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The FDA's Final Rule: Prescription Drug Labelling Requirements and Preemption of Failure-to-Warn Claims

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Chapter 2

The FDA'S Final Rule: Prescription Drug Labelling Requirements and Preemption of Failure-to-Warn Claims

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In the United States, the foundation of product liability litigation concerning the use of prescription medications is the allegation that the manufacturer failed to warn consumers and physicians about the dangerous side effects of its product. Failure-to-warn type allegations are found not only within the context of a typical negligence case, but also extend into claims based on strict liability, breach of warranty, and violation of state consumer fraud acts. Plaintiffs often assert that the manufacturer should have included a warning different from, or additional to, the ones already in the product label and, if that additional or different warning had been present, their physicians would never have prescribed the medication in the first place.

Plaintiffs' allegations seeking relief under a failure-to-warn theory are juxtaposed against a system of complex federal statutes and regulations that govern the testing, labelling, marketing, and monitoring of prescription medications via the Food, Drug and Cosmetic Act of 1938 ("FDCA"). The FDCA and its supporting regulations dictate what risk information shall be included in the label, where that information shall appear, and how changes to the label can be implemented. *See, e.g.*, 21 U.S.C. §§ 331, 352, and 355; *see also* 21 C.F.R. §§ 201.56 and 201.57. If a manufacturer deviates from this standard, then its product will be considered "misbranded" and the information deemed "false and misleading," making the product subject to removal from the market. 21 U.S.C. §§ 331 and 352.

Despite the extensive federal framework controlling prescription drug labels, courts have routinely permitted failure-to-warn actions to proceed against manufacturers even though the label has been approved by the FDA and each of the regulatory requirements has been satisfied. According to a recent pronouncement by the FDA, however, many such failure-to-warn actions are preempted by FDA regulations.

On January 24, 2006, the FDA promulgated a final rule entitled, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products. 71 Fed. Reg. 3922 (Jan. 24, 2006) (to be codified at 21 C.F.R. §§ 201, 314, and 601) ("Final Rule"). The Final Rule's purpose is to update and improve the readability of product labelling for prescription drugs. *Id.* at 3923. It makes extensive changes to how a prescription drug label will appear and what information shall be included. In addition to restructuring the product label, the FDA also announced that it "believes that under existing preemption principles, FDA approval of labelling under the act, whether it be in the old or new format, preempts conflicting or contrary State law." *Id.* at 3934. This position marks a change in FDA policy on preemption.

This article addresses the intersection between FDA regulation of prescription drug labelling and failure-to-warn claims and the arguments surrounding adoption of the FDA's Final Rule. The first section explains the basic framework of preemption and how the doctrine has been applied in prescription drug cases to date. The second section examines the context of the FDA's Final Rule and the evolution of the FDA's position on preemption. The third section explores several arguments opponents of preemption are likely to raise and how manufacturers can refute those arguments.

The Doctrine of Preemption, FDA Regulation of Prescription Drugs, and the Conflict between Federal and State Oversight

The doctrine of preemption flows from the Supremacy Clause, which provides that federal law "shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby …." U.S. Const. art. VI, cl. 2. Preemption can be divided into three categories: express; conflict; and field. Express preemption is found when Congressional intent to dominate the area is explicitly stated in the statute or regulation's language or implicitly found in the law's structure and purpose. *Fidelity Fed. Savings & Loan Ass'n. v. de la Cuesta*, 458 U.S. 141, 152-53 (1982) (citation omitted); *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985) (citations omitted) ("state laws can be preempted by federal regulations as well as by federal statutes"). Unlike express preemption, conflict preemption is implied within the statutory or regulatory scheme and is found when it would be impossible to comply with both the state and federal law. Conflict preemption also exists when the challenged law would act as an obstacle to the fulfillment of a federal law's purposes and objectives. *de la Cuesta*, 458 U.S. at 153. Field preemption is another type of implied preemption. It occurs when Congress has so occupied a legislative field that the only "reasonable inference" is that Congress intended to leave no room for states to legislate in the area. *Id.* (citation omitted).

Courts apply a presumption against preemption and assume that state law is not nullified unless the person or entity seeking to have the law preempted demonstrates that there is a clear Congressional intention to preclude the states from acting. *Geier v. Am. Honda Motor Co.*, 529 US. 861, 907

(2000). This presumption is strongest in areas where states have traditionally acted to protect and regulate their citizens, such as health and safety. Courts often have concluded that failure-to-warn claims fall within the state's traditional power over the health and safety of its citizenry and, thus, the presumption should be that the common law actions can co-exist with federal law. *Hillsborough County*, 471 U.S. at 715-16. Nevertheless, federal legislation in the area of health and safety has multiplied exponentially in the last century, setting the stage for protracted legal battles over which governmental authority has the right to govern areas such as prescription drug labelling.

Congress enacted the FDCA with the purpose, in part, of preventing the misbranding and mislabelling of prescription medications. *See, e.g.*, 21 U.S.C. §§ 352, 355, and 393(b). Over time, there have been numerous amendments to the law, including the Medical Device Amendments of 1976 ("MDA") and the Food and Drug Administration Modernization Act ("FDAMA"). 21 U.S.C. §§ 360 and 379. The MDA revised the laws pertaining to medical devices, while FDAMA sought, among other things, to provide uniformity for non-prescription medications. Both the MDA and FDAMA contain express preemption provisions, but both provisions also carve out exceptions that would allow some state-law claims against manufacturers to persist. 21 U.S.C. § 360k(a); 21 U.S.C. § 379r(a).

Congress has not enacted an express preemption provision for prescription drugs. It did, however, delegate authority to the FDA to promulgate and enforce regulations over a wide variety of products, including prescription drugs. 21 U.S.C. § 371(a). Acting under this authority, the FDA promulgated an extensive regulatory scheme that governs all aspects of pre-marketing and post-approval activities for prescription drugs. Before a prescription drug can be approved for marketing in the U.S., the manufacturer must submit a New Drug Application to the FDA for approval. 21 U.S.C. § 355(a), (b), and (d). The submission must contain data from all animal, pharmacologic, and clinical studies and the FDA will approve the drug only after its standards for safety and efficacy have been met. 21 U.S.C. § 355 and 21 C.F.R. § 314.105. The FDA also approves the labelling to be used with the medication, including what warnings, contraindications, precautions, and adverse event information must be communicated and where in the label the information should appear. *See, e.g.*, 21 C.F.R. §§ 201.56 and 201.57. Even after the medication is approved for use, the FDA is charged with monitoring the medication and can withdraw approval for the medication if it finds that the drug is unsafe or that the manufacturer's labelling is "false or misleading." 21 U.S.C. § 355(e).

Despite its vast array of regulations, the FDA had taken the position that its regulations did not preempt failure-to-warn claims. *See, e.g.*, Prescription Drug Labeling, 63 Fed. Reg. 66,378, 66,382-84 (Dec. 1 ,1998). However, when the Bush administration took office, the FDA's position changed. After 2000, the FDA began filing amicus curiae briefs in failure-to-warn cases asserting that the claims were preempted as conflicting with FDA statements and regulations. *See, e.g.*, *Motus v. Pfizer, Inc.*, Nos. 02-55372, 02-55498, 2002 WL 32303084 (Sept. 10, 2002) (amicus brief). These efforts produced mixed results with district courts dividing on whether implied conflict preemption existed. *Compare Zikis v. Pfizer Inc.*, No. 04 C 8104, 2005 WL 3019409, slip op. at *3 (N.D. Ill. Nov. 8, 2005) (rejecting FDA's position on preemption) *with Needleman v. Pfizer Inc.*, No. Civ. A. 3:03-CV-3074-N, 2004 WL 1773696, *3-*4 (N.D. Tex. Aug. 6, 2004) (granting summary judgment on grounds that plaintiff's proposed warnings would have conflicted with FDA findings); *and Dusek v. Pfizer Inc.*, No. Civ. A. H-02-3559, 2004 WL 2191804, *1 (S.D. Tex. Feb. 20, 2004) (same). Thus, while the FDA's position historically had been that federal law did not preempt state-law claims against manufacturers, its position has altered in the last six years.

The FDA's "Final Rule" on Prescription Medication Labelling

In December 2000, the FDA issued a proposed rule to revise the regulations governing the content and format of prescription drug labelling. Notice of Proposed Rulemaking, 65 Fed. Reg. 81082 (Dec. 22, 2000) ("NPRM"). The agency received comments from a variety of sources, including prescription drug manufacturers, health care and consumer advocacy organisations, individual physicians, and organisations representing local and state governments. Final Rule, 71 Fed. Reg. 3922, 3929 and 3969. While the agency's goal was to make prescribing information more accessible to health care providers, it also recognised that its efforts to restructure the product label could have unintended litigation consequences for manufacturers, particularly in the area of failure-to-warn claims. Manufacturers worried that a new label section "highlighting" selected risk information would allow plaintiffs to argue that the older product labels were legally inadequate by comparison and serve as the basis for failure-to-warn claims. Manufacturers thus sought a statement from the FDA that whatever label it approves, the act of approval would operate to preempt conflicting state laws, regulations, and court decisions. *Id.* at 3933-34.

The FDA obliged. It declared that the agency's "long standing" views were that regardless of whether the operative product label fell under the auspices of the old or new regulations, the FDA's approval of the product label preempts "conflicting or contrary State law". *Id.* at 3934. The agency's reasoning centres around its concern that if its regulations do not preempt failure-to-warn claims and positive state enactments requiring additional and different information be included in the label, then its system of regulation will be undermined and the product label itself will become ineffective. In other words, the FDA is now taking the position that its regulations act as both a floor and a ceiling. Accordingly, states may not "supplement" FDA regulations with requirements of their own that go beyond what the FDA has approved. *Id.* at 3934-35. The FDA reasoned that state laws seeking to protect citizens by requiring additional or different warnings could have the opposite result by diminishing the warnings already in the approved label and promoting "overwarning" by manufacturers. *Id.* at 3935. State laws also could create a conflict by requiring manufacturers to include information in the product label that the FDA would consider "false and misleading" making the product "misbranded." *Id.*

Accordingly, the FDA stated that, at a minimum, the following failure-to-warn claims would be preempted:

- failure to put in the Highlights section or otherwise emphasise any information the substance of which

appears anywhere in the label;

- failure to include in an advertisement any information the substance of which appears anywhere in the label;
- failure to include contraindications or warnings that are not supported by evidence that meets the standards set forth in the rule (e.g., that contraindications reflect "known hazards and not theoretical possibilities");
- failure to include a statement in labelling or advertising, the substance of which had been proposed to the FDA, but not included in the label (unless the FDA finds that the manufacturer withheld material information relating to the proposed warning);
- failure to include in labelling or advertising a statement the substance of which the FDA has prohibited in labelling or advertising; and
- inclusion of statements that the FDA approved for inclusion in the product's label.

Id. at 3935-36. The FDA recognised that its regulations would not preempt all failure-to-warn claims. Specifically, the FDA opined that state law requirements "paralleling" FDA requirements may not be preempted, acknowledging the Supreme Court's ruling in *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996).

Under the FDA's formulation, a variety of claims depending upon failures to include certain information in the label would be preempted. For example, plaintiffs could not recover for the claim that the manufacturer should have placed risk information in the warning section instead of the adverse events section of the label. *See also Bates v. DOW Agrosciences LLC*, 544 U.S. 431, 125 S. Ct. 1788, 1803-04 (2005) (finding FIFRA preempts failure-to-warn claims alleging risk information should have been under a "warning" section and not a "caution" section). Failure-to-warn cases based upon inconsistent epidemiological studies also may be precluded given that any risk that is not a "known hazard", as opposed to a "theoretical possibility", should not be included in the label. Also preempted would be claims such as those in *Motus*, *Needleman*, and *Zikis*, where the FDA explicitly rejected the plaintiff's proposed warning language.

The areas that would not be preempted, however, are as important as the areas that would be preempted. In particular, the FDA recognised that failure-to-warn claims and positive state enactments that run parallel to the federal regulations would not be preempted. Final Rule, 71 Fed. Reg. 3922, 3936. In other words, federal regulations would not preempt a failure-to-warn claim alleging that the product label failed to include information the FDA required to be present. This approach is also in line with the Supreme Court's 2005 decision in *Bates*, which held that failure-to-warn claims were preempted by FIFRA, except to the extent they "paralleled" a failure to comply with federal regulations. *Bates*, 125 S. Ct. at 1800-01. *See also Medtronic*, 518 U.S. at 495 (no preemption of failure-to-warn claims paralleling MDA).

Arguments for and against Preemption of State-Law Claims under the FDA's Final Rule

Opponents of federal preemption have a variety of arguments to offer against the FDA's position. Some of the most crucial arguments are sure to include the following. First, the FDA has exceeded the authority given to it by Congress. When Congress has wanted FDA regulations to have a preemptive effect, it has said so. Because Congress has chosen to remain silent in the area of prescription drug labelling, courts should assume that Congress did not intend for the FDA to have any such authority. Second, the FDA's Final Rule is an attempt to protect manufacturers retroactively from liability for acts that have harmed individuals. Such retroactive action is impermissible as Congress has never explicitly granted the FDA any such authority. Third, the FDA has improperly promulgated the Final Rule by failing to provide an adequate notice and comment period as required by the Administrative Procedures Act and Executive Order 13132. Each of these arguments is considered below in turn.

Argument #1: Congressional silence in the face of previously enacted preemption provisions elsewhere under the FDCA demonstrates that Congress did not grant the FDA authority to preempt state laws on prescription drug labelling.

One of opponents' more poignant arguments against preemption of failure-to-warn claims is the overall structure of the FDCA itself and previous Congressional action in this arena. Congress enacted express preemption provisions in both the MDA and FDAMA. Had Congress wished to do so for claims implicating prescription drug labels, it knew the mechanism for doing so. Accordingly, because Congress has chosen to remain silent on the issue, its silence should be interpreted as withholding such authority.

What opponents of preemption miss in this analysis is that the FDCA implicates more products than simply the three limited areas of medical devices, OTC medications, and prescription medications. Rather, it concerns everything from dog food to human tissue. If the opponents' argument was taken to its logical end, then Congressional silence would have to mean that no other aspect of the FDCA was intended to have a preemptive effect, even when state law directly conflicts with a federal regulation. The absurdity of this position is that within the context of the innumerable products governed by the FDCA and its regulatory scheme, opponents would have courts find that simply because Congress chose to speak in a few limited areas within this vast regulatory scheme, all other possible areas of preemption are a nullity. This position is also contrary to the Supreme Court's holding that when an actual conflict exists between state law and an agency regulation, the state law will fall regardless of whether express preemption language exists or not. *See Geier*, 529 U.S. at 869. Thus, Congressional silence should not be overread to deny an agency authority.

Argument #2: The FDA has no authority to promulgate a rule that would retroactively nullify an individual's right to seek relief for an injury caused prior to the Final Rule's promulgation.

The FDA's Final Rule does not limit itself to preemption of future failure-to-warn claims, but instead asserts that failure-to-warn claims based on either an "old or new" label are preempted. Final Rule, 71 Fed. Reg. 3922, 3933-34. Opponents can point to the Supreme Court's 1998 decision in *Bowen v. Georgetown University Hospital* for support on

this issue. 488 U.S. 204, 208 (1988). In *Bowen*, the Department of Health and Human Services promulgated a rule retroactively reducing the money hospitals received in Medicare reimbursement, meaning that hospitals would have to return millions of dollars to the federal government. *Id.* at 206-07. The Supreme Court worked from two fundamental principles: one, agencies may only promulgate rules when the authority to do so is delegated to them by Congress; and two, "[r]etroactivity is not favoured by the law". *Id.* at 208. Thus, the Court concluded that Congress must expressly grant an agency the authority to promulgate rules that apply retroactively and "rules will not be construed to have retroactive effect unless their language requires this result". *Id.* (citations omitted).

To counter this argument, manufacturers have two options. First, the FDA's Final Rule differs from *Bowen* in that it does not undo something that has already been done. In *Bowen*, hospitals already had been reimbursed for their Medicare costs based on transactions that had been completed years prior to the new rule's implementation. *Id.* at 206-07. The regulations at issue in that case forced the transactions to be "undone" after the hospital's vested interest had accrued. Here, manufacturers may seek to argue that there is no vested interest that has been disturbed in the context of a failure-to-warn claim. For example, failure-to-warn claims that parallel the Final Rule would not be subject to preemption. *See* Final Rule, 71 Fed. Reg. at 3936. However, in those failure-to-warn cases asserting that different or additional warnings should have been given, manufacturers will have to demonstrate that the plaintiff never had a "vested" interest in the first place. This latter position may be a significant hurdle for manufacturers as the case law in this area is not well-settled. *See, e.g., Fields v. Legacy Health Sys.*, 413 F.3d 943, 956 (9th Cir. 2005) (citation omitted) (finding that "a party's property right in any cause of action does not vest until a final unreviewable judgment is obtained" and rejecting argument that statute of repose violates the due process clause). *But see Opdyke Invest. Co. v. City of Detroit*, 883 F.2d 1265, 1274 (6th Cir. 1989) (citations omitted) ("We take it as given that a private cause of action, once it has accrued, is, for constitutional purposes, a species of property.").

A second argument approaches the issue from a different angle and may be more effective. Rather than confronting the issue from the standpoint that the FDA's statement on preemption in the Final Rule is a "new rule" subject to considerations of retroactivity, a better approach is to classify the preemption statement as an interpretation of already-existing regulations. Courts have long-recognised that agencies are entitled to offer interpretations of their own rules as they are the experts in their respective areas. *Chevron, USA, Inc. v. Nat'l Res. Defense Council, Inc.*, 467 U.S. 837, 865-66 (1984). Importantly, when an agency is acting within its delegated authority and offering an interpretation within its realm of expertise, the Supreme Court has held that its interpretations are entitled to deference. *E.g., Smiley v. Citibank*, 517 U.S. 735, 740-41 (1996); *Chevron*, 467 U.S. at 843-44. Regardless of whether the agency speaks in the regulation itself, or in the preamble and interpretive statement, the Supreme Court has held that when an administrative agency makes its position on preemption clear, then that position is entitled to deference. *See Hillsborough County*, 471 U.S. at 718. Even if a court disagrees with the agency's interpretation, it must defer to an agency's reasonable construction. *Nat'l Cable & Telecomm. Ass'n. v. Brand X Internet Serv.*, 125 S. Ct. 2688, 2699 (2005) (citation omitted). Thus, where the FDA has explicitly provided its opinion and interpretation that certain failure-to-warn claims are preempted, its interpretation should be granted deference, as long as the interpretation is neither arbitrary nor capricious. *See id.* at 2699-2700 (citation omitted).

Plaintiffs are likely to counter that even if one were to characterise the Final Rule as an "interpretation" and not a "new rule," it is entitled to no deference whatsoever because it is a complete reversal of the FDA's previous position. Yet, this argument has been rejected by the Supreme Court. *Chevron* itself, the landmark case laying the foundation for deference to an agency's interpretation of its own rules, involved a change in the agency's position. *Chevron*, 467 U.S. at 857-58. Later cases explained that while abrupt changes in agency policy having no reasonable basis might fall to claims of being arbitrary and capricious, a well-reasoned change in agency interpretation or policy was not grounds for disregarding the interpretation. *Smiley*, 517 U.S. at 740-42. Instead, the Supreme Court endorsed a system in which agencies can reevaluate their position given changes to the needs of the population they serve, even when the change is prompted by litigation. *Smiley*, 517 U.S. at 740-42 (citations omitted); *Brand X*, 125 S. Ct. at 2699-2700.

The Final Rule itself provides manufacturers with support for why preemption of failure-to-warn claims is necessary. It describes how the regulatory and litigation environment has changed in the five years between the time the rule was initially proposed and the time it was promulgated. "Since the proposed rule was published, FDA has learned of several instances in which product liability lawsuits have directly threatened the agency's ability to regulate manufacturer dissemination of risk information for prescription drugs in accordance with the act." Final Rule, 71 Fed. Reg. 3922, 3934. The FDA's position on preemption is grounded in the concern that failure-to-warn claims and positive state laws may contravene the FDA's expert determinations on what risk and benefit information should be included in product labels, which are based on well-regulated and controlled scientific studies. The agency also expressed the concern that even when states seek to add to already-existing warnings, they may be doing more harm than good by eroding the effectiveness of the FDA-approved warnings and including warnings that are not grounded in the same scientific rigor. *Id.* at 3934-95. The FDA notes its approach to preemption is not unexpected, but "represents the government's long standing views on preemption, with a particular emphasis on how that doctrine applies to State laws that would require labelling that conflicts with or is contrary to FDA-approved labelling". *Id.* at 3934. Additionally, the FDA cites to its series of *amicus curiae* briefs supporting preemption in certain circumstances. *Id.* Thus, while a change in the agency's position over time cannot be denied, Supreme Court precedent supports an agency's ability to alter its position when confronted with a good cause for doing so. *See, e.g., Chevron*, 467 U.S. at 857-58.

Argument #3: The Final Rule was improperly promulgated as it did not provide for an adequate notice and comment period and failed to adhere to Executive Order 13132.

Opponents of preemption will point to the FDA's December 2000 NPRM in support of its position that the FDA did not provide an adequate notice and comment period for a new rule on preemption. In fact, looking at the notice itself, all the FDA offers is that it was taking comment on a "proposed rule to revise its regulations governing the content and format of labelling for human prescription drug products". NPRM, 65 Fed. Reg. 81082, 81103 (Dec. 20, 2000). Opponents will argue they were never apprised that the new rule would affect failure-to-warn claims or state law enactments and, therefore, were denied the opportunity to comment. Language from the NPRM supports this position and states, "In addition, this rule does not preempt State law.". *Id.* Thus, opponents will argue they were never alerted to what the new FDA rule would encompass, which denied them the opportunity to be heard on the issue.

Opponents will further argue that the FDA failed to comply with Executive Order 13132, which instructs the FDA "to provide all affected State and local officials notice and an opportunity for appropriate participation in the proceeding" when it proposes to preempt state law. Final Rule, 71 Fed. Reg. 3922, 3969 (citing Exec. Order 13132). Opponents of the Final Rule already have lodged protests on this issue, including the National Conference of State Legislators ("NCSL"). The NCSL filed a statement shortly before the Final Rule was published claiming that it had never been given the opportunity to comment on the Final Rule, was not aware that it would implicate states' common-law and positive powers, and demanded either that the comment period be reopened or the preemption language be withdrawn. NCSL Statement, Jan. 19, 2006, http://www.ncsl.org/statefed/health/FDArule.htm (last visited Apr. 25, 2006). The NCSL specifically cited to FDA's statement that the Final Rule would have "little, if any, impact" on the states and would not preempt state law. *Id.* (citation omitted).

Under the Administrative Procedures Act, the FDA must allow a time for notice and comment before it promulgates new rules. 5 U.S.C. § 553(c). In that regard, the FDA notes that the agency solicited and received 97 comments since the NPRM was published in December 2000. Final Rule, 71 Fed. Reg. 3922, 3929. The Final Rule also notes that it requested comments on the product liability implications of revising its label, in addition to generally requesting comments on the label itself. *Id.* at 3933. With regard to the issue of Executive Order 13132, the Final Rule explains that states were provided with notice about the possibility of preemption when it "sought input from all stakeholders on new requirements for the content and format of prescription drug labelling through publication of the proposed rule in the Federal Register". *Id.* at 3969. Thus, while the proposed rule did not expressly state that the FDA was considering how failure-to-warn claims affect FDA regulation, it did invite comment on the product liability implications. State governments also must acknowledge an awareness that the agency's position on preemption had been evolving since 2001 when it began filing *amicus curiae* briefs in prescription drug labelling cases supporting preemption of failure-to-warn claims. Finally, the FDA notes that it did consult with a number of organisations "representing the interests of state and local governments and officials about the interaction between the FDA regulation of prescription drug labelling … and state law". *Id.* All of these arguments are available to proponents of preemption under the Final Rule if the approach is taken that the preemption language is actually a "new rule".

A better option is offered to proponents, however, if the position is taken that the Final Rule's statement on preemption is *not* a new rule, but an interpretation of already existing rules. Opponents' arguments regarding notice and comment, therefore, would be without force as an agency's interpretation of its rules does not trigger "notice and comment" requirements or Executive Order 13132. Accordingly, viewing the preemption statement as an interpretation and not a "new rule" offers proponents of preemption a more effective way of approaching the issue.

What Resolution Does the Final Rule Offer Manufacturers?

Although the FDA's Final Rule provides manufacturers with a powerful and effective new weapon to combat failure-to-warn claims, the outcome of this legal battle is anything but certain, as is demonstrated by a recent federal district court decision. In *Laisure-Radke*, the plaintiff alleged that the manufacturer had failed to warn her late husband about the risk of suicidality that she claimed was associated with taking fluoxetine, the generic form of Prozac. *Laisure-Radke v. PAR Pharm., Inc.*, No. CO3-365RSM, 2006 WL 901657, *1 (W.D. Wash. Mar. 29, 2006). The manufacturer moved for summary judgment arguing that the proposed warning would conflict with the FDA's regulatory scheme by requiring warnings different from, or in addition to, those mandated by the FDA label. The manufacturer cited the Final Rule for support. *Id.* at *1, *3. The district court denied the motion and concluded that because the FDA's own regulations allowed a manufacturer to change its label without FDA approval first, there could be no basis to preempt a failure-to-warn claim. *Id.* at *3, *5-*6 (citing 21 C.F.R. §§ 314.70(c)(6)(iii)(A)-(E)). While this case should not be read as a bellwether since it has been decided before the Final Rule takes effect in June 2006, it illustrates the difficult road that lies ahead for manufacturers.

The doctrine of preemption is relatively simple concept - when a federal and a state law conflict in an area where the federal government has been given authority to act, the state law must yield. Application of the preemption doctrine, however, is anything but simple and the issues surrounding the FDA's Final Rule will likely take U.S. courts years to resolve. Yet, it is important to remember that the FDA's Final Rule assists manufacturers in two vital ways. One, manufacturers now have an even stronger weapon with which to argue that many of the failure-to-warn claims that have plagued the industry with *post hoc* reassessments are preempted. Two, it offers manufacturers the ability to reduce their exposure to the morass of state laws and regulations imposing additional warning requirements with which they must now contend. Accordingly, while the resolution of this issue may take years, the benefit to the industry is well worth the investment.

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Clerkships: During law school, Ms. Kenney had an externship as a clerk for Judge R. Guy Cole, Jr., of the U.S. Court of Appeals for the Sixth Circuit. Following law school, Ms. Kenney clerked for the Honorable Judge David R. Battey of the Seventh Judicial District of Minnesota.

Bar Admissions: Member, Pennsylvania, Ohio, and New York Bars. Admitted to practice before the United States District Courts for the Western and Eastern Districts of Pennsylvania and the Third Circuit Court of Appeals.