
Rationalizing Product Liability for Prescription Drugs: Implied Preemption, Federal Common Law, and Other Paths to Uniform Pharmaceutical Safety Standards

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RATIONALIZING PRODUCT LIABILITY FOR PRESCRIPTION DRUGS: IMPLIED PREEMPTION, FEDERAL COMMON LAW, AND OTHER PATHS TO UNIFORM PHARMACEUTICAL SAFETY STANDARDS

*David R. Geiger**
*Mark D. Rosen***

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I. INTRODUCTION

Fairness as well as public policy demand that compliance with the comprehensive federal regulation of prescription drugs be conclusive evidence that pharmaceutical manufacturers have discharged their duty to provide the public with reasonably safe and effective products and appropriate warnings.¹ To subject companies to state tort and contract suits after they have complied with federal requirements is patently unfair. The United States Food and Drug Administration's ("FDA") requirements govern nearly every aspect of the testing,² design,³ manufacture,⁴ labeling⁵ and distribution of prescription drugs,⁶ as a general matter detailing specific duties with respect to which manufacturers are not permitted to deviate. Notwithstanding a pharmaceutical manufacturer's faithful compliance with this detailed

1. See *infra* note 11 and accompanying text (discussing public policy interest in limiting a company's liability when it has complied with federal regulations).

2. 21 U.S.C. § 355(b)(1)(A) (1994).

3. *Id.* § 355(b)(1)(C).

4. *Id.* § 355(b)(1)(D).

5. *Id.* § 355(b)(1)(F).

6. See 21 U.S.C. § 360(a)(1)(1994) (noting that "manufacturing" and "processing," governed by 21 U.S.C. § 355(b)(1)(D), includes distribution).

regulatory scheme, a sympathetic jury asked to judge the faceless “deep pocket” company, in light of an adverse effect suffered by a particular patient, frequently finds, after the fact, that the company should have performed some additional test or included some other warning and therefore finds the manufacturer negligent, or its product defective, under state law.

Allowing retrospective jury nullification of the FDA’s considered regulation on which manufacturers have relied is not only fundamentally unfair but is contrary to public policy.⁷ The FDA’s approval of a product for sale under particular labeling represents a deliberate balancing by the FDA of the public health benefits and risks of the product and constitutes a determination that marketing it under the approved label strikes the optimal balance. Moreover, second-guessing by individual juries subjects manufacturers to the impossible task of tailoring their complex products and product descriptions to fifty-plus different jurisdictions — a task that, in all likelihood, interferes with the provision of such products in interstate commerce. The associated costs — including litigation costs — inevitably are passed on to consumers, making the already costly pharmaceutical more expensive for all and unavailable for some.

The core of the current federal legislative scheme regulating pharmaceutical and medical devices, the Food, Drug, and Cosmetic Act (“FDC Act”),⁸ was enacted in 1938 — years before the explosion of state tort litigation that began in the 1970s. Since it was not an issue at that time, the original FDC Act was silent as to whether states could allow individuals to prevail against companies on state-based tort (or related warranty-based) theories even when a company had complied with federal standards.

Not surprisingly, when Congress completely reworked the medical devices portion of the FDC Act in 1976 when it passed the Medical Devices Amendments (“MDA”),⁹ it included an explicit preemption provision prohibiting states from imposing upon medical device manufacturers any legal requirements that are “different from, or in addition to” those mandated by federal law.¹⁰ The legislative history

7. See *infra* text accompanying note 11.

8. 21 U.S.C. §§ 301-392 (1994).

9. 21 U.S.C. §§ 360c-360k (1994).

10. The relevant section, 21 U.S.C. § 360k(a), provides:

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

explained that the above-mentioned public policy concerns were the basis for the provision.¹¹ Thus, since 1976 there has been virtually no question that manufacturers of so-called "class III" medical devices cannot be held liable under state tort and implied warranty claims if the manufacturers have complied with related federal requirements. Indeed, courts have construed the provision as providing nearly blanket preemption of state law touching on class III medical devices.¹²

However, Congress did not amend the pharmaceutical portion of the FDC Act in 1976. As a result, there remains no explicit Congressional statement as to whether states can impose on pharmaceutical manufacturers, through tort and warranty law, legal requirements that

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

Id.

It is well-established that this provision preempts both state legislative and common law. See *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 16-18 (1st Cir. 1994) (holding that the MDA preempt a plaintiff's state and common law claims; *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 542-43 (3d Cir.), *cert denied*, 115 S. Ct. 429 (1994) (holding that state law tort claims are preempted under the MDA, which prohibit states from establishing or continuing any requirements different from or in addition to federal requirements); *see generally* *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 247 (1959) (awarding damages pursuant to state law is "regulatory" in effect and therefore subject to preemption).

11. See H.R. REP. No. 853, 94th Cong., 2d Sess. 45-46 (1976) ("The Committee recognizes that if a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened.").

12. There is a "consistent line of developing authority" of blanket preemption of tort claims arising from so-called "class III" medical devices which receive pre-market approval from the FDA for sale under particular labeling under the MDA's preemption provision. *Ministry of Health v. Shiley*, 858 F. Supp. 1426, 1429 (C.D. Cal. 1994) (referring to a developing line of cases which holds that state law is preempted under federal law); *see, e.g.*, *King v. Collagen*, 983 F.2d 1130, 1134 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993) (finding preemption and discussing the specific requirements set out by the FDA on Zyderm, a class III device, in regard to labeling, designing, and manufacturing); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1422 n.3 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993) (noting that the class III Product Approval Process ("PMA") process constitutes a specific requirement applicable to a particular device under the Act and finding preemption). At least one recent case has provided a basis for extending preemption to *all* classes of devices. See *Mendes*, 18 F.3d at 17-19 (finding preemption on the basis of FDA good manufacturing practice standards, which are applicable to all medical devices). Courts have gone so far as to find that the MDA preempts claims that companies fraudulently obtained FDA approval by supplying false or misleading information to FDA. See *Reeves v. Acromed Corp.*, 44 F.3d 300, 301 (5th Cir. 1995) (noting the MDA preemption of "a failure to warn" claim against manufacturers of metal bone implants where information on the manufacturer's application to the FDA was inaccurate); *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1329 (3rd Cir. 1995) (holding that the MDA preempt plaintiff's cause of action where defendant made false representations to the FDA to obtain pre-market approval); *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 27-28 (1st Cir. 1995) (discussing the absence of a fraud exception to the preemption provision of the MDA). *But see* *Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1458 (9th Cir. 1995) (interpreting the MDA's preemption provision narrowly).

differ from the FDA's manufacturing, marketing and labeling requirements.

Since Congress did not rule out the possibility that the MDA's preemption provision merely clarified existing law, and given the fact that the same policies discussed in the MDA's legislative history are equally applicable to finding preemption with respect to pharmaceuticals, there is a strong argument that the FDC Act impliedly preempts state laws with respect to pharmaceuticals. After some early cases found implied preemption, however, the vast majority of courts that have subsequently examined the question have decided against implied preemption.¹³ Part II of this Article surveys this case law and identifies recurring flaws in the court opinions. After correcting these notable misconceptions, and showing why the issue of implied preemption should therefore not be viewed as a settled legal question, Part II argues that under a well-considered application of established preemption principles, state law should be impliedly preempted under the FDC Act.

Notwithstanding the strong reasons for implied preemption, it may be difficult to lead some courts to revisit a question they perceive to be settled.¹⁴ Part III, therefore, introduces and analyzes three heretofore unexplored alternatives to preemption that may be capable of accomplishing much the same effect of securing uniform legal duties for manufacturers of pharmaceuticals.

Subsection A of Part III examines the option of imposing federal common law negligence and strict liability standards equivalent to FDA standards in otherwise state law-based product liability claims. Displacing a single element of a state cause of action with a federal standard would be less disruptive of state law than preempting the entire state cause of action. Due to this and other differences between preemption and federal common law, a court that would be unwilling to preempt a state cause of action may very well be willing to modify it under federal common law.¹⁵ Subsection B of Part III explores a second alternative to preemption, under which compliance with FDA standards would be held to satisfy state tort (or contract based) standards as a matter of *state* law. This approach accords with well-settled legal principles codified in the *Restatement (Second) of Torts* as well as

13. See *infra* notes 25-33 and accompanying text.

14. See *infra* notes 28-33.

15. See *infra* note 182.

the most recent draft of the *Restatement (Third) of Torts* and already has been relied upon by the highest courts in several states.¹⁶

Subsection C of Part III examines several possible legislative solutions at both the federal and state levels. Discussed are two possible federal solutions: an explicit preemption provision akin to that found in the Medical Devices Amendments and a compensation system modeled on the National Childhood Vaccination Injury Act ("NCVI Act").¹⁷ Subsection C also surveys several state statutes that limit or altogether eliminate manufacturers' liability where the companies have complied with federal standards.

II. IMPLIED PREEMPTION OF STATE TORT CLAIMS WITH RESPECT TO PRESCRIPTION DRUGS

The section of the FDC Act governing prescription drugs,¹⁸ which largely dates back to 1938, more than thirty years before the tort revolution, does not have an explicit preemption provision. State tort and warranty claims will be preempted under the FDC Act, therefore, only if it can be shown that Congress impliedly intended to preempt such state law actions.

The first subsection will present an overview of the doctrine of implied preemption. Because implied preemption in a particular field is integrally tied to the nature and scope of federal regulation in that field, the second subsection of this part will explore in detail the statutory and regulatory scheme governing pharmaceuticals. The third subsection will point out the flawed reasoning that has been used in the cases that have rejected preemption arguments in the context of prescription drugs. The fourth subsection will articulate the affirmative argument why state law should be found to be preempted by the FDC Act.

A. *The Doctrine of Implied Preemption*

Preemption refers to the wholesale displacement by federal law of state law claims in a particular field of law.¹⁹ Preemption is found

16. See *infra* note 193 (discussing that compliance with FDA regulations establishes compliance with state tort or contract law standards) and note 198 (discussing FDA standards as guidelines for compliance).

17. See Part II.C.1 (discussing two federal legislative solutions to the question of implied preemption).

18. 21 U.S.C. §§ 351-366 (1994).

19. See *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608, 2617 (1992) (indicating that preemption occurs when state law directly conflicts with federal law and federal law is deemed controlling).

where Congress has indicated an intent to preempt.²⁰ Congress' intent may be "explicitly stated in the statute's language or implicitly contained in its structure and purpose."²¹ The source for Congress' preemption power, of course, is the Supremacy Clause of the United States Constitution, Article IV, clause 2, which "invalidates state laws that 'interfere with, or are contrary to' federal law."²² Preemption can apply to state common law, as well as to state statutes and regulations.²³

As stated above, implied preemption is solely a matter of ascertaining whether, as an objective matter, Congress intended to preempt state law.²⁴ Under the case law, implied preemption will be found where one (or more) of three conditions are satisfied. First, preemption will be implied where state law actually conflicts with federal law.²⁵ Second, implied preemption will be found where federal law so thoroughly occupies a legislative field "as to make reasonable the inference that Congress left no room for the States to supplement it."²⁶ Finally, preemption will be implied whenever the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.²⁷

To establish that Congress implicitly intended to preempt state law claims in connection with prescription drugs several presumptions against implied preemption must be overcome. First is the presumption that when Congress does not expressly state its intent, there is a presumption against preemption.²⁸ The presumption is even stronger when state or local regulation of matters related to health and safety is involved.²⁹ Further, courts are more reluctant to infer preemption

20. See *id.* ("The purpose of Congress is the ultimate touchstone of preemption analysis.") (internal quotation omitted).

21. *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977).

22. *Hillsborough County v. Automated Medical Labs.*, 471 U.S. 707, 712 (1985).

23. See *Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 325-26 (1981) (ruling that the interstate commerce clause preempts both Iowa statutes and Iowa common law).

24. See *Cipollone*, 112 S. Ct. at 2617; see also *Jones*, 430 U.S. at 525 (noting that Congress' intent may be inferred from a statute's "structure and purpose").

25. See *Nash v. Florida Indus. Comm'n*, 389 U.S. 235, 239 (1967) (invalidating state unemployment compensation law insofar as it denies benefits to otherwise eligible applicants solely because they file unfair labor practice charges with the NLRB).

26. *Pacific Gas & Elec. Co. v. Energy Resources Conservation & Development Comm'n*, 461 U.S. 190, 204 (1983) (quoting *Fidelity*, 458 U.S. at 153 (1982)) (finding implied preemption under the Home Owner's Loan Act).

27. See *Hines v. Davidowitz*, 312 U.S. 52, 62 (1941) (inferring intent to preempt from the dominance of the federal interest in foreign affairs because "the supremacy of the national power in the general field of foreign affairs . . . is made clear by the Constitution").

28. *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981) (stating that the basic assumption under the Supremacy Clause is that Congress did not intend to displace state law).

29. See *Hillsborough County v. Automated Medical Labs.*, 471 U.S. 707, 715 (1985).

from the comprehensiveness of regulations alone than from the comprehensiveness of statutes.³⁰ Moreover, when preemption by regulation is considered, courts are reluctant to find preemption by federal regulations when the agency does not make very clear an intent to preempt, since agencies normally address problems in a detailed manner.³¹ Finally, the presumption against preemption is even stronger when preemption would leave injured parties without a remedy.³²

The relationship between the three doctrinal bases for finding implied preemption, on the one hand, and the various presumptions against implied preemption, on the other hand, has not been established by the case law. No court opinions have attempted to construct, much less succeeded in constructing, a general analytic framework explaining what types of evidence or factors would be adequate to overcome the presumptions against implied preemption. Instead, courts have tended merely to identify the above-listed tests for finding implied preemption, enumerate the several presumptions against it, and then delphically pronounce a conclusion of no preemption.³³ In the end, implied preemption often seems to be largely a matter of judicial fiat.

B. *The Federal Statutory And Regulatory Framework*

Since the three doctrinal bases for implied preemption turn on the specific characteristics of the statutory and regulatory scheme at issue, it is necessary to explore in some detail the legal regime created by the FDC Act. In addition, because — as discussed below — much of the case law addressing preemption in the prescription drug field deals with a particular subset of such drugs, namely vaccines, it is also necessary to describe the legal regime relating to that subset because prescription drugs, in particular, and vaccines, in general, are not governed by identical statutory schemes. While prescription drugs are

30. *Id.* at 717.

31. *Id.* at 718.

32. See *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (ruling no preemption of state tort claims under the Atomic Energy Act where injured persons would have been left without remedy); *Abbot v. American Cyanamid Co.*, 844 F.2d 1108, 1112 (4th Cir.), *cert. denied*, 488 U.S. 908 (1988) (noting the presumption against preemption in tort recoveries where no federal remedy exists).

33. See, e.g., *Abbot*, 844 F.2d at 1112 (finding no preemption merely on the basis that there are several presumptions against preemption).

regulated solely by the FDC Act,³⁴ vaccines are governed not only by the FDC Act but also the NCVI Act.³⁵

1. *The Food, Drug, and Cosmetic Act*

The FDC Act and regulations thereunder³⁶ govern nearly every aspect of the testing, design, manufacture, labeling and distribution of prescription drugs. It has been estimated that it takes between seven and thirteen years to discover, develop, test, and gain final FDA marketing approval of a new drug, four to six years of which is devoted to clinical research to determine safety and efficacy, pursuant to FDA requirements.³⁷ The Office of Technology Assessment concluded that it takes \$194 million to bring a new drug to market, after taking into account tax deductions for research and development.³⁸

Under the FDC Act, no new drug may even be marketed unless it receives FDA approval.³⁹ The manufacturer initiates FDA review by submitting an Investigational New Drug Application ("IND"), which must contain information about the drug's chemistry, manufacturing, pharmacology, and toxicology on the basis of animal and *in vitro* studies.⁴⁰ Only after the FDA approves the IND may the drug's sponsor then gather the data on clinical safety and efficacy (*i.e.*, safety and

34. Although non-prescription, or "over-the-counter," drugs are also subject to the FDC Act, this Article does not attempt to examine the applicability of preemption to such drugs. Nor does this Article address the applicability of preemption to so-called "grandfathered drugs," that is, drugs marketed prior to the effective date of the FDC Act that were exempted from the statutory definition of "new drug" and corresponding regulatory requirements. See 21 U.S.C. § 321(p)(1) (defining the term "new drug"); see generally J. O'REILLY, FOOD AND DRUG ADMINISTRATION § 13.06 (1991) (discussing grandfathered drugs).

35. See Pub. L. 99-660, 100 Stat. 3755-3784 (1986) (establishing that vaccines are governed by the NCVI Act). For the purposes of the FDC Act, "drugs" are defined in 21 U.S.C. § 321(g)(1) and specifically include "articles intended for use in the . . . prevention of disease in man," e.g., vaccines. 21 U.S.C. § 321(g)(1) (emphasis supplied). The NCVI Act, however, provides a statutory framework applicable only to the vaccines enumerated in 42 U.S.C. § 300aa-14.

36. The FDC Act specifies that the approval must be by the Secretary of Health and Human Services. Under 21 C.F.R. § 5.10(a)(1) (1994), the Secretary's authority under the FDC Act has been delegated to the Commissioner of the FDA. All further references in the text will therefore be to the FDA rather than the Secretary.

37. Paul H. Sunshine, *The Preemptive Scope of the Medical Device Amendments of 1976*, 50 FOOD DRUG L.J. 191, 207-08 (1995) (citing HOUSE COMM. ON SCIENCE, RESEARCH AND TECHNOLOGY, 96th Cong., 2d Sess., REPORT ON THE FOOD AND DRUG ADMINISTRATION'S PROCESS FOR APPROVING NEW DRUGS (Comm. Print 1980)).

38. *Id.* at 208 (citing George Anders, *Vital Statistics: Disputed Cost of Creating a Drug*, WALL ST. J., Nov. 9, 1993, at B1, B5).

39. 21 U.S.C. § 355(a) (1994).

40. See 21 U.S.C. § 355(b)(1) (1994) (listing the required contents of an IND application, necessary for FDA approval of a new drug); 21 C.F.R. § 312.23 (1995) (stating the content requirements for an IND application).

effectiveness in human use) required by the application for marketing approval, the New Drug Application ("NDA").⁴¹

When eventually submitted for approval, the NDA by statute must include detailed reports of all animal studies and clinical testing done with the drug, reports of any adverse reactions, and any other pertinent information from the world-wide scientific literature.⁴² The NDA also must contain "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use,"⁴³ and "specimens of the labeling proposed to be used for such drug."⁴⁴

Moreover, the FDA has promulgated under these statutory provisions voluminous regulations that detail what a drug manufacturer must include in its NDA.⁴⁵ The application must contain all controlled and uncontrolled studies relating to the drug,⁴⁶ "an integrated summary of all available information about the safety of the drug product,"⁴⁷ and generally "[a] description and analysis of any other data or information relevant to an evaluation of the safety and effectiveness of the drug product obtained . . . from any source foreign or domestic."⁴⁸ Most important, the NDA must include "[a]n integrated summary of the benefits and risks of the drug, including a discussion of why the benefits exceed the risks under the conditions stated in the labeling."⁴⁹

Various provisions of the FDC Act and regulations also detail labeling requirements for prescription drugs.⁵⁰ FDA's approval of the labeling is a prerequisite to its approval of the NDA.⁵¹ The general requirements for the labeling of an FDA-regulated drug are that it "contain a summary of the essential scientific information needed for the safe and effective use of the drug,"⁵² "be informative and accurate

41. See 21 C.F.R. § 314.54 (1995) (discussing the requirement of obtaining an approved investigational new drug application prior to submitting an NDA for approval).

42. See 21 U.S.C. § 355(b)(1) (stating that reports of investigations indicating whether a drug is safe for use must be included in the application).

43. *Id.*

44. *Id.*

45. See generally 21 C.F.R. § 314.50 (1995) (listing the content and format requirements of an NDA application).

46. *Id.* § 314.50(d)(5)(ii)-(iii).

47. *Id.* § 314.50(d)(5)(vi)(a).

48. *Id.* § 314.50(d)(5)(iv).

49. *Id.* § 314.50(d)(5)(viii).

50. See generally, 21 U.S.C. § 355(a), (b)(1)(F) (noting FDA labeling requirements); see also 21 C.F.R. § 201.50-201.57 (1994) (listing the labeling requirements for prescription drugs).

51. See 21 U.S.C. § 355(b)(1)(F) (noting that labeling information must be submitted on a NDA).

52. 21 C.F.R. § 201.56(a).

and neither promotional in tone nor false or misleading in any particular,"⁵³ and "be based whenever possible on data derived from human experience."⁵⁴ Moreover, the labeling must address certain specific topics in a specific order, including "Indications and Usage," "Warnings," "Precautions," and "Adverse Reactions."⁵⁵ The language of the label is subject to FDA approval and, once approved, cannot permanently be changed without FDA approval.⁵⁶

Once an NDA is approved, the manufacturer thereafter has a continuing duty to "promptly review *all* adverse drug experience information obtained or otherwise received by the applicant from *any* source, foreign or domestic," and to promptly report such adverse drug experiences to the FDA.⁵⁷ In addition, the manufacturer must submit to the FDA an annual report that includes the current labeling for the drug,⁵⁸ copies of *all* published and unpublished clinical trials of the drug,⁵⁹ and a "summary of significant new information from the previous year that might affect the safety, effectiveness or labeling of the drug product."⁶⁰

53. *Id.* § 201.56(b).

54. *Id.* § 201.56(c).

55. *Id.* § 201.56(d)(1).

56. 21 C.F.R. § 601.12 (1995). Drug manufacturers have a limited right under FDA regulations to implement stronger warnings without awaiting the FDA's approval of the new language, but only where there is new evidence warranting a new or stronger warning. 21 C.F.R. § 314.70(c) (1995). Simultaneously with implementing the new language, however, the company must seek FDA approval of it. *Id.* Further, the company's right to change the label's language lasts only until the FDA acts on the manufacturer's request for approval of the change. *Id.* Thus, as noted in the text, no permanent changes to the label may be made without FDA approval. *Id.*

57. 21 C.F.R. § 314.80(b)-(c) (1995) (emphasis added). An "adverse drug experience" is defined as "any adverse event associated with the use of a drug in humans, *whether or not considered drug related.*" *Id.* § 314.80(a) (emphasis added). Any adverse drug experience that is both "serious" and "unexpected," or shows a significant increase in frequency, must be reported to FDA within 15 working days. *Id.* § 314.80(c)(1)(i)-(ii). Other reactions are to be reported quarterly for the first three years after approval of the NDA and annually thereafter. *Id.* § 314.80(c)(2).

58. 21 C.F.R. § 314.81(b)(2)(iii).

59. *Id.* § 314.80(b)(2)(vi)(a)-(b).

60. *Id.* § 314.81(b)(2)(i). Further, approval of an NDA is subject to withdrawal at all times based upon the current state of medical knowledge. 21 U.S.C. § 355(e). Indeed, the FDA is expressly *required*, "after due notice and opportunity for hearing" to the manufacturer, to withdraw approval of the NDA upon finding that the drug no longer appears to be safe or have substantial evidence of effectiveness under the conditions of use described in the labeling. *Id.* The FDC Act also permits the FDA, in its discretion, to withdraw approval of the drug upon finding that its labeling is false or misleading in any particular and has not been corrected after reasonable notice, or that the manufacturer has repeatedly failed to make required reports. *Id.*

Notably, these detailed requirements are nearly identical to the information required of manufacturers of class III medical devices,⁶¹ a context where federal regulation does, by express legislative provision, preempt state law.

2. *The National Childhood Vaccination Injury Act*

The NCVI Act outlines a dual remedial system for persons who sustain vaccine-related injuries.⁶² The NCVI Act establishes a no-fault fund from which injured persons may recover compensation.⁶³ Additionally, the NCVI Act specifically provides that the traditional state tort remedies are still available with respect to "avoidable" injuries⁶⁴

61. Class III is the category for medical devices the safety of which, by FDA determination, cannot be adequately assured through the combination of so-called general controls applicable to all devices and "special controls" such as performance specifications provided for that general type of device. Class III devices are therefore subject to both a requirement of FDA approval PMA and to post-approval regulation to keep the FDA informed of developing information on the device. See 21 U.S.C. §§ 360c(a)(1)(C) (requiring PMA for any device which cannot be classified as class I or II because of insufficient information and is to be used for the sustaining of human life or presents a potential unreasonable risk of injury). Section 360e(e) requires the Secretary to withdraw approval of an application upon new information about the safety device or upon finding a deficiency in the application. Section 360i(a) requires producers of a device to maintain records and make reports to the Secretary to assure that the device is not altered or misbranded and to assure its safety and effectiveness.

The extensive PMA procedure for a class III device requires that the manufacturer submit to the FDA detailed information on the device's design, components, properties and the principles of its operation; its manufacture, processing, packaging and installation; its performance standards, if any; samples of the device; samples of the proposed labeling; and any other information deemed relevant by the FDA. 21 U.S.C. § 360e; 21 C.F.R. § 814.20. Each PMA application is referred by the FDA to a panel of experts, 21 U.S.C. § 360e(c)(2), and the FDA may either approve the device for sale or return the application for additional information or testing. 21 U.S.C. § 360e(d). Approval is granted if the FDA finds that there is a "reasonable assurance" that the device is "safe and effective . . . with respect to the condition of use prescribed, recommended or suggested in the labeling of the device," "weighing any probable benefit to health from [the use of] the device against any probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2); 21 C.F.R. § 860.7(c)(1).

Once the device has been approved for sale, the manufacturer must maintain certain records and report to the FDA regarding the device, where the manufacturer "becomes aware of information that reasonably suggests" that one of its devices "caused or contributed to a death or serious injury," or malfunctioned in such a way likely to cause the same. 21 U.S.C. § 360i. Manufacturers also are required to report other specified "significant adverse device experiences." *Id.*

62. 42 U.S.C. § 300aa-11-15 (1994).

63. *Id.* Compensation for a vaccine-related injury or death is made from the Vaccine Injury Compensation Trust Fund established under Section 9510 of Title 28. 42 U.S.C. § 300aa-15(i) (1994).

64. See 42 U.S.C. § 300aa-22(b) (providing that "[n]o vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine . . . if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings").

and where a vaccine manufacturer does not comply in all material respects with the requirements under the FDC Act.⁶⁵ In such cases, injured parties may elect either to receive the no-fault compensation or to pursue a state law tort action.⁶⁶

Unlike the portion of the FDC Act governing drugs,⁶⁷ the NCVI Act — which Congress enacted in 1986 after the product liability explosion of the 1970s⁶⁸ — does contain a preemption provision, albeit an unusual one. It states that “[n]o State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part.”⁶⁹ Thus, the NCVI Act and its preemption provision actually operate in precisely the opposite manner as most other preemptive statutes. That is, with respect to those circumstances where a cause of action may exist for the injured vaccine user,⁷⁰ the effect of the NCVI Act’s express preemption provision is to prohibit states from eliminating the applicability of their own tort and contract laws *vis-a-vis* victims of vaccines.⁷¹ In other words, rather than prohibiting state law, the NCVI Act’s preemption provision appears to *require* that state law continue to be applicable to injured vaccine users.⁷²

C. *Limitations of the Case Law Rejecting Implied Preemption of Claims Involving Prescription Drugs*

I. *Overview of the Case Law*

The track record of advocates for implied preemption of state law claims involving prescription drugs at first glance appears to be quite

65. See 42 U.S.C. § 300aa-22(a) (“State law shall apply to a civil action brought for damages for a vaccine-related injury or death.”). An exception provides that there shall be no liability for “unavoidable” injuries if the manufacturer shows that it complied in all materials respects with all requirements under the FDC Act. *Id.* § 300aa-22(b).

66. 42 U.S.C. § 300aa-21.

67. 21 U.S.C. §§ 351-366 (1994).

68. Indeed, the NCVI Act’s legislative history explicitly states that the Act was intended to stem the tide of state tort actions, which were deterring companies from developing and manufacturing vaccines. H.R. REP. NO. 908, 99th Cong., 2d Sess. 4 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6345.

69. 42 U.S.C. § 300aa-22(e).

70. See 42 U.S.C. § 300aa-22(a) (stating that “[e]xcept as [otherwise provided] State law shall apply to a civil action brought for damages for a vaccine-related injury or death”).

71. See, e.g., *Stewart v. International Playtex, Inc.*, 672 F. Supp. 907 (D.S.C. 1987) (ruling that state law that attempts to regulate matters already addressed by the FDA is preempted by regulations promulgated by the FDA).

72. Although beyond the scope of this Article, it is an intriguing question as to whether Congress has the power to require states to retain state laws that are not constitutionally mandated.

weak.⁷³ Only one federal appellate court has ruled that the FDA's regulation of drug labeling preempts state tort liability for failure to warn.⁷⁴ At least two federal district courts have ruled more generally that a variety of state tort and contract claims were preempted under the FDC Act, but both have been subsequently limited or overruled.⁷⁵

It appears that all other courts before which the question has been brought have concluded that state tort and contract claims have *not* been impliedly preempted under the FDC Act.⁷⁶ Four circuits have decided the question, holding that state tort claims are not preempted by the FDC Act.⁷⁷ Numerous lower federal and state courts also have confronted the question and ruled against preemption.⁷⁸ Moreover,

73. See *infra* note 75 (noting federal circuit courts that have overruled district courts rulings of preemption).

74. See *Hurley v. Lederle Labs.*, 863 F.2d 1173, 1179 (5th Cir. 1988) ("It would be patently inconsistent [with the FDC Act] for a state . . . to hold the manufacturer liable for including [the] precise warning [approved by the FDA] when the manufacturer would otherwise be liable for *not* including it.").

Further, in one recent case that addressed preemption in passing, a federal district court held that the FDA's labeling regulations "control the nature of [the company's] duty to warn" and concluded that state law to the contrary would be "preempted." See *Walls v. Armour Pharmaceutical Co.*, 832 F. Supp. 1505, 1511-12 (M.D. Fla. 1993) (rejecting defendant's assertion that court had mistakenly instructed the jury on the basis of federal law and had refused to instruct the jury that only a known or reasonably foreseeable risk triggered a manufacturer's duty to warn, reasoning that the duty to warn was governed by federal labeling requirements, not the common law).

75. See *Hurley*, 863 F.2d at 1173. The *Hurley* Appellate Court overruled the District Court's ruling for preemption claiming that "to date, the great majority of United States District Courts . . . have ruled against preemption." *Id.* at 1176. The court claimed that neither the FDC Act nor the Public Health Services Act explicitly preempts state law and the court should be hesitant to find implied preemption. *Id.*; see also *Abbot v. American Cyanamid*, 844 F.2d 1108 (4th Cir.), *cert. denied*, 488 U.S. 908 (1988) (holding that federal law did not preempt a common-law action for defective design or failure to warn).

76. See *infra* notes 77-80 (discussing the preemption status of federal law).

77. See *Abbot*, 844 F.2d at 1108 (finding no preemption for state defective design or failure to warn claims); *Hurley*, 863 F.2d at 1173 (indicating defective design claims not preempted); *Tobin v. Astra Pharmaceutical Prods., Inc.*, 993 F.2d 528 (6th Cir.), *cert. denied*, 114 S. Ct. 304 (1993) (rejecting the argument that FDA approval preempts State product liability claims based on design defects); *Graham v. Wyeth Labs.*, 906 F.2d 1399 (10th Cir.), *cert. denied*, 498 U.S. 981 (1990) (holding that preemption did not apply).

78. See *e.g.*, *Feldman v. Lederle Labs.*, 479 A.2d 374 (N.J. 1984) (finding that plaintiff who suffered tooth discoloration after taking a tetracycline drug could pursue a state law cause of action against the manufacturer of the drug because state law actions are not preempted by federal regulation of the drug industry); *Jones ex rel. Jones v. Lederle Labs.*, 695 F. Supp. 700 (E.D.N.Y. 1988) (ruling claim of baby that suffered from permanent neurological damage from the administration of the pertussis vaccine was not preempted by federal law); *Foyle ex rel. McMillan v. Lederle Labs.*, 674 F. Supp. 530 (E.D.N.C. 1987) (finding parents action for injuries suffered by child as a result of the DPT vaccine was not preempted by federal law); *Wack v. Lederle Labs.*, 666 F. Supp. 123 (N.D. Ohio 1987) (ruling that products liability suit against manufacturer of DPT vaccine was not impliedly preempted by the Public Health Service Act or the Federal Drug and Cosmetic Act); *MacGillivray v. Lederle Labs.*, 667 F. Supp. 743 (D.N.M.

courts have begun to treat the issue of preemption as if the question is well-settled, merely citing to other courts' opinions without undertaking independent analysis.⁷⁹

2. *Limitations of the Case Law*

Notwithstanding the apparently strong negative case law to date, it still may be possible to convince courts to displace state law via preemption. A considered analysis reveals strong arguments both that permitting state tort law recovery directly conflicts with the policies undergirding the FDC Act, and that the comprehensive FDC Act occupies the field of drug regulation.⁸⁰ Moreover, the recent strong trend in favor of preemption in the closely analogous medical devices area,⁸¹ which admittedly benefits from a more recent statute that includes an express preemption provision, may be helpful in persuading courts to examine the issue in the pharmaceutical context.

Before articulating these arguments more fully, it is useful first to examine more closely why the preemption efforts up to this point have been largely unsuccessful. Answering this question immediately reveals a variety of shortcomings of the seemingly decisive case law.

a. Ignoring the Vaccine/Drug Distinction

A major reason why preemption claims to date have not succeeded is that the first preemption claims were (and indeed the vast majority of all preemption claims litigated to date have been) asserted in the context of vaccines.⁸² Implied preemption is a hopeless straw man

1987) (ruling comprehensive federal regulation did not preempt the strict products liability claim of a child vaccinated with the pertussis vaccine against its manufacturer); *Morris v. Parke, Davis & Co.*, 667 F. Supp. 1332 (C.D. Cal. 1987) (holding products liability suit for damages suffered from the administration of the DPT vaccine was not preempted by federal law); *Knudsen v. Connaught Labs.*, 691 F. Supp. 1346 (M.D. Fla. 1987) (holding that a wrongful death suit against manufacturer of DPT vaccine was not preempted by federal law).

79. See *Tobin*, 993 F.2d at 537-38 (“[T]he great majority of United States district courts which have addressed this issue have ruled against preemption”) (citing *Hurley*, 863 F.2d at 1173).

80. Although not examined further in this Article, state law also may be preempted on the basis of a dominant federal interest. After all, at issue is not state regulation of intra-state medical practice but of manufacturing and marketing activities that are almost always interstate in character, that are heavily regulated under federal law, and with respect to which uniform standards are important. This raises the intriguing question of the appropriate role of state products liability law with respect to nationally marketed goods that are regulated by the federal government.

81. See *infra* note 188 and accompanying text (discussing the trend towards preemption in the medical devices area).

82. See, e.g., *Hurley*, 851 F.2d at 1536 (involving a products liability action against manufacturer of the DPT vaccine after an infant suffered adverse effects to the vaccine); *Abbot v. American Cyanamid*, 844 F.2d 1108 (4th Cir.), cert. denied, 488 U.S. 908 (1988) (involving products liability action against manufacturer of diphtheria-tetanus pertussis vaccine after a child suffered

under the NCVI Act, given the fact that the statute *explicitly* states that state law is *not* preempted with respect to avoidable injuries and where the manufacturer has not complied with FDA standards.⁸³ Courts have cited to this and related statutory language in concluding that state law concerning vaccines has not been preempted.⁸⁴

Courts that subsequently addressed preemption with respect to prescription drugs have ignored the fact that there is no statute parallel to the NCVI Act dealing with drugs that explicitly makes state law applicable under discrete circumstances.⁸⁵ By failing to distinguish drugs from vaccines, courts have simply imported preemption conclusions concerning vaccines into the prescription drug context.⁸⁶

A more appropriate approach for the courts, therefore, would be to distinguish drugs from vaccines on the basis that each is governed by a different statutory scheme. Under this approach, most jurisdictions in fact can be said to have *no* governing law regarding drug preemption, and the few that do have relied on inapposite (*i.e.*, vaccine-related) authority.

b. Inapplicability of Various Presumptions Against Preemption

A second culprit behind the failed preemption claims in the case law is the variety of presumptions against preemption mentioned above. Each of those presumptions has been invoked by courts to deny preemption claims in the pharmaceutical context that were based on strong arguments under the established tests for implied preemption.⁸⁷ For example, in *Abbot v. American Cyanamid Co.*,⁸⁸ the Fourth Circuit alluded to the plausibility of concluding that there has been federal occupation of the field of drug regulation, acknowledging that the "FDA's regulation of prescription drugs and biological products is comprehensive, . . . encompass[ing] the licensing, production,

neurological damage from the vaccine); *Patten v. Lederle Labs.*, 655 F. Supp. 745 (D. Utah 1987) (involving a wrongful death action brought by parents against manufacturer of DPT vaccine which caused their son's death).

83. See 42 U.S.C. § 300aa-22(a) ("Except as [otherwise provided], State law shall apply to a civil action brought for damages for a vaccine-related injury or death.").

84. See, e.g., *Hurley*, 851 F.2d at 154 ("[T]he NCVI Act . . . is relevant as proof that Congress intends no preemption of the state law liability of vaccine manufacturers. The NCVI Act clearly states that state law remedies apply to the manufacturers and sale of vaccines.").

85. See, e.g., *Tobin*, 993 F.2d at 537-538 (holding that FDA approval of nitrodrine hydrochloride did not preempt a state action, based on the holding in *Hurley* dealing with a vaccine).

86. See *id.* (relying solely on a single vaccine case for the proposition that the FDC Act does not preempt state law); *In re Tetracycline Cases*, 747 F. Supp. 543, 548 (W.D. Mo. 1989) ("Preemption does not bar state common law tort actions of failure to warn adequately in a case about antibiotics.").

87. See *infra* notes 88, 93, 101 (addressing cases where courts invoked these presumptions).

88. 844 F.2d 1108 (4th Cir. 1988).

testing, distribution, labeling, review and approval of all drugs and biologicals.”⁸⁹ Nonetheless, continued the *Abbot* court, “[p]reemption does not follow immediately from the comprehensive federal regulation of prescription biological products.”⁹⁰ The Court then enumerated the five above-mentioned presumptions against preemption and simply asserted, without further analysis or elaboration, that Congress had not impliedly preempted state regulation of vaccine manufacture by occupying the field.⁹¹ Other courts have adopted this strategy of justification through mere enumeration.⁹²

There remain two fundamental facts ignored by the case law employing the multiple-presumptions-against-preemption approach. The first is that the presumptions are merely that — presumptions, not irrebuttable conclusions. Mere recitation of the presumptions, therefore, does not answer the question of whether implied preemption should be found. Instead, courts should recognize that under a principled analytical framework certain showings must be adequate to overcome the various presumptions.

Second, at an even more basic level, several of the above presumptions against preemption are simply inapplicable to the pharmaceutical context. Consider first the heavily relied upon presumption that “the regulation of health and safety matters is primarily, and historically, a matter of local concern.”⁹³ This mantra is a holdover from the days before the federal government became a major financier of medical costs through Medicare⁹⁴ and Medicaid⁹⁵. Indeed, the complex federal statutory schemes that govern health matters (such as the Public Health Service Act⁹⁶ and the NCVI Act) and the recent effort to reform health care on a national basis spotlight the powerful *federal* interests present in the regulation of health matters.⁹⁷ The federal interest is particularly strong here, moreover, because what is at issue is not the “local” issue of how a doctor treats a patient but the national question of whether states can burden the introduction of beneficial pharmaceuticals — “our most cost-effective input in supplying the de-

89. *Id.* at 1112.

90. *Id.*

91. *Id.*

92. *See, e.g.,* *Graham v. Wyeth Labs.*, 666 F. Supp. 1483, 1490 (D. Kan. 1987) (observing that “the FDA’s regulations of prescription drugs is indeed far-reaching, if not pervasive[,]” but nonetheless finding no preemption).

93. *Hillsborough County, Fla. v. Automated Medical Labs., Inc.*, 471 U.S. 707, 719 (1985).

94. *See* 42 U.S.C. § 1305.

95. *See id.* § 1396.

96. *Id.* § 215 (1988).

97. *See King v. Collagen Corp.*, 983 F.2d 1130, 1138 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993) (concurring opinion) (“Public health is a valid federal purpose.”).

mand for health"⁹⁸ — into interstate commerce by imposing different obligations on pharmaceutical manufacturers.⁹⁹ Consequently, since health concerns generally are no longer "primarily . . . a matter of local concern," and never were with respect to interstate commerce in prescription drugs, the force of this antiquated presumption against preemption is blunted.¹⁰⁰

Consider next the presumption against finding preemption due merely to the comprehensiveness of regulations as opposed to a statute.¹⁰¹ The fact is that the FDC Act statute *itself* comprehensively regulates drugs, and the FDA's regulations are merely more detailed elaborations of the FDC Act's requirements. For example, the statute specifically mandates that as part of an application for a new drug a company must file:

(A) *full reports of investigations* which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a *full description of the methods used* in, and the facilities and controls used for, the *manufacture*, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (F) specimens of *the labeling proposed to be used* for such drug.¹⁰²

The statute also mandates that all applications include "*adequate tests by all methods reasonably applicable* to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof."¹⁰³ The statute also requires that the drug manufacturer continue to "make such reports to the [FDA], of data relating to clinical experience and other data or information, received . . . by such applicant with respect to such drug, as the [FDA] may by general regulation . . . prescribe" to facilitate a determination whether there may be grounds to withdraw approval of the NDA under § 505(e) of the Act.¹⁰⁴ Similar exhaustive detail is

98. Yale Brozen, *Statements, in DRUGS AND HEALTH: ECONOMIC ISSUE AND POLICY OBJECTIVES* 305 (Robert B. Helms ed. 1981).

99. Cf. H.R. REP. NO. 853, *supra* note 11, at 45 ("The Committee recognizes that if a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened.")

100. Hillsborough County, Fla. v. Automated Medical Labs., Inc., 471 U.S. 707, 719 (1985).

101. See *Abbot v. American Cyanamid*, 844 F.2d 1108, 1112 (4th Cir.), *cert. denied*, 114 S. Ct. 304 (1993) ("Courts are more reluctant to infer preemption from the comprehensiveness of regulations than from the comprehensiveness of statutes.")

102. 21 U.S.C. § 355(b) (emphasis added).

103. *Id.* § 355(d) (emphasis added).

104. *Id.* § 355(k).

employed by the statute in specifying the grounds for refusing applications, approving applications, and withdrawing approval.¹⁰⁵

It is hard to imagine a more detailed statute. It cannot be the case that comprehensiveness for preemption purposes is defeated by the mere fact that a governmental body other than Congress (e.g., courts or administrative agencies) helps apply a statute. Indeed, if this were the case, then *no* statute would ever be found to be comprehensive for the purposes of preemption analysis, for no complex statutory scheme can be wholly self-executing; there always is need for a governmental body aside from the legislature to help specify a statute's concrete application. Other statutory schemes found to occupy a field certainly have been no more detailed than the FDC Act.¹⁰⁶

In any event, the presumption against inferring comprehensiveness from regulations alone is not, by definition, a *general* presumption against preemption, but is only a presumption against finding that Congress intended to occupy the field. Consequently, this presumption is, at the very least, inapplicable to arguments that state law conflicts with federal law.¹⁰⁷

Finally, consider the presumption against finding preemption when doing so would leave injured parties without a remedy. This presumption is inapplicable to the drug context because injured persons *do* have legal recourse.¹⁰⁸ First, injured parties may bring claims against their health providers where the decision to prescribe the drug was medically inappropriate or where the physician failed to obtain the patient's informed consent.¹⁰⁹ Second, in the event that the United

105. See *id.* § 355(d)-(e) (setting out the specific grounds for approval and withdrawal of approval of an application); see also *Abbot*, 844 F.2d at 1112 (detailing FDA requirements for regulating prescription drugs).

106. See, e.g., *Campbell v. Hussey*, 368 U.S. 297, 302 (1961) (holding that the Tobacco Inspection Act, 7 U.S.C. § 511(b), occupies the field of tobacco classification); *Castle v. Hayes Freight Lines*, 348 U.S. 61, 63 (1954) (finding that the Motor Carrier Act, 49 U.S.C. § 306, occupies the field of carrying goods by motor truck in interstate commerce).

107. See *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 248 (1984) (quoting *Florida Line & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963)) (explaining that even "[i]f Congress has not entirely displaced state regulation over the matter in question, state law is still preempted to the extent it actually conflicts with federal law").

108. See *infra* notes 109-111 (discussing cases where persons have recourse).

109. See, e.g., *King v. Ahrens*, 16 F.3d 265 (8th Cir. 1994) (finding the decision to prescribe drugs was inappropriate); *Mary v. Moore*, 424 So. 2d 596 (Ala. 1982) (wrongful death action for inappropriate prescription and treatment of new born baby); *Vandi v. Permanente Medical Group, Inc.*, 9 Cal. Rptr. 2d 463 (Cal. Ct. App. 1992) (finding liability where doctor failed to inform patient of the availability of a C.T. scan); *Lacy v. G. D. Searle & Co.*, 567 A.2d 398 (Del. 1989) (involving claim against a doctor who inserted IUD device too soon after plaintiff had given birth and doctor failed to warn of medical risks); *Kirk v. Michael Reese Hosp. & Medical Ctr.*, 513 N.E.2d 387 (Ill. 1987) (finding liability for failing to warn that the prescribed drug thiazine would diminish patient's physical and mental abilities); *Merlo v. Parisi*, 627 N.E.2d 309

States obtains a criminal judgment against a manufacturer who has failed to meet FDA standards, a court may, as part of any sentence, award restitution to those harmed.¹¹⁰ Lastly, parties may well be permitted to bring actions against the FDA where inadequate supervision of pharmaceutical marketing has deprived a person of life or liberty without due process.¹¹¹

D. Arguments for Implied Preemption of Claims Involving Prescription Drugs

Even if all the aforementioned presumptions were applicable, courts should find these presumptions overcome with respect to state based tort or contract claims involving drugs regulated by the FDC Act. Courts should find implied preemption because an analysis of the comprehensive FDC Act provisions demonstrates that federal law fully occupies the field of prescription drug regulation. Alternatively, state claims should be found preempted because permitting state tort claims, at least when the manufacturer has complied with the regulatory requirements, directly conflicts with the FDC Act.

1. Federal Law Occupies the Field of Drug Regulation

As noted above, courts will find implied preemption where federal law so thoroughly occupies a legislative field "as to make reasonable the inference that Congress left no room for the States to supplement it."¹¹² The federal regulatory scheme governing pharmaceutical products is no less comprehensive than other schemes found to have occupied the legislative field.

As discussed more fully above, the FDC Act and regulations thereunder govern the approval for sale, labeling, manufacture, distribution, and post-approval monitoring of all drugs and vaccines.¹¹³ Companies may not even clinically test new drugs, much less market

(Ill. App. Ct. 1993) (finding doctor liable for failing to properly diagnose condition and inappropriate treatment with antibiotics).

110. 18 U.S.C. § 3663(a)(1) (1994); see also *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 30 (1st Cir. 1995) ("Courts in future criminal proceedings will, or should, be aware that restitution may be the only redress for those harmed by manufacturers [of medical devices] who have failed to comply with the provisions of the MDA.").

111. See *Carlson v. Green*, 446 U.S. 14 (1980) (allowing suit against federal official for deprivation of constitutional rights where no alternative remedy available); *Bivens v. Six Unknown Named Agents of Fed. Bureau of Narcotics*, 403 U.S. 388 (1971) (establishing that victims of a constitutional violation by a federal official have the right to bring an action against the official in federal court even though no statute confers such a right).

112. *Fidelity Fed. Sav. & Loan Ass'n v. De la Cuesta*, 458 U.S. 141, 153 (1982) (quoting *Rice v. Sante Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

113. 21 U.S.C. §§ 351-360 (1994); 21 C.F.R. §§ 211, 310, 600 (1995).

them, without FDA approval.¹¹⁴ Companies are required to submit to the FDA extensive clinical, pharmacological, and toxicological information in the New Drug Application, as well as specimens of the labeling proposed to be used with the drug.¹¹⁵ Only upon determining that the new drug is “safe” and “effective” and that the labeling meets rigorous FDA standards, will the NDA be approved,¹¹⁶ and companies may not make any permanent changes to the labeling without FDA approval.¹¹⁷ Following approval by FDA, companies are subject to stringent requirements to monitor all adverse drug experiences and to submit a detailed annual report to the FDA containing information regarding such adverse reactions and other published and unpublished trials of the drug or vaccine, or other research information that might affect the safety, effectiveness, or labeling of the drug.¹¹⁸ FDA regulations also prescribe voluminous “good manufacturing practice regulations” that govern how companies are to manufacture drugs.¹¹⁹

In short, as one court has noted, the “FDA’s regulation of prescription drugs and biological products is comprehensive, . . . encompass[ing] the licensing, production, testing, distribution, labeling, review and approval of all drugs and biologicals.”¹²⁰ As another court has observed, “[t]he FDA’s regulation of prescription drugs is indeed far-reaching, if not pervasive.”¹²¹

Although courts have not proffered a framework for precisely comparing the level of complexity or comprehensiveness of different statutory schemes for the purpose of ascertaining whether a statute occupies the field under implied preemption doctrine, rough comparisons among statutes may be drawn on the bases of (1) the degree of specificity included in the statute and (2) the extent to which federal regulatory agencies have drafted regulations to oversee the statute’s implementation.

On the basis of these two criteria, federal law governing the drug industry is no less “pervasive” and “complex” than the National Labor Relations Act (“NLRA”), which was found to preempt state law in *Amalgamated Association of Street, Electric, Railway and Motor*

114. 21 U.S.C. § 355(a).

115. 21 U.S.C. § 355; 21 C.F.R. § 314.50 (1995).

116. 21 U.S.C. § 355(b)(1)(A).

117. 21 C.F.R. § 601.12 (1995).

118. *Id.* § 314.80 (1995).

119. *Id.* §§ 210, 211 (1995).

120. *Abbot v. American Cyanamid*, 844 F.2d 1108, 1112 (4th Cir.), *cert. denied*, 114 S. Ct. 304 (1993).

121. *Graham v. Wyeth Labs.*, 666 F. Supp. 1483, 1490 (D. Kan. 1987).

Coach Employees of America v. Lockridge.¹²² Indeed, the FDC Act is, if anything, more complex and comprehensive than the NLRA, both in terms of the specificity of the statute and the detail provided by applicable regulations.¹²³ The FDC Act is also more comprehensive on the basis of these criteria than the Federal Tobacco Inspection Act,¹²⁴ which was found to occupy the field of tobacco classification and inspection in *Campbell v. Hussey*,¹²⁵ and the Motor Carrier Act,¹²⁶ found to occupy of the field of transportation of goods by trucks in interstate commerce in *Castle v. Hayes Freight Lines*.¹²⁷

By virtue of the specificity and comprehensiveness of the FDC Act's regulation of prescription drugs, courts should find that state law touching on pharmaceuticals, in any respect, or at least in respect of their safety or efficacy, is preempted under the FDC Act. Accordingly, state tort law requirements concerning prescription drugs, which clearly and directly pertain to safety, should be held completely preempted.

2. State Tort Law Conflicts With the Requirements of the FDC Act

State law conflicts with federal law for purposes of implied preemption when either (1) there is a direct conflict such that compliance with both federal and state law is impossible or (2) state law stands as an obstacle to the accomplishment of the full purposes of Congress.¹²⁸ Under a careful analysis, state tort claims involving prescription drugs are preempted under the FDC Act because they both directly conflict with the federal regulatory scheme and because they stand as an obstacle to the realization of Congress' goals in enacting the FDC Act.¹²⁹

a. Direct Conflict

FDA decisions to allow a drug to be marketed under a specific label reflect a complex cost-benefit calculus designed to maximize public health and welfare. The FDA deliberately strikes a balance in its marketing and labeling decisions between the benefits of a drug for pa-

122. 403 U.S. 274, 296 (1971).

123. As a rough measure of the FDC Act's relative complexity, it should be observed that whereas regulations implementing that act exhaust more than 3,000 pages in the Code of Federal Regulations. By comparison, the regulations governing the NLRA occupy fewer than 110 pages.

124. 7 U.S.C. § 511 (1994).

125. See 368 U.S. 298, 302 (1961) (holding that the Tobacco Inspection Act occupies the field of tobacco classification).

126. 49 U.S.C. § 306 (1988).

127. See 348 U.S. 61, 63 (1954) (finding that the Motor Carrier Act, 49 U.S.C. § 306, occupies the field of transporting goods by motor truck in interstate commerce).

128. *Hillsborough County v. Automated Medical Labs.*, 471 U.S. 707, 713 (1985).

129. See *supra* notes 73-79 and accompanying text (discussing federal preemption).

tients in need of medical therapy and the inevitable risks of adverse effects in a certain number of those who will use it. FDA approval of a drug and its labeling signify the FDA's determination that the optimal public health benefit will be achieved by the availability of the drug and its use in accordance with the labeling.¹³⁰

State tort claims, on the other hand, whether premised on strict liability, negligence, or breach of warranty, are predicated on a challenge to the correctness of the FDA's decisions and as such directly conflict with the FDA's determination as to the optimal way to protect public health. Indeed, it is physically impossible for manufacturers to comply with both the FDC Act and state tort law when the former requires that a drug be marketed and labeled as approved by the FDA and the latter requires that it not be.

First, consider state tort actions for defective "design" (to the extent these might be recognized under state law as to prescription drugs).¹³¹ As just noted, the federal regulatory scheme is aimed at ensuring the optimal availability of appropriate drugs.¹³² Consistent with this, the FDA only permits new drugs to be marketed when it has determined that the drug is "safe" and "effective."¹³³ A state law defective design claim, however, is a determination that a given pharmaceutical should *not* have been marketed as designed.¹³⁴

As the Supreme Court has recognized, "state regulation can be as effectively exerted through an award of damages as through some form of preventive relief. *The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy.*"¹³⁵ As such, state law defective design claims are

130. See 21 C.F.R. § 314.50(d)(5)(viii) (requiring manufacturers to provide FDA a "summary of the benefits and risks of the drug, including a discussion of why the benefits exceed the risks" as part of the NDA); see also *United States v. Rutherford*, 442 U.S. 544, 555 (1979) (noting that the FDA "generally considers a drug safe when the expected therapeutic gain justifies the risk entailed by its use"); see generally Richard M. Cooper, *Drug Labeling and Products Liability: The Role of the Food and Drug Administration*, 41 *FOOD DRUG COSM. L.J.* 233, 237-38 (1986) (explaining that the FDA has an interest in avoiding "information overload" and encouraging "rational prescribing," which requires that the "risks and benefits of each particular drug be presented fairly so that they can be compared by physicians with those of alternative therapies").

131. See *Sprague v. Upjohn Co.*, Civ. A. No. 94-40035-NM6, 1995 WL 376934 (D. Mass. May 10, 1995) (dismissing negligent design claim because the drug had "only one possible formulation" and consequently could not have been alternatively designed).

132. See *supra* note 130 (discussing the FDA's risk/benefit analysis).

133. 21 U.S.C. § 355(b)(1)(A) (1994).

134. See *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1273-74 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974) (noting a product is defectively designed when it "so dangerous that a reasonable man would not sell the product if he knew the risk involved").

135. *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608, 2620 (1992) (quoting *San Diego Bldg. Trades Council v. Garman*, 359 U.S. 236, 247 (1959)) (emphasis added).

regulatory in effect and have the effect of influencing the conduct of manufacturers to market a product different from that approved by the FDA or to remove the product from the market. As the First Circuit has said in the closely related context of medical devices, “[i]t is clear that appellant’s [tort] claim would impose requirements . . . related to safety and effectiveness Appellant’s claim would force us to determine that [the product] is unsafe and dangerous, *in opposition to the contrary determination made by the FDA . . .*”¹³⁶ Consequently, defective design claims directly conflict with the FDA’s determination that an approved drug *is* safe and effective, and seek to realize policies different from those of the FDA.¹³⁷

Consider next the FDA’s labeling requirements. As discussed above, the FDA has the final say on what information is included in a drug’s labeling, including what associated adverse effects are reported and how the reporting is phrased.¹³⁸ The FDA has stated clearly that its labeling decisions reflect conscious policy choices not only about what information should be included in drug labels, but also what information should *not* be included.¹³⁹ Enough information must be given “for the safe and effective use of the drug,”¹⁴⁰ but excessive warnings should not be given lest there be “information overload” or over-deterrence of the use of the medication.¹⁴¹ Thus, drug labels are intended to provide “only a summary of essential scientific information [so that they are] as concise and clear as possible” and are “not intended to be a dispositive treatise of all possible data and information about a drug.”¹⁴² Also, the FDA allows “labeling statements with respect to safety only if they are supported by scientific evidence.”¹⁴³ Labeling should only warn of “[k]nown hazards and not theoretical possibilities,”¹⁴⁴ and warnings may not include “statement[s] of differences of opinion.”¹⁴⁵

136. King v. Collagen, 983 F.2d 1130, 1135 (1st Cir. 1993) (emphasis added).

137. The state policy behind defective design claims of protecting consumers by imposing strict tort liability on manufacturers’ products also conflicts with the FDA policy of ensuring that safe and effective drugs are readily available to consumers by not unduly burdening the development and marketing of such drugs.

138. See *supra* notes 114-19 and accompanying text (discussing labeling requirements).

139. See *infra* notes 144-48 and accompanying text (discussing labeling guidelines).

140. 21 C.F.R. § 201.56(a) (1994).

141. See Cooper, *supra* note 130, at 237-38.

142. 44 Fed. Reg. 37,440-41 (1979) (emphasis added).

143. 44 Fed. Reg. 37,441 (1979).

144. 21 C.F.R. § 201.57(d) (1995).

145. 21 C.F.R. § 1.21(c)(1) (1995).

State tort actions for failure to warn, however, are bottomed on the conclusion that the FDA-approved label is inadequate.¹⁴⁶ Given the regulatory consequences of state tort claims,¹⁴⁷ a failure-to-warn claim is aimed has the effect of encouraging companies to employ a different label than what the FDA has approved (generally, to include more warnings). As a result, state law failure-to-warn claims stand in direct conflict with the FDA's approval of a label.¹⁴⁸

Indeed, state law failure-to-warn claims relating to pharmaceuticals are nearly identical to the state law attempts to regulate tobacco labeling, which the Supreme Court held to be preempted in *Campbell v. Hussey*.¹⁴⁹ That case involved The Federal Tobacco Inspection Act, which provides standards for the classification and inspection of tobacco.¹⁵⁰ The State of Georgia passed a law requiring that one type of tobacco grown in Georgia, Florida or Alabama be labeled with a white tag.¹⁵¹ The Court rejected the claim that "labeling it by its geographical origin *merely supplements the federal regulation and does not conflict with it*," and held that the state law was preempted.¹⁵² Similarly, state failure-to-warn claims do not merely seek to supplement, but would directly conflict with, the labeling requirements set by the FDC Act and the decisions of the FDA under the act.

This conflict between state failure-to-warn claims and FDA labeling requirements is perhaps most acutely illustrated by instances, well known to many pharmaceutical manufacturers, where the FDA has

146. See, e.g., *Seley v. G.D. Searle & Co.*, 423 N.E. 2d 831, 836 (Ohio 1981) (finding that a drug may be considered "defective" and unreasonably dangerous if it fails to provide adequate warning of all inherent potential adverse reactions); see generally Note, *A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals*, 103 HARV. L. REV. 773, 788-789 (1990) (discussing that tort liability, undermining FDA standards and frustrating FDA objectives, are "particularly evident in cases premised on warning inadequacy").

147. See *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608, 2620 (1992) (finding that state regulation is effective through awarding damages or preventive relief).

148. 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 . . . where compliance with both federal and state regulations is a physical impossibility for one engaged in interstate commerce."); *Farmers Educ. & Coop. Union v. WDAY*, 360 U.S. 525, 534-35 (1959) (finding implied preemption of state defamation law under Section 315(a) of the Federal Communications Act, which required radio licensees to allow candidates for office "equal opportunity" access without the "power of censorship," because allowing state law defamation actions against the licensees would "sanction the unconscionable result of permitting civil and perhaps criminal liability to be imposed for the very conduct the statute demands of the licensee"); see also *Hurley v. Lederle Labs.*, 863 F.2d 1173, 1179 (5th Cir. 1988) ("It would be patently inconsistent for a state to hold the manufacturer liable for including [the] precise warning [approved by the FDA] when the manufacturer would otherwise be liable for *not* including it.") (emphasis added).

149. 368 U.S. 298, 302 (1961).

150. *Id.*

151. *Id.*

152. 368 U.S. at 300-01 (emphasis added).

expressly rejected stronger warnings proposed by the manufacturer itself — on the ground, for example, that the stronger warning is not scientifically supported, or would over-deter the drug's use — and the manufacturer has subsequently been faced with a lawsuit under a state law failure-to-warn theory for not employing that very warning. Such cases exemplify the fact that obeying both the FDA's requirements and state law labeling requirements is a physical impossibility, and that state tort suits for failure to warn or inadequate warnings must be held to be impliedly preempted.¹⁵³

b. Obstacles to Accomplishing Congress' Intent Behind the FDC Act

Even in the absence of a direct conflict between state and federal laws, state law that has the effect of discouraging conduct that federal law seeks to encourage also conflicts with federal law and is subject to implied preemption.¹⁵⁴ State tort law concerning prescription drugs should be held to be preempted under this principle as well.

As discussed above, the aim of the FDC Act is to maximize the health benefits of prescription drugs while minimizing the attendant risks.¹⁵⁵ In coming to its determination as to what label is sufficient, for example, the FDA balances the benefits of full disclosure against the risk that too much disclosure or overemphasis of adverse effects will lead to information overload on the part of the drug prescriber or may in fact over-deter drug use.¹⁵⁶ Similarly, FDA approval of the marketing of a drug (i.e., its NDA) indicates that, after weighing these complex factors, the FDA has determined that making the drug available will bring the optimal health benefit to society.¹⁵⁷

Against the background of FDA approval of a drug, state tort law recoveries directly conflict with the federal goal of ensuring prompt and affordable availability of reasonably safe drugs. Conceivably, the prospect of tort liability could well lead manufacturers to delay plac-

153. See *Hillsborough County v. Automated Medical Labs.*, 471 U.S. 707, 713 (1985).

154. See *Nash v. Florida Indus. Comm'n*, 389 U.S. 235, 239 (1967) (invalidating a state unemployment compensation law insofar as it denied benefits to otherwise eligible applicants solely because they had filed unfair labor practice charge with the NLRB on the basis that such law discouraged applicants from exercising their rights under the NLRB).

155. See *supra* note 130 and accompanying text.

156. See 44 Fed. Reg. 37,440-41 (1979) (emphasizing that drug labeling is intended to provide "only a summary of essential scientific information" and is "not intended to be a dispositive treatise of all possible data and information about a drug"); see generally Cooper, *supra* note 130, at 237-38 (explaining the FDA's regulatory objective that the risks and benefits be presented fairly while avoiding irrational decisions based on over-dramatization of the risks).

157. See *United States v. Rutherford*, 442 U.S. at 544, 555 (discussing the FDA's balancing between expected therapeutic gain and the risk entailed by the drug's use).

ing new products on the market even after receiving FDA approval in order to do additional testing, thereby delaying the introduction of new drugs beneficial to the public.¹⁵⁸ Further, the added expense of insuring new drugs against product liability claims could cause the cost of medication to increase to the extent that it would no longer be affordable to consumers.¹⁵⁹

Similarly, manufacturers in some instances may be led to stop producing valuable FDA-approved drugs because of the costs associated with state law-based product liability suits or the inability to secure adequate insurance.¹⁶⁰ Indeed, several FDA-approved drugs have been discontinued due to the costs of tort litigation.¹⁶¹ Additionally, fears of liability may inhibit the development of drugs in the first instance by skewing research and development incentives away from fields that contain high background risks, such as pregnancy.¹⁶²

For all these reasons, state tort law should be preempted because it may well discourage the development or marketing of beneficial drugs. The possibility of deterring development is contrary to the FDC Act's fundamental goal of making such drugs available.¹⁶³

III. THREE POSSIBLE ALTERNATIVES TO IMPLIED PREEMPTION

In the event that courts incorrectly view the inapplicability of implied preemption to prescription drug lawsuits as settled law, and re-

158. See *Brown v. Superior Court*, 751 P.2d 470, 479-80 (Cal. 1988) (determining that "[p]ublic policy favors the development and marketing of beneficial new drugs, even though some risks [are present] . . . because drugs can save lives and reduce pain and suffering").

159. See *id.* (determining that strict liability and costly insurance are likely to have a negative impact on research and development of new drugs by manufacturers and the affordability of those drugs actually marketed).

160. See *id.* (citing several potentially useful drugs that were withdrawn from the market or whose availability was severely curtailed because of tort liability); see also Note, *supra* note 146, at 774 (documenting that manufacturers removed the FDA-approved drugs Oculinum and Bendectin from the market due to tort lawsuits).

161. See Thomas Scarlett, *The Relationship Among Adverse Drug Reaction Reporting, Drug Labeling, Product Liability, and Federal Preemption*, 46 FOOD DRUG COSM. L.J. 31, 38 n.17 (1991) (noting that large product liability awards caused the discontinuation of specific products such as Bendectin and the CU-7 intrauterine device even though the manufacturer complied with FDA marketing regulations); Note, *supra* note 146, at 774 (documenting that manufacturers removed Oculinum and Bendectin, FDA-approved drugs, from the market due to tort liability).

162. See Note, *supra* note 146, at 775 (arguing that the state tort liability system undermines the availability of pharmaceuticals due to the fear of excessive liability and uninsurability).

163. See *Nash v. Florida Indus. Comm'n*, 389 U.S. 235, 239 (1967) (concluding that a state law which frustrates the purpose of federal legislation or impairs the efficiency of federal agencies cannot stand); *Grundberg v. Upjohn Co.*, 813 P.2d 89, 93 (Utah 1991) (noting problems of "delayed availability of needed drugs and imposition of the costs of research, development and marketing of new products beyond that which manufacturers, especially small manufacturers, might be willing to risk").

fuse to revisit and correct that law, there are at least three alternatives to preemption that can accomplish many of its desirable public policy objectives. These largely unchartered alternatives, two judicial and one legislative, are discussed below. Subsection A of this part will explore the possibility of imposing federal common law negligence and strict liability standards equivalent to FDC Act standards in otherwise state law-based product liability claims. Subsection B will examine the possibility of adopting FDC Act requirements as the standard for pharmaceutical manufacturers' duties as a matter of *state* law. Subsection C will briefly discuss several federal and state legislative options for achieving much the same public policy objectives.

A. Federal Common Law

Preemption is not the only doctrine by which federal law may displace state law. An alternative that may possess certain advantages over preemption and that, to date, does not appear to have been employed in the drug or vaccine context is to seek the creation and application of federal common law.

Under this approach, a federal common law of product liability providing uniform standards of behavior for the pharmaceutical industry should be recognized — with the standards supplied by the FDC Act and the FDA's regulations thereunder. By virtue of the Supremacy Clause, the standard would be substituted for any definition of the manufacturers' duties under state law. After an overview of the doctrine of federal common law generally in the first subsection below, the second subsection will explain the appropriateness of employing a uniform federal common law rule with respect to tort claims in the pharmaceutical context.

1. Overview of Federal Common Law

Federal common law, of course, refers to federal law that is created by judges. While *Erie Railroad Company v. Tompkins*¹⁶⁴ famously declared the demise of "federal *general* common law," federal common law to implement *particular federal statutes* still flourishes.¹⁶⁵

For example, in the case of *Textile Workers Union v. Lincoln Mills*,¹⁶⁶ a union brought an action in district court seeking to force an employer to arbitrate in accordance with the terms of the collective bargaining agreement negotiated in accordance with the Labor Man-

164. 304 U.S. 64, 82-83 (1938).

165. Henry J. Friendly, *In Praise of Erie—And of the New Federal Common Law*, 39 N.Y.U. L. REV. 383, 421 (referring to continued existence of specialized "federal common law").

166. 353 U.S. 448 (1957).

agement Relations Act ("LMR Act"). The Supreme Court rejected the state's general common law rule against enforcement of arbitration agreements and substituted a federal common law rule that arbitration clauses in contracts negotiated pursuant to the LMR Act *would* be enforceable, citing to the LMR Act's general grant of jurisdiction to the federal district courts as the sole source for its power to do so.¹⁶⁷ Although the LMR Act was silent with respect to arbitration, the Court reasoned that one of the Act's purposes was to avoid strikes, and that arbitration was the *quid pro quo* for the Union's promise not to strike under the collective bargaining agreement. Consequently, the policy behind the Act could be realized only by employing a federal common law rule upholding arbitration clauses in agreements within the scope of the LMR Act.¹⁶⁸ Federal common law displacing general common law also has been employed to implement many other federal statutes, including the Federal Communications Act,¹⁶⁹ the Lanham Act,¹⁷⁰ the Interstate Commerce Act,¹⁷¹ the Sherman Act,¹⁷² the Federal Water Pollution Control Act,¹⁷³ and the federal securities acts,¹⁷⁴ to name but a few.

Importantly, in contrast to pre-*Erie* federal common law, which was applicable only in federal courts (thus causing the problem of two inconsistent legal regimes, federal and state), contemporary federal common law is binding on states as well. As such, federal common law is uniform and binding in *every* judicial forum.¹⁷⁵ And, as has

167. *Id.* at 456.

168. *See id.* at 455 ("The substantive law to be applied under [the LMR Act] is federal law which the courts must fashion from the *policy* of our national labor laws.") (emphasis added).

169. *See Farmers Educ. & Coop. Union v. WDAY*, 360 U.S. 525, 531 (1959) (creating immunity from defamation as a matter of federal common law).

170. *See Huber Baking Co. v. Stroehmann Bros. Co.*, 252 F.2d 945, 952-53 (2d Cir.), *cert. denied*, 358 U.S. 829 (1958) (rejecting common law requirement of affixation and use for acquisition of a trademark and creating uniform federal rule for acquisition of a "collective mark" under the Lanham Act).

171. *See Francis v. Southern Pac. Co.*, 333 U.S. 445, 450 (1978) (federal common law overrides state common law affecting interstate carriers).

172. *See Sola Elec. Co. v. Jefferson Elec. Co.*, 317 U.S. 173, 176 (1942) (holding that whether a patent licensee is estopped to challenge a price-fixing clause in the license agreement under the Sherman Act is a matter of federal common law and that state law governing estoppel "must yield").

173. *See Illinois v. Milwaukee*, 406 U.S. 91 (1972) (law governing abatement of public nuisance is governed by federal common law).

174. *See, e.g., Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 737 (1975) (noting the federal common law development of the doctrine of "deceptive and manipulative" practices under section 10(b) of the Securities and Exchange Act of 1934).

175. *See Friendly, supra* note 165, at 405 ("By leaving to the states what ought be left to them, *Erie* led to the emergence of a federal decisional law in areas of national concern that is truly uniform because, under the supremacy clause, it is binding in every forum . . .").

been adverted to above, and as will be discussed below, it is precisely this type of uniformity that is so important in the field of prescription drugs.¹⁷⁶

As shown by the large number of cases where federal common law has displaced state common law for purposes of implementing a particular statute, courts appear somewhat more willing to employ federal common law than implied preemption. Courts' greater willingness to employ federal common law may be attributable to the fact that, in contrast to preemption, federal common law is not dependent solely on locating Congress' "intent" but is premised upon the practical necessity of filling the interstices left by Congressional enactments so that the statutory scheme may be effectuated.¹⁷⁷ Consistent with the fact that federal common law is not so tightly bound to the tether of Congress' "intent," courts often textually justify their development of federal common law solely on the basis of statutory language granting them jurisdiction in a particular field — even in the absence of substantive statutory provisions relating to the field at issue in the litigation.¹⁷⁸

Greater willingness to apply federal common law than preemption also may be due to the fact that federal common law is arguably less disruptive of state law than is preemption. Whereas preemption generally obliterates an entire state claim, federal common law generally displaces only a single *element* of the claim.¹⁷⁹

176. See *infra* note 199 and accompanying text (discussing the importance of uniform prescription drug laws).

177. See *Textile Workers Union v. Lincoln Mills*, 353 U.S. 448, 456 (1957) ("We conclude that the substantive law to apply . . . under [the statute] is federal law which the courts must fashion from the *policy* of our national labor laws.") (emphasis added); *D'Oench, Duhme & Co. v. FDIC*, 315 U.S. 447, 470 (1942) (Jackson, J., concurring) ("Were we bereft of the common law, our federal system would be impotent. This follows from the recognized futility of attempting all-complete statutory codes."); Paul J. Mishkin, *The Variousness of "Federal Law,"* 105 U. PA. L. REV. 797, 800 (1957) ("[E]ffective Constitutionalism requires recognition of power in the federal courts to declare as a matter of common law or 'judicial legislation', rules which may be necessary to fill interstitially or otherwise effectuate the *statutory patterns* enacted in the large by Congress.") (emphasis added); 19 CHARLES A. WRIGHT, et. al., *FEDERAL PRACTICE AND PROCEDURE* § 4514, at 220 (noting that "[u]sually, federal common law is exercised only when Congress has not spoken to an issue").

178. See *Lincoln Mills*, 353 U.S. at 456 (relying solely on a general jurisdictional grant as the source for its federal common law rule); see also *Texas v. New York*, 397 U.S. 674 (1965) (relying on jurisdictional grant to create federal common law regarding relations between states).

179. See e.g., *Sola Elec. Co. v. Jefferson Elec. Co.*, 317 U.S. 173 (1942) (addressing whether defendant may assert defense of invalid patent when sued for royalties); *Deitrick v. Greaney*, 309 U.S. 190, 201 (1940) (discussing whether party may raise defense of illegality against suit to compel payment of a promissory note under the National Bank Act is a question of federal common law); *Lincoln Mills*, 353 U.S. at 458 (displacing defense that agreements to arbitrate are unenforceable while not eliminating state contract law generally).

In short, whereas preemption is a doctrine focused on identifying Congress' intent, federal common law is primarily connected to what, as a practical matter, is necessary to implement a given federal statutory scheme. Moreover, federal common law only operates to the minimum extent necessary to effectuate the federal purpose.

2. *Federal Common Law's Application To Prescription Drugs*

In the case of product liability claims involving prescription drugs, rather than arguing that the FDC Act preempts all state tort actions, the proponent of federal common law need only point to the FDC Act's grant of jurisdiction to the federal district courts and the FDC Act's provisions concerning the design and labeling of prescription drugs as sources for generating federal common law.¹⁸⁰ The applicable substantive law would then have to be formulated from the policy of our federal drug laws.¹⁸¹ Substituting a uniform tort standard based on the federal statutes and regulations is necessary to realize the objectives underlying the FDC Act explored in greater detail above, for only a uniform FDC Act-based standard can avoid the danger of inhibiting the optimal availability of pharmaceuticals that would be caused by permitting differing state standards to coexist with the FDC Act standards.¹⁸²

In contrast to the result under preemption doctrine, state negligence and strict liability actions would *not* be wholly displaced under a federal common law approach. Compliance with federal standards, however, would satisfy a company's duty of care under negligence actions relating to the "design" of a drug and would be conclusive evi-

180. See 21 U.S.C. 334(a)(1) (1994) (providing that the manufacturer of "[a]ny . . . drug . . . that is . . . misbranded . . . or which may not . . . be introduced into interstate commerce, shall be liable to be proceeded against . . . in any district court of the United States"). Reliance on the jurisdictional grant to deploy federal common law to effectuate the policies of a statute is distinct from the legal question whether a statute provides a private right of action.

181. See, e.g., *Lincoln Mills*, 353 U.S. at 456 (asserting that the policy of the Labor Management Relations Act is best effectuated by enforcing arbitration clauses in collective bargaining agreements under federal, rather than state law). Indeed, the reasons for creating federal common law are even more compelling under the FDC Act than under the LMR Act in *Lincoln Mills*. After all, whereas the LMR Act was silent with respect to arbitration clauses, the subject of federal common law in that case, the FDC Act explicitly regulates design, manufacturing, and labeling of prescription drugs.

182. Cf. *Farmers Educ. & Coop. Union v. WDAY*, 360 U.S. 525, 531 (1959) (creating federal common law immunity to defamation suits in order to further statutory purpose); see also Leslie A. Rubin, *Confronting a New Obstacle to Reproductive Choice: Encouraging the Development of RU-486 Through Reform Liability Law*, 18 N.Y.U. REV. L. & SOC. CHANGE 131 (1990/91) (arguing that Senator Kasten's products liability bill then in Congress would resolve the uncertainties of varying state standards by introducing uniform products liability standards to promote balance and predictability).

dence that the design is not unreasonably dangerous under a strict liability claim.¹⁸³ Similarly, obeying the FDA's labeling requirements would be conclusive evidence that an adequate warning was provided.¹⁸⁴

The reasonableness of the federal common law approach outlined above is well illustrated by the fact that it is virtually identical to the approach taken to state tort law in the National Childhood Vaccine Injury Act.¹⁸⁵ In the NCVI Act, Congress gave access to state tort law claims to those injured by vaccines.¹⁸⁶ However, Congress federalized one element of the tort claim, providing in effect that compliance with FDA regulations generates an un rebuttable presumption of non-liability with respect to "unavoidable" side effects.¹⁸⁷ Federal common law operates the same way: state tort claims survive, but a single element of the claim is displaced by federal law.

Courts need not fear that by adopting federal common law they would be embracing an approach only semantically different from preemption, for there are real differences between federal common law and preemption (at least as applied by the majority of courts) that justify the different doctrinal frameworks employed by each. Under a federal common law approach, for example, companies that commit fraud in obtaining FDA approval could be held liable for state tort law actions. This stands in stark contrast to the line of medical device cases holding that because the Medical Device Amendments preempt state tort law, injured persons have no recourse to state law even where manufacturers have committed a fraud on the FDA by supply-

183. See *Ministry of Health v. Shiley, Inc.*, 858 F. Supp. 1426 (C.D. Ca. 1994) (ruling that to permit finding of negligence if manufacturer complied with FDA standards would be to imply that FDA standards are not sufficient).

184. See, e.g., *Ramirez v. Plough, Inc.*, 803 P.2d 167 (Cal. 1993) (finding that the FDA labeling requirements provide the appropriate standard of care).

185. Pub. L. 99-660, 100 Stat. 3755-3784 (1986).

186. See 42 U.S.C. § 300aa-22(a) (1988) ("Except as provided . . . , State law shall apply to a civil action brought for damages for a vaccine-related injury or death.").

187. Under the NCVI Act, if vaccine makers comply in all material respects with the requirements of the FDC Act, then the manufacturers can be held liable for injuries caused by vaccines only if the injury or death was "avoidable." 42 U.S.C. § 300aa-22(b) (To date, no case law has clarified what "avoidable" means in this context.). Even then, manufacturers are immune from punitive damages, if they have complied in all material respects with requirements under the FDC Act. 42 U.S.C. § 300aa-23(d)(2) (prohibiting the award of punitive damages if "manufacturer shows that it complied, in all material respects, with all requirements under the" FDC Act); 42 U.S.C. § 300aa-22(b)(2) ("A vaccine shall be *presumed to be accompanied by proper direction and warnings* if the vaccine manufacturer shows that it complied in all materials respects with all requirements under the" FDC Act.) (emphasis added).

ing incomplete or inaccurate information with their FDA applications.¹⁸⁸

In short, for courts that incorrectly perceive the preemption question to be settled, or persist in a flawed preemption analysis, the conclusion that federal common law controls the standard of liability nevertheless may be accepted. Federal common law is arguably less disruptive of state law than preemption, affords somewhat less absolute protection to pharmaceutical companies and is the minimum measure necessary to fulfill Congress' purposes in enacting the FDC Act.

B. Adopting Federal Standards As A Matter Of State Law

A second judicially available alternative to preemption for courts unwilling to address or accept a federal common law standard would be for courts to hold, as a matter of *state* law, that satisfaction of the FDC Act's requirements constitutes conclusive evidence that manufacturers have lived up to their duties. Under this approach, FDC Act compliance would satisfy state due care standards under negligent design claims and would be conclusive evidence that the design is not defective under strict liability doctrine. Similarly, compliance with FDC Act labeling requirements would satisfy state duty-to-warn standards.¹⁸⁹

Several state courts have in effect followed this approach as to various state law claims involving prescription drugs.¹⁹⁰ This approach is consistent with well-accepted principles of tort law found in the recent draft of the *Restatement (Third) of Torts*, under which a court may "properly conclude that a particular product safety standard set by statute or regulation adequately serves the objectives of tort law and therefore that the product that complies with the standard is not de-

188. See, e.g., *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 28 (1st Cir. 1995) (finding that because Congress did not intend to establish a fraud-on-the-FDA exception to the preemption provision, no state law cause of action can exist); *King v. Collagen Corp.*, 983 F.2d 1130, 1134 (1st Cir. 1993) (ruling allegations of fraud are expressly preempted by the MDA preemption provision, 21 U.S.C. § 360K).

189. *Ramirez v. Plough, Inc.*, 863 P.2d 167, 176 (Cal. 1993).

190. See, e.g., *id.* (holding that the FDA regulations establish the standard of care for packaging and labeling drugs); *Grundberg v. Upjohn Company*, 813 P.2d 89, 95 (Utah 1991) (holding that "all prescription drugs should be classified as unavoidably dangerous in design [and therefore exempt from strict liability as a matter of law under comment k of *Restatement (Second) of Torts* § 402A] because of their unique nature and value, the elaborate regulatory system overseen by the FDA, the difficulties of relying on individual lawsuits as a forum in which to review a prescription drug's design, and significant public policy considerations").

fective as a matter of law."¹⁹¹ Finding that compliance with regulation satisfies a manufacturer's duties under tort law is particularly "appropriate when the safety statute or regulation was promulgated recently, thus supplying currency to the standard therein established,"¹⁹² as is the case with the FDA's regulations. Finally, finding compliance to satisfy a manufacturer's tort duties as a matter of state law is "especially appropriate when the court is confident that the deliberative process by which the safety standard was established was thorough and responsible and reflected substantial expertise," as is undoubtedly the case with the FDA.¹⁹³

Indeed, as discussed earlier, allowing state tort liability could lead to many devastating public policy consequences. If tort liability were imposed atop the FDA's detailed regulatory controls, drug manufac-

191. RESTATEMENT (THIRD) OF TORTS § 7 (Tentative Draft March 13, 1995) (emphasis added).

192. *Id.*

193. *Id.* Similarly, the *Restatement (Second) of Torts* provided that a court may "adopt as the standard of conduct of a reasonable man the requirements of a legislative enactment or an administrative regulation" if the purpose of the statute or regulation is found to be exclusively or in part:

- (a) to protect a class of persons which includes the one whose interest is invaded, and
- (b) to protect the particular interest which is invaded, and
- (c) to protect that interest against the kind of harm which has resulted, and
- (d) to protect that interest against the particular hazard from which the harm results.

RESTATEMENT (SECOND) OF TORTS § 286 (1965).

The FDA's extensive application process and its labeling requirements both satisfy precisely these standards. See 21 U.S.C. § 355 (providing rigorous application procedures); see also 21 C.F.R. § 314.50 (setting forth rigorous requirements for an application's content). As discussed more fully above, a new drug may be marketed only upon FDA approval of its NDA, which requires clinical and other evidence that the drug is "safe and effective." 21 U.S.C. § 355(b)(1). In accordance with the *Restatement's* standard, FDA requirements are intended to protect the public's health and welfare against physical harm caused by unsafe drugs resulting in bodily injury or death. For a thorough discussion of the liability standards applied in drug cases see STUART M. SPEISER et al., *THE AMERICAN LAW OF TORTS*, § 18.378 (1989). Similarly, the FDA's labeling requirements, which are designed to protect prescription drugs users from avoidable harm resulting from adverse effects of the drug, also satisfy the *Restatement's* standard. See, e.g., 44 Fed. Reg. 37,437 (1979) (stating that the purpose of drug labeling is "to enable practitioners to use a drug safely and effectively for its intended purpose").

The *Restatement* rule is eminently sensible in the prescription drug context, where permitting state tort liability lawsuits may have direct public health implications. "Allowing individual courts and/or juries to continually reevaluate a drug's risks and benefits ignores the processes of [the] expert regulatory body [the FDA]." *Grundberg v. Upjohn Co.*, 813 P.2d 89, 97 (Utah 1991). Lay judges and juries are not the proper forum for making the complex public health risk/benefit analysis necessary to determining whether a drug ought to be marketed. *Id.* at 98; see James A. Henderson, *Judicial Review of Manufacturers' Conscious Design Choices: The Limits of Adjudication*, 73 COLUM. L. REV. 1531 (1973) (arguing that courts are "inherently unsuited to the task of establishing product safety standards: in cases involving product liability of manufacturers"); see also *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 17-19 (1st Cir. 1994) (stating that state common-law claims related to pacemaker's safety and effectiveness were preempted by MDA to the federal FDC Act).

turers might be led to delay placing new products on the market in order to do additional testing even after receiving FDA approval, thereby delaying the introduction of new drugs and undercutting the public's interest in the prompt availability of new medical treatment.¹⁹⁴ Further, the added expense of insuring against new products might lead to an increase in the cost of medication that would make certain pharmaceuticals unaffordable to consumers.¹⁹⁵ Most devastatingly, manufacturers might be led to stop producing, or to forego developing, valuable drugs altogether because of actual or anticipated lost profits resulting from lawsuits or the inability to secure adequate insurance.¹⁹⁶

None of these undesirable consequences should come as a surprise because, more generally, tort liability imposed on top of regulatory controls creates "a considerable danger of overdeterrence" of socially useful activities and "threatens to perpetuate some of the very problems that led to the creation of regulatory programs" in the first place.¹⁹⁷

Finally, a court that refuses to adopt preemption or the federal common law alternative discussed above may well be willing to adopt the FDC Act's regulatory standards as a matter of state law which, being a matter of *state* law, obviously is less disruptive of state sovereignty than either preemption of federal common law, both of which *displace* state law to some extent. From the perspective of the policies embodied in the FDC Act, however, the downside to this option is that it would have to be adopted on a piecemeal state-by-state basis. Even assuming ultimate success in convincing fifty separate state supreme courts of the merits of this position, there would be considerable uncertainty — with the attendant negative public health consequences — before their pronouncements.

194. See *Brown v. Superior Court*, 751 P.2d 470, 479-80 (1988) (noting that public policy favors the rapid development and marketing of new drugs, despite the possibility of risks, because such drugs have the ability to prevent deaths and reduce suffering).

195. *Id.*

196. *Id.* (listing several valuable drugs removed from the market due to tort liability including Bendectin, various vaccines, and a new drug designed to treat optical problems).

197. 2 AMERICAN LAW INSTITUTE, ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY 87 (Reporters' Study 1991); see, e.g., *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 448-49 (1976) ("[M]anagement's fear of exposing itself to substantial liability may cause it simply to bury the [public] in an avalanche of trivial information—a result that is hardly conducive to informed decision making.").

C. Several Legislative Options

Finally, in the event that courts unwisely refuse to adopt *any* of the judicial alternatives discussed above, there are various federal and state legislative options that also could accomplish much, if not all, of the aims sought by Congress in enacting the FDC Act.

1. Possible Federal Statutory Amendments

While Congress has begun contemplating piecemeal legislative reform that would limit, or in some instances eliminate, prescription drug manufacturers' punitive and non-economic damages,¹⁹⁸ the most desirable legislative solution would be the adoption of an explicit preemption provision akin to 21 U.S. Code § 360k, the FDC Act provision governing medical devices. It is telling that when Congress actually considered the need for preemption in the medical device context, it concluded that preemption was necessary. The appropriateness of having a similar provision in the pharmaceutical context is underscored by the fact that the *identical* policy concerns undergirding

198. While there is no certainty as to its ultimate contours, it is likely that some legislation affecting medical devices and drugs will be passed by the 104th Congress. Whether such legislation (if passed) will attract, and if so be able to overcome, a presidential veto, is also quite uncertain.

Under the bill that recently passed the House of Representatives, referred to as the "Common Sense Legal Standards Reform Act of 1995," punitive damages will be barred in actions against a manufacturer or seller of a drug or device, as defined under Section 201(g)(1) of the FDC Act, 21 U.S.C. § 321(g)(1), where: (1) the drug or device was subject to pre-market approval by the FDA "with respect to the safety of the formulation or performance of the aspect of such drug or device which caused the claimant's harm or the adequacy of the packaging or labeling of such drug or device, and such drug or device was approved by" the FDA; or (2) "the drug is generally recognized as safe and effective pursuant to conditions" established by the FDA. H.R. REP. NO. 956, 104th Cong., 1st Sess. § 201(f) (1995). The proposed legislation would apply to civil actions brought in state as well as federal courts. *Id.* § 201(c).

The proposed legislation, therefore, would operate to put into place blanket preemption of punitive damages claims with respect to both drugs and medical devices in state and federal courts, with fraud-on-the-FDA and bribery exceptions. *Id.* § 201(f)(1)(B). Moreover, even where punitive damages are permitted, they would be limited to the greater of three times the amount of damages awarded to the claimant for economic loss, or \$250,000. *Id.* § 201(b).

In addition to a bar or cap on punitive damages, the proposed legislation also would include a total cap of \$250,000 on noneconomic damages, such as pain and suffering or emotional distress, in all civil actions against a "manufacturer, distributor, supplier, marketer, promoter, or seller of a medical product"—which includes drugs and devices—regardless of the number of separate claims brought or number of parties against whom they are brought. *Id.* §§ 203(a), (c)(3). These limitations, as with those respecting punitive damages, would apply to both federal and state court actions. *Id.* § 203(b).

preemption in the medical device context are applicable to pharmaceuticals.¹⁹⁹

It is likely, however, that a legislative effort to obtain a provision like § 360k for pharmaceuticals would be met by efforts of the plaintiff's bar to implement some mechanism for providing compensation to injured parties. A plausible compromise would be a legislative package similar to the National Childhood Vaccination Injury Act, perhaps with additional refinements. As discussed above, the NCVI Act established a fund financed by the federal government that provides no-fault compensation to victims of vaccinations, thereby ensuring that no victims of vaccine-caused injuries are uncompensated.²⁰⁰ While those injured by vaccines still have access to the courts under the NCVI Act, no tort recovery can be had with respect to unavoidable injuries and deaths and no punitive damages are available with respect to avoidable injuries and deaths if a manufacturer has complied in all material respects with FDC Act requirements.²⁰¹

There may be similar Congressional support for a no-fault compensation fund for those injured by pharmaceutical products and that protects manufacturers that have complied with FDC Act requirements from liability. Driving adoption of the NCVI Act was a fear that companies were ceasing production of vaccines, and that this was a grave threat to national health.²⁰² As with vaccines, pharmaceuticals also save “[b]illions of medical and health-related dollars” and have “prevented thousands of” deaths.²⁰³ And, as with vaccines, massive state tort litigation has driven off the market some prescription drugs deemed safe and effective by the FDA and, in all likelihood, deterred

199. See H.R. REP. NO. 853, *supra* note 11, at 45 (“The Committee recognizes that if a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened.”).

200. See *supra* note 187 and accompanying text (discussing compensation for victims of vaccinations).

201. See 42 U.S.C. § 300aa-22(b)(1) (stating no liability for unavoidable deaths); see also § 300aa-23(d)(2) (providing no punitive damages except in a few narrow circumstances). Pending legislation before the Congress similarly would shield manufacturers that have followed FDA requirements from punitive damages. See *supra* note 204 (discussing pending litigation).

202. See H.R. REP. NO. 908, *supra* note 68, at 4, *reprinted in* 1986 U.S.C.C.A.N. 6344, 6345 (noting “a real concern about the future of Federal immunization initiatives” that are “[a]t least in part as a result of [an] increase in litigation,” as a result of which “the prices of vaccines have jumped enormously [and t]he number of childhood vaccine manufacturers has declined significantly”).

203. *Id.*; see Brozen, *supra* note 98, at 305 (“[D]rugs are our most cost-effective input in supplying the demand for health. A ten-dollar prescription is frequently a substitute for \$2,000 worth of hospital services—a substitute that produces a positive outcome with much higher frequency than hospital care”).

researchers from developing pharmaceuticals in intrinsically high-risk medical fields such as pregnancy.²⁰⁴

Were Congressional enthusiasm found to be only minimal for such a legislative scheme, Congressional support might materialize for a legislative regime under which the compensation fund was funded by the pharmaceutical industry itself. Such a statute still could be of benefit to the pharmaceutical industry by making its costs more predictable, sharply limiting litigation costs and eliminating punitive damages.

2. *Various State Legislative Options*

A final non-judicial option for achieving the public health aims of the FDC Act would be to pursue comparable legislative remedies at the state level. A number of states already have enacted legislation according conclusive, or at least partial, effect to FDA approval of a drug. For example, a recent New Jersey statute provides absolute immunity with respect to failure-to-warn claims where the FDA has approved a label and the manufacturer has not unlawfully kept information from the FDA,²⁰⁵ and affords manufacturers immunity against punitive damages if there was either FDA pre-marketing approval or if the product was recognized as "safe and effective" under applicable FDA conditions and regulations. At least one other state has adopted similar statutory provisions.²⁰⁶

IV. CONCLUSION

Congress turned its attention in 1976 to the question of whether state laws relating to medical devices are preempted by the FDC Act. It answered in the affirmative by noting that without preemption interstate commerce would be unduly burdened, enacting an explicit preemption provision. Under this provision, a broad and growing jurisprudence of preemption relating to medical devices has been developed by the courts whose contours stretch so far as to bar suits where companies have withheld information from the FDA.

204. See *Brown v. Superior Court*, 751 P.2d at 479-80 (noting the withdrawal of Bendectin, the anti-nauseant drug for women).

205. See N.J.STAT. ANN. § 2A:58(c-5) (Supp. 1995) (providing that punitive damages not awarded if the drug was subject to pre-market approval by the FDA).

206. See, e.g., UTAH CODE ANN. § 78-18-2 (1992) (stating punitive damages unavailable if drug approved by FDA or generally recognized as safe and effective under FDA guidelines); UTAH CODE ANN. § 78-15-6(3) (1992) (creating rebuttable presumption that product was not defective if manufactured according to applicable government standards).

Although the identical policy concerns are applicable to prescription drugs, courts have been far more reluctant to find preemption in this context. This has been a mistake, but one which the courts may be willing to revisit in light of the developing medical device case law and the analytical flaws in the pharmaceutical case law itself. Upon a considered analysis, state law should be found to be preempted because the comprehensive federal regulatory scheme governing prescription drugs fully occupies the field of drug safety regulation. Alternatively, state tort and contract claims should be preempted at least where they actually conflict with the FDC Act.

Many courts have recognized these concerns but have refused to find preemption on the basis of certain presumptions against preemption. Further examination, however, reveals that many of these presumptions are not even applicable to pharmaceutical drugs. Other courts have erroneously imported preemption decisions in the vaccine context — where there is an explicit statutory provision making state law applicable — into the pharmaceutical context, where there is *no* provision indicating that state law is still applicable. When the inapposite presumptions and vaccine cases are set aside, it becomes clear that most jurisdictions have no governing law on the question of whether or not state law relating to prescription drugs is preempted under the FDC Act. The question is thus fully open for judicial determination.

Further, there are several little-pursued alternatives to preemption in the pharmaceutical area that may be able to achieve nearly all of the vital public policy objectives embodied in the FDC Act. Courts could find that, as a matter of federal common law, adherence to FDA standards conclusively proves that companies have lived up to their obligations under state tort (and warranty) law. Alternatively, state courts could follow the path set by California and several other states and find, as a matter of *state* law, that fidelity to FDA standards satisfies companies' legal duties.

A final way to realize the public health goals pursued by Congressional enactment of the FDC Act is through additional legislation. Congress could adopt an explicit preemption provision, similar to 21 U.S. Code § 360k in the medical device arena, that applies to pharmaceutical products. Indeed, Congress currently is considering legislation that at least protects companies producing drugs and devices under FDA approval from punitive damages. Another option is that Congress could adopt a legislative scheme akin to the NCVI Act that establishes a compensation fund for those injured by drugs but largely shields companies that have abided by FDA requirements from tort

liability. Lastly, individual state legislatures could follow in the steps of New Jersey and Utah and enact legislation protecting companies that have followed FDA requirements from tort liability in their states.

In short, there remain many active legal options for eliminating the illogical distinction as regards preemption between medical devices and pharmaceuticals. The common denominator of all of those approaches to rationalizing the law governing drugs and devices is that they seek to ensure that companies are subject to a single set of requirements formulated by the FDA's experts processes. It is those processes, and not the individualized post-hoc judgments of lay judges and juries, that are best calculated to determine what availability of, and warnings concerning, drugs optimize public health.