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 and ABBVIE INC.,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
CASE NO. 13-CV-5865
HONORABLE SARA L. ELLIS

BRIEF FOR DEFENDANTS-APPELLEES

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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 et al.

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Abbott Laboratories

AbbVie Inc.

(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:

Patterson Belknap Webb & Tyler LLP, Kirkland & Ellis LLP

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

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

N/A

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

N/A

Attorney's Signature: s/ William F. Cavanaugh, Jr. Date: March 21, 2017

Attorney's Printed Name: William F. Cavanaugh, Jr.

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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Abbott Laboratories

AbbVie Inc.

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Patterson Belknap Webb & Tyler LLP, Kirkland & Ellis LLP

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

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

N/A

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

N/A

Attorney's Signature: s/ Jonah M. Knobler Date: March 21, 2017

Attorney's Printed Name: Jonah M. Knobler

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

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Abbott Laboratories, defendant

Abbvie Inc., defendant

(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:

Patterson Belknap Webb & Tyler LLP

Kirkland & Ellis LLP

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

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

Neither defendant has any parent corporations.

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

No publicly held company owns 10% or more of either defendant's stock.

Attorney's Signature: s/ D. Brandon Trice Date: 6/5/2017

Attorney's Printed Name: D. Brandon Trice

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

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INTRODUCTION

Two union-affiliated trust funds (the "Funds") purport to bring this RICO suit on behalf of every third-party payor ("TPP") in the United States. They allege that AbbVie Inc. and Abbott Laboratories (together, "AbbVie")[1] promoted a medication called Depakote for "off-label" uses. The Funds assert that this promotion ultimately caused TPPs to pay for too many Depakote prescriptions.

The Funds are not the first TPPs to invoke RICO in an attempt to recoup sums spent on their beneficiaries' healthcare. A generation ago, following the tobacco industry's settlement with state governments, TPPs filed a wave of "me-too suits" under RICO, contending that manufacturers' misrepresentations about smoking had made it more expensive for them to meet their insurance obligations. *Int'l Bhd. of Teamsters, Local 734 Health & Welfare Trust Fund v. Philip Morris Inc.*, 196 F.3d 818, 820 (7th Cir. 1999) ("*Teamsters*"). Courts—including this Court—dismissed these suits at the pleadings stage for lack of proximate cause: the "chain of causation" was too "long," the intervening choices of smokers too individualized, and damages too "hard to calculate." *Id.* at 825-26.

TPPs then shifted their sights to the pharmaceutical industry, filing a raft of RICO suits alleging off-label promotion. Like the tobacco suits, they have almost always followed a manufacturer's settlement of government charges, and have almost always parroted the government's allegations of wrongdoing. The liability theories, too, mirror the tobacco cases: TPPs allege that, by improperly marketing a

[1] In 2013, AbbVie was created as an independent company to operate Abbott's research-based pharmaceutical business. The distinction between companies is not relevant here.

product (now medications, rather than cigarettes) to third parties (now doctors, rather than smokers), the manufacturers increased their costs.

Almost all of these pharmaceutical suits have met the same end as their tobacco forebears: dismissal for lack of proximate cause. As before, courts have found the causal chains too lengthy, the intervening decisions of doctors (and others) too individualized, and damages too speculative. These courts include the Second, Ninth, and Eleventh Circuits, and many district courts.[2] Judge Ellis correctly reached the same conclusion here, as did Judge Herndon in the Southern District of Illinois before her. *See Yazmin & Yaz*, 2010 U.S. Dist. LEXIS 80758, at *22-27.

Tellingly, the Funds virtually ignore the proximate-cause factors applied in *Teamsters* and many other Supreme Court and Seventh Circuit decisions—all of which support the District Court's ruling below. Instead, they dwell on two outlier decisions from the First and Third Circuits that found proximate cause satisfied in

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[2] *See Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S., L.L.P.*, 20 F. Supp. 3d 305, 323 (E.D.N.Y. 2014), *aff'd*, 806 F.3d 71 (2d Cir. 2015); *Emp'r Teamsters-Local Nos. 17/505 Health Welfare Trust Fund v. Bristol Myers Squibb Co.*, 969 F. Supp. 2d 463, 473-76 (S.D. W. Va. Jan. 29, 2013); *In re Bextra & Celebrex Mktg., Sales Practices & Prods. Liab. Litig.*, 2012 U.S. Dist. LEXIS 111446, at *218-23 (N.D. Cal. Aug. 2, 2012); *Health Care Serv. Corp. v. Pfizer, Inc.*, 2012 U.S. Dist. LEXIS 89759, at *8-11 (E.D. Tex. Apr. 23, 2012), *adopted*, 2012 U.S. Dist. LEXIS 89758 (E.D. Tex. June 28, 2012); *Health Care Serv. Corp. v. Olivares*, 2011 U.S. Dist. LEXIS 117750, at *18-25 (E.D. Tex. Sept. 2, 2011), *adopted*, 2011 U.S. Dist. LEXIS 112544 (E.D. Tex. Sept. 30, 2011); *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 134 (2d Cir. 2010); *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, 2010 U.S. Dist. LEXIS 80758, at *22-27 (S.D. Ill. Aug. 5, 2010); *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 2009 U.S. Dist. LEXIS 58900, at *86-93 (D.N.J. July 10, 2009), *aff'd*, 678 F.3d 235 (3d Cir. 2012); *Se. Laborers Health & Welfare Fund v. Bayer Corp.*, 655 F. Supp. 2d 1270, 1280-84 (S.D. Fla. 2009), *aff'd*, 444 F. App'x 401, 410 (11th Cir. 2011); *Dist. 1199P Health & Welfare Plan v. Janssen*, 784 F. Supp. 2d 508, 523-25 (D.N.J. 2011); *UFCW Cent. Pa. & Reg'l Health & Welfare Fund v. Amgen, Inc.*, 400 F. App'x 255 (9th Cir. 2010); *Ironworkers Local Union No. 68 v. AstraZeneca Pharms. LP*, 585 F. Supp. 2d 1339, 1343-45 (M.D. Fla. 2008), *aff'd*, 634 F.3d 1352 (11th Cir. 2011).

superficially similar pharmaceutical cases. Those decisions are factually distinguishable: both involved allegations that the manufacturer *directly* targeted a TPP with misrepresentations, and that the TPP *directly* relied on those misrepresentations in making coverage decisions. Moreover, both decisions erroneously equated proximate cause with mere foreseeability—a proposition rejected in *Teamsters*, and one that the Supreme Court has repeatedly repudiated, including just days before the Funds filed their brief. This Court should join the dozen or more that have dismissed RICO claims involving off-label marketing on proximate-cause grounds.

In any event, there is an alternate basis for affirmance: as this Court observed in *Teamsters*, insurers are not "injured" in *their* "business or property" when their insureds receive allegedly unsafe or ineffective medications. "The Funds…are just financial intermediaries"; it is "purchasers of insurance, not the Funds," who actually "foot the…bill" for such prescriptions through their collective premiums. *Teamsters*, 196 F.3d at 823-24. As such, the Funds' claimed injury is illusory and cannot support a RICO claim.

JURISDICTIONAL STATEMENT

The Funds' statement is complete and correct.

COUNTERSTATEMENT OF THE ISSUES

1. Did the District Court err by dismissing the Funds' RICO claims for lack of proximate causation?

2. Did the Funds' RICO claims fail for lack of a plausible out-of-pocket injury because TPPs are "just financial intermediaries?"

COUNTERSTATEMENT OF THE CASE

A. Depakote

Depakote (divalproex sodium) is a prescription medication sold by AbbVie. It was approved by the U.S. Food and Drug Administration ("FDA") in 1983 (JA80, ¶2), and it went generic in 2008, *see* Kristina Fiore, *FDA Okays Generic Divalproex Sodium (Depakote)*, MEDPAGE TODAY, July 30, 2008. To this day, Depakote appears on the World Health Organization's Model List of Essential Medicines, which identifies the "most efficacious, safe and cost-effective medicines" that constitute the "minimum…needs for a basic health-care system." WHO MODEL LIST OF ESSENTIAL MEDICINES 5 (19th ed., Nov. 2015), http://goo.gl/6jbCL4.

At all relevant times, Depakote's official label has listed three uses (or "indications"): treatment of mania associated with bipolar disorder, treatment of various types of seizures, and treatment of migraines. (JA80, ¶3.) As with many drugs, physicians also choose to prescribe Depakote for off-label uses. Some of them—including certain uses challenged in this case—are accepted by authoritative drug-information compendia. (D.Ct. Dkt. 27-3 at 192-208; Dkt. 27-4 at 2297.)

B. "Off-Label" Promotion And Use

The sale and promotion of drugs are governed by the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, which is administered by the FDA. New drugs require FDA approval before sale. *Id.* § 355(a). To secure approval, the manufacturer must demonstrate safety and efficacy for the indications on the proposed label. *Id.* § 355(d)(4)-(5).

Post-approval, "[t]he FDCA…do[es] not expressly prohibit the 'promotion' or 'marketing' of drugs for off-label use." *United States v. Caronia*, 703 F.3d 149, 154-55 (2d Cir. 2012). However, it does prohibit "misbranding" of drugs, and the FDA maintains that off-label promotion is indicative of "misbranding." *Id.* That is now in serious doubt. *See id.* at 168-69 (off-label promotion protected by the First Amendment). But even assuming the FDCA prohibits off-label promotion, only "the Federal Government"—and not "private litigants"—may "file suit for noncompliance." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001).

Moreover, physicians may lawfully *prescribe* medications "for any…use that is appropriate in their medical judgment," including "non-FDA approved ('off-label') uses." *Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196, 200 (S.D.N.Y. 2015). And they routinely do: about 21% of all U.S. prescriptions are off-label. *Id.* at 200-01. For some conditions, off-label uses represent the standard of care. *See Buckman*, 531 U.S. at 350, 351 n.5. Thus, one cannot "draw any conclusion about" the "safety or effectiveness" of a use from its "status…as off-label." James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71, 84 (1998).

C. Third-Party Payors

TPPs are entities that make payments for medical care on patients' behalf—essentially, health insurers. They include large for-profit insurers such as UnitedHealthcare and Aetna; multiemployer ERISA trusts such as the Funds; mutual-insurance societies; HMOs; and self-insuring employers. Because it bears on this

appeal, AbbVie briefly describes how TPPs make coverage determinations and how money and goods change hands in this sector.[3]

1. Coverage Determinations

A formulary is a TPP's "list[] of medications approved for coverage." *AstraZeneca*, 634 F.3d at 1366; *see* Patricia M. Danzon, Ph.D., 2014 ERISA ADVISORY COUNCIL: PBM COMPENSATION AND FEE DISCLOSURE 1, U.S. Dep't of Labor, http://goo.gl/d5GYJi; FTC, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES 6 (Aug. 2005), http://goo.gl/S35jRP. TPPs ordinarily will not pay for drugs that are not on formulary. *Eli Lilly*, 620 F.3d at 126.

But formulary inclusion is just the starting point. TPPs also employ "utilization-management" restrictions to ensure that covered prescriptions are necessary and appropriate. For example, a "prior-authorization" requirement bars coverage unless the prescriber contacts the TPP and demonstrates that the prescription is proper, and a "step-therapy" requirement bars coverage unless the patient has tried and failed another regimen. *AstraZeneca*, 634 F.3d at 1366-67; FTC, *supra*, at 13-14. In 2013, approximately 35% of covered drugs were subject to a utilization-management restriction. Jeffrey Bendix, *The Prior Authorization Predicament*, MEDICAL ECONOMICS (July 8, 2014), http://goo.gl/VEiy6a.

The task of deciding which drugs to cover under which circumstances falls to a group of medical experts called a Pharmacy and Therapeutics ("P&T") Committee. *Eli Lilly*, 620 F.3d at 126; FTC, *supra*, at 10-11. P&T Committees "evaluate a wide

[3] The basic facts of how health insurance works are widely known, not subject to reasonable dispute, and thus, judicially noticeable. Fed. R. Evid. 201; *Teamsters*, 196 F.3d at 823-24.

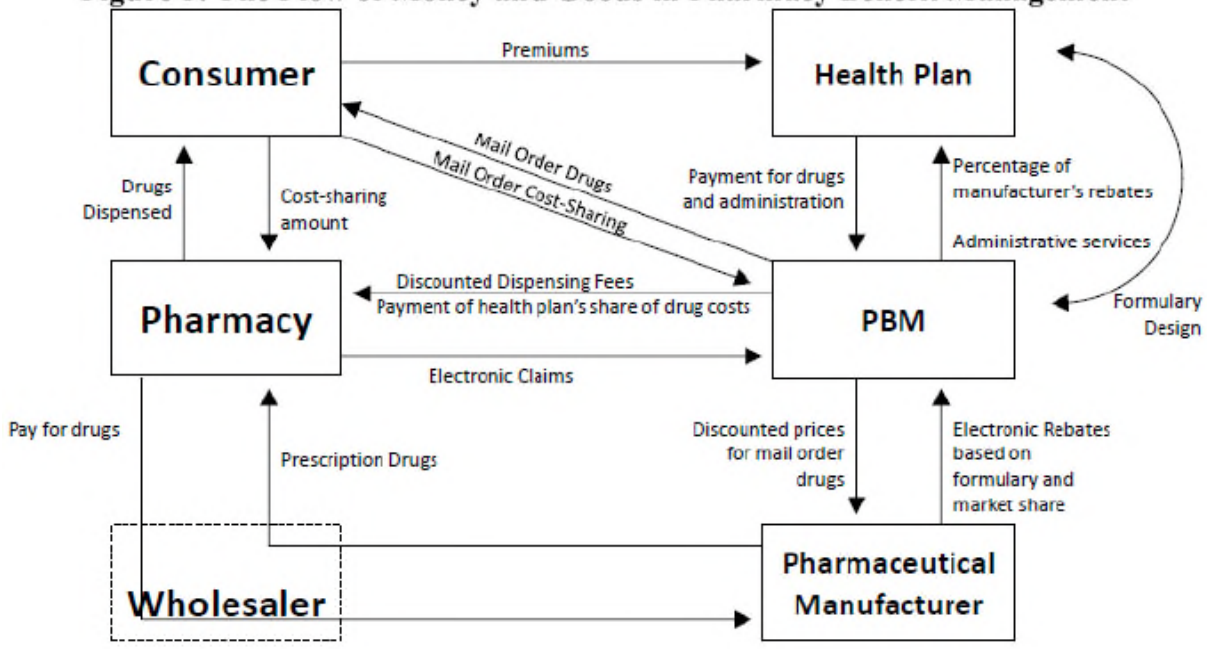
variety of available material bearing on the question of each drug's efficacy and safety"—from both the manufacturer and other sources. *Int'l Union of Operating Eng'rs Local No. 68 Welfare Fund v. Merck & Co.*, 929 A.2d 1076, 1080-81 (N.J. 2007); *In re Vioxx Class Cases*, 180 Cal. App. 4th 116, 132 (Cal. App. 2d Dist. 2009); FTC, *supra*, at 10-11. They may also "consider[] utilization data, financial information such as pricing and rebates," and "likely customer reaction." *Id.*

Larger insurers often have their own in-house P&T Committee that makes coverage decisions. Smaller TPPs such as the Funds retain a pharmacy benefit management company ("PBM"), such as CVS Health or Express Scripts, to provide this and other services. PBMs create formularies that their TPP clients may adopt outright or customize. *AstraZeneca*, 634 F.3d at 1366 & n.27; *Eli Lilly*, 620 F.3d at 126; Danzon, *supra*, at 1; FTC, *supra*, at 1-2, 12.

2. How Money And Goods Change Hands

There is no "market" for prescription drugs in the ordinary sense. *Eli Lilly*, 620 F.3d at 126. "[T]he process by which drug prices are determined is highly complex, involving numerous interactions and arrangements among manufacturers, wholesalers, retailers, insurers, [PBMs], and consumers." Dep't of Health & Human Services, REPORT TO THE PRESIDENT: PRESCRIPTION DRUG COVERAGE, SPENDING, UTILIZATION, AND PRICES 95 (Apr. 2000), http://goo.gl/lPDYJm. The following chart (from Danzon, *supra*, at 3) summarizes them:

Figure 1: The Flow of Money and Goods in Pharmacy Benefit Management



As the chart reflects, TPPs' payments for prescriptions are not ordinary bilateral transactions with manufacturers. Indeed, small TPPs such as the Funds generally do not deal with manufacturers at all. Instead, they contract with and pay PBMs to manage their pharmacy benefits. Danzon, *supra*, at 1-2; FTC, *supra*, at 1, 8-10. PBMs, in turn, contract with pharmacies to pay a negotiated price when the pharmacy fills a prescription for a covered patient. PBMs also contract with manufacturers to receive rebates for a portion of that price. PBMs sometimes pass a portion of these rebates along to their TPP clients, although these arrangements "var[y] significantly." Danzon, *supra*, at 6-7; FTC, *supra*, at 1, 4-7, 57-60; REPORT TO THE PRESIDENT, *supra*, at 95. Finally, manufacturers sell their medications either directly to pharmacies or to wholesalers that sell to pharmacies, and they pay the aforementioned rebates to PBMs. FTC, *supra*, at 4.

D. Procedural History

1. AbbVie Settles Government Proceedings Involving Depakote

Between 2007 and 2010, relators filed four False Claims Act suits alleging that AbbVie had promoted Depakote off-label to physicians in the Medicare and Medicaid programs. (JA127, ¶204.) The federal government and various state governments intervened, and the Department of Justice commenced an investigation. (*Id.*, ¶205.) In 2012, AbbVie resolved these proceedings by paying $1.6 billion and pleading guilty to misdemeanor violations of the FDCA. (JA82, ¶10; JA128, ¶207.)

In connection with the settlement, AbbVie admitted that it had promoted Depakote for two off-label uses (dementia and schizophrenia) in violation of the FDCA's prohibition on "misbrand[ing]" as then understood. (D.Ct. Dkt. 27-7 at 1.) AbbVie also admitted that certain studies had failed to demonstrate efficacy for these indications. (JA128, ¶207.) But AbbVie did not admit that Depakote is *actually unsafe or ineffective* for any use. AbbVie did not admit fraudulent intent. And AbbVie did not admit that it promoted Depakote inappropriately to *private* TPPs or caused them any damages.[4]

2. The Funds Sue; Their Complaint Is Dismissed And Reinstated

The following year, the Funds filed this lawsuit, represented by the same lawyers that filed the lead False Claims Act suit. Their allegations echoed those in the False Claims Act complaints, with large portions copied verbatim. (*See* D.Ct.

[4] The Funds misleadingly quote the settlement agreement to imply that AbbVie made broader admissions than it did. (Funds' Br. 6-7.) The quoted passages merely recite the government's "conten[tions]." The agreement was "not an admission of facts or liability" as to those contentions. (D.Ct. Dkt. 27-6 at 3-4.)

Dkt. 99-8.) The Funds asserted claims under RICO, state consumer-fraud statutes, and the common law of unjust enrichment.

In a nutshell, the Funds alleged that AbbVie promoted Depakote for various off-label uses to unidentified "physicians" and "patients" during a 14-year period "[f]rom 1998 through 2012." (Compl., D.Ct. Dkt. 1.) The Funds did not allege that AbbVie made misstatements *to them*, or that they had *relied on* any statements by AbbVie in taking any action. (Indeed, before this Court, the Funds concede that they "could not" have made such allegations. (Funds' Br. 8.))

AbbVie moved to dismiss on several grounds: failure to plead injury; failure to plead but-for or proximate causation; failure to plead conduct on behalf of a RICO "enterprise"; failure to plead fraud with particularity; and untimeliness. In August 2014, the District Court dismissed the Complaint with prejudice, finding it time-barred. *Sidney Hillman Health Ctr. of Rochester v. Abbott Labs.*, 64 F. Supp. 3d 1146 (N.D. Ill. 2014).

This Court reversed, holding that the relevant accrual date was not clear from the face of the Complaint. *Sidney Hillman Health Ctr. of Rochester v. Abbott Labs.*, 782 F.3d 922, 928 (7th Cir. 2015) ("*Hillman II*"). This Court recognized, however, that AbbVie's untimeliness argument "may eventually carry considerable weight," and held that the Funds had been insufficiently diligent to invoke equitable tolling or estoppel. *Id.* at 928, 930-31.

3. The Funds File Their Amended Complaint And The District Court Dismisses Without Prejudice

On remand, the Funds filed an Amended Complaint. (JA1.) It asserted the same misconduct as the original Complaint and "conclusorily alleg[ed]" that, as a result of that misconduct, the Funds had "paid or reimbursed [Depakote] prescriptions for ineffective and unsafe uses." *Sidney Hillman Health Ctr. of Rochester v. Abbott Labs.*, 192 F. Supp. 3d 963, 970-71 (N.D. Ill. 2016) ("*Hillman III*"). It "omitt[ed] any mention about [the Funds'] prescription reimbursement process or how they came to pay for Depakote." *Sidney Hillman Health Ctr. of Rochester v. Abbott Labs.*, No. 13-C-5865, Dkt. 128, at 2 (N.D. Ill. Feb. 6, 2017) ("*Hillman IV*").

AbbVie renewed its remaining arguments for dismissal. The District Court dismissed without prejudice, holding that the Amended Complaint flunked RICO's proximate-causation requirement, which demands a "causation theor[y]" that is "direct[]." *Hillman III*, 192 F. Supp. 3d at 968. The Funds' theory was not direct: there were too many "steps in[] the chain of causation"; their payments for Depakote were "attribut[able]" to "many factors" besides off-label promotion; and their damages were "speculative" and "difficult[] [to] assess." *Id.* at 970-72. The District Court refused the Funds' request to employ a foreseeability standard, noting that the Supreme Court had rejected such a test. *Id.*

4. The Funds File Their Second Amended Complaint And The District Court Dismisses With Prejudice

The Funds then filed a Second Amended Complaint. (JA77.) It was identical to their prior pleading "with the sole addition of five paragraphs." *Hillman IV* at 2. (JA132-33, ¶¶217-21.) Those paragraphs did not attempt to "cure the identified de-

fects in the chain of causation." *Hillman IV* at 2. Indeed, they conceded that AbbVie *did not* "direct false statements at TPPs." (JA132, ¶220.) Instead, they incorporated into the pleadings the foreseeability argument that the District Court had already rejected.

AbbVie again moved to dismiss. In response, the Funds "concede[d] that under the…proximate cause analysis" in *Hillman III*, "their [RICO claims] fail[ed]." *Hillman IV* at 3. They asked the District Court to dismiss those claims "with prejudice" so they could appeal and argue for a foreseeability standard before this Court. *Id.* In February 2017, the District Court did just that.[5]

SUMMARY OF ARGUMENT

Proximate cause "prevent[s]…intricate, uncertain inquiries from overrunning RICO litigation." *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 460 (2006). As the Supreme Court has repeatedly held, the test for RICO proximate cause is "*directness*." This notion encompasses the length of the causal chain, the presence of confounding causal influences, and the complexity and certainty of the damages analysis. The test is *not* whether the plaintiff's injury was foreseeable to, or intended by, the defendant. As the Supreme Court observed just weeks ago, those standards would "risk [the very] 'massive and complex damages litigation'" that RICO's proximate-cause requirement is meant to avoid.

Under the directness test, proximate cause was clearly lacking in this case. This Court explained in *Teamsters* why TPP RICO claims are indirect, and the

[5] Because the Funds did not plead any independent jurisdictional basis for their state-law claims, the District Court declined to reach them and dismissed them without prejudice.

same problems are present here. The causal chain is long, running through doctors, patients, pharmacists, PBMs, and TPPs themselves. Many factors besides AbbVie's promotion likely affected these parties' decisions. And for these reasons, among others, calculating damages reliably would be impossible. Other considerations also weigh against allowing the Funds' claims to proceed: they pose a risk of double recovery, and there are others better situated to deter improper pharmaceutical marketing. Indeed, some of those parties—federal and state governments, patients, and shareholders—*have already filed suit* over the challenged conduct.

The Funds cite only two binding decisions that they maintain support their claims: *Bridge v. Phoenix Bond & Indemnity Co.*, 553 U.S. 639, 654 (2008), and *BCS Services v. Heartwood 88, LLC*, 637 F.3d 750 (7th Cir. 2011). But neither decision helps them. While *Bridge* and *BCS* establish that "first-party reliance" is not literally an "element" of a RICO claim, they recognize that directness is the linchpin of RICO proximate cause, and that first-party reliance is *relevant* to the directness inquiry. And although both decisions found RICO's directness requirement satisfied on the facts before them, that was because the sole intermediate "step" in the causal chain was an automatic process that introduced no uncertainty. Here, by contrast, the causal chain has *many* intermediate steps, and each one involves volitional, multidimensional, and unpredictable choices.

The Funds also rely heavily on two out-of-circuit decisions: *Kaiser Foundation Health Plan, Inc. v. Pfizer, Inc.*, 712 F.3d 21 (1st Cir. 2013) ("*Neurontin*") and *In re Avandia Marketing, Sales Practices & Product Liability Litigation*, 804 F.3d 633

(3d Cir. 2015). Although *Neurontin* and *Avandia* bear some similarities with this case, there is a crucial distinction: the TPPs in those cases alleged that the defendants made misrepresentations *directly to them*, and that those misrepresentations *directly influenced* their coverage decisions. Here, such facts are concededly missing. And although *Neurontin* and *Avandia* contain broad *dicta* about foreseeability and intent that appear to help the Funds, those *dicta* conflict with the RICO decisions of the Supreme Court and this Court.

Without the law on their side, the Funds ultimately resort to policy arguments: affirmance would supposedly flout Congress's intent, strip them of any remedy for their claimed harms, and grant AbbVie a "free pass." Not so. Congress enacted RICO to combat the Mafia, not to replicate federal food-and-drug laws. Non-RICO theories remain available to remedy the Funds' purported harms. And AbbVie has already paid for the alleged wrongdoing to the tune of at least $1.6 billion. In reality, policy cuts the other way: relaxing RICO's proximate-cause requirement would invite an avalanche of novel treble-damages suits; upset the balance between FDA regulation and private tort litigation; and work a major judicial change to the healthcare sector that Congress could not have anticipated.

Lastly, even if the Funds were right on proximate cause, the Court should still affirm, as the Funds cannot allege a plausible "injury" to *their* "business or property." As this Court has recognized, TPPs are "just financial intermediaries"; it is their beneficiaries who "foot the…bill" through their insurance premiums. Any

recovery to the Funds in this case—let alone their requested recovery of "hundreds of millions of dollars," trebled—would be a windfall.

ARGUMENT

I. THE DISTRICT COURT'S PROXIMATE-CAUSE DISMISSAL WAS CORRECT AND SHOULD BE AFFIRMED

"Proximate cause" encompasses various "judicial tools used to limit… responsibility for the consequences of [a] person's own acts." *Holmes v. SIPC*, 503 U.S. 258, 268 (1992).[6] It "reflects," *inter alia*, "what is administratively possible and convenient." *Id.* In RICO suits, proximate cause "prevent[s]…intricate, uncertain inquiries from overrunning [the] litigation." *Anza*, 547 U.S. at 460. This is crucial, as civil RICO is subject to "widespread abuse." *Midwest Grinding Co. v. Spitz*, 976 F.2d 1016, 1025 (7th Cir. 1992).

Proximate cause is not merely an element of a RICO claim; it is part of RICO's threshold statutory-standing inquiry. *See Evans v. City of Chicago*, 434 F.3d 916, 924, 933 & n.27 (7th Cir. 2006), *disapproved on other grounds by Hill v. Tangherlini*, 724 F.3d 965 (7th Cir. 2013). As such, it plays a critical "gatekeeping role…at the outset of RICO litigation." David B. Smith & Terrance G. Reed, 1-6 CIVIL RICO § 6.04 (Matthew Bender 2017). Many decisions of the Supreme Court and this Court have dismissed RICO claims on the pleadings for lack of proximate cause. *See, e.g.*, *Hemi Grp., LLC v. City of New York*, 559 U.S. 1 (2010); *Anza*, 547

[6] The Funds doctor this quotation to state that proximate cause "should be used to *hold one responsible* for 'the consequences of that person's own acts.'" (Funds' Br. 10 (emphasis added).) The Court actually said the opposite.

U.S. 451; *James Cape & Sons Co. v. PCC Constr. Co.*, 453 F.3d 396 (7th Cir. 2006); *Teamsters,* 196 F.3d 818; *Mendelovitz v. Vosicky*, 40 F.3d 182, 185 (7th Cir. 1994).

The District Court did so here, too, and with good reason: This is "precisely the type of indirect, massive and complex damage litigation that the Supreme Court sought to preclude" through RICO's proximate-cause requirement. *Ore. Laborers-Emp'rs Health & Welfare Trust Fund v. Philip Morris, Inc.*, 17 F. Supp. 2d 1170, 1179 (D. Or. 1998), *aff'd*, 185 F.3d 957 (9th Cir. 1999).

A. RICO Proximate Cause Turns On Directness, Not Intent Or Foreseeability

Proximate cause can take on "many shapes." *Holmes*, 503 U.S. at 268. The "shape" that applies in a given case "is controlled by the nature of the statutory cause of action." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 134 S. Ct. 1377, 1390 (2014). "[The Supreme Court's] precedents make clear that in the RICO context, the focus is on the directness of the relationship between the conduct and the harm." *Hemi*, 559 U.S. at 12. The test is *not* what the defendant allegedly intended or should have foreseen.

1. RICO Proximate Cause Requires Direct Injury

The Supreme Court has repeatedly held that RICO "demand[s]" a "*direct* relation between the injury…and the injurious conduct." *Holmes*, 503 U.S. at 268 (emphasis added); *see also Bridge*, 553 U.S. at 654 ("the alleged violation [must have] led *directly* to the plaintiff's injuries" (emphasis added)); *Anza*, 547, U.S. at 460 (RICO "require[s]…a *direct* causal connection" (emphasis added)). Modeled on

the doctrine of antitrust standing, *see Teamsters*, 196 F.3d at 825, RICO's directness requirement encompasses several related ideas.

First and foremost, directness means that the defendant's predicate acts of racketeering—the specific conduct that RICO forbids—must have produced the plaintiff's injury in just one "step." *Holmes*, 503 U.S. at 271; *cf. Assoc. Gen. Contractors v. Cal. State Council of Carpenters*, 459 U.S. 519, 540 (1983) ("*AGC*") (antitrust standing considers number of "links" in "the chain of causation"). Directness is lacking if there are "intermediate steps" in the causal chain, *Teamsters*, 196 F.3d at 825-26—*i.e.*, if "the defendant's conduct and the plaintiff's injury are separated by intermediate pairs of cause and effect," *BCS*, 637 F.3d at 756. Thus, injury is indirect if it "require[s] actions and decisions by third parties before coming into being," *Mendelovitz*, 40 F.3d at 185, or "flow[s]…from the misfortunes visited upon a third person," *Holmes*, 503 U.S. at 268.

Second, directness means that the RICO violation must be the *sole* cause of the injury. The injury cannot be the product of a *combination* of the violation and other "independent factors." *Bridge*, 553 U.S. at 658; *see, e.g.*, *Anza*, 547 U.S. at 459 (no proximate cause because some of plaintiff's damages "could have resulted from factors other than [defendant's] fraud"); *James Cape*, 453 F.3d at 403 (same, where "[a] court could never be certain whether" plaintiff lost some contracts "for…reasons unconnected to the…fraud") (citing *Anza*); *cf. AGC*, 459 U.S. at 542 (antitrust standing considers whether damages "may have been produced by independent factors"). This requirement is closely connected with the single-step rule, because the longer

the causal chain, "the more difficult it becomes to ascertain" what portion of the harm is "attributable to the violation, as distinct from other, independent factors." *Holmes*, 503 U.S. at 269.

Third, directness means that damages cannot be "speculative" and must be calculable without a "complex assessment." *Anza*, 547 U.S. at 459; *see Teamsters*, 196 F.3d at 825 (no directness where "damages [would be] wickedly hard to calculate"); *James Cape*, 453 F.3d at 403 ("damages [cannot be] too difficult to ascertain"); *cf. AGC*, 459 U.S. at 542-44 (antitrust standing considers whether damages are "speculative" or require "complicated proceedings involving massive evidence and complicated theories"). Indeed, "speculative damages claims…are precisely [what] the Supreme Court was trying to avoid…when [it] instituted [RICO's] proximate cause requirement." *Evans*, 434 F.3d at 933. That is because "massive and complex damages litigation…not only burden[s] the courts, but…also undermine[s] the effectiveness of treble-damages suits." *Holmes*, 503 U.S. at 274.

This Court's most recent RICO proximate-cause decision, *Empress Casino Joliet Corp. v. Johnston*, 763 F.3d 723 (7th Cir. 2014), illustrates these principles. There, plaintiff casinos sued defendant racetracks, alleging that they had bribed then-Illinois Governor Rod Blagojevich to obtain passage of two bills that imposed a 3% tax on casino revenue. *Id.* at 725.

As to the so-called '08 Act, the casinos alleged a straightforward "*quid pro quo*": the racetracks paid Blagojevich to sign the bill. *Id.* at 731-32. This satisfied RICO's proximate-cause test, for the bill "became law as a *direct result* of" the race-

tracks' predicate act of bribery, *id.* (emphasis added), and once the bill became law, the casinos' injury—loss of 3% of their revenues—was complete. There were no "intervening acts of third parties" subsequent to Blagojevich's signature that were necessary to give rise to the casinos' damages. *Id.* Moreover, determining those damages was trivially easy: they were just the amount paid under the tax.

The situation regarding the so-called '06 Act "differ[ed] significantly." *Id.* at 728. The racetracks had allegedly "bribed [Blagojevich] to persuade the 150-member legislature to enact the bill." *Id.* at 725-26, 732. Thus, there were "intervening voluntary acts of third parties" between the defendants' predicate act (bribery) and the plaintiffs' injury (lost revenues): individual legislators' voting decisions. *Id.* at 732 (citation omitted). Perhaps some of those decisions were caused by the Governor's persuasion. But there were "[n]umerous [other] reasons" that "might explain" them, such as alterations to the bill's text or "the usual give-and-take of legislative lawmaking." *Id.* at 730. As such, proximate cause was lacking.

The basic question in this appeal is which of the two scenarios from *Empress Casino* the Funds' causal theory resembles. Do they allege a wrongful act that immediately injured them in an amount certain, without any intervening volitional decisions? Or do they allege a wrongful act whose impact was transmitted to the Funds through the actions of many nonparties, each of whom might have acted for a variety of reasons? As explained below, the answer is obviously the latter.

2. Directness Is Not The Same As Non-Derivativeness

The Funds argue that RICO's directness requirement bars recovery *only* for injuries that are "derivative of [an] injury suffered by" someone else. (Funds' Br. 19-20.) As discussed below, the Funds' alleged injuries *are* derivative. *Infra* at 26. But regardless, the Funds misconstrue the law.

Of course, "derivative" injuries are indirect: the presence of another injured party between the defendant and the plaintiff means that the causal chain has more than one "step." But the inverse does not hold true: injuries that are *not* "derivative" may "nevertheless [be] too remote." *City of New York v. Smokes-Spirits.com, Inc.*, 541 F.3d 425, 441 (2d Cir. 2008), *rev'd on other grounds*, 559 U.S. 1 (2010); *see also Canyon Cnty. v. Syngenta Seeds, Inc.*, 519 F.3d 969, 981 (9th Cir. 2008) ("[The] proximate cause requirement not only bars RICO suits by derivative victims…, but generally precludes recovery by those whose injuries are [causally remote]…."). Collapsing the directness inquiry to the single question of derivativeness would make little sense, as non-derivative liability theories may be just as "attenuated" and "uncertain" as derivative ones. *Anza*, 547 U.S. at 459-60.

Take *Anza* itself. There, the plaintiff sued its competitors, alleging that their nonpayment of taxes allowed them to undercut its prices and steal its customers. The plaintiff's lost profits were not a "derivative" harm—they did not flow from the State's loss of tax revenue. *See Anza*, 547 U.S. at 465-66 & n.2 (Thomas, J., dissenting) ("[I]t was not *New York's injury* that caused [plaintiff's] damages; rather, it was [defendants'] own conduct…."). The Court nonetheless found proximate cause lack-

ing, citing the "attenuated connection between [the] injury and [the] injurious conduct"; the fact that the plaintiff's lost business "could have resulted from factors other than" the defendants' predicate acts; and the "speculative nature of the proceedings" that would be required to calculate damages. *Anza*, 547 U.S. at 458-61; *accord Canyon Cnty.*, 519 F.3d at 981-83 (county's financial losses stemming from defendant's employment of undocumented workers were indirect, even though they were "not 'derivative of an injury suffered by any other party'").[7]

3. Foreseeability And Intent Are Not Relevant

The Funds also argue that proximate cause exists as long as the plaintiff's injury was "foreseeable" and/or the plaintiff was an "intended victim[] of [the] defendant's wrongful conduct." (Funds' Br. 9.) Again, the Funds are wrong.

In the tobacco cases, courts "rejected the contention" that "intent [to injure]…or…the foreseeable nature of the harms…is sufficient" to plead proximate cause. *SEIU Health & Welfare Fund v. Philip Morris Inc.*, 249 F.3d 1068, 1074 (D.C. Cir. 2001). This Court necessarily (if implicitly) rejected those standards in *Teamsters*, finding proximate cause absent even though the TPPs' injuries (increased healthcare costs) were foreseeable and allegedly intended. Indeed, *Teamsters* expressly "disapprove[d]" *Blue Cross & Blue Shield of N.J., Inc. v. Philip Morris, Inc.*, 36 F. Supp. 2d 560 (E.D.N.Y. 1999), which found RICO proximate cause

[7] The Funds cite *Lexmark* as "confirm[ing]" that only derivative injuries are indirect. (Funds' Br. 20.) But *Lexmark* said no such thing. It observed that the "question" underlying "[t]he proximate-cause inquiry" is "whether the harm alleged has a sufficiently close connection to the [prohibited] conduct." 134 S. Ct. at 1390-91. It then stated that "derivative" harms lack that "sufficiently close" connection. *Id.* It did not say that all other harms *possess* such a connection.

satisfied because the TPPs were "the target of the defendants' [scheme]" and their injuries were its "foreseeable and…intended consequence." *Id.* at 574-75, 579; *see Teamsters*, 196 F.3d at 827.

The Supreme Court confirmed these holdings in *Anza*. There, the lower court found proximate cause because the plaintiff was the "principal intended victim of the [defendants'] scheme." *Ideal Steel Supply Corp. v. Anza*, 373 F.3d 251, 257-64 (2d Cir. 2004).[8] The Supreme Court reversed, explaining that intent was immaterial: "A RICO plaintiff cannot circumvent the proximate-cause requirement simply by claiming that the defendant's aim was to [harm him]." *Id.*; *see also James Cape*, 453 F.3d at 403-04 (following *Anza*); *accord AGC*, 459 U.S. at 537 (antitrust standing "is not a question of…intent"). Rather, the question was "whether [defendants] took [a direct or] indirect route to accomplish their goal." *Anza*, 547 U.S. at 460. It follows *a fortiori* that the proximate-cause requirement cannot be "circumvented" by asserting that the claimed harm was merely foreseeable. *See id.* at 470 (Thomas, J., dissenting) (complaining that the majority's holding "permits a defendant to evade liability for harms that are…foreseeable"); *Empress Casino*, 763 F.3d at 733 ("[i]n *Anza*," proximate cause was lacking although defendant's acts "had the foreseeable effect of hurting the plaintiff[]").

If *Anza* was not clear enough, the Court drove the point home in *Hemi*:

> The dissent would…find that [Plaintiff] has satisfied [RICO's proximate-cause] requirement because "the harm is

[8] Notably, the parties in *Anza* were one another's chief competitors, rendering it plausible that the plaintiff was actually the defendants' "intended victim." Here, by contrast, the Funds pleaded no facts suggesting that AbbVie even knew they existed.

> foreseeable…[and] a consequence that [Defendant] intended, indeed desired"….[This] is precisely the argument lodged against the majority opinion in *Anza*….But the dissent there did not carry the day.…***Our precedents make clear that in the RICO context, the focus is on the directness of the relationship between the conduct and the harm.*** Indeed, *Anza* and *Holmes* never even mention the concept of foreseeability.

559 U.S. at 12 (emphasis added). As the Funds note, *Hemi*'s lead opinion drew only four votes. But this Court has treated it as authoritative, *see Empress Casino*, 763 F.3d at 732, and the Supreme Court has twice reaffirmed it.

First, in *Lexmark*, the Court addressed proximate cause under the Lanham Act. It borrowed RICO's test, relying on *Hemi* without noting its plurality status. *Lexmark* referred repeatedly to the requirement of "directness" and the number of "step[s]" in the "causal chain," without mentioning foreseeability or intent. 134 S. Ct. at 1390-91, 1393-94. The Court's opinion was unanimous—joined not only by Justice Ginsburg, who had concurred separately in *Hemi*, but by Justices Breyer and Kennedy, who had dissented.

And just weeks ago, in *Bank of America Corp. v. City of Miami*, 197 L. Ed. 2d 678 (2017), the Court again borrowed RICO's proximate-cause test for another statute—the Fair Housing Act. Quoting *Hemi*, the Court unanimously agreed that "foreseeability alone is not sufficient to establish proximate cause." *Id.* at 689; *id.* at 696 (Thomas, J., concurring in relevant part). The correct test, it explained, is "directness"—*i.e.*, whether the causal theory "go[es] beyond the first step." *Id.* at 690-91. Once again, Justices Ginsburg, Breyer, and Kennedy all subscribed to this

analysis. Thus, at least eight members of the present Court (everyone but Justice Gorsuch) either joined *Hemi*'s lead opinion or later ratified it.

The Court's rejection of an intent or foreseeability standard makes good sense. An intent test would eviscerate proximate cause as a gatekeeping requirement; any competent drafter could "circumvent" it merely by "alleg[ing]…improper motive." *Anza*, 547 U.S. at 460-61. Similarly, "[c]onditioning liability on foreseeability…is hardly a condition at all," for "[i]f one takes a broad enough view, *all* consequences of a [wrongful] act, no matter how far removed in time or space, may be foreseen." *Conrail v. Gottshall*, 512 U.S. 532, 552-53 (1994). Either of these standards "would risk [the very] 'massive and complex damages litigation'" that RICO proximate cause is meant to avoid. *Bank of Am.*, 197 L. Ed. 2d at 690.

The Funds argue for a foreseeability or intent standard notwithstanding these precedents. In support, they invoke *dicta* in *Bridge* and *BCS*. However, as explained below, the Funds misconstrue both decisions. Point I.C, *infra*. They also rely on the out-of-circuit decisions in *Neurontin* and *Avandia*. As explained below, these decisions were incorrectly reasoned, and binding precedent prohibits this Court from following them. Point I.D, *infra*. Finally, the Funds rely on two False Claims Act decisions: *United States v. King-Vassel*, 728 F.3d 707 (7th Cir. 2013), and *United States ex rel. Brown v. Celgene Corp.*, 2014 U.S. Dist. LEXIS 99815 (C.D. Cal. July 10, 2014). But because the "shape" of proximate cause depends on

the statute being invoked, *Lexmark*, 134 S. Ct. at 1390, those non-RICO decisions, which cite no RICO precedents, are irrelevant.[9]

B. The Funds' Asserted Injury Is Not Direct

As the District Court correctly held, the Funds' claimed injury is not direct. *Teamsters* is squarely on point—and, *Teamsters* aside, the Funds' liability theory satisfies none of the *Holmes*/*Anza*/*Hemi* directness factors. At least a dozen courts agree that "allowing [TPPs] to move forward on…RICO claims" premised on off-label promotion "would present precisely the types of problems the *Holmes* Court sought to avoid." *AstraZeneca*, 585 F. Supp. 2d at 1344; *see supra* note 2.

1. This Case Is Controlled By *Teamsters*

As explained in the introduction to this brief, this case is uncannily similar to *Teamsters*, where this Court dismissed the RICO claims of various TPPs at the pleadings stage. *Supra* at 1-2. Attempting to distinguish *Teamsters*, the Funds argue that, there, unlike here, the TPPs' injuries were "derivative" of harms to their beneficiaries. (Funds. Br. 20.) That argument fails for two reasons.

First, "derivativeness" was an afterthought to the *Teamsters* Court: it mentioned the term just once, in passing. 196 F.3d at 826. This Court's subsequent decisions confirm that *Teamsters*' holding did not turn on derivativeness. *See In re Synthroid Mktg. Litig.*, 264 F.3d 712, 717 (7th Cir. 2001) (noting *Teamsters*' likely applicability to claims involving payments for prescription drugs, and characteriz-

[9] Moreover, because RICO "cover[s] broader classes of potential injuries and complainants" than the False Claims Act, it is logical that RICO's proximate-causation requirement is more stringent. *CSX Transp., Inc. v. McBride*, 564 U.S. 685, 704 n.14 (2011).

ing its holding thusly: "insurers may not pursue [RICO] litigation against tobacco companies…*because the injuries are too remote, the chain of causation is too long, and the damages 'wickedly hard' to calculate*." (emphasis added)).

Second, the Funds' claimed injuries are just as derivative as those in *Teamsters*. Here, too, it is the beneficiaries, not the Funds, who allegedly "did not have access to a [safe] product." 196 F.3d at 823. Here, too, the Funds' claimed economic losses are contingent on the challenged product's impact on their beneficiaries: unless a given prescription had an unsatisfactory effect on a beneficiary's health, the Funds have no "basis to recover purchase costs" for it. *Janssen*, 784 F. Supp. 2d at 523; *see In re Avandia Mktg., Sales Practices & Prod. Liab. Litig.*, 639 F. App'x 866, 869 (3d Cir. 2016) (where "[a] drug d[oes] the job it was meant to do…, and it cause[s] no…physical injuries," the purchaser "receive[s] the benefit of the bargain" and "sustain[s] no…damages").[10] Finally, here, too, it is the Funds' beneficiaries who "pay for the medical costs, in advance, through [their premiums]"; the Funds are "just financial intermediaries." *Teamsters*, 196 F.3d at 824; *see* Point II, *infra*.

2. The Funds Cannot Satisfy The Directness Factors

Even if *Teamsters* were not controlling, the Funds' injury is indirect under the factors set forth in *Holmes* and its progeny: the causal chain is attenuated; there are many confounding causal influences; and damages are impossible to ascertain.

[10] The Third Circuit reached a seemingly contradictory conclusion in another *Avandia* opinion. *See* 804 F.3d at 644 (finding TPPs' injury "independent of any…injury suffered by Avandia users"). There, however, the TPPs alleged that they had paid an "inflat[ed]" price for Avandia, "regardless of" its effect on their beneficiaries. *Id.* at 640, 644 & n.71. Whatever that theory's merits, *cf. Eike v. Allergan, Inc.*, 850 F.3d 315, 317-18 (7th Cir. 2017), the Funds have expressly disclaimed it. (*See* Funds' Br. 21 n.9 ("[The Funds] claim damages for unnecessary prescriptions, *not* inflated prices.").)

a. The Causal Chain Is Attenuated

The causal chain in this case has many "steps"—far more than the single intervening link (doctors' prescription decisions) that the Funds acknowledge.[11] "Because [the] theory of causation requires us to move well beyond the first step, [it] cannot meet RICO's direct relationship requirement." *Hemi*, 559 U.S. at 10.

Consider all the "steps" that must occur before AbbVie's alleged statements to doctors[12] could result in injury to the Funds:

- ***First***, AbbVie makes statements to physicians, deceiving them about the safety and efficacy of Depakote for certain conditions.
- ***Second***, those physicians prescribe Depakote for Fund beneficiaries experiencing those conditions.
- ***Third***, those patients fill their prescriptions, rather than leaving them unfilled (*e.g.*, because their co-pay is too high or their symptoms are manageable). *See* Jane E. Brody, *The Cost of Not Taking Your Medicine*, N.Y. TIMES, Apr. 17, 2017 (20-30% of prescriptions go unfilled).
- ***Fourth*** (after 2008), the pharmacist decides to fill those prescriptions with Depakote, rather than the generic equivalent.
- ***Fifth***, the Funds' beneficiaries fail to receive the promised benefit from Depakote or experience an injury from taking it.
- ***Sixth***, the P&T Committees of the Funds' PBMs review information about Depakote and choose to place it on formulary, without imposing restrictions (*e.g.*, prior authorization) that would prevent reimbursement for improper prescriptions.
- ***Seventh***, the Funds adopt their PBMs' formularies without modifying them to remove Depakote or impose utilization restrictions.

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[11] As AbbVie argued below, the Funds failed to plead a causal chain *at all* beyond conclusory generalities, and therefore failed to demonstrate even *but-for* causation.

[12] The Funds' brief omits any mention of AbbVie's allegedly false statements to *patients*. Everything said below is true *a fortiori* for those statements, however, since they cannot possibly result in injury to the Funds unless they result in action by doctors.

- ***Eighth***, the Funds and/or their PBMs fail to obtain lower prices or higher rebates for Depakote in their contractual negotiations with one another and/or AbbVie.[13]

- ***Ninth***, the Funds fail to set their premiums high enough to cover all of the Depakote prescriptions at issue. *See Teamsters*, 196 F.3d at 824 ("[I]nsurers [may] collect only for [their] net outlay…; but there will *be* such a net outlay only if [they] are not calculating rates correctly.").

- ***Finally***, the Funds suffer an out-of-pocket loss.

Thus, the Funds' "theory of liability" impermissibly "rest[s] on the independent actions of third and even fourth parties" (and beyond), *Eli Lilly*, 620 F.3d at 134 (quoting *Hemi*), and their alleged damages impermissibly "require actions and decisions by third parties" (and beyond) "before coming into being," *Mendelovitz*, 40 F.3d at 185. Courts across the nation have held that this "attenuated link" between "misrepresentations made to doctors and…injury to…TPPs" defeats proximate cause. *Eli Lilly*, 620 F.3d at 134 (describing a five-step chain); *see also Amgen*, 400 F. App'x at 257 ("at least four independent links"); *Bristol Myers Squibb*, 969 F. Supp. 2d at 475 ("vast array of intervening events").[14]

Attempting to obscure this attenuation, the Funds collapse all of these steps into an overarching "scheme" and argue that their injuries resulted directly from *that "scheme."* (Funds' Br. 13-14.) The plaintiff in *Hemi* tried the same thing, but

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[13] Seeking to shorten the causal chain, the Funds disavow any claim that the price of Depakote was too high. (Funds' Br. 21 n.9.) Below, however, they argued just that. (D.Ct. Dkt. 103 at 7-8, 10-11.) Regardless, this single step is hardly dispositive.

[14] The Funds are remote from AbbVie on the purchasing side as well. As discussed above, small TPPs like the Funds do not contract directly with, or pay money directly to, manufacturers. The Funds' payments flow through PBMs, pharmacies, and perhaps also wholesalers before AbbVie sees any money. *Supra* at 7-8. *Cf. Teamsters*, 196 F.3d at 823 ("[O]nly the immediate purchaser of goods may sue under the antitrust laws.").

the Court rejected its attempt to manufacture directness by "broadly defin[ing] the violation." 559 U.S. at 13-14 ("[Plaintiff] cannot escape the proximate cause requirement merely by alleging that the fraudulent scheme embraced all those indirectly harmed…."). So too here: the question is whether AbbVie's allegedly "fraudulent *conduct*"—its alleged statements to doctors and patients—directly injured the Funds, not whether a "more general…scheme to defraud" directly injured them. *Id.* As the above discussion shows, the answer to that question is "no."

b. There Are Confounding Causal Influences

Not only is the causal chain lengthy, but many of the links in that chain are individualized, volitional decisions subject to multiple influences unrelated to AbbVie's alleged fraud. *Cf. Laborers Local 17 Health & Benefit Fund v. Philip Morris, Inc.*, 191 F.3d 229, 240 (2d Cir. 1999) ("On a fundamental level, [the lack of proximate cause] stem[s] from *the agency of the individual smokers* in deciding whether, and how frequently, to smoke." (emphasis added)).

The District Court focused on the prescription-writing step, and rightly so: Doctors' prescribing decisions are "multifaceted and individualized," *Sanofi-Aventis*, 806 F.3d at 92, and are "influenced by a number of things…[besides] representations by [the] manufacturer," *AstraZeneca*, 585 F. Supp. 2d at 1344. This includes years of study and training, first-hand clinical experience, word-of-mouth, independent medical literature, and "the personal medical history of [a given] patient." *Yasmin & Yaz*, 2010 U.S. Dist. LEXIS 80758, at *25-26; *see also AstraZeneca*, 634 F.3d at 1362-63; *Eli Lilly*, 620 F.3d at 135; *Vioxx*, 180 Cal. App. 4th at 125.

So too with the remaining steps in the chain. P&T Committees, for example, are staffed by experts with "ready access to medical…information" that goes far beyond manufacturers' literature, *Hillman II*, 782 F.3d at 927, and their decision-making "is almost as variegated as is individual physician/patient decision-making," *In re Vioxx Consolidated Cases*, No. JCCP4247, slip op. at 11 (Cal. Super. Ct. L.A. Cnty. Apr. 30, 2009). *Supra* at 6-7.

Finally, there are many influences other than AbbVie's alleged wrongdoing that bear on the prices that TPPs pay for medications. Again, those prices result from a "highly complex" web of contracts. *Supra* at 7-8. And because TPPs, PBMs, and pharmacies frequently sue one another for fraudulent and anticompetitive conduct,[15] the tortious wrongdoing of parties *other than* the manufacturer may contribute to a TPP's drug costs and must be accounted for.

Given all of these outside influences, it would be "difficult," if not impossible, "to ascertain" what portion of the Funds' Depakote costs were "attributable to" AbbVie's alleged fraud, "as distinct from other, independent factors." *Anza*, 547 U.S. at 458; *see AstraZeneca*, 585 F. Supp. 2d at 1344 (no proximate cause given "serious concerns" regarding the contribution of off-label marketing to TPP's costs, "as opposed to…other, independent, factors"); *cf. Laborers Local*, 191 F.3d at 240 (no proximate cause because there were "other reasons why individual smokers would continue smoking" besides manufacturers' fraud).

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[15] *See, e.g.*, *Independent pharmacies sue PBM over drug pricing*, CHAIN DRUG REVIEW, Feb. 12, 2015, http://goo.gl/WkhuKF; Anna Wilde Mathews, *Anthem Sues Express Scripts Over Drug Pricing*, WALL ST. J., Mar. 21, 2016, http://goo.gl/l8dw2O.

The Funds rejoin that "where a drug company spends millions of dollars on a scheme such as this," it is "implausible" that "[it] would have *no material impact* on the writing of prescriptions…." (Funds' Br. 16 (emphasis added).) But that is a straw man. AbbVie's point is that *many things* have a "material impact" on prescribing and on drug costs; as a result, isolating the contribution of AbbVie's alleged off-label statements raises the difficulties that RICO's proximate-cause requirement was intended to avoid. *Cf. Anza*, 547 U.S. at 459 (finding proximate cause lacking because competitors' pricing decisions are one of "many reasons" why "[b]usinesses lose and gain customers"—not because those decisions have *no impact*).

c. Damages Are Speculative And Impossible To Calculate

Given the winding causal chain and the many outside influences, consider the "intricate" and "speculative nature" of the calculations "that would follow if [the Funds] were permitted to maintain [their] claim," *Anza*, 547 U.S. at 459-60:

- ***First***, the Funds would have to establish how many of the Depakote prescriptions for which they paid were written for allegedly "unsafe" or "ineffective" off-label uses. This is already an uphill climb, because only "indirect…and incomplete data[]" are available. (JA132, ¶217.)
- ***Second***, because the Funds have no "basis to recover purchase costs" where Depakote performed as promised, *supra* at 26, the Funds would have to show how many of those prescriptions actually injured or failed to benefit the patients for whom they were written.
- ***Third***, the Funds would have to establish how many of these prescriptions were written as a result of the challenged promotional activities, which are diverse in nature, took place throughout the United States, and span a 14-year period.
- ***Fourth***, as the Funds cannot recover for losses they would have incurred absent the violation, *see Bastian v. Petren Resources Corp.*, 892 F.2d 680, 684-85 (7th Cir. 1990), they would have to determine how many of these prescriptions would still have been written even if

AbbVie had never engaged in the challenged promotion—*e.g.*, because of clinical experience, word-of-mouth, or independent publications.

- ***Fifth***, for each prescription that would not have been written, the Funds would have to show which "cheaper, safer, or more effective alternative[]" (Funds' Br. 5) would have been prescribed instead, and how much *that* drug would have cost in the but-for world on the relevant date. *See Eli Lilly*, 620 F.3d at 135-36; *Bayer*, 655 F. Supp. 2d at 1281, 1282 n.5.[16]

- ***Sixth***, the Funds would have to show what choices each downstream actor would have made in the but-for world throughout the 14-year period. For example, without the alleged off-label marketing campaign, would the Funds or their PBMs have imposed utilization-management restrictions, and when? *Cf. Teamsters*, 196 F.3d at 826 ("Just what *would* the insurers have done, had they known more earlier? How effective would this campaign have been?").

- ***Seventh***, because "it is necessary to consider both the income and the expenditure sides of the insurer's balance sheet," *id.* at 823-24, the Funds would have to establish what premiums they would have charged in the but-for world throughout the 14-year period.

- ***Eighth***, the Funds would have to establish how the network of contract negotiations among TPPs, PBMs, pharmacies, wholesalers, and manufacturers that determines pricing would have unfolded over the 14-year period absent the challenged promotion. For example, if Depakote's market share were lower or its uses were viewed as narrower, would AbbVie have been able to command the same prices from pharmacies? Would PBMs have been able to extract greater rebates?

By any analysis, damages would be "wickedly hard to calculate," and the results would be "hopelessly speculative." *Teamsters*, 196 F.3d at 825-26. This "is an independent obstacle to recovery." *Id.* at 823-24; *see also Ore. Laborers-Emp'rs*, 185 F.3d at 965 ("The difficulty of ascertaining [plaintiffs'] damages…and the complexity involved in calculating the[m]…weigh heavily, if not dispositively, in favor of barring plaintiffs' actions."); *AstraZeneca*, 585 F. Supp. 2d at 1345 ("The highly complex

[16] Notably, the only "alternative" drug that the Funds identified, Lamictal, was actually "much more costly" than Depakote. (JA45, ¶162.)

damages assessment…strongly weighs against a finding [of] direct[ness]…."); *cf. Canyon Cnty.*, 519 F.3d at 983 (no proximate cause where "the court would have to construct [a speculative] alternative scenario" to calculate damages).

This is not to say that an expert could not concoct a purported statistical model of these phenomena. But "[r]eliance on aggregate statistical proof" does not magically cure the problem of speculative damages. *SEIU*, 249 F.3d at 1073-74. Again, *Teamsters* is illustrative: There, the district court refused to dismiss the complaint on proximate-cause grounds, reasoning that the plaintiffs "may well be able to [adduce]…statistical and expert evidence" of damages at a later point. *Ark. Blue Cross & Blue Shield v. Philip Morris, Inc.*, 47 F. Supp. 2d 936, 939 (N.D. Ill. 1999). This Court granted interlocutory review and reversed, finding damages "hopelessly speculative," statistics or no. 196 F.3d at 825-26.

3. *Holmes*'s Additional Factors Support The District Court's Directness Determination

Courts sometimes discuss two further questions in connection with RICO's proximate-cause analysis: (1) whether there is a "risk of multiple recoveries," and (2) whether a RICO suit is necessary to "deter[]" the sort of "injurious conduct" alleged, or whether there are other, less "problem[atic]" ways to "vindicate the law." *Holmes*, 503 U.S. at 269. These questions are no substitute for the directness test: although they are "relevant," no particular answer is "need[ed]…for remoteness to bar recovery." *City of Cleveland v. Ameriquest Mortg. Sec., Inc.*, 615 F.3d 496, 503 (6th Cir. 2010); *see, e.g.*, *Anza*, 547 U.S. at 459-60 (no proximate cause despite "lack

of any appreciable risk of duplicative recoveries"). Here, however, the answers to both questions reinforce the District Court's decision.

a. Multiple Recoveries

First, there is a real danger of multiple recoveries. For starters, patients (*i.e.*, beneficiaries of TPPs) often file off-label-marketing lawsuits seeking economic damages. *See, e.g.*, *Intron/Temodar*, 678 F.3d at 239 ("There are two sets of plaintiffs….[One is] a putative nationwide class of third-party payors….[The other is] a putative nationwide class of individual patient-consumers….[Both] assert that they paid for Schering drugs that were ineffective or unsafe for…off-label uses"). Courts have cited patient claims as reason to preclude TPP suits. *See Teamsters*, 196 F.3d at 826 (noting concerns of "double recovery" because patients "could bring their own…suits"); *SEIU*, 249 F.3d at 1075; *Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris*, 171 F.3d 912, 934 (3d Cir. 1999); *Seafarers Welfare Plan v. Philip Morris*, 27 F. Supp. 2d 623, 632 n.22 (D. Md. 1998).

The interdependence of private TPPs and Medicare/Medicaid creates another double-recovery concern. Private TPPs receive large sums from the government to pay for some or all of the prescriptions of the 30% of Medicare beneficiaries and "well over half" of Medicaid beneficiaries who are on their insurance rolls. Robert Pear, *As Medicare and Medicaid Turn 50, Use of Private Health Plans Surges*, N.Y. TIMES, July 29, 2015, http://goo.gl/1H0puu. The cost-sharing arrangements between the government and private insurers are incredibly intricate. *See* Medicare Payment Advisory Commission, *Sharing Risk in Medicare Part D*, in REPORT TO THE

CONGRESS: MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM (June 2015) at 139-167, http://goo.gl/h4Qjhk. If this lawsuit proceeds, the District Court may have to "adopt complicated rules [of] apportion[ment]" to determine how much of the private TPPs' claims have been extinguished by AbbVie's settlement of the government's claims arising out of the challenged conduct. *Holmes*, 503 U.S. at 269.

b. Alternate Means Of Deterrence

Second, the "need to grapple with" the questions this suit raises is "unjustified by the general interest in deterring injurious conduct." *Holmes*, 503 U.S. at 269. That is because other, less "problem[atic]" methods exist to deter improper pharmaceutical marketing, *id.*—and they have already been invoked. *Cf. Mendelovitz*, 40 F.3d at 185-86 (RICO suit "unjustified by the general interest in deterr[ence]" given existing litigation over same events). The Funds' assertion that there is "no one else" with "incentive to sue" (Funds' Br. 17, 25) is baffling.[17]

For starters, the FDCA, False Claims Act, and analogous state statutes permit government authorities to penalize misleading drug promotion. *See generally* Lise T. Spacapan & Jill M. Hutchison, *Prosecution of Pharmaceutical Companies for Off-Label Marketing: Fueled By Government's Desire to Modify Corporate Conduct or Pursuit of a Lucrative Revenue Stream?*, 22 ANN. HEALTH L. 407 (2013). The United States and numerous states have already sued under those statutes. Civil RICO suits are not needed for deterrence where "the State can be expected to pur-

[17] Even if the Funds were correct, and no other party could sue, that would not create proximate cause. RICO's directness test is not "a quest for the 'best'…plaintiff"; there may be *no one* who satisfies it. *SEIU*, 249 F.3d at 1072, 1075-76.

sue" the underlying wrongdoing, *Anza*, 547 U.S. at 460—and *a fortiori* where the State has already done so. *Cf. Callahan v. A.E.V.*, 182 F.3d 237, 266 (3d Cir. 1999) (civil RICO claim unnecessary for deterrence where defendant had been "indicted" on criminal charges "ar[ising] out of the same activities"); *Se. Fla. Laborers Dist. Health & Welfare Trust Fund v. Philip Morris, Inc.*, 1998 U.S. Dist. LEXIS 5440, at *19 (S.D. Fla. Apr. 13, 1998) ("[T]he State's…tobacco settlement demonstrates that there are ample [non-RICO plaintiffs] who will vindicate the alleged wrongs.").

Non-RICO tort claims also deter improper pharmaceutical marketing. Most obviously, mismarketed drugs have long been the province of state product-liability law. *See, e.g.*, *E.R.G. v. Abbott Labs., Inc. (In re Depakote)*, 2017 U.S. Dist. LEXIS 74475, at *28-30 (S.D. Ill. May 16, 2017) (permitting product-liability plaintiff to "introduce evidence regarding [alleged] off-label marketing" of Depakote). Furthermore, there is "a cottage industry in shareholder suits against companies accused of off-label marketing," Spacapan & Hutchison, *supra*, at 439-40, and AbbVie shareholders have filed several derivative suits over the very marketing at issue, *see In re Abbott Depakote S'holder Derivative Litig.*, 2013 U.S. Dist. LEXIS 78841 (N.D. Ill. June 5, 2013). Finally, the manufacturers of the "cheaper, safer or more effective" drugs that supposedly would have been prescribed absent AbbVie's alleged off-label marketing (Funds' Br. 3) might also sue to recover the profits supposedly lost because of those missed sales. *See* Marie Bussey-Garza, *Say Hello to My Little Friend Civil RICO: The Third Circuit Green Lights Insurance Shakedown of Big Pharma with* In re Avandia, 61 VILL. L. REV. 625, 646-47 (2016).

Because other parties "can maintain actions predicated upon the same conduct for which the Funds bring suit" (and many already have), a RICO suit is unnecessary to "ensur[e] that [it] is punished." *Tex. Carpenters Health Benefit Fund IBEW-NECA v. Philip Morris, Inc.*, 21 F. Supp. 2d 664, 672 (E.D. Tex. 1998), *aff'd*, 199 F.3d 788 (5th Cir. 2000); *see also Laborers Local*, 191 F.3d at 241; *Ore. Laborers-Emp'rs*, 185 F.3d at 964; *Bayer*, 655 F. Supp. 2d at 1283-84. And the other available modes of deterrence are far less "problem[atic]," *Holmes*, 503 U.S. at 269, than RICO suits by insurers who are far removed from the alleged wrongdoing, and whose claimed damages are not just duplicative but illusory. *See* Point II, *infra*.

C. The Decision Below Is Consistent With *Bridge* and *BCS*

The Funds argue that the District Court's analysis conflicts with the Supreme Court's decision in *Bridge* and this Court's related decision in *BCS*. That is incorrect: *Bridge* and *BCS* applied the same directness test that the District Court applied. The outcomes of *Bridge* and *BCS* were driven by the unique facts of those cases—facts that do not resemble those alleged here.

1. *Bridge*

As the Funds note, *Bridge* held that "first-party reliance" is not "an *element* of [a RICO] cause of action." 553 U.S. at 659 (emphasis added). Stated otherwise, reliance by the plaintiff (as opposed to a third party) is not "*always* necessary." *Id.* (emphasis added). But the Funds read this holding far too broadly. *Bridge* did not hold that first-party reliance is irrelevant. To the contrary, it recognized that "the absence of first-party reliance *may in some cases tend to show that an injury was not sufficiently direct* to satisfy [RICO's] proximate-cause requirement." *Id.* (emphasis

added). The crucial question, in other words, is whether the *Holmes*/*Anza*/*Hemi* directness factors are satisfied; the existence of first-party reliance is *relevant* to that inquiry, although not "in and of itself dispositive." *Id.*

The District Court's analysis is consistent with this holding. Contrary to the Funds' characterization, Judge Ellis did not treat first-party reliance as an "element" of the Funds' RICO claims. As she explained, the dispositive question was whether there was "a direct relationship between" the alleged violation and the harm. *Hillman III*, 192 F. Supp. 3d at 971-72. This, in turn, depended on the number of "steps in[] the chain of causation"; whether the claimed harm was "attribut[able]" to "many factors" or just one; and whether damages would be "speculative" or "difficult[] [to] assess." *Id.* Judge Ellis correctly concluded that, on the facts of *this* case, lack of first-party reliance "tend[ed] to show" that these directness factors were not met. *Bridge*, 553 U.S. at 659. At bottom, however, it was the "failure to allege a direct relationship" that was "the fatal flaw in [the Funds'] RICO claims—not failure to allege first-party reliance." *In re Oil Spill by the Oil Rig "Deepwater Horizon*," 802 F. Supp. 2d 725, 730-31 (E.D. La. 2011).

The *Bridge* Court found the directness requirement satisfied on the facts before it, notwithstanding the lack of first-party reliance. But those facts were nothing like the facts of this case. *Bridge* involved a series of auctions conducted by Cook County that always resulted in many-way ties. To break those ties, the County chose winners "on a rotational basis." 553 U.S. at 643. To prevent any one entity from "obtain[ing] a disproportionate share" of the prizes, bidders were required to

affirm to the County that they were not affiliated with any other bidder in order to participate. *Id.* The defendants falsely attested compliance with this rule and entered multiple bidders, allowing them to come up excessively often in the rotation. The other, law-abiding bidders then filed suit under RICO.

There was technically an intervening "step" between the defendants' false affirmations to the County and the plaintiffs' loss of prizes—the County's selection of prizewinners. But that "step" did not involve any volitional act or exercise of judgment; to the contrary, it was predictable as clockwork. *See Hemi*, 559 U.S. at 14 (explaining how the "zero-sum nature of the auction[s]" and the "rotational" awarding of prizes rendered *Bridge*'s causal theory "straightforward"). Thus, there were no intervening "steps" *of the sort that matter* for purposes of RICO directness. *Cf. Lexmark*, 134 S. Ct. at 1394 (stating that an intervening "step" may be disregarded if damages "follow…automatically" despite its presence, but observing that this will be true only under "unique circumstances").

The remaining directness criteria were also met in *Bridge*. Because winners were chosen rotationally, there were "no independent factors" besides the presence of extra bidders "that [could] account for [the plaintiffs'] injury." 553 U.S. at 658. Calculating damages was simple: again, because prizes were awarded rotationally, determining how many extra prizes the defendants won was a matter of basic arithmetic. And there was "no risk of duplicative recoveries" and were no "victim[s]" of the scheme besides the other, law-abiding bidders. *Id.*

As the District Court recognized, this case is a far cry from *Bridge*. Here, there are *many* intervening "steps" in the causal chain—not just one. *Cf. Hemi*, 559 U.S. at 15 (distinguishing *Bridge* where "[m]ultiple steps…separate[d] the alleged fraud from the asserted injury"). Unlike in *Bridge*, the intervening steps here are unpredictable, volitional decisions: doctors, for example, do not prescribe medications "on a rotational basis." *Cf. Hemi*, 559 U.S. at 25 (Breyer, J., dissenting) ("[T]he majority…[concludes] that the intervening *voluntary* acts of third parties…cut[] the causal chain." (emphasis added).) Unlike in *Bridge*, AbbVie's alleged fraud is not the *only* possible cause of the Funds' claimed damages; other "independent factors" contribute to the Funds' payment for Depakote. *Cf. Hemi*, 559 U.S. at 15 (distinguishing *Bridge* where "independent factors [could have] account[ed] for" part of the injury). Unlike in *Bridge*, calculating damages would require modeling myriad intermediaries' hypothetical actions over a 14-year period in a counterfactual information environment. Finally, unlike in *Bridge*, there is a risk of double recoveries, and there are other alleged victims (*e.g.*, government payors, patients, shareholders, and competitors)—some of whom have already taken action.

The Funds make much of *Bridge*'s remark that the plaintiffs' injury "was a foreseeable and natural consequence" of the defendants' scheme. 553 U.S. at 658. But, as the Funds eventually concede, *Bridge* never held this was the test for proximate cause. (Funds' Br. 18.) To the contrary, *Bridge* stated that *directness* was "the central question"; it ratified "the proximate-cause principles articulated in *Holmes* and *Anza*" (neither of which mentioned foreseeability); and, as just dis-

cussed, it applied the directness factors. *Id.* at 654, 658; *see also Hemi*, 559 U.S. at 14 ("*Bridge* reaffirmed the requirement" of a "direct relationship").[18]

2. *BCS*

BCS was a subsequent decision in the *Bridge* litigation. Accordingly, it is distinguishable from this case for the same reasons that *Bridge* is. There was one factual twist: between *Bridge* and *BCS*, it had become clear that ties were broken by random selection, not "strict rotation[.]" *BCS*, 637 F.3d at 753. But this changed nothing: "random awards…are similar to awards made on a strictly rotational basis" because, given enough drawings (and there were 96,000 at issue), the outcome will be identical. *Id.* at 757. Thus, while any "individual [drawing]…[was] unpredictable," the plaintiffs' total damages were "predictable" as a matter of elementary math, just as in *Bridge*. *Sanofi-Aventis*, 20 F. Supp. 3d at 322-23 (discussing *BCS*).

Like *Bridge*, then, *BCS* represents a "unique" scenario where an intervening step can be "discounted" because it functions "more or less automatically." *Hillman III*, 192 F. Supp. 3d at 970 (quoting *Lexmark*, 134 S. Ct. at 1394). Not so here: Prescription decisions are not made by random selection any more than they are made by strict rotation. They are volitional, complex, and individualized. *See Sanofi-Aventis*, 20 F. Supp. 3d at 322-23 (finding *BCS* inapplicable to a TPP claim for this reason). So, too, with the other steps in the Funds' chain. *BCS* itself recognized that, ordinarily, "[t]here is…reason for worrying about imposing liability when the

[18] The Funds also state that *Bridge* "held" that proximate cause exists if the plaintiff was a "primary and intended victim[.]" (Funds' Br. 12 (quoting *Bridge*, 553 U.S. at 650).) But the quoted portion of *Bridge* did not address RICO's proximate-cause requirement at all, and *Bridge* did not overrule *Anza*, which expressly held that "intent" is irrelevant. *Supra* at 22.

defendant's conduct and the plaintiff's injury are separated by intermediate pairs of cause and effect." 637 F.3d at 756. This is one of those cases where there is "reason for worrying."

Like *Bridge*, *BCS* mentioned foreseeability. But this was *dictum*: it appeared in an introductory discussion of proximate cause *generally*. 637 F.3d at 754-56. That is not surprising; "foreseeability [is] of course [one] of the 'many shapes'" that proximate cause can take. *Hemi*, 559 U.S. at 12. However, the *BCS* Court did not go on to hold that RICO's proximate-cause requirement *was satisfied because* the plaintiffs' damages were foreseeable. It held that the requirement was satisfied because "[t]he only intermediate cause and effect pair" was equivalent to "strict[] rotation[.]" 637 F.3d at 757. (And, tellingly, this Court's post-*BCS* decision in *Empress Casino* did not mention foreseeability at all.)

Finally, *BCS* contained a discussion of "intervening" or "superseding causes" that must be read carefully. *BCS* held that the district court had erred by "requir[ing] the plaintiffs to prove the nonexistence of potential superseding causes rather than requiring the defendants to present evidence to support their [existence]." *Id.* Importantly, however, these "conjectured superseding causes" were "implausible speculations" and "beyond unlikely." *Id.* For example, the defendants hypothesized that, *if* their fraudulent affidavits had been brought to Cook County's attention (which they were not), the County *might* have "allow[ed] the[m]…to continue" their scheme with impunity. *Id.*

This discussion of "superseding causes" must be confined to the type of implausible or speculative chain-rupturing events addressed in *BCS*. It cannot apply to confounding causal influences that are routine or obvious: Again, both the Supreme Court and this Court have found proximate cause lacking *at the pleadings stage* where plain common sense indicated that some of the claimed damages "could have resulted from factors other than [the defendant's] alleged acts of fraud." *Anza*, 547 U.S. at 459; *James Cape*, 453 F.3d at 403; *accord AGC*, 459 U.S. at 542 (finding lack of antitrust standing at pleadings stage where "the alleged [injury]…may have been produced by independent factors").

Here, the confounding causal factors are not "implausible speculations," as in *BCS*. 637 F.3d at 757. The Funds do not (and cannot) dispute that doctors write prescriptions, patients fill them, and PBMs and TPPs cover them "for many reasons" beside manufacturers' promotion. *Anza*, 547 U.S. at 459. *BCS* does not require this case to proceed to summary judgment or trial just so that AbbVie can "present evidence" of what the District Court knew as a matter of "experience and common sense," *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009), and what the Funds do not dispute even now. *Cf. Anza*, 547 U.S. at 459 (recognizing at pleadings stage that "[b]usinesses lose and gain customers for many reasons," rather than requiring defendant to "present evidence" of this fact).

D. *Neurontin* And *Avandia* Should Not Be Followed

The Funds spend most of their brief discussing two non-binding decisions: the First Circuit's in *Neurontin* and the Third Circuit's copycat decision in *Avandia*.

While those cases resemble this one in some ways, their facts are distinguishable, and their reasoning contradicts Supreme Court and Seventh Circuit precedent. Thus, they cannot dictate the outcome here.

1. *Neurontin* And *Avandia* Are Distinguishable

As the District Court noted, the manufacturers in *Neurontin* and *Avandia* "specifically targeted" the plaintiff TPPs with misrepresentations, and those "misrepresentations directly affected [their] decisions about [the relevant drugs'] placement on formulary." *Neurontin*, 712 F.3d at 28-29, 37, 41; *see also Avandia*, 804 F.3d at 636, 644 (Plaintiffs "included Avandia in their formularies…in reliance on… misrepresentations by [GlaxoSmithKline]"). Because formulary inclusion is a prerequisite for coverage, every payment the plaintiffs made for Neurontin or Avandia was thus at least arguably "caused by" the defendants' RICO violations. *See Med. Mut. of Ohio v. AbbVie Inc.*, 159 F. Supp. 3d 898, 914, 919 (N.D. Ill. 2016).

Here, by contrast, AbbVie made *no* statements to the Funds—let alone any misrepresentations that affected the Funds' formulary decisions. That is a crucial difference: because AbbVie's alleged wrongdoing was separated from the Funds' coverage and payment decisions by multiple steps, it is far "more difficult" in this case "to ascertain" what portion of the drug costs are "attributable to the violation, as distinct from other, independent factors." *Holmes*, 503 U.S. at 269.

The District Court is not alone in drawing this distinction. As another Illinois district judge recently observed, the "consistent pattern" is that RICO claims "survive" in cases like *Neurontin* and *Avandia* "where TPPs allege…direct misrep-

resentations to them," and "fail where they do not." *Med. Mut.*, 159 F. Supp. 3d at 919; *see also Bristol Myers Squibb*, 969 F. Supp. 2d at 474 (finding lack of directness in misrepresentations-to-doctors case; distinguishing *Neurontin*); *Olivares*, 2011 U.S. Dist. LEXIS 117750, at *23 (same); *Bextra & Celebrex*, 2012 U.S. Dist. LEXIS 111446, at *216 n.7 (distinguishing cases alleging direct deception of TPPs from those alleging "misrepresentations…to third-party physicians"). Indeed, to AbbVie's knowledge, *no court anywhere* has found RICO's proximate-cause requirement satisfied in a pure misrepresentations-to-doctors case.[19]

2. *Neurontin* And *Avandia* Are Incorrectly Reasoned

The Funds note that *Neurontin* and *Avandia* contain some broad pronouncements that would seem to apply to pure misrepresentations-to-doctors cases like this one. To the extent those decisions opined about situations not before them, such statements are *dicta*. Those *dicta*, moreover, are inconsistent with Supreme Court and Seventh Circuit precedent.

For example, *Neurontin* and *Avandia* stated that "foreseeab[ility]" and/or status as an "intended victim" are sufficient to establish proximate cause. *Neurontin*, 712 F.3d at 21; *Avandia*, 804 F.3d at 637 (proximate cause exists "where a TPP is a primary and intended victim and the injury is foreseeable"). As discussed above, these statements of the law are incorrect. The Supreme Court has repeatedly held

[19] The Second Circuit suggested in *dicta* that proximate cause might exist in a misrepresentation-to-doctors case if the drug were "so dangerous that no physician would ever prescribe it" if the truth were known. *Sanofi-Aventis*, 806 F.3d at 92. In such an extreme case, much like in *Bridge* and *BCS*, the intermediate steps in the chain may become mere formalities. But this is not such a case: the Funds concede that Depakote is safe and effective for some uses, and it remains a widely prescribed medication today. *Supra* at 4.

(both before and after *Neurontin* and *Avandia*) that foreseeability and intent are *not* the tests for RICO proximate cause. Point I.A.3, *supra*. In *Anza*, for example, the Supreme Court *expressly disavowed* the lower court's statement that proximate cause exists as long as the plaintiff is an "intended victim of the [defendant's] scheme." *Supra* at 22. Remarkably, however, that is the very rule that *Neurontin* and *Avandia* endorsed.

The First and Third Circuits apparently thought that *Bridge* overruled the Supreme Court's directness precedents and proclaimed a foreseeability or intent test instead. As discussed above, however, *Bridge* did no such thing. Point I.C.1, *supra*; *Grange Mut. Cas. Co. v. Mack*, 290 F. App'x 832, 835 (6th Cir. 2008) ("*Bridge* did not change the overall standard for proximate cause."). Moreover, the Supreme Court's post-*Bridge* decisions in *Hemi*, *Lexmark*, and *Bank of America* agree that RICO proximate cause sounds in directness, not foreseeability or intent. So does this Court's post-*Bridge* decision in *Empress Casino*. *Supra* at 18-19.

Like the Funds here, the First and Third Circuits believed that *Bridge*'s treatment of first-party reliance "forecloses th[e] argument" that intervening "causal link[s]," such as doctors' prescription decisions, defeat proximate cause. *Neurontin*, 712 F.3d at 36-37; *Avandia*, 804 F.3d at 643. Again, that is wrong. As discussed above, *Bridge* held that first-party reliance is not an *element* of a RICO claim. But it did not hold that intervening causal links—especially individualized and unpredictable ones—do not matter. Indeed, *Bridge* expressly recognized that "absence of first-party reliance *may in some cases tend to show that an injury was*

not sufficiently direct," 553 U.S. at 659 (emphasis added)—the very argument that the First and Third Circuits somehow thought was "foreclosed."

Neurontin and *Avandia* also brushed aside the fact that "physicians…consider[] factors other than [manufacturers' statements] in making their prescribing decisions." *Neurontin*, 712 F.3d at 39. In those courts' view, "[r]ather than showing a lack of proximate causation," this merely raises a "damages question." *Id.*; *Avandia*, 804 F.3d at 644. However, as discussed above, "damages questions" have always been central to proximate cause under RICO. *Supra* at 18. Indeed, this Court has noted that "speculative damages claims…are precisely…[what] the Supreme Court was trying to avoid…when [it] instituted [RICO's] proximate cause requirement." *Evans*, 434 F.3d at 933.

How, then, did the First and Third Circuits get the idea that "proximate cause and certainty of damages" are wholly "distinct requirements"? For that proposition, they cited Justice Thomas's *dissent* in *Anza*—an opinion that no other Justice joined, and whose reasoning the majority rejected. *Neurontin*, 712 F.3d at 39 (quoting *Anza*, 547 U.S. at 466 (Thomas, J., dissenting)). (The Funds rely on that same dissent here. (Funds' Br. 21.)) That solo dissent is obviously not the law. Indeed, even Justice Thomas has changed his mind: He later wrote the Court's opinion in *Bridge*, which rested its finding of proximate cause on the fact that "there [were] no independent factors" that might "account for" any part of the plaintiffs' damages. 553 U.S. at 658. *Bridge* did not deem this an irrelevant "damages question," as the First and Third Circuits did.

Finally, the First and Third Circuits' treatment of *Holmes*'s subsidiary questions—duplicative recoveries and alternate means of deterrence—was cursory and unconvincing. *Neurontin* found that there was "no risk of duplicative recovery" because doctors and P&T Committees did not pay for Neurontin. 712 F.3d at 37. But it consciously ignored claims by beneficiaries, cryptically stating that the question of harm to "premium payers" was "not before us in this case." *Id.* at 38 n.12. *Neurontin* also found that "[h]olding Pfizer liable will…deter[] wrongful conduct," *id.* at 39, but it failed to consider the existence of other, less "problem[atic]" ways to "vindicate the law," *Holmes*, 503 U.S. at 269; *cf. supra* at 35-36 (addressing several such ways). *Avandia*, for its part, offered even less analysis: it summarily pronounced that "[t]here [was] no risk of duplicative recovery" and that "no one [was] better suited to sue." 804 F.3d at 646. Those unexplained statements were likely incorrect in *Avandia*; they are surely incorrect here.

E. The Funds' Policy Arguments Lack Merit

The Funds also raise several policy arguments. If this Court affirms, they maintain, a "fatal blow" will be dealt "to claims that RICO was designed to promote"; they will be "deni[ed] compensation" for their claimed injuries; and AbbVie will get "a free pass." (Funds Br. 23-25.) These arguments are meritless.

First, RICO was not "designed to promote" suits like this one. RICO was "aimed primarily at criminal enterprises such as the Mafia." *United States v. Masters*, 924 F.2d 1362, 1367 (7th Cir. 1991). Congress crafted a different statute (the FDCA) to regulate pharmaceutical marketing, and it entrusted an expert agency

(the FDA) with sole authority to enforce it. *Supra* at 4-5. Surely, RICO's drafters never envisioned that statute serving as a "super FDCA" with a private right of action and mandatory treble damages.

Second, the inability to sue *under RICO* does not preclude the Funds from "obtain[ing] compensation" for any purported injury. *See Mendelovitz*, 40 F.3d at 187 ("Our holding does not leave [Plaintiff] remediless for the actions [he] complains of; RICO just is not the proper vehicle."). Indeed, the Funds asserted several state-law claims, which were dismissed without prejudice; they remain free to pursue those claims even if this Court affirms.

Finally, the notion that affirmance would give AbbVie "a free pass" is farcical. The federal government, numerous states, patients, and shareholders have already sued over these facts. In the government proceedings alone, AbbVie has paid what the Funds' counsel touted as "one of the largest [settlements] ever in the history of the False Claims Act."[20]

If anything, policy considerations favor *affirmance*. Ruling for the Funds would unleash a torrent of novel RICO suits, clogging federal dockets. These suits would upend the scheme that Congress envisioned when it enacted the FDCA and entrusted sole enforcement authority to the federal government. *Cf. Hemi*, 559 U.S. at 13 n.1 (refusing to interpret RICO in a manner that would allow plaintiffs to circumvent the "limited remedies" of another federal statute). Finally, these treble-damages suits would work a "radical change" in the economics of the healthcare sec-

[20] *Grant & Eisenhofer Represents Lead Whistleblower in Historic $1.6 Billion Settlement*, PR NEWSWIRE, May 7, 2012.

tor—a policy choice that is properly "for legislatures…to consider" and "no part of the judicial function." *Teamsters*, 196 F.3d at 825.

II. IN THE ALTERNATIVE, THE FUNDS' RICO CLAIMS FAIL FOR LACK OF A PLAUSIBLE INJURY TO "BUSINESS OR PROPERTY"

This Court "may affirm on any basis fairly presented in the record," whether the District Court "consider[ed]" it or not. *Delatorre v. United States*, 847 F.3d 837, 843 (7th Cir. 2017). As AbbVie argued below, civil RICO affords relief only to "person[s] injured in [their] business or property." 18 U.S.C. § 1964(c). This requires an "actual…out-of-pocket loss." *Maio v. Aetna*, 221 F.3d 472, 483-84 (3d Cir. 2000); *McLaughlin v. Am. Tobacco Co.*, 522 F.3d 215, 227 (2d Cir. 2008). The Funds do not suffer any loss from *their own* "pockets" when they spend *their beneficiaries'* money to purchase allegedly unsafe or ineffective medicines.

TPPs, again, are "just financial intermediaries" who "collect…premiums" from their beneficiaries, pool them, "and spend them" on beneficiaries' collective treatment. *Teamsters*, 196 F.3d at 824. Because these premiums are calibrated to their expenditures, TPPs' "books balance" whether their spending on drugs is "high or low." *Id.* And that is true regardless of *why* costs are high—*e.g.*, because of an off-label marketing campaign. *See AstraZeneca*, 634 F.3d at 1368-69. Thus, it is "purchasers of insurance, not [TPPs]," who actually "foot the medical bill." *Teamsters*, 196 F.3d at 824; *see also Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris*, 1998 U.S. Dist. LEXIS 5951, at *5-7 (E.D. Pa. Apr. 22, 1998) ("[TPPs] are merely handling the payments with money provided by others, and have no genuine stake in the matter."). Sums that TPPs spend on prescriptions—even

fraud-induced prescriptions—are not an out-of-pocket loss *to them*. *AstraZeneca*, 634 F.3d at 1368-69; *Olivares*, 2011 U.S. Dist. LEXIS 117750, at *17-18; *Seafarers*, 27 F. Supp. 2d at 627-28; *Steamfitters*, 1998 U.S. Dist. LEXIS 5951, at *5-7.

Consider what would obtain today if AbbVie had never engaged in the alleged off-label scheme. The Funds might have spent less money on Depakote—but one must "consider both the income and the expenditure sides of [the] balance sheet." *Teamsters*, 196 F.3d at 824. Because the Funds' costs would have stayed low, they would have used *those* lower costs in calculating premiums, and they would have collected *those* lower premiums from their insureds—not the higher premiums they collected in the real world. Thus, the Funds would be exactly where they are now. Awarding them the "hundreds of millions of dollars" they seek would not place them "in the same position they would have been in but for the illegal conduct." *McLaughlin*, 522 F.3d at 227-28. It would be an enormous windfall.[21]

Below, the Funds objected that this argument is akin to the "passing on" defense that courts have rejected in antitrust law. *See Hanover Shoe, Inc. v. United Shoe Mach. Corp.*, 392 U.S. 481 (1968). But AbbVie does not argue that the Funds suffered a cognizable injury upon payment for Depakote, then "passed it on" to a downstream purchaser. The Funds *never* incurred an injury: their beneficiaries collectively "pa[id] for the [Depakote] costs, in advance," through their premiums,

[21] ERISA prohibits welfare-benefit funds from refunding trust assets outside of narrow circumstances inapplicable here. 29 U.S.C. § 1103(c); *Se. Fla. Laborers*, 1998 U.S. Dist. LEXIS 5440, at *6. Accordingly, "[i]f the Fund[s] recover[]" in this suit, they "would not reimburse" their beneficiaries "because [they are] statutorily prohibited from doing so." *Id.*

Teamsters, 196 F.3d at 824, and absent AbbVie's alleged scheme, that money would not have come into the Funds' hands at all.

The Funds also complained below that this argument is not suitable for resolution on the pleadings. But this Court did exactly that in *Teamsters*. Others have too. *See AstraZeneca*, 634 F.3d at 1368-69; *Olivares*, 2011 U.S. Dist. LEXIS 117750, at *17-18; *Seafarers*, 27 F. Supp. 2d at 627-28; *Steamfitters*, 1998 U.S. Dist. LEXIS 5951, at *5-7. After all, courts may rely on "experience and common sense" at the motion-to-dismiss stage. *Iqbal*, 556 U.S. at 679. And where a TPP "ple[ads] no facts…that suggest [it] established premiums in a way inconsistent with the insurance industry's conventional ratemaking procedures," the commonsense inference is that it *did* use those procedures. *AstraZeneca*, 634 F.3d at 1368. Here, the Funds never pleaded any such facts—even in their Second Amended Complaint, after AbbVie had already raised this argument twice.

CONCLUSION

For the reasons above, the judgment should be affirmed.[22]

[22] The Funds' request for reassignment in case of remand (Funds' Br. 25 n.10) lacks merit. Even if this Court disagrees with Judge Ellis's proximate-cause analysis, it was supported by ample authority and does not manifest "bias" or inability to "consider the issues fairly." *Volling v. Kurtz Paramedic Servs.*, 840 F.3d 378, 386 (7th Cir. 2016).

Dated: New York, New York
June 5, 2017

Respectfully submitted,

/s/ William F. Cavanaugh, Jr.

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I hereby certify, pursuant to Fed. R. App. P. 32(a)(7) and Circuit Rule 32(b), that the attached brief is proportionally spaced; uses a typeface (Century Schoolbook) of 12 points for the text and 11 points for the footnotes; and contains 13,938 words (excluding portions exempted by Fed. R. App. P. 32(a)(7)(B)), as counted by Microsoft Office Word 2010, which was used to produce this brief.

Dated: New York, New York
June 5, 2017

/s/ William F. Cavanaugh, Jr.

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