We Don't Recall

Thursday, August 11, 2011

We've been around the preemption block a few times – we know what happens when the mainstay claim in prescription medical product liability litigation, that being inadequate warnings, gets preempted.

We first saw it in DTP vaccine litigation. We made a little headway with preemption and plaintiffs responded with "design' claims based on non-FDA-approved formulations. It took the Vaccine Act to bury those.

We saw it again in Bone Screw litigation, pre-Lohr. Plaintiffs responded with fraud on the FDA claims. It took Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001), to do those in.

We saw it yet again in prescription drug litigation, pre-Levine. Plaintiffs responded with all manner of things – design defect claims with no alternative design at all, failure to test, illegal promotion, you name it. S ome of these we're still fighting, but with the preemption threat to warning claims removed, most of these have receded into the background.

We saw – and see – it a fourth time in PMA medical devices, especially after Riegel v. Medtronic, Inc., 552 U.S. 312 (2008). The plaintiff's alternative has been disguised private FDCA enforcement actions presented as "parallel violation" claims.

And we expect to see it again now that PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011), has knocked out warning claims in generic drug cases. So what's the non-traditional (a/k/a weird) claim of choice there going to be? The jury's still out on that, but judging from the Mensing reargument petition, which we discussed here, one oddball claim under serious consideration by the other side is the notion that a defendant can have a common-law obligation simply not to sell its product at all.

In other words, the flavor *du jour* in generic cases could be failure to recall, resurrected from what has to date been extensive and well-deserved judicial repudiation.

While we don't represent generics (there's a big legal divide between branded and generic manufacturers, that we need not go into), we don't really want them to lose this battle either,

because any weird claim that finds a foothold in generic litigation will eventually bleed over and be asserted against our clients, too. So we thought we'd do a number on failure to recall/negligent recall in the hope of nipping this one in the bud.

Probably the best place to start when thinking about common-law claims that defendants should remove their (FDA-approved) products from the market entirely, or face universal liability simply for selling them, is with the Third Restatement of Torts. In section 11 recall-related liability is recognized only in limited situations **after** a recall has **already** otherwise been instituted:

"One engaged in the business of selling or otherwise distributing products is subject to liability for harm to persons or property caused by the seller's failure to recall a product after the time of sale or distribution if:

(a)(1) a governmental directive issued pursuant to a statute or administrative regulation specifically requires the seller or distributor to recall the product; or

(a)(2) the seller or distributor, in the absence of a recall requirement under Subsection (a)(1), undertakes to recall the product; and

(b) the seller or distributor fails to act as a reasonable person in recalling the product."

Restatement (Third) of Torts, Products Liability §11 (1998).

By implication, the black letter law of the Restatement rejects any common-law obligation to remove a product from the market *ab initio* (that's how we lawyers say "in the first place"). That implication is made explicit by the very first comment to Restatement §11. One ground for not allowing plaintiffs to argue that products should be taken off the market altogether is that such after-the-fact recall duties would be excessively expensive:

"Duties to recall products impose significant burdens on manufacturers. Many product lines are periodically redesigned so that they become safer over time. If every improvement in product safety were to trigger a common-law duty to recall, manufacturers would face incalculable costs every time they sought to make their product lines better and safer."

Restatement (Third) of Torts, Products Liability §11, comment a (1998). A second reason is that decisions about whether the public, as a whole, should be deprived of access to a product is not something properly left to judges and juries in common-law tort litigation:

"[A]n involuntary duty to recall should be imposed on the seller only by a governmental directive issued pursuant to statute or regulation. Issues relating to product recalls are best evaluated by governmental agencies capable of gathering adequate data regarding the ramifications of such undertakings."

Id.

So that's one. But a restatement is supposed to restate the law, right? Does this one?

You betcha.

In state after state, whether product liability is common-law or statutory, and whether it's based on the Second or Third Restatement, courts have refused to allow plaintiffs to make claims asserting that legal products should not have been sold at all. This precedent includes decades-old cases, e.g., Women's Health Network, Inc. v. A. H. Robins Co., 545 F. Supp. 1177, 1181 (D. Mass. 1982) ("[n]o court has ever ordered a notification and recall campaign on the basis of state law"), and recent cases decided within the past year. See Murray v. General Motors, 2011 WL 52559, at *2 (S.D. Miss. Jan. 7, 2011) (plaintiffs "cannot show that [defendant] breached its duty by not recalling their vehicle").

While this precedent goes well beyond prescription drug and medical device cases, one of the best cases is from the same court that, long ago, invented strict liability. In Ramirez v. Plough, Inc., 863 P.2d 167 (Cal. 1993), the California Supreme Court refused to order one of the first drugs ever – aspirin – off the market. There was no duty to recall aspirin because of Reyes syndrome:

"The other alternative ground of liability is that defendant should not have marketed [aspirin] at all because the risks of Reye's syndrome clearly outweighed any benefit to be derived from the product, particularly in light of the availability of non-aspirin pain relievers. We conclude, however, as a matter of law, that defendant may not be held liable for failing to withdraw its product from the market. . . . A few scientific studies had shown an association between [the product] and [the condition] but the methodology of those studies had been questioned and the FDA had determined that further studies were needed to confirm or disprove the association. Pending completion of those studies, the FDA concluded that product warnings were an adequate public safety measure. Although the FDA's conclusion is not binding on us, we think it deserves serious consideration."

Id. at 177-78.

Another thorough treatment of the issue is in Ford Motor Co. v. Reese, 684 S.E.2d 279 (Ga. App. 2009), which we blogged about a couple of years ago. Obviously, Reese involved a car rather than a drug, but the considerations weren't much different from those in Ramirez.

"We conclude that absent special circumstances, no common law duty exists under Georgia law requiring a manufacturer to recall a product after the product has left the manufacturer's control. Under our products liability jurisprudence, a manufacturer's duty to implement alternative safer designs is limited to the time the product is manufactured, not months or years later when technology or knowledge may have changed. . . . [I]mportant public policy concerns support our decision not to impose a continuing duty to recall upon manufacturers. Because the cost of locating, recalling, and replacing mass-marketed products can be enormous and will likely be passed on to consumers in the form of higher prices, the recall power should not be exercised without extensive consideration of its economic impact. Courts, however, are constituted to define individual cases, and their inquiries are confined to the particular facts and arguments in the cases before them. Decisions to expand a manufacturer's post-sale duty beyond making reasonable efforts to warn product users about newly discovered dangers should be left to administrative agencies, which are better able to weigh the costs and benefits of such action."

Id. at 284-85 (lots of citations and quotation marks omitted).

Courts in fully half the states in the country have considered whether to recognize a duty to recall this or that kind of product. The sheer range of products against which recall claims have been asserted demonstrates how much of a change in the law this theory would represent if ever accepted. So far, however, the courts have uniformly rejected failure to recall as a basis of product liability. In the hope that they will continue to do so – when inveigled by generic plaintiffs looking for some non-preempted alternative – we provide this list, which we think is comprehensive:

- **Alaska**: Nelson v. Original Smith & Wesson Business Entities, 2010 WL 7125186, at *3-4 (D. Alaska May 18, 2010), reconsideration denied, 2010 WL 7125187 (D. Alaska June 14, 2010) (firearm).
- **California**: Ramirez, 863 P.2d at 177-78 (OTC aspirin).
- **Delaware**: Smith v. Daimlerchrysler Corp., 2002 WL 31814534, at *6 (Del. Super. Nov. 20, 2002) (automobile).
- **Florida**: Thomas v. Bombardier Recreational Products, Inc., 682 F. Supp.2d 1297, 1302 (M.D. Fla. 2010) (personal watercraft).

- **Georgia**: Ford v. Reese, 684 S.E.2d at 283-85 (automobile); Yarbrough v. Actavis Totowa, LLC, 2010 WL 3604674, at *4 (S.D. Ga. Sep. 13, 2010) (Digitek).
- **Hawaii**: Tabieros v. Clark Equipment Co., 944 P.2d 1279, 1301 (Hi. 1997) (marine cargo equipment).
- **Illinois**: Rogers v. Clark Equipment Co., 744 N .E.2d 364, 370 (Ill. App. 2001) (forklift); Modelski v. Navistar International Transportation Corp., 707 N.E.2d 239, 247-48 (Ill. App. 1999) (tractor); Smith v. BOC Group PLC, 2001 WL 477237, at *5 (N.D. Ill. May 4, 2001) (ethylene oxide); Moorehead v. Clark Equipment Co., 1987 WL 26158, at *2-3 (N.D. Ill. Dec. 2, 1987) (forklift).
- **Iowa**: Lovick v. Wil-Rich, 588 N.W.2d 688, 696 (Iowa 1999) (cultivator); Burke v. Deere & Co., 6 F.3d 497, 508 n.16 (8th Cir. 1993) (applying Iowa law) (combine).
- **Kansas**: Patton v. Hutchinson Wil-Rich Manufacturing Co., 861 P.2d 1299, 1315 (Kan. 1993) (cultivator); Kinser v. Gehl Co., 184 F.3d 1259, 1270 (10th Cir. 1999) (applying Kansas law) (baler); Langehennig v. Sofamor, Inc., 1999 WL 1129683, at *8 (D. Kan. May 28, 1999) (bone screws).
- **Kentucky**: Ostendorf v. Clark Equipment Co., 122 S.W.3d 530, 534 (Ky. 2003) (forklift).
- **Massachusetts**: Women's Health Network, 545 F. Supp. at 1181 (Dalkon shield).
- **Michigan**: Gregory v. Cincinnati Inc., 538 N.W.2d 325, 333-34 (Mich. 1995) (press); Eschenburg v. Navistar International Transportation Corp., 829 F. Supp. 210, 214-15 (E.D. Mich. 1993) (combine).
- **Minnesota**: Kladivo v. Sportsstuff, Inc., 2008 WL 4933951, at *5 (D. Minn. Sep. 2, 2008) (inflatable water tube); Hammes v. Yamaha Motor Corp., 2006 WL 1195907, at *11 (D. Minn. May 4, 2006) (motorcycle); Berczyk v. Emerson Tool Co., 291 F. Supp.2d 1004, 1016 (D. Minn. 2003) (power saw); McDaniel v. Bieffe USA, Inc., 35 F. Supp.2d 735, 743 (D. Minn. 1999) (motorcycle helmet).
- **Mississippi**: Murray, 2011 WL 52559, at *2 (automobile).
- **Missouri**: Horstmyer v. Black & Decker, (U.S.), Inc., 151 F.3d 765, 783-84 (8th Cir. 1998) (applying Missouri law) (power saw); Smith v. Firestone Tire & Rubber Co., 755 F.2d 129, 135 (8th Cir. 1985) (applying Missouri law) (tire); Stanger v. Smith & Nephew, Inc., 401 F. Supp.2d 974, 982 (D. Mo. 2005) (tibial implant); Efting v. Tokai Corp., 75 F. Supp.2d 1006, 1011 (W.D. Mo. 1999) (cigarette lighter); Davidson v. Besser Co., 70 F. Supp.2d 1020, 1027 (E.D. Mo. 1999) (concrete fabricator).

- **New Jersey**: Leslie v. United States, 986 F. Supp. 900, 913 (D.N.J. 1997), aff'd mem., 178 F.3d 1279 (3d Cir. 1999) (hollow point bullets).
- **New Mexico**: Morales v. E.D. Etnyre & Co., 382 F. Supp.2d 1285, 1287 (D.N.M. 2005).
- **New York**: Adams v. Genie Industries, Inc., 929 N.E.2d 380, 385 (N.Y. 2010) (personal lift vehicle).
- **North Dakota**: Eberts v. Kawasaki Motors Corp., U.S.A., 2004 WL 224683, at *2-3 (D.N.D. Feb. 2, 2004) (ATV).
- **Pennsylvania**: Lance v. Wyeth, 4 A.3d 160, 167 (Pa. Super. 2010), appeal granted, 15 A.3d 429 (Pa. 2011) (diet drugs); Padilla v. Black & Decker Corp., 2005 WL 697479, at *7 (E.D. Pa. Mar. 24, 2005) (power saw); Boyer v. Case Corp., 1998 WL 205695, at *2 (E.D. Pa. Apr. 28, 1998) (forklift); Girard v. Allis Chalmers Corp., 787 F. Supp. 482, 486 n.3 (W.D. Pa. 1992) (bulldozer); Grant v. Bridgestone/Firestone, Inc., 55 Pa. D. & C.4th 438, 445-46 (Pa. C.P. 2001) (tire); Engle v. BT Industries AB, 41 Pa. D. & C.4th 25, 27 (Pa. C.P. 1999) (forklift).
- **South Carolina**: Bragg v. Hi-Ranger, Inc., 462 S.E.2d 321, 331 (S.C. App. 1995) (aerial bucket truck).
- **South Dakota**: Robinson v. Brandtjen & Kluge, Inc., 2006 WL 2796252, at *8 (D.S.D. Sept. 27, 2006), aff'd, 500 F.3d 691 (8th Cir. 2007) (printing press).
- **Tennessee**: Spence v. Miles Laboratories, Inc., 810 F. Supp. 952, 959 (E.D. Tenn. 1992) (blood clotting factor concentrate).
- **Texas**: Syrie v. Knoll International, 748 F.2d 304, 311-12 (5th Cir. 1984) (applying Texas law) (stool); Guizhi v. Bell Helicopter Textron, Inc., 1997 WL 786494, at *3 n.4 (N.D. Tex. Dec. 16, 2009) (helicopter); Hernandez v. Ford Motor Co., 2005 WL 1574474, at *1 (S.D. Tex. June 28, 2005) (automobile); Flock v. Scripto-Tokai Corp., 2001 WL 34111725, at *8-9 (S.D. Tex. Sep. 11, 2001) (cigarette lighter).
- **Washington**: Bear v. Ford Motor Co., 2007 WL 870344, at *3 (E.D. Wash. Mar. 20, 2007) (automobile).

Frankly, we think failure to recall claims, when brought against FDA-approved products, are absolutely preempted, since the conflict between the FDA saying yes, and a plaintiff saying no, to marketing a product is pretty direct and total. But then, we think a lot of things should be preempted.

In the meantime, if anybody knows of additional recall cases, please let us know. In the meantime we hope that the generic manufacturers will repulse this latest attempt to create an extremely dangerous and overreaching cause of action out of nothing.