The Role of Consumer Protection Law in Prescription Drug Advertising
I. INTRODUCTION

State consumer protection law has long played a central role in ensuring that individuals harmed by prescription pharmaceuticals and their manufacturers have recourse to recover for those injuries through the judicial branch of government. For years, the Food and Drug Administration (“FDA”), the federal agency charged with approving and regulating prescription drug products, recognized the important function of state law claims in inducing manufacturers to avoid fraudulent behavior and enhance the safety of their products. But the FDA recently changed its tune and now argues that state claims against pharmaceutical manufacturers based on inadequate warnings of adverse side effects are preempted by federal law and thus cannot be prosecuted. Such an interpretation effectively closes the courtroom doors to individuals harmed by prescription drugs and provides near immunity to manufacturers. Fortunately, courts encountering the defense of preemption in prescription pharmaceutical litigation have generally responded to the FDA’s argument by reaffirming the significance of state consumer protection law and Congress’s intent that claims brought thereunder remain viable.

In Section II of this paper, I briefly outline the types and sources of claims typically raised in pharmaceutical litigation. Section III introduces the doctrine of preemption and examines the FDA’s historical and newly revised positions on the preemption of state law claims involving prescription drugs. Section IV provides examples of a number of recent decisions by federal and state courts rejecting the preemption defense and reiterating the importance of private rights of action, guaranteed by state law, in protecting consumers.

II. CLAIMS MADE UNDER STATE CONSUMER PROTECTION LAW

“Consumer protection law” encompasses common and statutory law. Both kinds of law, and the claims available under them, are critically important in protecting consumers and have been used to prosecute a variety of pharmaceutical-related litigation.

Traditionally, litigation involving personal injuries as a result of use of a prescription drug has been grounded in common law causes of action. These include negligence, strict or product liability, breach of warranty of merchantability, and fraud or deceit claims. This is particularly true where plaintiffs alleged the manufacturer of the pharmaceutical provided insufficient warnings or failed to disclose side effects. As one court recently noted, “failure to warn claims ‘have long been a part of traditional state tort law’.”

In recent years, attorneys have filed a number of cases against the manufacturers of pharmaceuticals alleging violations of state consumer protection statutes. All fifty states, as well as the District of Columbia, have at least one such statute (which are also referred to as “unfair and deceptive trade practices acts” or “consumer fraud acts”). These statutes typically prohibit

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unfair or deceptive trade practices in an attempt to protect consumers from abusive sales behavior and are, by and large, modeled on the Federal Trade Commission Act. With the exception of Iowa, a consumer protection statute in each state expressly or implicitly allows private actors to bring claims under the act. (Iowa’s statutes include provisions for the state’s Attorney General to bring suit.)

Most private actions brought under state consumer protection statutes do not seek damages for personal injuries caused by a defective pharmaceutical or other product. Rather, these claims frequently assert that the product is neither as safe or effective as advertised or, in the case of drugs and medical devices, that the drug or product was fraudulently promoted for “off label” or non-approved uses for which there is no proven benefit. Consumers allege they were harmed by fraudulent sales practices, did not receive the benefit of the bargain they sought, and thus should receive actual, as well as punitive and multiple, damages.

The growth of claims brought under state consumer protection statutes has seemingly come about as a result of three things: an increase in class actions (and the attendant reluctance of courts to certify classes based on personal injury); difficulties of proof in individual personal injury actions; and possibilities of recovering on behalf of those exposed to a dangerous device but not yet manifesting personal injury. More importantly, however, is the recognition by the plaintiffs’ bar that use of the consumer fraud acts is an effective method of providing additional incentives to pharmaceutical manufacturers to refrain from fraudulent practices in marketing and selling their products. State consumer protection laws – whether through common law claims or statutory enactments – provide consumers with private causes of action and real access to the civil justice system. Most federal laws regulating pharmaceuticals lack any such private cause of action thus without state consumer protection law, consumers would have no recourse when harmed by a prescription drug.


III. PREEMPTION AND ITS RISE AS A DEFENSE IN PRESCRIPTION DRUG LITIGATION

Regardless of the type and source of the consumer’s state law cause of action, the defense of preemption has become the hallmark reaction to such claims. In a number of cases, pharmaceutical manufacturers have argued that consumer claims relating to inadequate warnings of the risks of drugs are preempted by federal regulation and thus cannot be pursued. The following section briefly discusses the doctrine of federal preemption and its use in pharmaceutical litigation.

A. Federal Preemption of State Law Causes of Action

The Supremacy Clause of Article VI of the United States Constitution provides that “This Constitution, and the Laws of the United States which shall be made in Pursuance thereof… shall be the supreme Law of the Land… any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.” Accordingly, in the event of a conflict or inconsistency between state and federal law, federal law wins and state law is preempted. The preemptive effect extends to both state statutory and common law and may be triggered by both federal statutes and federal regulations.5

Preemption is grounded in federalism. America’s founding fathers were concerned about preserving the rights of states to enact and retain their own laws except in the limited instances in which federal law was needed. In Federalist Papers No. 45, James Madison wrote “The powers reserved to the several States will extend to all the objects which, in the ordinary course of affairs, concern the lives, liberties, and properties of the people, and the internal order, improvement, and prosperity of the State.” Article X of the Constitution reflects this understanding as well.6

In recognition of this desire not to intrude upon state sovereignty, particularly in areas traditionally regulated by the states (such as health and safety), unless the federal government has clearly manifested its intentions to do so, the Supreme Court has repeatedly asserted that there exists a presumption against preemption.7 And as Justice Stevens pointed out in his dissent in Geier v. American Honda Motor Company, Inc., 529 U.S. 861, 907 (2000), “The signal virtues of this presumption are its placement of the power of pre-emption squarely in the hands of Congress, which is far more suited than the Judiciary to strike the appropriate state/federal balance (particularly in the areas of traditional state regulation), and its requirement that Congress speak clearly when exercising that power.”

To overcome the presumption against preemption, a party must show that (1) Congress, or an agency acting on the delegated authority of Congress, has expressly stated that it intends to

6 “The powers not delegated to the United States by the Constitution, nor prohibited to it by the States, are reserved to the States, respectively, or to the people.”
7 Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449 (2005) (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996) and writing “[B]ecause the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action.”).
preempt state law in a particular area; (2) Congress explicitly or implicitly intended to occupy an entire field of legislation and leave no room for state regulation; or (3) state law conflicts with federal law to such a degree that it would be ‘impossible for a private party to comply with both state and federal requirements,’… or where state law ‘stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’” These types of preemption are referred to as express preemption, field preemption, and conflict or implied preemption, respectively.

Preemption, where found, is a complete defense to liability under state law, which has the effect of wiping out a victim’s ability to recover any compensation. Further, preemption of state law causes of action removes a powerful incentive to manufacturers of pharmaceuticals, devices, and other consumer goods to make their products safer. As such, courts entertaining a preemption defense must carefully scrutinize the language and intent of the federal government in regulations affecting a particular area.

B. **Preemption in the Context of Prescription Drugs**

1. **The FDA’s Pre-2002 Position**

Prior to 2002, the Food and Drug Administration’s long-standing and oft-stated position was that the federal Food, Drug and Cosmetic Act (“FDCA”) and its provisions would not be “construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of state law.” In fact, in 1994, the FDA’s Deputy Commissioner for Policy explained in comments regarding a proposed rule to protect the identity of individuals reporting adverse events or adverse reactions to drugs or medical devices (and thus preempting any state or local regulations requiring or permitting the disclosure of that identity) that the “FDA recognizes the sophistication and complexity of private tort litigation in the United States and the proposed preemption action is not intended to frustrate or impede tort litigation in this area. Indeed, FDA recognizes that product liability plays an important role in consumer protection.”

In 1998, the FDA further affirmed its views that federal law surrounding prescription drugs did not preempt state regulations. A number of drug manufacturers encouraged the FDA to “provide for Federal preemption of State regulation with respect to civil tort liability claims and other labeling requirements” and that “without preemption, FDA regulation would encourage ‘failure to warn’ claims and challenges to the adequacy of the… labeling.”

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9 The removal of incentives under state law causes of action is particularly dangerous given that the FDA’s enforcement actions, designed to manage postmarket safety issues, have dropped precipitously in the last several years. *See, e.g.*, *Prescription for Harm: The Decline in FDA Enforcement Activity*, U.S. House of Representatives Committee on Govt. Reform, Minority Staff, Special Investigations Division, June 2006, available at http://oversight.house.gov/story.asp?ID=1074.


response, the FDA, through its Lead Deputy Commissioner and the Secretary of Health and Human Services, wrote

Tort liability can not be a major consideration for FDA which must be guided by the basic principles and requirements of the act in its regulatory activities. Nevertheless, FDA does not believe that this rule would adversely affect civil tort liability…

FDA does not believe that the evolution of state tort law will cause the development of standards that would be at odds with the agency’s regulations. FDA’s regulations establish the minimal standards necessary, but were not intended to preclude the states from imposing additional labeling requirements. States may authorize additional labeling but they cannot reduce, alter, or eliminate FDA-required labeling.13

Finally, in December 2000, in a proposal of amendments to the requirements for the labeling of prescription drugs, published in the Federal Register, the FDA explicitly stated that it had “determined that this proposed rule does not contain policies that have federalism implications or that preempt State law.”14 That language did not make it into the final rule.

2. Recent Changes in the FDA’s Position on Preemption

The FDA’s public position on FDA changed substantially in 2002 when it submitted an amicus brief in litigation in California over the prescription drug Zoloft. In 1998, Victor Motus committed suicide after taking Zoloft, a drug made by Pfizer, for approximately one week. His widow brought suit against Pfizer and alleged, in part, that Pfizer failed to adequately warn consumers and the medical community of the suicide risk associated with the drug. Pfizer moved for partial summary judgment on those claims, arguing they were preempted and thus barred by the FDA’s approval of the labeling for the drug. In late 2000, the District Court for the Central District of California denied Pfizer’s motion for partial summary judgment on grounds of federal preemption.15

During the appeal process, the FDA submitted an amicus brief on behalf of Pfizer, urging the Court of Appeals to find that the plaintiff’s claims were preempted. While the case was decided on other grounds on appeal, the FDA’s brief marked a clear turning point.

Since 2002, the FDA has submitted amicus briefs in a number of cases asserting that the manufacturers of prescription drugs failed to adequately warn patients and the health care community of the risks associated with the pharmaceuticals.16 Frequently, the FDA contends, in

13 Id. at 66383-84.
parallel to the manufacturer’s argument, that drug makers are prohibited from modifying an FDA-approved label for a pharmaceutical thus the federal agency’s regulations necessarily preempt any efforts under state law to enhance the warnings on the product’s labeling.

In January 2006, the FDA increased the stakes. In the Preamble to its final rule governing the “Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products”, the agency declared that state law causes of action alleging inadequate warning were preempted by federal law where the warning had been expressly approved by the FDA.17 Instead of viewing FDA regulations as delineating the minimum or floor requirements for safety (as it had since the creation of the FDCA), the agency asserted that the regulations acted as both a floor and a ceiling for the content and format of prescription drug labels, obviating any state law failure to warn claims. The FDA explained its reasoning as follows:

State law actions… threaten FDA’s statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs. State actions are not characterized by centralized expert evaluation of drug regulatory issues. Instead, they encourage, and in fact require, lay judges and juries to second-guess the assessment of benefits versus risks of a specific drug to the general public – the central role of FDA – sometimes on behalf of a single individual or group of individuals. That individualized reevaluation of the benefits and risks of a product can result in relief – including the threat of significant damages awards or penalties – that creates pressure on manufacturers to attempt to add warnings that FDA has neither approved nor found to be scientifically required. This could encourage manufacturers to propose “defensive labeling” to avoid State liability, which, if implemented, could result in scientifically unsubstantiated warnings and underutilization of beneficial treatments.18

The Preamble to the final rule was not subject to the notice and comment period required for the enactment of federal rules. (Indeed, the FDA provided no notice of its intent to include this language in its final rule, in violation of Executive Order 13132.) Such language can be changed at any time. Accordingly, as many courts have recognized, the Preamble is not a binding portion of the regulations (which became effective June 30, 2006) but is instead an advisory opinion by the enacting agency.19 Yet since the publishing of the Preamble,


18 Id. at 3935. Going further, the agency declared that not only were claims against manufacturers preempted but so too were claims against physicians and other health care providers regarding the “dissemination of risk information to patients beyond what is included in the labeling.” Id. at 3935-36.

19 See 21 C.F.R. § 10.85(d)(1) (classifying as an advisory opinion “[a]ny portion of a Federal Register notice other than the text of a proposed or final regulation, e.g., a notice to manufacturers or a preamble to a proposed or final regulation.”).
manufacturers have speciously argued, and FDA amicus briefs have concurred, that courts should defer to the FDA’s interpretations of the regulations as expressed in the Preamble.

This complete reversal by the FDA on the issue of federal preemption, beginning with amicus briefs and culminating in the Preamble to the final rule, aims to strike a mighty blow at the heart of state consumer protection law, particularly where advertising and warnings related to prescription pharmaceuticals are concerned. While the FDA’s new opinion has gained some traction, most courts have recognized that Congress did not intend to exclude the states from protecting their citizens in this area and thus have rejected the FDA’s position on preemption.

IV. HOW THE COURTS ARE RESPONDING

Although courts in a small number of high profile cases have recently deferred to the FDA’s current view and found an implied Congressional intent to preempt certain state law claims (including failure to warn),20 more courts are recognizing the FDA’s position for what it is – an attempt by a federal agency, without the explicit authorization of Congress, to eliminate state law protections for consumers. Judges presiding over prescription drug cases, whether brought under the common law or under state statutory law, have begun to clarify a number of very important issues regarding the role of state law in protecting consumers in pharmaceutical litigation.

First, the vast majority of courts recognize that while the FDA must approve a drug’s label, including all warning information contained therein, before it can be marketed and sold to the public, current federal regulations allow manufacturers to add or increase a warning on a drug without FDA approval.21 Federal regulations further provide that the manufacturer has a duty to warn of a safety risk where there is “reasonable evidence of an association between a particular hazard and the drug.”22 Because the regulations provide a specific procedure for manufacturers to strengthen the warnings on the drug’s label, the “FDA’s approved label… can therefore be said to set the minimum labeling requirement, and not necessarily the ultimate label where a manufacturer improves the label to promote greater safety.”23 Accordingly, as the Supreme Court of Vermont recently noted,

There is thus no conflict between federal labeling requirements and state failure-to-warn claims. Section 314.70(c) 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.24

22 21 C.F.R. § 201.57(e).
Perhaps most significant, however, is the courts’ reaffirmation of the importance of state law causes of action and Congress’s intent that these state law remedies remain viable options for consumers. Below is a short survey of language and reasoning arising in prescription pharmaceutical failure-to-warn and consumer fraud litigation refusing to give deference to the FDA’s Preamble and finding the FDA’s regulations do not preempt state law claims.


In 2004, in the wake of numerous cases filed by individuals alleging personal injuries arising out of use of the prescription drug Zyprexa, the Judicial Panel on Multidistrict Litigation consolidated the cases for pre-trial purposes in front of Judge Jack Weinstein in the Eastern District of New York. Zyprexa is an atypical antipsychotic approved for use in treating schizophrenia and bipolar mania. Patients taking the drug claimed they suffered undisclosed health risks including significant weight gain, development of hyperglycemia and diabetes, and associated cardiovascular problems – risks allegedly known to Eli Lilly, the drug’s manufacturer, since the drug became available for sale in 1996. (Other parties, bringing claims under state consumer protection statutes as well as federal law, alleged Eli Lilly fraudulently misrepresented both the safety and efficacy of Zyprexa and illegally promoted the drug for off-label purposes, such as the treatment of dementia in the elderly and ADHD in children.)

Eli Lilly filed a motion for summary judgment on grounds of federal preemption of the plaintiffs’ claims that the company failed to adequately warn of the risks of Zyprexa. In denying Eli Lilly’s motion, Judge Weinstein recognized the importance of claims brought under consumer protection laws, writing “Jury verdicts and adequacy of warning claims serve an important regulatory role in the tort system. State law adequacy of warning claims may alert the FDA to potential inadequacies in product labeling. The current litigation against Lilly may be a testament to that.”25 Going further, the Court reaffirmed the critical role of the judiciary in ensuring that consumers are protected and pharmaceuticals are as safe and effective as possible:

> The lesson of prescription drug tort litigation cautions against permitting the FDA to sweepingly remove adequacy of warning claims from the prescription drug regulatory landscape:

> “Notwithstanding the structural inability of the FDA to carefully investigate and monitor drug safety, drug makers assert a preemption defense premised on the notion that FDA approval of a drug indicates a validation of the drug’s safety. This position shirks the responsibility of drug manufacturers to carefully monitor the adverse effects of their products. One could reasonably assume that Vioxx might still be on the market if Merck had not been

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concerned about its financial exposure in products liability lawsuits.

“The availability of courts to redress injuries provides the public powerful leverage against negligent drug manufacturers. The threat of litigation reduces the risk of misconduct by drug makers, providing the public with necessary protections against the effects of dangerous pharmaceuticals. If courts extended federal preemption to drug claims… manufacturers would have little incentive to conduct post-approval clinical studies to examine a drug’s safety. The FDA would also lose one of its few bargaining chips in pressuring companies to amend labels to warn of newly discovered risks.”


On September 30, 2004, five years after gaining approval for the drug, Merck & Co. withdrew its pain reliever Vioxx from the market. Vioxx had been promoted as a more effective pain reliever than traditional non-steroidal anti-inflammatory drugs (or “NSAIDs”), including ibuprofen, for treatment of arthritic and other chronic or acute pain. This was in part because traditional NSAIDs can lead to gastrointestinal perforations, ulcers, and bleeding and initial studies seemingly showed that patients taking Vioxx suffered from fewer gastrointestinal side effects. Yet studies also showed a significantly increased risk of adverse cardiovascular effects in patients on Vioxx. Merck continues to face innumerable personal injury and consumer fraud claims as a result of its failure to disclose and warn of the increased risk of cardiovascular side effects. The majority of these cases were consolidated for pre-trial proceedings before Judge Eldon Fallon in the Eastern District of Louisiana.

Merck filed a motion for summary judgment on federal preemption grounds in two individual Vioxx cases before Judge Fallon. In denying Merck’s motion, the Court acknowledged the Supreme Court’s admonition to be cautious in applying the doctrine of implied preemption because of the strong presumption against it:

In many preemption cases, finding state law preempted leaves plaintiffs with no make-whole remedy, creates inequitable results, or produces a dangerous regulatory gap…. Why choose the presumption against preemption as the pragmatic default rule instead of the opposite presumption? Because the presumption against preemption allows each state to satisfy the preferences of its own citizens, while a presumption in favor of preemption would

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impose a uniform national policy even when national preferences are unclear.\textsuperscript{27}

After reviewing the Preamble to the FDA’s final rule on labeling, Judge Fallon reiterated that historically, “the several States have… exercised their police powers to protect the health and safety of their citizens.”\textsuperscript{28} Accordingly,

Because there are no federal remedies for individuals harmed by prescription drugs, a finding of implied preemption in these cases would abolish state-law remedies and would, in effect, render legally impotent those who sustain injuries from defective prescription drugs.... Far from standing ‘as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,’ state-law claims against prescription drug manufacturers ‘necessarily perform an important remedial role in compensating’ injured individuals. \textit{Sprietsma v. Mercury Marine}, 537 U.S. 51, 64 (2002).\textsuperscript{29}


Although the majority of cases involving personal injury or consumer fraud claims regarding Vioxx were consolidated before Judge Fallon, several remain in state court. On June 8, 2007, Judge Carol Higbee of the Superior Court of New Jersey denied Merck’s motion for a new trial or judgment NOV. Merck claimed, in part, that the plaintiffs’ claims for failure to warn should have been preempted. The Court noted that the removal of Vioxx from the market prompted congressional hearings on prescription drug safety but Congress decided not to dismantle state remedies

The fact is that following the withdrawal of Vioxx from the market, congressional hearings were held specifically to address the concerns of some members of Congress about the failure of the FDA to provide adequate drug safety protection to the public. These hearings resulted in proposed changes in statutes governing the FDA itself, but no decision by Congress to preempt prescription drug tort law.\textsuperscript{30}

\begin{footnotes}
\footnotenum{28} \textit{In re Vioxx Prods. Liab. Litig.}, 2007 U.S. Dist. LEXIS 48367, at *33.
\footnotenum{29} \textit{Id.} at *33-34 (internal citations omitted).
\footnotenum{30} \textit{Cona v. Merck & Co., Inc.}, ATL-L-3553-05 MT, at *35; \textit{McDarby v. Merck & Co., Inc.}, ATL-L-1296-05 MT, at * 35.
\end{footnotes}
… Despite the large number of lawsuits filed, Congress has not moved to expressly preempt State law governing “failure to warn,” but has instead placed its focus on changing laws governing the FDA.


Prempro is a hormone replacement therapy drug manufactured and sold by Wyeth and has been the subject of a number of cases filed by patients alleging they developed breast cancer as a result of use of the product. In a recent decision of the Superior Court of New Jersey, Judge Bryan Garruto denied Wyeth’s motion for summary judgment on federal preemption grounds, noting

…numerous decisions in both state and federal law cases hold that FDA approval of a drug’s warning label alone is insufficient to preempt a state’s authority to provide laws that protect the health, safety, and welfare of its citizens and to deprive litigants injured by a product’s inadequate warning from a remedy at law.

This Court adopts U.S. District Judge Jack B. Weinstein’s reasoning and findings in *In re: Zyprexa Products Liability Litigation*, No. 04-MD-1596, 06-CV-1729 (E.D.N.Y. June 11, 2007) and Superior Court Judge Carol E. Higbee’s reasoning findings in *Cona/McDarby v. Merck*, Nos. ATL-L-3553-05 MT, ATL-L-1296-05 MT (N.J. Super. Law. Div., June 8, 2007), which both hold that the FDCA does not preempt state tort law claims based on a pharmaceutical company’s inadequate warnings of the risks involved in ingesting its FDA-approved product.31

V.  CONCLUSION

State laws and the causes of action they provide to individuals are of critical importance in protecting the rights and recovery of consumers harmed by prescription drugs and the manufacturers of such products. The FDA’s new view of preemption stands as a threat to those rights. Fortunately, however, courts are continuing to recognize the significant role of state law in inducing manufacturers to refrain from fraudulent behavior in the marketing and sale of their products and refusing to find state law claims preempted.

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