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Recent Pharmaceutical Cost Reimbursement Litigation

Monday, Feb 11, 2008 --- In the first wave of medical cost reimbursement litigation in the 1990s, third-party payers (TPPs) of medical costs – including states, private insurers, and union health and welfare funds – sued the tobacco companies to recover money they had spent to treat persons injured by smoking.

The tobacco companies settled the states' suits in 1998 at a cost estimated at more than $250 billion; the companies won dismissal of all the suits brought by private payers.

There is now a second wave of cost reimbursement litigation, this time targeting the pharmaceutical industry. The plaintiff TPPs are again the states, private insurers, and union funds, asserting claims under states' consumer protection statutes.

But this time around the plaintiffs are not seeking reimbursement of the costs of treating their insureds' personal injuries – indeed, in these new suits, the plaintiffs often concede that their insureds did not suffer personal injury.

Instead, the plaintiffs seek repayment of money they spent to purchase drugs for their insureds at prices alleged to have been inflated by manufacturers' fraudulent or deceitful statements.

In a 2003 decision, the Second Circuit held that these new cost reimbursement suits did not face the problem that sunk private TPP suits against the tobacco industry – the bar against an insurer directly suing its insured's tortfeasor to recover the costs of its insured's medical treatment. Desiano v. Warner-Lambert Co., 326 F.3d 339 (2d Cir. 2003).

But if the plaintiffs have found a way around this so-called "remoteness" doctrine, they still face significant hurdles. A series of decisions in 2007 has described some of these difficulties – in particular, in alleging causation and injury. At the same time, some of these decisions suggest ways that plaintiffs can overcome these problems.

Alleging Causation: Indirect Deception And Fraud On The Market

Most state consumer protection statutes require a proof that the defendant's fraudulent or deceptive acts caused injury to the plaintiff.

Few courts in this second wave of cost reimbursement suits have yet examined what statements or omissions by a pharmaceutical company can give rise to liability, but at least two courts have held that the plaintiffs' claims

were barred because the allegedly deceptive statements were consistent with the FDA-approved labels. Prohias v. Pfizer, 490 F. Supp.2d 1228, 1234-35 (S.D. Fla. 2007) (ads that stated or implied Lipitor reduces the risk of heart disease or heart attacks "derive from, and largely comport with, the approved label"); Pennsylvania Benefit Trust Fund v. Zeneca, 2005 WL 2993937 at *4 (D. Del. Nov. 8, 2005) (ads related to safety and efficacy of Nexium "comply with the FDA-approved labeling").

Litigation has thus far been largely focused on the causation and injury elements of a consumer fraud claim, which we will discuss in turn.

TPPs typically cannot allege that they saw or heard a defendant's alleged misrepresentations; instead they contend that they were injured as an indirect result of those misrepresentations. Two theories of indirect causation have emerged.

Judge Weinstein summarized the first theory in a June 2007 decision in the Zyprexa cost reimbursement litigation:

[P]laintiffs allege that Lilly represented that Zyprexa was safer and more efficacious than other available drugs; Lilly in fact knew this to be untrue; the misrepresentations led doctors to continue to prescribe, and plaintiffs to continue to pay for, greater amounts of Zyprexa than they would have absent the fraud; this kept the demand for Zyprexa as a higher level than it otherwise would have been; elevated demand allowed Lilly to keep prices higher than they otherwise would have been; and plaintiff paid more for Zyprexa than they otherwise would have. [In re Zyprexa Prods. Liab. Litig., 493 F.Supp.2d 571, 577-78 (E.D.N.Y. 2007).]

This is a "fraud on the market" or "market causation" theory, according to which Lilly's alleged misrepresentations increased demand for Zyprexa, causing it to sell at an artificially high price, thus indirectly injuring the purchasing TPPs.

Judge Weinstein expressed few reservations about importing this invention from federal securities law into a consumer fraud case, holding that the economic analysis the theory requires "appears to be within the competence of econometricians." Id. At 578.

But other courts have recently held that a plaintiff cannot rely on a fraud on the market theory of causation. In In re Rezulin Prods. Liab. Litig., 2007 WL 4165703 (S.D.N.Y. Nov. 26, 2007), the Louisiana Attorney General sued Warner-Lambert on behalf of the Louisiana Department of Health and Hospitals to recover amounts paid to fill Rezulin prescriptions for the state's Medicaid recipients.

The court characterized the Attorney General's theory of causation as follows: "They argue that they are entitled to recover because defendants misled patients and the medical community concerning the safety and efficacy of Rezulin in consequence of which, they claim, Louisiana was called

upon to reimburse for prescriptions that otherwise would not have been written at prices that otherwise could not have been charged." 2007 WL 4165703 at *2.

The court held that this was a "quintessential" fraud-on-the-market theory, and determined that Louisiana's Supreme Court would not allow the plaintiff to proceed on such a theory. Id. at *2-3. (The court also held that because a federal statute required Louisiana to reimburse pharmacies for Rezulin prescriptions, the alleged fraud could not have been the proximate cause of the state's damages. Id. At *3.).

The Southern District of New York cited to Int'l Union of Operating Engineers Local No. 68 Welfare Fund v. Merck & Co., 929 A.2d 1076 (N.J. 2007), an opinion issued just two months earlier, in which the New Jersey Supreme Court rejected a fraud on the market theory of causation outside the securities law context.

The plaintiff union fund sought to certify a nationwide class of TPPs who had paid for their insureds' Vioxx prescriptions. Plaintiffs argued that they could rely on expert testimony to show that Merck's conduct "created an effect on the price of Vioxx," thus causing them the "ascertainable loss" required by New Jersey's Consumer Fraud Act. Id. at 1087.

However, citing its earlier decision in Kaufman v. i-Stat Corp., 754 A.2d 1188 (N.J. 2000), and with no additional analysis, the court held that fraud on the market theories were only available in federal securities fraud actions. Id. at 1088.

The court concluded that without a fraud on the market theory of causation, the various plaintiff TPPs had to demonstrate that they individually were caused loss by defendants' statements. Causation was therefore not a common question supporting class certification and the court reversed certification of the plaintiff class.

In In re Bextra and Celebrex Marketing, Sales Practices and Prod. Liab. Litig., 2007 WL 2028408 (N.D. Cal. July 10, 2007), the court addressed a second theory of indirect causation in denying Pfizer's motion to dismiss claims brought by a proposed class of TPPs who paid for Bextra and Celebrex -- non-steroidal anti-inflammatory drugs ("NSAIDs").

The plaintiffs alleged that Pfizer falsely claimed that Bextra and Celebrex offered benefits beyond those delivered by other NSAIDs, and that those misrepresentations caused them to purchase Pfizer's drugs -- at approximately 10 times the cost of other NSAIDs. 2007 WL 2028408 at *2.

Pfizer argued that plaintiffs were asserting a fraud on the market theory of causation not allowed under Illinois law. Id. The court disagreed, holding that plaintiffs had alleged that Pfizer's misrepresentations had directly caused physicians to prescribe these drugs, and that these misrepresentations to physicians had indirectly caused the TPPs to buy the drugs at inflated prices.

Applying Illinois law, the court relied on an Illinois Supreme Court case, Shannon v. Boise Cascade Corp., 805 N.E.2d 213 (Ill. 2004), which, the Bextra court held, stated that misrepresentations by the manufacturer of a house's siding can indirectly cause injury to the house's purchaser if the manufacturer's misrepresentations were made to the builder, even though the builder did not relay these misrepresentations to the purchaser. Id. at *3, quoting Shannon, 805 N.E.2d at 218. Relying on its reading of Shannon, the court concluded that "defendants' alleged deceptions of the physicians ... caus[ed] the physicians to prescribe Celebrex," and the plaintiff TPPs were injured as a result.

But this theory of indirect causation is open to objection. In the first place, the court misapplied Shannon, for the Illinois Supreme Court there held that the house purchaser would have a claim under the Illinois Consumer Fraud Act only if the material manufacturer's misrepresentation "reached" the house purchaser, by, for example, being repeated to the purchaser by the builder. See Shannon, 805 N.E.2d at 218-19.

In Bextra there was no allegation that Pfizer's statements had reached the plaintiff TPPs. Second, if the plaintiff TPPs could allege causation without alleging that Pfizer's statements had reached them, the causal connection between physicians' prescriptions and the injury to TPPs seemingly has to be attributed to the inflated price of the drugs. The court's theory of indirect causation thus appears to collapse back into a fraud on the market theory.

Alleging Injury: Measuring Actual Value

Even if a manufacturer's deception caused a plaintiff TPP to purchase a drug, has the plaintiff suffered injury, and, if so, how is it to be measured? TPPs in these cases seek to recover their out-of-pocket damages – the difference between what they paid for the drug and the actual value of the drug. The problem, as always with out-of-pocket damages, is in determining actual value.

Moreover, proving actual value is not merely an element of plaintiff's case, at least in federal court: in Prohias v. Pfizer, the court held that plaintiff's "too speculative" theory of actual value meant that plaintiff lacked Article III standing. 485 F. Supp. 2d 1329, 1336-39 (S.D. Fla. 2007), discussing Rivera v. Wyeth-Ayerst Labs., 283 F.3d 315 (5th Cir. 2002).

The plaintiffs in Prohias contended that economic analysis could determine the price at which Lipitor would have sold if Pfizer's alleged misrepresentations had been corrected. The court rejected plaintiff's argument, holding that it rested "on the faulty premise that the price of Lipitor fluctuates based on the public's knowledge of Lipitor's benefits, even though drug prices (unlike stock prices […]) are fixed by the product's manufacturer." Id. at 1337, citing Heindel v. Pfizer, 381 F. Supp.2d 364 (D.N.J. 2004) ("The suggestion that consumers might be inclined to take a drug with certain side effects if they could pay less for it, or that drugs with certain side effects

should cost less, defies both reality and common sense.").

In addition, the court held, even if Lipitor's price were dependent on information about Lipitor, any determination of the price at which Lipitor would have sold without the alleged misrepresentations is too speculative. Id.

The New Jersey Supreme Court in International Union also warned about the difficulties in determining whether a TPP has been injured, and in what amount. In decertifying a class of TPPs, the court held that each TPP made individual decisions about what drugs to pay for, and at what prices, and, therefore, a single expert could not testify about the loss suffered by the class as a whole. 929 A.2d at 1088.

But Judge Weinstein in the Zyprexa litigation was unpersuaded by these obstacles to calculating actual value, holding that "[o]nce fraud has been proven, the burden of proving specifics of damages by the claimant is reduced." 493 F. Supp. 2d at 578.

Despite rejecting plaintiff's market-based determination of Lipitor's actual value, the court in Prohias suggested that TPPs might not face the same problem if they alleged that the defendants' misrepresentations caused them to buy Lipitor rather than another drug.

In such circumstances, the court noted, the plaintiffs are not seeking the difference between what they in fact paid and some speculative and hypothetical actual value, but the difference between what they paid and the cost of the alternative drug. 485 F. Supp.2d at 1338. But in cases where plaintiffs attempt to identify actual value by reference to the price of a competing drug, defendants can still argue that plaintiffs must show that the drug in question and the competitor share identical properties in order to allow the conclusion that they have equal value.

In many cases, such identity will not exist, thus the price of the competing drug cannot determine actual value.

But the suggestion that a drug's actual value can be determined by the price of a competing drug may have more weight when the competing drug is a generic version of the very same drug. See In re Warfarin Sodium Antitrust Litig., 391 F.3d 516, 531 (3d Cir. 2004) (finding defendant's misrepresentations caused plaintiff TPPs to pay higher price for Coumadin instead of generic equivalent).

In addition, plaintiffs in the recent spate of cases concerning Zetia and Vytorin claim that these drugs have no benefit, so no value at all, thereby seeking to avoid the need to determine actual value. E.g., Levy v. Merck, et al., No. 08-00491 (S.D.N.Y. Jan. 17, 2008).

Both Prohias and Bextra hold (surely correctly) that a plaintiff who continued to buy a drug after becoming aware of the manufacturer's alleged misrepresentations has no claim for damages. Prohias, 485 F.Supp 2d at

1334-36; Bextra, 2007 WL 2028408 at * 3-4. The court in Zyprexa gave little weight to this distinction, however, noting without discussion that it has "evidentiary relevance ... but it is not decisive." 493 F. Supp.2d at 577.

Finally, a 2007 decision from an Indiana trial court dismissed a consumer's lawsuit seeking to recover the excess price she allegedly paid for Vioxx. The decision rested on Indiana case law holding that a claim that a defendant's deceptive advertising caused buyers to pay more than they would have paid had there been no deception is not redressable under the state's Deceptive Consumer Sales Act. Kantner v. Merck & Co., 2007 WL 3092779 (Ind. Sup. Ct. April 18, 2007).

Conclusion

These recent cases suggest that cost reimbursement plaintiffs alleging a fraud on the market theory of causation are unlikely to prevail in most courts. Judge Weinstein's willingness to entertain expansive theories of mass tort liability is famous, but the Second Circuit is less open to such innovation.

As a consequence, plaintiffs are likely to explore alternative causation theories, such as that allowed by the court in Bextra; however, the theory that passed muster in Bextra is of doubtful validity. Even if plaintiffs can overcome their causation problem, these recent decisions show that they also face significant challenges in identifying the actual value of the drug in question.

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