Ugly Texas Decision Ignores Erie, Tramples State Law

Friday, November 11, 2011

We don't like it, but sometimes we have to present bad news. Such is the case with Murthy v. Abbott Laboratories, 2011 U.S. Dist. Lexis 129102 (S.D. Tex. Nov. 8, 2011). There's a lot of things wrong with Murthy, but one of the worst is that it's another poster child for a supposed "prediction" of state law that instead running roughshod over it and creates unprecedented liability according to the federal court's personal predilections.

We've posted many times that under the Erie doctrine, in the words of the Supreme Court:

"[a] federal court in diversity is not free to engraft onto those state rules exceptions or modifications which may commend themselves to the federal court, but which have not commended themselves to the State in which the federal court sits."

Day & Zimmerman, Inc. v. Challoner, 423 U.S. 3, 4 (1975). Not surprisingly, the Fifth Circuit, which includes Texas, agrees:

"[I]n hazarding an Erie guess, our task is to attempt to predict state law, not to create or modify it. The practical effect of adopting an exception like the one [plaintiffs] propose is the creation of a previously nonexistent state law cause of action. Therefore, [plaintiffs] carry a heavy burden to assure us that we would not be making law."

Memorial Hermann Healthcare System Inc. v. Eurocopter Deutschland, GmbH, 524 F.3d 676, 678 (5th Cir. 2008).

"As always, in conducting this inquiry our task is to predict state law, not to create or modify it – that is, we are to apply existing [state] law, not to adopt innovative theories for the state."

Holden v. Connex-Metalna Management Consulting GmbH, 302 F.3d 358, 365 (5th Cir. 2002) (quoting United Parcel Service, Inc. v. Weben Industries, Inc., 794 F.2d 1005, 1008 (5th Cir. 1986)).

Some decisions, however, like Murthy, just aren't with the program. The Murthy decision's disregard for established state law takes the form of creating an orgy of exceptions to the

learned intermediary rule.

Here's how it came about. The plaintiff in Murthy was somewhat unusual. She was a participant in an FDA-regulated clinical trial of an investigational drug. Her treating physician, who had initially treated her with a different drug, 2011 U.S. Dist. Lexis 129102, at *2, also participated (was an "investigator" in FDA parlance) in the study. As is always the case – and may well be required by FDA regulations – the manufacturer of the investigational drug (called the "sponsor" of the study) bore the costs the study. As is also customary, the sponsor also compensated the study's investigators. There's nothing in Murtha indicating that any of the financial arrangements were unusual or excessive in the context of clinical trials, simply:

> "[Defendant] initiated and paid for the . . . study. In exchange for their participation, [defendant] provided participating . . . patients with a free supply of [the drug] throughout the study's duration. [Defendant] also compensated the physicians involved in the study, including [plaintiff's physician]."

Murthy, 2011 U.S. Dist. Lexis 129102, at *2.

Anyway, since Murthy is a product liability case, the plaintiff alleges an injury from the study drug and that the warnings in the study materials were inadequate. One of the study materials, was a "14 minute, 50 second videotape, produced and provided by [defendant] to [plaintiff's physician]." Id. at *4. Of course, plaintiff claimed that this video was deficient as well. Id.

The defendant raised the learned intermediary rule as a defense. Here's where the legal stampede begins. As a federal district court charged with applying Texas law under the Erie doctrine, the Southern District of Texas was bound to follow: (1) decisions of the Texas Supreme Court, and (2) predictions of Texas law made by the Fifth Circuit. Beyond that, it's on its own, subject to the general constraints of Erie – including the federalist proposition that we discussed above.

Rather than apply the learned intermediary rule, Murthy starts making up exceptions that neither the Texas Supreme Court or the Fifth Circuit have ever adopted. The first of these is the "direct-to-consumer" exception. Indeed, the Fifth Circuit had held that Texas would **reject** such an exception:

"[Plaintiff] also argues that because [defendant] engaged in "aggressive" marketing, [defendant] should be liable for not providing adequate warnings in conjunction with that marketing. This argument is critically weakened by the absence of any evidence on the record that any of the five plaintiffs actually saw, let alone relied, on any marketing materials issued to them by [defendant]. . . . [E]ven if the facts were in [plaintiff's] favor, [plaintiff] would still lose. Two of our cases applying Texas law in this area have concluded that, as long as a physician-patient relationship exists, the learned intermediary doctrine applies."

In re Norplant Contraceptive Products Litigation, 165 F.3d 374, 379 (5th Cir. 1999) (citations omitted).

Murthy did not follow the Fifth Circuit, which it was bound by *stare decisis* to do, but instead followed a recent intermediate Texas appellate decision, Centocor, Inc. v. Hamilton, 310 S.W. 3d 476 (Tex. App. 2010), which had applied a DTC exception on similar – and similarly misguided – facts: those being that since the video was provided **to the prescribing physician**, and not directly to the patient, there was no "direct to consumer" marketing at all, since the physician decided to show plaintiff the video. Murthy, 2011 U.S. Dist. Lexis 129102, at *20-21. We've blasted Hamilton ourselves, and the DTC exception generally, but that's not the point of this post.

Murthy was aware that the Texas Supreme Court had accepted an appeal in Hamilton. 2011 U.S. Dist. Lexis 129102, at *22. That should have been the end of it. With: (1) the United States Supreme Court (and the Fifth Circuit on multiple occasions) imposing a conservative approach to expanding liability; (2) the Fifth Circuit on record against DTC-type exceptions under Texas law; and (3) the Texas Supreme Court poised to decide the very question – every jurisprudential consideration pointed in the same direction: wait and let the proper court decide the issue. At worst, a terse denial of the motion without prejudice would have been warranted.

But no, Murthy leapt in with both feet, preempting, as it were, the prerogatives of the Texas Supreme Court to declare the law of Texas:

"Given the underlying justifications for the learned intermediary doctrine, the Court believes that the Texas Supreme Court will likely agree with the Court of Appeals' reasoning in Centocor, Inc."

2011 U.S. Dist. Lexis 129102, at *23-24. To us, that's just wrong. Even if Texas law were to embrace a DTC exception to the learned intermediary rule (which we strongly doubt), Murthy

should have held its horses and left that state-law decision for the Texas Supreme Court - the court properly empowered to act as arbiter of Texas law.

And believe it or not, that's the lesser of Murthy's two evils.

Murthy goes on to make up – out of whole cloth – a supposed learned intermediary rule exception that applies any time a physician receives "compensation" from a drug company:

> "When a physician receives compensation or gifts from drug companies, his or her role as the neutral decision-maker is diminished. The Texas Supreme Court would surely not apply the learned intermediary doctrine when the physician's prescribing practice is compromised by a conflict of interest as overt as compensation by the defendant drug company. The Court thus concludes that because [plaintiff's] doctor was compensated by [defendant] at the time he enrolled [plaintiff] in the clinical trial and prescribed her [the drug], [defendant] cannot avail itself of the learned intermediary doctrine."

2011 U.S. Dist. Lexis 129102, at *27. While the adoption of the DTC decision in Murthy was a usurpation of judicial power properly belonging to the Texas Supreme court, this creation of a second, completely novel, exception is simply lawless.

In the literal sense.

"Surely" Murthy cites some law that supports the creation of create this exception.

Nope. Nothing.

Not a single case, anywhere in the country has adopted this one.

It's simply the court's policy predilections, as justified by a collection of snippets from various articles in "scholarly" literature. See Id. at 27-31 nn.5-6. In short. The Murthy decision made up the law as it went along to fit its notions of proper public policy – precisely what the Supreme Court explicitly forbade courts sitting in diversity jurisdiction from doing.

And this is anything but a narrow ruling. Since all investigators are compensated for their participation in clinical trials by the sponsors of those trials – with the full knowledge and approval of the FDA – Murthy amounts to a blanket exception barring application of the

learned intermediary rule to all clinical trials.

Moreover, the law that went uncited in Murthy has uniformly rejected the proposition that compensation by drug companies ipso facto displaces that learned intermediary rule.

Long ago the Ohio Supreme Court had the same situation before it – the routine receipt of compensation by physician participating in clinical trials. Tracy v. Merrell Dow Pharmaceuticals, Inc., 569 N.E.2d 875 (Ohio 1991). It held that per-patient payments to physicians who enrolled patients in a clinical trial did not compromise any physician's independence so as to justify ignoring the learned intermediary rule:

"[Plaintiff's physician] determined [plaintiff's] suitability for the [investigational] program. He performed a physical examination on [plaintiff] and elicited [her] medical history. . . . [The physician] retained the right to remove [plaintiff] from the [investigational] study if, in his medical judgment, he felt the circumstances warranted it. . . .

Although [defendant] paid [plaintiff's physician a fee] for each participant in the [investigational] study program, the evidence does not support a finding that [the physician] was an employee of [defendant] or that [defendant] was acting under the control of [defendant] rather than as a physician exercising his independent judgment. . . . [Defendant] did not control [the physician's] judgment, duties and responsibilities as he used [the drug] in the treatment of patients.

Accordingly, we find that [plaintiff's physician] was acting as an independent physician in dispensing [the drug] to [plaintiff], that he was a learned intermediary and that the trial court correctly instructed the jury on the learned intermediary doctrine."

Id. at 879. The exact same situation – a compensated investigator – and Tracy reached the opposite result. Accord Little v. Depuy Motech, Inc., 2000 WL 1519962, at *9 (S.D. Cal. June 13, 2000) (physician's participation as investigator in defendant manufacturer's clinical trial did not preclude him from learned intermediary status) (applying California law).

We faced the same issue in Bone Screw litigation. In Talley v. Danek Medical, Inc., 179 F.3d 154 (4th Cir. 1999), the plaintiff claimed that because her surgeon was also a paid consultant to the defendant, the learned intermediary rule could not apply. The court found no basis for displacing the rule:

"[Plaintiff] argues in this case that the learned intermediary doctrine should not apply because [her physician] was not independent of [defendant] in view of his financial connection with [defendant] as a consultant. She argues, therefore, that he cannot be considered an intermediary, learned or otherwise. . . . In this case, however, there is no evidence that the consulting relationship between [the prescriber and defendant] interfered with [the physician's] independent medical judgment in treating [plaintiff]. On the contrary, the evidence suggests otherwise. The record shows that [the prescriber] was not committed automatically to the installation of the [product]. In fact, during his first operation . . . he attempted a fusion without implanting any internal fixation device. . . . [D]epending on a patient's physical circumstances, he sometimes installed similar devices made by competing manufacturers. Finally, [plaintiff's physician's] consulting relationship with [defendant] involved devices other than [that implanted in plaintiff]."

Id. at 163-64 (applying Virginia law). Again, the opposite result on a fact pattern quite similar to Murthy – since both plaintiffs were initially treated with a different product.

Murthy's not looking like such a "sure" thing after all.

Tracy and Talley are hardly alone. There's even a case under Texas law. In Baker v. Smith & Nephew Richards, Inc., 1999 WL 811334 (Tex. Dist. June 7, 1999), aff'd mem., 2000 WL 991697 (Tex. App. July 20, 2000), another Bone Screw case, the prescribing surgeon had been a presenter at medical conferences for the defendant, and had been compensated with "fees." Id. at *20, 24. Allegations that this supposed "misconduct influenced [the prescriber's] treatment recommendations because of the fees he received" was "rejected" as a basis for avoiding the learned intermediary rule. Id. at *24 (citing In re Norplant Contraceptive Products Liability Litigation, 955 F. Supp. 700, 706 (E.D. Tex. 1997), aff'd, 165 F.3d 374 (5th Cir. 1999)).

In In re Zyprexa Products Liability Litigation, 2010 WL 348276 (E.D.N.Y. Jan. 22, 2010), Judge Weinstein was unimpressed by a similar argument, alleging that the plaintiff's prescriber had taken hundreds of thousands of dollars while "conduct[ing] paid research for at least ten pharmaceutical companies, including defendant," and "serv[ing] as a paid speaker for at least six pharmaceutical companies, including [defendant]. Id. at *11. None of those assertions "supports plaintiff's allegations of bias specific to [defendant] or suggests any motive that [the prescriber] would have to provide biased testimony in this case." Id. Thus, the court entered summary judgment under the learned intermediary rule. Id. (applying Illinois law).

Similarly in In re Trasylol Products Liability Litigation, 2011 WL 2117257 (S.D. Fla. May 23, 2011), the prescriber's paid consulting arrangement with the defendant did not preclude application of the learned intermediary rule under Alabama law. "The fact that he entered into a paid consulting agreement with [defendant] does not, in and of itself, render his decision to prescribe [the drug] for [plaintiff] biased and not based on his independent medical judgment." Id. at *4.

Likewise, in Vioxx litigation, a California state court flatly rejected the contention that payments – even large ones – somehow automatically precluded application of the learned intermediary rule:

"Plaintiffs argue defendant was aware that [plaintiff's] physician would not play the role of learned intermediary because it paid him hundreds of thousands of dollars over the years to conduct research and give lectures. Plaintiffs presented at trial no evidence of actual bias. On the contrary, [his] physician testified there was none.

Payment to a physician, standing alone, does not deprive the physician of learned intermediary status. Such payment for research is a widespread practice, yet the court was unable to find a case where a physician who was paid for research was considered to have abrogated his or her role of learned intermediary. Therefore, such payments alone do not constitute a "special circumstance" for purposes of setting aside the learned intermediary doctrine. Indeed, if such payments alone sufficed, a manufacturer would have to obtain the patient list of every physician it pays for research in order to somehow provide direct warnings."

In re Vioxx Cases, 2006 WL 6305292 (Cal. Super. Dec. 19, 2006),

Variants of the same argument have also failed when cloaked as attacks on the "credibility" of prescriber testimony that otherwise entitles the defendant to summary judgment under the learned intermediary rule. In Eck v. Parke, Davis & Co., 256 F.3d 1013 (10th Cir. 2001) (applying Oklahoma law), a challenge to credibility based on the prescriber's "formerly conduct[ing] research for several pharmaceutical companies" got nowhere, as it was "speculation" lacked any "evidence" of improper "influence." Id. at 1024. Similarly in Miller v. Pfizer, Inc., 196 F. Supp.2d 1095 (D. Kan. 2002), aff'd, 356 F.3d 1326 (10th Cir. 2004) (applying Kansas law), possible "bias" from the prescriber's "business relationship" with the defendant (a consulting agreement) was not enough, in the absence of any other evidence, to

prevent summary judgment. Id. at 1129 n.108.

Thus, in our estimation, this second aspect of the Murthy decision is not only wrong – because it runs roughshod over Erie federalism to reach its liability expanding result – but **loud wrong** – because it reached an outlier result, based upon no supporting precedent, while failing even to acknowledge any of the extensive precedent that rejects that result.