United States Court of Appeals
For the First Circuit

No. 11-1806

IN RE: NEURONTIN MARKETING AND SALES PRACTICES LITIGATION

HARDEN MANUFACTURING CORPORATION, individually and on behalf of itself and all others similarly situated; ASEA/AFSCME LOCAL 52 HEALTH BENEFITS TRUST; LOUISIANA HEALTH SERVICE INDEMNITY COMPANY, d/b/a Blue Cross Blue Shield of Louisiana,

Plaintiffs, Appellants,

INTERNATIONAL UNION OF OPERATING ENGINEERS, LOCAL NO. 68 WELFARE FUND, on behalf of itself and all others similarly situated; LORRAINE KOPA, on behalf of herself and all others similarly situated; GERALD SMITH, on behalf of himself and all others similarly situated; JEANNE RAMSEY, on behalf of herself and all others similarly situated; CAROLYN HOLLAWAY, on behalf of herself and all others similarly situated; GARY VARNAM, on behalf of himself and all others similarly situated; JAN FRANK WITYK, on behalf of herself and all others similarly situated,

Plaintiffs,

v.

PFIZER, INC.; WARNER-LAMBERT COMPANY LLC,

Defendants, Appellees.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Patti B. Saris, U.S. District Judge]

Before

Lynch, Chief Judge,
Souter,[*] Associate Justice,
and Lipez, Circuit Judge.

Thomas M. Greene, with whom Michael Tabb, Ilyas J. Rona, Ryan P. Morrison, and Greene LLP were on brief, for appellants.

John H. Beisner, with whom Mark S. Cheffo, Katherine A. Armstrong, and Skadden, Arps, Slate, Meagher & Flom LLP were on brief, for appellees.

April 3, 2013

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[*] Hon. David H. Souter, Associate Justice (Ret.) of the Supreme Court of the United States, sitting by designation.

LYNCH, Chief Judge. This appeal by Harden Manufacturing Corporation and others (together, "Harden plaintiffs") is one of three that arose from multidistrict litigation ("MDL") concerning the off-label marketing of Neurontin, an anticonvulsant drug manufactured by Pfizer, Inc. Today we issue our decisions in Kaiser Foundation Health Plan, Inc. v. Pfizer, Inc. (Kaiser), Nos. 11-1904, 11-2096 (1st Cir. _____, 2013), and Aetna, Inc. v. Pfizer, Inc. (Aetna), No. 11-1595 (1st Cir. _____, 2013), which are relevant to this appeal. We assume familiarity with both opinions, which dispose of many of Pfizer's arguments, and limit our discussion here to the issues particular to this appeal.

The Harden plaintiffs, representing a putative class of third-party payors ("TPPs"), ask us to reverse both the district court's grant of summary judgment to Pfizer and the court's denial of class certification on the plaintiffs' claims under section 1962 of the Racketeer Influenced and Corrupt Organizations Act (RICO), 18 U.S.C. §§ 1961-1968, the New Jersey Consumer Fraud Act (NJCFA), N.J. Stat. Ann. §§ 56:8-1 to 56:8-195, and state common law claims of fraud and unjust enrichment. The core of the plaintiffs' claims, as in Kaiser and Aetna, is the allegation that Pfizer engaged in a fraudulent off-label marketing campaign that caused the TPPs to pay for Neurontin prescriptions that were ineffective for the off-label conditions at issue, and that the plaintiffs suffered injury when they paid for those prescriptions. The

details of these allegations are described in the district court's opinion in In re Neurontin Mktg. & Sales Practices Litig. (Harden II), 257 F.R.D. 315, 317-18 (D. Mass. 2009). The Harden plaintiffs' appeal is limited to only the claims regarding the off-label use of Neurontin for bipolar disorder, as to both the summary judgment and the class certification issues.

The plaintiffs argue that the district court erred in concluding that they failed to present a genuine issue of material fact as to whether their injuries were caused by Pfizer's conduct. They also argue that the district court abused its discretion in denying class certification on the basis of a finding that individual issues of causation and damages would predominate.

Based on the same reasoning we set forth in Kaiser and Aetna, and applying the facts of record here, we reverse the grant of summary judgment as to the plaintiffs' RICO claim. Based on the record evidence, the Harden plaintiffs are not so differently situated from Kaiser that they should be precluded from proving their case to a jury. The district court considered the Harden plaintiffs' failure to show any direct reliance on Pfizer's misrepresentations in making decisions about their formularies, together with the plaintiffs' use of aggregate evidence of causation, to be inadequate to survive summary judgment. We disagree. We also vacate the grant of summary judgment as to the state law claims. In light of our decision regarding summary

judgment, we vacate the denial of class certification and remand for further proceedings consistent with this opinion.

I.

The putative class representatives in this appeal are Harden Manufacturing Corporation, a self-insured employer; ASEA/AFSCME Local 52 Health Benefits Trust, a public employee union health benefits trust; and Louisiana Health Service Indemnity Corporation, d/b/a Blue Cross Blue Shield of Louisiana, a nonprofit health insurance provider.[1] See In re Neurontin Mktg. & Sales Practices Litig. (Harden III), 754 F. Supp. 2d 293, 307-08 (D. Mass. 2010). The Harden plaintiffs are all TPPs; that is, they pay for the costs of drugs prescribed for their members. They currently seek to represent a nationwide class of TPPs who reimbursed for Neurontin prescriptions for the off-label condition of bipolar disorder between 1994 and 2004.

We review the record on summary judgment as it stood when the district court ruled. Lewis v. City of Boston, 321 F.3d 207, 214 n.7 (1st Cir. 2003). In this case, the district court completed the trial that formed the basis of the Kaiser appeal before rendering summary judgment as to the Harden plaintiffs, and the court relied on the facts adduced in that trial when granting

[1] In the district court, the putative class representatives also included International Union of Operating Engineers Local No. 68 Welfare Fund, another union health provider. This plaintiff has voluntarily withdrawn from the appeal.

summary judgment here.[2] See Harden III, 754 F. Supp. 2d at 296. Accordingly, in this decision we adopt the facts concerning Pfizer's development and marketing of Neurontin as we explained them in Kaiser, slip op. at 7-10, 16-17.

Harden filed its class action complaint against Pfizer[3] in U.S. District Court in Massachusetts on May 14, 2004. On August 8, 2005, the present named plaintiffs moved to certify a nationwide class under Fed. R. Civ. P. 23(a) and 23(b)(3). At that time, the proposed class consisted of all TPPs that had purchased or reimbursed for Neurontin for a number of off-label uses between January 1, 1994 and December 31, 2004.[4] In re Neurontin Mktg. & Sales Practices Litig. (Harden I), 244 F.R.D. 89, 91-92 (D. Mass. 2007). The district court initially denied the motion without prejudice on August 29, 2007, finding, inter alia, that the commonality requirement was not met. Id. at 105, 115.

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[2] This situation stands in contrast to the state of the record in Aetna, where the district court granted summary judgment on Aetna's claims before proceeding with the Kaiser trial. See Aetna, slip op. at 5.

[3] Warner-Lambert Company, a subdivision of Pfizer, was also named as a defendant. Warner-Lambert developed Neurontin in the 1980s and early 1990s before the company was acquired by Pfizer in 2000. In re Neurontin Mktg. & Sales Practices Litig. (Kaiser Findings), No. 04–cv–10739-PBS, 2011 WL 3852254, at *5 (D. Mass. Aug. 31, 2011).

[4] The class certification motion also included a class of individual patient-consumer plaintiffs. Since the consumers have not appealed, we do not address their claims.

Significantly, Pfizer had also argued in response to this motion that class certification was inappropriate because the Harden plaintiffs could not prove causation on a class-wide basis, but rather would have to prove for each class member: (1) that its physicians were personally exposed to off-label marketing that contained false statements or material omissions, (2) that such statements or omissions in the marketing materials caused those doctors to issue the prescriptions, and (3) that the prescriptions were ineffective for those doctors' patients. Id. at 109. At the time the district court decided the motion, the plaintiffs had commissioned, but had not yet received, an expert report from Dr. Meredith Rosenthal, which the plaintiffs expected to use to prove causation by aggregate data analysis.[5] Id. at 109-110. While the district court expressed some reservations about the Harden plaintiffs' proposed method of proof, it did not make any definitive rulings on causation due to the limited record. See id. at 110-15.

On December 19, 2007, the Harden plaintiffs renewed their motion for class certification. The district court denied the motion on May 13, 2009. Harden II, 257 F.R.D. at 333. The court found that the plaintiffs had overcome the commonality problem by splitting the TPP class into multiple subclasses that were specific

[5] Dr. Rosenthal's qualifications and the details of her completed report are discussed in Kaiser, slip op. at 13-15.

to the off-label indications for which Neurontin had been prescribed, id. at 319, but that this time, the motion failed on the basis of predominance, see id. at 317, 331-33. The court concluded that the plaintiffs could not use statistical evidence to establish class-wide causation in a consumer fraud claim under either RICO or the NJCFA. See id. at 323-33. While Dr. Rosenthal's regression analysis showed that "essentially all" Neurontin prescriptions for bipolar disorder were the result of Pfizer's off-label marketing, id. at 329, the court found that the Rosenthal report nonetheless could not provide class-wide evidence of causation because it did not take account of doctors' individual prescribing decisions or the possibility that some of Pfizer's off-label marketing might not have been fraudulent, see id. at 330-31. The court then reasoned that the TPPs could alternatively show causation by evidence that they had directly relied on Pfizer's misrepresentations in deciding how to treat Neurontin on their formularies (the lists of drugs for which TPPs agree to reimburse). See id. at 333. But because of the TPPs' heterogeneity in their processes of constructing and managing their formularies, id. at 332, such reliance could not be shown by proof common to the class, id. at 333.

On May 28, 2009, the Harden plaintiffs moved for reconsideration as to the bipolar subclass only. This motion would not be resolved until after a series of other proceedings.

In March 2009, while the second class certification motion was pending, Pfizer had moved for summary judgment on the Harden plaintiffs' claims, as well as on the claims of the other TPP plaintiffs in the MDL, including Kaiser and Aetna. Pfizer argued, as relevant in this appeal, "that [p]laintiffs ha[d] failed to create a triable issue of fact as to causation." In re Neurontin Mktg. & Sales Practices Litig. (Neurontin Coordinated SJ), 677 F. Supp. 2d 479, 485 (D. Mass. 2010). Similar to its arguments in the class certification context, Pfizer argued that Dr. Rosenthal's report was inadequate to raise a genuine issue of fact as to causation because it could not distinguish which prescriptions were actually influenced by the allegedly fraudulent marketing campaign. Id. at 493-96. Without the Rosenthal report, Pfizer argued, there was no evidence of causation, because the individual doctors who had provided evidence had not stated that they relied on any of Pfizer's alleged misrepresentations. Pfizer also contended that the TPP plaintiffs had failed to show a sufficiently direct relationship between Pfizer's alleged conduct and the plaintiffs' alleged injuries to support a finding of proximate causation, and that plaintiffs had failed to raise a genuine issue of fact as to whether Neurontin was ineffective for the off-label conditions at issue, which would preclude a finding of compensable injury.

The Harden plaintiffs responded that their statistical and circumstantial evidence sufficed to create a triable issue of fact as to causation because it demonstrated, as a general matter, that Pfizer's marketing was what caused doctors to prescribe Neurontin for off-label conditions, which led directly to the TPPs' injury of having to pay for prescriptions that were ineffective. See Harden III, 754 F. Supp. 2d at 310. They argued that it should be for a jury to weigh individual doctors' stated reasons for prescribing Neurontin against the Rosenthal report's data analysis and the plaintiffs' other evidence of Pfizer's fraudulent marketing campaign. Unlike in the Kaiser and Aetna cases, the Harden plaintiffs did not claim that they had directly relied on any misrepresentations by Pfizer in making decisions about whether to include or restrict Neurontin on their formularies. Id. at 307-08, 311. They also argued that they had introduced "overwhelming" evidence that Neurontin was ineffective for the off-label conditions at issue.[6]

On January 8, 2010, the district court granted Pfizer's summary judgment motion with respect to Aetna and denied it with respect to Kaiser, holding that "in a misrepresentation action involving fraudulent marketing of direct claims to doctors, a

[6] Significantly, neither Pfizer's memoranda in support of summary judgment nor the Harden plaintiffs' responses explicitly addressed the elements of the plaintiffs' claims under the NJCFA or state common law. The Harden plaintiffs cited only one case construing NJCFA, in passing, in a footnote.

plaintiff TPP or class must prove through individualized evidence that the misrepresentation caused specific physicians, TPPs, or consumers to rely on the fraud, and cannot rely on aggregate or statistical proof." Neurontin Coordinated SJ, 677 F. Supp. 2d at 494. Kaiser's claims were allowed to continue to trial because Kaiser had presented sufficient evidence that it had directly relied on Pfizer's published materials in determining which restrictions, if any, to place on Neurontin's formulary status. See id. at 496-97.

The district court went on to hold a five-week trial, at which a jury concluded that Pfizer had fraudulently marketed Neurontin for four off-label conditions, including bipolar disorder, and that this conduct had violated RICO. In re Neurontin Mktg. & Sales Practices Litig. (Kaiser Findings), No. 04-cv-10739-PBS, 2011 WL 3852254, at *1 (D. Mass. Aug. 31, 2011). The district court reached the same conclusion in a bench trial on Kaiser's state law claim. See id. at *60. During the Kaiser trial, the district court accepted Dr. Rosenthal's report as evidence and permitted Dr. Rosenthal to testify as an expert witness. Id. at *32-33. That and other evidence of causation is described in our Kaiser opinion. See Kaiser, slip op. at 12-19, 36-48. We affirmed the jury's and district court's verdicts. See id., slip op. at 3.

On December 10, 2010, after the Kaiser trial had concluded, the district court returned to Pfizer's summary judgment

motion respecting the Harden plaintiffs, and it granted summary judgment to Pfizer. Harden III, 754 F. Supp. 2d at 296, 311. The court reiterated its finding from the earlier summary judgment decision that the Rosenthal report alone could not support the TPPs' causation argument, concluding that while the report "demonstrates the likelihood of some injury, . . . it does not suffice to demonstrate the extent of harm caused by the fraud, as opposed to run-of-the-mill off-label detailing. Most courts have rejected such aggregate proof." Id. at 310-11. Because the Harden plaintiffs "ha[d] not directly relied on misrepresentations by defendants,"[7] and could not use the Rosenthal report to show reliance by physicians, the court held that the Harden plaintiffs had failed to present a triable issue of fact as to causation. Id. at 311.

Then, on May 17, 2011, the district court addressed the Harden plaintiffs' May 28, 2009 motion for reconsideration of the denial of class certification as to the subclass of TPPs who had paid for off-label prescriptions of Neurontin for bipolar

[7] On December 20, 2010, one of the Harden plaintiffs -- Blue Cross Blue Shield of Louisiana -- filed a motion to reconsider the summary judgment ruling, asserting that it had shown direct reliance on Pfizer's misrepresentations in the development of its formulary. The district court denied this motion on April 20, 2011. None of the other Harden plaintiffs moved the court to reconsider the summary judgment ruling on this basis, and none -- including Blue Cross Blue Shield of Louisiana -- challenge on appeal the finding that they failed to show direct reliance.

disorder.[8] In re Neurontin Mktg. & Sales Practices Litig. (Harden IV), No. 04-cv-10981-PBS, 2011 WL 1882870, at *1 (D. Mass. May 17, 2011). Relying on evidence adduced since the prior class certification denial, including evidence presented at the Kaiser trial, the district court determined that "[p]laintiffs have proved that it is more likely than not likely [sic] that they were harmed by Pfizer's conduct because many doctors would not have prescribed Neurontin for bipolar disorder if they had known there was no reliable scientific evidence supporting its use." Id. at *5. However, the court went on to find that the Rosenthal report still did not satisfy the predominance requirement as to causation or damages. Id. at *4-5. It held that, "in order to differentiate those prescriptions that were caused by fraud from those that were attributable to non-fraudulent off-label marketing or other independent factors, a factfinder would have to perform a granular doctor-by-doctor analysis." Id. at *5. Such an inquiry would be unmanageable in a class action litigation. Id. Moreover, "complex issues related to calculating damages" would also make the class unmanageable, and thus the Harden plaintiffs had failed to satisfy Fed. R. Civ. P. 23(b)(3)'s superiority requirement. Id. at *6.

[8] Pfizer argued that this motion was moot as a result of the December 2010 summary judgment decision, but the district court did not rule on this argument. In re Neurontin Mktg. & Sales Practices Litig. (Harden IV), No. 04-cv-10981-PBS, 2011 WL 1882870, at *1 (D. Mass. May 17, 2011).

On June 28, 2011, the district court entered a separate judgment in favor of Pfizer on all of the Harden plaintiffs' claims, and the plaintiffs filed a timely appeal on July 7, 2011.

II.

On appeal, the Harden plaintiffs argue that the district court erred in concluding that they did not raise a triable issue of fact as to but-for or proximate causation. We review a grant of summary judgment de novo, drawing all reasonable inferences in favor of the non-moving party. Podiatrist Ass'n, Inc. v. La Cruz Azul de P.R., Inc., 332 F.3d 6, 13 (1st Cir. 2003). We will reverse a grant of summary judgment if we find that the nonmovant has "established a genuine issue of material fact that a reasonable jury could resolve in [its] favor." Collins v. Univ. of N.H., 664 F.3d 8, 19 (1st Cir. 2011) (emphasis omitted) (quoting Coffin v. Bowater, Inc., 501 F.3d 80, 97 (1st Cir.2007)) (internal quotation mark omitted).

A. RICO Proximate Causation

The district court found that the Harden plaintiffs had presented adequate evidence that Pfizer fraudulently promoted Neurontin for off-label treatment of bipolar disorder; that this conduct likely caused harm to the plaintiffs; and that such harm would be the expected consequence of Pfizer's conduct. See Harden IV, 2011 WL 1882870, at *5; Harden III, 754 F. Supp. 2d at 310; Harden I, 244 F.R.D. at 111. Based on these findings, the Harden

plaintiffs argue, the court should have determined that the plaintiffs survived summary judgment on the proximate causation issue. Pfizer responds that the causal chain here is too attenuated to establish proximate cause because it is based on the individual prescribing decisions of thousands of physicians who exercise independent medical judgment.

As we explained in Kaiser, slip op. at 23, our RICO analysis is controlled by the Supreme Court's decisions in Holmes v. Securities Investor Protection Corp., 503 U.S. 258 (1992), and its progeny. See Anza v. Ideal Steel Supply Corp., 547 U.S. 451 (2006); Bridge v. Phoenix Bond & Indem. Co., 128 S. Ct. 2131 (2008); Hemi Grp., LLC v. City of New York, 130 S. Ct. 983 (2010). The proximate causation question in this appeal is essentially identical to the question presented in Kaiser's appeal, and we decide here, as we did there, that the causal chain is sufficiently direct to survive the Court's test at the summary judgment stage.

First, the Harden plaintiffs need not have demonstrated that they directly relied on Pfizer's misrepresentations in order to survive summary judgment. The Supreme Court has held that direct reliance is not an element of proximate cause in a civil RICO cause of action based on mail fraud, as the plaintiffs' case is here. See Bridge, 128 S. Ct. at 2134. It is true that Kaiser, unlike the Harden plaintiffs, presented evidence that it had directly relied on Pfizer's misrepresentations in the course of

managing its formulary, but that evidence, while helpful in Kaiser's presentation to the jury, was not essential to Kaiser's ability to prove proximate cause. See Kaiser, slip op. at 30,32-36. The absence of direct reliance evidence in this case does not mean that the Harden plaintiffs' remaining evidence of causation was insufficient, as a matter of law or fact, to reach a jury.

RICO's proximate cause inquiry includes both the question of whether there is "some direct relation between the injury asserted and the injurious conduct alleged," Holmes, 503 U.S. at 268, and the consideration of three functional factors that reflect concerns of justice and administrability, id. at 269-70. Here, a reasonable jury could have found that the injury to the Harden plaintiffs was direct because the plaintiffs have adduced evidence that they were "the primary and intended victims of [Pfizer's] scheme to defraud." Bridge, 128 S. Ct. at 2139. The causal chain in this case is not so attenuated as to support summary judgment for Pfizer because, as we explained in Kaiser, Pfizer knew that the structure of the American health care system meant that almost all off-label Neurontin prescriptions written by physicians would be paid for by TPPs. See Kaiser, slip op. at 34. The Harden plaintiffs' evidence showed that Pfizer's marketing strategy specifically aimed to increase Neurontin's market share in prescriptions for bipolar disorder -- prescriptions for which TPPs would pay. See Harden IV, 2011 WL 1882870, at *5 (finding that

Pfizer "engage[d] in a nationwide fraudulent marketing campaign" aimed at increasing the number of Neurontin prescriptions for bipolar disorder even though "there [was] no reliable scientific evidence to support the use of Neurontin to treat bipolar disorder"). Under these circumstances, drawing all reasonable inferences in the plaintiffs' favor, a factfinder could conclude that the Harden plaintiffs' injury was a "foreseeable and natural consequence" of Pfizer's scheme. Bridge, 128 S. Ct. at 2144; see BCS Servs., Inc. v. Heartwood 88, LLC, 637 F.3d 750, 758 (7th Cir. 2011) ("Once a plaintiff presents evidence that he suffered the sort of injury that would be the expected consequence of the defendant's wrongful conduct, he has done enough to withstand summary judgment on the ground of absence of causation.").

Pfizer argues that because doctors exercise independent medical judgment in making decisions about prescriptions, the actions of these doctors break the causal chain. But as we held in Kaiser, slip op. at 35, the fact that some physicians may have considered factors other than Pfizer's detailing materials does not add such attenuation to the causal chain as to eliminate proximate cause. Rather, this argument presents a question of proof, to be resolved at trial, regarding the total number of prescriptions (if any) that were attributable to Pfizer's actions.

As to the functional factors in the proximate cause analysis, see Holmes, 503 U.S. at 269-70, Pfizer likewise has not

shown that there are no genuine issues of material fact. The plaintiffs presented evidence at the summary judgment stage that they would be able to calculate damages attributable to Pfizer's conduct.[9] See Holmes, 503 U.S. at 269. While the parties dispute whether there is any risk of duplicative recovery and whether the Harden plaintiffs are in the best position to bring suit, see id. at 269-70, the Harden plaintiffs' evidence that they were among the primary victims of Pfizer's scheme is enough to raise triable issues on these questions.

B. RICO But-For Causation

The Harden plaintiffs argue that the district court erred in requiring them to provide doctor-by-doctor evidence of reliance in order to survive summary judgment on but-for causation. The but-for causation question here, as in Kaiser, is whether Pfizer's allegedly fraudulent marketing campaign caused the plaintiffs to pay for more Neurontin prescriptions for bipolar disorder than they otherwise would have paid for. The Harden plaintiffs maintain that the Rosenthal report, along with other circumstantial evidence, provided strong, admissible evidence of but-for causation, and once the plaintiffs made that showing, any burden of demonstrating that physicians actually prescribed Neurontin for non-fraudulent reasons

[9] The class plaintiffs submitted the report of damages expert Dr. Raymond Hartman. As with Dr. Rosenthal's report, the district court accepted Dr. Hartman's report as evidence of damages in the Kaiser trial. See Kaiser, slip op. at 19-20, 22.

-- i.e., that a superseding cause interrupted the chain of causation -- fell upon Pfizer. Pfizer argues that physicians' decisions to prescribe Neurontin are not "superseding causes," but essential links in the Harden plaintiffs' chain of causation, and that the individualized nature of physicians' prescribing decisions renders aggregate proof inappropriate.

These arguments again track the same ground we covered in Kaiser. We conclude here, as we did there, that the Rosenthal report is capable of providing proof of but-for causation.[10] The Harden plaintiffs need not prove causation through the testimony of individual doctors. The combination of the aggregate evidence and the circumstantial evidence was enough for the Harden plaintiffs to overcome summary judgment.

As we explained in Kaiser, slip op. at 49-50, Pfizer's argument misapprehends the nature of the but-for causation inquiry. A tort plaintiff need not "prove a series of negatives; he doesn't have to 'offer evidence which positively exclude[s] every other possible cause of the accident.'" BCS Servs., 637 F.3d at 757 (alteration in original) (quoting Carlson v. Chisholm-Moore Hoist

[10] In Kaiser, slip op. at 40-48, we analyzed the admissibility of Dr. Rosenthal's report and testimony under Fed. R. Evid. 702 and Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). Pfizer will, of course, have an opportunity to argue against its admissibility at the trial of the Harden plaintiffs' claims, if Pfizer has objections specific to this case. However, at this stage of the litigation, we adopt our conclusions from Kaiser in determining that the Harden plaintiffs could rely on the report to defend against summary judgment.

Corp., 281 F.2d 766, 770 (2d Cir. 1960) (Friendly, J.)). "Once a plaintiff presents evidence that he suffered the sort of injury that would be the expected consequence of the defendant's wrongful conduct," the burden shifts to the defendant to rebut this causal inference. Id. at 758.

Although Pfizer presented testimony from doctors who stated that they prescribed Neurontin for off-label uses without relying on Pfizer's misrepresentations, the existence of these individual doctors does not defeat the implication -- clearly presented through Dr. Rosenthal's regression analysis -- that Pfizer's misinformation had a significant influence on thousands of other prescribing decisions. And in addition to the aggregate statistical evidence, the Harden plaintiffs also presented circumstantial evidence that supported an inference of causation. For instance, the plaintiffs offered documents showing that psychiatrists had almost never prescribed Neurontin for bipolar disorder until after Pfizer began its marketing campaign, at which point prescriptions jumped by 1700% in two years. Ultimately, it is a jury's task to weigh the individual testimony presented by Pfizer against the aggregate and circumstantial evidence presented by the Harden plaintiffs.

More generally, Pfizer argues that the Harden plaintiffs' use of the Rosenthal report to show but-for causation was precluded by the decisions of other courts in pharmaceutical marketing RICO

fraud cases. We reject these arguments here for the same reasons we did in Kaiser. First, regression analysis is a widely accepted method of showing causation under several causes of action, and we see no reason to reach a different conclusion for a specific subset of RICO claims based on fraudulent pharmaceutical marketing. See Kaiser, slip op. at 41-43. Second, the other pharmaceutical RICO cases are largely inapposite to a case such as this, especially where the plaintiffs allege a "quantity effect" rather than an "excess price" theory.[11] See id. at 50-53; compare UFCW Local 1776 v. Eli Lilly & Co., 620 F.3d 121, 133-36 (2d Cir. 2010). To the extent that some district courts in other circuits may have endorsed Pfizer's position that aggregate evidence is legally insufficient to prove but-for causation, we disagree, at least on the facts of this case.

C. RICO Injury

Finally, Pfizer argues that the Harden plaintiffs did not show that Neurontin was always ineffective for all bipolar patients, and hence cannot show that they suffered any injury. Although the district court did not decide Pfizer's motion for summary judgment on this basis, Pfizer urges it as an alternate

[11] In the RICO pharmaceutical marketing context, a "quantity effect" theory is an allegation that a defendant's fraud caused a plaintiff to pay for more prescriptions than it would have absent the fraud, whereas an "excess price" theory is an allegation that the defendant's fraud caused the plaintiff to pay more for the drug than it was worth. See UFCW Local 1776 v. Eli Lilly & Co., 620 F.3d 121, 129 (2d Cir. 2010).

ground for affirmance. See Hoyos v. Telecorp Commc'ns, Inc., 488 F.3d 1, 5 (1st Cir. 2007) (appellate court may affirm summary judgment on any basis apparent in the record).

For the reasons stated in Kaiser, we reject Pfizer's position that these plaintiffs must prove the individual, subjective ineffectiveness of each off-label prescription in order to establish injury. See Kaiser, slip op. at 55-58. Given that conclusion, Pfizer's argument is premature. The Harden plaintiffs have proffered clinical trial evidence that Neurontin is ineffective for bipolar disorder, which is certainly enough to raise a genuine issue of fact on the effectiveness issue. The question of whether the Harden plaintiffs suffered injury is for the jury.

D. State Law Claims

The Harden plaintiffs' complaint included a claim under the NJCFA as well as state common law claims for fraud and unjust enrichment. Pfizer's summary judgment motion did not specifically argue that the plaintiffs had failed to raise a triable issue of fact as to their state law claims, and the plaintiffs' opposition to Pfizer's motion likewise did not argue that they had overcome the summary judgment hurdle on those claims. The district court granted summary judgment to Pfizer on the state law claims without

separate discussion.[12] See Harden III, 754 F. Supp. 2d at 311. In their opening brief to this court, the Harden plaintiffs did not explicitly argue that the district court erred in granting summary judgment on the state law claims, although they argued that the court erred in denying class certification on those claims. In response, Pfizer argued for the first time that the state claims failed as a matter of law, under a number of theories.

Under these circumstances -- where both the district court record and the briefing before us is substantially incomplete on the state law issues -- we believe the best course of action is to vacate the district court's grant of summary judgment on the Harden plaintiffs' NJCFA and state common law claims. We remand so that the district court may decide any questions of state law in the first instance.

III.

The Harden plaintiffs also appeal the district court's denial of class certification, arguing that the district court erred in concluding that (1) common evidence could not demonstrate causation and damages, and (2) a class action was not the superior method of adjudication. This court reviews denials of class

[12] The district court had earlier denied class certification on the NJCFA claim on the basis that, under New Jersey law, the plaintiffs could not rely on aggregate evidence to prove class-wide causation, see Harden II, 257 F.R.D. at 332, but the court did not address this issue on summary judgment, see generally Harden III, 754 F. Supp. 2d 293.

certification for abuse of discretion. Waste Mgmt. Holdings, Inc. v. Mowbray, 208 F.3d 288, 295 (1st Cir. 2000). An abuse of discretion may occur "when a court . . . relies upon an improper factor, omits consideration of a factor entitled to substantial weight, . . . mulls the correct mix of factors but makes a clear error of judgment in assaying them[,] . . .[or] adopts an incorrect legal rule." Id. (citation omitted).

Importantly, the district court's decisions on class certification cover very similar issues as those involved in the summary judgment decision. In particular, the district court's denials of the Harden plaintiffs' second motion for class certification and motion for reconsideration pivoted on the determination that the Rosenthal report could not provide proof of causation or damages. See Harden IV, 2011 WL 1882870, at *4; Harden II, 257 F.R.D. at 331-32. This conclusion is what led the court to decide that a class action would be "unmanageable" due to the requirement of a "granular doctor-by-doctor analysis." Harden IV, 2011 WL 1882870, at *5. The legal requirements to establish proximate and but-for causation under RICO were key factors across both the summary judgment and class certification decisions, and in both instances the district court relied on many of the same decisions from other circuits that we have found to be inapposite for the case at hand.

In light of our holdings in Kaiser regarding RICO causation principles, we vacate the district court's denial of class certification[13] and remand for further proceedings. We express no view as to whether the plaintiffs can, on remand, meet the requirements of Rule 23.

IV.

The district court's grant of summary judgment in favor of Pfizer is reversed as to the Harden plaintiffs' RICO claims and vacated as to their NJCFA and state common law claims. The district court's denials of the Harden plaintiffs' renewed motion for class certification and motion for reconsideration are vacated, and the case is remanded for further proceedings consistent with this opinion. So ordered.

[13] Because we reverse the district court's grant of summary judgment on the RICO claim and vacate summary judgment on the state law claims, we need not consider whether, as Pfizer has alleged, the summary judgment decision mooted the plaintiffs' motion for reconsideration. See Harden IV, 2011 WL 1882870, at *1.