17-1483

IN THE

United States Court of Appeals

FOR THE SEVENTH CIRCUIT

SIDNEY HILLMAN HEALTH CENTER OF ROCHESTER,
and TEAMSTERS HEALTH SERVICES AND INSURANCE PLAN LOCAL 404,

Plaintiffs-Appellants,

—v.—

ABBOTT LABORATORIES, INC. and ABBVIE INC.,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
CASE NO. 13 C 586
HONORABLE SARA L. ELLIS

BRIEF AND REQUIRED SHORT APPENDIX FOR PLAINTIFFS-APPELLANTS

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APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 17-1483

Short Caption: Sidney Hillman Health Center of Rochester, et al. v. Abbott Laboratories, Inc., et al.

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party or amicus curiae, or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.

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Sidney Hillman Health Center of Rochester ("Sidney Hillman")

Teamsters Health Services and Insurance Plan Local 404 ("Teamsters")

(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:

Grant & Eisenhofer P.A.

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Hausfeld

(3) If the party or amicus is a corporation:

i) Identify all its parent corporations, if any; and

Sidney Hillman and Teamsters are not subsidiaries of any other corporations.

ii) list any publicly held company that owns 10% or more of the party's or amicus' stock:

Sidney Hillman and Teamsters are not publicly traded

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Attorney's Signature: s/ James J. Sabella Date: March 17, 2017

Attorney's Printed Name: James J. Sabella

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** X **No** ____

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Attorney's Printed Name: Mary S. Thomas

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Attorney's Signature: S/ James J. Pizzirusso Date: April 24, 2017

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Attorney's Signature: s/ Date: April 24, 2017

Attorney's Printed Name: Frank R. Schirripa

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JURISDICTIONAL STATEMENT

A. The basis for the District Court's subject matter jurisdiction was 28 U.S.C. §1331, because this action arises under the laws of the United States, and 18 U.S.C. §1964(c), because this action alleges violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §§1962, *et seq*. The District Court had supplemental jurisdiction over Plaintiffs-Appellants' state statutory and common law claims pursuant to 28 U.S.C. §1367.

B. The basis for this Court's jurisdiction over the appeal is 28 U.S.C. §1291, because this is an appeal from a final judgment.

C. On February 6, 2017 the District Court issued an Order granting Defendant-Appellees' motion to dismiss the federal claims with prejudice and declining to exercise supplemental jurisdiction over the state law claims. SA2.[1] Final judgment dismissing the case was entered February 6, 2017. SA1. Plaintiffs-Appellants filed their Notice of Appeal on March 7, 2017.

D. The appeal is from a final judgment that disposes of all of the parties' claims.

STATEMENT OF THE ISSUES PRESENTED FOR REVIEW

The issue presented is whether the District Court erred in holding as a matter of law that the requirement of proximate causation under RICO is not satisfied where:

- a defendant drug company engaged in illegal off-label promotion of a drug and made false and misleading statements concerning the safety and efficacy of the drug, designed to cause physicians to prescribe the drug instead of other safer, cheaper and more effective treatments (or no drug at all); and

[1] Citations "SA___" are to the required Short Appendix that is annexed hereto. Citations "JA___" are to the separately-bound Joint Appendix.

- in so doing, the drug company knew and intended that the prescriptions would be paid for by third-party payors, such as health and welfare plans and medical insurers ("TPPs"); but
- the drug company's misrepresentations were not made directly to, or directly relied on by, the TPPs.

STATEMENT OF THE CASE

A. Statement of Facts

1. Introduction

As alleged in the Second Amended Complaint ("SAC") (JA1), Defendant-Appellee Abbott Laboratories[2] engaged in a scheme to illegally promote the drug Depakote for uses that were not approved by the Food & Drug Administration ("FDA"). In addition, Abbott falsely claimed that Depakote was safe and effective for certain treatments when it knew that not to be the case. This lawsuit followed a governmental investigation and Abbott's guilty plea in which it admitted the essential facts concerning its illegal conduct, including that it marketed and misbranded Depakote in violation of the Food, Drug & Cosmetic Act, 21 U.S.C. §§301 *et seq*., and concealed information showing that Depakote was neither safe nor effective for many off-label uses – effectively admitting the predicate acts underlying Plaintiffs' RICO claims. JA128-29 ¶207; *see* ECF Nos. 104-1 through 104-4 in District Court's docket. In connection with its guilty plea, Abbott paid $1.6 billion to settle the criminal and related governmental civil claims. *Id.*

[2] Defendant-Appellee Abbott Laboratories engaged in the activities alleged in the SAC. Defendant-Appellee AbbVie Inc. succeeded to certain of Abbott's liabilities. JA83 ¶¶15-16. The two entities are sometimes referred to collectively herein as "Abbott" or "Defendants."

Plaintiffs-Appellants Sidney Hillman Health Center of Rochester ("Hillman") and Teamsters Health Services and Insurance Plan Local 404 ("Local 404") (collectively "Plaintiffs" or the "Funds") are TPPs that are contractually obligated to provide prescription drug benefits to their beneficiaries. JA82-83 ¶¶12-14. The SAC alleges that Abbott's illegal marketing activities caused the Funds and other TPPs to pay for off-label uses of Depakote instead of cheaper, safer or more effective alternatives (or no drug at all). JA130-33 ¶¶213-23.

2. The Limited Uses for Which Depakote Was Approved by the FDA as Safe and Effective

Divalproex sodium, which Abbott markets as "Depakote," is FDA-approved for three limited indications: (1) treatment of partial seizures that occur either in isolation or in association with other types of seizures in adults and children age 10 and over (JA87-88 ¶¶33-34, 38); (2) treatment of acute manic or mixed episodes related to bipolar disorder (JA87-88 ¶¶35, 39); and (3) prophylaxis (prevention) of migraine headaches in adults (JA87 ¶¶36-37).

The FDA has never approved Depakote for treatment of (a) dementia or agitation and aggression associated with dementia in elderly patients; (b) schizophrenia in children or adults; (c) bipolar depression; (d) developmental delay, attention-deficit disorder, and psychiatric disorders in children; or (e) symptoms associated with narcotic drug withdrawal and addiction (JA80-81 ¶¶4; JA88 40-41). Plaintiffs allege that studies have shown Depakote is neither safe nor effective in treating: (i) elderly dementia patients (JA90 ¶¶47-49) (including one study showing increased deaths); (ii) schizophrenia (JA123-24 ¶¶182, 184-85); and (iii) children with bipolar disorder (JA116-17 ¶149). Notwithstanding these studies and the lack of FDA approval, Abbott illegally marketed Depakote for these and other off-label indications.

3. Abbott's Material Misrepresentations and Omissions Regarding the Safety and Efficacy of Depakote for Off-Label Uses

The SAC alleges the Abbott made material misrepresentations and omissions in order to promote the use of Depakote for conditions for which Abbott knew Depakote had not been shown to be safe or effective. *See, e.g.,* JA82 ¶9; JA141 ¶247; JA144 ¶263; JA147 ¶276.

For example, the SAC alleges that Abbott tried to establish that Depakote was effective for control of agitation and aggression in elderly dementia patients, but studies "failed to show that Depakote was effective in treating 'signs and symptoms of mania' in elderly dementia patients." JA93 ¶60; ECF No. 104-3 ¶¶15-16. The SAC further alleges that, despite these studies, Abbott – through the CENE Enterprise, PharmaCare Enterprise, and ABcomm Enterprise – promoted Depakote as an effective treatment for precisely those conditions. *See*, *e.g.*, JA107-08 ¶113 (CENE symposium "Effective Treatment of Behavioral Disturbances in the Elderly"); JA108-09 ¶119 (CENE webcasts concerning aggression in the elderly); JA112-13 ¶134 (CENE slideshow presentation entitled "The Role of Mood Stabilizers in the Treatment of Behavioral and Psychological Symptoms of Dementia"); JA113-14 ¶¶137-40; ECF No. 104-3 ¶¶22, 24-25.

The SAC also alleges that Abbott tried, but failed, to prove Depakote was safe and effective for treating schizophrenia. JA123-24 ¶¶181-85; ECF No. 104-3 ¶¶26-31, 34. One study showed that adding Depakote to treatment "did not result in statistically significant improvement in symptoms of psychosis associated with schizophrenia." JA123 ¶182. Despite the complete lack of efficacy data, Abbott nonetheless marketed and promoted Depakote for schizophrenia. *See*, *e.g.,* JA108 ¶116; JA110-11 ¶128; JA123 ¶¶181-83; ECF No. 104-3 ¶¶32-35.

These marketing strategies were intended to and did cause physicians to write significant amounts of Depakote prescriptions. Abbott did this by creating the impression that information concerning Depakote was coming from unbiased sources such as a community of neuroscientists organized for the purpose of training other doctors. JA84 ¶17. For example, Abbott, in conjunction with Access Medical Group ("Access"), created the CENE Enterprise in an effort to influence doctors to prescribe Depakote. JA84 ¶18; JA104-07 ¶¶103-12. The "Council for Excellence in Neuroscience Education" ("CENE") was not an independent group of neuroscientists; rather, it was a front. CENE was an organization fully funded by Abbott to promote Depakote for off-label uses for which Abbott knew Depakote was ineffective. JA106 ¶109; JA107-13 ¶¶113-35. The CENE Enterprise's activities were not openly conducted by Abbott; instead, CENE was run through a network of "Faculty Members" and "Council Members" to whom Abbott paid kickbacks in exchange for their leadership in CENE programs that promoted Depakote, but who never disclosed these payments. JA111-13 ¶¶131-35.

4. The Injuries to the TPPs

Abbott's conduct and the promotional activities it supervised through the Enterprises resulted in a dramatic increase in sales of Depakote for off label uses. JA81 ¶8; JA86 ¶29; JA130 ¶212; JA131-32 ¶¶214-16. As a result, thousands of TPPs were injured.

Abbott's misconduct directly injured the TPPs, which paid for Depakote instead of cheaper, safer or more effective alternatives (or no drug at all). JA130-33 ¶¶213-23. For example, Plaintiff Hillman specifically alleges that it paid for Depakote prescribed in nursing homes, the primary entities targeted by Defendants when they marketed Depakote for the off-label treatment of dementia. JA83 ¶13. While government entities recovered for injuries resulting from Abbott's conduct through a False Claims Act settlement, that settlement does not

account for or compensate Abbott's private victims, such as TPPs, who also suffered direct economic injuries as a result of Abbott's illegal tactics.

Abbott knew that the structure of the American health care system meant that a very large proportion of off-label Depakote prescriptions would be paid for by TPPs. JA133 ¶221. Thus, the intended and expected result of Abbott's conduct was that TPPs would foot the bill for Abbott's wrongdoing.

5. Abbott's Guilty Plea

On May 7, 2012, Abbott agreed to pay $1.6 billion to resolve a criminal investigation and governmental civil claims related to Abbott's illegal off-label promotion of Depakote. JA128-29 ¶207.[3] Abbott pleaded guilty to misbranding Depakote by promoting the drug to control agitation and aggression in elderly dementia patients and to treat schizophrenia when the FDA had approved none of these uses. *Id.*

In the statement of facts filed in the criminal action, Abbott *admitted* that, from 2001 through 2006, the company marketed Depakote in combination with atypical antipsychotic drugs to treat schizophrenia, even after its clinical trials failed to demonstrate that adding Depakote was any more effective than an atypical antipsychotic alone for that use. *Id.*

The civil settlement agreement, which Abbott signed, states that Abbott illegally marketed Depakote by:

> a. *knowingly promoting the sale and use of Depakote for uses that were not approved by the Food and Drug Administration as safe and effective* ("unapproved uses"), including behavioral disturbances in dementia patients, psychiatric conditions in children and adolescents, schizophrenia, depression, anxiety, conduct disorders, obsessive-compulsive disorder, post-traumatic stress disorder, alcohol and drug withdrawal, attention

[3] The relevant documents relating to the guilty plea are in the District Court record at ECF Nos. 104-1 through 104-4 in 13-cv-05865.

deficit disorder, autism, and other psychiatric conditions. Some of these unapproved uses were not medically accepted indications for which the United States and state Medicaid programs provided coverage for Depakote. This promotion included, in part:

i. *making false and misleading statements about the safety, efficacy, dosing, and cost-effectiveness of Depakote for some of these unapproved uses*;

ii. marketing Depakote to health care professionals to control behavioral disturbances in dementia patients in nursing homes by claiming that Depakote was not subject to certain requirements of the Omnibus Budget Reconciliation Act of 1987 (OBRA) designed to prevent the use of unnecessary drugs in nursing homes and that this use of Depakote would help nursing homes avoid the administrative burdens and costs of complying with OBRA regulatory restrictions applicable to anti psychotics.

b. offering and paying illegal remuneration to health care professionals and long term care pharmacy providers to induce them to promote and/or prescribe Depakote and to improperly and unduly influence the content of company sponsored Continuing Medical Education programs, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

JA128-29 ¶207.[4]

B. Procedural History

Plaintiffs originally filed their complaint on August 16, 2013, asserting claims under RICO and under certain provisions of state law on behalf of the Funds and a putative class of other TPPs. On October 24, 2013, Abbott moved to dismiss, asserting, among other things, that the complaint failed to state a claim and also based on the statute of limitations.

On August 14, 2014 the District Court filed an Amended Opinion and Order dismissing the complaint on the basis of the statute of limitations. The Funds appealed, and on April 13, 2015, this Court unanimously reversed the judgment of the District Court and reinstated the

[4] Unless otherwise noted, all emphasis in quoted material has been supplied.

RICO and state law claims. *See Sidney Hillman Health Ctr. v. Abbott Labs., Inc*., 782 F.3d 922 (7th Cir. 2015).

On September 10, 2015, the Funds filed an amended complaint in the District Court. Abbott moved to dismiss, and on June 29, 2016 the District Court granted the motion to dismiss, with leave to replead, on the ground that the amended complaint failed adequately to plead that the Funds' injuries were proximately caused by Abbott's alleged wrongdoing. SA5-20. In particular, the Court held that a TPP can show that its injuries were proximately caused by a drug manufacturer's misrepresentations *only* if the "drug manufacturer directly made misrepresentations to the TPP." SA16. The Court held that the causal chain here was "too attenuated," because of the presence of prescribing physicians in the chain in between Abbott and the TPPs. SA17.

Given that the Plaintiffs could not allege that Abbott had directly misrepresented Depakote to them and were instead using a third-party reliance theory, the Funds filed a substantially similar SAC on August 1, 2016, and Abbott again moved to dismiss. On February 6, 2017, relying on its original opinion dismissing the amended complaint, the Court again granted the motion to dismiss on the ground that the SAC failed to plead proximate causation. SA2-4.[5] The District Court entered final judgment dismissing the case with prejudice on February 6, 2017. SA1. This appeal followed.

SUMMARY OF THE ARGUMENT

The Court below erred in holding that where a TPP asserts RICO claims based on misrepresentations by a pharmaceutical company about the safety and efficacy of a drug, the proximate cause requirement can only be satisfied if the defendant "drug manufacturer directly

[5] The Court did not reach any other grounds asserted by Abbott for dismissal.

made misrepresentations to the TPP." SA16. In *Bridge v. Phoenix Bond & Indem. Co*., 553 U.S. 639, 656 (2008), the Supreme Court unanimously held that a RICO plaintiff who suffers economic injury "by reason of" a defendant's fraud may recover "even though it was a third party, and not the plaintiff, who relied on the defendant's misrepresentation." Applying such precedent, both the First and Third Circuits have held that the existence in the chain of causation of third-party doctors between TPPs and the drug manufacturers does *not* preclude a finding of causation under RICO with respect to claims by the TPPs against the manufacturers. *See In re Neurontin Mktg., Sales Prac. & Prod. Liab. Litig*., 712 F.3d 21, 39 (1st Cir. 2013); *In re Avandia Mktg., Sales Prac. & Prod. Liab. Litig*., 804 F.3d 633, 645 (3d Cir. 2015). As the First Circuit pointed out, accepting the argument that the interposition of doctors destroys causation "would undercut the core proximate causation principle of allowing compensation for those who are directly injured, whose injury was plainly foreseeable and was in fact foreseen, and who were the intended victims of a defendant's wrongful conduct." *Neurontin*, 712 F.3d at 38. In addition, it would run directly counter to the Supreme Court's holding in *Bridge*. As such, Plaintiffs-Appellants respectfully request that this Court reverse the District Court's decision and remand for further proceedings.

ARGUMENT

I. STANDARD OF REVIEW

This Court will "review de novo a district court's dismissal of a case under Rule 12(b)(6), accepting the well-pleaded allegations in the complaint as true and drawing all reasonable inferences in favor of the plaintiff." *Musunuru v. Lynch*, 831 F.3d 880, 887 (7th Cir. 2016).

II. THE DISTRICT COURT ERRED IN HOLDING THAT THE SAC DID NOT ADEQUATELY PLEAD PROXIMATE CAUSATION[6]

In a RICO case, the burden of proving "something which snaps the 'causal chain' . . . is on the defendant." *BCS Servs., Inc. v. Heartwood 88, LLC*, 637 F.3d 750, 757 (7th Cir. 2011). Abbott failed to carry that burden here, and the District Court erred in dismissing the SAC on the ground of a lack of proximate causation.

A. The Proximate Cause Requirement Under RICO

RICO's civil damages provision allows any person injured "by reason of" a violation to recover their losses in a civil action. 18 U.S.C. §1964(c). Courts have interpreted this "by reason of" language to require a RICO plaintiff to show that a defendant's conduct was the "proximate cause" of the injury. *Corely v. Rosewood Care Ctr., Inc. of Peoria*, 388 F.3d 990, 1005 (7th Cir. 2004); *see Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258, 265-68 (1992).

The proximate cause requirement has plagued the courts, but the Supreme Court provided guidance in 2008, holding that it is a flexible concept: "Proximate cause . . . is a flexible concept that does not lend itself to a black-letter rule that will dictate the result in every case." *Bridge*, 553 U.S. at 654 (internal citations and quotation marks omitted). Instead, proximate cause should be used to hold one responsible for "the consequences of that person's own acts." *Id.* (quoting *Holmes*, 503 U.S. at 268). As this Court has recognized, "[t]he doctrine of proximate

[6] Because the District Court's opinion dismissing the SAC essentially relied on its decision dismissing the amended complaint, SA4, this brief will focus primarily on the District Court's analysis as set forth in its decision dismissing the amended complaint. SA5-20. In addition, as the District Court did not address any of Abbott's other purported grounds for dismissal other than proximate causation, this brief will not discuss such other arguments. *See Hotel 71 Mezz Lender LLC v. Nat'l Ret. Fund*, 778 F.3d 593, 607 (7th Cir. 2015) (questions not addressed below will be left "to the district court in the first instance."); *see Hyatt Int'l Corp. v. Coco*, 302 F.3d 707, 718 (7th Cir. 2002) ("[T]he wiser course is to allow the district court to consider this issue in the first instance on remand"); *Midwest Cmty. Health Serv. v. Am. United Life Ins. Co.*, 255 F.3d 374, 379 (7th Cir. 2001) ("[W]e do not reach [Appellee's] remaining arguments because they were not addressed by the district court in the first instance.").

cause . . . protects the ability of primary victims of wrongful conduct to obtain compensation . . . ." *BCS*, 637 F.3d at 756.

B. The Decision Below Is Inconsistent With Supreme Court Precedent, This Court's Prior Decisions, and the Holdings of the First and Third Circuits

The District Court held that the causal chain between Abbott and Plaintiffs was "too attenuated to establish the required proximate causation" because of the presence of intermediaries, *i.e.*, doctors, in the chain of causation. SA17. According to the District Court, the SAC failed to allege proximate causation because it failed to allege that Abbott's misrepresentations were made directly to, or directly relied on by, the Funds. SA14; SA16; *see* SA4 (proximate cause requires a "direct tie between Abbott and the Funds"). The District Court's holding confuses a lack of direct contact with a lack of direct injury, however, the very mistake the Supreme Court identified in *Bridge*. As the First Circuit held in *Neurontin*, the Supreme Court's decision in *Bridge* "forecloses th[e] argument" that, because the "misrepresentations went to prescribing doctors," the "causal link . . . must have been broken." *Neurontin*, 712 F.3d at 37; *see also Avandia*, 804 F.3d at 645 ("*Bridge* precludes that argument.").

In *Bridge*, the plaintiffs alleged RICO claims based on being deprived of winning bids at county tax-lien auctions because of defendants' misrepresentations made – *not directly to the plaintiffs* – but instead to a third party, the county. 553 U.S. at 644, 655. The district court dismissed the case on the ground that the plaintiffs had not relied on the fraudulent representations and could not prove proximate cause, but this Court reversed[7] and the Supreme Court affirmed this Court's decision.

[7] *Phoenix Bond & Indem. Co. v. Bridge*, 477 F.3d 928 (7th Cir. 2007), *aff'd*, 553 U.S. 639 (2008).

The Supreme Court explicitly held that "RICO's text provides no basis for imposing a first-party reliance requirement." *Id.* at 660. The Court further held that first-party reliance is not necessary "to ensure that there is a sufficiently direct relationship between the defendant's wrongful conduct and the plaintiff's injury to satisfy the proximate-cause principles . . . ." *Id.* at 657-58; *see id.* at 659 ("Proof that the plaintiff relied on the defendant's misrepresentations may in some cases be sufficient to establish proximate cause, but there is no sound reason to conclude that such proof is always necessary."). Therefore, despite the fact that the plaintiffs in *Bridge* were not the direct target of the misrepresentations, the Supreme Court held that they were directly harmed because they were "the primary and intended victims of the scheme to defraud," *id.* at 650, and their injuries were "a foreseeable and natural consequence of petitioners' scheme . . . ." *Id.* at 658.

Following *Bridge*, both the First Circuit in the *Neurontin* cases, and the Third Circuit in *Avandia*, rejected the rule that the District Court adopted here. In the *Neurontin* cases, TPPs brought suit against Pfizer for "fraudulent[ly] marketing . . . Neurontin for off-label uses" that caused TPPs to pay for more prescriptions than they would have otherwise. 712 F.3d at 26. "At the heart of the appeal" was whether, "as a matter of law," the plaintiffs could meet RICO's "causation requirements." *Id.* at 33. Pfizer claimed that there could be "no proximate causation" because "there are too many steps in the causal chain connecting its misrepresentations to the injury." *Id.* at 34. This is essentially the position the District Court adopted here, when it held that causal chain between Abbott and Plaintiffs was "too attenuated to establish the required proximate causation." SA17. The First Circuit held that *Bridge* "forecloses" that argument. 712 F.3d at 37. Specifically, the First Circuit explained why Pfizer (like the District Court here) was wrong in concluding that the chain of causation was "too attenuated":

> [T]he causal chain in this case is anything but attenuated. Pfizer has always known that, because of the structure of the American health care system, physicians would not be the ones paying for the drugs they prescribed. Pfizer's fraudulent marketing plan, meant to increase its revenues and profits, only became successful once Pfizer received payments for the additional Neurontin prescriptions it induced. Those payments came from Kaiser and other TPPs.

Id. at 38-39. In a further holding directly relevant to the case at bar, the Court continued:

> Kaiser was likewise a primary and intended victim of Pfizer's scheme to defraud. Its injury was a foreseeable and natural consequence of Pfizer's scheme – a scheme that was designed to fraudulently inflate the number of Neurontin prescriptions for which TPPs paid. The evidence that Pfizer had specifically targeted Kaiser for Neurontin sales in general supports the conclusion that Kaiser's injury was a natural consequence of Pfizer's fraudulent scheme, *but such evidence was not required, given the mechanisms by which Pfizer's marketing plan operated*. As Judge Posner stated in the *Bridge* case, after remand: "The doctrine of proximate cause . . . protects the ability of primary victims of wrongful conduct to obtain compensation . . . ." *BCS Servs., Inc. v. Heartwood 88, LLC*, 637 F.3d 750, 756 (7th Cir. 2011). Here Kaiser was a primary victim.

Id. at 37.

The First Circuit highlighted that the individual physicians to whom Pfizer made misrepresentations never paid for Neurontin and that TPPs were in the "best position to enforce the law" and to seek damages caused by Pfizer's wrongful conduct. *Id.* at 38. Because the scheme assumed that marketing efforts would change doctors' prescribing habits, the First Circuit concluded that the "district court correctly concluded that Kaiser met the proximate causation requirement [of RICO]." *Id*. at 40. Specifically, the Court explained:

> Pfizer fraudulently marketed to physicians with the intent that those physicians would write prescriptions paid for by Kaiser. The fraudulent scheme worked as intended, inducing a huge increase in Neurontin prescriptions for off-label uses. *Pfizer now argues that because doctors exercise independent medical judgment in making decisions about prescriptions, the actions of these doctors are independent intervening causes.* But Pfizer's scheme relied on the expectation that physicians would base their prescribing decisions in part on Pfizer's fraudulent marketing. *The fact that some physicians may have considered factors other than Pfizer's detailing materials in making their prescribing decisions does not add such attenuation to the causal chain as to eliminate proximate cause. Rather than showing a lack of proximate causation, this argument presents a*

> *question of proof regarding the total number of prescriptions that were attributable to Pfizer's actions. This is a damages question*.

Id. at 39.

The Third Circuit reached a similar result in *Avandia*, where GlaxoSmithKline ("GSK") argued that "the presence of intermediaries, doctors and patients, destroys proximate causation because they were the ones who ultimately decided whether to rely on GSK's misrepresentations." 804 F.3d at 645. Like the First Circuit, the Third Circuit explicitly rejected that argument and concluded that the TPPs were the "primary and intended victims of the scheme to defraud" and that their injury was a "'natural consequence of [the] scheme,' regardless of whether they relied on the misrepresentations." *Id.* (quoting *Bridge*, 553 U.S. at 650, 658). GSK "deliberately misrepresent[ed] the safety of Avandia" so that TPPs "paid for this drug." *Id.* That "fraudulent scheme could have been successful only if plaintiffs paid for Avandia, and this is the very injury that plaintiffs seek recovery for." *Id.* As a result, the Third Circuit held that the plaintiffs' "alleged injury is sufficiently direct to satisfy the RICO proximate cause requirement." *Id.*

The District Court attempted to distinguish *Neurontin* and *Avandia*, but its holding rests on a fundamental misreading of those decisions. According to the District Court, the "distinguishing characteristic" between cases such as *Neurontin* and *Avandia*, which held that the proximate causation requirement was satisfied, and other cases that held it was not, is "whether the drug manufacturer directly made misrepresentations to the TPP." SA16. As the discussion above demonstrates, however, both the First Circuit and the Third Circuit explicitly *rejected* the notion that direct reliance by the plaintiff on the drug manufacturer's misrepresentations is necessary in order to satisfy the proximate causation requirement. *See Neurontin*, 712 F.3d at 39 n.13 (noting that "first-party reliance was not needed"); *Avandia*, 804 F.3d at 645. In a related

Neurontin case, the First Circuit drove this point home. *See In re Neurontin Mktg. & Sales Prac. Litig.*, 712 F.3d 60, 67 (1st Cir. 2013) (evidence that Kaiser "directly relied on Pfizer's misrepresentations . . . while helpful in Kaiser's presentation to the jury, was *not essential* to Kaiser's ability to prove proximate cause."). And, as discussed above, the Supreme Court already rejected the notion that the misrepresentations have to be made directly to a RICO plaintiff in order to satisfy proximate causation. *Bridge*, 553 U.S. at 657-59.

The District Court's decision is also inconsistent with this Court's opinion in *BCS*. On remand after the Supreme Court's decision in *Bridge*, the district court granted summary judgment in favor of the defendants on the ground that the plaintiffs could not prove proximate causation. In *BCS* (*Bridge*'s name in this Court), this Court again reversed. 637 F.3d 750. The Court reaffirmed that the intended victim of a RICO violation can satisfy the proximate causation standard notwithstanding that it did not rely directly on the alleged misrepresentations. *Id.* at 756-57. While the misrepresentations were made to county officials in *BCS*, those officials were indifferent as to who ultimately won the tax liens; the county would recover the back taxes regardless. The county "did not lose even a penny." *Phoenix Bond*, 477 F.3d at 931. The competing bidders, who did not rely on the misrepresentations, "were thus the only victims of the fraud." *BCS*, 637 F.3d at 756. At bar, Abbott's aim was to sell more Depakote for off-label indications. The physicians here, like the county officials in *BCS*, were the persons deceived, but they were not harmed. The economic victims of Abbott's racketeering activity were the persons who paid for the prescriptions – predominantly TPPs. This is enough to show proximate causation. As Judge Posner wrote in *BCS*:

> 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.

Id. at 758. *See also Torres v. S.G.E. Mgmt., L.L.C.,* 838 F.3d 629, 638 (5th Cir. 2016) (noting the Fifth Circuit's agreement with *BCS* that the proximate causation requirement is satisfied where the plaintiff's injury is the expected consequence of the defendant's wrongdoing and stating: "RICO claims . . . do not require proof of first-party reliance.").

The Court below attempted to distinguish this Court's decision in *BCS* on the ground that in *BCS*, "any intervening causes were predictable." SA16 (stating that in *BCS* the "intervening 'cause and effect' was 'straightforward' and predictable and as a result did not 'weaken the inference' of causation"). But the cause and effect here was as equally straightforward and predictable as that in *BCS*. It is simply implausible, and improper on a motion to dismiss, to reject the allegations of the SAC and conclude that where a drug company spends millions of dollars on a scheme such as this, the expenditure would have no material impact on the writing of prescriptions and their submission to TPPs for payment. For example, in *United States ex rel. Brown v. Celgene Corp.*, No. 10-cv-3165, 2014 WL 3605896, at *8 (C.D. Cal. July 20, 2014), the court concluded:

> While we certainly cannot infer that no . . . prescriptions for off-label uses would have been written absent [the pharmaceutical company's] alleged misconduct, this does not mean that [the complaint] has not plausibly alleged that at least some doctors were substantially influenced by [the pharmaceutical company's] marketing. To suggest that [the] expansive, multi-faceted efforts to create an off-label market . . . did not cause physicians to prescribe [the drugs] for non-reimbursable uses strains credulity. *It is implausible that a fraudulent scheme on the scope . . . alleged . . . would be entirely feckless.*[8]

See also United States v. King-Vassel, 728 F.3d 707, 714 (7th Cir. 2013) (holding that "reasonably foreseeable intervening forces will not break the chain of proximate causation").

[8] The District Court distinguished *Celgene* on the ground that it was a False Claims Act case, and that the causation standard under the False Claims Act differs from that under RICO. SA15 n.6. Assuming, *arguendo*, that that is so, this is a distinction without a difference insofar as the *Celgene* court's analysis of the straightforward and predictable relationship between drug company misrepresentations and an increased volume of prescriptions paid for by TPPs is concerned.

In dismissing this case, the District Court relied heavily on *Hemi Group, LLC v. City of N.Y.*, 559 U.S. 1 (2010) (SA15), but *Hemi* involved a very different situation from that presented here. The *Hemi* case involved a failure by the defendant to file required reports concerning cigarette sales with the State of New York. Under the statutory scheme, the State would then forward the reports to New York City, which in turn would use them to make sure required taxes were being paid to the City. Without the reports, the City did not know who had failed to pay the tax. *Id.* at 9. The City brought a RICO claim against Hemi alleging that Hemi's failure to file the proper forms caused the City to lose millions of dollars in uncollected cigarette taxes.

The Supreme Court held that the City's claim failed to satisfy the proximate causation requirement, but stressed as part of the rationale for finding a lack of proximate causation that "[t]he State certainly *is better situated* than the City to seek recovery from Hemi. And the State has an incentive to sue – the State imposes its own $2.75 per pack tax on cigarettes possessed within the State, nearly double what the City charges." *Id.* at 12. Here, in contrast, the persons to whom the misrepresentations were made – the doctors – have no financial incentive to sue. "[P]rescribing physicians did not suffer RICO injury from [Abbott's] marketing of [Depakote]." *Avandia*, 804 F.3d at 644. In *Neurontin*, the First Circuit distinguished *Hemi* from situations involving TPPs, noting that in *Hemi*, "if the defendant's scheme could even be said to have a foreseen or intended victim, it was New York State (to whom Hemi Group owed the Jenkins Act reports), not the plaintiff New York City." *Neurontin*, 712 F.3d at 38 n.12.

In declining to follow the holding in *Bridge* that a RICO plaintiff need not allege direct reliance on the misrepresentations in order to satisfy proximate causation, the District Court quoted a statement in *Hemi* that proximate cause turns on "'the directness of the relationship between the conduct and the harm,' with foreseeability not playing a role in the analysis." SA15.

Bridge, however, was not based merely on foreseeability. In *Bridge*, the Supreme Court recognized that RICO requires "some direct relation between the injury asserted and the injurious conduct alleged." *Bridge*, 553 U.S. at 654. But *Bridge* found that directness requirement can be satisfied notwithstanding that the misrepresentations were not made to or relied on by the plaintiff. *See Bridge*, 553 U.S. at 657-58 ("[F]irst-party reliance" is not "necessary to ensure that there is a sufficiently direct relationship between the defendant's wrongful conduct and the plaintiff's injury to satisfy the proximate-cause principles articulated in *Holmes* and *Anza* [*v. Ideal Steel Supply Corp*., 547 U.S. 451 (2006)]"). The Court referred to matters such as foreseeability as well as the absence of any more immediate victims better situated to sue (which, as noted above, is also true at bar) as part of the support for its conclusion that the directness requirement was satisfied. 553 U.S. at 658. The holding in *Bridge* that a RICO plaintiff need not allege direct reliance on the misrepresentations is based on and comports fully with the directness requirement.

Furthermore, *Hemi* was a 4-1-3 decision, with no majority on the proximate cause question. The deciding vote was by Justice Ginsburg, who concurred in the judgment "[w]ithout subscribing to the broader range of the Court's proximate cause analysis." *Hemi*, 559 U.S. at 19. In such circumstances, Justice Ginsburg's position may be best viewed as the "holding of the Court." *Marks v. United States*, 430 U.S. 188, 193 (1977); *see United States v. Dixon*, 687 F.3d 356, 359 (7th Cir. 2012) ("When a majority of the justices do not agree on a single rationale for deciding a case, 'the holding of the Court may be viewed as that position taken by those Members who concurred in the judgments on the narrowest grounds.'") (quoting *Marks*). Therefore, the statements from *Hemi* concerning foreseeability on which the District Court relied are of limited precedential value.

In any event, *Hemi* did not purport to overrule *Bridge*, and "the Supreme Court has refuted the possibility of overruling precedent by implication." *Freedom from Religion Found., Inc. v. Bugher*, 249 F.3d 606, 613 (7th Cir. 2001) (citing *Agostini v. Felton*, 521 U.S. 203, 237 (1997)). "[C]ourts should not conclude that the Supreme Court's 'more recent cases have, by implication, overruled [its] earlier precedent.'" *Stop Reckless Econ. Instability Caused By Democrats v. FEC*, 814 F.3d 221, 231 (4th Cir. 2016) (quoting *Agostini v. Felton*, 521 U.S. 203, 237 (1997)); *accord United States v. Jimenez-Banegas*, 790 F.3d 253, 259 (1st Cir. 2015); *Conover v. Aetna US Healthcare, Inc*., 320 F.3d 1076, 1079 (10th Cir. 2003); *see Tavoulares v. Piro*, 759 F.2d 90, 109 n.18 (D.C. Cir. 1985) (Courts of Appeals are "reluctant to read" a Supreme Court decision "as overruling, *sub silentio*, . . . a well-reasoned and well-established line of authority.").

The other Supreme Court cases relied on by the District Court are similarly inapposite. In *Anza* (SA12; SA15), the Court precluded recovery of profits that the plaintiff allegedly lost to a rival who lowered prices by failing to charge sales tax, because the "direct victim of this conduct was the State," which "was being defrauded and . . . lost tax revenue as a result." 547 U.S. at 458. At bar, the fraud did not cost the physicians any money.

And in *Holmes* (SA12), the plaintiff Securities Investor Protection Corporation ("SIPC") alleged that the defendant engaged in a stock manipulation scheme that caused two broker-dealers to become insolvent, which then required SIPC to reimburse the broker-dealers' customers' losses. 503 U.S. at 261-63. The Supreme Court held that the claim failed to satisfy the proximate causation requirement because "the link is too remote between the stock manipulation alleged and the customers' harm, being purely contingent on the harm suffered by

the broker-dealers." *Id.* at 271. Here, the injury to the TPPs is not derivative of any injury suffered by the prescribing physicians.

The Supreme Court recently confirmed that the basis for the results in *Holmes* and *Hemi* was that the harm to the plaintiffs in those cases was "derivative of 'misfortunes visited upon a third person by the defendant's acts.'" *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 134 S. Ct. 1377, 1390 (2014) (quoting *Holmes*, 503 U.S. at 268-69, and citing *Hemi*, 559 U.S. at 10-11). That is simply not the case here.

The District Court's reliance on *Int'l Brotherhood of Teamsters, Local 734 Health & Welfare Trust Fund v. Philip Morris Inc.*, 196 F.3d 818 (7th Cir. 1999) (SA13), was also misplaced. In *Philip Morris*, this Court found RICO proximate cause lacking in a suit by welfare benefits funds and health insurers against cigarette manufacturers, based on fraudulent marketing, for costs incurred in providing health care services to insured cigarette smokers. The facts here are plainly distinguishable. In *Philip Morris,* plaintiffs did not seek to recover money paid to the defendant tobacco companies for their tobacco products; instead they sought recovery of money paid to physicians and hospitals that treated their insureds for harm caused by the tobacco products their insureds purchased because of fraudulent marketing. Plaintiffs here, by contrast, paid money (directly or indirectly) to Abbott for Depakote. If Plaintiffs here were seeking recovery for paying to treat injuries to their insureds from taking Depakote, this case might be analogous to *Philip Morris*. But they aren't, they are seeking their out of pocket drug costs caused by Abbott's fraudulent marketing to doctors who prescribed Depakote to the Funds' insureds.[9]

[9] Other Circuit Court cases relied on by the District Court also do not support its decision. In *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121 (2d Cir. 2010) (SA13), the Second Circuit found class certification properly denied based on proximate cause problems with the plaintiffs' theory that Eli Lilly's *(Cont'd)*

Lastly, one additional reason given by the District Court for finding that the interposition of doctors between Abbott and the TPPs makes the chain of causation too attenuated is that the case would involve individualized inquiries into the prescribing physicians' decision making processes. SA18. Assuming *arguendo* that that would be the case (an issue which Plaintiffs-Appellants dispute and which is inappropriate for consideration of a motion to dismiss record), this merely raises "a question of proof regarding the total number of prescriptions that were attributable to [Abbott's] actions" and "is a damages question," not an issue relating to proximate causation. *Neurontin*, 712 F.3d at 39. The District Court recognized that this was a damages issue, but mistakenly viewed damages issues as central to the proximate cause analysis. SA18. This is incorrect. "Proximate cause and certainty of damages, while both related to the plaintiff's responsibility to prove that the amount of damages he seeks is fairly attributable to the defendant, are distinct requirements for recovery in tort." *Anza*, 547 U.S. at 466 (Thomas, J., concurring in part and dissenting in part).

In the *Neurontin* cases, the First Circuit specifically rejected the drug company's argument that "because doctors exercise independent medical judgment in making decisions about prescriptions, the actions of these doctors break the causal chain." *Neurontin*, 712 F.3d at 67. The Court held:

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misrepresentations caused the insurers to overpay for Zyprexa. But here, the TPPs claim damages for unnecessary prescriptions, *not* inflated prices. Furthermore, the Second Circuit refused to grant Eli Lilly summary judgment on proximate causation grounds regarding the insurers' claim that Eli Lilly's misrepresentations as to safety and efficacy caused excess prescriptions, instead remanding it. *Id.* at 136. The District Court also relied on *United Food & Commercial Works Central Pa. & Regional Health & Welfare Fund v. Amgen, Inc.*, 400 F. App'x 255 (9th Cir. 2010) (SA13), but that was a non-precedential opinion dismissing the complaint in part for failing plead fraud with the particularity required by FED. R. CIV. P. 9(b). Furthermore, the causal chain in that case contained many more links than that at bar, and the opinion contains no holding that doctors' decisions break the causal chain. At the class certification stage after remand and discovery, the District Court can properly consider any arguments on these issues.

> [T]he 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.

Id. In *Celgene*, the court similarly rejected the notion that the involvement of physicians interferes with the causal connection:

> That physicians exercised their independent judgment does not defeat the causal connection here – [the complaint] specifically alleges [the pharmaceutical company] manipulated physicians' judgment with misleading articles and studies such that they could not make "objective and informed decisions." (*See, e.g.*, TAC ¶ 176); *see also, e.g.*, *U.S. ex rel. Nathan v. Takeda Pharms. North Am., Inc.*, 2011 WL 3911095, at *5 (E.D. Va. Sept. 6, 2011), *aff'd*, 707 F.3d 451 (4th Cir. 2013) (noting that causation [is] sufficiently pled, notwithstanding independent judgment of physicians, where there are allegations "that the judgment of [the] physician was altered or affected by the defendant's fraudulent activities"). . . . . "Rather than showing a lack of proximate causation, [the pharmaceutical company's] argument presents a question . . . regarding the total number of prescriptions that were attributable to [the pharmaceutical company's] actions." *See In re Neurontin Mktg. & Sales Prac. Litig.*, 712 F.3d 21, 39 (1st Cir. 2013). Such an argument about the potential scope of [the pharmaceutical company's] liability is premature at this stage.

2014 WL 3605896, at *8.

As was the situation in *Avandia* and *Neurontin*, this case is "more akin to *Bridge* than to *Holmes*, *Anza*, or *Hemi*." *Avandia*, 804 F.3d at 643. It is respectfully submitted that this Court should join the First and Third Circuits in holding that in order to satisfy the proximate cause requirement under RICO, a TPP does not have to allege direct reliance on misrepresentations and off-label marketing by the drug company defendant, and hold that the pleading here was sufficient.

C. The Rule Adopted in *Neurontin* and *Avandia* Serve the Purposes of RICO and the Proximate Cause Requirement Far Better Than the Rule Adopted Below

This Court should not strain to import a first-party reliance requirement into RICO when "RICO's text provides no basis for imposing a first-party reliance requirement." *Bridge*, 553

U.S. at 660. The results reached in *Neurontin* and *Avandia* comport far better with the purposes and policies underlying RICO and the requirement of proximate causation than the rule adopted by the Court below.

A key purpose of civil RICO is "to compensate for economic and business injuries such as those claimed by" person harmed by racketeering activities, including medical insurers. *Blue Cross & Blue Shield of N.J., Inc. v. Philip Morris, Inc.*, 36 F. Supp. 2d 560, 573 (E.D.N.Y. 1999); *see Shearson/American Express Inc. v. McMahon*, 482 U.S. 220, 240-41 (1987) (RICO's legislative history reflects intent to provide a remedy to the victims of racketeering); *United States v. Lee Stoller Enter., Inc.*, 652 F.2d 1313, 1317 (7th Cir. 1981) ("Congress specifically directed that RICO 'shall be liberally construed to effectuate its remedial purposes.'"). The decision below improperly denies "compensation for those who are directly injured, whose injury was plainly foreseeable and was in fact foreseen, and who were the intended victims of a defendant's wrongful conduct." *Neurontin*, 712 F.3d at 38; *see Sedima v. Imrex Corp.*, 473 U.S. 479, 497-98 (1985).

To understand the proper scope and application of RICO's proximate causation requirement, in *BCS* this Court examined its purpose at common law. This Court explained that one of the most important rationales for the proximate causation requirement is to "protect[] the ability of primary victims of wrongful conduct to obtain compensation." *BCS*, 637 F.3d at 756. As stated in *BCS*, allowing

> secondary or tertiary or even more remote tort victims to obtain a judgment would dim the primary victim's prospects of obtaining redress for his injury. Any tortfeasor's resources are limited. The more plaintiffs there are clamoring for relief, the less in damages each one may be able to recover.
>
> * * * *
>
> The doctrine of proximate cause thus protects the ability of primary victims of wrongful conduct to obtain compensation; simplifies litigation; recognizes the limitations of deterrence (unforeseeable consequences of a person's acts will not

> influence his decision on how scrupulously to comply with the law); and eliminates some actual or possible but probably minor causes as grounds of legal liability. All this is true in RICO cases just as in other tort cases whether common law or statutory.

637 F.3d at 755-56 (emphasis omitted).

Here, the "primary victims" are the TPPs. Just like the plaintiffs in *Bridge*, they are the ones with the "direct financial injury." *Bridge*, 553 U.S. at 658; *see Neurontin*, 712 F.3d at 38 (the TPP plaintiff "is the party that directly suffered economic injury from Pfizer's scheme").

Furthermore, because increased payments by TPPs were foreseeable and, indeed, intended by Abbott, JA132 ¶219; JA133 ¶221, allowing the Funds to sue will have a deterrent effect. As the First Circuit concluded in *Neurontin*, holding a drug manufacturer liable to TPPs for misrepresentations and off-label marketing "will have an effect in deterring wrongful conduct" because "the effect of that wrongful conduct was clear in foresight, not hindsight." 712 F.3d at 39.

In addition, the Supreme Court cases that the District Court relied on all emphasize that a critical factor in determining whether a plaintiff's claims satisfy the proximate causation requirement is whether there is a better situated person with an incentive to sue. *See, e.g.*, *Hemi*, 559 U.S. at 12 ("One consideration we have highlighted as relevant to the RICO 'direct relationship' requirement is whether better situated plaintiffs would have an incentive to sue."); *Anza*, 547 U.S. at 460; *Holmes*, 503 U.S. at 269-70. No such person exists here. If, as the District Court held, the TPPs are only indirect economic victims of Abbott's fraud, who are the direct victims? Certainly not doctors, who did not use or pay for the Depakote prescriptions themselves. Nor are the insured consumers who used Depakote, since they did not pay for the drug (except perhaps sometimes a minimal co-pay). The TPPs are "in the best position to enforce the law," because they are the ones who suffered the true economic loss here.

Neurontin, 712 F.3d at 38. Indeed, no one else appears to have any comparable incentive to sue. Under the District Court's analysis, no one suffered direct economic injury, and Abbott gets a free pass. If the TPPs cannot sue under RICO, "[t]hat could mean that no viable plaintiffs would remain to 'vindicate the law as private attorneys general.'" *Id.* at 38 n.12 (quoting *Holmes*, 503 U.S. at 260-70).

CONCLUSION

Left standing, the rule adopted below deals a fatal blow to claims that RICO was designed to promote, and denies relief to "those who are directly injured, whose injury was plainly foreseeable and was in fact foreseen, and who were the intended victims of a defendant's wrongful conduct." *Neurontin*, 712 F.3d at 38.

Plaintiffs-Appellants respectfully submit that the District Court's February 6, 2017 Order should be reversed and its February 6, 2017 Judgment should be vacated, with costs.[10]

Dated: May 5, 2017

Respectfully submitted,

/s/ James J. Sabella

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[10] Rule 36 of this Circuit's Rules provides that where a judgment is reversed after trial, on remand it should be assigned to a different District Judge. While the Rule does not apply automatically to reversals where the judgment did not result from a trial, this Court will nevertheless "apply it in our discretion to avoid the operation of bias or mindset which seems likely to have developed from consideration and decision of motions to dismiss or motions for summary judgment and the like." *Cange v. Stotler & Co.*, 913 F.2d 1204, 1208 (7th Cir. 1990). If this Court decides to reverse again, application of Rule 36 and the assignment of a new judge would appear appropriate. *See BCS*, 637 F.3d at 761 ("As this is the second reversal of the district judge in the same case, we think it best to spread the pain and invoke our Rule 36").

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CERTIFICATE OF COMPLIANCE WITH RULE 32(a)(7)

I hereby certify pursuant to FED. R. APP. P. 32(a)(7) and Circuit Rule 32(b) that the attached brief is proportionally spaced, has a typeface (New Times Roman) of 12 points for the text and 11 points for the footnotes, and contains 8,083 words (excluding, as permitted by FED. R. APP. P. 32(a)(7)(B), the corporate disclosure statement, table of contents, table of authorities, and certificate of compliance), as counted by the Microsoft Word processing system used to produce this brief.

/s/ James J. Sabella
James J. Sabella

PROOF OF SERVICE

The undersigned, counsel for the Plaintiffs-Appellants, hereby certifies that on May 5, 2017, two copies of the Brief and Required Short Appendix of Appellants and one copy of the Stipulated Joint Appendix as well as a digital version containing the brief, were delivered by overnight mail to counsel for the Defendants-Appellees.

/s/ James J. Sabella
James J. Sabella

STATEMENT UNDER CIRCUIT RULE 30(d)

I hereby certify that the Short Appendix annexed hereto and the separately bound Stipulated Joint Appendix submitted herewith contain all of the material required by Circuit Rule 30(a)-(b)

/s/ James J. Sabella
James J. Sabella

SHORT APPENDIX

Table of Contents

IN THE UNITED STATES DISTRICT COURT
FOR THE
NORTHERN DISTRICT OF ILLINOIS

Sidney Hillman Health Center of Rochester et al,

Plaintiff(s),

v.

Abbott Laboratories et al,

Defendant(s).

Case No. 13-cv-5865
Judge Sara L. Ellis

JUDGMENT IN A CIVIL CASE

Judgment is hereby entered (check appropriate box):

☐ in favor of plaintiff(s)
and against defendant(s)
in the amount of $,

which ☐ includes pre–judgment interest.
☐ does not include pre–judgment interest.

Post-judgment interest accrues on that amount at the rate provided by law from the date of this judgment.

Plaintiff(s) shall recover costs from defendant(s).

☐ in favor of defendant(s)
and against plaintiff(s)

.

Defendant(s) shall recover costs from plaintiff(s).

☒ other: The Court dismisses the RICO claims with prejudice and the state law claims without prejudice subject to refiling in state court.

This action was *(check one)*:

☐ tried by a jury with Judge presiding, and the jury has rendered a verdict.
☐ tried by Judge without a jury and the above decision was reached.
☒ decided by Judge Sara L. Ellis on a motion to dismiss the second amended class action complaint.

Date: 2/6/2017

Thomas G. Bruton, Clerk of Court

Rhonda Johnson , Deputy Clerk

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

SIDNEY HILLMAN HEALTH CENTER OF ROCHESTER and TEAMSTERS HEALTH SERVICES AND INSURANCE PLAN LOCAL 404, on behalf of themselves and all others similarly situated,	)	
Plaintiffs,	)	No. 13 C 5865
v.	)	Judge Sara L. Ellis
ABBOTT LABORATORIES and ABBVIE INC.,	)	
Defendants.	)	

ORDER

The Court grants Defendants' motion to dismiss the second amended class action complaint [125]. The Court dismisses the RICO claims with prejudice and the state law claims without prejudice subject to refiling in state court. This case is terminated. See Statement for further details.

STATEMENT

Plaintiffs Sidney Hillman Health Center of Rochester and Teamsters Health Services and Insurance Plan Local 404 (collectively, the "Funds") are multi-employer benefit plans and health services funds that provide health benefits, including prescription drug coverage, to their members. The Funds seek to represent a nationwide class of such third-party purchasers or third-party payors ("TPPs") who from 1998 to 2012 reimbursed and paid all or some of the purchase price for Depakote, a drug developed and initially marketed by Abbott Laboratories and later by AbbVie, Inc. (collectively, "Abbott"), for indications not approved by the Food and Drug Administration (the "FDA").[1] The Funds also seek to represent subclasses of TPPs in New York and Massachusetts. The Funds bring claims for violation of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962(c), conspiracy to violate RICO, 18 U.S.C. § 1962(d), violation of the New York deceptive business practices act, N.Y. Gen. Bus. Law. § 349, and unjust enrichment under New York and Massachusetts law. The Court

[1] In 2012, Abbott Laboratories split into two separate companies, Abbott Laboratories, focused on the development and sale of medical products, and AbbVie, Inc., focused on the development and sale of pharmaceuticals. AbbVie, Inc. currently sells and markets Depakote in the United States, while Abbott Laboratories does so outside the United States. The Court will not differentiate between the two in this Order.

dismissed the Funds' initial complaint on statute of limitations grounds, Doc. 67, but the Seventh Circuit reversed that decision and remanded the case for further proceedings, *Sidney Hillman Health Ctr. of Rochester v. Abbott Labs., Inc.*, 782 F.3d 922 (7th Cir. 2015). The Funds then filed an amended class action complaint ("amended complaint"), which the Court also dismissed without prejudice. Doc. 117. In dismissing the amended complaint, the Court found that the Funds did not adequately allege proximate cause under RICO. *Id.* at 13–15. Having dismissed the RICO claims, the Court declined to address the state law claims, deferring consideration of Abbott's arguments on those claims until the Funds adequately alleged a basis for the Court's subject matter jurisdiction.

Specifically, in finding the Funds did not adequately allege the proximate cause required for a prescription drug TPP RICO case, the Court considered whether Abbott "directly made misrepresentations to the TPP," finding that without such direct representations, "intervening factors—such as a physician's independent medical judgment or a patient's decisionmaking—interrupt the chain of causation." Doc. 117 at 12. Because the Funds did not allege that Abbott made any direct misrepresentations to them, omitting any mention about the prescription reimbursement process or how they came to pay for Depakote and instead focusing on the alleged representations Abbott and its co-conspirators made to doctors, patients, and caregivers, the Court found the chain of causation too attenuated to establish the required proximate cause. *Id.* at 13.

The Funds responded by filing a second amended class action complaint ("second amended complaint"), asserting the same claims raised in the amended complaint. Indeed, the Funds' second amended complaint basically copies the amended complaint, with the sole addition of five paragraphs, Doc. 119 ¶¶ 217–21.[2] But instead of including allegations to cure the identified defects in the chain of causation, these additional paragraphs allege the following: physicians write prescriptions without specifying an indication for the medication, meaning that even the FDA must use incomplete data in estimating the percentage of prescriptions written for particular indications. Abbott knew this to be the case, and also knew that TPPs paid a substantial portion of the cost of all prescription drugs. Because drugs are commonly added to a TPP's formulary whenever the FDA approves the drug for any indication, and most TPPs do not inquire into the indication for which drugs are prescribed, this meant Abbott had not reason to direct false statements to TPPs whose drug coverage was not indication-dependent. Instead, Abbott directed its marketing of off-label Depakote prescriptions to doctors.

Based on the Funds' apparent failure to cure the defects identified by the Court in its June 29, 2016 Opinion and Order, Abbott filed a motion to dismiss the second amended complaint. Abbott highlighted that the Funds' new allegations acknowledged that they did not meet the Court's proximate causation test, as the Funds alleged that "Abbott knew there was no reason to direct false statements at TPPs whose drug coverage is not indication-dependent in order to induce coverage or a listing on a formulary." Doc. 119 ¶ 220. In Abbott's view, the Funds merely amended their complaint to further any future arguments they might make at the appellate

[2] The Court presumes familiarity with its June 29, 2016 Opinion and Order, Doc. 117. Because the second amended complaint mirrors the amended complaint in all but these five additional paragraphs, the Court does not repeat the factual allegations here but refers the reader to the background section in its June 29, 2016 Opinion and Order, Doc. 117 at 2–6.

level. In response, the Funds reinforced Abbott's point, acknowledging that their new allegations "explain why [the Court's standard] is nearly impossible to meet" and suggesting that the Court erred in its proximate cause analysis. Doc. 126 at 2–3. Giving short shrift to Abbott's motion, the Funds merely incorporated their arguments from prior briefing and stated that "[i]f, despite the new allegations and Plaintiffs' arguments (here and in earlier rounds of briefing on Defendants' dismissal motions), the Court still finds it appropriate to dismiss the case (presumably with prejudice), then this will be another issue to be resolved in the appellate arena." *Id.* at 3. Essentially, then, the Funds concede that under the Court's proximate cause analysis, their second amended complaint fails.

The Court sees no need to reengage in an extensive analysis of the proximate cause requirements, particularly where the Funds have not presented the Court with any reason to deviate from its prior analysis. The Court's conclusions were recently reaffirmed in another TPP case pending in this district recently, although in that case the court found the plaintiff satisfied the requirements by providing details regarding misrepresentations the defendants made to the TPP plaintiff and about the TPP's formulary procedures, in addition to "provid[ing] a better explanation . . . for why the complaint lacks certain details and for why certain seemingly extraneous details are actually relevant." *See In re Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, 14 C 8857, 2016 WL 4091620, at *2–5 (N.D. Ill. Aug. 2, 2016). Here, the Funds fall far short, instead alleging that Abbott had no reason to make representations to TPPs because, based on the fact that TPPs cover most prescriptions regardless of the indication for which they are prescribed, Abbott should have known that the Funds would pay for off-label Depakote. Without a more direct tie between Abbott and the Funds, the Court finds that the Funds have again failed to allege proximate cause so as to allow them to proceed on their RICO claim. *See* Doc. 117 at 12–15. This also means that the Funds' RICO conspiracy claim fails. *See United Food & Commercial Workers Unions & Emp'rs Midwest Health Benefits Fund v. Walgreen Co.*, 719 F.3d 849, 856–57 (7th Cir. 2013). The Court dismisses the RICO claims with prejudice, allowing the Funds the opportunity to challenge the seemingly "impossible" proximate cause standard on appeal. And because the Court dismisses the claims over which it has original jurisdiction and the Funds have not pleaded an independent basis for jurisdiction over the state law claims, the Court declines to exercise supplemental jurisdiction over the state law claims and dismisses them without prejudice.

Date: February 6, 2017 /s/ Sara L. Ellis

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

SIDNEY HILLMAN HEALTH CENTER OF ROCHESTER and TEAMSTERS HEALTH SERVICES AND INSURANCE PLAN LOCAL 404, on behalf of themselves and all others similarly situated,	)	
Plaintiffs,	)	No. 13 C 5865
v.	)	Judge Sara L. Ellis
ABBOTT LABORATORIES and ABBVIE INC.,	)	
Defendants.	)	

OPINION AND ORDER

Sidney Hillman Health Center of Rochester ("Hillman") and Teamsters Health Services and Insurance Plan Local 404 ("Local 404," and collectively with Hillman, the "Funds") are multi-employer benefit plans and health services funds that provide health benefits, including prescription drug coverage, to their members. The Funds seek to represent a nationwide class of such third-party purchasers or third-party payors ("TPPs") who from 1998 to 2012 reimbursed and paid all or some of the purchase price for Depakote, a drug developed and initially marketed by Abbott Laboratories and later by AbbVie, Inc. (collectively, "Abbott"), for indications not approved by the Food and Drug Administration (the "FDA").[1] The Funds also seek to represent subclasses of TPPs in New York and Massachusetts. The Funds bring claims for violation of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962(c), conspiracy

[1] In 2012, Abbott Laboratories split into two separate companies, Abbott Laboratories, focused on the development and sale of medical products, and AbbVie, Inc., focused on the development and sale of pharmaceuticals. AbbVie, Inc. currently sells and markets Depakote in the United States, while Abbott Laboratories does so outside the United States. The Court will not differentiate between the two in this Opinion and Order.

to violate RICO, 18 U.S.C. § 1962(d), violation of the New York deceptive business practices act, N.Y. Gen. Bus. Law. § 349, and unjust enrichment under New York and Massachusetts law.[2] Abbott has moved to dismiss the amended class action complaint. Because the Funds have not adequately alleged proximate cause under RICO, the Court dismisses the RICO claims. With the dismissal of the federal claims, the Court declines to address the state law claims, deferring consideration of Abbott's arguments on these issues until the Funds have adequately alleged a basis for the Court's subject matter jurisdiction.

BACKGROUND[3]

Since 1983, the FDA has approved Depakote (divalproex sodium), which is sold and marketed by Abbott, for the treatment of epileptic seizures, acute manic or mixed episodes associated with bipolar disorder, certain absence seizures for adults and children over ten years old, and adult migraine prevention and prophylaxis. The FDA has not approved Depakote for the treatment of dementia, including agitation associated with dementia, bipolar depression, schizophrenia, attention deficit hyperactivity disorder ("ADHD"), narcotic drug withdrawal, or any other uses.

Nonetheless, Abbott has marketed Depakote for such unapproved "off-label" uses. To do so, it has used intermediary marketing firms, allegedly independent entities, paid physician

[2] The Court previously dismissed the Funds' complaint on statute of limitations grounds, Doc. 67, but the Seventh Circuit reversed that decision and remanded the case for further proceedings, *Sidney Hillman Health Ctr. of Rochester v. Abbott Labs., Inc.*, 782 F.3d 922 (7th Cir. 2015). The Funds then filed the amended class action complaint currently before the Court.

[3] The facts in the background section are taken from the Funds' amended class action complaint and are presumed true for the purpose of resolving Abbott's motion to dismiss. *See Virnich v. Vorwald*, 664 F.3d 206, 212 (7th Cir. 2011); *Local 15, Int'l Bhd. of Elec. Workers, AFL-CIO v. Exelon Corp.*, 495 F.3d 779, 782 (7th Cir. 2007). Both parties have submitted declarations and exhibits in connection with their motions to dismiss. Although some of these documents are mentioned in the amended class action complaint or the Court could take judicial notice of them, the Court has not considered these documents in deciding the motion to dismiss, relying instead only on the allegations contained in the amended class action complaint.

spokespeople, as well as its own internal sales divisions. These efforts resulted in dramatically increased sales of Depakote, reaching $1.5 billion in 2007.

Abbott established and controlled three enterprises to promote off-label Depakote uses. First is what the Funds have termed the "CENE Enterprise," comprised of Abbott, associated physicians, the Council for Excellence in Neuroscience Education ("CENE"), and ACCESS Medical Group ("ACCESS"). CENE—a purportedly independent continuing education medical group with undisclosed ties to Abbott—disseminated materials and sponsored webinars and meetings on off-label Depakote uses. CENE also retained "faculty" and "council" physician members to promote Depakote for off-label uses. ACCESS aided CENE by creating continuing education materials, including slide show presentations for use by doctors in Abbott's speakers' bureau. The second—the so-called "PharmaCare Enterprise"—included Abbott, its sales representatives, and PharmaCare Strategies, Inc. ("PharmaCare Strategies"), a market development firm that trained Abbott employees to successfully promote Depakote for off-label uses. PharmaCare Strategies conducted its training off-site rather than at Abbott's headquarters. The third enterprise, the "ABcomm Enterprise," funneled kickbacks to physicians to increase Depakote prescriptions. The ABcomm Enterprise included physicians and other medical professionals, Abbott, and ABcomm, Inc. ("ABcomm"), a medical continuing education provider that created training materials and provided live activities. Abbott controlled and participated in each of these enterprises with the goal of increasing the amount of off-label Depakote prescriptions purchased by the TPPs.

Through these three enterprises, Abbott sponsored dinners and other programs where a physician would speak on off-label Depakote uses. Abbott directly or indirectly compensated the speaker, also paying for the meals of those physicians attending the dinners. Abbott funded

physicians' studies of Depakote, which served as a backdoor way of increasing Depakote prescriptions. Abbott also funded the development of clinical practice guidelines for Depakote that mandated its use as a first-line of defense for dementia and long-term agitation and sundown syndrome in patients suffering from dementia. The guidelines did not disclose Abbott's financial support, instead purporting to be independent. Similarly, Abbott issued supplements to medical journals disguised as peer-written articles free from pharmaceutical manufacturer influence that promoted Depakote's use for off-label indications.

In addition to working with these outside entities and physicians to promote off-label uses of Depakote, Abbott also had internal mechanisms in place to drive such sales. This included providing incentive packages to sales representatives based on their success in marketing Depakote. Abbott promoted standardized messaging among its sales representatives, providing them with scripts on how to sell physicians on prescribing Depakote for off-label uses. Abbott then had monthly contests for each district sales area, rewarding sales representatives for their delivery of the scripted messages. To optimize its targets, Abbott accessed and analyzed prescription data from Health Market Science, Inc. Abbott encouraged its sales representatives to discuss the lower cost of Depakote and its higher likelihood of reimbursement when compared to other medications such as Lamictal, an anticonvulsant used for maintenance treatment of bipolar I disorder (for which Depakote is not indicated). Abbott also instructed sales representatives to encourage physicians to use rapid loading or increased doses of Depakote in their patients, despite warning labels and other dosing instructions. Abbott blurred the lines between bipolar mania and agitation associated with dementia to make its sales appear legitimate, used data that did not relate directly to Depakote, and promoted Depakote directly to patients and caregivers at support group meetings. But because Abbott wanted to conceal its off-

label marketing, it instructed its sales representatives not to place their call notes—i.e., their summaries of sales calls with physicians—concerning off-label uses of Depakote into its computer system and instructed them to indicate discussions of on-label diagnoses instead.

Abbott marketed Depakote for off-label uses despite having no reliable evidence of its safety or efficacy for the treatment of these off-label conditions and, in some cases, having evidence that it was actually ineffective or unsafe for those conditions. For example, a study suspended in March 1999 for safety reasons "failed to show that Depakote was effective in treating the signs and symptoms of mania in elderly dementia patients." Doc. 92 ¶ 60. Abbott also started but did not complete another clinical trial to evaluate Depakote's safety and efficacy in treating agitation in elderly dementia patients in 2000 and received reports in May 2003 and December 2004 that Depakote made no meaningful difference in the treatment of elderly dementia patients when compared to a placebo group.

Nonetheless, Abbott persisted with its off-label marketing efforts. According to FDA projections, between March 2008 and February 2009, for retail outpatient Depakote prescriptions for patients over 61 years old, approximately 11% were associated with a schizophrenia diagnosis, 6.1% with a dementia diagnosis, and 5.4% with a depression diagnosis. Over the same time period, more than 12% of retail outpatient Depakote prescriptions for patients 17 years or older were associated with a schizophrenia diagnosis, nearly 17% of retail outpatient Depakote prescriptions for patients between 12 and 16 years old were associated with an ADHD diagnosis, and 25% of retail outpatient Depakote prescriptions for patients between 17 and 20 were associated with conduct disturbance or impulse control disorder diagnoses. From March 2002 to February 2009, approximately 11.3% of retail outpatient Depakote prescriptions for patients over 61 years old were associated with dementia, schizophrenia, or depression. During

this same time period, nearly 9% of retail outpatient Depakote prescriptions written for patients 17 years or older were for schizophrenia diagnoses.

Between 2007 and 2010, however, four sealed *qui tam* actions were filed against Abbott pursuant to the False Claims Act, 31 U.S.C. § 3730(b), asserting illegal marketing of Depakote for non-FDA approved uses. On February 1, 2011, the *qui tam* actions were unsealed as the United States and fifteen state governments intervened. Another state intervened two months later. After the consolidation of those actions, on May 7, 2012, Abbott agreed to pay $1.6 billion to resolve the criminal and civil claims against it.

Hillman is a multi-employer employee welfare benefit plan providing medical benefits to employees and retirees affiliated with the Rochester, New York Regional Joint Board of Workers United. Hillman paid or reimbursed its beneficiaries' use of Depakote, including Depakote prescribed by a nursing home medical director and other geriatricians whose patients were primarily over 60 years old and may have resided in nursing homes. Local 404 is a health services fund based in Springfield, Massachusetts, with over 1,000 beneficiaries. It paid tens of thousands of dollars for its beneficiaries' Depakote prescriptions between 1998 and 2012.

LEGAL STANDARD

A motion to dismiss under Rule 12(b)(6) challenges the sufficiency of the complaint, not its merits. Fed. R. Civ. P. 12(b)(6); *Gibson v. City of Chicago*, 910 F.2d 1510, 1520 (7th Cir. 1990). In considering a Rule 12(b)(6) motion to dismiss, the Court accepts as true all well-pleaded facts in the plaintiff's complaint and draws all reasonable inferences from those facts in the plaintiff's favor. *AnchorBank, FSB v. Hofer*, 649 F.3d 610, 614 (7th Cir. 2011). To survive a Rule 12(b)(6) motion, the complaint must not only provide the defendant with fair notice of a claim's basis but must also be facially plausible. *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct.

1937, 173 L. Ed. 2d 868 (2009); *see also Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678.

Rule 9(b) requires a party alleging fraud to "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). This "ordinarily requires describing the 'who, what, when, where, and how' of the fraud, although the exact level of particularity that is required will necessarily differ based on the facts of the case." *AnchorBank*, 649 F.3d at 615 (citation omitted). Rule 9(b) applies to "all averments of fraud, not claims of fraud." *Borsellino v. Goldman Sachs Grp., Inc.*, 477 F.3d 502, 507 (7th Cir. 2007). "A claim that 'sounds in fraud'—in other words, one that is premised upon a course of fraudulent conduct—can implicate Rule 9(b)'s heightened pleading requirements." *Id.* This includes fraud allegations in civil RICO complaints. *Slaney v. The Int'l Amateur Athletic Fed'n*, 244 F.3d 580, 597 (7th Cir. 2001).

ANALYSIS

I. RICO Claims

The Funds assert that Abbott violated 18 U.S.C. § 1962(c) by conducting the affairs of the CENE Enterprise, the PharmaCare Enterprise, and the ABcomm Enterprise through patterns of racketeering activity. To state a claim under § 1962(c), the Funds must demonstrate they have standing, as required by statute, and allege "(1) conduct (2) of an enterprise (3) through a pattern of racketeering activity." *DeGuelle v. Camilli*, 664 F.3d 192, 198–99 (7th Cir. 2011) (citation omitted). Additionally, to recover under RICO, the Funds must allege that their injuries arise "by reason of" a violation of § 1962, requiring both "but for" and proximate causation. 18 U.S.C. § 1964(c); *DeGuelle*, 664 F.3d at 199. Abbott argues that the Funds have not properly

alleged statutory standing, causation, racketeering activity on behalf of an enterprise, or the required two predicate acts of racketeering. Because the Court finds that the Funds have not adequately alleged proximate cause, it need not address Abbott's other arguments.

In determining whether the Funds have adequately alleged proximate cause, the Court considers "whether the alleged violation led directly to the plaintiff's injuries." *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 461, 126 S. Ct. 1991, 164 L. Ed. 2d 720 (2006). The "general tendency" is "not to go beyond the first step," i.e. to only allow those directly injured by a defendant's actions to recover under RICO. *Holmes v. Sec. Inv'r Prot. Corp.*, 503 U.S. 258, 271, 112 S. Ct. 1311, 117 L. Ed. 2d 532 (1992); *see also Hemi Grp., LLC v. City of N.Y., N.Y.*, 559 U.S. 1, 10, 130 S. Ct. 983, 175 L. Ed. 2d 943 (2010) (reiterating *Holmes*' instruction that causation theories that require going "beyond the first step . . . cannot meet RICO's direct relationship requirement"). "Such directness obviates the difficulty in assessing damages from indirect injuries; avoids complicated rules for apportioning damages among several injured parties with greater or lesser injuries; and provides the requisite level of deterrence for RICO tortfeasors." *RWB Servs., LLC v. Hartford Computer Grp., Inc.*, 539 F.3d 681, 688 (7th Cir. 2008); *see also Holmes*, 503 U.S. at 269 (setting forth justifications for direct relationship requirement). Requiring directness, however, does not mean that there cannot be multiple victims; "in fact, one of the hallmarks of a RICO violation is 'the occurrence of distinct injuries' affecting several victims." *RWB Servs., LLC*, 539 F.3d at 688 (quoting *Morgan v. Bank of Waukegan*, 804 F.2d 970, 975 (7th Cir. 1986)).

Courts considering TPPs' off-label RICO claims have reached differing conclusions as to whether the link between the alleged misrepresentations made by pharmaceutical company defendants and the ultimate injury suffered by TPP plaintiffs is sufficiently direct to meet

RICO's proximate cause requirement. Some courts have found that the chain of causation involves too many independent steps or actors. *See, e.g.*, *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 134 (2d Cir. 2010) (finding chain of causation too "attenuated" where TPPs did not "allege that *they* relied on Lilly's misrepresentations" but rather that Lilly directed its misrepresentations at doctors prescribing the drug at issue because "only the TPPs were in a position to negotiate the price paid for Zyprexa" and so "the only reliance that might show proximate causation with respect to price is reliance by the TPPs, not reliance by the doctors"); *United Food & Commercial Workers Cent. Penn. & Reg'l Health & Welfare Fund v. Amgen, Inc.*, 400 F. App'x 255, 257 (9th Cir. 2010) (TPPs failed to plead proximate causation linking alleged misconduct to alleged injury where it depended on "an attenuated causal chain that involved at least four independent links," including doctors' decisions to prescribe drug for off-label uses); *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, No. 3:09-CV-20071-DRH, 2010 WL 3119499, at *7 (S.D. Ill. Aug. 5, 2010) (finding that "multiple steps separate the alleged wrongful conduct . . . and the alleged injuries," with the "causal link necessarily involv[ing] the decision making process of the patient, the prescribing physician, and the third party payor").[4] Other courts have found proximate cause satisfied where the alleged misrepresentations concerning off-label uses of a drug caused TPPs to place the drug on their formularies and the TPP was the intended victim of the alleged scheme. *See In re Avandia Mktg., Sales Practices & Prod. Liab. Litig.*, 804 F.3d 633, 644–46 (3d Cir. 2015) (finding that

[4] Although not in the prescription drug context, the Seventh Circuit's decision in *International Brotherhood of Teamsters, Local 734 Health & Welfare Trust Fund v. Philip Morris Inc.*, 196 F.3d 818 (7th Cir. 1999), also aligns with these decisions. In *Philip Morris*, the Seventh Circuit found that the insurers sought recovery for a remote and indirect injury with a long chain of causation, as the alleged misstatements concerning the relationship between smoking and health were directed to the public in general and so affected the plaintiff insurers "(if at all) only because they may have influenced smokers." *Id.* at 825–26.

presence of intermediaries in causal chain did not destroy causal chain because the defendant "does not argue that a doctor's decision to prescribe Avandia or a patient's decision to take Avandia caused [the TPPs'] injuries" but rather "[t]he conduct that allegedly caused [the TPPs'] injuries is the same conduct forming the basis of the RICO scheme alleged in the complaint—the misrepresentation of the heart-related risks of taking Avandia that caused TPPs . . . to place Avandia in the formulary," representations made directly to the TPPs);[5] *In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21, 37 (1st Cir. 2013) (finding proximate cause where drug manufacturer directly targeted TPP for Neurontin sales and TPP was primary and intended victim of drug manufacturer's scheme, making its injury a natural consequence of that scheme). One key distinction between the facts in these groups of cases is whether the defendant pharmaceutical companies made the alleged misrepresentations directly to the TPPs or indirectly to physicians who then prescribed the drugs that the TPPs covered. *See Med. Mut. of Ohio v. Abbvie Inc.*, --- F. Supp. 3d ----, 2016 WL 427553, at *9 & n.3 (N.D. Ill. Feb. 5, 2016) (collecting cases discussing the "significance of such allegations of direct misrepresentations with respect to the outcomes reached" on proximate causation).

The Funds argue that the distinction drawn by courts relying on direct and indirect misrepresentations is misplaced and that the proximate cause analysis should turn instead on foreseeability. *See Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639, 657, 128 S. Ct. 2131, 170 L. Ed. 2d 1012 (2008) (describing the plaintiffs' injury as "the direct result" of the defendants' fraud because "[i]t was a foreseeable and natural consequence" of the defendants' scheme); *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

[5] The Supreme Court denied GlaxoSmithKline LLC's petition for a writ of certiorari in *Avandia* on June 6, 2016. --- S. Ct. ----, 2016 WL 740942.

consequence of the defendant's wrongful conduct, he has done enough to withstand summary judgment on the ground of absence of causation."); *In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 51, 58 (1st Cir. 2013) (finding sufficient evidence of proximate cause despite no direct representations to TPPs based on evidence that the alleged injury was a foreseeable and natural consequence of the defendant's scheme).[6] But *Bridge* did not change the direct relationship requirement; indeed, its mention of foreseeability arose in the context of addressing whether the alleged injury was the direct result of the claimed fraud. *Bridge*, 553 U.S. at 658. Moreover, the *Bridge* court found the justifications for the directness requirement satisfied in the circumstances before it, noting "no independent factors that account for respondents' injury, there is no risk of duplicative recoveries by plaintiffs removed at different levels of injury from the violation, and no more immediate victim is better situated to sue" because the respondents were indeed the only parties injured by the alleged misrepresentations. *Id.* at 657. And two years after *Bridge*, the Supreme Court reiterated that "in the RICO context, the focus is on the directness of the relationship between the conduct and the harm," with foreseeability not playing a role in the analysis. *Hemi Grp.*, 559 U.S. at 12 (plurality opinion noting that foreseeability test was rejected in *Anza*, that "no one has asked us to revisit *Anza*," and that "*Anza* and *Holmes* never even mention the concept of foreseeability"). Instead, only the dissent in *Hemi Group* advocated the position the Funds ask the Court to adopt. *See id.* at 25 (Breyer, J., dissenting) (arguing that the direct relationship test should "expand liability . . . *beyond* what was foreseeable, not . . . eliminate liability for what was foreseeable"); *see also Anza*, 547 U.S. at 470 (Thomas, J., concurring in part and dissenting in part) (criticizing majority for "permit[ting] a

[6] The Funds also cite to *United States ex rel. Brown v. Celgene Corp.*, No. CV 10-3165-GHK (SSx), 2014 WL 3605896, at *8 (C.D. Cal. July 10, 2014). But *Brown* discussed causation under the False Claims Act, not RICO, and so its adoption of the foreseeability standard and application of it to alleged misrepresentations made by a pharmaceutical company to physicians and the effect that had on reimbursement of off-label prescriptions does not apply here.

defendant to evade liability for harms that are not only foreseeable, but the *intended* consequences of the defendant's unlawful behavior).

Having carefully reviewed the case law and the parties' arguments concerning alleging proximate cause for prescription drug TPP RICO cases, the Court agrees that a line must be drawn to "distinguish the direct consequences in a close causal chain from more attenuated effects influenced by too many intervening causes." *Emp'r Teamsters-Local Nos. 175/505 Health & Welfare Trust Fund v. Bristol Myers Squibb Co.*, 969 F. Supp. 2d 463, 475 (S.D. W. Va. 2013). The Court finds the distinguishing characteristic to be whether the drug manufacturer directly made misrepresentations to the TPP because otherwise intervening factors—such as a physician's independent medical judgment or a patient's decisionmaking—interrupt the chain of causation:

> Where a drug manufacturer or supplier directly deceives a TPP into granting its drug favorable formulary status, the relationship between the misconduct and the harm is direct and immediate. Unlike in *Holmes* and *Anza*, the alleged misconduct (misrepresenting the safety and efficacy of a drug) is not wholly distinct from the injury (deciding to pay for the drug prescribed). Though other steps must occur for the payment to actually be made—for example, physicians' prescribing the drugs and patients' filling the prescriptions—they do not interrupt the relationship between the manufacturers' direct misrepresentations and the TPP's resulting formulary decision.

Med. Mut. of Ohio, 2016 WL 427553, at *13. The Court does not read the Seventh Circuit's decision in *BCS Services* to require a different result, because any intervening causes were predictable and so could essentially be discounted in the analysis. *BCS Servs., Inc.*, 637 F.3d at 757 (discussing that the only intervening "cause and effect" was "straightforward" and predictable and as a result did not "weaken the inference" of causation); *see also Lexmark Int'l, Inc. v. Static Control Components, Inc.*, --- U.S. ----, 134 S. Ct. 1377, 1394, 188 L. Ed. 2d 392 (2014) (noting "general tendency not to stretch proximate causation beyond the first step" unless

there are "unique circumstances" where causation "follow[s] more or less automatically" despite intervening causes (citations omitted) (internal quotation marks omitted)).

Here, the Funds have not alleged that Abbott made direct misrepresentations to them so as to cause them to place Depakote on their formularies or pay for Depakote when prescribed. Indeed, they do not mention anything about their prescription reimbursement process in the amended class action complaint or how they came to pay for Depakote, only conclusorily alleging that they have paid or reimbursed such prescriptions for ineffective and unsafe uses. The amended class action complaint instead focuses on allegations that Abbott and its co-conspirators made representations concerning Depakote's safety and efficacy for off-label uses to doctors, patients, and caregivers, encouraging them to prescribe or use Depakote in greater amounts. Such allegations introduce additional steps into the chain of causation. These additional intervening events between the alleged misrepresentations and the Funds' alleged overpayments for Depakote—doctors' independent medical decisions to prescribe Depakote over other medications and patients' decisions to fill those prescriptions, for example—make the causal chain too attenuated to establish the required proximate causation. *See UFCW Local 1776*, 620 F.3d at 134 (finding failure to allege that TPPs themselves relied on misrepresentations crucial to a lack of proximate cause); *Yasmin*, 2010 WL 3119499, at *2, 7 (absent allegations of direct communications to TPP, finding causal link too attenuated where it "necessarily involves the decision making process of the patient, the prescribing physician, and the third party payor"); *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 20 F. Supp. 3d 305, 323, 327 (E.D.N.Y. 2014) (finding chain of causation "interrupted" by the prescribing decisions of physicians, which are based on such factors as "the patient's diagnosis, past and current medications being taken by the patient, the physician's (and

the patient's) experience with a particular antibiotic, and the physician's knowledge of the side effects of the antibiotics"), *aff'd*, 806 F.3d 71 (2d Cir. 2015); *Bristol Myers Squibb Co.*, 969 F. Supp. 2d at 475 ("Between Defendants' alleged misleading marketing and Plaintiffs' prescription reimbursements lies a vast array of intervening events, including the 'independent medical judgment' of doctors." (citation omitted)); *Ironworkers Local Union No. 68 v. AstraZeneca Pharm. LP*, 585 F. Supp. 2d 1339, 1344 (M.D. Fla. 2008) ("establishing that Plaintiffs' injuries were caused by Defendants' misconduct would require an inquiry into the specifics of each doctor-patient relationship implicated by the lawsuit" because doctors use "their independent medical judgment to decide whether Seroquel is the best treatment for a given patient"), *aff'd*, 634 F.3d 1352 (11th Cir. 2011). And these intervening events are not like the automatic or predictable ones in *BCS Services* that could be discounted so as to find the Funds have adequately alleged that their injury is the expected consequence of Abbott's alleged misconduct. *See Sanofi-Aventis U.S. LLP*, 20 F. Supp. 3d at 323 (distinguishing *BCS Services* on the basis that the intervening acts in *BCS Services* were "calculable" and "predictable" while those in the TPP situation could not be readily predicted because "the prescribing decisions of physicians are based on so many factors as to defy any efforts to categorically attribute them to a particular cause"); *cf. BCS Servs., Inc.*, 637 F.3d at 757–58. As a result, as currently alleged, establishing damages would require individualized inquiries into the prescribing physicians' and individual patients' decisionmaking processes, creating difficulties in assessing damages that the directness requirement was intended to prevent. *See Yasmin*, 2010 WL 3119499, at *7 ("To assess damages, the Court would have to delve into the specifics of each physician patient relationship to determine what damages were caused by Bayer's alleged fraudulent conduct, as opposed to what damages were caused by the physician's independent medical judgment. . . . Attempting to

ascertain damages in this scenario[ ] would result in the type of speculative damages analysis the direct proximate cause requirement is intended to prevent."). Thus, the Court concludes that the Funds' allegations fail to establish a direct relationship between Abbott's misrepresentations and their alleged injury.

Because the Funds have not adequately pleaded proximate causation, the Court dismisses the RICO claim. This means their RICO conspiracy claim under § 1962(d) fails as well. *See United Food & Commercial Workers Unions & Emp'rs Midwest Health Benefits Fund v. Walgreen Co.*, 719 F.3d 849, 856–57 (7th Cir. 2013).

II. State Law Claims

The Funds also bring claims for violation of the New York Deceptive Business Practices Act, New York Gen. Bus. Law § 349, and unjust enrichment under New York and Massachusetts law. Abbott argues that these claims fail for the same reasons the RICO claims fail, namely that the Funds have not pleaded cognizable injury, materially deceptive conduct, causation, or fraud in accordance with Rule 9(b)'s pleading requirements. Additionally, it contends the Court should dismiss the unjust enrichment claims because the Funds have an adequate remedy at law. Finally, Abbott resurrects its argument that the New York claims are time-barred, despite the fact that the Seventh Circuit reinstated the Court's dismissal of the state law claims on statute of limitations grounds, binding this Court to that decision. *See Sidney Hillman Health Ctr.*, 782 F.3d at 931 ("Because the state law claims were dismissed based on similar reasoning, they are reinstated as well."); *Kovacs v. United States*, 739 F.3d 1020, 1024 (7th Cir. 2014) ("The lower court is bound, through the mandate rule, to the resolution of any points that the higher court has addressed.").

Here, the Funds have pleaded that the Court has original jurisdiction over the RICO claims pursuant to 28 U.S.C. § 1331 and supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367.[7] Because the Court dismisses the claims over which it has original jurisdiction at this time, the Court declines to exercise supplemental jurisdiction over the Funds' state law claims. The Court dismisses the state law claims without prejudice and defers consideration of the Funds' arguments on these claims until the Funds have adequately alleged a basis for the Court's subject matter jurisdiction. *See* 28 U.S.C. § 1367(c); *Groce v. Eli Lilly & Co.*, 193 F.3d 496, 501 (7th Cir. 1999) ("[I]t is the well-established law of this circuit that the usual practice is to dismiss without prejudice state supplemental claims whenever all federal claims have been dismissed prior to trial.").

CONCLUSION

For the foregoing reasons, Abbott's motion to dismiss [98] is granted. The Court dismisses the amended class action complaint without prejudice.

Dated: June 29, 2016

SARA L. ELLIS
United States District Judge

[7] The Funds do not plead that diversity jurisdiction exists, and the Court cannot proceed on the assumption that it does. *See Downs v. IndyMac Mortg. Servs., FSB*, 560 F. App'x 589, 591 (7th Cir. 2014) (refusing to find diversity jurisdiction when it was not pleaded in the complaint).