Some Good News On SSRI Preemption

Monday, June 13, 2011

Finally, a judge with some common sense....

We've always thought (and the FDA did too) that the adult suicide/SSRI warning claims were the strongest possible claims for implied preemption in the prescription drug context. C'mon, the FDA looked and looked again at the suicide data for these drugs and found that there was no scientific basis for the contention - and for adults, that's true today. But Levine got there first, and since then the courts seem to view all preemption claims involving prescription drugs, no matter how strong on the evidence, through the Supreme Court's sludge-colored glasses.

But now we have Dobbs v. Wyeth Pharmaceuticals, No. CIV-04-1762-F, slip op. (W.D. Okla. June 13, 2011), where the court actually bothered to look at the "clear" evidence. Anyway, in Dobbs the guy who killed himself was 53 years old when he did the deed in December, 2002. He was taking an SSRI for depression - the leading cause of suicide in any event - for only a few days.

Levine says there has to be "clear evidence" that the FDA would have rejected a warning if it had been proposed. Levine never defined what that was, finding no evidence of the likelihood of such a rejection. The lower courts have all applies a sort of "know it when we see it" standard, and never saw it. Dobbs, slip op. at 8-9. Well, in Dobbs the court saw it clearly.

- 1991 - the FDA says that unscientific suicide warnings would create "overall injury" to "public health" by deterring treatment of depression with beneficial SSRIs; any labeling change requires controlled trials (we've noted before that this is, in fact, precisely what has happened with the dubious child/young adult warning).
- 1991 - FDA rejects first citizen's petition seeking suicide warning on SSRIs because there was no valid scientific evidence.
- 1992 - FDA rejects second citizen's petition seeking suicide warning on SSRIs because there was no valid scientific evidence.
- 1993 - Approval of the drug (Effexor) with FDA, with specific directions how to treat the issue of suicide.
- 1997 - New type of Effexor required to have the same language regarding suicide.

- 1997 - FDA rejects third citizen's petition seeking suicide warning on SSRIs because there was no valid scientific evidence.
- 1999 - Ditto for same language on supplemental Effexor NDA.
- 2001 - Ditto for same language on another supplemental Effexor NDA.
- 2002 - FDA states that suicide rates for SSRIs don't significantly differ from placebo.
- 2002 - Wyeth requests suicide label change. The FDA rejects it.
- 2003 - FDA decides that additional statistical information from Wyeth also didn't provide a scientific basis for a stronger warning.
- 2003 - Ditto for same language on another supplemental Effexor NDA.
- 2003 - Wyeth submits CBE label change for pediatric suicide. The FDA rejects it.
- 2004 - FDA reconfirms controlled clinical trial requirement for changing adult suicide warning.
- 2004 - Wyeth submits revised CBE label change for pediatric suicide. The FDA rejects it.
- 2004 - Instead, the FDA examined well over 200 clinical trials of various SSRIs and concludes no scientific basis for any link to adult suicide.
- 2005 - FDA adds SSRI warning for pediatric suicide; does not change adult suicide labeling.
- 2007 - FDA adds SSRI warning for young adult suicide; does not change adult suicide labeling; finds "protective" effect agains adult suicide.

Slip op. at 11-20.

That's not even mentioning dozens of FDA approvals for other SSRIs during the same period, all with the same FDA-mandated language about suicide.

So the court found "clear evidence" that the FDA would not have permitted a stronger adult suicide warning in 2002, the relevant time in the case. The lack of scientific data, continuing well past the suicide in the case, was critical:

"Given the evidence of record, the court finds there is clear evidence that the FDA would have rejected an expanded Effexor warning for patients in Mr. Dobbs's age group prior to his 2002 suicide. In fact, it continued to conclude that there was no evidence to support a warning for his age group as late as 2007,

after additional studies were completed. The court finds that the record reflects clear evidence that the FDA would have rejected a 2002 warning of suicidality for 53-year-old Effexor patients."

Slip op. at 21. So were the FDA's rejections of the defendant's other attempts to change its suicide language:

"The court finds the FDA's rejection of the pediatric warning added by Wyeth under the CBE regulations to be highly persuasive evidence. Despite Wyeth's efforts to expand the pediatric suicidality precaution, the FDA initially found insufficient scientific evidence to support that enhanced warning; even when it later determined that sufficient evidence existed to support the precaution, it did not approve Wyeth's Effexor-specific label alteration, but dictated a warning that was required of all SSRI manufacturers."

Id.

The court also carefully reviewed the other preemption decisions. Mason v. Smithkline Beecham Corp., 596 F. 3d 387 (7th Cir. 2010), involved a young adult, part of a group where the label later was changed. Forst v. SmithKline Beecham Corp., 639 F. Supp.2d 948 (E.D. Wis. 2009), did not indicate how old the plaintiff was, and there was no evidence that the defendant had submitted any warning changes. Dorsett v. Sandoz, Inc., 699 F. Supp. 2d 1142 (C. D. Cal. 2010), was another young adult case, and involved a generic product with no history of unsuccessful label change attempts. Slip op. at 22-25. The court disagreed with the minimal analysis of the issue in two unpublished Effexor cases. Aaron v. Wyeth, 2010 WL 653984 (W.D. Pa. Feb. 19, 2010); Baumgarner v. Wyeth Pharmaceuticals, 2010 WL 3431671 (E.D. Pa. Aug. 31, 2010). Slip op. at 25-27. Impossibility preemption itself wasn't supposed to be impossible.

Bravo!

Will it hold up on appeal? We of course can't say, and the judicial urge to run away from prescription drug preemption has been strong after Levine. But one thing's certain. There's now a "best facts" case with a full record for the appellate courts to consider - and nothing else in the pipeline to interfere with full appellate review of preemption on those facts.

Congratulations, and thanks, to Mal Wheeler, of Wheeler Trigg - first and foremost for winning the case, and secondarily for remembering to send it along to us after he did.