Litigation

Preemption of Punitive Damages in Prescription Drug Litigation

*By Eric Lasker & Rebecca Womeldorf**

Over the past 16 years, the United States Supreme Court has repeatedly addressed the question whether state tort law claims against manufacturers of FDA-approved products are preempted by federal law. The Court's rulings have resulted in a patchwork legal quilt, with federal law preempting compensatory damages claims involving (1) Class III medical devices (*Riegel v. Medtronic*), (2) vaccines (*Bruesewitz v. Wyeth*), (3) generic prescription drugs (*PLIVA v. Mensing*), and (4) claims alleging fraud on the FDA (*Buckman Co. v. Plaintiffs' Legal Committee*), but allowing compensatory damages claims against (1) Section 510(k) medical devices (*Medtronic v. Lohr*) and (2) brand named prescription drugs (*Wyeth v. Levine*). The Court's varying treatment of these state tort law claims demonstrates that the question of FDA preemption is highly dependent on the particular nature of the legal claims presented. And the Court's willingness to repeatedly return to these preemption waters—demonstrated most recently by its decision in late November 2012 to accept certiorari in yet another preemption case involving generic prescription drugs (*Mutual Pharm. Co. v. Bartlett*)—suggests that that the full scope of preemption involving FDA-regulated drugs is yet to be defined.

In this article, we examine a preemption issue that has as yet received little attention from the courts: Whether the doctrine of preemption should bar punitive damages claims arising from FDA-regulated conduct in the labeling and marketing of brand name prescription drugs. To date, this legal question has arisen primarily in the context of state tort reform statutes that preclude punitive damages against FDA-compliant drug manufacturers absent evidence of fraud-on-the-FDA. In these cases, most (though not all) courts have held that, absent an FDA finding of non-compliance, the statutory fraud-on-the-FDA exceptions are preempted under the Supreme Court's reasoning in *Buckman*. These authorities are limited on their face to the particular state statutes under which they arise. However, because state choice-of-law rules often require courts from other states to apply the punitive damages law set forth in these tort reform statutes, the scope of punitive damages preemption extends well beyond that states in which such laws have been enacted. Moreover, as courts have grappled with the issue of punitive damages preemption in the statutory context, their legal analyses has extended more broadly to the inherent conflict between an FDA determination that a drug company has acted appropriately and a state law decree through a punitive damages award that would punish a drug company for the very same conduct. Below, we discuss one such opinion recently secured by the authors' client, Novartis Pharmaceuticals Corporation ("NPC"), in *Zimmerman v. Novartis Pharm. Corp.*,[1] and assess what this and similar opinions may portend on the broader question of punitive damages preemption in prescription drug litigation.

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I. The *Zimmerman* Court's Punitive Damages Preemption Analysis

In *Zimmerman*, a Maryland district court addressed the question of whether New Jersey statutory law governed a punitive damages claim brought by a Maryland personal injury plaintiff against a New Jersey-based pharmaceutical company and, if so, whether FDA regulation of prescription drugs preempted the fraud-on-the-FDA exception in the New Jersey statute that provided the sole path for an award of punitive damages. The court answered both questions in the affirmative.

On the issue of choice of law, the court applied the rule of depecage, by which courts examine competing states' significant relationships to the litigation issue-by-issue rather than for the case as a whole. As set forth in the Restatement (Second) of Conflicts of Law § 145 cmt. d, under the rule of depecage, "courts have long recognized that they are not bound to decide all issues under the local law of a single state." Thus understood, the question before the court was whether New Jersey or Maryland had the more significant relationship to the conduct giving rise to plaintiff's claim for punitive damages. In concluding that New Jersey had the more significant relationship, the court noted that the alleged improper conduct relating to the labeling of the drug and the defendant's dealings with the FDA had taken place in New Jersey.[2] Maryland's relationship to the litigation, in contrast, was based upon the locus of the alleged injury, a fact that was "simply fortuitous" with respect to the defendant conduct at issue.[3] The court further noted that application of New Jersey law to punitive damages and Maryland law to compensatory damages was consistent with the relevant state interests and party expectations because it respected New Jersey's policy decision (and its domestic corporations' expectations) regarding what type of conduct could give rise to *punishment* without disturbing the plaintiff's justified expectations that she would receive *compensation* for her injuries under her home state's law.[4]

The court then turned to the relevant punitive damages provision in the New Jersey Product Liability Act. Pursuant to N.J. Stat. § 2A:58C-5(c), "[p]unitive damages shall not be awarded if a drug or device . . . which caused the claimant's harm was subject to premarket approval . . . by the federal Food and Drug Administration . . . and was approved" except "where the product manufacturer knowingly withheld or

misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question, punitive damages may be awarded." Following the lead of the United States Supreme Court in *Buckman* and New Jersey state appellate courts that had applied *Buckman*'s fraud-on-the-FDA preemption ruling to Section 2A:58C-5(c),[5] the *Zimmerman* court concluded that the exception in the New Jersey statute was "preempted by federal law because it requires a jury to speculate whether Novartis misrepresented material information that was required to be submitted under the FDCA and applicable regulations."[6] In so holding, the court undertook its own independent analysis of the FDA's regulatory authority over prescription drugs and held that allowing a state tort law jury to reach its own conclusions about FDA's decisions in its communications with its regulated entities would impermissibly interfere with FDA's authority over those entities and its enforcement prerogatives to restrain violations of federal requirements.[7]

II. Broader Implications of the *Zimmerman* Analysis

Zimmerman sets forth the framework for a broader discussion of the role of preemption in precluding punitive damages in prescription drug product liability litigation. By correctly recognizing that the rule of depecage extends the reach of state punitive damages tort reform measures to out-of-state injuries arising from in-state conduct, *Zimmerman* demonstrates that the preemption holding in *Buckman* should preclude punitive damages awards against New Jersey-based pharmaceutical companies, no matter where in the country those claims are pursued. This fact alone secures a prominent role for preemption in precluding punitive damages awards in prescription drug litigation across the country. Fifteen of the world's largest pharmaceutical companies have their U.S. headquarters in New Jersey, including Johnson & Johnson, NPC, Merck, and Bayer HealthCare,[8] and greater than 90 percent of mass-tort claims against New Jersey pharmaceutical companies are brought by non-resident plaintiffs alleging injuries in other states.[9] Moreover, five other states (Arizona, North Dakota, Ohio, Oregon, and Utah) have similar statutes protecting FDA-compliant manufacturers from punitive damages absent evidence of fraud-on-the-FDA, and two states (Michigan and Texas) have broader statutory protections for FDA-compliant companies that, under the rule of depecage, would likewise require preemption of punitive damages claims brought against those states' resident drug companies by out-of-state plaintiffs.

Additionally, *Zimmerman*'s substantive analysis of the preemption issue under the New Jersey statute suggests that punitive damages claims in prescription drug litigation should properly be subject to preemption, even outside the context of fraud-on-the-FDA statutory provisions. Unlike compensatory damages, which "are intended to redress the concrete loss that the plaintiff has suffered by reason of the defendant's wrongful conduct," punitive damages, "which have been described as 'quasi-criminal,' operate as 'private fines' intended to punish the defendant and to deter future wrong doing."[10] The question whether punitive damages claims are preempted thus gives rise to a fundamentally distinct preemption analysis.[11] As a New Jersey appellate court recently explained in distinguishing a Second Circuit opinion that rejected preemption of a fraud-on-the-FDA statutory exception to a statute immunizing FDA-compliant drug companies from *compensatory* damages:

> [In seeking punitive damages] a plaintiff bringing a product liability action acts in a fashion akin to a private attorney general, since any damages awarded on his punitive damage claim do not compensate him for his injury, but instead vindicate societal interests . . . This limited claim for punitive damages, focused upon deterring a manufacturer's knowingly inadequate response to FDA informational requirements, thus differs from the common law compensatory claims at issue in *Desiano*, as to which a strong presumption against preemption applies.[12]

The Supreme Court's holding in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984), is not to the contrary. While the Court there rejected an argument distinguishing between preemption of compensatory and punitive damages, that holding arose in the analytically distinct nuclear regulatory context. As other courts have noted in rejecting FDA preemption reasoning in such cases, "[u]nlike the comprehensive FDA regulatory scheme, which functions independently of any state partnership, the NRC's authority is not exclusive."[13] As *Zimmerman* correctly notes, "the FDA enforces violations of the drug approval process, not private litigants."[14] And the FDCA vests the FDA—not private litigants—with significant discretion in determining when to exercise the myriad of enforcement tools at is disposal.[15] Moreover, in the years since *Silkwood*, the Supreme Court has moved away from its historical view that state law was the exclusive arbiter of punitive damages.[16] Accordingly, any argument that there should be a presumption against preemption of punitive damages awards in prescription drug litigation should carry far less weight today than it did when *Silkwood* was decided.

III. Conclusion

With decisions like *Zimmerman*, the question of preemption of punitive damages claims in prescription drug litigation is finally coming to the fore. The answer to this question may present the next major development in the evolving doctrine of preemption in pharmaceutical products liability litigation.

Endnotes

1 No. RWT 8:08-cv-02089, 2012 WL 3848545 (D. Md. Sept. 5, 2012),

2 *Zimmerman*, 2012 WL 3848545, at *5.

3 *Id.*, at *4.

4 *Id.* at *5. NPC has secured similar depecage rulings applying New Jersey punitive damages law in a number of other cases involving out-of-state plaintiffs. *See* Brown v. Novartis Pharm. Corp, No. 7:08-cv-00130-FL, 2011 WL 6318987, *4-9 (E.D.N.C. Dec. 16, 2011); Talley v. Novartis Pharm. Corp., No. 3:08-cv-361-GCM, 2011 WL 2559974 (W.D.N.C. June 28, 2011); Irby v. Novartis Pharm Corp., Nos. MID-L-1815-08, 278, 2011 WL 5835414 (N.J. Super. Ct. Nov. 18, 2011); Meng v. Novartis Pharm. Corp.,

Nos. L7670-07MT, L-6027-08MT, 278, 2009 WL 4623715 (N.J.Super. Ct. Law Div. Nov. 23, 2009).

5 *See* Cornett v. Johnson & Johnson, 998 A.2d 543, 566 (N.J. Super. Ct. App. Div. 2010), *aff'd on other grounds*, 48 A.3d 1041 (N.J. 2012); McDarby v. Merck, 949 A.2d 223 (N.J. Super. Ct. App. Div. 2008), *appeal dismissed*, 979 A.2d 766 (2009); *see also* Baker v. APP Pharm., *LLC*, Civil Action No. 09-05725, 2010 WL 4941454 (D.N.J. Nov. 30, 2010); Stanger v. APP Pharm., *LLC*, Civil Action No. 09-05725, 2010 WL 4941451 (D.N.J. Nov. 30, 2010). *But see* Forman v. Novartis Pharm. Corp., 793 F. Supp.2d 598, 608 (E.D.N.Y. 2011) (holding under Second Circuit authority that the N.J. statutory exception is not preempted).

6 *Zimmerman*, 2012 WL 3848545, at *7.

7 *Id.* at *9–12.

8 *See* Melanie Hill, *New Jersey Pharmaceuticals Industry Writes Prescription for Growth,* BusinessClimate.com, Dec. 5, 2012, *available at* http://businessclimate.com/new-jersey-economic-development/new-jersey-pharmaceuticals-industry-writes-prescription-growth.

9 *See* Rowe v. Hoffman-La Roche, Inc., 917 A.2d 767, 771 (N.J. 2007).

10 Cooper Indus., Inc. v. Leatherman Tool Grp., Inc., 532 U.S. 424, 432 (2001).

11 *See* Arizona v. United States, 132 S.Ct. 2492, 2502-03 (2012) ("Permitting the State to impose its own penalties for the federal offenses here would conflict with the careful framework Congress adopted."); Nat'l Meat Ass'n v. Harris, 132 S.Ct 965, 972-73 (2012) (federal preemption savings clause did not save state ban on certain types of slaughterhouses from preemption because the ban "is something more than an 'incentive' or 'motivator'" and acts as a command that differs from federal regulation).

12 *McDarby*, 949 A.2d at 275.

13 DOCA Co. v. Westinghouse Elec. Co., Civil No. 04-1951, 2011 WL 3476428, *11 (W.D. Pa. Aug. 9, 2011).

14 *Zimmerman*, 2012 WL 3848545, at *10; *see also* Bailey v. Johnson, 48 F.3d 965, 967 (6th Cir. 1995) ("The language of the [FDCA] and its legislative history clearly evidence Congress' intent that it should be enforced only by the government.").

15 *See* Heckler v. Chaney, 470 U.S. 821, 837-38 (1985); *see also* Schering Corp. v. Heckler, 779 F.2d 683, 685-86 (D.C. Cir. 1985) (decisions by FDA whether to exercise its enforcement authority "involve a complex balancing of an agency's priorities, informed by judgments 'particularly within its expertise,' and … are therefore ill-suited for judicial review") (internal citation omitted).

16 *See* State Farm Auto. Ins. Co. v. Campbell, 538 U.S. 408, 430 (2003) (Ginsburg, J., dissenting) ("Not long ago, this Court was hesitant to impose a federal check on state-court judgments awarding punitive damages."); BMW of N. Am., Inc. v. Gore, 517 U.S. 559, 605 (1996) (Scalia, J., dissenting) (noting that the "necessary effect" of the Court's opinion "is to establish federal standards governing the hitherto exclusively state law of [punitive] damages").