Back to the Future: Civil RICO in Off-Label Promotion Litigation

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IN THE 1980s, courts addressed a wave of "garden-variety" fraud cases brought under the private civil action provision of the Racketeer Influenced and Corrupt Organizations ("RICO") Act.[1] As these cases proceeded, a substantial body of case law developed limiting RICO's potentially vast scope. For example, many claims were dismissed on standing grounds for failure to allege a direct injury proximately caused by the alleged racketeering activity.[2] Others failed in the pleading stages for lack of the specificity required for allegations of fraud under Federal Rule of Civil Procedure 9(b).[3] Many courts also held that RICO could not be used to circumvent already-existing law governing business or securities fraud.[4]

More recently, plaintiffs have filed a new wave of civil RICO claims in class actions concerning pharmaceutical products. In this "Back to the Future" trend, pharmaceutical manufacturers now

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[1] *See* Sedima, S.P.R.L. v. Imrex Co. Inc., 473 U.S. 479, 500 n.16 (1985) (citing ABA SECTION OF CORP., BANKING, & BUS. LAW, REPORT OF THE AD HOC CIVIL RICO TASK FORCE 55-56 (1985) (finding that by 1985, seventy-seven percent of civil RICO cases at the trial court level involved fraud claims)).

[2] *See, for example*, Holmes v. Sec. Inv. Prot. Corp., 503 U.S. 258, 268 (1992).

[3] In addition to the specificity requirements for pleading fraud under Rule 9(b), some courts implemented local rules requiring plaintiffs to file "RICO case statements" containing the particular facts of their allegations. *See*, *e.g.*, Lyman Steel Co. v. Shearson Lehman Bros., Inc., No. C-86-355, 1986 U.S. Dist. LEXIS 29346 (N.D. Ohio Feb. 13, 1986). For example, in the Eastern District of Pennsylvania, RICO case statements are within the discretion of the court. Train, Inc. v. Pro-Ed, Inc., No. 92-CV-5510, 1993 WL 45084, at *5 (E.D. Pa. Feb. 22, 1993). The District of New Jersey similarly has a local rule for RICO case statements. *See* Northland Ins. Co. v. Shell Oil Co., 930 F. Supp. 1069, 1073-74 (D.N.J. 1996) (finding that under Local Rule 15B.6, a court may require the plaintiff to file a RICO case statement).

[4] *See* Sedima, S.P.R.L. v. Imrex, Co., 741 F.2d 482, 486 (2d Cir. 1984), *rev'd*, 473 U.S. 479 (1985).

face suits brought by third-party payors and individuals. These plaintiffs generally claim that the defendant manufacturers engaged in off-label promotion and/or acts of deception and allege acts of mail or wire fraud as the RICO predicate acts. Frequently, the theory offered is that off-label promotion caused plaintiffs to pay or reimburse more for prescription drugs or to pay for prescriptions that they claim should not have been written. The plaintiffs generally claim that the off-label promotion caused economic injury to the payors, rather than claiming that the prescriptions were harmful or caused personal injury. To establish class-wide proof of causation and injury, plaintiffs often attempt to rely on statistical models and variations of the fraud-on-the-market theory advanced in securities litigation.

Plaintiffs invoke civil RICO in this context for several reasons. First, a successful civil RICO claim can produce an award of treble damages, costs and attorneys' fees. Second, civil RICO plaintiffs potentially gain broad choices of venue because RICO claims generally may be brought against "any [liable] person" wherever "such person resides, is found, has an agent, or transacts his affairs" under 18 U.S.C. § 1965(c). Perhaps most importantly in the class-action context, civil RICO claims conceivably allow plaintiffs to sidestep the predominating choice-of-law issues that typically prevent nationwide class actions based on fraud or deceptive practice law after such decisions as *Castano v. American Tobacco Co.*[5] and *Matter of Rhone-Poulenc Rorer, Inc.*[6] The Supreme Court's 2008 ruling in *Bridge v. Phoenix Bond & Indemnity Co.*,[7] eliminating the requirement that plaintiffs plead and prove first-party reliance in RICO[8] mail fraud claims, also has encouraged potential plaintiffs to invoke RICO more frequently.

But like a new wax job on an old DeLorean, under the shiny new surface of such claims lie many of the same old problems. Most courts considering the issues in this context—including a wave of decisions following *Bridge*—have rejected class action claims for off-label marketing of prescription drugs under RICO. Several decisions have rejected complaints at the pleading stages by granting motions to dismiss.[9] Other courts have disposed of these claims by denying motions for class certification.[10] Only one reported opinion has granted class certification in this context; the presiding judge in that matter described the basis of the theory as "thin," and that matter is

[5] 84 F.3d 734, 740-44 (5th Cir. 1996).
[6] 51 F.3d 1293, 1300-04 (7th Cir. 1995).
[7] 128 S. Ct. 2131, 2138-2140 (2008).
[8] Simply omitting state common law claims for fraud in favor of a federal RICO claim, however, may raise serious claim-splitting issues, which either could render the class representative inadequate or the action to be an inferior means of resolving the controversy.
[9] *In re* Epogen & Aranesp Off-Label Mktg, No. 08-01934, 2009 WL 1703285, at *8 (C.D. Cal. June 17, 2009); *In re* Actimmune Mktg. Litig., 614 F. Supp.2d 1037, 1056 (N.D. Cal. 2009); Ironworkers Local Union No. 68 v. AstraZeneca Pharm., LP, 585 F. Supp.2d 1339, 1344-45 (M.D. Fla. 2008); District 1199P Health & Welfare Plan v. Janssen, No. 06-3044, 2008 WL 5413105, at *1 (D.N.J. Dec. 23, 2008).
[10] *In re* Neurontin Mktg., 257 F.R.D. 315, 333 (D. Mass. 2009).

currently pending in the Court of Appeals.[11]

Plaintiffs asserting these claims generally have encountered many of the same difficulties as plaintiffs who attempted to use civil RICO to bring traditional fraud claims in the 1980s. As a threshold matter, many courts have found that off-label promotion is not synonymous with fraud, and that civil RICO cannot be used to create a private right of action under the Federal Drug and Cosmetic Act ("FDCA"). When mere allegations of off-label promotion are stripped from the complaint, courts have rejected these claims for failure to plead fraud with sufficient particularity under Rule 9(b).

In addition, a number of courts also have rejected these claims on standing grounds for failure to plead or prove proximate cause or a cognizable direct injury. When considering causation, courts have largely rejected plaintiffs' attempts to establish reliance and injury on a class-wide basis by using a fraud-on-the-market or price-inflation theory of liability. In cases such as *Ironworkers Local Union No. 68 v. AstraZeneca Pharmaceuticals LP*,[12] courts also have concluded that the alternative to a fraud-on-the-market theory—determining why scores of physicians exercised their medical judgment to prescribe medicines for off-label uses for all of the prescriptions for which the payors seek reimbursement—asserts an injury too remote and speculative to sustain a RICO claim. This article will discuss these recent cases and analyze the legal principles which once again have limited attempted expansion of civil RICO.

I. Off-Label Promotion is Not the Same as Fraud

In most of these recently-filed cases, plaintiffs have principally based their claims on allegations that defendants engaged in off-label promotion of the medicines at issue. Civil RICO claims, however, must be based on violations of certain enumerated federal statutes. Alleged violations of federal regulatory laws concerning off-label promotion by pharmaceutical companies are not among the enumerated RICO predicate acts. Although acts of mail fraud or wire fraud can constitute RICO predicate sets, a number of courts properly have rejected plaintiffs' attempts to equate "off-label promotion" and fraud. In *In re Epogen & Aranesp Off-Label Marketing*,[13] for example, the plaintiffs alleged that Amgen committed mail and wire fraud based on a purported scheme to promote the prescription drugs at issue for off-label uses. The Court rejected the plaintiffs' attempts to equate off-label promotion with wire fraud, concluding that "[p]romotion of off-label uses is not inherently misleading simply because the

[11] *In re* Zyprexa Prods. Liab. Litig., 253 F.R.D. 69, 201 (E.D.N.Y. 2008); Jack B. Weinstein, *Preliminary Reflections on Administration of Complex Litigations*, 2009 CARDOZA L. REV. DE NOVO 1, 17 (2009), available at http://www.cardozolawreview.com/content/denovo/WEINSTEIN_2009_1.pdf (describing basis of theory as "thin").

[12] 585 F. Supp.2d at 1344-45 (hereinafter "AstraZeneca").

[13] 590 F. Supp.2d 1282 (C.D. Cal. 2008).

use is off-label."[14] Because the complaint lacked specificity regarding fraud, as opposed to alleged off-label promotion, the court dismissed the complaint without prejudice for failure to identify specific misrepresentations in the complaint.

After the plaintiffs filed an amended complaint, the court granted Amgen's motion to dismiss with prejudice.[15] The court found that the plaintiffs merely made cosmetic changes by adding the words "false" and "deceptive" throughout their complaint instead of providing specific allegations about allegedly false statements. Allegations that Amgen promoted the drug for unapproved uses could not satisfy plaintiffs' responsibility to plead fraud with particularity under Rule 9(b). Instead, the court held that these allegations were "puffery" or non-actionable statements of fact, concluding that "[t]o merely assert that Amgen promoted EPO for 'ineffective' or 'unapproved' uses, without more, will not pass muster" under Rule 9(b).[16] To state actual fraud, the Court held that plaintiffs "must show that Amgen's actions went beyond presenting its drugs in the best light possible and crossed the line into actionable fraud."[17] For example, plaintiffs would need to allege that defendants falsely represented that the drugs were approved by the Federal Drug Administration for the off-label uses or that the defendants falsely reported the results of scientific studies. Although plaintiffs claimed that the defendant did not disclose certain information such as its sponsorship of several studies, the court found that the defendant had no duty to disclose this information, and thus the omission was not actionable. Without more, the plaintiffs' allegations were too generalized to state a fraud claim.[18]

Epogen rejected the use of civil RICO as a vehicle to enforce existing federal law governing pharmaceuticals. The *Epogen* court held that "[a]llowing Plaintiffs to proceed on a theory that Defendants . . . made false or misleading statements, would, in effect, permit Plaintiffs to use RICO as a vehicle to enforce the FDCA and the regulations promulgated thereunder."[19] The court stated that the FDCA does not contain a private right of action, and that RICO should not be used to create a private remedy indirectly. After plaintiffs submitted the amended complaint, the court found that this problem persisted. The court again criticized the use of RICO to supplement already-existing remedies, finding that "the Amended Complaint constitutes yet another attempt to shoehorn allegations that Amgen engaged in off-label promotion in violation of the FCDA into RICO and state consumer fraud causes of action."[20]

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[14] *Id.* at 1289 (internal quotations omitted) (citing United States v. Caronia, 576 F. Supp. 2d 385, 397 (E.D.N.Y. 2008)).
[15] 2009 WL 1703285.
[16] *Id.* at *6.
[17] *Id.*
[18] *See also* Central Reg'l Employees Benefit Fund v. Cephalon, Inc., No. 09-3418, 2009 WL 3245485, at *4 (D.N.J. Oct. 7, 2009) ("Merely alleging that Cephalon marketed the drugs at issue for off-label purposes does not state a claim for fraud. . . . In the absence of any specific allegations of fraud, as opposed to the mere fact of off-label marketing, the plaintiffs' common law fraud claims must be dismissed.").
[19] 590 F. Supp.2d at 1289-90.
[20] 2009 WL 1703285, at *5.

Similarly, in *In re Actimmune Marketing Litigation*, the court recognized that off-label promotion is not inherently fraudulent and that the complaint lacked specificity under Rule 9(b): "many of plaintiffs' allegations conflate a false and misleading statement under the FDCA, i.e., one that occurs when the drug label does not match the promoted assertion about the drug, and a false and misleading statement about the drug itself that can give rise to a claim under RICO. The two types of statements are not the same."[21]

The court noted that it is lawful for doctors to prescribe medications for off-label uses,[22] and explained that "courts have routinely refused to find promotional marketing of off-label uses fraudulent when they are directed at sophisticated audiences, like physicians."[23] This is because doctors, as learned intermediaries, evaluate the qualities of a medicine based on their professional expertise. In addition, the "mere objective of a company or companies to maximize profits is not in and of itself evidence of fraud. It does not necessarily follow that off-label promotion plus resulting profits equals fraudulent conduct."[24] The court criticized the plaintiffs for making "tendentious leaps in concluding that defendant[s'] marketing efforts are false and misleading simply because defendants presented their drug product in the best light" and reasoned that "[t]here is a clear distinction in the law between puffery and fraud."[25] As in *Epogen*, the court refused to equate off-label promotion with fraud under RICO without pleading specific false representations.[26]

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[21] 614 F. Supp.2d at 1051 (emphasis omitted).

[22] *See also* Buckman Co. v. Plaintiffs' Legal Comm, 531 U.S. 341, 351 n.5 (2001) (recognizing that off-label prescribing and use "often is essential to giving patients optimal medical care") (internal citations and quotations omitted). Some forms of off-label communications are expressly permitted by FDA regulations. *See, e.g.*, 21 C.F.R. § 99.1 (2008) (exempting from regulation "a manufacturer's dissemination of information that responds to a health practitioner's unsolicited request"); FDA, Notice, *Decision in* Washington Legal Found. v. Henney, 65 Fed Reg. 14286,14287 (Mar. 16, 2000) (noting that "FDA traditionally has recognized the important public policy reasons to permit industry support for the full exchange of views in scientific and educational discussions, including discussions of 'new [off-label] uses'"); FDA, *Draft Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* (Jan. 2009), available at http://www.fda.gov/oc/op/goodreprint.html (creating a safe harbor for pharmaceutical manufacturers to, *inter alia*, disseminate specified materials on off-label uses subject to certain requirements). Furthermore, the First Amendment protects other truthful off-label communication. *See, e.g.*, Washington Legal Found. v. Friedman, 13 F. Supp.2d 51 (D.D.C. 1998), *vacated on other grounds*, 202 F.3d 331 (D.C. Cir. 2000).

[23] 614 F. Supp.2d at 1054.

[24] *Id.*

[25] *Id.* at 1054-1055.

[26] *See also In re* Schering-Plough Corp. Intron/Temodar Consumer Class Action, No. 2:06-cv-5774, 2009 WL 2043604, at *10 (D.N.J. July 10, 2009) ("[N]ot all off-label

Like many fraud claims brought under civil RICO in the 1980s, RICO class actions alleging off-label promotion have also failed due to a lack of particularity in pleading mail and wire fraud under Rule 9(b). In *District 1199P Health and Welfare Plan v. Janssen LP*,[27] for example, the court rejected plaintiffs' off-label marketing claims for this reason. The court found that the seventy-page complaint lacked information regarding the date, time and place of the alleged fraudulent acts. Although plaintiffs pointed to information in the complaint regarding the global sales of the drug and the estimated percentage sold for off-label use, these details did not supply particularity regarding fraud. The court also rejected plaintiffs' RICO conspiracy claim for lack of specificity, finding that plaintiffs failed to plead the particulars of the conspiracy, such as the time or length of the conspiracy, the actions the defendants took to further it, and what knowledge the defendants possessed.

In *Janssen*, the plaintiffs argued for a relaxed pleading standard because "the internal corporate mechanisms and activities engaged in by the Defendants in furtherance of their fraudulent scheme are within the exclusive knowledge and understanding of the Defendants."[28] The court held that plaintiffs would fail to meet even relaxed pleading standards because the complaint did not allege the nature and scope of the plaintiffs' efforts to obtain the information necessary to plead with specificity.

II. Plaintiffs Fail to Satisfy RICO's Direct Injury Requirements Due to the Intervening Medical Judgment of Physicians

Plaintiffs have failed in several recent decisions on proximate cause grounds. Under RICO, plaintiffs must prove a direct relationship between their injury and the defendant's conduct. The Supreme Court held in *Holmes* that courts may evaluate the potential absence of such a direct relationship at the motion to dismiss stage by examining the directness of the injury, difficulties in apportioning damages, and whether the claim could be brought by a better, more appropriate enforcer.[29] Although *Bridge* rejected the requirement of first-party reliance under RICO, the Court did confirm that its decision was not to be read as a departure from its prior precedent requiring a direct injury and further clarified that "none of this is to say that a RICO plaintiff who alleges injury 'by reason of' a pattern of mail fraud can prevail without showing that *someone* relied on the defendant's misrepresentations."[30]

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promotion involves misrepresentations or dishonesty. Rather, the off-label use of pharmaceutical products is both prevalent and is, often times, the best means for providing effective treatment for patients.").

[27] 2008 WL 5413105, at *1 (hereinafter "Janssen").

[28] *Id.* at *12 (internal quotations omitted).

[29] *Holmes*, 503 U.S. at 268-270.

[30] *Bridge*, 128 S. Ct. at 2144; *see also Bridge* at 2144 n.6 ("Of course, a misrepresentation can cause harm only if a recipient of the misrepresentation relies on it."). The Supreme Court also recently addressed this issue in Hemi Group, LLC v. City of New York, No. 08-969, 2010 WL 246151 (Sup. Ct. Jan. 25, 2010), where the plurality of the court concluded that the plaintiff's causal theory did not satisfy RICO's direct relationship

In *AstraZeneca*,[31] the company argued that all three *Holmes* factors supported dismissal: (1) plaintiffs' claims included multiple links in causation, including the exercise of independent medical judgment by the prescribing doctor as well as a determination regarding reimbursement by the payor and its expert pharmaceutical benefits manager; (2) difficult questions of apportionment arise because payors may pass on their "increased costs" through rate increases; and (3) the FDA is the more appropriate enforcer. Chief Judge Anne Conway of the Middle District of Florida held that the third-party payor plaintiffs' alleged injury was too remote from the defendant's alleged misrepresentations to establish proximate causation. Focusing exclusively on the first *Holmes* criterion, Judge Conway reasoned that the "key independent factor" was that a consumer must obtain a prescription from a doctor to purchase the prescription medicines at issue. Physicians make independent medical judgments when prescribing medications, and those judgments may take into account a variety of sources of information. Determining whether a defendant's representation caused a physician to write a prescription would thus require examining the specifics of each doctor-patient relationship for each prescription at issue. The many factors influencing the prescribing doctors' decisions—including the doctors' training, familiarity with the class of drugs, experience with the drug at issue and other factors—made such an analysis an "intricate, uncertain" inquiry.[32] As a result, the court recognized the serious difficulties in proving whether alleged over payments were caused by the defendant's conduct rather than other intervening factors. The court also noted that the named plaintiffs in the case continued to pay for the drug even after initiating the suit, making any causal connection even more tenuous.

In *Actimmune*,[33] the Northern District of California took a similar approach. The court recognized that doctors prescribe drugs based on "personalized conditions," while rejecting the plaintiffs' claims on causation grounds.[34]

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requirement because plaintiff's theory of liability impermissibly "rest[ed] not just on separate *actions*, but separate actions carried out by separate *parties*" and on the "independent actions of third and even fourth parties." *Id.* at *7, *9 (emphasis in original), Justice Ginsburg, concurring, agreed that the plaintiff failed to state a RICO claim. She wrote separately to express her "resist[ance] to reading RICO to allow the [plaintiff] to end-run its lack of authority . . . to reshape the quite limited remedies Congress has provided for violations of the Jenkins Act." *Id.* at *11. Similarly, Congress has provided limited remedies under the FDCA, where there is no private right of action for the "off-label" promotion of prescription medications.

[31] 585 F. Supp. 2d at 1344-45.

[32] *Id.* at 1344 (citing Anza v. Ideal Steel Supply Corp., 547 U.S. 451, 460 (2006)).

[33] 614 F. Supp.2d at 1054.

[34] *Id. See also In re* Schering-Plough Corp., 2009 WL 2043604, at *26 ("The TPP plaintiffs may not establish the requisite proximate cause through aggregate proof or generalized allegations of fraudulent conduct and resulting harm. Instead, a court or jury would have to determine whether each prescribing physician received fraudulent marketing information from the Defendants and whether each physician was influenced to prescribe the Subject Drugs on account of

The issue of intervening medical judgment is closely related to the learned intermediary doctrine. Under the learned intermediary doctrine, a prescription drug manufacturer fulfills its duty to warn of the potential risks associated with a drug by providing warnings to the prescribing physician, and has no duty to warn the patient directly.[35] The learned intermediary doctrine is well established in virtually every United States jurisdiction, although it has been under attack in recent years.[36] Both the *AstraZeneca* and *Actimmune* courts implicitly relied on the learned intermediary doctrine when considering the effect of doctors' independent medical judgment on causation issues. Other courts considering civil RICO claims for off-label advertising have explicitly discussed the learned intermediary doctrine when rejecting plaintiffs' claims, even in New Jersey where the learned intermediary doctrine has limited application to a product that has been mass-marketed.[37]

III. Courts Reject a Class-Wide Presumption of Reliance under a Fraud-on-the-Market Theory

In order to avoid the kinds of difficult problems described by the courts in *AstraZeneca* and *Actimmune* (and in an attempt to avoid substantial discovery concerning the prescriptions at issue), plaintiffs have attempted to argue that they do not need to establish that any doctor or any payor actually relied on any misrepresentation and that they can satisfy causation through "statistical proof" concerning either "purchasing trends" or "price inflation." Courts generally have refused to accept these theories as a means to overcome individual causation issues in these cases. In *Actimmune*, for example, Judge Patel of the Northern District of California rejected a presumption of reliance based on the fraud-on-the-market theory under

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Schering's conduct. This sort of inquiry is impermissible.").

[35] *See, e.g.*, State *ex rel.* Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899, 902-903 (W. Va. 2007).

[36] *See* Perez v. Wyeth Labs., Inc., 734 A.2d 1245, 1262-1263 (N.J. 1999) (holding that when manufacturers engage in the direct marketing of drugs to consumers, they have a corresponding duty to warn of the risks associated with the drugs).

[37] *See In re Zyprexa*, 253 F.R.D. at 150-51 (discussing how the prescription drug context is unique and how doctors act as a learned intermediary when exercising independent medical judgment); *In re* Neurontin Mktg., 244 F.R.D. 89,113 (D. Mass. 2007) (noting the difficulty in identifying members of the plaintiff class because the patients purchased drugs only with the prescription of a doctor who is a "learned intermediary."). At least one New Jersey court held that although the state rejected the learned intermediary doctrine in the context of direct-to-consumer advertising of prescription drugs, the intervening medical judgment of a physician still creates causation problems. N.J. Citizen Action v. Schering-Plough Corp., 842 A.2d 174, 178 (N.J. Super. Ct. App. Div. 2003). The court found that "[i]n this context, that is, within a highly regulated industry in which the ultimate consumer is not in fact free to act on claims made in advertising in any event, the relationship between words used in the advertising and purchase of the product is at best an attenuated one." *Id.* Although the case involved a state law fraud claim, it may provide guidance for other courts considering plaintiffs' claims under RICO.

both RICO and state law claims.[38] The court found that this theory does not apply in non-efficient markets and questioned whether prescription drugs have a "market" that is in any way equivalent to a securities matter. Judge Patel also found that this theory was inappropriate because the causal connection between the defendant's alleged conduct and the plaintiffs' alleged injuries was so attenuated that "it would effectively be non-existent."[39] Instead, to satisfy the causation requirements of RICO, plaintiffs would need to allege and establish what specific information individual plaintiffs and doctors had, the extent to which they relied on it, and what information was false, misleading, or otherwise fraudulent.

In *In re Neurontin Marketing*,[40] Judge Saris of the District of Massachusetts held that plaintiffs could not use an expert's statistical model based on a price inflation theory to establish causation, even if the model showed that nearly all the prescriptions written for the drug were for off-label uses. In doing so, the court relied on the growing body of law rejecting any presumption of reliance in the consumer fraud and prescription drug context.[41] The court also noted the wide variety of factors influencing a doctor's decision to prescribe medication and the differences among the formularies of the third-party payors. Without a class-wide presumption of reliance, the court held that individual issues predominated over common issues and thus denied the plaintiffs' motion for class certification. In *Janssen*,[42] Judge Wolfson of the District of New Jersey also noted that plaintiffs would likely have a proximate causation problem due to the individualized decision-making of physicians and could not proceed on a fraud-on-the-market or price-inflation theory.[43] Most recently, the Superior Court of Pennsylvania upheld the decertification of a third-party payor class action, holding that "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."[44]

IV. Plaintiffs Fail to Allege an Injury Cognizable Under RICO

Plaintiffs likewise have had difficulties in meeting RICO's injury requirement. Pursuant to 18 U.S.C. § 1964(c), a plaintiff must suffer an "injury to business or property" to recover under RICO. In *Janssen*, the court held that the alleged "overpayment" for prescription

[38] 614 F. Supp.2d at 1054.
[39] *Id.*
[40] 257 F.R.D. 315.
[41] *Id.* at *322-323 (citing McLaughlin v. Am. Tobacco Co., 522 F.3d 215 (2d Cir. 2008)). *See also In re* St. Jude Medical Inc. Silzone Heart Valve Prods. Litig., 522 F.3d 836 (8th Cir. 2008); *In re* TJX Cos. Retail Sec. Breach Litig., 246 F.R.D. 389 (D. Mass. 2007); Int. Union of Operating Eng'rs Local No. 68 Welfare Fund v. Merck & Co. Inc., 929 A.2d 1076 (N.J. 2007).
[42] 2008 WL 5413105.
[43] The court failed to address causation fully, however, because the claim failed on injury grounds. *Id*. at *9.
[44] Clark v. Pfizer, Inc., No. 754 EDA 2009, 2010 WL 163583, at *7 (Pa. Super. Jan. 19, 2010).

medicine was not a cognizable injury under RICO in the absence of allegations that the drug was inferior or injurious.[45] In reaching this conclusion, the court relied on *Maio v. Aetna, Inc.*,[46] in which the plaintiffs did not claim they received inadequate or harmful medical care as a result of the defendant's health insurance, but merely that they "overpaid" for their insurance policies. The Third Circuit held that claims of overpayment in the absence of inadequate healthcare are not a "concrete financial loss" as required under RICO. Based on this precedent, the *Janssen* court rejected plaintiffs' claims.

V. *In re Zyprexa* Stands Alone As A Class Certification Victory For Plaintiffs

A significant outlier among the recent wave of decisions rejecting purported civil RICO claims concerning the pharmaceutical market is *In re Zyprexa Products Liability Litigation*.[47] In *Zyprexa*, private third-party payors sought damages for alleged overpayment for prescription drugs under civil RICO based on the defendant's allegedly fraudulent off-label promotion. Eli Lilly argued on both a motion to dismiss and a motion for summary judgment that the plaintiffs failed to show proximate cause, lacked standing, and failed to suffer a direct injury as required under RICO. Lilly also challenged the plaintiffs' experts, arguing that their calculation of injuries was analytically flawed and failed to take into account both other factors influencing pricing and the realities of the prescription drug "market."

On class certification, Judge Weinstein allowed plaintiffs to introduce an expert using a statistical model to establish causation on a class-wide basis. Judge Weinstein held that a presumption of reliance was appropriate because "the total fraud resulted in an increased price as in securities cases, so the fact that some doctors, patients or others were unaware of the fraud is irrelevant."[48] Assuming plaintiffs proved that the fraud caused a difference in price, a jury could estimate damages based on the difference between what plaintiffs paid for the drug and its actual value. Thus, the court rejected the defendant's arguments regarding causation and found sufficient proof of injury under a "price impact theory" to certify the class.

This ruling is based on the same theory that Judge Weinstein adopted two years earlier in *Schwab v. Philip Morris USA, Inc*.[49] In *Schwab*, plaintiffs brought a RICO class action against a cigarette manufacturer claiming that the defendant's fraudulent promotion caused plaintiffs to pay more for the cigarettes, resulting in economic injury. Judge Weinstein certified the class using a price-inflation theory of causation. The Second Circuit reversed, holding that "causation, much like the issue of reliance, cannot be resolved by way of generalized proof." [50] Instead, plaintiffs could not establish direct injury, because factors other than the defendant's

[45] *Id.*
[46] 221 F.3d 472 (3d Cir. 2000).
[47] 253 F.R.D. at 75.
[48] *Id.* at 195.
[49] 449 F. Supp. 2d 992 (E.D.N.Y. 2006), *rev'd sub nom.* McLaughlin v. Am. Tobacco Co., 522 F.3d 215, 228 (2d Cir. 2008).
[50] 522 F.3d at 226.

misrepresentations contributed to the decision to purchase the cigarettes and several plaintiffs continued to purchase the cigarettes even after filing the suit. In overturning *Schwab*, the Second Circuit held that the "loss of value model is designed to award plaintiffs damages based on the benefit of their bargain. Such damages are generally unavailable in RICO suits ... [where the statute] compensates only for injury to business or property."[51]

In *Zyprexa*, Judge Weinstein attempted to distinguish the Second Circuit's reversal of his light tobacco decision, asserting that the Circuit Court decision is no longer good law in light of the Supreme Court's decision in *Bridge*.[52] Although Judge Weinstein reasoned that *Bridge* held that a plaintiff need not prove reliance on the defendant's misrepresentations, that rationale is hard to understand since *Bridge* took pains to reaffirm its prior decisions concerning the requirement of a direct injury under RICO and it expressly stated that plaintiffs usually have to show that "s*omeone* relied on the defendant's misrepresentation."[53]

Even Judge Weinstein has publicly characterized this theory of liability as "thin,"[54] and at least one subsequent opinion by Judge Weinstein clarified that his rationale extended only to "price inflation" claims and not to the other claims or theories in the case.[55]

Other courts addressing purported civil RICO off-label marketing claims have declined to follow *Zyprexa*. For example, Judge Wolfson explicitly rejected *Zyprexa* in *Janssen*,[56] noting that Judge Weinstein relied on the very theory of loss-causation from *Schwab* which had been explicitly rejected by the Second Circuit. Judge Wolfson also held that the alleged misrepresentations did not affect the value of the product, but merely could have encouraged the plaintiffs to purchase the product over others. Because the overall price of the drug was not affected, the court found that the plaintiffs' reliance on *Zyprexa* was misguided.

Judge Saris in *Neurontin* found *Zyprexa* inapplicable, reasoning that the plaintiffs' claims did not involve the same type of price inflation injury as alleged by the plaintiffs in Judge Weinstein's opinion.[57] *Zyprexa* is now on appeal to the Second Circuit and remains an outlier in the debate over the use of civil RICO to aggregate pharmaceutical product liability claims.

VI. Conclusion

The clear trend in this area has been to reject plaintiffs' attempts to prosecute civilly pharmaceutical off-label promotion claims through civil RICO. These claims have failed in the pleading stages because plaintiffs did not allege

[51] *Id.* at 228 (internal citations omitted).
[52] 128 S. Ct. 2131.
[53] *Id.* at 2144.
[54] *See* Weinstein, *supra* note 11, at 17.
[55] *See In re Zyprexa Prods. Liab. Litig*., No. 04-MD-1596, 07-CV-645, 2009 WL 4260857, at *60 (E.D.N.Y. Dec. 1, 2009) (dismissing on summary judgment all similar claims brought by the State of Mississippi against Lilly except for price inflation because statistical evidence was legally inadequate to demonstrate causation).
[56] 2008 WL 5413105, at *6.
[57] 257 F.R.D. at 327, n. 7.

fraud with specificity as required under Rule 9(b) and instead alleged off-label promotion which is not inherently fraudulent. They also have failed on causation grounds due to the lack of a direct causal connection in light of the many intervening factors involved in a doctor's professional decision to prescribe drugs and the valid unwillingness of courts to recognize a fraud-on-the-market theory of liability in this context. Finally, courts have rejected these claims for failure to state a cognizable injury to business or property under RICO. *Zyprexa* and *AstraZeneca* are on appeal to the Second and Eleventh Circuit Courts of Appeals. Although the outcomes of these cases remain to be seen, it appears unlikely that plaintiffs will succeed in future suits. Instead, plaintiffs will likely fail for many of the same reasons that courts rejected attempts to bring garden-variety fraud cases under civil RICO in the 1980s.