THE SUPREME COURT RESUMES ITS TREND OF RECOGNIZING THE PREEMPTION OF CLAIMS INVOLVING FDA-REGULATED PRODUCTS

By Jonathan Berman

The manufacture of drugs and medical devices is controlled by pervasive regulation, administered by the Food and Drug Administration ("FDA"). The FDA, on the basis of its independent evaluations of safety and efficacy, issues comprehensive mandates regarding what products may be sold, how they can be manufactured, and what manufacturers can say about them. But should patients using these products become injured, the manufacturers are frequently sued under state-law tort theories. In these cases, preemption is often a key defense.

Since 2001, the Supreme Court has decided five cases analyzing whether state tort claims involving FDA-regulated products are preempted by federal law.[1] Unsurprisingly, given the role of the FDA and its restrictions upon the manufacturers' freedom of action, the Supreme Court has found preemption in all but one of these cases.

The exceptional case, the 2009 *Wyeth* decision, held that consumers can sue the manufacturers of brand-name drugs for failure to provide adequate warnings. The most recent Supreme Court decision, *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), presented very similar facts except that the drugs in question were generics. Due to differences in the regulatory scheme governing generic drugs, the Court found that *Wyeth* was distinguishable and that for generics it was impossible to both satisfy the standard allegedly imposed by state law and comply with federal regulations. The Court therefore returned to the prevailing trend of finding tort claims to be preempted.

Pliva is hardly likely to be the last word on preemption. A variety of efforts are already underway by plaintiffs' lawyers and advocacy groups to undercut *Pliva*'s holding. But *Pliva* points the way toward unifying a fragmented area of law and points manufacturers toward a tool that could serve to strengthen preemption defenses.

PREEMPTION LAW

The doctrine of preemption stems from the Supremacy Clause of the United States Constitution (Art. VI, cl. 2). The Supremacy Clause declares that "the Laws of the United States … shall be the Supreme Law of the Land." A state law is thus preempted if it "directly conflict[s]" with federal law or if "it is impossible for a private party to comply with both state and federal requirements." *Pliva*, 131 S. Ct. at 2577. Federal law can preempt state law either expressly or "impliedly." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 & n.2 (2001). State law is preempted if it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496 (1996). Determining whether state law has been impliedly preempted can require an inquiry into Congress's intent in enacting the relevant statute, or even into what the FDA intended when enacting regulations that are said to conflict with state law. *Hillsborough County, Florida v. Automated Med. Labs., Inc.*, 471 U.S. 707, 716 (1985).

Preemption issues have come before the Supreme Court frequently over the last decade. In *Buckman*, the plaintiff had alleged that the manufacturer of bone screws had procured regulatory approval through fraudulent representations to the FDA. The Court rejected this "fraud on the FDA" theory, holding that it was in conflict with the section of the Food, Drug, and Cosmetic Act (the "Act") that gives the federal government exclusive jurisdiction to enforce the Act.[2] In the 2008 *Riegel* decision,[3] the Court held that the Act preempts tort claims relating to medical devices if the FDA had granted premarket approval. And only a few months before issuing *Pliva*, the Court held that the National Childhood Vaccine Injury Act immunizes the manufacturers of vaccines from design-defect claims.[4]

THE *WYETH* AND *PLIVA* DECISIONS

The *Wyeth* decision stands out from the general trend of recognizing preemption. The plaintiff in *Wyeth* received Phenergan to treat her nausea. Because the drug had been improperly administered, the plaintiff developed gangrene, necessitating amputation of her right forearm. She alleged, and a jury found, that the manufacturer had failed to provide adequate warnings regarding the proper method of administering Phenergan. Wyeth argued that failure-to-warn claims were preempted by federal labeling laws, which subject all prescription-drug labeling, including warnings, to FDA approval. Justice Stevens, writing for a five-judge majority, found that there was no conflict with state tort law obligations and therefore that the state-law claims were not preempted. Although warnings and other labeling cannot be changed without seeking the FDA's approval, once such approval is sought through a "changes being effected" supplemental application, a warning can be strengthened immediately, without awaiting the FDA's decision.[5]

Pliva presented similar facts but came to a different result. In *Pliva*, the plaintiffs' doctors had prescribed the drug Reglan, which is used to treat digestive-tract problems. The plaintiffs' pharmacists filled their prescriptions with the generic version of Reglan, metoclopramide. Both plaintiffs developed a severe neurological disorder known as tardive dyskinesia. In separate suits, the plaintiffs alleged that long-term use of metoclopramide caused their condition and that the generic manufacturers were liable under state tort law for failure to warn of this danger.

The Supreme Court held that generic drugs are required to provide exactly the same warning information on their labels that the FDA had approved for their brand-name counterparts.[6] Thus, the generic manufacturers were precluded from issuing any additional warnings, including the warnings that the plaintiffs alleged would have prevented their injuries. Because it was impossible for the generic manufacturers to

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comply with both federal and state mandates, the state-law tort claims were preempted.

The *Pliva* Court distinguished *Wyeth* on narrow, fact-specific grounds. While brand-name manufacturers can add a warning immediately upon submitting a "changes being effected" supplement to the FDA, that route is not available to generics. It is this difference in the regulatory scheme that makes it possible for brand names, but impossible for generics, to conform to the obligations established by state-law duty-to-warn claims. *See Pliva*, 131 S. Ct. at 2577–78, 2581.

EFFORTS TO UNDERCUT *PLIVA*

Several attempts to minimize *Pliva*'s impact are already afoot. Some plaintiffs, for example, have argued that even if generic-drug manufacturers cannot *change* the approved warnings, they can still be liable for failing to call the approved language to the attention of prescribing doctors. Thus, in recent months, two courts have held that *Pliva* did not preempt a claim asserting that a generic manufacturer should have sent a "Dear Doctor" letter, provided that the letter was "consistent with and not contrary to the drug's approved label."[7] Although this claim was not preempted, it remains unclear whether it was viable under state law. One of the two courts explicitly refrained from finding "whether or not the Defendants in fact had a 'duty' to send a 'Dear Doctor' letter, under any legal theory."[8]

Other plaintiffs who purchased generic drugs will refocus their attacks onto the brand-name manufacturers. Indeed, the very day *Pliva* was published, a group of plaintiffs' attorneys announced its intention to advance claims against brand-name manufacturers for injuries allegedly caused by ingesting generic drugs.[9]

The consumers' argument extends tort law regarding the duty of care. The brand-name manufacturers know that the generic manufacturers must copy onto their own labels, word for word, the safety information from the brand-name manufacturers' labels. Thus, all patients who ingest a drug (whether the drug is brand-name or generic) allegedly will be relying upon the brand-name manufacturer's safety warnings. Therefore, the argument runs, the brand-name manufacturers have a duty of care even to other manufacturers' customers and can be found liable to anyone's customers if the labels are deficient.

This is not a new argument, nor has it been particularly successful. The claims of generic customers against brand-name manufacturers are discussed in dozens of published decisions. While the consumer prevailed in California, consumers have lost almost everywhere else.[10] Generally, courts dismiss such claims upon the ground (among others) that product liability plaintiffs have no claim unless they can prove that they used the defendant's product.

But despite the lopsided track record, the *Pliva* decision is likely to encourage further litigation along these lines, since traditional duty-to-warn claims will not lie against generic companies that faithfully copied the approved labeling. Moreover, none of the existing case law comes from the highest court of any state, and most decisions are from trial courts. It is therefore open to the plaintiffs to try again, and if they fail in one state, they can try again in the others.

Another battle over the import of *Pliva* will be fought before the FDA. Public Citizen, a lobbying organization that purports to "defend[] democracy" by "resisting corporate power," has filed a lengthy citizen petition.[11] This petition asks the FDA to change its labeling regulations to permit generic manufacturers to supplement their safety warnings without prior approval. The petition points out that *Pliva*, in finding preemption, distinguished *Wyeth* on the grounds that the FDA regulation permitting immediate label changes applies only to brand-name manufacturers. Public Citizen seeks to render the regulation applicable to all manufacturers, with the explicit goal of eliminating generics' preemption defense.

One cannot know how the FDA will respond to this petition, but it is noteworthy that the Obama administration had filed an amicus brief in *Pliva* arguing against preemption. The FDA's deadline for responding to Public Citizen's petition is March 12, 2012. Interested parties can submit comments for the FDA's consideration.[12]

PLIVA AND THE PATH TOWARD STRENGTHENING PREEMPTION DEFENSES

The many recent Supreme Court cases on preemption in the FDA context reflect the fractured nature of this area of law. There is no single statute governing preemption issues for all FDA-regulated products, or even for all medical products. While different code sections directly address some preemption questions,[13] no one section applies across the preemption case law. Furthermore, due to the complexity of the underlying regulatory scheme, similar fact patterns can lead to disparate results. *Compare Pliva* with *Wyeth*. A further example of this phenomenon can be seen in the cases discussing medical devices. The manufacturer of a device that received "premarket approval"[14] can assert preemption defenses that are unavailable to the manufacturer of a device that received approval through the "510(k)" process.[15] *Compare Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), *with Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

The *Pliva* decision indicates that a more unified approach may be forthcoming. A plurality of the Court[16] opined that the Supremacy Clause contains a "*non obstante*" provision, meaning that courts should not strain to find a way to uphold both federal and state laws; state laws must give way if so indicated by the ordinary meaning of the federal law. Furthermore, an emphasis of the *Pliva* majority was that courts should not speculate as to what the FDA *might* do if asked to decide an issue pertinent to a claim. If the status of FDA regulations and approvals prevented a defendant from satisfying a standard imposed by state law, courts will not entertain conjecture as to what approvals or rule changes the defendant might have been able to obtain.

Lastly, *Pliva* and *Wyeth* point toward a way in which manufacturers can obtain more certainty regarding their liability exposures: where the proper course of conduct is unclear, one can always ask the FDA. In both *Wyeth* and *Pliva*, the defendants had not asked the FDA whether the drug warnings in question should be enhanced. Had the FDA provided a ruling, both cases would have been simple—no tort claim will lie for failing to provide a warning that the FDA expressly deemed to be inappropriate.[17]

Indeed, for another reason, the *Pliva* decision will likely encourage generics to ask the FDA to implement labeling changes. The majority noted the FDA's position that generic manufacturers are "required to propose[] stronger warning labels … if they believe[] such warnings [are] needed." *Pliva*, 131 S. Ct. at 2576–77.[18] Whether or not the FDA's view is correct, the industry is now on notice that the FDA may consider failure to request a labeling change to be a violation of applicable regulations. One can expect the generics to take this asserted obligation seriously, which may lead to more

dialogue between the FDA and all affected manufacturers regarding what warning should accompany drugs.

There may, of course, be good reason not to ask the FDA to look into a potential labeling change. For example, one should not discourage the use of a drug—through excessively dire warnings or otherwise—in circumstances where the drug's benefits are real and the potential harm is conjectural. But where a manufacturer faces a close call, getting the bad news out earlier may be better than waiting to see if a potential risk results in injured patients and punishing lawsuits.

CONCLUSION

The law of preemption remains difficult to apply to the complex regulatory schemes governing drugs and devices. In recognizing this reality, the *Pliva* court gave opponents of preemption a sound bite that they have already used extensively. The Court wrote: "We recognize that from the perspective of [plaintiffs], finding pre-emption here but not in *Wyeth* makes little sense." *Pliva*, 131 S. Ct. at 2581. Critics of the *Pliva* decision—judges (starting with the dissenting justices), plaintiffs' lawyers, and newspaper editorialists—have repeatedly quoted the "makes little sense" language in arguing that preemption is misguided.

The point the Court was trying to make, perhaps awkwardly, is that neutrally applying preemption principles to the existing regulatory scheme can yield disparate results. While that point may have been lost, the "makes little sense" language does serve to underscore that the law of preemption is still in flux. Until this area of law is better settled—until the case holdings become intuitive—we should expect the battles to shape preemption law to intensify. ■

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[1] *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (generic drugs); *Bruesewitz v. Wyeth LLC*, 131 U.S. 1068 (2011) (vaccines); *Wyeth v. Levine*, 555 U.S. 555 (2009) (brand-name drugs); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) (medical devices); *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001) (medical devices).

[2] FD&C Act, § 310(a).

[3] *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), applying FD&C Act § 521(a).

[4] *Bruesewitz v. Wyeth LLC*, 131 U.S. 1068 (2011), applying 42 U.S.C. § 300aa-22(b)(1).

[5] 21 C.F.R. § 314.70(c)(6)(iii)(A).

[6] FD&C Act, §§ 505(j)(2)(A)(v), 505(j)(4)(G).

[7] *Keck v. Endoscopy Center of Southern Nevada, LLC*, Case No. 08A575837 (Dist. Ct., Clark County, Nev. Aug. 19, 2011); *Brasley-Thrash v. Teva Pharmaceuticals USA, Inc.*, 2011 WL 4025734 (S.D. Ala. Sept. 12, 2011).

[8] *Keck v. Endoscopy Center of Southern Nevada, LLC*, Case No. 08A575837 (Dist. Ct., Clark County, Nev. Aug. 19, 2011).

[9] Conte Foundation: Supreme Court Focuses Reglan Liability Back on Brand-Name Company, *PR Newsweb* (June 23, 2011). http://www.prweb.com/releases/2011/6/prweb8597519.htm. A similar intention was posted on a blog maintained by plaintiffs' lawyers Rheingold, Valet, Rheingold, McCartney & Giuffra, LLP. http://www.rheingoldlaw.com/blog/2011/07/pliva-v-mensing-supreme-court-decision-huh.shtml (all web sites herein last visited Dec. 14, 2011).

[10] The leading case rejecting such claims is *Foster v. American Home Products Corp.*, 29 F.3d 165 (4th Cir. 1994). The claims succeeded in only two published cases: *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2008), and *Kellogg v. Wyeth*, 762 F. Supp. 2d 694 (D. Vt. 2010).

The "Drug and Device Law" blog attempted to compile a comprehensive list of all cases addressing "whether a name brand … drug manufacturer can be liable in a suit where the plaintiff only took a generic version." The list indicates that such claims failed at least 50 times, succeeding only in the *Conte* and *Kellogg* cases and in an unpublished state trial-court opinion. Two other courts dismissed product liability claims but permitted misrepresentation or fraud claims to proceed. http://druganddevicelaw.blogspot.com/2009/11/scorecard-non-manufacturer-name-brand.html.

[11] Public Citizen's petition is docketed as FDA-2011-P-0675-0001/CP and is also available at http://www.citizen.org/documents/Citizen-Petition-8-26.pdf.

[12] 21 C.F.R. § 10.30(d), (e)(2).

[13] *See* FD&C Act § 310(a) (federal government generally has exclusive jurisdiction to enforce the Act), FD&C Act § 521(a) (preemption regarding devices), 42 U.S.C. § 300aa-22(b)(1) (preemption regarding vaccines).

[14] The premarket-approval process is commonly required of "Class III" devices, which involve the highest risk of danger to the patient. *See* FD&C Act §§ 513(a)(1)(C), 515(a). The applicant must prove the safety and efficacy of the device. *See* FD&C Act § 515(d)(2)(A), (B). Doing so generally requires the submission of a detailed application, supported by appropriate data. *See generally* 21 C.F.R. Part 814.

[15] Under the "510(k)" process (which is named after section 510(k) of the Food, Drug, and Cosmetic Act), a manufacturer must establish that a new device is substantially equivalent to devices currently in commercial distribution. Approval does not require further proof of the device's safety or efficacy. *See generally* 21 C.F.R. Part 807 Subpart E. In general, the 510(k) process is available only after the FDA has ruled that a particular class of devices does not require more exacting scrutiny.

[16] Although five justices joined the bulk of the primary opinion in *Pliva*, only four joined the portion discussing *non obstante* clauses. The four dissenters are in express disagreement on this point, and the remaining justice, Justice Kennedy, expressed no views either way.

[17] *See Wyeth*, 555 U.S. 555 ("absent clear evidence that the FDA would not have approved a change to [the drug's] label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements").

[18] The FDA's assertion of an obligation to petition for label changes comes as something of a surprise. To be sure, all drug manufacturers must report adverse drug experiences and must report with some urgency adverse events that are both serious and outside the scope of known dangers. 21 C.F.R. §§ 314.80(c), 314.98. But no regulation directly spells out that *generics* have an obligation to ask for a labeling change. The *Pliva* record contains "no evidence of any generic drug manufacturer ever acting pursuant to any such duty." *Pliva*, 131 S. Ct. at 2577. Independent research confirms that petitions by generics to alter safety labeling are indeed rare, although not entirely unprecedented. The Supreme Court was careful neither to endorse nor to overrule the FDA's position on this point.