, *CONSTITUTIONAL LAW* §§ 9.1-4 (6th ed. 2000) (discussing federal preemption and its development); 1 LAURENCE H. TRIBE, *AMERICAN CONSTITUTIONAL LAW* §§ 6-28 to -33 (3d ed. 2000) (discussing the relationship between state law and federal legislation).

2. See, e.g., Richard C. Ausness, *Federal Preemption of State Products Liability Doctrines*, 44 S.C. L. REV. 187 (1993) [hereinafter Ausness, *Federal Preemption*]; Richard C. Ausness, *Preemption of State Tort Law by Federal Safety Statutes: Supreme Court Preemption Jurisprudence Since Cipollone*, 92 KY. L.J. (forthcoming 2004) [hereinafter Ausness, *Preemption Jurisprudence*]; Mary J. Davis, *On Preemption, Congressional Intent, and Conflict of Laws* (unpublished manuscript on file with author) [hereinafter Davis, *On Preemption*]; Mary J. Davis, *Unmasking the Presumption in Favor of Preemption*, 53 S.C. L. REV. 967 (2002); Viet D. Dinh, *Reassessing the Law of Preemption*, 88 GEO. L.J. 2085 (2000); Betsy J. Grey, *Make Congress Speak Clearly: Federal Preemption of State Tort Remedies*, 77 B.U. L. REV. 559 (1997); Robert B. Lefflar & Robert S. Adler, *The Preemption Pentad: Federal Preemption of Products Liability Claims After Medtronic*, 64 TENN. L. REV. 691 (1997); M. Stuart Madden, *Federal Preemption of Inconsistent State Safety Obligations*, 21 PACE L. REV. 103 (2000); Nelson, *supra* note 1; Lars Noah, *Reconceptualizing Federal Preemption of Tort Claims As the Government Standards Defense*, 37 WM. & MARY L. REV. 903 (1996); Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049 (2000); Susan Raeker-Jordan, *A Study in Judicial Sleight of Hand: Did Geier v. American Honda Motor Co. Eradicate the Presumption Against Preemption?*, 17 BYUJ. PUB. L. 1 (2002) [hereinafter Raeker-Jordan, *Sleight of Hand*]; Susan Raeker-Jordan, *The Pre-Emption Presumption That Never Was: Pre-Emption Doctrine Swallows the Rule*, 40 ARIZ. L. REV. 1379 (1998) [hereinafter Raeker-Jordan, *Pre-Emption Presumption*]; Marin R. Scordato, *Federal Preemption of State Tort Claims*, 35 U.C. DAVIS L. REV. 1 (2001); Smith & Grage, *supra* note 1. See generally 4 LOUIS R. FRUMER & MELVIN I. FRIEDMAN, *PRODUCTS LIABILITY* §§ 24.01-.05 (2003); 2 DAVID G. OWEN ET AL., *MADDEN & OWEN ON PRODUCTS LIABILITY* §§ 28:1-8 (3d ed. 2000); 2 *PRODUCTS LIAB. REP.* (CCH) ¶ 2810 (2001).

wallow in a state of utter chaos—"ad hoc, unprincipled . . . , seemingly bereft of any consistent doctrinal basis,"<sup>3</sup> "a muddle,"<sup>4</sup> "inexplicable,"<sup>5</sup> "opaque,"<sup>6</sup> "confusing and chaotic,"<sup>7</sup> "terrible,"<sup>8</sup> "indetermina[te],"<sup>9</sup> and "in a state of disarray"<sup>10</sup>—quite simply, in a "mess."<sup>11</sup>

Federal preemption is an affirmative defense, subject to waiver, on which the defendant has the burden of proof.<sup>12</sup> The federal preemption defense arises, and a products liability claim is foreclosed, when the claim somehow conflicts with a federal product safety statute or regulation specifying design, marketing, or manufacturing standards. When enacting product safety legislation, Congress normally vests regulatory authority over the matter in a federal administrative agency, often specifying in a preemption clause that state law may not interfere with safety standards or "requirements" in the statute itself or, more typically, as promulgated by the federal agency. Whether or not Congress in any particular statute expressly prohibits the states from interfering with implementation of the legislation, any state law that *in fact* interferes with the operation of a federal statute or regulation thereunder contravenes the Supremacy Clause of the United States Constitution. This clause provides that federal law "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 of any State to the Contrary notwithstanding."<sup>13</sup>

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3. William W. Bratton, Jr., Note, *The Preemption Doctrine: Shifting Perspectives on Federalism and the Burger Court*, 75 COLUM. L. REV. 623, 624 (1975).

4. Nelson, *supra* note 1, at 232.

5. Smith & Grage, *supra* note 1, at 415.

6. Davis, *On Preemption*, *supra* note 2, manuscript at 5.

7. Smith & Grage, *supra* note 1, at 392.

8. Ausness, *Preemption Jurisprudence*, *supra* note 2, manuscript at 3.

9. Dinh, *supra* note 2, at 2085.

10. Scordato, *supra* note 2, at 7. See also Raeker-Jordan, *Sleight of Hand*, *supra* note 2, at 33 (stating preemption doctrine is "still in disarray").

11. Dinh, *supra* note 2, at 2085.

12. See, e.g., *Hawkins v. Leslie's Pool Mart, Inc.*, 184 F.3d 244, 256 (3d Cir. 1999) (stating that preemption is an affirmative defense on which defendant has burden of proof); *Williams v. Ashland Eng'g Co.*, 45 F.3d 588, 593 n.7 (1st Cir. 1995) (discussing preemption and Rule 8(c), which requires pleading certain defenses); *Colon ex rel. Molina v. BIC USA, Inc.*, 136 F. Supp. 2d 196, 199-200 (S.D.N.Y. 2000) (noting, however, that a statement in the answer that the product met government standards may suffice). See also *Milanese v. Rust-Oleum Corp.*, 244 F.3d 104 (2d Cir. 2001) (upholding summary judgment for defendant on the ground that plaintiff's claims were preempted). Hence, a defendant who fails to assert preemption in a timely manner may waive the defense. See, e.g., *Violette v. Smith & Nephew Dyonics, Inc.*, 62 F.3d 8, 10-12 (1st Cir. 1995) (holding that although preemption was pleaded in defendant's answer, defendant did not raise the defense substantively until after adverse verdict); *Gonzales v. Surgidev Corp.*, 899 P.2d 576, 581-83 (N.M. 1995) (holding that federal preemption is waived if not raised before end of trial).

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

State statutes and administrative regulations are of course governed by the Supremacy Clause, but so too are products liability actions which can interfere, if less directly, with the administration of a federal safety statute. "[R]egulation 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."<sup>14</sup> Thus, a products liability claim is preempted if it is prohibited by or conflicts in some way with a federal statute or regulation.<sup>15</sup> In determining whether a products liability claim conflicts with federal law, courts must interpret the statute to ascertain its aims. "The purpose of Congress is the ultimate touchstone" in every preemption case.<sup>16</sup> Put otherwise, statutory construction is the cornerstone of preemption analysis.<sup>17</sup>

In general, federal courts are more willing than state courts to find preemption. State courts normally are more focused on protecting the right to compensation of their citizens harmed by the unlawful behavior of others (a right often protected by state constitutions), whereas federal courts of limited jurisdiction generally are more concerned about the doctrine of federal supremacy.<sup>18</sup>

#### *A. Types of Preemption*

Federal preemption of state law may be "express" or "implied." That is, preemption "is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose."<sup>19</sup> Express preemption may helpfully be viewed as textual, in contrast to implied preemption, which may be thought of as contextual.<sup>20</sup> What this means is that express preemption is discernable from the explicit language of a federal statute, whereas implied preemption must be deduced from the broader

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14. *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 247 (1959).

15. Federal administrative agencies may be authorized to preempt state law by regulation. *Hillsborough County, Florida v. Automated Med. Labs. Inc.*, 471 U.S. 707, 713 (1985) ("[S]tate laws can be pre-empted by federal regulations as well as by federal statutes."). See also *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 505 (1996) (Breyer, J., concurring) (stating that "administrative agenc[ies] possess[ ] a degree of leeway to determine which rules, regulations or other administrative actions will have pre-emptive effect").

16. *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 96 (1992) (quoting *Allis-Chalmers Corp. v. Lueck*, 471 U.S. 202, 208 (1985)).

17. See *NOWAK & ROTUNDA*, *supra* note 1, at 348; *TRIBE*, *supra* note 1, § 6-28, at 1176-79.

18. See *Smith & Grage*, *supra* note 1, at 412.

19. *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977). See also *Medtronic*, 518 U.S. at 486 (explaining that the structure and purpose of the statute is relevant in determining Congress' intent).

20. *Madden*, *supra* note 2, at 106.

purposes of a statute—whether or not it contains an express preemption clause.<sup>21</sup>

### 1. *Express Preemption*

Congress by statute may *expressly* preempt state law with a preemption clause that explicitly states the statute's preemptive scope—the extent to which it precludes state law.<sup>22</sup> In legislation regulating product safety, enacted mostly in the late 1960s, Congress was less concerned with the effects of common-law damages claims in products liability cases than with the possibility that state statutes or administrative regulations might somehow undermine the federal legislation.<sup>23</sup> Accordingly, as discussed below, preemption clauses in federal statutes typically provide that the states may not adopt conflicting “requirements” or “standards.” Phrasing of this sort has raised the question of whether the words “requirements” and “standards” mean only legislative and regulatory requirements and standards, or whether Congress intended these terms more broadly to include judicial rulings on common-law damages claims. As mentioned earlier, the Supreme Court has ruled definitively that these phrases in preemption clauses can indeed preclude products liability judgments as well as the more obvious and direct kind of state action through legislation and regulation by administrative agencies. Accordingly, to the extent that allowing a products liability claim would establish a form of common-law safety standard different from that imposed by federal law, an express preemption clause may preclude the claim.

Two types of clauses are particularly relevant in determining whether a statute expressly preempts a state-law products liability claim, preemption clauses, and savings clauses. A “preemption clause” describes the extent to which a statute precludes the application of state law, and a “savings clause” provides that compliance with the statute does not exempt a person from liability under state common law. These two provisions thus generally point in opposite directions: preemption clauses tend to deny, and savings clauses tend to allow, state-law products liability claims. Normally, therefore, the express preemption issue should be clearer if a federal safety statute has only a

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21. *See id.*

22. State law is expressly preempted “[w]hen Congress has considered the issue of preemption 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 . . . .’” *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992) (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 505 (1978)).

23. *See, e.g., Leflar & Adler, supra* note 2, at 746–48 (indicating that Congress added preemption language to federal statutes to displace inconsistent state legislation).

preemption clause<sup>24</sup> or only a savings clause.<sup>25</sup> Preemption determinations are complicated in statutes that contain *neither* type of clause, and thus are silent on the matter,<sup>26</sup> and in statutes that contain *both* types of clauses,<sup>27</sup> and so appear internally conflicted.

## 2. *Implied Preemption*

Even if a federal statute is silent with respect to the preemption issue, a products liability claim may be foreclosed by the doctrine of *implied* preemption. There are two forms of implied preemption, “implied *field* preemption” and “implied *conflict* preemption.” Implied *field* preemption arises if (a) federal regulation of a field is so complete and “so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it,”<sup>28</sup> or (b) Congress legislates in a field in which “the federal interest is so dominant that the federal system [must] be assumed to preclude enforcement of state laws on the same subject.”<sup>29</sup> Implied *conflict* preemption arises if (a) federal and state provisions directly conflict, making it impossible to comply with both requirements,<sup>30</sup> or (b) state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”<sup>31</sup> Thus, even if a federal product safety statute does not contain a clause expressly preempting damages claims under state law, the statute still may impliedly preempt such claims.<sup>32</sup>

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24. See Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. § 136v (2002). See discussion *infra* Part II.

25. See Occupational Safety and Health Act (OSHA), 29 U.S.C. § 653(b)(4) (2000). See discussion *infra* Part IV.D.2. However, a federal agency (such as OSHA) may, by regulation, preempt state law with respect to particular matters.

26. See Food, Drug and Cosmetic Act, 21 U.S.C. § 301 (2000). See discussion *infra* Part IV.B. Like OSHA, however, the FDA expressly preempts state law on certain issues.

27. See National Traffic and Motor Vehicle Safety Act of 1966, 49 U.S.C. § 30103(b), (e) (2000). See discussion *infra* Part IV.A.

28. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

29. *Id.*

30. See generally Louise Weinberg, *The Federal-State Conflict of Laws: “Actual” Conflicts*, 70 TEX. L. REV. 1743, 1753–54 (1992) (describing “actual” conflict preemption).

31. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). See also *Perez v. Campbell*, 402 U.S. 637, 649 (1971) (quoting *Hines* in discussing the meaning of the Supremacy Clause). This last form of conflict preemption is often aptly termed “obstacle” or “frustration-of-purpose” preemption. In addition to the conventional divisions, implied preemption also may result from federal common law and from the “dormant” commerce clause. See Dinh, *supra* note 2, at 2109–12.

32. See, e.g., *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 352 (2001); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869 (2000) (explaining that although the savings clause removes tort actions from the scope of express preemption, it does not foreclose implied preemption).



### B. *The Presumption Against Preemption*

Principles of federalism command congressional respect for the sovereignty of the states,<sup>33</sup> including their authority to render damages judgments in products liability and other litigation. In the words of the Supreme Court, "because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly preempt state-law causes of action."<sup>34</sup> From this premise, the Court has relied upon an "assumption that the historic police powers of the States were not to be superseded by [a] Federal Act unless that was the clear and manifest purpose of Congress."<sup>35</sup> At bottom, this "presumption against preemption" rests on the precept that the Constitution constrains the federal government, the powers of which are limited and specifically enumerated, from trampling on the reserved powers of the states.<sup>36</sup>

In the first two products liability preemption cases, the Court interpreted the federal product safety statutes against this backdrop assumption that disfavored preemption.<sup>37</sup> Recently, however, the Court has moved away from the presumption against preemption, noting its inapplicability when the matter regulated implicates federal interests as much or more than matters traditionally addressed by state law.<sup>38</sup> As the Supreme Court has strayed from its former regard for the presumption against preemption, commentators have increasingly questioned the meaning, strength, and legitimacy of any such presumption.<sup>39</sup>

It is true, of course, that Congress should be guided by principles of federalism in enacting legislation on health and safety, subjects that traditionally have resided largely under state control. However, if Congress has authority under the Commerce Clause to enact particular legislation regulating

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33. See Dinh, *supra* note 2, at 2085–86.

34. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

35. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). See generally *TRIBE*, *supra* note 1, § 6-28, at 1175 (discussing federal preemption of state action).

36. See *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 111–12 (1992) (Kennedy, J., concurring) (discussing state workplace safety standards challenged as preempted under OSHA). Justice Kennedy concurred only in the result because he believed the plurality's broad resort to implied preemption principles contradicted "two basic principles of our pre-emption jurisprudence. First, we begin 'with the assumption that the historic police powers of the States [are] not to be superseded . . . unless that was the clear and manifest purpose of Congress.' Second, 'the purpose of Congress is the ultimate touchstone' in all pre-emption cases." *Id.* at 111 (citations omitted).

37. See *Medtronic*, 518 U.S. at 485; *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). See generally Dinh, *supra* note 2, at 2085–86 (indicating that presumption against preemption was generally accepted).

38. See *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2000) (ruling on statute that regulates fraud on a federal agency); *Sprietsma v. Mercury Marine*, 337 U.S. 51 (2002) (ruling on statute that regulates boat safety, traditionally the domain of the Coast Guard).

39. See Davis, *supra* note 2; Dinh, *supra* note 2; Raeker-Jordon, *Pre-Emption Presumption*, *supra* note 2, at 1418; Raeker-Jordan, *Sleight of Hand*, *supra* note 2; Scordato, *supra* note 2, at 29–32.

health and safety, then the Supremacy Clause might seem to certify, automatically, the legitimacy of this federal incursion into a domain normally controlled by the states. If this view is correct, then the responsibility of courts is merely to interpret such a statute, untrammelled by any presumption for or against preemption, to determine whether and to what extent Congress intended to restrict common-law claims.<sup>40</sup>

Rather than being an independent principle of federalism, therefore, the doctrine of federal preemption might more accurately be viewed as a doctrine governing the interpretation of legislation which itself should be animated and bounded by principles of federalism embedded in the Commerce Clause.<sup>41</sup> Put another way, principles of federalism may help determine whether a federal statute is proper under the Commerce Clause, but if a statute is proper under the Commerce Clause, the statute properly occupies whatever space might otherwise have been occupied by state law and so is not further subject to challenge on federalism grounds. That said, however, where exactly principles of federalism may lie within the Constitution may be less important than the fact that such principles do oblige the Congress, when considering legislation on matters of health and safety, to respect the traditional sovereignty of the states. So, if federal legislation on product safety does not clearly state whether products liability claims under state law are prohibited or permitted, and if such claims do not truly conflict with federal regulation, Congress should be deemed to have intended to leave unmolested traditional state control over matters in this realm.<sup>42</sup> Whether or not a "presumption against preemption" is the best way to articulate this kind of backdrop deference that Congress and the federal courts should exhibit when they operate in a field traditionally ruled by the states, the presumption idea captures important structural truths about the republic that reside somewhere in the Constitution.

## II. STIRRINGS OF PREEMPTION—PESTICIDES AND INSECTICIDES

Rooted in statutory construction, the federal preemption defense rests upon a determination that Congress in a particular statute intended to preclude particular products liability claims. The preemption issue thus is both statute-specific and claim-specific, meaning that the resolution of this issue is governed in any given case by an interpretation of the relevant provisions of the particular

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40. *Cf.* *TRIBE*, *supra* note 1, § 6-28, at 1177 ("Perhaps, the most fundamental point to remember is that preemption analysis is, or at least should be, a matter of precise statutory construction rather than an exercise in free-form judicial policymaking."). *But see id.* at 1195 n.74.

41. *See generally* *Dinh*, *supra* note 2, at 2088-91 (stating that "the authority for the preemption provision must come from either the Commerce Clause alone or perhaps the Commerce Clause with a helping hand from the Necessary and Proper Clause").

42. *See, e.g.,* *Raeker-Jordan*, *Pre-Emption Presumption*, *supra* note 2, at 1468-69.

federal statute in relation to particular products liability claims.<sup>43</sup> While preemption analysis in every case will therefore turn on the meaning and purposes of a specific statute—as revealed by its express provisions, its structure, and its legislative history<sup>44</sup>—the basic issue in every case remains the same: whether Congress intended, expressly or implicitly, to prohibit products liability claims of the type asserted by the plaintiff. Because the preemption doctrine has thus evolved on a statute-specific basis,<sup>45</sup> the preemption defense in products liability litigation is helpfully informed by an examination of the doctrine's development over time as the courts have investigated the preemptive effect of particular federal statutes regulating the safety of particular types of products.

Prior to the Supreme Court's initial foray into the application of preemption doctrine to products liability law in 1992,<sup>46</sup> federal preemption rarely figured seriously in this type of litigation. Indeed, prior to this time, the Supreme Court had decided only a handful of preemption cases involving common-law damages claims of any type.<sup>47</sup> During the 1980s, as manufacturers scrambled for ways to avoid the rigors of products liability judgments, they increasingly asserted the preemption defense.<sup>48</sup> In part because of the Supreme Court's skeptical attitude at the time toward the preemption of state tort-law claims,<sup>49</sup> assertions of the preemption defense during most of this decade generally fell on deaf judicial ears.<sup>50</sup>

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43. See, e.g., Dinh, *supra* note 2, at 2092–97 (discussing preemption as statutory construction); Scordato, *supra* note 2, at 31 (providing two versions of a hypothetical regulation and discussing the interpretation and outcome of each).

44. See, e.g., *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 486 (1996) (remarking that courts must look to the structure and purpose of a statute as a whole “as revealed not only in the text, but through the reviewing court’s reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law”); *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 98 (1992) (explaining that the “ultimate task in any pre-emption case is to determine whether state regulation is consistent with the structure and purpose of the statute as a whole”); *Wis. Pub. Intervenor v. Mortier*, 501 U.S. 597, 621 (1991) (Scalia, J., concurring) (“[W]e should try to give the text its fair meaning, whatever various committees might have had to say—thereby affirming . . . that we are a Government of laws, not of committee reports.”). See generally Ausness, *supra* note 2, at 240–52 (explaining methodology for interpreting federal regulations by evaluating text, history, and legislative policy).

45. See, e.g., Dinh, *supra* note 2, at 2085 (“[T]he Court’s preemption decisions necessarily vary across the different statutory schemes at issue.”).

46. The first products liability preemption case was *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), *infra* Part III.

47. Davis, *supra* note 2, at 969 n.9.

48. *Id.* at 998.

49. See *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984) (ruling that a plutonium-contamination claim by worker at nuclear power plant was not preempted by Atomic Energy Act). *Silkwood* is examined in Davis, *supra* note 2, at 990–94.

50. See Davis, *supra* note 2, at 998 (“[D]efendants had rarely been successful in arguing that the existence of a federal statutory standard totally preempted the plaintiff’s state law based allegations of defectiveness or negligence.”). See generally Ausness, *Federal Preemption, supra*

The first reported decision concerning the preemptive effect of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) was *Ferebee v. Chevron Chemical Co.*<sup>51</sup> This prominent decision by the Court of Appeals for the District of Columbia Circuit involved a products liability claim against the distributor of a herbicide, Paraquat, on behalf of an agricultural worker who allegedly died from breathing and contacting the herbicide.<sup>52</sup> In FIFRA, Congress established a comprehensive regulatory scheme administered by the EPA for registering and labeling pesticides, insecticides, herbicides, and other toxic products.<sup>53</sup> Under the Act, a manufacturer must submit proposed labels to the EPA to assure that they are "adequate to protect health and the environment" and "likely to be read and understood."<sup>54</sup> FIFRA expressly prohibits the states from imposing any "requirements for labeling or packaging in addition to or different from those required" under the Act's provisions.<sup>55</sup>

In *Ferebee*, the plaintiff claimed that the label warnings on Paraquat were inadequate and caused the decedent's death, and the jury agreed. Rejecting the defendant's federal preemption arguments, the court concluded that the Act did not expressly preclude state common-law actions, nor did implied field or conflict preemption apply. Although a damages award for inadequate warnings might impose a dual obligation on the defendant, the court concluded that the defendant could comply with both federal and state law by using the EPA-approved warning labels while paying damages for insufficient warnings as required by the state products liability judgment.<sup>56</sup>

Although a growing number of decisions ruled against plaintiffs on the preemption issue,<sup>57</sup> most courts through the 1980s and early 1990s followed the *Ferebee* approach in holding that neither FIFRA<sup>58</sup> nor other federal safety

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note 2, at 191, 200-34 (examining case law applying preemption principles and concluding that most courts ignore important policy issues by applying a one-dimensional approach to preemption issues).

51. 736 F.2d 1529 (D.C. Cir. 1984).

52. See generally Madden, *supra* note 2, at 120-28 (explaining *Ferebee* and case law following or rejecting *Ferebee*).

53. See 7 U.S.C. §§ 136-136(y) (2000).

54. See *id.* at §§ 136(q)(1)(F), 136(q)(1)(E).

55. *Id.* at § 136v(b).

56. *Ferebee*, 736 F.2d at 1540-41.

57. See, e.g., *Papas v. Upjohn Co.*, 926 F.2d 1019 (11th Cir. 1991) (impliedly preempted), *vacated*, 505 U.S. 1215 (1992), *remanded to* 985 F.2d 516 (11th Cir. 1993) (expressly preempted), *cert. denied*, 510 U.S. 913 (1993); *Fitzgerald v. Mallinckrodt, Inc.*, 681 F. Supp. 404 (E.D. Mich. 1987) (FIFRA); *Taylor v. Gen. Motors Corp.*, 875 F.2d 816 (11th Cir. 1989) (no-airbag claim).

58. See, e.g., *Montana Pole & Treating Plant v. I.F. Laucks & Co.*, 775 F. Supp. 1339 (D. Mont. 1991); *Riden v. ICI Ams., Inc.*, 763 F. Supp. 1500 (W.D. Mo. 1991); *Evenson v. Osmose Wood Preserving, Inc.*, 760 F. Supp. 1345 (S.D. Ind. 1990); *Cox v. Velsicol Chem. Corp.*, 704 F. Supp. 85 (E.D. Pa. 1989); *Roberts v. Dow Chem. Co.*, 702 F. Supp. 195 (N.D. Ill. 1988).

statutes<sup>59</sup> preempted products liability claims. Yet, once the Supreme Court in 1992 energized the federal preemption defense in products liability litigation, as discussed below, the lower courts began to rethink the role of preemption under federal statutes such as FIFRA. In recent years, the decisions have turned sharply in the other direction. In cases where a manufacturer has complied with an EPA-required warning under FIFRA, the courts now are nearly unanimous<sup>60</sup> in holding that the Act preempts at least tort-law<sup>61</sup> warnings claims, the most common type of FIFRA claim.<sup>62</sup> However, the courts are generally in accord

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59. See, e.g., *Abbot v. Am. Cyanamid Co.*, 844 F.2d 1108, 1111–13 (4th Cir. 1988) (involving neurological injuries from inoculation of DTP vaccine manufactured by defendant where court held no express preemption by Public Health Service Act or Federal Food, Drug, and Cosmetic Act, nor any implied preemption because common-law vaccine claims do not frustrate federal statutory goals); *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 70 (Mass. 1985) (compliance with FDA labeling requirements on birth control pills—no preemption).

60. *Contra Sleath v. West Mont Home Health Services*, 16 P.3d 1042 (Mont. 2000) (holding that FIFRA does not preempt warnings claims). In *Sleath*, the court relied heavily on an amicus curiae brief that the EPA filed in *Etcheverry v. Tri-Ag Serv., Inc.*, 993 P.2d 366 (Cal. 2000). *Sleath*, 16 P.3d at 1050. In that brief, the EPA took the position that FIFRA does not preempt any state-law theories of liability, including failure to warn claims that implicate pesticide labels. *Id.* The Montana Supreme Court granted deference to the EPA's view because it is the agency responsible for administering FIFRA. *Id.* at 1048–49. Other courts have declined to grant the EPA deference, holding that the plain terms of 7 U.S.C. § 136v(b) expressly preempt state-law claims based on the failure to warn. See, e.g., *Netland v. Hess & Clark, Inc.*, 284 F.3d 895 (8th Cir. 2002) (holding that FIFRA preempts damage claims associated with certain pesticides); *Etcheverry*, 993 P.2d 366 (finding that state law failure to warn claims are preempted by FIFRA); *Eyl v. Ciba-Geigy Corp.*, 650 N.W.2d 744 (Neb. 2002) (“We determine that Eyl’s common-law failure-to-warn claims are labeling based and preempted by FIFRA”).

61. Most courts also bar warranty and misrepresentation claims if based on an EPA-required warning. See, e.g., *Andrus v. AgrEvo USA Co.*, 178 F.3d 395, 396 (5th Cir. 1999); *Nat’l Bank of Commerce v. Dow Chem. Co.*, 165 F.3d 602, 608 (8th Cir. 1999); *Grenier v. Vermont Log Bldgs., Inc.*, 96 F.3d 559, 563 (1st Cir. 1996). *Contra*, *Arnold v. Dow Chem. Co.*, 110 Cal. Rptr. 2d 722, 740 (Ct. App. 2001) (citing cases holding that implied warranty claims are not preempted); *Goeb v. Tharaldson*, 615 N.W.2d 800, 819 (Minn. 2000) (holding that FIFRA does not preempt negligent misrepresentation or negligent testing claims).

Courts addressing claims based on off-label statements generally hold that such claims are not preempted if the statement differs from the label, but that such claims are preempted if the statements merely reiterate language on the label. See, e.g., *Dillon v. Zeneca Corp.*, 42 P.3d 598, 601–02 (Ariz. Ct. App. 2002) (concluding that FIFRA preempts claims based on off-label statements that merely reiterate language on label); *Sun Valley Packing v. Consop, Inc.*, 114 Cal. Rptr. 2d 237, 239 (Ct. App. 2001) (ruling that FIFRA does not preempt implied warranty of fitness for particular purpose claim based on off-label statements about matters outside scope of required label); *Diehl v. Polo Coop. Ass’n*, 766 N.E.2d 317, 322 (Ill. App. Ct. 2002) (holding that FIFRA does not preempt claims based on off-label recommendations that differ from label).

62. See, e.g., *Lowe’s Home Centers, Inc. v. Olin Corp.*, 313 F.3d 1307 (11th Cir. 2002); *Netland*, 284 F.3d 895; *Hawkins v. Leslie’s Pool Mart, Inc.*, 184 F.3d 244 (3d Cir. 1999); *Nat’l Bank of Commerce*, 165 F.3d 602; *Kuiper v. Am. Cyanamid Co.*, 131 F.3d 656 (7th Cir. 1997); *Grenier*, 96 F.3d 559; *Etcheverry*, 993 P.2d 366 (citing cases); *Arnold*, 110 Cal. Rptr. 2d 722; *Eyl*, 650 N.W.2d 744 (citing cases); *Lewis v. Am. Cyanamid Co.*, 715 A.2d 967 (N.J. 1998). *But cf.* *Dow Chem. Co. v. Ebling*, 753 N.E.2d 633, 640 (Ind. 2001) (holding that FIFRA does not preempt claim that pest control applicator negligently failed to convey to pesticide’s ultimate user

that FIFRA neither expressly nor impliedly preempts claims that pertain to matters not regulated by the EPA, such as claims that truly are not based on labeling but on the defectiveness of the pesticide's design, packaging, or manufacture.<sup>63</sup>

### III. PREEMPTION'S ARRIVAL—*CIPOLLONE*

In *Cipollone v. Liggett Group, Inc.*,<sup>64</sup> the Supreme Court in 1992 for the first time applied federal preemption doctrine to a products liability case.<sup>65</sup> *Cipollone* was an action against three cigarette manufacturers on behalf of Rose Cipollone who died of lung cancer after smoking the defendants' cigarettes from 1942 to 1984. The products liability claims included design defectiveness; failure to provide adequate warnings; negligent research, testing, and

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information found on required label).

63. See, e.g., *Hawkins*, 184 F.3d 244 (gaseous fumes from chlorinator tablets used in pools; packaging claims not preempted); *Nat'l Bank of Commerce*, 165 F.3d at 609 ("defectively manufactured or designed products properly labeled under FIFRA may still be subject to state regulation, in the form of common law or other claims"); *Southern States Coop. Inc., v. I.S.P. Co., Inc.*, 198 F. Supp. 2d 807 (N.D. W. Va. 2002) (ruling that FIFRA does not preempt claim that horse feed was adulterated with rat poison); *Arnold*, 110 Cal. Rptr. 2d 722 (concluding that true design claims are not preempted); *Sally Baghdasarian, Recent Case, Arnold v. Dow Chem. Co.*, 110 Cal. Rptr. 2d 722 (Ct. App. 2001), 31 SW. U. L. REV. 441 (2002) (reviewing recent preemption decisions); *Jeffers v. Wal-Mart Stores, Inc.*, 171 F. Supp. 2d 617 (S.D. W. Va. 2001) (ruling design defect claims not preempted); *Ackerman v. Am. Cyanamid Co.*, 586 N.W.2d 208, 215 (Iowa 1998) (holding plaintiff's negligent design and testing claims not preempted). But see *Dow Agrosciences LLC v. Bates*, 332 F.3d 323 (5th Cir. 2003) (holding that FIFRA preempts breach of express warranty claim and warnings claims "disguised" as defective design and negligent testing claims); *Netland v. Hess & Clark, Inc.*, 284 F.3d 895 (8th Cir. 2002) (holding that FIFRA preempts manufacturing defect and design defect claims that were factually premised on inadequate labeling); *Johnson v. Monsanto Chem. Co.*, 129 F. Supp. 2d 189, 195 (N.D.N.Y. 2001) ("Claims of misdesign or mismanufacture which the Court regards as thinly veiled labeling or failure to warn claims will not stand."); *Traube v. Freund*, 775 N.E.2d 212 (Ill. App. Ct. 2002) (holding that FIFRA preempts nuisance and ultra-hazardous activity claims based on allegedly deficient label); *Eriksen v. Mobay Corp.*, 41 P.3d 488 (Wash. Ct. App. 2002) (ruling that consumer expectations design defect claim was effectively a warnings claim).

Courts disagree on whether FIFRA preempts claims based on a product's efficacy—whether a herbicide harms rather than helps a crop—that are outside the realm the EPA chooses to regulate. Compare *Am. Cyanamid Co. v. Geye*, 79 S.W.3d 21 (Tex. 2002) (finding no preemption) with *Etcheverry*, 993 P.2d 366 (finding preemption).

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

65. See generally Michael D. Green, *Cipollone Revisited: A Note So Little Secret About the Scope of Cigarette Preemption*, 82 IOWA L. REV. 1257 (1997) (examining *Cipollone* and its implications); Thomas C. Galligan, Jr., *Products Liability—Cigarettes and Cipollone: What's Left? What's Gone?*, 53 LA. L. REV. 713 (1993) (explaining *Cipollone* and discussing its ramifications); Jeffrey R. Steen, Note, *Preemption Doctrine and the Failure of Textualism in Cipollone v. Liggett Group*, 80 VA. L. REV. 979 (1994) (summarizing the court's reasoning and discussing the benefits of employing extra textual sources in statutory interpretation as opposed to the Court's strict textualism).

marketing; breach of express warranties in advertising; fraudulent misrepresentation of the hazards of smoking; and conspiracy to defraud by depriving the public of medical and scientific information on smoking.<sup>66</sup>

At issue in *Cipollone* was the preemptive effect of two cigarette labeling statutes. The preemption clause in the 1965 Cigarette Labeling and Advertising Act (the “1965 Act”) provided, “No statement relating to smoking and health” other than that required by the Act “shall be required” on cigarette packages or in advertising.<sup>67</sup> In 1969, Congress amended the 1965 Act in the Public Health Cigarette Smoking Act of 1969 (the “1969 Act”) to make the labeling requirements more stringent, to ban electronic cigarette advertising, and to modify the preemption provision to read:

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 chapter.<sup>68</sup>

Prior to *Cipollone*, the Supreme Court justices, and hence the lower courts, had been badly split on the role of both express and implied preemption in barring common-law claims.<sup>69</sup> Even in cigarette warnings cases, most pre-*Cipollone* decisions had rejected *express* preemption claims in favor of *implied* preemption.<sup>70</sup> Turning that approach on its head, *Cipollone* ruled that, where Congress speaks expressly to the preemption issue, a largely textual express preemption analysis—not implied preemption—should control.<sup>71</sup>

The Court held that the narrower 1965 Act did not preempt state-law damages actions but that the broader 1969 Act—which barred not simply “‘statement[s]’ but rather ‘requirement[s] or prohibition[s] . . . imposed under State law’”—barred at least some products liability claims because it imposed stiffer requirements on cigarette manufacturers in exchange for explicit limitations on rights to sue.<sup>72</sup> Reasoning that a products liability claim should

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66. *Cipollone*, 505 U.S. at 508–10.

67. 15 U.S.C. §§ 1331–1340 (2000).

68. *Id.* at § 1334(b). See *Cipollone*, 505 U.S. at 514–15.

69. See generally Davis, *supra* note 2 (tracing the history of preemption cases).

70. *Cipollone*, 505 U.S. at 508 n.2.

71. “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,’ ‘there is no need to infer congressional intent to pre-empt state laws from the substantive provisions’ of the legislation.” *Id.* at 517 (citations omitted).

72. *Id.* at 520.

be considered a “requirement” or “prohibition” under the Act,<sup>73</sup> and that the plaintiff’s inadequate warnings claim effectively asserted that the manufacturers’ “post-1969 advertising or promotions should have included additional, or more clearly stated, warnings,”<sup>74</sup> the Court concluded that the 1969 Act preempted the plaintiff’s warnings claim.<sup>75</sup> However, that Act did *not* preempt claims for *fraud*, or *conspiracy to defraud*—which were not predicated upon “a duty ‘based on smoking and health’ but rather on a more general obligation—the duty not to deceive,”<sup>76</sup> nor those based upon *express warranty*, because “the ‘requirement[s]’ imposed by an express warranty claim are not ‘imposed under State law,’ but rather imposed *by the warrantor*.”<sup>77</sup> Concurring and dissenting, Justices Blackmun, Kennedy, and Souter reasoned that the 1969 Act did not speak clearly enough to deny the petitioner’s common-law claims,<sup>78</sup> while Justices Scalia and Thomas asserted that the 1965 Act preempted the warnings claims and the 1969 Act barred them all.<sup>79</sup> Although the justices thus were widely split, *Cipollone* appears to put to rest most preemption issues in cigarette litigation.

#### IV. THE POST-CIPOLLONE EXPERIENCE

##### A. Motor Vehicles—Myrick and Geier

##### 1. Anti-Lock Braking Systems in Trucks

After *Cipollone*, the next Supreme Court case to address preemption in the products liability context was *Freightliner Corp. v. Myrick*<sup>80</sup> which concerned the preemptive effect of the National Traffic and Motor Vehicle Safety Act of 1966<sup>81</sup> and safety standards issued by its corresponding regulatory agency, the National Highway Traffic Safety Administration (NHTSA). Congress enacted the Safety Act to regulate the safety of motor vehicles in an effort to reduce the

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73. In rejecting petitioner’s argument that the 1969 Act’s preemption provision did not reach common-law actions, the Court observed that “[t]he phrase ‘[n]o requirement or prohibition’ sweeps broadly and suggests no distinction between positive enactments and common law.” *Id.* at 521 (citations omitted).

74. *Id.*

75. This is the accepted interpretation of *Cipollone*. But see Michael D. Green, *Cipollone Revisited: A Not So Little Secret About the Scope of Cigarette Preemption*, 82 IOWA L. REV. 1257 (1997) (arguing that claims asserting inadequate warnings on cigarette packages are not preempted under *Cipollone*).

76. *Cipollone*, 505 U.S. at 528–29.

77. *Id.* at 525. Nor does the Act preempt claims “that rely solely on respondents’ testing or research practices or other actions unrelated to advertising or promotion.” *Id.* at 524–25.

78. *Id.* at 531–44.

79. *Id.* at 544–56.

80. 514 U.S. 280 (1995).

81. 15 U.S.C. §§ 1381–1425 (1966) (recodified at 49 U.S.C. §§ 30101–30169 (1994)).



toll of injuries and deaths from traffic accidents.<sup>82</sup> The Safety Act's preemption clause prohibits the states from maintaining "motor vehicle safety standards" that are not identical to any federal standards "in effect."<sup>83</sup> The Act also contains a savings clause, which provides: "Compliance with any Federal motor vehicle safety standard issued under this subchapter does not exempt any person from any liability under common law."<sup>84</sup>

In 1970, NHTSA's predecessor agency issued Standard 121, which imposed certain stopping distances for trucks that could be achieved only if trucks were equipped with anti-lock braking systems (ABS). Various truck manufacturers challenged Standard 121, and the Ninth Circuit suspended it pending further study. *Myrick* involved design defect claims by plaintiffs who attributed their injuries to the absence of ABS in eighteen-wheel trucks. Notwithstanding the fact that Standard 121 had been previously suspended, the district court ruled that the plaintiffs' design defect claims were preempted by federal Standard 121 and the Safety Act.<sup>85</sup> The Eleventh Circuit reversed, holding that the plaintiffs' claims were not expressly preempted, nor were they impliedly preempted because of "*Cipollone*'s clear instruction that when there is an express pre-emption provision we should not consider implied pre-emption."<sup>86</sup>

The Supreme Court affirmed.<sup>87</sup> Speaking for a unanimous court, Justice Thomas reasoned that express preemption could not apply because no federal safety standard was "in effect" as required by the Safety Act's preemption clause. Nor were plaintiffs' design defect claims impliedly preempted because there was no conflict with the Act. Thus, because there was no federal standard with which the plaintiffs' products liability claims could conflict, *Myrick* may be viewed as a "false preemption" case. *Myrick*'s importance lies not in its holding, but in its dictum which resurrects and applies the doctrine of *implied* preemption to federal statutes containing express preemption clauses. Rejecting the court of appeals' interpretation of *Cipollone* "that implied pre-emption cannot exist when Congress has chosen to include an express pre-emption clause in a statute,"<sup>88</sup> the Court inscrutably observed: "At best, *Cipollone* supports an inference that an express pre-emption clause forecloses implied pre-emption; it does not establish a rule."<sup>89</sup>

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82. *Id.* at § 1381 (codified as amended at 49 U.S.C. § 30101).

83. *Id.* at § 1392(d) (codified as amended at 49 U.S.C. § 30103(b)(1)).

84. *Id.* at § 1397(c) (codified as amended at 49 U.S.C. § 30103(e)).

85. *Myrick*, 514 U.S. at 293.

86. *Myrick v. Freuhauf Corp.*, 13 F.3d 1516, 1522 (11th Cir. 1994).

87. *Freightliner Corp. v. Myrick*, 514 U.S. 280 (1995).

88. *Id.* at 287.

89. *Id.* at 289.

## 2. Airbags

Five years after *Myrick*, the Supreme Court tackled the preemption issue in another motor vehicle safety case, *Geier v. American Honda Motor Co.*,<sup>90</sup> which involved the preemptive effect of certain NHTSA regulations on the use of airbags in passenger cars.<sup>91</sup> *Geier* revealed the latent strength and resilience of the implied preemption doctrine that *Myrick* had suggested.

*Geier* involved the preemptive effect of Federal Motor Vehicle Safety Standard 208<sup>92</sup> (entitled "Occupant Crash Protection"), a NHTSA regulation pertaining to airbags and other passive restraints.<sup>93</sup> From its initial formulation in 1967, when it required only lapbelts, Standard 208 has evolved in fits and starts.<sup>94</sup> Beginning in 1975, Standard 208 began to offer manufacturers an evolving menu of passive restraint options, including airbags or various combinations of passive restraints, shoulder harnesses, lapbelts, and warning systems. It was not until 1997 that NHTSA finally mandated dual front-seat airbags in all passenger cars.<sup>95</sup> Beginning in the late 1980s, an increasing number of automotive products liability claims were based on the failure of manufacturers to equip their cars with airbags during this transitional period, before NHTSA required such devices in all cars. The courts were divided on the preemption issue; many state courts ruled that such airbag claims were not preempted<sup>96</sup> while all the federal circuit courts ruled that such claims were.<sup>97</sup>

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90. 529 U.S. 861 (2000).

91. See Stephen R. Bough & Lynn R. Johnson, *Crossing the Center Line: Preemption in Automobile Product Liability Cases*, 57 J. MO. B., Jan.-Feb. 2001, at 30; Stephen D. Lichtenstein & Gerald R. Ferrera, *Airbag Products Liability Litigation: State Common Law Tort Claims Are Not Automatically Preempted by Federal Legislation*, 45 CLEV. ST. L. REV. 1 (1997); Ralph Nader & Joseph A. Page, *Automobile-Design Liability and Compliance with Federal Standards*, 64 GEO. WASH. L. REV. 415 (1996); Raeker-Jordan, *Pre-Emption Presumption*, *supra* note 2, at 1445-68; John F. McCauley, Note, *Cipollone and Myrick: Deflating the Airbag Preemption Defense*, 30 IND. L. REV. 827 (1997); Dana P. Bobb, Note, *The Deployment of Car Manufacturers Into a Sea of Product Liability? Recharacterizing Preemption as a Federal Regulatory Compliance Defense in Airbag Litigation*, 75 WASH. U. L.Q. 1677 (1997).

92. Hereinafter "Standard 208" or "FMVSS 208."

93. 49 C.F.R. § 571.208 (2000).

94. See *Pub. Citizen v. Steed*, 851 F.2d 444, 445 (D.C. Cir. 1988) ("Passive restraint regulation (Standard 208) has advanced over the years along a protracted, winding, sometimes perilous course."). Standard 208's history is chronicled in *Hernandez-Gomez v. Leonardo*, 884 P.2d 183, 184-85 (Ariz. 1994), and *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 34-38 (1983).

95. 49 C.F.R. § 571.208.S4.1.5.3 (2000).

96. See, e.g., *Munroe v. Galati*, 938 P.2d 1114 (Ariz. 1997); *Wilson v. Pleasant*, 660 N.E.2d 327 (Ind. 1995); *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); *Minton v. Honda of Am. Mfg., Inc.*, 684 N.E.2d 648 (Ohio 1997).

97. See, e.g., *Harris v. Ford Motor Co.*, 110 F.3d 1410 (9th Cir. 1997) (express preemption); *Montag v. Honda Motor Co., Ltd.*, 75 F.3d 1414 (10th Cir. 1996) (implied preemption); *Pokorny v. Ford Motor Co.*, 902 F.2d 1116 (3d Cir. 1990) (same); *Taylor v. Gen. Motors Corp.*, 875 F.2d

The plaintiffs in *Geier* claimed that the driver's injuries were aggravated by a design defect in their 1987 Honda Accord because it was not equipped with a driver's-side airbag.<sup>98</sup> Honda argued that such an airbag claim was preempted by Standard 208 which, during the transitional period, permitted manufacturers to choose between seatbelts and airbags.<sup>99</sup> The district court granted summary judgment for Honda, ruling that the plaintiffs' no-airbag claims were *expressly* preempted, and the court of appeals affirmed on the basis that such claims were *impliedly* preempted because they conflicted with the objectives of federal Standard 208.<sup>100</sup>

The Supreme Court affirmed, agreeing with the court of appeals that "no-airbag" claims are impliedly preempted because they conflict with Standard 208.<sup>101</sup> The Court again was badly split, and Justice Breyer spoke for the five-judge majority which reasoned from "three subsidiary questions:"

First, does the Act's express pre-emption provision pre-empt this lawsuit? [No.] Second, do ordinary [implied] pre-emption principles nonetheless apply? [Yes.] Third, does this lawsuit actually conflict with FMVSS 208, hence with the Act itself? [Yes.]<sup>102</sup>

The Safety Act did not expressly preempt products liability claims, the Court reasoned, because the savings clause suggests that Congress believed that there were common-law claims that needed to be saved. For this reason, the Court narrowly construed the phrase "safety standard" in the express preemption clause to exclude common-law claims.<sup>103</sup> But the savings clause does not reach further, thought the majority, to foreclose the operation of *implied* preemption where common-law claims actually conflict with a statute or regulation.<sup>104</sup>

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816 (11th Cir. 1989) (same); *Wood v. Gen. Motors Corp.*, 865 F.2d 395 (1st Cir. 1988) (same).

98. *Geier*, 529 U.S. at 865.

99. *Id.*

100. *Geier v. Am. Honda Motor Co.*, 166 F.3d 1236 (D.C. Cir. 1999).

101. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 866 (2000).

102. *Id.* at 867.

103. *Id.* at 867-68.

104. *Id.* at 869-70. Applying *Geier*, courts have since focused on whether the claimed defect actually conflicts with a relevant FMVSS. *See, e.g.*, *Stewart v. Gen. Motors Corp.*, 222 F. Supp. 2d 845 (W.D. Ky. 2002) (finding actual conflict with FMVSS 208 and preemption of claim that airbag warning should have included language beyond that required by FMVSS 208); *Ysbrand v. DaimlerChrysler Corp.*, No. 97-469, 2003 WL 437160 (Okla. Feb. 25, 2003) (finding no conflict with FMVSS 208 and no preemption of claim that an airbag that was installed was defectively designed). *See also Volkswagen of Am., Inc. v. Gentry*, 564 S.E.2d 733 (Ga. Ct. App. 2002) (finding no conflict with FMVSS 208 and no preemption of claim that seatbelt system was defectively designed by the improper placement and angle of the shoulder strap and placement of the knee bolster); *Mejia v. White GMC Trucks, Inc.*, 784 N.E.2d 345 (Ill. App. Ct. 2002) (finding actual conflict with relevant standard and preemption of design defect claim based on design of

Because the plaintiffs alleged that the car was defectively designed because the manufacturer *failed* to equip it with an airbag, while the Safety Act *permitted* manufacturers at the time to choose between airbags and alternative passive restraints, the no-airbag claims actually conflicted with the federal standard and so were impliedly preempted.<sup>105</sup>

*B. Food, Drugs, Cosmetics, and Medical Devices—Medtronic and Buckman*

*1. Food, Drugs, and Cosmetics*

The Food and Drug Administration (FDA) regulates the preparation and labeling of food,<sup>106</sup> drugs, and cosmetics under the Food, Drug and Cosmetic Act (FDCA).<sup>107</sup> Because the FDCA does not contain a preemption clause relevant to drugs, the statute itself does not expressly preempt defective warning and other products liability claims against pharmaceutical manufacturers.<sup>108</sup> Nor, in general, have courts found that the FDCA *impliedly* preempts products liability claims against manufacturers of prescription

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doors and door handles of garbage truck); *Great Dane Trailers, Inc. v. Estate of Wells*, 52 S.W.3d 737 (Tex. 2001) (finding no conflict with FMVSS 108 and no preemption of claim that tractor-trailer was defectively designed for failing to have lighting in addition to lighting required by FMVSS 108).

105. *Geier*, 529 U.S. at 874–75, 881. “Because the rule of law for which petitioners contend would have stood ‘as an obstacle to the accomplishment and execution of’ the important means-related federal objectives that we have just discussed, it is pre-empted.” *Id.* at 881. A number of courts have applied *Geier* to likewise hold that claims based on the failure to equip a car with lapbelts or passenger side airbags are preempted under FMVSS 208. *See, e.g.*, *Griffith v. Gen. Motors Corp.*, 303 F.3d 1276 (11th Cir. 2002) (applying preemption in the context of a lapbelt); *Nelson v. Ford Motor Co.*, 761 N.E.2d 1099 (Ohio Ct. App. 2001) (finding preemption in the context of a passenger-side airbag).

106. In *Jones v. Rath Packing Co.*, 430 U.S. 519 (1977), the Supreme Court held that the Fair Packaging and Labeling Act and its regulations impliedly preempt inconsistent state food labeling regulations. *See also Boulahanis v. Prevo’s Family Mkt., Inc.*, 583 N.W.2d 509 (Mich. Ct. App. 1998) (ruling that a claim for illness from E. Coli bacteria was preempted by the Federal Meat Inspection Act).

107. 21 U.S.C. §§ 301–397 (2000).

108. *See Eve v. Sandoz Pharm. Corp.*, No. IP 98-1429-C-Y/S, 2002 WL 181972, at \*2 (S.D. Ind. Jan. 28, 2002) (“The portion of the FDCA that is applicable to drugs does not contain a preemption provision.”). On the preemption defense in claims against drug manufacturers, see OWEN, *supra* note 2, at § 28:6; Amanda Frost, *Judicial Review of FDA Preemption Determinations*, 54 FOOD & DRUG L.J. 367 (1999); David C. Geiger & Mark D. Rosen, *Rationalizing Product Liability for Prescription Drugs: Implied Preemption, Federal Common Law, and Other Paths to Uniform Pharmaceutical Safety Standards*, 45 DEPAUL L. REV. 395 (1996).

drugs.<sup>109</sup> However, the statute delegates authority to the FDA to preempt state law,<sup>110</sup> and the agency by regulation has expressly preempted state law by mandating certain warnings for over-the-counter drugs,<sup>111</sup> but generally not for prescription drugs.<sup>112</sup> Because preemption may so emanate from the edict of a mere administrative agency, a court will not find that an FDA regulation preempts state law unless the regulation clearly says so.<sup>113</sup> The courts have taken the view, as has the FDA itself,<sup>114</sup> that FDA drug labeling regulations generally impose only minimum standards—that these regulatory provisions provide merely a safety floor—and that state tort law beneficially supplements federal regulatory efforts to promote drug safety.<sup>115</sup>

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109. See, e.g., *Abbot v. Am. Cyanamid Co.*, 844 F.2d 1108 (4th Cir. 1988) (DTP vaccine); *Ohler v. Purdue Pharma, L.P.*, No. CIV.A. 01-3061, 2002 WL 88945 (E.D. La. Jan. 22, 2002) (OxyContin); *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018 (S.D. Ill. 2001) (Parlodel); *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65 (Mass. 1985) (birth control pills).

110. See *Hillsborough County, Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713, 721 (1985). Since the FDA is authorized to preempt state law, its failure explicitly to do so “should be taken as a strong sign that the state action does not threaten national policy and is not *impliedly* preempted.” *TRIBE*, *supra* note 1, § 6-32, at 1213 n.1.

111. See, e.g., *Kanter v. Warner-Lambert Co.*, 122 Cal. Rptr. 2d 72 (Ct. App. 2002) (describing inadequate warnings claim with respect to head lice treatment); *Green v. BDI Pharm.*, 803 So. 2d 68 (La. Ct. App. 2001) (addressing failure to warn of addictive nature of Ephedrine in “Mini Thins”). See also *Ohler*, 2002 WL 88945, at \*12–13 (quoting 63 Fed. Reg. 66382–66384) (concerning direct-to-patient warnings).

112. See *Ohler*, 2002 WL 88945, at \*12.

113. See *id.* at \*13 n.34.

114. See *id.* (warnings claim related to prescription pain medication, OxyContin); *Caraker*, 172 F. Supp. 2d at 1036 (quoting FDA’s recognition of tort litigation’s value and desire not to impede it). The FDA may have changed its position to favor preemption. See James Dabney Miller, “Failure to Warn”—Blocking Bad Claims, *NAT’L L.J.*, Nov. 10, 2003, at 31 (asserting that FDA has filed amicus brief in Ninth Circuit arguing that FDA approval of labeling for prescription drug should preempt failure-to-warn claims against manufacturer of drug).

115. See, e.g., *Eve v. Sandoz Pharm. Corp.*, No. IP 98-1429-C-Y/S, 2002 WL 181972, at \*3 (S.D. Ind. Jan. 28, 2002); *Caraker*, 172 F. Supp. 2d at 1033 (“Because there is no evidence that either Congress or the FDA intended on scraping state products liability claims based on a failure to warn . . . , it is reasonable to find that the FDA has imposed a minimum—as opposed to conclusive—standard of safety.”); *Motus v. Pfizer Inc.*, 127 F. Supp. 2d 1085 (C.D. Cal. 2000) (Zolof; court observed that manufacturer was unable to cite a single decision holding that FDA prescription drug requirements preempted state-law claims); *Merrell Dow Pharm., Inc. v. Orendine*, 649 A.2d 825, 828 (D.C. 1994) (Bendectin).

One aberrant trial court decision concluded that FDA labeling requirements for the drug Adderall preempted a failure to warn claim, reasoning that the FDA prohibited the manufacturer from changing the FDA-approved warning without prior FDA approval, “except in limited circumstances for a limited period of time.” See *Elis v. Shire Richwood, Inc.*, 233 F. Supp. 2d 1189, 1198 (D.N.D. 2002). The court did not address the relevant regulations which indicate that manufacturers may strengthen their drug warnings without prior FDA approval, that the FDA encourages manufacturers to take such initiatives on their own, and that the FDA Commissioner has memorialized the FDA’s view that manufacturers may be under a state-law duty to do so. See *Caraker*, 172 F. Supp. 2d 1018 (extensive discussion of FDA’s views on preemption and history of 1965 amendment to FDA regulations that allows supplemental warnings without prior FDA

## 2. *Medical Devices*

Prior to the mid-1970s, the FDA possessed limited regulatory power over manufacturers of medical devices.<sup>116</sup> In response to a number of safety problems with various medical devices during the early 1970s—including an IUD called the Dalkon Shield, catheters, artificial heart valves, defibrillators, and pacemakers—Congress enacted the Medical Device Amendments of 1976 (the MDA) to the FDCA, directing the FDA to classify and regulate the safety and effectiveness of medical devices.<sup>117</sup> The FDA divides medical devices among three categories depending on the potential health and safety implications of the device: Class I devices, such as tongue depressors and stethoscopes, contain minimal risk and are subject to minimal regulation; Class II devices, such as hearing aids and tampons, are potentially more harmful and so are subject to “special controls;” Class III devices, such as pacemakers and artificial hearts, pose considerable potential risk and thus are subject to substantial regulatory control.<sup>118</sup>

Prior to marketing a new Class III device, the manufacturer must submit the device to a rigorous, time-consuming, and expensive “premarket approval” (PMA) process in order to assure the FDA that the device is safe and effective and, so, proper for sale. Congress provided two exemptions to the premarket approval process: (1) a “grandfathering” exemption for devices marketed prior to the 1976 enactment of the MDA, until such time as the FDA initiates and completes the requisite PMA; and (2) an exemption for post-1976 devices that are “substantially equivalent” to pre-1976 devices, in order to prevent manufacturers of the grandfathered devices from obtaining an unfair competitive advantage over manufacturers of new devices, and to facilitate improvements to the designs of existing devices. Prior to marketing an exempted device under this second exemption, a manufacturer must submit a premarket notification to the FDA<sup>119</sup> to permit the agency to determine the new device’s “substantial equivalence” to an existing device. Quite simple and inexpensive, the “premarket notification” (or “§ 510(k)”) process usually results in prompt FDA approval of the new device.

Unlike the FDCA’s non-preemptive approach to regulating prescription drugs, the MDA expressly preempts inconsistent state law, providing that the states may not enforce any requirement for a medical device which is “different from or in addition to” any federal requirement “applicable . . . to the

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approval).

116. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475-80 (1996) (detailing the history of medical device regulation and FDA safety controls under MDA).

117. See 21 U.S.C. § 360 (2000).

118. See *Fowler v. Smith & Nephew Richards, Inc.*, No. 97-1380-CIV-J-10B, 1999 WL 1132967, at \*1 (M.D. Fla. Sept. 27, 1999).

119. See 21 U.S.C. § 360k (2000).

device.”<sup>120</sup> The FDA has interpreted this provision to mean that state requirements are preempted only if the FDA has a “specific” counterpart regulation or requirement, thereby rendering any divergent state requirements “different from or in addition to” the specific FDA requirements.<sup>121</sup>

In *Medtronic, Inc. v. Lohr*,<sup>122</sup> the plaintiffs alleged that the defendant’s pacemaker, which the FDA had approved under the substantial-equivalence § 510(k) process, failed due to a defectively designed and manufactured wire lead<sup>123</sup> and that the manufacturer failed to warn of this risk despite knowing of earlier failures. The district court dismissed the action, concluding that the MDA preempted all of the plaintiffs’ claims, and the court of appeals reversed in part, ruling that the design defect claims were preempted but that the manufacturing and warning defect claims were not.

The Supreme Court reversed in part, concluding that the MDA did not preempt *any* of the plaintiffs’ products liability claims. Applying an express preemption analysis, the *Medtronic* Court reasoned that, for a state safety requirement to be “different from, or in addition to” a corresponding FDA regulation, the federal regulation would have to be “specific” to the device, not a regulation of general applicability.<sup>124</sup> With respect to the plaintiffs’ design defect claims, the Court ruled that the FDA did not impose any specific design safety “requirements” by its cursory § 510(k) determination that the defendant’s product was a “substantially equivalent” device.<sup>125</sup> As for the defective manufacturing and warnings claims, the Court reasoned that both the FDA’s general “Good Manufacturing Practices” regulations, as well as its general labeling regulations that required manufacturers of almost every device to provide warnings appropriate to the device, were simply too general to be either “applicable to the device,” as required in the preemption clause, or “specific” to a “particular device,” as required by the FDA’s interpretation of that clause.<sup>126</sup>

Consistent with *Medtronic*’s holding that generalized FDA safety regulations are not preemptive, lower courts have ruled that state-law products liability claims are indeed preempted where the FDA’s regulations are exacting

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120. *Id.* at § 360k(a)(1).

121. 21 C.F.R. § 808.1(d) (2001).

122. 518 U.S. 470 (1996).

123. The lead carries the current into the heart muscle. *See* *Martin v. Medtronic, Inc.*, 254 F.3d 573, 575 (5th Cir. 2001).

124. *Id.* at 500.

125. *Medtronic*, 518 U.S. at 492–94.

126. *Id.* at 497–502. Nor were the plaintiffs’ claims based on a violation of FDA regulations preempted because the preemption clause precluded safety requirements that are “different from,” not identical to, the federal standards. *Id.* at 494–97.

or specific to a particular product.<sup>127</sup> For example, in a case involving a pacemaker that was an investigational device,<sup>128</sup> a context where the FDA imposes quite exacting standards,<sup>129</sup> the Sixth Circuit Court of Appeals held that the FDA's specific approval of the product's design was preemptive because a state-law design-defect claim "would thwart the [federal] goals of safety and innovation."<sup>130</sup> So, too, because the FDA labeling requirement for tampons (Class II devices) are specific to tampons, the Ninth Circuit has ruled that this "device-and-disease-specific" requirement accordingly preempts a products liability claim.<sup>131</sup> *Medtronic* does not directly address the preemption issue with respect to medical devices approved under the rigorous PMA process. A number of lower courts have found products liability claims concerning such devices to be preempted,<sup>132</sup> while other courts have not.<sup>133</sup>

In 2001, the Supreme Court decided a quite different medical device preemption case, *Buckman Co. v. Plaintiffs' Legal Committee*.<sup>134</sup> In the mid-1980s, the FDA rejected a § 510(k) substantial equivalency application by the Acromed Corporation for a variable screw spinal plate fixation system for use in spinal surgery, determining that the device was a Class III device that was not substantially equivalent to any other device. Acromed hired a regulatory

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127. *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 795 (8th Cir. 2001) (en banc) ("Most courts of appeal have interpreted *Lohr* to mean that the MDA preempts common-law claims to the extent that they interfere or conflict with specific federal requirements.").

128. The MDA exempts investigational devices from the PMA process "to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use." 21 U.S.C. § 360j(g)(1) (2000).

129. See, e.g., 21 C.F.R. §§ 812.20, 812.25 (2003).

130. *Martin v. Teletronics Pacing Sys., Inc.*, 105 F.3d 1090, 1099 (6th Cir. 1997). See also *Chambers v. Osteonics Corp.*, 109 F.3d 1243, 1248 (7th Cir. 1997) ("[T]hese claims are preempted by the MDA because they impose requirements . . . that are different from or greater than FDA requirements."). But see *Baird v. Am. Med. Optics*, 713 A.2d 1019, 1030 (N.J. 1998) ("Our reading of *Medtronic* and the proposed FDA regulations leads us to conclude that the United States Supreme Court, Congress, and the FDA do not intend that claims such as plaintiff's should be preempted.").

131. *Papike v. Tambrands Inc.*, 107 F.3d 737, 740 (9th Cir. 1997) (involving tampon-caused toxic shock syndrome; failure to warn and design defect claim based on consumer expectations preempted by labeling requirements). Accord, *Murphy v. Playtex Family Prods. Corp.*, 176 F. Supp. 2d 473 (D. Md. 2001) (holding that where a tampon caused toxic shock syndrome a failure to warn claim was preempted by tampon-specific labeling requirements but not a defective design claim that the tampon was made of highly absorbent viscose rayon).

132. See, e.g., *Brooks*, 273 F.3d at 799; *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 226 (6th Cir. 2000); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 913 (7th Cir. 1997); *Fry v. Allergan Med. Optics*, 695 A.2d 511, 517 (R.I. 1997); *Green v. Dolsky*, 685 A.2d 110, 117 (Pa. 1996).

133. See, e.g., *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1382 (11th Cir. 1999); *Woods v. Gliatech, Inc.*, 218 F. Supp. 2d 802, 806-07, 811 (W.D. Va. 2002) (citing split of authority, but ultimately finding no preemption); *Haidak v. Collagen Corp.*, 67 F. Supp. 2d 21 (D. Mass. 1999); *Weiland v. Teletronics Pacing Sys., Inc.*, 721 N.E.2d 1149, 1153 (Ill. 1999).

134. 531 U.S. 341 (2001).



consultant, the Buckman Company, to refile the application which the FDA again rejected. Acromed and Buckman then split the device in two and filed two new § 510(k) applications, one for the bone plates and one for the bone screws, and changed the intended use from the spine to the long bones of the arms and legs. Finding that the devices, when applied to these uses, met the test of substantial equivalence, the FDA approved the bone-plate and bone-screw devices for these purposes.<sup>135</sup>

Once Acromed marketed the bone-plate and bone-screw devices, surgeons widely began to use the devices for spinal surgery; thousands of persons eventually were injured from the implantation of orthopedic bone screws into the pedicles of their spines. During the 1990s, thousands of suits were filed, many of which were consolidated for pre-trial proceedings in the District Court for the Eastern District of Pennsylvania.<sup>136</sup> Many of the claims against Acromed and Buckman, styled “fraud on the FDA,” alleged that the defendants fraudulently misrepresented the product’s intended use to the FDA by seeking agency “approval of its VSP plates and screws for use in long bones simply as a pretext in order to market the device for its true intended use in the spine.”<sup>137</sup> The district court dismissed the fraud-on-the-FDA claims as preempted by the MDA, but the court of appeals reversed, ruling in a split decision that the claims were not preempted.<sup>138</sup>

Reversing, the Supreme Court held that the plaintiffs’ fraud-on-the-FDA claims were *impliedly* preempted because they conflicted with federal law.<sup>139</sup> There was no “presumption against the preemption” of state-law claims, reasoned the Court, because “[p]olicing fraud against federal agencies is hardly ‘a field which the States have traditionally occupied.’”<sup>140</sup> The state-law claims conflicted with federal law since “the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and . . . this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives.”<sup>141</sup> Because the FDCA expressly approves “off-label” use of medical devices by medical practitioners, “the FDA is charged with the difficult task of regulating the [safety] . . . of medical devices without intruding upon decisions statutorily committed to the discretion of health care

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135. *Id.* at 346.

136. *See In re Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d 817, 818 (3d Cir. 1998).

137. *Id.* at 820.

138. *Id.* at 829.

139. The Court in *Buckman* reiterated the point it made in *Geier v. American Honda Motor Co.*, 529 U.S. 861, 869 (2000), that the presence in a federal statute of an express preemption clause in no way precludes the operation of implied (“ordinary”) preemption principles. *Buckman*, 531 U.S. at 352.

140. *Buckman*, 531 U.S. at 347.

141. *Id.* at 348.

professionals.”<sup>142</sup> The Court reasoned that fraud-on-the-FDA claims would interfere with the FDA’s judgment on how best to achieve a sensitive balance between policing fraud without discouraging § 510(k) applications for “devices with potentially beneficial off-label uses for fear that such use might expose the manufacturer or its associates [such as Buckman] to unpredictable civil liability.”<sup>143</sup>

*Buckman* left unresolved the question whether the MDA impliedly preempts normal products liability claims—those grounded solely on state tort or warranty law rather than on a violation of federal law. Although the Court in its earlier *Medtronic* decision had only ruled on express preemption, the Court in *Buckman* distinguished *Medtronic* on the ground that “the *Medtronic* claims arose from the manufacturer’s alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements.”<sup>144</sup> The Court thus observed that *Medtronic* might be read to shelter from implied-preemption attack state-law claims that parallel federal safety regulations.<sup>145</sup> So reasoning, several courts have held that *Buckman* should be read to allow traditional products liability claims, even fraud claims that are based on a manufacturer’s misrepresentations to the plaintiff rather than to the FDA.<sup>146</sup>

### C. Recreational Boats—Sprietsma

In an effort to stem an increasing number of boat-related injuries and fatalities, Congress enacted the Federal Boat Safety Act of 1971 (FBSA)<sup>147</sup> to establish “a coordinated national boating safety program.”<sup>148</sup> The FBSA gives the Coast Guard authority to promulgate safety standards for boating equipment and recreational boats, thereby creating a uniform safety regulatory scheme to guide manufacturers in designing such equipment.<sup>149</sup> Before issuing a boat-safety regulation, the Coast Guard is required to consult with the National

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142. *Id.* at 350.

143. *Id.*

144. *Id.* at 352.

145. *Id.* at 353.

146. *See, e.g.,* *Eve v. Sandoz Pharm. Corp.*, No. IP 98-1429-C-Y/S, 2002 WL 181972 (S.D. Ind. Jan. 28, 2002) (citing other cases). *See also* *Dawson v. Ciba-Geigy Corp.*, 145 F. Supp. 2d 565, 572-73 (D.N.J. 2001) (“*Buckman* thus clarified that traditional state tort law claims . . . are not necessarily preempted by the FDCA . . . .”); *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018, 1040 (S.D. Ill. 2001) (holding that *Buckman* did not alter wealth of authority holding that FDA regulations do not impliedly preempt state-law claims).

147. 46 U.S.C. §§ 4301-4311 (2000).

148. S. REP. NO. 92-248, at 1333 (1971), *reprinted in* 1971 U.S.C.C.A.N. 1333.

149. S. REP. NO. 92-248, at 1333-35. Regulatory authority was delegated by the Secretary of Transportation to the Coast Guard. 49 C.F.R. § 1.46(n) (2002).

Boating Safety Advisory Council (the Advisory Council) to help determine whether the regulation is appropriate.<sup>150</sup>

A recurring safety problem in recreational boating is the risk to swimmers and persons falling from boats of being struck by the rapidly moving propeller blades on boat motors. Addressing this risk, the Coast Guard in 1988 decided to investigate the possibility of requiring manufacturers to install propeller guards to minimize the propeller danger to persons in the water.<sup>151</sup> The Coast Guard directed the Advisory Council to study the data, feasibility, advantages, and disadvantages of minimizing propeller-strike injuries with propeller guards. After holding public hearings and studying the issue, the Propeller Guard Subcommittee unanimously determined that the Coast Guard should *not* require propeller guards for reasons of safety, economics, and feasibility.<sup>152</sup> The Advisory Committee adopted the Subcommittee report and recommended to the Coast Guard that manufacturers not be required to install propeller guards, and the Coast Guard adopted the Advisory Committee recommendation in 1990.<sup>153</sup>

The FBSA contains both a preemption clause and a savings clause. The preemption clause prohibits state laws and regulations that are not identical to federal regulations promulgated under the Act.<sup>154</sup> The savings clause provides that “[c]ompliance with this chapter or standards, regulations, or orders prescribed under this chapter does not relieve a person from liability at common law or under State law.”<sup>155</sup>

During the 1990s and early 2000s, a number of “no-propeller-guard” claims were asserted against manufacturers of boats and motors for failing to equip boat motors with propeller guards. A large majority of courts, but not all,<sup>156</sup> held that the FBSA preempted such claims—most on the basis of express

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150. 46 U.S.C. § 4302(c)(4) (2000).

151. See generally Amy P. Chiang, Note, *The Federal Boat Safety Act of 1971 and Propeller Strike Injuries: An Unexpected Exercise in Federal Preemption*, 68 *FORDHAM L. REV.* 487, 494–97 (1999) (discussing preemption of propeller strike injuries).

152. See *Sprietsma v. Mercury Marine*, 757 N.E.2d 75, 78–79 (Ill. 2001), *rev’d*, 537 U.S. 51 (2002). The Subcommittee found that propeller guards tend to hinder steering, increase the risk of blunt contact with persons in the water, and create a risk that a person’s arm or leg could be “caught between the guard and the propeller blades.” *Id.* at 78.

153. *Id.* at 78–79.

154. “Unless permitted by the Secretary . . . , a State . . . may not establish, continue in effect, or enforce a law or regulation establishing a recreational vessel . . . safety standard . . . that is not identical to a regulation prescribed under section 4302 of this title.” 46 U.S.C. § 4306 (2000).

155. See, e.g., *id.* § 4311(g).

156. See, e.g., *Ard v. Jensen*, 996 S.W.2d 594, 601 (Mo. Ct. App. 1999) (affirming the presumption against preemption in the context of a waterskier); *Moore v. Brunswick Bowling & Billiards Corp.*, 889 S.W.2d 246, 252 (Tex. 1994) (recognizing that its “holding conflicts with the four courts that have considered” similar actions).

preemption,<sup>157</sup> but several, influenced by the savings clause, on implied conflict preemption grounds.<sup>158</sup> On both bases, many courts concluded that the Coast Guard's deliberative decision *not* to require propeller guards was preemptive of no-propeller-guard claims which effectively would require manufacturers to install such guards—a state “requirement” not “identical” to the federal requirement,<sup>159</sup> indeed, “in direct contravention to the Coast Guard’s policy against mandating such a device in favor of affording manufacturers flexibility in the matter.”<sup>160</sup>

In *Sprietsma v. Mercury Marine*,<sup>161</sup> the plaintiff’s wife fell from a boat and was killed when struck by the motor’s propeller blades. The plaintiff sued the manufacturer of the motor, claiming that it was unreasonably dangerous for not being equipped with a propeller guard.<sup>162</sup> The trial court held that the claims were impliedly preempted by the FBSA; the appellate court affirmed on the basis of express preemption; and the Illinois Supreme Court affirmed, ruling that the plaintiff’s claims conflicted with the Coast Guard’s no-propeller-guard decision and so were barred on implied preemption grounds.<sup>163</sup> Reversing, the Supreme Court unanimously held that the Boat Safety Act neither expressly nor implicitly preempted the plaintiff’s common-law products liability claims.<sup>164</sup>

The Court reasoned that, first, the Act’s *express* preemption clause, which referred to “a” state “law or regulation,” appeared to preempt only a state’s positive regulatory law, not common-law compensation claims, particularly in view of the savings clause provision that compliance with the Act “does not relieve a person from liability at common law or under State law.”<sup>165</sup> Nor was

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157. See, e.g., *Carstensen v. Brunswick Corp.*, 49 F.3d 430 (8th Cir. 1995) (finding express preemption in the context of a passenger falling from a boat and being struck by a propeller); *Moss v. Outboard Marine Corp.*, 915 F. Supp. 183, 187 (E.D. Cal. 1996) (finding express preemption in similar situation involving emotional distress claim by other passenger); *Shield v. Bayliner Marine Corp.*, 822 F. Supp. 81 (D. Conn. 1993) (finding express preemption); *Ryan v. Brunswick Corp.*, 557 N.W.2d 541 (Mich. 1997) (finding express preemption in the context of a swimmer struck by a propeller).

158. See, e.g., *Lady v. Neal Glaser Marine, Inc.*, 228 F.3d 598 (5th Cir. 2000) (finding implied preemption in the context of a jet skier colliding with a boat); *Lewis v. Brunswick Corp.*, 107 F.3d 1494 (11th Cir. 1997) (finding implied preemption where plaintiff was thrown from a boat); *Sprietsma v. Mercury Marine*, 757 N.E.2d 75, 78–79 (Ill. 2001), *rev’d*, 537 U.S. 51 (2002) (finding implied preemption in the context of a fall from a boat).

159. See, e.g., *Carstensen*, 49 F.3d at 432 (express preemption).

160. See, e.g., *Lady*, 228 F.3d at 614. Courts have found not preempted (and hence allowed) other types of claims against boat manufacturers based on unsafe features that the Coast Guard has not addressed. See, e.g., *LaPlante v. Wellcraft Marine Corp.*, 114 Cal. Rptr. 2d 196 (Ct. App. 2001) (finding that “the negligent installation of hand held devices . . . [is] not preempted by the FBSA”).

161. 537 U.S. 51 (2002).

162. *Id.* at 55.

163. *Sprietsma*, 757 N.E.2d at 77, 86, *rev’d*, 537 U.S. 51 (2002).

164. *Sprietsma*, 537 U.S. 51.

165. *Id.* at 63.

the plaintiff's claim *impliedly* preempted by conflict or field preemption principles.<sup>166</sup> The plaintiff's products liability claim did not conflict with the Coast Guard's decision not to require propeller guards in view of the Coast Guard's policy of leaving state-law regulations in place unless and until it adopted a conflicting regulation under the Act, which here it had not done.<sup>167</sup> Finally, Congress's effort to promote uniformity in boat safety regulation had to yield to the Act's primary goal of boat safety, a goal served by both the Coast Guard's policy of allowing broad state regulation of boat safety and by products liability claims like those in this case.<sup>168</sup>

#### *D. Other Types of Products*

The preemption issue has arisen in the lower courts in connection with a large number of other federal statutes that regulate the safety of many different types of products, and the diversity of approaches in the decisions reflects the failure of Congress to speak clearly to this issue together with the confused evolution of preemption in the Supreme Court.<sup>169</sup> The two most important

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166. *Id.* at 69–70.

167. *Id.* at 65–66

168. *Id.* at 69.

169. *See, e.g.,* *Adkins v. Ill. Cent. R.R. Co.*, 326 F.3d 828, 835 (7th Cir. 2003) (stating that the Locomotive Inspection Act can give rise to conflict preemption but not field preemption); *Choate v. Champion Home Builders Co.*, 222 F.3d 788 (10th Cir. 2000) (holding that the National Manufactured Housing Construction and Safety Standards Act does not preempt design defect and warnings claims based on lack of battery-powered backup in smoke detectors for mobile homes); *Symens v. SmithKline Beecham Corp.*, 152 F.3d 1050 (8th Cir. 1998) (finding the USDA's regulation of animal vaccines preempts claims of cattle infections); *Cleveland v. Piper Aircraft Corp.*, 985 F.2d 1438 (10th Cir. 1993) (finding that the FAA does not preempt state law); *In re Wireless Tel. Radio Frequency Emissions Prods. Liab. Litig.*, 248 F. Supp. 2d 452 (D. Md. 2003) (holding that a claim that cellular phones emitted unsafe levels of radiation was impliedly preempted because the suit would necessarily require both judge and jury to usurp the regulatory functions that Congress entrusted to the FCC under the Telecommunications Act); *King v. Aventis Pasteur, Inc.*, 210 F. Supp. 2d 1201, 1207 (D. Or. 2002) (finding no preemption under the National Childhood Vaccine Injury Compensation Act); *Lucia v. Teledyne Cont'l Motors*, 173 F. Supp. 2d 1253 (S.D. Ala. 2001) (finding no preemption, under the Federal Aviation Act, for defective crankshafts; distinguishing "complete preemption" doctrine, for assessing federal removal jurisdiction, from "ordinary preemption," which precludes state-law claims); *Gen. Motors Corp. v. Kilgore*, 853 So. 2d 171 (Ala. 2002) (finding that the Locomotive Inspection Act preempts claim based on asbestos exposure from locomotive components because Act occupies entire field of locomotive equipment and safety); *Scheiding v. Gen. Motors Corp.*, 993 P.2d 996 (Cal. 2000) (finding that the Locomotive Boiler Inspection Act preempts state-law actions against locomotive manufacturers); *Olson v. Prosoco, Inc.*, 522 N.W.2d 284 (Iowa 1994) (finding no preemption under the Hazardous Materials Transportation Act); *Schiffner v. Motorola, Inc.*, 697 N.E.2d 868 (Ill. App. Ct. 1998) (finding the Electronic Product Radiation Control Act did not preempt claims of diminished value from defective cellular phones); *Seaman v. A.P. Green Indus.*, 707 N.Y.S.2d 299 (Sup. Ct. 2000) (holding that the Locomotive Boiler Inspection Act preempts the entire field of locomotive safety); *Hall v. Fairmont Homes, Inc.*, 664 N.E.2d 546 (Ohio Ct. App. 1995) (finding that the NMHCSSA does not preempt claims that formaldehyde emission

categories of products not yet addressed that are subject to safety regulation by federal agencies are consumer products and workplace products.

### 1. Consumer Products

Consumer products are regulated by the Consumer Product Safety Commission (CPSC) under the Consumer Product Safety Act (CPSA),<sup>170</sup> the Federal Hazardous Substances Act,<sup>171</sup> and two other statutes.<sup>172</sup> The CPSA contains both a preemption clause<sup>173</sup> and a savings clause.<sup>174</sup> The preemption defense has arisen only infrequently in consumer products liability litigation. A couple of decisions involving warnings and design defect claims against power mower manufacturers have held that the plaintiffs' warnings claims were preempted because the CPSC had promulgated a specific regulation governing such warnings, but that the design claims were not,<sup>175</sup> and one court has ruled that the CPSA preempts all such claims.<sup>176</sup> In several cases involving injuries from fires caused by children playing with lighters, some courts have found no preemption,<sup>177</sup> while one court has ruled that the CPSA preempted the design defect claim but not the warnings claim.<sup>178</sup> And in a case involving injuries

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levels violated HUD regulations). *See generally* Sean S. Kelly, Comment, *Federalism in Flight: Preemption Doctrine and Air Crash Litigation*, 28 TRANSP. L.J. 107 (2000) (discussing federal preemption in aviation law).

170. 15 U.S.C. §§ 2051–2084 (2000).

171. *Id.* §§ 1261–1278.

172. The Federal Flammable Fabrics Act (FFA), *id.* §§ 1191–1204, and the Poison Prevention Packaging Act (PPPA), *id.* §§ 1471–1476. Although the FFA does have a preemption clause, the courts have ruled that a manufacturer's compliance with this statute does not preempt products liability claims for flammable clothing. *See, e.g.,* Wilson v. Bradlees of New England, Inc., 96 F.3d 552, 553 (1st Cir. 1996); Raymond v. Riegel Textile Corp., 484 F.2d 1025, 1028 (1st Cir. 1973); O'Donnell v. Big Yank, Inc., 696 A.2d 846, 853 (Pa. Super. Ct. 1997).

173. The preemption clause provides that, if the CPSC has established federal safety standards for a product, the states may not adopt 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." 15 U.S.C. § 2075(a) (2000).

174. The savings clause provides: "Compliance 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." *Id.* § 2074(a).

175. *See* Moe v. MTD Prod., Inc., 73 F.3d 179 (8th Cir. 1995); Cortez v. MTD Prod., Inc., 927 F. Supp. 386 (N.D. Cal. 1996).

176. *See* Frazier v. Heckingers, 96 F. Supp. 2d 486 (E.D. Pa. 2000).

177. *See, e.g.,* Colon v. BIC USA, Inc., 136 F. Supp. 2d 196 (S.D.N.Y. 2000); Hittle v. Scripto-Tokai Corp., 166 F. Supp. 2d 142 (M.D. Pa. 2001); Frith v. BIC Corp., 852 So. 2d 592, 593 (Miss. Ct. App. 2002); Phillips v. Cricket Lighters, 773 A.2d 802 (Pa. Super. Ct. 2001), *appeal granted*, 790 A.2d 1018 (Pa. 2001).

178. *See* Ball v. BIC Corp., No. 4:97CVO2467, 2000 WL 33312192, at \*2–\*3 (E.D. Mo. Feb. 8, 2000).

from the shattering of a glass shower door, the Ninth Circuit ruled that the CPSA did not preempt either the design or warnings claims.<sup>179</sup>

Pursuant to the Federal Hazardous Substances Act (FHSA), the CPSC establishes mandatory labeling requirements for certain hazardous substances intended for household use.<sup>180</sup> Because the structure and purpose of the FHSA is similar to the CPSA, the CPSC applies a single preemption regulation to both acts, interpreting the preemption of state "requirements" to mean statutory and regulatory requirements, not common-law holdings by the courts.<sup>181</sup> Although early decisions found no preemption,<sup>182</sup> courts in recent years have quite uniformly found that the FHSA preempts warnings claims when the manufacturer's warning complies with federal requirements,<sup>183</sup> but that the Act does not preempt design (or manufacturing defect) claims<sup>184</sup> or "misbranding" claims based on violation of FHSA regulations.<sup>185</sup>

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179. *Leipart v. Guardian Indus.*, 234 F.3d 1063, 1070–71 (9th Cir. 2000).

180. 15 U.S.C. §§ 1261–1278 (2000).

181. *See* Leflar & Adler, *supra* note 2, at 745 (citing 56 Fed. Reg. 3414, 3415 (1991) (preamble to 16 C.F.R. § 1061)).

182. *See, e.g.*, *Burch v. Amsterdam Corp.*, 366 A.2d 1079, 1085–86 (D.C. 1976) (finding no preemption, facts involved explosive floor tile adhesive); *Jonescue v. Jewel Home Shopping Serv.*, 306 N.E.2d 312, 316 (Ill. App. Ct. 1973) (finding no preemption, facts involved toxic cleaning agent).

183. *See, e.g.*, *Milanese v. Rust-Oleum Corp.*, 244 F.3d 104, 109 (2d Cir. 2001); *Comeaux v. Nat'l Tea Co.*, 81 F.3d 42 (5th Cir. 1996); *Moss v. Parks Corp.*, 985 F.2d 736, 740 (4th Cir. 1993); *Kirstein v. W.M. Barr & Co.*, 983 F. Supp. 753, 761 (N.D. Ill. 1997), *aff'd sub nom.* *Kirstein v. Parks Corp.*, 159 F.3d 1065 (7th Cir. 1998); *Pa. Gen. Ins. Co. v. Landis*, 96 F. Supp. 2d 408, 414–15 (D.N.J. 2000), *aff'd*, 248 F.3d 1131 (3d Cir. 2000) (table); *West v. Mattel, Inc.*, 246 F. Supp. 2d 640 (S.D. Tex. 2003) (involving a child's toy; Child Safety Protection Act amendment to FHSA preempts claim for inadequate warning of choking hazard, but not design defect claims); *Busch v. Graphic Color Corp.*, 662 N.E.2d 397, 408–09 (Ill. 1996); *Schrader v. Sunnyside Corp.*, 747 N.Y.S.2d 26 (App. Div. 2002) (warning on can of denatured alcohol); *Jenkins v. James B. Day & Co.*, 634 N.E.2d 998, 1004 (Ohio 1994).

184. *See* Smith & Grage, *supra* note 1, at 405–09. The Act probably does not preempt design and manufacturing defect claims that are bona fide, that is, claims that are not merely warnings claims dressed in sheep's clothing in an attempt to circumvent the Act's preemption of warnings claims. *See generally* *Arnold v. Dow Chem. Co.*, 110 Cal. Rptr. 2d 722 (Ct. App. 2001) (discussing the issue in FIFRA context); *Beadling v. William Bowman Assocs.*, 809 A.2d 188 (N.J. Super. Ct. App. Div. 2002) (holding that FHSA did not preempt design defect claim alleging that government-mandated warning for methanol should have been placed on side of drum rather than top); *Sally Baghdasarian*, Recent Case, *Arnold v. Dow Chem. Co.*, 110 Cal. Rptr. 2d 722 (Ct. App. 2001), 31 Sw. U. L. REV. 441 (2002) (discussing issue in FIFRA context).

185. *See, e.g.*, *Milanese v. Rust-Oleum Corp.*, 244 F.3d 104, 109 (2d Cir. 2001) (holding "a state cause of action alleging non-compliance with the FHSA would *not* be preempted by the Act"); *Kirstein v. W.M. Barr & Co.*, 983 F. Supp. 753, 761–64 (N.D. Ill. 1997), *aff'd sub. nom.*, *Kirstein v. Parks Corp.*, 159 F.3d 1065 (7th Cir. 1998); *Canty v. Ever-Last Supply Co.*, 685 A.2d 1365, 1374 (N.J. Super. Ct. Law Div. 1996).

## 2. *Workplace Products*

The safety of workplace products is regulated by the Occupational Safety and Health Administration under the Occupational Safety and Health Act (OSHA).<sup>186</sup> OSHA does not contain an express preemption clause,<sup>187</sup> but it does contain a savings clause that seems to make clear that it does not displace state tort-law claims for injuries.<sup>188</sup> When the savings clause is considered together with the fact that OSHA applies only to employers, not manufacturers, it is difficult to escape the conclusion that OSHA does not preempt injury claims against manufacturers of products in the workplace.<sup>189</sup> Were it not for one dubious case suggesting a contrary result,<sup>190</sup> it would be clear that OSHA has no preemptive effect on third-party products liability claims by injured workers against manufacturers of industrial products.

## V. CONCLUSION

The ever-shifting law of federal preemption is rife with perplexities. In attempting to unravel these perplexities, the first thing a judge or lawyer should do in any particular case is to determine if the Supreme Court has spoken definitively on the issue. If the Supreme Court has not done so, one must try to discern whether the particular products liability claims involved would contravene either an express preemption clause or the purposes of the particular act of Congress. Because regulatory objectives (and the phrasing of preemption and savings clauses) differ among the various federal product safety statutes, preemption issues normally are resolved by the growing jurisprudence applicable to the particular statute relevant to the plaintiff's particular products liability claims.

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186. 29 U.S.C. § 651(b) (2000).

187. But the Occupational Safety and Health Administration has adopted certain preemption regulations. See 29 C.F.R. § 1910.1200(a), (f)(1) (2003).

188. 29 U.S.C. § 653(b)(4) (2000). "There is a solid consensus that section 4(b)(4) operates to save state tort rules from preemption." *Pedraza v. Shell Oil Co.*, 942 F.2d 48, 53 (1st Cir. 1991). See also John J. Manna, Jr., Note, *The Extent of OSHA Preemption of State Hazard Reporting Requirements*, 88 COLUM. L. REV. 630, 641 (1988) (framing OSHA's savings clause); Note, *Getting Away With Murder: Federal OSHA Preemption of State Criminal Prosecutions for Industrial Accidents*, 101 HARV. L. REV. 535, 543 (1987) (discussing the extent of OSHA preemption).

189. See *Pedraza*, 942 F.2d at 53 n.6; *Cotto v. Estado Libre Asociado De Puerto Rico*, No. AC-2000-76, 2002 WL 1009685, at \*12 (P.R. 2002); *Wickham v. Am. Tokyo Kasei, Inc.*, 927 F. Supp. 293, 295 (N.D. Ill. 1996); *York v. Union Carbide Corp.*, 586 N.E.2d 861, 866 (Ind. Ct. App. 1992). See also *Jones v. Cincinnati, Inc.*, 589 N.E.2d 335, 340 (Mass. App. Ct. 1992) (discussing OSHA preemption).

190. *Torres-Rios v. LPS Labs., Inc.*, 152 F.3d 11 (1st Cir. 1998). See also *Smith & Grage*, *supra* note 1, at 408-09.



Because product safety is federally regulated to quite a large extent, widening the reach of the preemption doctrine erases more and more areas of products liability law. Such a shift toward safety regulation in substitution for compensating injuries caused by defective products, similar to the conventional European approach, may make some sense in terms of broad-scale social engineering. Yet, when courts interpret preemption and savings clauses in federal statutes that regulate product safety, they should be cautious not to foreclose unduly the state-law compensatory rights of persons injured by defective products to judicial remedies<sup>191</sup> protected by both federal and state constitutions. When Congress enacted most of the product safety legislation during the consumer protection period of the late 1960s and early 1970s, it probably intended only to preempt state regulatory law, not broadly to immunize manufacturers from their duties to consumers under state products liability law.<sup>192</sup> And there is in fact no reason, as a general matter, why product safety regulation and products liability litigation cannot comfortably co-exist.

Congress, if it wanted, could largely clean up the current "preemption mess." That is, if Congress truly desired to leave damages actions intact for persons injured by product hazards subject to federal regulation, it could explicitly limit the preemptive reach of its product safety statutes to legislative and regulatory activity while simultaneously providing, in a savings clause, that damages actions do not conflict with (indeed, may be complementary to) congressional purpose. Yet, while Congress fairly may be urged to speak clearly on whether federal legislation is intended to preempt common-law claims,<sup>193</sup> it seems quite unrealistic to expect Congress now to amend the product safety statutes of the 1960s and 1970s to cure the problem. As a practical matter, there is just no simple route out of the preemption thicket in which we now are largely lost. In any single case, courts and lawyers must simply do their best to ascertain whether the language of particular federal legislation or regulations bearing on a particular product safety issue in fact appears to bar particular products liability claims and, if not, whether such claims do or do not reasonably appear to interfere substantially with the particular statute's goals. In this, it is worth remembering that the key to federal preemption begins and ends with statutory interpretation, with figuring congressional intent.

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191. See Rabin, *supra* note 2.

192. See Leflar & Adler, *supra* note 2, at 746-48.

193. See, e.g., Davis, *supra* note 2, at 972; Grey, *supra* note 2, at 617-18; Raeker-Jordan, *Pre-Emption Presumption*, *supra* note 2, at 1381.

