

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

<p>IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION</p>	<p>MDL No. 2545 Master Docket Case No. 1:14-cv-01748 Hon. Judge Matthew F. Kennelly</p>
<p>This document relates to:</p> <p>MEDICAL MUTUAL OF OHIO, Plaintiff,</p> <p>v.</p> <p>ABBVIE INC., ABBOTT LABORATORIES, ABBOTT PRODUCTS, INC., SOLVAY AMERICA, INC., SOLVAY PHARMACEUTICALS, INC., SOLVAY S.A., UNIMED PHARMACEUTICALS, LLC, BESINS INC., BESINS S.A., AUXILIUM, INC., GLAXOSMITHKLINE LLC, OSCIENT PHARMACEUTICALS, INC., ELI LILLY AND COMPANY, LILLY USA, INC., ACRUX COMMERCIAL PARTY LTD., ACRUX DDS PARTY LTD., ACTAVIS PLC, ACTAVIS, INC., ACTAVIS PHARMA, INC., WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., ANDA, INC., and ENDO PHARMACEUTICALS, INC.,</p> <p>Defendants.</p>	<p>No. 1:14-cv-08857</p>

**DEFENDANTS' JOINT MEMORANDUM
IN SUPPORT OF THEIR MOTION TO DISMISS PLAINTIFF MEDICAL MUTUAL OF
OHIO'S SECOND AMENDED CLASS ACTION COMPLAINT**

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PRELIMINARY STATEMENT

Plaintiff Medical Mutual of Ohio (“MMO”) filed this nationwide class action against nearly every company that has sold a testosterone-replacement therapy (“TRT”) drug in the United States in the last 15 years, alleging that each Defendant group marketed its TRT drug fraudulently for “off-label” conditions—*i.e.*, conditions other than those for which the drug had received regulatory approval—and asserting claims under the federal RICO Act, state statutes, and the common law.

MMO’s action is legally unsustainable. In the last few years, third-party payors (“TPPs”) have filed numerous RICO suits based on the alleged off-label promotion of a drug. The overwhelming majority of these cases have been dismissed at the pleading stage¹—including a virtually identical RICO case in the Southern District of Illinois, *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, 2010 U.S. Dist. LEXIS 80758 (S.D.

¹ See *Ind./Ky./Ohio Reg’l Council of Carpenters Welfare Fund v. Cephalon, Inc.*, 2014 U.S. Dist. LEXIS 69526 (E.D. Pa. May 21, 2014); *Sergeants Benevolent Ass’n Health & Welfare Fund v. Sanofi-Aventis US LLP*, 20 F. Supp. 3d 305 (E.D.N.Y. 2014); *Employer Teamsters-Local Nos. 17/505 Health & Welfare Trust Fund v. Bristol Myers Squibb Co.*, 969 F. Supp. 2d 463 (S.D. W. Va. 2013); *In re Bextra & Celebrex Mktg., Sales Practices & Prods. Liab. Litig.*, 2012 U.S. Dist. LEXIS 111446 (N.D. Cal. Aug. 2, 2012); *Health Care Serv. Corp. v. Pfizer, Inc.*, 2012 U.S. Dist. LEXIS 89759 (E.D. Tex. Apr. 23, 2012), 2012 U.S. Dist. LEXIS 89758 (E.D. Tex. June 28, 2012); *Health Care Serv. Corp. v. Olivares*, 2011 U.S. Dist. LEXIS 117750 (E.D. Tex. Sept. 2, 2011), 2011 U.S. Dist. LEXIS 112544 (E.D. Tex. Sept. 30, 2011); *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121 (2d Cir. 2010); *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 2009 U.S. Dist. LEXIS 58900 (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 (S.D. Fla. 2009), *aff’d*, 444 F. App’x 401 (11th Cir. 2011); *In re Actimmune Mktg. Litig.*, 614 F. Supp. 2d 1037 (N.D. Cal. 2009), *aff’d*, 464 F. App’x 651 (9th Cir. 2011); *Cent. Reg’l Employees Benefit Fund v. Cephalon, Inc.*, 2010 U.S. Dist. LEXIS 29677 (D.N.J. Mar. 29, 2010); *S. Ill. Laborers’ & Employers Health & Welfare Fund v. Pfizer Inc.*, 2009 U.S. Dist. LEXIS 91414 (S.D.N.Y. Sept. 30, 2009); *Dist. 1199P Health & Welfare Plan v. Janssen*, 2008 U.S. Dist. LEXIS 103526 (D.N.J. Dec. 23, 2008), 784 F. Supp. 2d 508, 523-25 (D.N.J. 2011); *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282 (C.D. Cal. 2008), *aff’d*, 400 F. App’x 255 (9th Cir. 2010), 2009 U.S. Dist. LEXIS 58697 (C.D. Cal. June 17, 2009), *aff’d*, 400 F. App’x 255 (9th Cir. 2010); *Ironworkers Local Union No. 68 v. AstraZeneca Pharms. LP*, 585 F. Supp. 2d 1339 (M.D. Fla. 2008), *aff’d*, 634 F.3d 1352 (11th Cir. 2011).

Ill. Aug. 5, 2010) (Herndon, J.). These previous TPP cases involved just *one* pharmaceutical company and *one* drug. Here, by contrast, MMO seeks to maintain an action against *the entire industry* based on allegations of fraudulent off-label marketing of multiple TRT drugs. There is no precedent for such an industry-wide fraud action.

When Defendants moved to dismiss MMO's original complaint, MMO did not attempt to defend it. Instead, MMO filed an Amended Complaint and a Second Amended Complaint ("SAC"). The SAC spans 434 pages and 1,359 paragraphs. Yet, despite its length, the SAC changes nothing. The SAC does not allege any concrete facts indicating that MMO was the victim of any demonstrable act of mail or wire fraud by any Defendant, much less all of them. Instead, the SAC consists of generalizations that lump all Defendants together and anecdotes that are unconnected to any TRT prescription reimbursed by MMO. There are, for example, *no* concrete factual allegations that: MMO was induced to cover any TRT prescription because of any particular statement of fact attributable to any Defendant; the statement was false or misleading; the Defendant knew the statement was false and misleading and intended to defraud MMO; the alleged deception was the but-for cause of any injury to MMO; or the alleged deception directly caused the injury without any intervening actions. Similarly, there are no allegations that any identified doctor was deceived to write an inappropriate TRT prescription.

The SAC, in other words, does not actually state a claim for *fraud* against any Defendant, much less a violation of RICO (which requires allegations of two or more acts of mail or wire fraud directly causing injury to the plaintiff's business or property). MMO's failure to make the requisite concrete allegations is not a mistake. MMO is seeking to stretch RICO's private right of action to regulate the practices of an entire industry. Yet, RICO was not enacted to provide a sophisticated insurance company with industry-wide regulatory powers.

Not surprisingly, MMO's RICO claims suffer from irreparable defects. First, the SAC does not plead facts showing that MMO has standing to sue under RICO. Specifically, MMO does not plausibly allege facts that (1) MMO has sustained the type of injury protected by RICO or Article III of the Constitution or (2) Defendants' alleged conduct was a "but-for" cause of any purported RICO injury. Moreover, MMO cannot possibly allege facts showing a "direct" connection between Defendants' alleged conduct and any hypothetical injury as required by RICO's proximate cause standard. Second, the SAC does not plead with particularity any predicate act of mail or wire fraud by a Defendant. And third, MMO's claims are time-barred.

MMO's new claims of a conspiracy to violate RICO and claims based on state statutes and the common law also fail for these reasons and others.²

BACKGROUND

I. The Parties And The Products

Plaintiff MMO is "[t]he oldest health care insurer in Ohio." (SAC ¶ 36.) Defendants are five pharmaceutical companies, or groups of related pharmaceutical companies, that allegedly manufactured and distributed TRT drugs: (1) The "Actavis Defendants" (Actavis plc, Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc., Actavis Pharma, Inc., Watson Laboratories, Inc., n/k/a Actavis Laboratories UT, Inc., and Anda, Inc.) manufactured and distributed the TRT drug Androderm (a transdermal patch), starting September 29, 1995 (SAC ¶¶ 59-63); (2) The "AbbVie Defendants" (AbbVie Inc., Abbott Laboratories, Abbott Products, Inc., Solvay America, Inc., Solvay Pharmaceuticals, Inc., Solvay S.A., Unimed Pharmaceuticals, LLC, Besins Inc., and Besins S.A.) manufactured and distributed the TRT drug AndroGel (a topical application), starting February 28, 2000 (SAC ¶¶ 40-49); (3) Defendant Auxilium Pharmaceuticals, Inc. ("Auxilium") manufactured and distributed the TRT drugs Testopel (a subcutaneous pellet),

² Defendants offer additional arguments for dismissal in their individual supplemental briefs.

starting in 1972, and Testim (a topical application), (SAC ¶¶ 50, 69-70), and GlaxoSmithKline LLC (“GSK”) and Oscient Pharmaceuticals Corp. (“Oscient”) co-promoted Testim with Auxilium for limited durations (SAC ¶¶ 51-52);³ (4) Defendant Endo Pharmaceuticals, Inc. (“Endo”) manufactured and distributed the TRT drug Fortesta (a topical application), starting December 29, 2010 (SAC ¶ 64); and (5) The “Lilly Defendants” (Eli Lilly and Company, Lilly USA, Inc., Acrux Commercial Pty Ltd., and Acrux DDS Pty Ltd.) manufactured and distributed the TRT drug Axiron (a topical application), starting the first quarter of 2011 (SAC ¶¶ 54-58).

Each of these drugs has been approved by the U.S. Food and Drug Administration (“FDA”) “for the treatment of abnormally low testosterone in men, a condition known as hypogonadism.” *See In re Testosterone Replacement Therapy Prods. Liab. Litig.* (“TRT”), No. 1:14-cv-01748, Dkt. 526 at 2, 2014 WL 7365872, at *1 (N.D. Ill. Dec. 23, 2014). MMO alleges that none has been approved for treatment of diminished testosterone levels due to aging. (SAC ¶ 27.) In reality, the FDA approved each drug for the treatment of hypogonadism—*i.e.*, abnormally low testosterone—and the FDA’s approvals did not depend on the underlying cause of a patient’s hypogonadism. Furthermore, under applicable law, a doctor may prescribe an FDA-approved drug for any condition the doctor deems medically appropriate. *See* 21 U.S.C. § 396; *Weaver v. Reagen*, 886 F.2d 194, 198 (8th Cir. 1989). (SAC ¶ 67.)

³ The only allegations against Defendant GlaxoSmithKline LLC (“GSK”) (SAC ¶¶ 51, 69, 206, 513-531, 785) and Defendant Oscient Pharmaceuticals Corp. (“Oscient”) (SAC ¶¶ 52, 504-509) relate to separate co-promotion agreements that each had with Auxilium for short periods of time regarding an Auxilium TRT drug. The SAC does not assert any claims against either GSK or Oscient other than to the extent that the claims for common law fraud, negligent misrepresentation, and unjust enrichment are asserted against “All Defendants,” generally. Finally, upon information and belief, Oscient is no longer an ongoing business concern and has not been served with the SAC.

II. The Alleged Wrongful Conduct

The SAC alleges that the Defendant groups entered the market for TRT drugs at different times. (SAC ¶¶ 68-73, 139.) Beginning in 2000, as each group entered the market, it allegedly joined with third parties to form “associations in fact” to market the group’s TRT drug including: (1) a “TPP Formulary Access Enterprise” (SAC ¶¶ 145-92 (generalized), 286-307 (AbbVie), 484-501 (Auxilium), 616-23 (Lilly), 667-70 (Actavis), 706-11 (Endo)); (2) a “Peer Selling Enterprise” (SAC ¶¶ 193-234 (generalized), 308-448 (AbbVie), 502-37 (Auxilium), 624-42 (Lilly), 671-76 (Actavis), 712-28 (Endo)); (3) a “Publication Enterprise” (SAC ¶¶ 235-53 (generalized), 448-76 (AbbVie), 538-44 (Auxilium), 643-51 (Lilly), 677-83 (Actavis), 729-40 (Endo)); and (4) a “DTC [*i.e.*, Direct-to-Consumer] Enterprise” (SAC ¶¶ 254-79 (generalized), 477-83 (AbbVie), 545-611 (Auxilium), 652-62 (Lilly), 684-99 (Actavis), 741-54 (Endo)).

MMO alleges that each Defendant group used its marketing enterprises to convince doctors, consumers, and MMO that (1) the natural decline in testosterone commonly experienced by men over time is a treatable “disease state”—“variously called ‘Andropause,’ ‘late-onset male hypogonadism,’ and ‘age-related hypogonadism’”; (2) the Defendant group’s TRT drug was a medically appropriate treatment for age-related testosterone declines that were not abnormal; and (3) the Defendant group’s TRT drug also was a medically appropriate treatment for certain diseases other than “classical hypogonadism.” *Id.* (SAC ¶¶ 4-6.) The alleged goal was to increase sales of each Defendant group’s TRT drug.

MMO alleges that “Andropause” is a myth and that TRT drugs have “negligible efficacy” for those who do not suffer from “classical hypogonadism.” (SAC ¶¶ 5, 21-22, 31, 35.) MMO also alleges that TRT drugs have the potential for serious side effects, including stroke, myocardial infarction, and heart failure, especially for elderly men, diabetics, and consumers with a history of cardiovascular disease. (SAC ¶¶ 77-138.) Each Defendant group allegedly

knew or should have known that age-related testosterone decline was not a legitimate medical condition, that its TRT drug provided little or no benefit other than for “classical hypogonadism,” and that its TRT drug was not safe for certain patients. (SAC ¶¶ 28, 121) MMO alleges that each Defendant group nevertheless used the mails and wires in furtherance of its fraudulent marketing schemes. While MMO’s original complaint did not allege any conspiracy *across* the Defendant groups, MMO’s SAC alleges that the groups conspired with one another in an “unbranded advertising” campaign.

Allegedly as a result of these tactics, prescriptions for TRT drugs “skyrocketed[.]” (SAC ¶¶ 15-16, 276.) Yet, MMO insists that, until recently, it was “[un]aware” that this “astronomical spike in prescriptions” was “attributable to ineffective, unsafe, and/or non-useful off-label utilization,” rather than “classical hypogonadism.” (SAC ¶¶ 16-18, 145, 805-26.)

III. MMO’s Alleged Injury And Damages

The SAC alleges that, between 2007 and 2011, MMO paid \$7,380 for Androgel and Androderm prescriptions written by one physician for one of its beneficiaries (referred to under the pseudonym “Patient 2”) and paid \$32,069.18 to treat a myocardial infarction suffered by Patient 2 in 2011. (SAC ¶ 831.) The SAC does not allege that Patient 2 did not have hypogonadism, that the Androgel and Androderm prescriptions written for Patient 2 were medically inappropriate, or that any act of mail or wire fraud by the AbbVie Defendants, the Actavis Defendants, or any other Defendant caused a Patient 2’s physician to prescribe Androgel and Androderm for Patient 2. MMO does not point to any other prescription for any Defendant’s TRT drug reimbursed by MMO, although MMO does allege generically that, from November 2001 through April 2015, MMO paid approximately \$38.9 million for the TRT drugs of one or more Defendants. (SAC ¶¶ 37-39.) However, the SAC contains no concrete factual allegations that any of these prescriptions were medically inappropriate or caused by a Defendant.

LEGAL STANDARD

A complaint “must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). “[C]onclusory statements” and “naked assertion[s]” are properly ignored in this analysis. *Id.* If a complaint’s concrete, well-pleaded facts, taken as true, establish only a “possibility” of liability, or are “merely consistent with” liability, dismissal is required. *Id.* “[I]n a potentially complex litigation, or one that by reason of the potential cost of a judgment to the defendant creates [an] ‘in terrorem’ effect,” a heightened degree of substantiation is necessary. *Limestone Dev. Corp. v. Vill. of Lemont*, 520 F.3d 797, 803 (7th Cir. 2008) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007)). This concern is “applicable to a RICO case.” *Id.*; *Pa. Chiropractic Ass’n v. Blue Cross Blue Shield Ass’n*, 2010 U.S. Dist. LEXIS 107077, at *20 (N.D. Ill. Oct. 6, 2010) (Kennelly, J.). In addition, “allegations of fraud in a civil RICO complaint are subject to the heightened pleading standard of Fed. R. Civ. P. 9(b).” *Slaney v. Int’l Amateur Athletic Fed’n*, 244 F.3d 580, 597 (7th Cir. 2001).

A named plaintiff may not state a claim for itself based on allegations that pertain to putative class members or others not before the court. *Lewis v. Casey*, 518 U.S. 343, 357 (1996); *Magnuson v. City of Hickory Hills*, 933 F.2d 562, 565 (7th Cir. 1991). A named plaintiff also may not state a claim against one defendant based on allegations of independent conduct of another defendant. *Iqbal*, 556 U.S. at 676 (“a plaintiff must plead that each ... defendant, through [its] own individual actions,” has committed an actionable wrong).

ARGUMENT⁴

I. MMO Lacks Standing Under RICO And Article III Of The Constitution

MMO asserts four RICO claims and a RICO conspiracy claim against each of the Defendant groups based on alleged mail and wire fraud in connection with the alleged off-label promotion of their respective TRT drugs. In order to maintain these claims, MMO must plead facts showing that it has standing to sue under both Article III, *see Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992), and RICO, *see* 18 U.S.C. § 1964(c).

RICO, in particular, imposes stringent standing requirements. A RICO plaintiff must allege facts showing that it (1) has sustained an injury to its “business or property” (2) “by reason of” a violation of 18 U.S.C. § 1962. 18 U.S.C. § 1964(c); *see also In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 246 (3d Cir. 2012); *Evans v. City of Chicago*, 434 F.3d 916, 924 (7th Cir. 2006). In other words, a plaintiff must plead facts showing it has suffered an injury to its business or property and that the defendant’s “predicate act” was the “but-for” and direct proximate cause of the alleged injury. *Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258, 265-66, 268 (1992); *Pirelli Armstrong Tire Corp. Retiree Med. Benefits Trust v. Walgreen Co.*, 631 F.3d 436, 443-45 (7th Cir. 2011). Numerous courts have dismissed RICO claims brought by TPPs for lack of statutory or Article III standing. MMO’s RICO claims are not materially different and also should be dismissed.

A. MMO Fails To Plead A Cognizable Injury

A plaintiff asserting a claim under RICO must allege facts showing that it has been “injured in [its] business or property.” *Sedima, S.P.R.L. v. Imrex Co., Inc.*, 473 U.S. 479, 496 (1985). The phrase “injured in [its] business or property” has a “restrictive significance” and

⁴ Pursuant to Case Management Order No. 12, each Defendant reserves the right to challenge personal jurisdiction at the time of remand of this directly filed case.

“helps to assure that RICO is not expanded to provide a federal cause of action and treble damages to every tort plaintiff.” *Reiter v. Sonotone Corp.*, 442 U.S. 330, 339 (1979); *Ironworkers Local 68 v. AstraZeneca Pharm. LP*, 634 F.3d 1352, 1361 (11th Cir. 2011). Here, MMO has not alleged facts showing it sustained the type of injury against which RICO protects.

1. Pecuniary Losses Flowing From Alleged Personal Injuries Of MMO Beneficiaries Are Not Cognizable Injuries

A plaintiff may not sue a defendant under RICO for pecuniary losses “flowing” from personal injuries purportedly caused by a defendant’s predicate act. *Evans*, 434 F.3d at 927; *Doe v. Roe*, 958 F.2d 763, 770 (7th Cir. 1992). Thus, MMO may not support its RICO claims with allegations that it reimbursed for the medical treatment of an insured who allegedly took Androgel and Androderm between 2007 and 2011 and allegedly suffered a myocardial infarction in 2011. (SAC ¶ 831.) If MMO reimbursed for an insured’s medical treatment as a consequence of personal injuries allegedly caused by a particular TRT drug, MMO can attempt to recover its expenses by asserting a lien against any damages that the insured may recover or seek subrogation to the insured’s right of recovery against a liable party. What MMO may not do is sue a Defendant group for RICO violations based on such expenses.⁵

2. MMO’s Payments For TRT Prescriptions Are Not Cognizable Injuries

The mere reimbursement for a prescription drug does not constitute an injury to “business or property” within the meaning of 18 U.S.C. § 1964(c). This is true even if the drug was prescribed by a physician and purchased by a consumer to treat an “off-label” condition. *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 2009 U.S. Dist. LEXIS 58900, at *33-40 (D.N.J. July 10, 2009), *aff’d*, 678 F.3d 235 (3d Cir. 2012); *Ironworkers*, 634 F.3d at

⁵ Moreover, the SAC includes several allegations about medical expenses paid by *other* TPPs. (SAC ¶ 831.) These allegations have no bearing on whether MMO has alleged facts demonstrating that it sustained the type of economic injury that RICO protects.

1363. Courts have been “[un]willing to accept that a plaintiff could somehow be injured” within the meaning of RICO “simply because the drug [it reimbursed] was marketed off-label,” because off-label use of pharmaceuticals is “valu[able],” “prop[er],” and “often ... essential to ... optimal medical care.” *In re Schering-Plough*, 2009 U.S. Dist. LEXIS 58900, at *33-40 (alleged off-label promotion of FDA approved drugs is not actionable under RICO); *Buckman v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 350 n.5 (2001).

Rather, to allege a cognizable “injury to ... business or property” under RICO, a TPP must allege facts that show it (1) reimbursed for a prescription drug that was “unnecessary or inappropriate according to sound medical practice” at the time of the prescription and (2) did not assume the risk of reimbursing for such a prescriptions. *Ironworkers*, 634 F.3d at 1363. MMO has failed to meet this standard. For example, MMO alleges that it reimbursed for Androgel and Androderm prescriptions written by one physician for one insured, and reimbursed for the TRT drugs of “one or more” Defendant groups. (SAC ¶¶ 37, 831.) But the SAC does not allege any concrete facts that suggest that any reimbursement was for off-label prescriptions that were unnecessary or inappropriate according to sound medical practice. (SAC ¶¶ 21-22.)

Furthermore, in *Ironworkers*, 634 F.3d at 1364-65, the Eleventh Circuit observed that (1) TPPs are in the business of contracting to cover the costs of drugs prescribed to beneficiaries, (2) when TPPs agree to provide prescription-drug coverage, they impose conditions, limits, and exclusions, and (3) TPPs set their premiums based on “sophisticated actuarial” calculations about how much the coverage is likely to cost them over the life of the contract. *Id.*

In *Ironworkers*, the plaintiff TPPs admitted that they *could* have excluded the drug at issue from their formularies *or* limited coverage to “on-label” conditions *or* contracted for a right to “case-by-case evaluations ... to determine the necessity and appropriateness” of the

prescription prior to reimbursing for the drug. *Id.* at 1366-68. However, the TPPs voluntarily agreed to cover the costs of the drugs listed on their formularies *whenever* a physician decided to prescribe the drug. *Id.* In other words, the TPPs made a “conscious business decision” to reimburse for all drugs listed on their formularies whenever a physician prescribed the drug. *Id.* at 1366-68. Given the TPPs’ voluntary agreement, the TPP could not allege “facts suggesting that they plausibly suffered economic injury caused by [the defendant].” *Id.* at 1365, 1368-69.

So it is here. The SAC makes clear that MMO voluntarily contracted to cover the costs of the TRT drugs listed on its formulary whenever a physician decided to prescribe the drug. (SAC ¶¶ 136, 493, 495 (noting that some TPPs did exclude certain TRT drugs from their formularies and require letters of medical necessity for other TRT drugs).) RICO’s private right of action should not be stretched to allow a sophisticated insurer to recover treble damages based on reimbursements it voluntarily agreed to make under routine health insurance benefit contracts. RICO does not exist to make drug manufacturers “re-insurers” of a TPP’s “sophisticated actuarial decisions.” *See Ironworkers*, 634 F.3d at 1365, 1369. Because MMO has not, and cannot, allege facts demonstrating it sustained the type of economic injury that RICO protects, its RICO claims must be dismissed.

B. MMO Fails To Plead “But-For” Causation

The SAC also fails to plead facts that plausibly show that alleged mail and wire fraud by each Defendant was a “but-for” cause of MMO’s purported injury. To satisfy RICO’s “but-for” causation requirement, a plaintiff must plead facts establishing that its alleged injury would not have occurred absent the predicate act on which the claim is based. *Holmes*, 503 U.S. at 268; *Hemi Grp., LLC v. City of New York, N.Y.*, 559 U.S. 1, 9 (2010); *Bridge v. Phoenix Bond & Indemnity Co.*, 553 U.S. 639, 649 (2008).

This means that a TPP must plead concrete facts indicating that specific decision-makers were induced by the defendant's alleged predicate acts to prescribe and reimburse for the defendant's medication. *See In re Actimmune Mktg. Litig.*, 614 F. Supp. 2d 1037, 1051-53 (N.D. Cal. 2009) ("Plaintiffs need to allege what specific information ... *their* physicians had ... [and] the extent to which *they* relied upon that information The court will not make the unsupported inference that ... plaintiffs [reimbursed for] the drug as a result of defendants' [off-label promotion].") (emphasis added), *aff'd*, 464 F. App'x 651 (9th Cir. 2011). Courts have dismissed numerous RICO claims brought by TPPs against pharmaceutical companies because the TPPs failed to plead concrete, non-conclusory facts showing that *they* reimbursed for prescription drugs *as the result of* the mail or wire fraud allegedly committed by the defendant, and not the independent action of a doctor, patient, or other party. *See id.* at 1052-53; *In re Bextra & Celebrex Mktg. Sales Practices Litig.*, 2012 U.S. Dist. LEXIS 111446, at *220-23 (N.D. Cal. Aug. 2, 2012); *S. Ill. Laborers & Emprs. Health & Welfare Fund v. Pfizer Inc.*, 2009 U.S. Dist. LEXIS 91414, at *6, 19-20 (S.D.N.Y. Sept. 30, 2009); *Dist. 1199P Health & Welfare Plan v. Janssen, L.P.*, 784 F. Supp. 2d 508, 527 (D.N.J. 2011); *Intron/Temodar*, 2009 U.S. Dist. LEXIS 58900, at *90; *Olivares*, 2011 U.S. Dist. LEXIS 117750, at *24-25.

Here, the SAC makes *no* concrete allegations indicating that any particular doctor decided to prescribe a TRT drug to a MMO insured because of the alleged mail or wire fraud of any particular Defendant group and not because of the independent judgment of the prescribing physician, the independent actions of a different Defendant, or the actions of another party not before the Court. Nor does the SAC contain concrete allegations establishing that *each* Defendant's act of mail or wire fraud was the but-for cause of a doctor's decision to write an allegedly medically inappropriate TRT prescription. Because the SAC fails to make such

concrete allegations, MMO's RICO claims should be dismissed. *Actimmune*, 614 F. Supp. 2d at 1052.⁶

The SAC also makes only generalized allegations that the Defendant groups "caused" MMO's Pharmacy & Therapeutics ("P&T") Committee to include "one or more" TRT drugs in its formulary. (*E.g.*, SAC ¶¶ 30, 37, 136.) There are no concrete allegations that MMO received and relied on false or misleading information.⁷

In fact, the SAC makes a specific admission that belies any claim that MMO decided to include one or more of the Defendants' TRT drugs on its formulary because of false or misleading information allegedly disseminated by a Defendant group. The SAC alleges that

Because Defendants' TRT drugs are indicated for the treatment of classical hypogonadism, a disease that is very serious and sometimes difficult to treat, they have been widely accepted on most TPP formularies. Given the seriousness of this disease state, TPPs and their P&T committees have not created barriers that would prevent access to the TRT drugs on their formularies.

(SAC ¶ 175.) This allegation makes it clear that MMO decided to include TRT drugs on its formulary and to reimburse for those drugs whenever they were prescribed by a physician

⁶ MMO's allegations concerning Patient 2 illustrate the point. As noted above, the SAC makes no allegations that Patient 2 did not have hypogonadism, that the Androgel and Androderm prescriptions written for Patient 2 were medically inappropriate, or that any act of mail or wire fraud by the AbbVie Defendants, the Actavis Defendants, or any other Defendant caused Patient 2's physician to prescribe Androgel and Androderm for Patient 2. And MMO does not identify any other prescription for any Defendant's TRT drug reimbursed by MMO. (SAC ¶ 831.)

⁷ See SAC ¶¶ 182, 187-92 (generalized allegations of Defendants' marketing of TRT drugs to TPPs without any allegations of specific conduct by a Defendant group targeting MMO), 183-92 (allegations of a 2006 CME program funded by Solvay, but no allegations that MMO heard and relied on the presentation), 302 (allegations that the AbbVie Defendants identified MMO as a potential "target" for marketing efforts at some point, but no concrete allegations suggesting that the AbbVie Defendants' efforts were the but-for cause of MMO's decision to include Androgel on its formulary), 490 (same for Auxilium), 616-23 (no allegations that the Lilly Defendants ever marketed Axiron to MMO, that MMO included Axiron on its formulary, or that the Lilly Defendants' alleged conduct was the but-for cause of any decision to include Axiron on MMO's formulary), 667-70 (same for the Actavis Defendants), 706-11 (same for the Endo Defendants.)

because it viewed TRT drugs as a safe and effective treatment for hypogonadism and did not want to do anything that might deter or inhibit doctors from prescribing approved TRT drugs to patients for that “serious” condition. Indeed, even after supposedly “discovering” what it characterizes as “massive” fraud, MMO does not allege to have changed its practice of reimbursing for TRT drugs whenever they are prescribed by a physician. Given its admission, MMO cannot plausibly contend that a Defendant group’s alleged mail or wire fraud was a but-for cause of MMO’s decision to include TRT drugs on its formulary.⁸

C. MMO Cannot Establish Proximate Causation

MMO’s RICO claims also should be dismissed because it cannot satisfy RICO’s proximate cause standard, which limits standing to only those plaintiffs injured as a *direct* result of a defendant’s predicate RICO acts. In this case, the purported connection between each Defendant group’s alleged acts of mail or wire fraud and MMO’s alleged injury involves too many steps and too many independent decisions by unconnected intermediaries to support a civil RICO claim.

In *Holmes*, the Supreme Court held that, to establish RICO proximate cause, a plaintiff must demonstrate “some *direct* relation between the injury asserted and the injurious conduct alleged.” 503 U.S. at 268 (emphasis added). This requires an immediate causal relation; mere foreseeability of injury to the plaintiff is insufficient, even if that injury was specifically intended by the defendant. *Hemi*, 559 U.S. at 12; *see also Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 457-60 (2006) (plaintiff alleging foreseeable and intentional but indirect injuries did not show proximate cause under RICO).

⁸ The SAC is peppered with allegations concerning certain Defendant groups’ contacts with other TPPs and the costs allegedly incurred by other TPPs. (E.g., SAC ¶¶ 491-92, 499, 620, 710, 831). Allegations concerning a Defendant group’s dealings with other TPPs say nothing about whether a Defendant group’s conduct was a “but for” cause of an injury sustained by MMO.

A plaintiff cannot establish the requisite direct causal relation where “[m]ultiple steps separate the alleged fraud from the asserted injury,” because RICO’s standard for proximate cause “[does] not ... go beyond the first step.” *Holmes*, 503 U.S. at 271-72 (internal quotation marks and citation omitted); *Hemi*, 559 U.S. at 3. “[T]he less direct an injury is, the more difficult it becomes to ascertain the amount of a plaintiff’s damages attributable to the [RICO] violation, as distinct from other, independent factors,” and the more difficult it is to “apportion[] damages among plaintiffs removed at different levels of injury from the violative acts.” *Id.* at 269. The directness requirement is necessary so as not to “open the door to ‘massive and complex damages litigation, which would not only burden the courts, but would also undermine the effectiveness of treble-damages suits.’” *Id.* at 274.

In *Hemi*, a city filed RICO claims against a cigarette wholesaler that failed to submit customer information so that the city could collect sales taxes directly from the customers. 559 U.S. at 4. The Supreme Court plurality acknowledged that even if the city’s loss of tax revenue was foreseeable to—and, indeed, *specifically intended* by—the wholesaler, the city could not state a RICO claim because the multiple intervening steps between the wholesaler’s fraud and the city’s lost tax revenue precluded a finding of a “direct relationship” between the predicate acts and the alleged injury. *Id.* at 11-12. The customers’ intervening, independent decisions not to pay the taxes meant that proximate cause could never be established. *Id.* at 15-16.

In a case with facts close to this one, the Seventh Circuit held that TPPs could not bring claims against a cigarette manufacturer for deceptive marketing that allegedly increased the TPPs’ costs of providing healthcare to their beneficiaries. *Int’l Bhd. of Teamsters, Local 734 Health & Welfare Trust Fund v. Philip Morris Inc.*, 196 F.3d 818, 820-24 (7th Cir. 1999). In affirming dismissal of the RICO claims at the 12(b)(6) stage, the court held that proximate cause

was lacking: “[t]he injury for which the plaintiffs seek compensation is remote indeed, the chain of causation long” *Id.* at 825. The relationship between the predicate acts and the alleged damages “ha[d] too many intermediate steps.” *Id.* at 826; *Mendelovitz v. Vosicky*, 40 F.3d 182, 185 (7th Cir. 1994) (no proximate cause where causal chain “pass[ed] through many intermediaries” and damages “require[d] actions and decisions by third parties before coming into being”); *James Cape & Sons Co. v. PCC Constr. Co.*, 453 F.3d 396, 403-04 (7th Cir. 2006).

Other circuit courts have held that, the chain of causation between a manufacturer’s alleged off-label promotion and a TPP’s reimbursement for any particular prescription involves too many intermediate actors to satisfy RICO’s proximate cause standard. *See UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 134 (2d Cir. 2010) (the “attenuated link between the alleged misrepresentations made to doctors and the ultimate injury to the TPPs” made it impossible for the TPPs to establish proximate cause); *United Food & Commercial Workers Cen. Pennsylvania & Reg’l Health & Welfare Fund v. Amgen, Inc.*, 400 F. App’x 255, 257 (9th Cir. 2010) (TPP’s “complaint proffered an attenuated causal chain that involved at least four independent links” separating the alleged fraud and TPPs’ alleged injuries).

In *Yaz*, a district court in this Circuit granted a motion to dismiss a TPP’s RICO claims against a pharmaceutical company, alleging off-label promotion of a birth control drug, for failure to allege proximate cause. *Yasmin*, 2010 U.S. Dist. LEXIS 80758, at *23. The court concluded that “multiple steps separate the alleged wrongful conduct [off-label promotion] and the alleged injuries (paying ‘too much’ for ‘too many’) ... prescriptions, including patient preference, the independent judgment of the prescribing physician, and the reimbursement decision rendered by the third party payor and its benefits manager.” *Id.* at *23.

Other district courts similarly have dismissed RICO claims by TPPs. *See, e.g., Emp'r Teamsters-Local Nos. 175/505 Health & Welfare Trust Fund v. Bristol Myers Squibb Co.*, 969 F. Supp. 2d 463, 475 (S.D. W. Va. 2013) (“Plaintiffs’ [state-law] claims do not satisfy the ‘direct relation’ test found in *Holmes*” because “[b]etween [d]efendants’ alleged misleading marketing and [p]laintiffs’ prescription reimbursements lies a vast array of intervening events, including the ‘independent medical judgment’ of doctors”) (citation omitted); *Ironworkers Local Union No. 68 v. AstraZeneca Pharm. LP*, 585 F. Supp. 2d 1339, 1345 (M.D. Fla. 2008) (dismissing RICO and consumer fraud claims brought by TPPs against pharmaceutical companies because “[p]laintiffs’ alleged harm is simply too remote from [d]efendants’ alleged RICO violation to satisfy the proximate cause requirement”), *aff’d on other grounds*, 634 F.3d 1352 (11th Cir. 2011); *Pa. Employees Benefit Trust Fund v. Astrazeneca Pharms. LP*, 2009 U.S. Dist. LEXIS 76555, at *16 (M.D. Fla. July 18, 2009). As one court put it, given “the independent and individualized decision-making of physicians prescribing” a particular drug, there is “a substantial question as to whether [TPPs] could ever properly plead proximate causation.” *Dist. 1199P Health & Welfare Plan v. Janssen, L.P.*, 2008 U.S. Dist. LEXIS 103526, at *35 (D.N.J. Dec. 23, 2008) (emphasis added). After all, the attenuated causal chains posed by such theories would require “precisely the type of ‘intricate, uncertain inquir[y]’ the *Holmes* Court sought to prevent.” *Ironworkers*, 585 F. Supp. 2d at 1344 (citation omitted).

The SAC is no different than the legally deficient TPP complaints described above. It simply alleges: (1) each Defendant group disseminated misleading information to doctors, TPPs, and consumers to promote the sale of its TRT drug for treatment of off-label conditions; (2) MMO decided to place that TRT drug on its formulary (without any prior authorization requirement or other safeguard to prevent prescriptions for off-label uses under medically

unnecessary or inappropriate conditions); (3) unspecified physicians decided to prescribe a particular Defendant group's TRT drug to an unspecified MMO insured to treat an off-label condition; (4) the MMO insured decided to fill the TRT prescription and use the particular TRT drug; and (5) MMO decided to reimburse for that TRT prescription. (SAC ¶¶ 139-279.) Any connection between each Defendant group's alleged act of fraud and the alleged loss suffered by MMO thus involves multiple steps and actions by independent licensed professionals, consumers, and MMO. The connection between the challenged conduct and the purported loss is anything but "direct" as Supreme Court and Seventh Circuit case law requires. In keeping with these controlling precedents and the numerous district court decisions cited above, MMO's RICO claims against each Defendant group should be dismissed with prejudice because MMO cannot possibly satisfy RICO's proximate cause requirement.

Indeed, the lack of proximate cause is even clearer here than in other TPP RICO cases. Most (if not all) previous cases involved just *one* pharmaceutical company and *one* drug. Here, MMO alleges that *the entire industry* marketed multiple TRT drugs for off-label uses, and that *numerous* companies contributed to the collective demand for such drugs. Thus, any given doctor's decision to prescribe a particular TRT drug for any given patient might have been attributable to *any number* of independent industry actors (or, as in other TPP RICO cases, to no industry actor at all). This sort of situation is the very reason why RICO's directness requirement exists. *See Holmes*, 503 U.S. at 269.

In the face of this overwhelming authority, MMO may argue that the requirement of a direct causal connection can be ignored because it was a foreseeable or intended victim of each Defendant group's alleged scheme. MMO likely will argue that *In re Neurontin Mktg. & Sales Practices Litig. (Kaiser)*, 712 F.3d 21 (1st Cir. 2013), *cert. denied*, 134 S.Ct. 786 (2013),

endorsed this “foreseeability” approach to proximate cause in RICO actions and opined that this “foreseeability” approach was consistent with *Bridge*, 553 U.S. 639. Yet, *Neurontin*’s “foreseeability” approach “directly contradicts the relevant Supreme Court precedent,” which requires *directness*. *Bextra & Celebrex*, 2012 U.S. Dist. LEXIS 111446, at *225; *see also Yasmin*, 2010 U.S. Dist. LEXIS 80758, at *26-27 (rejecting foreseeability as test for proximate cause in TPP’s RICO claim).

In *Bridge*, 553 U.S. at 641, the Supreme Court held that allegations of first-party reliance were not necessary and that the plaintiff could state a claim based on a third-party’s reliance on the fraudulent acts. *See also Hemi*, 559 U.S. at 14. In this context, the Supreme Court remarked that the plaintiff’s injury “was a foreseeable and natural consequence of [the defendants’] scheme” to manipulate the process. *Id.* at 28. However, there is nothing in this offhand remark indicating an intent to abrogate *Anza*’s direct relationship requirement. Indeed, *Bridge* followed *Anza*, and took as given that “the central question” in the proximate-cause analysis is “whether the alleged violation led *directly* to the plaintiff’s injuries.” *Bridge*, 553 U.S. at 654 (emphasis added).

Two years after *Bridge*, in *Hemi*, a plurality of the Supreme Court noted *Anza*’s disavowal of “foreseeability” and “intent” in the proximate-cause analysis: “Our precedents make clear that ... 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. In *Hemi*, neither the plurality nor the dissent viewed *Bridge* as having overruled *Anza*. Thus, there is a uniform line of Supreme Court authority (1) holding that RICO’s proximate cause standard limits standing to those plaintiffs injured as a “direct” result of an alleged RICO

violation and (2) rejecting “foreseeability” or “intent” as a test for proximate cause.⁹ *See also Lexmark Int’l, Inc. v. Static Control Components, Inc.*, 134 S.Ct. 1377, 1391 (2014) (citing *Anza* with approval in a case concerning proximate cause under the Lanham Act).

Neurontin’s “foreseeability” holding is based entirely on a misreading of *Bridge*. 712 F.3d at 39. *Neurontin* thus conflicts with the Supreme Court’s decisions in *Anza*, *Bridge*, and *Hemi*, the Seventh Circuit’s decisions in *Philip Morris*, *Mendelovitz*, and *James Cape*, and numerous other cases, such as *Yasmin*, 2010 U.S. Dist. LEXIS 80758, at *26-27, which expressly reject foreseeability and intent as a legal test for proximate cause. This Court should follow the controlling law and dismiss MMO’s SAC with prejudice for inability to satisfy RICO’s proximate cause requirement.

D. Courts Have Dismissed Similar Actions For Lack Of Article III Standing

For similar reasons, many courts have held that TPPs fail to establish Article III standing to support their RICO and state law claims when they fail to (1) identify specific prescriptions for which they paid, (2) allege facts demonstrating that those prescriptions were actually medically unnecessary, inappropriate, or harmful as to a particular insured, and (3) allege that their alleged economic injuries were “fairly traceable to the challenged action ... and not the result of the independent action of some third party not before the Court.” *Lujan*, 504 U.S. at

⁹ MMO also may point to *BCS Services, Inc. v. Heartwood 88, LLC*, 637 F.3d 750 (7th Cir. 2011), but *BCS* is no help to MMO. *BCS* is nothing more than a replay of *Bridge*—an unusual situation where the intermediate party had no causal influence. Thus, unlike here, the causal relationship in *BCS* was direct. 637 F.3d at 756 (“[t]here is ... reason for worrying about imposing liability” when violation and injury “are separated by intermediate pairs of cause and effect”). As one district court has explained, *BCS* is not applicable to a TPP RICO claim, because “the intervening acts which interrupt the causal chain ... cannot be readily predicted.” *Sergeants Benevolent Ass’n*, 20 F. Supp. 3d at 322-24.

560.¹⁰ MMO's SAC suffers from the same deficiencies, and, accordingly, the Court should dismiss this entire action for lack of Article III standing under Rule 12(b)(1).

II. MMO Does Not Allege Mail Or Wire Fraud With The Particularity Required By Rule 9(b)

MMO's RICO claims also must be dismissed because MMO has not alleged any act of mail or wire fraud by any Defendant group with particularity.¹¹ To allege a "pattern" of mail or wire fraud by each defendant actionable under RICO, MMO must allege that each defendant engaged in two or more acts of mail or wire fraud. Each alleged act requires allegations (1) the defendant participated in a scheme to defraud; (2) the defendant intended to defraud; and (3) a use of mail or wire in furtherance of the fraudulent scheme. *United States v. Powell*, 576 F.3d 482, 490 (7th Cir. 2009); *United States v. Leahy*, 464 F.3d 773, 786 (7th Cir. 2006). Furthermore, each alleged act must be supported by allegations stating the circumstances of the fraud with particularity. *McDonald v. Schencker*, 18 F.3d 491, 495 (7th Cir. 1994). Allegations consistent with Rule 12(b) and *Iqbal* are not enough. *Vicom, Inc. v. Harbridge Merch. Servs., Inc.*, 20 F.3d 771, 777 (7th Cir. 1994). In a multi-defendant case, Rule 9(b) prohibits plaintiffs from "lumping together" the various defendants; each defendant's mail or wire fraud must be pleaded specifically and separately. *Id.*

¹⁰ See *Intron/Temodar*, 678 F.3d at 245-52; *Travelers Indem. Co. v. Cephalon*, 32 F. Supp. 3d 538, 546-49 (E.D. Pa. 2014); *Plumbers and Pipefitters Local 572 Health and Welfare Fund v. Merck & Co.*, 2013 WL 1819263, at *6-7 (D. N.J. Apr. 29, 2013); *New England Carpenters Health and Welfare Fund v. GlaxoSmithKline, LLC*, 2014 WL 4119410, at *1 n.1 (E.D. Pa. Aug. 8, 2014); *Actimmune*, 2010 U.S. Dist. LEXIS, at *30 (N.D. Cal. Sept. 1, 2010), *aff'd*, 464 F. App'x 651 (9th Cir. 2011); *S. Ill. Laborers*, 2009 WL 3151807, at *5-7, 8.

¹¹ This Court's recent decision denying motions to dismiss non-RICO, personal injury claims brought by TRT consumers is not to the contrary. *TRT*, 2014 WL 7365872, at *6-*8. The Court's decision concerned claims brought by plaintiff consumers who allegedly saw and relied on TRT advertisements and then sustained physical injuries allegedly as a direct result of taking TRT drugs. The claims here are very different.

To satisfy Rule 9(b), a RICO plaintiff must “state with particularity” “the who, what, when, where, and how” of the alleged fraudulent acts. *Vicom*, 20 F.3d at 777 (internal quotations and citations omitted). Put differently, the complaint must state “the identity of the person who made the misrepresentation, the time, place and content of the misrepresentation, and the method by which the misrepresentation was communicated to” the party that relied upon it. *Id.* (internal quotations and citations omitted). A claim may not be based on allegations of a mere omission of material information. Rather, the plaintiff must allege that the defendant knew the whole truth and intentionally omitted material information with the intent to conceal the whole truth and deceive and mislead the plaintiff or another party. *Powell*, 576 F.3d at 491; *United States v. Stephens*, 421 F.3d 503, 507 (7th Cir. 2005). Federal courts are particularly vigilant in scrutinizing pleading of RICO claims “because of the relative ease with which a plaintiff may mold a RICO pattern from allegations that, upon closer scrutiny, do not support it.” *Kolar v. Preferred Real Estate Invs., Inc.*, 361 F. App’x 354, 363 (3d Cir. 2010) (internal quotation marks and citation omitted).

Here, despite its extraordinary length, the SAC lacks concrete factual allegations concerning the basic elements of fraud as to any Defendant group. For example, the SAC does not: identify any doctor who allegedly wrote a TRT prescription for a MMO insured; allege that the doctor’s TRT prescription was medically inappropriate; allege that the doctor was induced to write that prescription by any false or misleading statements made by or attributable to any Defendant group; or allege the time, place, and content of the allegedly false or misleading communication. *See Janssen*, 784 F. Supp. 2d at 527.

The SAC likewise does not: identify any MMO agent who allegedly decided to include a Defendant group’s TRT drug on its formulary and have MMO reimburse for TRT drugs

whenever prescribed by a physician; allege that agent's decision to cover a TRT drug was induced by any false or misleading statements made by or attributable to any Defendant group; or allege the time, place, and content of the allegedly false or misleading communication. And there are no concrete factual allegations supporting the conclusion that any Defendant group acted with a specific intent to defraud MMO.¹² Indeed, even the SAC's generic and conclusory allegations indicate only that Defendant groups were "misinformed" and "should have known" that TRT drugs were not safe or effective treatments for certain conditions and for certain patient populations. (SAC ¶¶ 28, 97, 123.) MMO's RICO claims must be dismissed.¹³

III. MMO's Claims Of A Conspiracy Among All Defendant Groups To Violate RICO Through A Fraudulent "Unbranded" Marketing Campaign Are Not Supported By Concrete Factual Allegations.

In the SAC, MMO has alleged that the Defendant groups conspired with one another to violate RICO. (SAC ¶¶ 756-98, 1164-1229.) MMO's conspiracy claims must be dismissed because the SAC does not allege facts that make the claim plausible.

It is unlawful for a person to conspire with others to violate one of the substantive provisions of RICO (18 U.S.C. § 1962(a)-(c)). 18 U.S.C. § 1962(d). To state a claim for conspiracy to violate RICO's substantive provisions, a plaintiff must allege that the defendant made two agreements: (1) to maintain an interest in or control of an enterprise or to participate in the affairs of an enterprise through a pattern of racketeering activity and (2) to commit at least

¹² Although the SAC describes some details about CME courses, presentations, printed materials, and television and print advertisements (*see, e.g.*, ¶¶ 406, 424-28), it does not explain what made a particular statement false or misleading or identify who received and relied upon such information. Absent such facts, MMO cannot state a claim that complies with Rule 9(b). *See Midw. Grinding Co. v. Spitz*, 976 F.2d 1016, 1020 (7th Cir. 1992).

¹³ For the same reasons, MMO's claim against each Defendant group based on alleged conspiracies with unnamed third parties to commit a civil RICO violation must be dismissed. *Stachon v. United Consumers Club, Inc.*, 229 F.3d 673, 677 (7th Cir. 2000); *Walgreen*, 719 F.3d at 856-57.

two “predicate” acts to accomplish those goals. *Goren v. New Vision Int’l, Inc.*, 156 F.3d 721, 732 (7th Cir. 1998); *Pa. Chiropractic Ass’n*, 2010 U.S. Dist. LEXIS 107077 at*17-18. A plaintiff also must allege an overt act (that is itself a “predicate” act) in furtherance of the conspirators’ agreement. *Beck v. Prupis*, 529 U.S. 494, 495-96 (2000).

Concrete factual allegations of “agreement” among the conspirators are essential. To the extent that a plaintiff relies on allegations of conduct to show “agreement” to violate RICO’s substantive provisions, the allegations of conduct must show that the defendant “objectively manifested an agreement to participate, directly or indirectly, in the affairs of an enterprise, through the commission of two or more predicate crimes.” *United States v. Balzano*, 916 F.2d 1273, 1289 (7th Cir. 1990). Allegations of parallel conduct by defendants do not satisfy § 1962(d), *Twombly*, or *Iqbal*. *Am. Dental Ass’n v. Cigna Corp.*, 605 F.3d 1283 (11th Cir. 2010).

Here, the SAC includes only vague and conclusory allegations of agreement among the Defendant groups. (SAC ¶¶ 756-98, 1164-1229.) At most, the SAC alleges that the Defendant groups engaged in similar marketing practices, were members of certain trade associations and public interest groups, and periodically contributed to studies or conferences. These allegations fall far short of what is required to establish an agreement to violate RICO, particularly given that the Defendant groups are direct competitors. As the Supreme Court observed in *Twombly*, “when allegations of parallel conduct [by competitors] are set out ... they must be placed in a context that raises a suggestion of a preceding agreement, not merely parallel conduct that could just as well be independent action.” 550 U.S. at 557. “[W]ithout that further circumstance pointing to a meeting of the minds, an account of a defendant’s commercial efforts stays in neutral territory.” *Id.* Given MMO’s threadbare allegations of any agreement, its claims of a conspiracy among the Defendant groups to violate RICO must be dismissed. *See Goren*, 156

F.3d at 732 (affirming the dismissal of a RICO conspiracy claim based on vague allegations of an agreement to violate RICO); *Pa. Chiropractic Ass'n*, 2010 U.S. Dist. LEXIS at *17-18 (same).

IV. MMO's RICO Claims Are Time-Barred

Statutes of limitations “protect important social interests in certainty, accuracy, and repose.” *Cada v. Baxter Healthcare Corp.*, 920 F.2d 446, 453 (7th Cir. 1990). They are especially vital in RICO cases, because the “purpose” of RICO’s treble-damage awards is “encouraging potential plaintiffs diligently to investigate.” *Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 187 (1997).

A complaint may be dismissed as time-barred on the pleadings where, as here, “the issue c[an] be resolved ... based on the allegations in the complaint” and “facts within [the court’s] judicial-notice power.” *Ennenga v. Starns*, 677 F.3d 766, 773 (7th Cir. 2012). “Where the facts needed for determination of when a reasonable [plaintiff] ... would have been aware of [something] can be gleaned from the complaint and papers integral to the complaint, resolution of the issue on a motion to dismiss is appropriate, and [courts] have done so in a vast number of cases.” *LC Capital Partners, L.P. v. Frontier Ins. Grp.*, 318 F.3d 148, 156 (2d Cir. 2003) (ellipses, quotation marks, and citations omitted).

Civil RICO’s statute of limitations is four years, and it “beg[ins] to run once ... the plaintiffs knew *or should have known* that they were injured.” *McCool v. Strata Oil Co.*, 972 F.2d 1452, 1464-65 (7th Cir. 1992) (emphasis added). In other words, even if the plaintiff did not actually know of his injury, the statute begins to run if he “[w]ould have learned [of his injury] through the exercise of ordinary diligence in the protection of [his] legal rights.” *Fujisawa Pharm. Co. v. Kapoor*, 115 F.3d 1332, 1334 (7th Cir. 1997).

Crucially, “the focus is on the discovery of the harm itself.” *Cancer Found. v. Cerberus Capital Mgmt.*, 559 F.3d 671, 674 (7th Cir. 2009). Once the plaintiff knows (or should know)

that “something amounting to injury in fact” has occurred, “it [is] up to him to inquire further,” learn the details, and sue within four years. *Perry v. Globe Auto Recycling, Inc.*, 227 F.3d 950, 954 (7th Cir. 2000). He does not need to know that there is a pattern of racketeering, *Rotella v. Wood*, 528 U.S. 549, 555 (2000), or “who injured him” to start the clock running, *Fidelity Nat’l Title Ins. Co. v. Howard Sav. Bank*, 436 F.3d 836, 839 (7th Cir. 2006). He does not need to know that his injury is legally “actionable,” *Cancer Found.*, 559 F.3d at 674-75, or even “that he has been wronged” in a lay sense, *Wolin v. Smith Barney Inc.*, 83 F.3d 847, 852 (7th Cir. 1996). And it is not necessary that the “full extent of the injury [be] ... known or [even] predictable.” *Wallace v. Kato*, 549 U.S. 384, 391 (2007) (emphasis added). That is what the four-year limitations period is for.

In assessing what MMO should have known with reasonable diligence, this Court should bear in mind that MMO is a “sophisticated institution[]” with considerable “expertise in merchandising of [p]harmaceuticals.” *In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. 69, 195-96 (E.D.N.Y. 2008), *rev’d on other grounds*, 620 F.3d 121 (2d Cir. 2010); *cf. Philip Morris*, 196 F.3d at 826 (TPPs “have the best information” “[of] all entities in society” about healthcare matters). When the plaintiff is an “experienced corporate player,” a “forgiving application of the discovery rule” is not “justified.” *KDC Foods v. Gray*, 763 F.3d 743, 751 (7th Cir. 2014).

A. MMO’s RICO Claims Against The AbbVie Defendants, Actavis Defendants, And Auxilium Are *Prima Facie* Untimely

MMO’s alleged injury supposedly “coincid[ed] with the approval of AndroGel in early 2000.” (SAC ¶¶ 11, 37-38.) As of that date, Auxilium and the Actavis Defendants already had TRT products on the market. (*See id.* ¶ 70 (Auxilium since 1972); ¶ 72 (Actavis since 1995).) Thus, when this lawsuit was filed in 2014, MMO allegedly had been paying for the fraudulently marketed TRT drugs of these three Defendant groups—for well “more than [a] decade.” (*Id.*

¶ 4.) The claims against these Defendants are therefore time-barred as long as a reasonably diligent TPP would have known by November 5, 2010—*i.e.*, four years before MMO filed this suit—that “something amounting to injury in fact” had occurred. Accepting MMO’s allegations as true, there is no question that MMO should have known of some alleged injury in the exercise of reasonable diligence long before November 2010. The SAC itself describes how TRT drug prescriptions skyrocketed from 2000 to 2010 and how marketing of these Defendant groups’ TRT drugs was widespread.

The recent decision in *United States ex rel. King v. Solvay S.A.*, 2015 U.S. Dist. LEXIS 25132 (S.D. Tex. Mar. 3, 2015), illustrates the extent of information available to MMO. In 2003, former employees of Solvay Pharmaceuticals, Inc. (“SPI”) or a related entity challenged Solvay’s marketing of AndroGel. *Id.* at *5-6, *24-25 (alleging that Solvay had commissioned medical articles on off-label uses of AndroGel and influenced physician speakers to promote those uses); (*see* Decl. of William F. Cavanaugh, Jr. (“Cavanaugh Decl.”), Ex. 2.)

This March, the *King* court dismissed the portion of the complaint relating to AndroGel because the alleged off-label promotion of AndroGel was already a matter of public record before the plaintiffs filed suit in 2003:

[A July 2002 feature] *New Yorker* article, entitled “Hormones for Men: Is Male Menopause a Question of Medicine or of Marketing?,” discusses advertisements for male menopause that were [allegedly] paid for by Unimed, “a division of ... Solvay.” It notes that Unimed makes AndroGel. [It] discusses the possibility of the pharmaceutical industry “inventing” diseases, such as andropause or male menopause. It highlights a doctor that ... urged men who were experiencing a low sex drive or low energy to have their testosterone levels checked at his clinic. The advertisement and the tests were allegedly underwritten by ... Unimed

The article points out that a physician may prescribe a drug for any clinical condition once it is approved by the FDA, but that the “FDA prohibits drug companies from advertising ‘off label’ uses,” and “andropause” was not an approved use. It also discusses an andropause conference convened by the Endocrine Society that [allegedly] was solely financed by a Unimed/Solvay grant. Nine out of the thirteen

panelists in the final group [allegedly] had “significant financial ties to Unimed/Solvay.” The panel ultimately recommended that patients over fifty should be screened with [the ADAM] questionnaire about andropause These recommendations [allegedly] [did] not [disclose] the financial ties that the majority of the panelists had to Unimed/Solvay. The article ... also points out that there is “a lot of uncertainty about the effects of age-related lowering of testosterone,” questions ... testosterone’s effectiveness for preventing bone fractures, and points to many “worrisome” [alleged] side effects of testosterone treatment.

King, 2015 U.S. Dist. LEXIS 25132, at *21-23 (citations omitted). The *King* court concluded that this 2002 article, standing on its own, was “enough to put [a plaintiff] on the trail of the [alleged] fraud.” *Id.* at *22.

As a sophisticated entity, MMO “is presumed to have information available in the public domain,” especially feature stories published in prominent national magazines. *Whirlpool Fin. Corp. v. GN Holdings*, 67 F.3d 605, 610 (7th Cir. 1995).¹⁴ MMO, therefore, was on notice that it may have suffered “something amounting to an injury in fact” no later than July 2002—well over *twelve years* before it filed this suit. Indeed, the New Yorker article did not merely alert MMO to its alleged injury in fact; it outlined the alleged racketeering acts described in the SAC.

Nor was the 2002 New Yorker article a fluke. Submitted as exhibits to the Cavanaugh Declaration are dozens of news stories concerning TRT drugs published between February 2000 and June 2010, which address the gamut of allegations in this lawsuit. Indeed, one of those articles was prominently cited in MMO’s original Complaint. (See Compl. ¶ 6 (citing Gina Kolata, *Male Hormone Therapy Popular But Untested*, New York Times (Aug. 19, 2002) (Cavanaugh Decl., Ex. 28).) That article—a front-page story in the New York Times—was published over twelve years before this suit was filed, and over eight years before the November

¹⁴ Because the existence of these news sources is a matter of public record, the Court may take judicial notice of their publication. *Specht v. Google, Inc.*, 758 F. Supp. 2d 570, 586 (N.D. Ill. 2010), *aff’d*, 747 F.3d 929 (7th Cir. 2014), *cert. denied*, 135 S.Ct. 724 (2014); *see also Ennenga*, 677 F.3d at 773.

2010 cutoff date. After Defendants moved to dismiss and cited the Complaint's reliance on this article, MMO quietly deleted the citation from the SAC. But such pleading gimmicks do not save the suit from untimeliness; the Court may still take notice that the allegations in the SAC were already front-page news by 2002.

The FDA also noted off-label use of TRT drugs more than five years before this suit was filed. In May 2009, the FDA required TRT gel products to bear additional warnings. (See SAC ¶ 95.) See FDA Press Release (May 7, 2009), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ucm149580.htm>.¹⁵ Many news outlets reported on the FDA's action. (See, e.g., Cavanaugh Decl., Exs. 47, 48.) These allegations, which form part of MMO's alleged injury here (see SAC ¶¶ 379-84), were therefore widely publicized at least a year and a half before the November 2010 cutoff date.

Moreover, the *King* complaint was a matter of public record by December 7, 2009—nearly a year before the November 5, 2010 cutoff date. See Mem. and Order, No. 4:06-cv-02662, Dkt. 110 at 1 (S.D. Tex. July 20, 2010) (noting date of unsealing); *King*, 2015 U.S. Dist. LEXIS 25132, at *6 (same); cf. *Walgreen Co.*, 631 F.3d at 443 (“tak[ing] judicial notice of the complaint in [a related] *qui tam* case”).

In short, this lawsuit was hopelessly time-barred by the time MMO eventually got around to filing it in November 2014.¹⁶ Seeking to avoid this conclusion, MMO alleges that “[t]he

¹⁵ The Court may take judicial notice of this press release both because it is a publicly issued government document on an agency website, see *Bova v. U.S. Bank, N.A.*, 446 F. Supp. 2d 926, 931 n.2 (S.D. Ill. 2006), and because the SAC itself refers to the FDA warning at issue, see *U.S. v. Wood*, 925 F.2d 1580, 1582 (7th Cir. 1991).

¹⁶ In response, MMO may cite *Sidney Hillman Medical Center v. Abbott Laboratories*, 782 F.3d 922 (7th Cir. 2015), in which the Seventh Circuit reversed the pleadings-stage statute-of-limitations dismissal of a facially similar TPP RICO lawsuit based on off-label promotion. But *Sidney Hillman* is distinguishable. Notably, the defendant did not point the district court to

accrual of [its] claims is tied to the recent safety disclosures regarding TRT drugs' association with cardiovascular adverse events." (SAC ¶ 808.) Specifically, MMO alleged that "[i]t was only with" the "announce[ment]" in January 2014 that the FDA was "investigating the risk of stroke, heart attack, and death in men taking" TRT drugs "that [it] and TPP Class Members were put on notice" of the safety risks of TRT drugs. (*Id.* ¶¶ 810-11.)

Yet, the question of potential cardiovascular side effects of testosterone replacement therapy had been raised publicly since 2000 in numerous articles. Moreover, the clinical study that prompted the FDA's recent actions was published in the *New England Journal of Medicine* more than four years before MMO filed suit, as the SAC admits. (*Id.* ¶ 99; Basaria, *et al.*, *Adverse events associated with testosterone administration*, 363 *NEJM* 109-122 (2010); Cavanaugh Decl. Ex. 55 (complete copy of cited study).)¹⁷ As the Cavanaugh Declaration shows, the Basaria study touched off a firestorm of press concerning these cardiovascular findings, including a release by the National Institutes of Health and articles by the *Washington Post*, the *New York Times*, and industry publications. (*Id.* Ex. 56-70.) All of this was more than four years before this suit was filed.

The fact that the FDA did not take regulatory action until 2014 is beside the point. The clock began running when that alleged risk became a matter of public knowledge, and not when

judicially noticeable information showing that the very allegations forming the heart of the plaintiffs' complaint were already front-page news twelve or more years before the complaint was filed. *See In re AIG Workers Comp. Ins. Policyholder Litig.*, 2015 U.S. Dist. LEXIS 57159, at *13-14 (N.D. Ill. Apr. 27, 2015) (distinguishing *Sidney Hillman* on similar grounds).

¹⁷ The Court may take judicial notice that the Basaria study is what prompted the FDA to take action. *See* FDA, *Testosterone Replacement Therapy* (Sept. 17, 2014) at 5, <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/UCM416461.pdf>.

government regulators decided to act. *See Premium Plus Partners, L.P. v. Goldman, Sachs & Co.*, 648 F.3d 533, 537 (7th Cir. 2011); *Fujisawa*, 115 F.3d at 1335.

Moreover, while MMO focuses solely on alleged cardiovascular risks in an attempt to push the accrual date forward, it is settled that a claim accrues upon actual or constructive notice of *some* injury, and that the “*full extent* of the injury” need not be “known or [even] predictable.” *Wallace*, 549 U.S. at 391 (emphasis added). MMO’s alleged injury is broader than undisclosed cardiovascular risk. MMO alleges that, for 15 years before this suit was filed, Defendants marketed TRT drugs “off-label” for a broad array of unapproved conditions or populations (“andropause,” depression, osteoporosis, sexual dysfunction, diabetes, obesity, pain, HIV/AIDS, and women) for which TRT drugs provide “absolutely zero benefit.” (SAC ¶ 21.) The SAC alleges that MMO was injured by paying for these ineffective and unnecessary prescriptions—and this would have been the case even if TRT never caused a single heart attack or other cardiovascular event. Thus, accrual of MMO’s claims would not be “tied to the recent safety disclosures.” (*Id.* ¶ 808.)

B. The Statute Is Not Tolled

Aware that its claims are *prima facie* untimely, MMO attempts to invoke tolling doctrines to save them, alleging that “Defendants[] ... fraudulently concealed their illegal conduct.” (SAC ¶¶ 805, 806.) MMO’s tolling argument fails for at least two reasons.

First, the Supreme Court has held that “a plaintiff who is not reasonably diligent” may not invoke tolling doctrines to escape RICO’s statute of limitations. *Klehr*, 521 U.S. at 194-95. In other words, it is not enough that diligent investigation would have been futile; a plaintiff must *actually have made* a diligent effort. *Id.* Here, although MMO summarily claims that it “could not have acquired ... knowledge [of its injuries] through the exercise of reasonable diligence” (SAC ¶ 812), it does not allege that it *actually employed* any diligence to investigate

the widespread public reports about TRT drugs. Because diligent efforts are a prerequisite for tolling, they must be pleaded, and the failure to do so is fatal. *See Hentosh v. Herman M. Finch Univ.*, 167 F.3d 1170, 1175 (7th Cir. 1999); *Davenport v. A.C. Davenport & Son Co.*, 903 F.2d 1139, 1142 (7th Cir. 1990); *Dummar v. Lummis*, 543 F.3d 614, 622-23 (10th Cir. 2008).

Moreover, MMO cannot plausibly establish the requisite “causal” connection between Defendants’ supposed acts of concealment and MMO’S failure to sue timely. *Jay E. Hayden Found. v. First Neighbor Bank*, 610 F.3d 382, 385 (7th Cir. 2010); *see also Flight Attendants Against UAL Offset v. Comm’r*, 165 F.3d 572, 577 (7th Cir. 1999). As set forth above, there was more than enough information in the public record, years before the critical November 2010 date, for a “reasonable” TPP to perceive at least “the *possibility* that [its] rights ha[d] been violated”—and that is enough to preclude tolling. *Chapple v. Nat’l Starch & Chem. Co.*, 178 F.3d 501, 506 (7th Cir. 1999) (emphasis added); *Whirlpool*, 67 F.3d at 610 (“[Because] the information Whirlpool needed to uncover the fraud was in the public domain, GN’s continued attempts to [obfuscate] ... could not have prevented Whirlpool from filing its complaint on time.”); *Dummar*, 543 F.3d at 622 (same).

MMO does not—and cannot—deny this wealth of public information stretching back as far as 2000. Instead, it alleges that “[t]o the extent that anyone publicly called into question Defendants’ false and fraudulent promotional activities, Defendants were highly aggressive in their [responsive] attacks against such negative media.” (SAC ¶ 815.) But the only examples MMO provides of such a responsive “attack” are (1) a letter to the editor written by Dr. Abraham Morgantaler, which pointed out unspecified “inaccuracies” in the 2002 New Yorker feature article; (2) an “outreach” campaign coordinated by an outside vendor that responded to the 2002 New Yorker article with unspecified “positive information” about TRT; and (3) “talking points”

supposedly provided to the AbbVie Defendants' sales force claiming that the 2002 New Yorker article was "false" and contained "misrepresentations." (*Id.* ¶¶ 815-20.)

These allegations are insufficient to toll the statute of limitations for three reasons. First, they address only a single article—the 2002 New Yorker story—and do not address the steady stream of media reports, government agency press releases, and journal articles that predated the New Yorker story and continued for years after it. (*See generally* Cavanaugh Decl.)

Second, it is well settled that the denial of wrongdoing—even when "highly aggressive" and public—does not toll the statute of limitations. *Premium Plus*, 648 F.3d at 536-37; *Mitchell v. Donchin*, 286 F.3d 447, 451 (7th Cir. 2002); *Singletary v. Cont'l Ill. Nat'l Bank & Trust Co.*, 9 F.3d 1236, 1241 (7th Cir. 1993); *Stephan v. Goldinger*, 325 F.3d 874, 877 (7th Cir. 2003).

Third, and finally, these three responses to the 2002 New Yorker article provide no basis for tolling the statute of limitations for the simple reason that the SAC does not allege that MMO ever saw or relied on them. The causation element, therefore, remains unsatisfied. *See id.* (even if statements denying liability could form the basis for tolling, rejecting tolling where "[t]here [was] no evidence that [plaintiff] read the article [containing the statements] or otherwise learned of the statements, let alone that he relied on it or on them").

C. MMO's RICO Claims Against The Recent Market Entrants Fail As Well

The claims against two of the Defendant groups are not time-barred, because those groups entered the TRT market within four years of the filing of this lawsuit. (*See* SAC ¶¶ 71 (Lilly Defendants); 73 (Endo).) However, the public information discussed above scuttles MMO's claims against these recent market entrants on a different doctrinal ground.

By late 2010, when the Lilly and Endo Defendants entered the market, any reasonably diligent TPP in MMO's shoes would already have been aware of the allegations that TRT drugs were being promoted and prescribed for off-label uses, and of the allegations of cardiovascular

risk. There was never a time, in other words, when the Lilly and Endo Defendants could have *deceived* a reasonable TPP in the manner alleged. Thus, MMO could not plausibly plead that these Defendants committed the alleged predicate acts of mail and wire fraud, or that those predicate acts (rather than MMO's own intervening negligence or willful inaction) proximately caused MMO's alleged losses. See *Reynolds v. E. Dyer Dev. Co.*, 882 F.2d 1249, 1253 (7th Cir. 1989) (plaintiff's RICO claim failed because the facts allegedly concealed were a matter of public record; a RICO plaintiff "may not rely on misrepresentations when he has sufficient information to call the misrepresentation into question"); *Drobny v. JP Morgan Chase Bank*, 929 F. Supp. 2d 839, 849 (N.D. Ill. 2013) (a statement "upon which no reasonable person could rely" cannot "amount to wire or mail fraud for purposes of RICO").¹⁸

V. MMO's State Law Claims Must Be Dismissed

In addition to its RICO claims, MMO asserts state law claims against each Defendant. In particular, MMO asserts a claim against each Defendant for alleged violations of the consumer protection statute in the state where that Defendant allegedly is located. In separate counts, MMO also asserts claims against each Defendant under the laws of the consumer protection statutes of every other state, the District of Columbia, and Puerto Rico. In addition, MMO asserts claims against the AbbVie Defendants, Auxilium, the Actavis Defendants, and Endo for alleged violations of insurance fraud statutes of the states where those Defendants allegedly are located. MMO further asserts claims against each Defendant for common law fraud, negligent misrepresentation, unjust enrichment, and equitable relief. These claims should be dismissed.

¹⁸ In *Bridge*, the Supreme Court stated that "first-party reliance" is not, on its own, "an indispensable requisite" of a RICO claim predicated on mail fraud while at the same time noting that "the absence of first-party reliance" may "prevent the plaintiff from establishing [the required element of] proximate cause," because the voluntary assumption of an injury "break[s] the chain of causation between [a defendant's] misrepresentations and [the resulting] injury." 553 U.S. at 658-59. The cases cited in the text, therefore, remain good law.

A. MMO’s Consumer Protection And Insurance Fraud Claims Should Be Dismissed

1. The Consumer Protection And Insurance Fraud Statutes Of The States In Which Each Defendant Is Located Do Not Apply Under Governing Choice Of Law Principles

“In an MDL proceeding, ‘a transferee court applies the substantive state law, including choice-of-law rules, of the jurisdiction in which the action was filed.’” *TRT*, 2014 WL 7365872, at *10 (citations omitted). This action was filed under Case Management Order No. 12 (“CMO 12”) (Dkt. No. 440), which provides that any directly-filed case will be treated ‘as if it was originally filed in the federal district where the Plaintiff [is] a citizen’ and that direct filing “will have no impact on choice of law.” *Id.* at II.B.i and II.F.

MMO alleges that it is an Ohio citizen (SAC ¶ 36). Under CMO 12, this case should be treated as if it were filed in a federal district court in Ohio. A federal district court in Ohio would apply Ohio’s choice-of-law rules to determine the law that applies to MMO’s state law claims. *See Muncie Power Prods., Inc. v. United Techs. Auto., Inc.*, 328 F.3d 870, 873 (6th Cir. 2003).

Under Ohio law, the principles in the Restatement (Second) of Conflict of Laws govern choice-of-law determinations in tort cases. *See Morgan v. Biro Mfg. Co., Inc.*, 474 N.E.2d 286, 288-89 (Ohio 1984).¹⁹ As this Court explained in its decision on defendants’ motion to dismiss the TRT personal injury cases, “under the Second Restatement, the Court must apply a ‘two-step process in which the court (1) chooses a presumptively applicable law under the appropriate jurisdiction-selecting rule, and (2) tests this choice against the principles of § 6 in light of relevant contacts identified by general provisions like § 145 (torts).’” *TRT*, 2014 WL 7365872, at *10 (citations and internal quotation marks omitted). Applying that analysis to MMO’s tort claims, “the law of the place of injury controls unless another jurisdiction has a more significant

¹⁹ Illinois also has adopted the Second Restatement of Conflict of Laws. *TRT*, 2014 WL 7365872, at *10. Thus, the analysis would not differ under Illinois’ choice-of-law rules.

relationship to the lawsuit.” *Pilgrim v. Universal Health Card, LLC*, 660 F.3d 943, 946 (6th Cir. 2011) (quoting *Morgan*, 474 N.E.2d at 289); accord *TRT*, 2014 WL 7365872, at *11.

In its decision last year, this Court concluded that the law of the state where each plaintiff was located applied to that plaintiff’s state law tort claims seeking recovery for alleged personal injury. *Id.* The same result follows for MMO’s state law tort claims seeking recovery for alleged economic injury. As the Seventh Circuit has held, “if recovery for ... consumer fraud is possible, the injury is decidedly where the *consumer* is located, rather than where the seller maintains its headquarters.” *In re Bridgestone/Firestone, Inc.*, 288 F.3d 1012, 1017 (7th Cir. 2002) (emphasis in original). Similarly, the Sixth Circuit held in *Pilgrim*, considering the factors listed in sections 6 and 145 of the Restatement (Second), that “the State with the strongest interest in regulating [alleged deceptive] conduct is the State where the consumers—the residents protected by *its consumer* protection laws—are harmed by it.” 660 F.3d at 946 (emphasis by Court). Put simply, Ohio law, rather than the laws of the states in which each Defendant is allegedly located, applies to MMO’s state law claims. Accordingly, MMO’s claims under the consumer protection and insurance fraud statutes of the states in which each Defendant is allegedly located should be dismissed.²⁰

²⁰ MMO’s “‘catch-all’ listing” of various state consumer protection and other statutes “does not meet the most basic pleading requirements.” *Janssen*, 784 F. Supp. 2d at 531. And, MMO lacks standing to assert claims under state statutes and common law other than Ohio law. *See In re Actimmune Mktg. Litig.*, 2009 U.S. Dist. LEXIS 103408, at *22-58 (N.D. Cal. Nov. 6, 2009) (dismissing state statutory claims for all states lacking a representative plaintiff that could assert claims thereunder), *aff’d*, 464 F. App’x 651 (9th Cir. 2011). For these additional reasons, the Court should dismiss MMO’s consumer protection, insurance fraud and common law claims based on the laws of states other than Ohio.

2. MMO Has Not Engaged In A Consumer Transaction With Any Defendant

MMO's claims under the Ohio Consumer Sales Practices Act ("OCSPA")—the only statutory claims MMO could possibly assert—must be dismissed because MMO's allegations are outside the scope of the OCSPA's plain terms. The OCSPA provides a remedy against "suppliers" for "unfair or deceptive act[s] or practice[s] in connection with a consumer transaction." Ohio Rev. Code §1345.02(A). A "consumer transaction" is defined as "a sale, lease, assignment, award by chance, or other transfer of an item of goods, a service, a franchise, or an intangible, to *an individual* for purposes that are *primarily personal, family, or household*, or solicitation to supply any of these things." Ohio Rev. Code § 1345.01(A) (emphasis added). A "consumer," in turn, is defined as "a person who engages in a consumer transaction with a supplier." Ohio Rev. Code § 1345.01(D).

The OCSPA does not apply by its own plain text where, as here, the plaintiff is not "an individual." *Watkins & Son Pet Supplies v. Iams Co.*, 107 F. Supp. 2d 883, 893-94 (S.D. Ohio 1999) ("individual" in OCSPA "mean[s] a natural person," not a business entity), *aff'd*, 254 F.3d 607 (6th Cir. 2001); *Reeves v. PharmaJet, Inc.*, 846 F. Supp. 2d 791, 798 (N.D. Ohio 2012); *Williams v. Boston Scientific Corp.*, 2013 WL 1284185, at *6 (N.D. Ohio Mar. 27, 2013). Nor does it apply to a plaintiff, such as MMO, who made the disputed payment "for purposes that are [not] primarily personal, family, or household." *Williams*, 2013 WL 1284185, at *6; *Reeves*, 846 F. Supp. 2d at 798 n.2.²¹ Nor does the OCSPA apply where, as here, the plaintiff did not engage

²¹ See also *UFCW Local 1776 v. Teikoku Pharma USA, Inc.*, 2014 U.S. Dist. LEXIS 161069, at *93-94 (N.D. Cal. Nov. 17, 2014) (dismissing a similar consumer-protection claim brought by TPP where TPP "d[id] not link [its] purchase to *its own* personal, family or household use" (emphasis added)); *Actimmune*, 2010 U.S. Dist. LEXIS 90480, at *37-38 (same); *In re K-Dur Antitrust Litig.*, 2008 U.S. Dist. LEXIS 113310, at n.23 (D.N.J. Mar. 19, 2008) ("[I]t is doubtful that a TPP's claims ... could be construed to involve purchases made ... [for] personal, family or household purposes.").

in any transaction with the supplier. *Reeves*, 846 F. Supp. 2d at 798 n.2 (no claim where plaintiff's transaction was with pharmacy not manufacturer); *Williams*, 2013 WL 1284185, at *6 (same where a hospital and not the plaintiff purchased a medical device from the manufacturer).

3. MMO May Not Represent A Purported OCSPA Class

MMO purports to assert its OCSPA claims on behalf of a putative class of TPPs. Under the OCSPA, claims may not be brought “in a class action,” unless the asserted violation was either (1) “an act or practice declared to be deceptive or unconscionable by [Ohio administrative regulation] before the consumer transaction on which the action is based,” or (2) “an act or practice determined by a court of [the] state [of Ohio] to violate [the OCSPA] and committed after the decision containing the determination has been made available for public inspection” Ohio Rev. Code § 1345.09(B). In other words, “a consumer may qualify for a class action only when a supplier acted in the face of prior notice that its conduct was deceptive or unconscionable.” *McKinney v. Bayer Corp.*, 744 F. Supp. 2d 733, 743 (N.D. Ohio 2010) (citation omitted). “A general rule is not sufficient to put a reasonable person on notice of the prohibition against a specific act or practice.” *Volbers-Klarich v. Middletown Mgmt., Inc.*, 929 N.E.2d 434, 441 (Ohio 2010). Rather, a plaintiff seeking to represent a class must affirmatively plead that Ohio regulations or state court decisions put the defendant on notice that its specific acts and conduct were deceptive or unconscionable. *See Marrone v. Philip Morris USA, Inc.*, 850 N.E.2d 31, 35 (Ohio 2006) (“prior determination [must] be specific and ... involve conduct similar to the alleged conduct at issue”). That requirement is a substantive rule of Ohio law that applies in diversity actions pending in federal court. *See Phillips v. Philip Morris Cos. Inc.*, 290 F.R.D. 476, 480 (N.D. Ohio 2013) (“every court ... has concluded that the [O]CSPA’s notice requirement is not displaced by Fed. R. Civ. P. 23”) (citations omitted)).

MMO has not satisfied its burden to plead that any Defendant's specific conduct was deceptive or unconscionable under any preexisting Ohio regulation or previously decided Ohio state court decision. Accordingly, MMO's "claim seeking certification of a class action alleging violation of the OCSPA fails to state a claim upon which relief can be granted." *Volbers-Klarich*, 929 N.E.2d at 441; *accord Phillips*, 290 F.R.D. at 482 (granting defendants' motion for judgment on the pleadings); *McKinney*, 744 F. Supp. 2d at 749 (same).

B. MMO's State Law Claims Are Time-Barred

MMO's state law claims are barred under the governing statutes of limitations. Under Ohio law, MMO's common law fraud claims are governed by a four-year statute of limitations running from the date when "the plaintiff discovers or should have discovered the fraud." *Foster v. Wells Fargo Fin. Ohio, Inc.*, 960 N.E.2d 1022, 1025 (Ohio App. 8th Dist. 2011); Ohio Rev. Code § 2305.09(C). MMO's negligent misrepresentation claims are governed by a four-year statute of limitations running from the date of the alleged misrepresentation. *See Lasmer Indus., Inc. v. AM General, LLC*, 741 F. Supp. 2d 829, 836-37 (S.D. Ohio 2010); Ohio Rev. Code § 2305.09(D). MMO's claims under the OCSPA are governed by a two-year statute of limitations running from the date of the alleged violation. *See Foster*, 960 N.E.2d at 1024; Ohio Rev. Code § 1345.10(C). And MMO's unjust enrichment claims are governed by a six-year statute of limitations. *See Shury v. Greenaway*, 2014 WL 1513992, at *3 (Ohio App. 8th Dist. Apr. 17, 2014); Ohio Rev. Code § 2305.07. "The statute of limitations for an unjust enrichment claim is not subject to equitable tolling or a discovery rule." *Patel v. Krisjal, L.L.C.*, 2013 WL 1287344, at *7 (Ohio App. 10th Dist. Mar. 28, 2013).²² MMO incurred its claimed loss as early as 2000, and had reason to suspect potential wrongdoing by 2002 or earlier.

²² MMO's unjust enrichment claims should also be dismissed because they are duplicative of its fraud-based legal claims. (SAC ¶¶ 1340, 1343, 1346.) *Love v. City of Port Clinton*, 524 N.E.2d

C. MMO's State Law Claims Fail To Plausibly Allege Proximate Cause Or Justifiable Reliance

Proximate cause is an essential element of each of MMO's state law claims.²³ The causation principles that apply to MMO's RICO claims apply to its state law claims. *City of Cleveland v. Ameriquest Mortgage Secs., Inc.*, 621 F. Supp. 2d 513, 533 (N.D. Ohio 2009) (“Holmes controls the proximate cause analysis” under Ohio law), *aff'd*, 615 F.3d 496 (6th Cir. 2010); *Cleveland v. JP Morgan Chase Bank, N.A.*, 2013 WL 1183332, at *4 (Ohio App. 8th Dist. Mar. 21, 2013) (no claim exists “[w]here the injury is too remote or tenuous”). MMO has failed to allege proximate cause. (*See supra* pp. 14-20.)

Under Ohio law, justifiable reliance on the part of the plaintiff is also an essential element of MMO's claims for common law fraud, negligent misrepresentation, and under the OCSPA.²⁴ MMO has not alleged that it relied on any specific representation of any Defendant; nor does MMO allege that its P&T Committee or any doctor who prescribed a TRT drug to a MMO insured, or any MMO insured did so. MMO's allegations (SAC ¶¶ 1325, 1335) are “naked assertion[s],” which do not satisfy Rule 8(a), *Iqbal*, 556 U.S. at 678, let alone Rule 9(b).

CONCLUSION

For each of these reasons, the Court should dismiss MMO's Complaint with prejudice.

166, 167 (Ohio 1988) (citation omitted). Ohio law does not “allow[] a plaintiff to take advantage of a longer statute of limitations through creative pleading.” *Perez Bar & Grill v. Schneider*, 2010 WL 1227706, at *4 (Ohio App. 9th Dist. Mar. 31, 2010).

²³ *See Graham v. American Cyanamid Co.*, 350 F.3d 496, 507 (6th Cir. 2003) (common law fraud); *Phillips v. Philip Morris Cos., Inc.*, 298 F.R.D. 355, 366 n.15 (N.D. Ohio 2014) (unjust enrichment); *Butler v. Sterling, Inc.*, 210 F.3d 371, 2000 WL 353502, at *4 (6th Cir. 2000) (OCSPA claim); *Westfield Ins. Co. v. HULS Am., Inc.*, 714 N.E.2d 934, 951 (Ohio App. 10th Dist. 1998) (negligent misrepresentation).

²⁴ *See Mishler v. Hale*, 26 N.E.3d 1260, 1270 (Ohio App. 2d Dist. 2014) (fraud); *Heinz & Assoc., Inc. v. Diamond Cellar Holdings, L.L.C.*, 2012 WL 1079087, at *4-*10 (Ohio App. 10th Dist. Mar. 30, 2012) (negligent misrepresentation).

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 31, 2015, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which sent notification of such filing to all registered attorneys of record.

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