THE FDA: ADVOCATE OR REGULATOR OF THE PHARMACEUTICAL INDUSTRY? THE ATTEMPTED PREEMPTION BY THE FDA OF STATE TORT CLAIMS FOR FAILURE TO WARN ON PHARMACEUTICAL LABELING

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I. INTRODUCTION

> The [Food and Drug Administration] is responsible for protecting the public health by assuring the safety, efficacy, and security of human . . . drugs, biological products, medical devices. . . . The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines . . . more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines . . . to improve their health.[1]

The Food and Drug Administration (FDA) was created by the Food and Drug Act of 1906 (hereinafter "1906 Act"). In the 1906 Act and subsequent amendments, Congress charged the FDA with regulating the food, drug, and cosmetic industries in order to pursue the goal of protecting public health.[2]

The 1906 Act, was passed primarily to regulate the adulteration of food and drugs that entered into interstate commerce.[3] A major problem with the 1906 Act is that it left the newly created agency under the control of the Department of Agriculture, a food industry advocate.[4] As

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1. U.S. Food and Drug Administration, FDA's Mission Statement, http://www.fda.gov/opacom/morechoices/mission.html (last visited Aug. 20, 2006).

2. *See* JAMES T. O'REILLY, FOOD AND DRUG ADMINISTRATION § 3 (2d ed. 2006).

3. *Id*. § 3:2 (Describing the considerable effort by Dr. Harvey Whiley to gain passage of the Food and Drug Act of 1906. Dr. Whiley, the Head of the Bureau of Chemistry for the Department of Chemistry, was concerned with getting adulterants out of food products. To get the data needed to back his claims regarding the adulteration of food products, Dr. Whiley conducted a series of experiments that would very likely not be allowed today. He conducted experiments in which healthy human volunteers were fed common food preservatives in use at that time. From these experiments data were collected showing that many of these preservatives were harmful for human consumption); *See also* David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 LAW & CONTEMP. PROBS. 2 (1939).

4. O'REILLY, *supra* note 2, § 3:3 (an additional important problem with the 1906 Act was that it created a poorly funded agency that had little real authority to regulate the food and drug industries by requiring safety testing or by requiring the removal of adulterated products from the market).

a result, the head of the Department of Agriculture frustrated the purpose of the 1906 Act by placing significant impediments to its enforcement by the FDA.[5]

In addition to placing the FDA under the control of the Department of Agriculture, the 1906 Act had very weak enforcement mechanisms, no requirement for safety testing, and little funding.[6] A national tragedy occurred in 1936 as a result of the weak agency being placed under the control of a department that served as an industry advocate.[7] The Massengill Company marketed an elixir using a toxic solvent that resulted in the deaths of more than seventy-five people.[8] The tragedy could have been averted had safety tests been required before marketing the drug.[9] Additionally, because of weak enforcement powers delegated to the FDA in the 1906 Act, the FDA could not require the removal of the drug from the marketplace because of adulteration; instead, the agency had to rely on the product being misbranded.[10]

The role of the FDA as the protector of public health was compromised when its role as regulator was subverted by compromises made during the passage of the 1906 Act and by placing the agency under the control of the Department of Agriculture, the advocate for industry concerns.[11] In the years since the Massengill elixir affair, Congress has taken steps to strengthen the regulatory power of the FDA, removing it from under the control of the Department of Agriculture.[12] The purpose of strengthening the FDA powers was to make the FDA an independent regulator of the food and drug industries.[13] Based on the stated mission of the FDA as the protector of public health and regulator of the drug industry, recent efforts by the FDA to act as an industry advocate in state tort claims have come as a shock.[14]

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5. *Id*.

6. *Id*.

7. *Id*. § 3:4.

8. *Id*. (The elixir contained diethylene glycol as the solvent. Diethylene glycol is toxic to the kidneys resulting in kidney failure and death when consumed in high enough quantities).

9. *Id*. (The elixir was tested for flavor and fragrance, but no safety tests were performed. Had the elixir been fed to test animals, its toxicity would have been evident).

10. *Id*. (The FDA could only charge that the drug was misbranded because it was misleading to use the term "elixir" with a product that did not contain alcohol. The Chief Counsel for the FDA admitted later that the product would likely have not been misbranded had the label stated that the elixir contained diethylene glycol).

11. O'REILLY, *supra* note 2, § 3:3.

12. *Id*. § 3:5.

13. *Id*.

14. Press Release National Conference of State Legislatures, *NCSL: Proposed FDA Rule Preempts State Product Liability Laws; Back-Door Approach Seeks Powers Denied by Congress and the Courts*, U.S. NEWSWIRE (Jan. 13, 2006) *available at* http://releases.usnewswire.com/GetRelease.asp

On January 24, 2006, the FDA published long expected changes to the prescription drug labeling requirements.[15] The final rule contains language in the preamble asserting the FDA's belief that the rule should preempt state tort failure to warn claims against drug manufacturers and physicians.[16] The proposed rule, originally published in 2000, had specifically stated that none of its provisions would preempt state law.[17] The change of position sent shockwaves through the legal and political world. Plaintiffs' attorneys,[18] state legislators,[19] and federal legislators[20] argued that the FDA action was a "back door" [21] approach by the Bush Administration to tort reform.

This Comment will examine the validity of the FDA's argument for preemption of state failure to warn claims with respect to the Constitution, the Administration Procedure Act (APA), and Executive Order 13132 (EO 13132). Part II of this comment details the FDA's argument for preempting state tort law. This Part also describes the background of the drug approval process in order to provide a better understanding of the reasoning behind the FDA's assertion of preemption. Part III of this Comment examines whether the attempted preemption is unconstitutional, violates the APA and E.O. 13132, and whether the FDA's argument is deserving of deference from the court. Part IV discusses the policy implications of the preemption language. Finally, Part V concludes that although some of the reasoning supporting FDA preemption may be sound, inclusion of preemptive language in the preamble, which is not subject to judicial review and was not subject to a comments period, is unconstitutional, violates the APA and EO 13132, and is not worthy of deference from the court.

?id=59262; *Advocates, State Lawmakers Blast FDA Labeling Rule*, THE FOOD & DRUG LETTER, Feb. 3, 2006.

15. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3,922 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, and 601).

16. *Id*. at 3,933.

17. Requirements on Contents and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81,082 (Dec. 22, 2000) (proposed rule by FDA to revise regulations controlling the labeling of prescription drugs).

18. Marc Kaufman, *FDA Tries to Limit Durg Suits in State Courts; Agency's "Federal Preemption" Policy Included in Labeling Guidelines for Medications,* WASH. POST, Jan. 19, 2006, at A2

19. Press Release, National Conference of State Legislatures, *supra* note 14.

20. *Rep. Hinchey Issues Statement on FDA's New Rule that Protects Drug Companies from Liability Suits*, U.S. FED NEWS, Jan. 18, 2006, *available at* 2006 WLNR 1103087; *Democrats Consider Legislation to Stop FDA Labeling Preemption*, 5 CLINICAL TRIALS ADVISOR 14 (Jan. 20, 2006).

21. Press Release, National Conference of State Legislatures, *supra* note 14.

II. FDA ARGUMENT FOR PREEMPTION

A. Reasoning for Preemption

The FDA proposes three reasons why preemption of state tort failure to warn claims is justified by the new prescription drug label regulations.[22] First, the "FDA is the expert Federal public health agency charged by Congress with ensuring that . . . [drug] labeling adequately informs users of the risks and benefits of the product and is truthful and not misleading."[23] As such, the agency is solely responsible for regulating the content of the labels that manufacturers put on drugs.[24] A manufacturer wanting to change a label must inform the FDA and receive approval for the change.[25] Failure to warn claims are based on state laws that require more warning information than is required by the FDA.[26] The FDA argues that the state laws "directly threaten[] the agency's ability to regulate manufacturer dissemination of risk information for prescription drugs in accordance with the [Food, Drug and Cosmetic Act]."[27]

The second justification for the assertion of preemption is that state courts have incorrectly stated that FDA labeling requirements represent a minimum safety standard.[28] The state courts have held that state laws can supplement FDA regulations and require manufacturers to provide additional safety information.[29] The FDA asserts that the Food, Drug and Cosmetic Act (FDCA) gives the agency the power to establish both the floor and the ceiling of safety standards for drug labeling.[30] Thus, a manufacturer's warning containing information that satisfies state law but that is unapproved by the FDA may subject the manufacturer to an enforcement action from the FDA for including information that may be found to be unsubstantiated, false or misleading.[31]

22. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3,922, 3,934 (Jan. 24, 2006).

23. *Id*.

24. 21 U.S.C. § 355 (2006).

25. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products , 71 Fed. Reg. at 3,934; 21 C.F.R. 314.70(b) (2006); 21 C.F.R. 601.12(f)(1) (2006).

26. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products ,71 Fed. Reg. at 3,934.

27. *Id*.

28. *Id*.

29. *Id*.

30. *Id* at 3935.

31. *Id*.

The reasoning for this interpretation is that the FDA is charged with making determinations of a drug's safety and effectiveness, in association with its labeling, before allowing it on the market.[32] For a drug to be safely and effectively used, the labeling must adequately describe the appropriate use and the risks associated with the drug.[33] Disclosure of risk information that is not scientifically sound "[is] not necessarily more protective of patients . . . [and] . . . [e]xaggeration of risk could discourage appropriate use of a beneficial drug."[34] The FDA warns that state laws requiring "overwarning" of a drug's risks can negatively affect patient safety by "potentially discouraging safe and effective use of approved products."[35]

The third justification for preemption is that the "[s]tate law actions [may] threaten [the] FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs."[36] The FDA's expertise is the evaluation and regulation of drugs and their labels that enter the marketplace.[37] State courts and juries do not have this expertise, yet state laws require them to "second-guess" the risk-benefit analysis of the FDA.[38] These state laws subject manufacturers to liability for risks that may affect only a few individuals and lead to significant damages and penalty awards. The state laws "could encourage manufacturers to propose 'defensive labeling' to avoid State liability, which, . . . could result in scientifically unsubstantiated warnings and underutilization of beneficial treatments."[39]

Since 2002, the FDA has sought out private, civil litigation cases where it has argued for federal preemption of state failure to warn claims against drug companies based on the above reasoning.[40] As of July 2004, the FDA had spent over 622 hours working on these cases.[41] The FDA has stated that the preemption language was added to the preamble

32. *Id.*; Food, Drug and Cosmetic Act, 21 U.S.C. § 301 (2006).

33. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3,935.

34. *Id*.

35. *Id*.

36. *Id*.

37. *Id*.

38. *Id*.

39. *Id*.

40. Robert Cohen, *FDA Joins Suits on Side of Industry it Regulates*, Newhouse News Service, May 10, 2004; *FDA: Recent Involvement in Product Liability Suits Examined,* AMERICAN HEALTH LINE, May 11, 2004; *DOJ to Appeals Court: FDA Approval Preempts State Tort Claims*, FDA WEEK, May 21, 2004, *available at* 2004 WLNR 79837; *FDA: Newsday Examines FDA Intervention in Liability Lawsuits,* AMERICAN HEALTH LINE, Aug. 12, 2004; *Hinchey Rebuts Precedent Cited for FDA Intervention in Drug Suits*, DRUG INDUSTRY DAILY, Aug. 13, 2004.

41. 150 Cong. Rec. H5581 (2004) (Congressman Hinchey's remarks on house floor).

of the final rule because the preemption arguments had failed in several recent cases.[42] The FDA has also stated that the preemption language in the preamble is consistent with the arguments advanced in the civil cases.[43] The agency argues that the new labeling rule should preempt at least six types of failure to warn claims: 1) failing to place a risk in highlights if the risk is listed anywhere in the drug labeling; 2) failing to list risks in advertisements that also appear anywhere in the drug labeling; 3) failing to include contraindications or warning of adverse effects that are not supported by the evidence; 4) failing to include statements that the FDA did not require; 5) failing to include a statement that the FDA prohibited in the label; and 6) including any information that received FDA approval.[44]

B. Background on the FDA

To understand the rationale for FDA preemption of state tort failure to warn claims, it is important to understand how the FDA regulates the drug industry. One purpose of the FDA is to protect the public health by regulating the drug industry.[45] Congress delegated to the FDA the authority to require drug manufacturers to receive premarket approval before a drug can enter interstate commerce.[46] The purpose of pre-market approval is to determine that drugs are safe and effective at treating specified medical conditions.[47] In addition to safety and efficacy testing, manufacturers must receive FDA approval for all labeling that is to accompany the drug, including any post-approval changes that a manufacturer may wish to make to the labeling.[48] The FDA also has the authority to track adverse events of approved drugs and recommend changes to labeling and even the removal of a drug from the market.

42. *Executive Order May Be Used to Challenge Proposed FDA Labeling Rule*, DRUG INDUSTRY DAILY, Jan. 17, 2006.

43. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3,936–37.

44. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3,937.

45. *See* U.S. Food and Drug Administration, *supra* note 1.

46. Food, Drug and Cosmetic Act 21 U.S.C.. § 355(a) (2006).

47. *See* 21 U.S.C. § 355 (2006).

48. *See* 21 U.S.C. § 355 (2006).

1. Premarket Approval

To obtain pre-market approval, a drug manufacturer submits a new drug application (NDA) to the FDA. The NDA must contain full reports of all investigations into the safety and effectiveness of the drug, as well as all of the labeling that accompanies the drug.

The safety and effectiveness testing occurs in three phases of human trials, takes two to ten years, and must be completed before filing the NDA.[49] The first phase is designed to determine if the drug is safe in humans at various doses.[50] These experiments are performed on a limited number of volunteers over a fairly short period of time.[51] After the drug is determined to be safe in phase-one testing, it moves into phase two.[52] The second phase of testing is designed to test therapeutic efficacy.[53] Again, these studies are conducted on a limited number of people for a limited period of time.[54] If the drug is deemed safe and effective after phase two, then the drug moves into phase three.[55] Phase three is designed to examine safety and efficacy in a much larger population of carefully screened patients for a limited amount of time, regardless of the probable duration of treatment that may actually be required.[56]

The FDA bases the decision to approve a drug on the data collected from the human trials contained in the NDA.[57] Due to ethical, temporal, and financial limitations, these trials are limited in scope and can only detect the "most profound and overt risks" that may be associated with a drug.[58] More subtle but important risks likely will not be discovered until the drug is on the market.[59]

In addition to reviewing the safety and efficacy data, the FDA also reviews and approves the labeling that is to accompany the drug.[60] In general, the labeling must accurately describe the medical condition the drug is designed to treat, how the drug is to be taken, and any

49. Alan S. Nies & Stephen P. Spielberg, *Principles of Therapeutics*, *in* GOODMAN & GILMAN'S THE PHARMACOLOGICAL BASIS OF THERAPEUTICS 43, 56 (9th ed. 1996).

50. *Id*.

51. *Id*.

52. *Id*.

53. *Id*.

54. *Id*.

55. *Id*.

56. *Id.* at 56, 57 (Phase three studies include from 500 to 3,000 patients. Of these patients, a few hundred will be selected to take the drug for longer than three to six months.).

57. *Id*.

58. *Id.* at 57.

59. *Id.* at 56.

60. 21 U.S.C. § 355(b) (2006).

scientifically proven risks associated with the drug.[61] The contents of the labeling are based on the data collected during the three phases of human trials.[62] Thus, only "profound and overt risks" associated with a drug will meet the standard of being scientifically proven risks resulting in a warning in the label of a newly marketed medication.[63] Even though the FDA's scientific review of a drug is both "thorough and scientifically rigorous",[64] the potential exists that patients could suffer serious adverse effects for which they were not warned because the risks were not scientifically proven in the human trials.

Due to the inability to detect potentially serious risks associated with a new drug during the three phases of human trials, the FDA has enacted several regulations requiring the reporting of adverse events.[65] FDA regulations require drug manufacturers to keep records and to promptly file reports with the FDA of any serious adverse events that may be associated with the drug.[66] Failure to comply with the reporting regulations will subject the manufacturer to a variety of enforcement options available by statute to the FDA.[67]

The FDA reviews adverse event information to ensure that approved drugs are safe and effective once on the market.[68] In most cases, the FDA makes the determination of continued safety based on a review of the adverse event reports and a finding that there is no scientific basis for a causal relationship between the adverse event and the drug.[69] When the FDA makes a determination that a causal relationship exists between a drug and reported adverse events, the FDA will usually require the incorporation of additional warnings in the drug labeling describing the newly found risks associated with the drug.[70] In rare cases, the adverse event warrants withdrawal of an approved drug from the marketplace.[71]

61. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3,922, 3,934 (Jan. 24, 2006).

62. *See* Nies & Spielberg, *supra* note 49.

63. *Id*.

64. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3,967.

65. *Id.* at. 3,968 (adverse events are defined as "serious, unexpected drug experiences").

66. 21 C.F.R. § 314.80 (2006); 21 C.F.R § 314.81 (2006).

67. 21 U.S.C. § 331(e) (2006) (manufacturers in violation of reporting rules subject to enforcement action); 21 U.S.C.. §§ 332, 333(g)(1)(A) (2006) (FDA may seek injunctive relief and civil penalties).

68. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3,968.

69. *Id*.

70. 21 C.F.R. §201.57(e) (2005).

71. 21 C.F.R. 601.5(b)(1) (2006).

2. Approval of Labeling Changes

In most circumstances, changes to drug labeling are initiated by manufacturers.[72] However, as mentioned above, the FDA has the authority to mandate changes to drug labeling.[73] At the center of the current debate are changes to the current labeling regulations that took effect in June 2006.[74] The FDA claims to have the authority to regulate every word in the labeling that accompanies a drug.[75] Labeling includes the label that is placed on the vessel that contains the drug, as well as the sheets of paper accompanying the drug, which are meant to be read by the prescribing physician.[76]

According to FDA regulations, making substantive changes to prescription drug labeling requires the manufacturer to submit a supplemental application explaining the need for the change.[77] The FDA permits label changes using two different mechanisms: prior approval supplements and "changes being effected (CBE) supplements."[78] Prior approval supplements require FDA approval before the manufacturer can change the labeling.[79] CBE supplements allow the manufacturer to make changes to labeling prior to receiving FDA approval as long as the FDA is notified first.[80] The agency argues that manufacturers rarely pursue this option because they could subject themselves to an enforcement action if the FDA finds that the changed information makes the labeling false or misleading.[81] The FDA alleges that several products liability law suits in recent years have been based on state product labeling laws that required information be placed on the label that the FDA specifically rejected as being unsubstantiated scientifically.[82]

72. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3,934, 3,968.

73. *Id*.

74. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3,922.

75. *Id*. at 3,934–35.

76. *Id*.

77. *Id*. at 3,934.

78. *Id*.

79. *Id*.

80. *Id*.

81. *Id*. ("[T]he determination whether labeling revisions are necessary is, in the end, squarely and solely FDA's under the act."); 21 U.S.C. § 352 (2006).

82. *Id*. (discussing Dowhal v. SmithKline Beechum Consumer Healthcare, 2002 Cal. App. LEXIS 4384 (Cal. Ct. App. Jul. 12, 2002), *rev'd*, 2004 Cal. LEXIS 3040 (Cal. Apr. 15, 2004).

III. VALIDITY OF FDA ARGUMENT FOR PREEMPTION

A. Constitutionality of Preemption by FDA: Presumption Against Preemption

Any discussion of federal preemption of state law must begin with the Supremacy Clause of the Constitution.[83] The Supremacy Clause declares that the Constitution and the laws made by the Federal Government under the authority of the Constitution "shall be the supreme Law of the Land."[84]

The Tenth Amendment of the Constitution serves as a limitation on the power of the Federal Government to preempt state law.[85] The Tenth Amendment states that "[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the states, are reserved to the States respectively, or to the people."[86] Federal preemption of state law is valid only when the right is reserved in the Constitution. The Supreme Court has ruled that Congress can intrude on areas traditionally in the jurisdiction of the states by using the Commerce Clause of the Constitution.[87] Furthermore, Congress can delegate Commerce Clause authority to federal administrative agencies to regulate areas traditionally entrusted to the states.[88] Preemption of state laws using the Commerce Clause is in direct tension with the Tenth Amendment. The courts deal with this tension by using the Commerce Clause to preempt state law in areas traditionally under state regulation.

In preemption cases, the courts operate under the strong presumption that "Congress did not intend to displace state law."[89] To rebut the presumption against preemption, the federal government must

83. U.S. Const. art. VI, cl. 2.

84. *Id*.

85. Philip H. Corby & Todd A. Smith, *Federal Preemption of Product Liability Law: Federalism and the Theory of Implied Preemption*, 15 AM. J. TRIAL ADVOC. 435.

86. U.S. Const. amend. X.

87. Gibbons v. Ogden, 22 U.S. 1 (1824) (federal government is responsible for ensuring effective interstate commerce by the Constitution. State actions that threaten interstate commerce fall within the domain of preemption by federal laws).

88. Bethlehem Steel Co. v. N.Y. State Labor Relations Bd., 330 U.S. 767, 773 (1947) ("When Congress has outlined its policy in rather general and inclusive terms and delegated determination of their specific application to an administrative tribunal, the mere fact of delegation of power to deal with the general matter, without agency action, might preclude any state action if it is clear that Congress has intended no regulation except its own.").

89. Maryland v. Louisiana, 451 U.S. 725, 746 (1981); *see also* Corby & Smith, *supra* note 85 (for a detailed discussion of theories of implied preemption applied by the courts to tackle tension between the Tenth Amendment and intrusion on areas traditionally within the regulatory domain of the states).

demonstrate that Congress clearly manifested the intent to preempt state law.[90] The Court has stated four instances where such a congressional expression of intent may be found.[91] First, Congress can explicitly declare in statutory form that an agency is empowered to create regulations that preempt state law.[92] Second, state law is preempted where federal law directly conflicts with state law.[93] Third, state law may be preempted in the absence of explicit statutory language when the state rule intrudes on a field of law that Congress has intended for the Federal Government to exclusively occupy.[94] However, Congress must clearly manifest the intent to preempt state law when attempting to completely occupy a field traditionally occupied by the states. A fourth and more controversial method to show congressional intent to supercede state law is implied preemption.[95] The government may assert implied preemption when a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[96]

The FDA does not have explicit statutory authority to preempt state tort failure to warn claims for injuries caused by prescription drugs.[97] However, based on the principle of implied preemption, the FDA claims that state tort liability for failure to warn obstructs and frustrates the purpose of protecting public health by requiring warnings of risks in drug labels that have not been approved.[98]

The FDA cites two classes of cases where state courts have interfered with the ability of the FDA to protect the public health by rejecting FDA assertions of preemption.[99] First, state courts have held that manufacturers have the right to strengthen label warnings without approval of the FDA.[100] The FDA asserts that the FDCA gives them

90. Hillsborough County, Fla. v. Automated Med. Labs., Inc., 471 U.S. 707 (1985); *see also* Allis-Chalmers Corp. v. Lueck, 471 U.S. 202, 208 (1985).

91. English v. Gen. Elec. Co., 496 U.S. 72, 76 (1990).

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

93. *Id*. (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)).

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

95. 2 Food and Drug Admin. § 25:5 (2006).

96. Hillsborough County, Fla. v. Automated Med.Labs, Inc., 471 U.S. 707, 713 (1985) (citing *Hines*, 312 U.S. at 67); *see also* 2 Food and Drug Admin. § 25:5 (2005); Corby & Smith, *supra* note 85, at 448.

97. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3,922, 3,935 (Jan. 24, 2006).

98. *Id*. at 3,934.

99. *Id*.

100. *Id*. (citing Eve v. Sandoz Pharm. Corp., 2002 U.S. Dist. LEXIS 23965 (S.D. Ind. Jan. 28, 2002)); Ohler v. Purdue Pharma, L.P., 2002 U.S. Dist. LEXIS 2368 (E.D. La. Jan. 22, 2002); Motus v. Pfizer Inc., 127 F.Supp. 2d 1085 (C.D. Cal. 2000).

statutory authority to determine the necessity of revisions to drug labeling.[101] This argument is weakened by the admission that manufacturers do have the right to strengthen labels under the FDCA but rarely do so without consultation with the FDA due to the fear of an enforcement action based on the drug being misbranded. Notably, no records indicate that the FDA has ever sought an enforcement action against a drug manufacturer for increasing risk information on a drug label.[102] Additionally, the FDA does not have the authority to declare a drug misbranded. The FDA can have a drug declared misbranded only by bringing an enforcement action against a drug manufacturer in federal court. Thus, only the federal court system has authority to determine if the drug is misbranded.

The second line of cases that the FDA alleges interferes with the ability to protect the public health concerns "defensive labeling [by drug manufacturers] to avoid State liability."[103] Defensive labeling could lead to overwarning of scientifically unproven risks associated with a drug.[104] The FDA alleges that overwarning could have two detrimental effects on public health.[105] First, overwarning of speculative risks associated with a drug could decrease the significance of meaningful risk information.[106] Second, overwarning could discourage the use of a beneficial drug.[107] The FDA does not cite any studies to support claims that overwarning of potential side effects causes any significant detrimental effect on the public health. In addition, state tort actions do not interfere with the protection of public health by the FDA because unfavorable tort rulings do not amount to a requirement to change drug labeling.[108] In *Bates v. Dow Agrosciences*, the Supreme Court held that a "jury verdict, that merely motivates an optional decision is not a requirement."[109]

FDA preemption of state failure to warn claims is unconstitutional because Congress has not given explicit statutory authorization to preempt state law. Further, implied preemption is not justified because state tort jury awards that compel manufacturer actions are not legal

101. *Id*.

102. James T. O'Reilly, *Can Advice Preempt Tort Plaintiffs? States Lose to Advisory Opinions*, ABA NEWSLETTER, Spring 2006.

103. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3,935.

104. *Id*.

105. *Id*.

106. *Id*.

107. *Id*.

108. Bates v. Dow Agrosciences, 544 U.S. 431, 445 (2005).

109. *Id*.

requirements,[110] and the FDA has no evidence suggesting that overwarning is detrimental to public health. If warnings required to comply with state law do not have a negative impact on the public health, then they can not interfere with the FDA's statutory purpose.

B. Does FDA Preemption Violate the APA?

The FDA's preemption claim violates the notice and comment requirements of the APA and, as such, is not worthy of deference from the courts. A primary concern that state legislators have about the insertion of preemption language into the preamble of the final rule without having been in the proposed rule is that the public was not given the chance to comment on the language.[111] To understand the significance of this concern, a general understanding of notice and comment rulemaking is important. This raises the questions of how the FDA classifies assertions of authority raised in the preamble, and how much deference the courts are required to give to the FDA's interpretation of its own power.

1. Rulemaking Requires Notice

The Administrative Procedure Act (APA) prescribes the procedures that agencies must follow to make a binding rule or regulation.[112] An agency must publish a notice of the proposed rule in the Federal Register.[113] Statements of general policy are excepted from the notice requirement.[114] After notice is given, the agency is required to "give interested persons an opportunity to [comment on the rule] through submission of written data, views, or arguments . . . ."[115] After considering the comments, the agency may alter the rule based on the comments and then must provide a concise general statement of the basis and purposes for the rule.[116] The preamble to a rule is part of the concise general statement and contains the agency's views on comments received from interested persons.[117] The public should then be given

110. *Id*.

111. Press Release, *Advocates, State Lawmakers Blast FDA Labeling Rule, supra* note 14.

112. 5 U.S.C. § 553 (2006) (describing the procedures for notice and comment rule making).

113. 5 U.S.C. § 553(b) (2006).

114. 5 U.S.C. § 553(b)(3)(A) (2006); this exception may be important since the assertion of preemption occurs not in the body of the rule, but in the preamble. The significance of this will be discussed in further detail below.

115. 5 U.S.C. § 553(c) (2006).

116. *Id*.

117. *Id*.

notice of the final rule, typically through publication in the Federal Register, at least thirty days before the rule goes into effect.[118] Finally, interested persons have the right to petition the agency to amend or repeal the rule.[119]

For an agency to make a binding rule using notice and comment rulemaking as required by the APA,[120] it must faithfully apply each of the steps described above. As is true with many statutes, the language used by the APA is subject to different interpretations regarding what constitutes compliance by the agency. When a dispute arises, the courts must determine if the agency has sufficiently complied with the statute. One judicial rule is that the final rule must be a logical outgrowth of the proposed rule.[121] The purpose of this rule is to put interested persons on notice regarding the scope of the regulation that will be put into effect.[122]

The issue under consideration with the assertion of preemption in the preamble is that no language regarding preemption appeared in the propose rule. The final rule as adopted by an administrative agency must be a logical outgrowth of the proposed rule. The draft specifically stated that the new labeling regulations would not preempt state law.[123] The proposed rule requested comments on product liability concerns with the rule, but did not request comments regarding preemption.[124] State governments were not put on notice that the scope of the regulation would include an attempt to preempt state tort law. The attempt to preempt state tort failure to warn claims in the preamble represents a radical change in the position taken by FDA in the proposed rule. As such, it cannot be a logical outgrowth from the proposed rule and thus violates the APA.

2. How Much Deference Should Courts Give FDA Preemption in the Preamble?

Placing the preemption language in the preamble of the final rule has three primary effects. First, being in the preamble presumably shields

118. 5 U.S.C. § 553(d) (2006).

119. 5 U.S.C. § 553(e) (2006).

120. 5 U.S.C. § 553 (2006).

121. Chocolate Mfrs. Ass'n v. Block 755 F.2d 1098, 1107 (4th Cir. 1985).

122. *Id*.

123. Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81,082, 81,103 (Dec. 22, 2000).

124. *Id*.

the language from the notice and comment requirements of the APA.[125] Second, according to the 1976 procedural rules of the FDA, a preamble to a final rule is to be treated as an advisory opinion.[126] Advisory opinions are binding only on the agency, not state courts. Third, because the language of the preamble is treated only as an advisory opinion and is not binding on any entity but the FDA,the preamble is not subject to judicial review.

What does this mean to the plaintiff in state court attempting to bring a failure to warn claim against a manufacturer for injury by a drug? The plaintiff's attorneys will argue that state courts are not bound by an advisory opinion of the FDA. The defendant's attorneys will argue that the FDA is the government's expert body on drug labeling and that if FDA is of the opinion that the rule preempts the state tort claim, then the claim is preempted, and the court should dismiss the claim. Although an advisory opinion is not binding on a court, the court may give some level of deference to an agency's interpretation of a rule.[127] The problem for the court is determining how much deference to give to the FDA's assertion of preemption.

The Supreme Court decided two landmark cases that describe how much deference an agency should receive when interpreting the extent of their congressionally delegated authority, *Skidmore v. Swift & Co*.[128] and *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc*.[129] *Skidmore* dealt with the issue of how much deference the courts should give an agency's statutory interpretation that appears in the form of an advisory opinion.[130] The district court gave no deference to the agency and ruled solely on its own interpretation of the statute in question.[131] The Supreme Court reversed, stating that the courts should give some deference to the agency's interpretation of the statute.[132] The Court stated that determining the proper level of deference to give to the agency's opinion "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

125. Unless the argument is successfully made that the language in the preamble changes the final rule such that it is no longer a logical outgrowth of the draft rule.

126. O'Reilly, *supra* note 102.

127. Yates v. Hendon, 541 U.S. 1, 4 (2004) (citing Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944)).

128. 323 U.S. 134.

129. 467 U.S. 837 (1984).

130. 323 U.S. at 134.

131. *Id*. at 136.

132. *Id*. at 136–40.

persuade, if lacking power to control."[133]

In *Chevron*, the issue was whether the agency or the court should interpret the extent of authority that Congress delegated to the agency in the enabling statute.[134] The Supreme Court held that agencies are in a better position to make policy decisions since they are part of the political branches of government and have expertise in the field in which the statute is to be applied.[135] The Court established a two-part test to determine how much deference should be given to an agency's interpretation of the enabling statute. First, where Congress has spoken clearly on the issue, the congressional interpretation of the statute stands.[136] If Congress is silent as to the issue or ambiguous, then the agency has the right to interpret the statute, and the inquiry becomes whether the agency's interpretation is reasonable.[137]

The ruling in *Skidmore* requires courts to give some deference to an agency's interpretation of a statute, but it leaves to the court to decide the level of deference to be afforded in a particular case based on a sliding scale.[138] In *Chevron*, the Court established a bright line test: unless Congress has clearly stated its interpretation of the statute for the issue at hand, the agency's interpretation should receive considerable deference from the courts as long as the interpretation is reasonable.[139] To establish the level of deference that courts should give the FDA's assertion of preemption in the preamble of the final rule, it must be determined which of these cases is controlling, *Skidmore* or *Chevron*.

In *U.S. v. Mead Corp.*,[140] the Court was asked to determine the appropriate level of deference to give the statutory interpretation contained in a ruling letter by the Customs Service. The ruling letter contained the official opinion of the Customs Service regarding its interpretation of a statute.[141] The Court refused to give the letter the heightened *Chevron* deference and instead applied the lower *Skidmore* deference.[142] The Court reasoned that the ruling letter did not warrant *Chevron* deference because it was not based on a process of rulemaking or adjudication that gave interested parties an opportunity to participate

133. *Id*. at 140.
134. 467 U.S. 837.
135. *Id*. at.843–44.
136. *Id*. at 842–43.
137. *Id*. at 844.
138. 323 U.S. 134.
139. 467 U.S. 837.
140. 533 U.S. 218 (2001).
141. *Id*. at 230–31.
142. *Id*. at 231.

in the formulation of the opinion.[143] Thus, the Court reasoned that *Skidmore* deference was appropriate since the ruling letter represented the opinion of the administrative agency on the application of the statute.[144] The *Mead* case emphasizes the significance the court places on the "thoroughness evident in [an agency's] consideration"[145] when determining how much deference to give an agency's interpretation of a statute.[146]

Based on the procedural rules of the FDA, the preamble of a final rule is considered an advisory opinion.[147] Accordingly, the preamble should receive *Mead* or *Skidmore* deference, which is much less than *Chevron* deference.

Applying *Mead* deference, a court analyzing the preemption language in the preamble will consider the "formality, consistency, thoroughness, and persuasiveness of the agency's view."[148] Of relevance to this discussion are the requirements of formality, consistency, and persuasiveness.

Formality pertains to the process required for the promulgation of the rule, regulation, or, as in the current instance, advisory opinion. The FDA rule itself was subjected to the formality of notice and comment rulemaking, but the assertion of preemption was inserted into the preamble of the final rule without any opportunity for public comment. In fact, the proposed rule published in 2000 specifically stated the rule would not preempt state law.[149] Thus, preemption as asserted in the preamble fails the formality consideration of the *Mead* test.

The FDA will have a hard time convincing a court that this interpretation is consistent with previous pronouncements. First, as mentioned above, the proposed rule specifically stated that the labeling rule would not preempt state law. Second, until the FDA began filing amici briefs in support of preemption in 2002, the agency had never proposed the view that the FDA regulations preempted state tort claims.[150] Accordingly, the argument for preemption fails the

143. *Id*. at 229.

144. *Id*. at 231.

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

146. U.S. v. Meade Corp., 533 U.S. 218 (2001).

147. 21 C.F.R. § 10.85(d)(1) (2006) (originally issued in 1979).

148. Allison Zieve & Brian Wolfman, *The FDA's Argument for Eradicating State Tort Law: Why it is Wrong and Warrants No Deference*, 34 PRODUCT SAFETY & LIABILITY REPORTER 308, 315 (citing *Mead*, 533 U.S. at 228).

149. Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81,082, 81,103 (Dec. 22, 2000).

150. Zieve & Wolfman, *supra* note 148.

consistency prong of the *Mead* test for deference.

In addition, the assertion of preemption is not worthy of deference because the arguments proposed in the preamble are not persuasive.[151] The FDA argues that state tort laws interfere with their ability to regulate drug labels.[152] The basis for this argument is that the FDA, as part of its duty to protect the public health, has the right to approve all drug labeling. As the argument goes, drug companies subjected to state failure to warn claims will be compelled to add language to drug labeling that the FDA may consider scientifically meritless. Thus, if the manufacturers amend drug labeling to include the additional warnings, they would be in violation of FDA regulations and subject to administrative action for misbranding. In addition, the FDA argues that overwarning of risks that have not been scientifically validated may cause a drug to be underused and thus harm the public health.

These arguments fail for four reasons. First, during the nearly ninety-five years in which FDA regulation of the drug industry coexisted with state tort claims for failure to warn, no evidence has emerged to support the allegation that state tort law interferes with the agency's ability to regulate the drug industry.[153] Second, the FDA's claim to the right to declare both the "floor" and the "ceiling" of the drug-labeling warnings directly contradicts statements made in the 1998 publication of the final rule for the requirements for medication guides.[154] Third, the FDA has never brought an administrative action against a drug manufacturer for overwarning. Finally, no evidence exists to support the allegation that overwarning will decrease the use of a drug to the detriment of public health.

According to the rules adopted by the FDA, the preamble is equivalent to an advisory opinion.[155] Advisory opinions do not receive *Chevron* deference.[156] The preamble, as an advisory opinion, fails all prongs of the *Mead-Skidmore* test. Thus, the assertion of preemption in the preamble warrants no deference by the courts.

151. *Id*.

152. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products ,71 Fed. Reg. 3,922, 3,935 (Jan. 24, 2006).

153. Zieve & Wolfman, *supra* note 148, at 316.

154. Zieve & Wolfman, *supra* note 148, at 315 (quoting 63 Fed. Reg. 66,378, 66,384 (Dec. 1, 1998), "FDA's regulations establish the minimal standards necessary, but were not intended to preclude the states from imposing additional labeling requirements. States may authorize additional labeling requirements but they cannot reduce, alter, or eliminate FDA-required labeling.").

155. 21 C.F.R. § 10.85(d)(1) (2006).

156. Yates v. Hendon , 541 U.S. 1, 4 (2004).

C. Executive Order 13132

The assertion of preemption deserves no deference because it violates Executive Order 13132 (EO 13132).[157] EO 13132 is concerned with federalism.[158] EO 13132 requires the federal government to undertake a step-by-step analysis when creating rules and regulations that affect the states.[159] Section 4 of EO 13132 requires the federal government to strictly adhere to governing law when preempting state law.[160]

Section 4(a) allows an agency to preempt a state law only where expressly allowed by statute or where the exercise of state authority interferes with federal authority. Since the FDCA does not expressly give the FDA statutory authority to enact rules that preempt state law, the FDA relies on the assertion that state tort claims for failure to warn interfere with its ability to effectively regulate the drug industry.[161] However, this basis for preemption of state law is grounded in the faulty conclusion that the FDA has the authority to regulate every aspect of the labeling that accompanies marketed drugs.[162]

Due to the FDA's conclusion that preemption is allowed under Section 4(a) of EO 13132, it did not consider its authority to preempt state law as required by Section 4(b).[163] However, the FDA should have undertaken this analysis since the findings under Section 4(a) are based on a faulty interpretation of FDA authority. In instances where 4(a) does not apply, Section 4(b) authorizes preemption of state law through rule making only "where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute."[164]

There is no direct conflict between state law and the FDA's authority to regulate drug labeling. Before efforts to preempt state failure to warn claims began in 2002, the FDA specifically stated that it did not believe that "tort law will cause the development of standards that would be at odds with the agency's regulations."[165] State laws allow suits against drug manufacturers for failure to warn claims. The FDA asserts that

157. Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (Aug. 4, 1999).

158. *Id*.

159. *Id*.

160. *Id*. at 43,257.

161. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3,922, 3,967 (Jan. 24, 2006).

162. Zieve & Wolfman, *supra* note 148, at 315.

163. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3,967.

164. *Id*.

165. Prescription Drug Product Labeling; Medication Guide Requirements, 63 Fed. Reg. 66,378, 66,384 (Dec. 1, 1998).

these suits undermine its authority to regulate by requiring drug manufacturers to include warnings in drug labeling that may not have FDA approval.[166] The Supreme Court has ruled that a "requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement."[167] Because state failure to warn claims do not have the force of requiring drug companies to change prescription drug labeling, the state activity can hardly be said to be in direct conflict with the agency's statutorily mandated authority to regulate drug labels.

Even if a court were to find that the FDA had the authority to preempt state law under sections 4(a) and 4(b) of EO 13132, preemption fails under sections 4(c), 4(d), and 4(e). Section 4(c) restricts agency preemption of state law to the "minimum level necessary to achieve the objectives of the statute . . . ."[168] The FDA claims that state tort claims should be preempted in six instances: 1) failing to list a risk in the highlights section when the warning is listed elsewhere in the labeling; 2) failing to list risks that appear somewhere in the labeling in an advertisement; 3) failing to include risks not supported by the evidence; 4) failing to include risks not required by the FDA; 5) failing to include information prohibited by the FDA; or 6) including information approved by the FDA.[169] These six instances cover nearly all circumstances in which a person might bring a failure to warn claim. Although it is doubtful that any of these six instances are worthy of preempting state law, preemption is absolutely not justified for failing to include risks not supported by the evidence or failing to include risks not required by the FDA.

Many adverse effects of drugs are not discovered during the initial clinical trials and only become evident after a drug has been marketed for years.[170] A drug may be on the market for several years with inadequate warnings before adverse event reports provide sufficient evidence to justify the FDA requiring a change in labeling.[171] During that period, individuals will suffer from the adverse effects of the drugs without the benefit of notification even though there may be a growing body of knowledge that the drug is harmful. This contention is

166. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3,969.

167. Bates v. Dow Agrosciences, 544 U.S. 431, 445 (2005).

168. Exec. Order No. 13,132, 64 Fed. Reg. 43,255, 43,257 (Aug. 4, 1999).

169. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3,937.

170. Karen E. Lasser et al., *Timing of New Black Box Warnings and Withdrawals for Prescription Medications*, 287 JAMA 2215, 2218 (2002).

171. *Id*.

supported by the fact that many failure to warn claims are often consistent with labeling changes later required by the FDA.[172] Preemption of failure to warn claims in all cases where the evidence is insufficient to warn of risk would prevent claims by plaintiffs injured by a drug after the manufacturer knew of adverse events, but before those events were numerous enough to motivate the FDA to require or allow a change to the label. The application of preemption to cases such as this would not be limiting preemption of state law to the minimum level necessary to achieve the statutory mandates of the FDA.

The FDA has only recently claimed that its authority to regulate warnings in drug labeling is absolute.[173] In 1998, the FDA published a rule regulating medical guides to accompany prescription drugs in which it states in the preamble that the "FDA's regulations establish the minimal standards necessary, but were not intended to preclude the states from imposing additional labeling requirements."[174] Since the publication of the 1998 rule regulating medication guides, the FDA has not received additional authorization from Congress to "establish both a 'floor' and a 'ceiling'"[175] for disclosure of risk information. The only change is the agency's interpretation of the FDCA.[176] The FDA's sudden re- interpretation of the FDCA is expansive and inconsistent with many decades of precedent.[177] The preemption of all state tort claims for failing to include risks not required by the FDA would not limit preemption to the "minimum level necessary to achieve the objectives of the statute . . . ."[178]

Section 4(d) of EO 13132 requires an agency that foresees possible conflict between state and federal law to consult with the state in an effort to avoid the conflict.[179] The FDA notified the National Conference of State Legislatures by conference call in January 2006 of the insertion of preemption language into the preamble.[180] This "notification" occurred well after the closure of the comments period for

172. Zieve & Wolfman, *supra* note 148, at 311.

173. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3,935.

174. Prescription Drug Product Labeling; Medication Guide Requirements, 63 Fed. Reg. 66,378, 66,384 (Dec. 1, 1998).

175. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3,935.

176. *Id*.

177. O'Reilly, *supra* note 102.

178. Exec. Order No. 13,132, 64 Fed Reg. 43,255, 43,257 (Aug. 4, 1999).

179. *Id*.

180. Press Release, National Conference of State Legislatures, *supra* note 14.

the rule.[181] The FDA alleges that the request in the proposed rule for input from stakeholders on "product liability issues" was sufficient notice that preemption might be considered.[182] The proposed rule specifically stated, however, that it was not meant to preempt state law.[183] Thus, it should not be surprising that the FDA reports that no state governmental agency commented on preemption.[184] The very limited interaction between the FDA and state governments does not meet the EO 13132 requirement for consultation to avoid conflict.

Finally, Section 4(e) requires an agency proposing to preempt state law through rulemaking to give notice to state officials for an opportunity to participate in the process. As discussed with regard to Section 4(d), the FDA did not give sufficient notice to the state governmental officials regarding the preemption language. The proposed rule specifically stated that the rule would not preempt state law,[185] there was not a call for input regarding preemption,[186] and state officials were notified that preemption was an issue only by conference call shortly before the publication of the final rule.[187]

The FDA failed to meet any of the federalism requirements of EO 13132. Executive Orders are not intended to create any legally enforceable rights.[188] However, the failure of the FDA to follow the requirements of the Executive Order when creating the rule should be considered by the court when deciding the level of deference the rule should receive.

IV. DISCUSSION

The attempt to preempt state tort law was the result of manufacturer concerns that the new labeling requirements might leave them vulnerable to failure to warn claims.[189] Based on the concerns of drug

181. Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81,082 (Dec. 22, 2000).

182. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3,922, 3,969 (Jan. 24, 2006).

183. Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. at 81,103.

184. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3,969.

185. Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. at 81,103.

186. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3,969.

187. Press Release, National Conference of State Legislatures, *supra* note 14.

188. Exec. Order No. 13,132, 64 Fed. Reg. 43,255, 43,257 (Aug. 4, 1999).

189. Requirements on Content and Format of Labeling for Human Prescription Drug and

manufacturers, the FDA describes four policy reasons for asserting preemption. While the courts should not give the preemption claim any deference based on constitutional and procedural grounds, there are also several policy reasons that advance the argument against preemption. The FDA's failure to comply with EO13132 is yet another reason the courts should not give deference to the FDA's assertion of preemption.

A. Manufacturer Product Liability Concerns

In the proposed rule to change the prescription drug labeling regulations, the FDA requested comments on the product liability implications of changing the regulations.[190] The new rule requires highlighting selected information from the physician's inserts for inclusion on the drug package label.[191] The highlighted information will not contain all the information required to safely prescribe the drug.[192] The highlighted section will contain a prominent statement that prescribing physicians should consult the physician's package insert for complete prescribing information.[193] Manufacturers were concerned that the statement directing physicians to read the package insert would not provide a legal defense for failure to warn claims.[194] The agency responded by making the warning statement more prominent.[195]

The concern of some manufacturers was that older prescription drugs that are not required to have the new labeling format might be subject to product liability claims.[196] The stated concern is that plaintiffs would argue that older FDA-approved labeling is inferior to the new format, thus making the manufacturer liable for failure to warn claims.[197] The FDA responded to this comment by asserting that FDA approval of drug labeling under either the old rule or the new rule will preempt state failure to warn claims.[198]

Biological Products, 71 Fed. Reg. at 3,933–34.

190. *Id*. at 3,933.

191. *Id*. at 3,925.

192. *Id*.

193. *Id*.

194. *Id*. at 3,933–34.

195. *Id*. at 3,933.

196. *Id*. at 3,934.

197. *Id*.

198. *Id*. at 3,934–35.

B. Policy Reasons Cited by the FDA for Preemption

The FDA asserts four reasons why federal labeling regulations should preempt state tort failure to warn claims. First, Congress created the FDA to be the expert federal agency to ensure that drug labeling adequately informs users of risks.[199] State judges and juries who lack this expertise should not be allowed to second guess agency decisions regarding the inclusion of risk information that accompanies a drug.[200]

Second, the FDA claims to have the statutory authority to approve all warnings contained in drug labeling. Drug manufacturers are required to gain FDA approval of all labeling.[201] Thus, manufacturers should not be liable in state court for failure to include risks so long as the labeling is approved by the FDA.[202].

Third, the FDA asserts that state law actions threaten the role of the FDA as the expert federal agency for evaluating drugs for safety and effectiveness. The FDA argues that its position as the federal expert regulating the drug industry allows it to consider effects on the public health as a whole instead of focusing on a few individuals, which occurs in many jury trials.[203]

Finally, state failure to warn claims may result in overwarning by manufacturers concerned with litigation and lead to decrease use of helpful drugs to the detriment of public health.[204] The FDA asserts that the protection of public health extends to ensuring that drugs are taken when needed free from worry about risks that have not been proven with exacting scientific scrutiny.[205] This argument is grounded in the assertion that the FDA has the authority to approve all risk information to be included on the label.[206]

199. *Id*. at 3,934.
200. *Id*. at 3,934–36.
201. *Id*. at 3,934.
202. *Id*. at 3,933–36.
203. *Id*. at 3,934.
204. *Id*. at 3,935.
205. *Id*.
206. *Id*.

C. Policy Reasons Against Preemption

1. Drug Manufacturers Owe a Duty to Warn of Risks Associated with a Medication

The Restatement (Third) of Torts states that a drug manufacturer is liable for injuries caused by a drug marketed without reasonable warnings regarding "foreseeable risks of harm posed by the drug. . . ."[207] The courts have long recognized the duty of care owed by drug manufacturers to adequately warn of the risks associated with taking a drug.[208] Drug manufacturers have been held strictly liable for injuries caused by foreseeable risks for which they failed to warn.[209] The duty to warn of risks associated with the use of a drug extends to cases where only a very small number of people are at risk.[210]

The primary concern regarding the preemption of state tort claims for failing to warn is the foreseeability of the risk. The FDA argues that risk information should only be added to a drug label once is has been scientifically validated.[211] Based on the reasoning for preemption asserted in the preamble, the FDA appears to argue that a risk is not foreseeable for the purposes of tort liability until the risk is scientifically validated. Scientific validation requires the FDA's in-depth analysis of adverse event reports from a critical mass of injured individuals.[212] Contrary to the FDA's argument for preemption, the fact that some people are injured by a drug implies that there is a risk to a fraction of the population of having an adverse event, which should prompt the common law duty to warn.

2. Preemption Will Leave Injured Plaintiffs with No Redress for Damages

Preemption of state failure to warn claims would leave the injured plaintiff with no access to the courts for injuries caused by the drug industry.[213] The FDA has nearly complete immunity from suit for

207. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 8 (2005).

208. Davis v. Wyeth Labs., Inc. 399 F.2d 121 (1968).

209. *Id*.

210. *Id*.

211. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3,934–35.

212. *Id*.

213. O'Reilly, *supra* note 102; *see also* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 8 cmt B (2005) (stating that liability for inadequate warning claims are allowed only if "compliance with a governmental regulatory standard has not preempted the imposition of tort liability").

injuries caused by the products they regulate.[214] In many states physicians are protected by malpractice procedures and caps on jury awards.[215] Finally, manufacturers enjoy protection from design defects claims based on the Third Restatement of Torts § 8(c).[216]

The preemption language in the preamble may not eliminate failure to warn claims, but it could increase the cost of litigation and lengthen the duration of already very expensive and long trials.[217] The drug industry will file motions to dismiss failure to warn suits based on the alleged formality of the preemption assertion published in the preamble of the final rule. The plaintiff will be required to incur the added expense and wasted time to answer the industry's assertion of preemption. In addition, the already overburdened state and federal courts will be required to decide these motions.

3. Tort Claims Provide Additional Incentive to Keep Drug Companies Honest

The FDA has limited resources to enforce its regulations on drug manufacturers.[218] The FDA therefore relies on drug manufacturers to voluntarily provide information during the drug approval process and reporting of post marketing adverse events.[219] In March 2006, the Government Accountability Office (GAO) completed a study of how the FDA monitors adverse events to drugs in the post-marketing phase.[220] Post-marketing safety analysis is important to continued safe use of drugs because pre-market drug testing will uncover only very serious adverse effects of drugs. Most risks associated with drugs are discovered in the years after marketing approval.[221]

The GAO study reports that the FDA is not equipped to efficiently handle post-market safety analysis.[222] The FDA requires drug manufacturers to report serious adverse events within fifteen days of being made aware of the event.[223] For less serious adverse events,

214. O'Reilly, *supra* note 102 (citing 28 U.S.C.A § 2680 (2005), excepting federal agencies from liability for performing duties within their statutory mandates).

215. *Id*.

216. *Id*. (citing RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §8(c)).

217. O'Reilly, *supra* note 102.

218. *Id*.

219. *Id*.

220. U.S. GOVT. ACCOUNTABILITY OFFICE, DRUG SAFETY: IMPROVEMENT NEEDED IN FDA'S POSTMARKET DECISION-MAKING AND OVERSIGHT PROCESS, (2006) *available at* 2006 WL 1077185.

221. *Id*.

222. *Id*.

223. *Id*.

manufacturers must make quarterly reports to the FDA for the first three years of marketing and annually thereafter.[224] Reported adverse events are compiled in a database and analyzed by various offices within the FDA to determine if new warnings should accompany the drug or, in very rare circumstances, if a recommendation should be issued that a drug should be pulled from the market.[225] The FDA analysis requires compilation of adverse events, analysis of the data, and meetings between various offices and officials before a recommendation is made.[226] This can take a significant amount of time. Manufacturers, on the other hand, have ready access to the adverse event reports as they are reported to them by physicians. Manufacturers are the experts on the drugs that they are marketing and are in the best position to make a quick, reasoned decision regarding new risks associated with drug on the market.

So long as manufacturers can hide behind the veil of protection offered by the FDA, then they have no incentive to rapidly warn the public of new risks associated with their drugs. As noted by the FDA in the preamble to the new labeling regulations, increased warning can decrease the public's willingness to take a medication. A significant decrease in public faith in the safety of a medication can significantly cut into the profits for the drug manufacturer. Removing tort liability for failing to warn patients will eliminate a major incentive for drug manufacturers to push the FDA for timely inclusion of new risks as they are discovered in the post-marketing phase.[227]

4. Drug Makers Are in a Position to Know, Warn, and Compensate

Drug makers are in the best position to: 1) know of potential detrimental effects, 2) to warn of those side effects, and 3) to compensate victims of side effects. Drug manufacturers are required to track adverse events associated with drugs once they are approved for the market. Manufacturers are required to report the adverse events on a periodic basis for review by the FDA. Manufacturers are required to report serious adverse events to the FDA within fifteen days of learning of them.

Why should the burden of an undiscovered or unreported side effect fall on the individual taking the drug as prescribed by their physician when the drug companies profit from the streamlined approval process

224. *Id*.

225. *Id*.

226. *Id*.

227. Zieve & Wolfman, *supra* note 148.

of the FDA? The FDA requires only limited safety and efficacy testing.[228] As a result, only very serious adverse events are discovered during clinical trials.[229] Most adverse effects are discovered only after the drug is on the market.[230] The key reasons for limiting the required testing are to decrease the expense of bringing a drug to the market and to give drug manufacturers the greatest possible period of time to exclusively market the drug before the patent expires. Drug companies should not be allowed to profit by getting a drug rapidly to the market at the expense of the private individual who is harmed by an adverse effect of which he is not warned. One of the costs of drug approval after safety testing in limited numbers of people for limited periods of time is that manufacturers voluntarily subject themselves to the risk of being sued when their products harm people—something the proposed FDA preemption will eliminate.

V. CONCLUSION

The argument for preemption by the FDA in the preamble of the final rule on labeling regulations is not worthy of deference by the courts because it is unconstitutional, and it violates the APA and EO 13132. The major concern is that the FDA is the government agency charged with protecting the public health through regulating drug manufacturers. The FDA's recent change of course in the courts to intervene on behalf of drug manufacturers and the last-minute insertion of the preemption language into the new labeling rule, raises the concern that the public's protector from the drug industry has now become an industry advocate.

228. Nies & Spielberg, *supra* note 49.

229. *Id*.; Lasser et al., *supra* note 170.

230. Lasser et al., *supra* note 170.