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With the new drug labeling regulations announced in January, the Food and Drug Administration joined the parade of federal agencies that have promulgated rules seeking to preempt state tort claims. In this Analysis & Perspective, attorneys Allison M. Zieve and Brian Wolfman say the FDA's preemption position is bad law and bad policy. They argue that the agency's factual and legal analyses fail to justify the preemption position it has taken in the preamble to the new rule. Finally, the authors assert that the FDA's preamble merits no deference from the courts.

The FDA's Argument for Eradicating State Tort Law: Why It Is Wrong and Warrants No Deference

BY ALLISON M. ZIEVE AND BRIAN WOLFMAN

In January, the Bush administration took another step in its efforts to undermine the protections of state-law civil justice systems. Over the past few years, the Office of the Comptroller of the Currency has issued a variety of rules that purport to preempt state consumer protection laws with respect to banking. Over

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the past several months, the National Highway Traffic Safety Administration, in conjunction with two notices concerning proposed safety standards for cars, has stated that the new standards would preempt state product liability law. And in February, the Consumer Product Safety Commission issued a mattress flammability standard that purports to preempt state tort law.

The FDA, too, has jumped into the fray. On Jan. 18, 2006, in the preamble to a new rule about drug labeling, the FDA explained at length its view that state law—including both state labeling laws and state product liability laws—are preempted with respect to FDA-approved drugs.¹ The agency also stated that all tort claims against health care practitioners related to inadequate dissemination of risk information should be preempted. The FDA's theory is that common-law failure-to-warn claims are impliedly preempted because they "conflict with the agency's own interpretations and frustrate the agency's implementation of its statutory

¹ 71 Fed. Reg. 3922 (2006).

mandate.”² The FDA’s preamble does not have the effect of a law; but, as discussed below, courts sometimes give weight to an agency’s view of the preemptive effect of its regulations. Beginning in 2002, the agency filed a few amicus briefs supporting preemption of the claims alleged in specific lawsuits, but those briefs were largely unsuccessful in convincing the courts that preemption was warranted. The preamble is likely an attempt to state the preemption position in a more formal setting, in an effort to bolster the weight accorded FDA’s views.

The FDA’s preemption position is bad law and bad policy. This article will first outline the preemption principles established by the U.S. Supreme Court. It will then discuss the flaws in the FDA’s factual and legal analyses, which fail to justify the preemption position that it has taken in the preamble. Finally, the article will explain why the FDA’s preamble merits no deference from the courts.

I. The Supreme Court’s Preemption Jurisprudence

Consideration of preemption “starts with the basic assumption that Congress did not intend to displace state law.”³ Therefore, a party seeking preemption of state law bears a heavy burden, for “[p]reemption of state law by federal . . . regulation is not favored ‘in the absence of persuasive reasons—either that the nature of the regulated subject matter permits no other conclusion, or that Congress has unmistakably so ordained.’”⁴ The strong presumption *against* preemption may be overcome only by “clear and manifest” congressional intent to the contrary.⁵

The presumption against preemption is even stronger where “Congress [has] legislated . . . in a field which the States have traditionally occupied, [involving] the historic police powers of the States.”⁶ In other words, the presumption is “that state and local regulation of health and safety matters can constitutionally coexist with federal regulation” because “the regulation of health and safety matters is primarily, and historically, a matter of local concern.”⁷ The presumption applies where a defendant is seeking preemption of state tort remedies, because, in that situation, preemption would displace the historic power of the states to protect the health and safety of their citizens.⁸ Furthermore, where the allegedly preemptive federal regulatory scheme does not provide a damages remedy, preemption would leave injured individuals without any state or federal remedy. In that situation, the Supreme Court has ascribed preemptive intent to Congress only in the most compelling circumstances.⁹ This principle is important

here because, although the FDA is not expressly arguing that all common-law claims are preempted with respect to prescription drugs, its reasoning is susceptible to broad application and, if accepted by the courts, would open the door to sweeping preemption of state-law claims brought by patients seeking redress for injuries caused by approved drugs.

The federal government has regulated adulterated and misbranded drugs since 1906. However, damages suits pre-existed federal drug regulation.¹⁰ And the Supreme Court has applied the presumption in cases involving medical devices (federally regulated since 1938; premarket scrutiny since 1976),¹¹ the blood supply (federally regulated since 1944),¹² and other products that have been federally regulated for many years. As in those circumstances, the presumption applies here.

Congress understood the long tradition of the states providing compensation through their tort systems to individuals harmed by drugs and other products. When Congress was considering legislation that ultimately was enacted as the Food, Drug, and Cosmetic Act (FDCA) of 1938, it specifically rejected a proposal to include a federal private right of action for damages caused by faulty or unsafe products regulated under the Act on the ground that such a right of action already existed under state common law.¹³ “The case for federal preemption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of interest and has nonetheless decided to ‘stand by both concepts and to tolerate whatever tension there [is] between them.’”¹⁴ Thus, it is not surprising that, since passage of the first federal drug safety laws in 1906, no appellate court decision has held that the Act preempts common-law damages actions with respect to drugs.

II. The FDA’s Argument for Preemption Lacks Merit.

Suits seeking damages for injuries caused by drugs generally are based on theories of negligence and/or strict liability for product defects and/or inadequate warnings. The FDA’s argument for conflict preemption is based on the theory that compliance with both federal requirements and the state-law requirements on which a lawsuit is based will frustrate the purposes of federal regulation and, perhaps, that compliance with both federal and state requirements would be impossible. The FDA is not clear as to whether the purported conflict is with the state-law duties on which damages

common-law claims” when preempting state positive law because common-law claims “perform an important remedial role in compensating accident victims”).

¹⁰ See, e.g., *Halloran v. Parke, Davis & Co.*, 245 A.D. 727, 280 N.Y.S. 58 (1935); *Thomas v. Winchester*, 6 N.Y. 397 (1852).

¹¹ 21 U.S.C. § 360c *et seq.*; H.R. 94-853 at 6 (1976) (FDCA of 1938 “for the first time, authorized the regulation of . . . medical devices”); see *Medtronic*, 518 U.S. at 475, 484.

¹² 42 U.S.C. § 262; see *Hillsborough County*, 471 U.S. at 719.

¹³ *Adler & Mann, Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 924 & n. 130 (1995) (“Congress rejected a provision in a draft of the original FD&C providing a federal cause of action for damages because ‘a common law right of action [already] exists.’”) (quoting legislative history).

¹⁴ *Bonito Boats v. Thunder Craft Boats*, 489 U.S. 141, 167 (1989) (quoting *Silkwood*, 464 U.S. at 256).

² *Id.* at 3934.

³ *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981).

⁴ *Chicago & North Western Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981) (quoting *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142 (1963)).

⁵ *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 715 (1985); see also *Hawaiian Airlines, Inc. v. Norris*, 512 U.S. 246, 252 (1994); *Wisconsin Pub. Intervenor v. Mortier*, 501 U.S. 597, 605, 611 (1991).

⁶ *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

⁷ *Hillsborough County*, 471 U.S. at 716, 719.

⁸ See, e.g., *Medtronic v. Lohr*, 518 U.S. 470, 484-86 (1996).

⁹ See *English v. General Elec. Co.*, 496 U.S. 72, 87-90 (1990); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984); see also *Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002) (“perfectly rational for Congress not to pre-empt

claims are based (such as a duty to warn of known or foreseeable dangers) or the state-law obligation imposed by a verdict in the plaintiff's favor (the obligation to pay damages) or just the pressures on manufacturers from litigation.

The FDA's preemption argument appears in the regulatory preamble accompanying the issuance of a final rule that revises drug labeling regulations.¹⁵ The new regulations will require that prescription drug labeling include a section called Highlights, that states, among other things, the major warnings elsewhere discussed in the labeling. The FDA introduces its preemption discussion by expressing concern that patients injured because of drug-related harms not discussed in the Highlights section will sue drug manufacturers for failure to warn.¹⁶ The FDA also says that a few companies stated in comments on the proposed labeling rule that they were concerned that patients would bring failure-to-warn claims based on injuries caused by products that used the labeling format under the prior rule, under the theory that using the old format was an inferior method of conveying warnings. These companies asked the FDA to state that approval of labeling, whether in the old format or the new, preempts state law, including product liability law.¹⁷

Obliging the companies, the FDA then states that "FDA approval of labeling under the act, whether it be under the old or new format, preempts conflicting or contrary State law."¹⁸ The preamble then describes the FDA's authority over labeling and labeling changes. It concedes that companies may make some labeling changes—in particular, that they may add warnings and contraindications—without prior FDA approval.¹⁹ However, it seeks to minimize the import of its own regulation by suggesting that companies typically consult with the FDA prior to making changes, even if they do not have to do so.

Next, the FDA turns to lawsuits and purports to explain how recent product liability lawsuits have "threatened the agency's ability to regulate risk information for prescription drugs in accordance with the [FDCA]."²⁰ Notably, the only specific example that the agency offers was not a product liability case, but a case seeking to enforce a state labeling law, California's Proposition 65.²¹ Of five other cases cited in the preamble as illustrating the threat to federal regulation posed by product liability suits, three are cases that sought injunctive relief under state law to effect a change in a drug's labeling.²² Only two of the listed cases were suits seeking only damages—which is the only relief sought in most product liability lawsuits.²³

¹⁵ 71 Fed. Reg. 3933-36, 3967-69.

¹⁶ *Id.* at 3933.

¹⁷ *Id.* at 3933-34.

¹⁸ *Id.* at 3934.

¹⁹ *Id.*; see 21 C.F.R. § 314.70(c).

²⁰ *Id.*

²¹ *Dowhal v. SmithKline Beecham*, 32 Cal. 4th 910, 88 P.3d 1 (2004).

²² 71 Fed. Reg. 3934 nn. 5-7.

²³ *Id.* at nn. 5 & 7 (citing *Ehlis v. Shire Richwood*, 233 F. Supp. 2d 1189, 1198 (D.N.D. 2002) (decision finding preemption), *aff'd on other grounds*, 367 F.3d 1013 (8th Cir. 2004); *Motus v. Pfizer*, 127 F. Supp. 2d 1085 (C.D. Cal. 2000) (decision rejecting preemption), *subsequent dismissal on other grounds aff'd*, 2004 U.S. App. LEXIS 1944 (9th Cir. Feb. 9, 2004)).

About those two, the FDA says nothing in particular. It does not describe the cases or in any way explain how they posed a potential threat to FDA authority.

Significantly, the two cases were no different from typical product liability suits that have been brought against drug companies for more than a century: The only relief sought in the lawsuits was damages for injuries caused by a drug, and no design or labeling changes were requested. Therefore, if the claims in the two damages cases cited in the preamble were preempted, the claims in all product liability cases against pharmaceutical companies since 1906 (when the first drug laws were enacted) or at least since 1938 (when new drugs were first required to be safe before they entered the market) should have been preempted. Yet if the typical product liability case threatens the FDA's authority, as the agency claims, then surely the FDA should have been able to give numerous specific examples of instances in which a verdict for the plaintiff hampered the agency's ability to regulate or forced the defendant company to misbrand a label. Notably, the preamble does not offer a single example.

The reason for the FDA's inability to cite cases in which an inadequate-warning claim actually threatened to interfere with federal regulatory authority is that a damages claim does not challenge the FDA's decision to allow marketing of a product or its decision that the product could be labeled for certain indications. Instead, it challenges the company's decision not to include—either initially or later—a warning about a particular risk.²⁴ It is worth remembering that the vast majority of product liability claims against drug companies do not seek to require the company to change its product's label or seek any other form of injunctive relief; they seek only damages. In some circumstances, a drug manufacturer may choose to revise a label in response to an adverse jury verdict. However, as the Supreme Court recently stated, "[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."²⁵ And "there is no general inherent conflict between federal pre-emption of state [regulatory] requirements and the continued vitality of state common-law damages actions."²⁶ In other words, a verdict ordering the payment of damages does not require

²⁴ See 21 C.F.R. § 314.70(c)(2)(I) (manufacturer may add warning without prior agency approval).

²⁵ *Bates v. DowAgrosciences*, 125 S. Ct. 1788, 1799 (2005); see also *Sprietsma*, 537 U.S. at 64 (unanimous opinion) ("perfectly rational" for Congress to preempt state positive law, but not "common-law claims, which—unlike most administrative and legislative regulations—necessarily perform an important remedial role in compensating accident victims"); *Ferebee v. Chevron Chemical Co.*, 726 F.2d 1529, 1543 (D.C. Cir. 1984) ("Compliance with both federal and state law cannot be said to be impossible. Chevron can continue to sue the EPA-approved label and can at the same time pay damages to successful tort plaintiffs such as Mr. Ferebee.").

²⁶ *Cipollone v. Liggett Group*, 505 U.S. 504, 518 (1992) (plurality); *id.* at 533-34 (Blackmun, J., concurring); see also *Silkwood*, 464 U.S. at 256 (despite express federal preemption of state regulatory authority, state-law punitive damages awards not preempted, although "regulatory in the sense that a nuclear plant will be threatened with damages liability if it does not conform to state standards.")

a drug manufacturer to do anything inconsistent with any FDA requirement.²⁷

Further, a failure-to-warn claim is consistent with the fact, provided for in the regulatory scheme, that warnings set forth in the original FDA-approved labeling are not necessarily adequate. Thus, in many instances, neither the manufacturer nor the FDA initially determined that a certain warning should appear on a drug label, and one or both later changed its mind based on reports of adverse events in patients. For example, in 1997, the FDA approved the drug Rezulin for use in treating diabetes. The label noted under the heading “precautions” that some incidents of “liver function test abnormalities” had occurred during the clinical studies. However, Parke-Davis did not ask to include a warning about an association between Rezulin and liver problems, and the label did not do so.²⁸ By the next year, reports of liver failure in Rezulin patients prompted the FDA to require a boxed warning about the association between Rezulin and liver failure.²⁹ The warning was strengthened several times, always based on adverse event reports and not on clinical studies, before the drug was pulled from the market. Thus, the agency’s initial decision to allow Rezulin to be marketed without a warning about the association with liver failure was not a final decision to foreclose further consideration of a warning.

The above example is just one of a great many. Lotronex, Celebrex, Vioxx, Zoloft, Prozac, and Accutane are a few other well-known drugs that required post-approval labeling changes to add or strengthen warnings. In fact, “[m]any serious ADRs [adverse drug reactions] are discovered only after a drug has been on the market for years. Only half of newly discovered serious ADRs are detected and documented in the *Physicians’ Desk Reference* within 7 years after drug approval.”³⁰ Moreover, an association between a drug and an adverse reaction is often identified or identifiable from premarketing trials, but no warning is given until after the FDA receives adverse event reports from patients.³¹ As a result, a failure-to-warn claim is often consistent with labeling changes later required by the FDA.

Although the FDA cites no concrete examples—despite nearly a century of regulation—in which a damages verdict interfered with the agency’s ability to regulate, the preamble does describe two specific ways in which some courts have construed the federal requirements differently than the FDA construes them. Neither justifies preemption of damages suits. First, the FDA cites cases in which courts have rejected preemption on the ground that federal regulations allow companies to

add or strengthen label warnings without prior FDA approval. Second, the FDA cites opinions stating that federal labeling requirements impose minimum standards that companies are free to exceed.³² This point is not really distinct from the prior one, for the idea is that the company should strengthen warnings when information justifying a stronger warning becomes available.³³

Disagreeing with these cases, the FDA says that the decision whether ultimately to strengthen labels warnings is the FDA’s, and that even if the company changes its label as allowed under 21 C.F.R. § 314.70(c), the FDA can disagree and take enforcement action against the company. This response does not rebut the fact that, in the first instance, the companies can add or strengthen warnings. Concern that the FDA would disagree could be offered as a defense to a negligence claim, but it does not alter the plain text of Section 314.70(c). And in the usual case, it seems unlikely that where a company believed that a stronger warning was warranted, the FDA would prefer a weaker one. After all, the company’s objective is to sell more products; the FDA’s is to protect patients’ safety. Furthermore, the FDA has previously advised that FDA labeling requirements “do not prohibit” manufacturers from warning—through labeling, advertising, or “Dear Doctor” letters—as soon as harmful adverse effects, not stated in the labeling, are discovered.³⁴

In addition, if a new or stronger warning is not false or misleading, the label is not misbranded; and the agency has no basis for taking enforcement action against the manufacturer. Further, even if the FDA does want to take enforcement action based on the new warning, the determination that a drug is misbranded is, in the end, not the FDA’s to make. Rather, if the FDA wants to pursue enforcement action for alleged misbranding, the agency must file suit against the manufacturer in a federal district court.³⁵ The manufacturer is entitled to a jury trial³⁶—an irony, given that the FDA justifies preemption in part on its theory that juries should not be able to “second-guess” the agency.³⁷ And the company need not prove that the new warning was necessitated by a causal relationship between the drug and the newly-stated risk, but only that “there is reasonable evidence of an association” between the hazard and the drug.³⁸ Accordingly, because the filing of an enforcement action does not guarantee that the FDA will prevail, no conflict would exist until the FDA had won the action. As the Supreme Court has explained: “The existence of a hypothetical or potential conflict is insufficient to warrant the preemption of the state [law].”³⁹

Moreover, one of the cases cited by the FDA explains that the FDA had wanted the defendant company to place stronger warnings on the label, but the company

²⁷ See *Eve v. Sandoz Pharm. Corp.*, 2002 WL 181972 (S.D. Ind. Jan. 28, 2002); *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018 (N.D. Ill. 2001); see also *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 185-86 (1988) (“The effects of direct regulation on the operation of federal projects are significantly more intrusive than the incidental regulatory effects of such an additional award provision. Appellant may choose to disregard Ohio safety regulations and simply pay an additional workers’ compensation award if an employee’s injury is caused by a safety violation.”).

²⁸ *Physicians’ Desk Reference* at 2120 (52d ed. 1998).

²⁹ *Physicians’ Desk Reference* at 2310 (53d ed. 1999).

³⁰ Lasser, et al., *Timing of New Black Box Warnings and Withdrawals for Prescription Medications*, 287 J.A.M.A. 2215, 2218 (May 1, 2002).

³¹ *Id.*

³² Although the FDA now disagrees with those cases, it has previously stated that FDA labeling requirements set forth only minimum standards, which states are free to supplement. See 63 Fed. Reg. 66378, 66384 (1998), discussed *infra* at note 84 and accompanying text.

³³ *Caraker*, 172 F. Supp. 2d at 1033.

³⁴ 44 Fed. Reg. 37434, 37447 (1979).

³⁵ 21 U.S.C. §§ 332 (injunctions), 333 (criminal penalties), 334 (seizure).

³⁶ *Id.* §§ 332(b), 333, 334(b).

³⁷ 71 Fed. Reg. 3935.

³⁸ 21 C.F.R. § 201.57(e).

³⁹ *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982).

had successfully resisted the FDA's requests.⁴⁰ This case refutes the picture, drawn by the preamble, of powerless drug companies forced by the FDA to use particular labels. As the case shows, drafting of the label starts with the company and, although the FDA may revise the label, the process typically involves much back and forth. That is, the label is not mandated by the agency; rather, it is developed by negotiation between the agency and the company.

The FDA also expresses concern that lawsuits can create pressure on companies to bolster safety warnings, which may cause them to propose speculative warnings or to over-warn, which may cause important risk information to "lose its significance."⁴¹ To begin with, this argument runs counter to the FDA's assertion of complete control over labeling. In fact, this concern is a tacit concession that, under 21 C.F.R. § 314.70, a manufacturer may, on its own, alter a drug label without prior FDA approval. In any event, the concern about important information losing significance is alleviated by the new Highlights section of the label, through which labels will emphasize "the most important information that is part of a larger body of information" about risks and usage to be communicated through the labeling.⁴² Because the FDA has expressly provided that all changes to Highlights must be pre-approved by the agency,⁴³ the agency can ensure that less important warnings do not drown out more significant ones. And whether a new or stronger warning would make physicians think twice before prescribing a particular product or patients think twice before using a product, such a warning—as long as it were accurate—would not interfere with the FDA's authority over the content of labeling. Furthermore, physicians, not patients, make the decision about whether a prescription drug should be used, and they are qualified to handle this concern. Finally, the FDA is not perfect. Too often, the agency delays in forcing a drug from the market or requiring a new warning, and patients are injured as a result. (Consider the deaths and injuries caused by the diabetes drug Rezulin or the antidepressant Serzone, before those drugs were finally pulled from the market.) In such instances, the "pressure" that lawsuits can put "on manufacturers to attempt to add warnings,"⁴⁴ is a consequence of the FDA's reticence to act that is good for public health. It further illustrates the complementary roles of regulation and the common law, the latter coming into play when the former fails to prevent injury or death.

Moreover, the FDA's preamble overstates the regulatory effect of a verdict in a damages action. As mentioned above, a verdict for the plaintiff requires only that the defendant pay damages, not that it alter its product or label.⁴⁵ Indeed, a core principle of strict product liability is that, although some potentially dangerous products will cause harm on occasion, it is beneficial to society as a whole to keep them on the market

and to compensate injured parties through the tort system.⁴⁶

Finally, the FDA's preamble also claims that common-law claims against health care practitioners "related to dissemination of risk information" are preempted by the FDCA.⁴⁷ The FDA offers no justification, aside from saying that it "strongly believes that health care practitioners should be able to rely on prescription drug labeling for authoritative risk information and that health care practitioners should not be required to convey risk information that is not included in the labeling."⁴⁸ Regardless of whether a physician who limits his or her warnings to a patient to those items stated in the labeling could point to the label as a defense to liability on the facts of a particular case, the FDA's suggestion that health care practitioners should be immune from liability in such circumstances is frivolous.

To begin with, the FDA has no authority over the conduct of physicians and other health care practitioners. And by its own admission, the FDA "has long recognized" that "its role is not to regulate medical practice."⁴⁹ For example, the FDA has often stated that physicians are free to prescribe approved medicines for unapproved uses because the FDA does not regulate medical practice.⁵⁰ Likewise, when issuing a regulation with respect to patient information sheets that are prepared by manufacturers and handed out by pharmacists, the FDA confirmed that "the written patient medication information provided does not alter the duty, or set the standard of care for manufacturers, physicians, pharmacists, and other dispensers" and also that the "pharmacist may add to the information and discuss any aspect of the product with the patient, thereby promoting better communication between health care professionals and their patients."⁵¹ The FDA's long-standing view makes sense because physicians get their information from sources outside the approved labeling, such as from Dear Doctor letters (letters sent from manufacturers to physicians in advance of labeling changes to warn of newly recognized hazards) and medical journals, and they make their prescription decisions based in part on clinical experience.

Preemption is premised, at the very least, on the notion that an industry subject to federal regulation should, in some instances, not be subject to conflicting state regulation. Preemption cannot be justified for an industry—here, health care practitioners—that is not

⁴⁶ See Prosser & Keeton on Torts 536-57, 692-93 (5th ed. 1984).

⁴⁷ 71 Fed. Reg. 3936, 3969.

⁴⁸ *Id.* at 3969.

⁴⁹ *Id.*

⁵⁰ See, e.g., www.fda.gov/cdrh/LASIK/what.htm (2000, updated 2005) (FDA information sheet on Lasik eye surgery stating that "FDA does not have authority to . . . regulate a doctor's practice. In other words, FDA does not tell doctors what to do when running their business or what they can or cannot tell their patients."); Linda Suydam, Sr. Associate Commissioner of FDA, Keynote Address at FDLI Conference (Sept. 13, 1999), www.fda.gov/oc/speeches/offlabel.html ("I want to make the point that the legislative history of the Federal Food, Drug, and Cosmetic Act shows that Congress did not intend FDA to interfere with the practice of medicine, and FDA—whose Commissioners typically have been medical doctors, and which has many MDs on its staff—has never had such a goal.")

⁵¹ 63 Fed. Reg. 66382, 66384 (emphasis added).

⁴⁰ See *Salmon v. Parke-Davis & Co.*, 520 F.2d 1359 (4th Cir. 1975).

⁴¹ 71 Fed. Reg. 3935.

⁴² *Id.* at 3931.

⁴³ *Id.* at 3932 (FDA revising 21 C.F.R. § 314.70 to provide that all changes to highlights section need prior approval, "except for editorial changes or similar minor changes.")

⁴⁴ *Id.* at 3935.

⁴⁵ See also *supra* notes 25-27 and accompanying text.

subject to regulation under the statute at issue.⁵² As the Supreme Court recently observed with regard to the Controlled Substances Act, “[T]he statute manifests no intent to regulate the practice of medicine generally. The silence is understandable given the structure and limitations of federalism, which allow the States ‘great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.’”⁵³ Because the agency does not regulate medical practice, it is puzzling why the FDA would even speak to this issue.

Moreover, because, rather than mandating prompt labeling changes, the FDA often negotiates labeling changes with a drug manufacturer, many months can pass before the labeling reflects current knowledge about risks associated with a particular drug.⁵⁴ Therefore, both because the FDA does not regulate the practice of medicine and because product labeling does not necessarily reflect the current state of medical knowledge, the FDA’s contention that physicians should be immune from liability for failure to warn if they have provided the information included in the labeling is bad policy and bad medicine.

III. The FDA’s Position on Preemption of Tort Claims Is Not Entitled to Deference.

Because the legal theory behind the argument that product liability claims against drug manufacturers is quite weak, the theory has met with little success when presented to courts by drug companies over the past few years. Even amicus briefs from the FDA arguing that damages claims interfere with FDA regulation have had little impact on the courts.⁵⁵ To avoid careful scrutiny of the preemption argument, drug manufacturers faced with product liability suits will now argue that courts owe deference to the FDA’s view on preemption because the view is set forth in a regulatory preamble.⁵⁶ That argument is wrong.

Under Supreme Court case law, deference is premised on the assumptions that an ambiguity in the statute at issue reflects a gap within which Congress intended to delegate lawmaking discretion to the agency and that the agency’s interpretation reflects a lawful ex-

ercise of that implicitly delegated discretion.⁵⁷ Faced with such an ambiguity, courts will defer to the position of the federal agency charged with implementing the statute, unless that agency’s view is unreasonable. In other words, when deference is appropriate, the agency’s position is given considerable weight by a court engaging in statutory interpretation. As the Supreme Court stated in *Chevron, USA v. Natural Resources Defense Council*:

When a court reviews an agency’s construction of the statute which it administers, it is confronted with two questions. First, always, is the question whether Congress has directly spoken to the precise question at issue. 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.⁵⁸

A. Product Liability Cases

1. The FDA Lacks Authority to Override State Tort Law.

The drug manufacturers’ call for *Chevron* deference is meritless. To begin with, the argument for deference to the FDA’s views on preemption of state product liability laws overlooks the basic prerequisite for *Chevron* deference. Administrative agencies, because they are creatures of the executive branch, do not have the power to regulate with the force of law unless Congress has delegated that power to them. Thus, the starting point for considering whether deference is warranted is the statute that provides the agency authority on the subject matter in question. As the Supreme Court recently explained:

Deference in accordance with *Chevron* . . . is warranted only “when it appears that Congress delegated authority to the agency to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority.”⁵⁹

In other words, “*Chevron* deference . . . is not accorded merely because the statute is ambiguous and an administrative official is involved. To begin with, the rule must be promulgated pursuant to authority Congress has delegated to the official.”⁶⁰

With respect to drugs, Congress has not delegated to the FDA the authority to determine the preemptive effect of drug labeling rules on state damages actions. To be sure, the FDA has authority to issue labeling rules,⁶¹ but nowhere does the FDCA mention an ancillary power to patrol the border between federal substantive

⁵² See *Adams Fruit v. Barrett*, 494 U.S. 638, 650 (1990) (“[I]t is fundamental ‘that an agency may not bootstrap itself into an area in which it has no jurisdiction.’”); see also *Puerto Rico Dept. of Consumer Affairs v. Isla Petroleum Corp.*, 485 U.S. 495, 503 (1988) (“[T]here is no federal pre-emption *in vacuo*, without a congressional text of a federal statute to assert it.”).

⁵³ *Gonzalez v. Oregon*, 126 S. Ct. 904, 923 (2006) (quoting *Medtronic*, 518 U.S. at 475).

⁵⁴ For example, the FDA and Merck negotiated the language of labeling changes for the drug Vioxx for more than a year before the drug’s labeling was revised to reflect the serious risk of heart attack and stroke.

⁵⁵ See, e.g., *Witzczak v. Pfizer*, 377 F. Supp. 2d 726 (D. Minn. 2005); *Cartwright v. Pfizer*, 369 F. Supp. 2d 876 (E.D. Tex. 2005); *In re Paxil Litigation*, 2002 WL 31375497 at *1 (C.D. Cal. Oct. 18, 2002); *Motus v. Pfizer*, 127 F. Supp. 2d 1085 (C.D. Cal. 2000).

⁵⁶ See, e.g., Defendant Pfizer’s Reply to Plaintiff’s Memo. in Opp. to Pfizer’s Motion for SJ, filed Jan 31, 2006, No. 05-3414 at 6 (D.N.J.) (arguing that FDA’s preamble on preemption is entitled to “substantial deference”).

⁵⁷ See *United States v. Mead Corp.*, 533 U.S. 218, 227, 229 (2001); *Chevron, USA v. Natural Res. Def. Council*, 467 U.S. 837, 843 (1984).

⁵⁸ 467 U.S. at 842-43 (footnotes omitted).

⁵⁹ *Gonzalez*, 126 S. Ct. at 915 (quoting *Mead Corp.*, 533 U.S. at 226-27) (emphasis added).

⁶⁰ *Id.* at 916 (citing *Mead Corp.*, 533 U.S. at 226-27).

⁶¹ See 21 U.S.C. §§ 352, 355.

rulemaking authority regarding drug labeling and the state's historic power to compensate its citizens through the tort system for harms they sustain from drugs because the drug maker had failed to warn them and their doctors of the drugs' potential hazards.⁶² As the Supreme Court recently noted, if the relevant regulatory statute contains no delegation on the topic for which preemption is sought, no basis for deference exists.⁶³

This principle is well illustrated by *Adams Fruit Co. v. Barrett*. There, a migrant worker sued under the federal private right of action established by the Migrant and Seasonal Agricultural Worker Protection Act (AWPA), seeking compensation for injuries he sustained while being transported in a van owned by his employer. In an amicus brief, the Secretary of Labor argued that the federal remedy was unavailable where state workers' compensation law provided migrant workers a remedy. The Supreme Court declined to give deference to the Secretary's view because Congress had not given the agency authority to determine the preemptive scope of the AWPA's right of action. The Court held that the Secretary could not premise its call for deference on the AWPA's delegation of the right to issue safety standards for vehicles used by employers. To the contrary, the delegation did "not empower the Secretary to regulate the scope of the judicial power vested by the statute. Although agency determinations within the scope of delegated authority are entitled to deference, it is fundamental 'that an agency may not bootstrap itself into an area in which it has no jurisdiction.'" ⁶⁴

Adams Fruit applies here in spades. Just as the agency's authority to issue vehicle safety standards in *Adams* did not extend to determining the scope of civil remedies available to plaintiffs injured in vehicles, the FDA's authority to issue drug labeling does not extend to the question of civil remedies for failure to warn. Indeed, the claim to authority here is even weaker than in *Adams Fruit*. There, Congress had at least contemplated the issue of remedies, and it had supplied a federal remedy at the same time it gave the agency authority to issue vehicle safety standards. Here, as noted above,⁶⁵ Congress declined to provide a federal damages remedy in the FDCA precisely because state-law damages remedies were available. Having made no effort to legislate on the topic of drug-related damages remedies, Congress can hardly be said to have authorized the FDA to supercede the damages remedies traditionally provided by the states.

This point distinguishes the FDA's Jan. 18 preemption statement from the statement considered by the Supreme Court in *Hillsborough County*.⁶⁶ In that case, the operator of a blood plasma center sued Hillsborough County, arguing that county ordinances and regu-

lations governing blood plasma centers were preempted by FDA regulations on the same topic. When the FDA had issued its regulations, it had expressly stated the regulations did not preempt state and local authorities from regulating the same subject matter in their jurisdictions. Considering the preemption issue, the Supreme Court stated that the FDA statement that accompanied issuance of its regulations was dispositive on the question of implicit intent to preempt, unless inconsistent with clearly expressed congressional intent or unless subsequent developments showed a change in the agency's position.⁶⁷ However, the FDA's preemption statement went to a matter within the scope of the authority delegated to it by Congress—regulation of blood plasma centers. In other words, the FDA's authority to regulate blood plasma centers carried with it authority to address the preemptive effect of its regulation of blood plasma centers on state and local regulation of blood plasma centers. In contrast, here, the FDA's statement goes to a matter outside the scope of the authority delegated to the FDA—common-law claims. The authority to regulate drug labeling does not carry with it authority to address the preemptive effect of its regulation of labeling on state common-law compensation systems.

Tellingly, in discussing the preemptive scope of the new labeling rules, the FDA does not even claim any congressional delegation. In fact, the preamble suggests just the opposite. Tucked in a footnote, the FDA quotes from the Drug Amendments of 1962, which amended the FDCA to require applications for approval of new drugs to demonstrate effectiveness, as well as safety, as follows: "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."⁶⁸ At most, the FDA's preemption discussion describes an *indirect* and attenuated conflict. Moreover, many duty-to-warn cases involve drugs that have harmed many patients and whose hazards have become well known. Where the drug manufacturer has, prior to the plaintiff's suit, revised the label warning to warn of the relevant harm, or removed the product from the market altogether, the claim even to an indirect conflict is nonsensical. Notably, the Controlled Substances Act contains similar anti-preemption language, stating that Congress has no intent to preempt state law "unless there is a positive conflict" between the Act and the state law "so that the two cannot consistently stand together."⁶⁹ The Supreme Court recently cited this language in rejecting a different Bush Administration preemption argument.⁷⁰

2. Even Assuming the FDA Had Authority in The Realm of State Tort Law, Its Claim to Deference Must Be Rejected.

Even apart from the absence of congressional delegation to FDA of authority to override state common law, deference is inappropriate here. Where an agency is

⁶² Cf. *FDA v. Brown v. Williamson Tobacco Corp.*, 529 U.S. 120, 160 (2000) ("[W]e are confident that Congress could not have intended to delegate a decision of such economic and political importance to an agency in so cryptic a fashion.")

⁶³ See *Gonzalez*, 126 S. Ct. at 917 ("[T]he Attorney General's authority to make regulations for the 'control' of drugs . . . cannot sustain the Interpretive Rule's attempt to define standards of medical practice.")

⁶⁴ 494 U.S. at 650 (quoting *Federal Maritime Comm'n v. Seatrain Lines, Inc.*, 411 U.S. 726, 745 (1973)).

⁶⁵ See *supra* note 13.

⁶⁶ 471 U.S. at 714.

⁶⁷ *Id.* at 714-15.

⁶⁸ Pub. L. No. 87-781, Title II, Section 202, 76 Stat. 793 (Oct. 10, 1962) (emphasis added).

⁶⁹ 21 U.S.C. § 903.

⁷⁰ *Gonzalez*, 126 S. Ct. at 923.

acting within the scope of delegated authority, the degree of deference due to an executive agency government depends, among other things, on the formality, consistency, thoroughness, and persuasiveness of the agency's view.⁷¹ Applying these factors, the FDA's preamble warrants no deference.

First, as to "formality," drug manufacturers will argue that the FDA acted with a high degree of formality because its preemption statement accompanied issuance of a regulation promulgated through notice-and-comment rulemaking. Under the Administrative Procedure Act, the public had the opportunity to comment on the regulation before it was finalized.⁷² And because the rule was issued in accordance with the APA's procedures, it has the force of law, assuming that it is not arbitrary, capricious, contrary to statutory authority, or otherwise unlawful.⁷³ However, the preamble is not part of the regulation: It will not appear in the Code of Federal Regulations and does not have the force of law. In fact, a longstanding FDA regulation provides that a statement in a regulatory preamble constitutes only an "advisory opinion."⁷⁴ Although the FDA has "obligated" itself to follow its own advisory opinions,⁷⁵ the agency also recognizes that, in court proceedings seeking to bind a member of the public, an advisory opinion may be used to "illustrate acceptable . . . procedures or standard, but not as a legal requirement."⁷⁶ In this way, the FDA's own regulations acknowledge that regulatory preambles are not statements of law and caution that they should not be presented as such in legal proceedings.

Even without issuing a regulation with the force of law, agencies at times use notice-and-comment rulemaking to issue "interpretive rules"—rules that do not have the force of law, but that set forth the agency's understanding of a law that the Congress has authorized the agency to interpret or enforce. These rules, too, sometimes receive deference from the courts.⁷⁷ However, in its final drug labeling rule, the FDA did not purport to issue an interpretative rule, let alone a legislative rule, regarding preemption of state-law damages actions in drug injury cases. Rather, the agency stated its "belief" on a legal question.⁷⁸ Moreover, when the agency issued its proposed drug labeling rule in December 2000, it stated that "this proposed rule does not preempt State law."⁷⁹ The rule requested comment on product liability issues, but only by asking whether the new "Highlights" section of drug labeling raised liability concerns and, if so, how the FDA might alleviate those concerns without eliminating the Highlights section.⁸⁰ This request can hardly be called "notice" of the broad preemption statement that followed, particularly given the agency's plain statement that the proposed

rule "does not preempt state law."⁸¹ For this reason, the National Conference of State Legislators has complained to Congress and to the Department of Health and Human Services, FDA's parent, about FDA's failure to consult with the States before surprising them with the preemption statement.⁸² Thus, although presented in a *Federal Register* notice in the course of issuing a final regulation, the FDA's preemption statement lacks the formality necessary to sustain a claim for deference.

Second, the FDA's preemption statement lacks the "consistency" needed to warrant deference. Before 2002, the FDA's consistent view was that state common law was not preempted by federal drug regulation. For example, in both 1979 and 1998, in regulatory preambles accompanying various drug regulations, the FDA stated its view that state tort law did not interfere with federal regulation.⁸³ And although, as described above, the FDA now argues that its requirements are not "minimum" requirements but rather impose both a floor and a ceiling, the agency stated the opposite in 1998 when issuing regulations addressing pharmacists' provision of written patient information in the form of "Medication Guides" for certain types of prescription drugs.⁸⁴ Manufacturers are required to obtain FDA approval of the Medication Guides,⁸⁵ and the FDA has prescribed numerous specific requirements as to both form and content.⁸⁶ Nonetheless, when issuing the final rule, the FDA rejected comments calling for the FDA to express an intent to preempt state regulation of labeling requirements:

FDA regulations establish minimal standards necessary, but were not intended to preclude states from imposing additional labeling requirements. States may authorize additional labeling but they cannot reduce, alter, or eliminate FDA-required labeling.⁸⁷

The preamble cites three prior occasions on which an FDA preamble accompanying issuance of a new rule has stated that the rule would be preemptive.⁸⁸ None of the three prior statements, however, suggested that common-law claims would be preempted. All appear directed at state positive laws that specifically regulated

⁸¹ *Id.* at 81103; *cf. Environmental Energy Project v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005) (citing cases) (final rule must be "logical outgrowth" of proposed rule, in that proposal gives basis to reasonably anticipate that change is possible and parties need not "divine [agency's] unspoken thoughts") (citation omitted).

⁸² See Letter from Steven Rauschenberger, president, National Conf. of State Legis. to Michael Leavitt, secretary of HHS, dated Jan. 13, 2006.

⁸³ See 63 Fed. Reg. 66384 (regulation addressing Medication Guides, issued pursuant to FDA's authority over drug labeling) ("FDA does not believe that the evolution of state tort law will cause the development of standards that would be at odds with the agency's regulations."); 44 Fed. Reg. 37437 ("It is not the intent of the FDA to influence the civil tort liability of the manufacturer.")

⁸⁴ 63 Fed. Reg. 66384 ("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 but they cannot reduce, alter, or eliminate FDA-required labeling.") (emphasis added).

⁸⁵ 21 C.F.R. § 208.24(a).

⁸⁶ See *id.* § 208.20.

⁸⁷ 63 Fed. Reg.

⁸⁸ 71 Fed. Reg. 3935.

⁷¹ *Mead*, 533 U.S. at 228.

⁷² 5 U.S.C. § 553.

⁷³ 5 U.S.C. § 706(2)(A).

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

⁷⁵ *Id.* § 10.85(e).

⁷⁶ *Id.* § 10.85(j) (emphasis added).

⁷⁷ See *Gonzalez*, 125 S. Ct. at 914-16 (discussing deference to interpretative rules).

⁷⁸ See 71 Fed. Reg. 3934 ("FDA believes . . ."); *id.* at 3969 (same).

⁷⁹ 65 Fed. Reg. 81082, 81103 (2000).

⁸⁰ *Id.* at 81086.

the particular matter at issue.⁸⁹ For example, in expressing its view that the federal requirement for a Reye's syndrome warning on over-the-counter products containing aspirin preempted state requirements, the FDA noted that it was "unaware of any such requirements at this time."⁹⁰ The FDA was not, of course, unaware of state common-law failure-to-warn claims, and thus its statement must have been directed at state positive law label requirements concerning Reye's Syndrome. The FDA also cites one regulation that provides for preemption of state law.⁹¹ That regulation provides for confidentiality for those who report adverse events to the FDA and for patients identified in the reports and indicates that state disclosure requirements are preempted. Although this regulation could affect the availability of certain discovery in a damages suit, it has no potential to preempt damages claims, and the FDA's preemption discussion in that regulation does not suggest otherwise.⁹²

As evidence that its practice of submitting amicus briefs supporting preemption "is not new," the agency cites amicus briefs it filed in four cases prior to the Bush Administration.⁹³ Three of those briefs, however, did not address preemption of damages claims at all: Two briefs addressed preemption of state food labeling laws, which the industry argued and the FDA agreed were preempted by federal labeling laws.⁹⁴ And one brief concerned a plaintiff's request for discovery of the identities of those who had provided adverse reaction reports to the FDA.⁹⁵ The defendant argued that the request was preempted by an FDA regulation that provided that such information would not be disclosed; the FDA filed a brief in support of the defendant, but the court rejected the preemption argument.

In the last pre-Bush administration case cited by the FDA, *Buckman v. Plaintiffs' Legal Committee*,⁹⁶ the FDA did argue for preemption of a damages claim. The claim at issue in that case, however, was unusual, and the FDA's preemption argument was narrow. In *Buckman*, the only claim at issue was a so-called "fraud-on-the-FDA claim," the theory of which was that the defendant had defrauded the FDA to obtain marketing clearance for a medical device. Observing that the claim did "not focus on the device itself . . . [but] focuses, rather, on the relationship between the federal government and the entity it regulates,"⁹⁷ the agency argued that the fraud-on-the-FDA claim conflicted with "the strong federal interest in permitting the FDA to decide for itself whether it has been defrauded and, if so, what

statutorily authorized remedy to seek."⁹⁸ At the same time, the FDA reiterated its support for a narrow view of preemption of damages claims. Its brief emphasized the narrow scope of the agency's preemption argument in that case by explaining that, unlike claims of defective design or failure to warn, the fraud-on-the-FDA claim "does not depend on any claim that the product itself was independently defective under state law or on any claim that the distribution of the product independently violated any duty owed under state law."⁹⁹ Indeed, in direct contravention to its current position, the FDA also acknowledged "the historic primacy of state regulation of matters of health and safety" and the appropriateness of a presumption against preemption where the state-law claims allege defective design, negligent manufacturing, or failure to warn.¹⁰⁰ The Jan. 18 preamble is flatly inconsistent with the FDA's brief in *Buckman*.

Third, the "thoroughness" of the FDA's preemption analysis does not warrant *Chevron* deference. Although the preemption discussion takes up several pages of *Federal Register* text, it is superficial and factually flawed, as discussed in detail in Section II above. The discussion glosses over or simply ignores contrary statements made by the agency in the past, and it relies on cases and regulations that do not address preemption of common law to try to support a historical FDA view that does not exist.

Finally, the "persuasiveness" of the FDA's preamble does not justify deference. This factor is not so much a consideration with regard to whether deference should be accorded, but a consideration of the merits of the agency's view. As discussed in Section II, that view is unsupported by evidence that product liability lawsuits interfere with federal regulation, despite the many decades in which the two have co-existed. The Supreme Court has often reiterated the principle that state law "is superseded only where the repugnance or conflict is so 'direct and positive' that the two acts cannot be reconciled or consistently stand together."¹⁰¹ Surely, if so direct and positive a conflict existed, it would have manifested itself repeatedly over the years. Not surprisingly, the majority of courts to have considered the issue have rejected the argument that FDA regulation of drug labeling preempts common-law claims.¹⁰²

Accordingly, any call for deference to the FDA's preemption preamble with respect to product liability claims fails the *Chevron/Mead* analysis. For all the reasons discussed in Section II, and in light of the agency's past statements to the contrary, the view stated in the preamble should be rejected.

B. Medical Malpractice Cases

The FDA's attempt to assert authority with respect to claims against health care practitioners is, if anything, even more audacious and even more lawless than its attempt with respect to product liability claims. The

⁸⁹ See, e.g., 47 Fed. Reg. 54750, 54756-57 (1982) (discussing preemption of state over-the-counter drug pregnancy-nursing warning requirements by new FDA requirement and focusing on California law directed specifically to pregnancy-nursing warning requirements).

⁹⁰ 51 Fed. Reg. 5180, 5181 (1986).

⁹¹ 59 Fed. Reg. 3944, 3949 (1994).

⁹² See also *Eli Lilly and Co. v. Marshall*, 850 S.W.2d 155 (Tex. 1993) (in context of civil suit discovery request, rejecting view that FDA's confidentiality regulation was preemptive).

⁹³ 71 Fed. Reg. 3935.

⁹⁴ *Grocery Mfrs. of Am. v. Gerace*, 755 F.2d 993 (2d Cir. 1985); *Jones v. Rath Packing Co.*, 430 U.S. 519 (1977).

⁹⁵ *Eli Lilly and Co.*, 850 S.W.2d 155.

⁹⁶ 531 U.S. 341 (2001).

⁹⁷ Brief for the U.S. as Amicus Curiae in *Buckman v. Plaintiffs' Legal Comm.*, 2000 WL 1364441, at *17-18 (filed Sept. 13, 2000).

⁹⁸ *Id.* at *23.

⁹⁹ *Id.* at *20.

¹⁰⁰ *Id.* at *17.

¹⁰¹ *Jones v. Rath Packing Co.*, 430 U.S. 519, 544 (1977) (citation omitted); *Amalgamated Ass'n of Street, Elec., Ry. & Motor Coach Employees of Am. v. Wisconsin Employment Relations Bd.*, 340 U.S. 383, 403 (1951); accord *Missouri Kansas & Texas Ry. Co. v. S.O. Harris*, 234 U.S. 412 (1914).

¹⁰² See cases cited *supra* note 53.

FDA's statement with respect to health care practitioners deserves no deference because the FDA has no authority to regulate the practice of medicine, as it has consistently recognized,¹⁰³ or to speak authoritatively on the topic of state medical malpractice law.¹⁰⁴ In addition, courts should accord no deference to the FDA's position because the agency's statement lacks consistency, formality, and thoroughness. The inconsistency with the agency's prior longstanding view is acknowledged in the preamble itself and examples are provided in Section II, above. The FDA's position regarding liability of health care practitioners lacks the requisite

¹⁰³ See *supra* notes 49-51 and accompanying text.

¹⁰⁴ Cf. *Gonzalez*, 126 S. Ct. at 919 (rejecting contention that Attorney General's authority under Controlled Substances Act extends to defining substantive standards of medical practice).

formality for the same reasons as its position regarding liability of drug manufacturers. And the lack of thoroughness is beyond dispute, for the FDA attempt makes almost no attempt to justify its position.

V. Conclusion

Inadequate warning claims are often among the most important in product liability cases brought against drug manufacturers, and the FDA's preamble will undoubtedly embolden the manufacturers to argue that they are immune from liability in such cases. Although the manufacturers' preemption motions will delay the progress of many cases, the motions can and should be defeated. The preemption argument runs counter to Supreme Court jurisprudence on the topic and to the FDCA, and the courts should give no deference to the FDA's preamble.