Preemption Notes

Friday, September 16, 2011

A couple of recent preemption developments warrant mention.

Horned In; Horned Out

In Horn v. Boston Scientific Neuromodulation Corp., 2011 U.S. Dist. Lexis 102164 (S.D. Ga. Aug. 26, 2011), the defendant, a manufacturer of a PMA medical device, won preemption of a claim that's often lost, and lost preemption of a claim that's often won. The upside (from our defense standpoint) in Horn was the court's treatment of negligence *per se*, which can be a form of unpreempted "parallel violation" claim. To escape preemption, the plaintiff alleged that the defendant's representative violated an FDA "quality system regulation" about "storage areas" because she kept devices in her home overnight before delivering them to hospitals for use in surgery. The court held the claim preempted because that regulation – "or any QSR for that matter" – was too broad and vague to be a basis for a parallel claim. Id. at *20-25. So Horn is precedent for knocking out a whole category of FDA regulations (QSRs) for preemption purposes.

On the downside, the plaintiff's express warranty claim in Horn survived. That's because it wasn't the usual allegation of some sort of broad, generic guarantee of device "safety." Instead, the defendant offered an express five-year limited warranty. Because the plaintiff alleged that the device's battery malfunctioned less than five years after implantation, the court held that this warranty – not anything the FDA reviewed – gave rise to an unpreempted claim. Id. at *28-31. Then the court unilaterally changed the terms of the warranty, eliminating its warranty's express limitation remedies to replacement as "unconscionable," id. at *31-33, citing the UCC's provision regarding "consumer" products. We think that's wrong because prescription medical products, particularly implantable devices, can only be used by licensed doctors, and are not available to patients. Thus they're not "consumer" products. But the court in Horn decided that no good deed would go unpunished. The takeaway – a PMA manufacturer making a non-FDA warranty should expect to get sued.

Totally Useless, But Who Cares?

After PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011), generic plaintiffs are picking through the wreckage much like we had to do after Wyeth v. Levine, 555 U.S. 555 (2009). One straw that they seem to have grasped is the "Dear Doctor" or "DHCP (that stands for 'dear health care professional')" letter. Specifically, they're claiming that they can gin up a state-law duty obligating generic manufacturers to send out such letters as long as they are the same as existing drug labeling.

From a policy standpoint, we can hardly think of anything so useless. Doctors are overwhelmed with reading material already – now they're supposed to be inundated with Dear Doctor letters that don't even purport to tell them anything new? And how is such a thing supposed to be causal? Almost every state's law rejects claims based upon warnings that only tell people what they already know/have already been told.

Nevertheless, in Brasley-Thrash v. Teva Pharmaceuticals USA, Inc., 2011 U.S. Dist. Lexis 102858 (S.D. Ala. Sept. 12, 2011), the court held that such a futile claim is, at least, unpreempted. Only in March, 2008 did the FDA require pre-approval of Dear Doctor letters. Id. at *7. Therefore an allegation of a duty to send redundant Dear Doctor letters before that date is not preempted. Id. at *8. Fortunately, however, state law came to the rescue. Because state law only allows liability where the warnings are inadequate, and Mensing precludes any challenge to the adequacy of warnings, the claim nonetheless fails. 2011 U.S. Dist. Lexis 102858, at *9.

Then there's Henderson v. Sun Pharmaceuticals Industries, Ltd, ___ F. Supp.2d ___, 2011 WL 4015658 (N.D. Ga. Aug. 22, 2011), where the plaintiff attempted to retrench after Mensing with some sort of manufacturing defect claim. Although there was an FDA warning letter to the defendant, plaintiff couldn't link it to the drug in question – let alone the units of the drug actually ingested. Id. at *4. The same problem befell their negligence claim – nothing in their panoply of allegations had any relationship to the pills that the plaintiff took. Id. at *5.

While these cases knocked down a couple of off-the-wall theories, we expect for generic drug litigation to generate bizarre allegations for the foreseeable future.