One and a Half Learned Intermediary Victories

Tuesday, August 23, 2011

Not every decision we bring you is a quadruple scoop chocolate peanut butter sundae dripping in hot fudge sitting atop an extra fudgy brownie (OK, maybe we shouldn't be blogging with the Food Network's "The Best Thing I Ever Ate-Sweets" on in the background). But sometimes, just a little taste of vanilla satisfies the sweet tooth – and we are always satisfied when a prescription drug case is dismissed based on the learned intermediary doctrine. Last week, two courts (of which we are aware) rendered decisions regarding the learned intermediary doctrine and while both got the law right, because of the different procedural posture of the two cases, one was a total victory (a scoop of vanilla with whip cream and a cherry on top) and the other – well, let's just say there is still work to be done (no cherry yet).

First, the Northern District of Ohio, applying Louisiana law, granted defendant's motion for summary judgment on plaintiff's failure to warn claim in James v. Ortho-McNeil Pharmaceutical, Inc., 2011 U.S. Dist. LEXIS 91030 (N.D. Ohio August 12, 2011). In this case, discovery was complete and the defendant had scored some fantastic deposition testimony from the prescribing physician:

- He was aware of the risks associated with the drug at issue
- He had read the package insert and the Dear Healthcare Provider letters (which advised of the risk at issue
- He told the plaintiff about the risks
- He would still prescribe the drug to plaintiff today

James, 2011 U.S. Dist. LEXIS 91030 at *2. And, while that testimony would have been more than enough to top off any good meal, defendant here got the equivalent of adding a perfect cup of coffee to that already scrumptious dessert. Plaintiff testified that she "never reads package inserts" and that if she had read this package insert "she would have seen the numerous warnings" but she "would

have used the patch in any event because she relied on her doctor's decision." Id. at *3. Yummy stuff.

So, it is hardly surprising that the court granted summary judgment citing Louisiana law that "where a prescribing physician stands between the manufacturer and the ultimate user, the manufacturer satisfies its duty to warn by giving adequate warnings to the prescribing physician." Id. at *7 (citations omitted). The plaintiff here most certainly didn't meet her burden of showing that "a proper warning would have changed the decision of the treating physician; [and] but for the adequate warning, the treating physician would not have used or prescribed the product." Id. at *8 (citations and quotation marks omitted).

So, if James is a complete win -- Mardegan v. Mylan, Inc., 2011 U.S. Dist. LEXIS 89787 (S.D. Fla. August 12, 2011), is more like the defendant is leading at the end of the first quarter – still a lot of game (discovery) left that could go either way (yep, just changed channels to pre-season football).

Here, defendant moved to dismiss plaintiffs' strict liability and negligent misrepresentation claims based on Florida's learned intermediary doctrine. Mardegan, 2011 U.S. Dist. LEXIS 89787, at *10. The court correctly cited to and relied on Florida's learned intermediary law – "a prescription drug manufacturer's duty to warn of a drug's potential risks is directed to the physician rather than the patient." Id. at *11 (citations and quotation marks omitted). In so doing, the court agreed with the defendant that to the extent plaintiff's strict liability failure to warn claim alleged a failure to warn the ultimate consumer, it must be dismissed. Id. at *12-13. Similarly, plaintiff's allegation that defendant made negligent misrepresentations to the "FDA, Decedent, physicians, pharmacists, as well as the general public," was both "too broad and under the learned intermediary doctrine Defendants did not have a duty to warn the general public or the Decedent." Id. at *13. The court was unwilling to bar plaintiff's negligent misrepresentation claim in its entirety, agreeing with other courts that have held that such a claim can survive a motion to dismiss where plaintiff alleges a misrepresentation to her physician and it is the physician's reliance that is at issue. Id. at *13-14.

So, defendant won its motions to dismiss, right? Why aren't we doing a celebratory dance in the end zone? Because the court is allowing plaintiff to amend the complaint to properly allege failure to warn her physician and negligent misrepresentation to her physician. Id. at *19. Of course, that means the plaintiff (or her lawyer) should actually have to talk to the prescribing physician in order to obtain the facts necessary to file the necessary amendment. If the prescriber is as firm as the one in James, maybe there won't even be an amendment.

By the way, for sake of completeness, we note that the Mardegan court also dismissed plaintiff's breach of implied warranty claim for lack of privity, but denied defendant's motion as to plaintiff's express warranty claim citing conflicting decisions applying Florida law regarding the necessity of privity to the claim. Id. at *15-18.

We will have to wait and see if the defendant in Mardegan has the same good fortune as the defendant in James. If they can advance the ball through strong prescriber testimony, maybe we'll be back to report on a game-ending summary judgment motion – with a cherry on top.