Why Agency Fraud Is Like Fraud On The FDA

Friday, February 17, 2012

In our rather terse (due to firm involvement) post on Monday concerning Merck & Co. v. Ratliff, ___ S.W.3d ___, 2012 WL 413522 (Ky. App. Feb. 10, 2012) – beating both BNA and 360 by two days, BTW – we mentioned the "interesting" aspects of that case. Having noodled it a bit more, we've concluded that one of these deserves a little more attention.

We noted that, in Ratliff, the court recognized similarities between "fraud on the market" and agency fraud theories such as fraud on the FDA. Id. at *7. We agree, and we'd like to explain a bit why this is so.

"Fraud on the market" as our posts on that subject have discussed, is a legal doctrine, so far (thankfully) unique to securities litigation, that waters down the traditionally rather stringent standards for proving fraud by creating a "presumption" of reliance in certain limited circumstances. See Basic, Inc. v. Levinson, 485 U.S. 224 (1988) (4 justice majority of 7-justice court). "Fraud on the market" isn't a state-law claim. Neither the Supreme Court nor any state high court has extended the "fraud on the market" presumption to any state-law action, even in the securities realm. That proposition was what our 50-state fraud on the market post was intended to (and we think, did) establish.

In Basic, Inc., the Supreme Court bought a questionable proposition – that securities markets are uniquely "efficient" and "developed." In other words, because there are so many participants in national stock markets, and those participants have such a voracious appetite for information, then anything about a particular stock is essentially instantaneously reflected in that stock's price. Because of that (rather questionable) conclusion, any plaintiff in a securities fraud suit is "presumed" to rely on any material disinformation.

Even assuming that's true in the securities arena – a proposition we don't really accept – it's certainly not true where prescription medical products are concerned. Prescription products, being available only by prescription, necessarily require medical approval before their use. Doctors' knowledge and attitudes span a vast spectrum. We see that all the time in making causation motions under the learned intermediary rule. We can beat causation in a prescription medical product case by: (1) showing that the highly educated and motivated prescriber knew all about the risk from independent continuing review of relevant literature, or conversely, (2) that the prescriber isolated him or herself from the influence of our client by not reading warnings at all and not paying attention to pharmaceutical detailing.

Thus, there's absolutely no basis for a Basic, Inc. presumption of reliance on any different information that might have been disseminated by a pharmaceutical or medical device manufacturer. Any given prescriber might already know it – or might never rely on that source – or even both at the same time.

> *"[T]here is no prescription drug "market," at least as that term is understood in the securities context. . . . [T]he only "market" for a prescription drug is the potential group of patients who will be prescribed it by their physician, and if the side effects of the drug make it overly risky to ingest, the doctor will either not prescribe it or the patients will decide not to take it. . . . [T]he decision to take a particular drug is a medical one, not one based on an comparative analysis of risk versus price.*

Heindel v. Pfizer, Inc., 381 F. Supp.2d 364, 380 (D.N.J. 2004). For these reasons, differing degrees of physician

reliance have consistently defeated any presumption of reliance in learned intermediary situations. See De Bouse v. Bayer, 922 N.E.2d 309, 319 (Ill. 2009) (rejecting "market theory" of causation; plaintiff "fails to allege that her particular doctor was actually deceived by any of [defendant's] advertisements or statements"); International Union of Operating Engineers Local No. 68 Welfare Fund v. Merck & Co., 929 A.2d 1076, 1087-88 (N.J. 2007) ("to the extent that plaintiff seeks to prove only that the price charged for [the drug] was higher than it should have been as a result of defendant's fraudulent marketing campaign, and seeks thereby to be relieved of the usual requirements that plaintiff prove an ascertainable loss, the theory must fail"); Clark v. Pfizer, 990 A.2d 17, 27 (Pa. Super. 2010) ("statistical probability does not substitute for actual inquiry, as a general showing of percentages does not tend to prove that the class members' specific doctors relied upon Defendants' statements or that Defendants' statements were the proximate cause of an injury"); New Jersey Citizen Action v. Schering-Plough Corp., 842 A.2d 174, 177-78 (N.J. Super. A.D. 2003) ("the intervention by a physician in the decision-making process necessitated by his or her exercise of judgment whether or not to prescribe a particular medication protects consumers in ways respecting efficacy that are lacking in advertising campaigns for other products"); Commonwealth v. Ortho-McNeil-Janssen Pharmaceuticals Inc., 2010 WL 3548474 (Pa. C.P. June 25, 2010) ("application of the fraud on the market theory was rejected"; citing "evidence that doctors . . . prescribed off-label use of [the drug] to class members for reasons wholly unrelated to defendants' alleged fraudulent marketing"); UFCW Local 1776 v. Eli Lilly & Co., 620 F.3d 121, 133-34 (2d Cir. 2010) ("prescribing doctors do not generally consider the price of a medication when deciding what to prescribe for an individual patient"); In re St. Jude Medical, Inc., 522 F.3d 836, 839-40 (8th Cir. 2008) ("evidence concerning the reliance or non-reliance of individual physicians and patients" defeats generalized proof of causation); Zafarana v. Pfizer, Inc., 724 F. Supp.2d 545, 558 (E.D. Pa. 2010) ("there could be no justifiable reliance in general due to the operation of the learned intermediary doctrine"); In re Zyprexa Products Liability Litigation, 671 F. Supp.2d 397, 453-54 (E.D.N.Y. 2009) ("almost one million [drug] prescriptions, or . . . over one hundred thousand 'episodes of care' would necessarily require individualized consideration of the circumstances of each case"); In re Neurontin Marketing, Sales Practices & Products Liability Litigation, 257 F.R.D. 315, 326 (D. Mass. 2009) (given "individualized requirements for approval or reimbursement imposed on various plans' members and, to some extent, their prescribing physicians," "questions . . . regarding individual doctor's exposure to defendants' misrepresentations and the causal nexus between those misrepresentations and plaintiffs' injuries" involved "millions of disparate and varied human interactions").

So how does this precedent relate to fraud on the FDA? There isn't as much law because Buckman Co. v. Plaintiff's Legal Committee, 531 U.S. 341 (2001), held such claims preempted and thereby eliminated the need to come up with other defenses, but when one thinks about it, the theories bear considerable resemblance.

The fraud on the FDA theory in Buckman was typical. It alleged that "but for" the defendant's "fraud" committed on the agency, the product in question would not have been granted approval and therefore could not have been sold:

> *"Plaintiffs say petitioner made fraudulent representations to the Food and Drug Administration (FDA or Administration) in the course of obtaining approval to market the [devices]. Plaintiffs further claim that such representations were at least a "but for" cause of injuries that plaintiffs sustained from the implantation of these devices: Had the representations not been made, the FDA would not have approved the devices, and plaintiffs would not have been injured.*

531 U.S. at 343. Note the resemblance to the fraud on the market cases – no mention whatever of the intervening medical decisions of the prescribing/implanting physicians.

Just as "fraud on the market," through the imposition of a "presumption" of reliance, seeks to take the "learned intermediaries" out of the causation picture, so does fraud on the FDA. Instead of presuming reliance, fraud on the FDA presumes that the FDA would not have taken the regulatory step it was purportedly fraudulently induced to take – in most cases approval of a product. By so presuming that the FDA would have acted differently than it actually did (also why such claims inherently conflict with government decisions and must be preempted), fraud on the FDA would take the learned intermediary physicians out of the causal chain. If the product could not be legally marketed, then it would never have been available to the doctors in the first place.

Both fraud on the market and fraud on the FDA thus seek to bypass the individualized decision-making of prescribing physicians through use of generalized presumptions that don't correspond to the way things really work. Just as physicians have varied reactions to allegedly withheld information, so does the FDA. Revocation of approval of a drug or device is a serious step that the FDA rarely takes. It never revoked approval of any of the bone screws involved in Buckman. Not even a recall constitutes the revocation of approval:

> *"[T]he argument is predicated on the faulty assumption that the recall invalidated the [products'] PMA [pre-market approval]. Plaintiffs have cited no authority for that proposition, and [defendant] correctly notes that the PMA process is governed by a completely separate statutory and regulatory regime than that governing withdrawal of a PMA – a process to which the [products] have never been subjected.*

In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation, 592 F. Supp.2d 1147, 1155 (D. Minn. 2009), aff'd, 623 F.3d 1200, 1205 n.4 (8th Cir. 2010) (affirming for reasons stated by district court). Accord Blanco v. Baxter Healthcare Corp., 70 Cal. Rptr.3d 566, 579 (Cal. App. 2008) ("The fact the FDA implemented a Class I recall of the [product] does not alter our conclusion. . . . we have found no evidence in the record to support the conclusion the FDA revoked the [product's] PMA"); Erickson v. Boston Scientific Corp., 2011 WL 7036060, at *6 (C.D.Cal. Dec. 12, 2011) (recall not equivalent to revocation of approval); Theofanis v. Boston Scientific Corp., 2003 WL 24049229, at *2 ¶16 (S.D. Ind. 2003) (same). Thus, even if the FDA did determine that it had been defrauded, there's no reason to assume that revocation of approval would be the responsive action of the Agency.

Thus, no presumption of revocation is valid in fraud on the FDA cases. What happens when that presumption is eliminated? The same as with fraud on the market, that's what. Fraud on the FDA plaintiffs face exactly the same conundrum – non-reliance of most prescribing physicians on information directed to the FDA but not to them. That, too, arose in Bone Screw cases prior to Buckman. For example, a dozen or more opinions in Tennessee refused to apply any fraud on the FDA presumption, and threw out the claims on causation grounds, citing that state's rejection of fraud on the market presumptions:

> *"[E]ven Tennessee did recognize "third party" fraud, [plaintiff] cannot prove several necessary elements of his claim – reliance and proximate cause. Similar to negligent misrepresentation, reliance is an essential element of any action for fraudulent misrepresentation. Carter had provided no evidence that his physician . . . relied upon any misrepresentations to the FDA in deciding whether to use the . . . device in his spinal fusion surgery.*

Carter v. Danek Medical, Inc., 1999 WL 33537317, 5 (W.D. Tenn. June 3, 1999) (citing In re Sofamor Danek Group, Inc., 123 F.3d 394 (6th Cir. 1997), and analogizing to Tennessee's refusal to dispense with "actual reliance" through "a fraud-on-the-market theory of fraud"); accord, e.g., Ponthieux v. Danek Medical, Inc., 1999

WL 33486689, at *8 (W.D. Tenn. May 28, 1999) (same). There are another half-dozen or more cases cases decided by the same judge employing he same rationale.

Thus, we think that the court in Ratliff was indeed onto something when it analogized between fraud on the market and fraud on the FDA. Both are theories that seek to avoid the disparate medical decisions made by numerous treating physicians. Both do so by invoking presumptions that don't reflect what actually happens in the real world (at least in the world of drug and device litigation). Thus, if Buckman had never happened, many of the same reasons why courts reject fraud on the market in prescription medical product litigation would also apply to bar fraud on the FDA claims as well.