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Does the Failure of the Preemption Defense in *Wyeth v. Levine* Expose New Jersey-Based Drug Companies to Consumer Fraud Act Claims?

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The Supreme Court's recent opinion in *Wyeth v. Levine*, ___ U.S. ___, 129 S. Ct. 1187 (2009) (7 PLIR 249, 3/6/09), dashed the hopes of the pharmaceutical industry for a broad preemption defense against state-law claims involving pharmaceuticals. Even though drugs, their labels and advertising are comprehensively regulated by the Food and Drug Administration, *Wyeth* held that this regulation does not trump state-law claims contending that a drugmaker should have done more than what the FDA required. But does *Wyeth* mean that pharmaceutical companies are exposed to state-law claims, even if they complied with the FDA's labeling and advertising requirements?

At least with regard to the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 *et seq.* (NJCFCA), drugmakers can effectively still argue that the answer should be no. The NJCFCA frequently has been deployed as a weapon by plaintiffs suing over drug purchases. Often the NJCFCA is the centerpiece claim in class action suits by insurance companies, health maintenance organizations, and other third-party payers who seek to recover the purchase price of drugs by claiming that the language on a drug label or the wording of an advertise-

ment was misleading. With its mandatory treble-damage and attorneys-fee-shifting provisions and the absence of any reliance element, the NJCFCA allows a drug purchaser to plead an ordinary case of breach of warranty or contract as something far more threatening to the drug manufacturer—and much more attractive to the plaintiff's lawyer. The NJCFCA thus provides the plaintiffs' bar with a powerful tool to leverage settlements by drugmakers.

But there is ample authority to suggest that the NJCFCA does not apply to a highly regulated industry such as pharmaceuticals that already is subject to the FDA's comprehensive oversight. Properly viewed, the NJCFCA is a default scheme of regulation for consumer sales—and, therefore, it should not apply where the product or service at issue already is subject to comprehensive regulation. To do so would create a possibility of conflicting regulatory regimes that the state Legislature never intended. This "inverse preemption" defense provides drugmakers with a new way to argue the FDA regulation limits the reach of state law.

I. Wyeth and the Substantial Demise of Preemption in Pharmaceutical Cases

The facts of *Wyeth* amply demonstrate the quandary that drugmakers face when they comply with the FDA's regulations but still find themselves exposed to state-law claims contending that they should have done something more than what the FDA required. And *Wyeth* rejected the most obvious defense argument in this situation—that the FDA's system of regulation preempts the state-law claim.

In *Wyeth*, the defendant manufactured and sold an antihistamine drug used to control nausea, administered to patients intravenously. The physician assistant who administered the drug to the plaintiff did so incor-

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rectly, causing an infection that led to gangrene and the amputation of the plaintiff's hand and forearm. The plaintiff sued the physician assistant, who settled before trial. But she also sued Wyeth on a theory that the drug-maker should have warned clinicians to use a different method of administration. At trial, the jury awarded the plaintiff \$7.4 million in damages, finding the drug defective due to inadequate warnings on its label concerning the risks of intravenous administration.

Wyeth unsuccessfully pursued preemption arguments at the trial- and appellate-court levels, arguing that the FDA had approved the drug as safe and effective and had approved the specific warnings that appeared on the drug's label. Indeed, that label advised clinicians to use "extreme care" when administering the drug through intravenous injection, warning that "gangrene requiring amputation [is] likely" if a mistake was made (129 S. Ct. at 1225). Wyeth argued that if the FDA found that warning satisfactory and adequate, no state court jury sitting should be able to hold otherwise.

The majority opinion, however, rejected Wyeth's preemption claim. *First*, it held that Wyeth's use of the FDA-approved label was not dispositive of the product-liability claim, as Wyeth could have added stronger warnings concerning the dangers of intravenous injection. And the court rejected Wyeth's claim that it would have been impossible to amend the label without the FDA's prior approval, given the drugmaker's ability to make a temporary label change on notice to the agency and the "difficult[y in] accept[ing]" the notion that the FDA would take enforcement action in response to a stronger warning. *Id.* at 1997. Absent "clear evidence" that the FDA would not have approved the label change, the court refused to find the claim preempted (*id.* at 1998).

Second, the court rejected Wyeth's argument that a stronger warning would "obstruct the purposes and objectives of federal drug labeling regulation" (*id.* at 1199). The court held that Congress could have adopted an express provision into the Federal Food, Drug, and Cosmetic Act that preempted state law, and inferred from Congress's failure to do so act an intent that state-law claims would not be preempted.

Clearly, *Wyeth* means that the FDA's comprehensive jurisdiction over drugs will not preempt state-law claims, even when the drugmaker complied with all federal requirements. Evidently, preemption only will apply if the defendant drugmaker can proffer "clear evidence" that the FDA considered and rejected the very warning that the plaintiff claims the defendant should have given. And this presumably is as true for consumer fraud claims as it is for product liability claims. Indeed, after *Wyeth*, the Supreme Court almost immediately vacated and remanded a Third Circuit opinion holding a consumer fraud claim preempted by the FDA's regulation over drug labeling, *Pennsylvania Employees Benefit Trust Fund v. Zeneca Inc.*, 499 F.3d 239 (3d Cir. 2007).

II. Does State Law Even Reach Matters Subject to FDA Regulation? A Better, More Nuanced Attempt at Using Federal Regulation as a Defense

The blunt hammer of preemption—claiming that federal regulation overrides state law by dint of the Constitution's supremacy clause—clearly failed in *Wyeth*. But

perhaps a more nuanced argument can succeed where preemption fell short—given that pharmaceuticals already are subject to comprehensive regulation by the FDA, does state law in the form of the NJCFA even apply to claims pertaining to drugs?

A. The NJCFA's Origin as a Regulatory Scheme

Almost forgotten today is the NJCFA's origin as a form of regulation over consumer sales. The New Jersey Legislature enacted the NJCFA in 1960 "to permit the Attorney General to combat the increasingly widespread practice of defrauding the consumer" (*Kugler v. Romain*, 58 N.J. 522, 545 (1971)). In particular, the statute targeted "fly-by-night operators who travel from area to area perpetrating deceptive business practices upon prospective innocent buyers" (letter from Attorney General David D. Furman to Sen. George B. Harper (March 30, 1960)). According to the attorney general's statement in support of the bill, the NJCFA was needed to combat fraudsters "who simply invade an area . . . before law enforcement, under present legislative machinery, can detect and attempt to put a stop to their actions" (*Id.*). The NJCFA was most concerned with protecting "the poor, the naïve and the uneducated consumers who have yielded unwittingly to . . . high pressure sales tactics" (*Kugler*, 58 N.J. at 538).

For its first 12 years in effect, the NJCFA was purely a regulatory mechanism—it did not afford a private right of action to injured consumers. Rather, the statute provided the New Jersey attorney general with broad powers to police the field of consumer sales. Pursuant to the NJCFA, the attorney general could subpoena documents and testimony, secure injunctive relief against wrongdoers, and revoke corporate charters and licenses (N.J.S.A. 56:8-4, -8). He also could promulgate rules and regulations for consumer sales (N.J.S.A. 56:8-4).

There is nothing in the legislative history of the NJCFA to suggest that the statute ever was intended to address sales of products that already were subject to pervasive oversight by competent regulatory authorities. Certainly, nothing in the NJCFA's legislative history suggests an intent to regulate drugs. Indeed, given its focus on combating "fly-by-night operators" who preyed upon unsophisticated consumers, the legislative history impliedly suggests that the NJCFA was *not* intended to regulate the already-regulated business of pharmaceuticals.

B. New Jersey Decisions Limiting the Scope of the NJCFA When the Product at Issue is Already the Subject of Comprehensive Regulation

It was only in 1971 that the Legislature amended the NJCFA to provide injured consumers with a private right of action under the statute—including mandatory treble-damage and fee-shifting provisions for successful litigants. Creating as it did "private attorneys general" among the plaintiffs' bar, this amendment triggered the deployment of the NJCFA to many areas where the attorney general never before had attempted its application. Indeed, today the NJCFA is largely thought of as a remedial statute entitling injured consumers to sue—and its origin (and continuing status) as a regulatory mechanism often is forgotten by the courts applying its terms.

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But remembering the NJCFA’s status as a regulatory mechanism is important to understanding the statute’s proper scope—and to circumscribing an aggressive plaintiffs’ bar’s efforts to expand the NJCFA into areas it never was intended to intrude. Indeed, as a general principle of law, the specific provision controls over the more general provision. This principle applies not just to the interpretation of contractual provisions but also to the harmonization of different statutory and regulatory schemes (see, e.g., *State by State Highway Commission v. Dilley*, 48 N.J. 383, 387 (1967); *State v. Resorts International Hotel Inc.*, 173 N.J. Super. 290, 297 (App. Div. 1980)). Therefore, if the NJCFA is properly understood as a general scheme of regulation over consumer sales, then it should not apply where the product or service at issue already is the subject of specific regulation.

The New Jersey Supreme Court recognized this principle as early as 1978, a mere seven years after the NJCFA was amended to afford a private right of action. In a case alleging violation of the NJCFA in the way a public utility calculated customer charges under its tariff, the court emphasized that the specific regulatory authority overseeing utilities—the Public Utility Commission—had “ample authority to order corrective and remedial action” (*Daaleman v. Elizabethtown Gas Co.*, 77 N.J. 267, 272 (1978)). Accordingly, the court held that application of the NJCFA would create an untenable situation “where separate state agencies would have the right to exercise concurrent jurisdiction and control over [the utility’s] billings, with a real possibility of conflicting determinations, rulings and regulations affecting the identical subject matter” (*Id.*). Accordingly, the court found that the NJCFA did not apply to the calculation of utility charges.

Of course, the mere existence of any regulation does not defeat the NJCFA’s application. In *Lemelledo v. Beneficial Management Corp.*, 150 N.J. 255, 268 (1997), the Supreme Court reaffirmed its “understanding that the Legislature does not intentionally subject regulated entities to clearly conflicting administrative regimes.” However, the court clarified that courts should presume that the NJCFA applies to a covered practice, absent a finding of “direct and unavoidable conflict” with another source of regulation that “deal[s] specifically, concretely, and pervasively with the particular activity. . . .” (*Id.* at 270). Applying these principles, the Court held that a NJCFA claim alleging fraud in the sale of credit was not barred, even though the conduct at issue was subject to regulation by the Division of Banking under four other statutes (*Id.* at 270). The Court concluded

that the NJCFA “simply complements those statutes, allowing for regulation by the Division of Consumer Affairs and a private cause of action” that “in no way inhibits enforcement of other statutes” (*Id.* at 273; see also *Real v. Radir Wheels Inc.*, ___ N.J. ___, 2009 WL 961206, at *7 (April 8, 2009)).

Following *Daaleman* and *Lemelledo*, New Jersey courts have found that many areas are outside the purview of the NJCFA because they are subject to pervasive regulation: (1) A hospital’s dealings with a patient, since it is subject to regulation by the Department of Health, *Hampton Hospital v. Bresan*, 288 N.J. Super. 372 (App. Div. 1996); (2) advertising by physicians, given the regulation of such advertising already in place (*Macedo v. Dello Russo*, 178 N.J. 340 (2004)); (3) a claimed overcharge of sales tax by supermarkets, given its regulation by the Division of Taxation (*Elizabeth Kawa v. Wakefern Food Corp.*; *Shoprite Supermarkets Inc.*, 24 N.J. Tax. 39 (2008)); (4) casino gambling, given its regulation by the Casino Control Commission (*Doug Grant Inc. v. Grete Bay Casino Corp.*, 232 F.3d 173 (3d Cir. 2000)); and (5) the design of a motor vehicle, where it conforms to comprehensive federal regulations (*Green v. General Motors Corp.*, 2003 WL 21730592 (N.J. App. Div. July 10, 2003)).

C. The NJCFA and Pharmaceuticals

Is the FDA’s regulation of pharmaceuticals any different? Is it somehow less comprehensive than the regulation of gambling, hospitals, sales taxes, or the design of motor vehicles? And is the possibility of conflict between the NJCFA and the regulatory scheme any less real, such that the NJCFA and the FDA should concurrently apply to pharmaceuticals?

The resounding answer is no. Under the Federal Food, Drug, and Cosmetic Act, drugs cannot be marketed at all in the United States unless they first are subject to an exhaustive scientific review process at FDA that finds them to be both safe and effective based upon clinical and other data (see 21 U.S.C. § 355). The FDA specifically reviews and approves the indications for which a drug be prescribed, as well as the safety warnings that appear on the drug’s label (see, e.g., 21 C.F.R. §§ 314.50, 314.105). Drugmakers are required to file adverse event reports regarding any safety issues seen with the drug after it has been introduced to the marketplace, one purpose of which is to allow the agency to take action should safety issues manifest themselves (see 21 C.F.R. § 314.80). And the advertising of drugs to patients is exhaustively regulated by the FDA’s Division of Drug Marketing, Advertising, and Communications, including requirements that all ads be filed with the agency and optional procedures for preclearance of advertisements (see 21 C.F.R. §§ 202.1, 314.81(b)(3)). The FDA has a panoply of enforcement options if a drugmaker violates the federal regulations—including an action seeking a refund for all purchasers who bought a “misbranded” drug (see *U.S. v. Lane Labs-USA Inc.*, 427 F.3d 219 (3d Cir. 2005)).

Given this regulatory scheme—certainly as pervasive and systemic as for any product marketed to consumers—what need is there for the NJCFA to regulate the business of pharmaceuticals? As in *Daaleman*, the FDA has ample authority to order corrective and remedial action. As in *Lemelledo*, the FDA’s regulation deals “specifically, concretely, and pervasively with the

particular activity. . . .” If a drugmaker advertises the drug consistent with the statements approved by the FDA (as in *Wyeth*), does that not create a “direct and unavoidable” conflict if a jury were to conclude that the defendant violated the NJCFA by doing so?

One New Jersey appellate court has suggested that the FDA’s regulation leaves no room for the NJCFA. In *New Jersey Citizen Action v. Schering-Plough Corp.*, 367 N.J. Super. 8 (App. Div. 2003), the court examined a claim that the maker of Claritin violated the NJCFA by allegedly overstating the efficacy of that antihistamine drug in its direct-to-consumer advertisements. While affirming the dismissal of the complaint because the ads were not false and plaintiff failed to allege a cognizable loss, the appellate court also declined to apply the NJCFA given the FDA’s regulation over Claritin and its advertising:

[P]laintiff’s complaint overlooks an essential difference between the pharmaceutical industry and others. Regardless of the claims in the [direct-to-consumer] advertising campaign, the products in question remain subject to the strict regulation of the FDA (*see* 21 U.S.C. § 253; 21 C.F.R. 202.1).

Our Supreme Court has recognized, in an analogous context, that a pharmaceutical manufacturer’s compliance with FDA regulations, including regulation relating to DTC marketing campaigns may shield it from a failure to warn case. By analogy, the wording of the ads, to the extent that it is subject to FDA oversight (*see* 21 C.F.R. 202.1, is similarly not actionable).

Id. at 14 (citing *Perez v. Wyeth Labs Inc.*, 161 N.J. 1 (1999)). Embedded in these few sentences is the important finding that where practices of drug manufacturers

are subject to FDA regulation, those practices are not subject to regulation—or private causes of action—under the NJCFA. Indeed, a New Jersey trial court subsequently dismissed a NJCFA claim contending that a sunscreen manufacturer misrepresented the product’s efficacy in protecting against the sun’s harmful rays, given that sunscreens are drugs “under the dominion of” the FDA and its finding that the FDA’s regulation “overrode” the NJCFA’s otherwise expansive approach (*Ruhl v. Schering-Plough Corp.*, BER-L-1287-05, slip op. (N.J. Super. Ct. Jan. 20, 2006)).

III. Conclusions

In defending against consumer fraud claims, the pharmaceutical industry needs to shift tactics after *Wyeth*—except in the rare case when it can be shown by “clear evidence” that the FDA specifically disapproved of the action that the plaintiff contends the drugmaker should have taken. Instead of arguing that the FDA’s regulation preempts the NJCFA, the defendant should argue that state law does not reach the business of pharmaceuticals in the first place. Certainly, drugs are as highly regulated as the other areas exempted from the NJCFA’s reach (public utility charges, hospital care, physicians, sales taxes, gambling, and motor vehicle design).

Finally, it bears emphasizing that such a result does not necessarily leave injured plaintiffs without a remedy, as claims still may exist under warranty, contract, or product liability law. So the issue is not whether consumers have a remedy—instead, it is whether the extraordinary remedy of the NJCFA (treble damages, attorney fee-shifting, lenient standards of proof) is required when the FDA already is policing the conduct at issue. Plainly, it does not.