FDA's Regulation of Prescription Drug Labeling:  
A Role for Implied Preemption

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I. INTRODUCTION

On January 18, 2006, the Food and Drug Administration (FDA) issued a final rule on the content and format of prescription drug package inserts.1 In the preamble to the final rule, FDA asserts that its regulation of prescription drug labeling preempts state tort law claims for failure-to-warn. While FDA characterizes this position as “the government’s long standing views on preemption,”2 its preambular language is the agency’s most comprehensive and categorical statement on the issue to date. More importantly, it is the first articulation of the agency’s position in the context of notice-and-comment rulemaking. As such, the preamble raises important questions about how courts should respond to the agency’s views concerning the preemption of state tort law. Should the agency receive judicial deference with respect to its assertions about the preemptive power of its regulations? And, if courts are not deferential, how should they approach FDA’s preemption claims in the context state tort litigation?

This paper attempts to answer these questions. Part II provides a brief overview of FDA’s position and its legal and political context. Part III asks to what extent the agency’s position, as articulated in the regulatory preamble, merits judicial deference. It concludes that the preambular statement warrants neither Auer nor Chevron deference and thus, under Skidmore, must be evaluated for its persuasive power. Accordingly, Part IV examines the substantive merits of preemption. It argues that FDA’s governing statute and relevant Supreme Court precedent give rise to an implied preemption principle that allows for the exercise of preemption in the prescription drug labeling context, though on a narrower scale than that advocated in the recent preamble.

II. FDA’S PREEMPTION POSITION: CONTENT AND CONTEXT

FDA’s position, as laid out in the preamble to the new labeling rule, is that its approval of prescription drug labeling, under both the previous rule and the new rule, preempts “conflicting or contrary State law, regulations, or decisions of a court of law for purposes of product liability litigation.”3 This statement has both legal and political significance. Legally, it constitutes an implied preemption argument different from most courts’ traditional view of FDA and the agency’s historical conception of itself. Politically, it can be seen as part of a larger movement, within

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2 71 Fed. Reg. at 3934.
3 71 Fed. Reg. at 3933-3934 (emphasis added).
both FDA and other federal agencies, to assert the preemptive force of federal regulations over state tort law. This section sets out FDA’s position, as well as its legal and political significance.

A. Content of FDA’s Position

Viewed in the framework of preemption doctrine, FDA’s claim is one of implied preemption. Under the Supremacy Clause, federal law preempts state law when Congress intends for it to do so. Preemption may be either statutory or regulatory. In recognition of the federalism issues involved, courts have long held a presumption against the preemptive effect of federal statutes and regulations, but the presumption is overcome by evidence of Congress’s preemptive intent, whether that intent is express or implied. Express preemption occurs when Congress has explicitly stated its intent to preempt state law. In FDA’s case, its governing statute, the Federal Food, Drug, and Cosmetics Act (FDCA), does not include an express preemption provision applicable to prescription drugs. In the absence of an express provision, FDA points to its broad and detailed authority over prescription drug labeling to argue that its determinations impliedly preempt state law.

Implied preemption takes a variety of forms. One is field preemption, where federal law “has legislated comprehensively, thus occupying an entire field of regulation and leaving no room for the States to supplement federal law.” Other types of implied preemption are variously referred to as “conflict” or “obstacle” preemption; they denote instances in which clear incompatibilities between federal and state regulation invite the conclusion that Congress intended to preempt state law. Such preemption occurs

when there is outright or actual conflict between federal and state law, . . . where compliance with both federal and state law is in effect physically impossible, . . . where there is implicit in federal law a barrier to state regulation, . . . or where state law stands as an obstacle to the accomplishment and execution of the full objectives of Congress.

In the prescription drug-labeling context, FDA is making a claim of conflict preemption, with perhaps some overtones of field preemption. In the preamble, FDA states that, under the FDCA, “FDA is the expert Federal public health agency charged by Congress with ensuring that drugs are safe and effective, and that their labeling

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4 U.S. Const. art. VI, § 2.
5 La. Pub. Serv. Comm’n v. FCC, 476 U.S. 355, 369 (1986) (“Pre-emption may result not only from action taken by Congress itself; a federal agency action within the scope of its congressionally delegated authority may pre-empt state regulation.”).
6 See U.S. Const. amend. X.
7 See Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947) (preemption inquiries must “start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.”).
9 21 U.S.C. § 301 et seq.
adequately informs users of the risks and benefits of the product and is truthful and not misleading." In FDA's view, "[g]iven the comprehensiveness of FDA regulation of drug safety, effectiveness, and labeling under the act, additional requirements for the disclosure of risk information are not necessarily more protective of patients," and thus FDA requirements constitute "both a ‘floor’ and a ‘ceiling’" on labeling requirements. Indeed, the agency claims that imposition of certain state labeling requirements could render a drug “misbranded” under the FDCA.

These statements could be read as assertions of either field or conflict preemption: either the agency regulates so comprehensively that there is no room for states or, because the agency has so much expertise and regulates so rigorously, its determinations in many cases are such that additional state requirements can only be characterized as in conflict with them. Because FDA never explicitly asserts field preemption, and because it identifies discrete instances in which its requirements are preemptive (rather than claiming the entire field), it seems most accurate to characterize its claim as one of conflict preemption. (It is interesting to note, however, that FDA's claims about its expertise are quite broad and could support more unbounded assertions of preemptive force than the agency claims here. If everything that the agency says about its process is true, one might expect it to make similar preemption claims about its drug approval process as well as its labeling requirements.)

In elaboration of its position, FDA identifies “at least” six types of failure-to-warn claims that its labeling requirements should preempt, including claims arising from a manufacturer's

1. failure “to put in Highlights or otherwise emphasize any information the substance of which appears anywhere in the labeling;”
2. failure “to include in an advertisement any information the substance of which appears anywhere in the labeling, in those cases where a drug’s sponsor has used Highlights consistently with FDA draft guidance;”
3. failure “to include contraindications or warnings that are not supported by evidence that meets the standards set forth in this rule;”
4. failure “to include a statement in labeling or in advertising, the substance of which had been proposed to FDA for inclusion in labeling, if that statement was not required by FDA at the time plaintiff claims the sponsor had an obligation to warn (unless FDA has made a finding that the sponsor withheld material information relating to the proposed warning before plaintiff claims the sponsor had an obligation to warn),”
5. failure “to include in labeling or in advertising a statement the substance of which FDA has prohibited in labeling or advertising;”
6. “making statements that FDA approved for inclusion in the drug’s label (unless FDA has made a finding that the sponsor withheld material information relating to the statement).”

While this list seems fairly comprehensive and is alleged to be non-exclusive, FDA states that its regulation of labeling “will not preempt all State law actions.” The

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12 71 Fed. Reg. at 3934.
13 Id. at 3935.
14 Id.
15 Id. at 3935.
16 Id.
only examples it gives of non-preempted actions, however, are instances where manufacturers withheld information from FDA or where the state law “requirement” in question is the imposition of damages for violation of FDA requirements.  

B. Context of FDA’s Position

The agency’s position diverges sharply from most courts’ traditional view of FDA. In order to analyze this contrast, it is useful to acknowledge two preexisting conceptions of the agency’s regulatory activities: the minimum-standards conception and the optimality conception.  

Most state and federal courts ascribe to a minimum-standards conception of FDA’s regulation of prescription drugs and their labeling. According to these courts, FDA’s requirements set a minimum safety standard for drugs and drug labeling. Failure to comply with pertinent FDA regulations is per se tortious. But compliance with FDA requirements, while it may serve as evidence of due care, does not automatically exempt a manufacturer from liability. Instead, state tort law can impose duties higher than and independent of those of FDA. In the labeling context, this means that, “approval by the FDA of the language involved is not necessarily conclusive on the question of the adequacy of the warnings.” Under the minimum-standards conception, then, FDA requirements constitute a floor to regulation but not a ceiling.

In contrast, according to the optimality conception, FDA regulation represents not the minimum but the optimal level of regulation for a given drug. FDA’s consideration of a drug constitutes a risk-benefit calculation of all pertinent factors, and its labeling decisions represent a studied choice about the best amount of information to provide to doctors and patients. Its requirements thus do not represent a “minimum safety standard” but an optimal level of regulation, which additional state requirements threaten to disrupt. FDA’s preambular statement, with its assertion that agency regulation constitutes “both a ‘floor’ and a ‘ceiling’” on drug labeling, obviously embodies an optimality approach.

The fact that a majority of state courts ascribe to the minimum-standards approach is not necessarily an indication that FDA’s optimality-based position is incorrect. For one thing, some states have endorsed the optimality view, allowing compliance with FDA regulations to create a rebuttable presumption against tort liability.

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17 Id. This latter exception echoes the Supreme Court’s holding in Medtronic, Inc. v. Lohr, that state remedies for violation of federal regulations did not constitute additional “requirements” for the purposes of the FDCA’s express medical device preemption provision. 518 U.S. 470, 495 (1996).

18 See M. Elizabeth Magill and Richard A. Merrill, Food and Drug Law (draft ed. 2006), at 322 (“It is hornbook law that FDA’s requirements for the product establish ‘minimum standards’ for purposes of evaluating the manufacturer’s liability.”).


21 In addition to state courts, FDA itself has previously endorsed a minimum-standards conception of its regulatory role. See infra, text accompanying notes 26-32.

22 See Magill and Merrill, supra note 18, at 322.

view, FDA's decisions actually constitute optimality determinations. For example, Robert Rabin has noted:

Despite the continuing penchant of courts and some commentators to refer to the new drug application process as minimum standard setting, there is no warrant in the governing statute or the agency process for doing so. The FDA's determination of safety and efficacy in processing a new drug application is clearly premised on risk-benefit analysis.24

Thus there is disagreement among both courts and commentators regarding the accurate conception of FDA's role. The fact that the minimum-standards view has traditionally been dominant is not determinative; instead it simply underscores the significance of FDA's endorsement of the optimality conception.

Perhaps more important is the fact that FDA has not consistently held an optimality-based view of its own regulatory powers. Until recently, FDA's assertions of preemptive force were discrete, specific, and, compared to the present position, relatively minor.25 At times, the agency has endorsed a minimum-standards conception of its role and embraced state tort law as complementary to its regulatory mission. For instance, after the Medtronic decision, then-chief counsel of FDA, Margaret Jane Porter, said, "FDA’s view is that FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection.”26 During the Medtronic litigation, the agency filed an amicus brief arguing against preemption on this minimum-standards rationale.27 Indeed, in the proposed version to the new prescription drug-labeling rule, promulgated in 2000, FDA not only did not claim preemptive effect for the rule but explicitly

24 Robert L. Rabin, Keynote Address: Reassessing Regulatory Compliance, 88 Geo. L.J. 2049, 2074 (2000). But see id. at 2082 (“Despite the indisputable benefits of predictability and reliance on expertise, the case for a strong regulatory compliance defense ... is seriously compromised by real-world considerations.”). For more analysis supporting an optimality conception, see Michael D. Green, Statutory Compliance and Tort Liability: Examining the Strongest Case, 30 U. Mich. J. L. Reform 461 (1997).

25 See Jones v. Rath Packing Co., 430 U.S. 519 (1977); Grocery M. of America, Inc. v. Gerace, 755 F.2d 993 (2d Cir. 1985); Eli Lilly & Co., Inc. v. Marshall, 850 S.W.2d 155 (Tex. 1993); Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001). FDA cites these four cases as evidence of the long-standingness of its preemption views. 71 Fed. Reg. at 3935. In each case, the agency submitted an amicus brief arguing for preemption. But two involved state regulations rather than state tort liability (Jones and Gerace), and one involved agency confidentiality practice rather than state tort liability (Marshall). The only one that involved tort liability, Buckman, involved the preemption not of traditional tort claims but specifically of claims of "fraud on the FDA." Indeed, FDA in its amicus brief explicitly distinguished the fraud cause of action from traditional tort claims and argued that the presumption against preemption should apply to the latter. Brief for United States as Amicus Curiae Supporting Petitioner, 531 U.S. 341 (2001) (No. 98-1768), at 18 (citing Medtronic v. Lohr, 518 U.S. 470, 485 (1996)).

In addition to its claims about previous amicus briefs, in its recent preambulary statement FDA also noted three regulatory situations in which it had previously claimed preemptive effect for its determinations. 71 Fed. Reg. at 3935. One regulation codified the agency’s position on confidentiality in Marshall. 59 Fed. Reg. 3944 (Jan. 27, 1994). The two others were preambulary statements about the preemptive effect of specific regulations relating to over-the-counter drugs. See 47 Fed. Reg. 50442 (Nov. 5, 1982) (tamper-resistant packaging); 51 Fed. Reg. 8180 (Mar. 7, 1986) (aspirin products required to carry warning about Reye's syndrome). None of these regulations explicitly preempted the operation of state tort law. Moreover, on a general level they suggest that FDA has previously asserted preemptive force sparingly and narrowly.


stated that it had no such effect. It has only been in the past five years that FDA has routinely asserted the preemptive effect of its labeling regulations in state tort cases across the country. These claims have met with mixed success, and FDA officials have indicated that the new preambulary statement is meant to broaden the applicability of such claims while disposing of the necessity of filing amicus briefs in individual cases. Thus FDA's position in the preamble is consistent with its stance over the last five years but is divergent from its position previous to that time. In addition, while FDA has been making its preemption argument in amicus briefs, the preambulary statement represents its most significant articulation of the position to date, in both its substantive and its legal form.

Perhaps because of these aspects of its legal significance, FDA's position has met with strong reactions in the public arena. Some have welcomed it; others have deplored it. Democratic politicians have written letters of protest and threatened corrective legislation, while states have complained about being excluded from a determination of such consequence to them. Moreover, both supporters and opponents see FDA's position as one facet in a larger movement for "silent tort reform"—the diminution of the scope of tort duties through standards-setting federal regulations. Regulations claiming preemptive force have also recently issued from the Consumer Product Safety Commission and the National Highway Traffic Safety Association. Within FDA itself, Chief Counsel Sheldon Bradshaw has suggested that the agency would like to extend preemption principles to over-the-counter drugs and even cosmetics.

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31 See Marc Kaufman, FDA TRIES TO LIMIT DRUG SUITS IN STATE COURTS, WASH. POST (Jan. 19 2006), at A2 (FDA deputy commissioner for medical and scientific affairs characterized preambulary statement as a way to give the amicus brief arguments broader application).
32 See, e.g., id. at A2; Robert A. Clifford, Battle Brews over New FDA Rule Preempting State Law, CHICAGO LAWYER (Mar. 2006), at 10025; Robert G. Seidenstein, FDA to States: We're Opting Out, N.J. LAWYER (Mar. 20, 2006), at 1.; Peter J. Pitts, Unhealthy Litigation, WASH. TIMES (Jan. 24, 2006).
34 Letter from National Conference of State Legislatures, to Mike Leavitt, Secretary of the U.S. Dept. of Health and Human Services (HHS) (Jan. 13, 2006).
37 Bradshaw Says FDA Preempts State Tort Laws on OTC Drugs, FDA Week (Feb. 3, 2006).
Thus FDA's assertion of implied preemption is indisputably unprecedented in its scope. In addition, it can be placed in the context of a larger change in the relationship between federal regulation and state tort liability. For these reasons, FDA's position has garnered a great deal of political attention. The immediate question, however, is how much legal attention it should receive. The next section addresses the issue of judicial deference for FDA's preambulary statement.

III. FDA, PREEMPTION AND THE NEW PREAMBLE: THE DEFERENCE QUESTION

FDA's position has already had an impact with courts considering failure-to-warn claims, and its importance may continue to grow as more drug manufacturers cite the preamble in motions for dismissal and summary judgment. As the preemption argument wends its way through courts across the country, it is worthwhile to inquire into the level of deference it should receive. This is particularly urgent in light of a basic confusion about the nature of FDA's statement. Those familiar with FDA and administrative law are sensitive to the fact that the preemption position appears in the preamble to the new rule rather than the rule itself; furthermore, most conclude from this that the agency's position is not binding on courts. In the mainstream media, however, some news providers have characterized FDA's position as a “rule” or “regulation.” More importantly, a New Jersey court, one of the first to consider the effect of FDA’s position, found that it required deference, concluding, “this court must respect [FDA's] decision with regard to preemption of state claims for failure to warn.”

Such comments suggest that the role of judicial deference in this situation is by no means clear. This confusion is further complicated by the fact that it is a matter of some scholarly and legal debate how much deference agencies should receive in general for their interpretations of their own preemptive power. In this case, however, the particularities of FDA's position make the issue much simpler: FDA's preambulary statement is not entitled to substantial judicial deference.


39 See, e.g., Senate Democrats May Block FDA Rx Labeling Rule with Legislation, FDA Week (Jan. 20, 2006) (reporting that FDA deputy commissioner for medical and scientific affairs stated that the position was in the preamble and courts could choose whether to take it into consideration); Lisa Brennan, FDA Move May Aid Defense, LEGAL TIMES (Feb. 6, 2006), at 10 (quoting James O'Reilly as characterizing the preambulary statement as a nonbinding advisory opinion that "won't be persuasive to courts."). But see Reni Gertner, Prescription Drug Labeling Rule Asserts Federal Preemption, KANSAS CITY DAILY RECORD (Feb. 16, 2006) (quoting former FDA Chief Counsel Daniel Troy as saying, "If any court applies sound administrative law principles, it should find this is entitled to deference.").

40 See, e.g., Clifford, supra note 33; Gertner, supra note 40.


42 Though beyond the scope of this paper, substantial legal questions persist about the extent to which courts should defer to agency determinations of their own preemptive force. Such deference might present problems of self-aggrandizement or agency capture, or it might be considered a reasonable exercise of the political power of the executive branch, which is always subject to veto via the electoral process. See, e.g., Cass R. Sunstein, Nondelegation Canons, 67 U CHI L REV. 315 (2000) (arguing that constitutional concerns limit the exercise of agencies' political power in the preemption realm). In any case, the issue is not settled as a matter of law. See, e.g., Medtronic, Inc. v. Lohr, 518 U.S. 470, 512 (O'Connor, J., concurring in part and dissenting in part) ("It is not certain that an agency regulation determining the pre-emptive effect of any federal statute is entitled to deference.") (emphasis in original).
Under current Supreme Court doctrine, agency interpretations may be entitled to one of three types of deference: Auer,\textsuperscript{43} Chevron\textsuperscript{44} or Skidmore.\textsuperscript{45} Auer can be dispensed with expeditiously. "Auer deference" describes a line of cases holding that agencies' interpretations of their own regulations are entitled to deference in some circumstances.\textsuperscript{46} The new preamble it does not sit easily in this category. What courts are typically doing in Auer cases is deferring to an agency's interpretation of discrete language within a regulation. For example, Auer itself hinged in part on the interpretation of the phrase "subject to" in an agency regulation.\textsuperscript{47} FDA's preambulary statement, by contrast, is not anchored to any particular phrase in the regulation; indeed, the regulation itself says nothing about preemption. More importantly, while FDA's position could be characterized as an interpretation of the prescription drug regulation, because it is an assertion of preemption it is ultimately an interpretation of the agency's authority under the FDCA. Thus the issue, at bottom, is one of statutory rather than regulatory interpretation.\textsuperscript{48} As such, it is more plausibly a candidate for either Chevron or Skidmore analysis.

The famous two-step Chevron test grants agencies a generally high level of deference for interpretations of their governing statutes. Under the test, the court asks, first, "whether Congress has directly spoken to the precise question at issue."\textsuperscript{49} If so, then a differing agency interpretation must give way to "the unambiguously expressed intent of Congress."\textsuperscript{50} If, however, the statute is silent or ambiguous on the matter in question, then the court asks whether the agency's interpretation constitutes "a permissible construction of the statute."\textsuperscript{51} If the agency's interpretation of the statute is reasonable, the court will defer to it.

The Skidmore\textsuperscript{52} test, meanwhile, is much less deferential. Agency interpretations subject to Skidmore undergo a multi-factor consideration that yields a level of deference anywhere on a sliding scale from very little to practically Chevron level. The factors to be considered under Skidmore include "the thoroughness evident in [the interpretation's] consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control."\textsuperscript{53} Skidmore assures agencies that, even outside of the procedural contexts that create judicial deference, their "rulings, interpretations and opinions ... do constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance."\textsuperscript{54}

The question, then, is which agency interpretations receive Chevron and which Skidmore treatment. The Supreme Court supplied at least a partial answer in United

\textsuperscript{43} Auer v. Robbins, 519 U.S. 452 (1997).
\textsuperscript{47} 519 U.S. at 461 (deferring to agency's interpretation of the phrase "subject to" in regulation).
\textsuperscript{48} See Geier v. Am. Honda Motor Co., Inc., 529 U.S. 861 (2000) (considering an agency's position on its preemptive power on the merits rather than through the Auer framework); see also Gonzales v. Oregon, 126 S. Ct. 904, 916 (2006) (rejecting Auer deference for an interpretation by the Attorney General on the grounds that "the language the Interpretive Rule addresses comes from Congress, not the Attorney General").
\textsuperscript{49} 467 U.S. at 842.
\textsuperscript{50} Id. at 842-43.
\textsuperscript{51} Id. at 843.
\textsuperscript{52} Skidmore v. Swift & Co., 323 U.S. 134 (1944).
\textsuperscript{53} Id. at 140.
\textsuperscript{54} Id.
States v. Mead Corp. In Mead, the Court held that Chevron applies in two situations. First, Chevron governs "when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." Such exercise of delegated authority may be signaled "in a variety of ways as by an agency's power to engage in adjudication or notice-and-comment rulemaking, or by some other indication of comparable congressional intent." When an agency is engaged in formal adjudication, notice-and-comment rulemaking, or another activity that produces rulings with the force of law, its determinations will undergo Chevron analysis.

Mead also leaves open the possibility that Chevron may govern in other situations. While Chevron treatment clearly obtains under the circumstances just described, the Court says it may also be appropriate "when no such administrative formality was required and none was afforded." It is unclear whether the Court intends here to refer to determinations which, though not a product of formal adjudication or notice-and-comment, nevertheless have the "force of law" or whether, instead, the Court means to say that certain agency determinations lacking the force of law can still warrant Chevron deference. In Mead, the Court suggested that this category might include rulings that are binding as to third parties. In a subsequent case, Barnhart v. Walton, the Court listed other factors which in that case argued for Chevron analysis:

[the] interstitial nature of the legal question, the related expertise of the Agency, the importance of the question to the administration of the statute, the complexity of that administration, and the careful consideration the Agency has given the question over a long period of time all indicate that Chevron provides the appropriate legal lens through which to view the legality of the Agency interpretation here at issue.

While the precise scope of Chevron deference under Mead remains unclear, it is almost certainly the case that FDA's preambulary statement does not fit it. First, preambles to regulatory rules, like legislative preambles, are not understood to have force of law. FDA's own regulations have long treated regulatory preambles as advisory opinions, which bind the agency but no third party. This is consistent with the purpose of regulatory preambles in administrative law. Section 553(c) of the Administrative Procedure Act requires agencies to accompany final rules with

56 Id. at 226-27.
57 Id. at 231.
58 533 U.S. at 231.
59 Administrative law scholars split over these two interpretations. Lisa Bressman, for example, believes that this category refers to "more informal procedure[s]" where nevertheless "Congress would have intended the resulting interpretation to carry the force of law." Lisa Bressman, How Mead Has Muddled Judicial Review of Agency Action, 58 Vand. L. Rev. 1443, 1445 (2005). Meanwhile, according to Cass Sunstein, Mead suggests that Congress might, under unidentified circumstances, be best read to call for deference even when an agency is not using formal procedures and that agency's actions lack the force of law. Cass Sunstein, Chevron Step Zero, 92 Va. L. Rev. 187, 216 (2006).
60 533 U.S. at 232.
62 Id. at 222.
63 The Supreme Court has ruled that statutory preambles do not carry force of law. See Yazoo & Miss. Valley R.R. Co. v. Thomas, 132 U.S. 174, 188 (1889) ("[T]he preamble is no part of the act, and cannot enlarge or confer powers, nor control the words of the act, unless they are doubtful or ambiguous.").
preambles to "incorporate in the rules adopted a concise general statement of their basis and purpose." The preamble to a final rule is intended "to enable the public to obtain a general idea of the purpose of, and a statement of the basis and justification for, the rules." Significantly, it is the rule itself, not the preamble, which undergoes notice-and-comment. The preamble simply catalogues the results of the notice-and-comment period, along with the agency’s responses to concerns raised. To the extent that agency regulations gain their legitimacy from the participatory features of notice-and-comment procedure, only the rules themselves have a claim to this legitimacy. Thus a preamble does not itself constitute law; instead it constitutes a reason-giving supplement to a statement with force of law, a new rule.

Thus, to the extent that Mead grants Chevron deference to positions that either are products of notice-and-comment or otherwise have the force of law, FDA’s preambulary statement should not qualify. There is still the possibility that Mead intended to extend Chevron to other agency determinations, but even so, the preambulary statement does not meet either Mead’s or Barnhart’s description of this category. First, contra Mead, preambles are not binding on third parties. Indeed, even in their stated explicated role, they are optional rather than obligatory sources of agency purpose. Second, FDA's preambulary statement stands in contrast to Barnhart's list of considerations. The Barnhart factors suggest that Mead left open an exception for interstitial and technical agency interpretations necessary to the smooth operation of clearly delegated functions. Barnhart itself, for instance, involved the Social Security Administration’s definition of “disability” as covering only conditions lasting longer than one year. Meanwhile, FDA's position purports to decide the significance of an entire area of regulation for state tort law. If Mead and Barnhart are reliable indicators of the parameters of this category, FDA’s preambulary statement does not fit it.

Even if regulatory preambles were to merit Chevron deference in some circumstances, there would still be a strong case that this particular one should not. As mentioned above, in the preamble to the prior version of the new rule, FDA not

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65 5 U.S.C. § 553(c).
67 See, e.g., Solid Waste Agency of N. Cook County (SWANCC) v. United States Army Corps of Eng’rs, 531 U.S. 159 (2001) (rejecting the “Migratory Bird Rule,” an agency interpretation issued in the preamble to a rule). The only case, which even suggests the possibility of deference to a preamble is a pre-Chevron case, Fid. Fed. Sav. & Loan Assoc. v. de la Cuesta, 458 U.S. 141 (1982). In that case, the Federal Home Loan Bank Board, acting under the Home Owners’ Loan Act of 1933 (HOLA), promulgated a new regulation affirming that federal savings and loan associations were able to include “due-on-sale” clauses in their loan instruments. The preamble to the final regulation stated that federal law was completely preemptive of state law as to use of due-on-sale provisions by federal savings-and-loans. Appellees challenged the due-on-scale clause as inconsistent with California law. Id. at 147; see 41 Fed. Reg. 18286, 18287 (1976). The Supreme Court found that the Board’s regulation itself “unambiguously” intended to preempt state law, 458 U.S. at 154. It cited the preamble of the regulation as evidence of this unambiguous intent. Id. at 158. In a footnote, the Court said, “[A]ppellees characterize the preamble as an interpretative regulation that does not have the binding force of law and therefore cannot pre-empt state law. ...[W]e conclude that § 545.8-3(f) itself supersedes contrary state due-on-sale law; we look to the preamble only for the administrative construction of the regulation, to which deference is clearly in order. ...We need not consider, therefore, the pre-emptive effect of the preamble standing alone.” Id. at 158, n.13. Thus the Court did not say that a preamble alone could never have preemptive effect, but it also did not affirm that it could. All in all, because this case comes from the pre-Chevron era and differs so much from the FDAs position on its facts and in its scope, it seems unlikely that the door it apparently left open should have much relevance to a court facing this question today.
69 For a rationale for such a distinction between interstitial and larger questions, see Stephen Breyer, Judicial Review of Questions of Law and Policy, 38 ADMIN. L. REV. 363 (1986).
only did not mention the rule’s preemptive effect but affirmatively stated that it would have none. In promulgating the proposed rule in 2000, FDA stated,

Because enforcement of these labeling provisions is a Federal responsibility, there should be little, if any, impact from this rule, if finalized, on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of Government. In addition, this proposed rule does not preempt State law.

Accordingly, FDA has determined that this proposed rule does not contain policies that have federalism implications or that preempt State law.70

Thus, in submitting the prescription drug rule for notice-and-comment, FDA gave no notice that preemption was an issue to be considered in responding to the rule.

Such procedural history would weigh against deference in any circumstances, but because the underlying issue is federalism, it is also in violation of the policies of the executive branch. Under Executive Order 13132, a federal agency must notify and consult with state and local governments when it promulgates regulations with federalism implications.71 The order requires that “[w]hen an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.”72 As described above, the proposed rule in 2000 claimed no preemptive effect.73 Thus the agency did not solicit comments on the preemption issue as required under Executive Order 13132.

Notwithstanding the clear language in the 2000 preamble on this point, in the preamble to the new rule, FDA implies that it in fact fulfilled the consultation requirement of Executive Order 13132:

FDA sought input from all stakeholders on new requirements for the content and format of prescription drug labeling through publication of the proposed rule in the Federal Register. Although the proposed rule did not propose to preempt state law, it did solicit comment on product liability issues. FDA received no comments on the proposed rule from State and local governmental entities.74

FDA concludes that, “it has complied with all of the applicable requirements under Executive Order 13132 and has determined that this final rule is consistent with the Executive Order.”75 Yet the proposed rule not only did not invite comment on preemption; it explicitly assured states that it had no preemptive effect.76 The new rule can only accurately be described as falling short of the requirements of

72 64 Fed. Reg. at 43257.
73 65 Fed. Reg. at 81103.
75 Id.
76 65 Fed. Reg. at 81103.
Executive Order 13132. Because FDA's position was not a product of the procedures demanded of all new preemptive rules, courts should be hesitant to grant it 
*Chevron* deference.

Thus, for several reasons, FDA's preambulary statement does not warrant substantial judicial deference. The agency's position is more properly an instance of statutory rather than regulatory interpretation, and, as such, does not qualify for 
*Auer* deference. It does not qualify for *Chevron* deference by virtue of its occurrence in a preamble and its noncompliance with the procedural requirements for all agency actions with preemptive effect. Courts should thus analyze FDA's position under the 
*Skidmore* standard. To say this, however, is to say very little. *Skidmore* holds that an agency's interpretation is "entitled to respect" to the extent it has the "power to persuade." 77 Perhaps inevitably, this inquiry collapses into the consideration of the agency's position on its merits. Thus, the next section surveys the relevant legislative, judicial, and regulatory circumstances to assess how persuasive courts should find the case for preemption.

IV. FDA AND PREEMPTION: THE SUBSTANTIVE ISSUE

A. Preemption and FDCA

As previously mentioned, the FDCA 78 is silent as to the preemptive effect of FDA's regulation of prescription drugs. A number of other features of the statute, however, help to elucidate matters. One resource is the FDCA's legislative history. When Congress first enacted the FDCA in 1938, it considered a proposal to include in the statute a private cause of action for injury caused by products regulated by the act. Congress rejected the proposal precisely because state common law already provided such a cause of action. 79 While the status of legislative history as an interpretive tool is a matter of debate, it is worthwhile at least to note that when Congress passed the FDCA, it apparently intended to leave room for the independent operation of state tort law. Indeed, the rejection of a federal cause of action suggests that Congress not only tolerated but actually depended upon state tort law as part of its regulatory scheme. This would suggest a "minimum-standards" conception of FDA, with state tort law playing a necessary complementary role.

But even if one accepts this speculative characterization of congressional intent, it still leaves Congress's stance on preemption hazy in its details. It is not clear that Congress intended that no agency determination could ever have preemptive force over any state tort claim. Such a conclusion would be a great deal to infer from the mere rejection of a federal cause of action. In a later amendment to the FDCA's drug provisions, the Drug Amendments of 1962, Congress provided that

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77 *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944) ("The weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control."); *see also* Gonzales v. Oregon, 126 S. Ct. 904, 922 (2006) ("Under Skidmore, we follow an agency's rule only to the extent it is persuasive.").
78 21 U.S.C. § 301 et seq.
79 H.R. 6110, 73d Cong., § 25 (1933); S. 1944, 73d Cong., § 24 (1933); Hearings Before a Subcommittee of the Committee on Commerce of the United States Senate on S. 1944, 73d Cong., 400, 403 (1933) (cited in Robert S. Adler & Richard A. Mann, Preemption and Medical Devices: The Courts Run Amok, 59 Mo. L. Rev 895, 924 (1994)).
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.\textsuperscript{80}

In this legislation, Congress recognized the potential for direct conflict between FDA determinations and state law. While the law does not explicitly include state tort liability in its reference to "State law," its assertion of FDA's supremacy in instances of direct conflict suggests a potential scope of operation for traditional implied preemption principles.

But the legislative resource that provides the most insight into the preemption question is the comparison of the drug provisions to other parts of the FDCA. The FDCA provisions on medical devices contain an explicit preemption provision. In 1976, Congress supplemented the existing FDCA with the Medical Device Amendments (MDA).\textsuperscript{81} The MDA included an express preemption provision, which forbade states and localities from imposing upon medical devices any "requirement" different from or in addition to FDA requirements, without applying to FDA for an exemption. The comparison between the MDA, which contains as express preemption provision, and the FDCA's drug provisions, which do not, has led some observers to argue that "Congress knew how to enact a specific preemption provision as it did with respect to medical devices. ... Had Congress intended for FDA labeling regulations to preempt state failure to warn claims, it would have made explicit such a drastic change in the law."\textsuperscript{82}

The comparison with the MDA is not conclusive, however, nor does it preclude the operation of implied preemption principles.\textsuperscript{83} The medical device example is mainly instructive not because it refutes any role for preemption in the prescription drug context (it does not), but because it suggests a rational limit to the role preemption can play. Whatever preemptive scope Congress intended for FDA's regulation of prescription drugs under legislation in 1962, it seems unlikely that it would be greater than the scope of preemption for medical devices, where Congress later chose to speak explicitly. Thus it is worthwhile to explore the scope of preemption in the medical device context, as set forth by the Supreme Court and lower courts.

B. The Supreme Court and Scope of Implied Preemption

1. Medtronic, Inc. v. Lohr

The Supreme Court considered the preemptive effect of FDA's medical device requirements in Medtronic, Inc. v. Lohr.\textsuperscript{84} At issue in Medtronic was the application of the preemption provision to medical device approvals under FDA's "510(k)" process. FDA allows marketing of new medical devices in two ways: through a comprehensive premarket approval (PMA) process\textsuperscript{85} and through the more cursory

\textsuperscript{81} 21 U.S.C. § 360k(a).
\textsuperscript{82} James T. O'Reilly, Preemption of Tort Cases by FDA Activities, 2 Food & Drug Admin. § 26:9 (2005).
\textsuperscript{84} 518 U.S. 471 (1996).
\textsuperscript{85} 21 U.S.C. § 360e(d)(2).
510(k) premarket notification process.\textsuperscript{86} While the PMA process entails a level of rigorous scrutiny similar to FDA's new drug approval process (NDA), the 510(k) process simply requires a manufacturer to show that its device is substantially equivalent to one already on the market.\textsuperscript{87} In turn, many devices on the market were never subject to premarket approval but were instead already on the market when the MDA passed in 1976 and were allowed to remain so, subject to the condition that FDA might at a later date require PMA compliance.\textsuperscript{88} Thus devices in the 510(k) process neither undergo strict FDA scrutiny nor are necessarily related to devices that have done so.

The question in \textit{Medtronic} was whether the MDA preempted state tort claims for injuries related to a device approved under the 510(k) process. The Court found that such claims were not preempted. Examining the 510(k) process, it concluded that the "generality" of the manufacturing and labeling requirements for devices "left them outside the category of requirements" upon which the preemption provision was intended to operate. The \textit{Medtronic} decision did not explicitly say that approval via the PMA process would have preemptive effect, but it contrasted the cursory 510(k) process unfavorably with the rigors of an inquiry like the PMA process:

\begin{quote}
The generality of [the 501(k)] requirements make this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.\textsuperscript{89}
\end{quote}

This language implies that PMA determinations are preemptive, and indeed many lower courts have construed \textit{Medtronic} in that way.\textsuperscript{90}

The significance of \textit{Medtronic} for prescription drugs is twofold. First, it sets a floor for the operation of preemption: "general" requirements involving little scrutiny of particular products will not preempt state tort law, even in the context of an express preemption provision. Second, it suggests that preemption is appropriate when a regulatory agency affirmatively places a certain issue under regulation and arrives at a specific determination balancing the risks attendant to it. The extent to which the latter observation can be generalized beyond the MDA context has become clearer in a subsequent case, Geier v. American Honda Motor Co., Inc.\textsuperscript{91}


\textit{Geier} involved a Federal Motor Vehicle Safety Standard promulgated by the Department of Transportation under the Motor Vehicle Safety Act.\textsuperscript{92} The standard, known as FMVSS 208, required that manufacturers equip some but not all of their 1987 vehicles with passive restraint devices, such as airbags.\textsuperscript{93} The plaintiff in \textit{Geier}...
sued Honda after an auto accident, alleging in part that the lack of a driver’s-side airbag or other passive restraint in her 1987 Honda Accord amounted to negligent or defective product design.\textsuperscript{94}

The Supreme Court found Geier’s claims to be preempted by the federal safety standard.\textsuperscript{95} Moreover, they did so through an analysis directly relevant to the FDA prescription drug context. The case turned on the Court’s interpretation of the regulation’s governing statute, the Motor Vehicle Safety Act. The Act included both an express preemption provision\textsuperscript{96} and a saving clause.\textsuperscript{97} The preemption provision of FMVSS 208 said that the federal standard preempted any state or local “safety standard applicable to the same aspect of such vehicle or item of equipment.”\textsuperscript{98} This provision clearly preempted state and local statutes and regulations, but its impact on common-law tort claims was unclear.\textsuperscript{99} Meanwhile, the saving clause stated explicitly that compliance with federal safety regulations “[d]id not exempt any person from any liability under common law.”\textsuperscript{100} Interpreting the preemption provision in light of the saving clause, the Court found that the preemption provision did not pertain to common-law liability suits. Thus, the liability claims in Geier were not expressly preempted.

This did not end the matter, however. The Court found that the existence of the express preemption provision did not foreclose the operation of traditional implied preemption principles. Applying those principles, the Court found Geier’s tort claims impliedly preempted by FMVSS 208.\textsuperscript{101} The safety standard required only ten percent of an auto manufacturer’s nationwide fleet to include passive restraints; the rest were permitted to have manual lap and shoulder belts.\textsuperscript{102} The Court found that this combination constituted a “gradually developing mix of alternative passive restraint devices for safety-related reasons.”\textsuperscript{103} Meanwhile, Geier’s common-law claims were predicated on the notion that Honda had a duty to install passive restraints regardless of the requirements of FMVSS 208. In such a context, a state court’s imposition of a common-law duty on manufacturers to use passive restraints represented an “obstacle” to the pursuit of a reasoned federal safety standard.\textsuperscript{104}

\textbf{Geier} is instructive in the prescription drug context. First, it affirms the Court’s assertion in \textit{Medtronic} that agency determinations based on comprehensive risk assessments can be preemptive of state common law. Second, it extends this principle to agency determinations not encompassed by express preemption provisions. While \textit{Medtronic} has been taken to give PMA determinations preemptive force under the express preemption provision of the MDA, \textit{Geier} states that, in the absence of express preemption, comprehensive agency determinations can be impliedly preemptive. This holding could easily apply to the prescription drug context. Just as the Motor Vehicle Safety Act’s preemption provision and saving clause combined to create a “neutral” background for the operation of implied preemption principles,

\textsuperscript{94} See Geier, 529 U.S. at 865.
\textsuperscript{95} Id.
\textsuperscript{96} 15 U.S.C. § 1392(d) (1988 ed.).
\textsuperscript{98} 15 U.S.C. § 1392(d) (1988 ed.).
\textsuperscript{99} 529 U.S. at 868-869.
\textsuperscript{100} 15 U.S.C. § 1397(k) (1988 ed.).
\textsuperscript{101} 529 U.S. at 874.
\textsuperscript{102} Id. at 880-881.
\textsuperscript{103} Id. at 886.
\textsuperscript{104} Id. at 881.
so the FDCA’s silence about preemption does not foreclose the possibility of implied preemption. Where FDA has regulated in a comprehensive way, common law tort liability may constitute an obstacle to its reasoned safety goals and, on that basis, may be impliedly preempted.

Thus, the combination of Medtronic and Geier suggests that, even in the absence of an express preemption provision, an agency regulation could impliedly preempt conflicting state tort law. This possibility raises questions as to the scope of such implied preemption and what types of conflict must exist for it to apply. The next section addresses these questions.

3. Geier, Medtronic, and the Scope of Implied Preemption

From Geier and Medtronic, a picture of the scope of implied preemption under the FDCA begins to emerge. Geier suggests that agency regulations are preemptive of state tort law where an affirmative conflict exists between them. In the context of Geier itself, such a conflict existed when an agency had formulated a precise combination of passive restraint and ordinary restraint requirements, which rejected other possible approaches. Medtronic gives less direction on the question of what constitutes a properly preemptive regulation (after all, the case has been held to extend preemption to FDA’s PMA process only by implication), but it does suggest preemption is possible where the “Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.” Both cases seem to envision a particular regulatory situation: one in which an agency identifies a risk, intends to regulate that risk, has adequate information to do so, and on the basis of that information arrives at a specific regulatory determination.

If this characterization of Medtronic and Geier is correct, then the scope of preemption that they define is similar to the parameters suggested in the Restatement (Third) of Torts: Products Liability for a regulatory compliance defense. Regulatory compliance is a tort doctrine that differs from preemption procedurally but has similar implications substantively. Like preemption, it embodies an optimality conception of regulatory activity, in that it allows manufacturers to defend against tort liability by demonstrating that they complied with all relevant regulatory requirements. Unlike preemption, it is a feature of state rather than federal law. Few states recognize a regulatory compliance defense; it is the minority position to the majority “minimum-standards” approach. In the states that do recognize such a defense, FDA regulations effectively operate as both a floor and a ceiling: noncompliance is negligence per se, while full compliance establishes a presumption against tort liability. While regulatory compliance is a matter of state law and preemption one of federal law, their similarity is obvious. The ultimate result of both doctrines is to absolve manufacturers of tort liability on the basis of compliance with federal regulation.

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105 See, e.g., id. at 878-79 (“[T]he standard deliberately sought a variety—a mix of several different passive restraint systems . . . . [I]t also deliberately sought a gradual phase-in of passive restraints.”).
The Restatement (Third) of Torts addresses regulatory compliance in section 4(b). The text of that section says that regulatory compliance "is properly considered" in products liability suits, but "such compliance does not preclude [liability] as a matter of law."\(^{108}\) However, the commentary to section 4(b) outlines particular situations in which courts "may" conclude that compliance does foreclose liability as a matter of law, as when a statute or regulation was promulgated recently, thus supplying currency to the standard therein established; when the specific standard addresses the very issue of product design or warning presented in the case before the court; and when the court is confident that the deliberative process by which the safety standard was established was full, fair, and thorough and reflected substantial expertise.\(^{109}\)

The Restatement (Third) language echoes an earlier report of the American Law Institute entitled Enterprise Responsibility for Personal Injury.\(^{110}\) This report advocated for a regulatory compliance defense against tort liability when three conditions were met: 1) the agency had undertaken to regulate the risk in question in the litigation; 2) the manufacturer had made full disclosure of all information relating to the risk; and 3) the manufacturer had complied with all requirements imposed by the agency.\(^{111}\)

The ALI enterprise liability report was never incorporated into the Restatement, and the Restatement (Third) itself has no intrinsic legal force. These documents are significant not because they are legally controlling, but because they reflect the same concerns apparent in Medtronic and Geier, including the stipulation of adequate information and expertise, the affirmative placement of the relevant risk under regulation, and the subsequent determination of a "specific standard" that "addresses the very issue...presented in the case before the court." From the divergent starting points of federal regulatory law and state products liability law, the Supreme Court and a group of tort scholars would appear to have converged upon the same principle: that an agency's proactive regulation of a particular risk may trump litigation that seeks to impose duties that conflict with that regulation.

C. FDA and Implied Preemption

The previous section suggested that, under the principle set forth in Geier, agency regulations impliedly preempt state tort law when the two affirmatively conflict—that is, when the risk in question in litigation is one that the agency has placed under regulation and for which it arrived at a specific, well-informed standard. Not all of FDA's determinations fit within this category, despite the rigor of its drug approval process. Indeed, the Geier principle could be brought to bear on at least three distinct scenarios involving the FDA's exercise of its regulatory powers. These scenarios can be labeled the *affirmatively regulated risk*, the *after-arising risk*, and *agency silence*. The Geier principle applies differently to each and thus suggests that FDA's determinations are not uniformly preemptive.


\(^{109}\) Id. at § 4 cmt. e.

\(^{110}\) See Rabin, *supra* note 25, at 2051-2052 (discussing the similarities between the report and the Restatement (Third)).

1. Affirmatively Regulated Risks

The first and clearest scenario is that of the affirmatively regulated risk. This occurs when FDA has explicitly examined a specific risk and developed an informed and considered approach to it. In other words, this scenario is the FDA equivalent to Geier itself. A notable recent example is the widespread litigation against Pfizer, Inc., for failure to warn of the suicidality risks of Zoloft.112 When considering Zoloft’s NDA in 1990, FDA convened a panel of experts, which concluded that the drug had no significant suicide risk.113 In approving Zoloft in 1991, FDA gave Pfizer verbatim instructions for a suicide warning, which focused on the general suicide risk “inherent in depression.”114 Later, FDA requested and received from Pfizer a report on the relation between the drug’s use to treat obsessive-compulsive disorder and suicidality in teenagers, which concluded that suicidality rates were comparable to the normal adolescent population.115 In addition, FDA considered suicide risk and SSRI’s (the drug class to which Zoloft belongs) three times before 1997116 and again in an internal review in 2002, each time finding insufficient evidence of a link between the drugs and suicidality.117 Then, after requesting more data from SSRI manufacturers and amid public attention to anecdotal evidence of risk, FDA in March of 2004 issued a Public Health Advisory, asking nine manufacturers of SSRI’s to add a suicidality warning to their labeling.118

In cases arising out of suicides of Zoloft patients before March 2004, both FDA and Pfizer have argued that failure-to-warn claims are preempted. They argue that, in light of FDA’s continued monitoring of the relevant evidence, any suicide warning prior to March 2004 would have been false or misleading and thus would have rendered the drug misbranded under the FDCA.119 FDA has made this argument in two amicus briefs, one in Motus v. Pfizer,120 a California case in which the court ultimately rejected preemption, and the second at the invitation of the United States District Court of Utah in the still-pending case of Kallas v. Pfizer.121 These briefs have been considered in other cases across the country, but the preemption argument has had little success. Two federal district courts in Texas have accepted


114 Id. at 8.

115 Id. at 9.

116 Id.


121 See Brief for United States as Amicus Curiae Supporting Defendant, Kallas v. Pfizer, Case No. 2:04-CV-0998 PGC (D. Utah Sept. 15, 2005).
it.\textsuperscript{122} Another court denied Pfizer's motion for summary judgment without prejudice in order that Pfizer might reopen the preemption question after more discovery.\textsuperscript{123} Most Zoloft courts, however, have rejected the preemption claim outright.\textsuperscript{124}

Despite the lack of success in courts, the Zoloft scenario is the type anticipated by \textit{Geier}: the agency explicitly undertook to address the suicidality risk, took account of the available information, and held that no stronger warning was necessary. The later implementation of a new warning does not particularly complicate this depiction, because, as the new warning states, even now FDA has not concluded that the drugs at issue actually have increased suicidality risk. (The revised warning simply recommends "close observation" of patients.)\textsuperscript{125} This is not a case of new information so much as one of changed emphasis, and both before and after 2004, Pfizer was in compliance with FDA's specific directives. In such a case of affirmatively regulated risk, as in \textit{Geier}, FDA's determination should be preemptive.

\textbf{2. After-Arising Risks}

A second class of risks includes those that only arise after a drug has been approved, such that their analysis plays no part in the NDA process. This could be a significant category: one well-known study by the Government Accounting Office concluded that more than half of the 198 drugs approved by FDA from 1976 to 1985 had "serious post-approval risks that went undetected" in the pre-market approval process.\textsuperscript{126} Vioxx arguably presents a current example.\textsuperscript{127} At the time of Vioxx's approval in 1999, there was no evidence that the drug increased the risk of heart attacks. Thus FDA's approval of both drug and labeling did not purport to regulate the risk of heart attacks. The picture then grows murkier, because post-marketing studies revealed the heart attack risk to Vioxx's manufacturer, Merck & Co., Inc., which then communicated it to FDA. But regardless of whether FDA could be said to have placed the heart attack risk under regulation at a later date, it certainly had not done so at the time of its approval of Vioxx and its labeling. Thus, at least up to the point where FDA was informed of the risk, preemption

\begin{footnotes}
\item\textsuperscript{123} McNellis ex rel. DeAngelis v. Pfizer, Inc., 2005 WL 3752269 (D. N.J. 2000).
\item\textsuperscript{124} \textit{See}, e.g., Zikis v. Pfizer Inc., 2005 WL 3019409 (N.D. Ill. 2005); Miles v. Pfizer, Inc., Case No. 03-731-C (M.D. La. 2005); Witzczak v. Pfizer, Inc., 377 F. Supp. 2d 726 (D. Minn. 2005); Cartwright v. Pfizer, Inc., 369 F. Supp. 2d 876 (E.D. Tex. 2005); Szybinski v. Pfizer, Inc., Case No. YC 047439 (Los Angeles Sup. Ct. Jul. 12, 2005). In language that perhaps explains the appearance of the preambulary statement, numerous courts have pointed out that manufacturers have been unable to "cite[] any controlling case holding that the FDA's prescription drug warning standards were intended to preempt almost all product liability claims in every State of the Union in this matter that the FDA's prescription drug warning standards were intended to preempt pharmaceutical products liability claims." Caraker v. Sandoz Pharm. Corp., 172 F. Supp. 2d 1018 (S.D. Ill. 2001); \textit{see also} Eve v. Sandoz Pharm. Corp., 2002 WL 181972 (S.D. Ind. 2002); Motus v. Pfizer, 127 F. Supp. 2d 1085, 1092 (C.D. Cal. 2000). Courts have pointed out that, "FDA regulations as to design and warning standards are minimum standards which do not preempt state law defective design and failure to warn claims." Eve v. Sandoz Pharm. Corp., 2002 WL 181972 (S.D. Ind. (2002)) (quoting Motus v. Pfizer, Inc., 127 F. Supp. 2d 1085, 1092, 1096 (C.D. CA (2000))).
\item\textsuperscript{125} \textit{See} Brief for United States as Amicus Curiae Supporting Defendant, Kallas v. Pfizer, Case No. 2:04-CV-0998 PGC (D. Utah Sept. 15, 2005), at 21.
\item\textsuperscript{127} \textit{See}, e.g., Gertner, supra note 40; Clifford, supra note 33; \textit{Rx Lawyers Wonder What Other Laws FDA Could Preempt}, FDA Week (Jan. 27, 2006) (describing the approximately 9,200 pending Vioxx cases and speculating as to the impact of the FDA's preemption position).
\end{footnotes}
should not operate to foreclose product liability claims. In such a case, a court is considering facts very different from those that FDA had before it when it made its regulatory decision. A court’s decision on such facts cannot be said to conflict with FDA’s determination and thus cannot be preempted by it. For this reason, the Geier principle does not apply to after-arising risks.

3. Agency Silence

Perhaps the most difficult scenario involves risks that come within FDA’s ambit but are not explicitly addressed. The latter part of the Vioxx saga fits this description. After the point at which FDA received information about the drug’s heart-attack risk, the meaning or significance of the agency’s silence cannot be discerned by those outside the agency, including the courts. A related scenario might occur when FDA receives data regarding a risk during an NDA, but information relating to that risk does not appear in the final drug labeling. It might be unclear from this silence whether FDA thought that the need for a warning was unsubstantiated, or that a warning would be an overdeterrent, or that a warning would actually make a drug misbranded. It is possible that FDA, in conversation with the drug manufacturer, affirmatively rejected such labeling, and that the drug manufacturer would have detailed records about such exchanges. But in the absence of such evidence, a lack of a warning is another troubling instance of agency silence.

Although agency silence represents the hard case, implied preemption should not apply here for three reasons. First, interpretation of agency silence as affirmative regulation stretches the limits of the Geier principle. Geier suggests that implied preemption involves a concrete conflict wherein a lawsuit seeks to reopen an issue already settled by the regulating agency. It is reasonable to say that the agency must actually have spoken in order for the plaintiff to be in conflict with it. Also, Medtronic supplies a second consideration: to grant preemptive force to agency silence would be tantamount to the judicial adoption of a preemption provision as broad or broader than the express provision of the MDA. While it is not out of the question that implied preemption could ever be that broad, it is worthwhile to consider whether the MDA’s express provision offers a limiting principle in the context of the FDCA. Finally, extension of preemptive force to agency silence is arguably overprotective of FDA, given that the agency can choose when to speak and when to stay silent. If the agency wants broad preemptive force for its determinations, it is within its power to articulate those determinations explicitly. Thus implied preemption should not cover instances of agency silence.

4. Implied Preemption and the Regulatory Preamble

This discussion establishes bounds for the operation of implied preemption different from those claimed by FDA in its recent preambular statement. In the preamble, FDA gave a nonexclusive six-item list of situations in which preemption should apply. Under the Geier implied preemption principle, some cases falling in these categories would be preempted, some would not, and some would depend on their facts. The first and second categories—no liability for failure to empha-


size a risk in the labeling and in the drug advertising—would depend upon the extent to which labeling and advertising design was left up to the discretion of the manufacturer. The third—no liability for failure to include warnings not supported by evidence—would depend upon who made that assessment and how explicitly. A manufacturer's own assessment of the evidence should not be preemptive, nor should FDA's silence on the evidence be taken as an assessment by implication. Only if the agency affirmatively holds that a certain warning is unsubstantiated should its determination be preemptive. The fourth category—no liability for warnings proposed to FDA but not required by FDA—should be preemptive unless the agency was completely silent on the matter, in which case its silence might not constitute affirmative regulation. The fifth category—no liability for failure to include warnings prohibited by FDA—and the sixth category—no liability for warnings required by FDA—are clear instances of affirmatively regulated risks to which implied preemption principles apply.

Thus the principles of implied preemption as described by the Supreme Court would suggest a narrower scope for FDA's authority than the agency advocates. This outcome is consistent with FDA's position's receiving respect only to the extent that it has "power to persuade" under Skidmore. When the agency makes an informed and affirmative determination, its argument for preemption is strong. When agency action is less definitive, it has a less meaningful capacity to conflict with state court findings. In the absence of an express preemption provision, implied preemption is persuasive only in circumstances of concrete conflict.

V. CONCLUSION

The FDA preamble introduced in early 2006 raises important questions about how much preemptive power courts should ascribe to the agency's regulatory activities. This paper has argued that the agency's position does not merit substantial judicial deference by reason of its formal and procedural particularities. Nevertheless, despite the lack of deference for FDA's position and the absence of an express preemption provision in its governing statute, the FDA may be entitled to implied preemption in certain circumstances of risk regulation. After Geier, it is possible to discern, even if roughly, a three-part framework for determining the scope of implied preemption for prescription drug labeling regulations. Under this framework, where the agency has affirmatively regulated a risk, its regulations will be preemptive. Where a risk has developed after FDA approval, or where FDA has remained silent with respect to a risk, preemption should not apply. This framework may help courts, including those faced with FDA's preambulatory claims, to resolve conflicts between those favoring federal preemption and those who would enforce liability under state tort law.
