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Dobbs V. Wyeth: Are We There Yet, And At What Cost?

Law360, New York (November 15, 2012, 3:10 PM ET) -- The battle over preemption of state law failure-to-warn claims involving pharmaceuticals bearing U.S. Food and Drug Administration-approved warnings has been waged for more than a decade. It continues with efforts to secure preemption of state law claims involving the prescription anti-depressant Effexor in Dobbs v. Wyeth.

The United States Supreme Court's groundbreaking 2001 ruling in Buckman Co. v. Plaintiffs' Legal Committee, holding that state law fraud-on-the-FDA claims conflict with federal law and therefore are impliedly preempted, fostered hope among members of the defense bar that preemption of state law failure-to-warn claims might follow. Indeed, a number of state and federal courts found and upheld implied preemption of such state law failure-to-warn claims, although ultimately a split in authority developed.

That cautious optimism easily could have given way to despair when the United States Supreme Court held in Wyeth v. Levine that conflict preemption failed in the absence of clear evidence that the FDA would have rejected the proposed warning. Efforts to achieve preemption continued nonetheless, and, in the pending appeal to the Tenth Circuit in Dobbs v. Wyeth, the pharmaceutical industry is on the verge of an incremental victory in its quest for preemption.

Looking Back at Wyeth v. Levine

In Wyeth v. Levine, the Supreme Court held that absent "clear evidence" that the FDA would have rejected the plaintiff's proposed label change, imposing failure-to-warn liability on the pharmaceutical manufacturer under state common law did not conflict with federal law or make compliance with federal law impossible. The defendant's implied preemption defense thus did not apply. Courts left to interpret Wyeth v. Levine have engaged in a collective head-scratching over just what the Supreme Court meant by "clear evidence."

In the first instance, the Supreme Court's reference to "clear evidence" constituted a statement about the type and quality of evidence a pharmaceutical manufacturer must present to achieve implied preemption based on a finding of "impossibility" — not a new standard of proof for the preemption defense.

A pharmaceutical manufacturer must show, by a preponderance of such evidence, that the FDA would not have approved the warning proposed by the plaintiff had the manufacturer sought such a warning through the Changes Being Effected (CBE) regulatory process prior to the time the plaintiff was injured. According to the Supreme Court, this inquiry by the trial court is fact-intensive, focused solely on the particular regulatory and scientific record, and designed to ensure that an actual conflict exists between state and federal law.

Under Levine, one must only show, in the words of the Supreme Court, that the FDA "would not have approved" an enhanced warning had it been proposed. Thus, preemption applies not only where the proposed warning was in fact submitted to and rejected by the FDA, but also where the FDA would not have permitted enhanced labeling whether that labeling was in fact proposed to the FDA or not.

Moreover, Levine does not require that the main manufacturer continually "press" an enhanced warning which has been rejected by FDA. This leaves a large spectrum of scenarios to which implied preemption may apply, depending on the facts of the regulatory process, the state of the science, and the inclination of the court.

Looking Ahead At Dobbs v. Wyeth

Since Levine, the industry has continued to proceed with caution. In Dobbs v. Wyeth, for example, one amicus explained that there was a "tsunami of evidence" to support the argument that the FDA would have rejected an additional warning. In Dobbs, the court considered whether federal regulation preempted the plaintiff's claim that the prescription drug Effexor should have contained a warning that it could cause suicidality in adults, and that the CBE regulation negated "any contention that Wyeth could not comply with a common law duty to warn of suicidality because the FDA did not prevent Defendant from adding that warning after the initial approval of Effexor and its accompanying labeling information."

Even in its initial opinion, issued prior to Levine, the Dobbs court gave detailed consideration to the regulatory and scientific records of Effexor in particular, and SSRIs in general, as well as to the FDA's position on preemption. Ultimately, the district court in Dobbs concluded — not once but twice — that the regulatory record in the case was one where preemption was appropriate: the FDA had received the relevant data, considered the causality issue it presented, and — rejecting a statement of causality — mandated class labeling.

The "tsunami" of clear evidence that convinced the trial court — both pre- and post-Wyeth v. Levine — included (1) a strong label in the first instance; (2) the FDA's rejection of more than one Citizen Petition seeking additional warnings; (3) the FDA's continued post-market study of a possible relationship between Effexor and suicidality and a finding of no "signal" for an increased risk; (4) the FDA's statements in multiple amicus curiae briefs that it had found no credible scientific evidence of an increased risk of suicidality, and that the inclusion of such a warning label would have been false and misleading in violation of federal law; and (5) the FDA's continued vigilant monitoring of SSRIs, leading to the 2005 and 2006 requirements of pediatric-suicide-related "black box" warnings based on short-term scientific studies that showed an increased risk of suicidality as compared with patients up to, but not beyond, the age of 24.

Standing alone, perhaps none of these grounds would have convinced the Dobbs court to grant summary judgment; however, the totality of the regulatory record did. Accordingly, the district court concluded that, under the specific facts and circumstances of the case, the plaintiff's state law claims were preempted by federal labeling regulations.

Levine was decided shortly after and the Tenth Circuit vacated the district court's grant of summary judgment in Dobbs and remanded the case for reconsideration under the "clear evidence" standard. On Wyeth's renewed motion for partial summary judgment, the district court found that Wyeth had "satisfied the Levine evidentiary standard required to support preemption," and "plaintiff's claim that, in 2002, Wyeth had a duty to include on its Effexor label an enhanced suicidality warning for patients in Mr. Dobbs's [(over 24)] age group is preempted." In so doing, the district court distinguished the records in Dobbs from the records in other recent SSRI cases in which courts did not find preemption.

Dobbs appealed. Now before the Tenth Circuit, Dobbs contends in her opening brief that no "clear evidence" exists that the FDA would have rejected an added warning by Wyeth of an association between Effexor and an increase in suicidality in adult patients, and therefore Dobbs's state failure-to-warn claims are not preempted by federal regulation. In support of this position, Dobbs makes two principal arguments.

First, Dobbs argues that the district court record contained considerable evidence of a known association between Effexor and suicidality in adults as well as sufficient evidence that the FDA would not have rejected an added warning of suicidality in adults. According to Dobbs, Wyeth's own data on Effexor demonstrated a statistically significant risk of suicidal behavior in adults, and the FDA's responses to two similar warnings indicated that it would have allowed Wyeth to add the warning.

Second, Dobbs argues that the evidence actually relied upon by the district court was legally insufficient to constitute "clear evidence" that the FDA would have rejected an enhanced warning. According to Dobbs, the district court wrongly looked for a causal relationship between the drug and suicidality, rather than the applicable legal standard for an added warning — reasonable evidence of an association. Dobbs contends that the district court also wrongly interpreted past reluctance by the FDA to require the proposed warning as a prohibition of the warning by any manufacturer. As a result, according to Dobbs, the district court incorrectly ruled in favor of Wyeth.

In its response, Wyeth asserts that the district court's finding that the record satisfied the "clear evidence" requirement was correct and should be upheld.

First, Wyeth argues that Dobbs is improperly attempting to recast her claims and base them on evidence that was not part of the trial court record. According to Wyeth, Dobbs originally claimed — in her complaint as well as in her appellate brief — that the proposed warning was for an association between Effexor and adult suicidality. Dobbs now claims she has always sought a warning of a "need for vigilance," specifically early in treatment with Effexor, offering as evidence only expert testimony which the district court refused to admit into the record for procedural reasons.

Second, Wyeth argues that the record was sufficient to conclude that the FDA would have rejected an enhanced warning by Wyeth. According to Wyeth, the FDA concluded, after extensive research and analysis, that reasonable evidence of an association between Effexor and adult suicidality — the legal standard required for an added warning — did not exist and that it was important for the drug's label to say so. Accordingly, Wyeth contends the district court's grant of summary judgment should be affirmed.

Dobbs's reply brief asserts that she has consistently proposed the same warning and that the evidence on record clearly shows that Wyeth's evidence is not sufficiently "clear" to find that the FDA would have rejected an added warning. Dobbs rejects the contention that the language about vigilance and early treatment constitutes a reinvented warning. Rather, according to Dobbs, the need for vigilance early in treatment would not be necessary without a general association between Effexor and adult suicidality.

The parties have completed briefing before the Tenth Circuit and oral argument is scheduled for Jan. 16, 2013. The record before the Tenth Circuit that the FDA would have rejected a warning of an increased risk of suicidality among adults over 24 — at anytime during treatment — was sufficient to warrant summary judgment in the first instance, and satisfies the "clear evidence" rule under Wyeth v. Levine. Should the Tenth Circuit affirm (and it should), its ruling will represent a step in the right direction. Whether the regulatory and scientific record warrants the application of the preemption defense is a battle that must be fought on a case-by-case basis.

Note: Part II of this article will address the Tenth Circuit's pending ruling in Dobbs v. Wyeth.

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[1] Dobbs v. Wyeth Pharm., 530 F. Supp. 2d 1275 (W.D. Okla. 2008), vacated, 606 F. 3d 1269 (10th Cir. 2010). On remand, summary judgment was granted to Wyeth, Dobbs v. Wyeth Pharm., 797 F. Supp. 2d 1264 (W.D. Okla. 2011), and plaintiff appealed to the Tenth Circuit. See Dobbs v. Wyeth Pharm., No. 12-6077 (10th Cir. filed Mar. 21, 2012).

[2] 531 U.S. 341, 348 (2001). Even the Supreme Court's 2008 decision in Reigel v. Medtronic, 552 U.S. 312 (2008), holding that the Medical Device Amendments Act of 1976 to the Food Drug and Cosmetic Act expressly preempted state law product design and warning claims involving Pre-Market Approval (PMA) medical devices, contributed to the sense that preemption for FDA-approved pharmaceuticals was within reach. See JOHN S. ALLEE, THEODORE V.H. MAYER & ROBB W. PATRYK, Product Liability, § 8.09[3] [b] (2002).

[3] See ALLEE ET AL., supra note 2,. at § 8.09[3] [d].

[4] Federal Preemption of state laws, derived from the Supremacy Clause of the United States Constitution, falls into three categories: (1) "express" preemption, where Congress "has expressly stated that a federal law will preempt state law"; (2) "field" preemption, where Congress "has expressed its intent that federal law will exclusively occupy an entire field of regulation"; and (3) "conflict" preemption, where "it is either impossible ... to comply with both state and federal requirements, or where state [common or statutory] law stands as an obstacle" to carrying out the objectives of federal law or regulation. Dobbs v. Wyeth Pharm., 797 F. Supp. 2d 1264, 1268 n.3 (W.D. Okla. 2011) (citations omitted).

[5] 555 U.S. 555 (2009).

[6] Levine, 555 U.S. at 571. In light of its finding of preemption of failure-to-warn claims against generic pharmaceutical manufactures in PLIVA Inc. v. Mensing, 131 S. Ct. 2567 (2011), there can be no doubt that the Supreme Court did not rule that the defense of impossibility was unavailable to manufacturers in general.

[7] See 21 C.F.R. §314.70(c)(6)(iii) (2012).

[8] Levine, 555 U.S. at 571-72.

[9] Id.

[10] See Dobbs v. Wyeth Pharm., 797 F. Supp. 2d 1264, 1279 (W.D. Okla. 2011).

[11] Brief for the Product Liability Advisory Council, Inc., as Amicus Curiae Supporting Appellee 34, Dobbs v. Wyeth Pharm., No. 12-6077, on appeal to the United States Court of Appeal for the Tenth Circuit.

[12] Dobbs v. Wyeth, 530 F. Supp. 2d 1275, 1281-82 (W.D. Okla. 2008).

[13] The original 1992 FDA-approved Effexor label contained a caution regarding the inherent risk of suicide in the high-risk patient population. Id. at 1282.

[14] The record documented that the FDA had denied (1) a 1990 Citizen Petition seeking the FDA's withdrawal of approval for Prozac (also an SSRI) due to a greater risk of suicide than described on the Prozac label; (2) a 1991 Citizen's Petition seeking a "boxed warning" on Prozac stating that "Prozac had been associated with intense, violent suicidal preoccupation, agitation, and impulsivity in a small minority of patients"; and (3) a 1997 Citizen Petition seeking additional warnings that patients at risk of suicide be observed. Id. at 1282-83. In response to the 1997 Citizen Petition, the FDA found no credible scientific evidence warranting departure from the current labeling. Id. at 1283.

[15] Id. at 1282-84. In fact, the 2007 label included a statement that "[s]hort-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24." See id. at 1284; Dobbs, 797 F. Supp. 2d at 1275; see also Giles v. Wyeth Inc., 556 F.3d 596, 599 (7th Cir. 2009).

[16] The district court also examined, and concluded it must give "considerable deference to," the FDA's statement in the Preamble to its Final Rule issued in 2006, and reiterated in multiple amicus curiae briefs since 2000, that state law conflicted with and stood as an obstacle to the full achievement of its objectives under Federal law. Dobbs v. Wyeth, 530 F. Supp. 2d at 1288 (citing 71 Fed. Reg. 3922 at 3935 (Jan. 24, 2006). As the FDA stated, its regulations established both a "floor" and a "ceiling" for the content of drug labels. Id. at 1286. The Supreme Court in Wyeth v. Levine declined to give deference to the FDA's position as stated in the Preamble, thus precluding the district court from doing so on remand. Wyeth v. Levine, 555 U.S. 555, 577 (2009).

[17] Dobbs, 570 F. Supp. 2d. at 1291.

[18] Dobbs v. Wyeth Pharm., 606 F.3d 1269, 1269-70 (10th Cir. 2010).

[19] Dobbs v. Wyeth Pharm., 797 F. Supp. 2d 1264, 1280 (W. D. Okla. 2011). Of note, the plaintiff failed to put in a separate individually numbered statement of disputed facts; accordingly the facts submitted by Wyeth remained undisputed. Id. at 1268 n.2.

[20] Id. at 1277-80.

[21] Brief for Appellant at 22-23, 29-32 Dobbs v. Wyeth Pharm., No. 12-6077 (10th Cir. Jun. 22, 2012).

[22] Id. at 37.

[23] Id. at 39-40.

[24] Brief for Appellee at 29-32 Dobbs v. Wyeth Pharm., No. 12-6077 (10th Cir. Sept. 5, 2012).

[25] Id. at 33-35, 38-39.

[26] Reply Brief for Appellant at 3 Dobbs v. Wyeth Pharm., No. 12-6077 (10th Cir. Oct. 9, 2012). The district court, on Wyeth's renewed motion for summary judgment, had already found that Dobbs's "need for vigilance" enhancement was not part of her claim and, regardless, the Effexor labeling already included a warning to supervise high risk patients. Dobbs v. Wyeth Pharm., 797 F. Supp. 2d 1264, 1280 n. 12 (W.D. Okla. 2012).
