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Prescription Drug Litigation Pre-emption Following the FDA Preamble

The Defense Perspective

Part One of a Two-Part Series

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It has now been more than 9 months since the U.S. Food and Drug Administration ("FDA") issued its new labeling rule for prescription drugs with an extensive preamble analysis of how many state tort legal claims conflict with and accordingly are pre-empted by the its regulation of such drugs. The FDA re-emphasized its position that state tort law claims threaten its ability to pursue its statutory mandate of protecting public health through balanced labeling. It thus explained that "under existing pre-emption principles, FDA approval of labeling under the [FDCA] pre-empts conflicting or contrary State law." 71 Fed. Reg. 3922, 3933 (Jan. 24, 2006).

Although it is far too soon to predict the full impact of the FDA preamble, the initial judicial response and the resources being devoted on both sides of the courtroom make it clear that pre-emption arguments will play an increasingly important role in prescription drug litigation. This two-part article discusses the key legal issues — from a defense perspective — that are likely to shape the future debate, and provides a report on the divided case law that has emerged over the past several months.

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Future Battlegrounds over Prescription Drug Pre-emption

While sharply divided in outcome, the early round of case law on the FDA preamble provides a roadmap to some of the key battlegrounds upon which future FDA pre-emption arguments will be fought. Plaintiffs' counsel argue that the FDA's pre-emption position is not entitled to deference because it: 1) is contrary to congressional intent; 2) represents a dramatic change in the FDA's prior position; 3) is not set forth in a formal rule; and 4) is unreasonable as a matter of public health policy. As set forth below, each of these arguments is without merit.

FDA's Position Is Consistent With Congressional Intent

While plaintiffs' counsel argue that the FDA's pre-emption position is contrary to congressional intent, they cannot deny that Congress intended that FDA regulations of prescription drugs would pre-empt state law in certain circumstances. When Congress amended the FDCA in 1962, it made clear that the Act would invalidate state law if there were "a direct and positive conflict between such amendments and such provision of State law." Pub. L. No. 87-781, 76 Stat. 780, 793 (1962). The question, then, is what did Congress mean by the phrase "direct and positive conflict"?

Plaintiffs' counsel argue — without citation to any authority — that the phrase "direct and positive conflict" should be read as imposing a higher standard than required under ordinary principles of implied pre-emption. However, at the time of the 1962 amendments, the meaning of this phrase was clearly spelled out in a long line of Supreme Court authority. Those opinions make clear that by using the phrase "direct and positive conflict," Congress intended and expected that the ordinary principles of implied conflict pre-emption would apply to state law affecting prescription drugs. *See, e.g., Kelly v. Washington*, 302 U.S. 1, 14 (1937) (applying "direct and positive conflict" standard to determine whether "the federal laws and regulations ... carr[ied] any *implied* prohibition of state action") (emphasis added); *Savage v. Jones*, 225 U.S. 501, 533, 535-36 (1912) ("direct and positive conflict" occurs where operation of federal law is frustrated); *Sinnot v. Davenport,* 63 U.S. 227, 242-43 (1859) (finding state statute impliedly pre-empted because of "direct and positive" conflict whereby statute "interfere[d] with or is contrary to the laws of Congress"); *see also Beck v. Prupis*, 529 U.S. 494, 500-01 (2000) ("[W]hen Congress uses language with a settled meaning at common law, Congress presumably knows and adopts the cluster of ideas that were attached to each borrowed word in the body of learning from which it was taken").

Thus, as a number of courts have recognized in interpreting the identical phrase as used in other 1960s legislation, "[t]he 'direct and positive conflict' language … simply restates the principle that state law is superseded in cases of an actual conflict with federal law such that 'compliance with both federal and state regulations is a physical

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impossibility.'" *S. Blasting Servs., Inc. v. Wilkes County N.C.*, 288 F.3d 584, 591 (4th Cir. 2002); *see also Newark Gardens, Inc. v. Michigan Potato Indus. Comm'n*, 847 F.2d 1201, 1202 (6th Cir. 1988) (quoting "direct and positive conflict" language as addressing question whether state statute "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress").

Plaintiffs' counsel also argue that Congress only intended for the FDA to establish "minimum standards" for prescription drugs and has not authorized it to consider the public health impacts of over-warning on the availability of medically indicated drugs. However, Congress' recent enactment of a "mission statement" for the FDA is directly to the contrary. In the 1997 FDA Modernization Act, Congress amended the FDCA to include "a clearly defined, balanced mission for the FDA" which reflects both the federal objectives of "protecting the public health by ensuring that the products [FDA] regulates meet the appropriate FDA regulatory standards" and of "taking appropriate action on the marketing of regulated products in a manner that does not unduly impede innovation or product availability." Food and Drug Administration Modernization Act of 1997, S. Rep. 105-43, 1997 WL 394244, at *2-*3 (July 1, 1997); *see also Id.* at *10 (mission statement added to FDCA because "[c]lear statutory guidance is needed to assist the Agency to find this delicate balance"). Congress thus instructed: "the agency should be guided by the principle that expeditious approval of useful and safe new products enhances the health of the American people. Approving such products can be as important as preventing the marketing of harmful or ineffective products." *Id.* at *8, *15.

Congress' intent that the FDA pursue a "balanced approach," rather than a myopic focus on only one side of the public health equation, accords with the most recent Supreme Court analysis of the FDCA. In *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 (2001), the Supreme Court recognized that the FDA has been granted significant flexibility in its regulations of prescription drug approval and marketing in light of the "the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives." *See also Id* at 348. (FDA exercises its authority "to achieve a somewhat delicate balance of statutory objectives").

FDA's Position Is Consistent With Longstanding Agency Policy

The FDA's analysis in the 2006 preamble of the conflict between state tort law and FDA regulation of prescription drugs reflects a consistent position that the agency has set forth in numerous *amicus curiae* briefs dating back to 2002. While plaintiffs' counsel have attacked the FDA position as a dramatic reversal of FDA policy engineered by former FDA Chief Counsel Daniel Troy, this argument has been strongly rejected by all FDA Chief Counsel from both Democratic and Republican administrations dating back to the early 1970s (aside from one former Chief Counsel who was still in government and, accordingly, did not comment). *See* 150 Cong. Rec. E1505 (July 22, 2004). As these FDA Chief Counsels explained, the FDA's pre-emption position reflects the FDA's longstanding view of its regulatory authority in light of the ever-increasing conflicts posed by state tort litigation:

> The *amicus* curiae briefs ... protect FDA's jurisdiction and the integrity of the federal regulatory process. There is a greater need for FDA intervention today because plaintiffs in courts are intruding more heavily on FDA's primary jurisdiction than ever before. In our judgment, [these] actions are in the best interests of the consuming public and FDA. If every state judge and jury could fashion their own labeling requirements for drugs and medical devices, there would be regulatory chaos for these two industries that are so vital to the public health, and FDA's ability to advance the public health by allocating scarce space in product labeling to the most important information would be seriously eroded. *Id.* at 1506.

Plaintiffs counsel's argument that the FDA has changed its position rests primarily on FDA statements in prior regulatory preambles that do not, in fact, address pre-emption of state tort product liability claims. Plaintiffs counsel cite first to the preamble to a 1979 prescription drug labeling rule, but the FDA's focus there was on the alleged potential impact of prescription drug labels on medical malpractice litigation, an area not within the FDA's scope of regulatory authority. *See* 44 Fed. Reg. 37434, 3735 (June 25, 1979); *see also Buckman Co.,* 531 U.S. at 350-51 ("FDCA expressly disclaims any intent to directly regulate the practice of medicine"). The FDA's only reference to tort liability of drug manufacturers arose in its rebuttal to concerns that the FDA was consulting with manufacturers on labeling with the intent "to insulate manufacturer from liability by shifting the burden to the physician." 44 Fed. Reg. at 37437. The FDA explained that while it does consult with drug manufacturers on labeling, "[t]he purpose of these consultations ... is to fulfill the agency's mandate that the labeling bear adequate information." *Id.*

Plaintiffs counsel's citation to the FDA's disavowal of pre-emption in the preamble to its 1998 patient medication guide regulation fares no better. *See* 63 Fed. Reg. 66378 (Dec. 1, 1998). As the FDA recognized, patient medication guides generally are distributed by pharmacists to patients, not by drug manufacturers to physicians, and pharmacies have traditionally been regulated by the states, not the FDA. *See Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 530 (E.D. Pa. 2006).

Plaintiffs counsel also have placed significant weight on a comment made in 2000 in the FDA's preamble to the proposed new labeling rule. 65 Fed. Reg. 81082 (Dec. 22, 2000). However, the FDA's brief discussion of pre-emption in that preamble did not address state tort litigation. *See Id.* at 81103. Indeed, the FDA's only discussion of state tort litigation in that preamble was fully consistent with the position it expressed in the 2006 preamble to the final rule:

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> Although the format and content requirements for prescription drug labeling in §§201.56 and 201.57 have enabled health care practitioners to prescribe drugs more safely and effectively, the requirements, together with various developments in recent years, have contributed to an increase in the amount, detail, and complexity of labeling information. This has made it harder for health care practitioners to find specific information and to discern the most critical information in product labeling. ... [T]he use of labeling in product liability and medical malpractice lawsuits, together with increasing litigation costs, has caused manufacturers to become more cautious and include virtually all known adverse event information, regardless of its importance or its plausible relationship to the drug. *Id*. at 81083.

Further, the FDA made clear its position that "enforcement of these [prescription drug] labeling provisions is a Federal responsibility." *Id*. at 81103. Finally, the FDA's indication that the proposed rule would not *give rise* to pre-emption is not inconsistent with the FDA's 2006 preamble, which made clear the FDA's view that state tort claims already were pre-empted under the prior labeling regulations. *See* 71 Fed. Reg. 3933, 3934 ("FDA approval of labeling under the act, *whether it be in the old or new format*, pre-empts conflicting or contrary State law") (emphasis added).

FDA's Position Is Entitled to Significant Deference

Despite themselves relying (improperly) on allegedly inconsistent FDA statements on pre-emption in other regulatory preambles, plaintiffs counsel engage in mental jiujitsu to argue that preamble statements regarding the pre-emptive effect of agency regulations (or at least the 2006 preamble) are not entitled to deference because they are not the subject of formal notice and comment rulemaking. In pressing this argument, plaintiffs counsel rely on the holding in *United States v. Mead Corp*., 533 U.S. 218 (2001), that certain types of agency determinations are not entitled to full *Chevron* deference. This argument fails for at least four reasons:

First, *Mead* did not address a question of pre-emption. The Supreme Court has repeatedly held that pre-emptive intent may properly be communicated in preambles, *amicus* briefs, and interpretive statements, and *Mead* did not disturb these earlier holdings. *See Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 883 (2000); *Hillsborough County v. Automated Med. Labs., Inc*., 471 U.S. 707, 718 (1985).

Second, *Mead* does not stand for the proposition that agency interpretations are only entitled to deference when they are the result of formal notice and comment rulemaking. To the contrary, *Mead* expressly acknowledges that courts "have sometimes found reasons for *Chevron* deference even when no such administrative formality was required and none was afforded." 533 U.S. at 230. Rather, *Mead* holds that *Chevron* deference is inappropriate where there are no "circumstances reasonably suggesting that Congress" thought the particular agency statement "as deserving the deference claimed." *Id*. at 231. This argument plainly does not apply here. To the contrary, the Supreme Court has recognized, based on Congress' broad grant of authority, that the FDA "is uniquely qualified" to determine whether state tort law claims stand as an obstacle to federal objectives and should be pre-empted. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496 (1996).

Third, *Mead* does not address the situation where, as here, an agency is interpreting its own regulations. "[I]n a situation where state law is claimed to be pre-empted by federal regulation ... [a] pre-emptive regulation's force does not depend on express congressional authorization to displace state law." *City of New York v. FCC*, 486 U.S. 57, 64 (1988) (internal quotations omitted). "Instead, the correct focus is on the federal agency that seeks to displace state law and on the proper bounds of its lawful authority to undertake such action." *Id*. The FDA's interpretation of its own regulation is "controlling, unless plainly erroneous or inconsistent with the regulation." *Auer v. Robbins*, 519 U.S. 452, 461 (1997) (internal quotation omitted). The importance of this distinction can be clearly seen in plaintiffs counsel's heavy reliance on an interpretation of the FDA's "changes being effected" regulation, 21 C.F.R. §314.70(c), that is contrary to the FDA's own longstanding comprehension of the meaning and significance of the regulation. *See* Cooper, *Drug Labeling and Product Liability: The Role of the Food and Drug Administration*, 41 Food Drug Cosm. L.J. 233, 236 (1986).

Finally, even if the FDA's decision to set forth its pre-emption position in a preamble deprives the statement of full deference, the FDA's pre-emption position still would be entitled to significant deference under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944), in light of the thoroughness of the FDA's analysis, the validity of its reasoning, the consistency of its analysis with Congressional intent and longstanding agency positions, and the broad grant of authority vested to the agency by Congress. *See Mead*, 533 U.S. at 234 ("*Chevron* did nothing to eliminate *Skidmore's* holding that an agency's interpretation may merit some deference whatever its form").

FDA's Position Is Consistent With and in Furtherance of Public Health.

Courts should defer to the FDA's position on pre-emption regardless of their personal views on the wisdom of the FDA's decisions in its regulation of prescription drugs. A court's "task is not to decide which among several competing interpretations best serves the regulatory purpose." *Thomas Jefferson Univ. Hosp. v. Shalala*, 512 U.S. 504, 512 (1994). Instead, "the agency's interpretation must be given controlling weight unless it is plainly erroneous or inconsistent with the regulation." *Id*. (internal quotation omitted); *see also Colacicco*, 432 F. Supp. 2d at 536 (pre-emption holding based not on the conclusion that plaintiff's analysis is wrong "but rather that it is improper for a federal district court judge to engage in this analysis in the first place").

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That being said, plaintiffs counsel's oft-made argument that the FDA does not have a legitimate interest in protecting against the public health consequences of over-warning, *eg*, discouraging the use of medically needed drugs, is spurious. To the contrary, the FDA's concerns about the public health risks of underuse of prescription drugs are well founded in the medical literature. *See*, *e.g.*, McGlynn, *et al.*, *The Quality of Health Care Delivered to Adults in the United States*, N. Eng. J. Med. 348; 26: 2635 (June 26, 2003) (RAND study concluding that only two-thirds of adults were receiving clinically recommended prescription drugs); Higashi, *et al.*, *The Quality of Pharmacologic Care for Vulnerable Older Patients*, Annals of Internal Medicine 140(9): 714, 718 (May 2004) (observational cohort study concluding that "the underuse of potentially beneficial medications [by older patients] is a considerable problem, which is consistent with previous research").

As both the FDA and courts have recognized, "[t]rials of tort claims pose incentives to over-warn," because juries are not in a position to address, let alone comprehend, the broader public health consequences of their decisions. *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 797 (8th Cir. 2001); *Ackermann v. Wyeth Pharms.*, No. 4:05CV84, Report and Recommendation of Magistrate Judge, slip op. at 11 (E. D. Tex. Sept. 8, 2006) ("To usurp the FDA's regulation in this area offers the potential for far more harm than benefit to patients ... Patients would possibly be denied the benefits of a useful drug"); *see also* 71 Fed. Reg. at 3935. The FDA's ability to focus on the balanced goals underlying the FTCA, rather than the narrow, albeit emotional, appeal of individual tort litigants underscores and confirms the need for plenary FDA authority over drug labeling and the wisdom of the FDA's pre-emption position.

Part Two of this series will discuss the judicial response to the FDA preamble.

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