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## COMMENTS

### FEDERAL PREEMPTION OF PRESCRIPTION DRUG LABELING: ANTIDOTE FOR PHARMACEUTICAL INDUSTRY OVERDOSING ON STATE COURT JURY DECISIONS IN PRODUCTS LIABILITY CASES

#### I. INTRODUCTION

As a society, Americans insist on the best available medications to treat those suffering from illness. In response to this demand, Congress has entrusted the Food and Drug Administration ("FDA")<sup>1</sup> with the responsibility to ensure that drugs marketed in the United States are both safe and effective.<sup>2</sup> Pursuant to the federal Food, Drug and Cosmetic Act ("FDCA"),<sup>3</sup> the FDA is the sole decision maker concerning the safety and efficacy of drugs marketed in the United States.<sup>4</sup> Ultimately, every aspect of drug formulation, production, testing, and labeling is overseen through the comprehensive regulatory efforts of this agency.<sup>5</sup>

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1. Congress has delegated ultimate authority over prescription drug labeling to the Secretary of Health and Human Services. 21 U.S.C. §§ 352, 355, 371(a) (1984). This authority has been re-delegated to the Food and Drug Administration ("FDA"), and the FDA has proceeded to exercise that authority. 21 C.F.R. § 5.10(a)(1) (1988). The FDA has primary jurisdiction to make determinations on issues within its statutory mandate. *See Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653 (1973) (Supreme Court recognized FDA's primary jurisdiction). *See also Janssen, Toward a New Era in Consumer Protection: The Supreme Court Rulings on Drug Effectiveness*, FDA CONSUMER, Oct. 1973, at 19 (reviews the *Weinberger* decision and other Supreme Court cases involving the authority of the FDA).

2. *See* federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 335 (1984) (mandating a determination of safety and efficacy). Drug manufacturers must submit to the FDA detailed reports of all studies, the methods used, and the results obtained. *Id.*

3. 21 U.S.C. §§ 301-92 (1986).

4. Federal regulations require courts to defer to FDA expertise in the first instance. 21 C.F.R. §710.25(b) (1986).

5. The FDA must approve the manufacturing process before a manufacturer is permitted to produce a drug. 21 C.F.R. §314.50 (d) (1988). Prior to marketing a drug, a pharmaceutical manufacturer must submit a New Drug Application ("NDA") to the FDA. Maedgen & McCall, *A Survey of Law Regarding the Liability of Manufacturers and Sellers of Drug and Medical Devices*, 18 ST. MARY'S L.J. 395, 442 (1986). The

Nevertheless, courts continue to allow jurors, who are often baffled by scientific evidence,<sup>6</sup> to supersede FDA determinations with their verdicts in products liability cases. As a result, drug manufacturers have become caught between FDA regulations and court imposed standards under state tort law.<sup>7</sup> Juries reaching conclusions contradictory to FDA dictates, have placed pharmaceutical manufacturers in a compromised position.<sup>8</sup> Besides meeting FDA standards, these decisions are forcing manufacturers to consider state tort law requirements in their labeling.

Moreover, when the FDA has explicitly endorsed a pharmaceutical's labeling, and a jury subsequently finds such labeling inadequate, there is a patent conflict between federal law and local law.<sup>9</sup> The supremacy clause of the United States Constitution governs such conflicts between state and federal law,<sup>10</sup> stating that federal law "shall be the supreme Law of the Land."<sup>11</sup> It is, therefore, in-

NDA must contain documents of studies and testing that support the safety and efficacy of the drug. *Id.* The FDA also employs an ongoing validation process in the adverse drug experience report system. Walsh & Klein, *The Conflicting Objectives of Federal and State Tort Law Drug Regulation*, 41 FOOD DRUG COSM. L.J. 171, 183 (1986). After a manufacturer's NDA has been approved, it must continuously report any unexpected or new side-effects, adverse reaction, or toxicity, "whether or not considered drug related." 21 C.F.R. §310.303(a) (1988).

6. A jury reviewing complex areas of science lacks the technical competence to resolve scientific controversies. Bazelon, *Science and Uncertainty: A Jurist's View*, 5 HARV. ENVTL. L. REV. 209, 211-12 (1981).

7. See *infra* notes 147-48 and accompanying text for a discussion of cases requiring warnings other than those which the FDA has mandated.

8. See *Needham v. White Laboratories, Inc.*, 639 F.2d 394 (7th Cir. 1981)(FDA approval is not conclusive as to adequacy of labeling); *MacDonald v. Ortho Pharmaceuticals Corp.*, 394 Mass. 131, 475 N.E.2d 65 (1985) *cert. denied*, 474 U.S. 920; (drug manufacturer required to warn consumer directly; when the FDA not require that type of warning) *Wooderson v. Ortho Pharmaceutical Corp.*, 235 Kan. 387, 681 P.2d 1038, (1984) *cert. denied*, 469 U.S. 465 (1984)(courts may reevaluate scientific judgments of the FDA where product liability is at issue); *Feldman v. Lederle Laboratories*, 97 N.J. 429, 479 A.2d 374 (1984)(courts may reevaluate scientific judgments of the FDA where product liability is at issue).

9. Jury decisions in drug tort actions are in essence state regulations on pharmaceutical labeling. Landen, *Federal Preemption and the Drug Industry: Can Courts Co-Regulate?*, 43 FOOD DRUG COSM. L.J. 85 (1988). Such regulation is a direct conflict between state and federal law in that it frustrates the Congressional intent of uniformity and accuracy in drug labeling. *Cosmetic Toiletry and Fragrance Ass'n, Inc. v. State of Minn.*, 440 F. Supp. 1216 (D. Minn. 1977), *aff'd*, 575 F.2d 1256 (8th Cir. 1978).

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

11. *Id.* The full text of the supremacy clause states:

This Constitution, and the Laws of the United States which shall be made, under the authority of the United States, shall be the supreme Law of the Land; and the Judges of every state shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

*Id.* The earlier conflicts between state and federal law arose in commerce clause contexts. U.S. CONST. art. I, § 8. This clause gives Congress the power to "regulate Commerce with foreign Nations, and among the several States, and with Indian Tribes." *Id.* In *Gibbons v. Ogden*, 22 U.S. 1 (1824), Justice Marshall found an injunction against *Gibbons* invalid, on the ground that it was based upon a monopoly that con-

cumbent on the state courts to defer to FDA expertise in the field of pharmaceutical labeling. Thus, jurors should not be permitted to re-evaluate FDA scientific findings in the context of product liability actions.

It is the position of this comment that state courts should defer to FDA scientific findings concerning pharmaceutical labeling. This conclusion is primarily based on the premise that state tort rulings on drug labeling are federally preempted by the FDCA. Furthermore, beyond preemption, juries are simply less qualified to render scientific findings with the same level of impartiality and expertise as the FDA.

To illustrate the context in which this conflict arises, this comment will first review the common law standards for drug product liability. Next, this comment will present the federal preemption doctrine and the tests courts utilize to determine its applicability. Finally, this comment will conclude that FDA regulations, promulgated pursuant to congressional authority, preempt any state court ruling which would require warnings other than those which comply with federal standards.

## II. PRESCRIPTION DRUGS AND PRODUCTS LIABILITY LAW

Common law pharmaceuticals product liability actions center on an alleged breach of a manufacturer's duty to warn. In this regard, prescription drugs have a special status in products liability law.<sup>12</sup> They are the principle example of an "unavoidably unsafe" product, one which poses risks to the user even when used as intended. Prescription drugs are, therefore, not considered defective if they bear adequate warnings about their hazards.

In the usual case, Section 402A of the RESTATEMENT (SECOND) OF TORTS<sup>13</sup> imposes liability on sellers of products that are in a "de-

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flicted with a valid federal statute, and thus violated the supremacy clause. *Id.* Justice Marshall based his decision on the premise that the commerce clause gave Congress the power to regulate all commercial intercourse among the states. *Id.* Later cases expanded the scope of the supremacy clause to include powers of Congress beyond the regulation of interstate commerce. G. GUNTHER, CONSTITUTIONAL LAW 276 (11th ed. 1985). For example, in *Hines v. Davidowitz*, 312 U.S. 52 (1941), the Court evoked the supremacy clause to protect Congress' power to regulate immigration and naturalization laws from supplementary state action. *Id.*

12. See M.DIXON & F. WOODSIDE, DRUG PRODUCT LIABILITY §9.01 (1982) (the theory of liability is based upon failure of the manufacturer to warn). McClellan, Tate & Eaton, *Strict Liability for Prescription Drug Injuries: The Improper Marketing Theory*, 26 ST. LOUIS U.L.J. 381 (1981) (adequacy of warning is the appropriate negligence standard). But see Note, *Can a Prescription Drug Be Defectively Designed?*-Brochu v. Ortho Pharmaceutical Corp., 31 DE PAUL L. REV. 247 (1981) (exploring the possibility of courts adopting the defective design theory).

13. RESTATEMENT (SECOND) OF TORTS § 402A (1965).  
Section 402A provides:

fective condition unreasonably dangerous" to consumers or their property.<sup>14</sup> That is, under section 402A, a manufacturer is strictly liable for injuries caused by defects in their products.<sup>15</sup> Jurisdictions that have adopted the doctrine of strict liability in tort have found that the doctrine applies even though the product is faultlessly manufactured and designed, but nevertheless dangerous or likely to cause harm unless properly used.<sup>16</sup>

Although section 402A imposes strict liability on a seller who markets a product which courts deem to be unreasonably dangerous, comment k<sup>17</sup> provides an exception in the case of "unavoidably unsafe" products.<sup>18</sup> An "unavoidably unsafe" product is a product which cannot be made safe for its intended use. As comment k points out, there are some products which in the present state of human knowledge are incapable of being made safe for their intended use.<sup>19</sup> Products that come within the scope of comment k

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if  
(a) the seller is engaged in the business of selling such a product, and  
(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although

(a) the seller has exercised all possible care in the preparation and sale of his product, and

(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

*Id.* For Illinois cases discussing 402A's application see *Woodhill v. Parke Davis & Co.*, 79 Ill. 2d 26, 402 N.E.2d 194 (1980)(strict liability applies even when manufacturer uses all possible care); *Cunningham v. McNeal Memorial Hosp.*, 47 Ill. 2d 443, 266 N.E.2d 897 (1970)(found strict liability for contaminated product); *Suvada v. White Motor Co.*, 32 Ill. 2d 612, 210 N.E.2d 182 (1965)(Illinois adopts 402A).

14. *Cunningham*, 47 Ill. 2d at 443, 266 N.E.2d at 897 (1970).

15. *Id.*

16. AM. JUR. 2D *Products Liability* §537 (1964).

17. The exception for unavoidably unsafe products is discussed in REINSTATEMENT (SECOND) OF TORTS §402A (1965).

Comment k states in relevant part:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably dangerous*. . . . The seller of such products . . . is not to be held to strict liability for unfortunate consequences attending their use. . . .

RESTATEMENT (SECOND) OF TORTS §402A comment k (1965) (emphasis added in original).

18. Comment k provides two exceptions to the strict liability doctrine: (1) drugs that carry a known but apparently reasonable risk of injury of which the user has been adequately warned and (2) new or experimental drugs for which there is no knowledge of the risk and the user has been adequately warned of the drug's experimental nature. *Singer v. Sterling, Drug, Inc.*, 461 F.2d 288, 290 (7th Cir. 1972), *cert. denied*, 409 U.S. 878 (1972).

19. *But see Wells v. Ortho Pharmaceutical Corp.*, 615 F. Supp. 262, 295-96 (N.D. Ga. 1985), *aff'd*, 788 F.2d 741 (11th Cir. 1986) (if the product is unnecessarily dangerous, it is defective regardless of its utility).

are, therefore, immunized from strict liability claims.<sup>20</sup>

With rare exception, courts have summarily concluded that comment k exempts prescription drugs from strict liability claims.<sup>21</sup> The underlying reason for these findings is that although prescription drugs often impose risks, the health benefits they provide in treating illness outweighs their inherent danger.<sup>22</sup> Thus, courts have found that these products are "unavoidably unsafe." Judicial application of comment k to prescription drugs is so common and routine that it has become almost tautological.

Consequently, the basis for finding a prescription drug manufacturer liable to an injured consumer is not the existence of a defective drug, but rather, the failure to provide adequate warnings about the drug's risks.<sup>23</sup> As comment k stresses, strict liability may only be avoided when the sale of an "unavoidably unsafe" product is accompanied by proper warnings and directions.<sup>24</sup> When adequate warnings are given, the product cannot be deemed unreasonably dangerous. This remains the case even when certain inevitable risks are associated with its use.<sup>25</sup>

Ordinarily, a manufacturer of an "unavoidably unsafe" product is required to give warnings of its dangers to persons who will

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20. Strict liability can only be avoided through comment k when the sale is accompanied by proper warnings and directions. *Martinkovic v. Wyeth Laboratories, Inc.*, 669 F. Supp. 212, 216 (N.D. Ill. 1987).

21. See *Needham v. White Laboratories, Inc.*, 639 F.2d 394, 401 (7th Cir. 1981), *cert. denied*, 454 U.S. 927 (1981) (comment k generally applies to prescription drugs). Several other jurisdictions have interpreted comment k to apply to drugs. See, e.g., *Werner v. Upjohn Co. Inc.*, 628 F.2d 848 (4th Cir. 1980), *cert. denied*, 449 U.S. 1080 (1981); *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974), *cert. denied*, 419 U.S. 1096 (1974); *Davis v. Wyeth Laboratories Inc.*, 399 F.2d 121 (9th Cir. 1968). But see *Feldman v. Lederle Laboratories*, 97 N.J. 429, 479 A.2d 374 (1984) (whether a drug is unavoidably unsafe should be viewed on a case-by-case basis).

22. See Schwartz, *Products Liability Law and Pharmaceuticals: New Developments and Divergent Trends*, 43 FOOD DRUG COSM. L.J. 33 (1988) (detailed analysis of court acceptance of the comment k defense for prescription drugs).

23. M. DIXON & F. WOODSIDE, *DRUG PRODUCT LIABILITY* §9.01[2] (1982). There have been several scattered decisions, however, holding a manufacturer liable on grounds other than warnings. See, e.g., *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652 (1st Cir. 1981) (product design defect); *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132 (3rd Cir. 1973) (manufacturer recommended a drug for a use not approved by the FDA); *Tinnerholm v. Parke Davis & Co.*, 285 F.Supp. 432 (S.D.N.Y. 1968), *aff'd*, 411 F.2d 48 (2d Cir. 1969) (failure to adequately test a drug before marketing); *Toole v. Richardson Merrell Inc.*, 25 Cal. App. 2d 689, 60 Cal. Rept. 389 (1967) (withholding adverse test data from FDA).

24. *Basko v. Sterling Drug, Inc.*, 416 F.2d 417 (2nd Cir. 1969) (comment k makes an exception to the strict liability rule in the case of products that are unavoidably unsafe). See generally Willig, *The Comment K Character: A Conceptual Barrier to Strict Liability*, 29 MERCER L. REV. 545 (1978).

25. See Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning and Policy Behind Comment K*, 42 WASH. & LEE L. REV. 1139 (1985) (comment k provides absolute immunity from strict liability only when adequate warnings and direction are provided).

foreseeably come in contact with it.<sup>26</sup> However, courts have long accepted an exception to the general rule for warnings on prescription drugs.<sup>27</sup> The learned intermediary doctrine finds that manufacturers of prescription drugs duty to warn is satisfied when the treating physician has been adequately warned.<sup>28</sup> The doctrine is premised on the fact that patients primarily rely on the physician to make medical judgments about whether to take a drug.<sup>29</sup> Patients who play a limited role in prescription selection, do not need warnings from the manufacturer.<sup>30</sup> The fact that under federal law, consumers

26. RESTATEMENT (SECOND) OF TORTS § 402A comment j (1965) (requires manufacturers to give directions or warnings to prevent products from being unreasonably dangerous). A manufacturer or seller is subject to liability for failing either to warn or adequately warn about a risk or hazard inherent in the product. W. PROSSER & W. KEETON, *PROSSER AND KEETON ON THE LAW OF TORTS*, 697 (5th ed. 1984). Warnings should be related to the intended users as well as the reasonably foreseeable users. *Id.* at 698. There are two distinct purposes of adequate warnings. Twerski, Weinstein, Donaher & Piehler, *The Use and Abuse of Warnings in Product Liability-Design Defect Litigation Comes of Age*, 61 CORNELL L. REV. 495 (1976). These are risk reduction and the protection of individual decision making. *Id.* The defendant can be found liable in failure to warn settings in three ways: (1) no warning at all was given as to the particular risk or hazard related to the use of the product; (2) a warning was given but it was inadequate; (3) the means used to disseminate a warning were inadequate to reach all those to whom harm was reasonably foreseeable. *Id.*

27. Prescription drug manufacturers fulfill their duty to warn by providing adequate warnings to prescribing physicians. AM. LAW OF PROD. LIAB. 3d, DRUGS AND MEDICINE 89:6 (3d ed. 1987). See *Eldridge v. Eli Lilly & Co.*, 138 Ill. App. 3d 124, 485 N.E.2d 551 (1985) (reviews the history of Illinois acceptance of the learned intermediary rule). See also *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1971) (first judicial adoption of the learned intermediary rule).

28. A manufacturer's duty to warn in prescription drug cases is based on the learned intermediary doctrine. *Mahr v. G.D. Searle & Co.*, 72 Ill. App. 3d 540, 561, 390 N.E.2d 1214, 1233 (1979). The physician acts as a learned intermediary between manufacturers and the patient. *Id.* This exception to the duty to warn a consumer is justified because the manufacturer's reliance on an intermediary is reasonable. RESTATEMENT (SECOND) TORTS § 388 comment n (1965).

29. The court in *Reyes v. Wyeth Laboratories*, summarized the rationale behind the learned intermediary rule as follows:

Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as susceptibilities of his patient. His is the task of weighing the benefits of any medication against potential dangers. The choice he makes is an informed one, an individualized medical judgement bottomed on a knowledge of both patient and palliative.

*Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1276 (5th Cir. 1974), cert. denied, 409 U.S. 1096 (1974).

30. Direct to patient warnings are not only unnecessary, but counter productive. Rheingold, *Products Liability-The Ethical Drug Manufacturer's Liability*, 18 RUTGERS L. REV. 947 (1964):

Medical ethics as well as medical practice dictate independent judgement. . . on the part of the doctor. Were the patient to be given complete and highly technical information on the adverse possibility associated with the use of the drug, he would have no way to evaluate it, and in his limited understanding he might actually object to the use of the drug, thereby jeopardizing his life. It would be virtually impossible for a manufacturer to comply with the duty of direct warning, as there is no sure way to reach the patient.

*Id.* at 987.

must consult a physician to obtain a prescription drug, is paramount to this assessment.<sup>31</sup>

Federal law notwithstanding, courts have imposed new duties on pharmaceutical manufacturers. In a number of cases, state and federal courts have held that FDA approved product warnings have contained inadequate disclosure of risks.<sup>32</sup> Moreover, courts have held that drug manufacturers have a duty to warn patients directly and in language different from that which the FDA approved.<sup>33</sup> As a result, manufacturers are being held responsible for the adequacy of warnings that are under FDA control. Thus, juries supported by judicial authority, are imposing disclosure obligations on drug manufacturers that are inconsistent with federal regulations.<sup>34</sup> Such action under state law, is a violation of the supremacy of federal law, and should therefore be preempted.<sup>35</sup>

### III. FEDERAL PREEMPTION

The doctrine of federal preemption is derived from the supremacy clause of the United States Constitution.<sup>36</sup> The doctrine

31. See 21 U.S.C. § 353(b)(1) (1986) which provides:

A drug intended for use by man which-(A) is a habit forming drug. . . ; or (B) because its toxicity or other potentiality for harmful effect or the method of its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or (C) is limited by an approved application. . . to use under the professional supervision of a practitioner; shall be dispensed only (i) upon written prescription. . . , or (ii) upon an oral prescription. . . , or (iii) by refilling any such prescription . . . . The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

*Id.* See also Walsh & Klein, *supra* note 5, at 191-92 (the only access to prescription drugs is through physicians who should convey appropriate warnings to patients). The FDA has considered the need for patient labeling, and has decided patient labeling is unnecessary and unwarranted. Prescription Drug Products; Revocation of Patient Package Insert Requirements, 47 FED. REG. 39, 147 (1982).

32. *E.g.* Brochu v. Ortho Pharmaceutical Corp., 642 F.2d 652 (1st Cir. 1981); Needham v. White Laboratories, Inc., 639 F.2d 394 (7th Cir. 1981), *cert. denied*, 454 U.S. 927 (1981); Salmon v. Parke Davis & Co., 520 F.2d 1359 (4th Cir. 1975).

33. *E.g.* MacDonald v. Ortho Pharmaceutical Corp., 394 Mass. 131, 475 N.E.2d 65, (1985) *cert. denied*, 474 U.S. 920 (1985); *In re* Certified Question from the United States District Court for the Eastern District of Michigan, 419 Mich. 686, 358 N.W.2d 873 (1984).

34. See *infra* notes 143-45 for a discussion of the FDA's requirements for uniformity in drug labeling and how state courts requiring different labeling frustrates that purpose.

35. See *supra* notes 36-48 for a complete review of the federal preemption doctrine.

36. U.S. CONST. art. VI, cl. 2. "The Framers of the Constitution understood that supreme federal power was essential to coherent national government." Foote, *Administrative Preemption: An Experiment in Regulatory Federalism*, 70 VA. L. REV. 1429, 1432 (1984). "Because Congress alone of the three federal branches represents the states as states, the Framers gave it authority to balance, by choosing whether to preempt state laws with federal legislation. . . ." *Id.* at 1432-33. [T]he law of the United States is the Supreme law of the land; and the judges in every state "shall be

is essential to the preservation of federal authority in areas that Congress addresses which are of national dimension.<sup>37</sup> An act of Congress, which is directed at a field of dominant federal interest, precludes enforcement of state laws on the same subject.<sup>38</sup> Thus, the federal preemption doctrine is fundamental to our system of government as it provides the terms of basic allocation of power between national and state government.<sup>39</sup>

In the context of preemption, courts have broadly defined both state and federal law. The Supreme Court has construed federal law to include not only the United States Constitution and federal statutes, but also regulations federal agencies promulgate.<sup>40</sup> Further, the Court considers state law to include common law tort actions, as well as state statutes and regulations.<sup>41</sup> Accordingly, federal law preempts a state court action in tort if it conflicts with federal

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bound thereby". *Gibbons v. Ogden*, 22 U.S. 1, 6 (1824). The first reference to the preemption doctrine is found in the ARTICLES OF THE CONFEDERATION of 1781, art. II, reprinted in *THE FEDERALIST*, Appendix II at 175 (A. Hamilton, J. Jay, J. Madison). "Each state retains its sovereignty, freedom, and independence, and every power, jurisdiction, and right, which is not by this Confederation expressly delegated to the United States in Congress assembled." *Id.* See also *THE FEDERALIST* No. 46 (J. Madison) (the power of a federal system ultimately is with the national government). For a more detailed review of the origins of the preemption doctrine see Brighton, *Separating Myth from Reality in Federalism Decisions: A Perspective of American Federalism- Past and Present*, 35 VAND. L. REV. 161 (1982); and J. NOWAK, R. ROTUNDA, & J. YOUNG, *CONSTITUTIONAL LAW* 292-96 (2d ed. 1983).

37. *Fidelity Fed. Sav. & Loan Ass'n. v. De La Cuesta*, 458 U.S. 141 (1982).

38. When the disputed subject is in an area of dominant federal interest, preemptive intent will be inferred. "The relative importance to the State of its own law is not material when there is a conflict with a valid federal law, for the Framers of our Constitution provided that federal law must prevail." *Id.* at 153.

39. The preemption doctrine enables Congress to address problems of a national dimension by enacting comprehensive legislation that supplants state authority in that particular area. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 248 (1984). Furthermore, when Congress delegates its authority to federal agencies, agency regulations may also preempt state law. Foote, *supra* note 36, at 1429. Preemption by a federal agency is defined as administrative preemption. *Id.* at 1430 n.4. It refers to an agency's discretionary authority to preempt state laws that supplement federal regulation. *Id.* This type of federal preemption is supported by businesses that market their products in interstate commerce. *State Regulators Rush in Where Washington No Longer Treads: Will the New Federalism Create a 50-Headed Hydra?*, BUS. WK. SEPT. 19, 1983, at 124. Businesses believe that uniform federal regulation is the only means to insure compliance from state to state. *Id.* at 131. For example, the Securities Industry Association has asked the United States Task Force on Regulation of Financial Institutions to replace all state security regulation with a uniform federal law. *Business's War Against the States*, FORTUNE, Dec. 12, 1983, at 49.

40. The Supreme Court has held repeatedly that state laws can be preempted by federal regulations as well as by federal statutes. See, e.g., *Hillsborough County v. Automated Medical Laboratories*, 471 U.S. 707, 713 (1985); *Fidelity Fed. Sav. & Loan Ass'n. v. De La Cuesta*, 458 U.S. 141, 153 (1982); *United States v. Shimer*, 367 U.S. 374, 381 (1961).

41. Congress' authority to preempt state law "is no less . . . [because] the state[s] power is exercised by the state judiciary rather than by the state legislature." *Sperry v. Florida*, 373 U.S. 379, 403 (1963).

regulation.<sup>42</sup>

Under the preemption doctrine, federal law may supersede state law by either express preemption or implied preemption.<sup>43</sup> Express preemption occurs when Congress expresses an intent that federal law is to be dominant.<sup>44</sup> Explicit preemptive language may be found on the face of the statute itself, in legislative history, or in regulations promulgated pursuant to the statute.<sup>45</sup> Implied preemption occurs when Congress legislates the federal government into a dominant or all inclusive position in a particular field.<sup>46</sup> Courts are obliged to find implied preemption when the scheme of federal regulation is sufficiently comprehensive to make reasonable inferences that Congress "left no room" for supplementary state law.<sup>47</sup>

In analyzing an express preemption claim, courts have found that the unambiguous standard it applies renders those determinations rather obvious.<sup>48</sup> Conversely, federal courts have been required to establish tests which must be utilized to determine whether Congress intended to implicitly preempt, or occupy a particular field of law.<sup>49</sup> From varied case law, four basic tests have developed to determine implied preemptive intent.<sup>50</sup> A federal statute or regulation meeting any one of the four standards will sustain a finding of preemption.<sup>51</sup>

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42. *Id.* Preemption prohibits state common law as well as state statutory law from imposing requirements different from federal regulation. *Palmer v. Liggett Group, Inc.*, 825 F.2d 620, 625-26 (1st Cir. 1987).

43. *See Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)(intent of Congress to preempt state law may be express or implied). The Supreme Court has repeatedly referred to the these two types of preemption. *See, e.g., Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707 (1985); *Pacific Gas and Elec. Co. v. State Energy Resources Conservation and Dev. Comm'n*, 461 U.S. 190 (1983); *Northern States Power Co. v. State of Minn.*, 405 U.S. 1035 (1972).

44. *Northern States Power Co.*, 405 U.S. at 1035. Congress, when acting within constitutional limits, is empowered to preempt state law by stating so in express terms. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218 (1947).

45. *Fidelity*, 458 U.S. at 153.

46. *Rice*, 331 U.S. at 230.

47. *Id.*

48. *Jones*, 430 U.S. at 529. *See also, Palmer*, 825 F.2d at 625-26 (FIFRA clearly indicates express preemption state law); *but see Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529 (D.C. Cir. 1984)(FIFRA statute does not expressly preempt state tort actions).

49. *Hillsborough*, 471 U.S. at 713.

50. *See Pacific Gas & Elec. Co. v. Energy Resources & Dev. Comm'n*, 461 U.S. 190, 204 (1983)(where subject matter calls for national uniformity); *Fidelity* 458 U.S. at 153 (where federal regulation is pervasive); *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142 (1963) (where compliance with both state and federal law would create a direct conflict); *Campbell v. Hussey*, 368 U.S. 297, 299 (1961) (where the legislative history of the statute refers to a dominant national interest). *See also infra* notes 53-64 and accompanying text for a full discussion of the implied preemption standards.

51. Under the supremacy clause, federal law may supersede state law in several different ways. *Hillsborough*, 471 U.S. at 713. *See, e.g., Capital Cities Cable, Inc. v.*

## IV. PREEMPTION STANDARDS

The first test centers on the aim and intent of the statute or regulation itself.<sup>52</sup> In the absence of express preemptive language, Congress' intent to preempt state law may be inferred where a dominant federal interest is manifested in the legislative history.<sup>53</sup> Such manifestation is found in congressional language stressing the welfare and tranquility of all the states as the aim of the law.<sup>54</sup> Therefore, statutes shouldering this burden are presumed to have a national purpose.<sup>55</sup> State laws standing as an obstacle to the accomplishment and execution of the objectives of Congress are, therefore, preempted.<sup>56</sup>

Second, courts may infer a congressional intent to preempt state law if the legislation comprehensively occupies an entire field of regulation.<sup>57</sup> Courts have found the required comprehensiveness when the federal legislation is so pervasive that there is no room for additional state law.<sup>58</sup> Therefore, federal regulations that are thor-

Crisp, 467 U.S. 691 (1984); *KUVE, Inc. v. Moore*, 709 F.2d 922 (5th Cir. 1983), *aff'd sub nom.*, *Texas v. KUVE, Inc.*, 465 U.S. 1092 (1984).

52. *Northern States Power Co. v. State of Minn.*, 447 F.2d 1143, 1145 (8th Cir. 1971), *aff'd*, 405 U.S. 1035 (1972). The aim and intent of Congress, as revealed by the statute itself, or its legislative history can demonstrate preemptive intent. *Id.*

53. See *Campbell*, 368 U.S. at 301 (court found preemptive intent in the legislative history even though the Act did not specifically state preemption). *But see* Radin, *Statutory Interpretation*, 43 HARV. L. REV. 863 (1930) (opposing reliance on legislative history); Comment, *A Framework for Preemption Analysis*, 88 YALE L.J. 363, 384 (1978) (focusing on legislative history often introduces ambiguities into the process of deciding preemption cases).

54. Preemptive intent may be inferred when the statute in question is found to touch upon a field in which federal interest is so dominant that "the federal system [must] be assumed to preclude enforcement of state laws on the same subject." *Pennsylvania v. Nelson*, 350 U.S. 497, 504 (1956).

55. The relative importance to the state of its own law is not material when there is a conflict with a federal law intended to support a national interest. *Free v. Bland*, 369 U.S. 663, 666 (1962).

56. The Court in *Savage v. Jones*, 225 U.S. 501 (1912), succinctly articulated the rationale for implied preemption:

For when the question is whether a Federal act overrides a state law, the entire scheme of the statute must of course be considered and that which needs must be implied is of no less force than that which is expressed. If the purpose of the act cannot otherwise be accomplished-if its operation within its chosen field else must be frustrated and its provisions be refused their natural effect-the state law must yield to the regulation of Congress within the sphere of its delegated power.

*Id.* at 533.

57. Absent explicit preemptive language, Congress' intent to supersede state law may be inferred when "the scheme of federal regulation is so pervasive that there is no room for supplementary state law." *Rice v. Sante Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). See also *Conference of Federal Sav. & Loan Ass'ns v. Stien*, 604 F.2d 1256, 1260 (9th Cir. 1979) (regulatory control of the Bank Board is pervasive leaving no room for state control).

58. See, e.g., *Howard v. Uniroyal Inc.*, 719 F.2d 1552 (11th Cir. 1983) (Federal Rehabilitation Act is pervasive, preempting plaintiff's claim); *Northern States Power*

ough, precise, and detailed, implicitly express Congress' intention to exercise sole control over an area.<sup>59</sup>

Third, courts may find preemptive intent when the nature of the subject matter being regulated demands national uniformity.<sup>60</sup> National uniformity of certain regulations serve the vital function of promoting commerce,<sup>61</sup> liberty,<sup>62</sup> and human health.<sup>63</sup> Clearly, the fulfillment of such objectives would be frustrated if state-created laws were allowed to disrupt the uniformity essential to national interests.<sup>64</sup>

Finally, preemptive intent may be discerned when there is a direct conflict between state and federal law.<sup>65</sup> Direct conflict is found when compliance with both state and federal law is impossible.<sup>66</sup> Accordingly, state law must give way to federal regulation when both cannot be enforced without impairing the federal superintendence of the field.<sup>67</sup> Thus, state laws which interfere with or frustrate the operation of congressional acts are impliedly preempted.

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Co. v. Minn., 447 F.2d 1143 (8th Cir. 1971) (only the federal government has the authority to regulate construction of nuclear power plants).

59. *Chicago & N.W. Transp. Co. v Kalo Brick & Tile Co.*, 450 U.S. 311, 319 (1980) (state efforts to regulate industry must fall when they conflict or interfere with federal authority over same activity).

60. *See, e.g., Transcontinental Gas Pipe Line Corp. v. State Oil and Gas Bd. of Miss.*, 475 U.S. 1091 (1986) (state control of interstate gas pipelines disrupts the uniformity of the federal scheme); *Hines v. Davidowitz*, 312 U.S. 52, 73 (1941) (federal alien registration legislation requires uniformity among the states).

61. *See, e.g., California Retail Liquor Dealers Ass'n. v. Midcal Aluminum, Inc.*, 445 U.S. 97 (1980) (the Sherman Act preempts a California wine pricing program); *Bradley v. Public Utilities Comm'n.*, 289 U.S. 92 (1931) (no state may completely exclude federally licensed commerce).

62. *Hines*, 312 U.S. at 74. Congress, having the constitutional authority to do so, enacted a single and comprehensive alien registration system. *Id.* This uniform law was intended to protect personal liberties of law abiding aliens. *Id.* Any additional state regulations in this area would generate possible "inquisitorial practices" against loyal residents of our country. *Id.* *See also* *Pennsylvania v. Nelson*, 350 U.S. 497 (1955) (enforcement of state sedition acts would threaten comprehensive federal enforcement).

63. *See, e.g., Edmonson v. International Playtex, Inc.*, 678 F. Supp. 1571 (N.D. Ga. 1987). "Federal statutes and regulations pertaining to tampons evidence a congressional intent to preempt the field of warnings to be given to the public." *Id.*

64. *FCC v. Midwest Video Corp.*, 440 U.S. 689 (1979).

65. *See* *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963). "A holding of federal exclusion of state law is inescapable and requires no further inquires into congressional design where compliance with both federal and state regulations is a physical impossibility." *Id.*

66. *Id.* *See also* *Michigan Canners & Freezer Ass'n, Inc. v. Agricultural Mktg. & Bargaining Bd.*, 467 U.S. 461, 469 (1984) (federal law preempts state law to the extent of which there is a direct conflict).

67. *Florida Lime*, 373 U.S. at 142-43.

## V. FEDERAL PREEMPTION AND DRUG PRODUCT LIABILITY

Although not expressly stated,<sup>68</sup> Congress' intent to have FDA regulations preempt state law can be inferred.<sup>69</sup> Application of the four tests used to determine implied preemptive intent demonstrates the preemptive nature of FDA mandates. Nevertheless, courts have been reluctant to recognize FDA preemption over state tort actions.<sup>70</sup> They persist in attempting to regulate the drug industry from the courtroom.<sup>71</sup> Thus, there exists a conflict between state and federal law, precisely the reason why the preemption doctrine was developed.<sup>72</sup>

Courts have reviewed this conflict in several recent cases<sup>73</sup> involving diphtheria, pertussis, and tetanus "DPT" vaccine claims.<sup>74</sup>

68. See *Patten v. Lederle Laboratories*, 655 F. Supp. 745 (D. Utah 1987) (no language in the PHSE or FDCA which expressly preempts state tort actions).

69. *Hurley v. Lederle Laboratories*, 651 F. Supp. 993 (E.D. Tex. 1986) *rev'd on other grounds*, 851 F.2d 1536 (5th Cir. 1988). The *Hurley* court held that the pervasiveness of the regulation, the dominant federal interest, the agency's concern with uniformity, and the irreconcilable conflicts that state law determinations would have on FDA policies mandates preemption. *Id.* at 1007.

70. See *infra* notes 71-84 and accompanying text for a discussion of cases refusing to find FDA preemption of state law.

71. Courts have long recognized the regulatory function of product liability case law. See, e.g., *DeLuryea v. Winthrop Laboratories*, 697 F.2d 222, 228 (8th Cir. 1983) (courts motivate manufacturers to make safe products through their decisions in products liability cases); *Daley v. General Motors Corp.*, 20 Cal. 3d 725, 575 P.2d 1162 (1978) (court decisions in product liability cases provide stimulus for manufacturers to market safe products). Courts that impose a change in the manufacturer's behavior by imposing additional duties "arrogates to a single jury the regulatory power explicitly denied to all the fifty states' legislative bodies." *Fitzgerald v. Mallinckrodt, Inc.*, 681 F. Supp. 404, 407 (E.D. Mich. 1987).

72. See *supra* notes 33-44 and accompanying text for a complete discussion of the preemption doctrine.

73. See, e.g., *Abbot v. American Cyanamid*, 844 F.2d 1108 (4th Cir. 1988) (found no preemption); *Graham v. Wyeth Laboratories*, 666 F. Supp. 1483 (D. Kan. 1987) (found no preemption); *Morris v. Parke Davis & Co.*, 667 F. Supp. 1332 (C.D. Cal. 1987); *Hurley v. Lederle Laboratories*, 651 F. Supp. 993 (E.D. Tex. 1986) (found preemption); *MacGillivray v. Lederle Laboratories*, 667 F. Supp. 743 (D. N.M. 1987) (found no preemption).

74. The DPT vaccine is comprised of various component parts. 42 PHYSICIAN'S DESK REFERENCE 1172 (1988) [hereinafter PDR]. Those components are diphtheria toxoids, tetanus toxoids, and pertussis whole cell vaccine. *Id.* It is the pertussis component which causes severe reactions. *Ezagui v. Dow Chem. Corp.*, 598 F.2d 727, 731 (2nd Cir. 1979). The severe reaction from the pertussis component of the drug is due to the inability of the scientific community to determine which part of the pertussis cell contains the harmful neurotoxins. See Leibel, *Pertussis Vaccination: Benefits and Risks*, DRUG THERAPY, Oct. 1984, at 103. In the early part of the century, pertussis was one of the leading causes of death in children. Hinman & Koplan, *Pertussis and Pertussis Vaccine: Reanalysis of Benefits, Risks and Costs*, 251 J. OF THE AMERICAN MEDICAL ASS'N 3109 (June 15, 1984). In 1934 for example, there were over 250,000 reported cases of pertussis in the United States, and 7,500 deaths were caused by the disease. *Id.* In recent years, however, the widespread availability of the DPT vaccine has virtually eradicated the disease. *Id.* Tri-munol, manufactured by Lederle Laboratories, is the only FDA licensed DPT vaccine currently available. PDR, *supra*, at 1172. To compensate the victims of adverse reactions to the DPT

In each of these actions DPT manufacturers have been charged with failing in their duty to adequately warn of the dangers inherent in the use of that vaccine.<sup>76</sup> In all of these cases,<sup>78</sup> manufacturers were held to have provided inadequate warnings despite their compliance with FDA labeling requirements. These courts, in rejecting the manufacturers' preemption claim, have advanced a variety of fallacious rationales.

In denying preemption, several DPT courts reasoned that the FDA sets only minimum standards, thus compliance with the regulations is not dispositive of whether a warning is adequate.<sup>77</sup> Accordingly, these courts have found that while compliance with FDA regulations is admissible as evidence of adequate warnings, it does not affect the manufacturers common law duty to warn.<sup>78</sup> This erroneous reasoning fails to consider the pervasive role of the FDA as a regulatory authority, whose decisions on labeling manufacturers may not ignore.<sup>79</sup>

Other DPT courts have rejected the preemption argument by holding that there is no direct conflict between FDA standards and state tort liability.<sup>80</sup> In reaching this conclusion, the courts have noted that tort law is not regulatory, but rather remedial and compensatory in nature.<sup>81</sup> The obvious flaw in this reasoning is the courts' naivety concerning the effects of their findings in products

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vaccine, Congress enacted the National Childhood Vaccine Injury Act of 1986 ("NCVIA"). 21 U.S.C. § 300aa-1-33 (1986), *as amended by*, Pub. L. No. 99-660, 301-323, 100 Stat. 3743, 3755-84 (1986). The intent of the act is to protect DPT and other childhood vaccine manufacturers from litigation expenses that may force them to stop making the drugs. H.R. REP. NO. 99-90B, 99th Cong. 2d Sess. 6-7, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS 6344-48. This report states "the committee believes that once this system is in place and manufacturers have a better sense of their potential litigation obligations, a more stable childhood vaccine market will evolve." *Id.*

75. See *supra* note 70 for a list of cases where plaintiffs alleged that the manufacturers of the DPT vaccine did not adequately warn them of the danger of the drug.

76. The *Hurley* court has been the only court which has ruled in favor of preemption. 651 F. Supp. 993 (E.D. Tex. 1986). That ruling, though, has been questioned on appeal with the circuit court overruling part of the preemption holding. *Hurley v. Lederle Laboratories*, 851 F.2d 1536 (5th Cir. 1988).

77. See, e.g., *MacGillivray v. Lederle Laboratories*, 667 F. Supp. 743 (D. N.M. 1987) (pervasive regulation is not indicative of preemptive intent).

78. "FDA regulations set minimum standards, and thus compliance is not dispositive of whether a product is defective." *Id.* at 746.

79. See *Cosmetic, Toiletry & Fragrance Ass'n, Inc. v. State of Minn.*, 440 F. Supp. 1216 (D. Minn. 1977) (FDA regulations are binding and authoritative). See also *infra* notes 106-11 and accompanying text for a full discussion of the pervasiveness of FDA regulations.

80. See *Pattern v. Lederle Laboratories*, 655 F. Supp. 745 (D. Utah 1987) (Congress did not intend compliance with federal regulations to insulate manufactures from civil liability).

81. *Id.* at 749.

liability cases.<sup>82</sup> This naivety is the result of the courts' failure to recognize that juries are holding manufacturers to standards different from those required by the FDA.<sup>83</sup> This judicial imposition of conflicting duties on manufacturers on a case-by-case basis makes concurrent compliance with federal and state law virtually impossible.<sup>84</sup>

A third view opposing FDA preemption of state court actions was presented in *Wack v. Lederle*.<sup>85</sup> The *Wack* court, failing to recognize that preemption can be impliedly found, refused to find preemptive intent absent express congressional language.<sup>86</sup> The *Wack* court's narrow interpretation of the preemption doctrine ignores the Supreme Court's holdings which permit findings of implied preemptive intent.<sup>87</sup>

The courts' reluctance to acknowledge the preemptive intent of FDA regulations is perplexing. The reasoning the courts employed to reach their conclusions is conflicting, uncertain, and flawed.<sup>88</sup> Moreover, these courts have ignored Supreme Court preemption standards in their refusal to relinquish their regulatory power and accept the concept of FDA preemption.<sup>89</sup>

The courts' reluctance to find preemptive intent in FDA regulations is more confounding when considering cases where preemption has been found. For instance, in *Cipollone v. Liggett*,<sup>90</sup> the court

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82. State court rulings regarding adequacy of FDA approved labeling give juries the coercive power to affect the substance of the warnings manufacturers publish. *Edmonson v. International Playtex, Inc.*, 678 F. Supp. 1571, 1574 (N.D. Ga. 1987). The nature of warnings is basically a medical concern, which would best be resolved by medical professionals rather than by lay persons in the context of tort litigation. *Id.*

83. See generally Taylor, *Federal Preemption and Food and Drug Regulation: The Practical, Modern Meaning of an Ancient Doctrine*, 38 FOOD DRUG COSM. L.J. 306 (1983) (uniformity of regulation on national basis assures consistent level of public health protection).

84. FDA labeling requirements mandate that pharmaceutical labeling is to be entirely truthful, and that it omits no information that is pertinent to the safe and effective prescribing of the drug by physicians. Temple, *Legal Implications of the Package Insert*, 58 MED. CLIN. N. AM. 1151, 1155 (1974). If drug manufacturers follow state court requirements, they may violate FDA regulations and risk imposition of sanctions, including revocation of their license to market the drug. 21 C.F.R. § 201.59 (1988).

85. 666 F. Supp. 123 (N.D. Ohio 1987).

86. *Id.* at 127.

87. Implied preemptive intent can be found in the comprehensiveness and pervasiveness of the statute, in the dominant federal interest in the subject matter, and the desire to preclude enforcement of state laws on the same subject. *Sperry v. Florida*, 373 U.S. 379, 403 (1963).

88. See *supra* notes 49-64 and accompanying text for a review of the courts' holdings.

89. See generally Fern & Lewis, *Federal Preemption of Pharmaceutical Labeling*, FOR THE DEF., July, 1987, at 20 (courts should defer to the FDA's expertise and not try to regulate the drug industry on a case-by-case basis).

90. 789 F.2d 181 (3rd Cir. 1986).

found the Federal Cigarette Labeling and Advertising Act preempted a state court tort action for failure to warn of the dangers of cigarette smoking.<sup>91</sup> The *Cipollone* court held that the state court action would frustrate the "full purposes and objectives of Congress."<sup>92</sup> The court's willingness to find a dominant national interest in the context of cigarette smoking, but not for prescription drugs, is astonishing.

Furthermore, in cases involving congressional statutes and agency regulations dealing with auto safety, courts have readily discerned implied preemptive intent. In *Dawson v. Chrysler Corp.*<sup>93</sup> for example, the court held that the National Traffic and Motor Vehicle Safety Act ("NTMVSA") impliedly preempted state tort claims.<sup>94</sup> In support of its conclusion, the *Dawson* court noted that it would be impossible for car manufacturers to alter their designs in response to jury verdicts in these cases.<sup>95</sup> Thus, the court held that the regulatory effects of such findings create a direct conflict with the goals of the NTMVSA. and are, therefore, preempted.

Similarly, the court in *Wood v. General Motors Corp.*<sup>96</sup> held that Congress intended to preempt the field of auto safety standards through the NTMVSA.<sup>97</sup> The court reasoned, that to allow a local government to enforce safety standards different from those adopted in the federal act, would undermine the required uniformity of the regulation.<sup>98</sup> Moreover, the court recognized that preemptive intent must be inferred when the enforcement of state law would present a serious conflict with the administration of the federal program.<sup>99</sup>

The decisions in *Dawson* and *Wood* illustrate reasoning that is

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91. The Federal Cigarette Labeling & Advertising Act, 15 U.S.C. §§ 1331-40 (1982), prescribes the exact warning to be printed on cigarette packs, and expressly preempts state attempts to require further warnings. *Cipollone*, 789 F.2d at 182. Nevertheless, there is no express preemption as to common law damage claims for inadequate warnings or labeling. *Id.* The *Cipollone* court, therefore, held that the Cigarette Act impliedly preempted such claims, as they would "create an obstacle to accomplishing Congress' objectives." *Id.* But see *Cipollone v. Liggett Group, Inc.*, 649 F. Supp. 664 (D. N.J. 1986) (on remand the district court expressed vehement disagreement with the Third Circuit's conclusion).

92. *Cipollone*, 789 F.2d at 183.

93. 630 F.2d 950 (3rd Cir. 1980), cert. denied 450 U.S. 959 (1981).

94. *Id.*

95. "In effect, this permits individual juries applying varying laws in different jurisdictions to set nationwide automobile safety standards and to impose on automobile manufacturers conflicting requirements." *Id.* at 962. "It would be difficult for members of the industry to alter their design . . . in response to jury verdicts . . . because their response might well be at variance with what some other jury decides is a defective design." *Id.*

96. 865 F.2d 395 (1st Cir. 1988).

97. 15 U.S.C. § 1381 (1982).

98. *Wood*, 865 F.2d at 412 (1st Cir. 1988).

99. *Id.*

both persuasive and in conformity with Supreme Court preemption standards.<sup>100</sup> These holdings are representative of other well reasoned decisions regarding federal preemption.<sup>101</sup> However, most courts addressing the issue of FDA preemption persist in viewing the regulation of prescription drugs as an insignificant federal interest.<sup>102</sup> Thus, courts continue to formulate their own drug standards, disregarding the congressional objective of uniformity in prescription labeling.<sup>103</sup>

## VI. IMPLIED PREEMPTION STANDARDS AND FDA REGULATIONS.

Although the FDCA does not contain explicit preemptive language, the intent of the statute to supersede state tort actions is apparent. To determine the existence of implied preemptive intent in FDA regulations, courts must utilize judicially established standards. As previously discussed, those standards are: (1) the pervasiveness of the statute;<sup>104</sup> (2) the legislative intent;<sup>105</sup> (3) whether the subject matter of the statute demands national uniformity;<sup>106</sup> and (4) whether a direct conflict between state and federal law would exist.<sup>107</sup> A federal regulation or statute meeting any one of these tests impliedly preempts state law on the same subject.<sup>108</sup> This section of the comment provides an analysis of the FDCA and FDA regulation within the context of these four standards. The analysis will show that FDA labeling regulations meet all four of the tests for implied preemption and, therefore, preempt state law.

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100. See *supra* notes 49-64 and accompanying text for a discussion of the standards to be employed in determining implied preemption.

101. See, e.g., *Ray v. Atlantic Richfield Co.*, 435 U.S. 151 (1978) (Coast Guard regulations); *Sears v. Stiffel*, 376 U.S. 225 (1964) (federal patent laws); *Northern States Power Co. v. Minn.*, 447 F.2d 1143 (8th Cir. 1971), *aff'd* 405 U.S. 1035 (1972) (Atomic Energy Commission regulations).

102. See *supra* notes 70-84 and accompanying text for a review of decisions holding FDA regulations do not preempt state court tort actions.

103. *Id.*

104. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). See also *supra* notes 54-56 and accompanying text for a full discussion of the pervasiveness test for implied preemption.

105. *Cambell v. Hussey*, 368 U.S. 297, 301 (1963). See also *supra* notes 49-53 and accompanying text for a full discussion of the legislative intent test for implied preemption.

106. *Florida Lime and Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 143-44 (1963). See also *supra* notes 57-61 and accompanying text for a full discussion of the national uniformity test for implied preemption.

107. *Hines v. Davidowitz*, 312 U.S. 52, 67-8 (1941). See also *supra* notes 62-64 and accompanying text for a full discussion of the direct conflict test for implied preemption.

108. *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691 (1984).

### A. Pervasiveness

The FDCA<sup>109</sup> has set forth the most far reaching and pervasive regulations for prescription drugs in the world.<sup>110</sup> In fact, the current FDA regulations for New Drug Applications ("NDA")<sup>111</sup> express the most stringent standards of pharmacological investigation in use today.<sup>112</sup> The NDA standards include regulation of early phase animal trials, a thorough review of toxicity data before human testing is allowed, as well as specific requirements for tests regarding safety, efficacy, and optimum dosage.<sup>113</sup> Once these investigations have been completed in accordance with FDA requirements, drug manufacturers present the data, in form of an NDA, to the FDA for evaluation. FDA experts then analyze this data and determine whether the drug is safe and effective for its intended use.<sup>114</sup>

Moreover, when a manufacturer submits an NDA, he must also propose labeling that is to accompany the drug in the package insert ("PI"), a prescription drug's official labeling.<sup>115</sup> The FDA strictly regulates the PI's contents. In this regard the FDA dictates what topic headings must be used, what information must follow each heading, and in many instances the exact language to be employed.<sup>116</sup> Furthermore, if the labeling does not provide adequate

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109. 21 U.S.C. §§ 351-360 (1982).

110. See Simmons, *The Drug Regulatory System of the United States Food and Drug Administration*, 4 INT'L J. HEALTH SERVS. 95, 97 (1974) (FDA is recognized as the "most effective national drug regulatory agency in the world"). Stolley, *Assuring the Safety and Efficacy of Therapies*, 4 INT'L J. HEALTH SERVS. 131 (1974) (FDA requires the most careful testing of any regulatory agency in the world).

111. See 21 U.S.C. § 355(a) (1986), which states: "[n]o person shall introduce or deliver into interstate commerce any new drug, unless approval of an application filed pursuant to . . . this section is effective with respect to such drugs." *Id.*

112. The FDA's comprehensive regulatory requirements delay introduction of drugs in the United States for several years after their introduction in Western Europe. Wardell, *Introduction of New Therapeutic Drugs in the United States and Great Britain: An International Comparison*, 14 CLINICAL PHARMACOLOGY & THERAPEUTICS 773 (1973). From 1965 to 1969, new drugs appeared on the United States market one year later than in France, 1.6 years later than in West Germany, and 2.1 years later than in England. Lasanga, *Research, Regulation, and Development of New Pharmaceuticals: Present, Past, and Future*, 263 AM. J. MED. SCI. 67 (1972).

113. Federal regulations require the following data for an NDA: (1) all safety and efficacy data; (2) protocols for tests or studies; and (3) reports of all clinical tests. 21 C.F.R. § 314 (1988).

114. "Once a [NDA] has been submitted, the FDA, upon review, may determine that there is insufficient information in the application to make an adequate determination of whether the drug is effective or safe. General Accounting Office Report to the Secretary of Health and Human Services; March 8, 1982, reprinted in M. DIXON & F. WOODSIDE, *DRUG PRODUCT LIABILITY* §5.03[9] (1982). See also 21 C.F.R. § 314.150(a)(2) (1988) (defining what constitutes insufficient information in NDA); 21 C.F.R. § 314.125 (1988) (criteria for FDA refusal to approve NDA).

115. 21 C.F.R. § 314.50(e)(1)(ii) (1984). The term "labeling" includes not only printed materials attached to the drug container, but also printed materials accompanying the drug. *Id.*

116. 21 C.F.R. § 201.57 (1988). The FDA demands the following headings in

warnings and directions for use, the FDA will not allow the drug to be marketed.<sup>117</sup> Only after FDA review and approval of clinical data and labeling can a manufacturer place a new drug on the market.<sup>118</sup>

The FDA's pervasive control of the pharmaceutical industry is not limited to the approval of new drugs and their initial labeling. Also subject to FDA authority are post-marketing amendments to the PI.<sup>119</sup> Any information a manufacturer receives concerning an approved drug, including scientific literature of either formal clinical trials or epidemiologic studies, must be submitted to the FDA.<sup>120</sup> Furthermore, reports from practicing physicians concerning adverse reactions attributable to an approved drug, must be forwarded to the agency.<sup>121</sup> Pursuant to this regulation, the FDA has the authority to remove a drug from the market for failure to comply with these reporting requirements.<sup>122</sup>

It is through these reporting procedures that amendments to the PI are made. That is, only the FDA, through analysis of manufacturer supplied data, can alter labeling approved by way of the

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each physician package insert: (1) Description; (2) Clinical Pharmacology; (3) Indications and Usage; (4) Contraindications; (5) Warnings; (6) Precautions; (7) Adverse Reactions; (8) Drug Abuse and Dependence; (9) Overdosage; (10) Dosage and Administration; and (11) How Supplied. *Id.*

117. See 21 U.S.C. § 331.30 (1984), which states in pertinent part: "[t]he introduction or delivery into interstate commerce any drug that is misbranded is prohibited."

118. The FDA reviews and approves the NDA when it is satisfied that the drug is both safe and effective for its intended use. M. DIXON & F. WOODSIDE, *supra* note 114, at § 5.03[7] (1982). Manufacturers are forbidden from disseminating any information about the drug prior to the completion of the FDA's investigation. *Id.* A manufacturer may not promote the drug for an unapproved indication. *Id.*

119. A supplemental NDA must be submitted and approved for any change that may alter the previously approved labeling. 21 C.F.R. § 314.70 (1988). Section 314.70(c) of the C.F.R. provides a limited exception to the rule that all labeling revisions must be approved by the FDA. 21 C.F.R. § 314.70(c) (1988). However, only less important matters regarding drug labeling can be revised without the manufacturer filing a supplemental NDA. Cooper, *Drug Labeling and Products Liability: The Role of the Food and Drug Administration*, 41 FOOD DRUG AND COSM. L.J. 233, 235 (1986).

120. Pharmaceutical companies whose NDA's are approved must report to the FDA quarterly for the first year, semiannually the second year, and annually thereafter. PHARMACEUTICAL MFRS. ASSN, *PRESCRIPTION DRUG FACT BOOK* 36 (1980). Furthermore, a manufacturer must supply the FDA reports of toxicity, unexpected side-effects, and hypersensitivity reactions within fifteen days of their notice. M. DIXON & F. WOODSIDE, *supra* note 114, at § 5.03[B]. See also 21 C.F.R. § 310.303(a) (1988) (details the contents of the post-marketing reports).

121. Physician provides direct information to the FDA concerning adverse reactions to drugs by means of a form called the Drug Experience Report ("DER") or Form 1639. 21 C.F.R. § 310.303 (a) (1988). A properly documented DER contains a complete account of the injury suspected to be caused by a drug. Sills, Faich, Milstein & Turner, *Post-marketing Reporting of ADR's to the FDA: An Overview of the 1985 Guidelines*, 20 DRUG INFO. J. 150 (1986).

122. 21 C.F.R. § 310.305 (1988) (regulation for reports concerning adverse drug reactions).

NDA process.<sup>123</sup> Thus, a manufacturer violates federal law if it unilaterally changes an approved drug's labeling.<sup>124</sup> Moreover, where the FDA determines that a change in labeling is required, it may compose the exact language to be used.<sup>125</sup> Consequently, the manufacturer has no freedom to alter the PI by adding information different from what the FDA has endorsed.

Based on the preceding facts, it is clear that FDA regulation of the pharmaceutical industry is indeed pervasive.<sup>126</sup> The agency's precise standards regarding the testing, manufacturing, and labeling of drugs irrefutably support that position.<sup>127</sup> Moreover, the FDA's

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123. Labeling changes usually occur upon recommendation of the FDA through its analysis of DER's and other evidence of newly discovered adverse reactions. Cooper, *supra* note 119, at 236. Although FDA regulations provide a mechanism for a manufacturer's unilateral labeling changes, a supplemental NDA still must be filed first. *Id.* Even then, there is no guarantee the FDA will agree to the proposed labeling the manufacturer suggests. Walsh & Klein, *supra* note 5, at 185. The facts in *Feldman v. Lederle* demonstrate the FDA's refusal to accept a manufacturer's proposed labeling. *Feldman v. Lederle*, 97 N.J. 429, 479 A.2d 374 (1984). In *Feldman*, the defendant drug manufacturer persistently sought FDA approval to add a newly discovered adverse reaction to their drug's labeling. *Id.* at 431, 479 A.2d at 377. The FDA advised the manufacturer that the warning requested was not justified by the scientific evidence as it perceived it. *Id.* at 434, 479 A.2d at 379. Finally, after seven months of negotiating with FDA scientists, the manufacturer received FDA approval to add the proposed changes. *Id.* at 435, 479 A.2d at 380. The *Feldman* court, nevertheless, held that the defendant failed in its duty to adequately warn because the newly discovered adverse reactions were not included in the labeling at the time of the injury. *Id.* at 446, 479 A.2d at 392. The *Feldman* case underscores the difficulty a manufacturer encounters when seeking to alter FDA approved labeling and the associated increased risk of liability. Walsh & Klein, *supra* note 5, at 186.

124. A pharmaceutical manufacturer violates federal law by adding new information about a drug's risks without first filing a supplemental NDA. M. DIXON & F. WOODSIDE, *supra* note 114, at § 5.03[10]. Once the FDA has rejected the supplemental NDA, the manufacturer is prohibited from making any unilateral changes in the drug's labeling. Cooper, *supra* note 119, at 235.

125. For example, 21 C.F.R. § 369.20 (1988) requires all prescription oral antihistamines to have the following warning: "Caution - This preparation may cause drowsiness. Do not drive or operate machinery while taking this medication. Do not give to children under 6 years of age or exceed the recommended dosage unless directed by physician." *Id.*

126. Congress, through the FDCA, has mandated the FDA to ensure that all drugs placed in interstate commerce are safe and effective. Temin, *The Origins of Compulsory Drug Prescriptions*, 22 J. LAW & ECON. 91 (1979). The FDA has responded to this Congressional mandate by developing the most sophisticated system of drug regulation in the world. Crout, *The Drug Regulatory System: Reflections and Predictions*, 36 FOOD DRUG COSM. L.J. 106 (1981). Congress itself, has recognized the FDA's high standards for drug safety. HOUSE COMMITTEE ON SCIENCE AND TECHNOLOGY, 97th CONG., 2d Sess, FINAL REPORT OF THE COMMISSION ON THE FEDERAL DRUG APPROVAL PROCESS (1982). Furthermore, the effectiveness of the FDA's regulation has led several courts to recognize federal control of the drug industry to be pervasive and complete. See, e.g., *United States v. 1,048,000 Capsules of Afrodex*, 494 F.2d 1158, 1160 (5th Cir. 1974); *Cosmetic, Toiletries & Fragrances Ass'n Inc. v. Minn.*, 440 F. Supp. 1216 (D. Minn. 1977), *aff'd*, 575 F.2d 1256 (8th Cir. 1978).

127. A review of the FDCA as codified in section 21 of the C.F.R. reveals a most comprehensive system of drug regulation. The pervasiveness of this regulatory scheme has been well described in the following passage from M. DIXON & F. WOOD-

ultimate power in deciding which drugs are available to consumers unquestionably demonstrates its pervasive position in the field of prescription drugs.<sup>128</sup> Therefore, by meeting the pervasiveness test for implied preemption,<sup>129</sup> FDA regulation should supersede state laws in the area of prescription drugs.

### B. Legislative Intent

Physicians write over 1.3 billion prescriptions each year and Americans spend over 13 billion dollars on those drugs.<sup>130</sup> Several of these medications provide relief from serious illness and in many cases actually prolong life.<sup>131</sup> As a result, prescription drugs have become central to American lives, and are an absolute necessity for some people. Congress, in consideration of the importance of prescription drugs to national health, enacted the 1938 FDCA.<sup>132</sup> The

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SIDE, *supra* note 114, at § 5.02:

The FDA is the primary federal agency charged with regulation of drugs and devices in interstate commerce. The organizational structure of the FDA . . . underscores the complexity of the regulatory tasks of this agency. Under the regulations, the FDA is charged with monitoring drug research and experimentation and the introduction of new drugs into the market place. The FDA has established regulations under the act for the supervision of experimental animal tests, human experimentation prior to drug marketing, and the drug marketing itself. The FDA controls manufacturing procedures, drug advertising, drug labeling, and generally all communications between drug manufacturers and the practitioners who prescribe the drug. The FDA is also charged with evaluating the effectiveness of approved drugs.

*Id.*

128. See *supra* note 111 for a review of the FDA's pervasive control in determining which drugs can be legally marketed in the United States.

129. See *supra* notes 54-56 and accompanying text for a review of the pervasiveness standard in implied preemption.

130. These statistics were published in 47 FED. REG. 39, 249 (1982). More recently, Pharmaceutical Data Service determined that 1.5 billion prescriptions are written annually. Glasser, *45th Annual Prescription Survey*, 128 DRUG TOPIC MAG. 28 (1984). United States health care expenditures in 1987 were in excess of \$500 billion, or 10.7 percent of the gross national product ("GNP"). Gup, *Health Care: Beyond Bromides*, Time, Oct. 31, 1988, at 21. By 1990 health care cost will consume more than 12% of the nation's GNP. *Id.*

131. For example, 11 million Americans currently suffer from diabetes and many of these patients require daily insulin in order to live. AMERICAN DIABETES ASSOCIATION, *DIABETES MELLITUS 4* (1984). Furthermore, many drugs have proven valuable in disease prevention. One example is the drug cholestyramine. Coronary Drug Project Research Group, *The Lipid Research Clinics Primary Prevention Trial Results*, 251 J. AM. MED. ASSN 351 (1984). Cholestyramine, a cholesterol lowering medication, was shown to lessen the risk of coronary heart disease. *Id.* Another drug commonly used for preventative medical purposes is nicotine polacrilex, a medication used to aid cigarette smokers in their withdrawal from nicotine. 42 PDR, *supra* note 74, at 1122-23. As cigarette smoking continues to be associated with disease, the benefits of treatment with this compound are immeasurable. See generally G. OSTER, G. COLDITZ, & N. KELLY, *THE ECONOMIC COST OF SMOKING AND THE BENEFITS OF QUITTING* (1984).

132. The FDA, through the authority of Congress, promulgated regulations to protect the public health from unsafe and ineffective drugs. *Barnes v. United States*,

FDCA, primarily created to regulate the pharmaceutical industry, requires the FDA to ensure that marketed drugs are safe and effective.<sup>133</sup>

However, it was not until the 1962 FDCA amendments<sup>134</sup> that the FDA gained unequivocal authority to regulate the drug industry.<sup>135</sup> These amendments empower the FDA to create binding regulations which require drug manufacturers to demonstrate the safety and efficacy of their drugs.<sup>136</sup> Additionally, the 1962 amendments es-

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142 F.2d 648 (9th Cir. 1944). Prior to Congress' entrance into the field of drug regulation, state drug regulation had evolved in piecemeal fashion often resulting in unregulated local drug industries. 1 H. TOULMIN, *LAW OF FOOD DRUGS AND COSMETICS* § 1.1 (1977). During the period prior to federal control, the drug industry was saturated by unscrupulous manufacturers who often sold medicine that created more disease than it cured. M. DIXON & F. WOODSIDE, *supra* note 114, at § 5.01. The first federal attempt to correct this deplorable situation was the Pure Food and Drug Act of 1906, 4, 34 Stat. 768, 69 (1906). Although this legislation provided a partial solution by requiring registration of drug manufacturers, more stringent controls to regulate were needed. Landen, *Federal Preemption and the Drug Industry: Can Courts Co-Regulate?*, 43 *FOOD DRUG COSM. L.J.* 85, 96 (1986). A tragedy which resulted in over 100 deaths from a defective drug motivated Congress to strengthen its role in drug safety. M. DIXON & F. WOODSIDE, *supra* note 114, at § 5.01[1]. The public outcry from these deaths spurred Congress to legislate the Food, Drug, and Cosmetic Act of 1938. *Id.* This act empowered the FDA to require manufacturers to submit applications for scientific review before a new drug could be marketed. *Id.* Under this regulatory scheme, the FDA analyzed data supplied by the manufacturers, to ensure that all drugs placed into interstate commerce met minimum safety requirements. J. O'REILLY, *FOOD AND DRUG ADMINISTRATION* § 3.04 (1979).

133. A drug must undergo three phases of clinical testing before the FDA will approve it for marketing. W. KIMBLE & R. LESHER, *PRODUCTS LIABILITY* § 131 (1979). The first phase consists of trials on healthy volunteers. *Id.* at 373. The second requires tests on patients, and the third constitutes a variety clinical research. *Id.* The average time necessary to complete all FDA mandated testing is seven to ten years. Grabowski, *The Impact of Regulation on Innovation*, 34 *FOOD DRUG COSM. L.J.* 555 (1979). To comply with all FDA requirements, manufacturers spend over 50 million dollars to introduce a new drug into the market. *Id.*

134. PUB. L. No. 87-781 (1962) (codified in scattered sections of 21 U.S.C. (1962)).

135. The Drug Amendments of 1962 (sometimes referred to as the Kefauver-Harris Amendments) were instituted to create a major change in emphasis of the FDCA. M. DIXON & F. WOODSIDE, *supra* note 114, at § 5.01[1]. These amendments were created in response to the tragic injuries produced by thalidomide in Europe. M. SILVERMAN & P. LEE, *PILLS, PROFITS AND POLITICS* 94-98 (1974). Thalidomide, a sedative used in pregnancy, caused over 10,000 cases of limb deformities in children of users in Western Europe. *Id.* The 1962 FDCA Amendments were promulgated to ensure that such a tragedy would not occur in America. Wallace, *Outline of the History of the U.S. Drug Regulation and Labeling*, 36 *FOOD DRUG COSM. L.J.* 420, 437-38 (1981). Thalidomide was never marketed in the United States. *Id.*

136. M. DIXON & F. WOODSIDE, *supra* note 114, at § 5.01[1]:  
The Drug Amendments of 1962, which Congress passed unanimously, contained the following provisions:

- (1) Drug companies were required to prove a drug to be both safe and effective.
- (2) Manufacturers were required to promptly transmit to the FDA reports of adverse side-effects.
- (3) The manufacturers were required to employ scientific controls in manufacturing operations.
- (4) All persons involved in the manufacture, repackaging, or relabeling of drugs

tablished extensive requirements regarding drug labeling.<sup>137</sup> This statutory scheme for labeling is intended to lessen the risk of drug related injury by providing physicians the information they need to maximize a drug's effectiveness while minimizing its risk. Thus, Congress entrusted the FDA with the responsibility for assuring the nation that the drugs it approves are as safe and effective as humanly possible.

These statutory provisions, combined with the dominant federal interest of promoting national health, provide direct support for implied preemption. There is no question that Congress enacted the FDCA to accommodate the public demand for efficacious and safe drugs.<sup>138</sup> Pursuant to this act, the FDA has developed the special competence which places it in the unique position to expertly regulate the warning requirements of pharmaceutical products.<sup>139</sup> Juries, on the other hand, lack the needed technical knowledge to correctly evaluate the data regarding adequacy of a drug's labeling.<sup>140</sup> Therefore, it can be inferred that the legislative intent behind the FDCA impliedly preempts any state law which would supplant FDA authority in drug regulation.

### C. National Uniformity

The FDA has a well established policy of promoting uniformity in the area of pharmaceutical labeling.<sup>141</sup> Uniform federal standards

were required to register each year with the FDA. Retail druggist were exempt.

(5) Pharmaceutical manufacturers were required to make their records and files, and their process and control information available to the FDA.

*Id.* The results of the 1962 Drug Amendments have been far-reaching. Wallace, *supra* note 135, at 439. Over 700 prescription drugs have been removed from the market because they failed to meet the requirements of the amendments. *Id.* Furthermore, some 1,500 other drugs had their labels changed to bring them in line with this legislation. *Id.*

137. Wallace, *supra* note 135, at 439.

138. See *supra* note 130 and accompanying text for a discussion of the public demand for safe and effective drugs that led Congress to enact the FDCA.

139. The FDA's competence in drug regulation was set forth by FDA Commissioner Larrick when he informed Congress:

Every time the scientist on our staff allows a drug to come on the market, they have to take the sum total of scientific knowledge that they can muster about the drug, and reach a conclusion as to whether or not the good that the drug will do, the lives it will save or the suffering that it will prevent, outweighs the known side-effects.

HEARINGS ON H.R. 6245, 87TH CONG. 1st Sess. 158 (1962), reprinted in Walsh & Klein, *supra* note 5, at 180. To strengthen its expertise, the FDA's Commissioner, James Goddard, M.D., negotiated a contract with the National Academy of Sciences and its National Research Council in 1966. Wallace, *supra* note 135, at 438. This contract established panels of leading experts in therapeutics to review the effectiveness of prescription drugs. *Id.*

140. See generally, Bazelon, *supra* note 6, at 209-15 (discusses jury's lack of competence to decide scientific matters).

141. The FDCA sets forth a specific provision defining what constitutes a mis-

for drug labeling are essential to provide physicians around the nation with the information necessary to make important treatment decisions.<sup>142</sup> The FDA approves the contents of each package insert to ensure that only the most accurate, scientifically credible information is available to physicians to make these critical judgments.<sup>143</sup> State court decisions, which have the effect of imposing additional warning requirements on drug manufacturers, contravene the FDA's policy of uniform labeling. Indeed, effective and appropriate federal regulation of this field would be impossible if every judge and jury had the coercive power to affect the nature of the labeling.

Nevertheless, state courts ruling against preemption have argued that the more information demanded from the manufacturers regarding risks of drugs the better.<sup>144</sup> This assessment, however, fails

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branded drug. 21 U.S.C. § 352 (1986). A drug label not explicitly in accord with all FDA requirements is considered misbranded. 21 U.S.C. § 352 states in pertinent part: "A drug shall be deemed misbranded- If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon . . . ." *Id.* Thus, a manufacturer has no freedom to deviate from FDA mandated labeling. Furthermore, the FDA alone has the authority to require prescription status for a particular drug. Temin, *supra* note 126, at 95-97. Prescription products require the statement "[f]ederal [l]aw prohibits dispensing without prescription. 21 C.F.R. § 201.100 (1988). These products must be accompanied by a strictly controlled label which contains specific information. 21 C.F.R. §§ 201.100(d) and 201.57 (1988). The FDA's tight control over the labeling of prescriptions clearly reflects its intent to ensure accuracy and uniformity on a national level.

142. The FDA Commissioner articulated the utility of uniform labeling requirements as follows: "The statutory scheme for drug labeling is intended to provide physicians in straightforward and concise terms, the information they need to prescribe a drug under conditions that maximize the drug's effectiveness and minimize its risks." 44 Fed. REG. 37,436 (1979).

143. 21 C.F.R. § 1.21(c) (1988) provides the guidelines that ensure only scientifically credible information is contained in a drug's labeling:

"(c) Paragraph (a) of this section does not:

(1) Permit a statement of differences of opinion with respect to warnings (including contraindications, precautions, adverse reactions, and other information relating to possible product hazards) required in labeling for food, drugs, devices, or cosmetics under the act."

*Id.* The FDA explained this provision as follows:

It is . . . apparent that there are very few statements in prescription drug labeling on which some controversy could not be found within the medical profession. Not infrequently there are several points of view on the same issue. To permit or require statements of conflicting opinion on all these matters would destroy the present usefulness of prescription drug labeling.

39 Fed. REG. 33,232 (1974). In an article written by the Special Assistant to the Director of the Bureau of Drugs, the FDA announced that labeling references must be "substantiated by the material weight of medical opinion". Temple, *supra* note 84, at 1151. In a comment appearing in the Federal Register, the FDA described drug labeling as "an authoritative document which contains only those indications and usages which are based upon substantial evidence."

40 Fed. REG. 15,394 (1975).

144. See, e.g., *Needham v. White Laboratories*, 639 F.2d 394 (7th Cir. 1981) (court held that juries may find warnings inadequate even though in compliance with FDA standards); *Davis v. Wyeth Laboratories*, 399 F.2d 121 (9th Cir. 1968) (court held drug company failed to provide adequate warnings disregarding FDA labeling

to consider the confusion additional labeling requirements bring about.<sup>145</sup> That is, manufacturers attempting to insulate themselves from findings of inadequate labeling will be compelled to include in the package insert any possible risk a drug may impose.<sup>146</sup> The resulting additional warnings will be included even when their relationship to the drug is highly conjectural, thereby adding confusion and diminishing the utility of the labeling.

Furthermore, the inclusion of these additional warnings to a drug's labeling would result in overloading the package insert with irrelevant warnings.<sup>147</sup> Physicians would be literally inundated with superfluous information, providing them with no assistance in making risk-benefit assessments about the drug. The overload of extraneous material may lead physicians to ignore the package insert altogether because a substantial part of what it contains would be misleading and confusing.<sup>148</sup> As a direct result, this phenomenon would severely impede the FDA's interest in rational prescribing based on reliable labeling.

In support of its desire for reliable and uniform labeling, the FDA requires that all statements regarding a drug's safety contain only "clinically relevant information."<sup>149</sup> The FDA's expert scientists consider the sum total of all information known about the drug in making these decisions. In contrast, juries are forced to evaluate conflicting expert testimony without the requisite technical background needed to make accurate assessments. It is, therefore, not in

approval).

145. See generally Twerski, Weinstein, Donaher & Pichler, *supra* note 26, at 514-17 (discusses the self-defeating nature of sensory overload in warnings).

146. Drug manufacturers have a strong monetary incentive to issue warnings that have the best chance of satisfying juries in product liability actions. Cooper, *supra* note 119, at 237.

147. "If every conceivable adverse reaction were included in a drug's labeling, . . . the triviality would dilute the significance of the warning." Dunn v. Lederle, 121 Mich. App. 73, 77, 328 N.W.2d 576, 581 (1982). "Warnings, in order to be effective must be selective . . . the warning process, in order to have impact will have to be carefully selective." *Id.* (quoting Twerski, Weinstein, Donaher & Pichler, *supra* note 26, at 514). Twerski postulates that "he who warns of everything in effect warns of nothing" has gained increasing recognition in drug cases. *Id.* at 517. As stated by the Supreme Court of California in Finn v. G.D. Searle, 35 Cal. 3d 691, 677 P.2d 1147 (1984):

[I]t seems obvious that liability ought not to be imposed for failure to warn based on every piece of information . . . available . . . . Moreover, both common sense and experience suggest that if every report of a possible risk, no matter how speculative, conjectural, or tentative, imposed on a manufacture an affirmative duty to give some warning, a manufacturer would be required to inundate physicians indiscriminately with notice of any and every hint of danger, thereby inevitably diluting the force of any specific warning given.

*Id.* at 697, 677 P.2d at 1153.

148. Finn, 35 Cal. 3d at 697, 677 P.2d at 1153.

149. See *supra* notes 138-39 and accompanying text for discussion of FDA requirements regarding the contents of drug labeling.

the public's interest to allow juries to make these determinations on a case-by-case basis.<sup>150</sup> As such, to preserve Congress' intent of national uniformity, FDA determinations in drug labeling should preempt state court action in the same area.

#### D. Direct Conflict

State court actions in drug product liability create a direct conflict with federal law in two distinct ways. First, courts have extended manufacturers' duty to warn to consumers although FDA regulations permit warnings to physicians only.<sup>151</sup> Second, by holding manufacturers liable for inadequate warnings, courts are imposing duties conflicting with those the FDA requires.<sup>152</sup> These conflicts, in and of themselves, are grounds for finding implied preemptive intent.

As a matter of federal law, a pharmaceutical manufacturer fulfills its duty to warn by adequately informing physicians.<sup>153</sup> Acting as a learned intermediary,<sup>154</sup> the physician assesses the risks and determines the utility of a drug for the patient.<sup>155</sup> A long history of court rulings,<sup>156</sup> as well as the legislative history of the regulations

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150. State-by-state determinations of the adequacy of a drug's labeling would "obviously undermine or overrule the FDA's duty to establish a uniform nationwide system of useful product information as to the drug's effectiveness and risks." *Hurley v. Lederle Laboratories*, 651 F. Supp. 993, 1000 (E.D. Tex. 1986), *rev'd on other grounds*, 851 F.2d 1536 (5th Cir. 1988).

151. See *Stephens v. G.D. Searle & Co.*, 601 F.2d 379 (6th Cir. 1985) (court held the learned intermediary doctrine inapplicable); *Odgers v. Ortho Pharmaceutical Corp.*, 609 F. Supp. 867 (D.C. Mich. 1985) (holding a manufacturer liable for failure to directly warn consumer of risks of prescription drug); *MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass. 131, 475 N.E.2d 65 (1985) (manufacturer of birth control pills owes a direct duty to warn consumers). But see *Seley v. G.D. Searle*, 21 Ohio Op. 3d 121, 423 N.E.2d 831 (1982) (reversing a lower court decision to disregard the learned intermediary doctrine).

152. See *Wooderson v. Ortho Pharmaceutical Corp.*, 235 Kan. 387, 681 P.2d 1038 (1984) (court rejected defendant's contention that FDA determinations should be conclusive); *Feldman v. Lederle Laboratories*, 97 N.J. 429, 479 A.2d 374 (1984) (manufacturer must make labeling revisions without prior FDA approval).

153. 21 U.S.C. § 502(f) (1986) exempts prescription drugs from labeling requirements otherwise necessary for consumer products. A direct reference to the exemption provision came in Federal Security Administrator Oscar Ewing's remarks to the House and Senate subcommittees in which he states: "[T]he warning requirement . . . is unnecessary when there is a doctor's prescription on which the drug is given out." *Hearings on H.R. 3298 Before the House Committee on Interstate and Foreign Commerce*, 82nd Cong. 1st Sess. 20-21 (1951) quoted in, *Pharmaceutical Mfrs. v. Food & Drug Admin.*, 484 F. Supp. 1179, 1185 (D. Del. 1980).

154. See *supra* notes 26-28 and accompanying text for a review of the learned intermediary doctrine.

155. *Id.*

156. See e.g., *Sterling Drug v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966) (introduced the term "learned intermediary"); *Love v. Wolf*, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1964) (antibiotic manufacturer discharged its duty to warn by informing treating physician of drug risks); *Marcus v. Specific Pharmaceuticals*, 77 N.Y.S.2d 508

support this doctrine.<sup>157</sup> Several courts, however, have disregarded this long-standing rule by requiring manufacturers to communicate warnings directly to patients.<sup>158</sup>

Thus far, court decisions that extend the duty to warn to patients have been limited to oral contraceptives and vaccines.<sup>159</sup> However, the courts' reasoning suggests that direct warnings to patients may be required for other drugs as well. This reasoning focuses on tenets of consumerism that are not relevant in prescription drug settings.<sup>160</sup> In the case of prescription drugs, physicians alone have the

(App. Div. 1948) (first case to find physician warnings alone are adequate).

157. See *supra* notes 27-31 and accompanying text for a review of the learned intermediary doctrine.

158. A series of cases involving the polio vaccine brought the first break from the learned intermediary doctrine. Note, *Mass Immunization Cases: Drug Manufacturer's Liability for Failure to Warn*, 29 VAND. L. REV. 28 (1976). The rationale behind these decisions is that in the ordinary case, the physician can make an intelligent decision concerning the risks of a drug. However, where a vaccine is administered without the intervention of a physician, the duty to warn is necessarily extended to the public. *Id.* See *Givens v. Lederle*, 556 F.2d 1341 (5th Cir. 1977) (extended duty to warn to patients receiving polio vaccine); *Reyes v. Wyeth Laboratories*, 498 F.2d 1296 (5th Cir. 1974), *cert. denied*, 419 U.S. 1096 (1975) (manufacturer of vaccines required to warn patients of risks associated with use); *Davis v. Wyeth Laboratories*, 399 F.2d 121 (9th Cir. 1968) (court found manufacturer breached its duty to warn for failing to provide vaccine recipients with warnings of risks). Subsequently, other courts have expanded a manufacturer's duty to warn patients receiving oral contraceptives. See *Stephens v. G.D. Searle & Co.*, 602 F.2d 379 (E.D. Mich. 1985) (rejected learned intermediary doctrine); *Odgers v. Ortho Pharmaceutical Corp.*, 609 F. Supp. 867 (D.C. Mich. 1985) (rejected learned intermediary doctrine); Nevertheless many courts continue to recognize the learned intermediary doctrine. See *Dyer v. Best Pharmacal*, 118 Ariz. 465, 577 P.2d 1084 (1978) (anorexiant); *Stevens v. Parke-Davis & Co.*, 9 Cal. 3d 51, 507 P.2d 653 (1973) (Chloromycetin); *Hamilton v. Hardy*, 37 Colo. App. 375, 549 P.2d 1099 (1976) (oral contraceptives); *Buckner v. Allergan Pharmaceuticals, Inc.*, 400 So.2d 820 (Fla. Dist. Ct. App. 1981) (steroids); *Hawkins v. Richardson-Merrell*, 147 Ga. App. 481, 249 S.E.2d 286 (1978) (sulfa); *Ortho Pharmaceutical Corp. v. Chapman*, 388 N.E.2d 541 (Ind. Ct. App. 1979) (oral contraceptives); *Lingquist v. Ayerst Laboratories, Inc.*, 227 Kan. 308, 607 P.2d 1339 (1980) (anesthetic); *Mulder v. Parke-Davis & Co.*, 288 Minn. 332, 181 N.W.2d 882 (1970) (Chloromycetin); *Hill v. Squibb & Sons*, 181 Mon. 199, 592 P.2d 1383 (1979) (injectable steroids); *Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143 (Mo. 1967) (Aralen); *Calabrese v. Trenton State College*, 162 N.J. Super. 145, 392 A.2d 600 (1980) (rabies vaccine); *Hines v. St. Joseph's Hosp.*, 83 N.M. 763, 527 P.2d 1075 (1973), *cert. denied*, 87 N.M. 111, 529 P.2d 1232 (1974) (whole blood); *Baker v. St. Agnes Hosp.*, 70 A.D.2d 400, 421 N.Y.S.2d 81 (1979) (anticoagulant); *Seley v. G.D. Searle & Co.*, 21 Ohio Op. 3d 121, 423 N.E.2d 831 (1982) (oral contraceptives); *McKee v. Moore*, 648 P.2d 21 (Okla. Sup. Ct. 1982) (interuterine device); *McEwen v. Ewing*, 270 Or. 375, 528 P.2d 522 (1974) (oral contraceptives); *Incollingo v. Ewing*, 444 Pa. 263, 282 A.2d 206 (1971), *rev'd on other grounds*, 491 Pa. Super. 516, 421 A.2d 1027 (1980) (Chloromycetin); *Gravis v. Park-Davis & Co.*, 502 S.W.2d 863 (Tex. Civ. App. 1973) (anesthetic); *Pfizer, Inc. v. Jones*, 221 Va. 681, 272 S.E.2d 43 (1980) (Demerol and Vistaril). Despite this mammoth array of authorities, however, recent cases rejecting the learned intermediary doctrine places the future of the doctrine in doubt.

159. See *supra* note 158 for a list of representative decisions which extend the duty to warn.

160. While all other consumer products make claims about their products that are directed at the public, pharmaceutical manufacturers limit their promotion to physicians. Rheingold, *The Expanding Liability of the Drug Manufacturer to the*

competence necessary to analyze the individual risk variation present for a particular patient using a specific drug.<sup>161</sup> In contrast, patients who are normally unfamiliar with medical matters are likely to be confused by written drug warnings.<sup>162</sup> This confusion could very well lead patients to refuse necessary drug treatment or overlook the most serious safety aspects of the warnings.

It is, therefore, obvious that judicially imposed obligations on manufacturers to directly warn patients are not only practically imprudent, but are also federally preempted. The FDCA specifically provides that warnings for prescription drugs should only be given to physicians. Pursuant to this provision, manufacturers may not utilize direct-to-patient labeling without express permission of the FDA.<sup>163</sup> To comply with state court findings which require such warnings, manufacturers must violate federal law. This type of direct conflict between state and federal law is precisely why the preemption doctrine was developed and should therefore be imposed.

Secondly, a direct conflict between state and federal law exists when a state court finds FDA approved labeling inadequate.<sup>164</sup> The

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*Consumer*, 40 FOOD DRUG COSM. L.J. 135, 135-36 (1985). Moreover, even the physician advertisements are subject to FDA approval. 21 C.F.R. § 202.1 (1988). Therefore, there are no representations made either directly or indirectly to the consumer that have not passed FDA scrutiny. Rheingold, *supra*, at 141.

161. Rheingold, *Products Liability-The Ethical Drug Manufacturer's Liability*, 18 RUTGERS L. REV. 947, 985-86 (1964). This article explains the physician's role as an intervening party who exercises independent judgment in the patient's interest. This factor serves to make patient labeling by the manufacturer unnecessary. In *Terhune v. A.H. Robbins Co.*, 577 P.2d 975, 978 (Wash. 1978) the court described the rational of the learned intermediary doctrine: "It is [the doctor's] duty to inform himself of the qualities of the [drug] he prescribes . . . and to exercise judgment, taking into account his knowledge of the patient as well as the product." *Id.* The entire system of drug distribution is set up to place the responsibility for use on physicians. *Gravis v. Parke-Davis & Co.*, 502 S.W.2d 863, 870 (Tex. Ct. App. 1973).

162. See *In re Certified Question*, 419 Mich. 686, 691, 358 N.W.2d 873, 882 (1984) (Boyle J., dissenting) (patient labeling would frighten patients so they would not take necessary medications). See generally Curran, *Package Inserts for Patients: Informed Consent in the 1980's*, 305 NEW ENG. J. MED. 1564 (1981) (the decision to use a drug is a medical concern, patient involvement is counterproductive).

163. Under the FDCA, patient warnings are under the control of the FDA. Walsh & Klein, *supra* note 5, at 192. The FDA has determined that patient labeling is appropriate for only four types of medications. See 21 C.F.R. § 310.501 (1988) (oral contraceptives); *id.* at § 201.305 (isoproterenol inhalation preparations); *id.* at § 310.515 (estrogens); *id.* at § 310.516 (progestational drugs). Manufacturers may not utilize patient labeling for other drugs without express permission of the FDA. Walsh & Klein, *supra* note 5, at 192.

164. The FDA's intent and policy in the regulation of labeling of drugs is to promote uniformity and to insure a complete and accurate review of the drug's actions. *Hurely v. Lederle Laboratories*, 651 F. Supp. 993, 1000 (E.D. Tex. 1986), *rev'd on other grounds*, 851 F.2d 1536 (5th Cir. 1988). Labeling statements are not permitted unless supported by scientific evidence. *Id.* at 1000. FDA approved language reflects those standards. *Id.* Thus, any statutory or common law determination that FDA approved labeling is insufficient, inaccurate, or requires more documentation creates an irreconcilable conflict with federal regulation. *Id.*

conflict arises because the FDA labeling requirements prescribe precise controls from which the manufacturer is not free to deviate.<sup>165</sup> Therefore, if a manufacturer, in response to a state court ruling, made any change or addition to FDA approved labeling, the result would be a violation of federal law.<sup>166</sup> Consequently, state courts requiring drug labeling alterations make a manufacturers' compliance with federal law impossible. Accordingly, under preemption analysis, these state court actions should be preempted.

The preceding analysis clearly demonstrates that FDA regulations are impliedly preemptive. That is, while the standard for implied preemption is met when any one of the tests have been satisfied, this comment demonstrates that FDA regulations fulfill all four. Therefore, a court considering whether FDA regulations preempt state law should reach the identical conclusion.

### CONCLUSION

Since 1938 Americans have looked to the FDA for assurance of quality in the medicines they take. Pursuant to this task, the FDA has developed the highest level of competence in pharmaceutical investigation in the world. Nevertheless, technically incompetent state court juries are continuing to usurp federal authority by rejecting FDA standards in product liability cases. These state court actions clearly frustrate congressional interest in uniform national labeling and are, thus, contrary to the intent of the supremacy clause. Moreover, if pharmaceutical manufacturers follow court imposed regulations they will surely violate FDA standards and risk revocation of drug licenses. Conversely, if a manufacturer continues to follow FDA labeling mandates, ignoring state law, it runs the risk of increased tort liability for inadequate warnings. The only antidote to this drug regulation quandary is the courts' recognition of federal preemption of state law affecting pharmaceutical labeling.

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165. See *supra* notes 138-39 for a discussion of the FDA's control of the contents of drug labeling.

166. See *supra* note 121 and accompanying text for a review of a pharmaceutical manufacturer's duty to comply with FDA standards.