Too Bad Its Unpublished

Thursday, September 15, 2011

A reader recently recommended that we take a look at Rounds v. Genzyme Corp., ___ Fed. Appx. ___, 2011 WL 3925353, slip op. (11th Cir. Sept. 8, 2011) (applying Florida law), even though it's unpublished. We'd blogged about this case when the district court first dismissed it, but we confess we've missed the affirmance because our online check of Eleventh Circuit opinions only brings up opinions that are intended to be published. So we took a look, and we have to say we wish this opinion had been published. It addresses some interesting issues.

For one thing Rounds involves a biologic product, not a drug or medical device. That shouldn't make a legal difference, but plaintiffs (such as Ms. Rounds) occasionally argue that it does. In a footnote the court observed that, for purposes of the learned intermediary rule, drug/device/whatever makes no difference. As long as it's a prescription-only product, the learned intermediary rule applies, whether it's a drug, a device, or anything else:

> "Although Florida state case law regarding the learned intermediary has solely dealt with prescription drugs, we see no distinction in this instance between drugs, devices, or other prescription products. Prescription products . . . do not fall neatly into the category of drug or device, but like a drug or device, patients do not have access to such products without the intervention of a learned intermediary physician."

2011 WL 3925353, at *2 n.2. So Rounds is one more instance of the learned intermediary rule applying to a biological product – and not a vaccine.

The learned intermediary rule was a problem for plaintiff in Rounds, as we discussed in our earlier post, because: (1) her allegations pertained to patient selection, which the warnings covered in considerable detail, id. at *2; and (2) plaintiff's prescribing physician did not read the warnings in any event. Rounds v. Genzyme Corp., 2011 WL 692218, at *1 (M.D. Fla. Feb. 18, 2011). Thus, plaintiff couldn't prove either defect or causation.

It's tough to pursue a case without these essential elements, but plaintiff in Rounds was creative, if nothing else. Plaintiff argued that, beyond warnings, the manufacturer had some sort of duty to train (the opinion reads "failure to properly train") physicians in their patient selection skills. 2011 WL 3925353, at *2.

Rounds said "no." There's no nebulous duty to tell doctors how to practice medicine – only to provide them with adequate warnings. That occurred here, and the doctor failed to read them:

"[Plaintiffs] attempt to circumvent the learned intermediary doctrine by characterizing the issue as one of training rather than of warning. . . . [T]his is a distinction without a difference. . . . Thus, [defendant] satisfied its duty . . . by providing clear, unambiguous information concerning the contraindications for [the product], as well as the risks associated with it. Whether [defendant] was "training" or "warning" [the treater] of these risks when it provided him the package insert is, as the district court recognized, an issue of semantics only. As a matter of law [defendant] discharged its duty to advise [the treater] of the risks associated with [the product] by providing clear, unambiguous information about these risks in the . . . package insert. [The treater] then owed a duty to [plaintiff] to read the package insert and exercise judgment in discussing those risks with [her] and in using the [the] product to treat [her]."

2011 WL 3925353, at *3.

Thus Rounds evaluated, and rejected, an argument in the constellation of related but slightly different propositions that we lump under the general heading of "telling doctors how to practice medicine." That's something that we don't think we've ever comprehensively addressed before.

One of those issues is the supposed "duty to train" (as opposed to warn) those using the product, as rejected by Rounds. The Rounds court conducted its analysis chiefly as a matter of common sense, rather than law, but had the court felt the need to look, it would have concluded that its reasoning was reasonably well supported. In the absence of any special FDA requirement, no separate "duty to train" doctors using prescription medical products has been recognized:

"[T]he fact that individuals who have received training on medical equipment subsequently misuse the equipment to the detriment of a patient, standing alone, is insufficient to establish a breach of a duty to the injured patient on the part of the entity that provided the training. By providing training, [defendant] did not become a guarantor of the competence of [those it trained]."

Chamian v. Sharplan Lasers, Inc., 2004 WL 2341569, at *7 (Mass. Super. Sept. 24, 2004).

"[A] manufacturer should be able to presume mastery of basic operations by experts or skilled professionals . . . and should not owe a duty to warn or instruct such persons on how to perform basic operations."

Brown v. Drake-Willock International, Ltd., 530 N.W.2d 510, 515 (Mich. App. 1995) (plaintiff was a medical technician). See Woodhouse v. Sanofi-Aventis U.S. LLC, 2011 WL 3666595, at *3 (W.D. Tex. June 23, 2011) (allegation that defendant "failed to train, warn or educate" physicians failed to state a plausible claim because no such duty exists); Lemon v. Anonymous Physician, 2005 WL 2218359, at *2 (S.D. Ind. Sept. 12, 2005) (a manufacturer "does not automatically have a duty to properly train, instruct or assist a physician on the surgical implantation and use of the device" but "can affirmatively undertake that duty").

A second medical practice issue is when does the manufacturer's duty end and the learned intermediary's duty begin? The prevailing view is that, "a manufacturer has no duty to assist the learned intermediary in warning patients." Spychala v. G.D. Searle & Co., 705 F. Supp. 1024, 1033 (D.N.J. 1988). "One must also bear in mind that the warnings are intended to be read by learned intermediaries who are presumed to have considerable medical training as well as the ability to access the medical literature if they require additional information." Ames v. Apothecon Inc., 431 F. Supp.2d 566, 573 (D. Md. 2006). Makers of prescription medical products for use by licensed physicians are allowed to assume that such physicians understand how to practice medicine and know how communicate with their own patients. "A hospital's or medical staff's failures to perform their duties from that point [after having been warned] forward do not operate to create, or to extend, a manufacturer's duty to warn." Ellis v. C.R. Bard, Inc., 311 F.3d 1272, 1283 (11th Cir. 2002) (applying Georgia law). "If the doctor is sufficiently warned, the product is not defective. . . . Nor is a manufacturer responsible for how a learned intermediary conducts his business." Prohaska v. Sofamor, S.N.C., 138 F. Supp.2d 322, 344 (W.D.N.Y.2001); see also Donovan v. Centerpulse Spine-Tech Inc., 2010 WL 1269751, at *8 (W.D.N.Y. March 31, 2010), aff'd, 416 Fed. Appx. 104 (2d Cir. 2011); Billone v. Sulzer Orthopedics, Inc., 2005 WL 2044554, at *5 (W.D.N.Y. Aug. 25, 2005); Lawrence v. Sofamor, S.N.C., 1999 WL 592689, at *4 (N.D.N.Y. Aug. 2, 1999); Krasnopolsky v. Warner-Lambert Co., 799 F. Supp. 1342, 1346 (E.D.N.Y. 1992) (all New York decisions containing similar statements).

"How the physician communicates the medicine's dangers to the patient is the physician's own decision, and his or her independent duty. There is no legal support for imposing upon a drug manufacturer an "advisory"

role in that decision. Education of the physician, on the one hand, and communication to the patient, on the other, are distinct processes, and the manufacturer's duty involves only the former."

Polley v. Ciba-Geigy Corp., 658 F. Supp. 420, 421 (D. Alaska 1987). "[Defendant] was entitled to rely on the [plaintiff's doctors to properly relay the warnings . . . thereby relieving [it]of any liability for failure to warn." Kernke v. The Menninger Clinic, Inc., 173 F. Supp.2d 1117, 1122 (D. Kan. 2001).

A third argument is what we call the "duh" factor. Some things are just obvious – particularly to doctors. Matters that are "common knowledge to all doctors" need not be warned of at all. Guevara v. Dorsey Laboratories, Division of Sandoz, Inc., 845 F.2d 364, 368 (1st Cir. 1988) (applying Puerto Rico law). There is "no authority which requires a manufacturer to warn of a risk which is" "a matter of general and elemental medical knowledge" and thus "readily known and apparent to the consumer, in this case the physician." Plenger v. Alza Corp., 13 Cal. Rptr.2d 811, 819 (Cal. App. 1992) (death due to untreated infection).

"[C]onsidering the slight risk of contact polio, the variability of risks of harm (depending on many personal factors, including cleanliness and frequency and type of contact with a recently-vaccinated child), the introduction of individualized medical judgment, and . . . other policy reasons . . ., we do not accept plaintiffs' invitation to add new requirements to a manufacturer's duty to warn."

Plummer v. Lederle Laboratories, 819 F.2d 349, 358 (2d Cir. 1987) (applying New York and California law) (quoting Dunn v. Lederle Laboratories, 328 N.W.2d 576, 581 (Mich. App. 1982)). See Meridia Products Liability Litigation v. Abbott Laboratories, 447 F.3d 861, 867 (6th Cir. 2006) (no duty to warn of "risks associated with high blood pressure") (applying multiple state's laws); Stahl v. Novartis Pharmaceuticals Corp., 283 F.3d 254, 268 (5th Cir. 2002) (no need for separate warnings about what are "widely recognized to be possible outcomes") (applying Louisiana law); Banner v. Hoffmann-La Roche Inc., 891 A.2d 1229, 1239-1240 (N.J. Super. App. Div. 2006) ("it is beyond dispute that an individual who has been previously sexually active may be unable to remain abstinent and the possibility that a woman may become pregnant following sexual relations are risks 'already known'"); Harrington v. Biomet, Inc., 2008 WL 2329132, at *7 (W.D. Okla. June 3, 2008) (no duty for manufacturer's representative present during surgery to "advise [the surgeon] as to what size and type of components to use"); Harris v. Purdue Pharma, L.P., 218 F.R.D. 590, 596-97 (S.D. Ohio 2003) (where doctors allow plaintiffs to use a drug so frequently as to become addicted to it, that is "a

practice for which [defendant] cannot be held liable"); Brumley v. Pfizer, Inc., 149 F. Supp.2d 305, 312 (S.D. Tex. 2001) (no liability for not giving a warning that "merely alert[ed] physicians to a risk of which they should already be aware"); Hunt v. Hoffmann-La Roche, Inc., 785 F. Supp. 547, 550 (D. Md. 1992) (no duty to tell doctors that, to exclude pregnancy, they should run a pregnancy test; whether pregnancy was adequately excluded was a medical malpractice issue).

A fourth, relatively rare, contention is the "oops" factor – where a patient falls between the cracks. If by some quirk of the plaintiff's medical treatment, no physician actually becomes involved in a particular administration of the defendant's product, the defendant is not liable for that lapse:

"In such a case, the manufacturer fulfills its duty under the learned intermediary doctrine at the time it sells the product with adequate warnings directed to a physician. No new duty is created by the fact that after the sale no physician actually becomes involved in prescribing the drug. Although liability of a variety of kinds might then attach to the person providing the drug without the intervention of a physician, the manufacturer has no liability. . . . [T]o hold otherwise would be to confuse the duties of the manufacturer and of those other persons who later become involved in the provision of the drug."

Taurino v. Ellen, 579 A.2d 925, 928 (Pa. Super. 1990). Accord Mazur v. Merck & Co., 767 F. Supp. 697, 711 n.20 (E.D. Pa. 1991) (quoting Taurino), aff'd, 964 F.2d 1348 (3d Cir. 1992),

The fifth and final argument in this set is the most intrusive – when plaintiffs demand that our clients affirmatively interfere with what doctors choose to do. Doctors are not required to obtain our clients' consent, nor are prescription medical product manufacturers required to give consent, to the clinical use of prescription medical products in medical treatment:

"It would be a significant burden to require [defendant] to monitor the conditions under which a doctor performs surgery. . . . It would be unreasonable, and potentially harmful, to require [a manufacturer's representative] to delay or prevent a medical procedure simply because she believes the setting is not appropriate or the doctor is unqualified. To hold otherwise would place a medical device manufacturer . . . in the middle of the doctor-patient relationship."

Kennedy v. Medtronic, Inc., 851 N.E.2d 778, 786 (Ill. App. 2006).

"It is both impractical and unrealistic to expect drug manufacturers to police individual operating rooms to determine which doctors adequately supervise their surgical teams. . . . The defendant cannot control the individual practices of the medical community, even if it is the prevailing practice, and we decline to impose such a duty. Drug manufacturers must adequately warn physicians of the potential side-effects of their prescription drugs; thereafter, the physician, with his special knowledge of the patient's needs, assumes the burden of presiding over the patient's best interests."

Swayze v. McNeil Laboratories, Inc., 807 F.2d 464, 472 (5th Cir. 1987) (applying Mississippi law). No court has imposed a "duty on the [pharmaceutical] defendants to interfere with the physician-patient relationship, even if they were aware that the product may have been prescribed inappropriately." Labzda v. Purdue Pharma, L.P., 292 F. Supp.2d 1346, 1355 (S.D. Fla. 2003) (applying Florida law). The same is true in off-label use situations. Davenport v. Medtronic, Inc., 302 F. Supp.2d 419, 439-440 (E.D. Pa. 2004) (applying Pennsylvania law) (manufacturers do not "allow" physicians to use products off-label in their "practice of medicine"); Little v. Depuy Motech, Inc., 2000 WL 1519962, at *9 (S.D. Cal. June 13, 2000) (physician decisions to use products off-label "do[] not subject the manufacturer to liability, even if it knows of the off-label use"); Cox v. Depuy Motech, Inc., 2000 WL 1160486, at *8-9 (S.D. Cal. March 29, 2000) (same).

We're thankful that Rounds (and our reader) gave us the excuse to marshal the law refuting these uniformly specious arguments. In one way or another each of them seeks to blur the distinction drawn by the learned intermediary rule – that prescription medical product manufacturers are responsible for providing adequate warnings concerning their products, and thereafter, it's the professional duty of doctors to use that information in their own treatment of their patients.