5-16-2012

In re: Schering Plough

PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

_____

Nos. 10-3046 and 10-3047

_____

IN RE: SCHERING PLOUGH CORP.
INTRON/TEMODAR CONSUMER CLASS ACTION

Angela Montgomery,
Appellant in No. 10-3046

International Brotherhood of Teamsters Local No. 331
Health & Welfare Trust Fund,
Appellant in No. 10-3047

_____

On Appeal from the United States District Court
for the District of New Jersey
(D.C. Civil No. 2-06-cv-05774)
District Judge: Honorable Stanley R. Chesler

_____

Argued December 15, 2011

Before: SLOVITER, VANASKIE and GREENBERG,
Circuit Judges

(Filed: May 16, 2012)

Donald E. Haviland, Jr., Esq. (*Argued*)
Michael J. Lorusso, Esq.
Haviland Hughes
111 South Independence Mall East
The Bourse, Suite 1000
Philadelphia, PA 19106

Counsel for Plaintiff-Appellant Angela Montgomery

Stephen G. Grygiel, Esq. (*Argued*)
John E. Keefe, Jr., Esq.
Stephen T. Sullivan, Jr., Esq.
Keefe Bartels
170 Monmouth Street
Red Bank, NJ 07701

Counsel for Plaintiff-Appellant International Brotherhood of Teamsters Local No. 331 Health & Welfare Trust Fund

Douglas S. Eakeley, Esq.
Natalie J. Kraner, Esq.
Alan S. Modlinger, Esq.
Kristin A. Muir, Esq.
Gavin J. Rooney, Esq. (*Argued*)
Lowenstein Sandler
65 Livingston Avenue
Roseland, NJ 07068

Counsel for Defendant-Appellee Schering Plough Corp.

OPINION

VANASKIE, *Circuit Judge*.

At issue in these consolidated appeals is the standing of third-party payors of drugs prescribed for "off-label" purposes, *i.e.*, uses not approved by the Food and Drug Administration ("FDA"), as well as the standing of individual patients prescribed drugs for off-label purposes, to pursue claims against a pharmaceutical company and its affiliated marketing entities under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961, *et seq.*, the New Jersey RICO statute, N.J.S.A §2C:41-1, *et seq.*, as well as other state statutory and common law causes of action. Both groups of plaintiffs claim that the defendants pursued illegal marketing campaigns to persuade physicians to prescribe certain drugs for off-label uses. The District Court found that both groups of plaintiffs lacked standing because, *inter alia,* they did not allege a plausible nexus between the assailed marketing campaign and the physicians' decisions to prescribe certain drugs for off-label use. Having carefully considered the parties' contentions in the context of the entire record, we agree that dismissal of both actions for want of standing is warranted. Accordingly, we will affirm the District Court's well-reasoned decisions.

I.

A. The Parties

There are two sets of plaintiffs in these consolidated appeals. One set of Plaintiffs consists of a putative

nationwide class of third-party payors ("TPPs").[1] The other set of Plaintiffs is comprised of a putative nationwide class of individual patient-consumers who paid for prescriptions of certain drugs for off-label uses, with the named class representative being Angela F. Montgomery.[2] Separate Amended Complaints were filed on behalf of each set of Plaintiffs. The Defendants common to both Amended Complaints are the Schering-Plough Corporation, a manufacturer of pharmaceutical products, and its affiliated marketing and sales companies, the Schering Sales Corporation and Schering Corporation. The TPP Amended Complaint also names as defendants another Schering subsidiary, Integrated Therapeutics Group, Inc., individual Schering executives Richard J. Kogan, William K. Heiden, and Mary Naughton, as well as unnamed individuals ("John Doe" and "Jane Doe" defendants), and unknown business entities ("ABC Corporations"), who purportedly participated in the alleged illegal and false sales and marketing campaigns. For sake of simplicity, we shall refer to the

[1] There are four TPPs named as plaintiffs: the International Brotherhood of Teamsters Local No. 331 Health & Welfare Fund ("Local 331"), Heavy and General Laborers' Local Union 472/172 Welfare Fund, United American Insurance Company, and Blue Cross Blue Shield of Alabama. Local 331 is the only third-party payor to appeal. We are thus concerned only with the standing of Local 331.

[2] This action originally included five named patients: Angela F. Montgomery, Harold Estelle, Beryl A'Dare Bratton, Dorothy Bratton, and John Huston. Only Angela F. Montgomery has continued to pursue this matter. We are thus concerned only with Montgomery's standing.

Defendants collectively as "Schering." Both sets of Plaintiffs assert that they paid for Schering drugs that were ineffective or unsafe for the off-label uses for which they were prescribed.

B. FDCA Labeling and Marketing Regulations

The off-label marketing claims are at least partially predicated on Schering's alleged violations of the labeling and marketing restrictions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"). The FDCA regulates the manufacturing, marketing and sale of prescription drugs, and provides that a drug cannot be sold in interstate commerce unless it is approved by the FDA for the specific medical use, or "indication," listed on the drug's labeling. *See* 21 U.S.C. § 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug."). To obtain FDA approval, drug companies generally must submit evidence from clinical trials and other testing that evaluate the drug's risks and benefits and demonstrate that it is safe and effective for all of the indications "prescribed, recommended, or suggested" on the drug's label. *See id.* at § 355(d).

Prescription drugs frequently have therapeutic uses other than their FDA-approved indications. The FDCA, however, generally prohibits manufacturers from marketing, advertising, or otherwise promoting drugs for such unapproved or "off-label" uses. *See* 21 U.S.C. § 331(a) and (d) (prohibiting manufacturers from introducing a drug into interstate commerce with an intent that it be used for an off-

label purchase, or by "misbranding" it by including information about unapproved uses on its label).

Because the FDCA does not regulate the practice of medicine, physicians may lawfully prescribe drugs for off-label uses. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (recognizing off-label usage as "an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine."); *Wash. Legal Found. v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000) ("A physician may prescribe a legal drug to serve any purpose that he or she deems appropriate, regardless of whether the drug has been approved for that use by the FDA."). Thus, there is a certain "asymmetry" in the regulation of off-label uses: while physicians may lawfully prescribe drugs for off-label uses, the FDCA generally prohibits manufacturers from marketing these uses to physicians. *See id.* at 332-33 (referring to the FDCA's "asymmetrical—if not necessarily inconsistent—regulatory treatment" of off-label uses). Indeed, the FDCA's regulatory regime prohibits manufacturers from directly advertising off-label uses, such as through labeling claims or explicit statements made by sales representatives. Moreover, it is also unlawful for manufacturers to engage in certain indirect methods of off-label marketing. For example, in certain circumstances it is unlawful for manufacturers to sponsor continuing medical education ("CME") courses that focus on off-label uses. The FDCA does, however, permit manufacturers to distribute information about off-label uses in certain limited circumstances. *See id.* at 333.

The drugs involved in these consolidated appeals (the "Subject Drugs") are certain oncology and Hepatitis drugs,

including Intron®-A ("Intron-A"), PEG-Intron® ("PEG-Intron"), Rebetol® ("Rebetol") and Rebetron® ("Rebetron") (collectively the "Intron Franchise Drugs"), and Temodar® ("Temodar"). The FDA has approved these drugs for specific purposes.

C. Criminal Case Against Schering

In June 2001, the FDA's Division of Drug Marketing, Advertising, and Communications sent Schering Sales a letter notifying it that the FDA had "identified various promotional activities that [were] in violation of the [FDCA] and its implementing regulations." (Information at 12-16, United States v. Schering Sales Corp., No. 06-CR-10250 (D. Mass. Aug. 29, 2006)). The letter cited a May 2001 American Society of Clinical Oncology Annual Meeting in San Francisco at which the FDA witnessed Schering sales representatives give purportedly "false or misleading efficacy information about Temodar to visitors at the commercial exhibit hall booth," and "promote[] Temodar for the unapproved use in first line therapy of anaplastic astrocytoma." (*Id.* at 12-13). The FDA's letter requested that Schering "immediately cease making such violative statements and any other promotional activities or materials for Temodar that make the same or similar claims or presentations." (*Id.* at 13).

In August 2006, the United States Attorney for the District of Massachusetts charged Schering Sales with conspiracy to make false statements to the federal government, in violation of 18 U.S.C. § 371. (*Id*. at 12-16). The Government's one-count Information alleged that "Schering Sales and its co-conspirators knowingly and willfully made material false statements to the FDA." (*Id.* at

8). It stated that Schering Sales' response to the FDA June 2001 letter specifically asserted that Schering's home office had "aggressively pursued sales of Intron A and Temodar for unapproved uses" through numerous methods, including training the sales force to seek off-label sales, requiring the sales force to "create business plans that emphasized detailed promotional goals to obtain off-label sales," and compensating the sales force partly on their success in achieving off-label sales. (*Id.*)

Schering Sales pleaded guilty to the one-count Information pursuant to a written Settlement Agreement. (*See* Amended Judgment, United States v. Schering Sales Corp., 06-CR-10250 (D. Mass. Feb 7, 2007)). Under the Settlement Agreement, Schering Sales agreed to pay fine of $180 million. (*Id.*) It also agreed to pay $255 million to resolve civil claims that it defrauded U.S. Government health benefit programs, including Medicare, Medicaid, and the Veteran's Administration. (*Id.*)

D. Consolidated Putative Class Action

Following Schering's settlement with the Government, various civil suits were filed across the country by consumer plaintiffs who were prescribed, consumed, and paid for the drugs, and by TPPs who paid for the Subject Drugs prescribed to their plan members. The Judicial Panel on Multi-District Litigation ordered the cases to be transferred to the District of New Jersey, where Schering is incorporated, and consolidated pursuant to 28 U.S.C. § 1407.

The District Court directed that the various actions transferred to it be consolidated for pretrial management and that a consolidated complaint on behalf of all plaintiffs be

filed. In December 2007, the nine named plaintiffs (the four TPPs and five patients identified in footnotes 1 and 2, *supra*) filed a Consolidated Class Action Complaint (the "Complaint") on behalf of themselves and others similarly situated, alleging that the Defendants engaged in illegal promotion of the Subject Drugs in violation of the federal and New Jersey RICO statutes (Counts I and II), and the New Jersey Consumer Fraud Act ("NJCFA"), N.J. Stat. Ann. § 56:8-1, *et seq.* (Count III). The Complaint also asserted common law claims for unjust enrichment (Count IV); civil conspiracy (Count V); fraud (Count VI); negligent misrepresentation (Count VII); aiding and abetting breach of fiduciary duty (Count VIII); and equitable accounting (Count IX).

In an Order and Opinion issued on July 10, 2009, the District Court dismissed the Complaint in its entirety pursuant to Fed. R. Civ. P. 9(b), 12(b)(1) and 12(b)(6), for failure to state a claim and lack of standing, but granted leave to file an amended complaint. *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, Slip Copy, 2009 WL 2043604 (D.N.J. 2009) ("*Schering I*"). The Court found that the Complaint lacked sufficient factual allegations to plausibly assert an injury-in-fact that was cognizable under any of the asserted causes of action and fairly traceable to the Defendants' alleged misconduct.

In September 2009, two separate Amended Complaints were filed, one by Montgomery and the other by the four TPP plaintiffs identified in footnote 1, *supra*. Montgomery filed an Amended Civil Consumer Class Action Complaint ("MAC") individually and on behalf of a putative nationwide class of similarly situated patient-consumers who purchased,

were reimbursed, and/or paid for any of the Subject Drugs during the class period. The MAC asserted violations of the Washington State Consumer Protection Act, Wash. Rev. Code § 19.86.010, *et seq*. (Count I), and the consumer protection statutes of the remaining 49 states, the District of Columbia, and Puerto Rico (Count II), as well as claims of civil conspiracy (Count III), aiding and abetting breach of fiduciary duty (Count IV), and unjust enrichment (Count V).

The TPP plaintiffs filed an Amended Consolidated Class Action Complaint ("TPP Complaint") on behalf of a proposed class of health and welfare funds and other TPPs who paid any portion of the purchase price for the Subject Drugs during the class period. The TPP Complaint asserted violations of the federal and New Jersey RICO statutes, (Counts I and II), in addition to common law claims for intentional interference with contractual relations (Count III) and unjust enrichment (Count IV).

The Plaintiffs' Amended Complaints allege that Schering engaged in a widespread marketing campaign that employed illegal techniques to promote prescriptions of the Subject Drugs for off-label uses. They contend that these illegal practices included: (1) promoting certain of the Subject Drugs for off-label uses; (2) using false and misleading statements to promote certain of the Subject Drugs as effective, safe, and cost-effective for off-label uses; and (3) providing physicians with disguised and undisguised bribes, kickbacks and other illegal inducements to encourage them to prescribe the Subject Drugs for off-label uses.

Plaintiffs claim that Schering used a variety of methods to effectuate this marketing scheme and disseminate its false claims. For example, they allege that Schering

trained its sales representatives to mislead medical professionals about the Subject Drugs' effectiveness for off-label uses by distorting contrary scientific data and the results of clinical studies. They also claim that the Schering sales force promoted off-label prescriptions by disseminating false and misleading statements in private sales meetings with doctors, at medical conferences, and in CME programs. Plaintiffs also assert that Schering promoted these off-label prescriptions through both disguised and undisguised bribes to induce doctors to prescribe the Subject Drugs.

Plaintiffs aver that Schering's unlawful marketing practices caused physicians to prescribe the Subject Drugs for off-label uses instead of equally effective alternative treatments that were approved for the prescribed uses or no medication at all. They assert that these marketing techniques led to a significant increase in prescriptions of the Subject Drugs for off-label uses, and contend that this caused the Plaintiffs "ascertainable loss" because they paid "hundreds of millions, if not billions, of dollars for the Subject Drugs that they otherwise would not have paid."

On October 28, 2009, Schering filed separate motions to dismiss each Amended Complaint. On June 9, 2010, the District Court issued separate Orders and Opinions (collectively, "*Schering II*") granting both motions. The Court dismissed the TPP Complaint because it failed to adequately plead the injury-in-fact and causation elements required to establish standing to assert its RICO, interference with contractual relations, and unjust enrichment claims. The Court also held that even if the Complaint had established standing to pursue non-RICO claims, its two common law claims of interference with contractual relations and unjust

enrichment would still fail under Rule 12(b)(6). The Court dismissed the MAC for failure to show a causal link between Montgomery's alleged injury and Schering's alleged misconduct.

II.

We have jurisdiction over this appeal pursuant to 28 U.S.C. § 1291. We exercise plenary review over the District Court's dismissal of the Amended Complaints. *See United States ex rel. Atkinson v. Pa. Shipbuilding Co.*, 473 F.3d 506, 514 (3d Cir. 2007) (review of dismissal for lack of subject matter jurisdiction under Rule 12(b)(1) is plenary); *Howard Hess Dental Labs. Inc. v. Dentsply Int'l, Inc.*, 602 F.3d 237, 246 (3d Cir. 2010) (review of Rule 12(b)(6) dismissal is plenary).

Under Fed. R. Civ. P. 12(b)(1), a court must grant a motion to dismiss if it lacks subject-matter jurisdiction to hear a claim. "A motion to dismiss for want of standing is . . . properly brought pursuant to Rule 12(b)(1), because standing is a jurisdictional matter." *Ballentine v. United States*, 486 F.3d 806, 810 (3d Cir. 2007). In evaluating a Rule 12(b)(1) motion, a court must first determine whether the movant presents a facial or factual attack. *Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977). In reviewing a facial challenge, which contests the sufficiency of the pleadings, "the court must only consider the allegations of the complaint and documents referenced therein and attached thereto, in the light most favorable to the plaintiff." *Gould Elec. Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000). The Defendants' Rule 12(b)(1) motions are properly understood as facial attacks because they contend that the

Amended Complaints lack sufficient factual allegations to establish standing.

In evaluating whether a complaint adequately pleads the elements of standing, courts apply the standard of reviewing a complaint pursuant to a Rule 12(b)(6) motion to dismiss for failure to state a claim: "Court[s] must accept as true all material allegations set forth in the complaint, and must construe those facts in favor of the nonmoving party." *Ballentine*, 486 F.3d at 810 (citing *Warth v. Seldin*, 422 U.S. 490, 501 (1975)); *see also Baldwin v. Univ. of Pittsburgh Med. Ctr.*, 636 F.3d 69, 73 (3d Cir. 2011) ("A dismissal for lack of statutory standing is effectively the same as a dismissal for failure to state a claim."). The Supreme Court most recently explained this standard in *Bell Atl. Corp v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 129 S.Ct. 1937 (2009): "[A] complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 129 S.Ct. at 1949 (quoting *Twombly*, 550 U.S. at 570). We have outlined a three-step approach to evaluating whether a complaint satisfies this standard:

> First, the court must "tak[e] note of the elements a plaintiff must plead to state a claim." Second, the court should identify allegations that, "because they are no more than conclusions, are not entitled to the assumption of truth." Finally, "where there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief."

Santiago v. Warminster Twp., 629 F.3d 121, 130 (3d Cir. 2010) (quoting *Iqbal*, 129 S.Ct. at 1947-50) (footnote omitted).

While the plausibility standard does not impose a "probability requirement," it does demand "more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 129 S.Ct. at 1949 (citing *Twombly*, 550 U.S. at 556). Pursuant to *Iqbal*'s clarification of the plausibility determination as a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense," *id.*, this Court has found that "[s]ome claims require more factual explication than others to state a plausible claim for relief." *West Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 98 (3d Cir. 2010). We have reasoned that, "[f]or example, it generally takes fewer factual allegations to state a claim for simple battery than to state a claim for antitrust conspiracy." *Id.*

"A complaint has to 'show' such an entitlement with its facts." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 211 (3d Cir. 2009). With respect to 12(b)(1) motions in particular, "[t]he plaintiff must assert facts that affirmatively and plausibly suggest that the pleader has the right he claims (here, the right to jurisdiction), rather than facts that are merely consistent with such a right." *Stalley v. Catholic Health Initiatives*, 509 F.3d 517, 521 (8th Cir. 2007).

III.

Article III of the Constitution limits the scope of the Federal judicial power to the adjudication of "cases" or "controversies." U.S. Const. art. III, § 2. This "bedrock requirement," *Valley Forge Christian Coll. v. Ams. United for*

Separation of Church & State, Inc., 454 U.S. 464, 471 (1982), protects the system of separated powers and respect for the coequal branches by restricting the province of the judiciary to "decid[ing] on the rights of individuals." *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 170 (1803). Indeed, "'[n]o principle is more fundamental to the judiciary's proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies.'" *Raines v. Byrd*, 521 U.S. 811, 818 (1997) (quoting *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 37 (1976)).

The courts have developed several justicability doctrines to enforce the case-or-controversy requirement, and "perhaps the most important of these doctrines" is the requirement that "a litigant have 'standing' to invoke the power of a federal court." *Allen v. Wright*, 486 U.S. 737, 750 (1984). "[T]he standing question is whether the plaintiff has 'alleged such a personal stake in the outcome of the controversy' as to warrant his invocation of federal-court jurisdiction and to justify exercise of the court's remedial powers on his behalf." *Warth*, 422 U.S. at 498-99 (citing *Baker v. Carr*, 369 U.S. 186, 204 (1962)).

The plaintiff bears the burden of meeting the "irreducible constitutional minimum" of Article III standing by establishing three elements:

> First, the plaintiff must have suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical. Second, there must be a causal connection between the injury and the conduct complained of—the injury has to be fairly

> traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court. Third, it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61 (1992) (internal quotations, alterations, and citations omitted).

We have recognized that of the three required elements of constitutional standing, "the injury-in-fact element is often determinative." *Toll Bros., Inc. v. Twp. of Readington*, 555 F.3d 131, 138 (3d Cir. 2009). To satisfy this requirement, the alleged injury must be "particularized," in that it "must affect the plaintiff in a personal and individual way." *Lujan*, 504 U.S. at 560 n.1. "[T]he 'injury in fact' test requires more than an injury to a cognizable interest. It requires that the party seeking review be himself among the injured." *Id.* at 563 (quoting *Sierra Club v. Morton*, 405 U.S. 727, 734-35 (1972)). The injury must also be "an invasion of a legally protected interest." *Id.* at 560. Since "standing is not dispensed in gross," *Lewis v. Casey*, 518 U.S. 343, 358 n.6 (1996), a plaintiff who raises multiple causes of action "must demonstrate standing for each claim he seeks to press." *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006). Furthermore, "the standing inquiry requires careful judicial examination of a complaint's allegations to ascertain whether the particular plaintiff is entitled to an adjudication of the particular claims asserted." *Allen*, 468 U.S. at 752.

A. Local 331

The District Court dismissed the TPP Complaint in its entirety for lack of standing and failure to state a claim. Local 331 contends that the Court applied the wrong standard of review and consequently erred in finding that the TPP Complaint fails to adequately plead facts to establish an injury-in-fact that is fairly traceable to the Defendants' alleged misconduct. Local 331 also argues that the Court erred in finding that it failed to state a claim for tortious interference with contract and unjust enrichment. We address each of these arguments in turn.

Counts I and II of the TPP Complaint assert causes of action under the federal and New Jersey RICO statutes, respectively. The federal RICO statute creates a civil remedy, including an award of treble damages, costs, and attorneys fees, for "any person injured in his business or property" by a violation of one of RICO's substantive provisions. 18 U.S.C. §1964(c). Pursuant to 18 U.S.C. § 1962(c), it is unlawful for "'any person' who is employed by or associated with 'any enterprise' affecting interstate commerce to 'participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity.'" *Genty v. Resolution Trust Corp.*, 937 F.2d 899, 906 (3d Cir. 1991) (quoting 18 U.S.C. § 1962(c)). The RICO statute defines racketeering activity by a list of crimes, or "predicate offenses," including several state felonies such as murder, kidnapping, and bribery that are punishable by imprisonment for more than one year, and federal crimes such as bribery, mail fraud and wire fraud. 18 U.S.C. § 1961(1).

The TPP Complaint also alleges violations of the New Jersey RICO statute, N.J. Stat. Ann. § 2C:41-4(c), based on the same alleged enterprises, predicate offenses, and pattern

of racketeering activity as those alleged in support of the federal RICO claims. (TPP Compl. ¶¶396-403.) Since the TPP Complaint's federal and New Jersey RICO claims parallel each other, and because the two RICO statutes are intended to be coextensive, we follow the District Court's approach and analyze the two claims concurrently. (*See* A. 86, n.3); *see also Cetel v. Kirwan Fin. Grp., Inc.*, 460 F.3d 494, 510 (3d Cir. 2006) ("[T]he New Jersey Supreme Court believed the New Jersey RICO statute was and should be consistent with the federal RICO statute.") (citing *State v. Ball*, 661 A.2d 251 (N.J. 1995)).

In addition to meeting the constitutional standing requirements, "plaintiffs seeking recovery under RICO must satisfy additional standing criterion set forth in section 1964(c) of the statute." *Maio v. Aetna, Inc.*, 221 F.3d 472, 482 (3d Cir. 2000). Section 1964(c) confers standing upon "any person injured in his business or property by reason of a violation of section 1962 of this chapter . . ." 18 U.S.C. § 1964(c). We have interpreted this language as requiring RICO plaintiffs to "make two related but analytically distinct threshold showings" to establish standing: "(1) that the plaintiff suffered an injury to business or property; and (2) that the plaintiff's injury was proximately caused by the defendant's violation of 18 U.S.C. § 1962." *Maio,* 221 F.3d at 483.

The District Court in this case conducted an extensive analysis of the TPP Complaint to determine if it complied with the RICO standing requirement of alleging injury to business or property. It concluded that the TPP Complaint did not allege a concrete injury to TPP business or property because it did not contain sufficient allegations that they paid

for prescriptions of the drugs that were actually ineffective or otherwise worth less than what they paid for them. On appeal, the parties focused their arguments, in significant part, on debating this conclusion.

Although we agree with the District Court's conclusion in this respect, we need not reach the question of standing under RICO. It is well-established that a plaintiff's Article III standing is a prerequisite for the federal courts to decide the merits of a suit. *See Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, 109-10 (1998). Therefore, prior to considering whether Local 331 has standing to bring a RICO claim, we must determine whether it has Article III standing to invoke the jurisdiction of this Court. Because we find that Local 331 has not established that its alleged injury is fairly traceable to Schering's alleged wrongful conduct, we conclude that the Complaint was properly dismissed for lack of Article III standing.

The District Court held that the TPP Complaint fails to sufficiently allege facts to establish that the plaintiffs' off-label purchases of the Subject Drugs—"assuming one were to constitute injury-in-fact"—is fairly traceable to Schering's allegedly unlawful marketing practices, and "specifically to misrepresentations about the [drugs] and/or to conduct characterized as bribery." (A. 95.) On appeal, Local 331 argues that if the Court had "properly applied [the causation] standard to the plausibility test, it would have determined that there is a traceable connection from Local 331's injuries to the Defendant's illegal marketing scheme." (Local 331 Br. at 18.)

We limit our analysis to the injury and causation theories that Local 331 raises on appeal.[3] In the Statement of Case section of its Brief, Local 331 mentions three distinct injuries. First, it paid for off label prescriptions that were ineffective. Second, it paid for off label prescriptions when less expensive but equally effective medication was available. And third, it "paid for elevated drug prices that recouped the costs of Schering's illegal marketing." (Local 331 Br. At 4.) The argument section of its Brief, however, is limited to economic loss based on paying for ineffective drugs. Accordingly, we further limit our analysis to the question of whether the TPP complaint alleges a causal link between the challenged conduct and the injury that Local 331 actually argues on appeal.

On appeal, Local 331 defends its standing to sue in large part on the basis of drug purchases made by the other TPP Plaintiffs. It cites allegations that the Defendants made false claims about Temodar and Intron-A, and the other TPP Plaintiffs' purchases of those drugs for off-label indications. (Local 331 Br. at 14-17.) Such allegations are unhelpful to Local 331, which does not allege that it ever paid for a Temodar or Intron-A prescription. *See Lewis v. Casey*, 518 U.S. 343, 347 (1996) (requiring named plaintiffs in a putative class action to allege "that they personally have been injured, not that injury has been suffered by other, unidentified members of the class . . . ."). Accordingly, we will assess whether the TPP Complaint contains sufficient factual

[3] We, of course, have no jurisdiction to decide the standing of those TPP Plaintiffs who have not appealed. *See Torres v. Oakland Scavenger Co.*, 487 U.S. 312, 317 (1988); *Nocula v. UGS Corp.*, 520 F.3d 719, 725 (7th Cir. 2008).

allegations to confer standing upon Local 331 based upon its alleged purchases.

According to the TPP Complaint, Local 331's damages are limited to two prescriptions of Rebetol:

> Member Kraft and Member Maurone were both prescribed Rebetol during the Class Period which were paid for in large part by Local 331. Upon information and belief, these prescriptions were written for off-label uses by physicians improperly influenced by the false and misleading statements, bribes, and other dishonest inducements brought to bear by Defendants' illegal off-label marketing scheme.

(TPP Compl. ¶21.)[4] Accordingly, to establish standing, Local 331 must allege facts showing a causal relationship between the alleged injury—payments for Rebetol that was ineffective or unsafe for the use for which it was prescribed—and Schering's alleged wrongful conduct.

To show the requisite causal connection, Local 331 must allege sufficient facts to plausibly support "a causal connection between the injury and the conduct complained

[4] Local 331 claims that the TPP Complaint "alleged with requisite specificity that [Local 331] paid for Intron Franchise Drugs *like* Rebetol." (Local 331 Reply at 9) (emphasis added). However, Local 331 does not cite any portion of the TPP Complaint that states that Local 331 paid for any Intron Franchise Drugs other than two Rebetol prescriptions. (*See* Local 331 Br. at 15, citing ¶¶ 19, 20, 21, 117, 127, 128).

of—the injury has to be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court." *Lujan*, 504 U.S. at 560. In other words, the Amended Complaint must allege facts that plausibly support a causal connection between Local 331's injury-in-fact and Schering's allegedly illegal marketing or bribery schemes.

In arguing that the TPP Complaint meets this burden, Local 331 essentially repeats the reasoning that the District Court rejected. Specifically, it states that the TPP Complaint alleges both "an overwhelming and reprehensible pattern of deceit by the defendants," including false marketing and illegal inducements to doctors, and that this scheme was aimed at the TPPs. (Local 331 Br. at 18-19.) Local 331 refers to allegations that Schering "falsely marketed the Intron Franchise Drugs as efficacious" for off-label uses, but cites only to paragraphs that discuss Intron-A. (*See* TPP Compl. ¶¶178, 181, 182.) Likewise, Local 331 argues that Schering paid doctors to prescribe the drugs to patients who did not need them, but cites only to paragraphs referring to Intron-A, Temodar, or Rebetron. (*See* TPP Compl. ¶¶15-16, 18, 36, 317-60, 278-89); (Local 331 Br. at 19). Local 331 apparently believes that these allegations are an adequate basis to conclude that, but-for Schering's illegal conduct that increased off-sale prescriptions, "Local 331 either would not have had to pay for them, or would not have had to pay for them at increased prices over readily-available therapies." (*Id.* at 19.)

Local 331's suggestion that the claims about the other drugs are what caused the doctors to prescribe Rebetol for off-label uses is inadequate to establish causation. Local 331

claims that the allegations about the other Subject Drugs, paired with the fact that "Schering alone marketed Rebetol," together reasonably support the inference that "discovery will almost certainly confirm" that Schering also made "false statements about all the drugs described in the Complaint." (Local 331 Reply at 11.) Local 331 must allege facts sufficient to show that the Rebetol which it paid for was prescribed to its members for ineffective off-label uses *because of* Schering's alleged misconduct. There are no averments that come close to satisfying this standard. It is pure conjecture to conclude that because Schering's misconduct caused other doctors to write prescriptions for ineffective off-label uses for other products, Local 331 ended up paying for two prescriptions for Rebetol due to the same kind of misconduct. Accordingly, Local 331 has failed to show the requisite causal relationship between the alleged misconduct and its alleged injury. Therefore, dismissal for lack of standing is warranted.[5]

B. Montgomery

Montgomery, a consumer of Rebetol and PEG-Intron, brought the MAC on behalf of a putative nationwide class of consumers of the Subject Drugs. The MAC alleges facts

[5] The District Court also held that the failure to allege an injury-in-fact traceable to the alleged misconduct compelled the conclusion that the TPP Plaintiffs lacked standing to assert the common law tort claims of interference with contractual relations and unjust enrichment. We concur. Accordingly, there is no need to address the question of whether Local 331 alleged viable claims for interference with contractual relations or unjust enrichment.

particular to her experience and use of two of the Subject Drugs, as well as the various legal theories pursued on behalf of the consumer plaintiffs.

Montgomery suffered from Hepatitis C, a viral liver infection, and after tests conducted in 1999 showed that she was asymptomatic, her physician, Dr. Jeffrey R. Willis, decided not to prescribe her a combination therapy of Rebetol and Intron-A. At a follow-up visit in September 2001, Dr. Willis recommended a different treatment plan,[6] even though Montgomery was still asymptomatic. A few months after this consultation, Dr. Willis prescribed Montgomery the PEG-Intron and Rebetol combination therapy, also called the "PEG-Intron Combination Therapy." (MAC ¶75.)

The MAC avers that at the time she was prescribed the Subject Drugs, they were only approved for patients with

[6] The District Court observed an apparent inconsistency in the MAC regarding which drugs Dr. Willis decided not to prescribe in 1999—Intron-A and Rebetol, according to introductory parts of the MAC—and the drugs he decided to prescribe in 2001—Rebetol and PEG-Intron. (MAC ¶23.) The Court drew the "reasonable inference that the treatment discussed in 1999 involved Rebetol and/or Intron-A, but not PEG-Intron" based on other information in the MAC. It also stated: "despite the [MAC's] assertion that the 'same drugs' that Dr. Willis had rejected as unsuited to Montgomery's condition in 1999 were under consideration in 2001, the records attached to the [MAC] and specifically referenced in paragraph 29 state that Dr. Willis recommended in 2001 that Montgomery receive . . . PEG-Intron, not Intron A." (A. 109-110.)

compensated liver disease, and that since she was healthy and did not need treatment, she suffered from the serious side effects of the drugs and lost weeks of work due to these side effects. The MAC further claims that Dr. Willis changed his mind about her treatment plan because of Schering's improper marketing of the Rebetol/PEG-Intron combination therapy. Specifically, it alleges: "Dr. Willis' new plan for Mrs. Montgomery's treatment for her asymptomatic Hepatitis C evidences that he was subjected to the marketing and sales scheme by Schering alleged in this Amended Complaint." (MAC ¶30.)

The MAC reaches this conclusion based on the alleged facts that: (1) due to Schering's off-label marketing techniques, Dr. Willis mistakenly believed that the combination therapy was the standard treatment for Montgomery's condition; (2) Dr. Willis prescribed the combination therapy before sending Montgomery for two tests that he suggested were necessary before beginning the treatment; (3) Dr. Willis received misinformation from a nurse on his staff who was believed to be a Schering-paid nurse.

The MAC contains extensive factual allegations regarding the types of improper marketing techniques that Schering used, which Montgomery alleges must have influenced Dr. Willis between 1999, when he declined to prescribe her the drugs, and 2001, when he changed his treatment plan. The MAC reasserts many of the same allegations about Schering's techniques alleged in the TPP Complaint. The MAC also incorporates by reference all of the factual allegations made in a Qui Tam action brought against Schering in the District of Massachusetts, and the

allegations in the Criminal Information, discussed above, to which Schering pleaded guilty. (MAC ¶¶ 99-101.) The allegations include claims about Schering's scheme for providing kickbacks to doctors for prescribing the drugs, false promotional claims made by sales representatives, and the placement of a Schering-paid nurse on Dr. Willis' staff. The MAC further alleges that Montgomery "would not have been prescribed and would not have paid for such a costly, noxious, and dangerous medication cocktail had she known all the facts that were concealed by Defendants and her doctors . . . ." (MAC ¶¶ 4, 5.)

The Defendants moved to dismiss the MAC under Rule 12(b)(1). The District Court dismissed the MAC for lack of jurisdiction under Rule 12(b)(1), finding that it failed to establish a sufficient nexus between her alleged injury and Schering's alleged misconduct.

In reaching this conclusion, the Court first found that Montgomery had alleged an adequate injury-in-fact for her claims under the Washington Consumer Protection Act and various common law theories. The District Court held, however, that her "standing to bring suit founders on her inability to establish any nexus between her purported injury—be it the needless purchase of the Rebetol/PEG-Intron, the side-effects she claims to have suffered and/or the lost work time—and the wrongful conduct in which Schering was allegedly engaged." (A. 117.) Montgomery's theory that the Defendants injured her is premised on whether Dr. Willis shifted his opinion about the appropriate treatment plan due to Schering's marketing practices. The District Court found that the MAC "fails to provide any factual allegations that would support [this] conclusion." (A. 118.)

On appeal, Montgomery challenges the Court's dismissal of the MAC on several grounds. She argues that the Court improperly failed to consider certain factual allegations, some of which she claims establish the necessary causal link. Moreover, with respect to the factual allegations that the Court did consider, Montgomery argues that it applied an improper standard in rejecting those allegations as inadequate, and claims that when reviewed under the proper standard, they do adequately allege a causal nexus.

Montgomery first challenges the District Court's decision on the ground that it erred in not fully considering "the entirety of the record" and taking all factual allegations as true. Montgomery notes that the MAC "incorporates several other documents that set forth in great detail—beyond the extraordinary detail contained in the complaint itself—the nature and extent of Schering's alleged unfair deceptive acts and practices." (Montgomery Br. at 25.) These documents include: (1) factual averments based on the personal knowledge of three former Schering employees in their related qui tam case filed in the District of Massachusetts (incorporated in the MAC at ¶105); (2) factual allegations about the Subject Drugs detailed in the related TPP Amended Complaint (incorporated in the MAC at n 1, A. 987); (3) the Criminal Information to which Schering pleaded guilty (incorporated in the MAC at ¶101); (4) the factual averments in the Settlement Agreement in the criminal case (incorporated in the MAC at ¶102); and (5) the Corporate Integrity Agreement and addendum to the same in the criminal case (incorporated in the MAC at ¶103). (Montgomery Br. at 25-26.) Montgomery asserts that "it is not clear from the district court's opinion that it took proper

account of these documents, and the substantial facts contained therein, in its ruling." (*Id.* at 26.)

In regard to these documents, the District Court stated:

> Plaintiff apparently believes that somehow, through the incorporation of allegations made in other proceedings, such as the False Claims Act action filed by three qui tam relators, she can pursue her own relief against Schering. The irreducible minimum of Article III standing, however, requires Montgomery to demonstrate that she, personally, has suffered a concrete injury, that her injury can be traced to Schering's misconduct and that it is capable of redress by the Court.

(A. 120.) This statement suggests that the District Court did not permit Montgomery to rely on factual allegations that pertain to the standing of other parties in order to establish her own standing. The Court also stated that it did not ignore those documents: "Assuming Schering engaged in all of the marketing practices detailed in [the MAC] and in documents incorporated by reference, and assuming that the practices might be deemed unlawful, none of the factual allegations she makes establish the required nexus between her injury and Schering's actions." (A. 120-21.)

It is thus clear that the District Court did not ignore the documents that Montgomery sought to incorporate by reference in her Amended Complaint. It is also clear that the District Court properly concluded that the averments of misconduct did not support a non-conjectural conclusion that Dr. Willis had been induced by such misconduct to order the

PEG-Intron Combination Therapy. Moreover, as a general matter, even if the Court did decline to consider some of these documents, this was not necessarily an error. Under Fed. R. Civ. P. 8(a)(2), a complaint should set forth a "short and plain statement" of the claim to relief. Plaintiffs cannot be permitted to incorporate an endless series of external documents into a complaint simply "by reference" to them, as this would lead to an impossible task for defendants in filing their answers, and for courts in reviewing the sufficiency of complaints. In any event, to the extent that Montgomery specifically claims that this alleged failure to consider particular allegations in the incorporated documents has prejudiced her—that is, that such allegations would have cured any of the deficiencies in stating causation—we discuss those arguments *infra*.

To establish standing, the MAC sought to allege a causal nexus between Dr. Willis' decision to prescribe the drugs to Montgomery, and the Defendants' alleged fraudulent marketing and bribery schemes. The District Court held that the MAC failed to adequately allege any connection between Schering's alleged bribery scheme and Montgomery's experience. The Court explained that the MAC "lacks any allegation either directly accusing or even plausibly suggesting that . . . Dr. Willis received [illegal] remunerations." (A. 120.) The Court also rejected the MAC's allegation about Dr. Willis's involvement in a clinical trial:

> In the case of Mrs. Montgomery and other asymptomatic Hepatitis C patients at [Dr. Willis' practice], upon information and belief based upon the evidence of record, it is alleged

> that Defendants engaged Dr. Willis in a phony clinical trial respecting Rebetron Combination Therapy beginning shortly after the August 2001 FDA approval letter issued.

(MAC ¶93.)

The Court found this allegation inadequate because it was "conclusory." (A. 120.) Even "assum[ing] the truth of fact asserted," and "credit[ing] the allegation that Dr. Willis was involved in a clinical trial," the Court refused to "credit the bald assertion that the trial was 'phony,' presumably meaning that Dr. Willis was not actually gathering data and studying patients. . . but [was only a] subterfuge for collecting payments from Schering for prescribing the drugs being studied." (A. 120.) It rejected this assertion because "[n]othing in the [MAC] supports this characterization." (A. 120.)

On appeal, Montgomery argues that the Court wrongly refused to accept this allegation as true. In our view, even if we found these arguments to be meritorious, they are still unavailing. Even if we accepted the MAC's allegation that Dr. Willis was involved in a "phony" clinical trial for Rebetron Combination Therapy, this fact does not establish the necessary causal connection between Schering's misconduct and Montgomery's injury, because she was not prescribed the Rebetron Combination Therapy. To the contrary, she was prescribed the PEG-Intron Combination Therapy, a combination of Rebetol and another longer-lasting form of interferon, PEG-Intron. (*See* MAC ¶¶23, 64-66, 74.)

Thus, as Schering observes: "Dr. Willis's thoughts or clinical experiences with that drug therapy are of no moment

here." (Schering Br. at 26.) Notably, Montgomery does not apparently challenge this contention in her Reply Brief. In our view, the fact that the allegedly "phony" trial did not even concern a treatment regimen that her doctor prescribed to her is dispositive. There is no allegation of fact that supports a connection between Schering's unlawful conduct of involving Dr. Willis in a "phony" trial, and Montgomery's prescription for a different drug therapy.

Montgomery's other arguments are equally unpersuasive. She contends that the Court "unfairly rebuke[d] [her] for not 'directly accusing her doctor of a crime—i.e., engaging in a phony clinical trial—and defrauding his patients and the government." (Montgomery Br. at 27.) She also invokes Rule 11 to argue that her lawyers were not permitted to make such an allegation about Dr. Willis at this time. (*Id.* at 28.) She continues: "[t]he fundamental problem with the district court's dismissal is that the court required some direct accusation of criminal conduct by a non-party at the pleading stage. It was wrong to do so." (*Id.*)

This argument misconstrues the District Court's analysis, which did not require the MAC to charge Dr. Willis with a crime. Rather, the Court considered the allegation that the trial was "phony" to be conclusory because there was simply no other allegation in the MAC to support the assertion that this particular trial was in fact a disguised bribery scheme. To satisfy the standard, the MAC would not have to allege that Dr. Willis had committed a crime, but state factual allegations suggesting that the clinical trial was in fact somehow fraudulent or undertaken in bad faith.

Montgomery argues that the MAC contains allegations that support the claim that the trial was "phony," including an allegation citing to a memorandum from one of the qui tam relators, a Schering employee who stated that "his job is secure" in part because he had "over 50 [Hepatitis] trials underway." (Montgomery Br. at 30, citing MAC ¶ 94-95.) This general assertion that 50 Hepatitis clinical trials were underway, however, does not support the conclusion that Dr. Willis's trial was one of those phony trials. These allegations therefore do not "bolster the main allegation" that Dr. Willis was involved in a "phony" clinical trial. (*Id.* at 30.)

Montgomery points to no other factual allegations in the MAC that support the conclusion that Dr. Willis was in any way connected with phony trials. The allegation therefore does appear to be a speculative conclusion that falls short of stating facts that raise a "plausible" right to relief. We conclude that the Court did not err in rejecting the assertion, without other supporting factual claims, that Dr. Willis was involved in a phony clinical trial. *See Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) (holding that a court reviewing a complaint need not credit "bald assertions" or "legal conclusions").

The MAC also claimed that three other Schering-sponsored programs associated with Montgomery's treatment under Dr. Willis were the causal link between his prescription and Schering's false marketing campaign. First, the MAC alleges that a Schering-paid nurse in Dr. Willis' office, identified in the MAC as "D.S." or "Diana S.," was part of the marketing scheme that affected her treatment. (MAC ¶ 42-25.) The Court held that this allegation that Diana S. "was part of Schering's deceitful marketing scheme and somehow

caused Dr. Willis to prescribe Rebetol/PEG-Intron to Montgomery is purely conclusory." (A. 119.) The Court reasoned that, at most, it could accept as true the alleged facts, which stated that this nurse was paid by Schering to provide patient support in matters concerning injection-training and side effects; however, the Court concluded, "there is no indication that Schering executed the alleged misrepresentations or kickbacks through this PCC." (A. 119.)

The MAC makes numerous allegations about "Diana S." based on "information and belief"; it never explains, however, the basis for its conclusion that she was in fact employed by Schering, or that she disseminated any false information to Dr. Willis about the Subject Drugs. In our view, the MAC fails to allege sufficient facts to "show" that her treatment plan was influenced by Diana S. at the behest of Schering.

The District Court also discredited the MAC's allegations with respect to two other Schering-sponsored programs, the "Access Assurance Program" and "Be in Charge Program." According to the MAC, the "Access Assurance Program" supported patients who were undergoing treatments by the Subject Drugs by ensuring they had a consistent supply of the product, and also allegedly to serve as a marketing technique. (MAC ¶ 48-51.) Similarly, the "Be in Charge" program was designed to help support patients on Rebetron therapy by providing them with a nurse to ensure "such patients were 'compliant'" with the therapy program, so that Schering could "ensure that [it] sold as much Rebetron Combination Therapy as possible." (MAC ¶ 52.) However, the MAC provides no factual allegations describing how either of these programs interfered with Dr. Willis'

decision to prescribe Montgomery the Subject Drugs through any false information, or that it gave her any false claims about the drugs that otherwise injured her. Accordingly, we conclude that these allegations are not sufficient to form the necessary causal nexus.

Montgomery also raises a handful of other claims that are ultimately unavailing. She argues that the MAC properly pleaded causes of action for statutory consumer fraud, common law conspiracy, aiding and abetting and unjust enrichment. (Montgomery Br. at 45.) Montgomery argues that the Court should have evaluated her standing to bring the claims with regard to each particular claim, and notes that other than a brief discussion of the Washington Consumer Protection Act, the Court's opinion contains "no discussion of the elements of the plaintiff's four claims, or the sufficiency of her allegations of the same in the MAC." (*Id.* at 46.) She requests that we vacate the decision and remand it "for failure to adequately address the first step of the requisite two-step process under Rule 12." (*Id.*, quoting *Fowler*, 578 F.3d at 210 ("First, the factual and legal elements of a claim should be separated.")). Montgomery then proceeds to exhaustively discuss how the MAC pleads all of the requisite elements of each of her claims.

Montgomery's focus on the pleading standards for each of her claims is secondary to the threshold issue that the Court addressed when determining that the MAC did not adequately allege an injury fairly traceable to Schering's alleged misconduct. Although the MAC is replete with factual allegations and indeed asserts them with greater specificity than the TPP Complaint, they do not present a plausible allegation actually linking Montgomery's injuries to

any type of miscommunication or false claim about the drugs that were actually prescribed to her. Accordingly, we will affirm the Court's conclusion that the MAC failed to adequately allege causation.

IV.

Neither appellant – Local 331 nor Montgomery – has alleged facts sufficient to confer standing to seek relief for Schering's marketing of certain drugs for off-label uses. Accordingly, we will affirm the District Court's rulings.