Aredia/Zometa – One Step Forward, One Step Back

Friday, November 25, 2011

On November 18, 2011, the defense scored a victory in the New Jersey Zometa/Aredia mass tort program, when the court granted a motion to apply New Jersey punitive damages law. The plaintiff was a Virginia litigation tourist who brought suit in New Jersey state court despite his treatment having nothing to do with the state. See Irby v. Novartis Pharmaceuticals Corp., 2011 WL 5835414, slip op. (N.J. Super. Nov. 18, 2011). Both sides had agreed on Virginia substantive law governing the plaintiff's causes of action, but they scuffled over choice of law in punitive damages.

Why? This isn't the first time we've considered choice of law in punitive damages. New Jersey has a statute that precludes punitive damages against FDA approved drugs. N.J.S.A. 2A:58C-5(c). Not only that, but the New Jersey appellate courts have held that the only significant statutory loophole – fraud on the FDA – is preempted. See McDarby v. Merck & Co., 949 A.2d 223, 272 (N.J. Super. A.D. 2008). So, where a product is FDA approved, application of New Jersey law is tantamount to a dismissal of the punitive damages claim.

The defense even had to overcome a presumption that the law of the place of injury (Virginia, in Irby) governs. The court considered the various factors laid out by Restatement (Second) of Torts §145 (1965), to find that the presumption was defeated. The court held that New Jersey had a more significant relationship than Virginia to the issue of punitive damages. The location of plaintiff's injury was "'fortuitous' because the place of injury bears little relation to [defendant's] alleged punitive conduct," given that it "is headquartered in New Jersey," that the drug (Zometa) "was widely distributed throughout the United States," and "nothing in NPC's sales, marketing, or distribution practices suggests that the alleged injury was more likely to occur in Virginia than in any other state." Slip op. at 7.

The court also held that the next §145 factor, location of the allegedly injurious conduct, favored New Jersey because conduct at issue for punitive damages would have occurred in the defendant's New Jersey corporate headquarters. Id. at 8-9. The plaintiff failed to prove that the conduct occurred in the company's international Swiss headquarters. Id. at 9 & n.4. Irby also held that the relationship between plaintiff and defendant was centered on New Jersey because plaintiff's punitive damages claims "stem from [defendant's] New Jersey

business activities." Id. at 10.

A serious comity issue also popped up, since "punitive damages are generally intended to regulate conduct within the bounds of an interested state" and, based on the finding that the alleged misconduct occurred in New Jersey, "interstate comity would be least offended by the application of New Jersey law to the issue of punitive damages." Id. at 12. That's a bit of a bootstrap, but it worked. More importantly, New Jersey has decided to limit punitive damages by statute when FDA-approved drugs are involved, and plaintiff, having chosen to come to New Jersey when she could have filed suit in Virginia, was not really in a position to assert comity. Id. at 15-16. Finally, the court held that prior law was basically split concerning the punitive choice of law question. Id. at 17.

Thanks to Joe Hollingsworth, of Hollingsworth LLP, both for winning the motion and passing it along.

Why there's such a fierce fight over choice of law in punitive damages in the Aredia/Zometa litigation is demonstrated by another recent decision that's not so favorable to our side. In Fussman v. Novartis Pharmaceuticals Corp., 2011 WL 5836928 (M.D.N.C. Nov. 21, 2011), the court denied post-trial motions – most of them – in a case that had produced a verdict of $287,000 in compensatory damages, and $12,600,000 in punitive damages. Id. at *1. When you've got runaway juries awarding blatantly unconstitutional punitives that run almost 44 times compensatories, there's good reason to fight such claims tooth and nail.

Fortunately, North Carolina has a statute (N.C.G.S. §1D-25) that limits punitives to three times the compensatory award, so that post-trial motion, at least, was granted in Fussman. Id.

The other motions were denied. As to the motions for judgment, it's hard to say exactly why, except that the court was not about to reverse the jury's verdict. Fussman, 2011 WL 5836928, at *3-4. Where's the beef?

There's not much more meat to the discussion of punitive damages in Fussman. The court finds those claims unpreempted in light of Wyeth v. Levine, but doesn't really explain itself. Fussman, 2011 WL 5836928, at *4 (still where's the beef). But we did find an interesting footnote about fraud on the FDA, which states, in pertinent part:

"[T]he claim presented in the present case was not based on alleged fraud on the FDA or alleged violation of any federal laws or regulations. . . . Thus, while it is undisputed that "fraud on the FDA" claims are preempted by federal law, the present case does not involve "fraud on the FDA" claims. Instead, the willful and wanton conduct alleged . . . involved . . . investigating side effects and communicating with medical professionals."

Id. at *4 n.6. On one hand, Fussman sheds some light on Irby – since it doesn't look like the plaintiffs could muster a case under the New Jersey fraud on the FDA exception, even if it wasn't preempted under McDarby. On the other hand, since plaintiff was not claiming a violation in Fussman, we're a bit surprised not to see anything about N.C.G.S. §99B-6(b)(4), which specifically requires consideration of "[t]he extent to which the labeling for a prescription . . . drug approved by the United States Food and Drug Administration conformed to any applicable government . . . standard that was in effect when the product left the control of its manufacturer." We've already posted on the effect of governmental compliance on punitive damages.

In another interesting, and more disturbing, footnote, Fussman essentially nullifies the "reasonable likelihood" statutory (N.C.G.S. §1D-35) standard for risk of harm in punitive damages claims out of existence. 2011 WL 5836928, at *7. The court holds that no particular percentage likelihood is required for a *prima facie* case of punitive damages to exist, only that there be an unspecified "connection." That seems pretty shaky to us, since it would theoretically allow an increased risk from one in a bazillion to two in a bazillion to support a punitive award, notwithstanding the inclusion of a "likelihood" of harm element in the statute. Nor is the cited precedent particularly persuasive. Everhart v. O'Charley's Inc., 683 S.E.2d 728, 738 (N.C. App. 2009), discussed an entirely different statute – "related to" as used in N.C.G.S. §1D–15 – and so is not at all on point. Benedi v. McNeil-P.P.C., Inc., 66 F.3d 1378, 1389 (4th Cir. 1995), was decided under **Virginia** common law, and thus has no conceivable relevance to the interpretation of a North Carolina statute.

It's hard to say, given the vagueness of other parts of the Fussman opinion, but the likelihood point looks like a good appellate issue to us. Maybe we'll look into it in some future post

The evidentiary rulings in Fussman are more of "where's the beef?" If the defendant actually did open the door to subsequent remedial measures by asserting them affirmatively, then we

can't fault that ruling. See 2011 WL 5836928, at *7.

We can't be as charitable to the court's hearsay ruling, though. The facts aren't particularly important, but we don't see how use of hearsay "to establish what information [defendant's] employees had received from [its] consultants, and the actions [those] officials took in response," id., can possibly be anything other than relying upon such evidence for "the truth" of what it states. Id. Unless the information is considered to be true, then it's not capable of proving any of those things.

The decision on admission of "national sales figures" to prove anything "related to" the plaintiff doesn't make any sense. How national sales could be relevant to one individual is beyond us. Id. at *8. We've heard of this kind of thing being admitted in punitive damages cases on various reprehensibility grounds, but never on the rationale offered in Fussman.

So within three days of one another, each side won one in Aredia/Zometa. That dance seems unlikely to end anytime soon.