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THE FDA PREAMBLE: A BACKDOOR TO FEDERALIZATION OF PRESCRIPTION WARNING LABELS?

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I. INTRODUCTION

Perhaps one of the most compelling defenses today in pharmaceutical labeling litigation is that of federal preemption. The doctrine of federal preemption is grounded in the Supremacy Clause, which sets forth that any state law conflicting with the exercise of an enumerated federal power is preempted.[1] Although the issue of federal preemption of state law is utilized as a strong defense today, it was not until recently that this doctrine became so highly debated in the realm of drug litigation. Recently, federal agencies have increased the use of preambles as a way to attempt preemption of state regulations or common law. This increase in preemption has been coined as "backdoor federalization."[2]

In January 2006, the Food and Drug Administration (FDA) issued a statement on labeling regulations for human prescription drugs. The preamble to the January statement unequivocally establishes the FDA's position on preemption by stating that "under existing preemption principals, *FDA approval of labeling* under the [Federal Drug and Cosmetic Act]. . . whether it be in the

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

2. Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227, 229 (2007); *see also* Samuel Issacharoff & Catherine M. Sharkey, *Backdoor Federalization*, 53 UCLA L. REV. 1353 (2006) (explaining "backdoor federalization").

old or new format *preempts conflicting or contrary state law*.[3] The FDA's recent position on federal preemption contrasts with its former views, as set forth in 1998 and in 2000, which stated that FDA approval does not have a preemptive effect on state failure-to-warn claims.[4]

With such a definitive position on federal preemption of pharmaceutical-related state tort claims, an increase in litigation regarding the issue of federal preemption has ensued. Since the publication of the FDA preamble, courts seem to be divided on whether deference should be granted to the FDA preamble and the agency's most recent position on preemption.

To date, Congress has remained silent on the issue of federal preemption of prescription labeling claims. The Food Drug and Cosmetic Act (FDCA), which provides the FDA with the authority to regulate the prescription drug industry, does not expressly contain a preemption clause. Under general preemption analysis, implied preemption occurs where state and federal law conflict, where state law presents obstacles to accomplishing Congress's purposes, or where Congress has so completely occupied the field that there is no room for state law. Most common law state prescription drug claims are not in direct conflict with federal law. Furthermore, it is difficult to make the case (despite the FDA's position) that actions brought under state common law present an obstacle to accomplishment of the FDA's mission, or that Congress intended to completely occupy the field of drug safety regulation.

This Article will examine the FDA's role in regulating drug safety and explore its position on the preemptive power of FDA regulation. Part II will provide an overview of the federal regulatory process of obtaining approval from the FDA to market and sell prescription drugs and highlight some criticisms of this process. Part III will discuss general preemption principles related to pharmaceutical labeling. Part IV will describe and explore the FDA's current position on preemption, including whether courts should defer to the FDA's preamble in its January 2006 statement. Part V will discuss the judicial response to the FDA preamble. Finally, the politics of the FDA's evolving position on preemption will be further explored.

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3. Requirements on Content and Format Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3933 (Jan. 24, 2006) (emphasis added).

4. Prescription Drug Product Liability; Medication Guide Requirements, 63 Fed. Reg. 66378, 66384 (Dec. 1, 1998); Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologies; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81082, 81103 (Dec. 22, 2000).

II. BRINGING A NEW DRUG TO THE MARKET: CRITICISMS OF THE FEDERAL REGULATORY PROCESS

In 1938, Congress enacted the Food, Drug, and Cosmetic Act (FDCA) in response to the deaths of approximately one hundred children from the consumption of an elixir sulfanilamide, a medication that was formulated using anti-freeze.[5] The FDCA established that drug manufacturers must conduct animal toxicity testing and submit safety data to the FDA prior to the approval of a drug.[6] In 1962, Congress enacted the Kefauver-Harris Amendments to the FDCA, which increased the requirements for toxicity testing and submission of safety information to the FDA.[7] The Kefauver-Harris Amendments also required that substantial evidence must be submitted to the FDA regarding the efficacy of a drug.[8]

Today all prescription drugs in the United States must be approved by the FDA. However, it is the responsibility of the pharmaceutical company seeking to market a new drug to submit evidence that it is safe and effective.[9] The route a drug travels from the laboratory into an individual medicine cabinet is quite long. First, the drug must undergo preclinical (animal) testing.[10] Then, the drug sponsor submits an Investigational New Drug Application with the drug's preclinical data to the FDA for approval to conduct clinical (human) trials.[11] A local institutional review board that consists of a panel of scientists and non-scientists in hospitals and research institutions also approves the clinical trial protocols.[12] Once the clinical data is collected, a drug sponsor submits a New Drug Application (NDA) to the FDA. An NDA includes all preclinical and clinical data analyses of the proposed new drug.[13] Submission of an NDA is the formal step

5. *History of the FDA: The 1938 Food, Drug and Cosmetic Act*, U.S. FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/oc/history/historyoffda/section2.html (last visited Oct. 19, 2006).

6. Federal Food, Drug and Cosmetic Act, 21 U.S.C.A. §§ 301-397, § 360 (e)(c) (1938).

7. *History of the FDA: Drugs and Foods Under the 1938 Act and Its Amendments*, U.S. FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/oc/history/historyoffda/section3.html (last visited Oct. 19, 2006).

8. *Id.*

9. *Drug Approval Application Process*, CENTER FOR DRUG EVALUATION AND RESEARCH, http://www.fda.gov/cder/regulatory/applications/ (last visited Oct. 19, 2006).

10. *The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective, From Test Tube to Patient: A Special Report from FDA Consumer Magazine*, U.S. FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/fdac/ special/testtubetopatient/drugreview.html (last visited Oct. 19, 2006).

11. *Id.*

12. *Id.*

13. *Id.*

that a drug company takes so that the FDA can consider a new drug for marketing within the United States.[14]

When the FDA approves a new drug, the agency has determined that the benefits of the drug outweigh its risks.[15] Although the FDA maintains one of the most rigorous drug approval processes in the world, clinical trials cannot determine every adverse drug effect.[16] Due to the limited size and length of pre-marketing clinical trials, only the most common adverse effects will be identified and included on a drug's label.[17] Thus, a limited amount of information on determining possible adverse effects of a new drug also limits the FDA's ability to evaluate warning labels for potential new drugs that are submitted by drug sponsors as part of an NDA.

Furthermore, the scientific standards utilized by the FDA to determine if a drug is safe have been criticized, even by its own officials.[18] The FDA's review of a new drug depends substantially

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14. *Id.*

15. *MedWatch: Managing Risks at the FDA, From Test Tube to Patient: A Special Report from FDA Consumer Magazine*, U.S. FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/fdac/special/testtubetopatient/medwatch.html (last visited Oct. 19, 2006).

16. Stephen A. Goldman, Dianne L. Kennedy & Ronald Lieberman, *Clinical Therapeutics and the Recognition of Drug-Induced Disease*, A MEDWATCH CONTINUING EDUCATION ARTICLE, 1 (1995), http://www.fda.gov/medwatch/articles/dig/ceart.pdf.

17. *See id.*, ¶ 9. (explaining that clinical trials do not provide for all information on a drug's safety but rather are designed primarily for assessing efficacy and risk-benefit ratio); *see also* Robert Temple, *Commentary on "The Architecture of Government Regulation of Medical Products"*, 82 VA. L. REV. 1877, 1886-87 (1996) (criticizing the argument that the FDA tends towards excessive caution and towards the belief that the FDA's job is to prevent harm to consumers, rather than facilitate innovative medical products). Dr. Temple states:

> [I]t is often said . . . that FDA, because it will be blamed if a drug proves more toxic than expected (and perhaps will be subjected to public, i.e., congressional, abuse), is excessively cautious and fails to weigh appropriately the benefits of the drugs against their risks. This is so much the conventional wisdom that even suggesting that it is an unsupported myth seems almost impertinent. But myth it is and no one has ever even attempted to demonstrate its truth, either through an analysis of FDA decisions or, at least, by a comparison of FDA decisions with decisions by other regulatory authorities.
>
> Evidence of such excessive caution could perhaps be found in applications that were not approved because the drugs were considered unsafe. It is, in fact, relatively unusual for drugs to be rejected on safety grounds.

Id.

18. *FDA, Merck and Vioxx: Putting Patient Safety First?* Hearing Before Comm. on Finance, 108th Cong. (2004) (statement of David J. Graham, MD, MPH, Associate Director for Science and Medicine, FDA Office of Drug Safety) "[T]he scientific standards CDER [Center for Drug Evaluation Research] applies to drug safety guarantee that unsafe and deadly drugs will remain on

upon statistical tests.[19] Two statistical tests used to evaluate a given drug are efficacy measures and safety measures. In general, a drug is approved if it shows a ninety-five percent or greater probability that it is effective.[20] This statistical measure is reasonable; it sets a high standard so that the drug a patient receives actually works. However, the statistical test for determining the safety of a drug may be problematic. Under the safety statistical test, a drug will be considered unsafe only if it can be shown that the drug is unsafe with ninety-five percent certainty.[21] This standard is extremely high and has been compared to the legal standard of beyond a reasonable doubt.[22] The congressional testimony of Dr. David Graham, an Associate Director for Science and Medicine for the FDA Office of Drug Safety, illustrates this point with the following analogy:

> If the weather-man says there is an 80% chance of rain, most people would bring an umbrella. Using the CDER's [Center for Drug Evaluation and Research] standard, you wouldn't bring an umbrella until there was a 95% or greater chance of rain.[23]

Others have criticized the FDA for its focus on industry profits over public health concerns.[24] More specifically, the FDA has been criticized for what is called "agency" or "industry" capture.[25] For instance, the FDA relies on advisory committees composed of outside experts who offer scientific and technical advice on drug approvals.[26] However, it is not uncommon that committee members are scientists who have a direct financial relationship to the company that manufactures the drug being screened for approval.[27] For example, in a committee of thirty-two outside experts selected to review the controversial class of drugs, COX-2 inhibitors (including Vioxx), ten of the panelists had a

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the US [sic] market." *Id.*

19. *Id.*

20. *Id.*

21. *Id.*

22. *Id.* "This is an incredibly high, almost insurmountable barrier to overcome. It's the equivalent of 'beyond a shadow of a doubt.'" *Id.*

23. *Id.*

24. *See FDA Fails to Protect Americans from Dangerous Drugs & Unsafe Food, Watchdog Groups Say: Agency Captured by Industries It Should Be Regulating, According to Rep. Waxman, Public Citizen, and CSPI*, June 27, 2006, http://www.citizen.org/pressroom/print_release.cfm?ID=2227 (explaining that the FDA should enforce the law, thereby placing public health concerns ahead of profits).

25. *See* Robert Glicksman & Christopher H. Schroeder, *EPA and the Courts: Twenty Years of Law and Politics*, 54-AUT LCPR 249, 264-68, 276-79 (1991) (discussing "agency capture" and how it affects the integrity of regulatory agencies).

26. *FDA Fails to Protect Americans from Dangerous Drugs & Unsafe Food*, *supra* note 24.

27. *Id.*

direct relationship with the drug manufacturers of COX-2 inhibitors.[28]

Recently, the U.S. House of Representatives released a report that evaluated the FDA's enforcement responsibilities during the Bush Administration.[29] The report concluded that there has been a decrease in FDA enforcement actions in the past five years.[30] More specifically, there has been a decrease in the number of warning letters issued for federal violations and a decline in the number of seizures of mislabeled, defective and dangerous drugs.[31] Even further, enforcement recommendations of field offices within the FDA have often been rejected.[32]

The FDA has also been criticized for lacking a clear and effective process for managing the oversight of post-market drug safety issues.[33] Although the FDA has the authority to withdraw its approval of a drug on the market, it has only limited authority to require that drug sponsors conduct specific actions such as post-market safety studies.[34] Thus, the FDA has to rely on the drug sponsor to voluntarily conduct post-market safety studies.[35] However, even if a drug sponsor begins to conduct a post-market safety study, it oftentimes does not complete the study and the FDA cannot enforce completion of the research.[36]

In light of strong FDA criticism, the agency has undertaken some initiatives to improve drug safety. For example, the FDA MedWatch program encourages health professionals to voluntarily report adverse effects of a drug.[37] Based on the voluntary reports received, the FDA may take the following actions: issue safety alerts, make labeling changes, require product withdrawals, send letters to healthcare professionals, or require further post-marketing research.[38] However, it may not be until after a drug has been approved for sale to the public that one can determine

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28. *Id.*

29. Comm. on Oversight & Gov't Reform, U.S. H.R., *Prescription for Harm: The Decline in FDA Enforcement Activity* (2006), *available at* http://oversight.house.gov/story.asp?ID=1074.

30. *Id.*

31. *Id.*

32. *Id.*

33. *Drug Safety: Further Actions Needed to Improve FDA's Postmarket Decision-making Process*, Subcommittee on Heath, Comm. on Energy and Commerce, House of Representatives, 2, 108th Cong. (2007) (statement of Monica Crosse, Director, Health Care).

34. *Id.* at 5.

35. *Id.* at 9.

36. *Id.*

37. *MedWatch: Managing Risks at the FDA*, FDA CONSUMER MAGAZINE: FROM TEST TUBE TO PATIENT (4th ed. 2006), *available at* http://www.fda.gov/fdac/special/ testtubetopatient/medwatch.html.

38. *Id.*

whether the drug carries substantial risks. The FDA has also implemented changes to its post-market drug safety decision process. For example, the FDA has proposed revisions to its draft policy on major post-market drug safety decisions.[39] Also, the FDA is in the process of developing a tracking system to oversee post-market drug safety issues and is receiving guidance on the Office of Drug Safety's role in scientific advisory committees.[40] Despite the FDA's efforts to make improvements on drug safety, the reality is that every product the FDA approves carries some risks that often go undiscovered until the product is on the market. With so many risks and the dangers of adverse effects discovered after a drug is placed on the market, state tort law may be an important avenue of protection for citizens' health and well-being.

III. GENERAL PRINCIPLES OF FEDERAL PREEMPTION

The Supremacy Clause of the United States provides that federal law "shall be the supreme Law of the Land."[41] Thus, if any state law conflicts with current federal law, the federal law prevails. Federal preemption can be express or implied. Express preemption occurs when Congress explicitly preempts state law. Generally, a preemption clause in a statute will provide that states "may not adopt conflicting 'requirements' or 'standards.'"[42] In contrast, implied preemption must be discerned from the general purpose of a statute.[43] There are two types of implied preemption: field and conflict preemption. Field preemption occurs when Congress intended the Federal Government to occupy an entire field of lawmaking. With conflict preemption, an actual conflict between state and federal law exists. There are two ways to establish implied conflict preemption. First, state and federal law may directly conflict such that it is impossible to comply with both laws.[44] Second, a conflict may exist when state law interferes or "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[45]

In the context of pharmaceutical labeling, federal preemption is based upon the authority of the federal government. This authority exists "in the form of drug approval adjudications by [the] FDA," to supersede the powers of the states in determining what prescription drug label warnings are required.[46] If a federal

39. *Drug Safety: Further Actions Needed to Improve FDA's Postmarket Decision-making Process*, *supra* note 33, at 3.
40. *Id.*
41. U.S. CONST. art. VI, § 1, cl. 2.
42. DAVID OWEN, PRODUCT LIABILITY LAW 897 (Thomson West 2005).
43. *Id.*
44. *Id.* at 898.
45. *Id.*
46. James T. O'Reilly, *A State of Extinction: Does Food and Drug*

regulation does not prohibit a state claim, or if the claim does not conflict with a federal regulation, then Congress probably intended for the state claim to remain valid.[47]

Currently, Congress has not expressly preempted state failure-to-warn prescription labeling claims. Thus, in the absence of an express preemption clause, Congress did not intend general preemption. Without any delegation of authority concerning preemption of prescription labeling laws to the FDA, Congress did not intend for the FDA to make such decisions. Consequently, implied preemption is the only possibility that may exist. However, there is a presumption against finding implied preemption without a clear sign of congressional intent.[48]

The only indication of congressional intent regarding preemption in the context of pharmaceutical drugs is stated in the "Effect on State Laws" provision of the 1962 amendments to the FDCA:

> Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law.[49]

Despite its clear conflict preemption language, the "Effect on State Laws" provision has a limited application because it only applies to the 1962 amendments of the FDCA as opposed to the entire act.[50] Furthermore, the preemption provision of the 1962 amendments relates to issues of safety, effectiveness, and reliability of prescription drugs and factory inspections – not prescription drug labeling. Notwithstanding the 1962 Amendment's limited application, it may be reasonable, by analogy and extension, that the savings clause in the 1962 amendments suggests a general congressional intent that other parts of the FDCA do not preempt state law in the absence of a direct conflict.

The basic issue with respect to federal preemption of state failure-to-warn prescription labeling claims can be expressed best as whether Congress implicitly intended to prohibit state tort

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Administration Approval of a Prescription Drug Label Extinguish State Claims for Inadequate Warning?, 58 FOOD & DRUG L.J. 287, 288 (2003).

47. OWEN, *supra* note 42, at 900.

48. Jackson v. Pfizer, Inc., 432 F. Supp. 2d 964, 966 (D. Neb. 2006) (citing Mo. Bd. of Examiners v. Hearing Help Express, Inc., 447 F.3d 1033 (8th Cir. 2006)).

49. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780, 793.

50. H.R. REP. NO. 87-2526, at 26 (1962) (Conf. Rep.), *reprinted in* 1962 U.S.C.C.A.N. 2927, 2935. "The conference substitute retains the House provision but makes the provision applicable only to the amendments made by this act to the Federal Food, Drug, and Cosmetic Act." *Id.*

claims, and whose answer to that question – the FDA's or the courts' – should prevail. The next sections discuss the FDA's position and the judicial response.

IV. THE FDA'S POSITION ON FEDERAL PREEMPTION

In the past decade, the FDA has issued several statements that indicate its position on federal preemption of state failure-to-warn tort claims. In general, the FDA's position on preemption has shifted from one respecting state failure-to-warn labeling claims, to a view that advocates federal preemption. The following section discusses the FDA's former views and its current position on federal preemption of state failure-to-warn prescription labeling claims. Part IV.A focuses on the FDA's views of preemption prior to 2000. Part IV.B discusses the FDA's recent 2006 statement on human prescription drug labeling. Finally, Part IV.C discusses deference to the FDA's recent statement on preemption.

A. Prior to 2000

In general, prior to 2000, the FDA appeared to consistently recognize that its regulations (promulgated through the FDCA) did not preempt state law in the area of pharmaceutical drug litigation. In its 1998 statement on new regulations regarding consumer medication guides, the FDA stated that the "FDA's regulations establish the minimum standards necessary, but were not intended to preclude the states from imposing additional labeling requirements. States may authorize additional labeling but they cannot reduce, alter, or eliminate FDA-required labeling."[51] Basically, a state could make labeling standards more stringent than the FDA, but could not reduce the FDA standards. Later in December of 2000, the FDA released its proposed rules on the labeling requirements for prescription drugs.[52] The 2000 proposal explicitly stated that its regulations *did not* have a preemptive effect on state failure-to-warn claims.[53] Furthermore, the FDA stated that its 2000 proposal did not have federalism implications:

> Because enforcement of these labeling provisions is a Federal responsibility, there should be little, if any, impact from this rule, if finalized, on the States, on the relationship between the National Government and the States, or on the

51. Prescription Drug Product Liability; Medication Guide Requirements, 63 Fed. Reg. at 66384.

52. Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologies; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81082.

53. *Id.* at 81103.

distribution of power and responsibilities among the various levels of Government.[54]

As the FDA came closer to publishing its 2000 proposed rules, the agency received numerous comments expressing concerns about the proposed labeling requirements and requests for a final rule on prescription labeling stating, "FDA approval of labeling . . . preempts conflicting or contrary State law, regulations, or decisions of a court of law."[55] The FDA determined that the labeling of prescription drugs had become too complex and was becoming increasingly difficult for doctors to decipher.[56] Furthermore, product liability litigation had "caused manufacturers to become more cautious and include virtually all known adverse event information, regardless of its importance or its plausible relationship to the drug."[57] The FDA also indicated that it became aware of some product liability suits that threatened its ability "to regulate manufacturer dissemination of risk information for prescription drugs."[58] As a result, the FDA released its final rule on labeling requirements of prescription drugs on January 18, 2006 ("January 2006 Statement"),[59] a rule that would supposedly clarify the preemption issue with respect to pharmaceutical litigation.

B. The FDA's 2006 Statement on Human Prescription Drug Labeling

In response to requests for a different statement about federal preemption of state failure-to-warn claims, the FDA issued the new labeling requirements for prescription drugs and reversed the agency's position on preemption of state court warning claims.[60] In the preamble, the FDA unequivocally stated that, "under existing preemption principles, FDA approval of labeling under the act . . .

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54. *Id.*

55. McNellis v. Pfizer, Inc., No. Civ. 05-1286, 2006 WL 2819046, at *8 (D.N.J. Sept. 29, 2006) (quoting Requirements on Content and Format Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3933-34).

56. Requirements on Content and Format Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3972.

57. Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologies; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. at 81083.

58. Requirements on Content and Format Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3934.

59. Joseph J. Leghorn, Christopher Allen, Jr., & Tavares Brewington, *Defending an Emerging Threat: Consumer Fraud Class Action Suits in Pharmaceutical and Medical Device Products-Based Litigation*, 61 FOOD & DRUG L.J. 519, 525 (2006).

60. Requirements on Content and Format Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3933-34.

whether it be in the old or new format, [the Federal Drug and Cosmetic Act] *preempts conflicting or contrary state law.*"[61] Furthermore, in the preamble, the FDA explained that state law decisions rejecting preemptive authority of the labeling requirements "rely on and propagate interpretations and frustrate the agency's implementation of statutory mandate."[62]

The FDA further reasoned that it was the "expert Federal public health agency charged by Congress" to ensure that drugs are safe and effective.[63] In the FDA's view, state law requirements could undermine its role as the expert Federal agency and its ability to regulate the safety and effectiveness of prescription drugs.[64] It was the FDA's position that, ultimately, state law requirements could lead to labeling that does not portray a "product's risks, thereby potentially discouraging safe and effective use of approved products."[65] Furthermore, the FDA added:

> State actions are not characterized by centralized expert evaluation of drug regulatory issues. Instead, they encourage, and in fact require, lay judges and juries to second-guess the assessment of benefits versus risks of a specific drug to the general public – the central role of the FDA – sometimes on behalf of a single individual or group of individuals. That individualized reevaluation of the benefits and risks of a product can result in relief – including the threat of significant damage awards or penalties – that creates pressure on manufacturers to attempt to add warnings that FDA has neither approved nor found to be scientifically required. This could encourage manufacturers to propose "defensive labeling" to avoid State liability, which, if implemented, could result in scientifically unsubstantiated warnings and underutilization of beneficial treatments.[66]

In its January 2006 Statement, the FDA provided a list of the types of claims that would be preempted:

> (1) Claims that a drug sponsor breached an obligation to warn by failing to put in Highlights or otherwise emphasize any information the substance of which appears anywhere in labeling;
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> (2) [C]laims that a drug sponsor breached an obligation to warn by failing to include in an advertisement any information the substance of which appears anywhere in the labeling . . . ;

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61. *Id.* at 3934 (emphasis added).

62. Leghorn, *supra* note 59, at 525 (quoting Requirements on Content and Format Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3934).

63. Requirements on Content and Format Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3934.

64. *Id.* at 3935.

65. *Id.*

66. *Id.*

> (3) [C]laims that a sponsor breached an obligation to warn by failing to include contraindications or warnings that are not supported by evidence that meets the standards set forth in this rule . . . ;
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> (4) [C]laims that a drug sponsor breached an obligation to warn by failing to include a statement in labeling or in advertising, the substance of which had been proposed to FDA for inclusion in labeling, if that statement was not required by FDA at the time plaintiff claims the sponsor had an obligation to warn (unless FDA has made a finding that the sponsor withheld material information relating to the proposed warning before plaintiff claims the sponsor had the obligation to warn);
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> (5) [C]laims that a drug sponsor breached an obligation to warn by failing to include in labeling or in advertising a statement the substance of which FDA has prohibited in labeling or advertising;
>
> (6) [C]laims that a drug's sponsor breached an obligation to plaintiff by making statements that FDA approved for inclusion in the drug's label (unless FDA has made a finding that the sponsor withheld material information relating to the statement).[67]

The agency emphasized that not all state law actions are preempted.[68] The state law claims that should be allowed include claims based on state requirements that parallel federal requirements.[69] For example, a claim that alleges failure of a drug manufacturer to comply with a federal requirement would not be preempted by the FDCA.[70]

The FDA's January 2006 Statement was definitive regarding its position on federal preemption of state tort claims related to pharmaceutical litigation. Since the publication of the FDA preamble, courts have been divided on whether deference should be granted to the FDA preamble and its position on preemption.

C. Deference to the FDA's 2006 Statement on Prescription Drug Labeling

How much deference is afforded to a federal agency's statements has been heavily debated in the realm of administrative law. The FDA's 2006 statement on prescription drug labeling certainly does not escape such a debate, especially with respect to its preamble.

There are two levels of deference that courts commonly apply to agency statements: *Chevron* and *Skidmore* deference.[71] *Chevron*

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67. *Id.*
68. *Id.*
69. *Id.*
70. *Id.*
71. For a discussion of *Auer* deference, see *Auer v. Robbins*, 519 U.S. 452 (1997). *Auer* deference (deference given to an agency's statements that clarify

deference can be summarized into a two-part test. First, if congressional intent is clear, courts and agencies must give effect to that intent.[72] Second, when there is silence or ambiguity in a statute, courts must give considerable weight to an agency's construction of a statutory scheme to the extent that it is reasonable.[73] However, a finding of reasonableness does not necessarily mean that an agency's interpretation is the only interpretation possible or that an agency's interpretation should be the same as that of a court's.[74] Thus, the Court has held that great deference should be given to the interpretations of statutes and regulations by the agencies that administer those statutes and regulations.[75]

Instead of applying *Chevron* deference, a court may choose to apply *Skidmore* deference to an agency's statement. With *Skidmore* deference, a court should take into account an agency's decision. More specifically, the Supreme Court stated in *Skidmore*:

> We consider that the rulings, interpretations and opinions of the Administrator under this Act, while not controlling upon the courts by reason of their authority do not constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance. The weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.[76]

Thus, *Skidmore* deference provides that an agency's statement or interpretation is persuasive, but not controlling. Consequently, *Skidmore* deference is a much weaker form of

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ambiguities in its own regulations) will not be addressed in this paper as most courts have focused on *Chevron* and *Skidmore* deference with respect to the issue of federal preemption of state failure-to-warn prescription labeling claims.

72. Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 843 (1984).

73. *Id.*

74. *Id.* at 842-43.

> If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. If, however, the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute, as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.

Id.

75. *Id.* at 844.

76. Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944).

deference than *Chevron* deference. In conclusion, the level of deference that is applied, either *Chevron* or *Skidmore*, can influence whether a court defers to an agency's statement or interpretation of a statute.

Although the rules on *how* to apply *Chevron* or *Skidmore* deference are clear, the rules on *when* to apply either level of deference are more vague. Until recently, a "force of law" test that was established in *United States v. Mead Corp.*, determined when to apply *Chevron* or *Skidmore* deference.[77] The Court in *Mead* held that *Chevron* deference should be applied when it appears that Congress delegated authority to the agency to make rules carrying the force of law and the agency interpretation was carried out in exercise of that authority.[78] Thus, *Chevron* deference would be applied in formal rulemaking adjudications as well as informal notice-and-comment rulemaking.[79] In instances that lack the force of law (such as policy statements, agency manuals and enforcement guidelines), *Chevron* deference does not apply.[80] In this situation, an agency's interpretation may warrant some deference and, as a result, *Skidmore* deference can be applied. With *Skidmore* deference, an agency's thoroughness, experience, and expertise are relevant and may persuade the court to defer to the agency. There is definitely more flexibility when a court applies *Skidmore* deference – essentially, the court may choose to afford significant or minimal deference to the agency.

The *Mead* opinion clarified that an agency receives deference for rulemaking and formal adjudication. Also, an agency may receive *Chevron* deference for more informal statements if the agency is exercising law-making authority.[81] However, a recent decision by the United States Supreme Court suggests that the "force of law" test is not dispositive for *Chevron* deference.[82] Instead, a new test for agency deference was discussed that considers the interpretive method used by the agency and the nature of the question at issue.[83]

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77. United States v. Mead Corp., 533 U.S. 218, 227 (2001).

78. *Id.* at 226-27.

79. *Id.* at 227.

80. *Id.* at 234.

81. WILLIAM F. FUNK, SIDNEY A. SHAPIRO & RUSSELL L. WEAVER, ADMINISTRATIVE PROCEDURE AND PRACTICE 402 (3rd ed. 1997).

82. In *Barnhart v. Walton*, the Supreme Court stated:

> Indeed, *Mead* pointed to instances in which the Court has applied *Chevron* deference to agency interpretations that did not emerge out of notice-and-comment rulemaking. It indicated that whether a court should give such deference depends in significant part upon the interpretive method used and the nature of the question at issue.

535 U.S. 212, 222 (2002) (internal citations omitted).

83. *Id.*

Currently, it is unclear if a multi-faceted inquiry utilizing the "force of law" test, the new test focusing on the "interpretive method used" and the "nature of the question at issue" is necessary to determine which level of deference is applicable. Furthermore, it is undetermined if the new test should replace the "force of law" test when considering what level of deference should be applied to non-legislative rules. What seems to be clear is that the court will use *Chevron* deference if Congress intended an agency's interpretation or decision to receive deference.[84] Thus, if it is reasonable to assume that Congress intended the courts to defer to an agency's interpretation, then *Chevron* deference will be applied.[85]

With respect to the FDA's 2006 statement on prescription drug labeling, courts have differed as to what level of deference (if any) to apply to the preamble of the FDA's statement.[86] In making

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84. FUNK, ET. AL, *supra* note 85, at 401.

85. *Id.*

86. *See* Dobbs v. Wyeth Pharmaceuticals, No. CIV-04-1762D, 2008 WL 169021, at *13 (W.D. Okla. Jan. 17, 2008) ("The Court finds that, on the particular facts of this case, deference to the relatively broad scope of preemption set forth in the Preamble and *amicus* briefs filed since 2000 is not required because this case presents a narrower issue."); *In re* Zyprexa Products Liability Litigation, 489 F. Supp. 2d 230, 273 (E.D.N.Y. 2007) ("The Preamble accompanying the Final Rule is not entitled to deference under *Chevron* or *Auer*, and controls this court only insofar as it has the 'power to persuade.' . . . The Preamble's assertion of preemption is not persuasive."); Perry v. Novartis Pharma. Corp, 456 F. Supp. 2d 678, 683 (E.D. Penn. Oct. 16, 2006) (quoting Desiano v. Warner-Lambert & Co., 467 F.3d 85, 97 (2d Cir. 2006)).

> Thus, to the degree that the FDA seeks to address ambiguities in the FDCA or in its own regulations, we will give that opinion great weight. Where, however, the agency attempts to 'supply, on Congress's behalf, the clear legislative statement of intent required to overcome the presumption against preemption,' no deference is warranted.

Id.; *see* Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation, No. M:05-1699, 2006 WL 2374742, slip op., at *8 (N.D. Cal. Aug. 16, 2006) (citing *Chevron*, 467 U.S. at 863-64).

> [T]he fact that the agency had from time to time changed its interpretation of a term does not mean no deference is accorded the agency's view: 'On the contrary, the agency, to engage in informed rulemaking, must consider varying interpretations and wisdom of its policy on a continuing basis.'

Id.; *see* Sullivan v. Wyeth, No. 20033314F, 2007 WL 1302589, at *4 (Mass. Super. Ct. April 12, 2007) ("The 'Preemption Preamble' and the FDA amicus brief are not entitled to the heightened deference afforded to an agency's rules."); Levine v. Wyeth, No. 2004-384, 2006 WL 3041078, ¶ 25 (Vt. Oct. 27, 2006) ("Under either standard, the FDA's statement deserves no deference. We have already concluded . . . that Congress intended the FDCA to preempt only those state laws that would make it impossible for manufacturers to comply with both federal and state requirements."); Colacicco v. Apotex, 432 F. Supp. 2d 514, 526 (E.D. Penn. 2006) (noting that *Chevron* deference was accorded here based on the reasoning that "a revised interpretation by an

such an analysis, one could apply either the "force of law" test or the newer test that incorporates an evaluation of the "interpretive method used" and the "nature of the question at issue."

Under the "force of law" test, the first determination is whether preambles are considered law. The Code of Federal Regulations indicates that a preamble is an advisory opinion, defined as "any portion of a Federal Register Notice other than the text of a proposed or final regulation, e.g., a notice to manufacturers or a preamble to a proposed or final regulation."[87] Moreover, "an advisory opinion may be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards *but not as a legal requirement*."[88] Thus, the preamble is not considered law. Without having a force of law, the preamble will most likely be entitled to limited deference. Three recent federal cases have also concluded that the FDA's preamble is an advisory opinion and warrants either no deference[89] or limited deference.[90]

Under the newer test, the FDA's "interpretive method used" and the "legal question at issue" is considered in determining what level of deference is warranted. To date, no court has applied this newer test to determine what level of deference should be afforded to the FDA's preamble. However, one can evaluate the legal question of issue. Can an agency delegate to itself the power to preempt state failure-to-warn prescription labeling claims? Certainly heightened deference should be afforded to the FDA's interpretation of its own statutes and regulations as it is an authority on matters of safety of prescription drugs. However, the FDA has not been granted the authority, nor is it an expert, in the allocation of state and federal powers.[91] Given the aforementioned, it seems reasonable that limited deference should be applied to the FDA's preamble.

When determining what level of deference (if any) should be applied to the FDA's preamble, some courts have by-passed the "force of law" test and the newer test considering "the interpretive method" an agency uses and "the legal question at issue" in favor

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agency is [still] entitled to deference because an initial agency interpretation is not instantly carved in stone"); *McNellis*, WL 2819046, at *7-8 (noting that the preamble is not entitled to deference because the FDA's position on preemption has not been consistent); Weiss v. Fujisawa Pharmaceutical Co., 64 F. Supp. 2d 666, 674 (E.D. Ky. 2006) ("FDA's position has not been consistent and is therefore entitled only to *Skidmore* deference.").

87. 21 C.F.R. § 10.85 (d)(1) (2000).

88. 21 C.F.R. § 10.85 (j) (2000) (emphasis added).

89. *Perry*, 456 F. Supp. 2d at 683-84.

90. *Weiss*, 464 F. Supp. 2d at 673-74; *In re* Vioxx Products Liability Litigation, 501 F. Supp. 2d 776, 787 (E.D. La. 2007).

91. *See infra* Part V.B, (discussing whether the FDA has the authority to decide matters of preemption).

of focusing on Congress's intent (or lack of intent) to delegate the authority to the FDA to allocate state and federal power. The Central District of California, in *Bextra,* gave full deference to the FDA's preamble by reasoning that the FDA has implied authority to determine which state laws conflict with its regulations because Congress delegated the responsibility of implementing the FDCA to the FDA.[92] Similarly, the Eastern District of Pennsylvania in *Colacicco* gave full deference to the FDA preamble, but based its reasoning on other factors.[93] The court based its opinion on recent precedent where the Supreme Court deferred to the FDA's preemption position when questioning whether the FDCA preempts state law.[94] However, in the precedent that the *Colacicco* court relied upon, the courts deferred to the FDA's interpretation of its own regulations, not statements on preemption. The *Colacicco* court also emphasized *Chevron* precedent indicating that an agency can change its position and still be entitled to deference.[95]

Unquestionably, one should begin an analysis of determining what level of deference should be afforded to the FDA's preamble by evaluating Congress's intent to delegate to the FDA the power to preempt state prescription labeling laws. To date, there is no express intent from Congress to delegate to the FDA the power to preempt state failure-to-warn prescription labeling claims. Furthermore, "the issuance of the Preamble does not change the fact that Congress has not expressed an intent to preempt state failure-to-warn laws with respect to pharmaceutical drugs."[96] Thus, the question is whether there is an implied intent from Congress to supply the FDA with the power to preempt state law.

Undoubtedly, the FDA has the authority to implement the FDCA; however, this authority does not include the power to make decisions of allocation of state and federal powers. Although some courts, such as the court in *Bextra,* extrapolate and extend the implied power to implement the FDCA to include a power to make decisions of allocation of state and federal powers, implied preemption seems unlikely. Congress's primary goal in enacting the FDCA is to "protect consumers from dangerous products."[97] With this goal in mind, it is unlikely that Congress would agree to preemption of state failure-to-warn claims when the FDCA lacks a

92. *Bextra,* 2006 WL 2374742, at *7.

93. *Colacicco,* 432 F. Supp. 2d at 525-32.

94. *Id.* at 525 (citing Medtronic Inc. v. Lohr, 518 U.S. 470 (1996); Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001); Hillsborough County v. Automated Med. Labs Inc., 471 U.S. 707 (1985)).

95. *Colacicco,* 432 F. Supp. 2d at 525.

96. *McNellis,* 2006 WL 2819046, at *9.

97. Levine v. Wyeth, No. 2004-384, 2006 WL 3041078, ¶ 25 (quoting United States v. Sullivan, 332 U.S. 689, 696 (1948)).

remedy for an injured consumer.[98] Thus, the preemption preamble would not be entitled to heightened deference. Even if one could make a strong argument for the presence of an implied intent from Congress to delegate preemption powers of state law to the FDA, the preamble is still not afforded heightened deference under the "force of law" or the newer test incorporating "the interpretive method" and "the legal question at issue," as previously discussed. Instead, the FDA's preamble merely has the power to persuade any decisions made by the courts and consequently receive *Skidmore* deference at best.

A court's view of a regulatory agency can be a key component in its analysis of litigation involving that agency. To examine whether state failure-to-warn prescription labeling claims should be preempted, the degree of deference afforded to the FDA's January 2006 Statement must be determined. The Supreme Court has addressed arguments of whether an FDA regulation preempts state law in four cases over the past thirty years.[99] In each of those cases, the FDA's statements have been accorded significant weight in determining if its substantive rules preempt state law.[100] However, it is important to recognize that in these recent cases the Court deferred to the FDA's interpretation of its own regulations, not the FDA's statement on preemption. Also, unlike the latter precedents, the FDA's preamble is not a regulation and there is no question of a conflict between the preamble and state law. To date, the U.S. Supreme Court has not ruled on the position of FDA preemption in state failure-to-warn pharmaceutical labeling claims, and lower court holdings on prescription drug preemption vary. Regardless of the argument

98. *See infra* Part V.C (discussing the absence of a remedy for consumers under the FDCA).

99. Eric G. Lasker, *How Will FDA's New Label Rule Impact Drug Litigation?* 10 ANDREWS DRUG RECALL LITIG. REP. 9, 1, 3 (2006).

100. *Id.*; *see* Jones v. Rath Packing Co., 430 U.S. 519, 543 (1977) (giving deference to the FDCA standard and held that state law should yield to federal law); Hillsborough County v. Automated Med. Labs. Inc., 471 U.S. 707, 714-15 (1985) (ruling against preemption of local ordinances governing collection of blood plasma from paid donors). The Supreme Court recognized that the "FDA's statement is dispositive on the question of implicit intent to pre-empt unless either the agency's position is inconsistent with clearly expressed congressional intent or subsequent developments reveal a change in that position." *Id.*; *see also* Medtronic Inc. v. Lohr, 518 U.S. 470, 495-96 (1996) (recognizing the "unique role" the FDA has in determining an FDA regulation's preemptive effect). Furthermore, the Supreme Court recognized that "state requirements are pre-empted 'only' when the FDA has established 'specific counterpart regulations or . . . other specific requirements applicable to a particular device." *Id.*; *see also* Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 342 (2001) (favoring preemption of state law claims of fraud on the FDA which conflicted with the "FDA's responsibility to police fraud consistently with the Administration's judgment and objectives").

that is set forth on the position of FDA preemption of state failure-to warn pharmaceutical labeling claims, each side references FDA statements to support their argument.[101]

V. THE EFFECT OF THE FDA PREAMBLE IN THE COURTS

Whether a court rules in favor of or against federal preemption of state failure-to-warn claims largely depends on the amount of deference afforded to the FDA preamble. There are several recurring arguments when the issue of federal preemption of state prescription drug labeling is at stake. A discussion of these arguments follows.

A. The FDA's Lack of Consistency on the Issue of Preemption

As discussed previously, the FDA changed its position on preemption between 2000 and 2006. Opponents of preemption of state failure-to-warn labeling claims emphasize that the FDA's interpretation of regulations in 2006 in its Final Rules on Prescription Drug Labeling are completely inconsistent with the FDA's 2000 Proposed Rules, and because of this change, deference should not be accorded to the FDA preamble.[102] The primary reason for opposing acceptance of the FDA's 2006 preamble is based on the position that the U.S. Supreme Court has taken on inconsistent interpretations of an agency's statute and its regulations. The U.S. Supreme Court has held that a court should give less deference to an agency's interpretation of its regulations if the interpretations have not been consistent.[103]

Although a court may not grant great deference to an agency's position when an agency has shown inconsistency in its interpretations,[104] proponents of federal preemption of state failure-to-warn labeling claims argue that there is no justification for precluding deference to an agency's interpretation simply because the interpretation has not been the agency's "longstanding position."[105] Furthermore, an agency's interpretation that is

101. Lasker, *supra* note 103.

102. *McNellis*, 2006 WL 2819046, at *8.

103. *See, e.g.*, Good Samaritan Hosp. v. Shalala, 508 U.S. 402, 417 (1993) ("[T]he consistency of an agency's position is a factor in assessing the weight that position is due"). *Hillsborough County*, 471 U.S. at 714. "The FDA's statement is dispositive on the question of implicit intent to pre-empt unless either the agency's position is inconsistent with clearly expressed congressional intent or subsequent developments reveal a change in that position." *Id.*

104. *See In re* Zyprexa Products Liability Litigation, 489 F. Supp. 2d at 273 ("The Preamble's assertion of preemption is not persuasive . . . . Prior interpretations of the FDCA by the FDA contradict the current view adopted by the agency.").

105. *Colacicco*, 432 F. Supp. 2d at 531 (citing *Chevron*, 467 U.S. at 863-64).

categorized as "new" or "changing" should not be suspect.[106] The Court has also recognized that an agency's view may change over time as the agency acquires more knowledge and experience regarding the interrelationship of its regulations and state laws.[107] With regard to the differences in the FDA's 2000 Proposal and the FDA's 2006 Final Rule, the FDA explained that the same longstanding principles of preemption were being applied, but to a different set of facts.[108] Since its publication of the 2000 Proposal, the FDA recognized that there were several instances in which product liability lawsuits "directly threatened the agency's ability to regulate manufacturer dissemination of risk information for prescription drugs in accordance with the act."[109] The latter explanation has been one of the FDA's principle reasons for shifting its position on preemption of failure-to-warn state claims. Despite an inconsistency in the FDA's position of preemption of failure-to-warn state claims, some courts have accepted this inconsistency and change of view.[110]

B. The FDA's Lack of Authority on the Issue of Preemption

Certainly, deference should be accorded to the FDA on matters regarding safety of prescription drugs. The FDA is uniquely qualified to determine the risks and benefits of prescription drugs that are placed on the market. The underlying reasoning for this view is that "the subject matter is technical; and the relevant history and background are complex and extensive."[111] Therefore, the FDA is more "likely to have a thorough understanding of its own regulation and its objectives.[112] Although some courts have viewed the FDA as uniquely qualified to comprehend the likely impact of state requirements,[113] the FDA does not have the authority to make decisions about its power to preempt state law. Deference to the FDA's position should only be warranted when the agency "speaks in the exercise of *its* authority

106. *Id.*
107. *Bextra*, 2006 WL 2374742, at *8.
108. Requirements on Content and Format Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006).
109. Robert N. Weiner, *Pharmaceutical Law: 2006: Across the Product Life Cycle: Preemption and the FDA Preamble, Practicing Law Institute*, 878 PLI/PAT 847, 860 (Oct. 2006) (quoting Requirements on Content and Format Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3934).
110. *See Colacicco*, 432 F. Supp. 2d at 529 (extending deference to the FDA's position).
111. *Bextra*, 2006 WL 2374742, at *6 (quoting Geier v. American Honda Motor Corp., 529 U.S. 861, 883 (2000)).
112. *Id.*
113. *Id.*

'to make rules carrying the force of law.'"[114] Therefore, deference to the FDA's position should be accorded when the FDA addresses ambiguities in the FDCA or in its own regulations[115] – not matters of preemption. Simply put, the FDA is not an expert in the allocation of federal and state power. A recent decision reinforces the latter when addressing the issue of FDA preemption of state failure-to-warn prescription labeling claims. The decision clearly and correctly stated that where the agency "attempts to 'supply, on Congress's behalf, the clear legislative statement of intent required to overcome the presumption against preemption,' no deference is warranted."[116] There is no question that significant deference should be afforded to the FDA's interpretation of its governing statute and regulations, but matters of federal and state allocation of power are outside of the purview of the FDA.

C. Preemption – Absence of a Remedy for Consumers Under the FDCA

The states have a long-standing interest in protecting the health and welfare of their citizens. Because the FDCA lacks a remedy for an injured consumer,[117] a finding of preemption will not provide such a remedy, and will foreclose traditionally favored remedies that "have been historically reserved by the states."[118] Thus, the state's interest in protecting its citizen's health and well-being will be curtailed. Furthermore, with a near elimination of most prescription drug failure-to-warn claims, drug manufacturers will be absolved of liability from such claims by simply complying with the FDA regulations. With immunity from liability of failure-to-warn prescription labeling claims, a manufacturer would not only reduce their liability exposure, but they would have reduced

114. *Perry*, 456 F. Supp. 2d at 683 (quoting *Mead*, 533 U.S. at 226-27).

115. *Id.*

116. *Id.*; *In re* Aredia and Zometa Products Liability Litigation, No. 3:06-MD-1760, 2007 WL 649266 at *6 n.14 (M.D. Tenn., Feb. 27, 2007) (citing *Perry*, which noted that the FDA preamble did not have preemptive effect because "[C]ongress, not federal agencies, have the power to preempt state law claims"); *Kelley v. Wyeth*, No. 20033314F, 2007 WL 1302589, at *3-4 (Mass. Super. April 12, 2007) (rejecting the FDA preamble and the position in the *Colacicco* amicus brief as "unpersuasive" because the agency could not "supply clear legislative intent on Congress's behalf" and because the agency's interpretation had changed frequently diminishing the "persuasive force of the argument").

117. *Kelley*, 2007 WL 1302589, at *5; *see also Vioxx*, 501 F. Supp. 2d at 788 ("[b]ecause there are no federal remedies for individuals harmed by prescription drugs, a finding of implied preemption in these cases would abolish state law remedies and would, in effect, render legally impotent those who sustain injuries from defective prescription drugs.")

118. Marilyn P. Westerfield, *Federal Preemption and the FDA: What Does Congress Want?*, 58 U. CIN. L. REV. 263, 272 (1989).

insurance costs for new drugs.[119] However, the idea that a drug manufacturer merely has to comply with FDA regulations in order to avoid liability seems to go against the thrust of the policy statements of the Third Restatement of Torts which state that compliance with a federal regulation does not necessarily preclude a finding of a product defect.[120] The latter statement refers to compliance with a federal statute or regulation that is found to be nonpreemptive.[121] There is no indication that Congress intended to deprive injured consumers of a form of compensation that has long been available without any legislative enactment or comment.[122] Although Congress did delegate the authority to ensure the safety and efficacy of prescription drugs to the FDA, there is nothing to support the proposition that Congress has delegated the power of general preemption of state law to the FDA. In fact, the 1962 Amendments to the FDCA are the only indication of any preemption of state law with respect to prescription drug labeling in the Act. The amendments state that absent a direct and positive conflict, nothing in the amendments are intended to invalidate state law.[123] Moreover, in the preamble of the FDA's January 2006 statement on labeling of prescription drugs, the FDA cites itself as the authority on its position of preemption of state failure-to-warn prescription labeling claims.[124] However, even

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119. O'Reilly, *supra* note 46, at 289.

120. *See* RESTATEMENT (THIRD) OF TORTS: PROD. LIABILITY § 4(b) (1998).

> [A] product's compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, but such compliance does not preclude as a matter of law a finding of product defect.

Id.

121. See *id.* at cmt. e. This portion of the Restatement:

> addresses the effects of compliance with a federal statute or regulation found to be nonpreemptive. It addresses the question, under state law, of the effect that compliance with product safety statutes or regulations – federal or state – should have on the issue of product defectiveness. Subsection (b) reflects the traditional view that the standards set by most product safety statutes or regulations generally are only minimum standards. Thus, most product safety statutes or regulations establish a floor of safety below which product sellers fall only at their peril, but they leave open the question of whether a higher standard of product safety should be applied. This is the general rule, applicable in most cases.

Id.

122. *Perry*, 456 F. Supp. 2d at 684 (citing *Bates v. Dow Agrosciences*, 544 U.S. 431, 449 (2005)). "If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly." *Id.*

123. Drug Amendments of 1962, Pub. L. No 87-781, 76 Stat. at 793.

124. *See* Requirements on Content and Format Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg at 3935 (explaining the interplay between state law actions and FDA's role of regulating drugs).

the FDA's preamble does not claim that Congress has granted the FDA the power to make decisions on federalism. The bottom line is that Congress likely did not intend to preempt state common law remedies when there is an absence of any other possible remedy.[125] Given the lack of a remedy for consumers in the FDCA, the FDA's position is not particularly persuasive nor is it entitled to deference.

D. Preemption – Blocking Additional Warnings on Prescription Labels

One of the most common issues debated is whether manufacturers can add or strengthen label warnings. Opponents of the FDA Preamble's position on preemption maintain that the FDA labeling requirements represent a minimum safety standard that allows manufacturers to add or strengthen prescription labels without FDA approval. A strengthened label would not be considered "false or misleading." Instead, state consumer protection laws would complement rather than frustrate the FDA's job.[126] Recent cases have cited the rulings from state courts that recognize that the FDA sets forth only minimum safety standards.[127]

"State law actions also threaten FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs. State actions are not characterized by centralized expert evaluation of drug regulatory issues." *Id.*

125. *See Zyprexa Products Liability Litigation*, 489 F. Supp. 2d at 275 ("The need for a 'clear statement from Congress' is imperative where, as in this case, a finding of preemption 'will foreclose a remedy that was traditionally available and for which federal law provides no substitute.'") (quoting *Perry*, 456 F. Supp. 2d at 684). "Where congress has preempted the states' traditional regulation of public health, it has done so explicitly. Two federal statutes passed in this area contain express preemption provisions, in clear contrast to the FDCA." *Id.* at 276. "While a direct statement of legislative intent is not essential for preemption, it would be odd for Congress to include express preemption provisions in amendments to the FDCA regarding state-law tort claims in certain contexts (i.e., for medical devices) if it intended *all* FCA claims to be preempted." *Id.*

126. *Jackson*, 432 F. Supp. 2d at 969 (noting Witczak v. Pfizer, Inc., 377 F. Supp. 2d 726, 732 (D. Minn. 2005)).

127. *Id.* at 967 (citing *Cartwright v. Pfizer, Inc.*, 369 F. Supp. 2d 876, 882 (E.D. Tex. 2005). "Numerous courts over the years have recognized that the FDCA and its associated regulations set out minimum requirements that drug manufacturers must follow which may be supplemented by state tort laws which are stronger." *Id.*; *Witczak*, 377 F. Supp. 2d. at 732. "Federal labeling laws are minimum standards; they do not necessarily shield manufacturers from state law liability." *Id.*; *Bextra*, No. M:05-1699 CRB, 2006 WL 2374742, at *4 (quoting Motus v. Pfizer Inc., 127 F. Supp. 2d 1085, 1091 (C.D. Cal. 2000)). "[M]ost courts have found that FDA regulations as to design and warning standards are minimum standards which do not preempt state law . . . failure to warn claims." *Id.*

While the FDA recognizes that a manufacturer may strengthen a label warning and distribute a drug with additional labeling changes, the FDA emphasizes in its preamble that it has the authority to disapprove of the changes to the label or even order the manufacturer to stop distributing the drug.[128] Furthermore, a different label from the one dictated by the FDA would be considered "false and misleading."[129] The FDA preamble specifically addresses this issue by stating that the "FDA interprets the act to establish both a 'floor' and a 'ceiling,' such that additional disclosures of risk information can expose a manufacturer to liability under the act if the additional statement is unsubstantiated or otherwise false or misleading."[130] Moreover, "[s]tate law attempts to impose additional warnings can lead to labeling that does not accurately portray a product's risk, thereby potentially discouraging safe and effective use of approved products or encouraging inappropriate use and undermining the objectives of the act."[131]

In recent rulings on the issue of federal preemption of failure-to-warn state prescription labeling claims, a narrower rule in determining if a drug is misbranded has been adopted.[132] The narrow rule allows "state law to require the addition of warnings so long as there has been no specific FDA determination as to the sufficiency of the scientific evidence to support a particular warning."[133] In other words, a plaintiff may proceed with a state law failure-to-warn prescription labeling claim so long as the FDA has not already rejected the plaintiff's proposed warning.

E. The FDA Preamble as an Advisory Opinion

Opponents of the FDA's position on preemption of failure-to-warn state prescription labeling claims argue that the FDA preamble "is not a binding portion of the regulations, but is instead an advisory opinion."[134] As stated in the Code of Federal

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128. *Bextra,* 2006 WL 2374742, at *8.

129. *Id.* at *9.

130. Requirements on Content and Format Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3935.

131. *Id.*

132. *Perry*, 456 F. Supp. 2d at 685; *Dobbs*, 2008 WL 169021, at *13.

133. *Perry*, 456 F. Supp. 2d at 685; *see also Dobbs*, 2008 WL 169021, at *13.

> Where the FDA has evaluated scientific evidence regarding an alleged risk associated with a drug, has considered whether that evidence warrants a labeling warning, and has expressly rejected the need for such warning as not supported by credible evidence, a state law determination that such a warning is required creates a conflict for the manufacturer as between federal and state law, and imposes inconsistent federal and state obligations.

Id.

134. *Id.* at 683; *see also Vioxx*, 501 F. Supp. 2d 776, 787. "At best, the preamble merely offers an opinion on the viability of the plaintiffs' state-law

Regulations, "any portion of a Federal Register notice other than the text of a proposed or final regulation" is considered an advisory opinion.[135] Although an advisory opinion must be followed by the agency until it is amended or revoked, "it can be changed at any time and a change does not require notice."[136] Moreover, the preamble's words contradict the plain language of the regulations in the 2006 Final Rule on Prescription Drug Labeling.[137] More specifically, the preamble sets forth that the FDA's labeling requirements are not minimum standards and that the regulations "establish a floor and a ceiling."[138] The FDA explains in its preamble that additional disclosures of risk information that are unsubstantiated could lead to manufacturer liability and would "not necessarily be more protective of patients."[139] In contrast, the 2006 Final Rule on Prescription Drug Labeling states that a manufacturer should revise a label to "include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved."[140]

Proponents of the FDA preamble and its preemption position argue that the preamble is a formal statement of the FDA and that deference can be accorded to an agency's preamble. Although the FDA cannot impose legal requirements through advisory opinions, regulatory interpretations do not lack legal force.[141] However, whether the FDA preamble carries a legal force is a prominent factor in determining what level of deference should be applied by the courts to its position on preemption of state failure-to-warn claims. But as discussed previously, the FDA preamble is not considered law and more likely deserves *Skidmore* deference.[142]

VI. THE POLITICS OF THE FDA'S EVOLVING POSITION ON PREEMPTION

The reasons behind the FDA's change in position with respect to preemption are not entirely clear. Perhaps a change in political

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claims given the existence of the federal regulatory scheme as a whole; it does not purport to interpret any specific statutory or regulatory provision, nor is it a regulation itself." *Id.*

135. 21 C.F.R. § 10.85(d)(1) (2006).

136. 21 C.F.R. § 10.85(g) (2006).

137. *McNellis*, 2006 WL 2819046, at *6.

138. *Id.* at *7 (citing Requirements on Content and Format Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3935).

139. *Id.*

140. Specific Requirements on Content and Format Labeling for Human Prescription Drug and Biological Products, 21 C.F.R. § 201.80(e) (2006).

141. Weiner, *supra* note 112, at 860.

142. *See supra* Part IV.C (analyzing what level of deference should be applied to the FDA's preamble of its 2006 statement on human prescription drugs and biological products).

climate and problems within the FDA's drug approval process may have influenced the FDA's recent shift toward preemption of state failure-to-warn prescription labeling claims. However, between 1998 and 2004, the pharmaceutical industry spent $673,701,988 on lobbying expenditures.[143] In addition, drug company contributions to President Bush during the 2000 and 2004 elections totaled $801,532.[144] Of course the change in rationale from 2000 to 2006 may not be entirely due to a change in the political landscape and the FDA may certainly have other reasons to support its position on preemption of state failure-to-warn prescription labeling claims.

Problems with the FDA drug approval process may also provide some insight for the FDA's position on preemption. As previously explained, when a new drug is placed on the market, it carries some risk despite being FDA-approved. These risks may not be known until the drug is widely available on the market.[145] The FDA's MedWatch program has been utilized so that health professionals receive voluntary reports regarding possible adverse effects of a drug.[146] It is questionable whether a voluntary program relying upon overworked physicians and other healthcare professionals provides an efficient method for the discovery of adverse effects of a new drug.[147] Certainly, it is understood that the FDA's concern with additional warnings on prescription labels relates to tension between its potentially conflicting goals of balancing "the need for safety with a desire to encourage widespread use of effective treatments."[148] However, if an adverse risk is reported through the MedWatch program, or if initial research studies conclude that an adverse risk may be associated with a particular drug, it would be beneficial to place a warning on the prescription label. With all of the current information about the possible adverse effects of a drug at hand, a physician will be better able to determine the appropriate drug treatment/therapy for his/her patients.

In addition to the fact that a new drug on the market may carry risks, and in light of the FDA's view on additional warnings

143. Lobby Watch: Pharmaceuticals and Other Health Products, The Center for Public Integrity: Investigative Journalism in the Public Interest, http://www.publicintegrity.org/lobby/profile.aspx?act=industries&in=78 (last visited Dec. 8, 2006).

144. Pharmaceutical Manufacturing: Top 20 Presidential Candidates, http://www.opensecrets.org/industries/recips.asp?Ind=H4300&Cycle=2004&recipdetail=P&Mem=N&sortorder=U (last visited Dec. 8, 2006).

145. *MedWatch*, *supra* note 15.

146. *Id.*

147. *See* Goldman, et. al, *supra* note 16 (discussing the effectiveness of depending on physicians and healthcare professionals voluntarily to report adverse effects of drug).

148. *Perry*, 456 F. Supp. 2d at 685.

for a prescription drug label, other problems may occur within the FDA drug approval process. Take for instance the recent litigation on Vioxx, a pain relief medication used for treatment of arthritis and acute pain conditions that was removed from the market following an association with an increased risk of heart attacks and strokes. The congressional testimony of Dr. David Graham, an Associate Director for Science and Medicine for the FDA Office of Drug Safety, highlights some of these other problems within the FDA drug approval process.[149] In his testimony, Dr. Graham described research that he conducted in collaboration with Kaiser Permente concluding that high-dose Vioxx significantly increased the risk of heart attacks and sudden death, and that high doses of the drug should not be prescribed or used by patients.[150] When Dr. Graham informed his office, the FDA Office of Drug Safety, of the results and his intention to present the data at an international conference, he was "pressured to change [his] conclusions and recommendations" and threatened that if he did not make the appropriate changes to his presentation, he would not present the results at the meeting.[151] At the same time, Dr. Graham received an e-mail from the Director of the FDA Office of New Drugs suggesting that "since the FDA was not contemplating a warning against the use of high-dose Vioxx, [his] conclusions should be changed."[152] Furthermore, Dr. Graham wrote a manuscript reporting his research on Vioxx, and it was approved for publication in a prestigious journal after extensive peer-review.[153] Despite acceptance of the manuscript, the senior managers in the Office of Drug Safety did not initially grant clearance for its publication.[154]

The actions of the FDA relating to Dr. Graham raise the appearance of a conflict of interest within FDA drug approval process. The FDA is the same agency charged with approving new drugs to go on the market (FDA Office of New Drugs), and it is also responsible for taking regulatory action after a new drug is placed on the market (FDA Office of Drug Safety). According to Dr. Graham, the Office of New Drugs "is the single greatest obstacle to effectively protect the public against safety risks."[155] When the Office of New Drugs is informed by the Office of Drug Safety that a safety issue has occurred, the immediate reaction is

149. *See FDA, Merck and Vioxx: Putting Patient Safety First?*, *supra* note 18 (discussing Dr. Graham's personal experiences and opinions on the FDA approval process).
150. *Id.*
151. *Id.*
152. *Id.*
153. *Id.*
154. *Id.*
155. *Id.*

"almost one of denial, rejection, and heat."[156] Dr. Graham suggests that the second greatest obstacle in protecting the public against safety risks is "often the senior management within the Office of Drug Safety, who either actively or tacitly goes along with what the Office of New Drugs wants."[157]

With the internal problems of the FDA's drug approval process and the influence of politics on the FDA, consumers will need a method of keeping a check on the FDA. Adversary litigation provides a way to check and balance problems with the FDA drug approval process that can affect consumers. However, if deference is given to the FDA's position on preemption, adversary litigation will not be an option.

VII. CONCLUSION

Although it is Congress' authority to determine if state failure-to-warn prescription labeling claims should be preempted, it has not spoken on this issue. In the absence of any direction from Congress and with an increase in litigation related to federal preemption of prescription drug labeling failure-to- warn claims, the U.S. Supreme Court will ultimately have to address this issue. Regardless of how the U.S. Supreme Court stands on federal preemption of state failure-to-warn prescription labeling claims, its decision will have a significant impact on pharmaceutical litigation. More importantly, the U.S. Supreme Court's decision will bind lower courts even if Congress does not speak on the issue of preemption.

156. *Id.*
157. *Id.*