Pursuing FDA Preemption: The Supremacy Clause and State Tort Law

Federal preemption of state tort laws has been, and continues to be, one of the most important and controversial defenses available to drug and medical devise manufacturers in defending against product liability lawsuits. This defense rests on the operation of the constitutional Supremacy Clause to invalidate state laws that conflict with federal laws. The Supreme Court has explained that conflict preemption occurs either “where it is impossible for a private party to comply with both state and federal law” or where state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”[1] Although the applicability of this doctrine to state product liability actions against medical drug and devise manufacturers has been a significant issue for a number of years, the FDA’s newest statement on the matter has reignited this debate and may allow for the successful widespread use of preemption defenses.

The FDA’s Pre-2006 Stance on Preemption

The FDA’s position on federal preemption until 2002 was that tort law complemented, rather than conflicted with, its regulatory duties. As Margaret Jane Porter, the FDA’s Chief Counsel in 1997, explained, “[the] 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.”[2] In 2002, the FDA announced a major shift in its position regarding federal preemption. Daniel Troy, Chief Counsel for the FDA at that time, explained that allowing state judges and juries to establish additional requirements on the manufacturers of medical drugs and devises conflicted with the FDA’s statutory duty to determine safe product design and labeling. Furthermore, he warned that the FDA would take an active role in pursuing its federal preemption argument through amicus briefs in actions against drug or medical devise manufacturers relying on state law tort claims.[3]

The FDA acted on this warning and began intervening with amicus briefs in drug and medical devise cases around the country. In these amicus briefs, the FDA argued for federal preemption of the plaintiff’s claims under both prongs of conflict preemption. First, the FDA argued that state tort law required the product manufacturer to either avoid tort liability or comply with federal law, and therefore conflicted with federal law.[4] This argument
rests on the FDA's assertion that providing stronger warnings, which would comply with state tort law as argued by plaintiffs, would be false and misleading and violate misbranding prohibitions under the Federal Food, Drug, and Cosmetic Act if those warnings had been rejected by the FDA for a lack of scientific basis. This argument also reflects the FDA's fear that warnings of unproven dangers could lead to under-utilization of medical drugs or devises that could be beneficial to the public. The FDA felt that its guidelines must establish not only minimum standards, a floor, but also maximum standards, a ceiling. The FDA's argument also highlights basic considerations of fairness. As Scott Gottlieb, the FDA's commissioner for medical and scientific affairs, explained, drug makers “should not be second-guessed by state courts that don’t have the same scientific knowledge.”[5] The FDA also pursued its theory of preemption under the second prong of conflict preemption by arguing that state tort law would significantly obstruct the FDA's regulatory purposes and objectives.[6] In making this argument, the FDA argued that state law requiring greater warnings conflicted with the FDA's interpretation of the FDCA, allowing for maximum standards to prevent under-utilization of beneficial drugs and medical devises.[7]

The receptiveness of various courts to these arguments varied as courts split over the issue of FDA preemption of state tort law claims. For example, in 2004 two Federal District Courts in Texas ruled that federal law preempted state law claims for failure to give adequate warnings in two cases against Pfizer stemming from the use of the drug Zoloft.[8] Just the next year, in 2005, two cases were handed down that rejected these same arguments in connection with Zoloft and allowed the plaintiffs' claims to proceed.[9] The courts that rejected that argument often declined to give the statements found in a single legal brief the full preemptive force of law. This hesitancy on the part of some courts to accept the FDA's arguments led the FDA toward the pronouncement of its views in a more established and concrete method.

The FDA Preamble

In January of this year, the FDA provided the legal and medical community with a major surprise. As expected, the FDA promulgated a final rule establishing guidelines for the content and format of prescription drug labeling.[10] However, the FDA unexpectedly inserted into the preamble of that rule its strongest statement to date concerning federal preemption of state tort claims against medical drug and devise manufacturers. In that preamble the FDA concludes that “under existing preemption principles, FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary State law.”[11] Furthermore, the preamble includes a catalogue of examples of claims that the FDA feels would be preempted by its labeling review. These include claims that a manufacturer breached an obligation to the plaintiff by making statements that the FDA approved and claims that a manufacturer breached an obligation to adequately warn the plaintiff by failing to include a statement that the FDA has prohibited in labeling or advertising.[12]

Although the FDA relied on the nearly identical arguments it had made in amicus briefs in support of its views on preemption, the preamble to the 2006 labeling amendments presents new issues not raised by those briefs. First, following the promulgation of the final rule, there has been significant debate concerning the binding nature of the FDA's preamble. Many commentators believe that, since the FDA's assertions are contained in a preamble rather than the final promulgated rule, they are not binding but are merely advisory.[13] However,
other commentators argue that under general principles of federal administrative law, courts should defer to clear agency opinions, even in a preamble.[14] Second, it is uncertain whether the FDA’s preamble can be applied to pending cases or whether it must be applied only to cases initiated after the release of the preamble. Lastly, it is unclear whether courts will apply the preamble only to drug manufacturers or whether, as suggested by the preamble itself, federal preemption can also apply to medical personnel who provide standard warnings approved by the FDA.

Acceptance and Rejection of the FDA Preamble

Almost immediately following the release of the FDA statement on federal preemption in the preamble to the 2006 labeling amendments, defendants in pharmaceutical litigation began to rely on that statement as a defense to pending state failure-to-warn claims. Therefore, courts were almost immediately required to confront the validity and implication of the FDA’s position. There have only been a handful of cases to undertake this task. Those decisions that have been handed down make clear that courts will likely split over this issue as courts did in assessing the FDA’s amicus arguments.

The most widely discussed case to have examined the arguments in the FDA’s preamble is the decision of the Eastern District of Pennsylvania in Colacicco v. Apotex, Inc.[15] In that case, the court dismissed the claims of a plaintiff who sued GlaxoSmithKline (the manufacturer of Paxil) and Apotex, Inc. (the manufacturer of the generic version of Paxil) after his wife ingested the generic version of Paxil and committed suicide. The plaintiff asserted that GlaxoSmithKline and Apotex had failed to warn the plaintiff and his wife of a link between Paxil usage and suicide. Both defendants asserted that the failure to warn claims were preempted by the preamble to the 2006 labeling amendments. As a preliminary matter, the court determined that it could properly consider the preamble in a pending case. In analyzing the substantive impact of the 2006 preamble, the court explained that the “FDA has acted within its authority, and this Court must respect its expert judgment that an October 2003 warning label other than approved by the FDA would have been in direct, actual conflict with federal law.”[16] Deferring to the views of the FDA, the court dismissed the failure to warn claims against the defendants.

Not all courts have regarded the preamble in such a deferential manner. Two other major cases that have addressed the preamble have refused to defer to the FDA’s position in that document and allowed failure to warn suits to proceed. In the first of these cases, Coutu v. AstraZeneca[17], the Superior Court of Rhode Island relied on the rejection of the FDA amicus arguments by other courts and the fact that the FDA had dramatically shifted positions regarding preemption in refusing to defer to the agency’s position in the 2006 preamble.[18] In the second of these cases, Jackson v. Pfizer, Inc.,[19] the District Court for the District of Nebraska refused to defer to the FDA’s position in the 2006 preamble because the FDA “failed . . . to allow the states an opportunity to participate in the proceedings prior to a preemption decision.”[20]

This split will likely continue to divide courts as this issue is addressed by other courts throughout the United States. However, many questions remain for courts to address. These include whether federal preemption, if accepted at all, extends to medical professionals that provide warnings directly to patients regarding
medications and whether those courts that defer to the FDA's view of federal preemption for pharmaceutical drug labeling are willing to extend this deference to medical devise warnings as well. However, it is clear that the issue of FDA preemption will be a central focus in drug and medical devise litigation for the foreseeable future as courts struggle to strike a balance between the interests of individual states in providing tort remedies for their citizens and the interests of the federal government in having critical drug therapies available and a national uniform policy for the review and approval of those therapies.


[7] Id.


[11] Id. at 3934.

[12] Id. at 3935-36.


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[16] Id. at 41.


[18] Id. at *10-11.


[20] Id. at *12.