When It's The Plaintiff, Not The Doctor

Thursday, June 09, 2011

Earlier this week we posted about the learned intermediary aspects of Shaw v. Bayer, U.S. Dist. Lexis 57057 (S.D. Fla. May 23, 2011), which confusingly bears a completely different caption on Westlaw: In re Trasylol Products Liability Litigation, 2011 WL 2117257 (S.D. Fla. May 23, 2011). We said then that there was more to Shaw/Trasylol than just the learned intermediary rule, and promised to return to the case later.

Now is later.

The alternative holding in Shaw/Trasylol illuminates another lurking causation issue in our sandbox – what happens when the focus turns away from the prescribing physician to the plaintiff. For all the plaintiff side's attacks on the learned intermediary rule, their clients often don't fare much better when, for one reason or another, the rule doesn't apply.

Shaw/Trasylol is exhibit A.

Let's review the bidding. Trasylol is a drug used to put the brakes on internal bleeding during heavy duty surgery, often (as here) involving the heart. Allegedly, Trasylol can cause damage to the kidneys, and that's what plaintiff Shaw alleged. 2011 WL 2117257, at *1. The surgeon who prescribed Trasylol, however, gave all the testimony necessary to establish an ironclad warning causation defense – that an allegedly adequate renal warning wouldn't have made the slightest difference:

- The prescriber doesn't think the plaintiff suffered from a kidney related injury, but rather from unrelated conditions caused by many years of smoking. Id.
- The prescriber would do the same thing – that is, use Trasylol in the decedent's surgery – today. Id.
- The surgeon didn't rely on the label in deciding to prescribe Trasylol, but rather upon his own clinical experience with the drug. Id. at *5.
- Knowing about the allegedly omitted information, the surgeon would still prescribe Trasylol. Id.

That kind of testimony made the case a stone, cold loser on causation grounds under the learned intermediary rule – which, of course, is why the plaintiff unsuccessfully alleged that a tiny, one-meeting $500 consulting agreement somehow compromised the independence of the prescriber, a cardiacthoracic surgeon. The court, as our prior post discussed, essentially said, "Yeah ... right." to that. Id. at *4.

But out of an abundance of caution the court was willing to assume, for the sake of argument, that somehow the learned intermediary rule didn't apply.

The result wasn't any better for the plaintiff. Why? Because as dozens of ordinary (non-pharma) product liability cases hold, if the plaintiff didn't read and heed the allegedly inadequate warning him or herself. then plaintiff wasn't harmed by the purported failure to warn. That's the rule with owner's manuals and warning stickers on every product from ladders to lawn mowers to Lincoln Continentals.

Well, the average plaintiff is even less likely to read thirty-two warnings in a prescription drug label than s/he is to read thirty-two warning stickers on a step ladder. That's because, unlike step ladders, plaintiffs have to go through doctors to use prescription medical products, and – surprise, surprise, surprise – most patients actually do rely on their prescribers and don't bother to read all that stuff themselves.

For every plaintiff who happens to be a registered nurse (usually the cherry-picked first case up for trial in a 1,000+ plaintiff MDL), and actually might read a drug warning, there are scores of ordinary people who don't. Even then, the nurse plaintiff might lose – if the defendant can prove that the s/he in fact knew about the risk in question and kept on using the product. In re Prempro Products Liability Litigation, 514 F.3d 825, 829-30 (8th Cir. 2008); Treuchel v. Eli Lilly & Co., 2009 WL 5216930, at *12 (E.D.N.Y. Dec. 21, 2009); Guillen v. Eli Lilly & Co., 2009 WL 5062114, at *14 (E.D.N.Y. Dec. 10, 2009); Harrington v. Biomet, Inc., 2008 WL 2329132, at *6 (W.D. Okla. June 3, 2008). But the number of actual knowledge plaintiffs is relatively few.

In the more usual situation, if the learned intermediary rule somehow does not apply, then the prescribing doctor is out of the picture. That means that most plaintiffs should lose because they never read the warnings themselves. That's exactly the alternative (what if the rule didn't apply) holding in Shaw/Trasylol. The plaintiff didn't know that Trasylol was even used in the surgery until after the decedent died. The decedent might not have either. Neither the plaintiff nor the decedent ever had any contact with Trasylol's manufacturer, nor did they see anything that could be construed as warranty language. 2011 WL 2117257, at *3. These facts killed proximate cause because there wasn't any showing that the plaintiff – any more than the prescribing doctor – ever relied on the allegedly inadequate information:

> "I also find that even if the learned intermediary doctrine did not apply to Plaintiff's failure to warn claims, she does not present evidence that [the decedent] relied on an inadequate warning, or that she would have read and heeded an adequate warning."

Id. at *5.

So the other takeaway from Shaw/Trasylol is that, even if the learned intermediary rule somehow is ousted, most plaintiffs won't end up any better off, causation-wise.

And Shaw/Trasylol is hardly the only case making this point. For instance, in Crayton v. Rochester Medical Corp., 2011 WL 475009 (E.D. Cal. Feb. 4, 2011), the plaintiff (an imprisoned convict) was apparently using a prescription medical device without medical

oversight – something that's arguably an exception to the learned intermediary rule. He didn't personally see any warnings, however, and thus lost on summary judgment:

"Plaintiff obtained the catheter from prison officials and no information was ever provided to Plaintiff regarding the proper use and removal of the [device]. Plaintiff opines that for security reasons . . . the products are removed and searched for contraband and the boxes are discarded. . . . No matter what the "Instruction for Use Sheet" would have said, based on Plaintiff's representations, he would never have seen it, further undercutting his claim."

Id. at *13. Accord Dyson v. Winfield, 113 F. Supp.2d 35, 41 n.3 (D.D.C. 2000) (claim based on alleged inadequacy of patient package insert failed where "by plaintiff's uncontradicted testimony, she did not read the warning"; "an unread warning cannot serve as a basis for a claim that the warning affected one's behavior"), aff'd, 21 Fed. Appx. 2 (D.C. Cir. 2001).

Meade v. Parsley, 2010 WL 4909435 (S.D.W. Va. Nov. 24, 2010), arose under West Virginia law – the only jurisdiction in the country that globally rejects application of the learned intermediary rule. Thus, the court looked to how the challenged warning instead affected the plaintiff patient. The plaintiff "never read any written materials accompanying her . . . prescriptions." Id. at *2. That killed the plaintiff's case:

"[Plaintiff] testified that she never read [the] package insert or any other documents accompanying her . . . prescription. . . . Many courts have declined to find proximate causation in pharmaceutical failure-to-warn suits when the patient (or the prescribing physician if the learned intermediary doctrine is applicable) did not read the defendant manufacturer's allegedly inadequate warning. These courts reasoned that if the patient or physician did not read the drug warning in the first instance, then there is no basis for finding that a stronger warning would have affected their behavior."

Id. at *9 (footnote omitted). See also In re Zyprexa Products Liability Litigation, 2009 WL 1514628, at *12 (E.D.N.Y. June 1, 2009) (another West Virginia law case granting summary judgment where "there is no evidence that [plaintiff] ever read any of defendant's warnings"). Who knows? In some ways West Virginia plaintiffs might end up worse off without the learned intermediary rule than with it.

In an alternative holding similar to that in Shaw/Trasylol, the court in Mulhall v. Hannafin, 841 N.Y.S.2d 282 (N.Y.A.D. 2007), held that a plaintiff's admitted failure to inform herself about relevant risks independently barred a warning claim – regardless of physician-related issues:

"[T]he result would have been no different even if [defendant] were chargeable with warning plaintiff directly. Under well settled law, to prove proximate cause, a plaintiff has the obligation to adduce proof that had a warning been provided, she would have read the warning and heeded it. . . . As [plaintiff] admitted, reading the forms would not have dissuaded her from undergoing the surgery because her arm was "killing" her and she "had made up [her] mind to have [the] surgery." As is apparent, even if plaintiffs had been warned as to the possibility of the exact injury that occurred here, the warning would have been futile. Thus, the record demonstrates that even if [plaintiff's] duty to warn ran directly to this patient, her proof on the issue of proximate cause fails."

Id. at 287. A second New York intermediate appellate decision agrees. Summary judgment against the plaintiff's warning-based claims was affirmed where "plaintiff's deposition testimony was clear that he had not read defendant manufacturer's warnings until after he had stopped

using [the drug] and sustained the complained-of injury." Sosna v. American Home Products, 748 N.Y.S.2d 548, 549 (N.Y.A.D. 2002).

Likewise, in Mendez Montes De Oca v. Aventis Pharma, 579 F. Supp.2d 222, (D.P.R. 2008), the plaintiff argued that she could avoid the learned intermediary rule on the basis of the defendant's direct to consumer advertising. The court held that the DTC ads didn't matter because the plaintiff never saw them. Id. at 230 ("the record in this case is devoid of any evidence intimating that decedent even saw [DTC] informational material" before seeing the prescriber). Summary judgment was thus granted.

The lesson to be learned from all these cases is that the same warning causation arguments that work in learned intermediary cases – chiefly failure to read – also work in prescription drug cases where, for whatever reason, the rule is not available. Most plaintiffs do what the learned intermediary rule presupposes, that is, they rely upon their physicians for medical advice, despite legal arguments that the learned intermediary rule should not be applied to their cases. Thus, even if a plaintiff is successful in giving the learned intermediary rule the slip in a particular case, that hardly means that s/he is home free on causation. That's why we found the alternative holding in Shaw/Trasylol so interesting.

Finally, we'd be remiss (especially since one of the cases is ours) not to point out another way in which plaintiffs can get themselves in trouble if, for some reason, they shift the focus away from prescribers and onto themselves. This is an argument that defendants can't usually assert in straight learned intermediary rule cases.

Most serious medical treatment now requires written informed consent documentation. If the plaintiff's own knowledge is at issue, we should be able to use that plaintiff's signed informed consent form to our client's benefit. There's not a lot of law, but what law there is holds that, once a plaintiff signs an informed consent form acknowledging a risk, the form is conclusive to establish that the plaintiff had in fact been warned and elected to go forward with medical treatment notwithstanding the risk. Taylor v. Pharmacia-Upjohn Co., 2005 WL 3502052, at *5 n.9 (S.D. Miss. Dec. 19, 2005) (signed informed consent form conclusively establishes that the plaintiff was warned about the relevant risk); McMurdie v. Wyeth, 71 Pa. D. & C.4th 225, 230-235 (Pa. C.P. 2005) (same result; decision couched in terms of assumption of the risk).

Sure – we love the learned intermediary rule – but we like to keep lots of arrows in our quivers. Take away the rule and most plaintiffs will lose anyway, maybe even more than under the rule. That's because the learned intermediary rule reflects day-to-day practice in the great majority of cases. Most patients, and thus most plaintiffs, in fact do rely upon their physicians to tell them what they need to know about drugs and don't independently read warnings about prescription medical products.