A Call for Continued State Law Tort Reform

Compliance with FDA Regulations As a Bar to Pharmaceutical Product Liability Litigation

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The recent federal trial court decision in *Dusek v. Pfizer Inc.*, Civil Action No. H-02- 3559 (S.D. Tex. 2/20/04) dismissing plaintiffs' products liability claims against Pfizer in connection with the prescription drug Zoloft® on the ground of conflict preemption has given the pharmaceutical industry some hope that compliance with Food and Drug Administration (FDA) regulations will afford protection from common law failure-to-warn claims. The court granted summary judgment on the ground that a cause of action based on the plaintiff's proposed additional warning to the product label that Zoloft can cause suicidal ideation would conflict with the FDA's decision not to add such a warning because no causal link had in fact been established and it would in effect be false and misleading in violation of federal law. This should not deter continued efforts to obtain tort reform at the state level, however, where the continued influx of pharmaceutical product liability claims continues to burden courts and the pharmaceutical industry. With the exception of Michigan, no other jurisdiction has codified compliance with FDA regulations as a bar to common law failure-to-warn claims. Instead, a handful of states have adopted modified versions of the defense, which, for example, bar punitive damages for drugs approved by the FDA (or for other products that otherwise meet government standards) or create a rebuttable presumption of non-liability in light of FDA approval. Although these statutes are helpful, they lack the force that a true "FDA compliance" defense offers and have failed to stem the tide of state court product liability filings against the pharmaceutical industry.

Behind The 'FDA Compliance' Defense

To understand why the "FDA compliance" defense is different, it is important to focus on the unique characteristics not only of a pharmaceutical products liability case, but of the regulation of the industry as a whole. The allegations regarding product liability for prescription drugs infrequently focus on a manufacturing or design defect. Instead, most claims challenge the sufficiency of warnings that accompanied the drug. Thus, an "FDA compliance" defense essentially will dispose of an entire case if the product is labeled in accordance with the FDA approval.

Such a defense makes sense because the pharmaceutical industry is among the most heavily regulated industries in the United States. Critics of an "FDA compliance" defense ignore the unique approval process required by law before a prescription drug can be marketed, as well as the FDA's continued involvement in evaluating product labeling during the post-marketing phase. Instead, critics contend that government standards are minimum standards, and that they can become outdated and irrelevant. Michigan Senate, Senate Fiscal Agency Bill Analysis, S.344, at 13 (8/28/95). As the Michigan legislature recognized, however, these complaints are inapplicable to the unique case of prescription drugs.

First, FDA regulations encompass virtually all areas of safety and potential risk reduction. Thus, the FDA standards are not "minimum standards." To obtain approval to market a drug, a pharmaceutical company must submit to the FDA a New Drug Application (NDA). 21 U.S.C. § 355(a). Title 21 of the Code of Federal Regulations, Part 314, sets forth very detailed requirements for an NDA. The NDA must include, *inter alia*, descriptions of all the study results as well as the data itself, patent information, and all post-marketing information such as results of clinical studies, advertising and marketing materials, and packaging and labeling. 21 C.F.R. § 314.50. This is in addition to the significant initial requirements of an Investigational New Drug Application (IND), which include, *inter alia*, submission of a plan of investigation, study protocols for each phase of investigation conducted in humans (Phase 1 mechanistic studies as well as Phase 2 and Phase 3 safety and efficacy studies), information about drug chemistry, manufacturing, pharmacology, and toxicology (including animal studies), information regarding previous human experience with the investigational drug, as well as

updated protocols as new studies are contemplated. 21 C.F.R. § 312.21. Proposed labeling for the drug must include, *inter alia*, the following information: 1) warnings; 2) precautions; and 3) adverse events. 21 C.F.R. § 201.56.

Within 180 days after filing an NDA pursuant to the provisions of 21 U.S.C. § 355(b), the FDA may approve the application if it does not find statutory grounds for denial. In so doing, the FDA must find, *inter alia*¸ that there is sufficient reliable scientific evidence to make a determination that the drug is safe, and that there is "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." *See* 21 U.S.C. § 355(d).

Accordingly, if a drug is approved by the FDA, it has implicitly met stringent government standards, and there already has already been an "expert" determination that the warning is adequate. Additionally, because of this stringent regulatory scheme, public safety is adequately protected.

Indeed, unlike in many other regulatory contexts, the FDA extensively regulates drugs throughout a drug's lifetime. FDA regulations not only govern the pre-approval process, but also a drug's post-marketing period, and require, among other things, NDA supplementation in the event of a change affecting the approval application (21 C.F.R. § 314.70), labeling changes (21 C.F.R. § 314.81) and adverse event reporting (21 C.F.R. § 314.80). Moreover, if evidence comes to light indicating that the drug is unsafe or not efficacious, or simply if a drug manufacturer fails to comply with the reporting requirements of 21 C.F.R. § 314.81, the FDA may withdraw its approval of the application and prohibit its continued marketing. *See* 21 U.S.C. § 355(e) and 21 C.F.R. § 314.81(d), respectively. Thus, the criticisms of this defense are without merit.

As the court observed in *Dusek*, *supra*, the issue is "whether the FDA's repeated decisions to require certain labeling is entitled to deference sufficient to preempt state law claims that contradict FDA's conclusions." *Dusek v. Pfizer Inc.*, Civil Action No. H-02-3559, slip op. at 18 (S.D. Tex. 2/20/04). The answer is yes, and this deference should become a formal part of each state's statutory scheme.

Michigan's Absolute 'FDA Compliance' Defense

Michigan is the only state that has codified compliance with FDA regulations as a bar to product liability claims. Michigan law expressly prohibits pharmaceutical products liability claims that challenge the safety of FDA-approved drugs that are labeled in compliance with that approval. M.C.L.A. § 600.2946(5) states, in pertinent part: "In a product liability action against a manufacturer or seller, a product that is a drug *is not defective or unreasonably dangerous, and the manufacturer or seller is not liable*, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left control of the manufacturer or seller." (emphasis added.)

The statute has two exceptions. A plaintiff may nevertheless pursue product liability claims arising out of the ingestion of a prescription drug if: 1) FDA approval was obtained through bribery of an FDA official; or 2) a manufacturer "intentionally withholds from or misrepresents to the United States Food and Drug Administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act, [citations] and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted." M.C.L.A. § 600.2946(5)(a) (b).

In providing a true defense for compliance with FDA regulations, Michigan's legislature "determined that a drug manufacturer or seller that has properly obtained FDA approval of a drug product has acted sufficiently prudently so that no tort liability may lie." *Taylor v. SmithKline Beecham Corp.*, 468 Mich. 1, 7, 19; 658 N.W.2d 127, 131, 137 (2003). The legislature struck what it viewed as an appropriate balance between the public's need for effective and affordable medications and the right to sue for injuries allegedly caused by such medications. *Id*. at 19, 658 N.W. 2d at 137 (provision "represents a legislative determination as a matter of law of when a manufacturer or seller of a prescription drug has acted sufficiently reasonably). Michigan "decid[ed] that the federal regulatory scheme furnishes its citizens protection enough against potential injury from the unanticipated effects of a new medication." *Garcia v. Wyeth-Ayerst Labs*, 265 F. Supp. 2d 825, 833 (E.D. Mich. 2003). The Supreme Court of Michigan since has upheld the law in the wake of a state constitutionality challenge. *Taylor*, 468 Mich. at 19, 658 N.W.2d at 137. Additionally, a federal court in Michigan upheld it in a challenge under the U.S. Constitution. *Garcia*, 265 F. Supp. 2d at 833.

Watered-Down Versions of The Absolute 'FDA Compliance' Defense

New Jersey and several other states have adopted what might be viewed as weaker versions of the "FDA compliance" defense. For example, New Jersey law creates a rebuttable presumption in a pharmaceutical products liability case that the drug's warnings or instructions are adequate. N.J.S.A. § 2A:58C-4. This presumption "does not change the burden of proof" in a pharmaceutical failure-to-warn case, and, though a court may instruct them otherwise, jurors remain "free to disregard evidence of 'approval' by the FDA." *Feldman v. Lederle Labs*, 125 N.J. 117, 157; 592 A.2d 1176, 1197 (1991).

Colorado's law applies generally to compliance with government standards and is not specific as to FDA compliance, but also creates a rebuttable presumption that a product was not defective if, at the time of sale, it complied with any applicable state or federal "code,

standard, or regulation." Col. Rev. Stat. § 13-21-403. By contrast, Arkansas merely permits introduction of evidence of compliance with "any federal or state statute or administrative regulation existing at the time a product was manufactured and prescribing standards of design, inspection, testing, manufacture, labeling, warning, or instructions for use." Ark. Code Ann. § 16-116-105.

The final variation on the FDA compliance defense are those laws that bar punitive damages against manufacturers of drugs manufactured and labeled in compliance with FDA regulations. New Jersey and Oregon are examples of states that have enacted such laws. N.J.S.A. § 2A:58C-5; Or. Rev. Stat. § 30.927.

These examples of defenses that, unlike the Michigan statute, do not act as a complete bar to product liability claims appear to have been largely ineffective in halting, or even slowing, the influx of products liability claims against the pharmaceutical industry. New Jersey, for example, which has had a rebuttable presumption law in effect for over 15 years, has promulgated court rules that specifically address mass tort case management, suggesting a continued rise in the number of prescription drug product liability cases being filed against New Jersey manufacturers. *See generally*, N.J. Ct. R. 4:38A and the State of New Jersey Judiciary Web site at www.judiciary.state.nj.us.

Why An Absolute 'FDA Compliance' Defense Is Necessary

Although bars on punitive damages and rebuttable presumptions are useful, state tort reform efforts in New Jersey (with its significant community of pharmaceutical companies) and elsewhere should focus, among other things, on codification of compliance with FDA regulations as an absolute bar to product liability claims. As with medical malpractice claims in the state of New Jersey, plaintiffs who bring pharmaceutical product liability claims should be required to submit an affidavit of merit from an expert, at minimum, as to medical causation. N.J.S.A. § 2A:53A-27. As the Michigan legislature recognized, the threat of product liability litigation is a powerful disincentive to new drug development. Michigan Senate, Senate Fiscal Agency Bill Analysis, S.344, at 9 (8/28/95). Moreover, new theories of liability and the proliferation of mass torts and related class actions have made the defense of lawsuits increasingly onerous for pharmaceutical defendants. Complex and voluminous litigation also can divert company resources. Thus, liability concerns steer drug manufacturers, both large and small, away from developing and introducing new drugs for fear of potential civil liability. Additionally, defense costs have largely driven up the cost of prescription medications. This affects not only manufacturers of pharmaceutical products, but also, ultimately, consumers. In sum, pharmaceutical companies must be able to rely on the FDA's determinations with respect to new drug approval and post-marketing labeling decisions. Codification of an absolute "FDA compliance" defense at the state level is a step in the right direction.