Does FDA Approval of a Drug Completely Shield the Pharmaceutical Manufacturer from Tort Liability in State Court? U.S. Supreme Court to Decide.

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The long-awaited showdown over preemption – the concept that FDA approval completely shields pharmaceutical companies from compensatory and punitive damages in product liability suits filed in state courts – is finally going to be reviewed by the United States Supreme Court. The issue of whether federal regulation of pharmaceuticals completely preempts state law is of critical importance to health law attorneys and health care consumers alike, given the virtual blizzard of bad press and pending litigation involving drug manufacturers and FDA’s apparent failures to perform due diligence to safety data during the new drug approval process and post-marketing surveillance.

On September 25, 2007, the Court announced that it will decide the case of *Warner-Lambert v. Kent* a product liability case against Pfizer’s Warner-Lambert unit which manufactured the diabetes drug Rezulin. Rezulin is a good candidate for a products liability suit against a pharmaceuticals manufacturer: after entering the U.S. market following FDA approval in 1997, use of Rezulin was linked to hundreds of patient deaths and thousands more cases of drug-related liver damage until it was ordered off the market by FDA in March 2000.

The case against Pfizer was initially brought by a group of plaintiffs in Michigan and California state courts. The case directly impacted on the issue of federal attempts to shield pharmaceutical manufacturers from state attempts to regulate. Under Michigan state law, drug manufacturers were immune to product liability claims so long as their drugs were approved by FDA. Submission of fraudulent data to FDA, however, negated the liability immunity shield if the drug would not have been approved without the false data. The plaintiffs brought various common law claims not limited to fraud against the manufacturer, including negligence, negligent misrepresentation, defective design, and defective manufacturing. The drug company removed the actions to federal court, and all of the claims were consolidated and transferred to federal district court in the Southern District of New York.

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The federal decisions in this case all turn on the interpretation of *Buckman Co. v. Plaintiffs’ Legal Comm*⁶, a product liability case which dealt with the specific issue of whether the 1938 federal Food, Drug and Cosmetic Act (FDCA) and the 1976 Medical Device Act preempted tort claims in state court if device manufacturers had provided fraudulent data to the FDA without which the medical device would never have been approved. In *Buckman*, the Supreme Court held that state fraud-on-the-FDA claims were preempted by federal law because, among other things, they could potentially interfere with how FDA itself might want to police manufacturer fraud. For the Rezulin litigation, the U.S. District Court for the Southern District of New York felt there was no real difference between the fraud claims and the non-fraud tort claims the plaintiffs were making against the drug manufacturer. Applying the rational of *Buckman*, all liability claims against the manufacturer were thus dismissed.⁷ On appeal, the 2nd U.S. Circuit Court of Appeals in New York overturned the federal district court decision.⁸ The 2nd Circuit found significant differences between the fraud-on-FDA state statutory and common law claims brought by the plaintiffs, noting that “all of the claims advanced by Appellants in this case are premised on traditional duties between a product manufacturer and Michigan consumers. None of them derives, or is based on, a newly concocted duty between a manufacturer and a federal agency.” In fact, the 2nd Circuit found that the presumption against preemption is strongest in just the types of traditional, general common law tort claims plaintiffs such as Kimberly Kent had brought against the manufacturers in state court. In recognition of the traditional ability of states to protect the health and welfare of their citizens, these claims are not preempted⁹.

The basis for the Supreme Court’s granting of certiorari is the difference between the 6th U.S. Circuit Court of Appeals and the 2nd U.S. Circuit Court of Appeals on the preemption issue. Unlike the 2nd Circuit, the 6th Circuit found the differences between the general common law tort claims against pharmaceutical manufacturers and the specific cause of action fraud-on-the-FDA claims immaterial,¹⁰ and held under *Buckman* that if the latter are preempted so also must be the former.

There is some statutory basis for express preemption of claims against manufacturers in United States food and drug law. Although there is no provision in the FDCA as amended which expressly preempts state tort actions regarding drugs, the Medical Device Amendments of 1976 do appear to provide at least some federal liability shield for medical device manufacturers. Under the 1976 amendments, §521 of the FDCA prohibits a state from promulgating “any requirement regarding a medical device intended for human use” that is “different from or in addition to” the requirements within the FDCA. Based on a “newer” interpretation of this language over the past decade, FDA has changed its position from viewing state tort law and claims against medical device manufacturers as “complimentary” to its regulatory power over device manufacturers to one in which traditional common law remedies against medical device manufacturers in

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⁹ *Id.* at 94.
state court are completely preempted. FDA has had some success already in federal court with this new express preemption doctrine for medical devices. Since the recent tenure of former FDA Chief Counsel Dan Troy however, the Bush administration has taken an even more aggressive position on the preemption issue, expanding the notion of implied preemption to drug injury or failure to warn tort suits against pharmaceutical manufacturers in state court.

This newer pro-industry legal posture has manifested itself in two major ways. First, in a departure from all past practices, FDA has proactively filed amicus briefs without solicitation from the courts in numerous tort liability suits on behalf of the defendant pharmaceutical companies,\(^\text{11}\) claiming complete preemption of claims against the drug manufacturers because they have complied with federal new drug approval (NDA) requirements. In effect, FDA is now claiming that state products liability laws are no longer complimentary to federal regulations on the pharmaceutical industry but rather are unnecessary and potentially misleading. The reaction to this claim from the medical profession has been hostile,\(^\text{12}\) and at least one former FDA Chief Counsel has pointed out\(^\text{13}\) that preemption has never before been FDA’s position on regulation of drugs.

Second, FDA has stated that its new prescription drug labeling rule (first proposed in 2000 and finalized in 2006) completely preempts conflicting or contrary state law on what information is determined necessary for doctors and patients to assess the risks and benefits of drugs.\(^\text{14}\) In effect, the agency’s formal, authoritative conclusions concerning the conditions under which a prescription drug may be used are both the floor and the ceiling for any regulations on labeling for drug safety. The flip side of this position is that consumer claims that they were injured because critical information was omitted from the drug label are no longer meritorious since, by definition, if FDA did not put it in the new label it was not important. Under implied preemption, “this new policy could help companies argue that they weren’t required to warn consumers about a potential risk when the FDA had determined that the safety issue didn’t warrant inclusion on a medicine’s label.”\(^\text{15}\)

FDA has argued that consumers may be “misled” if there is a discrepancy between the labeling safety and patient warning information which appears under federal versus individual state laws, and that once a drug or device has been approved juries do not have either the expertise or experience necessary to overrule decisions by the Agency. For its

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\(^{12}\) Editorial, Ejecting the FDA from the Courtroom, 364 LANCET 638, 638 (August 20, 2004).

\(^{13}\) Rep. Maurice D. Hinchey (D., N.Y.). Torts Play a Vital Role in Protecting Public Health, WALL STREET JOURNAL, August 12, 2004, at A12. “Chief Counsel Troy’s immediate predecessor, Margaret Jane Porter, clearly stated in 1997 that FDA did not view its regulations as pre-emptive of state and local law: ‘even the most thorough regulation of a product such as a critical medical device may fail to identify potential problems presented by the product…Pre-emption of all such claims would result in the loss of a significant layer of consumer protection.’”


part, the pharmaceutical industry and its defenders have rolled out the old argument that diverting financial resources to tort litigation will simply lessen the amount available for additional testing and development of innovative drugs. Some states have argued that they can move faster than a federal agency if new information about adverse events from drugs and devices becomes known, and that they have a traditional right to protect the health and safety of their citizens, the Supremacy Clause notwithstanding. FDA’s new drug labeling rule will prevent any state from making changes to drug labels it felt was necessary to better protect the health of its citizens. Not all states are opposed to preemption though; Texas (as well as others) have supported efforts to limit product liability lawsuits against pharmaceutical companies.

There are several problems with FDA’s preemption argument. First, in the real world, FDA decisions do not happen in a vacuum, and not all FDA approval and regulatory decisions are purely scientific. The current Bush administration has frequently been accused of sacrificing or ignoring straightforward scientific data when the results did not fit its political agenda, as evidenced by the long-running battle over the emergency contraceptive drug Plan B. Second, although FDA clearly possesses enormous scientific expertise and experience in many medical areas, there are some newer areas such as commercial laboratory genetic testing for cancer risk where the medical experience and expertise of FDA is limited or even lacking. Third, FDA’s judgment, even on purely scientific questions, has never been error-free. Lastly, not all state law regulating pharmaceuticals are in the strictest sense “conflicting”; some rules regarding safety information for drugs clearly supplement federal information which has historically operated as a “floor”, or minimum, for citizens.

How all of this is going to play out when the Supreme Court decides the preemption issue is anybody’s guess. It is unclear how much deference the current Court may be willing to give to a federal agency that is now claiming to own a playing field it has historically shared with the states, particularly given that Congress never clearly indicated that it wanted to wipe the slate clean of state law. Based on the clear right-leanings of the current Court’s majority, the deference FDA scientific decisions have often been given under *Chevron*, and some District and Appellate Court decisions on preemption-related issues, it is possible that consumers may find that the legal remedies they have for severe injuries caused by drug and device manufacturers’ products will be severely limited by the end of the Court’s 2007-2008 term.

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