Federal preemption of pharmaceuticals and medical devices

By William S. Roberts

Over the last several years both federal and state courts have struggled with the issue of whether approval of a drug or medical device by the FDA ensures safety and effectiveness. More commonly, the FDA specification and approval of instructions and warnings associated with those products, preempts state courts from applying common law principals to adjudicate the safety and efficacy of the product or the adequacy of the warnings. These issues have now reached the U. S. Supreme Court. They have recently ruled definitively on the issue of medical devices and ruled on a relatively narrow issue of one statute regarding pharmaceuticals. In October of this year they will hear oral argument on a pending pharmaceutical case which should provide definitive guidance on this issue as well.

The concept of federal preemption is rooted in the Supremacy Clause of the U.S. Constitution. As such, state law is preempted to the extent that it actually conflicts with federal law. This includes preemption of state statutes, regulations and common law civil actions. There are generally two types of preemption; express and implied. Express preemption arises when a federal statute specifically provides that it preempts state law. Implied preemption arises when the federal statute or regulation essentially provides no room for the states to supplement it or where state law stands as an obstacle to the accomplishment and execution of the full purpose and objectives of Congress.

The federal Food and Drug Administration, FDA, was tasked with broad powers and responsibilities to regulate pharmaceuticals and medical devices in the Food Drug and Cosmetics Act (FDCA). This Act, and the resultant FDA Regulations, require the FDA to determine if proffered drugs and medical devices are "Safe and Effective" and, if so, approve them for sale provided they contain specific labeling for dosage, use and specific warnings. The FDCA does not expressly preempt state regulation. Under the FDA regulations, once approved, a product's label may not be changed by the manufacturer without FDA approval except under specific circumstances involving significant safety concerns.

Innumerable state and federal civil actions have been brought against manufacturers of pharmaceuticals and medical devices claiming that the products were, in fact, not safe if taken or used as directed on the label and that the warnings were inadequate. In most circumstances, plaintiffs attempt to produce evidence of individual case reports of adverse reactions to the products and then claim that the manufacturers should have warned of this risk. The manufacturers have, with increasing frequency in recent years, claimed that the FDA approval either expressly, in the case of medical devices, or impliedly, in the case of drugs, preempted states from requiring additional warnings or juries from determining that additional or modified warnings should have been on the products. Plaintiffs claim that the FDA labeling requirements are a minimum standard or "floor." Defendants claim that the FDA requirements are an absolute standard and are both a "ceiling and a floor." Both state and federal courts have been split on this issue for a number of years.

In 1996 the U.S. Supreme Court held in the case of Medtronic Inc. v. Lohr 518 U.S. 470 that there is a general presumption against preemption where Congress has not expressly called for preemption. This did not, however, bar such arguments being raised. However, this presumption lessened significantly over time. In 2001 the Supreme Court ruled in the Buckman v. Plaintiff's Legal Committee 531 U.S. 341, a medical device case alleging "fraud on the FDA," that there was no presumption against federal preemption since regulation of submission to the FDA is "inherently federal in character." Manufacturers found additional arguments in the somewhat older case of Chevron USA Inc. v. Natural Resources Defense Council Inc. 467 U.S. 837 (1984) wherein the Supreme Court held that if there was ambiguity in a federal statute, deference should be given to the interpretation by the federal agency which implemented the statute. As of 1995, FDA regulations regarding the Medical Device Amendment (MDA) specifically stated that it does not preempt state and local regulations which were substantially similar to theirs.
The field of battle began to shift markedly in 2005 when the FDA began to file Amicus Briefs in federal actions stating that it was the intent of the FDA requirements to preempt state regulation or civil actions. Then, in January 2006, new FDA drug regulations were promulgated. The Preamble of those regulations stated “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,” and that this “represents the government’s long standing views on preemption, with a particular emphasis on how that doctrine applies to State laws that would require labeling that conflicts with or is contrary to FDA-approved labeling.” There followed a long series of cases in both state and federal courts interpreting whether this statement was binding. Those courts were split along the same lines as earlier rulings. This was exacerbated by a number of members of Congress, most notably Representative Henry A. Waxman and Senator Edward M. Kennedy, both long-term critics of the FDA, publicly stating that the FDA was overstepping its bounds and not reflecting the intent of Congress.

Although those courts ruling that there was no federal preemption through FDA approvals expressed a variety of arguments supporting those rulings, the most common rationale was that the FDA Regulations allow a manufacturer to unilaterally add or modify a warning or label for safety reasons. This requires the manufacturer to first submit a supplemental New Drug Application (sNDA) recommending the change in the case of drugs or supplemental BLA or PMA in the case of biologics or medical devices, respectively. The manufacturer may then implement the change as a safety measure as a “change being effected supplement” (CBE) while awaiting FDA action on their recommendation.

The stage was then set for resolution, at least in the courts, in 2008. The U.S. Supreme Court agreed to hear three key cases: *Riegel v. Medtronic Inc*; *Warner-Lambert Co. LLC v. Kent*; and *Levine v. Wyeth*.

The first case to be heard and decided by the Supreme Court was *Riegel*. In that case Reigel sued Medtronic after their catheter ruptured in Charles Riegel's coronary artery during surgery. The catheter was a Class III medical device approved by the FDA. Medtronic claimed the FDA approval preempted a product liability action against it under New York law. The District Court agreed and, on appeal, the Second Circuit Court of Appeal affirmed. In February, 2008 the Supreme Court affirmed. In an 8-1 decision, the Supreme Court affirmed, holding that the preemption provisions of the MDA applied. In reaching its decision, the Court ruled, significantly, that state common law claims of liability sounding in both negligence and strict liability impose state "requirements" that are different from or in addition to the FDA requirements. It appears that this ruling definitively establishes federal preemption of most product liability suits against medical device manufacturers where the device was determined to be safe and effective by the FDA and that the warnings or instructions approved by the FDA were adequate, at least in the case of products approved through the PMA process.

The second case to be decided was *Kent*. In that action, a Michigan law was at issue which provided that, in Michigan, common law product liability suits are preempted where the FDA has approved a medical device except in cases of fraud or bribery. The issue before the Court was whether these remaining exceptions were also preempted by the federal law. Chief Justice Roberts recused himself from both the argument and the decision. Oral argument focused frequently on issues related to allowing lay juries to decide technical issues of safety, which are the purview of the FDA. However, the Court quickly ruled with a 4-4 decision, and without an opinion, to deny and let the Michigan law stand.

The remaining case should be the definitive one for issues of federal preemption of pharmaceuticals. Since, unlike medical devices, covered by the MDA, pharmaceutical products are not given express preemption under the FDCA, the primary arguments for preemption of pharmaceuticals sound in implied preemption. However, the policy arguments that this is a technical decision best left to the experts at the FDA, rather than lay juries, still applies. In *Levine v. Wyeth* in state court in Vermont, plaintiff Diana Levine was given two injections of Wyeth's drug Phenergan, an antihistamine; the first by intramuscular injection and the second by intravenous IV push. The second injection went into an artery, which was damaged, became gangrenous, and her arm was amputated. After settling with co-defendant hospital, the case went to trial against Wyeth on claims that Wyeth failed to warn of the known dangers of the drug when injected intravenously. The jury awarded plaintiff $6.77 million. Wyeth appealed to the Vermont Supreme Court on grounds of federal preemption. The state Supreme Court affirmed the judgment in a 4-1 decision stating that "federal labeling requirements create a floor, not a ceiling, for state regulation." Noting that Federal Regulations "allows, and arguably encourages, manufacturers to add and strengthen warnings that, despite FDA approval, are insufficient to protect customers. State tort claims simply give these
manufacturers a concrete incentive to take this action as quickly as possible." This section of FDA regulations, Code of Federal Regulations (CFR) Section 314.70(c) addresses the CBE procedure discussed above.

After accepting the Writ of Certiorari, the U.S. Supreme Court set oral argument for next term, in October 2008. Whether it was the intention of the Court or not, this could allow time for Congress to address this issue if they were to choose to. Coincidental with these Supreme Court cases, on January 16, 2008, the FDA published a Notice of Proposed Rules. In that proposal the FDA notes that the 2007 Food and Drug Administration Amendments Act, (FDAAA) provides streamlined procedures for the FDA to rapidly review and approve safety related drug labels and warnings based on new information. In a footnote, it notes that "federal law governs not only what information must appear in labeling, but also what information may not appear" and that "FDA interprets the act to establish both a 'floor' and a 'ceiling,' such that additional disclosures of risk information can expose a manufacturer to liability under the act if the additional statement is unsubstantiated or otherwise false or misleading"

The key measure in the proposed regulations will be the unequivocal statement that changing a label under the CBE procedure prior to a formal decision by the FDA "may be used only to implement labeling changes regarding contraindications, warnings, precautions, or adverse reactions in circumstances when there is sufficient evidence of a causal association with the drug, biologic, or medical device." It further states that the amendment "ensures that only scientifically justified information is provided in the labeling for an approved product."

This regulation, if finalized later this year, goes to the heart of a significant percentage of the pharmaceutical cases that industry has had to defend in recent years. In those cases, plaintiffs use individual case reports from doctors, or single studies, to claim that there is a risk the manufacturer should have known of and warned against. The FDA wording of "causal association" and "scientifically justified" are relatively well-defined technical terms. They essentially limit it to instances where there is epidemiologically significant data supporting the conclusion. While it would not preclude a plaintiff from making the argument that a manufacturer should have unilaterally added a warning, it makes the defense of such a claim much easier.

The stage has been set for Congress to act this year to state categorically that FDA approval of these products does not preclude state common law actions, to state that it does, or to allow the Supreme Court to decide it this Fall. The plaintiff's bar has already begun to complain that the proposed FDA Rule will deny injured parties their day in court. While it is impossible to predict how the Supreme Court will eventually rule on the Levine case, their holding and discussion in Riegel and the questions posed in oral argument in Kent clearly indicate that many of the members of the Court are cognizant of the problem that, if lay juries are allowed to continue to determine what warnings are to be placed on approved drugs, the effective regulation of those labels by the FDA could be effectively destroyed and certainly reduced or eviscerated.

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